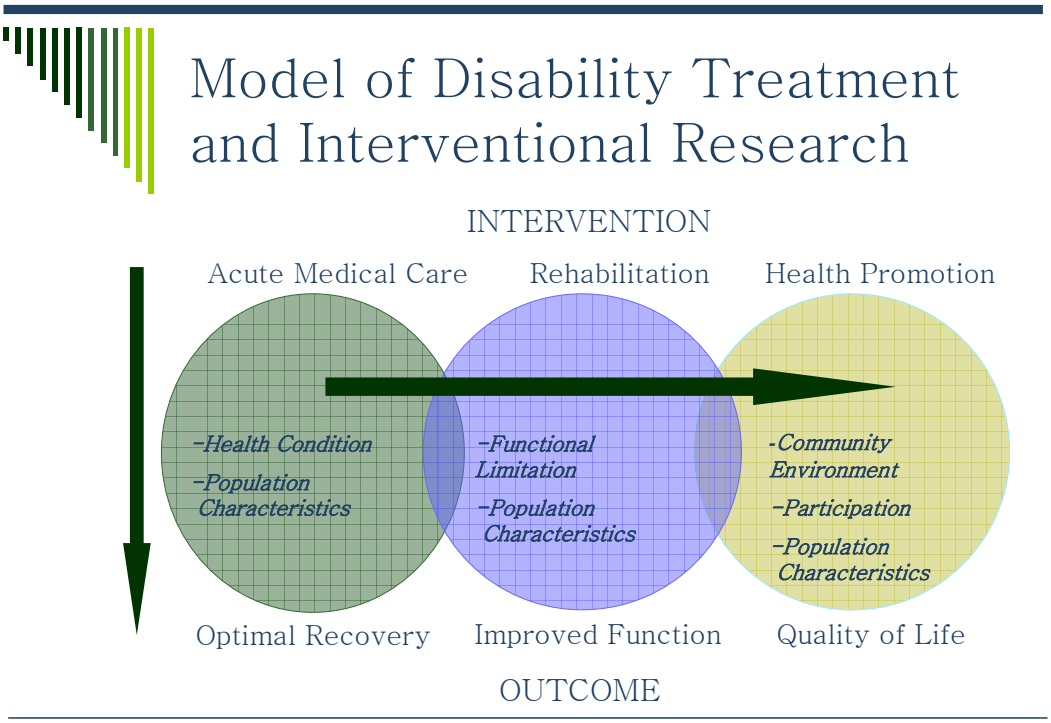
PROPOSAL FOR A DISABILITY COMPARATIVE EFFECTIVENESS RESEARCH PROGRAM

Disability and Health Intervention Research Organizational Framework

The ideal outcome for a comprehensive healthcare system is good health-related quality of life (HRQOL) for all participants. Medical and Public Health research over the past 100 years has led to enormous gains in health-related quality of life around the world.

For the 54 million Americans with disability, the gold standard of HRQOL is participation in community life. The World Health Organization's International Classification of Function, Disability, and Health (ICF) specifies this outcome as a result of an interaction between the individual with a disability and his or her environment. Three practice disciplines with scientific foundations address the dimensions of the ICF, including medicine, rehabilitation, and health promotion. Each addresses the individual and the environment at different levels.

The figure below depicts a conceptual continuum of intervention research in disability and rehabilitation that encompasses interventions at both the individual and environmental levels. It begins with acute medical services and shows linkages through rehabilitation to health promotion and quality of life. Notice the areas of overlap where research may address questions that encompass both Acute Medical Care and Rehabilitation Treatments and Therapies. The model may be used to organize the development of comparative effectiveness research in disability and rehabilitation that leads to improved health-related quality of life.



Reading the diagram from left to right, medical research examines treatment of acute conditions. The outcome of these experimental medical procedures is a function of patient characteristics such as existing health condition and population characteristics (e.g., age, gender, race). When medical interventions are 100% effective, individuals are returned to full health and pre-intervention levels of participation and quality of life. Of course, not all medical procedures lead to 100% recovery, or cure.

The value of medical interventions is determined by the interaction of effect by cost. For example, the cost-effectiveness of treating a broken leg is not debated as these treatments are nearly 100% effective and relatively inexpensive. On the other hand, the cost of some late stage cancer treatment is debated. These debates are often framed in terms of quality adjusted life years, a metric of life expectancy by expected quality. However, use of this metric for medical procedures is flawed. Future quality of life following an acute medical procedure is related to a variety of factors beyond the intervention itself. These factors are addressed in the next two circles of the framework.

When medical outcomes do not lead to full recovery, rehabilitation interventions may be used to improve functional outcome for accessing the community. These interventions range from increasing the function of particular body structures (e.g., vocal cords via speech therapy) through the use of assistive technology like wheelchairs. Again, the outcome from rehabilitation procedures is considered a function of patient characteristics (i.e. impairment type and age). Disciplines involved in rehabilitation include medicine, psychology, physical and occupational therapy, social work, engineering, and speech.

When rehabilitation outcomes are100% effective the patient has regained full function to participate in the community. Using the best available rehabilitation technology, full function could be a common rehabilitation outcome. However, like medical interventions, rehabilitation outcomes have a range of cost-effectiveness. Often, the cost of providing assistive technology for accessing the environment is prohibitive. This can be viewed as either a technological or an environmental problem. Accessible environments require less expensive rehabilitation equipment for participation. For example, the Ibot, an expensive wheelchair that can climb stairs, is unnecessary in ramp and lift equipped environments. Likewise, adequately structured work environments require less job coaching for people with intellectual disabilities.

The last block of the framework picks up where the previous two blocks end. Ultimately, the translation of medical and rehabilitative procedures into health-related quality of life depends on the behavioral choices available to the individual. These choices occur at the intersection of the individual in interaction with his or her environment; the richer and more accessible the environment, the greater the, opportunity to participate in community life. Traditionally, health promotion interventions aim to reduce health risk factors and increase health protective factors to reduce morbidity and mortality. When considering health-related quality of life outcomes for people with functional loss, health-related quality of life also must include features of the environment that facilitate or impede participation. From this perspective, the absence of participation opportunities is a health risk factor.

The outcomes of experimental health promotion interventions to increase health-related quality of life for people with functional loss result from the interaction of personal and environmental characteristics, an interaction effect exemplified by the International Classification of Functioning, Disability, and Health (WHO, 2001). More importantly, in a comprehensive

healthcare system, health promotion engages medical and rehabilitation patients to maximize functional outcome via personal and environmental interventions. For example, the symptom presentation from many chronic illnesses interrupts participation through both functional limitations due to untreatable symptoms and from the demands of rigorous medical and self-management procedures. For these individuals, health promotion supports self-management of the disease process as well as participation in community life. Health-related quality of life and other factors associated with HRQOL also may be addressed by interventions that focus at the systems level, as well as the individual level. For example, a health promotion intervention might target the establishment of programs or polices that increase the accessibility of the built environment (such as trails or public places) or address social environments (such as modifying negative attitudes).

Three Categories of Recommended Disability Comparative Effectiveness Research:

Category I: Rehabilitation Therapies and Treatments

Rehabilitation is a concept that has at its core, the promotion of the highest health, physical, psychologic, cognitive, vocational, educational, avocational, and social function possible consistent with the physiologic or anatomic impairment or environmental barriers for those with disabilities. There is a dynamic interplay among the many components of rehabilitation (e.g. medical and pharmacologic interventions, nursing, speech-language/occupational and physical therapies, education, orthotics and prosthetics, counseling, social service support, durable medical equipment, spiritual support, and vocational counseling), as the individual's condition stabilizes and skills develop. Realistic and practical goals are established, and usually change over the course of the disability evolution and the individual's lifetime. There may be a variety of sites of service and components of rehabilitation, based on medical and functional needs, which also change with time.

Rehabilitation and disability research has expanded the measurement instruments used to identify impairment and function levels (e.g. classification of spinal cord injury [ASIA], NIH Stroke Scale); burden of care (e.g. functional independence measure [FIM™]); barriers to

function, social interaction, or work involvement; and outcome measurements in the context of health, function, and societal participation. It has also become clear that people with disabilities assess their health, quality of life, and satisfaction within a different context than do those without disabilities (Drum et al, 2008; Palsbo, 2007).

Rehabilitation intervention research typically examines either very broad (e.g. timing of rehabilitation initiation, care settings, organizational milieus, the full array of rehabilitation care) or very specific intervention strategies (e.g. constraint induced therapy, intrathecal baclofen pump medication delivery, body weight support therapy, use of floor reaction ankle foot orthoses, neuromuscular electrical stimulation). It is difficult to assess discreet interventions, their timing or dosing, when they are delivered within a multidisciplinary, comprehensive program. However, efforts are now being made to examine individual services within the context of the full range of rehabilitation programs (LivnehH, 1989; DejongG et al, 2004). Also medical informatics offers a means to assess the benefit of individual services within the context of a multiple service program through the analysis of very large databases.

An area of rehabilitation intervention that is often overlooked is the dynamic rehabilitation medical demands in early or acute phases of disability onset or diagnosis, or in progressive or chronic conditions. These interventions focus on optimizing physiologic function (e.g. treatment of evolving agitation after brain injury, management of changing spasticity and tone with cerebral palsy) and addressing ongoing co-morbidities (e.g. hypertension and diabetes management following stroke) and medical issues (e.g. infection, neurogenic bladder, nutritional management with dysphagia) while supporting participation in the function-restorative rehabilitation process. People with lifelong disabilities should anticipate aging changes and susceptibility to secondary conditions, that may require acute and ongoing rehabilitation interventions. There are also transitions of care that require facilitation through the rehabilitation process. Those with acute onset disabilities or adults with childhood onset disabilities require support, education, and empowerment to be able to effectively manage their care or to determine someone with capacity to partner in achieving ongoing care.

Rehabilitation and disability science has established a sufficient core of knowledge during the past two decades, such that comparative effective research is now warranted.

Examples of suggested areas of CER are found in Appendix A.

Category II: Environmental Interventions: Assistive Devices and Technologies

Examination of the effectiveness of environmental modifications or interventions is needed to improve the health, physical function and participation of people with disabilities. Categories of environmental interventions include but are not limited to provision of assistive technologies, personal assistants, home modifications and community access.

The narrow focus on restorative rather than compensatory care is a well documented problem for people with chronic diseases and disabilities despite a growing consensus that the primary outcome measure of rehabilitation effectiveness is community participation. For millions of Americans with disabilities, assistive technologies (AT) are key environmental factors in helping them to return to or remain in their homes and communities. AT has been defined as "any item, piece of equipment, or product system whether acquired commercially or off the shelf, modified, or customized that is used to increase, maintain, or improve functional capabilities of people with disabilities" (Technology-Related Assistance for Individuals with Disabilities Act, 1988). Studies have found that provision of AT can enhance performance of self care activities, independent communication, work skills, mobility and community participation. However, comparative analyses of the differential effectiveness are limited since few currently used measurements assess AT use even for prevention of health conditions (e.g. skin ulcers, shoulder injuries, obesity, urinary tract infections, scoliosis).

Studies of different approaches to the provision of AT that enhances performance (e.g. advanced communication devices, lightweight manual wheelchairs, multifunction power wheelchairs, pressure sensitive seating cushions and advanced prosthetics) could provide guidance on the most effective approach to enabling people with significant disabilities to live in their homes and communities instead of in costly nursing homes. Advanced AT may help to reduce secondary conditions, improve the rate of people who return to work and allow people to remain in their homes. Assistive technology holds promise as a means of improving self-care and may reduce the need for both paid and unpaid help.

Examples of suggested areas of research for Category II are found in Appendix B.

Category III: Health Promotion and Wellness Interventions for People with Disabilities

It is only within the last decade or so that contemporary public health efforts such as the International Classification of Functioning, Disability and Health (WHO 2001) and the Surgeon General's Call to Action to Improve the Health and Wellness of Persons with Disabilities (USDHHS 2005) have resulted in broader recognition that disability is **not** equivalent to ill health and that people can experience disability and good quality health. Traditionally, public health approaches measure health outcomes in terms of reducing cases and symptoms of disease (reducing morbidity rates) and avoiding early deaths (reducing mortality rates). For example, children born with genetic or congenital anomalies and adults acquiring disabilities through injury or chronic disease are tallied within a morbidity count. Health promotion in this context focuses on primary prevention and views disability as incompatible with health and the ability to achieve health.

What is health promotion and does it differ in the context of disability? Last (2007, p. 159) defines health promotion as "The policies and processes that enable people to increase control over and improve their health. These address the needs of the population as a whole in the context of their daily lives, rather than focusing on people at risk for specific diseases, and are directed toward action on the determinants or causes of health." According to the Ottawa Charter for Health Promotion (World Health Organization, 1986), health promotion is the process of enabling people to increase control over, and to improve, their health. As adopted by the *(American Journal of Health Promotion (1989),*"Health promotion is the science and art of helping people change their lifestyle to move toward a state of optimal health. Optimal health is defined as a balance of physical, emotional, social, spiritual, and intellectual health. Lifestyle change can be facilitated through a combination of efforts to enhance awareness, change behavior and create environments that support good health practices. Of the three, supportive environments will probably have the greatest impact in producing lasting change."

These contemporary definitions of health promotion seem to have been developed precisely for people with disabilities rather than as a means of excluding them. Compared to the general population, people with disabilities experience important health differences such as lower levels of general health, higher levels of unmet health care needs, lower levels of preventive services,

and higher levels of preventable secondary conditions, chronic conditions, and early mortality. There are also recognized differences in health behaviors, including higher rates of cigarette smoking and lower participation in physical activity and exercise than the general adult population. It is also evident that the social determinants of health differentially impact people with disabilities, including socioeconomic determinants (e.g., education, income, and employment); psychosocial determinants (e.g., stress, social isolation, and level of control); and community and societal determinants (e.g., social support, community participation, and income inequality).

The challenge for health promotion in the context of people borne with or who acquire disabilities is to develop a better understanding of the reasons why people with disabilities experience health differences and to develop individual, systems, and policy level interventions that are effective in addressing the determinants of health.
Examples of suggested studies under Category III are found in Appendix C.

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APPENDIX A

Examples of CER in the area of Rehabilitation Therapies and Treatments

Attention Deficits in TBI: Methylphenidate vs. Attention Process Training

Nature of Problem or Research Question: Attention deficits are common after TBI across the spectrum of severity. There have been several behavioral/experiential approaches taken to attention retraining, and there has been considerable pharmacologic research. However, the multifaceted nature of attention and attention deficits and the small sizes of the studies conducted to date make it difficult to assess the differential effects of these approaches or the wisdom of combining them.

Impact/Utilization: Subtle attention deficits are among the most frequent complaints after mild TBI, and clinically obvious attention deficits are characteristic in moderate to severe injury. The most clearly described problems are slowness of information processing, difficulty with divided attention, and difficulty in maintaining attention to task in ongoing performance environments such as work.

Nominated Intervention (1): Methylphenidate

Summary of Research Findings to date: Methylphenidate is, of course, the leading agent for treatment of Attention Deficit (Hyperactivity) Disorder, and its benefit in that setting has been repeatedly replicated. The literature in TBI is smaller, with no large multicenter parallel group trials conducted to date. However, there have been several small but well controlled studies by Whyte, et al, and Willmott et al, with very consistent findings of efficacy in particular subdomains. In particular, speed of processing, caregiver ratings of attentiveness, and individual work productivity, have been seen to respond to drug in these studies.

Nominated Intervention (2): Attention Process Training

Summary of Research Findings to date: Attention Process Training is the most well described and extensively studied behavioral/experiential treatment of attention deficits after TBI. Developed by Sohlberg and Mateer and distilled into a treatment manual, the treatment focuses on exercises that "stress" specific attentional domains, but also includes a considerable amount of "metacognitive coaching" from the therapist to help the patient identify situations that are susceptible to attentional lapses and strategic compensations to be employed. APT has been evaluated in several pre-post designs, and impact appears to be less when compared to an untreated control group. However, there do appear to be process-specific benefits. That is, APT appears to have greater impact on strategic aspects of "Executive Attention" than simple vigilance or processing speed domains.

In summary, there is moderately strong support for both forms of attention treatment, but a suggestion that their primary impacts may appear in different facets of the complex array of attentional functions. Ultimate clinical recommendations, therefore, may be in the form of

defining which outcomes are most powerfully affected by which treatment in which patient subgroups.

Proposed Study Design:

Design: Parallel 3-group design with an APT group, a medication group, and a combined medication and APT group. Further discussion is needed regarding the control condition(s). It would be very difficult and expensive to create a "sham APT" treatment, since the treatment would need to be plausible to patients and therapists, distilled into a manual, and yet unlikely to have positive effects on attentional function. The best compromise may be to use placebo and active methylphenidate, but to have "open-label" APT.

Sample (include target disability group, age group) Adults with self-reported or clinician-reported attention deficits and a history of moderate to severe TBI .

Inclusion/Exclusion: Individuals with moderate to severe TBI > 6 months post-injury with persistent complaints related to attention. Individuals would be excluded for significant cardiac disease or uncontrolled hypertension that would make treatment with methylphenidate unwise, for a history of stimulant abuse, for concurrent treatment with drugs that would antagonize the effects of methylphenidate or make its administration unsafe, for language comprehension deficits that would preclude active participation in APT, for severe memory impairment that precludes retention of learned strategies, or for severe behavior problems that prevent participation in treatment.

Timeline: Depends on how many centers included. Subjects would be treated in 8 week blocks, but would have an additional follow up assessment at 12 weeks (i.e., 1 month follow up).

Data Collection Plan Anticipated: Subjects screened and enrolled in 8-week program. APT program delivered in 2-hour blocks 3X/week in an outpatient setting. Methylphenidate given at dose of .3 mg/kg BID. Baseline assessment conducted with a neuropsychological test battery of attention and speed of processing measures, as well as observational rating scales (Rating Scale of Attentional Behavior, Moss Attention Rating Scale, and the Cognitive Failures Questionnaire). Follow up at 4 weeks, 8 weeks, and 12 weeks (4 weeks after completing treatment).

Data Analysis Plan Anticipated: Primary outcome would be a composite score (average of ranks across measures or average of z scores across meausures) based on the attentional rating scales, since these ratings bear the strongest relationship to real-world benefits. This would be Kruskal-Wallis comparison of the 3 treatment groups. Secondary analyses would involve assessment of treatment effects and effect sizes in each of the neuropsychological measures, as well as drop outs and adverse events, with particular attention to the possibility of differential domains of maximal treatment response for the 2 treatments. Specifically, we would predict that the drug may produce greater effects on speed of processing, whereas the APT may produce

greater benefits in executive attention measures and specific improvement on the Cognitive Failures Questionnaire.

Feasibility Assessment:

Threats to Implementation: subject recruitment, hiring and/or training therapists to deliver the APT.

Threats to study completion: subject recruitment

Potential Threats to Generalizability: exclusion of patients on many medications, patients with coexisting impairments.

Comparison of Compensatory and Restorative Remediation for Attention Deficits after Traumatic Brain Injury

Impact/Utilization: The proposed research will evaluate interventions derived from two different theoretical models proposed to underly the rehabilitation of cognitive impairments after TBI. The research will impact the field on several levels: (1) comparison of theoretical models of improvement based on either compensation / adaptation to deficits vs. neuroplasticity / restoration of function. (2) comparison of different instructional components based on increasing metacognitive regulation and strategy use through distributed learning and error management, versus reliance on massed practice and errorless learning. (3) comparison of different service models, requiring specialty trained therapists versus automated, computerized interventions with minimal therapist involvement. The study will have implications for understanding the mechanisms of action of treatment as well as practical issues related to portability and service delivery.

Nominated Intervention (1): Compensatory attention and metacognitive strategy training.

Summary of Research Findings to date: A combination of direct attention training and metacognitive training to develop compensatory strategies for attention deficits after traumatic brain injury (TBI) is currently considered a "practice standard" within the field of cognitive rehabilitation. Sohlberg et al [1] used a crossover design to compare the effectiveness of "attention process training" (APT) brain injury education and support for 14 patients with acquired brain injury. Self-reported changes in attention and memory functioning as well as improvement on neuropsychological measures of attention-executive functioning were greater following APT than following therapeutic support. Another RCT [2] investigated the effectiveness of APT and cognitive-behavioral psychotherapy for participants with persisting complaints after mild or moderate TBI. Participants in the active treatment group demonstrated improved performance on a measure of complex attention and reduced emotional distress compared with the no-treatment control group, although there was no effect of treatment on community integration. Another RCT [3] taught 22 patients with severe TBI to compensate for slowed information processing and the experience of "information overload" in daily tasks. Participants were randomly assigned to receive either "Time Pressure Management" (TPM) or an alternative treatment of generic "concentration" training. Participants receiving TPM showed significantly greater use of self-management strategies and greater improvement of attention and memory functioning compared with participants who received the alternative treatment. Several observational studies have reported success in the use of interventions developed to address the central executive component (CE) of working memory. [4, 5] Both of these latter studies emphasize the development of compensatory strategies to manage processing demands, and training in the application of this intervention approach to participants everyday functioning. Thus, although the precise nature of

the interventions in all of these studies differ, they share a common emphasis on the combination of direct attention training and metacognitive training, and the development of strategies to compensate for residual cognitive deficits ("strategy training") rather than attempting to directly restore the underlying impaired function ("restorative training").

Nominated Intervention (2): Computerized, restorative attaining training.

Summary of Research Findings to date: There is an emerging science and body of evidence documenting neuroplasticity in the adult brain, and a corresponding interest in developing and evaluating cognitive interventions that promote neuroplasticity as a means of restoring function. One small RCT developed also interventions based on the central executive operations of working memory, and compared this with a general stimulation approach. [6] Improvements in cognitive functions dependent on the CE as well as reduced cognitive symptoms were noted after CE training but not general stimulation. These gains were attributed to the effects of "massive practice" on CE tasks and the recovery of the underlying attentional functions, which then generalized to related cognitive operations and daily functioning. Another RCT used automated, computerized training on various working memory tasks to treat the cognitive deficits of 18 adults after stroke. [7] The intervention was based on intense, systematic practice with minimal therapist involvement, [8] under the assumption that the training leads to increased cortical activation and restoration of the underlying function. [9] This study again demonstrated gains on several measures of working memory as well as a reduction in cognitive symptoms.

Proposed Study Design:

Design: RCT

Sample (include target disability group, age group) Adults with TBI, 18 to 60 years old, minimum 6 months post injury

Inclusion/Exclusion: will include formal assessment of pre-treatment cognitive functioning. Treatment compliance will be assessed as a study variable.

Timeline. 8 week intervention period with 3 month follow-up.

Data Collection Plan Anticipated. Pre-post and follow-up testing of cognitive functioning to include working memory storage and working memory manipulation tasks; other attention, memory and executive tasks; subjective complaints. Potential for subset of participants to be evaluated with fMRI.

Data Analysis Plan Anticipated. Mixed model MANOVA

Feasibility Assessment:

Threats to Implementation. Recruitment of appropriate subjects; ability to control for other simultaneous treatments received.

Threats to study completion. Recruitment and retention of subjects

Potential Threats to Generalizability: Intervention arms may be conducted within specialized rehabilitation research centers.

Comparative Effectiveness Research Proposal for Autism Interventions

Nature of Problem or Research Question

There is empirical support demonstrating the efficacy of a range of approaches for enhancing the communication skills of individuals with autism spectrum disorders (ASD) (Dawson & Osterling, 1997; NRC, 2001; Prizant & Wetherby, 1998; Rogers, 1998). However, there are no large-scale studies directly comparing the effectiveness of different approaches using randomly assigned, matched control samples with sufficient sample sizes and adequate statistical power. Therefore, evidence that any one approach is more effective than another approach is not available to date. The proposed research question offers a comparison of different intervention approaches and suggests outcome measures that are ecologically valid. Specifically, they measure meaningful changes within natural learning environments and across natural communication partners and address the core deficits of autism—communication and social interaction (National Research Council, 2001):

> **Compare the effectiveness of social interaction approaches versus highly structured behavioral approaches on the verbal, social and nonverbal functional communication skills of preschool children with autism spectrum disorders, in terms of (a) gains made in the frequency of self-initiated spontaneous communication during functional activities and (b) the generalization of gains made across activities, interactants, and environments.**

Impact/Utilization

Comparative effective research should deepen our understanding of the types of intervention approaches that provide the most meaningful communication and social interaction outcomes for with young children with autism. Given that the core features of ASD revolve around social communication and language use, the field of speech-language pathology has much to contribute to future research evaluating the comparative effectiveness of approaches to treating social, communication, and cognitive impairments in ASD.

Nominated Intervention

There are many different intervention approaches that have been used for individuals with ASD. Programs differ in how goals are prioritized and the techniques used to target goals. Some programs rely heavily on singular strategies, while others are more comprehensive or eclectic. Most important is how the environment and instructional strategies support individualized goals and objectives for the individual with ASD and his or her family and other communication partners (NRC, 2001).

The major approaches currently in use are highly structured behavioral approaches (e.g., Applied Behavioral Analysis approaches) and more social interactive developmental approaches, such as (e.g., Social Communication Emotional Regulation Transactional Supports (SCERTS) and Developmental, Individual Differences, Relationship Based approach (DIR).

Summary of Research Findings to Date

Massed discrete trial methods, based on the theory of applied behavioral analysis (ABA) have been used with children with autism to teach verbal behavior (Lovaas, 1987; see summary by Koegel, 1995). Applied behavior intervention is intensive, with 30 to 40 hours of one-on-one intervention recommended on a weekly basis. Recently, a systematic review of the efficacy of applied behavior intervention was conducted with preschool children (18 months to 6 years) with autism. Outcome measures were cognition, language, and adaptive behavior (Spreckey & Boyd, 2009). Four studies had adequate data and were of sufficient quality to be included in a meta-analysis. Results of the meta-analysis did not demonstrate significant improvements in any of the outcome measures compared to other interventions for preschool children with autism. A clear need for more controlled clinical trials with additional outcomes (e.g., addressing family functioning) was demonstrated.

A major limitation of a discrete trial approach for language acquisition is the lack of spontaneity and generalization. More contemporary behavioral approaches use more naturalistic teaching methods for teaching speech, language, and communication, such as natural language paradigm (R. L. Koegel, O'Dell, & Koegel, 1987), incidental teaching (Hart, 1985; McGee, Krantz, & McClannahan, 1985; McGee, Morrier, & Daly, 1999), time delay and milieu intervention (Charlop, Schreibman, & Thibodeau, 1985; Charlop & Trasowech, 1991; Hwang & Hughes, 2000b; Kaiser, 1993; Kaiser, Yoder, & Keetz, 1992), and pivotal response training (L. K. Koegel, 1995; R. L. Koegel, Camarata, Koegel, Ben-Tall, & Smith, 1998; Whalon & Schreibman, 2003).

There are only a few studies, all using single-subject design, that have compared traditional discrete trial with naturalistic behavioral approaches. These studies have reported that naturalistic approaches are more effective at leading to generalization of language gains to natural contexts (R. L. Koegel et al., 1998; R. L. Koegel, Koegel, & Surratt, 1992; McGee et al., 1985).

Other intervention approaches also incorporate naturalistic behavior approaches and are more comprehensive and are consistent with a social interactive and developmental approach to intervention: Social Communication Emotional Regulation Transactional Supports comprehensive educational model for children with ASD (Prizant, Wetherby, Rubin, Laurent, & Rydell, 2003, 2006) and Developmental, Individual Differences, Relationship Based approach (DIR). Although the empirical support for developmental approaches is more limited than for behavioral approaches, there are a growing number of research studies that provide support for using developmental strategies (Aldred, Green, & Adams, 2004; Hwang & Hughes, 2000b; Lewy & Dawson, 1992; Mahoney & Perales, 2005; Rogers & DiLalla, 1991; Rogers & Lewis, 1989), and there are many case studies, with Greenspan and Wieder (1997) being the largest case

review. Developmental approaches share many components of contemporary naturalistic behavioral approaches and are compatible along most dimensions (Prizant & Wetherby, 1998).

Proposed Study Designs

- Single-subject cross-over designs to further investigate efficacy in specific populations not previously studied*
- Group designs comparing these approaches to further investigate generalization in specific populations not previously studied
- Random assignment, matched control samples, double-blind clinical trial

*Single-subject designs may be provide evidence of efficacy or effectiveness through multiple replications (Odom, Brown, Frey, Karasu, Smith-Canter, & Strain, 2003).

Inclusion Criteria
Preschool children with ASD

Exclusion Criteria
Preschool children with ASD with significant intellectual/cognitive challenges

Timeline
Two-to-Five years

Feasibility Assessment
The literature already contains investigations attesting to feasibility but further feasibility efforts may be needed for some sub-groups of pre-school children with autism.

Threats to implementation
Ensuring treatment fidelity (as well as collecting data to evaluate treatment fidelity)

Threats to study completion
Recruitment and retention of subjects
Requires agreement to participate by parents. Requires randomization to different treatment approaches.

Potential Threats to Generalization
Heterogeneity of population
May not generalize to older population

Comparative Effectiveness Research Proposal for Oropharyngeal Dysphagia

Nature of Problem or Research Question

Many patients with neurological conditions experience dysphagia as a result of neurologic illnesses or injuries such as traumatic brain injury, stroke or Parkinson's disease [1-3]. Speech-language pathologists (SLPs) trained in dysphagia management play an integral role in the evaluation and treatment of swallowing disorders for adults with neurologically induced dysphagia. The type of treatments provided by SLPs to improve swallowing function depends on the cause, type and severity of dysphagia as well as other factors such as the extent to which the patient can attend, follow directions, and comply with the SLPs instructions, especially when eating alone. Evidence concerning the efficacy of behavioral treatment approaches for individuals with neurologically-induced dysphagia is accumulating but much more research is needed to determine the best interventions for each of the various patient groups as determined by the etiology, dysphagia symptoms, and other case mix factors. Although at present, there are a limited number of studies, there is some positive evidence for the efficacy of these treatments on various swallowing outcomes. Treatment to improve disordered oropharyngeal deglutition has traditionally centered on behavioral interventions, with the intended purpose of facilitating safe and efficient oral feeding. Behavioral therapeutic approaches have been used clinically by SLPs trained in dysphagia management [4] for over 20 years and include posturing of the head and neck, physical maneuvers altering oral and pharyngeal physiology, tactile, thermal and electrical stimulation, oral and facial exercises, and diet modifications [5]. The goal of postural treatments is to alter the flow of the bolus by repositioning the body, head and/or neck prior to the onset of the pharyngeal phase of the swallow, with maintenance of the position until the swallow was completed. Postures included the *side lying* posture, *chin tuck*, or neck flexion posture, and the *head rotation* posture. Maneuvers were defined as volitional movement of the oral, pharyngeal, or laryngeal structures before or during the pharyngeal phase of the swallow that are intended to increase swallow force, or alter airway protection mechanisms. Maneuvers included in the present proposal include the *effortful swallow* maneuver, the *Mendelsohn* maneuver, *supraglottic* maneuver, and the *super supraglottic* maneuver. In constructing the clinical questions, various outcomes should be considered. Outcomes can be classified in terms of effects on *swallow physiology* (e.g. timing, efficiency, pressure and elimination of aspiration); *functional swallow ability* (e.g. oral feeding and quality of life); and *health* outcomes (e.g., weight and nutritional status, and the incidence of adverse outcomes such as aspiration pneumonia and immunocompromised health conditions).

To date, there have been a number of published guidelines and evidence-based systematic reviews (EBSRs) focusing on dysphagia within various populations and treatment settings [6-9]. The seven behavioral treatments being proposed as the focus of this comparative effectiveness proposal are three postural interventions (side lying, chin tuck and head rotation) and four

swallowing maneuvers (effortful swallow, Mendelsohn maneuver, supraglottic swallow and super supraglottic swallow).

The specific question to be addressed is:

For patients with neurological disorders and evidence of oropharyngeal dysphagia, what is the comparative effectiveness of postural techniques (i.e. the *side lying* posture, *chin tuck*, or neck flexion posture, and the *head rotation* posture) versus volitional swallowing maneuvers (i.e., effortful swallow, the Mendelsohn maneuver, supraglottic swallow or super supraglottic swallow) as delivered by SLPs trained in dysphagia management on swallowing physiology, functional swallow ability, and health outcomes?

Impact/Utilization

Common etiologies of dysphagia include cerebrovascular accidents (CVAs), traumatic brain injuries and degenerative neurological diseases. These conditions often cause oropharyngeal dysphagia and can lead to serious and life threatening consequences such as aspiration pneumonia, malnutrition and immunocompromised health. Data from the Agency of Health Care Policy and Research (1999) report an estimated 300,000 to 600,000 individuals each year exhibited some form of dysphagia as a result of neurological illnesses or injuries [1]. Kuhlemeier [11] reports that dysphagia is a frequent complication of cerebrovascular accidents. An incidence rate of 37% to 78% has been reported for this population [12]. Moreover, findings from the American Speech-Language-Hearing Association's (ASHA's) National Outcomes Measurement System (NOMS) indicate swallowing as the most commonly treated disorder for individuals with neurological diagnoses [13]. NOMS data reveal that 47.6% of patients receiving SLP intervention in healthcare settings are being treated for dysphagia secondary to neurological diagnoses; the majority of whom (66.8%) make measurable functional progress in swallowing ability after receiving SLP services [2]. The primary aim of SLP intervention is to reduce the risk of aspiration and improve swallow function for safe and efficient oral intake [14]. To do this, SLPs employ a number of behavioral therapeutic approaches, including the use of compensatory swallowing postures and/or swallowing maneuvers. Increasing our knowledge concerning *what works best for whom* is much needed to reduce the incidence of avoidable adverse effects associated with oropharyngeal dysphagia secondary to neurological conditions.

Nominated Interventions

<u>Postural techniques</u>

- *side lying* posture, *chin tuck,* or neck flexion posture, and the *head rotation* posture

<u>Volitional swallowing maneuvers</u>

- effortful swallow, the Mendelsohn maneuver, supraglottic swallow or super supraglottic swallow

Summary of Research Findings to Date

According to the five-phase model of investigating clinical outcomes for behavioral interventions developed by Robey [15] prior to introducing interventions as treatments for specific patient groups, it is necessary to establish the existence of an intervention effect, and determine if that effect is sufficient to warrant further testing. Establishing such an effect in the case of oropharyngeal dysphagia begins with defining the physiologic changes that occur during the treatment; this identifies the ability of the treatment to modify function, and establishes a knowledge base from which to formulate hypotheses regarding the potential effects the treatment may have on specific types of disorders. Physiologic changes can include changes in oral or pharyngeal pressures, duration and timing of swallow events, structural movement or displacement, and muscle activation.

A systematic search conducted by the National Center for Evidence-based Practice at the American Speech-Language-Hearing Association of the peer-reviewed literature published between 1985 and 2008 yielded 17 studies which met predetermined inclusion criteria (cite article in press). Of those studies, five examined postural techniques [16,17,18,19,20] and 13 examined swallow maneuvers [16,18-32]. Five studies provided data to address swallowing postures. Of those, three studies investigated the chin tuck [20, 22,23] and two examined the use of head rotation [18,19]. Thirteen studies provided data addressing swallowing maneuvers with the majority (62%, 8 of 13) investigating the effortful swallow intervention [22,25-28,30-32]. Three studies examined the Mendelsohn maneuver [21,24,29], three examined the supraglottic swallow [21,22,33], and three examined the super supraglottic swallow [20,21,33]. Physiologic variables which were addressed by these studies fell into one of four categories, including oral or pharyngeal pressures, duration and timing of swallow events, structural movement or displacement, and muscle activation. The body of literature included in this systematic review collectively indicates that there is physiologic evidence to support existing hypotheses regarding the role of behavioral interventions in treating specific aspects of oropharyngeal dysphagia.

Proposed Study Designs

- Single-subject cross-over designs to further investigate efficacy in specific populations not previously studied
- Group designs comparing these approaches to further investigate generalization in specific populations not previously studied
- Random assignment, matched control samples, double-blind clinical trial

Inclusion/Exclusion

Inclusion criteria: Patients with a diagnosis of oropharyngeal dysphagia secondary to a neurological condition.
Exclusion criteria: Patients with moderate or severe cognitive impairments affecting compliance.

Timeline
Two-to-Five years

Feasibility Assessment
The literature already contains investigations attesting to feasibility, but as not all settings and populations are represented, further feasibility study may be warranted.

Threats to implementation
Maintaining double-blinding
Ensuring treatment fidelity (as well as collecting data to evaluate treatment fidelity)

Threats to study completion
Recruitment and retention of subjects

Potential Threats to Generalization
Heterogeneity of population (even within a given diagnosis)

Comparing Physical Therapy Interventions for Treating Chronic Pain Among People with Disabilities

Nature of Problem or Research Question:

Chronic pain is consistently listed among the most common secondary conditions reported by people with mobility impairments (1-3). While treatment of pain conditions has a strong evidence base, there has been little comparative effectiveness research on evidence-based treatments for people with disabilities. One of the key strategies for treating chronic pain is physical therapy; however, long-term maintenance of chronic pain requires ongoing physical activity (4). This study will examine the incremental cost-effectiveness of providing regular physical activity following standard physical therapy to manage pain reported by individuals with mobility impairments.

Impact/Utilization: Study results will help to determine the value of providing access to regular physical activity services for people with mobility impairments.

Nominated Intervention (1): Physical Therapy

Physical Therapy including modalities such as ultrasound, heating and icing, massage and physical activity are standard components of pain management (4)(5).

Summary of Research Findings to date:

Physical therapy has consistently shown effectiveness in reducing pain (6, 7) across health conditions.

Nominated Intervention (2): Physical Therapy supplemented with physical activity.

Summary of Research Findings to Date: Clinical practice (8), correlational studies (9) and intervention trials all support the efficacy of physical activity (10, 11) for managing chronic pain among people with diverse health conditions.

Proposed Study Design: A multi site randomized controlled trial with repeated measures. Subjects will be randomly assigned to either physical therapy alone or physical therapy with a supplemental physical activity program.

Sample: People with disabilities ages 18-70

Exclusion: People with co morbid psychiatric conditions other than depression.

Timeline: 2- year cost-effectiveness study with 6-months post-intervention follow-up data collected.

Data Collection Plan: Self-report staggered baseline design with pre-, post-, and 6-month follow-up.

Data Analysis Plan Anticipated: Repeated measures analysis of variance

Feasibility Assessment: *Threats to Implementation* - Effective randomization and subject recruitment. *Threats to study completion*- subject attrition.

Potential Threats to Generalizability: Treatment protocols will be controlled for the study to detect any incremental effectiveness of proving physical activity. Hence, the degree to which the model reflects actual clinical practice will affect generalization of results.

Comparison of the outcomes and length of speech-language pathology services when benchmarked NOMS data or individualized estimates are applied to care planning

Interventions compared: The study compares the services needed and outcome achieved for Medicare beneficiaries when a speech-language pathologist plans goals and amount of services while using, or not using, the American Speech-Language Hearing Association's (ASHA) National Outcomes Measurement System (NOMS) predictive data to identify the services and outcomes for similar patients.

Background: The Adult Component of the NOMS collects communication or swallowing function measurements according to a series of seven-point scales called Functional Communication Measures (FCM). Speech-language pathologists (SLP) are certified to reliably administer the measures. Functional gain is determined by the difference in an FCM score from admission to discharge. These data, in turn, provide clinicians with national comparisons on which to base clinical decisions. However, utilization of the benchmarks in planning or treatment is thought to vary greatly across SLPs and facilities.

In 2005, The Centers for Medicare and Medicaid Services issued Benefit Policy Manual instructions for outpatient therapy services that required documentation of improvement during treatment.[1] The NOMS was the only tool that met the criteria for measuring speech-language disorders: established psychometrics, clinical utility, ability to use computer interfaces, acceptance by therapists, and ability to provide predictive data.

In 2007, the Centers for Medicare and Medicaid Services established a research project titled "Developing Outpatient Therapy Payment Alternatives" (DOTPA). The purposes of this 5 year project are to identify, collect, and analyze therapy-related information tied to beneficiary need and the effectiveness of outpatient therapy services. The ultimate goal is to develop payment method alternatives to the current financial cap on outpatient therapy services.

In 2008, CMS contracted with Computer Sciences Corporation for a study titled Short Term Alternatives to Therapy Services (STATS). Before October, 2010, this project is tasked to: Collect and analyze quarterly and annual claims data; partner with stakeholders in analysis of utilization, policies, and clinically appropriate limitations or guidelines that may be used to develop options for short term alternatives to therapy caps.

The proposed research project would complement both of these projects by using electronic data collection and by focusing exclusively on outcomes measurement. This study creates a platform for linking appropriate payment to necessary services, and for reporting quality measures.

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[1] Medicare Benefit Policy Manual, Chapter 15, sections 220.3.

Impact/Utilization: If benchmarking information improves care planning, it would be likely to affect not only the estimated half million Medicare beneficiaries treated annually by speech-language pathologists, but all of their patients. Clinicians would be motivated by better outcomes to utilize this data and they could rely on the data to justify appropriate services.

NOMS is the only tool for speech-language pathology services that is approved by the National Quality Forum and is part of the National Quality Measures Clearinghouse. It is available without cost to speech-language pathologists. Since there is little financial incentive to the tool sponsor, this study addresses a question that is unlikely to be addressed through other funding mechanisms.

The comparison of NOMS outcomes to Medicare claims results will create a unique database with potential for valuable future research relevant to creation of patient registries, comparative study of the effect of treatment choices, and affect on utilization.

Nominated Intervention (1): National Outcomes Measurement System

Summary of Research Findings to date:

The Adult component of NOMS (the National Outcomes Measurement System) has been collecting data on over 220,000 patients since late 1998. Communication or swallowing function is measured according to a series of seven-point scales called Functional Communication Measures, which were endorsed by the National Quality Forum in 2008, and added to the National Quality Measures Clearinghouse in 2009.

The American Speech-Language Hearing Association has unpublished research data on this tool which they will share as requested.

In 2004, the NOMS was used to identify changes in patient care following the introduction of the Inpatient Rehabilitation Facility Prospective Payment System for Medicare beneficiaries.[2] The study found that following introduction of the IRF PPS

more patients with cognitive, communication, and swallowing disorders were discharged from inpatient rehabilitative care with less than adequate functional skill levels.

Nominated Intervention (2): Control Group tested with NOMS but treated without knowledge of the NOMS test results.

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[2] Frymark, Tobi B., Mullen, Robert C., *Influence of the Prospective Payment System on Speech-Language Pathology Services.* Am.J. Phys. Med. Rehabil. December, 2004, Vol. 83, No. 12, Pg 1-10.

Nominated Intervention (3): Control Group treated without performance of NOMS.

Proposed Study Design: Identify a sample of providers or suppliers of services who will utilize the NOMS, provide one group with benchmarking information to use in care planning. Identify a control group not utilizing NOMS. Match the patient characteristics. Analyze the NOMS groups for known group construct validity, sensitivity to change, responsiveness and feasibility (practicality, ease of use, frequency of use). Compare outcomes, service utilization and cost of treatment when NOMS is performed and benchmark information is utilized in planning to a similar group where benchmarks are not utilized. Compare services utilized and cost when NOMS is not performed.

Sample: Medicare beneficiaries age 65 and over with communication and swallowing disorders.

Inclusion/Exclusion

- Include all Medicare beneficiaries with SLP disorders in clinic in study groups

Timeline: 18-24 months

Data Collection Plan Anticipated

- Identify providers/suppliers who are using NOMS by using tool sponsor contact information.
- Obtain Data Use Agreements, extract processed claims data from CMS Data Repository.
- From the universe of Medicare therapy claims, identify controls with similar characteristics to those beneficiaries whose therapists utilized NOMS with benchmark information.
- Collect initial and discharge information using NOMS on both sample groups. Collect utilization and cost data from control group.
- Match Medicare claims data to clinical data.
- Develop chart review and interview procedure (for feasibility measure).

Data Analysis Plan Anticipated

- Compare the study to the control group for functional outcome, number of visits, number and type of services, episode length in calendar days, recidivism, allowed charges, paid amount.
- Determine differences in the type, and number of treatment techniques, value of tools to treatment planning, burden of tools.
- Prepare and present Report.

Feasibility Assessment:

Threats to Implementation

Therapists may have but not use the information on cohort expectations.

Threats to study completion

Difficulty obtaining cooperation of provider/suppliers who are NOT using the target tools without an incentive.

Potential Threats to Generalizability:

- The Medicare population, while large, differs in some respects from the geriatric population of the nation as a whole.

- Some of the therapists who have not utilized a tool to identify cohort expectations may have a level of training and expertise that allows them to effectively estimate expectations without use of the tool.

Comparative Effectiveness of Neuromuscular Hyperactivity Non-Responders Receiving Locomotor Training

Overview

The NeuroRecovery Network (NRN)* consists of specialized Centers at 7 rehabilitation sites in the U.S. that provide a standardized Locomotor Training (LT) program designed from scientific and clinical evidence for recovery of posture, standing and walking and improvements in health and quality of life in individuals with spinal cord injury (SCI). This program admits patients with incomplete SCI (AIS C and D) whose spasticity medications are titrated to only require an evening dose at bedtime. There have been a group of patients who demonstrate such high muscular activity ("non-responders") demonstrating dominant flexor, dominant extensor, or combined patterns where LT becomes difficult to provide consistently and with appropriate intensity. The question posed is whether treatment FES cycling in combination with LT compared to antispasticity medications in combination with LT would reduce the degree of neuromuscular hyperactivity and thus improve walking outcomes. The impact and utilization of providing evidence to answer this question would be improved walking outcomes for a greater number of the more severely affected patients. These patients are sometimes either too difficult to wean from anti-spasticity medications and consequently not admitted into the NRN program due to the physical challenges of rendering LT.

All patients would receive standardized LT as provided throughout the NRN and would be randomized into 1 of the 2 nominated treatments (described below). A standardized LT session includes *step training* that is comprised of task specific retraining for standing and walking on a treadmill using a harness to provide BW support with verbal and manual facilitation, *overground assessment* that transfers the current capacity in mobility, posture and walking skills to over ground and establishes priorities for further retraining, and finally *community integration* that provides instruction on daily activities in the home and community environments. Treatments follow the LT principles and are also progressed in a standardized way.

Nominated Intervention (1):

Functional electrical stimulation (FES) cycling will be initiated for 30 minutes before the LT session (1.5 hours) to total a 2 hour intervention 3-5 days a week. The frequency of LT is dependent on the level of independence of proximal to distal segments in producing functional activities. Research Findings to date: To date, evidence has supported the use of LT and FES cycling alone in single subjects and small samples and not in combination and not for individuals with moderate to severe spasticity. This study will be the first to evaluate the impact of cycling on the reduction of spasticity and improvement of waking outcomes.

Nominated Intervention (2):

Steady state anti-spasmodics (e.g. Baclofen) as opposed to the standardized LT selection criteria requiring patients to be weaned of these medications. Patients would continue to receive their existing level of anti-spasmodics or be placed on these medications if medically appropriate, throughout their LT program.Studies have implicated that anti-spasmodics may inhibit spinal neuroplasticity however not study to date has examined if these medications inhibit recovery of walking in combination with LT. Our proposed study will examine walking outcomes while spasticity medications remain.

Proposed Study Design:

This will be an RCT which will screen, select and enroll a minimum of 42 individuals with incomplete SCI (ISCI), AIS C and D. Subjects will be enrolled from all 7 NRN centers who demonstrate significant spasticity on the modified Ashworth scale (Grades 3 or greater) in at least 2 muscle groups bilaterally. Participants must have finished their rehabilitation and currently not receiving any physical rehabilitation. Subjects will be tested for walking outcome measures before the study intervention begins, every 20 sessions, at discharge and 6 months later. The walking outcome measures include the 6 minute walk, 10 M walk, step length and time, gait speed, and the SCI functional assessment inventory. Repeated measures ANOVA will be used to evaluate change in the walking outcome measures and covariates such as injury level, AIS level, time since injury, age and will be explored. The termination of treatment is based on a discrete discharge algorithm where no improvements in key areas require clinical discharge. If insurance support is denied, grant funds would be encumbered to allow patients to continue until no further change is evident.

Feasibility Assessment:

There may be some challenges to implementing this study in identifying patients willing to commit the time for LT in combination with the 2 nominated interventions. Therefore, the compliance may be somewhat diminished. Other challenges may include the physical demand of rendering LT if the 2 nominated treatments do not alter the spasticity. Recruitment may also be challenging however requiring only 6 patients/site/year should be a reasonable. The treatments proposed should be generalizable given clinics have access to supported walking and FES cycling equipment.

High-repetition doses of task-specific training to improve upper extremity activity and participation

Nature of Problem or Research Question:
Stroke and brain injury are major health problems in the United States. Nearly 800,000 new strokes occur each year, and 50% of stroke survivors have persistent dysfunction that disrupts their ability to participate in home and community life. As soldiers return home from conflicts overseas with traumatic brain injuries, and fewer people die from acute strokes or brain traumas as a result of improved acute care, the number of people living with disability after brain injury is rapidly increasing.
Innovative approaches to rehabilitation are needed to reduce the disabling consequences of stroke and brain injury. Neuroscience and rehabilitation findings are now converging to suggest that extended, task-specific practice is critical for producing lasting changes in motor system networks, motor learning, and motor function. Our recent work, however, shows that there is little use of the upper extremity after stroke and little task-specific practice during neurorehabilitation. In our observational studies, people with stroke or traumatic brain injury performed < 50 repetitions of task-specific practice during therapy sessions. In comparison, animal models of stroke and human motor learning studies employ 300-600 repetitions of task-specific practice per session. This discrepancy in the dose of task-specific practice is cause for concern because recent clinical trials suggest that dose of practice may be the key factor in optimizing motor recovery in a variety of neuromuscular conditions. If the remarkable plasticity of the nervous system is to be harnessed to improve motor rehabilitation, then we must provide an adequate stimulus (i.e. adequate dose of practice) to people with stroke and brain injury. We propose to translate the high-repetition doses of task-specific upper extremity training used in animal models to the human experience of stroke.
Impact/Utilization:
This project will contribute to a new understanding of the dose of movement practice that can be tolerated and if high doses of task-specific practice will stimulate better outcomes. A major advantage to our approach is that, if effective, it could be economically implemented in any setting in a very short period of time. Clinics would not need to purchase expensive equipment (e.g. robotics) and therapists would not need to undergo extensive training. This means that our approach could be implemented in all types of clinics, not just those affiliated with academic medical centers.
The long-term goal of this line of research is to improve functional outcomes in neurorehabilitation by determining optimal dosing of task-specific practice. As new advances in cell replacement therapies and pharmaceutical interventions for neurological injuries proceed, our work on investigation of dose will be critical. These new advances will not be beneficial on their own but will need to be paired with an optimal training program. We aim to develop this training program now, so that it is ready as new advances emerge.
The importance of understanding dosing transcends the upper extremity, the motor domain, and stroke and brain injury. Investigations into optimal dosing are needed for all movements and for all domains of neurorehabilitation. Our results will have profound implications for motor rehabilitation aimed at improving function and minimizing disability in people with other disorders/conditions, such as cerebral palsy, spinal cord injury, and multiple sclerosis.
Nominated Intervention:

The intervention is 300-400 repetitions of task-specific upper extremity training in one hour sessions, 3 days/week. The intervention is individually-tailored to each participant, so that practiced tasks match the activity and participation goals of the individual. The chosen activities are graded to challenge the capacity of the participant and difficulty is progressed according to established motor learning principles. As designed, the intervention can be provided within the current delivery system of outpatient neurorehabilitation services.

Summary of Research Findings to date:

Our pilot work indicates that this high-repetition intervention is feasible and beneficial in 10 people with chronic (> 6 months) stroke. The high number of repetitions of task-specific training is achievable, as indicated by average numbers of repetitions per session that were > 300 for all subjects. Participating in the intervention did not result in negative consequences such as pain (e.g. shoulder pain from doing large amounts of activity) or undue fatigue. Changes in upper extremity activity, as measured by the Action Research Arm test, were greater than the estimated minimal clinically important change in the majority of subjects and greater than the published average changes due to Constraint Induced Movement Therapy. More importantly, participation in daily life, as measured by the Activity Card Sort and the Canadian Occupational Performance Measure, had improved at the end of the 6 week intervention and at the 1 month follow-up.

Proposed Study Design:

We propose a single-blind, randomized, controlled trial with a repeated measures design. Benefits of high repetition doses will be compared to the benefits of standard rehabilitation care, where both groups will receive the same frequency and duration of therapy. We will recruit people with upper extremity paresis and upper extremity activity limitations due to stroke or traumatic brain injury. Potential subjects will be between 18-90 years of age and have experienced a stroke or brain injury in the previous 1-3 months. The time within the first few months after stroke and brain injury is within the critical period when this intervention could have its greatest impact on activity and participation. Data from our pilot project have informed specifics design parameters regarding sample size, inclusion/exclusion criteria, duration of the intervention, outcome measures, and clinically-meaningful changes on those measures. Subjects will be randomized to the high-repetition dose or standard care groups using an adaptive randomization scheme to minimize baseline differences. Therapy will be provided in 1 hour sessions, 3 times per week for 8 weeks. Post-intervention assessments will occur at the end of the 8 week intervention and 3 months later. A timeline for the project is provided in the table.

Activity		
Year 1	Q1	Hire & train personnel; finalize recruitment materials, protocol, data collection forms, etc.
	Q2	Enroll subjects
	Q3	Enroll subjects
	Q4	Enroll subjects
Year 2	Q1	Enroll subjects
	Q2	Complete subject enrollment, with any additional subjects to replace drop-outs

		as needed
	Q3	Complete interventions and follow-up assessments on enrolled subjects
	Q4	Data analyses, manuscript preparation, plan next phase

Our hypothesis is that high-repetition doses of task specific upper extremity training will result in greater improvements in activity and participation than standard rehabilitation treatment. We will test our hypothesis using well-established outcome measures. The primary endpoint will be the Action Research Arm Test score at the 3 month follow-up point. Secondary endpoints will include the Stroke Impact Scale, Canadian Occupational Performance, and Activity Card Sort scores at 3 months post intervention. Analyses will be done using mixed model repeated measures ANOVAs to look for differences between groups and across time. Additional data on the success of delivering the interventions (e.g. compliance with the intervention, repetitions achieved, fatigue, etc.) will also be collected and analyzed. Extensive statistical resources are available on our campus to assist with the randomization, data management, and data analysis processes.

Feasibility Assessment:

The biggest barrier to clinical trials is subject recruitment. Our partner outpatient rehabilitation facility treated over 300 people with stroke and brain injury in each of the last 3 years. In our pilot project we met our recruitment goals and even had a waiting list at one point. Thus, enrollment will be limited by the amount of personnel available and not by the availability of participants. We have previous experience with managing and organizing a multi-site observational study of rehabilitation post stroke and previous experience with stroke rehabilitation clinical trials. These experiences will help us overcome the expected and unexpected challenges of the proposed project. Furthermore, we have a strong track record of successfully completing and publishing results from funded projects.

Potential Threats to Generalization:

Our results will generalize directly to people with stroke and traumatic brain injury. Generalization beyond these populations will need to be explicitly tested in future studies. Unlike most studies evaluating motor rehabilitation interventions, we have included people in our pilot work who also have deficits in other domains, such as cognition and language dysfunction. We intend to include individuals with deficits in multiple domains in the proposed project because this is the reality for most patients with stroke and brain injury. Having a sample that is representative of what is seen in rehabilitation clinics will greatly improve the generalization of our findings to current stroke rehabilitation practice.

Further information regarding rationale, significance and detailed methodology for this project are available on request.

The comparative effectiveness and cost-effectiveness of SNF-, IRF-, and home health agency-based rehabilitation for individuals with hip fracture.

Nature of Problem or Research Question: What is the relative effectiveness, cost-effectiveness (or expenditure-effectiveness) of SNF-, IRF-, and HHA-based rehabilitation for individuals with hip fracture?

It would also be important to examine the effectiveness/cost-effectiveness of episodes of post-acute care by looking at various combinations of post-acute care since there is considerable evidence that hip fracture patients go on to use additional forms of post-acute care after leaving the initial post-acute setting.

Impact/Utilization: Individuals with hip fracture are one the fastest growing groups receiving post-acute rehabilitation care. Among all IRF patients, for example, they are the 3rd most commonly served group after those with stroke and joint replacement. However, there is little evidence that one setting of care is more effective than others. CMS and other payers want to know which setting is most effective and cost-effective for different cohorts of post-acute patients.

Nominated Intervention (1): SNF-based hip fracture rehabilitation

Nominated Intervention (2): IRF-based hip fracture rehabilitation

Nominated Intervention (3): Home health-based hip fracture rehabilitation

Summary of Research Findings to date:

Studies to date have had mixed results with neither setting providing a clear advantage over others. One of the more extensive studies on hip fracture rehabilitation is based on 1990s data prior to the implementation of the Medicare PPS for each of the 3 post-acute settings—SNFs, IRFs, and HHAs.

Proposed Study Design:

> **Design:** Retrospective observational cohort design
>
> **Sample (include target disability group, age group):** All Medicare hip fracture patients served in SNFs, IRFs, and HHAs in 2006 and 2007. May limit sample to those over 50 years of age.
>
> **Inclusion/Exclusion:** No exclusion criteria currently anticipated although there will be some exclusion criteria in the final study design.

Timeline: Study can be completed within 12 to 18 months. This study can be done relatively quickly since it can rely in large part on administrative data, namely on MedPAR and Medicare claims data.

Data Collection Plan Anticipated: Will use Medicare claims data from 2006 and 2007. These data become routinely available within 18 months.

Data Analysis Plan Anticipated: These data cannot address functional outcomes but can address outcomes such as hospital readmissions, institutionalization, and mortality since patients with hip fracture are at considerable risk for all three (compared to joint replacement patients where the incidence of these outcomes is quite low and therefore not as relevant when examining outcomes). We will use propensity scoring or instrumental variables to control for selection effects.

Feasibility Assessment:

Threats to Implementation: None anticipated.

Threats to study completion: This is a study that can be completed within 12 to 18 months. The main uncertainty is the timely negotiation of data use agreement with CMS and timely acquisition of Medicare claims data.

Potential Threats to Generalizability: This study would be limited to Medicare patients only and more specifically, fee-for-service Medicare patients. Nearly 20% of Medicare participants obtain their coverage through a private Medicare-sponsored plan under the Medicare Advantage program.

Cognitive deficits after TBI

Impact/Utilization: High

Nominated Intervention (1): Comprehensive cognitive rehabilitation (class I)

Summary of Research Findings to date: Retrospective comparison of this to alternative strategies suggests benefits, but controlled clinical trial in military population did not (Ciccerone et al., 2005)

Nominated Intervention (2): Psychosocial interventions (class I)

Summary of Research Findings to date:

Proposed Study Design:

Design – Phase III, multicenter RCT

Sample (include target disability group, age group) – adult

Inclusion/Exclusion

Timeline – postacute, chronic

Data Collection Plan Anticipated – battery of tests as recommended by the workshop on TBI Common Data Elements (2009) or NIH toolbox (available in 2011)

Data Analysis Plan Anticipated – something like a T-test but leave that to statisticians

Feasibility Assessment:

Threats to Implementation - none

Threats to study completion – competition with other ongoing TBI studies

Potential Threats to Generalizability: heterogeneity of TBI

The comparative cost-effectiveness of SNF- and IRF-based rehabilitation for individuals with hip and knee replacements.

Nature of Problem or Research Question: What is the comparative cost-effectiveness of SNF versus IRF-based rehabilitative care for individuals following a hip or knee replacement?

In 2008, acute care hospitals performed more than a million joint replacements, a doubling from 10 years ago. About 75% of these patients go on to use some form of post-acute rehabilitative care such as a SNF, and IRF, or home health. We are on course to do 3 million joint replacements by the Year 2030. This represents an enormous expense to the Medicare program.

Impact/Utilization: CMS has a strong interest in bringing the costs of hip and knee replacements under control by making sure that patients are channeled to the right post-acute setting.

Nominated Intervention (1): SNF-based rehabilitation

Nominated Intervention (2): IRF-based rehabilitation

Summary of Research Findings to date: Research shows that IRF care is only marginally more effective than SNF care, which leaves open the question of whether it is also more cost-effective since SNF-level care presumably costs less. A comparative cost-effectiveness study can quickly build on what has already been found with respect to effectiveness.

Proposed Study Design:

Design: Comparative observational cohort study

Sample (include target disability group, age group): Hip and knee replacement patients discharged from a cross-section of SNFs and IRFs from across the US.

Inclusion/Exclusion: All hip and knee replacement rehabilitation patients except:

1. Hip replacement patients who had their replacement following a hip fracture, i.e., non-elective hip replacements.
2. Those who died in the follow-up period (death unlikely due to hip or knee replacement or subsequent care). Cannot obtain follow-up data on these patients. Also, comparative expenditure data may be problematic for these patients.
3. Those who had a subsequent joint replacement and obtained their rehabilitation in a different facility other than the facility from which they obtained their initial rehabilitation.

Timeline: 2200 patients discharged from SNFs or IRFs in 2006-07

Data Collection Plan Anticipated: Use of two secondary data sources: (1) outcome data collected as part of an earlier observational cohort study and (2) Medicare claims data on same patients for 6 months following admission to a SNF or an IRF.

Data Analysis Plan Anticipated: Marry outcome data from earlier study with 2006-07 Medicare claims data. Adjust data for differences in case mix. Evaluate relative or comparative cost and expenditure effectiveness analyses. Also use stochastic frontier analysis to evaluate the comparative cost-effectiveness when considering two or more outcomes concurrently.

Feasibility Assessment:

Threats to Implementation:

1. There are few if any.
2. Possible low representation in select case-mix groups.

Threats to study completion: This is a study that can be completed within 12 to 18 months. The main uncertainty is the timely negotiation of data use agreement with CMS and timely acquisition of Medicare claims data.

Potential Threats to Generalizability: Participating 20 facilities are a self-selected. Smaller SNFs and freestanding IRFs are underrepresented due to facility selection criteria but study sample does represent geographic diversity with each major region of the nation well represented.

Improving the benefits of rehabilitation for those with paralysis of and impairment to lower limbs.

Impact/Utilization: 5.6 million people are paralyzed to some degree

Nominated Intervention (1): Standard rehabilitation is carried out at hospitals and rehabilitation facilities with little effort made on returning the patients to full participation in their communities.

Summary of Research Findings to date: High rates of unemployment, high health services use, high rehospitalization rates, high rate of secondary conditions, high rates of informal care provider injuries, high divorce rates, high rates of institutionalization, low income, low quality of life and low community participation.

Nominated Intervention (2):

Wheelchair skills assessments and training

Skills for community mobility (wheelies, up/down slopes/curbs, etc.)

Seating evaluation and recommendations (pressure mapping, provision of air cushions with pressure alert systems

Exercise evaluation and ongoing experience in learning how to use different types of adapted equipment for functions

Transfers, mobility device propulsion, lifting, reaching, driving

Enrollment into physical exercise and wellness programs

Evaluation of and training provided for personal assistance needs

Informal family member, link to paid personal assistants and training informal and formal personal assistants

Evaluation for and introduction to recreational opportunities

Competitive sports, nature trails and parks sand travel

Evaluation of and experience in community participation

Assess 20 sites in the home communities and travel with participant to the sites and make recommendation for site changes in receptivity

Evaluation of and experience in computer skills

Software options, voice entry - Naturally Speaking, keyboard adaptations, social networking via internet

Summary of Research Findings to date: No published studies in this country

Proposed Study Design:

Design: Controlled treatment, multicenter trials

Sample (include target disability group, age group):

Paralysis of upper and/or lower limb impairments, over18

Inclusion/Exclusion:

Paralysis of upper and/or lower limb impairments exclusion of individuals with minimal loss of movement function due to paralysis

Timeline: 2 yr planning, 3 yr implementation

Data Collection Plan: functional outcomes, recurrent hospitalization, health care utilization, secondary conditions, health and well being, quality-of-life and community participation

Data Analysis Plan: Inferential statistics

Feasibility Assessment:

Threats to Implementation:

Requires innovative collaborations with health insurance plans, rehabilitation centers, community agencies

Threats to study completion:

Provider acceptance, consumer acceptance, funding mechanism that require cost sharing between traditional medical based and community based service providers.

Potential Threats to Generalization:

May not generalize to non-paralyzed populations

Comparative Effectiveness Research Proposal for Newborn Hearing Screening Loss to Follow-Up

Nature of Problem or Research Question

Congenital, permanent childhood hearing loss affects 2%–4% of infants who spend time in neonatal intensive care units (NICUs) and 1–3 of every 1,000 infants in well-baby nurseries (Baroch, 2003, CDC, 2008). In an attempt to improve outcomes for children with hearing loss and their families, the National Institutes of Health and the Joint Committee on Infant Hearing (JCIH) in 1993 and 1994, respectively, and the United States Preventive Services Task Force (2008) endorsed the goal of universal detection of hearing loss in infants. The American Academy of Pediatrics (AAP) Task Force on Newborn and Infant Hearing (1999) and JCIH (2000, 2007) endorsed universal newborn hearing screening (UNHS) and the early hearing detection and intervention (EHDI) goals of screening no later than 1 month, confirmation of hearing loss no later than 3 months, and receipt of appropriate intervention no later than 6 months of age. Today, it is estimated that newborn hearing screening is provided to 92%–95% of babies born in the United States and its territories (CDC, 2008; National Center for Hearing Assessment and Management [NCHAM], 2007).

In order to maximize the effectiveness of services and prevent negative developmental impact on children with hearing loss, a positive screening result must be followed by timely diagnostic confirmation and initiation of services. Of infants born in the United States in 2006 who did not pass their newborn hearing screening, it is estimated that nearly half were lost to follow-up (CDC, 2008).

There is very limited research on the effectiveness of different approaches to limiting loss to follow-up. Therefore, the specific question to be addressed is

> **For parents or caregivers of newborns with a positive screen for hearing loss at birth, what is the optimal timing and nature of interventions by health care professionals to increase the likelihood of timely follow-up for a diagnostic evaluation and, if indicated, intervention.**

Impact/Utilization

Previous research has indicated that delays in the diagnosis of and intervention for hearing loss are associated with subsequent delays in children's receptive language development. A 2008 systematic review sponsored by the Agency for Healthcare Research and Quality concluded that "Children with hearing loss who had UNHS have better language outcomes at school age than those not screened." Specifically, children with hearing impairment confirmed by ≤ 9 months of age had significantly better age-adjusted scores than those confirmed later on 2 tests of receptive language and 1 of 2 tests of expressive language but not on the speech scale (USPSTF, 2008).

Nominated Intervention

Approaches to parental education and the timing and content of educational materials vary widely across the country. Most parents learn of newborn screening programs while in the hospital, not prenatally (Arnold et al., 2006). Through a series of focus groups and interviews, Arnold and colleagues found that stakeholders (i.e., parents of infants experiencing the newborn hearing screening (NHS) process, parents of children with hearing loss, audiologists, technicians, nurses, PCPs) preferred having communication about the newborn hearing screening process occur before birth and preferred that user-friendly patient education materials be used. A 2006 survey of parents by Alexander and van Dyck found that parents preferred to be informed prior to the screening of what the screening entails, the urgency of early diagnosis, and what the follow-up process will be (Alexander & van Dyck, 2006).

It is recommended that research be undertaken on the optimal timing of the parental education (pre-natal versus pre-screening versus post-screening) and whether written materials, oral communication, or a combination is most effective in promoting follow-up.

Summary of Research Findings to Date

A 2008 systematic review (ASHA, 2008) found virtually no scientific evidence that could be used by clinicians, administrators, or policy makers to identify the infants at highest risk of loss to follow-up or of the effectiveness of different approaches to promoting follow-up. While there were a small number of studies related to risk factors for loss to follow-up, vague definitions of terminology, absence of experimental controls and other manifestations of problematic study quality inhibited the drawing of any strong conclusions. No studies at all were found relating to follow-up from newborn hearing screening to diagnostic evaluation or to intervention. The authors then searched for studies on interventions designed to promote follow-up from initial hearing screenings to re-screenings, and identified three studies in the peer-reviewed literature. One found no difference in follow-up rates among mothers who had received individual versus group counseling, and a second found no improvement in follow-up among parents who had watched a 20-minute video on hearing screening during pre-natal classes. The third study found a significant increase in follow-up in an experimental group who received written materials, individual counseling, computer tracking of compliance, and reminder telephone calls compared to a control group who just received the written materials. That study did not attempt, however, to discern the relative contributions of each of the specific components of the “bundled” interventions.

Proposed Study Designs

Random assignment, matched control samples, double-blind clinical trial

Inclusion Criteria
Families or caregivers of infants with a hearing screening at birth suggesting possible hearing loss.

Exclusion Criteria
Family history of hearing loss
Infant death or medical complications making follow-up more difficult.

Timeline
1- 3 years

Feasibility Assessment
The literature already contains investigations establishing feasibility, but further study may be warranted.

Threats to implementation
Ensuring treatment fidelity (as well as collecting data to evaluate treatment fidelity)

Threats to study completion
Recruitment and retention of subjects

Potential Threats to Generalization
Heterogeneity of population, settings

Comparative Effectiveness Research Proposal for Intensity of Language Intervention for Adults with Acquired Brain Injury

Nature of Problem or Research Question

Intensity of treatment has been a topic of interest for some time in aphasia treatment studies (Poeck, Huber, & Willmes, 1989) and treatment for language disorders due to traumatic brain injury. Findings from Robey's (1998) meta-analysis of the aphasia literature reported large effect sizes (ESs) associated with treatment provided for 2 or more hr per week. In a review focused on intensity and outcomes, Bhogal, Teasell, and Speechley (2003) reported better treatment outcomes in studies that provided intensive treatment schedules. On average, the more intensive treatment schedules equaled 8.8 hr per week for 11 weeks, compared with the less intensive schedules of 2 hr per week for 23 weeks of treatment. Although both reviews and several efficacy studies included in those reviews have examined the impact of the intensity of service delivery, large scale comparative effectiveness studies have yet to be accomplished.

> **Compare the effectiveness of 30 hours of language intervention delivered over 3 weeks as compared to over 10 weeks on the rate of acquisition, response generalization (across language tasks and communication settings), and maintenance of targeted language processing skills six weeks after therapy is teminated.**

Impact/Utilization

Approximately 700,000 people in the United States survive cerebral vascular accidents (CVA), or strokes, per year, and approximately two-thirds of these stroke survivors require subsequent rehabilitation for a number of impairments including motor deficits, cognitive deficits, and speech and/or language deficits (e.g., NIH, 2006). Specifically, approximately 1,000,000 individuals in the United States suffer from aphasia, with the majority of these cases resulting from stroke (Holland, Fromm, DeRuyter, & Stein, 1996, ASHA, 2004). In a large prospective study involving over 1000 participants with a diagnosis of CVA, aphasia was observed to occur in 38% of the sample, with the incidence rising to 40% when only participants with left-hemisphere lesions were assessed (Pedersen, Jorgensen, Nakayama, Raaschou, & Olsen, 1995). Furthermore, Pedersen and colleagues found that of the participants with aphasia who survived the stroke, 44% completely recovered by the time they were discharged from the hospital. At a six month follow-up, 50% of participants with an initial diagnosis of aphasia continued to present with aphasia; that is after six months of recovery time, only an additional 6% of participants with aphasia had completely recovered their language function. Knowing whether the intensity of service delivery has an impact on outcomes for individuals with acquired brain injury would provide a rather simple solution to enable providers to adjust their methods of

delivering services to achieve more effective outcomes without altering the economic burden of these services.

Nominated Intervention

There are many different intervention approaches that have been used for adults with language impairments secondary to acquired brain injury. For the purposes of this comparison, the type of language intervention delivered can vary and would be determined by the speech-language pathologist in consultation with the patient and family. Programs differ in how goals are prioritized and the techniques used to target goals. Some programs rely heavily on singular strategies, while others are more comprehensive or eclectic. Most important to the goals of this proposal is that the intensity of the service delivery be systematically varied such that half of the cohort enrolled would receive 30 hours over 10 weeks (spaced) and the other half over 3 weeks (massed).

Summary of Research Findings to Date

A systematic search of the literature was conducted (Cherney, Patterson, Raymer, Frymark, and Schooling, 2008) to identify studies that directly investigated intensity of language intervention for individuals with acquired brain injury and directly compared conditions of higher and lower intensity treatment. Of the 10 studies that met inclusion criteria for the systematic review, 5 studies investigated treatment intensity (Basso & Caporali, 2001; Denes, Perazzolo, Piani, & Piccione, 1996; Hinckley & Carr, 2005; Hinckley & Craig, 1998; Raymer et al., 2006). Five of these studies contained sufficient data for calculation of treatment ESs. The effect of intensity in Denes et al. (1996), Pulvermuller et al. (2001), and Hinckley and Carr (2005) was derived from between-group comparisons for groups receiving intensive and nonintensive treatment. The effect of intensity in Study 3 of Hinckley and Craig (1998) was derived from within-group comparisons of the pre- and post difference scores from each intensive 6-week training session compared with the nonintensive 6-week training session. In Raymer et al. (2006), the effects came from within-subject comparisons across the individual participants. Four group studies used impairment outcome measures for which eight effect sizes (ESs) were calculable, including seven large ESs, all in favor of more intensive treatment. In the single-participant design of Raymer et al. (2006), ESs were larger in the more intensive condition for picture-naming acquisition and larger in the less intensive condition for word/picture verification. ESs could not be calculated for Basso and Caporali (2001), who described case studies of three pairs of individuals. In summary, individuals receiving more intensive treatment showed greater gains on language impairment tasks than did the comparison individuals who received a less intensive schedule. Thus, the language impairment outcome measures favored more intensive treatment for all language measures.

Proposed Study Designs

- Group designs comparing these approaches to further investigate generalization in specific populations not previously studied
- Random assignment, matched control samples, double-blind clinical trial

Inclusion Criteria
Adults with language impairments secondary to acquired brain injury

Exclusion Criteria
Pre-morbid history of psychiatric, neurological, and/or communication impairments

Timeline
Two-to-Five years

Feasibility Assessment
The literature already contains investigations attesting to feasibility but further feasibility efforts may be needed for some sub-groups of individuals with acquired brain injury.

Threats to implementation
Ensuring treatment fidelity (as well as collecting data to evaluate treatment fidelity)

Threats to study completion
Recruitment and retention of subjects

Potential Threats to Generalization
Heterogeneity of population
May not generalize to all etiologies of acquired language impairment

High rates of HIV infection among individuals with psychiatric disabilities.

Impact/Utilization: Rates of HIV among individuals with psychiatric disabilities are documented at 5-75 times the rate of the general population. In the published literature, studies of individuals with psychiatric disabilities indicate that testing prevalence, access to testing, knowledge about HIV testing, and other relevant correlates are lacking and that additional research is warranted specifically for this population. In fact, comparing different types of HIV testing among individuals with psychiatric disabilities has been noted as a focal area for comparative effectiveness research (Senn & Carey, 2009). Findings from research identifying effective models for HIV testing among individuals with psychiatric disabilities have the potential to assist in the early detection of HIV, subsequently resulting in earlier engagement in treatment to reduce illness progression and mortality, prevention of transmission to others, and reductions in overall costs of HIV-related health services to treatment systems.

Nominated Intervention (1): Rapid HIV testing.

Summary of Research Findings to date: A rapid HIV test is an enzyme-linked immunosorbent assay (ELISA) test (OraQuick®); however, rather than being analyzed in larger batches with other individual tests, rapid tests are analyzed alone. For a rapid HIV test, a finger stick sample of blood is collected and transferred to a vial. This sample is mixed with a developing solution. The test device, resembling a "dipstick," is inserted into the vial. In as little as 20 minutes, the test device will indicate if HIV–1 antibodies are present in the solution. These are standard procedures tested, outlined, and endorsed by the Centers for Disease Control & Prevention (CDC).

Nominated Intervention (2): Traditional, Blood Assay HIV Testing.

Summary of Research Findings to date: Traditional HIV tests (ELISA) use blood to detect HIV infection. In all of these tests, a small amount of blood is drawn from the arm and sent to an outside laboratory for evaluation. The traditional ELISA test takes approximately one week to complete, depending on where the test is performed. With a positive result, a confirmatory Western Blot assay is performed. These also are standard testing procedures documented by the CDC.

Proposed Study Design:

Design Randomly assign 300 individuals with psychiatric disabilities to rapid HIV testing versus traditional HIV testing and follow them for 9 months after testing.

Sample (include target disability group, age group) Individuals with psychiatric disabilities who are 18 years or older.

Inclusion/Exclusion Inclusion: Being 18 years or older, have a psychiatric disability, willingness to be tested for HIV; Exclusion: younger than 18 at time of study entry, already diagnosed with HIV/AIDS.

Timeline This could be a 2-year project with a 9-moth follow up. However, the project could be extended to 3-4 years with an additional 12- or 18-month follow up. Both are longitudinal desnigns and would provide valuable information regarding testing methods.

Data Collection Plan Anticipated: HIV risk assessment data will be collected at in-person meetings. Separate research interviews also will be conducted longitudinally at study entry, and again at 3- and 9-months after testing to examine other co-factors to HIV risks, including health beliefs and psychiatric symptoms. Testing outcome data also will be collected to examine overall rates of HIV infection within this population, but also to examine rates at which testing participants receive the test outcomes based on testing modality (i.e., rapid vs. traditional).

Data Analysis Plan Anticipated: Given the nature of the data to be collected, rates of HIV testing will be compared by modality using nonparametric analyses (e.g., chi square); longitudinal differences among outcomes including psychiatric symptoms, health beliefs, and other co-factors will be evaluates using repeated measures analysis of variance as well as randomized regression analyses.

Feasibility Assessment:

Threats to Implementation: Implementation threats include individuals' unwillingness to engage in HIV testing, as well as the potential that HIV positive individuals who are randomly assigned to the traditional testing group may not return to learn their results.

Threats to study completion: A threat to study completion would be attrition post-HIV testing, regardless of testing mode, by participants who are not interested in participating in the two follow up research interviews.

Potential Threats to Generalizability: One threat to generalizability would be that the population in this study may not be representative of a national sample of individuals with psychiatric disabilities. Despite the high-impact of HIV infection in the population, more rural and non-metropolitan areas may be differentially affected by the HIV epidemic. Likewise, areas with more concentrated representation of people from diverse ethnic and cultural backgrounds than the Chicago-area may demonstrate different rates of participation. A larger, national multisite study would strengthen the external validity of this proposal.

Comparative Effectiveness Research Project Proposal for Family-centered Interventions in Autism

Nature of Problem or Research Question

A philosophical mandate for family-centered practices has permeated both health care and educational fields. This philosophy offers a foundation for effective family—professional collaborations in assessment, diagnosis, and treatment of individuals with ASD (Prelock, Beatson, Bitner, Broder, & Ducker, 2003). Family-centered practices include careful attention to family priorities and concerns in planning interventions (e.g., Marshall & Mirenda, 2002), as well as to learning about the family system that includes an individual with autism, and developing contextualized assessments and interventions that respect the family system and preferences (Hecimovic, Powell, & Christensen, 1999; Moes & Frea, 2000). Families of individuals with ASD have assumed increasingly important roles in promoting a broader-based awareness and understanding of the disorders, and in the search for effective treatments through their collaborations with professionals to set a national research agenda, ensure the availability of research funding, and encourage participation in research (e.g., Anders, Gardner, & Gardner, 2003; Hollander, Robinson, & Compton, 2004.

Given the nature of autism and the needs of individuals with ASD, families often become teachers and interventionists (NRC, 2001). Family involvement in teaching children with ASD has been documented since the 1960s (Turnbull, Turnbull, Erwin, & Soodak, in press), though some families today place less importance on their roles as teachers and instead want more information on varying topics (Turnbull, Blue-Banning, Turbiville, & Park, 1999). Most comprehensive programs for individuals with autism offer parents training (National Research Council [NRC], 2001).

Families are consistent communication partners who should be provided with opportunities to give information about their child, to learn new skills, and to receive information about available resources. How and what families are taught have been influenced by a shift from the “expert” model of parent education, in which the professional directs the parents, to a more collaborative model, in which family individuality is recognized and families define their own needs and level of involvement (Becker-Contrill, McFarland, & Anderson, 2003; Turnbull et al., in press).

Although research indicates that having families play a critical role in the intervention process is an important part of effective programs for children with autism, research is not available yet to indicate which services and support strategies or what combination is most effective (NRC, 2001). Concerns, priorities, and perspectives of the family need to actively shape educational planning. All of the comprehensive intervention programs with the best treatment outcomes include a strong family component. Family members should be supported to be effective members of the educational team and provided with the opportunity to learn strategies for teaching their child new skills and reducing problem behaviors (NRC, 2001). Sources of support

may include teachers, other interventionists, formal support groups, informal networking with other caregivers of persons with ASD, and families, friends, and neighbors (NRC, 2001).

Geographic location (R. L. Koegel, Symon, & Koegel, 2002) and lack of financial resources (NRC, 2001) can be constraints on access. In a study of Medicaid-eligible children with autism, for instance, Mandell, Literud, Levy, and Pinto-Martin (2002) found that African American children received diagnoses 1 year later than Caucasian children, on average, with a mean age of diagnosis of 7.9 years for the African American children with autism. Although this study did not include a comparison group of higher income children, the relatively late mean age of diagnosis for all the Medicaid-eligible children included in the Mandell et al. study suggests that few children in low-income families received services during their preschool years, regardless of race.

Other cultural and linguistic factors may play roles in families' access to or use of services (Dyches, Wilder, Sudweeks, Obiakor, & Algozzine, 2004; Wilder, Dyches, Obiakor, & Algozzine, 2004). For example, there is variability in the rate at which children from racial and ethnic minority groups are served under the label of autism in the public schools (Dyches et al., 2004). This variability may be due to complex interactions between the values of families from different cultural backgrounds, and linguistic and cultural differences, which may contribute to an over- or under-identification of ASD among certain groups. Ultimately, the diagnostic label of an individual will influence the information and resources that will be offered to families or that the families will seek on their own. When a diagnosis of ASD is given, families will have different understandings of what the diagnosis means, views of etiology, attitudes toward the disability, and motivations regarding accessing services. Families with limited English proficiency may face linguistic barriers to navigating information and service systems in the United States. In addition, families of individuals with ASD may choose alternative forms of treatment based on individual values or cultural background. For example, one study reported that Latino families were more likely to access complementary and alternative medical treatments for their children than were Caucasian or African American families (Levy, Mandell, Merhar, Ittenbach, & Pinto-Martin, 2003

Families of individuals with autism benefit from support beyond the learning of new skills. They benefit from formal and informal supports as well (NRC, 2001). Formal supports emerge from collaborative partnerships between families and professionals, while informal supports include support groups, informal parent networks, and family members and friends (NCR, 2001). Support for families is an ongoing process that takes different forms with different families based on their individual concerns, priorities, and interests (Blue-Banning, Summers, Frankland, Nelson, & Beegle, 2004; Dunlap & Fox, 1999; Sandall, Hemmeter, Smith, & McLean, 2005). Activities such as learning intervention strategies or working with the child in an intervention program are associated with reports of decreased stress by mothers of children with ASD (Bristol, Gallagher, & Holt, 1993; R. L. Koegel, Bimbela, & Schreibman, 1996). Stress also is

alleviated by perceived social support from both informal networks and formal support systems (NRC, 2001).

Do family-centered services and support strategies improve social communication outcomes for preschool children with autism? Contrast standard services with and without family-centered services on social communication outcomes.

Impact/Utilization

Comparative effectiveness research involving families of children with autism will demonstrate how cultural, linguistic, and socioeconomic factors affect families' access to or use and selection of services. Effective practices that involve families can incorporate family preferences and address family priorities.

Nominated Interventions

- Single-subject cross-over designs to further investigate efficacy in specific populations not previously studied
- Group designs comparing these approaches to further investigate generalization in specific populations not previously studied
- Random assignment, matched control samples, double-blind clinical trial

Summary of Research Findings to Date
In progress

Proposed Study Design
Randomly assigned, matched control samples. Single-subject designs may be provide evidence of efficacy or effectiveness through multiple replications (Odom, Brown, Frey, Karasu, Smith-Canter, & Strain, 2003).
Inclusion/Exclusion
Preschool children with ASD and their families from diverse cultural backgrounds
Timeline
Two-to-Five years
Data Collection Plan Anticipated
In progress
Feasibility Assessment
In progress
Threats to implementation
In progress
Threats to study completion
Recruitment and retention of subjects
Potential Threats to Generalization
In progress

Optimal organization and delivery of post-acute care for hip fracture patients

Impact/Utilization: 500,000 new hip fractures cases/year

Nominated Intervention (1): Acute care followed by conventional rehabilitation

Summary of Research Findings to date: Rehabilitation improves hip fracture outcomes but excess mortality of 15% in first year

Nominated Intervention (2): Bundled acute and rehabilitation care with rehabilitation setting determined by need

Summary of Research Findings to date: unknown

Proposed Study Design:

Design RTC

Sample (include target disability group, age group) hip fracture 65+

Inclusion/Exclusion all hip fractures secondary to fall or trauma, exclude pathological fracture

Timeline 2 yr planning, 3 yr patient accrual

Data Collection Plan Anticipated functional outcomes, recurrent hospitalization, health care utilization, mortality, quality-of-life

Data Analysis Plan Anticipated intention-to-treat analysis

Feasibility Assessment:

Threats to Implementation requires collaboration w/CMS, requires innovation by providers

Threats to study completion provider acceptance, requires randomization

Potential Threats to Generalizability: may not generalize to younger populations

Optimal organization and delivery of post-acute care for stroke patients

Impact/Utilization: 750,000 new stroke cases/year

Nominated Intervention (1): Acute care followed by conventional rehabilitation

Summary of Research Findings to date: Rehabilitation improves stroke outcomes

Nominated Intervention (2): Bundled acute and rehabilitation care with rehabilitation setting detrmined by need

Summary of Research Findings to date: unknown

Proposed Study Design:

Design RTC

Sample (include target disability group, age group) stroke ages 65+

Inclusion/Exclusion exclude other co-existent neurological diseases

Timeline 2 yr planning, 3 yr patient accrual

Data Collection Plan Anticipated functional outcomes, recurrent hospitalization, health care utilization, mortality, recurrent stroke, quality-of-life

Data Analysis Plan Anticipated intention-to-treat analysis

Feasibility Assessment:

Threats to Implementation requires collaboration w/CMS, requires innovation by providers

Threats to study completion provider acceptance, requires randomization

Potential Threats to Generalizability: may not generalize to younger populations

Optimal organization and delivery of post-acute care for complex medical patients

Impact/Utilization: may help to revise treatment guidelines

Nominated Intervention (1): Acute care followed by SNF/home care

Summary of Research Findings to date:

Nominated Intervention (2): Intense inpatient rehabilitation followed by home care

Summary of Research Findings to date: unknown except for very select populations e.g., metastatic disease to spine with paralysis where clear improvemtns in quality of life demonstrated

Proposed Study Design:

Design RTC

Sample (include target disability group, age group) multiple organ transplant patients, severely decondtioned patients following cancer treatments

Inclusion/Exclusion TBD

Timeline 1 yr planning, 1 yr patient accrual

Data Collection Plan Anticipated functional outcomes, recurrent hospitalization, health care utilization, mortality, quality-of-life

Data Analysis Plan Anticipated intention-to-treat analysis

Feasibility Assessment:

Threats to Implementation requires collaboration w/CMS, requires innovation by providers

Threats to study completion provider acceptance, requires randomization

Potential Threats to Generalizability: will depend on diagnostic criteria

Enhancing Motor Training with Transcranial Direct Current Stimulation

Traumatic Brain Injury (TBI) is a major world-wide public health problem. The Center for Disease Control and Prevention (CDC) estimates that 235,000 people in the U.S. alone are hospitalized annually with a TBI and survive. Approximately 80,500 of TBI survivors are left with long-term disability. Another 10,000 or more who sustain a TBI, but are not hospitalized, are estimated to become disabled each year. Long-term disability after TBI includes problems with motor control (weakness, spasticity, and instability), cognition (thinking, memory, and reasoning), sensory processing (sight, hearing, touch, taste, and smell), communication (expression and understanding), and behavior or mental health (depression, anxiety, personality changes, aggression, acting out, and social inappropriateness). The CDC estimates the prevalence of disability resulting from TBI in the U.S. to be 5.3 million. The annual direct and indirect costs including those due to work loss and disability have been estimated at $60 billion. These costs recently increased very significantly due to the high number of veterans who require treatment because of TBIs they sustained during the war in Iraq. There is therefore an urgent and ongoing need for better strategies to minimize motor impairments as a consequence of TBI and promote the recovery of function in TBI survivors.

Upper extremity impairment and related functional limitations are important targets of the rehabilitation of individuals who suffered a TBI. Recent literature emphasizes the need for studies assessing the benefits of interventions aimed at improving motor function in TBI survivors. Only a small number of studies has been focused on assessing motor gains associated with rehabilitation in TBI survivors. The few studies focused on the use of traditional rehabilitation techniques have shown that limited motor gains are associated with traditional interventions. Recent research has explored the use of rehabilitation approaches based on high intensity and specificity of targeted movements (such as constraint-induced movement therapy) in TBI survivors. Preliminary results are very encouraging as they show that clinically significant gains can be achieved via intensive motor therapy. Based on these considerations, our research team recently carried out a pilot study that combined non-invasive electrical stimulation of the brain (i.e. transcranial direct current stimulation, tDCS) with robotic motor training aimed at upper extremity motor recovery in a group of TBI survivors. *Figure 1* shows the setup we utilized in our preliminary investigation. The combination of tDCS and robotics was motivated by recent scientific evidence that points at the benefits of these technologies.

Based on the outcome of our pilot study, we propose to perform a randomized sham-controlled clinical trial to assess the clinical and neurophysiological effects of therapy that combines motor training using a robotic device (ARMEO, Hocoma AG) specifically designed for upper extremity rehabilitation, which allows one to perform therapeutic exercises based on an interactive gaming environment, and the use of noninvasive brain stimulation achieved via tDCS. The proposed study will allow us to perform a comparison of therapy based on the above-mentioned

technology and traditional physical therapy as currently delivered in an outpatient setting. The project will be carried out over a period of two years. During Year 1, we will focus on comparing robotic therapy combined with tDCS versus robotic therapy alone. During Year 2, we will compare traditional physical therapy with physical therapy augmented by the above-mentioned technologies. The decision of whether we will use robotic therapy alone or a combination of robotic therapy and tDCS will be made based on the results of Year 1 of the project.

Parkinson's Disease Medication Management

Parkinson's disease affects about 3% of the population over the age of 65 years and more than 500,000 US residents. The characteristic motor features of the disease include tremor, bradykinesia (i.e. slowness of movement), rigidity (i.e. resistance to externally imposed movements), and impaired postural balance. Current therapy is based on augmentation or replacement of dopamine, using the biosynthetic precursor levodopa or drugs that activate dopamine receptors. These therapies are successful for some time, but most patients eventually develop motor complications. Complications include wearing-off, the abrupt loss of efficacy at the end of each dosing interval, and dyskinesias, involuntary and at times violent writhing movements. Wearing-off and dyskinesias produce substantial disability, and frequently interfere with medical therapies. Furthermore, fluctuations in the severity of symptoms and motor complications (referred to as "motor fluctuations") are observed during dosing intervals.

Currently available tools for monitoring motor fluctuations are limited. In clinical practice, information about motor fluctuations is usually obtained by asking patients to recall the number of hours of ON (i.e. when medications effectively attenuate tremor) and OFF time (i.e. when medications are not effective). This kind of selfreport is subject to perceptual bias (e.g. patients often have difficulty distinguishing dyskinesia from other symptoms) and recall bias. Another approach is the use of patient diaries, which can improve reliability by recording symptoms as they occur, but does not capture many of the features useful in clinical decision-making.

Over the past few years, we have developed a wearable monitoring system that tracks changes in the severity of symptoms and motor complications in patients with Parkinson's disease. The system is equipped with wireless body-worn sensors that can gather data continuously over a period of up to 5 days. We have developed algorithms that identify ON-OFF periods and estimate UPDRS (Unified Parkinson's Disease Rating Scale) scores on the basis of the analysis of sensor data (i.e. accelerometer data) recorded during performance of motor tasks such as pronation/supination movements of the forearms, reaching movements, walking, sitting, etc. We have recently augmented the capability of our system by developing a web-based portal that provides clinicians with remote access to the data and videoconferencing capability so that a patient examination can be performed via the Internet. Preliminary results we have gathered over the past few years in a pilot study on about 20 patients with late stage Parkinson's disease indicate that the tools we have developed and tested could facilitate and improve medication management in this patient population.

We propose to perform a comparative effectiveness study aimed at assessing whether medication management can be improved in patients with late stage Parkinson's disease by relying upon the tools described above. Patients recruited in the study will be randomized to one of two groups: 1) receiving standard clinical services by which medication management is achieved via clinical visits and patient's report of his/her satisfaction with medication effectiveness, and 2) undergoing field monitoring to assess the severity of symptoms and motor complications during

motor fluctuation cycles via the use of the system we have developed and tested over the past few years as described above. The study will be carried out over a period of two years. During the first six months of the study, we will focus on the deployment of the technology in the field. We have extensive experience with the use of this technology and we are confident that we can address all the challenges of deploying the system based on our experience and our collaborations with Dr. Matt Welsh, who serves as Director of the Harvard Sensor Networks Laboratory, and Mr. Doug McClure, who serves as Corporate Manager of the Partners Center for Connected Health. The remainder of the study will be focused on the proposed comparative assessment of the anticipated clinical impact of the technology we have developed. We have extensively collaborated with Dr. John Growdon, Director of the Motor Disorders Center at Massachusetts General Hospital, and Dr. Dan Tarsy's team at Beth Israel Medical Deaconess Center. We will rely on these collaborations to achieve the goals of the proposed study.

Comparison of two outcome measurement tools providing benchmark predictive data to identify the utilization patterns for physical or occupational therapy rehabilitative services.

Nature of Problem or Research Question: To compare the psychometric properties of two outcome measurement tools. Also to compare the use of these tools for evaluating changes in utilization patterns among therapists when benchmark predictive data is, or is not provided for planning outpatient physical and occupational therapy treatment.

Background: Section 4541 of the Balanced Budget Act of 1997 (BBA) (Pub.L. 105-33) imposed financial limitations on outpatient therapy services and requested development of payment alternatives. In an effort to reduce errors in therapy claims, in 2005, the Centers for Medicare and Medicaid Services issued Manual instructions for outpatient therapy services that required documentation of improvement during treatment. The transmittal recommended, but did not require, measurement tools that address physical and/or occupational therapy services. Two of those tools, Focus On Therapeutic Outcomes, Inc. (FOTO), and Boston University's AM-PAC (administered by CRE Care) have extensive psychometric research, are widely used, and have amassed large data sets. Since the tools were developed using different patient data and manage the information obtained in different ways, they may address the needs of therapists for use in patient care in different ways.

In 2007, the Centers for Medicare and Medicaid Services established a research project titled "Developing Outpatient Therapy Payment Alternatives" (DOTPA). The purposes of this 5 year project are to identify, collect, and analyze therapy-related information tied to beneficiary need and the effectiveness of outpatient therapy services. The ultimate goal is to develop payment method alternatives to the current financial cap on outpatient therapy services.

In 2008, CMS contracted with Computer Sciences Corporation for a study titled Short Term Alternatives to Therapy Services (STATS). Before October, 2010, this project is tasked to : Collect and analyze quarterly and annual claims data; partner with stakeholders in analysis of utilization, policies, currently available measurement tools to develop clinically appropriate limitations or guidelines that may be used to develop options for short term alternatives to therapy caps.

The proposed research project would complement both of these projects by using electronic data collection and by focusing exclusively on outcomes measurement. This study creates a platform for linking appropriate payment to necessary services, and for reporting quality measures.

Impact/Utilization: During CY 2007, Medicare paid $4.37 billion for outpatient therapy services. If providing benchmark data to therapists improves quality and controls costs, 4.4

million beneficiaries who utilize therapy services annually would benefit[3] . Specific outcome measurement items with strong scientific credentials for specific patient conditions would be useful in identifying appropriate payment for quality services. It is unlikely that comparison of these two proprietary tools using Medicare claims would be feasible without federal support. This study will serve as a base from which future comparative effectiveness research questions may be formulated, for example, using the most appropriate tool to compare treatment options for specific groups of patients.

Nominated Intervention (1): Focus On Therapeutic Outcomes, Inc.

The Functional Outcome Score of FOTO is based on 2.4 million patient episodes obtained over 17 years. The outcomes instruments are currently being administered in over 2,000 clinics nationally and over 70 clinics in Israel. FOTO measures have been approved by the National Quality Measures Clearinghouse, given time-limited endorsement by the National Quality Forum, and used in the CMS funded (2006) a pay-for-performance study.

Nominated Intervention (2): AM-PAC

The AM-PAC's psychometric properties have been extensively evaluated in inpatient as well as outpatient post acute care patient patients with major medical, neurologic, as well as major orthopedic impairments. The AM-PAC has demonstrated a high degree of reliability, known groups and construct validity, as well as shown a high degree of sensitivity to change across all three functional domains across.

The Basic Mobility and Daily Activity scales have been given time-limited endorsement by the National Quality Forum.

Proposed Study Design:

Design: To compare the psychometric properties of the AM-PAC and FOTO measures, the study will identify a sample of providers of physical or occupational therapy outpatient services who are interested in utilizing both tools. Data will be collected at initiation of treatment and discharge using the two instruments simultaneously for all patients with a variety of neuromusculoskeletal conditions. Results for the two tools will be compared for the psychometric properties of test-retest reliability, validity (known group construct validity), sensitivity to change, responsiveness, usability (practicality, ease of use, frequency of use) and feasibility. To compare the effect of the knowledge of benchmark data from a similar cohort, provide two group of therapists outcome and benchmark data for one tool each to use in treatment planning. Compare outcomes, cost, the ability of the tools to classify clinics by effectiveness (based on outcome), and efficiency (based on utilization of time or resources to

[3] Amy Kandilov, Ph.D., Brieanne Lyda-McDonald, M.S., Edward M. Drozd, Ph.D., RTI International "Developing Outpatient Therapy Payment Alternatives (DOTPA): 2007 Utilization Report" Date 2009

achieve outcomes) for both groups. Also compare the cost and utilization of services for similar patients whose therapists do not utilize either tool.

Sample: Medicare Part B beneficiaries age 65 and over with a variety of neuromusculoskeletal disorders.

Inclusion: All Medicare Part B beneficiaries in the cooperative clinics who are receiving physical or occupational therapy.

Exclusion: Patients without cognitive ability or surrogate to participate. Patients with less than 3 therapy visits in an episode.

Timeline: 18-24 months

Data Collection Plan Anticipated

Identify providers/suppliers who are using the target tools by using tool sponsor contact information. Collect initial and discharge information using both tools on a sample group.

Extract processed claims data from CMS Data Repository. From the universe of Medicare therapy claims, identify controls. Match claims data to clinical data. Develop and execute chart review and interview procedure for clinical feasibility.

Data Analysis Plan Anticipated

Describe the functional status change, number of visits, number and type of services, episode length in calendar days, recidivism, allowed charges and paid amount.

Compare the differences in the tools psychometrics and compare instrument usability/practicality, feasibility, burden on patients/staff and other differences that arise.

Feasibility Assessment:

Threats to Implementation: Lack of cooperation among tool sponsors is very unlikely, but possible. Difficulty finding beneficiaries whose interventions were similar except the tools is possible, but also unlikely due to the huge universe of Medicare claims.

Threats to study completion: Recruitment of providers, unless incentive to participate is offered or burden is low (such as focusing upon therapists who already use the instrument).

Potential Threats to Generalizability: The Medicare population, while large, differs from the general population in race, and possibly in socioeconomic level.

Therapists who already have adopted these tools may be different than therapists who have not adopted these tools. There is no evidence or theory, however, that the differences in willingness to adopt a given assessment tool would affect the sensitivity of the tool.

APPENDIX B

Examples of CER in the area of Assistive Devices and Technologies

Comparative Effectiveness of two approaches to treating footdrop in post-stroke population

Nature of Problem or Research Question:

Footdrop or the inability to adequately clear the toes/forefoot during the swing phase of gait is a major rehabilitation problem following stroke. The standard of care in the US for the treatment of footdrop is the ankle-foot-orthosis (AFO) which constrains movement by preventing relative plantar flexion. However, emerging evidence indicate that motor recovery is activity dependent; specifically, repetitive movement therapy that is novel, functionally relevant and applied early during recovery is effective in facilitating motor recovery following UMN lesions. Thus, although an AFO clearly provides functional benefit, it may also hinder motor recovery. An important alternative to an AFO is the peroneal nerve stimulator (PNS) which actively dorsiflexes the ankle during the swing phase of gait and may facilitate motor recovery. However, these approaches have not been directly compared during the critical early post-stroke phase with respect to their effect on motor recovery (1-12 weeks).

Impact/Utilization:

Nominated Intervention (1): Articulated AFO.

Summary of Research Findings to date:

The standard of care for post-stroke foot drop is an AFO. Approximately 20% of stroke survivors discharged from acute inpatient rehabilitation are prescribed an AFO. [1, 2] Options include off the shelf plastic AFO, double upright metal AFO, solid ankle custom molded AFO and the articulated custom mold AFO. There are no studies that compare the relative efficacy of these devices. However, the community consensus appears to be the articulated custom molded AFO.

There is now sufficient evidence demonstrating the efficacy of AFO relative to no device in enhancing the functional mobility of stroke survivors.[3-7] However, there are no randomized clinical trials with long-term follow-up demonstrating their effectiveness. Most studies utilized cross-sectional design that randomly assigned the AFO condition vs no AFO condition. Nearly all studies evaluated chronic stroke survivors with acute stroke survivors evaluated only rarely.[8]

While an AFO is effective in enhancing functional ambulation relative to no device, the constraints of an AFO, even an articulated AFO, might inhibit neurologic recovery. Two studies that evaluated the effect of AFO usage on motor activation of the ankle dorsiflexors seem to support this concern.[4, 5] In agreement with prior studies, both demonstrated the functional benefit of an AFO. However, both studies also reported reduced activation of the ankle dorsiflexors (tibialis anterior) during gait. One of these studies concluded “The study…supports the functional benefit of a rigid AFO in hemiparetic subjects…However, the reduced activity in the

tibialis anterior muscle may lead to disuse atrophy and hence long-term dependence on the orthosis."[4]

Nominated Intervention (2): Surface peroneal nerve stimulator

Summary of Research Findings to date:
In 1961, Lieberson and associates[9] described the first single channel surface PNS to provide ankle dorsiflexion during the swing phase of gait. Burridge and associates[10] reported the only randomized clinical trial of surface PNS compared to no device and demonstrated that the treatment group exhibits significantly greater increases in walking velocity than the control group. Since then numerous case series have reported similar improvements in gait parameters based on a variety of commercially available surface PNS, including the Odstock Dropped Foot Stimulator,[11-13] the tilt sensor based WalkAide[14-16]and the wireless Bioness L300.[17-19] Several evidence based reviews concluded that there was strong evidence that PNSs improve hemiplegic gait parameters.[20-22]

Researchers investigating PNS have long understood that the primary barrier to clinical implementation in the US is the AFO. Accordingly, several studies compared the functional benefits of PNS to an AFO.[19, 23-25] For the most part, the two devices were similar with respect to functional ambulation.

In contrast to the AFO where there is concern regarding inhibiting motor recovery, the PNS may facilitate motor recovery by providing novel, repetitive movement therapy in the context of the functionally relevant task of walking. Lieberson and associates were also the first to describe an apparent "carry-over" effect after use of a PNS. Some participants who previously did not exhibit ankle dorsiflexion were able to volitionally dorsiflex the ankle after using the PNS.[9] This initial observation of an apparent motor relearning effect has now been corroborated by several case series.[12, 14, 26] These studies showed after a period of use of the PNS, some stroke survivors experience modest improvements in gait parameters even when not using the PNS. However, there are no longitudinal RCT to confirm the presence and clinical relevance of PNS mediated motor relearning effect. Further, all studies were conducted during the chronic phase of stroke when the environment for influencing substantial motor recovery is far from optimal.[27]

Proposed Study Design:

Design: Single-blinded RCT; PNS vs AFO during acute/subacute phase with 3-mo FU for pilot trial and 6-9-mo FU for full trial.

Sample (include target disability group, age group): Adult strokes (45-75)

Inclusion/Exclusion:

Inclusion	Exclusion
• 45-75 yrs old	• LE edema or skin breakdown

• Hemorrhagic or nonhemorrhagic • Medical stability • Unilateral hemiparesis • Presence of footdrop during ambulation • Minimum ambulation ability of standing and stepping within the parallel bars with or without an assistive device • Ankle dorsiflexion to neutral with PNS while standing	• LMN lesion of the peroneal nerve • Severely impaired cognition • Significant visual-spatial deficits • Aphasia with impaired comprehension • DVT • Potentially life-threatening cardiac arrhythmias • Demand pacemakers or defibrillators, or other implanted electronic device. • Pregnancy

Timeline: This depends on whether the study is a pilot or a large scale trial. A pilot can be 3 yrs; a full trial will likely require 5-yrs.

Data Collection Plan Anticipated: Outcomes that span the WHO continuum of impairment (e.g. gait speed, quantitative gait analysis, EMG, fMRI, metabolic cost), activities limitation (e.g. laboratory based measures of functional mobility) and participation (e.g. real life measures of mobility, measures of stroke specific QOL). For a pilot study, outcomes should be assessed at baseline and monthly thereafter for 3 mo. For a full trial, outcomes should be assessed at baseline and at 2-3 mo intervals for 6 to 9-mo, respectively.

Data Analysis Plan Anticipated: longitudinal analysis using linear mixed models

Feasibility Assessment:

Threats to Implementation:

- Medical and neurological instability of acute stroke survivors
- Confounding effect of multiple therapies: PT, OT, speech

Threats to study completion:

- Loss to follow-up
- Noncompliance
- Poor recruitment

Potential Threats to Generalizability:

- Use of a PNS requires high level of support from skilled personnel in order to ensure proper electrode location, reduce or minimize electrical stimulation mediated discomfort and enhance overall compliance. In a clinical trial this support is provided. However, in real life this may be difficult to maintain and thus study results may not easily translate to the real world.

- Although surface PNS is FDA approved, it is not CMS approved. Thus even if this study demonstrates significant benefit of PNS over an AFO, the lack of 3rd party reimbursement may render the study clinically irrelevant. On the other hand, the study results may influence CMS decisions.

Children with disabilities (e.g. autism, Down syndrome, mental retardation, cerebral palsy) often also have co-morbid hearing loss.

Some of this group of children will have moderate to profound hearing loss and may be candidates for cochlear implants. Although both cochlear implants and amplification devices (e.g. hearing aids) are used in this population, the question of which is preferable related to efficacy and broad issues of cost and benefit is not known.

Impact/Utilization: High impact disorders of low frequency.

Nominated Intervention (1): Cochlear implants

Summary of Research Findings to date: limited in this population although perhaps 30-50% of children who received cochlear implants have an additional disability.

Nominated Intervention (2): Amplification devices

Summary of Research Findings to date: limited in this population

Proposed Study Design:

Design descriptive

Sample (include target disability group, age group) children with disability 5yrs of age of less

Inclusion/Exclusion: progressive neurological disease

Timeline: 1 year of amplification followed by offer of cochlear implant if slow probress

Data Collection Plan Anticipated Anticipate the spectrum of speech and language, cognitive, social adaptive, and quality of life funciton.

Data Analysis Plan Anticipated determined by statistician

Feasibility Assessment:

Threats to Implementation finding comparable children

Threats to study completion being able to control for cochlear implant intervention

Potential Threats to Generalizability: each child with a disability is unique

Improving the benefits of assistive technology use by those with lower limb impairments.

Impact/Utilization: Over 7 million people use mobility devices

Nominated Intervention (1): Mobility devices are distributed at rehabilitation hospitals/centers or by durable medical supply dealers using medical benefits and brief assessments of functional loss as criteria for distribution of devices.

Summary of Research Findings to date: Nonuse rates ranging from 12% to 80% depending on the type of mobility device and the method of device acquisition.

Nominated Intervention (2): Acquisition of mobility device based on functional and participation benefits in environments where mobility devices are used including home, work and community frequented sites.

Summary of Research Findings to date: No published studies in this country

Proposed Study Design:

Design: Controlled treatment, multicenter trials

Sample (include target disability group, age group):

Lower limb impairments, over18

Inclusion/Exclusion:

All individuals with lower limb impairments who use mobility devices

except those who use canes, crutches or walkers

Timeline: 2 yr planning, 3 yr implementation

Data Collection Plan: Nonuse of mobility device, functional outcomes, recurrent hospitalization, health care utilization, secondary conditions, quality-of-life and community participation

Data Analysis Plan: Inferential statistics

Feasibility Assessment:

Threats to Implementation:

Requires innovative collaborations with health insurance plans,

rehabilitation centers, community agencies. Requires removal of in-home CMS rule for use of mobility devices

Threats to study completion:

Provider acceptance, consumer acceptance, funding mechanism that

require cost sharing between traditional medical based and community based service providers.

Potential Threats to Generalization:

May not generalize to younger populations

Improving Immediate Responses to In-Home Falls

Improving the response to in-home falls in the elderly population is of paramount importance. Falls are the sixth leading cause of death in elderly people in the United States. A key factor to minimize the severity of fall-related injuries is to promptly detect the fall event and alert clinical personnel. During the past few years, a number of devices for fall detection have been introduced on the market. These devices are based on body-worn units (e.g. pendants, wrist-watch units) equipped with an accelerometer. The units are programmed to detect falls based on the analysis of accelerometer data and to send an alarm message to a caregiver. Unfortunately, the potential benefit of these systems is limited by poor compliance likely because subjects are overwhelmed by the large number of false fall detections (i.e. false positives) that mark commercially available systems.

We propose to develop a new system for fall detection that combines home robotics with the use of body-worn units and to compare the newly-developed system with a commercially available device (i.e., the Philips Lifeline system). In the proposed system, the body-worn unit will send a message to the robot (see *Figure 1*) when it detects a fall event and the robot will respond by acquiring and processing video and audio information to assess whether the subject actually fell. When the subject does not wear the body-worn unit, the robot can utilize additional sensors to detect fall events (e.g. via detection of vibrations of the floor). Although we anticipate that the combined use of the body-worn unit and the robot will be superior to the use of the robot alone, we believe that it would be unrealistic to assume that subjects will use the body-worn unit all the time. The proposed system has great potential in providing effective monitoring and prompt interventions in the prevention of fall-related complications.

The system will rely on wireless units that we have recently developed in collaboration with Intel Digital Health and researchers at Harvard University's School of Engineering. The wireless units can transmit data via an IEEE 802.15.4 protocol or using Bluetooth. Additionally, the units are equipped with a microprocessor of the MSP430 family that allows one to derive features from the accelerometer data and to estimate the likelihood of a fall. Patterns of accelerometer data associated with a fall will be established based on an existing biomechanical model.

We plan to recruit a group of elderly individuals who report frequent falls. We will compare the proposed system and the Philips Lifeline product. Subjects will be given two weeks to familiarize themselves with each of these technologies. They will be tested with both technologies via a cross-over design. The order in which the technologies are presented to the subjects will be randomized. A questionnaire will be completed for each technology and results concerning wearability of the systems, subject's compliance with the use of the system, level of acceptance and perceived usefulness of the system, and obtrusiveness of the system will be compared for the newly-developed technology and the Philips Lifeline product.

Year 1 of the project will be focused on finalizing the development of the above-described system. As part of the development of the system, we will carry out extensive biomechanical simulations related to falls detection. Year 2 of the study will be devoted to collecting data in the field and carrying out extensive data analyses. Simulated fall conditions will be analyzed using receiver operating characteristics to determine operating points of the algorithm for fall detection to be implemented on the body-worn units. Simulated falls will also be analyzed on the robotic platform to test the ability of the robot of identifying false positives without compromising the sensitivity of the system. These simulations will include video and audio data. Questionnaires will be gathered from individuals participating in the study and analyzed to compare the two technologies undergoing assessment.

We have already performed a preliminary evaluation of the robotic platform that we propose to use in the study. However, we still plan to perform an extensive assessment of the robot shown in *Figure 1* and opt for a different platform if necessary. Home robotics is a fast growing field and there are a number of platforms that we could rely upon if the one manufactured by iRobot is deemed to be inadequate. The proposed study will allow the development of a new system and its comparison with an off-the-shelf system for fall detection in the home environment.

Using Interactive Tabletop Technology to Direct Home Rehabilitation

The development of tabletop and interactive surfaces has revolutionized human-computer interaction. Tabletop and interactive surfaces are ideal for the implementation of interactive games. The physical interaction of a single user or multiple users with the interactive surface is particularly appealing in rehabilitation. Reaching movements and the manipulation of objects are essential elements of therapeutic interventions aimed at improving motor functions in individuals with mobility-limiting conditions such as cerebral palsy. The use of interactive surfaces provides an unprecedented opportunity to motivate the subject to reach for virtual objects and manipulate them on the screen. Interactive gaming has been utilized extensively in rehabilitation to motivate subjects to perform motor tasks that are important in rehabilitation. An example of the use of this technology in rehabilitation is the use of the Nintendo Wii, which has elicited a great deal of interest in the rehabilitation community. The use of interactive gaming is particularly appealing in the pediatric population where traditional therapeutic interventions have failed in engaging the child. This limits the benefits possible with the therapeutic exercise undertaken. On the contrary, children will likely respond well to stimuli provided within an interactive gaming context with the potential for significant therapeutic benefits.

Presently interactive gaming platforms (like the Nintendo Wii) are not totally suitable for the implementation of rehabilitation interventions. This is because interactive gaming platforms are not designed for rehabilitation and therefore do not provide control of the type and quality of movements performed by patients. For instance, the tennis video game on the Nintendo Wii platform allows patients to play either with limited movements of the wrist (i.e. waving the Wii Remote) or properly swing the arm with a large range of motion at the shoulder. In a standard therapeutic scenario, clinicians need to have control of the type and quality of movements performed by patients and assign the patient to specific exercises that target the execution of shoulder and elbow movements and other exercises that are specific of wrist and hand movements. Recent advances in miniature sensor technology have the potential to address the above-summarized limitations of existing interactive gaming platforms. Specifically, wearable sensors are currently available that allow one to track movements of the body and determine the type and quality of movements performed by patients.

In the proposed project, we plan to utilize tabletop and wearable technologies to implement therapeutic interventions based on interactive gaming. The project will be carried out over a period of two years. During Year 1, we will focus on assessing the suitability of the above-described platform for the implementation of games aimed at improving motor functions in children with cerebral palsy. This part of the study will be focused on fine-tuning the platform to maximize efficacy of the tools we are developing. We will rely on games that children can play on their own as well as games aimed at improving their interaction with others, including the therapist, their parents, and other children. During Year 2 of the

project, we will focus on a comparative assessment of interventions based on tabletop and wearable technologies and standard physical therapy interventions. Spaulding Rehabilitation Hospital has a large pediatric program overseen by Dr. Donna Nimec with whom we have been collaborating on clinical projects over the past six years. Dr. Nimec works very closely and provides pre-surgical clinical gait evaluations for the surgical team at Children's Hospital, Boston. About 1000 children with cerebral palsy receive clinical services through the unit directed by Dr. Nimec. We will work with Dr. Nimec to recruit children with cerebral palsy showing impaired reaching and hand dexterity. A group of children will undergo a rehabilitation program based on the use of tabletop interactive games. A second group will undergo physical therapy in the outpatient setting. Functional outcomes will be compared in the two groups to test the hypothesis that improved function can be provided via the intensity of motor training delivered by using interactive gaming tools. Future studies will explore the use of these tools for home-based therapy.

APPENDIX C

Examples of CER in the area of Health Promotion and Wellness Interventions for People with Disabilities

A Comparison of Traditional Community Based Mentoring Interventions and Efficacy- Based Wellness Coaching in Promoting Healthful Physical Activity and Nutrition for Overweight/Obese Adolescents with Disabilities

Nature of Problem or Research Question:

The prevalence of overweight and obesity in children and adolescents has increased dramatically in recent decades. Data from the National Health and Nutrition Examination Surveys (NHANES) collected in 2003–2004 indicate the prevalence of overweight individuals by ages 2–5, 6–11, and 12–19 are 13.9%, 18.8%, and 17.4%, respectively. Examination of historical NHANES data reveals that the prevalence of childhood obesity has approximately tripled during the past 30 years, mirroring the increased prevalence among adults. Our current research at the University of Illinois at Chicago (NIDRR Grant No. H133A060066) examined the prevalence of obesity and obesity-related secondary conditions in a national sample of 662 youth with disabilities ages 12-18 years. Prevalence of obese youth with disabilities was found to be significantly higher (17.5%) compared to youth without disabilities (13.0%), and more than 70% of the participants reported having at least one secondary condition including gastrointestinal problems, sleep apnea, asthma, depression, low self-esteem, and fatigue. Youth with disabilities are also more likely to live sedentary lifestyles than their non-disabled peers and there is compelling evidence showing an association of physical activity, sedentary behavior, and overweight/obesity (Zoeller, 2009). Obesity is a major public health issue among youth with disabilities. Despite this urgent need for interventions, there is a void in the literature on successful interventions for overweight youth with physical disabilities.

Impact/Utilization:

Adolescence is an important developmental period during which youth with and without disabilities develop much of the self-concept, attitudes and behaviors they will carry into adulthood. Effective, evidence-based health promotion interventions during this developmental period are direly needed so that youth and their families can establish the requisite self-management skills and health behaviors that will promote good health and reduce the risk of chronic and secondary conditions in adulthood.

Nominated Intervention (1):

Effectiveness of a one-to-one, community-based youth mentoring program to increase physical activity and promote healthier nutrition among overweight youth with disabilities.

Summary of Research Findings to date:

One-to-one youth mentoring programs such as *I can do it-You can do it* and *Kids Enjoying Exercise Now (KEEN)* have been shown to have a significant and positive impact on young people's lives, particularly for those youth found to be at highest risk (Catalano, et al 2004; Beir, et al 2000). Despite the popularity of such programs, few existing programs have been evaluated with the necessary methodological rigor to determine efficacy of program practices. Well-controlled, carefully designed comparative effectiveness studies are needed to establish the utility and efficacy of these programs within the broader health promotion programming context. A preliminary evaluation of the *I can do it-You can do it* program has shown mixed results and indicates the need for further research (Final Report on the Evaluation of the I Can Do It, You Can Do it Health Promotion Intervention, 2007).

Nominated Intervention (2):

Effectiveness of a telephone-based personal health behavior coaching intervention (Personalized Exercise/Nutrition Prescription or "PEP") to increase physical activity and promote healthier nutrition among overweight youth with disabilities.

Summary of Research Findings to date:

Findings from adherence and motivational research indicate that participation in health promotion (i.e., physical activity and nutrition) is far more likely when the programs are customized to address the unique needs and concerns of the individual user. Our previous research has shown that an intensive telephone-based personal health behavior coaching intervention can empower severely obese participants with mobility disabilities to make substantial increments in physical activity and improved nutritional habits, resulting in a significant reduction in BMI. The strength of person-centered programming lies in being able to develop recommendations for the individual that are realistic and achievable within the context of his/her circumstances and environment.

The proposed PEP + youth wellness coaching intervention uses information technology to provide wellness coaches with rapid access to evidence-based strategies for increasing physical activity, improving nutritional habits and improving the overall health status of participants. The PEP+ approach focuses on empowering youth to self-manage key health behaviors through positively focused steps toward developing greater self-efficacy for these behaviors (Rimmer & Rowland, 2007).

Proposed Study Design:

The proposed randomized controlled trial will assign participants to one of two physical activity and nutrition intervention conditions: (1) a traditional community-based mentoring approach such as *I Can Do it – You Can Do it*, or 2) *PEP+ Youth Wellness Coaching*.

Sample: Stratified random sampling will be employed in assigning participants to the two treatment conditions to assure the groups are comparable in terms of type and severity of disabilities represented. Recruitment size will depend on the amount of funding allocated for this comparative effectiveness study.

Inclusion/Exclusion: Participants must also meet the following eligibility criteria: (a) age 14-18 yrs; (b) have written permission from their physician to participate in the study; (c) have the ability to use hands and arms independently to exercise; (d) Percent Body Fat $\geq 85^{th}$ percentile based on triceps skinfold measurement; (e) have the ability to converse in English and complete activity monitoring report forms; (f) not be currently enrolled in a health promotion program; (g) have a parent or guardian sign the agreement to support recommendations of the wellness coach and; (h) have a sedentary lifestyle over the past 6-months as measured by the module on moderate and vigorous physical activity from the CDC Youth Risk Behavioral Surveillance System (YRBS).

Data Collection Plan Anticipated: Primary Outcome measures will include physical activity levels, nutrition intake, and self efficacy to exercise. Secondary outcome measures include quality of life and participation. Other data collected include barriers to physical activity and healthy eating, medications, and demographics. Data will be collected at the following points: screening, pre-testing, post-testing, and follow-up.

Data Analysis Plan Anticipated: To test the hypotheses concerning the effects of the intervention on primary and secondary outcome measures, a series of 2 (treatment 1 vs. treatment 2) by 2 (pre-test vs. post-test) mixed factorial analyses of variance (ANOVA) will be performed, employing Type III sums of squares. Significance will set at the .05 level. Any significant interaction effects will be evaluated through post-hoc t-tests. Adherence to and success of the intervention condition will be assessed using select criteria that are based on questions asked during the follow-up interview related to their participation in physical activity and adopting healthy eating behaviors.

Feasibility Assessment:

Threats to Implementation: A threat to implementation of this research would include any issue that would prevent or inhibit the recruitment of study participants or the ability to reach participants for data collection or coaching calls.

Threats to study completion: Threats to study completion may include any problems with participant retention or an inability to complete follow up measures with participants.

Potential Threats to Generalizability: Generalizability, or external validity, may be threatened on the ecological or population level. Threats to population validity could include the possibility that our youth with disabilities are misrepresentative of the general population of youth with disabilities. Potential threats to ecological validity include the possibility that the intervention is

affected by factors related to the period of time (historical, seasonal, etc.) in which the intervention takes place, by personal attributes of the staff implementing the intervention, or by effects related to the act of participating in a study itself, such as the Hawthorne effect or testing sensitization.

Comparing two established health promotion interventions; the Chronic Disease Self-management program and the Living Well with a Disability Program

Nature of Problem or Research Question:

The barriers people with disabilities encounter in maintaining and improving their health status are numerous and interrelated (1, 2). For these individuals, functional loss leads to unique self-management needs even as it limits opportunities for health improvement. Even more, ability to participate in the vast array of community activities enjoyed by most people who achieve and maintain good health status is limited for those with disabilities. Hence, the reinforcement contingencies to develop and maintain a healthy lifestyle are less salient and available to people with disabilities. Lorig et al. (3) reported those who did not complete the Chronic Disease Self-Management Program reported significantly fewer minutes of aerobic exercise per week and higher levels of activity limitation, pain/physical discomfort, fatigue, and health distress than completers.

The benefit of developing a healthy lifestyle is essentially two-fold. First, healthy lifestyles can reduce and even eliminate symptoms of chronic disease and permanent injury. Second, improved health status improves an individual's ability to fully participate in community. This research project will compare two evidence-based health education programs; the Chronic Disease Self-Management Program (CDSM; 3) and the Living Well with a Disability Program (LWD; 4-6). The CDSM program focuses primarily on symptom reduction while the LWD program addresses both symptom reduction and improved participation. The study will compare the effectiveness of each program on the health status of people with a disability compared to those without a disability.

Impact/Utilization: Study results will lead to a better understanding of how disability interacts with health behavior change. For people with a disability, a Living Well with a Disability may be more effective than the Chronic Disease Self-Management Program.

Nominated Intervention (1): Living Well with a Disability

The Living Well with a Disability health promotion program is a health education intervention that was developed from the premise that people with functional loss will be more apt to make healthy behavior choices when those choices are organized to facilitate achievement of specific important long-term goals.

Summary of Research Findings to Date: In a randomized staggered baseline design, workshop participants (i.e. people with mobility impairments) reported numerous statistically significant changes including a 13% reduction in limitation due to secondary conditions, a 13% improvement in health related quality of life (i.e. symptom days), a 5% increase in healthy

behavior and a 67% reduction in healthcare costs during the intervention period. Many of these effects were maintained over 12 months (5). Comparing these outcomes to individuals not receiving the intervention, workshop participants were three times more likely to be below the median on limitation from secondary conditions (AOR = 1.94 (1.03, 3.67)) twice as likely to be below the median of unhealthy days and (AOR = 3.05 (1.33, 7.01)), twice as likely to be below the median for health care costs (AOR = 1.96 (0.91, 4.26)) than those who did not receive the intervention (4). These results on secondary conditions mirrored those of a separate study (6).

Nominated Intervention (2): The Chronic Disease Self-Management Program is a health education program designed to address common symptoms of chronic disease. The intervention utilizes self-efficacy theory to guide interventions that elicit health behavior change.

Summary of Research Findings to Date: "As compared with controls, the treatment group demonstrated significant improvement in four health behavior variables ($P < 0.01$; number of minutes per week of stretching/strengthening and aerobic exercise; increased practice of cognitive symptom management; and improved communication with their physician). They also demonstrated significant improvement in five health status variables (self-rated health, disability, social/role activities limitation, energy/fatigue, and health distress; $P < 0.02$). No significant differences were demonstrated for pain and physical discomfort, shortness of breath, or for psychological well-being. The treatment group, as compared with the control group, had fewer hospitalizations ($P < 0.05$) and spent, on average, 0.8 fewer nights in the hospital ($P = 0.01$)" (3).

Proposed Study Design: A randomized controlled trial with repeated measures. Subjects will be stratified by disability status and randomly assigned to either the CDSM or the LWD program. Outcomes will be collected using known outcome measures to examine health behavior change, health outcome, health related quality of life and healthcare utilization and life satisfaction.

> ***Sample:*** People with chronic illness or permanent injuries ages 18-70 stratified by disability defined by regular use of mobility equipment.
> ***Exclusion:*** People with co morbid psychiatric conditions other than depression.
> ***Timeline:*** 2- year cost-effectiveness study with 6-months post-intervention follow-up data collected.
> ***Data Collection Plan:*** Self-report staggered baseline design with pre-, post-, and 6-month follow-up.

Data Analysis Plan Anticipated: Repeated measures analysis of variance with between subject factors to include disability status and intervention group

Feasibility Assessment: *Threats to Implementation* - Each of the interventions have been implemented successfully in both research and dissemination frameworks. Subject recruitment

will need to be addressed with significant staff time devoted to recruitment and maintenance of the study sample. *Threats to study completion*- slow rate of subject recruitment.

Potential Threats to Generalizability: Treatment fidelity and sample recruitment will be key to assure results are not merely a reflection of the most motivated community-dwelling adults who receive a standardized treatment within a research protocol. Each intervention uses facilitator training and a curriculum to maintain program fidelity.

Low employment rate of individuals with psychiatric disabilities

Impact/Utilization: The development of effective models to help individuals with psychiatric disabilities enter the workforce has the potential to enhance their economic security, quality of life, and community inclusion. The labor force participation of such a sizable group of individuals on the SSI/SSDI roles would also stimulate our nation's economy in the form of economic contributions through federal and state income taxes as well as sales tax paid on purchases, and growth of the economy's sales sector through an increased ability to make purchases.

Nominated Intervention (1): Supported Employment (SE)

Summary of Research Findings to date: SE is an evidence-based practice in the field of psychiatric disability, supported by numerous single randomized controlled trials (RCTs) as well as one large national multi-site study called the Employment Intervention Demonstration Study or EIDP (http://www.psych.uic.edu/eidp/).

Nominated Intervention (2): Customized Employment (CE)

Summary of Research Findings to date: CE is a promising practice developed by the USDOL, ODEP and evaluated in a national demonstration program with a non-randomized, pre-post design.

Proposed Study Design:

Design - Randomly assign 300 subjects with psychiatric disabilities to SE vs. CE and follow them for 1 to 2 years.

Sample (include target disability group, age group) – Individuals with psychiatric disability age 18-55 (or older)

Inclusion/Exclusion – Desire to work, willingness to participate in the research, willingness to allow access to service utilization data, earnings data, spending patterns, and clinical data

Timeline – This could be a 2 to 3-year project with a 12 month follow-up; or a 3 to 4-year project with a 24 month follow-up. Either would be valuable.

Data Collection Plan Anticipated – Vocational outcome data would be tracked weekly via telephone of employment, using the EIDP protocols. Services could be tracked on a monthly basis via telephone or electronically if service data are available and subjects provide consent. Changes in psychosocial outcomes (self-esteem, recovery) and behavioral changes (monthly spending, taxes paid) could be tracked through semi-annual interviews.

Data Analysis Plan Anticipated – Given the nature of outcome variables (interval level measures such as earnings and job tenure, and ordinal measures such as employment status and job benefits), longitudinal random regression analysis would be the appropriate statistical technique for use with these data.

Feasibility Assessment:

Threats to Implementation – Implementation threats include the unwillingness of subjects to allow access to sensitive mental health clinical data; fear of loss of SSI/SSDI and other benefits and entitlements; and hesitation to allow access to private earnings data and information regarding job loss. Money would have to be made available to fund the SE and CE service delivery and some level of assurance would need to be provided that employment services and supports would be ongoing following the completion of the research study.

Threats to study completion- Completion could be threatened by the uncertain economy and high unemployment rate in many parts of the U.S.

Potential Threats to Generalizability: Unless this was a national study with a larger sample size, the results would only be generalizable to the local area from which the sample population is drawn. A multi-site study would ameliorate this somewhat, although it would still not constitute a nationally representative sample.

Comparative Effectiveness of Work on Improving Health Status and Quality of Life for Low Income Persons with Disabilities Insured by Medicaid

Nature of Problem or Research Question: Poverty and unemployment for persons with disabilities are much higher than that of the general population, at least in part because increased employment can jeopardize individuals' federal disability cash benefits, health care coverage and health status through Medicare and/or Medicaid. Medicaid Buy-In programs allow people with disabilities to work, accumulate assets, and maintain Medicaid coverage. In 2007, nearly 106,000 people with disabilities participated in Medicaid Buy-In programs in 34 states. Although enrollment in these Buy-In programs has consistently grown over the years, little is known about how integrated employment affects health outcomes. Many researchers have documented the relationship between poverty and poor health status, but little research has focused on poverty in combination with disability. Our research question is: does working improve or diminish health status and quality of life for low-income people with disabilities who are insured by Medicaid?

Impact/Utilization: Because of the existing dearth of evidence related to the effectiveness of work programs for persons with disabilities, findings from this research will impact the way in which front line service providers and medical practitioners support work efforts of low income people with disabilities. Results can be shared with service providers and medical practitioners through dissemination to relevant professional organizations and databases both in this country and around the world, where many industrial economies are grappling with similar issues related to integrating their disability populations into the modern workforce. It is unknown at this time how significant the joint effects of insurance and work are on the health of low-income people with disabilities.

Nominated Intervention (1): Integrated employment for low income persons with disabilities being insured with Medicaid

Summary of Research Findings to Date: Liu, Ireys, and Thornton (2008) reported profiles of Medicaid Buy-In participants in 27 states, finding that Buy-In participants tended to be older than other persons with disabilities insured with Medicaid, and that about one-third had mental illness. No studies to date have utilized a comparison group analysis in order to understand social determinants such as age, gender, disability type, work history and attitudes, education level, self esteem, and quality of life factors as they relate to participation in a Buy-In program. Nor have any studies compared health outcomes of Buy-In enrollees with non-enrollees. Preliminary findings among persons enrolled in the Kansas Buy-In, Working Healthy, indicate that participation not only allowed for increased income, but more consistent access to Medicaid coverage and services (Hall & Fox, 2004; Hall, Fox, & Fall, 2009). Participants' average annual earnings, while still very low at under $8,000, increased over time and contributed to a sizable

increase in state and federal payroll taxes. But the degree to which work enriches health status and quality of life for persons with disabilities who are insured by Medicaid remains unknown.

Nominated Intervention (2): Traditional Medicaid insurance coverage for low income persons with disabilities that does not include integrated employment.

Summary of Research Findings to date: Hanson, et al., 2003 documented the hardships faced by persons with disabilities who have no insurance. They also identify the unique challenges that low income persons with disabilities face in assuring adequate medical care, even if they have Medicaid, because so few providers are willing to accept Medicaid payment. Once working-age people with disabilities have qualified for Medicaid, they are subject to strong incentives to remain poor, being forced to avoid working at gainful employment levels to remain eligible. Weiner (2003) suggests that working may put persons with disabilities at higher risk for adverse health outcomes. This line of reasoning suggests that not working while receiving Medicaid benefits could enhance health status and quality of life for persons with disabilities.

Proposed Study Design:

Design: Quasi-experimental, longitudinal case-comparison study

Sample: Data will be collected for the entire enrolled population of Working

Healthy (approximately 1,100 people as of April, 2009) and data for a comparison group of 1,200 individuals who are working age, disabled, and dually-eligible for Medicaid and Medicare.

Inclusion/Exclusion: The sampling frame includes all persons eligible for enrollment in the Kansas Medicaid Buy-In program (*Working Healthy)*, so that persons who enroll (cases) and persons who do not enroll (comparison group) are selected.

Timeline: We will access four years of historical and one year of current data, giving us the ability to examine longitudinal trends in health care utilization and costs as well as earnings.

Data Collection Plan Anticipated: We will utilize both administrative and self-reported data to fully understand the effect of enrollment in Working Healthy on health outcomes for low income individuals with disabilities. The International Classification of Functioning (ICF) framework for disability classifications will guide our selection of specific data elements in order to produce findings that are comparable to other disability research. Baseline and follow-up surveys of both enrollees and non-enrollees will address respondents' self-reported levels of self-esteem, quality of life, work attitudes, health status, and various demographics including gender, age, race, ethnicity, disability type(s), number of disabilities, employment history, earned and unearned income, and educational level. Some health status and quality of life items will be drawn from the SF-12v2 and WHO-QOL instruments (Bonomi & Patrick, 1997). These items will be added to an existing annual survey of the Working Healthy participants and incorporated into a new survey instrument for the comparison group. Various state and federal administrative

data including Medicaid, Medicare, as well as income tax and unemployment compensation records will be obtained through a business associate relationship with the state Medicaid agency and interagency/data use agreements with the Region VII office of the Centers for Medicare and Medicaid Services (CMS), and the Kansas Departments of Revenue and Labor. Data will include Medicare and Medicaid utilization and expenditure levels for outpatient, inpatient, and, for Medicaid records, pharmaceutical services, and gross income levels and earnings levels.

Data Analysis Plan Anticipated: We will use mixed model analyses. The mixed model framework will allow differences in initial levels of the dependent variable as well as differential change over time between groups to be modeled. The quality of life outcome variables of interest with respect to health care utilization over time are relative disease burden; inpatient, outpatient, and emergency department use; co-morbidities; and overall costs. Baseline scores will be used as covariates in the models with group membership and time as the primary independent variables. Relative disease burden will be calculated using Johns Hopkins Adjusted Clinical Group (ACG) Case-Mix System software, version 8.2 (2009). We will use mixed models to compare adjusted gross income (AGI) and earned income for both sample groups over time, using tax and unemployment compensation information as dependent variables, baseline scores as covariates, and group membership and time as independent variables. Logistic regression will be used to identify disparities in social determinants of health.

Feasibility Assessment:

Threats to Implementation: Integration of data from multiple sources has historically posed a major barrier to this type of comparative effects research. Past research either has been confined to using Medicare, Medicaid, self-reporting, or income data (such as Social Security or unemployment compensation data) to capture items such as health care services or monthly income. By linking these data sources to follow participants' health and personal experiences over time, we hope to address many of the shortcomings typically encountered when using selected administrative data sets for persons with disabilities. We will build upon our previous work in this area. More general difficulties associated with the use of administrative data for health services research are well known. They include issues related to confidentiality, linkage technology, costs, uniformity of and access to data, among others (Black & Roos, 1998; Roos et al., 1999).

Threats to study completion: None.

Potential Threats to Generalizability: While efforts will be made to describe the population and adjust for all measurable cofactors, there may be limitations to generalizability based on our one state sample.

Comparing established weight-loss interventions with a promising alternative

Nature of Problem or Research Question:

Research has shown that people with IDD have poorer health than peers without disabilities (Horwicz, Kerker, Owens, & Zigler, 2001; U.S. Office of the Surgeon General, 2002). In the past decade, government initiatives such as Closing the Gap: a National Blueprint to Improve the Health of Persons with Mental Retardation (2002) and Call to Action to Improve the Health and Wellness of Persons with Disabilities (2005) have helped to set the policies later described in Healthy People 2010. A recent review of work to date on translation of these policies into practice with people with IDD (Krahn & Drum, 2007) indicates that health promotion programs have been effective in improving quality of life, especially in the self-reported lifestyle behaviors. One area that has not shown improvement, however, is the teaching of good nutrition choices of persons with IDD, especially those living in group homes. Our observations lead us to conclude that many persons with IDD want to lead a healthy lifestyle, including eating and drinking in a healthier manner. Their environment makes choosing healthy alternatives difficult however. As a result, adults with IDD have more than 1.5 times the prevalence of obesity than in the general population (Rimmer & Yakima, 2006). Krahn and Drum conclude that in order for future health promotion strategies to be effective, environmental factors must be considered. This study will compare the effectiveness of two programs that promote weight loss, one through environment change and teaching ( ), and another through teaching along (usual care).

Impact/Utilization: Funding and Implementation of this proposal will have the following known and possible impacts:

1. Over a 2-year project, infuse hundreds of thousands of dollars into rural and generally depressed areas of Kansas.

2. Anticipated results, based on our pilot data include:

   a) significant weight reduction by 85%or more of IDD participants in Intervention 2.

   b) an increased empowerment of the IDD participants in Intervention 2 to be responsible for and in control their energy consumption

   c) reductions in costs for medical services and medications under Medicaid for the participants in Intervention 2.

3. Promote a “sea change” in the attitudes of those most invested in supporting people with IDD with regard to what individuals with IDD want in the way of healthier lifestyles and what they are willing to do to achieve them.

Nominated Intervention (1): Using the principles of volumetrics, the diet approach (Pictorial 5-3-2) involves teaching and coaching the participants about better nutritional habits, and changing the environment by using portion control and by replacing unhealthy foods available with health alternatives. This study has been studied extensively with typical adults (cites) and we recently conducted a pilot study of 77 individuals, funded by the Kansas Council on Developmental Disabilities and the U.S. Administration on Developmental Disabilities.

To match the level of understanding of the participants with IDD, the instructions for following the diet were modified from their usual printed form to be nearly entirely pictorial. Pictures were used in materials that were intended to guide the dieter in food planning, purchase and preparation. Pictures also were used in materials that participants used to record what they consumed each day. Where pictures were not relevant, we used extensive use of color-coding to guide the dieters (e.g., individual weight charts).

Summary of Research Findings to Date: Weight loss in this pilot averaged 6% of baseline weight at 6 months. Thru March, 2009, some early enrollees have completed 18 months in the project and others 12 or 9. The current data are shown in the table below. Starting average Body Mass Index (BMI) was 37.0. BMI is calculated as weight (kg)/height (m^2) and a healthy, normal BMI is considered to be under 25.

Time in diet	**Percentage loss from baseline weight**		
	Mean	Median	Range
6 mo (N=77/77)	6.1%	6.09%	0 - 19.55%
9 mo (N= 56/77)	9%	7.71%	0 - 27.08%
12 mo (N=30/77)	9.3%	8.18%	0 - 28.05%
18 mo (N=18/77)	12%	11.53%	0 - 28.5%

As part of our pilot, we provided a questionnaire that is required by all projects funded by the Administration on Developmental Disabilities. The results were:

- "I was treated with dignity and respect during the project activity." Yes=100%; No=0%
- "I have more choice and control as a result of this project activity." Yes = 98%; No=2%
- "I can do more things in the community as a result of this project activity." Yes=92%; No=8%

- "My life is better because of this project. Strongly Agree=72%; Agree=26%, Strongly Disagree=2%

Nominated Intervention (2): The Usual Care (UC) diet, as recommended by the National Heart Lung and Blood Institute (National Institutes of Health) (1998), should be compared with any novel approach because it is the standard diet recommended by health promotion programs for all people, including those with IDD.

Summary of Research Findings to Date: To date, little data on the effects of these programs on weight loss with individuals with disabilities have been published.

Proposed Study Design: This study will use a randomized controlled trial with repeated measures. Subjects will be stratified by type of residential accommodation and randomly assigned to either Intervention 1 or 2. Outcomes will be collected using known outcome measures to examine weight loss, changes in health (e.g, disease status, medication change, etc.), and changes in community participation.

Sample: People with disabilities who are overweight and between ages 18-70

Exclusion: People with cancer, heart disease, or metabolic disorders

Timeline: 2- year cost-effectiveness study with 6-months treatment and comparison of 12 month pre-treatment health care utilization data (Medicaid) with 12 months post-treatment follow-up.

Data Collection Plan: Monthly measurement for 18 months

Data Analysis Plan Anticipated:

Weight loss after 6 month weight loss intervention	• Descriptive statistics • Two sample t-tests comparing difference between Pictorial 5-3-2 and UC diet groups • Multiple linear regression to assess impact of covariates
Weights measured at 6, 12, and 18 months after intervention	• Linear mixed model to evaluate weight change over time • Mixed linear model to assess impact of covariates
SPARC score indicating level of community participation	To analyze pre and post- intervention data: • Wilcoxon-Mann-Whitney U test • Independent samples t-test
Using Medicaid claims data, measure change in disease prevalence and health care utilization, including pharmaceutics, lab, in patient, and out	• Descriptive statistics, Chi2 and t-tests, as appropriate • Multivariate models to assess impact of covariates

patient pre- and post-intervention	

Feasibility Assessment: *Threats to Implementation:* None; study has already been completed with pilot sample with considerable success. Current waiting list for future funded projects. *Threats to study completion*- slow rate of subject recruitment.

Potential Threats to Generalizability: The pilot achieved equal success with both genders, individuals with varied diagnoses, individuals on medications with weight gain as a known side effect, individuals with and without physical disability, individuals with and without diagnosis of mental illness, and individuals from various types of residential accommodations.

Nomination Form for Tobacco Control Comparative Effectiveness Research Project

Nature of Problem or Research Question:

Individuals with a range of disabilities experience differential levels of health and health-related quality of life compared to the general population. McGinnis, Williams-Russo, and Knickman (2002) reviewed U.S. research on five key factors (genetics, social circumstances, environment, individual behaviors, and access to medical care) that contribute to overall health among the general population. Their estimates of the contribution of each factor included: genetic predispositions (30%); social circumstances (15%); environmental conditions (5%); access to medical care (5%); and individual behaviors (40%). Although McGinnis makes a reasonable case for these estimates as applied to the general population, it is unlikely that they are accurate estimates for persons with disabilities. Nevertheless, individual behaviors, such as tobacco use, are likely to have similar or greater effects on the heath of persons with disabilities.

Cigarette smoking remains the leading preventable cause of death in the United States,[1] accounting for approximately 1 of every 5 deaths (438,000 people) each year.[2,3] An estimated, 20.8% of all adults (45.3 million people) smoke cigarettes in the United States.[4] Despite widely recognized negative consequences associated with tobacco use, there are higher rates of cigarette smoking among disability populations compared to the general adult population. According to the Centers for Disease Control and Prevention (CDC) using data from the Behavioral Risk Factor Surveillance System (BRFSS), approximately 30% of people with disabilities are smokers.

Although tobacco control has been a major health promotion focus and includes a number of evidence-based interventions, little research has been conducted to determine the effectiveness of tobacco control health promotion measures when tailored toward individuals with disabilities compared to tobacco control interventions that do not tailor activities to persons with disabilities.

Impact/Utilization:

Tobacco use accounts for more than $190 billion annually in direct and indirect medical costs, and at least 8.6 million Americans are living with at least one serious illness caused by tobacco use. Furthermore, exposure to secondhand smoke causes premature death and disease in nonsmokers, with costs in the United States estimated at $10 billion per year (CDC, 2007). Of the approximately 54 million adults with a disability, extrapolating from CDC prevalence estimates, over 16 million are smokers. Reduction in smoking rates among individuals with disabilities should result in decreases in medical costs and reduction in mortality.

Nominated Intervention (1):

State based comprehensive tobacco control programs (TCP) encompass coordinated efforts to establish smoke–free policies and social norms, promote and assist tobacco users to quit, and work to prevent initiation of tobacco use. The four components of TCP are:

- Population-based community interventions
- Counter-marketing
- Program policy/regulation
- Surveillance and evaluation

Summary of Research Findings to date:

Greater investments in state tobacco control programs are independently and significantly associated with larger and more rapid declines in adult smoking prevalence, according to the CDC. According to a CDC report ("The Impact of Tobacco Control Programs on Adult Smoking," also published in the February 2008 issue of the *American Journal of Public Health*) using data from all 50 states and the District of Columbia, declines in adult smoking prevalence among individual states were directly related to increases in state per person investments in tobacco control programs, independent of price increases (CDC, 2007). These results re similar to reports issued in 2007 from the Institute of Medicine, the National Institutes of Health, and the President's Cancer Panel that all concluded that comprehensive state tobacco control programs are effective public health investments (CDC, 2007).

Nominated Intervention (2):

State based comprehensive tobacco control programs that include disability issues in their initiative.

Summary of Research Findings to date:

No published reports that include people with disabilities as a target group, the State of Oregon obtained disability data in developing their TCP but no results are available.

Proposed Study Design:

Design- Embedded multi-site case study with matched comparisons

Sample (include target disability group, age group)- 2 to 6 states.

Inclusion/Exclusion- inclusion factors for matched comparisons could include population size, racial and ethnic factors, SES, and type of disability.

Timeline- Because of the time lag between TCP initiation and measurable results, this most feasible as a five year project or longitudinal.

Data Collection Plan Anticipated- Baseline and annual comparisons of matched states.

Data Analysis Plan Anticipated- The CDC has developed a range of recommended surveillance (health status, quitline data sets, etc), evaluation (e.g. process and outcome measures, etc), and expenditure measures for TCP. Qualitative assessments of disability

enhanced initiatives should also be conducted. Case reports should include comparisons between all data elements.

Feasibility Assessment:

Threats to Implementation- Although all 50 states and DC receive CDC funds for tobacco control, only a handful of states' total funding is at levels recommended by the CDC. States would have to agree to include disability as a target group.

Threats to study completion- Decreases in TCP funding due to economic issues or re-allocation of resources.

Potential Threats to Generalizability:

Use of case study approach.

Exergame cycling compared to standard exercise cycling.

Nature of Problem or Research Question: Diabetes mellitus is a major clinical and public health problem. This research aims to investigate what are ethnic group differences in physical activity, functional mobility and self-management among older women with type 2 diabetes, and if these can be mitigated with an innovative exercise strategy versus traditional strategy.

Impact/Utilization: Regular participation in moderately intense physical activity is associated with a substantially lower risk of type 2 diabetes and improved functional outcomes (Jeon et al 2007).

Nominated Interventions: Exergame cycling compared to standard exercise cycling.

Summary of Research Findings to date: The *Games for Health* Initiative is a project that applies cutting edge games and game technologies to develop a community and best practices platform for the numerous games being built for health care applications (www.rwj.org).

Proposed Study Design:

> **Specific Aim 1:** To characterize ethnic group differences in physical activity and functional mobility among older African American women and non-Hispanic white women with Type 2 diabetes.
>
> **Specific Aim 2:** To characterize potential psychosocial and sociocultural contributions to ethnic group differences in physical activity, functional mobility and diabetes self-management among African American and non-Latino White women ages 50-75 years.

Study Setting and Number of Subjects. Measures of physical activity, functional mobility and self-management will be conducted.

Sample. Wmen aged 50-75 years of age with doctor-diagnosed type 2 diabetes will be recruited from two ethnic groups (African American women and non-Hispanic White women).

Data Collection Plan. Physical Activity (Measure of clinical pain). Acute exercise provides an

experimental model for manipulating naturally occurring pain (Cook et al 2004). Measures of clinical pain, physical activity and functional mobility will be assessed using two types of light cycle fitness activities; exergame cycling (cycling while playing an on-screen video game), and standard cycling (cycling without playing the game activity) for approximately 15 minutes each; a total of 30 minutes. Healthy People 2010 recommends physical activity for at least 30 minutes, 3 times per week. Cycling activity will be standardized across participants to achieve mild to moderate levels of exertion. After each 15 minutes exercise period, participants will rate pain intensity from 0-100 using a Visual Analog Scale (VAS). Participants will have two 15-minute rest periods. During the rest periods, participants will provide VAS ratings (0-100) of pain every

five (5) minutes for 3 resting pain scores (rps). Each participant will engage in both types of cycling activity. In one exercise, participants will ride on the stationary bike for up to 15 minutes. In the other exercise, participants will ride the same stationary bike for up to 15 minutes, but will be playing a video game while exercising. This video game will be shown on a TV in front of the bike and will work with the bike to make the exercise more like a game. Which ride the participant will do first will be randomly selected. Participants will practice on the cycle before beginning the exercises.

Blood Pressure and Heart Rate. Blood pressure levels, heart rate readings will be recorded during each resting period. A wrist or arm mounted automated blood pressure device will be used. To assess hear rate from cycling activity, a wrist or chest-attached, heart rate monitor will be used.

Distance and Time. A record of the distance in miles and amount of time that the individual pedaled will be collected.

BioPsychoSocial Questionnaires/Inventories: Several biopsychosocial questionnaires will be used: (1) Diabetes Care Profile (DCP), (2) Diabetes Attitude Questionnaire (DAQ)—(U of Michigan, 2000), (3) Diabetes Knowledge Test (DKT), (4) Brief Pain Inventory (BPI), (5) McGill Pain Questionnaire (MPQ), (6) Michigan Neuropathy Screening Instrument (MNSI-Part I), (7) Multi-Ethnic Identity Measure (MEIM).

Data Analysis Plan: Specific Aim 1: To characterize ethnic group differences in physical activity and functional mobility among older African American women and non-Hispanic white women with Type 2 diabetes. A series of analyses of variance (ANOVA) will be used to test for differences between the ethnic groups in physical activity and functional mobility. **Specific Aim 2:** To characterize potential psychosocial and sociocultural contributions to ethnic differences in physical activity, functional mobility and diabetes self-management. A series of ANOVAs will be used to test for differences between the groups on each of the psychosocial variables. Pearson product-moment correlation coefficients will be calculated to determine associations among clinical pain, pressure pain thresholds and the psychological variables. To determine whether psychological variables mediate ethnic group differences in pain perception, for each pain measure on which group differences emerge, psychological variables that are significantly correlated with that measure will be used as covariates in a series of analyses of covariance

(ANCOVAs).

Feasibility Assessment: Threats to study completion: Recruitment and retention of participants

Potential Threats to Generalizability: May be generalizable to other rural and other ethnic groups.

Timeline. three year study

Compilation of comments submitted online at www.blsmeetings.net/mayfcc

Submitted by
Martyn Howgill
InHealth
mhowgill@inhealth.org

Comment Type: *Definition*

Thank you for the opportunity to comment on the Council s definition of Comparative Effectiveness Research. On behalf of the Institute for Health Technology Studies (InHealth), we offer the following comments:

- We applaud the proposed assessment of a comprehensive array of health-related outcomes for diverse patient populations and want to affirm that this must include comparisons of the broader, longer-range socioeconomic effects of different interventions. We suggest that studies which concentrate on clinical and disability effects alone may ignore important, longer-term values produced for patients, families and employers.
- The Council s first criterion for scientifically meritorious research and investments calls for measurement of impacts based on prevalence of condition, burden of disease, variability in outcomes, and costs of care. We wish to underscore that if these four definitional areas of impact were to exclude either broader or longer-term socioeconomic consequences, then comparisons and contrasts between diagnostic and therapeutic alternatives would be impaired.

Submitted by
Tony Principi
Pfizer Inc
anthony.principi@pfizer.com

Comment Type: *Definition*

Note: we also are submitting these comments in the form of a letter.

On behalf of Pfizer, I am submitting the following comments to the Federal Coordinating Council s (Council) proposal for a framework on comparative effectiveness research (CER). Pfizer is a research based drug developer that sponsors numerous trials in the U.S. and around the world, to support marketing approvals and to assess comparative effectiveness, post-approval.

Pfizer supports the Council s continued commitment to transparency and public engagement through its solicitation of public input on the definition, prioritization criteria, and strategic framework for CER.

Our comments are structured to respond to three elements contained within the draft documents released by the Council. They build on comments we are submitting related to the Council s proposals on prioritization of comparative effectiveness research.

Draft Definition of CER
Comparative effectiveness research is the conduct and synthesis of systematic research comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions. The purpose of this research is to inform patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances. To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations. Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions. This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness.

Pfizer recommends that the definition of CER emphasize that the primary intent of CER is to inform patients and providers about which interventions are most effective for a patient s individual circumstances. The inclusion of the term decision-makers following patients and providers detracts from this primary focus and may cause confusion over the primary use of CER. To that end, we recommend deleting the reference to other decision-makers from the second sentence of the definition.

Submitted by
Jay Lin
jay.lin1@yahoo.com

Comment Type: *Definition*

Health resource utilization and cost should be explicitely stated to be included in the scope of the CER.

Submitted by
Belinda Ireland
BJC HealthCare
bireland@bjc.org

Comment Type: *Definition*

The definition seems to presume the need for de novo research in the way it is constructed. Surely the Council does not mean to ignore the vast body of existing science that may contribute to the development of a body of evidence that informs questions of comparative effectiveness for prevention, diagnosis, treatment, and health maintenance. A broad definition should encompass the synthesis of existing knowledge, the identification of gaps in that knowledge, and a process for continual refreshing of the body of evidence as the science advances.

Submitted by
Victoria Dohnal
Biotechnology Industry Organziation (BIO)
vdohnal@bio.org

Comment Type: *Definition*

Dear gentlemen,
I am submitting these comments on behalf of the Biotechnology Industry Organization (BIO).

BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO is pleased to have the opportunity to submit comments to the Federal Coordinating Council (FCC) on the draft definition of Comparative Effectiveness Research for the FCC.

As a representative of an industry committed to discovering new cures and ensuring patient access to them, BIO strongly supports efforts to increase the availability of accurate, scientific evidence to inform clinical decision-making. BIO believes that individual patients and their doctors should be armed with the best available information to help assess the relative clinical benefits and risks of various treatment alternatives. When appropriately applied, comparative effectiveness information is a valuable tool that, together with a variety of other types of medical

evidence, can contribute to improving health care delivery. However, BIO is concerned that comparative effectiveness information will be used increasingly as a means to contain costs, rather than deliver health care value by improving patient health outcomes. BIO appreciates the opportunity to comment to the FCC.

We submit the following comments for your consideration on the definition of comparative effectiveness research, draft prioritization criteria, and the strategic framework. We look forward to continuing to work constructively with you in order to realize the full value of comparative effectiveness research.

Draft Definition:

Comparative effectiveness research is the conduct and synthesis of systematic research comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions.

BIO is pleased that the FCC envisions using comparative effectiveness research to examine strategies to prevent and monitor health conditions. Prevention and wellness strategies are critical to bending the cost curve of health care expenditures in the future. Further, given that 75% of health care costs are related to chronic disease, it is critically important for comparative effectiveness research to examine strategies surrounding chronic disease care.

The purpose of this research is to inform patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.

It is important that the draft definition states the purpose to comparative effectiveness research is to inform patients and providers. BIO believes that comparative effectiveness information should inform clinical judgment and individual needs in medical decision making.

Suggested Modification: BIO is concerned with the vagueness of the term decision- makers in the same sentence. It should be made explicitly clear in the definition that the term decision-makers refers to those involved in the provider-patient interaction (e.g., provider, patient or guardian, as appropriate), and may appropriately be referred to as patient advocates. BIO suggests that the wording be modified to the following: The purpose of this research is to improve patient-outcomes by informing patients, patients advocates, and their providers, responding to their expressed needs, about which interventions and strategies are most effective for which patients under specific circumstances.

The purpose of this research is to inform patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances. To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations.

It is good that the definition recognizes the potential for comparative effectiveness research to advance the goals of personalized medicine through the inclusion of phrases such as which patients under specific circumstances and diverse patient populations.

Suggested Modification: BIO suggests that the definition include the term subpopulations in these sentences so that it would read: The purpose of this research is to improve patient-outcomes by informing patients, patients advocates, and their providers, responding to their expressed needs, about which interventions and strategies are most effective for which patients under specific circumstances. To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patent populations and subpopulations. Consistent with our previous comment, BIO also suggests that the term decision-makers be replaced with a clearer reference to patient advocates.

Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions.

BIO is pleased to see the expansive nature of the interventions that are included in the draft definition ranging from medications to behavioral change strategies and from procedures to delivery system interventions.

Suggested Modification: However, BIO believes that comparative effectiveness research should focus on the totality of the health care delivery system not just interventions. Comparative effectiveness information that reflects the interactions among all of the various components of the health care system has the greatest potential to empower clinicians and patients to make more appropriate decisions when faced with real world clinical situations. In addition to comparing specific treatment interventions, research should also focus on how innovations in care delivery models, such as disease management programs, may produce better health outcomes. An explicit inclusion of the phrase totality of the health care delivery system would be worthwhile here.

Submitted by
Victoria Dohnal
Biotechnology Industry Organziation (BIO)
vdohnal@bio.org

Comment Type: *Definition*

Dear gentlemen,
I am submitting these comments on behalf of the Biotechnology Industry Organization (BIO).

BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States.

BIO is pleased to have the opportunity to submit comments to the Federal Coordinating Council (FCC) on the draft definition of Comparative Effectiveness Research for the FCC.

As a representative of an industry committed to discovering new cures and ensuring patient access to them, BIO strongly supports efforts to increase the availability of accurate, scientific evidence to inform clinical decision-making. BIO believes that individual patients and their doctors should be armed with the best available information to help assess the relative clinical benefits and risks of various treatment alternatives. When appropriately applied, comparative effectiveness information is a valuable tool that, together with a variety of other types of medical evidence, can contribute to improving health care delivery. However, BIO is concerned that comparative effectiveness information will be used increasingly as a means to contain costs, rather than deliver health care value by improving patient health outcomes. BIO appreciates the opportunity to comment to the FCC.

We submit the following comments for your consideration on the definition of comparative effectiveness research, draft prioritization criteria, and the strategic framework. We look forward to continuing to work constructively with you in order to realize the full value of comparative effectiveness research.

Draft Definition:

Comparative effectiveness research is the conduct and synthesis of systematic research comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions.

BIO is pleased that the FCC envisions using comparative effectiveness research to examine strategies to prevent and monitor health conditions. Prevention and wellness strategies are critical to bending the cost curve of health care expenditures in the future. Further, given that 75% of health care costs are related to chronic disease, it is critically important for comparative effectiveness research to examine strategies surrounding chronic disease care.

The purpose of this research is to inform patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.

It is important that the draft definition states the purpose to comparative effectiveness research is to inform patients and providers. BIO believes that comparative effectiveness information should inform clinical judgment and individual needs in medical decision making.

Suggested Modification: BIO is concerned with the vagueness of the term decision- makers in the same sentence. It should be made explicitly clear in the definition that the term decision-makers refers to those involved in the provider-patient interaction (e.g., provider, patient or guardian, as appropriate), and may appropriately be referred to as patient advocates. BIO suggests that the wording be modified to the following: The purpose of this research is to improve patient-outcomes by informing patients, patients advocates, and their providers,

responding to their expressed needs, about which interventions and strategies are most effective for which patients under specific circumstances.

The purpose of this research is to inform patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances. To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations.

It is good that the definition recognizes the potential for comparative effectiveness research to advance the goals of personalized medicine through the inclusion of phrases such as which patients under specific circumstances and diverse patient populations.

Suggested Modification: BIO suggests that the definition include the term subpopulations in these sentences so that it would read: The purpose of this research is to improve patient-outcomes by informing patients, patients advocates, and their providers, responding to their expressed needs, about which interventions and strategies are most effective for which patients under specific circumstances. To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patent populations and subpopulations. Consistent with our previous comment, BIO also suggests that the term decision-makers be replaced with a clearer reference to patient advocates.

Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions.

BIO is pleased to see the expansive nature of the interventions that are included in the draft definition ranging from medications to behavioral change strategies and from procedures to delivery system interventions.

Suggested Modification: However, BIO believes that comparative effectiveness research should focus on the totality of the health care delivery system not just interventions. Comparative effectiveness information that reflects the interactions among all of the various components of the health care system has the greatest potential to empower clinicians and patients to make more appropriate decisions when faced with real world clinical situations. In addition to comparing specific treatment interventions, research should also focus on how innovations in care delivery models, such as disease management programs, may produce better health outcomes. An explicit inclusion of the phrase totality of the health care delivery system would be worthwhile here.

Submitted by
Richard I. Smith
Senior Vice President, Policy
AcademyHealth
april.falconi@academyhealth.org

Comment Type: *Definition*

AcademyHealth, as the nonpartisan, professional society for nearly 3,600 health services researchers, policy analysts, and practitioners, welcomes the opportunity to submit feedback to the Federal CER Council concerning the draft definition and prioritization criteria for comparative effectiveness research.

We would like to offer our support for your proposed definition, which recognizes that CER goes beyond the evaluation of clinical treatments and includes comparing different interventions and strategies to prevent, diagnose, treat, and monitor health conditions.

We strongly support the development of research that informs not only patients and providers, but also decision makers. A wide variety of public and private policy makers will need this research to inform decisions about coverage and payment. As the Council continues its deliberations with key stakeholders, it will be important to delineate these groups specific expressed needs and how future research will be designed to meet these needs.

AcademyHealth supports having the defined interventions &include& behavioral change strategies, and delivery system interventions. Ultimately we will need to have not only research on which treatments work better, but also research pertaining to the comparative quality and cost-effectiveness of alternative ways to deliver specific services. This research is vital for understanding how to improve health system quality and achieve needed improvements in efficiency.

AcademyHealth commends the Council for highlighting the need to tailor treatments for different populations, assessing a comprehensive array of health-related outcomes for diverse patient populations. We agree that recognizing the heterogeneity of diverse populations will require an extensive evidence-base from which to make informed decisions.

The effectiveness of CER is hinged upon the quality of data and methods used to produce the research. An AcademyHealth study, Lack of Coordination in Comparative Effectiveness Research Risks Redundancy and Unnecessary Cost revealed the significant need for more formal training in the range of methods used in comparative effectiveness, as there are very few formal training programs in comparative effectiveness research. Training needs are exacerbated by what many view as a fundamental philosophical difference between researchers academically trained to do observational research, and those trained on the job to conduct clinical trials. Furthermore, the ability of health services research to contribute operationally to safety, quality and efficiency of care delivered within particular delivery organizations depends on new training content and modes.

The current lack of methodological training creates problems for the funding, conduct, and review of current comparative effectiveness studies. Because infrastructure is vital to the success of CER, we support the prioritization criteria of potential for multiplicative effect (e.g. lays foundation for future CER or generates additional investment outside government). This is why we are pleased you included the need for a properly-developed infrastructure in order to assess this research, recognizing the necessity to develop and use a variety of data sources and methods to assess comparative effectiveness research.

AcademyHealth represents and supports many of the people who will be called upon to conduct comparative effectiveness research. We believe that your definition and focus on infrastructure will provide much needed support for building the capacity of the field to respond to the growing demand for this research.

Submitted by
Richard I. Smith
Senior Vice President, Policy
PhRMA
adouglas@phrma.org

Comment Type: *Definition*

Dear Federal Coordinating Council Members:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments to the Federal Coordinating Council for Comparative Effectiveness Research on the draft definition of comparative effectiveness research (CER), priority setting criteria, and strategic framework released by the Council.

PhRMA is a voluntary, nonprofit association representing the country s leading research-based pharmaceutical and biotechnology companies, which are devoted to discovering new medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA s member companies play a leading role in discovery of new therapies and advancement of scientific and clinical knowledge.

PhRMA appreciates the Federal Coordinating Council s posting of its draft CER definition, prioritization criteria and strategic framework as a further step in promoting openness and transparency as it carries out its duties under the American Recovery and Reinvestment Act (ARRA). Specifying a CER definition and criteria for research priorities are important initial steps in establishing a sound CER research program.

As the Council continues implementing its mandate under ARRA, we urge it to maintain open and transparent procedures. In particular, as the Council prepares to submit a report by June 30 making recommendations for CER research to the President, Congress, and the Secretary of the Department of Health and Human Services (HHS), we ask that it explain the substantive reasons for its recommended research priorities. This will enable members of the public to understand how the priorities correspond to the input received from stakeholders, respond to the information needs of patients and providers and meet the other criteria established by the Council. In addition, the Secretary should establish a similar policy as it considers the Council s recommendations, and those of the Institute of Medicine, in establishing research priorities. Open, transparent processes advance research that is credible and relevant to the real-world

decisions facing patients and providers as well as reflecting the different needs of racial, ethnic and other patient sub-populations.

PhRMA supports the focus on patient and provider needs in the Council s draft CER definition and criteria for research priorities. This focus also is evident in HHS Secretary Kathleen Sebelius April 21, 2009 comments at the Senate Finance Committee: The goal of such research is to improve the database of information available to a patient and his or her provider so they can make informed decisions about care. The goal is to empower patients and providers with the best information on protocols, procedures, and other relevant issues, not to enable the federal government to dictate broad coverage decisions." In addition, the Council s emphasis on the expressed needs of patients and providers will help ensure that their input is given sufficient weight in the CER process.

The Council appropriately recognizes the importance of accounting for differences in individual patients throughout its draft material. This will help facilitate study designs that recognize and generate data on different patient subgroups, and communication of results that reflect differing patient needs based on genetic, clinical and other factors. These factors are very important to patients but, unless expressly recognized, can be minimized in study designs and communication of results. In a letter last year, the Congressional Black Caucus highlighted the importance of accounting for individual differences in CER research result: All research supported by a comparative effectiveness initiative must recognize variation in individual patients needs, circumstances, and responses to particular therapies. Comparative effectiveness research must enrich our understanding of these variations, rather than ignoring them by focusing on population averages that mean little for any individual patient or subgroup. Without this focus, the results of research could inappropriately be used as a rationale for restricting the treatment choices of those who fall outside the average response.

In addition, PhRMA supports the scope of research included in the draft definition of CER, which encompasses the full range of medical treatments, behavioral change strategies, and delivery system interventions. This broad scope of research is consistent with the Act s mandate for research on health care treatments and strategies. This scope of research reflects the growing recognition that addressing the needs of patients, particularly those with chronic illnesses, requires greater scrutiny of healthcare delivery systems. This includes comparing the effectiveness of different approaches to care processes, disease management services, care coordination, benefit designs, and other components that directly impact care quality and patient outcomes.

The importance of this aspect of comparative effectiveness research was emphasized in Atul Gawande, MD s, June 1, 2009 New Yorker article: "Congress has provided vital funding for research that compares the effectiveness of different treatments, and this should help reduce uncertainty about which treatments are best. But we also need to fund research that compares the effectiveness of different systems of care to reduce our uncertainty about which systems work best for communities. These are empirical, not ideological, questions.

While the draft definition, prioritization criteria, and strategic framework include many positive elements, we offer the following recommendations to help ensure that CER remains centered on improving health care quality and supporting patient and provider decision-making:

1. Clarify the references to decision makers from the draft definition and federal needs as a basis for setting research priorities.

Defining research priorities and study questions that respond to the information needs of patients and providers is an important, and challenging, early step in CER. While decisions at the policy level should be informed by best available evidence, including comparative effectiveness research, it is important that government-supported CER conducted under ARRA is centered on supporting patient and provider decision-making and improving the quality of patient and provider care. This will help ensure that federally-funded CER meets the goal described in HHS press release announcing the Council, Comparative effectiveness research provides information on the relative strengths and weakness of various medical interventions. Such research will give clinicians and patients valid information to make decisions that will improve the performance of the U.S. health care system. The Council should clarify how federal and other decision making needs will be recognized while maintaining a focus on patients and providers.

2. The council should clarify how the separate elements of the prioritization criteria will be weighed against each other and the minimal feasibility of research criteria should be clarified and moved to secondary list.

The feasibility of research criterion should be moved to the second category of criteria for ensuring scientifically meritorious research and investments, and the Council should clarify how time necessary for research will be used as part of this criterion. The length of the study is an important consideration, but should not be a minimal criteria, as both long- and short-term research can yield findings that are more or less useful to patients and providers. For example, the seven years it took to complete the federally supported Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) reduced its impact, because of the ways the practice of medicine evolved during the study period . At the same time, the time necessary for research should not be used to rule out studies that are longer-term but yield high-value information. Some long-term studies, such as the Women s Health Initiative, provided important information about women and osteoporosis, cardiovascular disease, and cancer and had a significant impact on patient and provider treatment decisions, even though it had a 15 year time frame.

3. Additional recommendations: clarify variability in outcomes, weighting of criteria, and range of data sources.

The Council should clarify the types of outcome variability it will consider when setting CER priorities. This will facilitate consideration of outcomes variation related to a range of factors, including geographic location, treatment site, provider type, and patient sub-group, consistent with the FCC s definition of CER. Conducting research to address these variations represents a significant opportunity to improve health care.

For example, Addressing this issue October 8, 2007 at the Institute of Medicine annual meeting, Eliot Fischer, MD, MPH, Dartmouth Medical School, said: We need better evidence, both about biologically targeted interventions, but also about care delivery...There is an emerging consensus on need for comparative effectiveness research. I think it s critically important that we broaden that focus to include evidence-based care management and evidence-based care delivery, because that s where all the money is and that s where all the waste is in U.S. health care.

In addition, addressing variability in outcomes within minority groups could help reduce health care disparities . There is a broad range of research that indicates racial and ethnic minorities are less likely to receive medical care we know works very well and experience a lower quality of health services. For instance, the Institute of Medicine report, Unequal Treatment found that racial and ethnic minorities are less likely to be given appropriate cardiac medications or to undergo bypass surgery, and a more likely to receive certain less-desirable treatments, such as limb amputations for diabetes. This is not because of any lack of knowledge about appropriate treatments for conditions such as diabetes or heart disease. Rather, it is because our health system does not implement effective strategies to organize and deliver care to minority populations. Placing a high priority on research to identify the strategies that the health system can use regarding issues such as disease management, use of information technology, benefits design, community outreach, to close this gap is important to improving care in minority communities.

In the definition, the Council should describe the range of data sources and methods it will consider to assess comparative effectiveness, such as randomized controlled trials, meta-analyses, observational analysis or other methodologies. Each research methods offers different strengths and limitations, and providing additional detail in this area could facilitate research that provides information on diverse populations and patient sub-populations, helping to reinforce the Council s commitment to assessing outcomes related to these populations.

4. The process step Potential capacity for translation through Federal delivery systems and public private partnerships under Translation and Adoption of CER should be clarified in the CER Strategic framework.

The Council s strategic framework should maintain a focus on translation and adoption of CER results widely to patients and providers in timely, usable formats. This will help orient research towards the needs of patients and providers, and avoid access barriers based on average study results that may overlook differences in the needs of diverse patient groups. The strategic framework should clarify how translation of CER through federal delivery systems will support this goal.

The $1.1 billion included in ARRA for CER represents an important opportunity to establish a broad research agenda that supports patient and provider decision-making and improves health care quality. PhRMA supports the steps the Council has taken to help achieve this goal, including high quality, credible CER that has public buy-in. We ask that the Coordinating Council adopt our suggested revisions to the draft definition, priority setting criteria, and strategic framework.

PhRMA looks forward to continued participation in your important work to recommend CER research priorities. Please do not hesitate to contact me if I can be of any other assistance.

Submitted by
Chunliu Zhan
AHRQ
chunliu.zhan@ahrq.hhs.gov

Comment Type: *Definition*

I suggest the following edits to the definition:

1. Remove ", responding to their expressed needs," which is redundant (to inform doctors is to respond to their needs).

2. Remove "under specific circusmtances," which is also redundant. It is straightforward and sufficient to state that "which treatment is most effective to which patients", where "which patients" could be with any specific circumstance.

3. The last sentence should end with "and methods to adequately control for confounding" (replacing "method to assess comparative effectiveness"). With this change, the definition highlights two crucial areas in conducting credible CER -- data sources and confounding control.

4. Should "cost" be at least implied in the definition? We could give "cost" a little room by adding "efficient" in the second sentence, "about which interventions are most effective and/or efficient for which patients".

Submitted by
Nancy Smith
Health Advancement Collaborative of Central New York
nsmith@hac-cny.org

Comment Type: *Definition*

We recommend that the definition of research include studies of alternative vehicles for translating findings into practice. Our community, for example, is piloting a physician-driven effectiveness review mechanism for the analysis of local variation in practice patterns relative to best practice standards, and the dissemination of findings to the medical community.

Submitted by
Andrew Sperling
National Alliance on Mental Illness
andrew@nami.org

Comment Type: *Definition*

The National Alliance on Mental Illness (NAMI) is pleased to submit the following comments to the Federal Coordinating Council (FCC) on Comparative Effectiveness Research (CER) on the proposed definition of CER and priorities for CER as part of the $1.1 billion allocated in the American Recovery and Reinvestment Act (ARRA).

NAMI is the largest national organization representing individuals living with serious mental illness and their families. Through our more than 1,100 affiliates in all 50 states NAMI is engaged in support, education and advocacy around serious mental illness.

NAMI Comments Recommendations Regarding the Coordinating Council s Draft Definition of CER

1) Including the voice of patients
NAMI supports the inclusion of voices of patients, family members of patients and disease advocacy organizations as part of any definition CER. Too often in healthcare, the determination of what s best for the patient is made by others, while the patient s views of his or her own needs is ignored or minimized. By identifying the importance of expressed needs, the Council takes an important step towards policy that truly is centered on the needs of the patient and caregiver. The proposed definition could be strengthened by an explicit inclusion of both family members of patients and disease advocates as part of the CER process moving forward.

2) Communicating results to improve patient care
NAMI feels strongly that CER must focus on communicating research results to patients, providers and other decision-makers, not making centralized coverage and payment decisions or recommendations. This focus is consistent with the goal of CER as described in HHS press release announcing the FCC such research will give clinicians and patient s valid information to

make decisions that will improve the performance of the U.S. health care system. NAMI would urge additional clarification to the proposed definition of decision-maker. With many competing voices discussing CER, it is important to know which decision-makers are being included in this central definition.

3) Scope of CER

NAMI supports the broad scope of research included in the proposed definition, which states, Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions. This definition is consistent with the views expressed by many stakeholders, including NAMI, at FCC listening sessions. NAMI believes that in order to improve patient care, CER research should examine the range of issues that affect the quality of patient care. This includes the range of medical tests and treatments, as well as questions related to healthcare delivery and organization such as benefit designs and care management programs. All of these healthcare elements affect patients quality of care.

4) Preventing Misuse of CER by public and private payers

While NAMI supports the focus on patient and provider needs in the draft definition, we also are concerned that, in stating that the purpose of CER is to inform patients, providers and decision-makers, the FCC draft definition of CER has the potential to shift the focus of research away from patients and their doctors towards other decision-makers such as health insurance companies, government agencies and other policy-makers. The strategic framework released on HHS web site on June 1 includes language that underscores this concern. In particular, NAMI is troubled by language in the framework that describes CER research priorities that respond to the expressed public and federal needs for CER, and potential capacity for translation through Federal delivery systems and public private partnerships.

This shift in focus has enormous potential to result in research projects that do not address the clinical information needs of patients and providers, and instead lead to research that is used to restrict patient access to treatment options. This concern is heightened by recent commentary describing the link between CER and these types of access restrictions. For example, a recent Washington Post commentary says, What's known as comparative effectiveness research, which tracks what works and what doesn't, would also require outside boards directing doctors and hospitals about what procedures they could and couldn't use. The language in the proposed CER definition and strategic framework document appears to be at odds with the goal of CER as described by HHS in its press release announcing the FCC.

NAMI is troubled by this shift in focus to CER that restricts patient access to medical care or treatment choices. NAMI would urge the Council to delete the language referencing decision-makers and federal needs as a CER focus. The Council should consider revising the strategic framework so that it focuses on communication and dissemination strategies, rather than use of CER by government agencies.

4) Clinical v. cost effectiveness

Consistent with focus on patient and provider needs, NAMI urges the Council to clarify that research should examine clinical outcomes, not cost-effectiveness. As reflected in the wide range

of views expressed during the Coordinating Council listening sessions, inclusion of cost-effectiveness remains controversial for good reason. Cost-effectiveness analysis traditionally has been a tool used by insurance companies and government payers to impose access restrictions based on broad population averages, and some of the most common cost containment tools tend to obscure differences in patient subgroups by including all patients in a single, average value determination. Particularly given the importance that ARRA and the Coordinating Council have placed on considering the needs of patient subpopulations, NAMI recommends that the Council clarify that it will focus on clinical outcomes.

NAMI Recommendations for Comparative Effectiveness Research Priorities

Within the realm of mental illness treatment, NAMI would like to make the following recommendations for critical priorities designed to improve quality of care and prospects for recovery for individuals living with illnesses such as schizophrenia, bipolar disorder, major depression and severe anxiety disorders.

1) An examination of the real world challenges associated with treatment adherence in serious mental illness --
Major mental illnesses present unique vulnerabilities and challenges. One of the most difficult challenges is a condition known as anosognosia, or literally, the inability to see one's own illness. Anosognosia dramatically reduces medication adherence, and occurs in about half of people with serious psychiatric illnesses. This condition also called lack of insight and is virtually exclusively a concern in our population.

Anosognosia makes research about adherence strategies especially crucial for this population. As noted above, CATIE raises a number of important questions related to treatment adherence with schizophrenia. NAMI believes that this should be a major priority for comparative effectiveness, especially in the context of serious mental illness. The very symptoms of these disorders auditory hallucinations, paranoia, delusional thinking, mania, severe anxiety can make treatment adherence a challenge. Likewise, the difficult side effects associated with psychotropic medications can create enormous barriers to adherence. NAMI would strongly recommend that the Coordinating Council emphasize the need for examination of strategies and treatment models that can improve adherence and ensure better outcomes.

2) An examination of best practices treatment decisions in public programs --
Currently state Medicaid programs across the nation are undertaking cost control strategies that involve strict protocols for prescribing of psychotropic medications. These typically involve aggressive utilization management techniques such as preferred drug lists, prior authorization requirements for specific compounds, fail first requirements for specific medications and step therapy. In NAMI s view, these rules often place the most vulnerable members of our society at risk of poor outcomes such as psychiatric decompensation and re-hospitalization, with little evidence that they save money or improve quality of care over the long-term.

The reality is that these utilization management decisions are driven by cost, not sound clinical research. For the most part, state Medicaid programs are flying blind in undertaking these strategies as there is little if any research out there demonstrating how clinicians can make

informed decisions about which medication works best for a particular patient. NAMI believes that comparative effectiveness can be very useful in examining treatment algorithms and prescribing protocols that work best in real world treatment settings where patients (especially Medicaid beneficiaries) experience multiple medical co-morbidities that complicate the effectiveness of psychiatric treatment.

There are promising alternatives out there such as monitoring outlier prescribing patterns and evidence-based protocols that can help a state control pharmacy costs without resorting to inflexible rules such as prior authorization and step therapy. NAMI would recommend investment in research that compares these strategies to see which is more effective in improving patient outcomes and promoting quality of care.

Thank you for the opportunity to offer NAMI s views on this important issue. NAMI looks forward to assisting the Federal Coordinating Council in moving a sound comparative effectiveness research agenda forward.

Submitted by
Susan Ross
SDRoss Consulting
sdross720@gmail.com

Comment Type: *Definition*

In the Definition I suggest you:
1) clarify difference between effectiveness and efficacy
2) clarify whether "...a comprehensive array of health-related outcomes..." includes safety outcomes? patient-reported outcomes, including preferences? compliance/adherence? utilization outcomes? economic outcomes?

Submitted by
Tim Rebbeck
Univ of Pennsylvania
rebbeck@mail.med.upenn.edu

Comment Type: *Definition*

I am aware of another statement/definition from the NCI that seems different (and possibly inconsistent) with the definition proposed here. The NCI priorities for CER, as stated in the Grand Opportunities FOA (RC2), are as follows:

A wide range of clinically-based preventive, screening and treatment interventions have been shown to be efficacious for many types of cancer. However, evidence is less complete on the effectiveness of these interventions in actual community practice, among populations and

treatment settings and using techniques and practices that may differ markedly from those of initial controlled clinical trials. Effectiveness includes not just the standard core clinical outcomes such as survival, adverse clinical events, quality of life and symptoms, but also domains that affect the use of the treatment, or health care strategy. Factors that affect how treatment is used, and whether one treatment is preferred over another include patient-reported outcomes, acceptability and adherence to treatment, patient-physician communications, health system capacity and organization factors, medical and other resource use, economic cost, financial stress and broader impacts on the family, work and community, such as impacts on economic productivity and the ability to return to work and resume other normal social functions. Some of these domains have been investigated by NCI, but research in these areas remains underdeveloped in terms of data resources, methodology and research personnel. Also the field remains fragmented in terms disciplinary areas, phases of the cancer continuum explored, and cancer sites investigated.

For the purposes of this announcement, comparative effectiveness research (CER) is defined as a rigorous evaluation of the impact of different options that are available for treating or preventing a given medical condition for a particular set of subjects. Such a study may compare similar treatments or other interventions, such as competing drugs, or it may analyze very different approaches, such as surgery, drug therapy and behavioral interventions. Such research may include the development and use of clinical and population level registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data as they apply to CER.

Submitted by
Glen Schumock
Univ Illinois at Chicago
schumock@uic.edu

Comment Type: *Definition*

I believe the the definition (first sentence) needs to include reference to the research being done under conditions our actual practice (effectiveness) so as to clearly distinguish it from the controlled research settings (efficacy) such as that in a traditional RCT.

Submitted by
Nancy Dreyer
Outcome Sciences Inc.
ndreyer@outcome.com

Comment Type: *Definition*

I believe that your proposed definition of comparative effectiveness (CE) is overly and unnecessarily broad. Specifically

1) the word "systematic" in the first sentence is vague. Systematic is generally used to refer to systematic reviews and CE research may well be a purpose-driven investigation of various interventions. Although such a study could technically be described as "systematic," this adjective is not generally used to describe a research project.

2) More troublesome is the proposed requirement that CE research "must assess a comprehensive array of health-related outcomes for diverse patient populations." CE research that assesses alternative therapies that may not include a COMPREHENSIVE set of alternatives can still provide excellent, useful information. Similarly, if CE is evaluated for a particular population that may not be diverse but is well described, this still could constitute meaningful, reliable, useful research. e.g., a study in latinos may not include other ethnic groups but would be informative nonetheless.

Submitted by
Steven Mersch
smersch@pointsource-inc.com

Comment Type: *Definition*

The wording of the definition is excellent! May want to consider adding a sentence to the definition related to evaluation of new medical therapies and devices as they emerge from the research labs.

The prioritization draft is OK. Some points are a little unclear/vague.

Submitted by
American Medical Association American Medical Association
American Medical Association
sylvia.trujillo@ama-assn.org

Comment Type: *Definition*

The physician and medical student members of the American Medical Association (AMA) commend the Federal Coordinating Council for Comparative Effectiveness Research (Council) for convening a series of public meetings and reaching out to clinicians and medicine to solicit our input on national comparative effectiveness research (CER) priorities as well as comments on the Council s draft CER definition, prioritization criteria, and draft strategic framework. Concerted stakeholder and public engagement will ensure that the funding to support CER will be allocated in an optimal fashion and increase the utilization of CER findings by physicians and patients.

All aspects of the CER process, including priority setting and capacity-building measures, must be transparent and include a central role for physicians in their oversight and governance. Given the nascent nature of this endeavor, the perception among physicians that the CER agenda is being driven by payers who only have cost containment as their goal will seriously undermine efforts to cement physician support as we continue forward on comprehensive health care system reform. It is imperative that physicians, including clinicians and their organizations, have an active, ongoing, and central role at all stages of the CER process. To be clear; the AMA strongly supports CER and looks forward to results that will guide shared decision-making by patients and their physicians.

Physicians today have access to a wide array of medical information. However, there remains far too little rigorous evidence available about which treatments work best for which patients. The AMA strongly supports increased federal funding of CER. Though there is a broad array of areas where CER would bring benefits, we must strategically target support for CER where it will significantly improve health care value by enhancing physician clinical judgment, foster the delivery of patient-centered care, and produce substantial benefit to the health care system as a whole. As outlined in more detail below, the AMA strongly supports the Council s Draft Definition, Draft Prioritization Criteria for Comparative Effectiveness Research as well as the Draft Comparative Effectiveness Research Strategic Framework.

The AMA supports the view that the priority areas of CER should focus on high volume, high cost diagnostic and treatment modalities, and other health services and strategies for which there is significant variation in practice.

The AMA supports a broad definition of CER that involves a comparison of different modalities to prevent, manage, or treat a specific health problem, condition, or disease. Besides the more typical areas of research such as pharmaceuticals and medical devices, CER should also focus on implementation and dissemination issues that would shed light on the most effective strategies that promote a learning health care system and improved clinical outcomes including behavioral change strategies, and delivery system interventions.

In terms of methodology and study design, CER should include long-term and short-term assessments. CER should not be limited to new treatments. In addition, the findings should be re-evaluated periodically, as needed, based on the development of new alternatives and the emergence of new safety or efficacy data.

AMA Recommended Priority Areas & Infrastructure

Much of the expertise for setting CER priorities focusing on specific diseases and interventions lies within the medical specialty societies. Nonetheless, the AMA offers the following recommendations for CER priorities and offers suggestions concerning two mechanisms that would help build the necessary infrastructure to sustain work in this area.

The AMA strongly believes that the national CER priorities should address the prevention, management, and treatment of preventable disease which collectively represent a major cost driver in today s health care system. Key areas in need of further study and research include

cardiovascular, endocrinology and metabolism disorders (including diabetes), and nutrition (including obesity). For example, in the area of wellness, prevention, nutrition, and obesity there is a paucity of CER findings. It is an area with a wide range of available interventions with little clarity about which is most effective.

CER usually considers technology and pharmaceuticals, but behavioral interventions potentially could have the greatest impact for individual patients and the system as a whole. Prioritizing interventions designed to change physician behavior and to effect behavioral change in patients, in addition to other clinical interventions, technologies, and pharmaceutical remedies, is necessary. Because prevalence rates and the most effective interventions for many diseases vary greatly by race, ethnicity, gender, age, geography, and economic status, the AMA strongly supports the inclusion of racial and ethnic health disparities and health disparities more generally as a CER priority area.

In addition to the foregoing, the National Priorities and Goals report put forth by the National Priorities Partnership (NPP) convened by the National Quality Forum (NQF) provides a rich source of information for the Council to consider. The NPP, comprised of 28 national organizations, focused on achievable goals that would, if implemented broadly, reduce harm, improve patient-centered care, eliminate health care disparities, and remove waste from the system. In preparing the report, the NPP solicited extensive input from broad array of individuals and organizations. Utilizing the NPP National Priorities and Goals as a reference point will help the Council to identify national CER priorities that will build the evidence base in a targeted fashion in the areas that are likely to produce substantial system-wide improvements.

In addition to the NPP report, the AMA convened Physician Consortium for Performance Improvement (PCPI) has developed a valuable survey mechanism that can be utilized by the Council to gather additional detailed information concerning national CER priorities. In order to obtain timely, quality responses from the more than 100 national medial specialty and state medical societies, experts in methodology and data collection, and many others involved in quality improvement and performance measurement, the PCPI constructed a survey mechanism. It is a powerful new tool to identify variations in practice, to assess the evidence base in a wide array of areas, and to identify areas where there are gaps in knowledge. The PCPI plans a significant expansion of these efforts. This provides much needed capacity and infrastructure for priority setting. We would welcome the opportunity to have the Council work with the PCPI to utilize this survey mechanism as it develops the recommendations concerning national CER priorities.

The AMA urges the Council to consider two powerful infrastructure mechanisms, clinical registries and data networks. These have been used by specialty societies such as the Society of Thoracic Surgeons and the American College of Cardiology, and have markedly improved quality and patient safety. The National Surgical Quality Improvement Program (NSQIP) and the Northern New England Cardiovascular Collaborative are examples of utilizing these two mechanisms to advance quality and obtain research data at the point of care, and create what our country needs, a learning network. Expansion of existing clinical registries and databases would provide a strong foundation when conducting CER and at the same time these registries would also provide an excellent beginning point for CER. Utilizing, replicating, expanding, or

integrating existing clinical registries would constitute an invaluable investment in the much needed infrastructure for accurately comparing clinical outcomes based on real life conditions where delivery of care settings vary, patients may have numerous co-morbidities, and the patient population is diverse. In turn the clinical registries are not identical and may to greater or lesser extent be able to promote a learning health care environment; thus, evaluating the comparative clinical effectiveness of various clinical registry models and alternatives to them remains a vital priority. Building CER infrastructure and capacity in part upon registries and clinical data networks will leverage CER resources and boost the capacity of the system as a whole to learn and adapt in real time.

AMA Support of Council s Draft Strategic Framework

The AMA generally supports the Council s effort to develop a strategic framework for CER activity and investments in order to categorize current activity, identify gaps, and inform decisions on high priority recommendations with a couple of caveats.

First, the AMA urges the Council to ensure public access to the detailed inventories of Federal CER activities and research/data infrastructure that the Council proposes to create. The AMA agrees that the Council s organizing framework will foster consideration of the balance of activities and priority themes and allow the government to focus on the most pressing needs expressed by patients and clinicians, and allow identification of gaps in the current landscape of CER. We urge the Council to work with the AMA convened PCPI which is already engaged in this activity as discussed above.

Second, the AMA concurs with the Council that CER activities should be grouped into the following four major categories as detailed in the proposed framework:

" research, (e.g., comparing medicines for a specific condition or discharge process A to discharge process B for readmissions).
" human and scientific capital, (e.g., training new researchers to conduct CER, developing CER methodology).
" CER data infrastructure, (e.g., developing a distributed practice-based data network, linked longitudinal administrative or electronic health records databases, or patient registries.)
" translation and utilization of CER, (e.g., building tools and methods to translate CER into practice and measure results.)

While all the above categories are essential components of timely, valid, useful CER, it is important to underscore the essential and central role physicians must play vis-à-vis the last component translation and adoption of CER. The AMA supports the development of practice guidelines by medical specialties and other clinicians in medicine, but would oppose the development of guidelines by the government or another centralized entity. Consistent with the foregoing, to the extent that medical specialties design, implement, and play a central role in clinical registries such as NSQIP that rely upon clinicians to conduct CER, the AMA would support utilization of CER findings generated through clinical registries by the specialties to modify practice guidelines and decision support vis-à-vis the clinical registries.

Conclusion

There is a final cautionary tale. In the February 12, 2009, issue of Journal of American Medical Association there is a description of what can happen when science and politics collide. The Infectious Disease Society of America (IDSA) studied the evidence base for the treatment of Lyme disease and in 2006 issued new guidelines advising against the long-term use of antibiotics. The IDSA was promptly sued by the Connecticut Attorney General alleging violations of antitrust laws and restraint of trade. The case was settled without IDSA admitting any fault and assenting to an ombudsmen-reviewed panel to assess the 2006 guidelines. If we cannot separate science and politics in a case such as this, how will we ever manage to deal with the really hard issues?

CER has the potential to have a profoundly positive impact on the quality of the information available to physicians and patients and, when used appropriately and with care, will address escalating health care costs. The AMA welcomes the opportunity to work closely with the Council to ensure that physicians remain engaged, enthusiastic, and involved stakeholders in this process.

Submitted by
Joe Kanter
Joseph H. Kanter Family Foundation/Health Legacy Partnership
joe.kanter@healthlegacy.org

Comment Type: *Definition*

The Joseph H. Kanter Family Foundation welcomes the opportunity to offer feedback to the Federal Coordinating Council for Comparative Effectiveness Research (Council) on the draft definition of and prioritization criteria for comparative effectiveness research (CER). We heartily endorse the efforts of the Council and other policymakers to improve the evidence base on health outcomes by investing in CER. We believe CER is a necessary first step in our nation s long range goal to harness real time data from personal electronic health records and provide health care providers and average Americans with easily accessible and understandable scientific data to make evidence-based health care decisions and choices.

The Kanter Family Foundation is a nonprofit organization established in 1998 by Joseph H. Kanter following his personal battle with prostate cancer. Unable to quickly and accurately determine the best course of treatment despite access to the best medical resources available, Mr. Kanter recognized that improved access to better health care data could significantly enhance medical treatment for all Americans.

Since then, Mr. Kanter has committed his time and money to his vision for better health and health care. Through The Health Legacy Partnership with the Agency for Healthcare Research and Quality (AHRQ), the Kanter Family Foundation has strived to improve healthcare decision-making. Specifically, we have worked to develop a National Health Outcomes Database that

would provide health care professionals and patients useful, scientific evidence on the best treatment options available. When paired with deidentified data from electronic health records, evidence generated through federally funded CER would populate this user-friendly information tool to help providers, patients, policymakers and other decision makers determine what works best, when, under what circumstances, for whom.

The Kanter Family Foundation offers its support for the Council s proposed definition of CER and the accompanying prioritization criteria for research funding. We are pleased that your definition encompasses a broad array of:

" Methodologies and data sources to provide timelier and more comprehensive information about health treatments especially in underrepresented populations than traditional randomized clinical trials currently provide;

" Interventions to be compared including medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions to ensure providers and patients have access to information on the full range of treatment options available; and

" Information users to facilitate shared decision-making and engagement in health care treatment.

We especially support the patient-centeredness of the proposed CER definition, e.g., the purpose of this research is to inform patients, providers, and decision-makers, responding to their expressed needs. We are pleased that this patient-centric approach is also reflected in your threshold minimal criteria to prioritize research funding, e.g., responsiveness to expressed needs and preferences of patients, clinicians, and other stakeholders, including community engagement in research. Too often, decisions about research funding are made in a vacuum with little consideration to the priorities and needs of the end users, or the practical applications of the information in the real world. As a result, many current research studies only evaluate the experiences of a narrow group of patients under tightly controlled conditions. As you have defined it, CER will study the real world experiences of diverse patient populations, many of whom may be taking multiple prescriptions or have experience with several different approaches to treatment. Knowing how patients respond to treatments and how treatments compare to meet these patients needs is crucial to understanding what works best for patients from diverse backgrounds.

The Kanter Family Foundation also supports the Council s proposed minimal criteria for federal funding: feasibility of research topic, (including the time necessary for research). In our rapidly evolving medical landscape, untimely CER loses relevance and utility as new and ever more innovative treatments enter the market. As the Council evaluates the feasibility of research, we urge the Council to consider not only timeliness but also the usability and translatability of CER. The principal goal of CER is to improve health care quality and value by generating information that is readily accessible and understandable by key users. CER that is likely to be used by patients and providers and can be readily translated to facilitate use by these individuals should receive priority for funding over studies that do not.

The Kanter Family Foundation commends the Council for highlighting the need to tailor treatments for different populations, e.g., CER must assess a comprehensive array of health-related outcomes for diverse patient populations. Studies by federal watch dogs and academics have shown that randomized clinical trials conducted to bring new medical innovations to the market typically do not include diverse populations. Women, elderly, and minorities are underrepresented as companies determine whether or not their new drugs and devices are safe and effective. Such deficiencies can diminish the utility and applicability of drugs and devices in these groups. CER, as the Council has defined it, will help us move beyond does the treatment work? toward for whom does the treatment work? This shift in medical decision-making is crucial as our society becomes increasingly diverse and disparities in health care remain pervasive.

Patients want and deserve a greater voice in their health care. Advances in information technology have given individuals unprecedented access to health-related information. Individuals can now learn about diagnoses and available treatments, find local support groups, rate physicians and medical institutions, and research dietary and exercise practices. Unfortunately individuals with access to myriad health information often feel they are drinking from a fire hose. With so much information available how does a provider or patient determine what s most appropriate? The next step on the health information continuum is to ensure patients and their providers have access to more and better information about how all available treatments medical and otherwise perform compared to one another in different subpopulations. CER, and its widespread availability and usability, will help get us there.

The Kanter Family Foundation looks forward to collaborating with the Council to ensure evidence generated by federally funded CER is widely disseminated to patients and providers through our National Health Outcomes Database. If you have any questions, please contact Mr. Kanter or the Kanter Family Foundation s Washington representative, Emily Holubowich of Cavarocchi Ruscio Dennis Associates, at eholubowich@dc-crd.com or 202.484.1100.

Submitted by
Richard I. Smith
Senior Vice President, Policy
University of Pennsylvania
carrb@upenn.edu

Comment Type: *Definition*
Although the definition uses the language "delivery system interventions", I fear that this is not precise enough. Delivery systems could mean intranasal vs. intramuscular flu vaccine. What it seems to me is missing from the definition is the appreciation that we are planning to redesign a healthcare system. In my work, I explore health care decision making for diseases (trauma, stroke, cardiac arrest) that require emergent medical intervention from the population level. I interpret delivery systems interventions to include air vs. ground transport of acute stroke patients and tele-medicine with subspecialists not located at the parent facility, but believe the

possibility exists to include such broad thinking given the current definition. The institute of medicine called explicitly for a coordinated and regionalized emergency care system - I believe some recognition of the importance of regional or regionalized systems planning is warranted in the definition.

Submitted by
John Cuddeback
Anceta - AMGA's Collaborative Data Warehouse
jcuddeback@anceta.com

Comment Type: *Definition*

We commend the Council on its efforts to clarify definitions and priorities for CER Funding per the ARRA. We are pleased to see the reference to delivery system interventions, but we are concerned that the word interventions could be interpreted to include only projects that prospectively change the delivery system, such as the CMS Physician Group Practice (PGP) demonstration.

Such projects are important, but we should also take advantage of the natural experiments that current practice offers. Care is currently delivered under a wide range of organizational structures, and provider organizations have initiated many changes in care process and supporting infrastructure.

We believe delivery system interventions could be better stated as delivery system strategies, reflecting the phrase comparing different interventions and strategies in the first sentence.

Critical insights can be obtained by studying the replicable factors that drive success in EXISTING delivery systems that engage in organized processes to improve quality and control costs and are willing to bear accountability for results.

As stated in written testimony provided to the Council on April 14, The Delivery System Matters, by Dr. Samuel Lin, on behalf of the American Medical Group Association (AMGA), we need to understand the comparative effectiveness of the organizational structures and processes under which care is delivered. They affect safety, timeliness, efficiency, effectiveness, equity, and patient-centeredness (IOM s STEEEP). We should test the hypothesis that optimal outcomes are attained in delivery systems that exhibit specific aspects of care coordination. Recent papers have suggested that organized systems of care, or accountable care systems, are instrumental in ensuring STEEEP (1-4).

Since Dr. Lin s testimony was submitted, a coalition of organized systems of care has been formed to assess the comparative effectiveness of delivery systems as a priority component of

health reform. We are prepared to present oral testimony as to the value and feasibility of this kind of research at the Council s June 10 listening session and to respond to the Council s questions at that time.

-- John Cuddeback, MD, PhD, Chief Medical Informatics Officer, Anceta, AMGA s Collaborative Data Warehouse, on behalf of participating AMGA member medical groups: multi-specialty medical groups and integrated delivery systems ranging from fewer than 200 to more than 1,200 physicians, in rural and urban settings across various regions of the country, including multiple participants in on-going CMS demonstration projects.

1. Shortell SM, Casalino LP. Health Care Reform Requires Accountable Care Systems. JAMA 300(1): 95-97 (July 2, 2008).
2. Fisher ES, Berwick DM, Davis K. Achieving Health Care Reform--How Physicians Can Help. N Engl J Med 10.1056/NEJMp0903923 (published online May 20, 2009).
3. Fisher ES, McClellan MB, et al. Fostering Accountable Health Care: Moving Forward in Medicare. Health Affairs 28(2): w219-w231 (published online January 27, 2009; 10.1377/hlthaff.28.2.w219).
4. Pham HH, O Malley AS, Bach PB, Saiontz-Martinez C, Schrag D. Primary Care Physicians Links to Other Physicians through Medicare Patients: The Scope of Care Coordination. Ann Intern Med 150(4): 236-242 (February 17, 2009).

Submitted by
Vincent Stine
American Association for Clinical Chemistry
vstine@aacc.org

Comment Type: *Definition*

AACC recommends that the definition be modified. We suggest that "diagnostic tests and testing modalities" be included in the following sentence to read:

"Defined interventions compared may include medications, diagnostic tests and testing modalities, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions."

The term modalities is used to reference point-of-care testing, home testing, continuous monitoring.

Submitted by
James Benefiel
VitalSpring Technologies
jbenefiel@vitalspring.com

Comment Type: *Definition*

Threshold Minimal Criteria (i.e. must meet these to be considered)
1. Included within statutory limits of Recovery Act and FCC definition of CER
2. Responsiveness to expressed needs and preferences of patients, clinicians, and other stakeholders, including community engagement in research
[Comment:] Expressed needs would seem extremely difficult to evaluate, except to include representatives of each group on each grant application review. No single grant could be expected to meet the expressed needs of all patients, clinicians, and other stakeholders. (Note that this is listed as a Minimal Criterion.)
The report from the Listening Session of the Federal Coordinating Council noted in part the need to enable people to trace backwards from results to inputs, to ensure themselves that the process was fair. Fairness is probably a better measure than expressed needs. Further, in the Listening Session, there was a citation to assist in clinical decisionmaking by providers and patients. I would add the words informed, rational ahead of clinical. In this way, this stated threshold criterion is not subject to a particular activist community s agenda. Thus, I would re-word this criterion as:
Ability to assist in the rational, informed clinical decisionmaking by patients, clinicians, and other stakeholders, including community engagement in research
I believe the re-worded criterion will lead to many fewer challenges by interested parties.

3. Feasibility of research topic (including time necessary for research)

Prioritization Criteria
The criteria for scientifically meritorious research and investments are:
1. Potential Impact (based on prevalence of condition, burden of disease, variability in outcomes, and costs of care)
[Comment:] The variability of outcomes or variability in costs of care among the total U. S. population is more relevant than the prevalence of the condition or the total costs (e.g 30,000 people with a condition at an average cost of $50,000/patient and a standard deviation of $2,000/patient probably provides less opportunity than 20,000 people with a condition at an

average cost of $20,000/patient but a standard deviation of $10,000/patient). If variability can not be traced to the differing illness burdens (i.e.\, co-morbidities) among the population with the condition, then variability indicates that certain treatments don t seem to work as well on a portion of the population. Conversely, variability indicates that some treatments seem to work better than others or better in selected situations.

Submitted by
Jean Iacino
CA Dept. of Public Health
Jean.Iacino@cdph.ca.gov

Comment Type: *Definition*

The California Department of Public Health is concerned that the draft definition and prioritization criteria are too clinical in focus and seem to preclude public health intervention effectiveness research.

Submitted by
Brian Strom
University of Pennsylvania
bstrom@cceb.med.upenn.edu

Comment Type: *Definition*

1) Does not clearly include methodological work
2) Does not look at subgroups of patients likely to benefit or be hurt by one treatment vs the other
3) the requirement for a comprehensive array of health-related outcomes for diverse patient populations, is likely not practical within one study

Submitted by
Jennifer Reck
Prescription Policy Choices
jreck@policychoices.org

Comment Type: *Definition*

The final sentence of the draft definition should be amended as follows:

This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness, as well as the active dissemination of results.

Submitted by
Judith Cahill
Academy of Managed Care Pharmacy
jcahill@amcp.org

Comment Type: *Definition*

AMCP believes that it is essential to the success of comparative effectiveness research that the cost effectiveness of treatments not be precluded as a component of overall research efforts. The Academy s members use various tools and strategies, including the cost effectiveness of treatments, as a means of combating the increasingly high cost of health care. It is vital that research on cost effectiveness be included in any effort to conduct comparative effectiveness research. The Academy strongly recommends that the cost effectiveness of treatments be included in the definition of comparative effectiveness research.

Submitted by
Thomas Novelli
Medical Device Manufacturers Association
tnovelli@medicaldevices.org

Comment Type: *Definition*

The Medical Device Manufacturers Association (MDMA) is a national trade association representing over 200 small to mid-size manufacturers of innovative and lifesaving medical technologies. MDMA appreciates the opportunity to comment on behalf of our membership, and we commend the Federal Coordinating Council (Council) for engaging all stakeholders on the issue of comparative effectiveness research (CER).

MDMA supports the principles of evidence-based medicine and CER. We believe that patients, physicians and the public should have access to the best information and data on which treatments work best in addition to which treatments are less effective. The availability of this information will be in the best interest of the patient and all stakeholders. As Congress and the Administration work to build upon the Council s efforts on CER, it is important to also examine other areas of the health care delivery system, including wellness, prevention and education.

Definition of Comparative Effectiveness Research

Recently, the Council released its draft definition for CER. Specifically, the Council proposed the following definition:

Comparative effectiveness research is the conduct and synthesis of systematic research comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions. The purpose of this research is to inform patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances. To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations. Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions. This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness.

MDMA believes that the proposed definition is a step in the right direction. However, we believe that a few terms within the definition warrant further clarification or modification.

Recommendation #1

The purpose of this research is to inform patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.

MDMA believes that further clarification is needed for the term decision-makers. Specifically, the Council should further define who decision-makers would entail, whether it is the Congress, private insurers, Medicare, Medicaid or other Federal healthcare programs. It is critically important to know which parties will be utilizing this data and for what purposes. MDMA believes decision-makers should be patient s guardians, and family members who may be involved in making health care decisions and not payers.

Recommendation #2

This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness.

MDMA strongly believes that the Council should further clarify the definition for CER, especially as it relates to the types of data sources and methods to be used to assess comparative effectiveness. The Council should publically state the type of data sources and methods it intends to utilize or exclude. Moreover, it should state whether it is the intention of Federal agencies to generate original data for purposes of CER or if agencies will utilize existing clinical data.

General Comments

The Council would be amiss if it were not to study all factors that are contributing to increased costs within the healthcare system, including the examination of the inherent root causes. For example, we are all sadly aware of the growing obesity epidemic among the nation s adolescent

population. Our children are living less-healthier lifestyles than in generations past; they are less physically active and are consuming more unhealthy foods. If our country continues on this path, we can only begin to try to speculate what the related costs will be for treating obesity related conditions, such as diabetes, pulmonary hypertension and heart disease in general. The positive news is that this is a controllable condition, and by increasing education and awareness, we can make an impact. Tackling these issues early-on will likely have a far greater impact on cost savings in the future than our current thinking on CER. To this end, efforts on CER should not be focused exclusively on efforts such as technology assessment. This back-end approach is analogous to trying to plug the dam after it has sprung a leak. Rather, focusing research efforts on wellness and prevention should be complimentary to the current thinking on CER. In this sense, a primary focus of CER and the Council should be to examine the root causes of increased health care spending.

CER should also be used to address disparities in the health care system. Too often is the case that varying patient populations receive disproportionate health care treatment and coverage. The Council has a tremendous opportunity to conduct studies and use the research to address these disparities to ensure that all Americans are receiving the appropriate care.

Finally, the manner in which the Council and related agencies conducts its work and generates data must be as transparent as possible. As is apparent, the work produced by the Council will likely have a significant impact on numerous entities, including patients, payers and the industry. In keeping with President Obama s pledge for transparency in government, it is absolutely critical that the work of the Council remain open and transparent for all stakeholders. This includes allowing stakeholders to submit public comments on the Council s processes and methodologies for comparative studies as well as its results. To this end, it is important that expanded CER initiatives include a formal infrastructure to ensure public input on the work of the Council and related agencies.

The Council should yield caution in expanding the definition of CER to include the study of the cost effectiveness for competing medical therapies and interventions. Although there may be a tendency for studies to focus on a single episode of care, the costs associated with such care should be measured over a long enough time horizon to capture the true savings of a procedure or therapy. It will be important to consider long-term savings and cost reductions including potential decreased frequency of hospital/physician interactions, increased patient productivity in the workforce, and other measures that would be difficult to capture in a short time horizon.

MDMA greatly appreciates the opportunity to address the panel today. We strongly believe in the goals and mission of the Council and believe that there is a tremendous opportunity to improve the health care delivery system for America.

Submitted by
Francesco Chiappelli
fchiappelli@dentistry.ucla.edu

Comment Type: *Definition*

Firstly, I applaud the concerted effort of the Federal Coordinating Council in producing a draft definition of Comparative Effectiveness Research, and accompanying Prioritization Criteria.

I would propose minor editing to reflect the fact that "research synthesis" is a scientific endeavor in its own right. Therefore, the first sentence should perhaps better read as: "Comparative effectiveness research is the conduct of systematic research synthesis comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions."

I would also suggest that the last sentence be expanded just a bit to provide unequivocal information as to "how" the purpose of comparative effectiveness research is obtained. The last sentence could read: "This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness by means of systematic reviews of the evidence, and acceptable sampling and meta-analysis of the best available evidence."

Furthermore, and pertaining to the criteria (Threshold Minimal AND Prioritization), it seems to me that mention should be made of the ultimate goals of comparative effectiveness research, that is to improve both treatment interventions and policies in light of optimal benefit with minimal costs & risks. As it now stands, neither are mentioned in the list of priorities.

Lastly, I wish to express that I am honored to be part of this critical and timely discussion.

Submitted by
Ron Keren
CHOP/UPenn
keren@email.chop.edu

Comment Type: *Definition*

Another Prioritization Criteria that should be considered is the degree to which there is variability in practices for managing a condition proposed for study, and the degree to which that variability drives excess cost without any demonstrated improvement in outcome (value).

Submitted by
Carmella Bocchino
America's Health Insurance Plans
cbocchino@ahip.org

Comment Type: *Definition*

America s Health Insurance Plans (AHIP) appreciates the opportunity to share its member companies perspectives on the proposed definition for comparative effectiveness research (CER) and the strategic framework for such research. AHIP is the national trade association representing approximately 1,300 health insurance plans that provide coverage to more than 200 million Americans. Our members offer a broad range of products in the commercial marketplace including health, long-term care, dental, disability, and supplemental coverage and also have a long history of participation in public programs.

Proposed CER Definition
Comparative effectiveness research, both through the conduct of original research and synthesis of existing studies, compares treatment, drugs, devices, or procedures and evaluates the benefits and risks of different treatment options for different medical conditions across different patient populations.

The information generated from this research would be made available to clinicians, payers, innovators and most importantly to consumers, to aid in decision-making and selecting therapies.

AHIP Statements on Comparative Effectiveness Research
Unfortunately, there continues to be major gaps in care for diverse populations, many of which have not been part of the traditional clinical research model. Our members support the direction of this definition and offer additional comments to clarify both scope and depth. Therefore, there needs to be a better understanding of these populations and how their culture, race, and ethnicity impact access to care and acceptance of treatment interventions. The development of comparative effectiveness information should focus on both broad and specific sub-populations, to balance the needs of culturally diverse populations.

If we are to change clinical practice, we need to build a sustainable infrastructure not only for robust scientific evidence but for disseminating reliable comparative information to clinicians that can be easily translated into care and discussed with patients at the point of care. While health plans and physicians groups have created disease registries, observational databases and decision-support tools to inform decision-making, much more needs to be done.

Submitted by
Carmella Bocchino
America's Health Insurance Plans
cbocchino@ahip.org

Comment Type: *Definition*

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health plans and physicians groups have created disease registries, observational databases and decision-support tools to inform decision-making, much more needs to be done.

Submitted by
Richard I. Smith
Senior Vice President, Policy
Advanced Medical Technology Association (AdvaMed)
tlee@advamed.org

Comment Type: *Definition*
AdvaMed recommends that the purpose of the research in the definition of CER be made consistent with the purpose statement in the draft strategic framework. The current draft definition s purpose statement is vague as to who decision-makers are. By contrast, the draft strategic framework states that the research is to inform health care decision-making by patients, clinicians, and others in the clinical and public health communities. AdvaMed supports articulating a purpose that makes clear that the generation of comparative effectiveness research is intended to assist patients, physicians and other health care professionals. Consequently, AdvaMed recommends replacing the second sentence of the draft definition with the following:

The purpose of this research is to inform health care decision-making by patients, clinicians and other health care professionals, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.

Submitted by
Charles Branas
University of Pennsylvania
cbranas@upenn.edu

Comment Type: *Definition*

In the Draft Definition of Comparative Effectiveness Research for the Federal Coordinating Council the following sentence appears: "Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions." This sentence makes no mention of comparing the effectiveness of different approaches to broadly organizing medical care for an entire region. Regionalization has been very successfully done with specialty trauma care and trauma centers, whose patients experience a significant 25% reduction in mortality because of better regional triage and medical system organization (see Branas CC, et al. Access to trauma centers in the

United States. JAMA 2005;293(21):2626-33 and MacKenzie EJ, et al. A national evaluation of the effect of trauma-center care on mortality. N Engl J Med 2006;354(4):366-78). The same successes are also possible for many other types of medical specialty care in the US (see for instance Kahn JM, et al. Regionalization of medical critical care: what can we learn from the trauma experience? Crit Care Med 2008 Nov;36(11):3085-8). These broad, system-wide regionalization strategies that change the fundamental ways in which patients access medical care hold perhaps the greatest promise in improving health and outcomes.

As such, I am requesting that the aforementioned sentence be change to: "Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, delivery system interventions, and regionalization strategies." Thank you for your consideration.

Charles C. Branas, PhD
Associate Professor of Epidemiology
University of Pennsylvania School of Medicine
Room 936 Blockley Hall
Philadelphia, PA 19104 USA
(215) 573-5381

Submitted by
Carol Sakala
Childbirth Connection
sakala@childbirthconnection.org

Comment Type: *Definition*

Thank you for the important work done to date on the nation's CER program. My organization has since 1999 carried out a national long-term program to promote evidence-based maternity care. Based on our considerable experience, we feel strongly that the purpose of Comparative Effectiveness Research in the federal definition must include examination of comparative benefits *and* comparative harms. For example if A and B are equivalent in expected effectiveness for an outcome of interest or A is slightly superior, but A is also associated with increased risk of serious morbidity, many decision makers would be concerned about selecting A.

There is extensive evidence that patients/consumers want to know most or all known harms before making key decisions. Further, when available, information about harms often impacts their decision making. When notable risk of harm is known to be involved in an intervention, many prefer less invasive options or watchful waiting. By law and within the ethical precepts of leading health care organizations, patients/consumers have the right to know about benefits and harms, and make an informed decision on the basis of this knowledge, their own values, their

care options, and so forth. It is appropriate for the federal definition to support rights to informed decision making and informed refusal.

Many cases studies, such as the story of the widely prescribed Vioxx, suggest that we should try to avoid standard use of interventions prior to adequate investigation of harms as well as benefits. Hasty implementation can endanger the public, waste scarce resources, and undermine the integrity and authority of agencies and organizations.

Harms are underresearched and underreported both in the literature as a whole and in the promotional efforts of industry. Specifically calling out the importance of knowledge about comparative harms of interventions in the CER definition would provide an important opportunity to help correct this pervasive bias and improve health care decision making for all stakeholders.

Thank you for considering these concerns.

Submitted by
Michael Pavalock
Department of Veterans Affairs
michael.pavalock@va.gov

Comment Type: *Definition*

CER Council members,

As Comparative Effectiveness Research is building, its order demands intellectual integrity and its strength will rely upon the collective awareness of many. I applaud the opportunity for constructive feedback and input.

If I were to offer a pedantic suggestion, I would suggest a closer look at the second sentence. Responding to their expressed needs continues to seem awkward to me.

Food for thought here& what if the need is not expressed? For example:

Only minutes ago reviewing data from Analysis of VA Health Care Utilization Among US Southwest Asian War Veterans, VHA Office of Public Health and Environmental Hazards (August 2006) it shows the highest percentage diagnosis of returning Iraq and Afghanistan Veterans is 41.7% - Diseases of Musculoskeletal System/Connective System.

This information shows a need yet it s not expressed. Would it still fit into the definintion?

I ask because with musculoskeletal disorders ranking highest in returning Veterans and national concerns of opioid usages coupled with chronic pain prevalence, this issue has become a high

priority. As one of less than 20 DCs in the entire Dept of Veterans Affairs, and as a musculoskeletal expert and chronic pain manager, the demand of service far out weighs the supply. I see where CER would be feasible and effective in identifying the potential impact of not meeting with demand of service by DCs.

Submitted by
Geoffrey Mumford
American Psychological Association
gmumford@apa.org

Comment Type: *Definition*

The American Psychological Association (APA) is writing to provide comment on the draft definition of comparative effectiveness research (CER). Within a list of defined interventions the draft definition indicates that those interventions may include &behavioral change strategies& APA would prefer replacing behavioral change with psychological, psychosocial, and behavioral to provide a more comprehensive description of the interventions research. In addition we recommend that the CER definition include implementation studies and that the Prioritization Criteria also include implementation potential. Thank you for your consideration of our recommendations.

Submitted by
Tina Grande
Healthcare Leadership Council
tgrande@hlc.org

Comment Type: *Definition*

HLC Comment on Draft Definition

The Healthcare Leadership Council (HLC) agrees that the primary purpose of comparative effectiveness research should be the creation of new knowledge to inform patients and their health care providers and empower them to make smarter decisions to the maximum benefit of the patients health, quality of life, and general livelihood. Where this goal can be reached by

synthesizing, within tested and proven methodologies for doing so, existing sources of knowledge, it makes sense to do so.

As the definition implies, no two patients are identical in all respects, and therefore this research should be a useful tool, not a yes or no determinant, in guiding health care decisions. We therefore agree that comparative effectiveness research must consider potential differences among diverse patient populations. As medicine becomes more individualized, assessments should recognize that various interventions may work for specific subgroups of the population but not for others, based on genetic variability and other factors. Thus, research must be flexibly designed to target smaller populations with certain characteristics, and the definition should reflect that.

We respectfully ask that effectiveness be further clarified within this definition. In order to be truly patient-centered, it may be necessary to include, beyond medical efficacy, other outcomes in this research. Comparative effectiveness assessments could involve, whenever possible, considerations about quality of life, functional status, economic productivity, and other factors that are important to patients, providers, and society.

HLC also agrees that beyond simply comparing product A vs. product B, properly designed comparative effectiveness research should assess a wide variety of interventions. We agree that delivery system design and patient behaviors, which are usually two very important determinants of health outcomes, should be included for study. In this way, the definition suggests that this research should examine the entire health system, not just a specific sector, which we feel is the correct approach.

We respectfully suggest that the definition should also provide that this type of research, in order to maintain its objectivity and validity, will necessitate that data sources be both timely and accurate. Further, studies will need to be both transparent and periodically reassessed to ensure patients have proper authority on new and emerging interventions and strategies to improve health outcomes.

Submitted by
Alan Gambrell
Consultant
gambrell@aol.com

Comment Type: *Definition*

SUGGESTED REVISION
Comparative effectiveness research examines the relative efficacy of different interventions and strategies to prevent, diagnose, treat and monitor health conditions. This type of research entails use of various data sources/methods; compares an array of interventions (e.g., medications,

procedures, medical and assistive devices and technologies, behavioral change strategies, delivery systems); and assesses resulting health-related outcomes for diverse patient populations.

COMMENTS ABOUT DRAFT DEFINITION

* It is too long.

* This phrase s meaning is unclear: responding to their expressed needs.

* This phrase is overly descriptive and cumbersome: conduct and synthesis of systematic research.

* This phrase seems to be expanding upon a sub-issue (varied data methods) that is not central to the task at hand figuring out what medical procedures are most efficacious - This research necessitates the development, expansion, and use of a variety of:.

* This phrase can be dropped as it s reallynot necessary (i.e., to inform patients, providers, and decision-makers). We can assume that the purpose of the research is to inform for purposes of efficacy for use by many parties.

Submitted by
Susan Snyder
CDC
ssnyder@cdc.gov

Comment Type: *Definition*

Include "testing" in the second to last sentence of the definition following "Defined interventions compared may include."

"Testing" is certainly consistent with all of the applications stated in the text of the first sentence of the definition concerning "comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions." Much testing and its results are used to support clinical care that is unnecessary, ineffective and even harmful, thus providing an excellent opportunity for comparative effectiveness research.

Submitted by
Linda Emanuel
Northwestern University Feinberg School of Medicine
l-emanuel@northwestern.edu

Comment Type: *Definition*

The notion of cost-warranted care should be included in cost effectiveness definitions and research.

That is, the cost should be warranted by considerations such as the patient's goals for care.

Effectiveness can be defined to include the patient perspective, but it should be more explicit that currently the case.

Thank you for inviting feedback.

Submitted by
STANLEY WISHNER MD FACC
SWISHNERMD@AOL.COM

Comment Type: *General Comment*

Studies comparing new rx. Against placebo is poor science, poor economics , and poor medicine;this is especially true of "me too" drugs in any therapeutic classes.

One potential harm however is the tendency to make "guidelines" the "standard" of care and limit individual physician tailoring therapy to the individual patient!the ultimate inclusion of drugs in any plan's "formulary" is often so restrictive that some truly best drugs based on research papers is often denied as "not approved".

A weakness is the absence of of qualified MDs as the providers of authorization of drugs requiring "prior authorization";these decisions are usually made by nurses,clerks with protocls,or retired general or even pediatric mds ruling on sophisticated medical judgements that would be better made by aqualified specialist withou incentive to be reimbursed a % of revenue created by thei "senials".

Submitted by
Phoebe Cottingham
Institute of Education Sciences
phoebe.cottingham@ed.gov

Comment Type: *General Comment*

The general statement regarding "comparative effectiveness research" is devoid of serious content. For those who know the existing systems of systematic reviews of evidence regarding medical treatments, interventions, etc., that hold to clinical trial standards of evidence, it appears

the intent is to introduce low-level, non-scientific "standards", that if applies seriously would produce ineffective investments or consumption of treatment and mislead the American public. In short, there is nothing here to comment on.

Submitted by
Elena Casas
Advocate for the Community
ecstats15@yahoo.com

Comment Type: *General Comment*

I just want to make a general comment regarding the form. I am submitting the registration form and you will notice I am not part of any organization. I hope I do qualify to be part of the Federal Coordinating Council for the Comparative Effectiveness Research project. I have many years of experience working with state and federal programs.

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Submitted by
Richard I. Smith

Senior Vice President, Policy
American Occupational Therapy Association
slin@aota.org

Comment Type: *General Comment*

Statement of Susan H. Lin, ScD, OTR/L
Director of Research, American Occupational Therapy Association
Submitted to the Federal Coordinating Council on
Comparative Effectiveness Research
May 29, 2009

Thank you for this opportunity to provide comments on behalf of the American Occupational Therapy Association regarding the priorities for comparative effectiveness research. AOTA, representing the interests of over 140,000 occupational therapists, occupational therapy assistants and students of occupational therapy, is concerned about the health, active engagement in daily activities, and participation of all individuals. .
Comparative effectiveness research plays a critical role for health professionals, policy-makers, and consumers. However, comparative effectiveness research should be conducted beyond primary care settings, because important health care questions need to be answered in rehabilitation, long-term care, and community settings as well. Occupational therapy practitioners work with infants and elderly, in schools, homes, nursing facilities and hospitals. We strive to improve people s abilities to perform the daily activities that are most meaningful to them, thus improving their functional activities and quality of life. Occupational therapy enables Living Life To Its Fullest; and research has shown that occupational therapy, by improving life, can positively affect health outcomes and costs (Hay et al., 2002).

AOTA has completed systematic reviews on Occupational Therapy and children and adolescents with autism, children with behavioral and psychosocial needs, adults with stroke, driving and community mobility for older adults, adults with Alzheimer s disease, and children and adolescents with sensory processing/sensory integrative disorders. However, more reviews are needed to examine the evidence for different health conditions in different health care settings. Additionally, resources are needed to disseminate and promote use of evidence at the point of care, especially in rehabilitation, which can vary among inpatient, outpatient, home, and community settings.

Dr. Carolyn Clancy, Director of AHRQ underscored the need to focus on patients with multiple chronic illnesses, a group of people for whom we spend the most money and provide the worst care (Clancy, 2008). The diagnoses of autism, stroke, and dementia are often chronic, requiring multiple interventions, including occupational therapy services. Research is needed to determine the optimal dose, frequency, duration and type of occupational therapy interventions for individuals with conditions such as autism, stroke, and Alzheimer s. Such research would aid occupational therapy practitioners to deliver services efficiently and effectively, which is especially important in the context of the current economic climate and the workforce shortage

that we are experiencing in occupational therapy. The following studies are examples of research that is needed based upon AOTA s systematic reviews.

Autism

Research Question: Is behavioral intervention with occupational therapy intervention more effective than behavioral intervention (without occupational therapy) to improve the performance of daily tasks and participation in school, home, and community in children diagnosed with autistic spectrum disorders (ASD)?

Justification: Behavioral interventions are commonly used to treat autism, but given the high prevalence of sensory issues in children with Autistic Spectrum Disorders (ASD), this approach fails to address what are believed to be underlying reasons for these children s behaviors: i.e., problems with processing sensory information. Occupational therapists can assess and treat sensory processing problems that negatively influence children s behaviors and daily performance. They also can modify environments (e.g., reduce sensory overload) and tasks so that children can perform them as independently and functionally as possible, whether the task is dressing or completing a class assignment.

Stroke

Research Question: Does rehabilitation with special focus on cognition for functional activities result in better outcomes, long-term recovery, increased productivity, and greater participation in the community, compared to standard rehabilitative care? And does greater cognitive rehabilitation emphasis result in any cost savings over the long-term recovery of individuals who have had a stroke?

Justification:
Each year, 795,000 people have a stroke in the United States, and stroke is the third leading cause of death. Early interventions and rehabilitation post-stroke are crucial to better functional outcomes. And yet, there are variability in the rehabilitation treatment approaches, depending upon professionals knowledge of the literature, rehabilitation equipment and staffing availability, and even reimbursement policies. Thus, funding for CER should address knowledge translation or knowledge transfer, or else valid effective interventions will not be utilized and patients potential for better functioning could be unnecessarily limited.
Research suggests that cognition is a mediator of functional outcomes in stroke rehabilitation, but more studies are needed to compare outcomes of rehabilitative approaches. Concurrently, these studies should measure use of health care services and its associated costs, so that we can compare interventions not only in terms of outcomes but costs as well.

Dementia

Research Question: Are intervention programs that facilitate routines and environmental cueing, as provided under the supervision of an occupational therapist and under an occupational therapy plan of care, more effective than standard care to improve the performance of daily

activities (e.g., toileting, sleeping, taking medications) in people with dementia? And does the improvement help promote health for caregivers?

Justification: Research suggests that routines are beneficial to performance of daily occupations (e.g., sleep) in people with early dementia. While some studies have examined the intervention of routines on behavior and performance, few studies have investigated the effect of routines and environmental cues on performance of activities of daily living (e.g., toileting, sleeping,) and mortality. If the maintenance of daily routines and provision of environmental cues provide purposeful and meaningful activity throughout the day, people with dementia could live longer, have fewer health problems and higher quality of life, which could decrease the stress of caregivers and lower costs.

Summary

Occupational therapy promotes the performance of daily activities and participation of individuals who have illnesses or injuries that limit their daily performance and participation in society. We have recommended specific CER studies for autism, stroke, and dementia, but occupational therapy practitioners work with people of all ages, across educational, business, and health care settings. Further research is needed to identify the most effective and efficient occupational therapy interventions, especially in rehabilitative settings and other contexts in which individuals with chronic illnesses are served.

The American Occupational Therapy Association greatly appreciates this opportunity to comment and looks forward to forming partnerships with other organizations to promote the health, productive living, and quality of life of all individuals.

Submitted by
Bill Springer
University of Rhode Island
wspringer@mail.uri.edu

Comment Type: *General Comment*

I have some concerns about the FCC's ability to operate independently of Congressional intervention should they rule adversely towards a mode of treatment backed by financially and politically connected interests. Health care is very big business and the players protect their revenue streams fiercely.

Towards this end, I think that the FCC should try to work with Congress to avoid the equivalent of "line item veto" interventions. One approach that I favor is to present the FCC findings and recommendations to Congress not on an individual study basis, but in the aggregate each year, asking Congress to vote up or down on the entire body of work rather than specific findings relative to a single treatment modality.

The FCC's main objective over the next several years has to be survival and credibility. Good luck in achieving this direction.

Submitted by
Jim Gartner
Ingenix Consulting
jim.gartner@ingenixconsulting.com

Comment Type: *General Comment*

As I review information about Comparative Effective Research, I am excited to hear about the emphasis given on driving Medication Therapy Management. It is great to see that MTM has become a greater requirement within our Medicare Part D programs for 2010 and I see it rapidly expanding. Given that, I feel that you should strongly consider either adding a Phamacist to your Council to help provide guidance in the area of MTM or seek input from pharmacists engaged in that area. As a pharmacist with a strong interest in this area, I feel this is something that should be considered and would consider being an expert in the area if needed.

Submitted by
Robert Cihak
rjcihak@gmail.com

Comment Type: *General Comment*

Maintain perspective.

In particular, remember that patients, their needs and their options change continually, as do the insights, discoveries and innovations of medical and clinical science.

In other words, any results of this research will be outdated long before publication.

Therefore, mandatory obedience, such as by putting any results into legislative or regulatory concrete, is doomed to be counterproductive and very often harmful.

Submitted by
Mary Pendergast
Pendergast Consulting
marykpendergast@aol.com

Comment Type: *General Comment*

The Food and Drug Administration currently takes the position that no pharmaceutical, biological, or medical device company may make any statement regarding the comparative effectiveness of its product to any other product until the company has conducted one or more head-to-head clincal trials of the two products and FDA has approved the "claim." Few entities, including AHRQ, hold themselves to that high a standard of evidence for making a comparative effectiveness evaluation. If the US Government or private entities conduct comparative effectiveness studies or analyses, or issue reports on the comparative effectiveness of an FDA-approved medical product using standards less strict than FDAs, then a medical product company may find itself in a position where its product is criticized as less effective, but the company would not be able to respond using the same type of data or analyses. Rather, the company would have to conduct large, long, expensive head-to-head clinical trials to respond to the comparative effectiveness report. It seems to me that there has to be a consistent standard for the conduct, analysis, and reporting of comparative effectiveness research for both the US government, private organizations, and companies so that everyone can speak using the same standards of proof. Simply stated, to do otherwise would be unfair.

Submitted by
Susan Bertolino
Change.org
sadness2joy22@aol.com

Comment Type: *General Comment*

We appreciate your support.

Submitted by
C. Michael White
University of Connecticut EPC
cmwhite@harthosp.org

Comment Type: *General Comment*

I appreciate the work that the council has put into these priorities. I think this is a good framework and wouldn't remove anythingt hat you have written but... I worry that it would miss preclude the use of comparative effectiveness for rare diseases where the data is gathered in collections of small trials or studies and a systematic review (comparative effectiveness review) can really help clarify therapies for people without evidence based therapies. I am thinking about disorders such as vasovagal syncope or connective tissue diseases.

Submitted by
Myles Rosenthal
Health Care Education
rosenthalmyles@yahoo.com

Comment Type: *General Comment*

President Obama and I are committed to changing the Political process by growing an organization Founded on broad of support from ordinary Americans. This organization is about the people's interests ahead of the special interests,but to do that,Barack needs help from people like you and me. I've set my own personal fundraising goal for the organization,which you can see in the thermoneter on the website: {http://my.barackobama.com/page/outreach/view/main/rosenthalmyles}.

Submitted by
Christina Campbell
Private Citizen
ccc215@gmail.com

Comment Type: *General Comment*

Given the wasteful spending in our health care system, it is more important than ever to engage in robust research on what treatments work and what do not. Doing so empowers doctors and patients, and helps make our practice of medicine more evidence-based. Having read your definition, I am relieved to say I heartily agree with it.

Submitted by
Syreeta Batiste
syreeta_batiste@yahoo.com

Comment Type: *General Comment*

Hello,

The Federal Coordinating Council For Comparative Effectiveness Research will help Congress realize that different Health Care Reform policies can either assist or harm people, who are in need of medical insurance.

Sincerely,
Syreeta Batiste

Submitted by
Tom Gadient
member of AMA
tmgadient@yahoo.com

Comment Type: *General Comment*

This needs skills and authorities already found in American College of Wurgeons, American of Academy Science, FDA, DEA, and HHS.

Submitted by
Timothy Foley
Change.org
tim@commanderfoley.com

Comment Type: *General Comment*

Given the wasteful spending in our health care system, it is more important than ever to engage in robust research on what treatments work and what do not. Having read your definition, I am relieved to say I heartily agree with it.

I am particularly glad to see that you have stuck to your evidence-based guns in the face of political pressure and included "cost" as a factor in determining comparative effectiveness. Although it is no means the only factor, I strongly feel that it must be considered where appropriate. I appreciate and applaud you for recognizing that comparative effectiveness research must also look at how much we're paying when treatments are otherwise roughly as effective as one another in terms of health outcomes. Keep up the good work.

Submitted by
Timothy Foley
Change.org
tim@commanderfoley.com

Comment Type: *General Comment*

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Submitted by
Richard I. Smith
Senior Vice President, Policy
Frederick Memorial Hospital
Dquirke@fmh.org

Comment Type: *General Comment*
Inclusion of allergy data and possibly immunization data would be helpful also I believe.

Submitted by
Manuela Rodrigues
Change.org
manuela.in.wonderland@gmail.com

Comment Type: *General Comment*

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Submitted by
Rox Fowlie
change.org
nluvwBiLL@hotmail.com

Comment Type: *General Comment*

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Submitted by
roxie schliesman
change.org
snookies_ou812@msn.com

Comment Type: *General Comment*

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Submitted by
Matt Milholland
SD
MattMilholland@yahoo.com

Comment Type: *General Comment*

Thank you for supporting comparative effectiveness research.

Submitted by
Ron Keren
CHOP/UPenn
keren@email.chop.edu

Comment Type: *General Comment*

To date very little has been written about the need to use CE research to enhance our evidence base for interventions targeted at children. This is disappointing as the evidence base for managing pediatric conditions is appallingly weak, particularly for children with complex chronic conditions, who place a disproportionate financial burden on the healthcare system. Resources from ARRA should be specifically targeted at studying best practices in the management of children's health, both for high volume common pediatric conditions (screening, common infections, mental health) as well as less common but high morbidity/cost conditions (prematurity and its sequelae, neurological disorders, congenital syndromes, congenital heart disease). Research networks will be required to study many of the less common conditions, and money should be dedicated to funding such collaborative research networks. Success in understanding and then implementing best practices through collaborative networks has been demonstrated in cystic fibrosis, which could serve as a model for other relatively uncommon but high morbidity/cost pediatric conditions.

Submitted by
Michael Westrich
Starvin Marvin Recycling
mtwestrich@earthlink.net

Comment Type: *General Comment*

I use naturopathic drugs and am feeling good these daus after wasting $35,000 trying to diagnose cause and not treat cause.

Submitted by
Tamzin Rosenwasser
AAPS
juperbeatrix@aol.com

Comment Type: *General Comment*

None of this bureacracy was around during the nineteenth and twentieth centuries when American physicians put this nation at the very cutting edge of surgical techniques, pharmaceuticals, and innovations of every other kind. It is precisely what we do not need.

It sounds like something out of the old Soviet Union.

Our nation has excellent medical care. When we measure infant mortality, we measure every infant with signs of life, whereas other nations inflate their numbers by NOT doing so- in some cases the child has to live 3 days to be counted a live birth.

We have excellent lifespans when violence is deleted; physicians cannot control the social pathologies involved in violence.

We have much better cancer survival statistics than other industrialized nations.

What we DO NOT need is more government interference in medical care. The more there is, the worse things become. I have seen that very clearly in 27 years of practice, including 8 years emergency room experience in a big city hospital, which went broke because of Medicare and Medicaid.

Let's see this "Comparative Effectiveness " stuff adapted for Congress and the Executive and Judicial branches before we further cripple the nation's physicians with it. Those physicians are getting fed up.

What is needed is a return to true insurance to protect against big losses, not pre-paid medical care in which every cut and sore throat is run through a gigantic, costly bureaucracy.

Submitted by
lauren serven
PDA
ls072456@aol.com

Comment Type: *General Comment*

CER will be an important component in any reform measure. Hopefully, the agency will, remain true to it's mission and protect the public from those who wish to manipulate medical markets for their personal gain.

As the Administration's efforts towards reform proceed over the next several weeks, it is my hope that ALL proposals be considered, ie, Single Payer Medicare for All. Failure of this Administration to enact true reform for the American people will result in a weakening, not only of our economy, but the very fiber that holds our democracy together.

Submitted by
Ida Sim
ida.sim@ucsf.edu

Comment Type: *General Comment*

I note the following statement in the draft CER definition:"This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness."

I implore the council to set aside proportionate funds to build the methods and informatics base for the scale and quality of comparative effectiveness research that this country needs. In particular, funds should be targeted to ensuring that the design and results of primary comparative effectiveness studies (e.g., interventional and observational studies) are available in standardized computable form, not just in PDF. Such an informatics infrastructure would increase the efficiency and therefore the value of each dollar spent on CER.

Submitted by
ray yar
valley medical center, san jose
royala@pol.net

Comment Type: *General Comment*

Need to educate public more that doctors don't have time to review hundreds of articles and then make the smartest choice avialable. We are drowning in commericials and pharm rep detailing and super expensive medications and treatments are administered due to lack of information. Media likes sensational news, they will make a huge issue of isolated cases where treatment was difficult to get because of this process. The best defense is offense, so more publicity should be given how this will help far more people than hurt them.

Submitted by
Harold Pincus
Columbia University
hap2104@columbia.edu

Comment Type: *General Comment*

Overall, the focus seems to be on conducting specific CER studies on particular clinical topics. Given the early stage of the formalized CER efforts in the US, more priority might be placed on buliding an infrastructure to facilitate CER across topical areas. While priority 5 alludes to this, the language suggests that the broader benefit would be on top of the conduct of a specific study. Thus neither the definition nor the priority statements make explicit reference to infrastructure elements such as: developing new methods for data analysis and modeling, improving the utility of secondary data sets for CER, establishing practice-based research networks,training new investigators in CER, etc.

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Columbia University
hap2104@columbia.edu

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Submitted by

Richard I. Smith
Senior Vice President, Policy
individual
solitarydragon77@yahoo.com

Comment Type: *General Comment*
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Submitted by
Sandra Oliver
Bayer HealthCare LLC
pcurrie@sidley.com

Comment Type: *General Comment*

Dear Council Members,

Bayer HealthCare LLC (Bayer) is pleased to submit the following comments for consideration to the Federal Coordinating Council for Comparative Effectiveness Research (the Council). Bayer appreciates the opportunity to engage in the process by which the Council will develop a national program for coordinating comparative effectiveness research (CER). We believe that CER, if undertaken properly, has the potential to improve clinical outcomes and to improve medical decisions. It is important, however, that CER be conducted appropriately, with the utmost scientific rigor and with all the necessary safeguards in order to ensure that CER does not inadvertently impede patient access to medically appropriate and necessary health care products and services. Without these key elements, CER could harm vulnerable patient subpopulations or

interfere inappropriately with the clinical judgment of health care professionals and their interactions with their patients. Bayer looks forward to the opportunity to contribute to the dialogue between the Council, Congress and other relevant stakeholders in developing comprehensive and effective national CER policies.

For over 100 years, Bayer has been dedicated to the development and production of high-quality drugs, medical devices and biologicals that have helped patients lead healthier lives. Bayer is a worldwide leader, with research and business activities focused on oncology, diagnostic imaging, diabetes care, hematology/cardiology, primary care, specialized therapeutics and women s health care. We are committed to providing patients with high quality, safe products and to ensuring appropriate access to our products.

Bayer supports CER initiatives. However, we remain concerned that the Council will inextricably link cost and clinical evaluations. We strongly believe that cost effectiveness should be separate from CER. Comparative effectiveness will be most successful in changing behaviors if these initiatives are designed to enhance health care practitioners clinical judgment in order to promote patient-centered care. Accordingly, Bayer does not support the proposed CER initiatives that are cost-centric, as we believe that this approach would be unnecessarily contentious and subjective. Further, because there is no consensus as to how to value clinical outcomes, the effect of moving forward now with a cost-focused CER program could impede patient access to treatments without any standards for proper assessment. We fear that a cost-based CER initiative would inevitably lead to a one size fits all solution that would not respect independent health care practitioner clinical judgment and the needs of individual patients and vulnerable patient subpopulations.

As the Council develops CER policies and initiatives, Bayer respectfully urges the Council to consider the following principles:

Informed Medical Decisions: CER should not replace individualized medical decisions with rigid treatment formulas for patient care that do not reflect the needs of individual patients. Health care practitioners must maintain their independent clinical judgment. CER should promote the more effective exercise of that judgment, not seek to eliminate or minimize the value of it. CER should not limit a health care practitioner s medical decisions to a uniform approach. Health care practitioners must be able to continue to evaluate individual factors, subpopulation needs, social and cultural influences, complicating psychological issues and a myriad of other special circumstances which often have a significant impact on care.

Protecting Appropriate Patient Access: Bayer believes that CER can improve the quality and efficacy of health care. However, such research should not be used for coverage decisions by public or private payors. Similarly, CER should not imply or make recommendations to such payors regarding coverage or benefits. To the extent that CER becomes a direct or indirect tool to limit access to care and to ration health care services, it will be rejected by patients and practitioners alike, and it will fail to realize its potential to support appropriate access by educating patients and practitioners.

Inclusive and Transparent Process: Given the Obama Administration s commendable commitment to transparency, we believe that all CER decisions must be developed in a transparent manner. Thus, all assumptions, data, and findings must be made readily available to the public. The public and other interested stakeholders should be permitted to comment on all phases of CER projects, from prioritization of topics through the evaluation phase to the final report. The Council also should hold public forums to allow for stakeholders to provide meaningful input regarding the standards to be used in undertaking CER. Only this kind of complete transparency will permit CER information to be positively viewed by the public. Otherwise, CER will inevitably be viewed with suspicion as a means to surreptitiously ration care. If, however, CER and its limitations are clearly communicated and debated, CER will, we believe, have a pervasive and critical impact on health care.

Accordingly, Bayer urges the Council to ensure that CER is developed through an inclusive and transparent process, which allows for consultation and input from practicing health care practitioners, patients, patient advocacy groups, employers, manufacturers, allied health care professionals, and trade organizations.

Appropriate Oversight: Bayer believes that any government funded CER initiative, whether conducted through existing agencies or a newly formed organization, should be subject to Congressional and executive branch oversight. For example, the Council should, at a minimum, institute a formal mechanism for the appeal of CER findings, hold an annual public meeting to solicit complaints and proposals for improvements, and implement a mechanism to challenge methods and biases, to raise concerns about human subject protection, and address other threats to the integrity of the process. This will ensure that CER is conducted in a manner that is ethical, transparent, scientifically appropriate, and consistent with applicable law.

Evaluating the Circumstances of Clinical Trials: Bayer believes that CER policies should require clinical trials used for CER purposes to accurately reflect real world circumstances. Without such a requirement, there is a potential for CER to lead patients and practitioners in a clinical direction which is inappropriate, ineffective, and potentially unsafe. Accordingly, we strongly urge the Council to review the circumstances under which any evidence is collected to ensure that it is appropriate for consideration in this context.

Interconnectivity: We recommend that the Council require that, wherever appropriate, CER be undertaken in a manner that considers how various interventions work in collaboration with one another. Bayer believes that reviewing interventions in isolation will unnecessarily produce misleading and inaccurate findings.

Evaluations Should Be Promptly Reexamined When New Evidence Is Available: CER policies must recognize the ongoing nature of innovation and that technology, therapeutic treatments and medical devices are constantly evolving. Accordingly, the determination of comparative effectiveness must be considered against the backdrop of this evolution or CER results will not adequately evaluate quality or efficacy. The Council must allow for a mechanism by which prior evaluations are promptly reconsidered in light of new technological advances or additional data. Stakeholders should have the ability to petition for a re-review of a decision based on new

research and/or data that has become available. The Council or the agency responsible for the research should also be required to respond to such petitions within a reasonable time period. In order to be clinically relevant, the Council and the agencies undertaking CER must be prepared to reexamine their findings as new data, technologies, and therapeutic treatments and medical devices become available.

Evaluate the Spectrum of Health Care: To improve patient outcomes, CER should be applied to the full range of factors that influence health care and delivery systems, and not just to pharmaceuticals and medical devices, as is all too often the case under some comparative effectiveness or cost effectiveness systems. This should include, for instance, an analysis of the impact of different types of formularies, insurance benefit designs, institutional service models, health care practitioner services, the use of performance and quality measures, adoption of electronic medical records, greater use of information technology, tools to reduce medical errors, improved discharge planning, and the impact of government payors failure to adequately cover or reimburse medically appropriate services and prevention, compliance, and persistency programs.

Communicating with Practitioners, Payors, Patients and Others: As the Council considers CER priorities, Bayer believes that the Council must communicate clearly with practitioners, payors, patients, patient advocacy groups, and others regarding the limits of CER studies and the appropriate interpretation of the resulting data. The risks of over-interpreting CER are all too real. Findings and preliminary reports should prominently and conspicuously describe any limitations in the data and analysis.

* * *

Bayer strongly believes in patient-centered care and urges the Council to use CER as a mechanism to enhance clinical judgment to promote such care. Only through improved health care practitioner and patient awareness can comparative effectiveness improve health care. We hope that the Council strongly considers our concerns regarding CER initiatives that focus on cost as a factor, as such an approach could seriously compromise patient access to innovative therapies, stifle the exercise of clinical judgment, impede adoption of CER findings, and contribute to the creation of a second-tier level of care for the poor and other vulnerable populations.

We thank the Council for the opportunity to comment on the ongoing development of CER policies and initiatives. We look forward to working with the Council as national CER policies and initiatives are developed.

Submitted by
Pete Zawadzki
Blue Torch Medical Technologies
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Comment Type: *General Comment*

The importance of standardization seems to be neglected in these definitions. When making a comparison, the standard measures of that analysis have a direct value on the bias in the effectiveness. Providing a statement or reference to standardization may greatly benefit your mission.

Thanks for the opportunity to comment. Our CaverMap device is a unique standard in surgical technique comparative effectiveness, haven been verified in a Phase 2 multi-center randomized clinical study trial in radical prostatectomy.

Submitted by
Bernard Yablin
URMC(retired
Baruch38@yahoo.com

Comment Type: *General Comment*

It is worthwhile to consider some of the studies presented online by the NEJM.

Submitted by
Tom Maxwell
care2.com
aliastom@gmail.com

Comment Type: *General Comment*

Given the wasteful spending in our health care system, it is more important than ever to engage in robust research on what treatments work and what do not. Doing so empowers doctors and patients, and helps make our practice of medicine more evidence-based. Having read your definition, I am relieved to say I heartily agree with it.

I am particularly glad to see that you have stuck to your evidence-based guns in the face of political pressure and included "cost" as a factor in determining comparative effectiveness. Although it is no means the only factor, I strongly feel that it must be considered where appropriate. I appreciate and applaud you for recognizing that comparative effectiveness research must also look at how much we're paying when treatments are otherwise roughly as effective as one another in terms of health outcomes. Keep up the good work.

Submitted by
Bernard Yablin
URMCPedsRetired
baruch38@yahoo.com

Comment Type: *General Comment*

1)Validity of screening for colorectal and prostate cancer in nursing home resident populations.2)Management of acute cardiovascular episodes in nursing home populations---criteria for hospitalization

Submitted by
Alan Haggard
n/a
quantumcipher@gmail.com

Comment Type: *General Comment*

Given the wasteful spending in our health care system, it is more important than ever to engage in robust research on what treatments work and what do not. Doing so empowers doctors and patients, and helps make our practice of medicine more evidence-based. Having read your definition, I am relieved to say I heartily agree with it.

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Submitted by
Rachel Groman
American Association of Neurological Surgeons/Congress of Neurological Surgeons/Congress of Neurological Surgeons
rgroman@neurosurgery.org

Comment Type: *General Comment*

Re: Draft Definition, Prioritization Criteria, and Strategic Framework for Comparative Effectiveness Research

Dear Federal Coordinating Council Members,

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), which together represent 4,000 practicing neurosurgeons across the United States, we would like to thank the Federal Coordinating Council for Comparative Effectiveness Research for giving us the opportunity to comment on its draft definition, prioritization criteria, and strategic framework for comparative effectiveness research (CER).

The AANS and CNS recognize that CER can serve as a valuable tool to guide sound clinical decision-making by both patients and physicians. As such, our members are committed to determining what medical treatments work best for their patients and our specialty is taking a variety of steps to ensure that the care neurosurgeons deliver is evidence-based. The AANS and CNS actively participated in previous Council listening sessions and recently presented the Institute of Medicine (IOM) with specific clinical research recommendations focusing on spinal diseases for which there is little high quality clinical research to guide practice. Organized neurosurgery also has a robust practice guidelines development program and recently created a new clinical data registry entity called NeuroPoint Alliance, which is partnering with Outcome Sciences, Inc. to build a database platform for a specialty-wide patient registry that will serve multiple purposes, including Maintenance of Certification, clinical research, pay-for-performance and other quality improvement programs.

The AANS and CNS support a well-designed CER system that is transparent, improves quality, relies on public input, supports continued medical progress, and strengthens physician and patient decision-making while preserving individualized treatment. We greatly appreciate that the Council s definition and framework recognize diverse patient populations and the need to

respond to the expressed needs of both patients and providers. CER programs must account for the unique circumstances of patients and preserve the independent judgment of physicians. However, we request that the Council clarify its intent when it refers to the need for CER to respond to the expressed needs of decision-makers. It is critical that CER focus on communicating research results to patients, providers and other decision-makers, and not on making centralized coverage and payment decisions or recommendations. Without further clarification of this statement, decision-makers could be interpreted as giving the Centers for Medicare and Medicaid Services (CMS) or any other public or private payer the authority to use CER to make coverage and payment decisions.

The AANS and CNS also appreciate that the Council s definition and framework recognize a broad scope of research, including medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions. However, we encourage the Council to further strengthen the definition so that it indicates that research on each of these interventions focus on all patient subpopulations and not just a few particular patient groups.

We are very pleased that the Council recognizes the need to rely on a variety of data sources and data assessment methodologies. We encourage the Council to specifically consider prospectively obtained outcomes data collected through patient registries, such as the NeuroPoint Alliance, as one example of a data source that can help to better define indications for certain procedures. Directing comparative effectiveness research funds to the creation and/or administration of patient registries, such as the NeuroPoint Alliance, will ultimately result in the production of meaningful data that will help guide clinical decision-making, determine best practices, improve quality, and ultimately lower costs.

While the AANS and CNS support the Prioritization Criteria outlined in the framework, we are concerned that it fails to specify how these priorities should be developed, reviewed and finalized. It is critical that all relevant stakeholders, particularly those who are clinical subject matter experts and provide direct patient care, have a voice in the process through which CER topics are prioritized.

Finally, we request that the Council s definition explicitly state that the purpose of CER is to provide information on clinical effectiveness and patient health outcomes, not cost-effectiveness assessments. CER must not ebb into cost containment, where life or death medical decisions can be based upon the government s financial considerations. The AANS and CNS believe that if CER is carried out in a sound and transparent fashion, it will naturally rid of inefficiencies in our health care system by directing providers and patients to care that is most effective.

Moving forward, we encourage the Council to continue to preserve transparency throughout the many of aspects of the CER process by ensuring that stakeholders have input into research priorities and design and have an equal voice in the governance of a CER entity.

The AANS and CNS appreciate the opportunity to offer these comments, and we look forward to working cooperatively with the Council to develop a fair and meaningful process through which

to compare clinical effectiveness and to ultimately improve patient care. If you have any questions about our comments, please contact Rachel Groman, MPH, 202-628-2072, rgroman@neurosurgery.org

Sincerely,

Troy M. Tippett, MD, President
American Association of Neurological Surgeons

P. David Adelson, MD, President
Congress of Neurological Surgeons

cc: Robert Harbaugh, MD, Chair, AANS/CNS Washington Committee
Dan Resnick, MD, Chair, AANS/CNS Quality Improvement Workgroup

Submitted by
Ulyana Vjugina
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Comment Type: *General Comment*

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To: Federal Coordinating Council on Comparative Effectiveness Research

June 10, 2009

The American Society of Hematology (ASH) appreciates the opportunity to comment on Comparative Effectiveness Research (CER) to the Federal Coordinating Council (Council). ASH represents over 16,000 clinicians and scientists committed to the study and treatment of malignant and non-malignant blood and blood-related diseases such as leukemia, lymphoma, sickle cell disease, anemia and hemophilia.

ASH commends the Council for creating a public forum that underscores the importance of input from a broad range of stakeholders interested in priorities for CER. The Council s charge is consistent with ASH s mission to promote the understanding, prevention and treatment of blood disorders, and improve healthcare and patient outcomes with hematologic disease.

ASH believes that timely CER on the following topics will have the highest impact in hematology based on prevalence, disease burden, variability in outcomes in diverse populations and costs of care. Research in these areas has the potential to address the gaps in knowledge and uncertainty within the clinical and public health communities, ultimately leading to improved quality of care, outcomes and cost-effectiveness.

I. Management of Patients with Sickle Cell Disease (SCD).

The survival of children with SCD has improved with early identification of affected infants and enrollment in comprehensive pediatric hematology programs. However, there is a paucity of comparable adult-oriented programs and the growing young adult sickle cell populations face ongoing challenges in obtaining effective and comprehensive care. CER should evaluate health care transition training programs for adolescent patients. Many adult patients do not have access to physicians with expertise in sickle cell disease on an ongoing basis. There is a need to evaluate alternative medical care models for patients in the community setting. Examples include co-management with primary care physicians and utilization of telemedicine.

The few randomized clinical studies that have been performed addressing management of patients with SCD have had high impact on improving outcomes. Observational studies have also had major influence on clinical practice (e.g., treatment of acute chest syndrome). There are opportunities to use CER to identify optimal approaches to encourage the adherence to proven preventive and treatment interventions. Administrative and clinical data sets such as state Medicaid claim and hospital discharge files would provide useful resources to assess current

practices and measure outcomes of interventions. The following topics are examples to be considered:

A. Pain management. The utility of clinical pathways in the outpatient, emergency department, and inpatient settings needs to be addressed. CER analysis of multidisciplinary and multimodality approaches to pain management for patients with SCD compared with conventional pharmacological therapies would provide opportunities to identify treatments resulting in improved patient quality of life and cost-effectiveness.
B. Hydroxyurea therapy. Hydroxyurea therapy is underutilized in the management of symptomatic adult patients. CER can be employed to evaluate programmatic interventions at the patient, provider, and health care system levels to enhance appropriate use of hydroxyurea therapy.
C. Red blood cell transfusions. Guidelines are available for the use of transfusions in the management of sickle cell complications but they are based on limited data. CER can be used to address questions such as the extent of phenotype matching of red cells used for chronic transfusion and techniques of transfusion administration (simple vs. exchange) for specific acute indications.
D. Clinical decision support tools. Adults often receive their care from physicians with few sickle cell patients in their practices (e.g., community based hematology/oncology and primary care physicians). Management of sickle cell-related issues such as hydroxyurea therapy and health maintenance (e.g., screening for pulmonary hypertension, renal disease, ophthalmologic complications) can be challenging in these settings. CER can be employed to address the utility of clinical assessment tools, electronic health record reminder systems, and other approaches to optimizing receipt of appropriate intervention.

II. Specialized Challenges in Thrombosis.

Insertion of inferior vena cava filters (IVCF) is widely performed in patients with, or at risk of, venous thromboembolism. IVCF likely prevent pulmonary embolism (PE) in highly selected patients with acute venous thromboembolism (VTE) who have absolute contraindications to therapeutic dose anticoagulation. However, the majority of IVCF are placed in patients with either no active VTE (prophylactic IVCF) or those with acute VTE who do not have an absolute contraindication to anticoagulation.

However, there is little evidence to guide the use of IVCF. Only one randomized trial has been performed in which patients with acute VTE were randomized to anticoagulation with or without IVCF. The study demonstrated an acute reduction in PE, with no impact on mortality and an increase in VTE over 8 years of follow-up, leading the authors to recommend against routine use of filters in patients who can be anticoagulated. There have been no randomized controlled trials examining the use of retrievable filters or the use of filters for the prevention of pulmonary embolism in patients who do not have acute venous thromboembolism. Evidence-based guidelines have recommended against the use of IVCF for the prevention of pulmonary embolism in patients who do not have acute DVT. Despite this guideline recommendation, the majority of IVCF in the United States are placed for this indication. For example, IVCF use is routine in some trauma centers. This practice occurs despite the fact that insertion of IVCF is

expensive (estimated to cost in excess of US$5000 per use), that IVCF cause otherwise avoidable deep vein thrombosis (at an estimated US$5000 to US$10,000 per event) and that IVCF may provide physicians with an excuse to neglect the administration of a pharmacologic prophylaxis, which is proven to be the most effective and cost-effective treatment for patients at high risk of VTE.

Data on insertion of IVCF should be easily accessible. Indications and complications of their use should be discernible. Comparison of event rates in patients with and without IVCF matched for other co-morbidities should also be available. Such an analysis would likely establish definitively that IVCF use is both more expensive and more toxic than alternate, effective therapies currently recommended by consensus guidelines.

III. Management of Patients with Myelodysplastic Syndrome.

Myelodysplastic syndromes (MDS) affect older adults with a rapidly rising national disease burden owing to the aging of the American population. Patients with MDS have a chronic bone marrow failure disorder often associated with other co-morbidities, and are cared for by primary care and hematology subspecialists. Patients and health care providers must address complications related to the disease process itself that include cytopenia-associated risks for infection or bleeding, the risk for evolution to acute myeloid leukemia (AML), and secondary organ complications arising from red blood cell transfusions and iron overload.

Although evidence-based guidelines provide management pathways for physicians that utilize an array of FDA approved therapeutics, the impact of these costly treatments on the disease natural history and co-morbidities remains largely undefined. Large prospectively randomized therapeutic trials represent the benchmark to define the benefit for most interventions, but size and the ethical challenge of non-treatment arms prohibits such definitive studies. Important insight into the clinical benefit of interventions could be obtained from the analysis of large federal health claims databases such as the Medicare Standard Analytic File. Data from patients diagnosed in a given year can be mined for subsequent billings for acquired co-morbidities such as diabetes mellitus, cardiac and liver complications, survival and red blood cell transfusions.

Given the large size of the database, important insight can be gathered regarding the success of health care delivery strategies in the U.S. that is applicable to the population of patients at large, rather than to those that meet the restrictive eligibility of registration trials. CER comparing usual supportive care versus care by protocol-driven community-based, advanced health practitioners and teams may lead to a reduction of variability of care, costs, and improved quality of life. Examples of CER that would have an impact on care and provide insight as to the cost benefit of treatments include those related to current management practices for iron loading and disease modifying therapies:

1. Does the use of an iron chelator delay or prevent end-organ co-morbidities, or extend survival in lower risk transfusion-dependent patients?
2. If so, what proportion of patients that may benefit have access to such treatment?

3. Using current practice regimens for hypomethylating agents such as azacitidine or decitabine, is there a demonstrable survival benefit or difference in resource utilization in patients with higher risk disease?
4. How often is the use of an erythropoietic stimulating agent (ESA) effective in preventing the need for transfusion in the lower risk MDS population? What is the impact of ESA response on the natural history of low risk MDS?

Information from an analysis of the latter may support prior ASH recommendations to the CMS against the restriction of ESA access to those individuals with the greatest potential for benefit. Such CER analyses would provide critical information as to the best management strategy for the MDS population at large to modify disease natural history, the magnitude of benefit to patients, and cost-effectiveness.

IV. Use of Transfusions.

Transfusion therapy remains essential to the successful treatment of oncologic and hematologic disorders, many surgical procedures, and traumatic injuries. However, the appropriate threshold for transfusions in various clinical situations as well as the appropriate dose of the blood component transfused remains unclear. Modification of blood components by procedures such as irradiation or leukocyte reduction have an important role in improving transfusion safety; however the indications for such procedures are unclear in many patient populations and are applied heterogeneously. The risks of transfusion beyond that of transfusion-transmitted infection and transfusion reaction remain controversial. For example, there continues to be considerable debate about whether transfusion is associated with an increased rate of cardiac morbidity and multiorgan failure. CER comparing outcomes with different red blood cell transfusion thresholds in patients with cardiac disease, hematologic malignancy or surgery will help to most effectively manage a blood supply that frequently must address shortages. A better understanding of adverse outcomes related to transfusion will allow physicians to better weigh the risks and effectiveness of transfusion therapy.

Thank you for the opportunity to submit these comments. Please contact ASH Scientific Affairs Manager, Ulyana Vjugina, PhD, at (202) 776-0544 or uvjugina@hematology.org for any additional information.

Submitted by
Andrew Whitman
andrew.whitman@varian.com

Comment Type: *General Comment*

Varian s Medical Systems is the world s leading manufacturer of medical devices and software for treating cancer and other medical conditions with radiotherapy, radiosurgery, proton therapy, and brachytherapy.

We greatly appreciate the opportunity to comment on HHS s implementation of comparative effectiveness research funds allocated to AHRQ, NIH and the Secretary in the American Recovery and Reinvestment Act of 2009.

Varian supported the inclusion of funding for comparative effectiveness research in the American Recovery and Reinvestment Act of 2009. This funding was an important first step that will bring increased quality and transparency to our health care system.

As we continue to reform our health care system, Varian supports the creation of a non-governmental, independent Comparative Effectiveness Institute comprised of experts in the appropriate medical and academic fields to advise and recommend to Congress and the Centers for Medicare and Medicaid Services the procedures that are effective for treatment. These recommendations will be based on research occurring in government agencies, academia, and the private sector. This research will determine the therapies, treatments and diagnostic procedures that are considered a standard of care and should be available to all Americans. In addition, Varian hopes that Comparative Effectiveness Research will lead to a process that rationalizes treatment alternatives. We would like to offer some specific comments and recommendations on comparative effectiveness as it relates to cancer care, and specifically radiation therapy.

Measuring Outcomes

When comparing the outcome of different cancer therapies, survival is the simplest but not always the key metric for measuring outcomes. For example, when comparing the outcomes for early stage prostate cancer, survival from radical prostatectomy and radiation therapy is similar, so one could contend that the outcomes are the same. However, comparative side effects of the treatments are vastly different. As a result, comparative effectiveness studies need to focus not only on survival as an outcome, but also side effect toxicities. This is also true when comparing radical mastectomy with lumpectomy followed by radiation. Patients will differ widely in their perception of the importance of these side effects.
Some women will be intolerant of losing an entire breast, and some will find it acceptable. When the council compares outcomes from diverse therapies, it will need to accommodate these differences as valid, even though there is no objective standard to compare them.

In addition, outcomes at many small clinics may differ significantly from the outcomes achieved by major research hospitals. When comparing the outcomes of different approaches, the council should not just consider the outcomes of major trials at research institutions, but also the outcome at smaller, lower volume facilities and physicians.

Allowance for the Development of New Technologies

In the case of cancer treatments using radiation therapy, improvements are often made based on input from customers, retrospective studies of the likely causes of poor outcomes, and extensive understanding of the way radiation acts on healthy and diseased organs. Since at times it can take five to ten years to know whether an innovation is clinically effective, physicians use calculated dose distributions and/or imaging techniques as a surrogate to predict improved outcomes. We recommend that the Council develop ways to predict the potential value of new technologies using means other than short term data, and then verify these predictions using long term follow-up studies. In recognition of the fact that new technologies are continually introduced and older ones are modified, the Council should monitor this and allow for comparative effectiveness research to accommodate these developments.

Varian Medical Systems looks forward to working with the Federal Coordinating Council on Comparative Effectiveness and appreciates the opportunity to comment on this important topic.

Submitted by
Andre Williams
Association of Black Cardiologists, Inc
awilliams@abcardio.org

Comment Type: *General Comment*

Patients, doctors and providers with a voice at the table to discuss the future of CER. Moving forward, this is the only way comparative effectiveness will work properly. And when patients come to the table, we must see to it that all patient populations are represented. We will work to ensure that the government includes all people people of color, the elderly and people with disabilities, among others when designing new CER studies. It is only fair that medical innovation and future research benefit the needs of all Americans.

We applaud the Congress for introducing a CER bill that puts patients first. Moreover, we are confident that this approach to new CER will enable patients and healthcare providers of all backgrounds to continue to have access to the best possible care and most accurate information.

The ABC, located in Atlanta, GA, was founded in 1974 to bring special attention to the adverse impact of cardiovascular disease on African Americans. A nonprofit organization, the ABC has an international membership of more than 600 health care professionals. The ABC is dedicated to eliminating the disparities related to cardiovascular disease in all people of color. For more information, call 404-201-6600 or visit www.abcardio.org.

Submitted by

Alexandra Clyde
Medtronic, Inc.
alexandra.clyde@medtronic.com

Comment Type: *General Comment*

Dear Secretary Sebelius and Distinguished Council Members:

Medtronic is the world s leading medical technology company, specializing in implantable therapies that alleviate pain, restore health, and extend life. Our technologies combine advanced therapeutics and diagnostics to assist physicians and patients in the management of chronic conditions such as heart failure, diabetes, Parkinson s disease, and other debilitating illnesses.

Medtronic supports increased investments in comparative effectiveness research (CER) to better inform physicians about treatment options and help patients make decisions about the clinical effectiveness of medical care. We understand the value of using evidence-based approaches to ensure that the right patient receives the right care at the right time, and we are firmly committed to the principles of evidence-based medicine and the continual research and development necessary to support innovative therapies that improve health outcomes for patients and bring value to the healthcare system. Toward that end, our technologies and therapies have withstood rigorous health assessments around the globe.

Medtronic believes that CER should be conducted in a consistent, transparent, and methodologically rigorous manner, allowing input from a broad group of stakeholders at key junctures throughout the topic selection, study design, results interpretation and results dissemination processes. It is clear that broad consensus exists surrounding these principles as evidenced in documents such as the policy options for delivery system reform outlined by the Senate Finance Committee, the Comparative Effectiveness Research Act of 2008 (S.3408), as well as the recently introduced Comparative Effectiveness Research Act of 2009 (H.R.2502)and the Patient-Centered Outcomes Research Act of 2009. This consensus is encouraging as we believe these aspects are critical to ensure that CER findings become a useful and reliable factor in clinical decision-making.

In keeping with the principles outlined above, we offer comments on the following questions outlined in the April 10, 2009 Federal Register notice:

" What information on the Coordinating Council s activities would be most useful?

In order to ensure an appropriate level of transparency the Council should post the following information on a public website:

?A schedule of all meetings the Council is planning over the next year;
?A draft and final list of recommended areas for investment, including the rationale the Council used to identify them;

?A draft of the June 30 report to Congress and Secretary of HHS and solicitation of public comment on this report;
?Drafts of all government-sponsored CER and solicitation of public comment at critical intervals in the process (topic selection and prioritization, draft key questions, study design, and draft report); and
?All public comments the Council receives on its activities and its publications, as well as its responses to these comments;

"What steps should the Coordinating Council consider to help ensure that public-and private-sector efforts in the area of CER are mutually supportive?

Medtronic appreciates the Council s efforts in coordinating public listening sessions to gather input from a broad range of stakeholders. While the listening sessions provide a basic forum for public input, as was emphasized in a number of instances at these sessions, there should be more formal opportunities for broader levels of stakeholder input.

A broad set of stakeholders should be continually consulted to ensure that CER and its findings are relevant to the needs of patients and clinicians. To support this, all public and private agencies receiving American Recovery and Reinvestment Act (ARRA) funds to conduct CER should adhere to the following standards for stakeholder engagement:

?Establishment of a 30-day public comment period on the topic selection, draft key questions, study design, and draft report
?Public posting of comments received, including information on how those comments will be addressed

In addition, the Council should recommend a process to ensure that HHS contracting agencies conducting comparative effectiveness research will follow the methodological standards and processes (e.g., posting reports for public comment, etc.) determined by the Council. We suggest that the Council recommend processes for monitoring and enforcing adherence of the agencies to these standards and processes.

"What types of investments in infrastructure for CER should the Coordinating Council consider?

It is critical that the Council develop and periodically update methodological standards (and procedures for the use of such standards) regarding outcomes measures, risk adjustment, statistical protocols, evaluation of evidence, and conduct of research to ensure accurate and scientifically based CER.

When developing the methodological standards to guide for CER, Medtronic recommends the following:

?Include patient advocates, professional societies, practicing clinicians, leading academic researchers, and industry representatives, in the development of these standards.

?Interventions should be studied in a comprehensive fashion and research should be tailored to the specific intervention being evaluated.
?All study limitations and limitations of the underlying data should be disclosed in the research report in order to prevent confusion and potential misinterpretation by users. All agencies generating research reports appropriately communicate limitations and consider including a formal peer-review of the draft research report in order to ensure that the research limitations have been appropriately disclosed.
?The methodological standards should include a detailed discussion of the research challenges posed by device-related studies and recommendations for how to account for these challenges in the CER methodology. This discussion should include the challenges of randomization and blinding in devices-related studies and the importance of considering the effect of device implant training and experience of the physicians on clinical outcomes.

Medtronic commends the Council for its efforts to coordinate and guide the increased investment in CER. We appreciate the opportunity to provide these comments. If you have any questions related to these comments, please contact me at 763.505.2660 or at alexandra.clyde@medtronic.com .

Sincerely,

Alexandra T. Clyde

Submitted by
Alexandra Clyde
Medtronic, Inc.
alexandra.clyde@medtronic.com

Comment Type: *General Comment*

Dear Secretary Sebelius and Distinguished Council Members:

Medtronic is the world s leading medical technology company, specializing in implantable therapies that alleviate pain, restore health, and extend life. Our technologies combine advanced therapeutics and diagnostics to assist physicians and patients in the management of chronic conditions such as heart failure, diabetes, Parkinson s disease, and other debilitating illnesses.

Medtronic supports increased investments in comparative effectiveness research (CER) to better inform physicians about treatment options and help patients make decisions about the clinical effectiveness of medical care. We understand the value of using evidence-based approaches to ensure that the right patient receives the right care at the right time, and we are firmly committed to the principles of evidence-based medicine and the continual research and development necessary to support innovative therapies that improve health outcomes for patients and bring

value to the healthcare system. Toward that end, our technologies and therapies have withstood rigorous health assessments around the globe.

Medtronic believes that CER should be conducted in a consistent, transparent, and methodologically rigorous manner, allowing input from a broad group of stakeholders at key junctures throughout the topic selection, study design, results interpretation and results dissemination processes. It is clear that broad consensus exists surrounding these principles as evidenced in documents such as the policy options for delivery system reform outlined by the Senate Finance Committee, the Comparative Effectiveness Research Act of 2008 (S.3408), as well as the recently introduced Comparative Effectiveness Research Act of 2009 (H.R.2502)and the Patient-Centered Outcomes Research Act of 2009. This consensus is encouraging as we believe these aspects are critical to ensure that CER findings become a useful and reliable factor in clinical decision-making.

In keeping with the principles outlined above, we offer comments on the following questions outlined in the April 10, 2009 Federal Register notice:

" What information on the Coordinating Council s activities would be most useful?

In order to ensure an appropriate level of transparency the Council should post the following information on a public website:

?A schedule of all meetings the Council is planning over the next year;
?A draft and final list of recommended areas for investment, including the rationale the Council used to identify them;
?A draft of the June 30 report to Congress and Secretary of HHS and solicitation of public comment on this report;
?Drafts of all government-sponsored CER and solicitation of public comment at critical intervals in the process (topic selection and prioritization, draft key questions, study design, and draft report); and
?All public comments the Council receives on its activities and its publications, as well as its responses to these comments;

"What steps should the Coordinating Council consider to help ensure that public-and private-sector efforts in the area of CER are mutually supportive?

Medtronic appreciates the Council s efforts in coordinating public listening sessions to gather input from a broad range of stakeholders. While the listening sessions provide a basic forum for public input, as was emphasized in a number of instances at these sessions, there should be more formal opportunities for broader levels of stakeholder input.

A broad set of stakeholders should be continually consulted to ensure that CER and its findings are relevant to the needs of patients and clinicians. To support this, all public and private agencies receiving American Recovery and Reinvestment Act (ARRA) funds to conduct CER should adhere to the following standards for stakeholder engagement:

?Establishment of a 30-day public comment period on the topic selection, draft key questions, study design, and draft report
?Public posting of comments received, including information on how those comments will be addressed

In addition, the Council should recommend a process to ensure that HHS contracting agencies conducting comparative effectiveness research will follow the methodological standards and processes (e.g., posting reports for public comment, etc.) determined by the Council. We suggest that the Council recommend processes for monitoring and enforcing adherence of the agencies to these standards and processes.

"What types of investments in infrastructure for CER should the Coordinating Council consider?

It is critical that the Council develop and periodically update methodological standards (and procedures for the use of such standards) regarding outcomes measures, risk adjustment, statistical protocols, evaluation of evidence, and conduct of research to ensure accurate and scientifically based CER.

When developing the methodological standards to guide for CER, Medtronic recommends the following:

?Include patient advocates, professional societies, practicing clinicians, leading academic researchers, and industry representatives, in the development of these standards.
?Interventions should be studied in a comprehensive fashion and research should be tailored to the specific intervention being evaluated.
?All study limitations and limitations of the underlying data should be disclosed in the research report in order to prevent confusion and potential misinterpretation by users. All agencies generating research reports appropriately communicate limitations and consider including a formal peer-review of the draft research report in order to ensure that the research limitations have been appropriately disclosed.
?The methodological standards should include a detailed discussion of the research challenges posed by device-related studies and recommendations for how to account for these challenges in the CER methodology. This discussion should include the challenges of randomization and blinding in devices-related studies and the importance of considering the effect of device implant training and experience of the physicians on clinical outcomes.

Medtronic commends the Council for its efforts to coordinate and guide the increased investment in CER. We appreciate the opportunity to provide these comments. If you have any questions related to these comments, please contact me at 763.505.2660 or at alexandra.clyde@medtronic.com .

Submitted by
Richard I. Smith
Senior Vice President, Policy
Institute for the Advancement of Social Work Research
jzlotnik@naswdc.org

Comment Type: *General Comment*

The Institute for the Advancement of Social Work Research offers the following comments on the Definition and Framework. If you need additional information, we will be pleased to provide it, as Comparative Effectiveness Research must deal with the complexity of not only the individual needs of those requiring health care services, but also the complexity and diversity of service delivery system(s) themselves.

The Institute for the Advancement of Social Work Research (IASWR) would like to commend the Council for its work in providing a broad definition of Comparative Effectiveness Research (CER). As stated in the draft definition, CER is not only an important piece in helping doctors and patients identify the best strategies for treating certain conditions, but it also goes beyond the bounds of physical health. It is valuable to the field and to consumers, to see a definition that encompasses vulnerable and underserved populations, behavioral change strategies, and delivery system interventions. However, these are complex areas that will require sophisticated and multi-method CER research efforts.

CER needs to be at the forefront in increasing our understanding of how to best meet the health, mental health and psychosocial needs of underserved populations. In a report released on June 9, 2009, HHS Secretary Sebelius reported that:

" Forty-eight percent of all African Americans adults suffer from a chronic disease compared to 39 percent of the general population.
" Eight percent of white Americans develop diabetes while 15 percent of African Americans, 14 percent of Hispanics, and 18 percent of American Indians develop diabetes.
" Hispanics were one-third less likely to be counseled on obesity than were whites -- only 44 percent of Hispanics received counseling.
" African Americans are 15 percent more likely to be obese than whites.

These statistics are not just a snapshot, but a clear picture of the wide array of conditions facing different populations, many of which are vulnerable or underserved. CER strategies must ensure attention to these populations and study mechanisms for receiving adequate and efficient health care.

As highlighted in the definition, assumptions and framework, underserved and vulnerable populations are a priority of CER. This then requires that there be planning to determine studies across and within populations, to fully understand diversity and health disparities. For example, one cannot categorize all Asian populations or African American populations but rather must take into account genetic history, socio-economic and education status health literacy, economic self-sufficiency, access to health care services and health, mental health and psychosocial status.

That discussion cannot focus on medical conditions alone, but must also look at the intersection of medical, psychosocial, and mental health, community supports and the organization and availability of relevant health care services.
The provision of services provided to patients is just as vital as the patients themselves. Within the Prioritization Criteria Section there needs to be greater clarification in the third criterion which states:
Uncertainty within the clinical and public health communities regarding management decisions.
From this criterion, it is unclear whether the statement refers to mismanagement of services being provided or something different.
In addition to comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions, CER also needs to include service systems in those comparisons. Without effective service systems, it does not matter how effective the treatment may prove to be. IASWR welcomes the opportunity to work with the Council and with HHS on furthering the utility of Comparative Effectiveness Research, especially in working with individuals and families with complex and co-occurring needs.
The Council also should be commended for recognizing the importance of capacity building related to CER, in regard to both researcher training and methodology. Social work researchers, working in communities, using quantitative, qualitative and action research methodologies can contribute to and also benefit from such capacity development efforts
Once again thank you to the Council for all of its hard work on CER.

Submitted by
Les Paul
National Pharmaceutical Council
lpaul@npcnow.org

Comment Type: *General Comment*

On behalf of the National Pharmaceutical Council (NPC), thank you for the opportunity to comment on the draft comparative effectiveness research (CER) definition, prioritization criteria, and the proposed strategic framework that was developed by the Federal Coordinating Council on Comparative Effectiveness Research (FCCCER). The definition, prioritization criteria, and the strategic framework for CER can play an important role in improving patient health outcomes, and we congratulate the FCCCER on this critical effort.

About the National Pharmaceutical Council

Briefly, the National Pharmaceutical Council sponsors and conducts scientific analyses on the appropriate use of pharmaceuticals and the clinical and economic value of improved health outcomes through pharmaceutical innovation. CER and its foundation of high quality scientific evidence are important areas of focus for NPC. It is our goal to ensure that sound evidence is recognized by independent experts, considered appropriately by private and public payers, reflected adequately in benefit designs, and incorporated into clinical practice. NPC was

established in 1953 and is supported by the nation s major research-based pharmaceutical companies.

Draft Definition of CER

When the $1.1 billion in federal funding was first allocated for CER, there were many unanswered questions regarding which projects would be prioritized, what kind of strategic framework would be developed, and how the research would be conducted and disseminated. To address those questions, NPC and other health care stakeholders provided recommendations in previous testimony that priorities for CER should:

* Focus on conditions with the greatest impact on morbidity and cost, such as chronic conditions like cardiovascular disease, chronic respiratory diseases, cancer, diabetes, arthritis, and serious mental health conditions.

* Include all major therapeutic options used to treat those conditions such as drugs, medical and surgical procedures, diagnostics, and medical devices.

* Take into account the needs of patient subgroups who may respond differently to therapeutic options based on demographic characteristics, genetic variation, and coexisting medical conditions; and

* Express clear support for the development of new CER methodologies, such as analysis of non-randomized studies of treatment effects using secondary databases, practice-based clinical practice improvement studies, more accurate modeling and simulation techniques, and methodologies that ensure optimal interpretation and application of CER in a variety of patient care settings.

NPC is pleased that the draft definition of CER encompasses these important concepts in a broad and thoughtful manner.

Draft Prioritization Criteria

The general nature of the prioritization criteria allows for considerable flexibility in their interpretation. While they represent a good foundation, clarification is needed to ensure that CER funding decisions will be made in the best possible manner and result in useful information that improves clinical decision making for health care providers and patients.

In particular, NPC is concerned about the reference to the "time necessary for research," and whether this would preclude lengthy or more in-depth projects from consideration. Proposed prioritization of research topics and studies, their associated research time frames, final study outcomes, and related information should be made transparent to all stakeholders and should be disseminated in a timely manner To maximize this potential, the FCCCER should prioritize the

funding of an assessment of strategies to ensure the continuous evaluation of new evidence related to specific health care technologies -- for example, how best to determine when a health technology assessment should be revised based on new clinical information.

The criteria also suggest that CER "lays the foundation for future CER or generates additional investment." CER not only lays the foundation for future CER, but also the foundation for future innovation. How the agenda and conduct of CER develops has the potential to influence incentives for innovation and we would recommend that the study of this important question be an explicit interest of publicly funded CER.

Additional Factors for Consideration in Priority Setting Under the Strategic Framework

Moving forward, it also will be important to consider other key factors in the selection of the highest priority research.

* First, it will be important to conduct research to define rigorous, high quality, and validated CER methodologies that are focused on providing timely, accurate and balanced information in order to assist clinical decision making.

-- These questions include, but are not limited to, defining how best to address the full range of health effects of a new technology including quality of life, functionality, and productivity, as well as how best to appropriately characterize the strengths, weaknesses, and limitations of various underlying health technology assessment analytic techniques.

-- In order to minimize the likelihood for inaccurate or inappropriate interpretation of CER, we suggest the inclusion of a transparent and readily accessible description of the strengths, weaknesses, limitations, and potential for generalizability of the findings of CER utilizing varied experimental and non-experimental research designs.

* Second, and consistent with our comment on the prioritization of the study of the impact of CER on innovation, the strategic framework should implicitly assume that innovative technology is an external input to the CER framework. It should be encompassed within and considered integral to the framework.

* Third, the agenda for CER should be driven by the condition and the "key unanswered questions" in the context of that condition. Answering these questions may require comparisons between different types of technologies, processes, or procedures that may be considered to treat the condition; for example, the framework should reflect the need for comparisons of drug vs. surgery, drug and diagnostic vs. procedure, procedure vs. surgery, or other combinations.

* Fourth, comparisons should also include delivery system architecture options, insurance plan designs, methods for primary/secondary prevention, and approaches to provider incentives to effect improvements in health.

The National Pharmaceutical Council appreciates the opportunity to take part in this critical dialogue and stands ready to assist FCCCER as it moves forward with the development of the CER definition and criteria. Thank you.

Submitted by
Fred Pane
Premier Inc.
fred_pane@premierinc.com

Comment Type: *General Comment*

I wanted to share a HECON model, that I have been working on for almost 7 years, around this area. WHen I worked at a large teaching hospital in Pa, we began to address issues this way. Thanks

Replacing pharmacoeconomics with 'thereconomics'In urging health system pharmacists to move toward a return-on-investment model to rationalize their expenditures, Fred Pane, RPh, of Premier, has coined the term "thereconomics" by combining the words therapy and economics. "For years, pharmacy managers have dealt with the budgetary issues surrounding pharmaceuticals," says Pane. "That economic model is called pharmacoeconomics, created to try to explain the value of drugs. However, it is very difficult to meet with hospital finance staff and explain pharmacoeconomics. It relates only to pharmaceuticals and doesn't address the big issue, which is the various patient treatment options, both drugs and non-drugs, and how they replace each other or support clinical outcomes."
The National Library of Medicine's Medical Subject Headings (MeSH) defines pharmacoeconomics as "economic aspects of the fields of pharmacy and pharmacology as they apply to the development and study of medical economics in rational drug therapy and the impact of pharmaceuticals on the cost of medical care. Pharmaceutical economics also includes the economic considerations of the pharmaceutical care delivery system and in drug prescribing, particularly of cost-benefit values. [sic]"
Pane defines thereconomics as "measuring both the financial and clinical quality outcomes associated with various treatment options, including drugs, devices, and surgical and interventional procedures." He says: "It is therefore all inclusive, which pharmacoeconomics is not, and can be applied to any patient treatment. It maintains a balanced scorecard approach to all pharmaceutical operations, both clinical and financial."

Submitted by
Naomi Aronson, PhD
Executive Director
Technology Evaluation Center
Blue Cross Blue Shield Association
naomi.aronson@bcbsa.com

Comment Type: *General Comment*

The Technology Evaluation Center of the Blue Cross and Blue Shield Association (BCBSA), an association of 39 independent Blue Cross and Blue Shield Plans that collectively provide health insurance benefits to more than 100 million Americans, appreciates the opportunity to comment on the Draft Definition of Comparative Effectiveness Research (CER) for the Federal Coordinating Council.

We support the Federal Coordinating Council for Comparative Effectiveness Research, as authorized by the American Recovery and Reinvestment Act (ARRA), in its work to coordinate research and guide investments in comparative effectiveness research funded by the Recovery Act.

The draft definition, we believe, will result in research that will give clinicians and patients valid information to make decisions that will improve the performance of the American healthcare system

Thank you for giving us this opportunity to express our support.

Submitted by
Mary Denison
US citizen
maryekdenison@qwestoffice.net

Comment Type: *General Comment*

What doesn't work for one, amy work for another. Keep all options open - it could be you, or your family who needs them.

Submitted by
Barbara Kulig
Self - Part 2 of 2
bk.u@hotmail.com

Comment Type: *General Comment*

The news that the new health plan will in part contain a singular national insurance plan available to Americans of low income is a favorable and necessry step to address the health care crisis in the US.

I will participate in that program, rejecting the private insurance of Congressional Repulicans who apparently are supporting the status quo of expensive medical industry costs which ONLY benefit practioners and insurance companies.

Once again, I was tortured by SSA/CMS and would appreciate a total revamping of both agencies, who at best have been unresponsive to my needs and decisions.

Submitted by
Joyce Mithcell
American College of Medical Informatics
joyce.mitchell@hsc.utah.edu

Comment Type: *General Comment*

We appreciate the efforts of the Federal Coordinating Council in drafting the definition, prioritization criteria, and strategic framework for comparative effectiveness research (CER), and we are grateful for the opportunity to provide feedback on these documents.

Feedback on the definition:

" The Fellows of the American College of Medical Informatics have a vested interest in these documents, specifically as they relate to the role of information systems in CER.

" Currently the nation is embarking on a massive investment to improve the state of Healthcare Information Technology (HIT) throughout the healthcare enterprise. HIT has the potential to fundamentally change the healthcare delivery process. Evaluating the effectiveness of various HIT interventions will be an integral part of evaluating and guiding this massive investment.

" We are concerned that HIT-based interventions are not specifically mentioned in the draft definition. Although some may argue that HIT might be included under any of the phrases, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions none of these phrases have traditionally been applied to HIT-based interventions, such as Decision Support Systems, Heath Information Exchanges, or Computerized Order Entry. Thus, whether HIT interventions are ultimately evaluated is left to later interpreters of the definition. This seems to be an unnecessarily high-risk approach.
o We hope that the Council will consider our request to include "information systems and technology" with the examples of interventions provided in the definition of CER.

Feedback on the strategic framework:
" In the third paragraph of the description of the framework (CER investments and activities), we would request that the research example be re-phrased so that it suggests a broader sphere of research than medication-related CER. This could be written as (change is in quotes): Research, e.g., comparing interventions for a specific condition or discharge process A to discharge process B for readmissions.

" In the CER themes: type of intervention should include "information systems": Type of interventions, e.g. devices, information systems, behavioral change, delivery system.

" Figure 2: in the Cross-Cutting Investment Opportunities box, "Under-researched interventions" should include information systems in the list of examples.

Submitted by
Theresa Smith
Citizen
Thevail@hotmail.com

Comment Type: *General Comment*

Thank you for all the hard work that you do over there at HHS. Unfortunately most Americans, myself included, have little idea of what DOES actually happen at HHS.

But we do know that our perscription drugs cost too much, and have side effects far scarier than the conditions they are meant to treat. Rectal bleeding from a nasal allergy medication?! Seriously?

We also know that many of the allowable additives in our food cause everything from cancer to diabetes, to obesity, and beyond. I'm not trying to to be too fussy, but is there really a reason my dessert should contain several of the same ingredients as my shampoo, and I'm not talking about coconut oil here..

We are 29th on the scale of medical goodness in the world, but we spend more than anyone else. So a part of the healthcare problem, the main part, is that we're not getting a good deal. Americans are doing the equivalent with medical care of someone shopping at the 7-11 for their monthly groceries.

Good luck and keep up the good work, but a word to the wise, you might want a dang good speech explaining some of this stuff.

Submitted by
Ned Norris Jr.
Tohono O'odham Nation
pete.delgado@tonation-nsn.gov

Comment Type: *General Comment*

TOHONO O ODHAM NATION
ARRA/COMPARATIVE EFFECTIVENESS RESEARCH RECOMMENDATIONS

ISSUES:
The American Recovery and Reinvestment Act (ARRA)/Comparative Effectiveness Research (CER) debate has elicited concern by tribal health leaders and health care professionals who conduct research in Indian Country. American Indian tribal leadership will ask, first, How will the Obama Executive Branch implement the standing Presidential Executive Order for tribal consultation (Clinton 2000) and supporting implementation memoranda that require that all Executive agencies ensure that there is meaningful and timely tribal input in formulating and implementing the ARRA of 2009, and subsequent Sec. 804 to establish the Federal Coordinating Council (FCC) CER? Secondly, does the FCC for the CER fully understand the special circumstances that Tribes face, which include the inability of tribal people to access primary, specialty, emergency services due to geographic constraints and by the historic and continuing under funding of the Indian health care system?

The U.S. federal government recognizes the debt owed to tribal governments. In 2000, President William J. Clinton issued the Executive Order #13175, Consultation and Coordination with Indian Tribal Governments , and the Department of Health and Human Services (DHHS) reissued an earlier Department Tribal Policy, requiring that each HHS Operating and Staff Division have an accountable process to ensure meaningful and timely input by tribal officials in the development of policies that have tribal implications. Certainly, the ARRA s CER Policy would be under this umbrella .

RECOMMENDATIONS:
The FCC for CER is charged to develop recommendations to coordinate research and guide the use of resources contained in ARRA to advance improvement in the U.S. health care system. The following recommendations focus on the inclusion of Indian health, tribal and urban Indian health programs in this process

" Allow additional time for HRAC to consider developing a tribal consultation process in order for interested Tribes to provide their input into the FCC/CER plan and implementation.

" Request that AI/AN representative be assigned to FCC/CER from the Indian Health Service of the DHHS.

" Consider establishing separate research guidelines and measures for Complementary and Alternative Medicine (CAM) and AI/AN traditional healing practices, but do not exclude them from future CER consideration.

" Concentration by CER in the areas of health promotion, disease prevention and community based interventions will benefit tribal communities.

" Concentration by CER on clinical effectiveness rather than cost effectiveness will benefit tribal communities.

? CER studies should be broad enough to include an assessment of minority and disability groups and other smaller populations such as American Indian Tribes as it has been noted that in CER minority and disability groups have not been given a broad enough population sample. (Cancer Policy Monitor, 2009).

BACKGROUND:

There are more than 560 federally recognized Tribes in the U.S and a coalition of over 50 health and academic organizations, and individuals dedicated to improving the health care of AI/AN report that the disparity in health care for Indian people continues to escalate nationwide as AI/AN live almost four years less when compared to other U.S. populations because;

1. AI/AN youth are more than twice as likely to commit suicide,
2. AI/AN people are 670% more likely to die from alcoholism,
3. 650% more likely to die from tuberculosis,
4. 318% more likely to die from diabetes, and
5. 204% more likely to suffer accidental death.

(Friends of Indian Health, 2009).

The poor state of health among many Tribes requires community based and culturally appropriate treatment and research methodologies that can help to break the cycle of chronic illness and related disease including addiction.

i. Improving the Quality of Care in the Indian Healthcare System:

The FCC is concerned about the quality of care experienced by individual patients served in federal health care systems. This component of CER is applicable to the Indian healthcare system and would help to identify measures that are needed to improve the quality of care. The IHS Strategic Plan (2011) states that a major strategic objective of the agency is to improve the safety and quality of care in IHS, tribal and urban Indian health care settings. Steps to improve

the system include: 1) the identification and reduction in adverse medical events; 2) integration of evidence based practices into clinical, public health and administrative practices; 3) timely adoption of new medical technologies; 4) advance electronic medical record keeping and connectivity within the system; and 5) ongoing cost effectiveness analysis. Should the CER Council recommend an assessment of the strengths and weakness of the Indian health care system this will provide the opportunity for IHS Quality Management (QM) Program to pursue the steps needed to accomplish meeting its own strategic objectives and implement needed systemic changes to resolve problems areas. The IHS QM goals are integrating, evaluating and tracking best practices and expanding best practice administrative and clinical models known as Centers of Excellence that already exist in the system.

ii. Complementary and Alternative Medicine (CAM):

The use of alternative therapies is now appearing in many hospitals, managed care plans, and conventional practitioners are incorporating CAM therapies into their practice, and schools of medicine, nursing, and pharmacy are beginning to teach CAM (National Academy of Science, 2005). The influence of CAM on and off Indian Country is substantial yet much remains unknown about these therapies, particularly with regard to scientific research studies that might convincingly demonstrate the value of CAM in the treatment of diabetes and other chronic disease. Several Tribes incorporate CAM modalities in their healthcare systems. The Pascua Yaqui Tribe of Arizona s alternative healing program has been in existence for a number of years and the San Carlos Apache Tribe in Arizona provides naturopathic services to individuals with diabetes.

iii. American Indian and Alaska Native Traditional Healing and Practices

It should be noted that for AI/AN traditional medicine use and practices are not an alternative (CAM), it is only alternative to allopathic medicine (conventional Western Medicine) and therefore should not be considered a category of CAM; but it s own diverse and culturally-specific healing system(s). AI/AN Traditional Medicine distinction was further discussed among Indian health educators, researchers and practitioners and the consensus was that each tribe's traditional medicine and practices comes from their particular environment whether it be desert, coastline, or forested homelands (20th Annual Native Health Research Conference, 2008)

For example, at its broadest interpretation, the Tohono O odham (Desert People) of southern Arizona, way of viewing the world Himdag embraces an interconnected worldview where healing from medicinal plants, songs and storytelling, spiritual healing, curing and traditional songs, and beliefs and values like respect, games, harvesting traditional foods and hunting, incorporating songs into ceremonies are intricately interwoven (Tohono O odham Nation Constitution 1986, Tohono O odham Nation Language Policy, 1986).

1. For many tribal members of the Tohono O odham Nation and many other U.S. Tribes, it is the community, which recognizes who its healers are, not a Federal or State licensing body (Sequieros, 2009).

2. Several Veteran's Administration regional medical centers have formal agreements with certain Tribes (e.g. Dineh/Navajo Nation) to provide culturally-appropriately compensation to the Dineh Medicine Men for certain ceremonies for veterans (Trujillo, 2009).

3 The Medicine Wheel concept is comprehensive and incorporates mental, physical, spiritual, emotional wellbeing. This concept has been widely adapted by many Native and non-Indian communities to promote wellness.

The IHS established a traditional healing policy that allows the IHS to provide, at the patient s request, an opportunity for traditional healers to conduct healing services within a health care facility. Some Service Units carry out the policy without question; however, at some IHS facilities, patients that request this assistance are sometimes met with reluctance and skepticism by providers unknowledgeable of AI/AN healing ceremonies and tradition. While the openness of the policy allows for varied tribal healing practices to be conducted as appropriate within the confines of the health care facility, systemic barriers exist that include lack of funding for the program, inability to acquire Medicaid reimbursement for the expenses incurred by traditional healers, lack of participation of the traditional healer as a member of the health care team and lack of information to individual patients that the policy exists. The CER may provide an opportunity to further evaluate the effectiveness of culturally based interventions that are utilized in the Indian health care system and thereby further the development of these interventions as recognized best practices.

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Submitted by
Rachel Groman
rgroman@neurosurgery.org

Comment Type: *General Comment*

Re: Draft Definition, Prioritization Criteria, and Strategic Framework for Comparative Effectiveness Research

Dear Federal Coordinating Council Members,

On behalf of the undersigned members of the Alliance of Specialty Medicine, a coalition of 11 medical societies, we appreciate the opportunity to comment on the Federal Coordinating Council s draft definition, prioritization criteria, and strategic framework for comparative effectiveness research (CER). The Alliance recognizes that CER can serve as a valuable tool to guide sound clinical decision-making and to better inform both patients and physicians about what works best in health care.

The Alliance supports a well-designed CER system that is transparent, improves quality, relies on public input, supports continued medical progress, and strengthens physician and patient decision-making while preserving individualized treatment. We greatly appreciate that the Council s definition and framework recognize diverse patient populations and the need to respond to the expressed needs of both patients and providers. It is critical that any CER program account for the unique circumstances of patients and preserve the independent judgment of physicians. However, we request that the Council clarify its intent when it refers to the need for CER to respond to the expressed needs of decision-makers. It is critical that CER focus on communicating research results to patients, providers and other decision-makers, and not on making centralized coverage and payment decisions or recommendations. Without further clarification of this statement, decision-makers could be interpreted as giving the Centers for Medicare and Medicaid Services (CMS) or any other public or private payer the authority to use CER to make coverage and payment decisions.

The Alliance also appreciates that the Council s definition and framework recognize a broad scope of research, including medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions. However, we encourage the Council to further strengthen the definition so that it indicates that research on each of these interventions focus on all patient subpopulations and not just a few particular patient groups.

We also thank the Council for recognizing that CER must rely on a variety of data sources and data assessment methodologies. We encourage the Council to specifically consider prospectively obtained outcomes data collected through robust patient registries as one example of a data source that can help to better define indications for certain procedures. Directing comparative effectiveness research funds to the creation and/or administration of patient registries will ultimately result in the production of meaningful data that will help guide clinical decision-making, determine best practices, improve quality, and ultimately lower costs through feedback reports that compare individual data to equivalent comparison groups. The Alliance cautions the Council and other policymakers against linking patient registries to claims data since current privacy laws do not allow for one-to-one linkages, which introduces error and dilutes the sound clinical methodology needed for CER.

While the Alliance supports the Prioritization Criteria outlined in the framework, we are concerned that it fails to specify how these priorities should be developed, reviewed and finalized. It is critical that all relevant stakeholders, particularly those who are clinical subject matter experts and provide direct patient care, have a voice in the process through which CER topics are prioritized.

Finally, we request that the Council s definition explicitly state that the purpose of CER is to provide information on clinical effectiveness and patient health outcomes, not cost-effectiveness assessments. CER must not ebb into cost containment, where life or death medical decisions can be based upon the government s financial considerations. The Alliance believes that if CER is carried out in a sound and transparent fashion, it will naturally rid of inefficiencies in our health care system by directing providers and patients to care that is most effective.

Moving forward, we encourage the Council to continue to preserve transparency throughout the many aspects of the CER process by ensuring that stakeholders have input into research priorities and design and have an equal voice in the governance of a CER entity.

The Alliance of Specialty Medicine appreciates the opportunity to offer these comments, and we look forward to working cooperatively with the Council to develop a fair and meaningful process through which to compare clinical effectiveness and to ultimately improve patient care. If you have any questions about our comments, please contact Rachel Groman, MPH, 202-628-2072, rgroman@neurosurgery.org

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American Association of Neurological Surgeons
American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Urological Association
Congress of Neurological Surgeons
Heart Rhythm Society
Society for Cardiac Angiography and Interventions

Submitted by
Margaret Anderson
FasterCures
manderson@fastercures.org

Comment Type: *General Comment*

Thank you for the opportunity to comment on the Council's Draft Prioritization Criteria and Strategic Framework. They are both very concise and thoughtful documents with which we substantially concur. We did, however, want to highlight some issues which we don't feel are directly addressed that may inform your thinking going forward.

-- In addition to informing better point-of-care decisions by patients and providers, building the evidence base through comparative effectiveness research can elucidate critical clinical research questions deserving investigation, which will accelerate the development of new and improved diagnostics and therapeutics. If that can be reflected in the prioritization criteria in some way (perhaps under #5, "potential for multiplicative effect"), we believe that would be of great value.

-- We are pleased that the Strategic Framework addresses not only the research studies themselves, but also the human and scientific capital necessary to execute the research -- including, very importantly, developing methodologies needed to conduct the research efficiently and effectively. We urge you to give this issue the attention it requires. The scientific underpinnings of comparative effectiveness research are still being developed, and it will be important to monitor the progress of the field as early studies funded through ARRA yield results.

-- Also addressed in the Strategic Framework is the data infrastructure supporting CER, another area we hope will be given careful attention. In particular, we hope the Council will make an effort to ensure that investments in health information technology being advanced separately

with ARRA funds are supportive of the requirements for conducting CER to the greatest extent possible.

-- We are also pleased to see recognition of the fact that translation, dissemination, and adoption of the results of CER are as important as the studies themselves and hope that funding will be devoted to pursuing this critical goal.

-- We hope and expect that the vision driving federal spending on CER will continue to be enhancing and customizing care for patients, and that it will not be used to limit access to or availability of effective treatments on an individualized basis.

FasterCures' mission is to identify ways to accelerate the discovery and development of new therapies for the treatment of deadly and debilitating diseases both in the United States and around the globe. The organization was founded in 2003 under the auspices of the Milken Institute to aggressively catalyze systemic chance in cure research and to make the complex machinery that drives breakthroughs in medicine work for all of us faster and more efficiently. FasterCures is independent and non-partisan. We do not accept funding from companies that develop pharmaceuticals, biotechnology drugs, or therapeutic medical devices. Our primary mission is to improve the lives of patients by improving the research environment, research resources, and research organizations.

Submitted by
Bart Barefoot
GlaxoSmithKline
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Comment Type: *General Comment*

GlaxoSmithKline ("GSK") is pleased to submit these comments to the Federal Coordinating Council on Comparative Effectiveness Research (the Council) regarding the Council s draft definition of comparative effectiveness research (CER), draft prioritization criteria for CER funding, and draft strategic framework.

GSK is a world-leading research-based pharmaceutical company whose mission is to improve the quality of human life by enabling people to do more, feel better and live longer.

GSK thanks the Council for soliciting public input on CER generally and on the development of these important guideposts for CER investments under the American Recovery and Reinvestment Act (ARRA). We believe the Council s willingness to engage interested stakeholders through listening sessions and written comment opportunities will produce a strong, credible foundation for CER investments which can improve the quality of clinical decisionmaking and in turn improve patient health outcomes. Indeed, it is apparent from these drafts that the Council has given careful consideration to the public input received thus far and has, working under tight time constraints, proposed a definition, prioritization criteria, and

strategic framework that contain many positive elements. Accordingly, the comments we submit today are primarily limited to targeted recommendations to improve specific elements of these draft materials.

DRAFT DEFINITION OF CER

The Council s proposed definition of CER is appropriately broad in scope, encompassing a wide range of interventions and strategies, including prevention, care management, and delivery system interventions, that can affect health outcomes and patient experiences. GSK also appreciates the Council s recognition of the importance of responding to patient and provider needs, accounting for differences among individual patients and subpopulations, conducting research using a variety of data sources, and developing and expanding research infrastructure and methods. We urge the Council to retain these elements in the final definition.

At the same time, we offer for the Council s consideration several small but meaningful modifications that we believe will strengthen the definition.

1. We propose that the Council revise the first sentence to read: Comparative effectiveness research is the conduct and synthesis of systematic ANALYSIS comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions AND APPROACHES TO THE DESIGN AND IMPLEMENTATION OF CARE DELIVERY SYSTEMS. We recognize that the definition s fourth sentence (Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions) incorporates delivery system interventions ; however, the care delivery system is more than just a form of disease intervention. Rather than define CER strictly in relation to disease, we advocate a holistic approach that also seeks to identify approaches to improving care delivery systems in themselves and the quality of care delivered.

2. We suggest that the Council revise the second sentence to read: The purpose of this research is to IMPROVE HEALTH CARE QUALITY AND HEALTH OUTCOMES by identifying, in response to patient, CAREGIVER, provider, and PUBLIC HEALTH needs, which interventions are HIGHLY effective for which patients under specific circumstances. As revised, this purpose statement incorporates these important additions:

" Improve health care quality and health outcomes GSK believes improvements in health care quality and patient health outcomes ought to be the polestar for federally-supported CER. Accordingly, we believe the definition of CER should explicitly reference this guiding principle.

" Caregiver Although patients and providers typically form the nucleus for health care decisionmaking, in many instances, others play a significant role in care decisions and delivery. Alzheimer s and cancer care are just two prominent examples of conditions where caregivers frequently play prominent roles and are impacted by intervention choices. Caregivers offer a

unique perspective which too often is overlooked. We believe good CER design and implementation takes into account caregivers perspectives and circumstances where appropriate.

" Public health We recommend substitution of public health for decision-makers. In our view, public health is a broader term that encompasses all who have a particular stake in the improvement of health care decisionmaking, quality of care, and health outcomes.

" Highly effective The draft definition s use of the term most effective implies that CER will conclusively identify a best intervention for a particular circumstance. In actuality, even with respect to patient subpopulations, it is unlikely that CER can pinpoint the most effective intervention for a particular patient. Even among patients who share certain characteristics, each patient is an individual, and there can be no guarantee that an intervention will prove effective. Therefore, it is more accurate to state that CER can help to identify interventions that are highly effective for patients in a particular circumstance.

3. Finally, we propose that the Council revise the definition s last sentence to read: This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative CLINICAL effectiveness. The addition of clinical will more closely align the definition with Congress s stated intent that ARRA funding support research to evaluate and compare clinical outcomes, effectiveness, risk, and benefits.

THRESHOLD MINIMAL CRITERIA

" Please clarify how these minimal criteria would function in practice. For example, are the criteria equally weighted? Can one criterion assume more importance than another? How will research feasibility be measured, and what factors other than time are potentially relevant to feasibility considerations (e.g., cost of the research, methodological challenges, available infrastructure, patient privacy and other legal and ethical issues?)?

" Revise criterion (2) to read: Responsiveness to expressed needs and preferences of patients, caregivers, clinicians and other health care providers, and other stakeholders, including community engagement in research. This change will more closely align this criterion with the definition of CER (see above).

PRIORITIZATION CRITERIA

" In criterion (1), replace costs of care with total cost of care. This change clarifies that it is the total cost burden of a disease or condition, not specific intervention costs, which is a relevant and appropriate factor in prioritizing federal investments in CER. This clarification will ensure that federally-supported research remains appropriately focused on the needs of patients, caregivers, and clinicians and other health care providers.

STRATEGIC FRAMEWORK FIGURES 1 & 2

" Add a fifth category of CER investments and activities CER Evaluation. Equally as important as the four categories of investments and activities outlined in the draft framework is the need to regularly review and evaluate government-supported CER and its impact on clinical care and health care quality. We must understand whether our CER investments produce positive changes. Do the funding choices actually reflect the prioritization criteria? Are the research questions the correct questions? How are the CER results used and by whom? Do patients, caregivers, clinicians and other providers, and the public find the results useful, practical, and actionable? If not, why not? Most importantly, have the CER studies improved the quality of clinical decisionmaking and promoted care of higher value and quality? What changes are needed to improve the conduct and translation of the CER studies? For CER to fulfill its potential to improve health care quality and patient health outcomes, there must be a formal mechanism for continuous evaluation and improvement a feedback loop that incorporates the answers to these and other questions. GSK believes such a mechanism is vital to the success of CER and thus warrants a defined space in the strategic framework.

STRATEGIC FRAMEWORK FIGURE 2

" In column one, Human & Scientific Capital for CER, specify that Methods for patient/consumer engagement includes federally-supported CER education and training for patients and consumers. GSK shares the Council s belief that patient and consumer engagement is critical to the design, credibility, and adoption of CER, and we applaud the Council s focus on developing methods for seeking public input. However, the quality of this engagement depends on patients and consumers awareness of CER design and implementation considerations. Simply put, if they do not possess an adequate understanding of these issues which frequently are complex many patients and consumers will not be equipped to contribute meaningfully to dialogue with other CER stakeholders. Therefore, GSK recommends that the Council explicitly recognize the importance of CER education and training for patients and consumers and identify options for providing this education and training.

" In column two, CE Research Priorities, replace Expressed public and federal needs for CER with Expressed needs of patients, caregivers, clinicians and other health care providers, and other stakeholders. This change will more closely align the strategic framework with the definition of CER (see above).

" In column three, CER Data & Research Infrastructure :
? Clarify and elaborate on the scope of the inventory of existing CER infrastructure (e.g., will this include public and private infrastructure as well as information from other countries?).
? Clarify and elaborate on the scope of evidence generation (e.g., will evidence generation include public and private sources?, will these sources be domestic only?).

" In column four, Translation & Adoption of CER, clarify and elaborate on the scope of the inventory of existing CER translational and dissemination activities (e.g., will this include activities in the public and private spheres as well as information from other countries?).

" In columns one, three, and four, replace Funding based on identified high-priority gaps with Funding based on identified high-value opportunities. This change would create greater consistency among the investment and activity categories and would reinforce the importance of investing federal dollars in areas offering the greatest potential for meaningful improvements in clinical decisionmaking, quality of care, and patient health outcomes.

In conclusion, GSK again thanks the Council for this opportunity to express our views on the draft CER definition, prioritization criteria, and strategic framework. We look forward to continuing to work with the Council in a similarly open and inclusive manner to ensure the fulfillment of our shared goal that our nation s investments in CER will result in improvements in clinical decisionmaking, health care quality, and, ultimately, patient health outcomes.

Please contact Bart Barefoot, Senior Manager, Public Policy and Advocacy at (919) 468-2973 or BARTLEY.L.BAREFOOT@GSK.COM if you have any questions concerning these comments.

Submitted by
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Senior Vice President, Policy
Advanced Medical Technology Association (AdvaMed)
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Comment Type: *General Comment*
AdvaMed has a recommendation regarding the process for collecting comments on these CER topics. AdvaMed greatly appreciates the opportunity to comment and recommends that longer public comment periods (for example, 30 days) be offered to ensure a greater ability to provide meaningful feedback. Many individuals and small organizations have limited resources to expend, and providing additional time would provide an equal opportunity to consider and offer thoughtful comments that could improve the Department s CER-related initiatives.

Submitted by
Emily Wilson
ASTRO
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Comment Type: *General Comment*

ASTRO supports the draft definition of comparative effectiveness research and applauds the leadership of the Federal Coordinating Council (FCC). We also appreciate the FCC's patience during the listening session and its dedication to sorting through various comments to come to broad visionary framework.

Submitted by
Janelle Behny
Private Citizen
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Comment Type: *General Comment*

To Whom It May Concern;

I am writing to comment on the possible changes this presidential administration is seeking to make in the health care system of our country.

While the current system is rife with difficulties, there are insurance plans available that make accessing necessary health care easier than others. Much of the time the availability of these better insurance plans can be dependant upon where a citizen resides because some states have been more proactive than others in establishing basic insurance provisions. I find that leaving this issue to the states is a step in the right direction toward preserving liberty in our nation because it is the responsibility of the federal government to respect and preserve states rights.

That said I absolutely do not believe rationed, centrally-pooled healthcare that is facilitated by our federal government would be an effective or efficient means to improve our current health care system. Neither is so-called evidence based medicine. While these may look good to some on paper, the fact is that they cause more harm than good. This is because they would actually diminish in a significant way the freedom of Americans to choose and pursue what we each believe to be the best approach to caring for ourselves. When it comes right down to it, this freedom falls under the umbrella of our rights to "life, liberty, and the pursuit of happiness" as declared in our Declaration of Independence.

Frankly speaking, limiting our choices in healthcare by these means would be another mode of robbing our liberty. It truly is as simple as that. Whether or not it is done under the guise of good intentions is arguable depending upon which political lens you choose to wear. Well I don t wear a political lens, so I don t care about that point of view. It is for this reason I can see this issue from a clear perspective, and that point of view is that government needs to stay out of the health care business. Establishing a federal centrally-pooled, nationalized, socialized, or whatever-you-want-to-call-it medical system is a mistake.

I passionately believe these statements because my family and I have stayed healthy for years. We have had our challenges, but we have always been able to overcome them not because of

what someone in the government has figured out for me or dictated to us but because of what we have researched, learned, and implemented on our own to proactively care for ourselves. Yes, what you put into your body is absolutely a key factor, but that is only one of many simple choices we make must daily that play a huge part in wellness. In fact, thanks to all that is provided at public libraries, every citizen, regardless of their income, has equal access to figure out how to improve their health for themselves. Even if you had health insurance, you don t need to it be proactive with caring for yourself. The only requirement is that you possess the desire and patience to learn what to do and make the effort to carry it out. It really isn't difficult.

If the policies promoted by Dr. Steven Eastaugh and our current administration are carried out, I truly believe the state of American citizens health will actually worsen. I know something needs to be done to help our citizenry, but I firmly feel the policies that are the backbone of the healthcare he is promoting are the completely wrong direction for America to go. That is because it would diminish the available resources for consumers to choose from in one way or another. We are a country that promotes choice and freedoms, so do not take steps that would negatively impact our freedom of choice in health care freedoms. I am someone who has not had health care insurance at two different points in my life, yet I still do not want nationalized health care because I strongly believe there is a better way than the paradigm recommended by Dr. Eastaugh.

I know leaning toward a quick fix like nationalized health care is easy because it may appear to be a practical means to address this issue, but in the final analysis, I honestly believe it would be anything but practical for the average citizen to utilize. That would definitely be a step backward from the current goal of improving what is currently available. Thank you for the opportunity to comment on this issue. I appreciate your time and consideration to my views regarding this issue, and I will be following how it transpires.

Submitted by
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Comment Type: *General Comment*

Federal Coordinating Council for Comparative Effectiveness Research
Listening Session
June 10, 2009

Thank you for giving the National Organization for Rare Disorders (NORD) the opportunity to address this Council regarding comparative effectiveness research. NORD represents the estimated 30 million men, women and children in the United States affected by one of the nearly 7,000 known rare diseases. For those who may not know what a rare disease is, it is any disease, syndrome or condition affecting fewer than 200,000 people in the United States, or

approximately one in ten. For many it can take many years to be diagnosed, some estimate as many at seven years. Others are never properly diagnosed.

I would like to preface my remarks by saying that NORD strongly supports comparative effectiveness for drugs, biologics and medical devices and treatment protocols. If this country is to address the growing disparities in care, we must find a way to ensure that every American receives the care they need and rightly deserve.

By way of background, there are currently 339 orphan drugs and biologics that treat (according to the FDA) about 12 to million across the country. It is unfortunate that the remaining 18 million have no therapy or treatment protocol addressing their specific disease. It s a hit or miss proposition. As a consequence, most are treated off-label because there is nothing specific to their disease.

As a consequence, many of these people have difficulty gaining access to the treatments they need because the indication is not on the label of the product. Comparative effectiveness research could have a profound impact on these patients should labeling changes be required. Already, insurers continue to deny access to care simply because their disease state is not specified on any labeling.

As you deliberate, we do have a number of general suggestions. We ask that you consider a number of factors:

? Comparative effectiveness research typically compares average results of one therapy or treatment protocol versus another for a study population. However, these do not take into account differences between patients due to genetics, co-morbidities and other important factors.

? Comparative effectiveness research should focus on questions that reflect the interactions among all of the various components of the healthcare system and have the greatest potential to empower medical specialists and patients to make the most appropriate decision when faced with real world clinical situations.

There are specific issues surrounding rare diseases and orphan products that we think are addressed in the newly introduced Patient-Centered Outcomes Research Act of 2009 that was introduced by Senators Baucus and Conrad yesterday.

Specifically, the legislation says that, in the case of comparative effectiveness research studies for rare diseases, that an expert advisory panel assist in the design of such research studies and determine the relative value and feasibility of conducting such research studies.

Draft language we have proposed to the U.S. House of Representatives goes a step further and asks that an Ombudsman be appointed to serve as the single point of contact to patients with rare diseases regarding funding by the Department of Health and Human Services or the Institute of proposed comparative effectiveness studies on rare diseases.

NORD strongly supports this language and we ask that as you remain mindful of those who are considered as outliers, and as you continue your deliberations you remain mindful of the unique needs of rare disease patients and the challenges they face.

Patient-Centered Outcomes Research Act of 2009 introduced by Chairmen Baucus and Conrad. Section (5) (A) (iii) outlines the expert advisory panel for rare diseases.

EXPERT ADVISORY PANEL FORRARE DISEASE. In the case of a comparative effectiveness research study for rare disease, the Institute shall appoint an expert advisory panel for purposes of assisting in the design of such research study and determining the relative value and feasibility of conducting such research study.
(B) COMPOSITION.
(i) IN GENERAL. An expert advisory panel appointed under subparagraph
(A) shall include individuals who have experience in the relevant topic, project, or category for which the panel is established,
including
(I) practicing and research clinicians (including relevant specialists and subspecialists), patients, and representatives of patients; and
(II) experts in scientific and health services research, health services delivery, and evidence-based medicine.

SEC. ___. SPECIALIZED PROCESS FOR COMPARATIVE EFFECTIVENESS RESEARCH ON RARE DISEASES

(a) IN GENERAL. The Institute shall convene a specialized review panel(s) of experts and patients, the Rare Disease Review Panel, to provide technical assistance and make recommendations for any proposed comparative effectiveness studies of orphan drugs, biologics, or humanitarian use devices. The HHS Secretary shall also designate a Rare Disease Ombudsman to serve as the single point of contact to patients with rare diseases and to coordinate with the Institute.

(b) DEFINITIONS.

(1) The term rare disease means a disease that has a prevalence of less than 200,000 persons in the U.S.

(2) The term Rare Disease Ombudsman means the person or office designated by the Secretary from the NIH Office of Rare Diseases to serve as the single point of contact to patients with rare diseases regarding funding by the Department of Health and Human Services or the Institute of proposed comparative effectiveness studies on rare diseases.

(c) DUTIES. The Panel shall

(1) provide technical assistance to the Institute during the public comment process regarding the decision within the Institute on whether to fund a proposed comparative effectiveness study on a rare disease;

(2) review, evaluate and make a recommendation on whether to proceed to fund the study under consideration for comparative research effectiveness purposes;

(3) report to the Board (or appropriate head) and the Rare Disease Ombudsman the reasons why it determined that each proposed study meets or does not meet the standards in subsection (d).

(d) STANDARDS FOR REVIEW, EVALUATION AND RECOMMENDATION. In conducting its review and evaluation and in making its recommendation on each proposed comparative research effectiveness study, the Panel shall assess whether

(1) the study will potentially lead to reduced mortality, morbidity, and/or disability for the condition;

(2) if the study under consideration is not a randomized clinical trial
(A) the clinical evidence is sufficient for the study to proceed; and
(B) it compares current medically accepted treatments for the rare disease; and
(C) it captures the evidence needed to reflect the appropriate time horizon for the use of the treatment in that patient population; and
(D) it gives appropriate consideration to factors that could effect the true comparability of the comparison groups; and
(E) it is sufficiently robust to reasonably be expected to provide relevant information regarding the short and long term clinical benefits and risks of each evaluated treatment.

(3) if the study under consideration is a randomized clinical trial
(A) it is of sufficient duration and the clinical or the surrogate endpoints are sufficiently robust to assess the long term impact on and potential harm or benefits for patients; and
(B) the collected data are sufficiently robust to provide information on potential secondary benefits or side-effects in subpopulations if the Panel believes such data are required or useful for clinical practice and treatment; and,
(C) it compares current medically accepted treatments for the rare disease.

(4) other parameters are considered related to special characteristics for a specific rare disease that are clinically important for the proposed study.

(e) COMPOSITION OF THE PANEL.

(1) IN GENERAL. The members of the Panel shall consist of

(A) at least 4 consumer members (or a family member of such consumer) for that disease;
(B) at least 4 active practitioners in that disease;

(C) a physician or scientific expert from the relevant agency.

(2) QUALIFICATIONS.

(A) each consumer member (or a family member of such consumer), selected as a result of a public solicitation and outreach by the Rare Disease Ombudsman, of the Panel must have been diagnosed with the rare disease that is the subject of the proposed comparative research effectiveness study;

(B) each practitioner member of the Panel shall be a clinical expert, as determined by the Institute after soliciting recommendations from the clinical, scientific and patient community, and shall be currently treating patients with the specific condition or disease that is the subject of the proposed comparative research effectiveness study; and,

(3) CONFLICT OF INTEREST. In appointing members of the Panel, the Institute shall take into account any financial conflicts of interest and apply the relevant standards.

(d) REPORT. If the Panel recommends that a proposed study not be funded, but the Institute nevertheless funds the study, the Institute shall publicly report on the appropriate web site the reasons for the decision to fund the study. Regardless, the Ombudsman will conduct outreach through the media and public meetings to the patient community on the rationale for funding the studies that were recommended or not recommended by the panel.

Submitted by
Mark Calney
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Comment Type: *General Comment*

Perhaps the members of the Council believe that there are enough Americans who are so ignorant of history that this program will be enacted by flying under the radar. However,those of us who are knowledgeable of history know that what is being proposed here is exactly how Adolph Hitler began his program of mass murder. This is simply a fascist policy which is completely un-American. Not only should this Council be ashamed, but you are in fact all indictable under the Nuremberg Laws for crimes against humanity.

Submitted by
Joseph Allen on behalf of ACC
American College of Cardiology

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Comment Type: *General Comment*

The American College of Cardiology (ACC) strongly supports investment in comparative effectiveness research (CER). Given the high prevalence of heart disease-related illnesses, along with the documented variability in the use of procedures used to treat and/or diagnose it, comparative effectiveness research could yield high returns in terms of improving patient outcomes and reducing costs.

The draft definition, prioritization criteria, and strategic framework outline a reasonable approach to comparative effectiveness research. ACC applauds the clarity and conciseness of the current definition and prioritization criteria. However, to further elucidate the intent of CER, the ACC suggests the Federal Coordinating Council consider clarifying and expanding the current draft in the following ways:

1. The Council may consider explicitly defining the relationship between comparative clinical efficacy research and CER. Clinical efficacy research in many cases will form the basis for informing the design of CER.

2. The Council may consider adding tests (laboratory and imaging) to the list of defined interventions. ACC commends the Council for including diagnosis in the list of focus areas, and the addition of tests explicitly to the list of interventions may clarify the intent as not all tests may be viewed as procedures. Imaging and laboratory tests often determine the clinical management of a patient, and thus, comparative methods for diagnosis and risk management facilitated by testing are a crucial component of understanding the appropriate clinical pathway for a patient.

3. The Council may consider modifying the stated purpose of CER to be focused on the relative effectiveness (rather than most effective) of interventions for specific patients under certain circumstances. In many cases, CER may not yield a single most effective intervention or strategy but rather inform decision making about reasonable alternatives. The field of cardiology has many studies which have found interventions to be equally effective for certain patients, including recent studies on stenting compared to bypass surgery and stenting compared to medical therapy.

The Council also may consider modifying the second figure. Currently, it is represented as individual pillars only connected by the priority themes. It also may be productive to view the strategic framework as continuous cycle with each component informing the others. A lack of interaction between these pillars may result in identifying gaps within each area but fail to leverage the knowledge contained in the other pillars. For example, inventories of human and scientific capital can inform the development and framing of research priorities. Translations of prior CER and clinical efficacy may be used to inform the gaps in research. CER data and research infrastructure can be used to both inform research priorities and help monitor translation

and adoption. Implementation can help inform the rest of the process. The strategic framework may be able to target research funding more effectively if gaps are identified not only for each area but also through understanding the interactions of the pillars represented in the figure.

Submitted by
Eduardo Siguel
optimalpolicies
coolfoods@hotmail.com

Comment Type: *General Comment*

A substantial proportion of current diagnosis and treatment and alleged best evidence is likely to be based on flawed models and data (according to my research). Current approaches focus on biomarkers that are not the causes but the consequences of the disease.
For many Americans, eating too many calories, bad diets and inadequate exercise contributes to hardening and thickening of arteries. This means the arteries are no adequately flexible, they do not expand appropriately, they have narrow sections. The body feeds cells via its vast system of arteries (pipes). When they are hard and narrow, the heart has to pump harder for the blood to reach places far away. This means the blood pressure inside the arteries has to be higher than normal. We call it hypertension. It is a compensatory mechanism that allows the body to feed far away cells in the brain, kidneys, etc. Hard arteries can also become brittle. High blood pressure carries the risk that the arteries can break. If we treat too much hypertension with drugs, we prevent arteries from breaking but we prevent blood from reaching all cells. Brain and kidney cells die over time (a slow process). It is a trade off, lowering the risk of a bleeding stroke vs. increasing the risk of lower IQ and kidney failure.
Besides increasing blood pressure, the body produces more cholesterol. Cholesterol softens the membranes of the cells, makes them more flexible (I am simplifying things to explain complex concepts in a short space, so key issues are omitted). High cholesterol in many cases is not a disease but a compensatory mechanism.
Diabetes type II is primarily a consequence of eating too many calories, bad diets and inadequate exercise. Hypertension and high cholesterol are some of the ways the body seeks to compensate. The best treatment is to eliminate its causes. Preventing future complications via complex regimes of drugs is unlikely to solve the problem. In my neighborhood, some railings were moldy inside and getting rotted. They did not look good. One solution was to remove the rotted parts, inject wood with mold killing stuff. A lot of work. Another solution was to paint them well. That was easy and the wood railings looked great for a while. In a few years, the mold ate them from the inside and they fell apart. With railings we had a solution not available to people: we replaced them.
It is impossible to conduct clinical trials testing most treatments against other treatments. It is also impossible to evaluate the long term consequences of treatments (20 years into the future). No pair of subjects in a clinical trial will maintain almost identical conditions for 20 years (or 10, or even 5!). Thus, long term evaluations are impractical. Before we proceed with comparative

effectiveness research (CER) we need better models of disease. Based on our understanding of disease we can predict what works well and what works poorly. Fortunately, we know the factors involved and have the answers for the conditions responsible for most of the costs and deaths in the US. Smoking. Bad diet. Too many calories. Bad exercise. Eating too many processed foods (particularly highly processed fat and carbohydrates). Not enough fruits and vegetables. Drug, alcohol abuse. Risky behavior (drunk driving, etc.). There is practically no dispute on the risk factors and how to prevent them (and save 100s of billions). Pose yourself this question: you are the CEO of a large corporation. Would you rather invest R&D to market drugs and devices to treat those problems or would you rather train people to grow their own and eat organic vegetables? (getting exercise and healthy food). Surely Ms. Michelle Obama can do, but they don t live like the rest of us. To get the answer, make a business plan and present at a venture capital meeting. See how many buy the idea of an IPO for growing and eating organic vegetables (selling seeds and organic compost) vs. drug Potentum, a mixture that lowers blood pressure, cholesterol, high glucose, enhances erections, makes you hyper, improves bad breath and includes pheromones. Consider the commercials. People pulling weeds and dispersing organic compost (dirty, smelly) vs. clean people enjoying life, kissing each other, having fun. If you get it, you know why CER and health reform will fail to substantially cut costs or improve outcomes.
E Siguel, MD, PhD, JD
Posted at
http://online.wsj.com/article/SB124441644145192397.html#articleTabs_comments%26articleTabs%3Dcomments

Submitted by
Meryl Bloomrosen
AMIA
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Comment Type: *General Comment*

I am pleased to submit comments about the draft definition of comparative effectiveness (CE) on behalf of the American Medical Informatics Association (AMIA). AMIA is the professional home for biomedical and health informatics and is dedicated to the development and application of informatics in support of patient care, public health, teaching, research, administration, and related policy. AMIA seeks to enhance health and healthcare use through the transformative use of information and communications technology. AMIA s 4,000 members advance the use of health information and communications technology in clinical care and clinical research, personal health management, public health/population, and translational science with the ultimate objective of improving health. Our members work throughout the health system in various clinical care, research, academic, government, and commercial organizations.

In general we are supportive of the proposed definition but are pleased to submit the following suggestions for your consideration. We believe that one topic that is not addressed is the assurance of the quality and rigor of the science conducted. Also, it is not clear to what extent health information technology (including electronic health records, disease registries, telehealth

application such as home health monitoring) is considered as one of the potential defined interventions .

The prioritization criterion #1 (Potential Impact (based on prevalence of condition, burden of disease, variability in outcomes, and costs of care) might leave out some key issues that warrant study. We suggest that not all CE questions involve common diseases, and arguably there are less frequent diseases that are particularly likely to raise questions of optimal workup or management.

Again, we applaud the Department s efforts to oversee this important national and public discourse. If I can answer any questions for you, or offer additional information on this subject, please feel free to contact me at detmer@amia.org or 301 657-1291.

Submitted by
Matthew Farber
Association of Community Cancer Centers
mfarber@accc-cancer.org

Comment Type: *General Comment*

The Association of Community Cancer Centers (ACCC) is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC s more than 700 member institutions and organizations treat 45% of all U.S. cancer patients. Combined with our physician membership, ACCC represents the facilities and providers responsible for treating over 60% of all U.S. cancer patients.

ACCC thanks the Federal Coordinating Council (Council) for releasing its Draft Definition of Comparative Effectiveness Research (CER), Draft Prioritization Criteria, and Draft Strategic Framework. ACCC appreciates and agrees with the Threshold Minimal Criteria and also with the Prioritization Criteria laid out in the draft document. ACCC also agrees with the basic framework and cross cutting priorities, such as cancer, announced by Council. We appreciate the Council s transparency and willingness to seek stakeholder input to this important process.

However, ACCC remains concerned that cost effectiveness may be included in future CER. Although the Draft Definition does not refer to cost effectiveness, there still could be opportunities for cost effectiveness to be taken into account in CER. ACCC requests that any guidance on CER include explicit language preventing cost from being considered.

In addition, we are concerned that the Draft Definition s reference to decision-makers, along with patients and providers, as the users of CER could be construed as support for the use of CER in payers coverage decisions. This would be contrary to the American Reinvestment and Recovery Act s (ARRA) express prohibition against the Council mandating coverage, reimbursement, or other policies for any public or private payer. The ARRA conference report also notes that Congress did not intend for CER funding to be used for such purposes. We ask that the definition of CER include explicit language preventing coverage decisions from being based on CER. The Council should clarify that decision-makers refers to patients advocates, including a patient s parents, guardians, and family members who may be involved in making health care decisions.

We are pleased that the Draft Definition appears to recognize that all patients with the same disease may not benefit from the same treatment option. This is especially important in oncology, where the most effective treatment for one person, may not be the same for another person with the same diagnosis. To further clarify that CER must assess a comprehensive array of health-related outcomes for diverse patient populations, we suggest that the word subpopulations be added to the end of this sentence.

ACCC also is concerned with some of the aspects of comparative effectiveness that were not included in the Draft Definition, Prioritization Criteria, or Strategic Framework. ACCC remains concerned that there is still some confusion as to where this research will take place. The Agency for Healthcare Research and Quality (AHRQ) already is conducting some CER, and the National Institutes of Health (NIH) is also in line to conduct research. We ask the Council to clarify whether other agencies will be involved in CER. We also ask for clarification about the application of the Draft Definition, Prioritization Criteria, and Strategic Framework. Will these terms and structures apply to research already underway, or will they apply only to new research?

ACCC would like to thank the Council for the opportunity to submit comments on the draft definition of CER. If you would like to discuss our concerns further, please contact Matt Farber at mfarber@accc-cancer.org.

Thank you

Submitted by
Nancy Spannaus
nancyspannaus@verizon.net

Comment Type: *General Comment*

By Nancy Spannaus, U.S. branch of the Club of Life

First, let me say that the Club of Life is an international organization founded in 1982, by Helga Zepp-LaRouche, and dedicated to the promotion of the inalienable right to life for all peoples on this planet, and the defeat of the Malthusian outlook which has taken hold of many too many of our institutions over the past 40 years. We have dedicated our efforts to fighting {for} a new, just world economic system, as a moral and economic imperative, and against the evils of cultural pessimism, which have contributed to the spread of such evils as assisted suicide, the drug plague, and other degradations of the sanctity of human life.

The central question that must be addressed by this Council, I believe, is the question of {mission}. My reading of the work in the area of Comparative Effectiveness has led me to the conclusion that, protestations to the contrary, it is a process dedicated to {reducing} the investment in saving human lives to the lowest possible denominator, in the spirit of cost-effectiveness. Such a mission leads inexorably to the disease which Dr. Leo Alexander, a U.S. psychiatrist aiding the prosecution of the Nazi doctors at the post-war Nuremberg Tribunals, called utilitarianism, an attitude which itself leads down the slippery slope toward designating some lives as ``not worthy to be lived.

Dr. Alexander, who saw the danger of such an idea invading U.S. society as early as 1949,
defined this attitude as Hegelian and cold-blooded. He observed that the Hegelian rational attitude has led [doctors] to make certain distinctions in the handling of acute and chronic diseases. The patient with the latter carried an obvious stigma as the one less likely to be fully rehabilitable for social usefulness. In an increasingly utilitarian society, these patients are being looked down upon with increasing definiteness as unwanted ballast. From that small beginning, that shift in viewpoint, he said, ``the acceptance of the attitude, basic in the euthanasia movement, that there is such a thing as a life not worthy to be lived, comes the horror of mass murder, which Hitler, and his expert Nazi doctors ultimately carried out.

We cannot tolerate any institution that promotes such an attitude, in the governmental structure of the United States.

Dr. Alexander also emphasized that this shift in attitude did not arise primarily within the medical profession, but was imposed by the shortage of funds available, both private and public, for the care of the very sick.

Today s work in comparative effectiveness clearly is proceeding from the standpoint of reacting to a shortage of funds, and making hard choices over who should get care, and who not.

What s the alternative? It begins with valuing every human life, and then fighting to create the thriving economy which is required to provide the hospitals, technicians, researchers, medicines, and
medical equipment required to take care of all of our population. Surely, no one can say that we can t afford quality health care for all if we are throwing trillions of dollars into saving financial derivative markets on Wall Street.

My conclusion is this: If the Comparative Effectiveness Council cannot find a mission in

expanding medical resources for all parts of the country, rather than applying Nazi-like cost-cutting
measures on our population, it should be disbanded forthwith.

Submitted by
Al Cors
RetireSafe
acors@retiresafe.org

Comment Type: *General Comment*

On behalf of 400,000 senior-citizen supporters across America, RetireSafe urges you to make every possible effort to ensure that the use of comparative effectiveness research (CER) is never used to deny seniors and others the treatments and therapies they need based on cost. That said, we also urge you to consider the aging of America in all of your studies, as seniors will soon represent a huge portion of our total population, roughly 25 percent. No large study will be valid without that consideration. Because of the huge number of co-morbidities in the senior population, as well as the massive number of senior subgroups, these studies will be complex, but ever so important to quality health care. We urge your complete consideration of all of these critical factors. Thank you for the opportunity to comment.

Submitted by
Linda Stanton
Private citizen
mnlas@msn.com

Comment Type: *General Comment*

Healthcare choices must be made by the individual and their chosen doctor, not by insurance companies or government bureaucrats.

The government should not expand its role of providing healthcare it should make every effort to reduce it. Neither should it set itself up as the one to decide what is or isn't the most effective treatment.

The individual can be trusted to make wise decisions about their care. The individual must be allowed to make his or her own choices as to health care providers, treatments, etc. not be

dictated to by the insurance company. Currently, the health plan decides what is covered and what is not. If the person wants an alternative treatment, they can pay for it on their own.

The high cost of care is partly due to a double standard. If you do not have coverage or have a high deductible, then the provider charges you less, but if you have insurance the provider charges more. No wonder we are paying too much! We need to get back to a market economy for healthcare.

Insurance should provide less. The amount of care covered by insurance should be reduced. It should be for catastrophic care and major illnesses. Not for preventive care. Because we try to provide too much, it is costing too much.

Individuals should be given the option of a Health Savings Account, preferably begun when they are an infant to save for their own care, which the person spends at their own discretion: choosing providers and treatments of their own choice.

Any effort to create comparative effectiveness takes the choice away from the patient and creates the path to drastic rationing.

The US has one of the best health care systems in the world. Please drop the idea of 'pay for performance', comparative effectiveness, or any such nonsense, it will only end up ruining the great system we have now.

Linda Stanton
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Submitted by
Chip Amoe
American Society of Anesthesiologists
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Comment Type: *General Comment*

The American Society of Anesthesiologists (ASA) Comments on Comparative Effectiveness Research and the Anesthesia Quality Institute (AQI) Data Registry

In order to produce meaningful and ongoing comparative effectiveness research, it is important to establish the necessary infrastructure. To this end, the American Society of Anesthesiologists (ASA), through its leadership and House of Delegates, has recognized the importance of

establishing a national clinical data registry and has created a related but separate organization focused on quality improvement in anesthesiology. The organization, the Anesthesia Quality Institute (AQI), has a vision to become the primary source of information for quality improvement in the clinical practice of anesthesiology. The organization will allow anesthesiologists to maintain and enhance their well earned reputation as the leading medical specialists in terms of quality of care and patient safety. This assistance could be expanded to include other anesthesia service providers and perhaps other perioperative care providers. The AQI seeks to accomplish three primary objectives.

1. Improvement of Patient Outcomes and Quality of Care

The development of a data registry for anesthesiology will help improve patient outcomes and thus raise the quality of care in the specialty in three main ways. First, more anesthesiologists will be able to collect and monitor their own practice data, which is the foundation of quality improvement. Without solid data a physician, practice, or hospital cannot accurately know his or her true level of performance and outcomes. Benchmarking reports will provide anesthesiologists with a mechanism to assess their own practice relative to their peers and will facilitate the development of meaningful report cards on physician and team performance.

Second, the data registry will support the development of products or services to assist anesthesiologists whose practices are achieving relatively lower performance. A number of current data registries collect voluminous amounts of data, but lack a comprehensive ability to analyze and translate that data back into practice and performance improvement. The AQI intends to go beyond mere data collection and close the loop on identified shortcomings through practice improvement materials and processes developed in partnership with ASA and the American Board of Anesthesiology.

Finally, a comprehensive national data registry for anesthesiology would provide new resources for improving the practice of anesthesiology through related research. Researchers could utilize the data registry to answer clinical questions of importance to patients and the specialty. While peer benchmarking will require a stable and standardized collection of data, specific, focused research initiatives can be provided temporary access to the registry to very rapidly acquire a broad-based sample of clinical information designed to address priority research interests, including comparative effectiveness research. Some of these priority research topics might include the relationship of anesthetic management to tumor biology and cancer survival; the optimal strategies to prevent unintended intraoperative awareness and the impact of anesthetic exposure on cognitive function in the very young and very old.

Much of the potential of an anesthesiology-based clinical registry will be realized through interoperability and partnership with datasets collected by our partners in perioperative care, especially surgical colleagues. These linkages will be challenging and complex and invite a unified, nationally coordinated effort to integrate the related clinical registries.

2. Dissemination of Anesthesiology Specific Information

The data registry will allow the Anesthesia Quality Institute to develop reports for interested parties on either aggregate outcomes information or physician-level measures. As the data set grows increasingly robust and achieves validation, the AQI could partner with public and commercial payers who wish to learn more about anesthesiologists and the quality of perioperative care. Such reports could be used as an alternative to claims-based and administrative datasets which are weaker data sources in anesthesiology than in most other fields of medicine. Finally, ASA and the AQI could use the database to support organizational statements and public understanding about the safety and quality of the practice of anesthesiology.

3. Develop and Further the Specialty of Anesthesiology for the General Elevation of the Standards of Medical Practice

The data registry will elevate the standards of practice by providing evidence for use in future ASA practice statements and guidelines. The registry will demonstrate the validity of the collected data through a risk adjustment methodology and data validation process. Such data could then be sufficient for multiple purposes, including focused research queries, peer-review publications, and evidence to support ASA practice guidelines.

Although it is widely known that anesthesiologists have raised patient safety to nearly the Six Sigma level, this achievement is almost entirely related to the reduction of anesthetic mortality rates. The data registry will help define the current state of practice of anesthesiology by identifying rates of other, less dramatic but still important events and outcomes. Data reporting and comparative analysis is the only route to understanding clinical practice variation, a fruitful route to quality improvement.

Variations are seen throughout medicine and every medical specialty. Registry data will permit understanding of such variation and reduce it through the identification of outliers and dissemination of best practices, which will address important, but currently difficult to recognize, clinical problems in the specialty.

In conclusion, anesthesiologists are deservedly proud of their reputation as leaders in patient safety; however we do not intend to rest on our reputation. We recognize that the time has come to take the next step and develop a national data registry for anesthesia to help improve the health of our patients, communities and the performance of our practices and hospitals. We therefore request that a portion of the funds, authorized for comparative effectiveness research, be dedicated towards the development of national clinical data registries, such as the Anesthesia Quality Institute. There are many unanswered questions and gaps in knowledge across all specialties and we recognize the federal government cannot fund research in all of these areas at once. However, by funding such registries now, the Administration can build the infrastructure and data sets needed to support comparative effectiveness research today, while also laying the foundation for maintenance and expansion of such research in the future.

Submitted by
Jane Wicklund
Berkeley HeartLab
jwicklund@bhlinc.com

Comment Type: *Listening Sessions*

Can you tell me what time the June 10th listening session begins and ends? Also, is this done in person or via conference call?

I'm trying to schedule travel around this and I'm traveling from the West coast.

Thanks,
Jane

Submitted by
Mary Steele Williams
Association for Molecular Pathology
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Comment Type: *Listening Sessions*

Dear Coordinating Council Members:

The Association for Molecular Pathology is pleased to have the opportunity to provide comments to the Federal Coordinating Council for Comparative Effectiveness Research (the

Coordinating Council) on the subject of comparative effectiveness research (CER) and share our recommendations on priority areas on which to focus CER activities.

AMP is an international medical professional association representing approximately 1,600 physicians, doctoral scientists, and medical technologists who perform laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Since the beginning of our organization we have dedicated ourselves to the development and implementation of molecular diagnostic testing, which includes genetic testing in all its definitions, in a manner consistent with the highest standards established by CLIA, the College of American Pathologists (CAP), the American College of Medical Genetics (ACMG), and FDA. Our members populate the majority of clinical molecular diagnostic laboratories in the United States. They are frequently involved in the origination of novel molecular tests, whether these are laboratory developed or commercially developed. Our members proudly accept their responsibilities in assessing the analytical validity, clinical validity, clinical utility, and the clinical utilization of these tests for each specific patient.

CER is garnering substantial attention in Congress and among other policy makers who see it as a method to examine the comparative effectiveness of treatments, including how they relate to coverage and reimbursement decisions. Diagnostic tests will most definitely be included in this paradigm, especially when the effectiveness of treatments will vary among different population subgroups. Unfortunately, the value of diagnostics in improving clinical outcomes has not been appreciated adequately in the past; therefore, considering the role of genomics under CER will be critical.

In order for CER to be a success, it will be essential to train experts in diagnostics (including molecular diagnostics) in current health services research methods as well as to train health services researchers in the technical areas they will assess. This cross training will be essential to ensure that the research methods are technology appropriate. For example, in molecular diagnostics, there are situations where a prospective, randomized clinical trial will not be feasible and/or a research outcome could be achieved through an alternative study design such as a retrospective analysis of available data. Further, outcomes studies conventionally assess technologies as interventions, often using the diagnostic test as a benchmark or endpoint, without consideration of the characteristics of the diagnostic. There is much less experience in assessing the role of the diagnostic test itself in appropriate and cost effective management of individual patients. Therefore, AMP encourages the Coordinating Council to invest in the cross-training of researchers and diagnostics experts as well as to build the infrastructure within the agencies to understand and review data from different types of technologies.

While not specifically requested for the listening session, AMP would like to provide the Coordinating Council with the following list of high priority areas of CER identified by the Association s membership:

1. Infrastructure. Infrastructure should be developed to design a model and process for CER regarding laboratory tests. This should include the following:

" The creation of a panel of experts consisting of physicians and scientists, including laboratorians with molecular diagnostics expertise, economists, and reimbursement specialists.

" AMP encourages the creation of an electronic clearinghouse for information on CER projects similar to www.clinicaltrials.gov. Reliable tracking and coordination of CER activities will be crucial to avoid duplication and redundancy and to ensure appropriate use of CER funds. Moreover, access to the tracking data should be available to all entities conducting CER, both from the private and public sector.

" AMP encourages the development and adoption of standards for the collection and storage of data from genetic testing laboratories in order to establish an archive, and to ensure interoperability among databases. Moreover, these databases should include information on the reason for the test, the type of test, test results and availability of genetic counseling and testing centers.

" It should be required that data from technologies and tests being assessed be generated from CLIA-, CAP-, ISO-, or FDA- certified institutions. Consulting with or recruiting professionals from the molecular pathology community will aid the assessment committees in evaluating the quality of proposals and the data generated.

2. Clinical Outcomes in Pharmacogenetic Molecular Pathology. As information becomes available that relates clinical outcomes to genetic variations, the regulatory, medical and lay communities expect that it will be immediately incorporated into routine clinical care. FDA labeling that relates pharmacogenomic response to maintenance dose, for example, has created demand for both testing and reimbursement in the absence of large clinical trials that demonstrate the effectiveness of such laboratory testing by comparison with either usual care or alternative approaches. An example of this is the use of daily home prothrombin time testing under medical supervision during the first few weeks of anticoagulation versus CYP2C9/VKORC1 mutation testing. Funding for large, carefully designed comparative effectiveness trials for molecular tests should be coupled with funding for observational comparative effectiveness studies that complement randomized controlled trials by including patients who may be tested, but do not meet the inclusion criteria for prospective trials.

3. Evaluating the Effectiveness of Genomic Tests and Clinical Molecular Diagnostics Laboratories. For the public to reap the benefits of effective molecular tests, it is critical that all laboratories meet high performance standards and participate in proficiency testing programs utilizing appropriate reference and control materials.

" Development of reference materials. AMP recommends funding for a program to develop reference materials, exploiting traditional and innovative methodologies, to aid the continued advancement of quality measures in the field of laboratory medicine.

" Novel ways to evaluate laboratory proficiency. AMP supports the development of proficiency testing methods as alternatives to distributing surrogate test specimens. As is evident in cytogenetics, it is impossible to send out surrogate specimens for every known translocation

and rearrangement. Categorical methodologic proficiency testing should be evaluated as one such alternative.

" Methods to evaluate novel and emerging types of genomic testing. AMP believes efforts should be taken to develop appropriate quality assurance for new technologies such as whole genome sequencing, using carefully designed methods to determine the relative effectiveness of various quality assurance methods in improving laboratory testing and ultimately clinical outcomes.

4. Interpretation and Reporting of Molecular Pathology Test Results. The data collected by AMP s Clinical Practice Committee in recent years indicates there is room for improvement regarding the transmission of genetic test information. The influence of this information on ultimate clinical outcomes cannot be overstated and could be an important area for CER. Studies to evaluate the use of information by clinicians are critical to understanding clinical utility and effectiveness.

5. Valuation and Reimbursement. Government and healthcare payers should use CER to identify which laboratory services add benefit to patient care and work to implement valuation and reimbursement strategies to help improve clinical outcomes. Reimbursement of diagnostics, including molecular based tests, is extremely poor. Despite the possibility of saving the healthcare system thousands of dollars per patient and improving the quality of care, diagnostics have been historically under valued. AMP hopes that any CER activities will include research to explore the value, beyond simply cost, of diagnostic tests to patients, providers, payers and the larger health care system. . It has been noted that the value of diagnostics in general is not well studied. Assessing the role of laboratory information in medical decision making could improve appropriate utilization of laboratory tests and clinical outcomes, with potential savings to healthcare. Although reimbursement is one important function of the current coding system (CPT), these codes are also intended to reflect clinical evaluation and management practices. AMP believes the health care system is in need of an entirely new coding vocabulary to describe the types of "evaluation" and "management" practices that are emerging with regard to molecular and genomic testing.

6. Comparative Methodology Research. Many different technical approaches are available for generating the same genetic test result. Relating testing approaches to health outcomes is a neglected area of comparative effectiveness research. AMP supports the evaluation of a multiplicity of platforms in the development and evaluation of companion diagnostics. This approach is not only good science in that it promotes refinement and improvement in methodologies, but is critical to the evolution of medicine. There is no question that therapeutic effectiveness is influenced by test methodology. A prime example of this is the selection of patients with breast cancer for treatment with Herceptin. Determination of eligibility for treatment can be through fluorescence in situ hybridization (FISH) testing or through imunohistochemical methods. Discrepancies between the two methodologies have resulted in patients being inappropriately treated, either exposing them to potential drug side effects without therapeutic benefit, or simply in not treating them with a potentially beneficial drug. These data can be obtained using retrospective studies, but they do need to be pursued.

Thank you for your attention and consideration of our comments. AMP hopes to continue to be a valuable resource to you as the Coordinating Council works to implement and advance CER. Please contact us if you need any clarification or further information.

Sincerely,
Jan A. Nowak, MD, PhD
President

Submitted by
Harry Selker
Society of General Internal Medicine
hselker@tuftsmedicalcenter.org

Comment Type: *Listening Sessions*

Society of General Internal Medicine Statement for Federal Coordinating Council for Comparative Effectiveness Research Listening Session, June 10, 2009
Harry P. Selker, MD, MSPH

The Society of General Internal Medicine, an organization of academic general internists focused on research, education, and primary care, and which has a long history of researchers in comparative effectiveness research (CER), is delighted to have the opportunity to provide a statement to the CER Federsal Coordinating Council. Today SGIM wishes to urge the Council that, to preserve the highest standards of science and independence from conflicts of intereset, the American Recovery and Reinvestment Act (ARRA) of 2009 funds for CER should be directed in a way that preserves the conduct of CER at AHRQ, NIH, and other extant federal science agencies. We believe this will be in the best interest of the healthcare system and it will serve as a model for future CER activities at a time when the quality and integrity of CER will become of increasing national interest.

Potential outcomes of CER include scientific knowledge, improved health, and financial impact. Across the spectrum of CER, from structured analyses of prior studies, databases, and registries, to the conduct of large clinical effectiveness trials, the scientific objective is rigorous reliable information about what treatments are best for what patients, and under what circumstances. Unless the conduct or public release of such research is compromised by poor quality or conflicts of interest, such information should have a direct positive impact on health.

The economic consequences are likely to be substantial, but vary for different stakeholders. For the nation, even if total costs of healthcare do not fall, CER should have a positive impact on cost-effectiveness we would be spending healthcare dollars more wisely, on the most effective care. For those who sell treatments, the consequences are mixed. Pharmaceutical manufacturers may benefit financially because CER will compare drugs to not only other drugs, but also to medical devices and procedures, which could expand the number of conditions for which their drugs might be used, and enlarge their market. However, CER might show that some new on-patent drugs are not more effective than earlier off-patent versions available at far less cost, and

this could compromise sales of pharmaceutical manufacturers most profitable drugs. For medical device companies also, profits could be reduced. Because currently FDA s statute mandates less evidence of treatment benefit for medical devices than for drugs, a new requirement for rigorous testing of effectiveness would require extra time and money, and ultimately likely would likely show that at least some devices have undiscernable treatment benefits, which would curtail sales.

These adverse effects on manufactures profits are the other side of the coin that should result in greater cost-effectiveness, which should be attractive to healthcare payers, including insurers, self-insured companies, the government, and utlitmately, the public. Reliable well-accepted information on treatment effectiveness on which to base payment decisions would be very helpful. Also, there is general consensus that generating such information without insurers using their own funds, and without violating anti-trust rules against colluding with competitors about business decisions, but rather, using public funds, is very attractive. However, for insurers, that they may be mandated to provide access to treatments found to be effective, and that their decision-making about coverage would be potentially limited based on such data, are concerns.

Some healthcare industry advocates want stakeholder governance input into the conduct of CER rather than as now done at Federal medical or healthcare research agencies. What are the alternatives? Currently, the private sector puts a relatively small amount of into CER, generally focused on their own products or services. The objectivity of this research is suspect, and results may be buried if not in concert with a company s objectives, even if they would have been helpful to the healthcare system and to the health of the public. In comparison, the Agency for Healthcare Research and Quality (AHRQ), already mandated by law to do CER, and the National Institutes of Health (NIH), where CER is also done, both have long-standing high standards of research transparency and disclosure, with results available for public scrutiny. The credibility of these science agencies has led to acceptance of their findings by the medical community and dissemination of practice improvements, supporting improved care by all clinicians and payers.

The stakes are very high, not only for industry, but more importantly, for the nation and for the public. There is a high road that has made the biomedical research of this nation the best on the planet: the retention of the long-developed peer-review processes and increasingly strict protections against conflicts of interest embedded in the operations of the NIH, AHRQ, National Science Foundation (NSF) and other Federal research agencies. On the other hand, industry concern about healthcare coverage decisions based on CER being done in a research agency does have merit. Payment coverage decisions should not be the purview of science agencies this would only distract -- these decisions should be made by other entities under the extant rules for healthcare coverage.

These considerations lead to specific recommendations for the conduct of CER:

1) Comparative effectiveness research is research intended to affect treatments of people, and for that reason, like all biomedical research, it deserves to be done at the highest standards of science and free from conflicts of interest. Thus it should be done at a science agency, not at a

new hybrid entity that will have to build an entirely new science infrastructure and that will involve in its governance those with a direct stake in the results. Indeed, the latter risks a situation rife with conflict of interest and compromised scientific quality.

Public input to research agenda is a social good, and should be sought. It is very reasonable that agencies doing CER and healthcare research have a high-level public/private advisory board. However, it must not be a governing board, which would constitute an avenue for conflict of interest that scientists, clinicians, policy-makers, and the public would, and should, find objectionable.

The AHRQ has the most broad experience and expertise for CER, and could continue as a lead agency for CER. The NIH also has a very important role to play, and both are likely to benefit from collaboration with FDA, CDC, and other agencies. For example, based on these agencies respective expertise, AHRQ could be responsible for research looking at effectiveness, harm, and safety done by analyses of current evidence, healthcare databases, and healthcare delivery, and NIH could be responsible for large randomized comparative effectiveness trials needed to do accurately assess benefits of a treatment. A joint committee could coordinate these efforts, much as there is currently cooperation between program staff among the agencies for joint projects, and this would presumably be in synchrony with the CER Federal Coordinating Council. Also, this link may be facilitated by the NIH Clinical and Translational Science Awards (CTSAs). With the mission of promoting of the wide spectrum of research that can improve the public s health, many CTSA institutions already have AHRQ CER centers (e.g., AHRQ Evidence-based Practice Centers, AHRQ/FDA Centers for Education and Research on Therapeutics, and AHRQ DeCIDE [Developing Evidence to Inform Decisions about Effectiveness] Network centers), and thus could be an excellent link to AHRQ around CER and a portal to NIH Institutes and Centers and potentially to other agencies.

2) Coverage decisions should not be the purview of the CER done at these research agencies; those decisions would be made at the Centers for Medicare and Medicaid Services (CMS) and by other payers, as they are now. For the future, presumably this will be addressed as part of the Healthcare Reform effort. Assessments of the effectiveness of treatments should be central to the output of CER; specific payment decisions about issues of policy, cost, equity, compassionate care, among many, should done by and overseen by agencies under long-established procedures.

We believe it was an excellent sign that ARRA recognized the importance of CER, and that its natural home is in science agencies, viz., AHRQ in conjunction with NIH, where peer review processes and research infrastructure are in place to ensure the highest quality science. This will benefit the entire healthcare system and the public through promoting more effective care. As the impact CER might have on payments plays out in politics, it is important that this research type not be divided from the rest of the biomedical research enterprise. Thus we encourage the Coordinating Council to allocate the ARRA funds for CER in a way that preserves the conduct of CER at AHRQ, NIH, and other extant federal science agencies, and that serves as a model that will serve future CER activities, and will thereby maximize the important impact of CER on healthcare and the public s health.

Submitted by
Sarah Hicks
National Congress of American Indians
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Comment Type: *Listening Sessions*

The National Congress of American Indians (NCAI) appreciates this opportunity to provide comments to the Department of Health and Human Services (DHHS) on comparative effectiveness research (CER). DHHS listening sessions are an important step in the consultative process in deciding how to award the $1.1 billion in ARRA-appropriated CER research grants.

NCAI is the oldest, largest and most representative organization of American Indian and Alaska Native (AI/AN) tribal governments in the nation. DHHS policies on CER have significant potential impacts on AI/AN communities, some of which might improve the quality of health care while other unintended impacts could be detrimental. Consistent with the larger DHHS policy of tribal consultation, we recommend that there should be ongoing discussion with a broad range of stakeholders in AI/AN communities about CER. These consultations should continue throughout all phases of CER policy development and implementation, including: 1) defining the scope of CER and methodologies for this kind of research, 2) the drafting of grant announcements and awarding of funds, 3) and the application of research findings to clinical practice, including changes to reimbursement rates or clinical priorities given to different treatment options. The way that CER is defined will impact what kinds of research will be funded and likely will also affect what kinds of treatments will be supported by federal health care systems, including the Indian Health Service.

CER is generally defined as a research method for comparing the clinical efficacy of different kinds of drugs, treatments, medical devices, and medical procedures, as well as different approaches to the same procedure. These types of studies could have a positive impact on AI/AN communities if they are included in these kinds of research studies. The clinical efficacy of medications, for example, can vary by ethnic group, and so study results in non-Indian populations should be cautiously interpreted and cannot always be reliably applied to AI/AN individuals. CER studies examining clinical efficacy of different treatments should purposively include AI/AN individuals, who should be included as a large enough proportion of the sample to ensure adequate statistical power. Studies might also be conducted on existing clinical data available through the Indian Health Service s (IHS) medical records system. The outcomes for patients receiving different treatments could be compared using this large existing data set. Similarly, Tribal Epidemiology (Epi) Centers might also be able to conduct regional studies evaluating clinical outcomes of different treatments.

Due to their relatively small population and other factors, AI/AN communities have historically not always been included in research which could be of substantial benefit to them. We

recommend that DHHS require researchers conducting national CER studies to include members of ethnic minority groups in those studies, and specifically to oversample diverse AI/AN populations. Furthermore, we also recommend that grant funds be made available to tribal governments, tribal colleges, the IHS, the Native American Research Centers for Health program, Tribal Epi Centers, urban Indian organizations, and other institutions with a history of conducting culturally-sensitive and respectful research in AI/AN communities. Given the mixed history of research in AI/AN communities, it may be difficult to include AI/AN individuals in CER research without involving trusted organizations and institutions in such studies. Studies conducted on tribal lands should also be required to have the approval and support of tribal governments, and tribal processes for research review should be respected. Similarly, studies conducted in urban Indian communities should be approved by and involve urban Indian organizations when applicable. In the evaluation of grant applications for studies to be conducted in AI/AN communities, the potential risks and benefits to both individual community members and the community as a whole should be considered. If possible, AI/AN reviewers or other individuals with knowledge of AI/AN communities should be included on grant review panels. Finally, grant announcements should require community-collaborative research methods, such as community-based participatory research (CBPR), as these methods prioritize community needs.

The chronic underfunding of the IHS is a critical context for considering the broader potential impacts of CER on AI/AN communities. If specific treatments are found to be more clinically efficacious in AI/AN communities, these communities could benefit from having those treatments made more widely available in IHS clinics. The IHS limited financial resources could be better used if channeled toward treatments that have been shown to be clinically efficacious in AI/AN populations. However, even if the treatments found to be clinically effective are relatively expensive, adequate funding should be provided to IHS to support the use of these treatments. Furthermore, it is critical that funding to IHS be increased to an adequate level for the provision of needed medical services, both related to treatment and prevention of disease. Adequate funding for all necessary medical treatments is a prerequisite for the scientific evaluation of those treatments. Without an increase in resources for the IHS, CER could result in increased emphasis on cost-cutting and rationing of medical care. This potential negative outcome should be proactively avoided by increasing funding for IHS and by focusing the application of CER in IHS clinics primarily toward clinical efficacy with cost-containment as a secondary priority. CER studies conducted in AI/AN communities and elsewhere should not focus on cost-effectiveness at the expense of clinical efficacy.

Definitions of CER and associated research methodologies should be broad and flexible enough to incorporate the worldviews of culturally-diverse communities, including AI/AN peoples. In order to maximize the potential benefits of CER to AI/AN communities, it is important that local contexts and community perspectives are part of determining research topics and methods. Different communities may have diverse forms of healing that they wish to evaluate as part of CER. For example, traditional healers provide care in many AI/AN communities along with Western medical providers. Complementary and alternative medical (CAM) practices (e.g., acupuncture, naturopathy) are also used in some AI/AN communities. Traditional healing and CAM should be included as potential study topics in CER grant announcements. The methods used to evaluate such healing methods may be different from standard biomedical research

designs. Established biomedical research designs, such as randomized clinical trials, are not always culturally appropriate for AI/AN communities because some of them find placebo groups (i.e., lack of treatment) unacceptable. In addition, it may not be culturally appropriate to observe or record some traditional ceremonies. These cultural norms do not always preclude the scientific study of traditional healing, but new and creative research methodologies may need to be developed to evaluate its use in AI/AN communities. Finding new ways to study traditional healing and CAM is important for increasing the scientific evidence base for these health systems, and by extension, support for these kinds of healing by federal funding sources and private insurance payers.

Community knowledge and values are important resources in defining study questions, research design, and measures of efficacy or success. As sovereign governments, tribes should be able to determine what healing practices should be studied, what kinds of data should be collected, and how clinical efficacy is defined. Healing practices that are used widely in a community often are successful for community members, which is why these practices are prevalent (regardless of whether they have been scientifically studied). Accumulated community knowledge and evidence of these healing practices success might best be studied by research methodologies other than clinical trials. Such research designs could include long-term observation of the impacts of traditional healing practices (ethnographic research) or using the paradigm of practice-based evidence, where commonly-used healing practices and community knowledge are used as the starting point for study design and data variables, rather than beginning with a priori hypotheses. The scientific strength of these research designs is that they are grounded in community knowledge and provide information specific to local contexts.

While CER specifically is focused on comparing different treatments, treatments are always prescribed and used in a broader context. We recommend that CER study designs and policy applications of studies take into account broader contextual factors for communities and individuals, including socioeconomic status, cultural beliefs, the health of families, and other aspects of patients environments. We also suggest that CER grant proposals examine the intersection of physical and mental health (e.g., comparing physical and mental outcomes in situations where trauma and mental health concerns are addressed versus when they are not treated). CER study results should also be applied with caution in different local contexts. Available resources and the structure of local health care delivery systems vary widely, and so local communities and health care providers should have some autonomy in determining how to implement CER study results. Similarly, individual patients often have complex medical conditions which do not match the idealized characteristics of study populations, and so health care providers should be free to use their clinical judgment in individualizing treatments for their patients.

In sum, given the wide variation in local contexts, AI/AN communities should be consulted as DHHS defines CER, prepares related grant announcements, and as national health care guidelines and federal reimbursement rates for treatments/interventions are reshaped using CER study findings. Thank you again for the opportunity to provide comments on CER.

Submitted by
Jill Metcalf
Society for Med. Decision Making
jill.metcalf@smdm.org

Comment Type: *Listening Sessions*

Hello,

I would like to nominate someone to give comment at the June 10th listening session. Can you please tell me how to make the nomination?

Submitted by
Jill Metcalf
Society for Med. Decision Making
jill.metcalf@smdm.org

Comment Type: *Listening Sessions*

Hello,

I would like to nominate someone to give comment at the June 10th listening session. Can you please tell me how to make the nomination?

Thank you.
Jill Metcalf
Executive Director
Society for Medical Decision Making

Submitted by
Richard I. Smith
Senior Vice President, Policy

Nomad Research, Inc.
mmccarren@nomadresearch.com

Comment Type: *Listening Sessions*

Re: Reading level of participant materials

If potential subjects are given written materials that are above the 8th-grade reading level, many will not be able to read and understand the information. Will subjects say, I can t read this, will you explain it to me? Probably not. They will just sign the forms. This is not informed consent.

The National Institutes of Health Plain Language Coordinating Committee recommends a reading level of 4th-8th grade for public information materials and public notices. http://execsec.od.nih.gov/plainlang/guidelines/engaging.html

I have been a medical writer for 18 years and have written materials for clinical studies for 4 years. My goal is 6th-grade reading level. I often meet with resistance. Researchers tell me: We don t want to sound unprofessional or unscientific. Or this gem: We re more comfortable above 8th grade level. Of course they are more comfortable; they have advanced degrees. Unlike many Americans, they do not struggle with two- and three-syllable words.

Most researchers simply do not understand the scope of the problem of low health literacy in this county, so they will not voluntarily produce easy-to-read participant materials. Thus, we need to set a rule.

I call on the Federal Coordinating Council to require that all materials for participants in clinical studies be at a reading level of 4th to 8th grade.

Submitted by
Merrick Zwarenstein
Sunnybrook Health Sciences Centre, Toronto, Canada
merrick.zwarenstein@ices.on.ca

Comment Type: *Prioritization Criteria*

I am surpised by the lack of a criterion which allows you to prioritise a proposal that uses more rigorous research designs over one whihc uses less rigorous study designs.

I suggest that a criterion should be included which says something like the following:

The most rigorous design possible is used, appropriate to the question and circumstances.

Submitted by
Tony Principi
Pfizer Inc
anthony.principi@pfizer.com

Comment Type: *Prioritization Criteria*

Note: we also are submitting these comments in a separate letter.

On behalf of Pfizer, I am submitting the following comments to the Federal Coordinating Council s (Council) proposal for a framework on comparative effectiveness research (CER). Pfizer is a research based drug developer that sponsors numerous trials in the U.S. and around the world, to support marketing approvals and to assess comparative effectiveness, post-approval.

Pfizer supports the Council s continued commitment to transparency and public engagement through its solicitation of public input on the definition, prioritization criteria, and strategic framework for CER.

Our comments are structured to respond to three elements contained within the draft documents released by the Council. They build on comments we are submitting related to the Council s proposals on prioritization of comparative effectiveness research.

Draft Prioritization Criteria for CER
" The prioritization criteria are divided into two categories:
o Threshold Minimal Criteria (i.e., investment must meet these to be considered)
? Included within statutory limits of the Recovery Act and Council s definition of CER
? Responsiveness to expressed needs and preferences of patients, clinicians, and other stakeholders, including community engagement in research
? Feasibility of research topic (including time necessary for research)
o Prioritization Criteria (i.e., the criteria to be deemed scientifically meritorious)
? Potential impact (based on prevalence of condition, burden of disease, variability in outcomes, and costs of care)
? Potential to evaluate comparative effectiveness in diverse populations and patient sub-populations
? Uncertainty within the clinical and public health communities regarding management decisions
? Addresses need or gap unlikely to be addressed through other funding mechanisms
? Potential for multiplicative effect (e.g., lays foundation for future CER or generates additional investment outside government)

Pfizer agrees with the criteria to be used to prioritize investments and agrees with the proposed criteria and offer two comments.

First, we recommend the Council call for development of a detailed priority-setting framework that implements rather than just informs the proposed criteria. As it stands now, it is unclear how the proposed criteria are interrelated and how they will be used when the Council identifies CER investments. As the only entity mandated by Congress in the American Recovery and Reinvestment Act to prioritize and coordinate Federal efforts in CER, the Council must develop a clearly defined, agreed-upon, and actionable priority-setting process.

The priority-setting process must:

1. Integrate the values of the users of the research.

2. Consider the information needs of the user by conducting CER on the full spectrum of healthcare interventions used to manage conditions.

3. Be efficient by seeking broad input at the outset, but also having a relatively simple mechanism to identify important research topics.

4. Be sensitive to its political context; be objective, open, and fair; invite input from a broad spectrum of stakeholders; and present the logic of the process clearly and carefully to others.

5. Maintain a transparent process in which methods are explicitly defined, consistently applied, and publicly available for comment.

6. Allow for multiple points of engagement from a diverse group of stakeholders throughout the priority-setting process.

7. Allow for meaningful input from patients and clinicians.

Second, specifically related to the proposed criteria, we recommend the Council make three clarifications: (1) clearly define the term feasibility in the third threshold criteria; and (2) include both public and private funding mechanisms in the fourth prioritization criteria and (3) recommending an explicit emphasis on known gaps in evidence.

1. While we recognize that all research needs to be done in an efficient and economical manner, we believe that the merit of research projects should be judged, first and foremost, on their potential benefit to the patient or patient population. As presented, the criterion may be interpreted to suggest that research that is expensive, difficult or time consuming may not be considered or prioritized. To that end, we recommend the Council clarify the definition of feasibility so that it is explicit that it is the Council s intent is to fairly and appropriately consider research projects and to balance the cost, complexity or time-frame for completion against the benefit or likely benefit to the patient population or to improving public health.

2. With respect to the fourth prioritization criterion, we are concerned that it does not explicitly recognize CER investments made by the private sector (e.g., industry, private plans,

professional societies, and academic research centers). To ensure that the Council appropriately identifies unmet needs or gaps in research, it is important that any analysis take into account the work of the private and public sector. To that end, we recommend the criterion should be re-worded to include public and private before the term funding.

Third, while we recognize that the prioritization criteria emphasize research that is unlikely to be addressed through other funding mechanisms, we would like the Council to prioritize investments in interventions, populations, and conditions where known gaps exist. This is an important distinction because the program s ability to have maximum impact is predicated upon investing in those areas where current incentives, opportunities, and capacity are limited. Furthermore, the inclusion of such a criterion is actually consistent with the strategic framework that was proposed by the Council; it explicitly calls for investments in under-studied populations and interventions (e.g. procedures).

Submitted by
Tina Grande
Healthcare Leadership Council
tgrande@hlc.org

Comment Type: *Prioritization Criteria*

HLC Comment on Draft Criteria

The Healthcare Leadership Council (HLC) applauds the inclusion, as a minimal criterion, the requirement that comparative effectiveness research studies be responsive to the needs and preferences of patients. We believe this reflects the spirit of the American Recovery and Reinvestment Act (ARRA) and is an important primary goal towards ensuring comparative effectiveness research is used to improve individual patient and public health.

While we question the rationale behind using time necessary as a prioritization factor, we understand that pursuing low-hanging fruits might be the most attractive option when deciding how best to spend the substantial yet limited amount of ARRA funds appropriated for federal CE projects. We respectfully note however, that in some instances, while a study may require a relatively longer length of time to conduct, the benefits of the information generated may be valuable enough so as to more than outweigh the cost in funds and time needed to reach completion. In this instance, prioritizing according to time needed may discourage valuable and important research questions.

We also agree that this research should, in setting priorities, target diseases and conditions with the greatest prevalence, including those that impose the greatest clinical and economic burden on patients and health care spending, respectively. We also note that, while variability in outcomes

is an important phenomenon on which to focus these efforts, the research should not necessarily equate this with variability in intervention utilization.

We wish to re-emphasize the importance of designing this research to ensure it can evaluate and discern differences within appropriate subpopulations and we therefore strongly support using the potential to do so as a prioritization factor.

Submitted by
Thomas Wilson
Population Health Impact Institute
twilson@phiinstitute.org

Comment Type: *Prioritization Criteria*

EIGHT SUGGESTED ADDITIONS TO STATEMENT: IN QUOTES BELOW (placed within original statement)

Comparative effectiveness research is the conduct and synthesis of systematic research comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions. The purpose of this research is to inform

SUGGESTED ADDITION #1: and positively impact

patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients

SUGGESTED ADDITION #2: and consumers

under specific circumstances. To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations

SUGGESTED ADDITION #3) and methods to effectively communicate the results to significant stakeholder in the health care marketplace.

Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions. This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness,

SUGGESTED ADDITION #4) as well as to assess the value of comparative effectiveness research itself to the public.

Threshold Minimal Criteria (i.e. must meet these to be considered)

1. Included within statutory limits of Recovery Act and FCC definition of CER
2. Responsiveness to expressed needs and preferences of patients, clinicians, and other stakeholders, including community engagement in research
3. Feasibility of research topic (including time necessary for research)

SUGGESTED ADDITION #5: "4. Commitment to timely and public reporting of baseline methods, preliminary results, and final results

Prioritization Criteria
The criteria for scientifically meritorious research and investments are:
1. Potential Impact (based on prevalence of condition, burden of disease, variability in outcomes, and costs of care)
2. Potential to evaluate comparative effectiveness in diverse populations and patient

SUGGESTED ADDITION #6: and consumer

sub-populations

SUGGESTED ADDITION #7: and to effectively communicate methods and results to these groups.
3.

SUGGESTION ADDITION #8: Different levels of

uncertainty within the clinical and public health communities regarding management decisions
4. Addresses need or gap unlikely to be addressed through other funding mechanisms

Submitted by
Alan Gambrell
Consultant
gambrell@aol.com

Comment Type: *Prioritization Criteria*

EDIT SUGGESTIONS FOR THRESHOLD MINIMAL CRITERIA

PUT THIS SECOND AS IT S A HIGHER CONSIDERATION AND MODIFY PARENS EXPLANATION AS NOTED BELOW
Feasibility of research topic (e.g., cost, time necessary to complete research)

PUT THIS THIRD BUT ALSO CLARIFY AS NEEDS AND PREFERENCES SHOULD BE TIED TO PUBLIC WELFARE PRINCIPLES AND NOT BE LOOSELY DETERMINED BY VARIOUS PARTIES SUGGESTED EDITS AS FOLLOWS.
Responsiveness to tangible research priorities (e.g., disease prevalence, cost of care) that are identified by various parties
NOTE: WITH CURRENT CRITERON, THIS PHRASE IS UNCLEAR AS TO MEANING >>including community engagement in research

PRIORITIZATION CRITERIA
THESE ARE GENERALLY FINE AS IS. HOWEVER, CLARIFY MEANING OF THIS CRITERION: Uncertainty within the clinical and public health communities regarding management decisions

Submitted by
Carmella Bocchino
America's Health Insurance Plans
cbocchino@ahip.org

Comment Type: *Prioritization Criteria*

America s Health Insurance Plans (AHIP) appreciates the opportunity to share its member companies perspectives on the proposed definition for comparative effectiveness research (CER) and the strategic framework for such research. AHIP is the national trade association representing approximately 1,300 health insurance plans that provide coverage to more than 200 million Americans. Our members offer a broad range of products in the commercial marketplace including health, long-term care, dental, disability, and supplemental coverage and also have a long history of participation in public programs.

Prioritization Criteria Comments
Our members question how the National Priorities Partnership and their significant contribution to focus all stakeholders on key areas of overuse and gaps in care can be considered or incorporated into the draft prioritization criteria.

Submitted by
Andrea Douglas
PhRMA
adouglas@phrma.org

Comment Type: *Prioritization Criteria*

Wednesday, June 10, 2009

VIA E-MAIL

Dear Federal Coordinating Council Members:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments to the Federal Coordinating Council for Comparative Effectiveness Research on the draft definition of comparative effectiveness research (CER), priority setting criteria, and strategic framework released by the Council.

PhRMA is a voluntary, nonprofit association representing the country s leading research-based pharmaceutical and biotechnology companies, which are devoted to discovering new medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA s member companies play a leading role in discovery of new therapies and advancement of scientific and clinical knowledge.

PhRMA appreciates the Federal Coordinating Council s posting of its draft CER definition, prioritization criteria and strategic framework as a further step in promoting openness and transparency as it carries out its duties under the American Recovery and Reinvestment Act (ARRA). Specifying a CER definition and criteria for research priorities are important initial steps in establishing a sound CER research program.

As the Council continues implementing its mandate under ARRA, we urge it to maintain open and transparent procedures. In particular, as the Council prepares to submit a report by June 30 making recommendations for CER research to the President, Congress, and the Secretary of the Department of Health and Human Services (HHS), we ask that it explain the substantive reasons for its recommended research priorities. This will enable members of the public to understand how the priorities correspond to the input received from stakeholders, respond to the information needs of patients and providers and meet the other criteria established by the Council. In addition, the Secretary should establish a similar policy as it considers the Council s recommendations, and those of the Institute of Medicine, in establishing research priorities. Open, transparent processes advance research that is credible and relevant to the real-world decisions facing patients and providers as well as reflecting the different needs of racial, ethnic and other patient sub-populations.

PhRMA supports the focus on patient and provider needs in the Council s draft CER definition and criteria for research priorities. This focus also is evident in HHS Secretary Kathleen Sebelius April 21, 2009 comments at the Senate Finance Committee: The goal of such research is to improve the database of information available to a patient and his or her provider so they can make informed decisions about care. The goal is to empower patients and providers with the best information on protocols, procedures, and other relevant issues, not to enable the federal government to dictate broad coverage decisions." In addition, the Council s emphasis on the expressed needs of patients and providers will help ensure that their input is given sufficient weight in the CER process.

The Council appropriately recognizes the importance of accounting for differences in individual patients throughout its draft material. This will help facilitate study designs that recognize and generate data on different patient subgroups, and communication of results that reflect differing patient needs based on genetic, clinical and other factors. These factors are very important to patients but, unless expressly recognized, can be minimized in study designs and communication of results. In a letter last year, the Congressional Black Caucus highlighted the importance of accounting for individual differences in CER research result: All research supported by a comparative effectiveness initiative must recognize variation in individual patients needs, circumstances, and responses to particular therapies. Comparative effectiveness research must enrich our understanding of these variations, rather than ignoring them by focusing on population averages that mean little for any individual patient or subgroup. Without this focus, the results of research could inappropriately be used as a rationale for restricting the treatment choices of those who fall outside the average response.

In addition, PhRMA supports the scope of research included in the draft definition of CER, which encompasses the full range of medical treatments, behavioral change strategies, and delivery system interventions. This broad scope of research is consistent with the Act s mandate for research on health care treatments and strategies. This scope of research reflects the growing recognition that addressing the needs of patients, particularly those with chronic illnesses, requires greater scrutiny of healthcare delivery systems. This includes comparing the effectiveness of different approaches to care processes, disease management services, care coordination, benefit designs, and other components that directly impact care quality and patient outcomes.

The importance of this aspect of comparative effectiveness research was emphasized in Atul Gawande, MD s, June 1, 2009 New Yorker article: "Congress has provided vital funding for research that compares the effectiveness of different treatments, and this should help reduce uncertainty about which treatments are best. But we also need to fund research that compares the effectiveness of different systems of care to reduce our uncertainty about which systems work best for communities. These are empirical, not ideological, questions.

While the draft definition, prioritization criteria, and strategic framework include many positive elements, we offer the following recommendations to help ensure that CER remains centered on improving health care quality and supporting patient and provider decision-making:

1. Clarify the references to decision makers from the draft definition and federal needs as a basis for setting research priorities.

Defining research priorities and study questions that respond to the information needs of patients and providers is an important, and challenging, early step in CER. While decisions at the policy level should be informed by best available evidence, including comparative effectiveness research, it is important that government-supported CER conducted under ARRA is centered on supporting patient and provider decision-making and improving the quality of patient and provider care. This will help ensure that federally-funded CER meets the goal described in HHS press release announcing the Council, Comparative effectiveness research provides information

on the relative strengths and weakness of various medical interventions. Such research will give clinicians and patients valid information to make decisions that will improve the performance of the U.S. health care system. The Council should clarify how federal and other decision making needs will be recognized while maintaining a focus on patients and providers.

2. The council should clarify how the separate elements of the prioritization criteria will be weighed against each other and the minimal feasibility of research criteria should be clarified and moved to secondary list.

The feasibility of research criterion should be moved to the second category of criteria for ensuring scientifically meritorious research and investments, and the Council should clarify how time necessary for research will be used as part of this criterion. The length of the study is an important consideration, but should not be a minimal criteria, as both long- and short-term research can yield findings that are more or less useful to patients and providers. For example, the seven years it took to complete the federally supported Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) reduced its impact, because of the ways the practice of medicine evolved during the study period . At the same time, the time necessary for research should not be used to rule out studies that are longer-term but yield high-value information. Some long-term studies, such as the Women s Health Initiative, provided important information about women and osteoporosis, cardiovascular disease, and cancer and had a significant impact on patient and provider treatment decisions, even though it had a 15 year time frame.

3. Additional recommendations: clarify variability in outcomes, weighting of criteria, and range of data sources.

The Council should clarify the types of outcome variability it will consider when setting CER priorities. This will facilitate consideration of outcomes variation related to a range of factors, including geographic location, treatment site, provider type, and patient sub-group, consistent with the FCC s definition of CER. Conducting research to address these variations represents a significant opportunity to improve health care.
For example, Addressing this issue October 8, 2007 at the Institute of Medicine annual meeting, Eliot Fischer, MD, MPH, Dartmouth Medical School, said: We need better evidence, both about biologically targeted interventions, but also about care delivery...There is an emerging consensus on need for comparative effectiveness research. I think it s critically important that we broaden that focus to include evidence-based care management and evidence-based care delivery, because that s where all the money is and that s where all the waste is in U.S. health care.

In addition, addressing variability in outcomes within minority groups could help reduce health care disparities . There is a broad range of research that indicates racial and ethnic minorities are less likely to receive medical care we know works very well and experience a lower quality of health services. For instance, the Institute of Medicine report, Unequal Treatment found that racial and ethnic minorities are less likely to be given appropriate cardiac medications or to

undergo bypass surgery, and a more likely to receive certain less-desirable treatments, such as limb amputations for diabetes. This is not because of any lack of knowledge about appropriate treatments for conditions such as diabetes or heart disease. Rather, it is because our health system does not implement effective strategies to organize and deliver care to minority populations. Placing a high priority on research to identify the strategies that the health system can use regarding issues such as disease management, use of information technology, benefits design, community outreach, to close this gap is important to improving care in minority communities.

In the definition, the Council should describe the range of data sources and methods it will consider to assess comparative effectiveness, such as randomized controlled trials, meta-analyses, observational analysis or other methodologies. Each research methods offers different strengths and limitations, and providing additional detail in this area could facilitate research that provides information on diverse populations and patient sub-populations, helping to reinforce the Council s commitment to assessing outcomes related to these populations.

Finally, the council should clarify how individual priority setting criteria are weighted. This will help stakeholders further understand the rationale behind recommended priorities.

4. The process step Potential capacity for translation through Federal delivery systems and public private partnerships under Translation and Adoption of CER should be clarified in the CER Strategic framework.

The Council s strategic framework should maintain a focus on translation and adoption of CER results widely to patients and providers in timely, usable formats. This will help orient research towards the needs of patients and providers, and avoid access barriers based on average study results that may overlook differences in the needs of diverse patient groups. The strategic framework should clarify how translation of CER through federal delivery systems will support this goal.

The $1.1 billion included in ARRA for CER represents an important opportunity to establish a broad research agenda that supports patient and provider decision-making and improves health care quality. PhRMA supports the steps the Council has taken to help achieve this goal, including high quality, credible CER that has public buy-in. We ask that the Coordinating Council adopt our suggested revisions to the draft definition, priority setting criteria, and strategic framework.

PhRMA looks forward to continued participation in your important work to recommend CER research priorities. Please do not hesitate to contact me if I can be of any other assistance.

Submitted by
Teresa Lee
Advanced Medical Technology Association (AdvaMed)
tlee@advamed.org

Comment Type: *Prioritization Criteria*

Consistent with the comment AdvaMed submitted regarding the definition of CER, AdvaMed recommends that the second threshold minimal criterion be clarified to specify who the other stakeholders are. AdvaMed recommends that the second criterion read as follows:

2. Responsiveness to expressed needs and preferences of patients, clinicians, and other health care professionals, including community engagement in research.

AdvaMed also has the following three comments on the draft prioritization criteria. First, AdvaMed supports consideration of potential impact in prioritizing research and has the following comments to offer regarding this criterion.

" Potential impact should include consideration of outcomes such as change in quality of life or functional status, risk reduction, and treatment satisfaction. Therefore we suggest adding this language to the current parenthetical.
" Prevalence of condition is an appropriate factor. The Federal Coordinating Council should explain, in subsequent reports and plans, how rare diseases (with small population impacts) will be addressed in comparative effectiveness research initiatives.
" The term costs of care should be defined inclusively to take into consideration all costs of care, including reduced hospital admissions, length of stay, and other resource utilization. Therefore we suggest total cost of care rather than costs of care .

Second, AdvaMed supports evaluating comparative effectiveness in diverse patient populations and sub-populations, however greater clarification as to how this criterion will be made a factor would be helpful in subsequent reports and plans. Depending on the study objectives and the study design, there may be challenges in assessing diverse patient populations in a manner that yields statistically significant results for every sub-population. For example, assessing diverse patient populations may be best accomplished through the development of clinical registries, analysis of clinical data networks and electronic health data, and other methods. The observational nature of such study designs and data sources, however, might potentially present

issues with drawing definitive conclusions about which interventions are most effective under which circumstances, a significant objective of CER.

Third, regarding consideration of uncertainty within the clinical and public health communities regarding management decisions, AdvaMed recommends better defining the term uncertainty. The following parenthetical should be added following the word decisions : (e.g., areas for which there is insufficient evidence to guide clinical decision-making or patient management).

Submitted by
David Nau
dnau@humana.com

Comment Type: *Prioritization Criteria*

The Comparative Effectiveness Research Workgroup for Humana has reviewed the proposed definition of Comparative Effectiveness Research (CER) and prioritization criteria. We agree with the coordinating council that the definition of CER should encompass a broad array of interventions and strategies; however, we suggest that CER should also include measurements of standardized cost or relative resource consumption of interventions of strategies when comparing their effectiveness. This will allow an assessment of the overall value of various interventions and could identify important differences in the cost-effectiveness of interventions between different sub-populations. Thus, we suggest the following change to the third sentence of the definition:

To provide this information, comparative effectiveness research may include a broad array of health-related and cost-related outcomes for diverse patient populations.

If the aforementioned change is made to the definition of CER, then we believe that the threshold minimum criteria and prioritization criteria are appropriate. However, we are concerned that the current wording of the first threshold minimum criterion would appear to exclude anything not explicitly mentioned in the definition and therefore may exclude the measurement of cost and/or relative resource consumption in CER studies. While measurement of costs may not be required of every CER study, it should also not be excluded from consideration as a useful variable in a CER study.

Submitted by
American Medical Association American Medical Association
American Medical Association
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Comment Type: *Prioritization Criteria*

The physician and medical student members of the American Medical Association (AMA) commend the Federal Coordinating Council for Comparative Effectiveness Research (Council) for convening a series of public meetings and reaching out to clinicians and medicine to solicit our input on national comparative effectiveness research (CER) priorities as well as comments on the Council s draft CER definition, prioritization criteria, and draft strategic framework. Concerted stakeholder and public engagement will ensure that the funding to support CER will be allocated in an optimal fashion and increase the utilization of CER findings by physicians and patients.

All aspects of the CER process, including priority setting and capacity-building measures, must be transparent and include a central role for physicians in their oversight and governance. Given the nascent nature of this endeavor, the perception among physicians that the CER agenda is being driven by payers who only have cost containment as their goal will seriously undermine efforts to cement physician support as we continue forward on comprehensive health care system reform. It is imperative that physicians, including clinicians and their organizations, have an active, ongoing, and central role at all stages of the CER process. To be clear; the AMA strongly supports CER and looks forward to results that will guide shared decision-making by patients and their physicians.

Physicians today have access to a wide array of medical information. However, there remains far too little rigorous evidence available about which treatments work best for which patients. The AMA strongly supports increased federal funding of CER. Though there is a broad array of areas where CER would bring benefits, we must strategically target support for CER where it will significantly improve health care value by enhancing physician clinical judgment, foster the delivery of patient-centered care, and produce substantial benefit to the health care system as a whole. As outlined in more detail below, the AMA strongly supports the Council s Draft Definition, Draft Prioritization Criteria for Comparative Effectiveness Research as well as the Draft Comparative Effectiveness Research Strategic Framework.

The AMA supports the view that the priority areas of CER should focus on high volume, high cost diagnostic and treatment modalities, and other health services and strategies for which there is significant variation in practice.

The AMA supports a broad definition of CER that involves a comparison of different modalities to prevent, manage, or treat a specific health problem, condition, or disease. Besides the more typical areas of research such as pharmaceuticals and medical devices, CER should also focus on implementation and dissemination issues that would shed light on the most effective strategies that promote a learning health care system and improved clinical outcomes including behavioral change strategies, and delivery system interventions.

In terms of methodology and study design, CER should include long-term and short-term assessments. CER should not be limited to new treatments. In addition, the findings should be

re-evaluated periodically, as needed, based on the development of new alternatives and the emergence of new safety or efficacy data.

AMA Recommended Priority Areas & Infrastructure

Much of the expertise for setting CER priorities focusing on specific diseases and interventions lies within the medical specialty societies. Nonetheless, the AMA offers the following recommendations for CER priorities and offers suggestions concerning two mechanisms that would help build the necessary infrastructure to sustain work in this area.

The AMA strongly believes that the national CER priorities should address the prevention, management, and treatment of preventable disease which collectively represent a major cost driver in today s health care system. Key areas in need of further study and research include cardiovascular, endocrinology and metabolism disorders (including diabetes), and nutrition (including obesity). For example, in the area of wellness, prevention, nutrition, and obesity there is a paucity of CER findings. It is an area with a wide range of available interventions with little clarity about which is most effective.

CER usually considers technology and pharmaceuticals, but behavioral interventions potentially could have the greatest impact for individual patients and the system as a whole. Prioritizing interventions designed to change physician behavior and to effect behavioral change in patients, in addition to other clinical interventions, technologies, and pharmaceutical remedies, is necessary. Because prevalence rates and the most effective interventions for many diseases vary greatly by race, ethnicity, gender, age, geography, and economic status, the AMA strongly supports the inclusion of racial and ethnic health disparities and health disparities more generally as a CER priority area.

In addition to the foregoing, the National Priorities and Goals report put forth by the National Priorities Partnership (NPP) convened by the National Quality Forum (NQF) provides a rich source of information for the Council to consider. The NPP, comprised of 28 national organizations, focused on achievable goals that would, if implemented broadly, reduce harm, improve patient-centered care, eliminate health care disparities, and remove waste from the system. In preparing the report, the NPP solicited extensive input from broad array of individuals and organizations. Utilizing the NPP National Priorities and Goals as a reference point will help the Council to identify national CER priorities that will build the evidence base in a targeted fashion in the areas that are likely to produce substantial system-wide improvements.

In addition to the NPP report, the AMA convened Physician Consortium for Performance Improvement (PCPI) has developed a valuable survey mechanism that can be utilized by the Council to gather additional detailed information concerning national CER priorities. In order to obtain timely, quality responses from the more than 100 national medial specialty and state medical societies, experts in methodology and data collection, and many others involved in quality improvement and performance measurement, the PCPI constructed a survey mechanism. It is a powerful new tool to identify variations in practice, to assess the evidence base in a wide array of areas, and to identify areas where there are gaps in knowledge. The PCPI plans a

significant expansion of these efforts. This provides much needed capacity and infrastructure for priority setting. We would welcome the opportunity to have the Council work with the PCPI to utilize this survey mechanism as it develops the recommendations concerning national CER priorities.

The AMA urges the Council to consider two powerful infrastructure mechanisms, clinical registries and data networks. These have been used by specialty societies such as the Society of Thoracic Surgeons and the American College of Cardiology, and have markedly improved quality and patient safety. The National Surgical Quality Improvement Program (NSQIP) and the Northern New England Cardiovascular Collaborative are examples of utilizing these two mechanisms to advance quality and obtain research data at the point of care, and create what our country needs, a learning network. Expansion of existing clinical registries and databases would provide a strong foundation when conducting CER and at the same time these registries would also provide an excellent beginning point for CER. Utilizing, replicating, expanding, or integrating existing clinical registries would constitute an invaluable investment in the much needed infrastructure for accurately comparing clinical outcomes based on real life conditions where delivery of care settings vary, patients may have numerous co-morbidities, and the patient population is diverse. In turn the clinical registries are not identical and may to greater or lesser extent be able to promote a learning health care environment; thus, evaluating the comparative clinical effectiveness of various clinical registry models and alternatives to them remains a vital priority. Building CER infrastructure and capacity in part upon registries and clinical data networks will leverage CER resources and boost the capacity of the system as a whole to learn and adapt in real time.

AMA Support of Council s Draft Strategic Framework

The AMA generally supports the Council s effort to develop a strategic framework for CER activity and investments in order to categorize current activity, identify gaps, and inform decisions on high priority recommendations with a couple of caveats.

First, the AMA urges the Council to ensure public access to the detailed inventories of Federal CER activities and research/data infrastructure that the Council proposes to create. The AMA agrees that the Council s organizing framework will foster consideration of the balance of activities and priority themes and allow the government to focus on the most pressing needs expressed by patients and clinicians, and allow identification of gaps in the current landscape of CER. We urge the Council to work with the AMA convened PCPI which is already engaged in this activity as discussed above.

Second, the AMA concurs with the Council that CER activities should be grouped into the following four major categories as detailed in the proposed framework:

" research, (e.g., comparing medicines for a specific condition or discharge process A to discharge process B for readmissions).
" human and scientific capital, (e.g., training new researchers to conduct CER, developing CER methodology).

" CER data infrastructure, (e.g., developing a distributed practice-based data network, linked longitudinal administrative or electronic health records databases, or patient registries.)
" translation and utilization of CER, (e.g., building tools and methods to translate CER into practice and measure results.)

While all the above categories are essential components of timely, valid, useful CER, it is important to underscore the essential and central role physicians must play vis-à-vis the last component translation and adoption of CER. The AMA supports the development of practice guidelines by medical specialties and other clinicians in medicine, but would oppose the development of guidelines by the government or another centralized entity. Consistent with the foregoing, to the extent that medical specialties design, implement, and play a central role in clinical registries such as NSQIP that rely upon clinicians to conduct CER, the AMA would support utilization of CER findings generated through clinical registries by the specialties to modify practice guidelines and decision support vis-à-vis the clinical registries.

Conclusion

There is a final cautionary tale. In the February 12, 2009, issue of Journal of American Medical Association there is a description of what can happen when science and politics collide. The Infectious Disease Society of America (IDSA) studied the evidence base for the treatment of Lyme disease and in 2006 issued new guidelines advising against the long-term use of antibiotics. The IDSA was promptly sued by the Connecticut Attorney General alleging violations of antitrust laws and restraint of trade. The case was settled without IDSA admitting any fault and assenting to an ombudsmen-reviewed panel to assess the 2006 guidelines. If we cannot separate science and politics in a case such as this, how will we ever manage to deal with the really hard issues?

CER has the potential to have a profoundly positive impact on the quality of the information available to physicians and patients and, when used appropriately and with care, will address escalating health care costs. The AMA welcomes the opportunity to work closely with the Council to ensure that physicians remain engaged, enthusiastic, and involved stakeholders in this process.

Submitted by
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Comment Type: *Prioritization Criteria*

As the Federal Coordinating Committee deliberates regarding priorities for comparative effectiveness research, the Academy for Medical Development and Collaboration (AMDeC) would like to offer its perspective.

AMDeC is a non-profit consortium of 28 of New York s premier research institutes, medical schools, and universities seeking to collaborate to advance biomedical research. We believe that greater coordination of the various research efforts and the cross-institutional data collection and analysis are keys to optimizing patient outcomes and containing costs. AMDeC has developed innovative research models and infrastructure toward that end. We hope that the suggestions we offer based on our experience in this field will add value to your decision-making process.

We believe that the Coordinating Council should consider investing in projects that leverage existing infrastructures and research methodology that are proven. The infrastructures should be flexible in terms of their ability to be replicated and scaled/expanded, as well as to provide ease of use across institutions. Architectures such as a federated virtual data warehouse that allows for a single, unified interface to data from multiple sources without additional expensive investments in new hardware, software packages, databases, or personnel re-training is ideal. AMDeC believes a number of criteria should be considered as investment decisions are made. Comparative Effectiveness Research inherently appreciates the value of sharing information. Therefore, projects based on meaningful collaboration and leverage health information technology (HIT) infrastructure/tools among institutions should receive priority. Public investments must focus on projects that can demonstrate the practice of sound science to ensure quality outcomes. In addition, it is critically important that federal and state governments invest in CER data infrastructure and translation/adoption of CER in conjunction with their HIT efforts so that a comprehensive, inter-operable data infrastructure and implementation strategy are in place to produce multiplicative effect by exponentially advancing the utility of the electronic data collected in this new digital, prevention-driven environment. Stakeholder incentives including CMS payments for data reporting, provider needs for an improved understanding of best care processes, and payor calls for accountability and improved metrics for healthcare utilization need to be built as part of the overall CER strategic framework to ensure that CER research findings can effectively be translated into clinical outcomes and health care improvements.

Quality and quantity of the data to be analyzed and evaluated should be carefully considered in terms of the diversity of the population that is included in studies. Clearly there are many factors that affect health care and response to treatment. The more factors that can be taken into consideration and effectively analyzed, the better research outcomes can be derived to effectively improve health care delivery and treatments, including pharmacy, lab tests, demographic information, compliance indicators, claims data, and other medical record data. Comparison of the cost and clinical effectiveness as well as the safety of different treatments, medications, care delivery, etc. should enable specific focuses on un- or under-studied populations as defined by co-morbidities and demographics.

A primary concern with any data collection is security and privacy. Any project that is funded should meet the highest standards of patient confidentiality and data security. Extensive safeguards should be introduced at every step of the process for all involved parties while building trust among clinicians, patients and other stakeholders for full acceptance, support, and involvement.

Finally, evaluation measures should be considered. A critical component to ensuring successful impact of CER is to build in evaluation measures from the initial stage. Regular and timely reporting of assessment and evaluation progress should be established to ensure that priorities and implementation activities are indeed aligned or re-aligned with periodic evaluation results and performance standards.

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Comment Type: *Prioritization Criteria*

Consider revising both the Threshold Minimal Criteria and the Other Criteria based on pragmatic considerations in operationalizing these and to more specifically indicate that comparative effectiveness research needs to improve decision making applicability.

Suggested Revisions to Threshold Minimal Criteria:

a. Included within the statutory limits of Recovery Act and FCC definition of CER
b. Responsive to expressed needs and preferences of patients, clinicians, OR OTHER DECISION-MAKERS TO ADDRESS UNCERTAINTY WITHIN CLINICAL AND PUBLIC HEALTH COMMUNITIES REGARDING MANAGEMENT DECISIONS.
c. Feasibility of research topic (including ETHICAL CONSIDERATIONS, RESEARCH INFRASTRUCTURE REQUIREMENTS, AND time necessary for research)

Suggested revisions to the Prioritization Criteria (based on moving up the original criterion c and adding an additional criterion):

a. Potential Impact (based on prevalence of condition, burden of disease, variability in outcomes, cost of care)

b. ADDRESSES comparative effectiveness in diverse populations and patient subpopulations, WITH POTENTIAL TO IMPROVE EXISTING HEALTH DISPARITIES OR TO INFORM PERSONALIZED MEDICINE.

c. POTENTIAL FOR IMPROVEMENT IN HEALTH CARE DECISION-MAKING OR PRACTICE WITH ADDITIONAL RESEARCH

d. Addresses need or gap unlikely to be addressed through other funding mechanisms

e. Potential for multiplicative effect (e.g., lays foundation for future CER or generates additional investment outside government)

Submitted by
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Comment Type: *Prioritization Criteria*

Council:
"Prevention and wellness" must be our top priority. It is the best way to impact the use of resources and to improve the health and wellness of our citizens.

The recent NIH Challenge Grant priorities were listed in a 52-page document; only a handful related to prevention and wellness. We have got it backwards when we allocate $90B to "Improving and Preserving Health Care," but only $1B to prevention and wellness.

We will all benefit from a much closer look at prevention strategies and the comparative effectiveness of wellness-related interventions.

Submitted by
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Comment Type: *Prioritization Criteria*

It is critical to put in place means that reduce duplication and allow better coordination of comparative effectiveness research (CER) investments and activities across the federal government and, to the greatest extent possible, with the private sector and with international bodies. The volume of research questions and critical comparative effectiveness needs outstrip our ability to fund and conduct new research in a timely manner. It is critical to increase our ability to access planned, in-progress, and completed comparative effectiveness research of all types (systematic reviews, trials, observational studies of all types). This could occur by registries/databases of protocols for all types of CER studies and via better library and database tagging. Otherwise, it is nearly impossible to ensure that we do not duplicate existing applicable work in response to requests from the public, nor to take advantage of piggy-backing additional questions onto in-process projects. There is a growing understanding of this critical need to improve CER information retrieval in both the US and internationally.

Submitted by
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Comment Type: *Prioritization Criteria*

BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO is pleased to have the opportunity to submit comments to the Federal Coordinating Council (FCC) on the draft definition of Comparative Effectiveness Research for the FCC.

As a representative of an industry committed to discovering new cures and ensuring patient access to them, BIO strongly supports efforts to increase the availability of accurate, scientific evidence to inform clinical decision-making. BIO believes that individual patients and their doctors should be armed with the best available information to help assess the relative clinical benefits and risks of various treatment alternatives. When appropriately applied, comparative effectiveness information is a valuable tool that, together with a variety of other types of medical evidence, can contribute to improving health care delivery. However, BIO is concerned that comparative effectiveness information will be used increasingly as a means to contain costs, rather than deliver health care value by improving patient health outcomes. BIO appreciates the opportunity to comment to the FCC.

We submit the following comments for your consideration on the definition of comparative effectiveness research, draft prioritization criteria, and the strategic framework. We look forward to continuing to work constructively with you in order to realize the full value of comparative effectiveness research.

Draft Prioritization Criteria

Responsiveness to expressed needs and preferences of patients, clinicians, and other stakeholders, including community engagement in research

BIO is pleased that the FCC wishes to be responsive to the expressed needs and preferences of patients, clinicians, and other stakeholders, including community engagement in research.

Suggested Modification: In order for the research to have the greatest possible benefit, as BIO has previously commented to the Institute of Medicine (IOM) on the composition of the Committee to establish Comparative Effectiveness Research Priorities (Committee), it is critical that all stakeholders be involved and represented in these efforts. Including all stakeholders at the table will enhance the Committee s discussions and deliberations. Each group of stakeholders brings different and valuable perspectives, and it is important that all perspectives are able to have a voice and be heard as part of the Committee. The IOM Roundtable recognized this principle and stated, The determination of the priorities to pursue is a policy exercise in which all relevant stakeholders have a right to engage and to which they can add value. Therefore, stakeholders should be afforded the opportunity to serve on the Committee as well as provide meaningful input into all steps along the study process, including the identification of priority areas to research, study design and research methods, and dissemination of results. Having all stakeholders at the table with full disclosure of potential conflicts of interest is a good way to manage potential biases and conflict of interest. Disclosure and broad representation are critical to ensure a balanced end product.

Submitted by
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Comment Type: *Strategic Framework*

The strategic framework seems developed from a perspective of the need for de novo research. While we certainly need to invest in more research that evaluates the effectiveness of interventions and how they compare, we should first examine the vast science (including all study designs that are well executed and relevant to the clinical question) already available to determine where gaps exist. I propose that a framework for action allows for the synthesis of existing knowledge and supports improvements in methodology to do so with minimum bias. When gaps in knowledge are identified, and they will be, we can focus our limited resources

toward the conduct of studies to generate new knowledge where the greatest gaps exist. We must also plan for identification of new areas for research and for continually staying current with the best science. We may consider translating existing knowledge to action even while we plan for new knowledge generation, as we may have sufficient evidence to guide some action ahead of the results of studies to provide more complete guidance strategies.

Prioritization of which topics remains important throughout.

Submitted by
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Comment Type: *Strategic Framework*

CER
The definition is inappropriate. which interventions are most effective for which patients under specific circumstances.

Strategic framework. Too many diagrams. Not operational (see term from operations research).
First task is to create methods to evaluate CE
It is impossible to study all possible diagnosis and treatments. Create a method to establish priorities.

Create mathematical models for decision making under CE conditions.
Create mathematical models that predict disease and outcome. At least $300M should be devoted to this task, the most important and promising one to improve outcomes and save costs. Today the technology exist to drastically improve diagnosis by minimizing the use of diagnostic tests (using decision theory and biochemical models). Same for treatment.

Identify data bases that are useful for diagnosis and treatment.
Provide $50M for seed money to develop prototype data bases for conditions. Provide guidelines for data to be gathered as part of Health IT, medical records. Uniform, standard output formats for medical records for data analysis on conditions, outcomes.

Medical/research data are very difficult to interpret. All recipients of federal funding ought to provide their results in a manner that can be incorporated into models of disease diagnosis, treatment.

All data from federally funding research ought to be available for further research.

Focus on the 10 conditions that account for most morbidity, mortality, # of people, and costs. If uncertain, rank on each factor and chose the top 10 in each group.

Focus on getting CER results that substantially improve health care outcomes and lower costs.

Spend $100M on population models to evaluate the impact of alternative diagnosis, treatment, behavioral choices, etc.
See articles by Siguel for how to make these models. Ask him
Siguel E, Seubold F. Potential 10 Year Savings from HMO Development Part 1, Health Maint Org. Hearings before Subcom. on Public Health and Env, 92nd Congress, US Gov Print Off, p. 92-95, 1972.
Siguel E. The Application of Computer Simulation to the Evaluation of Income Maintenance Programs. Inst. of Electr. and Electronic Eng, Trans. on Systems, Man and Cybernetics, 1976: 695-98.

Spend $100M on models of preventive health care. What is the impact (benefits, outcomes) of different types of prevention.
Ex: perhaps eating fewer trans fats prevents heart disease. The cost of changing foods is huge. Furthermore, trans fats are replaced by other fats that could be more dangerous. Perhaps the cost of treating the few who get heart disease due to trans fats is smaller than the cost of changing the food industry.

If we had to focus, what are the best recommendations for people? What is the range of ideal weight? At what weight disease starts to increase dramatically? What is the impact of eating healthy foods? What do models predict about disease prevention associated with eating vegetables and fruits, vs. more disease associated with French fries (if any)

The definition is inappropriate. which interventions are most effective for which patients under specific circumstances.
It is not interventions for patients, but interventions for a population of similar patients given known environmental, genetic, financial, social, etc.
Patients may chose what is best for them without regard for the consequences or costs to society and health consequences for others.

$1B spent providing 3 months extra life to 10 people could be better spend providing speech therapy to 10 children and correct a developmental delay problem.

If costs are irrelevant as a screen, then CE would spend all its time and money evaluating the most expensive and high tech arm replacement or brain replacement or cancer treatment optimized for specific cells (feasible today).

A grandfather with prostate cancer may chose to postpone treatment for several years rather than risk death until his grandson is 3 years old. Or he may have a grandson that is 16 and may chose to wait until he is 18 and takes over the management of family trusts. Or a 50 yo who just met a wonderful girl and is planning to have a family may chose to wait 1 year (even though he could freeze semen) before starting a treatment that could alter his genes or damage reproductive ability. The examples are endless.

CE does not exist in a vacuum of costs, behavior, environment, and accurate models.
Every statistical analysis, every clinical trial has an implicit mathematical model. It starts with the selection of variables to consider or ignore, markers to measure or ignore. Many trials involve drastic assumptions.
Beware of the physicist who seeks to predict horse races by assuming that horses are symmetrical balls moving on a surface with constant friction.

Population issues. Consider an ear or throat bacterial infection. There are 3 antibiotics, Ab1, Ab2, Ab3. Assume they all have the same risks. Ab1 costs $3 and has a 70% cure rate. Ab2 costs $100 and has a 85% cure rate. Ab3 costs $1,000 and has a 99% cure rate. Without treatment, cure rate is 60% (numbers are fictitious). If everyone chose Ab2, soon Ab2 would lose its effectiveness and resemble Ab1. If every patient chooses Ab1 (instead of nothing), soon Ab1 could be less effective than nothing. If many people chose Ab3, it would lose its effectiveness as bacteria evolve.

Who decides? IF only the individual s perspective matter, if costs are not an issue, Ab3 is the best choice. From a population and public health, for the benefit of most people, the best choice is to treat only the most complex cases, and start with Ab1, limiting Ab3 to very rare cases even if more people die of infection. This approach maximizes population benefits for the long term, but not individual benefits, particularly those who died who could have been cured if immediately treated with Ab3.

If we add costs to the decision, then who should make the decision? If payors pay all costs, so costs are distributed across the population, and everyone is allowed to use Ab3, costs would be beyond reason. Because resources are not infinite, the decision of one patient affects the decisions of other patients.

The appropriate model to evaluate CE is Bayesian statistics or Bayesian inference statistical inference in which evidence or observations are used to update or to newly infer the probability that a hypothesis may be true. The name "Bayesian" comes from the frequent use of Bayes' theorem in the inference process. See Wikipedia.

CE definition should be operational, something measurable. It should be along these lines:
Probability of (Disease/Diagnosis) = ..?
Probability of (treatment improve outcome/disease, alternative treatments) =
In CE we seek to identify the relative effectiveness of treatment. But those probabilities are not constant over time. They change according to data, treatments used by other people, etc. The effectiveness of Ab3 depends on how many people used it. Because that data is not available real-time, the effectiveness depends on models of use of Ab3. If suddenly Ab3 is given away for free and everyone starts using it as the first choice, then bacteria are likely to change and Ab2 replaces Ab3 for serious cases.

Submitted by
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Comment Type: *Strategic Framework*

The Association of Clinical Research Organizations (ACRO) appreciates the opportunity to provide additional comments to the Federal Coordinating Council on Comparative Effectiveness Research. Our previous comments and testimony focused on broad policy issues of comparative effectiveness research (CER), including prioritization, methods of research and models for public-private coordination of research.

In this comment, we want to focus the Council on certain data use disincentives resulting from provisions of the American Recovery & Reinvestment Act (ARRA) that could severely limit the ability to conduct CER. These data use restrictions go well beyond the privacy rules established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and constitute a de facto transition to HIPAA 2.

Under current HIPAA regulations, Covered Entities (CEs) - such as health care providers, health plans, and claims clearinghouses use or disclose Personal Health Information (PHI) without consent for treatment, payment and health care operations. With some exceptions, including for public health and research activities, all other uses or disclosures of data require an individual s authorization. Business Associates (BAs) may work under contract for or on behalf of CEs, but have the same limitations on uses and disclosures of PHI as do CEs.

In general, clinical research organizations (CROs) are neither CEs nor BAs; we receive clinical trial data and other PHI from a CE an investigator - under an individual s authorization and informed consent. CEs may disclose PHI for research purposes with individual authorization or, under limited circumstances, without individual authorization. For instance, PHI may be disclosed without individual consent: if a waiver is obtained from an Institutional Review Board (IRB) or Privacy Board; if the PHI is of decedents; if the PHI is used for preparatory research, such as patient screening; if the PHI is used for the purposes of activities related to the quality, safety or effectiveness of (emphasis added) FDA-regulated products; or the PHI is part of a limited data set that does not include direct identifiers and is used with a data use agreement that prohibits re-identification or attempts to contact individuals.

De-identified data removes all names and 17 other identifiers, including all dates (DOB, admission date, discharge date, prescription date, etc.). Fully de-identified data is often of minimal utility for research. A limited data set , on the other hand, removes names and other direct identifiers, but allows zip codes and dates of service, for instance. Limited data sets are extremely useful in many areas of research, including CER.

One ARRA privacy provision prohibits a CE from receiving any remuneration for electronic health data, including limited data sets. While exceptions to this prohibition are made for public health and research , the research exception limits the remuneration to the costs incurred in preparing and transmitting the data set, thus creating a serious financial disincentive to make the data available.

Further, recent guidance from the Department of Health and Human Services regarding the definition of when data can be considered unusable, unreadable or indecipherable to unauthorized individuals has the effect of imposing breach reporting requirements on CEs that use or disclose limited data sets, establishing another significant disincentive to working with large clinical databases.

The unintended consequence of these disincentives to the creation and use of limited data sets will create substantial barriers to conducting comparative effectiveness research. For example, the use of retrospective chart reviews to perform CER would be restricted because, to conduct optimal analysis, data elements such as age, service dates and geography are needed. Similarly, these same data elements would be desired for administrative claims research related to CER using data from Medicare (de-identified), AHRQ Nationwide Inpatient Sample (limited data set) and the Behavioral Risk Factor & Surveillance System (de-identified).

ACRO urges the Council to use its authority and charter to alert the agencies of the Federal government regarding these onerous restrictions to research data that do little if anything to protect personal privacy. Specifically, we hope that the Council will work with the Department of Health and Human Services to pursue a policy of ensuring the use of limited data sets for research purposes, including CER.

Thank you for your consideration of this important issue, which we feel has been overlooked in the recent discussion surrounding comparative effectiveness research. Please do not hesitate to contact ACRO for additional information.

Submitted by
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Comment Type: *Strategic Framework*

America s Health Insurance Plans (AHIP) appreciates the opportunity to share its member companies perspectives on the proposed definition for comparative effectiveness research (CER) and the strategic framework for such research. AHIP is the national trade association representing approximately 1,300 health insurance plans that provide coverage to more than 200 million Americans. Our members offer a broad range of products in the commercial marketplace including health, long-term care, dental, disability, and supplemental coverage and also have a long history of participation in public programs.

General
In general, our members believe that the draft CER strategic framework provides solid, unifying principles for CER. However, there are some concerns regarding the scope and clarity within the framework. In terms of simple readability, we recommend that the order within both graphics for the CER Investments and Activities (Research, Human and Scientific Capital, CER Data & Research Infrastructure, Translation and Adoption) remain the same for both versions, as the first two categories have been transposed within the graphics, potentially leading to confusion.

While the purpose of CER is clearly stated within the framework, there is no overarching goals statement. We recommend a goal statement that aligns with the purpose, but addresses the needs of those who will be using CER data the most frequently, such as:

"The goal of comparative effectiveness research is to inform patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances and produce the best outcomes for the best value, within a given level of resources.

While this framework was developed by the Federal Coordinating Council for CER, to coordinate CER across the federal government and to make recommendations for federal funding priorities, the stated purpose is to inform patients, providers, and decision-makers about which interventions are most effective. As such, the descriptions of necessary inventories of CER activities only mention inventories of federal activities. Our members strongly believe that any CER strategic framework should be inclusive to both public and private CER efforts and activities, and, therefore, we recommend that the framework be revised to include private CER efforts. While the original charter for the Federal CER Coordinating Council directed efforts for federal programs, private sector CER efforts also need to be considered.

For example, concerning the heading, Inventories of Existing CER Infrastructure, our members are concerned with the potentiality that any federal effort to develop an inventory would not include current and existing CER capacities in both the public and private sector. We recommend that the fourth process step bullet (Inventories of existing federal CER translation & dissemination activities; funding based on identifies high-priority gaps) be revised to state, Inventories of existing federal, public (e.g., state activities), and private CER efforts& in order to encompass all current CER efforts. In addition, under the heading, Human and Scientific Capital for CER, an inventory of existing CER capabilities and personnel in the public and private sectors should be added, since investment in training and methods development should start with understanding the current baseline status.

Within Figure 2, under the CER Data & Research Infrastructure box, our members are concerned with building future CER efforts on a medical research enterprise which is currently researcher-centric and not always focused on asking the most appropriate questions that get to the answers that improve outcomes for patients. There should be a step taken prior to Inventories of Existing CER Infrastructure, where current research methods are reviewed and best practices and barriers to providing useful and beneficial CER results are considered. There still remain major questions that can only be answered by large multicenter, multi-specialty, multi-population, and

competitively bid randomized controlled trials. Instead of the current focus on the publish-or-perish mentality of the researcher-centric model, incentives should be developed for performing CER with societal impact, credit for updating research with emerging evidence, and improvements in diverse clinical trial enrollment. In addition, there should be mention of the need to develop an infrastructure for priority setting, such as a box between Inventories of Existing CER Infrastructure and Evidence Generation. As mentioned above, there are multi-stakeholder efforts underway, such as the National Priorities Partnership, whose contributions to the discussion should be recognized.

Also in Figure 2, under Human & Scientific Capital for CER, we recommend that there should be mention of training researchers in the evaluation of clinical evidence, not only CER methods and development. It will be very important to ensure that the strategic framework does not ignore utilizing the scientific evidence that already has been developed, and provides the required infrastructure for re-evaluating that data.

Realizing that this is a framework, and cannot detail every aspect of CER that should be considered, our members have concerns that there are several important topics that are not addressed, neither within the graphics nor the narrative, which are believed to be vital to the successful development and implementation of a CER infrastructure to the US healthcare system. These topics include: the development of a hierarchy of clinical evidence; identification of health services in common use that are not supported by clinical evidence; addressing bias and conflict of interest in the development and review of clinical evidence.

Translation and Adoption
Of the four CER Investments and Activities headings detailed within the draft framework, our members are most concerned with the efforts organized under Translation & Adoption, as this is the main purpose of CER and has been the most difficult CER action to accomplish. Currently, the headings under this category include: Inventory of Existing CER Translational & Dissemination Activities and Potential Capacity for Translation through Federal Delivery Systems and Public-Private Partnerships. Our members have raised questions regarding the inadequacy of these headings and the fundamental need to understand best practices and barriers to adoption of CER, which we recommend be the third heading under Translation & Adoption. Within the draft strategic framework narrative, we also recommend that the different settings in which CER should be translated and adopted should be highlighted: clinical practice, consumer decision-making, and coverage and reimbursement systems (both public and private).

Resource Use and Cost
While the focus of comparative effectiveness research must necessarily be on clinical impact, there must also be consideration of resource allocation (including cost effectiveness). Our members believe that comparative information on cost is equally important especially in today s economic environment, and believe that the value of medical devices, medications, and procedures should be a required facet of CER. Understanding the clinical effectiveness and cost of a service or technology as well as its potential impact on reducing the need for other health care services and expenditures will help consumers and physicians in selecting the right treatment for each patient.

Submitted by
Gina de Miranda
Citizen
freedomchik12@gmail.com

Comment Type: *Strategic Framework*

There is no point in having universal health coverage if the current practice of permitting "military experiments" and "no liability" vaccines is continued. We the people would simply end up paying for the diseases caused by these two factors. We have no idea if our vaccines are actually safe. The statistics suggest that they are useless in preventing disease for animals and people (i.e. people get just as sick with or without vaccines and they almost always get the illness that they have been innoculated against). We get sick from the many military experiments that include the use of electronic frequencies to monitor their effects. These experiments are documented by many Congressional hearings and many complaints. There have even been lawsuits awarding money to Canadians for some of these experiments.

We need honest medical information that includes the importance of nutrition. We need our farmers to use more natural and restorative means of planting and forego the "factory" farm approach that doesn't permit land to be rotated and minerals to be returned to the soil, but relies on nitrogenous fertilizers that further deplete the soil and poison the air. We also need for "fluoridization of the water to be stopped." Not only is this practice useless for teeth health (as many studies have revealed), but it has been correlated with bone cancer in young men, breast cancer and brittle bones in women and problems with hormone balance across the board.

The people are not stupid. The people are not the ones who IRRESPONSIBLY dump pollutants into the water and air and conduct unsafe tests on human subjects.

Submitted by
Tony Coelho
Partnership to Improve Patient Care (PIPC)
csheeron@improvepatientcare.org

Comment Type: *Strategic Framework*

Dear Federal Coordinating Council Members:

The Partnership to Improve Patient Care (PIPC) appreciates this opportunity to respond to your recently released draft definition and prioritization of comparative effectiveness research (CER).

PIPC is a diverse coalition of over 40 organizations representing patients, healthcare providers, research institutions and medical research companies. PIPC was formed in November 2008 to advance proposals for CER that are focused on supporting providers and patients with the information they need, improving healthcare quality and supporting continued medical progress. Our members are united by a common set of CER principles in support of this goal.

Our partnership appreciates the Federal Coordinating Council s posting of its draft CER definition, prioritization criteria and strategic framework as a further step in promoting openness and transparency. Providing continued openness and transparency in the Council s activities and those of the Department of Health and Human Services will ensure that the perspectives of patients, providers and other stakeholders are considered.

We also commend the focus on the expressed needs and perspectives of patients and providers in your draft definition. PIPC reaffirms our belief that CER must focus on communicating research results to patients, providers and other decision-makers, not making centralized coverage and payment decisions or recommendations. This focus is consistent with the goal of CER as described in HHS press release announcing the Federal Coordinating Council, which stated, Such research will give clinicians and patients valid information to make decisions that will improve the performance of the U.S. health care system.

We support your recognition of the importance of having patients and providers play a central role in defining their own healthcare needs. Too often in healthcare, the determination of what s best for the patient is made by others, while the patient s views of his or her own needs is ignored or minimized. By identifying the importance of expressed needs, the Council takes an important step towards policy that truly is centered on the needs of the patient and caregiver.

PIPC also supports the broad scope of research included in the Council s definition, which states, Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions. This definition is consistent with PIPC s principles in support of CER and reflects the views expressed by many stakeholders at FCC listening sessions. PIPC believes that in order to improve patient care, CER research should examine the range of issues that affect the quality of patient care. This includes the range of medical tests and treatments, as well as questions related to healthcare delivery and organization such as benefit designs and care management programs. All of these healthcare elements affect patients quality of care.

While PIPC supports the focus on patient and provider needs in the draft definition, we also are concerned that, in stating that the purpose of CER is to inform patients, providers and decision-makers, the Council s draft definition of CER has the potential to shift the focus of research away from patients and providers towards other decision-makers such as health insurance companies, government agencies and other policy-makers. The strategic framework released on HHS web site on June 1 includes language that underscores this concern. In particular, PIPC is troubled by language in the framework that describes CER research priorities that respond to the expressed public and federal needs for CER, and potential capacity for translation through Federal delivery systems and public private partnerships.

This shift in focus likely will result in research projects that do not address the clinical information needs of patients and providers, and instead lead to research that is used to restrict patient access to treatment options. This concern is heightened by recent commentary describing the link between CER and these types of access restrictions. For example, a recent Washington Post commentary says, What's known as comparative effectiveness research, which tracks what works and what doesn't, would also require outside boards directing doctors and hospitals about what procedures they could and couldn't use.

The language of your CER definition and strategic framework document is inconsistent with the goal of CER as described by HHS in its press release announcing the Coordinating Council. PIPC is opposed to the shift in focus to CER that restricts patient access to medical care or treatment choices. We strongly urge the Council to delete the language referencing decision-makers and federal needs as a CER focus. PIPC also urges you to revise the strategic framework so that it focuses on communication and dissemination strategies, rather than use of CER by government agencies.

Consistent with focus on patient and provider needs, we urge the Council to clarify that research will examine clinical outcomes, not cost-effectiveness. As reflected in the wide range of views expressed during the Coordinating Council listening sessions, inclusion of cost-effectiveness remains very controversial. Cost-effectiveness analysis traditionally has been a tool used by insurance companies and government payers to impose access restrictions based on broad population averages, and some of the most common CEA tools obscure differences in patient subgroups by including all patients in a single, average value determination. Particularly given the importance that the American Reinvestment and Recovery Act (ARRA) and the Coordinating Council have placed on considering the needs of patient subpopulations, PIPC recommends that the Council clarify that it will focus on clinical outcomes.

PIPC looks forward to continue working with the Council to foster good and fair processes that will allow future comparative clinical effectiveness research to improve the health and well being of all Americans.

Once again, thank you for the opportunity to participate in this transparent comment process.

Sincerely yours,

American Recovery and Reinvestment Act of 2009
Comparative Effectiveness Research
Health Resources and Services Administration Concept Paper

Research on the comparative effectiveness of different treatment options is critical for weighing the medical benefits and risks of each option and to learn which treatments work best for all Americans. The ARRA explicitly calls attention to the need to include minority populations and women not well represented in traditional study approaches. Moreover, as the Congressional Budget Office (CBO) Report[1] noted, clinical effectiveness research "requires a demonstration in real-world settings" where treatment choices are compared for a wide variety of participants across a range of practice settings.

HRSA programs provide direct health care to millions of American and reach into every corner of the country. The agency's health center program supports medical, oral and behavioral health services to uninsured and underinsured individuals through a nationwide network of community-based clinics and mobile medical vans. HRSA also funds medication and primary care to about half of the estimated number of people living with HIV/AIDS in the United States. The Maternal and Child Health Bureau in HRSA provides funds and expertise to improve the lives of millions of mothers and children, including children with special health care needs.

Rather than providing services directly, HRSA works through partnerships with community health centers and other safety net providers, State and local governments, academic institutions, professional associations, and other interested stakeholders. In the search for best practices of caring for these populations, HRSA has a variety of mechanisms to fund research projects and disseminate the results. Of particular importance is the fact that the topics emerge from HRSA's grantees and other partners in the practice community serving safety net populations. Consequently, there are built-in conduits for disseminating the research knowledge to the providers and patients for whom they are intended. For example, HRSA's grant program, Special Projects of Regional and National Significance (SPRANS) supports research, training, and a broad range of innovative strategies related to maternal and child health. This existing funding mechanism currently has approved but unfunded research proposals that fall under the rubric of comparative effectiveness research and focus on treating priority conditions prevalent in the target population.

HRSA programs and data have relevance for comparative effectiveness research in the following ways:

1. Study Populations: HRSA programs provide services to and collect clinical data on low-income populations, minority populations, the uninsured, children with special health care needs, individuals with limited English proficiency; and other special populations. More than one third of community health center patients are Hispanic, and 70% of health center patients are at or below the poverty level. The Title V Block Grant for Maternal and Child Health provided services to more than 29 million children in 2007; 11 million of these children were low income

[1] Congressional Budget Office. 2007. *Research on the Comparative Effectiveness of Medical Treatments: Issues and Options for an Expanded Federal Role.* http://www.cbo.gov/ftpdocs/88xx/doc8891/12-18-ComparativeEffectiveness.pdf (accessed March 9, 2009).

and also had Medicaid and SCHIP coverage. HRSA's Ryan White program provides care and treatment services to a substantially high proportion of minorities. In 2006, more than 70% of clients served by the Ryan White HIV/AIDS Program were people of color. The movement toward client level data in the Ryan White Program and the increasing use of electronic health records based data warehouses among health centers could provide information unavailable elsewhere for research on these vulnerable populations.

2. Clinical Best Practices and Systems of Care: In soliciting public input, the Institute of Medicine (IOM) Committee on Comparative Effectiveness Research Priorities describes alternative interventions in terms of comparators "which might include systems of care as well as specific interventions to address the prevention, diagnosis, treatment, monitoring or delivery of care." HRSA's orientation towards alternative interventions often focuses on comparing differing approaches to find what is most efficacious in helping high risk populations adhere to treatment regimens through differing approaches to case coordination services as well as behavioral approaches. Research can also focus on specific aspects of systems of care that influence treatment interventions in safety net clinical settings. An aspect of this is the need to develop rigorous methods of incorporating cultural competence variables into research designs.

Another focus which should merit expansion involves special populations that often are not addressed in preventive guidelines; a 2008 IOM Report[2] notes that the US Preventive Services Task Force (USPSTF) has concluded that for almost 40% of their preventive service recommendations, there is insufficient evidence for specific subpopulations. Research is needed to examine under what circumstances alternative screening patterns compared to usual practice are warranted if the nation is to close health disparities gaps.

3. CER Infrastructure: HRSA relies on registries and distributed clinical research data networks that have emerged as a byproduct of its various program missions. In some cases, established mechanisms have backlogs of relevant CER studies that could be accelerated and enhanced (e.g., Emergency Services for Children, American Academy of Pediatrics). In other cases, additional resources could be successfully deployed to capitalize on existing relationships and experience to build capacity (Community Health Center Research networks). In some instances HRSA maintains registries such as in the area of Transplantation that are essential for other OPDIVs that fund clinical research.

The development of analytic techniques for utilizing clinical databases efficiently and appropriately for CER is another dimension of infrastructure building. HRSA proposes to work with other OPDIVs to ensure that there is an appropriate investment in the development of methodologies and strategies for extracting and analyzing data from electronic clinical databases and patient registries.

4. Dissemination: Following the completion of rigorous research activities in comparative effectiveness, the results must be communicated and disseminated to the practice community for use in making decisions for treatment and care. Translating findings into practice requires the dissemination and integration of the clinical evidence from the best systematic research with

[2] IOM (Institute of Medicine). 2008. *Knowing What Works in Health Care: A Roadmap for the Nation.* Washington, D.C.: The National Academies Press.

individual clinical expertise in the practice setting. The broad range of HRSA programs and initiatives provides a valuable opportunity for comparative effectiveness research with the potential for Department wide collaboration, and HRSA's close ties to communities of practice greatly facilitates the translation of research results into practice in the clinical setting.

An example of a mechanism HRSA uses to disseminate findings is the AIDS Education and Training Centers (AETC) Program. The Ryan White HIV/AIDS Program supports a network of 11 regional centers and more than 130 associated sites that conduct targeted, multidisciplinary education and training programs for health care providers treating people living with HIV/AIDS. Rapid dissemination of late-breaking advances in treatment, changes to treatment guidelines, and critical review of patient education materials is provided through a cooperative agreement with the National Quality Center.

Specific Areas of Study

Emergency Medical Services for Children (EMSC): The EMSC Program supports a multi-institutional network for research in pediatric emergency medicine in the prevention, treatment, and management of acute illnesses and injuries in children and youth in all phases of emergency medical care. Starting in 2001, the Emergency Medical Services for Children (EMSC) Program awarded four competitive cooperative agreements to academic medical centers through a competitive funding mechanism known as the Network Development Demonstration Project (NDDP). These cooperative agreements form the Pediatric Emergency Care Applied Research Network (PECARN), the first federally-funded, multi-institutional network for research in pediatric emergency medicine.

PECARN's goal is to conduct meaningful and rigorous multi-institutional research into the prevention and management of acute illnesses and injuries in children and youth across the continuum of emergency medicine health care. PECARN has several projects that fall within the framework of comparative effectiveness research:

- Decreasing unnecessary use of head CT scans in children after blunt head trauma: Comparative effectiveness of computer based decision support to standard education strategy.
- Comparative analysis of progesterone for treatment of serious traumatic brain injuries (TBI) in children to standard treatment.
- Formation of a Patient Safety Collaborative to reduce medication errors in the Emergency Department.

Pediatric Research in Office Settings (PROS) Network: PROS is a national practice-based research network of primary care practitioners who care for children. Founded by the American Academy of Pediatrics, PROS conducts both observational studies and clinical trials on a wide variety of topics important to the health of U.S. children. PROS is in a unique position to carry out highly generalizable pediatric comparative effectiveness research because participating practices and clinic sites are not part of a single health care system, but are spread across all fifty states, the District of Columbia, the Commonwealth of Puerto, and several Canadian provinces.

Network practices and clinics around the country represent a substantial opportunity to examine the comparative effectiveness of various therapies and preventive strategies in child health, and in particular, those strategies that EHRs might uniquely facilitate. An estimated 20% of the 1800 clinicians at the 750 PROS practice sites currently have electronic health records (EHRs), with an accelerating number making the change each year. As a program of the American Academy of Pediatrics, PROS has a proven track record of building ancillary infrastructure to address new areas of research, and is in an ideal position to disseminate the findings of its research and influence both guidelines and policy.

PROS will undertake a stepwise process to build an EHR-based comparative effectiveness research infrastructure. Steps will involve formal up-to-date assessment of EHR use and planned use among network practices. The EHR subnetwork (PROS-EHR) will be recruited from practices that use EHR systems from a limited number of vendors (estimated at five) willing to collaborate with the network. PROS-EHR will be initially constructed around a project to test

the comparative effectiveness of different strategies to yield up-to-date immunization status among patients less than two years of age.

Autism and Other Developmental Disabilities: HRSA grants support Autism Intervention Research Networks to develop evidence-based guidelines, conduct research on interventions, and disseminate results to clinicians and other health professionals. The Autism Treatment Network (ATN) was established in 2005 to provide the clinical evidence to improve care and outcomes for children and adolescents with ASD. The Network, along with activities such as guideline development and dissemination, is proceeding with two research studies. The first is a parent-mediated joint engagement intervention for young children with ASD. The second is a study of peer relationships at school for younger elementary school aged children with high functioning ASD. The resulting evidence will be used to develop guidelines and tools that will inform practitioners, and disseminate findings to the broader community of families and primary care physicians.

The Network proposes two significant additional comparative effectiveness research aims comparing standard treatment to experimental treatment: 1) an alternating treatment design for non-responders to early intervention for study number one above, and 2) a novel joint engagement/play intervention for school-aged low functioning children with ASD.

Healthy Start: The Healthy Start Program is an initiative mandated to reduce the rate of infant mortality and improve perinatal outcomes through grants to project areas with high annual rates of infant mortality in one or more subpopulations. The program focuses on the contributing factors which research shows influence the perinatal trends in high-risk communities.

All 99 Healthy Start projects provide postpartum depression counseling services, through varied treatment modalities that include individual, group therapy and client support groups. A scarcity of treatment providers and long waiting lists for treatment have prompted projects to provide more services in-house, but the effectiveness of many of the therapeutic interventions have not been adequately evaluated. The program is in an ideal position to examine the effectiveness of different treatment interventions for postpartum depression. The effectiveness of mental health support networks would be compared with treatment services provided by the traditional nurse-counselor therapists.

Community Health Center program: There has been a history of collaborative practice based clinical research projects among consortia of health center clinical leaders working with academically based researchers. In the past, HRSA developed a data warehouse through the Sentinel Centers Network (SCN) program. Built on the practice-based research network (PBRN) model, the network has data from a nationally representative network of primary care service delivery sites serving vulnerable populations and has detailed data on patients, encounters, and practitioners that could be used for comparative effectiveness research and quality improvement efforts. These networks and warehouses have been limited in number due to lack of sufficient funding. However, with the growing adoption of Electronic Health Records (EHRs), Community Health Centers could today more easily participate in such research. Health Center Controlled Networks (HCCNs) support the creation, development, and operation of networks of safety net providers to improve effectiveness and clinical quality in Federally Qualified Health

Centers (FQHCs). There are high levels of collaboration among network members, and networks engage in a range of activities, from sharing protocols and guidelines for clinical treatment among collaborators to working together to develop infrastructure.

There are data warehouses now present in some HCCNs that hold great promise for analyzing detailed, longitudinal clinical data. To cite an example of how these resources could be deployed, information from EHRs and data warehouses could be used to examine Preventative Task Force recommendations and for comparing alternative combinations of services that could reduce disparities.

In addition, to capitalizing on health center databases, HRSA could build on the human capital that is a product of many years of organized Patient Care Collaboratives. These have aspired to: 1) generate and document improved health outcomes for the underserved populations; 2) transfer knowledge to promote positive breakthrough changes; and 3) develop infrastructure, expertise, and leadership to support and drive improved health, access, and cost outcomes. Collaborative participation has been successfully implemented in over 500 health centers nationwide to share and analyze data to improve the care of patients with asthma, cancer, cardiovascular disease, diabetes, and depression. This represents an opportunity to generate comparative effectiveness research that has enhanced capability to be rapidly disseminated in the places where it is most needed.

Electronic Client-based Records in the HIV/AIDS Bureau: The CBO Report noted that electronic health records could facilitate effectiveness research by providing additional information about patients and their health histories. The HIV/AIDS Bureau is moving toward client level data that are stored electronically as follows:

1) HRSA has developed CAREWare, an electronic health services information system for Ryan White HIV/AIDS program grantees and providers. CAREWare is a free, scalable software system for managing and monitoring HIV clinical and supportive care, using standard code sets, and includes a generic HL7 lab interface to receive/transmit lab data. This electronic system can be used to connect a network of clinics to monitor care, analyze patient outcomes and use clinical data to engage in evidence-based care. HRSA provides a wide range of technical assistance activities for this system, including online tutorials, webcasts, email listservs, conferences, newsletters and publications to provide the most current information to providers.

2) The HIV Research Network (HIVRN) is a consortium of 19 academically affiliated or community-based sites that provide primary and subspecialty care to HIV-infected individuals throughout the U.S. The Network is sponsored by the Agency for Healthcare Research and Quality (AHRQ), the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Office of AIDS Research (OAR) at the National Institutes of Health (NIH). Each participating site collects information on the clinical and demographic characteristics of their patients with HIV-infection, prescribed medications, frequency of outpatient visits, and number of inpatient admissions. The information is sent to a data

coordinating center at the Johns Hopkins School of Medicine, where the data are compiled and consolidated into a longitudinal database.

3) The HIV/AIDS Bureau is implementing a client level reporting system in 2009 to collect data on the characteristics of all Ryan White HIV/AIDS program funded grantees, their services providers, and clients served with program funds. Each client record includes socio-demographic status, medical, health, and support services received, and HIV clinical data.

HRSA supports the following two systems that provide national statistics on transplant recipients through which agencies fund scientific research: 1) The **Scientific Registry of Transplant Recipients (SRTR),** a longitudinal national database of transplantation statistics supporting the ongoing evaluation of the scientific and clinical status of solid organ transplantation, including kidney, heart, liver, lung, intestine, and pancreas. The SRTR contains current and past information about the full continuum of transplant activity, from organ donation and waiting list candidates to transplant recipients and survival statistics. This information is used to help develop evidence-based policy and to support analysis of transplant programs and Organ Procurement Organizations. 2) The **Stem Cell Therapeutic Outcomes Database (SCTOD),** containing outcomes data on all allogeneic transplants in the United States, related and unrelated, and data on individuals with a marrow toxic injury. The SCTOD system uses electronic data exchange between transplant centers and the Center for International Blood and Marrow Transplant Research, and work is ongoing with NCI's cancer data standards repository (caDSR) such that all data exchanged will comply with a national data standard.

From: Lapan, Jarel (OS)
Sent: Wednesday, March 18, 2009 7:37 PM
To: Clancy, Carolyn M (AHRQ); Valuck, Thomas B (CMS); Nabel, Elizabeth (NIH/NHLBI) [E]; Hunt, David R (OS); Goodman, Jesse L (FDA); Haddix, Anne C. (CDC); Scanlon, Jim (OS); Delany, Peter (SAMHSA); Graham, Garth (HHS/OPHS); Marge, Michael (OS); Tanden, Neera (OS); Parham Hopson, Deborah (HRSA); Ezekiel_j._Emanuel@omb.eop.gov; Joel.kupersmith@va.gov
Cc: Childress, Mark (OS); Corr, Bill (OS); Lambrew, Jeanne (OS); Conway, Patrick H (OS); Backus, Jenny (OS)
Subject: Federal Coordinating Council

On behalf of the Mark Childress, the Chief of Staff, I am informing you that you will be announced tomorrow as a member of the Federal Coordinating Council for Comparative Effectiveness Research. We look forward to your contribution to the central mission of the council: coordinating research across the government to ensure maximum effectiveness of the new robust federal investment. Patrick Conway, who is cc'ed on this note, will be the staff director for the Council and will be in touch regarding the first meeting. We are going to be holding a public listening session on April 14th as well.

We do expect press inquiries regarding the Council and ask that you direct them to Jenny Backus at ASPA.

Meanwhile, thank you again for participation.

All the best,
Jarel

Ps. We were unable to track down an email for Micahel Kilpatrick, if someone has his contact info please forward this note to him.
***
Jarel LaPan
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From: Hunt, Lauren (OS)
Sent: Thursday, March 19, 2009 3:00 PM
To: Lambrew, Jeanne (OS); Clancy, Carolyn M (AHRQ); Goldstein, Naomi (ACF); Millman, Mike (HRSA); Kington, Raynard (NIH/OD) [E]; Henry, Diana (AHRQ); Jones, Carla (AHRQ); Monarque, Brenda (NIH/OD) [E]; Willis, Patricia (CMS); Brooks, Karen (OS); Williams, Kristina (OS); Holt, Yolonde P. (CDC); Gazdik, Tanya (HRSA); Ward, Connie (OS); Valuck, Thomas B (CMS); Diggs, Patricia (OS); Johnson, Asara (OS); Engel, Elizabeth (OS); Spencer, Lorine M. (CDC); Crump, Debbie (SAMHSA); Munson, Aaron (OS); Smith, Monica (CDC); Bart, Sandra (CDC); Pazinski, Seth (OS); Petillo, Jay (OS); Sisk, Jane E. (CDC); Hunt, David R (OS); Huttinger, Alexandra (HRSA); Cochran, Norris (OS); Devoss, Liz (OS); Goldstein, Mitchell (OS); Richardson, Michele N (OS); Palm, Andrea (OS); Scanlon, Jim (OS); Tanden, Neera (OS); Enomoto, Kana (SAMHSA); Church, Richard M. (IHS); Wiggins, Cliff N. (IHS); Bartley, Paul S (PSC); Haddix, Anne C. (CDC); Goodman, Jesse L (FDA); Kolodner, Robert (OS); Jackson, Karen Y (CMS); Carlini, Elizabeth (SAMHSA); Brand, Marcia (HRSA); Parham Hopson, Deborah (HRSA); Wood, Gretchen (NIH/OD) [E]; Rothwell, Charles J. (CDC); Hodes, Richard (NIH/NIA) [E]; Skirboll, Lana (NIH/OD) [E]; Nabel, Elizabeth (NIH/NHLBI) [E]; Kendrick, Kathleen (AHRQ); Delany, Peter (SAMHSA); Conway, Patrick (NIH/NCI) [F]; Acton, Kelly J. (IHS); Cullen, Theresa (IHS); Slutsky, Jean R (AHRQ); Woodcock, Janet (FDA); Williams, Dennis (OS); Funston, Robin (OS); Elder, Mark (OS); Lum, Ben (OS); Handley, Elisabeth A (FDA)
Cc: Bennett, Jason (OS); Roos, Paola S (OS); Zucker, Phyllis M (AHRQ); Hawkins, Jamar (OS)
Subject: Announcement of ARRA Federal Coordinating Council

A note from Carolyn Clancy to the Comparative Effectiveness subgroup:

As you know, ARRA requires that members of the Federal Coordinating Council be selected by 3/19/09; the press announcement is posted at http://www.hhs.gov/news/press/2009pres/03/20090319a.html. Many people expressed strong interest in participating in the Council, but with a limit of 15 members it was not possible to name all highly knowledgeable individuals with interest and expertise.

The Council will make recommendations to the Secretary regarding the $400 million to be allocated at her discretion – and we have discussed the importance of holding multiple listening sessions to obtain input from a broad array of stakeholders. Consistent with this focus on transparency and inclusiveness, you are all welcome to attend Council meetings and will be notified of specific times.

Our next subgroup meeting will be next week. I look forward to our continued discussions.

Carolyn

Lauren R. Hunt
Policy Coordinator
Office of the Secretary, IOS/ES
Department of Health and Human Services
202.205.5446

From: Hunt, Lauren (OS)
Sent: Tuesday, March 31, 2009 11:13 AM
To: Clancy, Carolyn M (AHRQ); Henry, Diana (AHRQ); Jones, Carla (AHRQ); Conway, Patrick H (OS); Reiser, Margaret (OS); Delany, Peter (SAMHSA); Goodman, Jesse L (FDA); Graham, Garth (HHS/OPHS); Haddix, Anne C. (CDC); Parham Hopson, Deborah (HRSA); Hunt, David R (OS); Lambrew, Jeanne (OS); Marge, Michael (OS); Watson, Lee A (OS); Nabel, Elizabeth (NIH/NHLBI) [E]; Scanlon, Jim (OS); Williams, Kristina (OS); Tanden, Neera (OS); Valuck, Thomas B (CMS); Jackson, Karen Y (CMS); Ezekiel_J._Emanuel@omb.eop.gov; EBafford@OMB.eop.gov; Michael.Kilpatrick@tma.osd.mil; Karen.soto.ctr@tma.osd.mil; Joel.Kupersmith@va.gov; Nazneen.mama@va.gov; Smith, Monica (CDC); Bart, Sandra (CDC); Hennessy, Kevin (SAMHSA); Mercadel, Acesa (CDC); Hayes, Leslee M (SAMHSA); Lewellyn, Marsha (HRSA); Munson, Aaron (OS); Burke, Julie (NIH/FIC) [E]; Wells, Connie (NIH/NHLBI) [E]; Hall, Renee (OS); Susan.Cohen@fda.hhs.gov
Cc: Wiggins, Cliff N. (IHS); Engel, Elizabeth (OS); Backus, Jenny (OS); Papas, Nicholas W (OS); Parekh, Anand (OS); Galson, Steven K (OS); Lauren_aronson@who.eop.gov; Robert_Kocher@who.eop.gov; jcrowley@who.eop.gov; hhigginbottom@who.eop.gov; crouse@cea.eop.gov; jabraham@cea.eop.gov; Hunt, Lauren (OS); Hawkins, Jamar (OS); Shea, Maureen (OS); Roos, Paola S (OS)
Subject: MEETING ANNOUNCEMENT: Federal Coordinating Council on Comparative Effectiveness

Please confirm attendance*

MEETING ANNOUNCEMENT:

SUBJECT: **Next Meetings of the Federal Coordinating Council on Comparative Effectiveness**

AGENDA: **TBD**

DATE: **Friday, April 10**
Friday, May 1
Friday, May 29
Friday, June 12
Friday, June 26
Friday, July 10

TIME: **1:30 PM – 3:00 PM**
LOCATION: **Executive Secretary's Conference Room, 614-H**
The Hubert H. Humphrey Building
200 Independence Avenue, S.W.

Call-in # 866-762-7985; participant passcode: 6866388

INVITED PARTICIPANTS

Carolyn Clancy, AHRQ.
Patrick Conway, ASPE
Peter Delany, SAMHSA
Jesse Goodman, FDA
Garth Graham, OPHS
Anne Haddix, CDC
Deborah Hopson, HRSA
David Hunt, ONC
Michael Marge, OD
Elizabeth Nabel, NIH
James Scanlon, ASPE
Neera Tanden, OS
Tom Valuck, CMS
Ezekiel Emanuel, OMB
Michael Kilpatrick, DoD
Joel Kupersmith, VA

FOR FURTHER INFORMATION: Please contact Lauren Hunt at Lauren.hunt@hhs.gov or 202.205.5446

Lauren R. Hunt
Policy Coordinator
Office of the Secretary, IOS/ES
Department of Health and Human Services
202.205.5446

From: Hunt, Lauren (HHS/IOS)
Sent: Tuesday, March 31, 2009 1:26 PM
To: Hunt, Lauren (HHS/IOS); Clancy, Carolyn M. (AHRQ); Henry, Diana (AHRQ); Jones, Carla (AHRQ); Conway, Patrick H. (HHS/ASPE); Reiser, Margaret (HHS/ASPE); Delany, Peter (SAMHSA/OAS); Goodman, Jesse L. (FDA); Graham, Garth (HHS/OPHS); Haddix, Anne (CDC/OD/OSI); Parham Hopson, Deborah (HRSA); Hunt, David R. (HHS/ONC); Lambrew, Jeanne (HHS/IOS); Marge, Michael (HHS/OS); Watson, Lee (HHS/OS); Nabel, Elizabeth (NIH/NHLBI) [E]; Scanlon, Jim (HHS/ASPE); Williams, Kristina (HHS/ASPE); Tanden, Neera (HHS/IOS); Valuck, Thomas B. (CMS/CMM); Jackson, Karen Y. (CMS/CMM); 'Ezekiel_J._Emanuel@omb.eop.gov'; 'EBafford@OMB.eop.gov'; 'Michael.Kilpatrick@tma.osd.mil'; 'Karen.soto.ctr@tma.osd.mil'; 'Joel.Kupersmith@va.gov'; 'Nazneen.mama@va.gov'; Smith, Monica A. (CDC/OD/OSI) (CTR); Bart, Sandra (CDC/OD/OSI) (CTR); Hennessy, Kevin (SAMHSA/OA); Mercadel, Acesa (CDC/COTPER/OD) (CTR); Hayes, Leslee M. (SAMHSA/OAS); 'Marsha.Lewellyn@HRSA.hhs.gov'; Munson, Aaron (HHS/); Burke, Julie (NIH/FIC) [E]; Wells, Connie (NIH/NHLBI) [E]; Hall, Renee (HHS/OPHS); 'Susan.Cohen@fda.hhs.gov'
Cc: Wiggins, Cliff N. (IHS/HQE); Engel, Elizabeth (HHS/IOS); Backus, Jenny (HHS/IOS); Papas, Nicholas (HHS/IOS); Parekh, Anand (HHS/OPHS); Galson, Steven (HHS/OPHS); 'Lauren_aronson@who.eop.gov'; 'Robert_Kocher@who.eop.gov'; 'jcrowley@who.eop.gov'; 'hhigginbottom@who.eop.gov'; 'crouse@cea.eop.gov'; 'jabraham@cea.eop.gov'; Hawkins, Jamar (HHS/OS); Shea, Maureen (HHS/IOS/ES); Roos, Paola (HHS/IOS); 'sherry.wolozyn@va.gov'; Holland, Howard (AHRQ); Goforth, Prudence (HHS/ASPA); Migdail, Karen J. (AHRQ)
Subject: MEETING ANNOUNCEMENT: Listening Session for the Federal Coordinating Council on Comparative Effectiveness

Please confirm attendance*

MEETING ANNOUNCEMENT:

SUBJECT: Listening Session for the Federal Coordinating Council on Comparative Effectiveness

AGENDA: TBD

DATE: **Tuesday, April 14**

TIME: **2:00 – 5:00 PM**

LOCATION: **The Hubert H. Humphrey Building, Room 800**
200 Independence Avenue, S.W.

FOR FURTHER INFORMATION: Please contact Lauren Hunt at Lauren.hunt@hhs.gov or 202.205.5446

Lauren R. Hunt
Policy Coordinator
Office of the Secretary, IOS/ES
Department of Health and Human Services
202.205.5446

From: Conway, Patrick H (OS)
Sent: Tuesday, April 07, 2009 5:06 PM
To: Clancy, Carolyn M (AHRQ); Delany, Peter (SAMHSA); Goodman, Jesse L (FDA); Graham, Garth (HHS/OPHS); Haddix, Anne C. (CDC); Parham Hopson, Deborah (HRSA); Hunt, David R (OS); Marge, Michael (OS); Nabel, Elizabeth (NIH/NHLBI) [E]; Scanlon, Jim (OS); Tanden, Neera (OS); Valuck, Thomas B (CMS); Ezekiel_J._Emanuel@omb.eop.gov; Michael.Kilpatrick@tma.osd.mil; Joel.Kupersmith@va.gov
Cc: Backus, Jenny (OS); Papas, Nicholas W (OS); Migdail, Karen J (AHRQ); Holland, Howard (AHRQ); Lambrew, Jeanne (OS); Conway, Patrick H (OS)
Subject: Listening Session

Federal Coordinating Council Members,

The website with registration link for the public listening session on April 14th is up as of this afternoon. The link is: http://www.hhs.gov/recovery/programs/cer/index.html. A HHS press release and federal register notice will also help publicize the session. I wanted to highlight a few important points for the listening session which we will discuss in more detail on Friday:

1. The Listening Session is from 2-5pm on Tuesday April 14th in Humphrey Room 800. Each of you will have namecard. Please let Lauren Hunt and I know if you cannot attend and plan to send your alternate.
2. Please share the above link with individuals and organizations that might want to share their input on comparative effectiveness research for the benefit of the Council. This link can and should be shared widely. It allows both submissions of comments online as well as self-nomination to speak at the session. If you have specific people or organizations that you want to hear from, encourage them to nominate themselves to speak.
3. The planned format for the session will be short introduction/background on Council and CER followed by three panels of 10 speakers (3 minutes for each speaker). Council members will be able to ask questions of panel-members after each panel.

I look forward to seeing you at 1:30pm on Friday (10th) for the next Council working meeting. We will send out an agenda shortly and documents for meeting on Thursday.

patrick

From: Hunt, Lauren (HHS/IOS)
Sent: Wednesday, April 08, 2009 9:47 AM
To: Hunt, Lauren (HHS/IOS); Clancy, Carolyn M. (AHRQ); Henry, Diana (AHRQ); Jones, Carla (AHRQ); Conway, Patrick H. (HHS/ASPE); Reiser, Margaret (HHS/ASPE); Delany, Peter (SAMHSA/OAS); Goodman, Jesse L. (FDA); Graham, Garth (HHS/OPHS); Haddix, Anne (CDC/OD/OSI); Parham Hopson, Deborah (HRSA); Hunt, David R. (HHS/ONC); Lambrew, Jeanne (HHS/IOS); Marge, Michael (HHS/OS); Watson, Lee (HHS/OS); Nabel, Elizabeth (NIH/NHLBI) [E]; Scanlon, Jim (HHS/ASPE); Williams, Kristina (HHS/ASPE); Tanden, Neera (HHS/IOS); Valuck, Thomas B. (CMS/CMM); Jackson, Karen Y. (CMS/CMM); 'Ezekiel_J._Emanuel@omb.eop.gov'; 'EBafford@OMB.eop.gov'; 'Michael.Kilpatrick@tma.osd.mil'; 'Karen.soto.ctr@tma.osd.mil'; 'Joel.Kupersmith@va.gov'; 'Nazneen.mama@va.gov'; Smith, Monica A. (CDC/OD/OSI) (CTR); Bart, Sandra (CDC/OD/OSI) (CTR); Hennessy, Kevin (SAMHSA/OA); Mercadel, Acesa (CDC/COTPER/OD) (CTR);

Hayes, Leslee M. (SAMHSA/OAS); 'Marsha.Lewellyn@HRSA.hhs.gov'; Munson, Aaron (HHS/); Burke, Julie (NIH/FIC) [E]; Wells, Connie (NIH/NHLBI) [E]; Hall, Renee (HHS/OPHS); 'Susan.Cohen@fda.hhs.gov'; Millman, Mike (HRSA); 'Wolozyn, Sherry (EG&G)'
Cc: Wiggins, Cliff N. (IHS/HQE); Engel, Elizabeth (HHS/IOS); Backus, Jenny (HHS/IOS); Papas, Nicholas (HHS/IOS); Parekh, Anand (HHS/OPHS); Galson, Steven (HHS/OPHS); 'Lauren_aronson@who.eop.gov'; 'Robert_Kocher@who.eop.gov'; 'jcrowley@who.eop.gov'; 'hhigginbottom@who.eop.gov'; 'crouse@cea.eop.gov'; 'jabraham@cea.eop.gov'; Hawkins, Jamar (HHS/OS); Shea, Maureen (HHS/IOS/ES); Roos, Paola (HHS/IOS); 'brian.alexander2@va.gov'
Subject: AGENDA: April 10 Federal Coordinating Council on Comparative Effectiveness

Attached to this message is the agenda for the Council's next meeting on Friday, April 10. Please also note the room change to 425-A.

If you have received this as a non-council member, please let us know if you want to be removed from this email distribution list.

From: Conway, Patrick H (OS)
Sent: Thursday, April 09, 2009 3:50 PM
To: Hunt, Lauren (OS); Clancy, Carolyn M (AHRQ); Henry, Diana (AHRQ); Jones, Carla (AHRQ); Reiser, Margaret (OS); Delany, Peter (SAMHSA); Goodman, Jesse L (FDA); Graham, Garth (HHS/OPHS); Haddix, Anne C. (CDC); Parham Hopson, Deborah (HRSA); Hunt, David R (OS); Lambrew, Jeanne (OS); Marge, Michael (OS); Watson, Lee A (OS); Nabel, Elizabeth (NIH/NHLBI) [E]; Scanlon, Jim (OS); Williams, Kristina (OS); Tanden, Neera (OS); Valuck, Thomas B (CMS); Jackson, Karen Y (CMS); 'Ezekiel_J._Emanuel@omb.eop.gov'; 'EBafford@OMB.eop.gov'; 'Michael.Kilpatrick@tma.osd.mil'; 'Karen.soto.ctr@tma.osd.mil'; 'Joel.Kupersmith@va.gov'; 'Nazneen.mama@va.gov'; Smith, Monica (CDC); Bart, Sandra (CDC); Hennessy, Kevin (SAMHSA); Mercadel, Acesa (CDC); Hayes, Leslee M (SAMHSA); Lewellyn, Marsha (HRSA); Munson, Aaron (OS); Burk, Judith (NIH/NHLBI) [E]; Wells, Connie (NIH/NHLBI) [E]; Hall, Renee (OS); 'Susan.Cohen@fda.hhs.gov'; Millman, Mike (HRSA); 'Wolozyn, Sherry (EG&G)'
Cc: Wiggins, Cliff N. (IHS); Engel, Elizabeth (OS); Backus, Jenny (OS); Papas, Nicholas W (OS); Parekh, Anand (OS); Galson, Steven K (OS); 'Lauren_aronson@who.eop.gov'; 'Robert_Kocher@who.eop.gov'; 'jcrowley@who.eop.gov'; 'hhigginbottom@who.eop.gov'; 'crouse@cea.eop.gov'; 'jabraham@cea.eop.gov'; Hawkins, Jamar (OS); Shea, Maureen (OS); Roos, Paola S (OS); 'brian.alexander2@va.gov'
Subject: Materials for April 10 Federal Coordinating Council on Comparative Effectiveness

Federal Coordinating Council Members and invited guests,

Attached are the materials for tomorrow's Council Meeting:

1. Agenda (same as previous)
2. CER background, framework, and listening session format
3. AHRQ CER Overview
4. NIH CER Overview
5. VA CER Overview

As FYI, I am also attaching per some members request, the following 3 documents as background. We will not go over them at the meeting but they may be useful.

1. CBO Report on Comparative Effectiveness
2. CER Definitions and Domestic examples in public and private sector
3. International examples of CER in practice.

I look forward to seeing those who can attend tomorrow at 1:30pm in 425-A. Please let me know if you have questions or concerns. Thanks.

patrick

Patrick Conway, MD, MSc
Chief Medical Officer
OS/ASPE
202-690-7388

From: Hunt, Lauren (HHS/IOS)
Sent: Monday, April 13, 2009 1:47 PM
To: Hunt, Lauren (HHS/IOS); Clancy, Carolyn M. (AHRQ); Henry, Diana (AHRQ); Jones, Carla (AHRQ); Conway, Patrick H. (HHS/ASPE); Reiser, Margaret (HHS/ASPE); Delany, Peter (SAMHSA/OAS); Goodman, Jesse L. (FDA); Graham, Garth (HHS/OPHS); Haddix, Anne (CDC/OD/OSI); Parham Hopson, Deborah (HRSA); Hunt, David R. (HHS/ONC); Lambrew, Jeanne (HHS/IOS); Marge, Michael (HHS/OS); Watson, Lee (HHS/OS); Nabel, Elizabeth (NIH/NHLBI) [E]; Scanlon, Jim (HHS/ASPE); Williams, Kristina (HHS/ASPE); Tanden, Neera (HHS/IOS); Valuck, Thomas B. (CMS/CMM); Jackson, Karen Y. (CMS/CMM); 'Ezekiel_J._Emanuel@omb.eop.gov'; 'EBafford@OMB.eop.gov'; 'Michael.Kilpatrick@tma.osd.mil'; 'Karen.soto.ctr@tma.osd.mil'; 'Joel.Kupersmith@va.gov'; 'Nazneen.mama@va.gov'; Smith, Monica A. (CDC/OD/OSI) (CTR); Bart, Sandra (CDC/OD/OSI) (CTR); Hennessy, Kevin (SAMHSA/OA); Mercadel, Acesa (CDC/COTPER/OD) (CTR); Hayes, Leslee M. (SAMHSA/OAS); 'Marsha.Lewellyn@HRSA.hhs.gov'; Munson, Aaron (HHS/); Burk, Judith (NIH/NHLBI) [E]; Wells, Connie (NIH/NHLBI) [E]; Hall, Renee (HHS/OPHS); 'Susan.Cohen@fda.hhs.gov'; Millman, Mike (HRSA); 'brian.alexander2@va.gov'; Fuell, Tia (HHS/ASPE)
Cc: Wiggins, Cliff N. (IHS/HQE); Engel, Elizabeth (HHS/IOS); Backus, Jenny (HHS/IOS); Papas, Nicholas (HHS/IOS); Parekh, Anand (HHS/OPHS); Galson, Steven (HHS/OPHS); 'Lauren_aronson@who.eop.gov'; 'Robert_Kocher@who.eop.gov'; 'jcrowley@who.eop.gov'; 'hhigginbottom@who.eop.gov'; 'crouse@cea.eop.gov'; 'jabraham@cea.eop.gov'; Hawkins, Jamar (HHS/OS); Shea, Maureen (HHS/IOS/ES); Roos, Paola (HHS/IOS)
Subject: ADDITIONAL MEETINGS: Federal Coordinating Council on Comparative Effectiveness

In addition to those listed below, please hold the following dates/times for upcoming meetings of the Federal Coordinating Council:

Wednesday, May 6th 1:00 PM – 4:00 PM: Listening Session # 2 in Washington, DC
Wednesday, May 13th 1:00 PM – 4:00 PM: Listening Session # 3 in Midwestern city to be named later
Friday, June 5th from 1:30 PM – 3:00 PM: Federal Coordinating Council meeting in room 425A of Humphrey Building
Friday, June 19th from 1:30 PM – 3:00 PM: Federal Coordinating Council meeting in room 425A of Humphrey Building

Agendas and necessary documents will be circulated prior to these meetings.

We also plan to have a one-hour meeting/conference call to debrief after our first listening session during the week of April 20th. A date and time for this will be confirmed shortly.

Please feel free to contact me with any questions.

Lauren Hunt
202-205-5446

From: Hunt, Lauren (OS)
Sent: Tuesday, April 21, 2009 1:19 PM
To: Hunt, Lauren (OS); Clancy, Carolyn M (AHRQ); Henry, Diana (AHRQ); Jones, Carla (AHRQ); Conway, Patrick H (OS); Reiser, Margaret (OS); Delany, Peter (SAMHSA); Goodman, Jesse L (FDA); Graham, Garth (HHS/OPHS); Haddix, Anne C. (CDC); Parham Hopson, Deborah (HRSA); Hunt, David R (OS); Lambrew, Jeanne (OS); Marge, Michael (OS); Watson, Lee A (OS); Nabel, Elizabeth (NIH/NHLBI) [E]; Scanlon, Jim (OS); Williams, Kristina (OS); Tanden, Neera (OS); Valuck, Thomas B (CMS); Jackson, Karen Y (CMS); Ezekiel_J._Emanuel@omb.eop.gov; EBafford@OMB.eop.gov; Michael.Kilpatrick@tma.osd.mil; Karen.soto.ctr@tma.osd.mil; Joel.Kupersmith@va.gov; Smith, Monica (CDC); Bart, Sandra (CDC); Hennessy, Kevin (SAMHSA); Mercadel, Acesa (CDC); Hayes, Leslee M (SAMHSA); Lewellyn, Marsha (HRSA); Munson, Aaron (OS); Burk, Judith (NIH/NHLBI) [E]; Wells, Connie (NIH/NHLBI) [E]; Hall, Renee (OS); Susan.Cohen@fda.hhs.gov; Millman, Mike (HRSA); brian.alexander2@va.gov; Fuell, Tia (OS); margaret.cary@va.gov; madhulika.agarwal@va.gov; Pisner, Pamela E (FDA); Wolozyn, Sherry (EG&G)
Cc: Wiggins, Cliff N. (IHS); Engel, Elizabeth (OS); Backus, Jenny (OS); Papas, Nicholas W (OS); Parekh, Anand (OS); Galson, Steven K (OS); Lauren_aronson@who.eop.gov; Robert_Kocher@who.eop.gov; jcrowley@who.eop.gov; hhigginbottom@who.eop.gov; crouse@cea.eop.gov; jabraham@cea.eop.gov; Hawkins, Jamar (OS); Shea, Maureen (OS); Roos, Paola S (OS); Migdail, Karen J (AHRQ); Holland, Howard (AHRQ); Zimmerman, Jaime (AHRQ); Slutsky, Jean R (AHRQ); Kendrick, Kathleen (AHRQ)
Subject: CALENDAR UPDATE: Federal Coordinating Council on Comparative Effectiveness

Please note the following changes for upcoming listening sessions and meetings of the Federal Coordinating Council:

1) Listening Sessions
   a. We will NOT hold one on May 6th as previously mentioned
   b. # 2 on May 13th – outside of DC
   c. # 3 on June 10th – back in DC

2) Additional Working Meetings (all will be 1:30-3:00 PM in room 425A of Humphrey Building)
   a. Friday, May 8th
   b. Friday, June 5th
   c. Friday, June 19th

Feel free to contact me with any questions.

Thank you,
Lauren

From: Conway, Patrick H (OS)
Sent: Wednesday, May 06, 2009 12:34 PM
To: OS - FCC_Members
Cc: Poelman, John (OS); Hunt, Lauren (OS)
Subject: Listening session

Council Members,
We have confirmed the time and location for the Chicago Listening Session. It will be held at the **University of Illinois at Chicago Forum** from **2:30 pm – 5:30 pm CDT on Wednesday May 13th**. This venue meets our objective of holding a session outside the beltway and in a recognized community setting. We looked into multiple community setting locations (e.g. Rush, Public library, etc.) and there were no other closer locations available in the community. We apologize if late notice causes any issues but our contractor just confirmed and signed contract with location today.

The time and location presents some logistical issues that may shape your travel arrangements. Below is a summary. Please note that we will need to know whether you intend to stay the night in Chicago on either the 12th or the 13th by cob tomorrow.

LOCATION
University of Illinois at Chicago Forum
725 W Roosevelt Rd. (MC 126)
Chicago, IL 60608

FLIGHTS
The venue is located in Chicago proper and is a 45 minute taxi ride from Chicago O'Hare without traffic. You should plan for an hour if traveling immediately after the session ends. Direct flights back to the DC area depart around 7 pm and then around 9 pm however the 7 pm flights would likely not be possible to make. The 9 pm flights get into DC around 11:30 pm.

HOTEL
We will identify a hotel near the venue with government rates and make reservations for all those who request it for either May 12th or May 13th. We will need this information from you by Thursday COB if you intend to hold a room.

LOCAL TRANSPORTATION
A taxi ride from Chicago O'Hare to the venue will take 45 minutes without traffic and cost approximately $40.
Public transportation is available with a short walk to the venue but will take about 90 minutes.

Please let me know if any questions or issues. If you do need hotel, please include John Poelman in cc line as he is the Logistics Director for the Council and the Listening Sessions.

From: Parham Hopson, Deborah (HRSA)
Sent: Wednesday, May 06, 2009 3:54 PM
To: Conway, Patrick H. (HHS/ASPE)
Subject: CER

Patrick,

One last question from me today. I need to give some brief comments next week about the FCC and CER at the National Patient Advocate Foundation meeting. May I have a copy of your slides that you used at the first listening session – and may I use some of them next week? Thanks
DPH

Deborah Parham Hopson, PhD, RN, FAAN
Associate Administrator | HIV/AIDS Bureau | Health Resources and Services Administration | Department of Health and Human Services | 5600 Fishers Lane, Suite 7-05, Rockville, MD 20857 | dparhamhopson@hrsa.gov | 301-443-1993 | www.hrsa.hab.gov

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From: Conway, Patrick H (OS)
Sent: Wednesday, May 06, 2009 3:56 PM
To: Parham Hopson, Deborah (HRSA)
Subject: RE: CER
Sure. Here are slides – feel free to use.

From: Parekh, Hemangi [mailto:Hemangi.Parekh@i3global.com]
Sent: Wednesday, May 20, 2009 4:51 PM
To: Parham Hopson, Deborah (HRSA)
Cc: Dennen, Taylor; Poelman, John (OS); Moore, Carol; Parekh, Hemangi; Millman, Mike (HRSA); Queen, Susan G (HRSA)
Subject: Comparative Effectiveness Research Interview
Dear Deborah,
I am with the Lewin Group team conducting the inventories of comparative effectiveness research and CER data infrastructure for the Federal Council on Comparative Effectiveness Research. As John Poelman of the Office of the ASPE/Health Policy mentioned in his email to you last week, we have a very abbreviated time frame for collecting information on your programs and providing a report to the FCCCER.

I am contacting you in advance of calling you to schedule time for your interview. We will need 2 hours of your time to get the information from you that the FCCCER seeks. To make the best use of your time for the interview, we are enclosing the definition of CER provided in draft by the FCCCER (see attachment), as well as a working definition of CER Data Infrastructure we have provided to the FCCCER. These definitions are important to keeping our interview focused. Also for your preparation, we are attaching a summary of the list of topics that will be covered by the interview.

Please provide us with additional contact individuals from your agency in instances where you will have limited availability to respond.

Thank you for your assistance in this important process. Please call me (215.699.1935) or John Poelman (202.205.0329) if you have any questions.

Taylor Dennen, PhD

Vice President • i3 Pharma Informatics/Ingenix
580 Abbey Court Blue Bell, PA 19422
Direct: (215) 699 1935 • Cell: (267) 575 2411
Fax: (215) 699 1972

-----Original Message-----
From: Conway, Patrick H (OS)
Sent: Tuesday, June 09, 2009 8:36 PM
To: OS - FCC_Members
Subject: listening session
Council,
Attached is the list of selected panelists (3 sets of 8) for tomorrow's listening session. As a reminder, the session is from 12pm-3pm. The session will be at:
Embassy Suites Convention Center

Room: Capital Ballroom BCD
900 10th St. NW
Washington, DC 20001

If you cannot attend, please let us know who your alternate will be.
If you plan to call-in, please let us know.

As FYI, the following is phone/webcast info.
The phone number for Council members dialing in and those making comments is 1-888-469-9312, passcode 27955#.
Web cast is located at http://nmr.rampard.com/fcc/20090610/
The phone number for participants joining the session via conference call: 1-800-779-9312, passcode 7462188#. This line is for listening only.

Thanks.

patrick

-----Original Message-----
From: Conway, Patrick H (OS)
Sent: Thursday, June 11, 2009 6:48 PM
To: OS - FCC_Members
Subject: FCC meeting tomorrow

Attached are the materials for the Council meeting tomorrow at 1:30pm.
1. Agenda
2. Powerpoint
3. Revised definition and criteria for Council consideration based on listening session and significant online feedback (in track changes and no track). We will discuss this at meeting.
4. Minutes from last meeting

Please remember that we need any feedback on Council Report to Congress by COB tomorrow, friday, so report can go into clearance on Monday. Thanks.

patrick

From: Karmen Lewis [mailto:KLewis@blseamon.com]
Sent: Thursday, June 11, 2009 11:59 PM
To: Poelman, John (HHS/)
Cc: Conway, Patrick H. (HHS/ASPE)
Subject: FCC Comments

Hello John –

Attached please find the compilation of comments that were submitted via e-mail and Web. We have gathered 148 e-mailed submissions and 170 online submissions. As we discussed, please note that general formatting has been applied to the documents; however, BLS has not reviewed individual comments for content, grammar, or language.

Thank you, and please let me know if you have any questions
Best Regards,

Karmen R. Lewis
Project Manager
Phone: (301) 577-0244, ext. 38
Fax: (301) 577-5261
E-mail: klewis@blseamon.com
Web: www.blseamon.com

B L SEAMON
Connecting Global Communities

9001 Edmonston Road, Suite 200 | Greenbelt, MD 20770
Please consider the environment. Do you really need to print this e-mail?

From: Conway, Patrick H (OS)
Sent: Friday, June 12, 2009 10:49 AM
To: OS - FCC_Members
Subject: FCC Comments

Attached in zipped format due to size is the over 300 comments received regarding CER and the Federal Coordinating Council. The main themes are captured in the section in the appendix of our Report to Congress but we wanted to pass on the comments in their entirety to all Council members. We received comments via email, PDF, and though an online webpage. In the attached you will find two Word documents with the bulk of the comments submitted via email and the webpage (last two files named "emailed comments" and "FCC comments submitted by web". Some persons and organizations submitted multiple comments. Thanks.

Original Message-----
From: Conway, Patrick H (OS)
Sent: Thursday, June 18, 2009 8:14 PM
To: OS - FCC_Members
Subject: Council meeting tomorrow, friday, at 1:30

Please find attached:
1. Agenda
2. Powerpoint for discussion
3. Minutes from last meeting

I would guess that this meeting will be shorter than previous meetings and we will end early. Please let me know if you have any questions. Thanks.

patrick

From: Conway, Patrick H (OS)
Sent: Thursday, June 25, 2009 8:00 PM

To: OS - FCC_Members
Subject: FCC final report

Attached is final report from FCC that will be printed tomorrow so we can do Hill briefings and release on Monday. The printer will finish formatting and put cover on it. Thank you for all of your hard work and dedication to this effort!

From: Conway, Patrick H (OS)
Sent: Monday, June 29, 2009 5:35 PM
To: OS - FCC_Members
Subject: fyi

The final FCC report was released today and is attached in pdf format. We also briefed the Hill and it went well. Thanks.

From: Hunt, Lauren (HHS/IOS)
Sent: Wednesday, July 01, 2009 5:22 PM
To: Acton, Kelly J. (IHS/NPA); Bart, Sandra (CDC/OD/OSI) (CTR); Bartley, Paul (PSC/OD); Bennett, Jason (HHS/OS); Brand, Marcia (HRSA); Briss, Peter (CDC/CCEHIP/OD); Brooks, Karen (HHS/ASAM); Burk, Judith (NIH/NHLBI) [E]; Cabezas, Miriam (HHS/ASRT); Casale, Cecilia (AHRQ/OEREP/Priority Populations); Choucair, Jordana (HHS/OS); Church, Richard M. (IHS/HQE); Clancy, Carolyn M. (AHRQ); Cochran, Norris (HHS/ASRT); Cohen, Susan (FDA); Conway, Patrick H. (HHS/ASPE); Correa-de-Araujo, Rosaly (HHS/IOS); Crump, Debbie (SAMHSA/OA); Cullen, Theresa (IHS/HQE); Delany, Peter (SAMHSA/OAS); DeVoss, Liz (HHS/ASRT); Diggs, Patricia (HHS/ONC); Elder, Mark (HHS/ASRT); Engel, Elizabeth (HHS/IOS); Enomoto, Kana (SAMHSA/OA); Funston, Robin (HHS/ASRT); Gazdik, Tanya (HRSA); Goldstein, Mitchell (HHS/ASRT); Goldstein, Naomi (ACF); Goodman, Jesse L. (FDA); Goodrich, Kate (HHS/ASPE); Gracia, Nadine (HHS/IOS); Graham, Garth (HHS/OPHS); Haddix, Anne (CDC/OD/OSI); Handley, Elisabeth A. (FDA); Handrigan, Michael T. (HHS/ASPR/OPEO); Hawkins, Jamar (HHS/OS); Hennessy, Kevin (SAMHSA/OA); Henry, Diana (AHRQ); Hodes, Richard (NIH/NIA) [E]; Holt, Yolonde P. (CDC/OCOO/OSEP); Hunt, David R. (HHS/ONC); Hunt, Lauren (HHS/IOS); Huttinger, Alexandra (HRSA); Jones, Carla (AHRQ); Kendrick, Kathleen (AHRQ); Kington, Raynard (NIH/OD) [E]; Kolodner, Robert (HHS/ONC); Lambrew, Jeanne (HHS/IOS); Lipman, David (NIH/NLM/NCBI) [E]; Lum, Ben (HHS/ASRT); Miller, Scott (CDC/OD/OSI) (CTR); Millman, Mike (HRSA); Monarque, Brenda (NIH/OD) [E]; Munson, Aaron (HHS/); Nabel, Elizabeth (NIH/NHLBI) [E]; Palm, Andrea (HHS/IOS); Parekh, Anand (HHS/OPHS); Parham Hopson, Deborah (HRSA); Pazinski, Seth (HHS/ONC); Pereira, Esmeralda (HHS/ASPR/RPE); Petillo, Jay (HHS/ASPR/RPE); Poelman, John (HHS/); Queen, Susan G (HRSA); Rice, Patricia (SAMHSA); Richardson, Michele (HHS/ASRT); Rollins, Rochelle (HHS/OPHS); Roos, Paola (HHS/IOS); Rothwell, Charles J. (CDC/CCHIS/NCHS); Scanlon, Jim (HHS/ASPE); Shea, Maureen (HHS/IOS/ES); Sisk, Jane E. (CDC/CCHIS/NCHS); Skirboll, Lana (NIH/OD) [E]; Slutsky, Jean R. (AHRQ); Smith, Monica A. (CDC/OD/OSI) (CTR); Spencer, Lorine M. (CDC/OD/OSI); Stickell, Michele W. (CMS/CMM); Tanden, Neera (HHS/IOS); Thompson, Donna (HHS/ONC); Valuck, Thomas B. (CMS/CMM); VanLare, Jordan (HHS/ASPE); Ward, Connie (HHS/ASRT); Ware, Jayne C. (FDA); Wasserman, Jill; Wells, Connie (NIH/NHLBI) [E]; Wiggins, Cliff N. (IHS/HQE); Williams, Dennis (HHS.OS); Williams, Kristina (HHS/ASPE); Willis, Patricia (CMS); Wong, Hui-Hsing (HHS/ASPE); Wood, Gretchen (NIH/OD) [E]; Woodcock, Janet (FDA); Zarin, Deborah (NIH/NLM/LHC) [E]
Subject: CER proposals for tomorrow

Attached are additional documents we will discuss during tomorrow's meeting. Including the proposal documents sent this morning, you should now have:

1. Creation of an All-Payor, All-Claims Database to Enable Innovative Comparative Effectiveness Research
2. Dissemination and Translation of Comparative Effectiveness for Patients and Health Consumers through the Internet and Other Media
3. Dissemination of CER to Physicians and other Providers through Partnerships with Existing Online Medical Information Resources and Academic Detailing Pilot
4. Expanding Chronic Care Model Networks and Registries for Patients with Multiple Chronic Conditions
5. revised OMH proposal: Reducing Oral Health Disparities
6. new OMH proposal: Improving Patient/Provider Health Information
7. revised AHRQ proposal: Assessing and Accelerating Implementation Strategies in AHRQ Networks
8. revised AHRQ proposal: Clinically-Enhanced State Data for Analysis and Tracking of Comparative Effectiveness Impact
9. revised AHRQ proposal: Grants to Expand State All-Claims Data

10. revised HRSA proposals (4 proposals in one document)

We'll meet at 11am in room 425A.

CONFERENCE LINE: 1.866.762.7985; passcode: 686.6388

Lauren R. Hunt
Policy Coordinator
Office of the Secretary, IOS/ES
Department of Health and Human Services
202.205.5446

From: Hunt, Lauren (OS)
Sent: Thursday, July 02, 2009 10:41 AM
To: Hunt, Lauren (OS); Acton, Kelly J. (IHS); Bart, Sandra (CDC); Bartley, Paul S (PSC); Bennett, Jason (OS); Brand, Marcia (HRSA); Briss, Peter (CDC); Brooks, Karen (OS); Burk, Judith (NIH/NHLBI) [E]; Cabezas, Miriam (OS); Casale, Cecilia (AHRQ); Choucair, Jordana (OS); Church, Richard M. (IHS); Clancy, Carolyn M (AHRQ); Cochran, Norris (OS); Cohen, Susan (FDA); Conway, Patrick H (OS); Correa-De-Araujo, Rosaly (OS); Crump, Debbie (SAMHSA); Cullen, Theresa (IHS); Delany, Peter (SAMHSA); Devoss, Liz (OS); Diggs, Patricia (OS); Elder, Mark (OS); Engel, Elizabeth (OS); Enomoto, Kana (SAMHSA); Funston, Robin (OS); Gazdik, Tanya (HRSA); Goldstein, Mitchell (OS); Goldstein, Naomi (ACF); Goodman, Jesse L (FDA); Goodrich, Kate (OS); Gracia, Nadine (OS); Graham, Garth (HHS/OPHS); Haddix, Anne C. (CDC); Handley, Elisabeth A (FDA); Handrigan, Michael T (OS); Hawkins, Jamar (OS); Hennessy, Kevin (SAMHSA); Henry, Diana (AHRQ); Hodes, Richard (NIH/NIA) [E]; Holt, Yolonde P. (CDC); Hunt, David R (OS); Huttinger, Alexandra (HRSA); Jones, Carla (AHRQ); Kendrick, Kathleen (AHRQ); Kington, Raynard (NIH/OD) [E]; Kolodner, Robert (OS); Lambrew, Jeanne (OS); Lipman, David (NIH/NLM/NCBI) [E]; Lum, Ben (OS); Miller, Scott A. (CDC); Millman, Mike (HRSA); Monarque, Brenda (NIH/OD) [E]; Munson, Aaron (OS); Nabel, Elizabeth (NIH/NHLBI) [E]; Palm, Andrea (OS); Parekh, Anand (OS); Parham Hopson, Deborah (HRSA); Pazinski, Seth (OS); Pereira, Esmeralda (OS); Petillo, Jay (OS); Poelman, John (OS); Queen, Susan G (HRSA); Rice, Patricia (SAMHSA); Richardson, Michele N (OS); Rollins, Rochelle (OS); Roos, Paola S (OS); Rothwell, Charles J. (CDC); Scanlon, Jim (OS); Shea, Maureen (OS); Sisk, Jane E. (CDC); Skirboll, Lana (NIH/OD) [E]; Slutsky, Jean R (AHRQ); Smith, Monica (CDC); Spencer, Lorine M. (CDC); Stickell, Michele W (CMS); Tanden, Neera (OS); Thompson, Donna M (OS); Valuck, Thomas B (CMS); Vanlare, Jordan (OS); Ward, Connie (OS); Ware, Jayne C (FDA); Wasserman, Jill (OS); Wells, Connie (NIH/NHLBI) [E]; Wiggins, Cliff N. (IHS); Williams, Dennis (OS); Williams, Kristina (OS); Willis, Patricia (CMS); Wong, Hui-Hsing H (OS); Wood, Gretchen (NIH/OD) [E]; Woodcock, Janet (FDA); Zarin, Deborah (NIH/NLM/LHC) [E]
Subject: RE: CER proposals for tomorrow

One last attachment for our discussion today: a PowerPoint presentation featuring the results from the survey. We'll have copies for those attending the meeting in person.

Lauren

From: Conway, Patrick H (OS)
Sent: Thursday, July 16, 2009 2:59 PM
To: OS - FCC_Members
Subject: meeting tomorrow
Council,

Attached is the agenda and powerpoint for tomorrow's meeting. We think this will be a relatively brief meeting, so please feel free to just call-in if it is a trip for you to get to the Humphrey building. We look forward to seeing you tomorrow. Thanks.

patrick

Critical Access Hospital - Health Information Technology Network
Implementation of Electronic Health Records (EHR) Systems in Critical Access Hospitals

HRSA Grant Program Overview

The Department of Health and Human Services has identified furthering the use of health information technology (HIT) as a key priority. This focus also supports the President's goal of universal adoption of electronic health records for all Americans by 2014. This Critical Access Hospital- Health Information Technology Network Implementation Grant promotes the implementation of HIT and electronic health records (EHR) in Critical Access Hospitals (CAHs) and the providers they work with directly.

The funding for this opportunity is in accordance with Section 1820(g) of the Social Security Act.

Program Purpose

The purpose of the FLEX CAH HIT Network grant is to provide funds to support the development of a (1) Flex CAH-HIT Network pilot programs in States receiving the grant. Examples of HIT may include practice management systems, disease registry systems, care management systems, clinical messaging systems, personal health record systems, electronic health record systems and health information exchanges.

HRSA's experience has shown that it is cost effective to utilize networks of health care providers to develop health information technology systems. HRSA is interested in programs that can measure the impact of HIT in terms of outcomes that support the aims of this funding opportunity. Each of the grantees has past experience with the use of quality improvement programs. HRSA requires at least five performance outcome measures two of which HRSA defines to include diabetes control and heart disease risk reduction. The grantees will utilize measures to support the aim of enhancing the effectiveness, efficiency, safety and quality as related to HIT implementation.

Grantees

NAME OF NETWORK
An Electronic Health Record Implementation for Critical Access Hospitals and Clinics in the Kaua`i Region of the Hawai`i Health Systems Corporation

Name of Grantee
Hawaii State Department of Health, Hawaii State Office of Rural Health

Principal Investigator/Project Manager
Norman Okamura

Address 2424 Maile Way, Saunders 713 Honolulu, HI 96822
Phone 808.956.2909
Fax 808.956.8019
E-mail norman@tipg.net

Project Purpose
This FLEX CAH HIT Network Implementation project, submitted by the Department of Health of the State of Hawai'i, the Kaua'i Region of the Hawai'i Health Systems Corporation (HHSC), and the Telecommunications

Kaua'i Region Network. The project will establish a continuity of care and improve quality, patient safety, and cost-effectiveness.

The project seeks to (1) develop necessary enhancements to the existing VistA EHR system, and establish infrastructure in areas with limited or no connectivity to improve the accessibility of clinical information and results for clinicians; (2) implement security protocols in the VistA EHR to enable the HHSC Kaua'i Region network authorized access to patient records; (3) implement chronic disease care management tools to improve disease management and patient care; (4) develop application interfaces with patient management and billing systems to improve efficiencies; (5) develop internal resources to further deploy and sustain EHR implementations in Hawai'i; (6) evaluate the implementation and usability of the EHR to provide lessons learned for future VistA (or other EHR) implementations.

Outcome Measures/Expectations
This project seeks to provide a functioning EHR based off of the Hui OpenVista (HOV) software. Towards that end the expected outcomes are as follows:

1. System Implementation and Customization—the base HOV software will be modified to meet the workflow requirements of the CAHs and clinics.
2. Chronic Disease Care Management—this project will implement a chronic disease care management capability focused on diabetes and cardiovascular disease.
3. Outpatient Billing Interface—the project team will assess if HHSC's current outpatient billing system, TeamPraxis, is capable of interfacing with HOV and / or McKesson Series. If these capabilities are not possible, alternative solutions will be implemented since billing for services is fundamental to the functioning of these systems.
4. Resource Development—the Partners will work to ensure that the project team can support the long-term needs for ICT personnel that can support the system.

Service Area
The service area will bring together two critical access hospitals (CAH) and four clinics in the county of Kaua'i. The Kaua'i County encompasses the islands of Kaua'i and Ni'ihau. Both CAHs and the clinics are on the island of Kaua'i and service the population of Ni'ihau, which has no medical facilities.

Network Members

Organization Name / Provider Type	**County/ Parish**	**Address**	**City,**	**State**	**Zip Code**
Hawai'i State Office of Rural Health	Hawai'i	PO Box 1675	Honokaa	HI	96727
Contact	**Phone**		**Email**		
R. Scott Daniels, PhD	808.775.8883		scott.daniels@doh.hawaii.gov		

Organization Name / Provider Type	**County/ Parish**	**Address**	**City,**	**State**	**Zip Code**
Telecommunications and Information Policy Group	Honolulu	2424 Maile Way, Saunders 713	Honolulu	HI	96822

Contact	Phone	Email
Norman Okamura, PhD	808.956.2909	norman@tipg.net

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Hawai'i Health Systems Corporation	Honolulu	3675 Kilauea Ave.	Honolulu	HI	96816
Contact	**Phone**		**Email**		
Thomas M. Driskill, Jr.	808.733.4020		tdriskill@hhsc.org		
Organization Name / Provider Type	**County/ Parish**	**Address**	**City,**	**State**	**Zip Code**
West Kaua'i Medical Center	Kaua'i	4643 Waimea Canyon Rd.	Waimea	HI	96796
Contact	**Phone**		**Email**		
Orianna Skomoroch	808.338.9431		oskomoroch@hhsc.org		
Organization Name / Provider Type	**County/ Parish**	**Address**	**City,**	**State**	**Zip Code**
Samuel Mahelona Memorial Hospital	Kaua'i	4800 Kawaihau Rd.	Kapa'a	HI	96746
Contact	**Phone**		**Email**		
Orianna Skomoroch	808.338.9431		oskomoroch@hhsc.org		

NAME OF NETWORK
Alabama Cardiovascular Disease Network

Name of Grantee
Alabama Department of Public Health

Principal Investigator/Project Manager
Harold R. Brown, Jr.

Address
RSA Tower Suite 710, 201 Monroe Street Montgomery, Alabama 36104

Fax (334) 206-5434
Phone (334) 206-5430
E-mail hbrown@adph.state.al.us
Organizational Website http//:adph.org/ruralhealth/

Project Purpose Acquire and implement an Health Information Technology (HIT) network based at one of the State's four Critical Access Hospitals (CAHs), Randolph Medical Center (RMC) in Roanoke, to improve health outcomes of cardiac patients in the three county service area. Cardiovascular Disease has been the number one killer since 1928. The network will leverage a Toshiba 64 Slice CT Scanner and other equipment previously acquired by RMC to improve health outcomes through prevention education, screening, treatment, and follow up. The project has four distinct tracks: an Electronic Health Record (EHR) for RMC, data links among the partners, a database for trending and analysis, and direct patient intervention to improve cardiac patient disease compliance.

Outcome Measures/Expectations Performance measures include High Blood Pressure Management, Cholesterol Management, Incidence of Smoking, Diabetes Compliance, and others. Over time, expectations include a significant reduction in cardiovascular disease in the three county service area.

Service Area Three counties in East Alabama: Randolph, Chambers, and Clay

Network Members

Alabama Department of Public Health	All Alabama Counties	201 Monroe St	Montgomoery	AL	36104
Contact	**Phone**		**Email**		
Harold R. Brown, Jr.	(334) 206-5430		hbrown@adph.state.al.us		

Randolph Medical Center /	Randolph	59928 Highway 22, PO Box 670	Roanoke	AL	36274
Contact	**Phone**		**Email**		
Tim Harlin	(334) 863-4111 x 1501		tharlin@randolphmc.org		

East Alabama Medical Center	Lee	2000 Pepperell Parkway	Opelika	AL	36801
Contact	**Phone**		**Email**		
Laura Bell	(334) 749-3411		Laura.Bell@eamc.org		

Institute for Advanced Cardiovascular Care	Lee	2375 Champion Blvd	Auburn	AL	36830
Contact	**Phone**		**Email**		
Michael Kincaid	(334) 704-0307		mkincaid9@gmail.com		

Equipment/Vendors or Collaborative Partners EHR vendors being considered include CPSI, MediTech, and Dairyland. The Health Information Exchange will be direct logins across the partner's HIS systems. Access will be limited to select zip codes for impacted patients in three county area. Southern Family Health Care, LLC, a Rural Health Center in Randolph County, will help populate the registry.

NAME OF NETWORK
Illinois Patient Health Information Network

Name of Grantee
Illinois Department of Public Health, Center for Rural Health,
and Illinois Critical Access Hospital Network

Principal Investigator/Project Manager
Mary Catherine Ring

Address
245 Backbone Road East Princeton, IL 61356
Phone 217/243-5055
Fax 217/243-5055
Organizational Website icahn.org
E-mail mring@icahn.org

Project Purpose
The Illinois PHIN project will demonstrate that the electronic medical record requirements of selected critical access hospitals can be well served by a single, hybrid product that manages patient information in both the inpatient and outpatient settings. Project funds will be used to implement an electronic medical record system at Washington County Hospital in Nashville and at Salem Township Hospital in Salem, and a picture archiving and communications system at Washington County Hospital. A health information exchange will be established that will enable area health care providers, including those at one of the key referral partners – SSM St. Mary's Good Samaritan in Mount Vernon, to electronically share patient information. The health information exchange infrastructure will be available for use by other Illinois critical access hospitals and their

community partners.

Outcome Measures/Expectations
The Illinois PHIN project will demonstrate the following:

1. cost efficient, nondisruptive integration of the selected electronic medical record software into a hospital's existing best of breed information system
2. feasibility of user adaptation of an ambulatory electronic medical record system for use in the inpatient setting
3. implementation of an easily scalable health information exchange that will be available to project participants and their partners
4. on-going expansion of health information exchange users to include small area networks of all critical access hospitals in the state and their local health care partners

Service Area
The two critical access hospitals are located in southwestern Illinois. Washington County Hospital is 55 miles east of St. Louis, Missouri and Salem Township Hospital is 96 miles east of St. Louis. Washington County has a population of slightly more than 15,000 (27/square mile), and Marion County, home of Salem Township Hospital, has a population of nearly 42,000 (73/square mile). Both counties have economic bases comprised of light manufacturing, agriculture, and tourism. The referral hospital, SSM St. Mary's Good Samaritan, is located in Mount Vernon in Jefferson County, population of approximately 40,000 (70/square mile). Mount Vernon is 26 miles from Salem and 31 miles from Nashville.

Network Members

Salem Township Hospital / Critical Access Hospital	Marion	1201 Ricker Drive	Salem	IL	62881
Contact	**Phone**		**Email**		
Richelle Rennegarbe, CEO	618-548-3194 x 8186		rrennegarbe@salemtownhosp.org		

Washington County Hospital /Critical Access Hospital	Washington	705 S. Grand Ave.	Nashville	IL	62263
Contact	**Phone**		**Email**		
Nancy Newby, CEO	618-327-2200		nnewby@washingtoncountyhospital.org		

SSM St. Mary's Good Samaritan	Jefferson	605 N. 12th Street	Mount Vernon	IL	62864
Contact	**Phone**		**Email**		
Bruce Merrell, President	618-241-2200		Bruce_Merrell@ssmhc.com		

Equipment/Vendors or Collaborative Partners

NextGen Healthcare was selected to provide both the electronic medical records and the health information exchange software.

Sectra was selected for the PACS installation.

NAME OF NETWORK:
St. Vincent Health

Name of Grantee:
Indiana State Department of Health

Project Manager:
John Winenger, Regional Network Development

Phone: 317.583.3244

Principal Investigator:
Dr. Alan Snell, Medical Infomatics Director

Phone: 317.583.3248
Address: 10330 North Meridian Street Indianapolis, IN 46290
Fax: 317.583.3255
Organizational Website: www.stvincent.org
E-mail: jawineng@stvincent.org

Project Purpose
The Indiana State Office of Rural Health (SORH) proposes to improve health care delivery in rural areas of the state by enhancing health information technology (HIT) and related linkages between primary care providers, critical access hospitals, and tertiary care hospital providers. The overall purpose of the project is to improve the safety, quality, efficiency, and effectiveness of health care in rural areas.

Outcome Measures/Expectations
Project Phase One: Allscripts (outpatient) Implementation
St. Vincent Health will plan and implement the installation of Allscripts, a state-of-art electronic health record system, in two (2) rural health clinics (RHC) locations affiliated with St. Vincent CAH sites in North Vernon, IN., and Winchester, IN. The project will also include installation of Allscripts in a federally qualified health center (FQHC) location in Elwood, IN. that works closely with the CAH at that Elwood location.

Project Phase two: Eclipsys (inpatient) CAH Implementation
St. Vincent Health will plan and implement the Eclipsys electronic patient record /clinical management software system at each CAH location. Implementation will begin at the St. Vincent Jennings location in North Vernon, IN location; will then proceed to SV Mercy in Elwood, IN.; then to SV Randolph location in Winchester, IN. Within each hospital, multiple other information management systems including those in Emergency departments, Imaging and Radiology departments, Picture Archival and Communications (PACS), Pharmaceutical management, and Laboratory information management systems will be interfaced with the new clinical management system.

Project Phase Three: Clinical Integration and Data Sharing
The existing physician practice systems in the RHC locations will be linked electronically to the Eclipsys clinical management system at the CAH sites so that critical components of the patient record information in the physician practices can be electronically shared, upon admission and discharge, with the CAH sites. In addition, data from visits made to the CAH Emergency departments and other primary care entry points can be shared between providers.

Project Phase Four: Health Information Exchange
Lastly, connectivity will be established to the Indiana Health Information Exchange (IHIE) network, which will further demonstrate the future state of healthcare in sharing patient vital statistics and exam results among providers. It is the collective belief that with this information, physicians can help reduce duplication of testing thus lowering costs and improve quality of care to patients. IHIE is currently delivering over one million clinical messages per month within the central Indiana healthcare market.

Project Phase Five: Evaluation
The Indiana State Office of Rural Health and St. Vincent Health, along with its CAH locations will utilize several operational and clinical measures to support the aim of enhancing effectiveness, efficiency, patient safety, and quality as related to the HIT project implementation. Quality indicators will be addressed with pre/post implementation levels, and will include the required indicators for disease management of diabetes and cardiovascular disease. The five targeted project outcomes will be focused on:

- Diabetes;
- Cardiovascular disease;
- Medical safety / Medication reconciliation;
- Pediatric Asthma; and,
- Adult immunizations (flu and pneumonia).

Service Area

1) St. Vincent Randolph, a CAH located in Winchester, Indiana (Randolph County). Included in this target area is:

- Rural health clinics integrated into their regional delivery system within Randolph County located in the Indiana cities of Union City, Ridgeville, Winchester and Lynn,

2) St. Vincent Mercy Hospital, a CAH located in Elwood, Indiana (Madison County). Included in this target area is:

- A free-standing Federally Qualified Health Center (FQHC) in Elwood, Indiana that has operational and clinical program integration with St. Vincent Mercy Hospital that includes shared clinical support staffing, shared medical direction, reduced rent/lease on property, and shared services such as laboratory and radiology.

3) St. Vincent Jennings Hospital, a CAH located in North Vernon, Indiana (Jennings County). Included in this target area is:

- A provider-based RHC located in North Vernon, Indiana.

4) St. Vincent Hospital – Indianapolis will serve as the tertiary care facility. It is a 650 bed hospital located in Marion County and provides tertiary level patient care services for the St. Vincent CAH Network.

Network Members:

St. Vincent Jennings Hospital (Critical Access Hospital)	Jennings Co.	301 Henry Street	North Vernon	IN	47265-1097
Contact	**Phone**		**Email**		
Joe Roche, Administrator	812.352.4231		jeroche@stvincent.org		

St. Vincent Mercy Hospital (Critical Access Hospital)	Madison Co.	1331 South A Street	Elwood	IN	46036-0041
Contact	**Phone**		**Email**		
Deborah Rasper, Administrator	765.552.4594		dyrasper@stvincent.org		

St. Vincent Randolph Hospital (Critical Access Hospital)	Randolph Co.	473 Greenville Avenue	Winchester	IN	47394
Contact	**Phone**		**Email**		
Cheech Albarano, Administrator	765.584.0107		fgalbara@stvincent.org		

Madison County Community Health Center	Madison Co.	1547 Ohio Street	Anderson	IN	46015
Contact	**Phone**		**Email**		
Anthony Malone, Administrator	765.641.0255		amalone@mcchc.org		

Indiana Health Information Exchange	Marion Co.	846 N. Senate Avenue, Suite 300	Indianapolis	IN	46202
Contact	**Phone**		**Email**		
Debbie Banik, Program Director- Clinical Messaging Services	317.644.1734		dbanik@ihie.com		

Equipment/Vendors or Collaborative Partners

- **Chosen Billing System - IDX:** **IDX Systems Corporation** (IDX) was a healthcare software technology company that formerly had headquarters in South Burlington, Vermont, United States. It was founded in 1969 by Robert Hoehl, Richard Tarrant, and Paul Egerman. IDX was acquired by General Electric and incorporated into its GE Healthcare business unit in 2006. http://en.wikipedia.org/wiki/IDX_Systems

2. **Chosen Outpatient Electronic Medical Record System - Allscripts:** The award-winning TouchWorks™ Electronic Health Record (EHR) from Allscripts radically simplifies the art, science, and process of caring for patients. TouchWorks is the "EHR of Choice" for large medical groups (25 doctors and up) and has been nationally recognized as the leading provider of clinical software, connectivity and information solutions that physicians use to improve healthcare. More than 30,000 physicians in over 3,500 clinics nationwide use our solutions every day to inform, connect and transform healthcare. http://www.allscripts.com/as_emrupdate.html
3. **Chosen Inpatient Electronic Patient Record System - Eclipsys**: The Eclipsys **Sunrise Clinical Manager™** solutions connect the numerous caregivers involved in a single patient's care for improved quality, efficiency and turnaround times. Eclipsys is a leading provider of information solutions that help hospitals and health systems more-effectively *manage the business of healthcare* and achieve measurable and sustainable, improved outcomes. http://www.eclipsys.com/aboutus/
4. **Chosen Physician Order Set Provider – Zynx Health:** The Zynx team of physicians, nurses, and allied health professionals rigorously review the latest peer-reviewed literature to develop clinical summaries and distill evidence-based best practices. Zynx helps hospitals and physicians make evidence actionable in the form of physician order sets, interdisciplinary plans of care, alerts, and reminders. Clinical teams utilize our online content management tools to collaborate and efficiently customize this information to adhere to local best practices, guidelines, and formularies. More than 1,400 hospitals nationwide trust evidence-based clinical decision support from Zynx Health to address

regulatory initiatives, optimize pay-for-performance reimbursement, and measurably improve the quality and safety of patient care. http://www.zynx.com/

NAME OF NETWORK:
Pointe Coupee Parish Health Information Technology

Partnership

Name of Grantee
Louisiana Department of Health and Hospitals

Bureau of Primary Care and Rural Health

Principal Investigator:
Margaret Shipman, State Office of Rural Health Director

Address: 628 North 4th Street, 8th Floor Baton Rouge, LA 70802
Phone: (225) 342-1889
FAX: (225) 342-5839

E-Mail : mshipman@dhh.la.gov
Organizational Website: www.pcrh.dhh.louisiana.gov

Project Purpose
The purpose of the proposed network is to fully implement functional electronic health records within each network partner organization and to enable appropriate sharing of health information among all partner organizations. The primary partners include a critical access hospital (CAH), home health and hospice agency (HHA), two locations of a federally qualified health center (FQHC), four rural health clinics (RHC), one community clinic, two private physician practices and a 761-bed tertiary care center (TCC). The network will allow qualified providers to access the patient data located in any and all of the network member systems.

Outcome Measure/Expectations
The objective of this grant is unique in that it is built on the premise of data sharing not data exchange.

I. Implement a functional Electronic Medical Record for each of the partners
II. Develop a Community Portal that integrates systems at the network level. The portal will employ a federated data model that allows each network member system to access and present data without having to move data from its local database.
III. The Community Portal will present data from all partner applications via a single web-based portlet which will create a data view specific to the clinician's workflow

Service Area
The Pointe Coupee HIT Network will serve the Pointe Coupee Parish service area, which is located in south central Louisiana approximately 1 hour from the capital of Baton Rouge. Agricultural production is a mainstay of the economy. Pointe Coupee is one of the most diverse agricultural parishes in the state. Close to 165,000 acres of land are used to farm cotton, sugarcane, soybeans, corn, milo, wheat, cattle, hay, vegetables, rice, crawfish and pecans. The 2006 estimated population for Pointe Coupee Parish was 22,648 (U.S. Census, 2007). The largest town in Pointe Coupee Parish is New Roads (home to Pointe Coupee General Hospital), with close to 5,000 residents. Only 69% of the population aged 25 years and older has earned a high school diploma. The unemployment rate is high, with only 55% of residents at age 16 or older in the labor force. Consequently, 23%

of all individuals and 19% of all families in the parish are below the poverty level. Over 40% of area residents receive some form of public assistance and 27% of the community is enrolled in Medicaid.

Network Members

Pointe Coupee General Hospital / CAH	Pointe Coupe	2202 False River Rd.	New Roads	LA	70760-2621
Contact		Phone	Email		
Chad Olinde, CEO		225-638-6331	colinde@pcgh.org		

Pointe Coupee Homebound Health and Hospice / HHA	Pointe Coupe	350 Hospital Rd	New Roads	LA	70760-2621
Contact		Phone	Email		
Jeanne LeJune, RNC, CNS Admin		225-638-5717	homebound@eatel.net		

Innis Community Health Center /FQHC	Pointe Coupe	6450 LA Hwy 1	Batchelor	LA	70715
Contact		Phone	Email		
Linda Matessino, Exec Director		225-492-3775	Linda@inchc.org		

BACH Urgent Care Clinic/Community clinic	Pointe Coupe	230 Roberts Dr.	New Roads	LA	70760-2621
Contact		Phone	Email		

Lynn David, Executive Director	225-638-8900	lynn@pcbach.com

Lake Primary Care Physicians / RHC (4)	Pointe Coupe	160 Hospital Rd	New Roads	LA	70760-2621
Contact		Phone	Email		
Keeley Chustz, Regional Manager		225-638-3781	KChustz@ololrmc.com		

Donald Doucet, MD & Associates / private (2)	Pointe Coupe	230 Roberts Dr, Suite I	New Roads	LA	70760-2621
Contact		Phone	Email		
Donald Doucet, MD		225-638-4585	drdoucet@bellsouth.net		

Our Lady of the Lake / TCC	Baton Rouge	5000 Hennessey Blvd.	Baton Rouge	LA	70808
Contact		Phone	Email		
Dr. Murphrey, Medical CIO		225-765-6565			

Equipment/vendors

Hospital CPSI
Home Health – Lewis
FQHC – EHS
BACH – Not selected
Portal – Fusion CareFx

NAME OF NETWORK
Thumb Region CAH-HIT Network

Name of Grantee
Michigan Department of Community Health

Principal Investigator/Project Manager
Donald A. Wheeler, FACHE

Address 2180 Commons Parkway Okemos, MI 48864
Phone 517-347-8917
Fax 517-347-8950
Organizational Website wwrhcc.org
E-mail DAWheeler77@AOL.com

Project Purpose
The purpose of Michigan's FLEX CAH-HIT project is to create an effective health data exchange between two Critical Access Hospitals and their tertiary referral center, in order to improve the safety, quality, efficiency, and effectiveness of health care delivery through a full continuum of care. The two Critical Access Hospitals include Deckerville Community Hospital in Sanilac County and Harbor Beach Community Hospital in Huron County, while the primary tertiary partner has yet to be selected from 3 possible facilities that serve the region. An existing 16-member "Thumb Rural Health Network" is providing governance and oversight of the project. The proposed HIT Network planning and implementation activities of this project will be used as a template for adoption and/or expansion to Michigan's other Critical Access Hospitals, as well as those in other states.

Outcome Measures/Expectations
Specific goals of the Network currently include: (1) Use HIT as a tool to improve the safety, quality, efficiency, and effectiveness of health care delivery in the Thumb region of Michigan; (2) Adopt the effective use of a clinical information system through an integrated system with a common architecture; (3) Create sustainable business model for deploying HIT in the Thumb region; (4) Improve the quality and performance of our organizations both individually and jointly; (5) Improve healthcare quality through the elimination of handwritten clinical data; (6) Successfully deploy or enable the deployment of hospital HIT practices that reduce medical errors and improve overall patient safety; (7) Increase the identification and reporting of medical errors and adverse events; (8) Develop HIT systems that support the regional collection and assessment of patient care data as part of the Michigan Critical Access Hospital Program's Quality Committee for the measurement of healthcare quality; (9) Enhance the Network's ability to collect data regarding the impact of HIT on healthcare outcomes, improving patient safety and quality of care; (10) Identify and support local and regional HIT collaborative projects that lead to standards-based data sharing across healthcare delivery sites; and (11) Share our HIT implementation experiences with other organizations and networks.

Service Area
The service area for the "Thumb Region CAH-HIT Network" lies on the eastern Lake Huron shoreline of Michigan's "thumb" region.

Network Members
The two Critical Access Hospitals include Deckerville Community Hospital in Sanilac County and Harbor Beach Community Hospital in Huron County. The tertiary-level partner has yet to be selected from three possible facilities that serve the region. The Network is seeking to identify an "open architecture" that will enable connectivity to all tertiary facilities serving the region.

The Thumb region of Michigan is surrounded by six potential tertiary referral hospitals including Covenant Medical Center in Saginaw, Saginaw St Mary's Hospital, Bay Medical Center in Bay City, Genesys Health System in Flint, and Mercy Hospital or Port Huron Hospital in Port Huron (in the lower right corner of the map,

just below Gardendale). All these tertiary hospitals are geographically remote (45 to 90 minutes driving time) from the rural service area.
The Thumb Rural health Network (TRHN) is a 16-member organization located in the rural counties of Huron, Sanilac and Tuscola, typically referred to as Michigan's "Thumb." TRHNs membership includes seven Critical Access Hospitals and one sole-community provider; two health departments; six tertiary hospitals surrounding the region; and one Multipurpose Collaborating Council.

There are no Federally Qualified Health Centers or Certified Rural Health Clinics in the targeted service area. The two CAH facilities operate 3 primary care clinics in the region that will be included in the HIT systems developed at those hospitals.

Both the Huron County and the Sanilac County Health Departments serve the target region. Together, these health departments provide health screening, preventions and surveillance services as required by state and federal mandates. Most of the surveillance reporting is provided for through "on-line" reporting systems operated by the state of Michigan. Their need for interaction with hospitals focuses on the receipt of "reportable disease" incidents and on the need to alert health providers about regional/local health risks.

Deckerville Community Hospital	Sanilac	3559 Pine St	Deckerville	MI	48427
Contact	**Phone**		**Email**		
Ed Gamache, CEO	810-376-2835		gamachee@deckervillehosp.org		

Harbor Beach Community Hospital	Huron		Harbor Beach	MI	
Contact	**Phone**		**Email**		
Ed Gamache, CEO	810-376-2835		gamachee@deckervillehosp.org		

Equipment/Vendors or Collaborative Partners
Operating systems being used at by the CAHs: CPSI at Harbor Beach;

Health Information Exchange - No equipment or vendors have been chosen at this time. Vendors responding to our RFP include Microsoft, Open HRE, First Gateway. Klinitek's UPCare and Covisent. We expect to select the HIE vendor by May 2008.

NAME OF NETWORK
Lac qui Parle Health Network

Name of Grantee
Minnesota Department of Health/Office of Rural Health and Primary Care

Principal Investigator/Project Manager
Mark Schoenbaum

Address PO Box 64882 St. Paul, MN 55164-0882
Phone 651.201-3859
Fax 651-201-3830
Organizational Website http://www.health.state.mn.us/divs/orhpc/
E-mail mark.schoenbaum@state.mn.us

Project Purpose
The Lac qui Parle Health Network (LqPHN) project goal is to implement a shared electronic health record (EHR) among three critical access hospitals in the communities of Madison, Dawson, and Appleton, Minnesota. The Lac qui Parle Health Network, an incorporated non-profit organization, has a strong history of collaboration in areas of physician recruitment, shared staffing, and training that forms the foundation for this project. Each facility represents a full service community health care delivery system, including clinic, hospital, long term care, and emergency medical services, and the EHR project reflects the breadth of services. Hospital leadership, strong project teams, and outside assistance from experts will ensure that collaborative efforts meet individual provider, facility and community needs. A common EHR product, a shared data storage and retrieval, and shared IT staff will provide leverage, create efficiencies, and support long term success.

Outcome Measures/Expectations
The Lac qui Parle Health Network CAH HIT Implementation project is driven, ultimately, by goals of providing high quality care and improving patient outcomes as the guiding principles. To that end, the following project goals and timelines have been identified, and measures developed to assess progress in achieving those goals:

1. Completion of collaborative long range health information technology strategic plan, including change management strategies and verification of organizational readiness.
2. Selection of EHR vendor/product, including vendor selection process, RFP development, and contract negotiation and approval.
3. Implementation, including kick-off, application design, infrastructure build, testing, and training.
4. Development of patient quality of care measurement through a) data collection and analysis of patient primary and secondary data, focusing on 5 performance indicators for heart failure, pneumonia, diabetes, cardiovascular care, and adverse events, and b) participation in Hospital Compare.

Service Area
LqPHN facilities serve residents of Swift, and Lac qui Parle counties, and are located in the west central part of Minnesota's large 8th Congressional District. Each of the three network facilities are located in areas designated as "rural" or "exceptionally rural" per USDA rurality scoring.

Network Members

Lac qui Parle Health Network	900 2nd Ave	Madison	MN	56256
Contact	**Phone**	**Email**		

Mark Roisen	320-598-7536 x110	mroisen@farmerstel.net

Johnson Memorial Hospital	1282 Walnut Street	Dawson	MN	56232
Contact	**Phone**	**Email**		
Kathy Johnson	320-769-4323	admin@jmhsdawson.com		

Madison Lutheran Home	900 - 2nd Ave.	Madison	MN	56256
Contact	**Phone**	**Email**		
Scott Larson	320-598-7556	slarson@madisonlutheranhome.org		

Appleton Area Health Services	30 S. Behl Street	Appleton	MN	56208
Contact	**Phone**	**Email**		
Dan Swenson	320-287-2422	dswenson@mchsi.com		

Equipment/Vendors or Collaborative Partners
Equipment/vendors: Integrated solutions TBD (currently considering Dairyland, HMS/Medinotes, and CPSI.

Stratis Health: Minnesota's QIO is a contracted partner, assisting LqPHN with final organizational planning and readiness, needs identification, communications, process mapping, RFP development and analysis, contract negotiation, implementation preparation, training, optimization, and quality measures.

Charles River Consultants is a contracted partner, assisting LqPHN with the RFP cost spreadsheet analysis and vendor contract negotiating.

Eide Bailly, LLC, an accounting and business consulting firm, is a contracted partner, providing temporary CIO staffing support and project management.

ORHPC: The Minnesota Office of Rural Health and primary care provided early support and resources for Lac qui Parle Health Network and continues to be a key collaborative partner.

Greater Minnesota Telehealth Broadband Initiative: Minnesota's FCC Rural Health Care Pilot Program project will support the project's telecommunications needs.

NAME OF NETWORK: North Dakota CAH HIT Network

Name of Grantee: Center for Rural Health, University of North Dakota

Principal Investigator:
Marlene Miller, Flex Program Director
701-777-4499
marlenemiller@medicine.nodak.edu

Principal Investigator:
Lynette Dickson, SORH Program Director
701-777-6049
ldickson@medicine.nodak.edu

Address:
501 N Columbia Rd. Stop 9037 Grand Forks, North Dakota 58202-9037
Phone: 701-777-3848
Fax: 701-777-6779
Organizational Website: http://ruralhealth.und.edu/
E-mail: (see above)

Project Description: The overall project goal is to facilitate the exchange of health information by implementing EMR along the continuum of care that is patient-centered, facilitating patient safety, efficiency, and effectiveness of health care services. Three ND Critical Access Hospitals (CAHs), (Northwood Deaconess Health Center, Northwood; Pembina County Memorial, Cavalier; First Care Health Center, Park River), one tertiary(Altru, Grand Forks) referral hospital, and ancillary providers (Valley Community Health Centers, Northwood and Larimore; Wedgwood Manor, Cavalier and First Care Rural Health Clinic, Park River) will serve as the network model in this pilot project.

Service Area The intent of the project is to eventually impact a regional network in North Dakota and Minnesota consisting of 18 CAHs, 1 rural non-CAH, 1 tertiary facility and 1 mental health agency. The immediate network participants have approximately 3,100 common patient encounters each year. Eventually, the regional impact will cover 20,000 square miles serving a population of over 207,000 residents in 17 counties.

Need: North Dakota has 34 CAHs, none of which is involved in an HIT network with its tertiary. Statewide data indicates that CAHs are supportive of HIT; however, they struggle with resource development and allocation. For example, only 16% of ND CAHs have a formal HIT plan; yet, 68% are starting to budget for HIT. In addition, 89% do not use EMRs.

Outcome Measures/Expectations:
1) Complete planning process and implementing of EMR for first CAH.
2) Orchestrate the exchange of health information along the continuum of care.
3) Use lessons learned from each facility to improve the implementation process of EMR.
4) Improve efficiencies in the health care system through performance management.
5) Improve efficiencies through the integration of clinical quality improvement measures to facilitate better health outcomes for rural residents.

Network Members

Northwood Deaconess Health Center/ Critical Access Hospital	Grand Forks	PO Box 190	Northwood	ND	58267
Contact	**Phone**		**Email**		
Pete Antonson, Administrator	701-587-6060		pete.antonson@ndhc.net		

Valley Community Health Center/ Community Health Center	Grand Forks	104 N Park St.	Northwood	ND	58267
Contact	**Phone**		**Email**		
Sharon Ericson, Administrator	701-587-6000		sharon.ericson@valleychc.org		

First Care Health Center /Critical Access Hospital	Walsh	115 Vivian St.	Park River	ND	58270
Contact	**Phone**		**Email**		
Louis Dryburgh, Administrator	701-284-7500		stald@polarcomm.com		

First Care Rural Health Clinic /Rural Health Clinic	Walsh	115 Vivian St.	Park River	ND	58270
Contact	**Phone**		**Email**		
Louis Dryburgh, Administrator	701-284-7500		stald@polarcomm.com		

Pembina County Memorial /Critical Access Hospital	Pembina	301 Mountain E.	Cavalier	ND	58220
Contact	**Phone**		**Email**		
Everett Butler, Administrator	701-265-8461		Everettb@cavalierhospital.com		
Wedgewood Manor /Long Term Care Facility	Pembina	804 M St. W	Cavalier	ND	58220
Contact	**Phone**		**Email**		
Everett Butler, Administrator	701-265-8453		Everettb@cavalierhospital.com		
Altru Health System /Tertiary facility	Grand Forks	1200 S. Columbia Rd.	Grand Forks	ND	58206-6002
Contact	**Phone**		**Email**		
Mark Waind, CIO	701-780-5000		mwaind@altru.org		

Equipment/Vendors: Critical Access Hospitals – Two have selected Dairyland; one American Healthnet

Health Information Exchange – no vendor selected at this time.
They are considering Orion Health Systems, Intersystems (Clinical Workstation – a system already in place at the tertiary facility however it is not being used by two of the three CAHs within this project and needs enhancement to facilitate two-way exchange of information).

Collaborative Partners:
North Dakota Healthcare Review (Quality Improvement Organization)
North Region Health Alliance
Rural Health Information Technology, Inc.

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NAME OF NETWORK:
Southeast Nebraska Health Information Exchange (SENHIE) Network

Name of Grantee:
Nebraska State Office of Rural Health
(DHHS, Public Health Division)

Principal Investigator/Project Manager:
Dennis Berens (Program Director)
David Palm (Project Director)

Address: 301 Centennial Mall So Lincoln, NE 68509
Phone:
402-471-0142 (Dennis Berens);
402-471-0146 (David Palm)

Fax: 402-471-0180

Organizational Website: www.dhhs.ne.gov/orh
E-mail: dennis.berens@dhhs.ne.gov
Website: *www.thayercountyhealth.com*
Email: david.palm@dhhs.ne.gov

Project Purpose: The focus is on developing and implementing a sustainable interoperable system which will improve the flow of clinical information along the continuum of care in order to provide a seamless process of health care delivery for patients and providers. The system will improve the quality of care by creating an electronic linkage which will allow each provider to make more informed treatment decisions based upon current patient data and information. Services will include implementation of electronic prescribing for medical providers, electronic transmission of transfer/discharge forms, implementation of bedside charting for staff, access at the bedside for medical providers to consult with specialists, computerized medication administration forms, electronic access for EMTs of appropriate patient information in the field, and access to mental health providers for acute and long term care. It will be an opportunity to explore the benefits of an electronic personal health record so that consumers can communicate electronically with their providers.

Outcome Measures/Expectations: Seven project goals were identified:

1. Improve the connection to share information with the network tertiary hospital.
2. Build a bridge with EMTs to improve communication and share information.
3. Improve communication and share clinical information with long-term and assisted living facilities.
4. Improve connection to share information with satellite rural health clinics.
5. Improve the electronic connection with pharmacies to strengthen patient safety, quality, effectiveness, and efficiency.
6. Improve the efficiency and effectiveness of the critical access hospital operations to strengthen patient quality and market position.
7. Address the safety and security of clinical health information.

The project is anticipated to:

- Improve the flow of clinical information along the continuum of care
- Reduce medication errors and improve medication reconciliation (e-prescribing/electronic connection)
- Improve coordination of care and efficiency for the continuum of care (electronic information/connection)
- Reduce duplication and cost regarding radiology tests (electronic transfer tests)
- Decline in patient transfers and medical complications (electronic connections)

- Increase patient days by 10% (fewer patient transfers)
- Improve health outcomes for patients with diabetes, heart failure and stroke

The project provides an opportunity to develop and share evidence-based practice protocols and standard order sets (quality improvement) areas of diabetes, heart failure, coronary artery disease, hypertension, osteoarthritis and preventive care along a continuum of care.

Service Area: The initial network participants are located in the vicinity of Hebron, Nebraska (Thayer County, 2006 population estimate 5,317) and include the Thayer County Health Services located in Hebron and the surrounding communities in Nebraska. All of the communities are rural and are located in the second and third congressional districts of Nebraska. Wherever the patient enters the health care system along this continuum of care, the intent is to have current information accessible for all of these providers.

Network Members: Local partners will include a critical access hospital, five rural healthy clinics, a home health agency, a nursing home and an assisted living facility, several EMS units, a hospital-owned retail pharmacy and an independent retail pharmacy, and a network tertiary hospital.

Thayer County Health Svs/ Critical Access Hospital (19 beds); In-House Pharmacy; Home Health Agency; Rural Health Clinics; LTC Facility;	Thayer Co.	120 Park Ave	Hebron	NE	68370
Contact	**Phone**		**Email**		
Joyce Beck, CEO	402-768-6041		tchs@alltel.net		

Blue Valley Lutheran Homes Society, Inc/ Nursing Homes and Assisted Living	Thayer Co.	755 S 3rd St	Hebron	NE	68370
Contact	**Phone**		**Email**		
Bill Taylor, CEO					

EMS & Rural Health Clinic Medical Representatives /EMS Squads; Rural Health Clinics	Thayer Co.		Hebron Deshler	NE NE	68370 68340
Contact	**Phone**		**Email**		
Dr. Tim Sullivan, EMS squads Medical Director; RHC medical staff representative			tjsullivan@thayercountyhealth.com		

Priefert Pharmacy /Independent Pharmacy	Thayer Co.		Hebron	NE	68370
Contact	**Phone**		**Email**		
Jack Priefert, RP					

St. Elizabeth Regional Medical Center/network-tertiary hospital	Lancaster Co	245 S 84th St Suite 110	Lincoln	NE	68510
Contact	**Phone**		**Email**		
Richard Waller/Amy Thimn	402-219-7320		dwaller@stez.org athimn@stez.org		

Equipment/Vendors or Collaborative Partners

Healthcare Management System – HMS, a CCHIT certified inpatient system vendor, will provide the hardware, software, and related implementation services for the project. Includes: Electronic Medication Administration Record (EMAR), CPOE Provider Orders with Clinical View, Material Management Point-off-Issue, Surgical Manager, Setting up Comprehensive Training Environment; Ascent Capture & Scan Station, Client Report, Server/Backup Server and Transfer setup, Annual Maintenance and Support 24/7, Medical Grade 4-Port Concentrators, E-Forms, Digital Medical Records, and HMS to MediNotes interfaces

Medi-Notes – Provide the physician practice EMR and related implementation services for the project. MediNotes to HMS interface, V-chart scanning module, Annual Maintenance for V-chart, MediNotes eRX

Ice Technologies – Information technology technical assistance, hardware, software and cabling, including connections for HD high definition video conferencing

Zoll – E Series 12 lead ECGs with accessories to be used with Tough Books by EMS (transmission)

Alltel/Windstream – T-1 Line setup and Installation, wireless provider

Protex Central – Fire Suppression & HVAC for 3 data Centers – 2 in Hebron and 1 in Deshler (Deshler is backup system)

Nebraska Office of Rural Health – Provided early planning, technical assistance and serves as a bridge and the key collaborative partner

Nebraska Telehealth Network – The existing statewide network of 88 hospitals, 19 Public Health Departments and 6 Rural Health Clinics is expanding to enhance network coverage in the area with T1 lines

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NAME OF NETWORK

Name of Grantee
Oklahoma State University Center for Health Sciences

Principal Investigator/Project Manager
Jason W. Bray

Address 2345 SW Blvd.Tulsa, OK. 74107
Phone 918-269-1065
Organizational Website http://www.healthsciences.okstate.edu/index.cfm
E-mail Jason.bray@okstate.edu

Project Purpose-The project will create a Critical Access Hospital (CAH) Electronic Health Record (EHR) Network in Northeastern Oklahoma (the "Northeastern Oklahoma CAH EHR Network" or the "Network"). The Network will consist of the following partners:
• Saint Francis Hospital South (urban tertiary hospital);
• Cleveland Area Hospital (Cleveland) (CAH);
• Drumright Regional Hospital (Drumright) (CAH);
• Holdenville General Hospital (Holdenville) (CAH)
• The private practice physicians who staff at each hospital and are responsible for the bulk of the hospital's referrals

The Network members' vision for the EHR network is to ensure that patient clinical information is easily accessible to providers within a healthcare organization and to other providers as patients migrate from ambulatory care to acute service delivery sites within the region. This improved access to patient information that is integrated into a coordinated system of care will result in more effective and efficient health care delivery that will ultimately lead to improved safety and quality of care for patients. Based on this vision, CAHs are including licenses for their physician staff that most often refer patients to their hospital.

Outcome Measures/Expectations

Through this effort, the Network will improve patient:

- Safety thru reducing adverse drug events by knowing more quickly patient allergies
- Quality by having patient information accessible more quicker
- Paperwork because the patient will only have to fill out patient information one time

The Network will also make the CAH more effective and efficient in operational expense, which can be directly returned back to improving patient quality of care.

All of these hospitals are currently reporting quality data to the Centers for Medicare & Medicaid Services (CMS) Hospital Compare. As a result, they have demonstrated a commitment to improving quality and reporting data that will be used to measure the projects impact.

Vision for Developing and Implementing HIT

The Network members' vision for the EHR network is to ensure that patient clinical information is easily accessible to providers within a healthcare organization and to other providers as patients migrate from ambulatory care to acute service delivery sites within the region. Improved access to patient information integrated into a coordinated system of care will result in more effective and efficient health care delivery that will ultimately lead to improved safety and quality of care for patients.

Service Area

The Network will provide electronic health records to three critical access hospitals and their regional tertiary center to which they typically make referrals. The functionality of the EHR system will likely include:

- Health data and record management;
- Results management;
- Order management;
- Electronic communication and connectivity; and
- Administrative processes and reporting.

Holdenville General Hospital is located in southeast Oklahoma. The hospital services rural Oklahoman and around Hughes County.

Drumright Regional Hospital is also located in central/northeastern Oklahoma. The hospital serves Creek County and is the only medical center servicing that county.

Cleveland Area Hospital is located in southern Oklahoma. The hospital services over a 20 mile radius for rural healthcare patients.

Network Members

Cleveland Area Hospital	Pawnee	1401 West Pawnee	Cleveland	OK	74020
Contact	**Phone**		**Email**		
Mike Christian	918-358-2501		mchristian@community-partners.com		

Drumright Regional Hospital	Creek	610 West Bypass	Drumright	OK	74030

		Street			
Contact	**Phone**		**Email**		
Darrell Morris, CEO	918-382-2300		dwmorris@drumrthosp.org		

Holdenville General Hospital	Hughes	100 McDougal Drive	Holdenville	OK	74848
Contact	**Phone**		**Email**		
Bridget Cosby, CFO	405-379-4200		bcosby@hghospital.com		

Saint Francis Hospital South	Tulsa	10501 East 91st Street	Tulsa	OK	74133
Contact	**Phone**		**Email**		
Jason Bray, CMIO	918-561-1136		jason.bray@okstate.edu		

Physicians Participating:

Drumright will be extending their EMR to Drumright Medical Clinic:
Dr. Brant
500 Lou Allard Dr.
Drumright, OK 74030
918-352-2555

Holdenville will be extending their EMR to (All employed by Holdenville General Hospital):
RHC - 100 McDougal Drive, Holdenville, OK 74848
Dr. Tom Osborn
Earl Dunkleberger
Dr. Preston Hucks
405-379-4201

Physician Health Clinc - 100 McDougal Drive, Holdenville, OK 74848
Dr. Fred Sanders
Mike Gibson, PA (to start July 1 pending board approval)
405-379-4202

Allen Health Clinic - 200 West Broadway, Allen, OK 74825
Dr. Michelle Barlow
580-857-2424

Equipment/Vendors or Collaborative Partners

1. **Chosen EMR System for Drumright- Cerner: Cerner Healthcare Systems.**
2. **Chosen Electronic Medical Record Systems for Cleveland: Meditech**
3. **Chosen Electronic Medical System for Holdenville: HMS Health Information Exchange- Covisent's HIE system**

NAME OF NETWORK
Lakeland Rural Health Network

Name of Grantee
South Carolina Office of Rural Health

Co-Principal Investigator
Graham Adams, PhD

Address: 107 Saluda Pointe Drive
City, State, Zip: Lexington, SC 29072
Phone: (803) 454-3850
Fax: (803) 454-3860
Organizational Website: www.scorh.net
E-mail: adams@scorh.net

Co-Principal Investigator
Mark Van Swol, MD

Address: 155 Academy Avenue
City, State, Zip: Greenwood, SC 29646
Phone: 864-725-4865
Fax: 864-725-4883
Organizational Website: www.greenwoodfp.org
E-mail: vanswol@selfregional.org

Project Purpose

The Lakelands Rural Health Network (LRHN) is a nonprofit, multi-county vertical network that was developed in 2004 with the guidance and financial assistance of the South Carolina Office of Rural Health, the state Flex grantee, to achieve efficiencies, expand access, coordinate and improve the quality of essential health care services, and strengthen the rural health care system as a whole.

The Lakelands partner organizations include a regional referral hospital, two Critical Access Hospitals, a Federally Qualified Health Center organization with nine medical practices, several Rural Health Clinics, a private foundation, a family practice and residency program, the local public health agency, and the South Carolina Office of Rural Health. The LRHN consists of five segments: 1) a Clinical Leadership Council which is a physician-led, multi-county forum to address clinical issues impacting the service area; 2) a Public Information Collaborative which promotes the LRHN and its initiatives; 3) a Financial Subgroup which plans for long-term network financial viability; 4) an HIT Collaborative which implements the LRHN technology projects; and 5) an HIE Governance and Policy Committee. LRHN's geographic area includes Abbeville,

Edgefield, Greenwood, Laurens, McCormick, and Saluda Counties.
The primary purpose of the project is to use HIE to assist health care providers and patients in improving their health status. Other secondary purposes for use of the HIE will include aggregated, de-identified information for the purpose of regional quality improvement initiatives, research grants, and population health outcome measures.

Outcome Measures/Expectations

Quality Improvement Goals:

1. Diabetics will decrease their mortality from stroke and myocardial infarction by improving control of blood pressure, cholesterol and blood sugar.
2. Individuals with cardiovascular disease will improve life expectancy by improving tobacco smoking cessation, anti platelet use, and blood pressure control.

Quality Improvement Objectives:

1. Decrease HgA1c average by 10% in the MCFM and CHC diabetic population within the first year with the ultimate goal of having an average HgA1c of less than 7 by 18 mos.
2. Decrease average LDL by 12% in the MCFM and CHC diabetic population within the first year with the ultimate goal to have greater than 70% of patients with an LDL less than 100 by 18 mos.
3. Increase the number of patients by 15% in the MCFM and CHC diabetic population within the first year to have systolic blood pressure less than 130 and diastolic blood pressure less than 80 with the ultimate goal to have greater than 40% of diabetic patients with a blood pressure less than 130/80 by 18 mos.
4. Increase by 50% the reporting of an eye examination in the past year in the MCFM and CHC diabetic population within the first year with the ultimate goal to have greater than 80% of patients with a documented eye exam.
5. Decrease the number of patients by 10% who are currently smoking in the MCFM and CHC diabetic population within the first year and with the ultimate goal of <12% be current smokers by 18 mos.
6. Increase the number of patients by 15% in the MCFM and CHC diabetic population within the first year to have a documented Nephropathy assessment with the ultimate goal to have greater than 80% of patients with a documented nephropathy assessment
7. Increase the number of patients by 50% in the MCFM and CHC diabetic population within the first year to have a documented foot exam with the ultimate goal to have greater than 80% of patients with a documented foot exam in the past year.

Technology Goals

1. A cost-effective HIE will be developed through contract negotiations with a vendor.
2. The implementation process will run smoothly due to careful planning and a complete purchase, setup, configuration and testing equipment and software between Self Regional Healthcare (SRH) and Montgomery Center for Family Medicine (MCFM).
3. The HIE will be able to be activated through the building of the LRHN HIE infrastructure.
4. The residents of the 6-county region will receive enhanced quality of health care by sustaining the LRHN HIE.

Technology Objectives

1. The LRHN will contract with cost-sensitive and knowledgeable vendors to support the HIE by Oct 1, 2007.

2. The LRHN will purchase, setup, configure and test equipment and software to perform web view of registration, lab results and dictated summaries for SRH and MCFM by May 2008.
3. The LRHN will purchase, setup, configure and test equipment and software between SRH/MCFM and Carolina Health Centers (CHC) for minimally defined scope (Web view/discrete data availability of registration, lab results and dictated summaries).

Service Area

The Lakelands Rural Health Network (LRHN) is a vertical network of health care providers located in a rural, economically depressed region of western South Carolina. LRHN was established in January 2004 and consists of a variety of partner organizations: a regional referral hospital, two Critical Access Hospitals (CAH), a Federally Qualified Health Center (FQHC) organization with nine medical practices, two Rural Health Clinics (RHC), a private health foundation, a family practice residency program, the local public health agency, and the South Carolina Office of Rural Health. LRHN's service area is Abbeville, Edgefield, Greenwood, Laurens, McCormick, and Saluda counties.

Network Members

Self Regional Healthcare	Greenwood, SC	421
Name of CAHs	**Location**	**Number of Beds**
Abbeville Area Medical Center	Abbeville, SC	25
Edgefield County Hospital	Edgefield, SC	25
Ancillary Providers	**Location**	**Provider Type**
Laurens County Health Care System	Laurens, SC	Acute care hospital
Carolina Health Centers 1. Calhoun Falls Family Practice 2. Lakelands Family Practice 3. Uptown Family Practice 4. The Children's Center 5. McCormick Family Practice 6. Saluda Family Practice 7. Ridge Spring Family Practice 8. Ware Shoals Family Practice	Calhoun Falls, SC Laurens, SC Greenwood, SC Greenwood, SC McCormick, SC Saluda,SC Ridge Springs, SC Ware Shoals, SC	FQHC " Family Practice " Family Practice " Family Practice " Pediatrics " Family Practice " Family Practice " Family Practice

		" Family Practice
Ware Shoals Center for Family Medicine	Ware Shoals, SC	Family Practice
Montgomery Center for Family Medicine	Greenwood, SC	Family Practice and Residency Program
Riley Family Practice	Saluda, SC	RHC
Due West Family Medicine	Abbeville, SC	RHC
Family Healthcare Center	Laurens, SC	Family Practice
Family Health Care	Greenwood, SC	Family Practice

# Annual Common Patient encounters expected between CAH-HIT Network Providers	250,000 (Shared Service Area)
# Total Network Provider FTEs	77.5 FTE

Equipment/Vendors or Collaborative Partners

CareEvolution Inc. —Vik Kheterpal software for Health Information Exchange
Self Regional Healthcare—Patrick Stewart—housing LRHN hardware and building of adapters to client sites and security around LRHN database.

NAME OF NETWORK
Middle Tennessee Rural Health Information Network (MTRHIN)

Name of Grantee
Tennessee Department of Health, Office of Rural Health

Principal Investigator/Project Manager Angie Allen
Address 425 5th Ave North Nashville, TN 37247
Phone (615) 741-5226
Fax (615) 253-2100
E-mail angie.allen@state.tn.us

Project Purpose
MTRHIN will support the two-way sharing of electronic medical information among three Critical Access Hospitals, (Trousdale Medical Center, Macon County General Hospital, and Riverview Regional Medical Center South) an FQHC (United Neighborhood Health Care) and their tertiary provider (Sumner Regional

Medical Center). HIE software will enable these sites and other local providers to share patient information generated in different systems to enhance patient care. The project will be constructed in a fashion that will allow for expansion beyond the pilot participants.

Outcome Measures/Expectations

1. Implement an effective health information exchange network among the participating CAHs and the area rural community providers.
2. Develop a system that provides quality patient health information exchange to support patient transfers and consultations from the rural hospitals and referring physicians to the designated tertiary care facility.
3. Expand the project scope beyond the end of the pilot period to support other regions of the state, to include linkage with existing HIEs along with the Tennessee Department of Health Department Clinic sites and other existing telehealth projects.
4. Participate in the State's eHealth initiatives and work closely with the Governors eHealth Advisory Council to ensure compliance and compatibility with the State's master roadmap for promoting electronic health data sharing in Tennessee.

Service Area

The hospitals and their patients reflect the variety of Tennessee's regions and geography from Appalachia to the Cumberland Plateau to the upper Mississippi Delta. Health care in the outlying rural areas of the network is limited primarily to small critical access and primary care hospitals and clinics. Often patients must travel miles to larger facilities for routine tests and treatments provided by facilities in metropolitan areas. Health disparities impact this population, with high rates of diabetes, asthma, hypertension, cancer and black lung among subpopulations.

The majority of the counties in the service area have also been designated as federal shortage areas in terms of mental health services, dental care, medical professionals and medically underserved geographical areas and populations in general.

Network Members

Sumner Regional Medical Ctr / Tertiary Care Ctr	Sumner	555 Hartsville Pike	Gallatin	TN	37066
Contact	**Phone**		**Email**		
Bruce James, CEO	(615) 328-5519		bruce.james@sumner.org		

Macon County General Hospital/CAH	Macon	204 Medical Drive	LaFayette	TN	37083
Contact	**Phone**		**Email**		

Dennis Wolford, Administrator	(615) 666-2147	dwolford@mcgh.net

Riverview Regional Medical Center-South/CAH	Smith	130 Lebanon Hwy	Carthage	TN	37030
Contact	**Phone**		**Email**		
Scott Tongate, Assistant Administrator	(615) 735-5240		scott.tongate@sumner.org		

Riverview Regional Medical Center North/CAH	Smith	158 Hospital Drive	Carthage	TN	37030
Contact	**Phone**		**Email**		
Edward Sanford, Administrator	(615) 735-5250		chip.sanford@sumner.org		

United Neighborhood Health Care / FQHC	Trousdale	100 Damascus	Hartsville	TN	37074
Contact	**Phone**		**Email**		
Mary Bufwack, CEO	(615) 228-8902		maryunhs@aol.com		

Trousdale Medical Center	Trousdale	500 Church Street	Hartsville	TN	37074
Contact	**Phone**		**Email**		

Bill Mize, Administrator	(615) 328-6704	Mizeb@sumner.org

Equipment/Vendors or Collaborative Partners
The Community Health Network is in the process of completing a Request for Quote (RFQ) for the acquisition of Health Information Exchange (HIE) software. This RFQ will be sent to a select list of HIE vendors. The RFQ responses will then be used to select two HIE vendor finalists for site visits and/or onsite demos with the goal of signing a purchase contract in June, 2008.

The Tennessee Department of Health has formed a coalition of partners to work on this project. These partners include the State of Tennessee eHealth Initiative, the Community Health Network (CHN), the State of Tennessee Office of Information Resources, the Tennessee Hospital Association, the Vanderbilt University Center for Better Health, and Qsource (Tennessee's designated CMS Quality Improvement Organization).

In conjunction with this project, the State of Tennessee has contracted with the Community Health Network (CHN) to purchase, install and host a health information exchange (HIE) solution for sending and receiving electronic health data between the target systems below:

Meditech- used by Sumner Regional, Trousdale and Riverview hospitals
CPSI Healthcare Information and Patient Care System – used by Macon County General Hospital
QS Technologies Patient Tracking Billing System – used by the Tennessee Department of Health
NextGen Ambulatory System – used by CHN (Community Health Network) member clinics

In addition, CHN will be working with the State of Tennessee for providing high speed broadband access to the participating healthcare providers that will include utilization of funds from a FCC Telehealth grant.

NAME OF NETWORK
FLEX CAH HIT Network Implementation (Improving Texas Rural Community Healthcare Through HIT Implementation)

Name of Grantee
Texas Office of Rural Community Affairs

Principal Investigator - Theresa Cruz (ORCA)
Address 1700 N. Congress Avenue –Ste 220 Austin, Texas 78701
Phone 512. 926.6719
Fax 512.936.6776
Organizational Website www.orca.state.tx.us
E-mail tcruz@orca.state.tx.us

Project Manager –
Kathy Mechler (Texas A&M Health Science Center-Rural and Community Health Institute)
Address 3833 Texas Avenue –Ste 150 Bryan, Texas 77802
Phone 979.862.5004
Fax 979.862.5015
Organizational Website www.rchitexas.org
E-mail mechler@tamhsc.edu

Project Purpose The goal of this project is to improve health care delivery and quality of life through HIT implementation in two rural communities as a demonstration model for all rural Texas communities. The objectives are to improve the safety, quality, efficiency and effectiveness of health care delivery through

implementation of health information technology. The project is intended to connect health information within each individual community and to their tertiary care facility in Amarillo, Texas. Additionally, the project intends to improve access to healthcare services through the use of telemedicine.

Outcome Measures/Expectations

1. **Disease Management Indicators**

The ability to collect and measure the disease specific measures for diabetes and heart disease as indicated below (a & b) will only be possible once the clinical information system is installed in each community. Baseline findings from these measures will be obtained at the time of clinical information system implementation (Phase 2, Month 5) and monitored throughout the grant period.

a. Diabetes: Average patient HbA1c at or below the American Diabetes Association and Physician Consortium for Performance Improvement Measurement Set goal of 7.0%. **Per Patient** – Trend of HbA1C values over 12 months. **Per Patient Population - Numerator:** Number of Patients with one or more HbA1C tests. **Denominator:** All patients diagnosed with diabetes. The study will also provide the opportunity to evaluate the distribution of HbA1c values by range: <6.0, 6.0-6.9%, 7.0-7.9%, 8.0-8.9%, 9.0-9.9% ≥10%

b. Cardiovascular: Average patient LDL at or below 100. Measurement standards established by the American College of Cardiology, American Heart Association and the Physician consortium for Performance Improvement will be utilized. **Per Patient** – Trend of LDL values over 12 months. **Per Patient Population – Numerator:** Number of patients who received at least one lipid profile to include LDL. **Denominator:** All patients with cardiovascular disease. The study will also provide the opportunity to evaluate the distribution of LDL values by range: ≥160, 130-159, 100-129,<100.

1. **Patient Safety Indicator**

The ability to collect and measure the ***decubitus ulcer patient safety indicator*** will continue to be monitored and evaluated through the use of administrative data utilizing the AHRQ algorithms currently available through the rural data warehouse.

a. Decubitus Ulcer: Cases of decubitus ulcer per 1,000 discharges with a length of stay of 4 or more days. **Numerator:** Discharges with ICD-9-CM code of decubitus ulcer in any secondary diagnosis field among cases meeting the inclusion and exclusion rules for the denominator. **Denominator:** All medical and surgical discharges 18 years and older defined by specific DRGs. **Exclusions:** Length of stay of less than 5 days, ICD-9-CM code of decubitus ulcer in the principle diagnosis field or in a secondary diagnosis field if present on admission, MDC 9, 14, ICD-9-CM diagnosis of hemiplegia, paraplegia, or quadriplegis, spina bifida, debridement or pedicle grants before or on the same day as the major operating room procedure, admission from a long-term care facility or transferred from an acute care facility.

3. Inpatient Quality Indicator

Pneumonia: The ability to collect and **measure the pneumonia inpatient quality indicator** will continue to be monitored and evaluated through the use of administrative data utilizing the AHRQ Pneumonia mortality rate algorithms as currently available through the rural data warehouse. Baseline data for this measure is provided. Pneumonia mortality will be measured utilizing mortality in discharges with a principle diagnosis code of pneumonia. **Numerator:** Number of deaths among cases meeting the inclusion and exclusion rules for the denominator. **Denominator:** All discharges, age 18 years and older, with a principal diagnosis of pneumonia. **Exclusions:** Missing discharge disposition, transferring to another short-term hospital, MDC 14, 15.

4. Effectiveness and Efficiency Indicator

Medication Errors: Currently data collected regarding medication errors that ultimately impact the

effectiveness and efficiency of medical care in both Collingsworth and Friona is a paper-based system. Through the implementation of a community-wide patient information system, medication error is expected to be reduced and the efficiency of treatment enhanced through information sharing throughout the continuum. Medication errors will be measured by evaluating the number of medication errors monthly. **Numerator:** Number of medication or dispensing errors per month. **Denominator:** Number of medications dispensed per month.

Service Area This project intends to impact the two frontier communities of Wellington and Friona, Texas located in the Texas panhandle. Both of these community hospitals and local providers offer limited specialty care, forcing local residents to drive more than 70 miles from one community and more than 100 miles from the other to access specialty care in Amarillo.

Network Members

Texas Tech University /Telemedicine	Lubbock	3601 4th St STOP 9416	Lubbock	TX	79430
Contact	**Phone**		**Email**		
Debbie Voyles	806.743.4440		Debbie.voyles@ttuhsc.edu		

Northwest Texas Health System / Tertiary Hosp	Potter	1501 S. Coulter	Amarillo	TX	79106
Contact	**Phone**		**Email**		
Michael Smith	806.351.6608		michael.smith@nwths.com		

Collingsworth General Hospital/CAH	Collingsworth	1015 15th St	Wellington	TX	79095
Contact	**Phone**		**Email**		
Mike Easley Or Candy Powell	806.277.0176 806.447.2521		mikeeasley@austin.rr.com CandyPowell@collingsworthgeneral.net		

Parmer County Hospital/CAH	Friona	1307 Cleveland St	Friona	TX	79035

Contact	**Phone**	**Email**
Mike Easley Or Lance Gatlin	806.277.0176 806.250.2754	mikeeasley@austin.rr.com lgatlin@trhta.net

Equipment/Vendors or Collaborative Partners:

OPUS is the selected vendor for this project.
Contact: Chris Mountzouris
VP, Marketing & Business Development
Opus Healthcare Solutions, Inc.
12301 Research Blvd., Bldg. IV, Suite 200
Austin, TX 78759

Toll Free: 800.676.3371
Phone: 512.336.4410
Fax: 512.336.4799
Email: cmountzouris@opushealthcare.com
Web: www.opushealthcare.com

NAME OF NETWORK
Virginia Acute Stroke Telehealth Network (VAST)

Name of Grantee
Virginia Department of Health, Office of Minority Health and Public Health Policy
Principal Investigator/Project Manager
Cynthia Barrigan, Executive Director, Virginia Telehealth Network
Address PO Box 2356 Centreville, Virginia 20122
Phone 703-802-4878
Fax 1-888-205-0114
Organizational Website www.ehealthvirginia.org
E-mail cbarrigan@ehealthvirginia.org

Project Purpose

Virginia's incidence and mortality rates for stroke are among the highest in the nation – a vexing problem for the State's health care providers. The Institute of Medicine of the National Academy of Science and the American Stroke Association has concluded that the fragmentation of stroke systems of care contributes to the magnitude of this health problem—especially in rural and underserved communities.

The American Stroke Association, a division of the American Heart Association, says that a community's stroke system of care must include certain fundamental components ((*Stroke.* 2005; 36:690.) http://stroke.ahajournals.org/cgi/content/full/36/3/690):

- Primary prevention
- Community education
- Notification and response of emergency medical services
- Acute stroke treatment
- Subacute stroke treatment and secondary prevention
- Rehabilitation
- Continuous Quality Improvement Initiatives

The lack of focused health information technologies (HIT) that enable health information exchange (HIE) and the delivery of remote telehealth/telemedicine services (TH/TM) are partially responsible for serious disruptions in continuity of care as stroke patients move from one level of care and care provider to another throughout Virginia's health care system. Further, the lack of integrated HIT capabilities that enable the rapid and efficient transfer of patient data and digital images impedes the timely diagnosis and treatment of stroke victims.

The purpose of the Virginia Acute Stroke Telehealth Network (VAST) is to design, development, test and evaluate a model stroke network across the Central Shenandoah Region. HIT will be implemented at Bath Community Hospital—a critical access hospital-- and its supporting hospitals as part of a regional stroke quality improvement initiative. The intent of this project is to examine the first four components of the stroke continuum of care—Prevention, Community Education, EMS Notification and Acute Treatment—and introduce HIT solutions--along with other interventions-- to strengthen , improve and more tightly integrate these components of the stroke systems of care. It is envisioned that this model would be considered for state-wide adoption.

Primary Objectives

- Increase awareness of stroke signs and symptoms and best practices in stroke care.
- Improve the stroke EMS response.
- Accelerate time to diagnosis and treatment of acute stroke

Outcome Measures/Expectations

Prevention/Community Education

- Develop and implement a centralized stroke website for Virginia (virginiastrokenetwork.org) that patient/providers can use to access information on national and state-level stroke initiatives, stroke policy, best practices, VAST, and receive on-line stroke education and training.

EMS Notification and Response

- Develop a Stroke EMS Plan for the Region
- Develop electronic stroke training materials and standardized protocols.
- Implement a web-based learning management system.
- Deliver on-line stroke training to EMS providers.

Acute Treatment

- Deploy critical tele-stroke infrastructure which includes: the RP-7 Remote Presence System to facilitate remote neurology stroke consults; the implementation of PACS and integrated tele-radiology solutions to enable the digital capture, transfer, archiving and on-going sharing of CT scans for rapid interpretation across the network; and improvements to the existing CPSI electronic medical record system for enhanced medical documentation of stroke in the Emergency Department.

Service Area

The service area for the project spans the entire Central Shenandoah Valley---- with a special emphasis on Bath County which is a designated Medically Underserved Area (MUA). The Central Shenandoah Valley Region is located in the middle of the historic and scenic Shenandoah Valley in west-central Virginia. It has a land area of 3,439 square miles; the Region is home to some 246,400 persons. Geographically, the Region is the largest health planning district in the state.

The Region is comprised of five counties (Augusta, Bath, Highland, Rockbridge and Rockingham); five independent cities (Buena Vista, Harrisonburg, Lexington, Staunton, and Waynesboro); and eleven towns (Bridgewater, Broadway, Craigsville, Dayton, Elkton, Glasgow, Goshen, Grottoes, Monterey, Mt. Crawford and Timberville).

According to the U.S. Census, Bath County's population is approximately 4,814. Persons over age 65 make up 19.4% of the county as compared to 11.4% of the State's population. The median household income in Bath County (2000) was $38,145 as compared to the State median of $51,103.

Network Members

Bath Community Hospital / Critical Access Hospital	Bath	P O Drawer Z	Hot Springs	VA	24445
Contact	**Phone**		**Email**		
Debbie Lipes, CEO	540-839-7059		bcchdl@bcchospital.org		

Rockingham Memorial Hospital-Community Hospital	Rockingham	235 Cantrell Avenue	Harrisonburg	VA	22801
Contact	**Phone**		**Email**		
Dr. Dennis Carroll, Chief Medical Officer	540-433-4100		dcarroll@rhcc.com		

Augusta Medical Center	Augusta	78 Medical Center Drive	Fishersville	VA	22939
Contact	**Phone**		**Email**		
Dr. Fred Castello, Chief Medical Officer	540-332-4251		fcastello@augustamed.com		

University of Virginia / Tertiary Care Academic Medical Center.	Albemarle	1215 Lee Street	Charlottesville	VA	22908
Contact	**Phone**		**Email**		
Dr. Nina Solenski	**434-924-8374**		NJS2J@virginia.edu		

Central Shenandoah EMS Council / EMS	Augusta	2312 West Beverly Street	Staunton	VA	24401
Contact	**Phone**		**Email**		
Dr. Asher Brand, Medical Director	540-886-3676		Asher.Brand@gmail.com		

Equipment/Vendors or Collaborative Partners

Vendors

- **InTouch Health**: RP-7 Remote Presence System: Uses a mobile robot with live untethered video-teleconferencing capability and allows a stroke neurologist to immediately initiate an assessment from any location using a remote control joystick to pilot the robot in the remote environment without assistance from the remote community ED.

- **Computer Programs and Systems, Inc (CPSI):** Electronic Forms Module: Replaces paper-based patient data and care forms with user-defined electronic ones. Displayed and completed on-line using Microsoft's Internet Explorer, the module's forms are easy to use and can be customized to meet such

needs as ED triage, trauma, assessments, modality worksheets, consent for treatment, information release requests, transfers, etc.

- **PACS Vendors being evaluated include DR Systems, CPSI and Carestream.**

Collaborative Partners

- American Heart Association (Mid-Atlantic Affiliate)
- Edward Via Virginia College of Osteopathic Medicine (VCOM)
- Virginia Department of Health - Division of Chronic Disease & Control
- Virginia Department of Health – Office of Minority Health and Public Health Policy
- Virginia Health Quality Center
- Virginia Stroke Systems of Care Collaborative
- Virginia Telehealth Network
- Winchester Medical Center - Valley Health

NAME OF NETWORK
Western Washington Rural Health Care Collaborative (WWRHCC)

Name of Grantee
Washington State Department of Health, Office of Community and Rural Health

Principal Investigator/Project Manager
Elizabeth Floersheim

Address PO Box 55451 Seattle, WA
Phone 206-769-5871
Fax 206-881-7730
Organizational Website wwrhcc.org E-mail efloersheim@msn.com

Project Purpose
WWRHCC proposes to develop a network for Health Information Exchange among three CAHs and their community partners. The rural pilot sites, Jefferson Healthcare (Port Townsend), Whidbey General (Coupeville), and Morton General (Morton), serve areas with combined rural populations totaling almost 100,000 people. These CAHs were chosen due to the variety of local clinics/services they operate – i.e., Rural Health Clinics, home health, diabetes education, etc. – and also because each currently operates a different patient information system. WWRHCC has identified Harborview Medical Center as the project's tertiary referral partner, which as the State's only Level I trauma referral destination, is important to CAHs statewide.

Outcome Measures/Expectations
This HIT project will develop a universal data exchange/interfacing capability on multiple levels, expressed in the project's goals:
I. Develop a seamless patient information exchange capability among local rural providers for each CAH participant.
II. Develop a seamless patient information exchange capability between the CAH participants.
III. Develop a seamless information exchange capability to support rural trauma and inpatient consultations and transfers to Harborview Medical Center.
IV. After the grant project period, support the expansion of the project's HIT system to other WWRHCC members, and to other rural hospitals statewide.

Service Area
Each of the three HIT CAHs serves a rural community/service area that is itself unique within Western Washington. Jefferson Healthcare is located in Port Townsend, at the northwest area of the Olympic Peninsula. Forks Community Hospital is located in Forks and serves western Clallam and southwestern Jefferson counties. Forks Community Hospital is the most far northwestern hospital in the contiguous US. Forks is located the heart of the Olympic Peninsula, between the Olympic Mountains and the Pacific Ocean beaches. Morton General Hospital is located in Morton and serves the rugged, densely forested area between Mt. Rainier and Mt. St. Helens. Harborview Medical Center located in Seattle is the only Level I Trauma Center in the State of Washington.
Counties involved include Jefferson, Clallam, Lewis and King.

Network Members
Note - please identify provider types as Tertiary Care Center, Critical Access Hospital (CAH), Medicare Certified Rural Health Clinic (RHC), Federally Qualified Health Centers (FQHC), Home Health Agency (HHA), Public Health Department, Emergency Medical Service (EMS), Family Practice Group/Practitioner, Private Practice Physicians, Nursing facilities, Pharmacy or other appropriate provider type. If the entity is receiving funds from the CAHHIT grant it is appropriate to list them as a Network

Organization Name /
Provider Type County/
Parish Address City, State Zip Code
Western Washington Rural Health Care Collaborative/
PO Box 55451 Seattle WA 98155-0451
Elizabeth Floersheim 206-769-5871

Organization Name County/
Parish Address City, State Zip Code
Jefferson Healthcare/ Jefferson
834 Sheridan Avenue Port Townsend WA 98368-2443
Contact Phone Email
Roger Harrison 3
60-385-2200 ext 3392

Organization Name County/
Parish Address City, State Zip Code
Forks Community Hospital Clallam
300 Bogachiel Way Forks WA 98331
Andrea Perkins-Pepper
360-374-6271

Organization Name County/
Parish Address City, State Zip Code
Morton General Hospital/ Lewis 521 Adams Street Morton WA 98356
Contact Phone Email
Stephen Morton
360-496-5112

Organization Name County/
Parish Address City, State Zip Code
Harborview Medical Center/ King University of WA
Box 357110 Seattle WA 98195
David Chou

Equipment/Vendors or Collaborative Partners
Operating systems being used at by the CAHs: Meditech (Client Server and Magic) and Healthland (Dairyland).

Health Information Exchange – Orion Health

Equipment-Servers: HP and Dell. We are considering Omnicell Automatic Dispensing Devises.

Clinics: Clallam Bay Medical Clinic. 74 Bogachiel, Clallam Bay, WA 98326 , Fork's Women's Clinic, 231 Lupine Way, Forks, WA 98331, 530 Bogachiel Way, Forks, WA 98331 and West End Outreach, 551 Bogachiel Way, Forks 98331 and 601 Bogachiel Way (Adult Day Treatment), Forks, WA 98331 and Oak Street Center (Chemical Dependency) 109 Oak Street, Port Angeles, WA. 98362.
Forks Community Hospital also operates a Long Term Care Facility and an ambulance service.

NAME OF NETWORK
RWHC Information Technology Network

Name of Grantee
Board of Regents of the University of Wisconsin System

Principal Investigator/Project Manager
Louis Wenzlow

Address 880 Independence Lane Sauk City, WI 53583
Phone 608.644.3237
Fax 608.643.4936
Organizational Website rwhc.com
E-mail lwenzlow@rwhc.com

Project Purpose
The Wisconsin CAH network is working to implement a collaborative electronic health record (EHR) environment (initially consisting of a hospital information system and a physician practice EMR system) that is shared by multiple critical access hospitals from a common datacenter and supported by a pooled staff. The Rural Wisconsin Health Cooperative Information Technology Network (RWHC ITN) is the non profit consortium organization that operates the collaborative EHR environment. CEOs of participant hospitals serve as the ITN Board of Directors; and project leaders from each ITN participant hospital work with ITN staff to align collaborative efforts with facility needs. The RWHC ITN's mission is "to provide community hospitals and their affiliates with health information technology (HIT) applications and support services that promote high quality, cost effective healthcare."

Outcome Measures/Expectations
Primary ITN goals include: to drive improvements to patient safety and the quality of care and service; increase secure access to healthcare information; increase healthcare cost effectiveness, and eventually provide all Wisconsin CAHs with an integrated, cost-effective option to meet their EHR needs.

In working to achieve its goals, the RWHC ITN will provide the following services and benefits:

- Advanced clinical systems such as E-MAR, medication verification through barcoding, inpatient charting, CPOE, physician practice EMR with e-prescribing, and an EHR web portal
- Data exchange capabilities between shared system participants
- Reduced datacenter, hardware, software, implementation, support, and operating costs due to group volume purchasing and a shared data center model

- Improved support quality with a shared HIT staff

Service Area
The initial network participants are located in south central and western Wisconsin, including in Sauk, Dane, Monroe, Vernon, Grant, and Lafayette counties, which are parts of Wisconsin's second and third congressional districts. Each of the 4 network participant facilities are located in areas designated as "rural" or "exceptionally rural" per USDA rurality scoring.

Network Members

RWHC Information Technology Network	880 Independence Lane	Sauk City	WI	53583
Contact	**Phone**	**Email**		
Louis Wenzlow	608.644.3237	lwenzlow@rwhc.com		

St Joseph's Community Health Services	400 Water Avenue	Hillsboro	WI	54634
Contact	**Phone**	**Email**		
Donavan Decot	608.489.8177	ddecot@stjhealthcare.org		

Tomah Memorial Hospital	321 Butts Avenue	Tomah	WI	54660
Contact	**Phone**	**Email**		
LaVonne Smith	123.123.1234	ljsmith@tomahhospital.org		

Boscobel Area Health Care	205 Parker Street	Boscobel	WI	53805
Contact	**Phone**	**Email**		
Toni Brown	608.375.4112	tbrown@boscobelhealth.com		

Memorial Hospital of Lafayette County	800 Clay Street	Darlington	WI	53530
Contact	**Phone**	**Email**		
Kevin Glass	608.776.4466	kevin.glass@monroeclinic.org		

Equipment/Vendors or Collaborative Partners
Healthcare Management Systems – HMS, a CCHIT certified inpatient system vendor, will be providing the hardware, software (including advanced clinical systems such as E-MAR, medication verification through barcoding, inpatient charting, CPOE, an EHR web portal, as well as data exchange functionality), and related implementation services for the project.

Medinotes – Medinotes will be providing the physician practice EMR and related implementation services for the project.

PhaseWare – PhaseWare will be providing the web-enabled helpdesk software for the project.

RWHC – RWHC (to be distinguished from RWHC ITN), a collaborative organization of 32 non-profit Wisconsin hospitals, provided the early planning and startup resources for RWHC ITN; and will be providing ITN shared staffing services.

WORH – The Wisconsin Office of Rural Health has also provided early planning and startup resources for RWHC ITN and serves as a key collaborative partner.

FCC Pilot Program – The FCC Pilot Program will be providing 85% of eligible costs relating to the project telecommunications aspects.

Critical Access Hospital - Health Information Technology Network
Implementation of Electronic Health Records (EHR) Systems in Critical Access Hospitals

HRSA Grant Program Overview

The Department of Health and Human Services has identified furthering the use of health information technology (HIT) as a key priority. This focus also supports the President's goal of universal adoption of electronic health records for all Americans by 2014. This Critical Access Hospital- Health Information Technology Network Implementation Grant promotes the implementation of HIT and electronic health records (EHR) in Critical Access Hospitals (CAHs) and the providers they work with directly.

The funding for this opportunity is in accordance with Section 1820(g) of the Social Security Act.

Program Purpose

The purpose of the FLEX CAH HIT Network grant is to provide funds to support the development of a (1) Flex CAH-HIT Network pilot programs in States receiving the grant. Examples of HIT may include practice management systems, disease registry systems, care management systems, clinical messaging systems, personal health record systems, electronic health record systems and health information exchanges.

HRSA's experience has shown that it is cost effective to utilize networks of health care providers to develop health information technology systems. HRSA is interested in programs that can measure the impact of HIT in terms of outcomes that support the aims of this funding opportunity. Each of the grantees has past experience with the use of quality improvement programs. HRSA requires at least five performance outcome measures two of which HRSA defines to include diabetes control and heart disease risk reduction. The grantees will utilize measures to support the aim of enhancing the effectiveness, efficiency, safety and quality as related to HIT implementation.

Grantees

NAME OF NETWORK
An Electronic Health Record Implementation for Critical Access Hospitals and Clinics in the Kaua`i Region of the Hawai`i Health Systems Corporation

Name of Grantee
Hawaii State Department of Health, Hawaii State Office of Rural Health

Principal Investigator/Project Manager
Norman Okamura

Address 2424 Maile Way, Saunders 713 Honolulu, HI 96822
Phone 808.956.2909
Fax 808.956.8019
E-mail norman@tipg.net

Project Purpose
This FLEX CAH HIT Network Implementation project, submitted by the Department of Health of the State of Hawai'i, the Kaua'i Region of the Hawai'i Health Systems Corporation (HHSC), and the Telecommunications

and Information Policy Group of the University of Hawai'i as partners, seeks to implement the open source version of the VistA EHR system for two Critical Access Hospitals and four clinics that are part of the HHSC Kaua'i Region Network. The project will establish a continuity of care and improve quality, patient safety, and cost-effectiveness.

The project seeks to (1) develop necessary enhancements to the existing VistA EHR system, and establish infrastructure in areas with limited or no connectivity to improve the accessibility of clinical information and results for clinicians; (2) implement security protocols in the VistA EHR to enable the HHSC Kaua'i Region network authorized access to patient records; (3) implement chronic disease care management tools to improve disease management and patient care; (4) develop application interfaces with patient management and billing systems to improve efficiencies; (5) develop internal resources to further deploy and sustain EHR implementations in Hawai'i; (6) evaluate the implementation and usability of the EHR to provide lessons learned for future VistA (or other EHR) implementations.

Outcome Measures/Expectations

This project seeks to provide a functioning EHR based off of the Hui OpenVista (HOV) software. Towards that end the expected outcomes are as follows:

1. System Implementation and Customization—the base HOV software will be modified to meet the workflow requirements of the CAHs and clinics.
2. Chronic Disease Care Management—this project will implement a chronic disease care management capability focused on diabetes and cardiovascular disease.
3. Outpatient Billing Interface—the project team will assess if HHSC's current outpatient billing system, TeamPraxis, is capable of interfacing with HOV and / or McKesson Series. If these capabilities are not possible, alternative solutions will be implemented since billing for services is fundamental to the functioning of these systems.
4. Resource Development—the Partners will work to ensure that the project team can support the long-term needs for ICT personnel that can support the system.

Service Area

The service area will bring together two critical access hospitals (CAH) and four clinics in the county of Kaua'i. The Kaua'i County encompasses the islands of Kaua'i and Ni'ihau. Both CAHs and the clinics are on the island of Kaua'i and service the population of Ni'ihau, which has no medical facilities.

Network Members

Organization Name / Provider Type	**County/ Parish**	**Address**	**City,**	**State**	**Zip Code**
Hawai'i State Office of Rural Health	Hawai'i	PO Box 1675	Honokaa	HI	96727
Contact	**Phone**		**Email**		
R. Scott Daniels, PhD	808.775.8883		scott.daniels@doh.hawaii.gov		
Organization Name / Provider Type	**County/ Parish**	**Address**	**City,**	**State**	**Zip Code**

Telecommunications and Information Policy Group	Honolulu	2424 Maile Way, Saunders 713	Honolulu	HI	96822
Contact	**Phone**		**Email**		
Norman Okamura, PhD	808.956.2909		norman@tipg.net		

Organization Name / Provider Type	**County/ Parish**	**Address**	**City,**	**State**	**Zip Code**
Hawai'i Health Systems Corporation	Honolulu	3675 Kilauea Ave.	Honolulu	HI	96816
Contact	**Phone**		**Email**		
Thomas M. Driskill, Jr.	808.733.4020		tdriskill@hhsc.org		
Organization Name / Provider Type	**County/ Parish**	**Address**	**City,**	**State**	**Zip Code**
West Kaua'i Medical Center	Kaua'i	4643 Waimea Canyon Rd.	Waimea	HI	96796
Contact	**Phone**		**Email**		
Orianna Skomoroch	808.338.9431		oskomoroch@hhsc.org		
Organization Name / Provider Type	**County/ Parish**	**Address**	**City,**	**State**	**Zip Code**
Samuel Mahelona Memorial Hospital	Kaua'i	4800 Kawaihau Rd.	Kapa'a	HI	96746
Contact	**Phone**		**Email**		
Orianna Skomoroch	808.338.9431		oskomoroch@hhsc.org		

NAME OF NETWORK
Alabama Cardiovascular Disease Network

Name of Grantee
Alabama Department of Public Health

Principal Investigator/Project Manager
Harold R. Brown, Jr.

Address
RSA Tower Suite 710, 201 Monroe Street Montgomery, Alabama 36104

Fax (334) 206-5434
Phone (334) 206-5430
E-mail hbrown@adph.state.al.us
Organizational Website http//:adph.org/ruralhealth/

Project Purpose Acquire and implement an Health Information Technology (HIT) network based at one of the State's four Critical Access Hospitals (CAHs), Randolph Medical Center (RMC) in Roanoke, to improve health outcomes of cardiac patients in the three county service area. Cardiovascular Disease has been the number one killer since 1928. The network will leverage a Toshiba 64 Slice CT Scanner and other equipment previously acquired by RMC to improve health outcomes through prevention education, screening, treatment, and follow up. The project has four distinct tracks: an Electronic Health Record (EHR) for RMC, data links among the partners, a database for trending and analysis, and direct patient intervention to improve cardiac patient disease compliance.

Outcome Measures/Expectations Performance measures include High Blood Pressure Management, Cholesterol Management, Incidence of Smoking, Diabetes Compliance, and others. Over time, expectations include a significant reduction in cardiovascular disease in the three county service area.

Service Area Three counties in East Alabama: Randolph, Chambers, and Clay

Network Members

Organization Name / Provider Type	**County/ Parish**	**Address**	**City**	**State**	**Zip Code**
Alabama Department of Public Health	All Alabama Counties	201 Monroe St	Montgomoery	AL	36104
Contact	**Phone**		**Email**		
Harold R. Brown, Jr.	(334) 206-5430		hbrown@adph.state.al.us		

Organization Name / Provider Type	**County/ Parish**	**Address**	**City,**	**State**	**Zip Code**
Randolph Medical Center /	Randolph	59928 Highway 22, PO Box 670	Roanoke	AL	36274
Contact	**Phone**		**Email**		
Tim Harlin	(334) 863-4111 x 1501		tharlin@randolphmc.org		

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
East Alabama Medical Center	Lee	2000 Pepperell Parkway	Opelika	AL	36801
Contact	**Phone**		**Email**		
Laura Bell	(334) 749-3411		Laura.Bell@eamc.org		

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Institute for Advanced Cardiovascular Care	Lee	2375 Champion Blvd	Auburn	AL	36830
Contact	**Phone**		**Email**		
Michael Kincaid	(334) 704-0307		mkincaid9@gmail.com		

Equipment/Vendors or Collaborative Partners EHR vendors being considered include CPSI, MediTech, and Dairyland. The Health Information Exchange will be direct logins across the partner's HIS systems. Access will be limited to select zip codes for impacted patients in three county area. Southern Family Health Care, LLC, a Rural Health Center in Randolph County, will help populate the registry.

NAME OF NETWORK
Illinois Patient Health Information Network

Name of Grantee
Illinois Department of Public Health, Center for Rural Health,
and Illinois Critical Access Hospital Network

Principal Investigator/Project Manager
Mary Catherine Ring

Address
245 Backbone Road East Princeton, IL 61356
Phone 217/243-5055
Fax 217/243-5055
Organizational Website icahn.org
E-mail mring@icahn.org

Project Purpose
The Illinois PHIN project will demonstrate that the electronic medical record requirements of selected critical access hospitals can be well served by a single, hybrid product that manages patient information in both the inpatient and outpatient settings. Project funds will be used to implement an electronic medical record system at Washington County Hospital in Nashville and at Salem Township Hospital in Salem, and a picture archiving

and communications system at Washington County Hospital. A health information exchange will be established that will enable area health care providers, including those at one of the key referral partners – SSM St. Mary's Good Samaritan in Mount Vernon, to electronically share patient information. The health information exchange infrastructure will be available for use by other Illinois critical access hospitals and their community partners.

Outcome Measures/Expectations
The Illinois PHIN project will demonstrate the following:

1. cost efficient, nondisruptive integration of the selected electronic medical record software into a hospital's existing best of breed information system
2. feasibility of user adaptation of an ambulatory electronic medical record system for use in the inpatient setting
3. implementation of an easily scalable health information exchange that will be available to project participants and their partners
4. on-going expansion of health information exchange users to include small area networks of all critical access hospitals in the state and their local health care partners

Service Area
The two critical access hospitals are located in southwestern Illinois. Washington County Hospital is 55 miles east of St. Louis, Missouri and Salem Township Hospital is 96 miles east of St. Louis. Washington County has a population of slightly more than 15,000 (27/square mile), and Marion County, home of Salem Township Hospital, has a population of nearly 42,000 (73/square mile). Both counties have economic bases comprised of light manufacturing, agriculture, and tourism. The referral hospital, SSM St. Mary's Good Samaritan, is located in Mount Vernon in Jefferson County, population of approximately 40,000 (70/square mile). Mount Vernon is 26 miles from Salem and 31 miles from Nashville.

Network Members

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Salem Township Hospital / Critical Access Hospital	Marion	1201 Ricker Drive	Salem	IL	62881
Contact	**Phone**		**Email**		
Richelle Rennegarbe, CEO	618-548-3194 x 8186		rrennegarbe@salemtownhosp.org		

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Washington County Hospital /Critical Access Hospital	Washington	705 S. Grand Ave.	Nashville	IL	62263

Contact	Phone	Email
Nancy Newby, CEO	618-327-2200	nnewby@washingtoncountyhospital.org

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
SSM St. Mary's Good Samaritan	Jefferson	605 N. 12th Street	Mount Vernon	IL	62864
Contact	**Phone**		**Email**		
Bruce Merrell, President	618-241-2200		Bruce_Merrell@ssmhc.com		

Equipment/Vendors or Collaborative Partners

NextGen Healthcare was selected to provide both the electronic medical records and the health information exchange software.

Sectra was selected for the PACS installation.

NAME OF NETWORK:
St. Vincent Health

Name of Grantee:
Indiana State Department of Health

Project Manager:
John Winenger, Regional Network Development

Phone: 317.583.3244

Principal Investigator:
Dr. Alan Snell, Medical Infomatics Director

Phone: 317.583.3248
Address: 10330 North Meridian Street Indianapolis, IN 46290
Fax: 317.583.3255
Organizational Website: www.stvincent.org
E-mail: jawineng@stvincent.org

Project Purpose
The Indiana State Office of Rural Health (SORH) proposes to improve health care delivery in rural areas of the state by enhancing health information technology (HIT) and related linkages between primary care providers, critical access hospitals, and tertiary care hospital providers. The overall purpose of the project is to improve the safety, quality, efficiency, and effectiveness of health care in rural areas.

Outcome Measures/Expectations
Project Phase One: Allscripts (outpatient) Implementation

St. Vincent Health will plan and implement the installation of Allscripts, a state-of-art electronic health record system, in two (2) rural health clinics (RHC) locations affiliated with St. Vincent CAH sites in North Vernon, IN., and Winchester, IN. The project will also include installation of Allscripts in a federally qualified health center (FQHC) location in Elwood, IN. that works closely with the CAH at that Elwood location.

Project Phase two: Eclipsys (inpatient) CAH Implementation
St. Vincent Health will plan and implement the Eclipsys electronic patient record /clinical management software system at each CAH location. Implementation will begin at the St. Vincent Jennings location in North Vernon, IN location; will then proceed to SV Mercy in Elwood, IN.; then to SV Randolph location in Winchester, IN. Within each hospital, multiple other information management systems including those in Emergency departments, Imaging and Radiology departments, Picture Archival and Communications (PACS), Pharmaceutical management, and Laboratory information management systems will be interfaced with the new clinical management system.

Project Phase Three: Clinical Integration and Data Sharing
The existing physician practice systems in the RHC locations will be linked electronically to the Eclipsys clinical management system at the CAH sites so that critical components of the patient record information in the physician practices can be electronically shared, upon admission and discharge, with the CAH sites. In addition, data from visits made to the CAH Emergency departments and other primary care entry points can be shared between providers.

Project Phase Four: Health Information Exchange
Lastly, connectivity will be established to the Indiana Health Information Exchange (IHIE) network, which will further demonstrate the future state of healthcare in sharing patient vital statistics and exam results among providers. It is the collective belief that with this information, physicians can help reduce duplication of testing thus lowering costs and improve quality of care to patients. IHIE is currently delivering over one million clinical messages per month within the central Indiana healthcare market.

Project Phase Five: Evaluation
The Indiana State Office of Rural Health and St. Vincent Health, along with its CAH locations will utilize several operational and clinical measures to support the aim of enhancing effectiveness, efficiency, patient safety, and quality as related to the HIT project implementation. Quality indicators will be addressed with pre/post implementation levels, and will include the required indicators for disease management of diabetes and cardiovascular disease. The five targeted project outcomes will be focused on:

- Diabetes;
- Cardiovascular disease;
- Medical safety / Medication reconciliation;
- Pediatric Asthma; and,
- Adult immunizations (flu and pneumonia).

Service Area

1) St. Vincent Randolph, a CAH located in Winchester, Indiana (Randolph County). Included in this target area is:

- Rural health clinics integrated into their regional delivery system within Randolph County located in the Indiana cities of Union City, Ridgeville, Winchester and Lynn,

2) St. Vincent Mercy Hospital, a CAH located in Elwood, Indiana (Madison County). Included in this target area is:

- A free-standing Federally Qualified Health Center (FQHC) in Elwood, Indiana that has operational and clinical program integration with St. Vincent Mercy Hospital that includes shared clinical support staffing, shared medical direction, reduced rent/lease on property, and shared services such as laboratory and radiology.

3) St. Vincent Jennings Hospital, a CAH located in North Vernon, Indiana (Jennings County). Included in this target area is:

- A provider-based RHC located in North Vernon, Indiana.

4) St. Vincent Hospital – Indianapolis will serve as the tertiary care facility. It is a 650 bed hospital located in Marion County and provides tertiary level patient care services for the St. Vincent CAH Network.

Network Members:

Organization Name / Provider Type	**County/ Parish**	**Address**	**City,**	**State**	**Zip Code**
St. Vincent Jennings Hospital (Critical Access Hospital)	Jennings Co.	301 Henry Street	North Vernon	IN	47265-1097
Contact	**Phone**		**Email**		
Joe Roche, Administrator	812.352.4231		jeroche@stvincent.org		

Organization Name / Provider Type	**County/ Parish**	**Address**	**City,**	**State**	**Zip Code**
St. Vincent Mercy Hospital (Critical Access Hospital)	Madison Co.	1331 South A Street	Elwood	IN	46036-0041
Contact	**Phone**		**Email**		
Deborah Rasper, Administrator	765.552.4594		dyrasper@stvincent.org		

Organization Name / Provider Type	**County/ Parish**	**Address**	**City,**	**State**	**Zip Code**
St. Vincent Randolph Hospital (Critical Access Hospital)	Randolph Co.	473 Greenville Avenue	Winchester	IN	47394
Contact	**Phone**		**Email**		
Cheech Albarano, Administrator	765.584.0107		fgalbara@stvincent.org		

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Madison County Community Health Center	Madison Co.	1547 Ohio Street	Anderson	IN	46015
Contact	**Phone**		**Email**		
Anthony Malone, Administrator	765.641.0255		amalone@mcchc.org		

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Indiana Health Information Exchange	Marion Co.	846 N. Senate Avenue, Suite 300	Indianapolis	IN	46202
Contact	**Phone**		**Email**		
Debbie Banik, Program Director- Clinical Messaging Services	317.644.1734		dbanik@ihie.com		

Equipment/Vendors or Collaborative Partners

- **Chosen Billing System - IDX:** **IDX Systems Corporation** (IDX) was a healthcare software technology company that formerly had headquarters in South Burlington, Vermont, United States. It was founded in 1969 by Robert Hoehl, Richard Tarrant, and Paul Egerman. IDX was acquired by General Electric and incorporated into its GE Healthcare business unit in 2006. http://en.wikipedia.org/wiki/IDX_Systems

2. **Chosen Outpatient Electronic Medical Record System - Allscripts:** The award-winning TouchWorks™ Electronic Health Record (EHR) from Allscripts radically simplifies the art, science, and process of caring for patients. TouchWorks is the "EHR of Choice" for large medical groups (25 doctors and up) and has been nationally recognized as the leading provider of clinical software, connectivity and information solutions that physicians use to improve healthcare. More than 30,000 physicians in over 3,500 clinics nationwide use our solutions every day to inform, connect and transform healthcare. http://www.allscripts.com/as_emrupdate.html
3. **Chosen Inpatient Electronic Patient Record System - Eclipsys**: The Eclipsys **Sunrise Clinical Manager™** solutions connect the numerous caregivers involved in a single patient's care for improved quality, efficiency and turnaround times. Eclipsys is a leading provider of information solutions that help hospitals and health systems more-effectively *manage the business of healthcare* and achieve measurable and sustainable, improved outcomes. http://www.eclipsys.com/aboutus/
4. **Chosen Physician Order Set Provider – Zynx Health:** The Zynx team of physicians, nurses, and allied health professionals rigorously review the latest peer-reviewed literature to develop clinical summaries and distill evidence-based best practices. Zynx helps hospitals and physicians make evidence actionable in the form of physician order sets, interdisciplinary plans of care, alerts, and

reminders. Clinical teams utilize our online content management tools to collaborate and efficiently customize this information to adhere to local best practices, guidelines, and formularies. More than 1,400 hospitals nationwide trust evidence-based clinical decision support from Zynx Health to address regulatory initiatives, optimize pay-for-performance reimbursement, and measurably improve the quality and safety of patient care. http://www.zynx.com/

NAME OF NETWORK:
Pointe Coupee Parish Health Information Technology

Partnership

Name of Grantee
Louisiana Department of Health and Hospitals

Bureau of Primary Care and Rural Health

Principal Investigator:
Margaret Shipman, State Office of Rural Health Director

Address: 628 North 4th Street, 8th Floor Baton Rouge, LA 70802
Phone: (225) 342-1889
FAX: (225) 342-5839

E-Mail : mshipman@dhh.la.gov
Organizational Website: www.pcrh.dhh.louisiana.gov

Project Purpose
The purpose of the proposed network is to fully implement functional electronic health records within each network partner organization and to enable appropriate sharing of health information among all partner organizations. The primary partners include a critical access hospital (CAH), home health and hospice agency (HHA), two locations of a federally qualified health center (FQHC), four rural health clinics (RHC), one community clinic, two private physician practices and a 761-bed tertiary care center (TCC). The network will allow qualified providers to access the patient data located in any and all of the network member systems.

Outcome Measure/Expectations
The objective of this grant is unique in that it is built on the premise of data sharing not data exchange.

I. Implement a functional Electronic Medical Record for each of the partners
II. Develop a Community Portal that integrates systems at the network level. The portal will employ a federated data model that allows each network member system to access and present data without having to move data from its local database.
III. The Community Portal will present data from all partner applications via a single web-based portlet which will create a data view specific to the clinician's workflow

Service Area
The Pointe Coupee HIT Network will serve the Pointe Coupee Parish service area, which is located in south central Louisiana approximately 1 hour from the capital of Baton Rouge. Agricultural production is a mainstay of the economy. Pointe Coupee is one of the most diverse agricultural parishes in the state. Close to 165,000 acres of land are used to farm cotton, sugarcane, soybeans, corn, milo, wheat, cattle, hay, vegetables, rice, crawfish and pecans. The 2006 estimated population for Pointe Coupee Parish was 22,648 (U.S. Census, 2007).

The largest town in Pointe Coupee Parish is New Roads (home to Pointe Coupee General Hospital), with close to 5,000 residents. Only 69% of the population aged 25 years and older has earned a high school diploma. The unemployment rate is high, with only 55% of residents at age 16 or older in the labor force. Consequently, 23% of all individuals and 19% of all families in the parish are below the poverty level. Over 40% of area residents receive some form of public assistance and 27% of the community is enrolled in Medicaid.

Network Members

Organization Name/ Provider Type	County/ Parish	Address	City	State	Zip code
Pointe Coupee General Hospital / CAH	Pointe Coupe	2202 False River Rd.	New Roads	LA	70760-2621
Contact		Phone	Email		
Chad Olinde, CEO		225-638-6331	colinde@pcgh.org		

Organization Name/ Provider Type	County/ Parish	Address	City	State	Zip code
Pointe Coupee Homebound Health and Hospice / HHA	Pointe Coupe	350 Hospital Rd	New Roads	LA	70760-2621
Contact		Phone	Email		
Jeanne LeJune, RNC, CNS Admin		225-638-5717	homebound@eatel.net		

Organization Name/ Provider Type	County/ Parish	Address	City	State	Zip code
Innis Community Health Center /FQHC	Pointe Coupe	6450 LA Hwy 1	Batchelor	LA	70715
Contact		Phone	Email		
Linda Matessino, Exec Director		225-492-3775	Linda@inchc.org		

Organization Name/ Provider Type	County/ Parish	Address	City	State	Zip code
BACH Urgent Care Clinic/Community clinic	Pointe Coupe	230 Roberts Dr.	New Roads	LA	70760-2621

Contact	Phone	Email
Lynn David, Executive Director	225-638-8900	lynn@pcbach.com

Organization Name/ Provider Type	County/ Parish	Address	City	State	Zip code
Lake Primary Care Physicians / RHC (4)	Pointe Coupe	160 Hospital Rd	New Roads	LA	70760-2621
Contact		Phone	Email		
Keeley Chustz, Regional Manager		225-638-3781	KChustz@ololrmc.com		

Organization Name/ Provider Type	County/ Parish	Address	City	State	Zip code
Donald Doucet, MD & Associates / private (2)	Pointe Coupe	230 Roberts Dr, Suite I	New Roads	LA	70760-2621
Contact		Phone	Email		
Donald Doucet, MD		225-638-4585	drdoucet@bellsouth.net		

Organization Name/ Provider Type	County/ Parish	Address	City	State	Zip code
Our Lady of the Lake / TCC	Baton Rouge	5000 Hennessey Blvd.	Baton Rouge	LA	70808
Contact		Phone	Email		
Dr. Murphrey, Medical CIO		225-765-6565			

Equipment/vendors

Hospital CPSI
Home Health – Lewis
FQHC – EHS
BACH – Not selected
Portal – Fusion CareFx

NAME OF NETWORK
Thumb Region CAH-HIT Network

Name of Grantee
Michigan Department of Community Health

Principal Investigator/Project Manager
Donald A. Wheeler, FACHE

Address 2180 Commons Parkway Okemos, MI 48864
Phone 517-347-8917
Fax 517-347-8950
Organizational Website wwrhcc.org
E-mail DAWheeler77@AOL.com

Project Purpose
The purpose of Michigan's FLEX CAH-HIT project is to create an effective health data exchange between two Critical Access Hospitals and their tertiary referral center, in order to improve the safety, quality, efficiency, and effectiveness of health care delivery through a full continuum of care. The two Critical Access Hospitals include Deckerville Community Hospital in Sanilac County and Harbor Beach Community Hospital in Huron County, while the primary tertiary partner has yet to be selected from 3 possible facilities that serve the region. An existing 16-member "Thumb Rural Health Network" is providing governance and oversight of the project. The proposed HIT Network planning and implementation activities of this project will be used as a template for adoption and/or expansion to Michigan's other Critical Access Hospitals, as well as those in other states.

Outcome Measures/Expectations
Specific goals of the Network currently include: (1) Use HIT as a tool to improve the safety, quality, efficiency, and effectiveness of health care delivery in the Thumb region of Michigan; (2) Adopt the effective use of a clinical information system through an integrated system with a common architecture; (3) Create sustainable business model for deploying HIT in the Thumb region; (4) Improve the quality and performance of our organizations both individually and jointly; (5) Improve healthcare quality through the elimination of handwritten clinical data; (6) Successfully deploy or enable the deployment of hospital HIT practices that reduce medical errors and improve overall patient safety; (7) Increase the identification and reporting of medical errors and adverse events; (8) Develop HIT systems that support the regional collection and assessment of patient care data as part of the Michigan Critical Access Hospital Program's Quality Committee for the measurement of healthcare quality; (9) Enhance the Network's ability to collect data regarding the impact of HIT on healthcare outcomes, improving patient safety and quality of care; (10) Identify and support local and regional HIT collaborative projects that lead to standards-based data sharing across healthcare delivery sites; and (11) Share our HIT implementation experiences with other organizations and networks.

Service Area
The service area for the "Thumb Region CAH-HIT Network" lies on the eastern Lake Huron shoreline of Michigan's "thumb" region.

Network Members
The two Critical Access Hospitals include Deckerville Community Hospital in Sanilac County and Harbor Beach Community Hospital in Huron County. The tertiary-level partner has yet to be selected from three possible facilities that serve the region. The Network is seeking to identify an "open architecture" that will enable connectivity to all tertiary facilities serving the region.

The Thumb region of Michigan is surrounded by six potential tertiary referral hospitals including Covenant

Medical Center in Saginaw, Saginaw St Mary's Hospital, Bay Medical Center in Bay City, Genesys Health System in Flint, and Mercy Hospital or Port Huron Hospital in Port Huron (in the lower right corner of the map, just below Gardendale). All these tertiary hospitals are geographically remote (45 to 90 minutes driving time) from the rural service area.
The Thumb Rural health Network (TRHN) is a 16-member organization located in the rural counties of Huron, Sanilac and Tuscola, typically referred to as Michigan's "Thumb." TRHNs membership includes seven Critical Access Hospitals and one sole-community provider; two health departments; six tertiary hospitals surrounding the region; and one Multipurpose Collaborating Council.

There are no Federally Qualified Health Centers or Certified Rural Health Clinics in the targeted service area. The two CAH facilities operate 3 primary care clinics in the region that will be included in the HIT systems developed at those hospitals.

Both the Huron County and the Sanilac County Health Departments serve the target region. Together, these health departments provide health screening, preventions and surveillance services as required by state and federal mandates. Most of the surveillance reporting is provided for through "on-line" reporting systems operated by the state of Michigan. Their need for interaction with hospitals focuses on the receipt of "reportable disease" incidents and on the need to alert health providers about regional/local health risks.

Organization Name / Provider Type	**County/ Parish**	**Address**	**City,**	**State**	**Zip Code**
Deckerville Community Hospital	Sanilac	3559 Pine St	Deckerville	MI	48427
Contact	**Phone**		**Email**		
Ed Gamache, CEO	810-376-2835		gamachee@deckervillehosp.org		

Organization Name	**County/ Parish**	**Address**	**City,**	**State**	**Zip Code**
Harbor Beach Community Hospital	Huron		Harbor Beach	MI	
Contact	**Phone**		**Email**		
Ed Gamache, CEO	810-376-2835		gamachee@deckervillehosp.org		

Equipment/Vendors or Collaborative Partners
Operating systems being used at by the CAHs: CPSI at Harbor Beach;

Health Information Exchange - No equipment or vendors have been chosen at this time. Vendors responding to our RFP include Microsoft, Open HRE, First Gateway. Klinitek's UPCare and Covisent. We expect to select the HIE vendor by May 2008.

NAME OF NETWORK
Lac qui Parle Health Network

Name of Grantee
Minnesota Department of Health/Office of Rural Health and Primary Care

Principal Investigator/Project Manager
Mark Schoenbaum

Address PO Box 64882 St. Paul, MN 55164-0882
Phone 651.201-3859
Fax 651-201-3830
Organizational Website http://www.health.state.mn.us/divs/orhpc/
E-mail mark.schoenbaum@state.mn.us

Project Purpose
The Lac qui Parle Health Network (LqPHN) project goal is to implement a shared electronic health record (EHR) among three critical access hospitals in the communities of Madison, Dawson, and Appleton, Minnesota. The Lac qui Parle Health Network, an incorporated non-profit organization, has a strong history of collaboration in areas of physician recruitment, shared staffing, and training that forms the foundation for this project. Each facility represents a full service community health care delivery system, including clinic, hospital, long term care, and emergency medical services, and the EHR project reflects the breadth of services. Hospital leadership, strong project teams, and outside assistance from experts will ensure that collaborative efforts meet individual provider, facility and community needs. A common EHR product, a shared data storage and retrieval, and shared IT staff will provide leverage, create efficiencies, and support long term success.

Outcome Measures/Expectations
The Lac qui Parle Health Network CAH HIT Implementation project is driven, ultimately, by goals of providing high quality care and improving patient outcomes as the guiding principles. To that end, the following project goals and timelines have been identified, and measures developed to assess progress in achieving those goals:

1. Completion of collaborative long range health information technology strategic plan, including change management strategies and verification of organizational readiness.
2. Selection of EHR vendor/product, including vendor selection process, RFP development, and contract negotiation and approval.
3. Implementation, including kick-off, application design, infrastructure build, testing, and training.
4. Development of patient quality of care measurement through a) data collection and analysis of patient primary and secondary data, focusing on 5 performance indicators for heart failure, pneumonia, diabetes, cardiovascular care, and adverse events, and b) participation in Hospital Compare.

Service Area
LqPHN facilities serve residents of Swift, and Lac qui Parle counties, and are located in the west central part of Minnesota's large 8th Congressional District. Each of the three network facilities are located in areas designated as "rural" or "exceptionally rural" per USDA rurality scoring.

Network Members

Organization Name	Address	City	State	Zip Code

Lac qui Parle Health Network	900 2nd Ave	Madison	MN	56256
Contact	**Phone**	**Email**		
Mark Roisen	320-598-7536 x110	mroisen@farmerstel.net		

Organization Name	**Address**	**City**	**State**	**Zip Code**
Johnson Memorial Hospital	1282 Walnut Street	Dawson	MN	56232
Contact	**Phone**	**Email**		
Kathy Johnson	320-769-4323	admin@jmhsdawson.com		

Organization Name	**Address**	**City**	**State**	**Zip Code**
Madison Lutheran Home	900 - 2nd Ave.	Madison	MN	56256
Contact	**Phone**	**Email**		
Scott Larson	320-598-7556	slarson@madisonlutheranhome.org		

Organization Name	**Address**	**City**	**State**	**Zip Code**
Appleton Area Health Services	30 S. Behl Street	Appleton	MN	56208
Contact	**Phone**	**Email**		
Dan Swenson	320-287-2422	dswenson@mchsi.com		

Equipment/Vendors or Collaborative Partners
Equipment/vendors: Integrated solutions TBD (currently considering Dairyland, HMS/Medinotes, and CPSI.

Stratis Health: Minnesota's QIO is a contracted partner, assisting LqPHN with final organizational planning and readiness, needs identification, communications, process mapping, RFP development and analysis, contract negotiation, implementation preparation, training, optimization, and quality measures.

Charles River Consultants is a contracted partner, assisting LqPHN with the RFP cost spreadsheet analysis and vendor contract negotiating.

Eide Bailly, LLC, an accounting and business consulting firm, is a contracted partner, providing temporary CIO staffing support and project management.

ORHPC: The Minnesota Office of Rural Health and primary care provided early support and resources for Lac qui Parle Health Network and continues to be a key collaborative partner.

Greater Minnesota Telehealth Broadband Initiative: Minnesota's FCC Rural Health Care Pilot Program project will support the project's telecommunications needs.

NAME OF NETWORK: North Dakota CAH HIT Network

Name of Grantee: Center for Rural Health, University of North Dakota

Principal Investigator:
Marlene Miller, Flex Program Director
701-777-4499
marlenemiller@medicine.nodak.edu

Principal Investigator:
Lynette Dickson, SORH Program Director
701-777-6049
ldickson@medicine.nodak.edu

Address:
501 N Columbia Rd. Stop 9037 Grand Forks, North Dakota 58202-9037
Phone: 701-777-3848
Fax: 701-777-6779
Organizational Website: http://ruralhealth.und.edu/
E-mail: (see above)

Project Description: The overall project goal is to facilitate the exchange of health information by implementing EMR along the continuum of care that is patient-centered, facilitating patient safety, efficiency, and effectiveness of health care services. Three ND Critical Access Hospitals (CAHs), (Northwood Deaconess Health Center, Northwood; Pembina County Memorial, Cavalier; First Care Health Center, Park River), one tertiary(Altru, Grand Forks) referral hospital, and ancillary providers (Valley Community Health Centers, Northwood and Larimore; Wedgwood Manor, Cavalier and First Care Rural Health Clinic, Park River) will serve as the network model in this pilot project.

Service Area The intent of the project is to eventually impact a regional network in North Dakota and Minnesota consisting of 18 CAHs, 1 rural non-CAH, 1 tertiary facility and 1 mental health agency. The immediate network participants have approximately 3,100 common patient encounters each year. Eventually, the regional impact will cover 20,000 square miles serving a population of over 207,000 residents in 17 counties.

Need: North Dakota has 34 CAHs, none of which is involved in an HIT network with its tertiary. Statewide data indicates that CAHs are supportive of HIT; however, they struggle with resource development and allocation. For example, only 16% of ND CAHs have a formal HIT plan; yet, 68% are starting to budget for HIT. In addition, 89% do not use EMRs.

Outcome Measures/Expectations:
1) Complete planning process and implementing of EMR for first CAH.
2) Orchestrate the exchange of health information along the continuum of care.
3) Use lessons learned from each facility to improve the implementation process of EMR.
4) Improve efficiencies in the health care system through performance management.

5) Improve efficiencies through the integration of clinical quality improvement measures to facilitate better health outcomes for rural residents.

Network Members

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Northwood Deaconess Health Center/ Critical Access Hospital	Grand Forks	PO Box 190	Northwood	ND	58267
Contact	**Phone**		**Email**		
Pete Antonson, Administrator	701-587-6060		pete.antonson@ndhc.net		

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Valley Community Health Center/ Community Health Center	Grand Forks	104 N Park St.	Northwood	ND	58267
Contact	**Phone**		**Email**		
Sharon Ericson, Administrator	701-587-6000		sharon.ericson@valleychc.org		

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
First Care Health Center /Critical Access Hospital	Walsh	115 Vivian St.	Park River	ND	58270
Contact	**Phone**		**Email**		
Louis Dryburgh, Administrator	701-284-7500		stald@polarcomm.com		
Organization Name / Provider Type	**County/ Parish**	**Address**	**City,**	**State**	**Zip Code**
First Care Rural Health Clinic /Rural Health Clinic	Walsh	115 Vivian St.	Park River	ND	58270

Contact	Phone	Email
Louis Dryburgh, Administrator	701-284-7500	stald@polarcomm.com

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Pembina County Memorial /Critical Access Hospital	Pembina	301 Mountain E.	Cavalier	ND	58220
Contact	**Phone**		**Email**		
Everett Butler, Administrator	701-265-8461		Everettb@cavalierhospital.com		
Organization Name / Provider Type	**County/ Parish**	**Address**	**City,**	**State**	**Zip Code**
Wedgewood Manor /Long Term Care Facility	Pembina	804 M St. W	Cavalier	ND	58220
Contact	**Phone**		**Email**		
Everett Butler, Administrator	701-265-8453		Everettb@cavalierhospital.com		
Organization Name / Provider Type	**County/ Parish**	**Address**	**City,**	**State**	**Zip Code**
Altru Health System /Tertiary facility	Grand Forks	1200 S. Columbia Rd.	Grand Forks	ND	58206-6002
Contact	**Phone**		**Email**		
Mark Waind, CIO	701-780-5000		mwaind@altru.org		

Equipment/Vendors: Critical Access Hospitals – Two have selected Dairyland; one American Healthnet

Health Information Exchange – no vendor selected at this time.
They are considering Orion Health Systems, Intersystems (Clinical Workstation – a system already in place at the tertiary facility however it is not being used by two of the three CAHs within this project and needs enhancement to facilitate two-way exchange of information).

Collaborative Partners:
North Dakota Healthcare Review (Quality Improvement Organization)
North Region Health Alliance
Rural Health Information Technology, Inc.

NAME OF NETWORK:
Southeast Nebraska Health Information Exchange (SENHIE) Network

Name of Grantee:
Nebraska State Office of Rural Health
(DHHS, Public Health Division)

Principal Investigator/Project Manager:
Dennis Berens (Program Director)
David Palm (Project Director)

Address: 301 Centennial Mall So Lincoln, NE 68509
Phone:
402-471-0142 (Dennis Berens);
402-471-0146 (David Palm)

Fax: 402-471-0180

Organizational Website: www.dhhs.ne.gov/orh
E-mail: dennis.berens@dhhs.ne.gov
Website: *www.thayercountyhealth.com*
Email: david.palm@dhhs.ne.gov

Project Purpose: The focus is on developing and implementing a sustainable interoperable system which will improve the flow of clinical information along the continuum of care in order to provide a seamless process of health care delivery for patients and providers. The system will improve the quality of care by creating an electronic linkage which will allow each provider to make more informed treatment decisions based upon current patient data and information. Services will include implementation of electronic prescribing for medical providers, electronic transmission of transfer/discharge forms, implementation of bedside charting for staff, access at the bedside for medical providers to consult with specialists, computerized medication administration forms, electronic access for EMTs of appropriate patient information in the field, and access to mental health providers for acute and long term care. It will be an opportunity to explore the benefits of an electronic personal health record so that consumers can communicate electronically with their providers.

Outcome Measures/Expectations: Seven project goals were identified:

1. Improve the connection to share information with the network tertiary hospital.
2. Build a bridge with EMTs to improve communication and share information.
3. Improve communication and share clinical information with long-term and assisted living facilities.
4. Improve connection to share information with satellite rural health clinics.
5. Improve the electronic connection with pharmacies to strengthen patient safety, quality, effectiveness, and efficiency.
6. Improve the efficiency and effectiveness of the critical access hospital operations to strengthen patient quality and market position.
7. Address the safety and security of clinical health information.

The project is anticipated to:

- Improve the flow of clinical information along the continuum of care
- Reduce medication errors and improve medication reconciliation (e-prescribing/electronic connection)

- Improve coordination of care and efficiency for the continuum of care (electronic information/connection)
- Reduce duplication and cost regarding radiology tests (electronic transfer tests)
- Decline in patient transfers and medical complications (electronic connections)
- Increase patient days by 10% (fewer patient transfers)
- Improve health outcomes for patients with diabetes, heart failure and stroke

The project provides an opportunity to develop and share evidence-based practice protocols and standard order sets (quality improvement) areas of diabetes, heart failure, coronary artery disease, hypertension, osteoarthritis and preventive care along a continuum of care.

Service Area: The initial network participants are located in the vicinity of Hebron, Nebraska (Thayer County, 2006 population estimate 5,317) and include the Thayer County Health Services located in Hebron and the surrounding communities in Nebraska. All of the communities are rural and are located in the second and third congressional districts of Nebraska. Wherever the patient enters the health care system along this continuum of care, the intent is to have current information accessible for all of these providers.

Network Members: Local partners will include a critical access hospital, five rural healthy clinics, a home health agency, a nursing home and an assisted living facility, several EMS units, a hospital-owned retail pharmacy and an independent retail pharmacy, and a network tertiary hospital.

Organization Name / Provider Type	**County/ Parish**	**Address**	**City,**	**State**	**Zip Code**
Thayer County Health Svs/ Critical Access Hospital (19 beds); In-House Pharmacy; Home Health Agency; Rural Health Clinics; LTC Facility;	Thayer Co.	120 Park Ave	Hebron	NE	68370
Contact	**Phone**		**Email**		
Joyce Beck, CEO	402-768-6041		tchs@alltel.net		

Organization Name / Provider Type	**County/ Parish**	**Address**	**City,**	**State**	**Zip Code**
Blue Valley Lutheran Homes Society, Inc/ Nursing Homes and Assisted Living	Thayer Co.	755 S 3rd St	Hebron	NE	68370
Contact	**Phone**		**Email**		
Bill Taylor, CEO					

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
EMS & Rural Health Clinic Medical Representatives /EMS Squads; Rural Health Clinics	Thayer Co.		Hebron Deshler	NE NE	68370 68340
Contact	**Phone**		**Email**		
Dr. Tim Sullivan, EMS squads Medical Director; RHC medical staff representative			tjsullivan@thayercountyhealth.com		

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Priefert Pharmacy /Independent Pharmacy	Thayer Co.		Hebron	NE	68370
Contact	**Phone**		**Email**		
Jack Priefert, RP					

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
St. Elizabeth Regional Medical Center/network-tertiary hospital	Lancaster Co	245 S 84th St Suite 110	Lincoln	NE	68510
Contact	**Phone**		**Email**		
Richard Waller/Amy Thimn	402-219-7320		dwaller@stez.org athimn@stez.org		

Equipment/Vendors or Collaborative Partners

Healthcare Management System – HMS, a CCHIT certified inpatient system vendor, will provide the hardware, software, and related implementation services for the project. Includes: Electronic Medication Administration Record (EMAR), CPOE Provider Orders with Clinical View, Material Management Point-off-Issue, Surgical Manager, Setting up Comprehensive Training Environment; Ascent Capture & Scan Station, Client Report, Server/Backup Server and Transfer setup, Annual Maintenance and Support 24/7, Medical Grade 4-Port Concentrators, E-Forms, Digital Medical Records, and HMS to MediNotes interfaces

Medi-Notes – Provide the physician practice EMR and related implementation services for the project. MediNotes to HMS interface, V-chart scanning module, Annual Maintenance for V-chart, MediNotes eRX

Ice Technologies – Information technology technical assistance, hardware, software and cabling, including connections for HD high definition video conferencing

Zoll – E Series 12 lead ECGs with accessories to be used with Tough Books by EMS (transmission)

Alltel/Windstream – T-1 Line setup and Installation, wireless provider

Protex Central – Fire Suppression & HVAC for 3 data Centers – 2 in Hebron and 1 in Deshler (Deshler is backup system)

Nebraska Office of Rural Health – Provided early planning, technical assistance and serves as a bridge and the key collaborative partner

Nebraska Telehealth Network – The existing statewide network of 88 hospitals, 19 Public Health Departments and 6 Rural Health Clinics is expanding to enhance network coverage in the area with T1 lines

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NAME OF NETWORK

Name of Grantee
Oklahoma State University Center for Health Sciences

Principal Investigator/Project Manager
Jason W. Bray

Address 2345 SW Blvd.Tulsa, OK. 74107
Phone 918-269-1065
Organizational Website http://www.healthsciences.okstate.edu/index.cfm
E-mail **Jason.bray@okstate.edu**

Project Purpose-The project will create a Critical Access Hospital (CAH) Electronic Health Record (EHR) Network in Northeastern Oklahoma (the "Northeastern Oklahoma CAH EHR Network" or the "Network"). The Network will consist of the following partners:
• Saint Francis Hospital South (urban tertiary hospital);
• Cleveland Area Hospital (Cleveland) (CAH);
• Drumright Regional Hospital (Drumright) (CAH);
• Holdenville General Hospital (Holdenville) (CAH)
• The private practice physicians who staff at each hospital and are responsible for the bulk of the hospital's referrals

The Network members' vision for the EHR network is to ensure that patient clinical information is easily accessible to providers within a healthcare organization and to other providers as patients migrate from ambulatory care to acute service delivery sites within the region. This improved access to patient information that is integrated into a coordinated system of care will result in more effective and efficient health care delivery that will ultimately lead to improved safety and quality of care for patients. Based on this vision, CAHs are including licenses for their physician staff that most often refer patients to their hospital.

Outcome Measures/Expectations

Through this effort, the Network will improve patient:

- Safety thru reducing adverse drug events by knowing more quickly patient allergies

- Quality by having patient information accessible more quicker
- Paperwork because the patient will only have to fill out patient information one time

The Network will also make the CAH more effective and efficient in operational expense, which can be directly returned back to improving patient quality of care.

All of these hospitals are currently reporting quality data to the Centers for Medicare & Medicaid Services (CMS) Hospital Compare. As a result, they have demonstrated a commitment to improving quality and reporting data that will be used to measure the projects impact.

Vision for Developing and Implementing HIT

The Network members' vision for the EHR network is to ensure that patient clinical information is easily accessible to providers within a healthcare organization and to other providers as patients migrate from ambulatory care to acute service delivery sites within the region. Improved access to patient information integrated into a coordinated system of care will result in more effective and efficient health care delivery that will ultimately lead to improved safety and quality of care for patients.

Service Area

The Network will provide electronic health records to three critical access hospitals and their regional tertiary center to which they typically make referrals. The functionality of the EHR system will likely include:

- Health data and record management;
- Results management;
- Order management;
- Electronic communication and connectivity; and
- Administrative processes and reporting.

Holdenville General Hospital is located in southeast Oklahoma. The hospital services rural Oklahoman and around Hughes County.

Drumright Regional Hospital is also located in central/northeastern Oklahoma. The hospital serves Creek County and is the only medical center servicing that county.

Cleveland Area Hospital is located in southern Oklahoma. The hospital services over a 20 mile radius for rural healthcare patients.

Network Members

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Cleveland Area Hospital	Pawnee	1401 West Pawnee	Cleveland	OK	74020
Contact	**Phone**		**Email**		
Mike Christian	918-358-2501		mchristian@community-partners.com		

Organization Name /	County/	Address	City,	State	Zip Code

Provider Type	Parish				
Drumright Regional Hospital	Creek	610 West Bypass Street	Drumright	OK	74030
Contact	**Phone**		**Email**		
Darrell Morris, CEO	918-382-2300		dwmorris@drumrthosp.org		

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Holdenville General Hospital	Hughes	100 McDougal Drive	Holdenville	OK	74848
Contact	**Phone**		**Email**		
Bridget Cosby, CFO	405-379-4200		bcosby@hghospital.com		

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Saint Francis Hospital South	Tulsa	10501 East 91st Street	Tulsa	OK	74133
Contact	**Phone**		**Email**		
Jason Bray, CMIO	918-561-1136		jason.bray@okstate.edu		

Physicians Participating:

Drumright will be extending their EMR to Drumright Medical Clinic:
Dr. Brant
500 Lou Allard Dr.
Drumright, OK 74030
918-352-2555

Holdenville will be extending their EMR to (All employed by Holdenville General Hospital):
RHC - 100 McDougal Drive, Holdenville, OK 74848
Dr. Tom Osborn
Earl Dunkleberger
Dr. Preston Hucks
405-379-4201

Physician Health Clinc - 100 McDougal Drive, Holdenville, OK 74848
Dr. Fred Sanders
Mike Gibson, PA (to start July 1 pending board approval)
405-379-4202

Allen Health Clinic - 200 West Broadway, Allen, OK 74825
Dr. Michelle Barlow
580-857-2424

Equipment/Vendors or Collaborative Partners

1. **Chosen EMR System for Drumright- Cerner: Cerner Healthcare Systems.**
2. **Chosen Electronic Medical Record Systems for Cleveland: Meditech**
3. **Chosen Electronic Medical System for Holdenville: HMS Health Information Exchange- Covisent's HIE system**

NAME OF NETWORK
Lakeland Rural Health Network

Name of Grantee
South Carolina Office of Rural Health

Co-Principal Investigator
Graham Adams, PhD

Address: 107 Saluda Pointe Drive
City, State, Zip: Lexington, SC 29072
Phone: (803) 454-3850
Fax: (803) 454-3860
Organizational Website: www.scorh.net
E-mail: adams@scorh.net

Co-Principal Investigator
Mark Van Swol, MD

Address: 155 Academy Avenue
City, State, Zip: Greenwood, SC 29646
Phone: 864-725-4865
Fax: 864-725-4883
Organizational Website: www.greenwoodfp.org
E-mail: vanswol@selfregional.org

Project Purpose

The Lakelands Rural Health Network (LRHN) is a nonprofit, multi-county vertical network that was developed in 2004 with the guidance and financial assistance of the South Carolina Office of Rural Health, the state Flex grantee, to achieve efficiencies, expand access, coordinate and improve the quality of essential health care services, and strengthen the rural health care system as a whole.

The Lakelands partner organizations include a regional referral hospital, two Critical Access Hospitals, a Federally Qualified Health Center organization with nine medical practices, several Rural Health Clinics, a private foundation, a family practice and residency program, the local public health agency, and the South Carolina Office of Rural Health. The LRHN consists of five segments: 1) a Clinical Leadership Council which

is a physician-led, multi-county forum to address clinical issues impacting the service area; 2) a Public Information Collaborative which promotes the LRHN and its initiatives; 3) a Financial Subgroup which plans for long-term network financial viability; 4) an HIT Collaborative which implements the LRHN technology projects; and 5) an HIE Governance and Policy Committee. LRHN's geographic area includes Abbeville, Edgefield, Greenwood, Laurens, McCormick, and Saluda Counties.
The primary purpose of the project is to use HIE to assist health care providers and patients in improving their health status. Other secondary purposes for use of the HIE will include aggregated, de-identified information for the purpose of regional quality improvement initiatives, research grants, and population health outcome measures.

Outcome Measures/Expectations

Quality Improvement Goals:

1. Diabetics will decrease their mortality from stroke and myocardial infarction by improving control of blood pressure, cholesterol and blood sugar.
2. Individuals with cardiovascular disease will improve life expectancy by improving tobacco smoking cessation, anti platelet use, and blood pressure control.

Quality Improvement Objectives:

1. Decrease HgA1c average by 10% in the MCFM and CHC diabetic population within the first year with the ultimate goal of having an average HgA1c of less than 7 by 18 mos.
2. Decrease average LDL by 12% in the MCFM and CHC diabetic population within the first year with the ultimate goal to have greater than 70% of patients with an LDL less than 100 by 18 mos.
3. Increase the number of patients by 15% in the MCFM and CHC diabetic population within the first year to have systolic blood pressure less than 130 and diastolic blood pressure less than 80 with the ultimate goal to have greater than 40% of diabetic patients with a blood pressure less than 130/80 by 18 mos.
4. Increase by 50% the reporting of an eye examination in the past year in the MCFM and CHC diabetic population within the first year with the ultimate goal to have greater than 80% of patients with a documented eye exam.
5. Decrease the number of patients by 10% who are currently smoking in the MCFM and CHC diabetic population within the first year and with the ultimate goal of <12% be current smokers by 18 mos.
6. Increase the number of patients by 15% in the MCFM and CHC diabetic population within the first year to have a documented Nephropathy assessment with the ultimate goal to have greater than 80% of patients with a documented nephropathy assessment
7. Increase the number of patients by 50% in the MCFM and CHC diabetic population within the first year to have a documented foot exam with the ultimate goal to have greater than 80% of patients with a documented foot exam in the past year.

Technology Goals

1. A cost-effective HIE will be developed through contract negotiations with a vendor.
2. The implementation process will run smoothly due to careful planning and a complete purchase, setup, configuration and testing equipment and software between Self Regional Healthcare (SRH) and Montgomery Center for Family Medicine (MCFM).
3. The HIE will be able to be activated through the building of the LRHN HIE infrastructure.
4. The residents of the 6-county region will receive enhanced quality of health care by sustaining the LRHN HIE.

Technology Objectives

1. The LRHN will contract with cost-sensitive and knowledgeable vendors to support the HIE by Oct 1, 2007.
2. The LRHN will purchase, setup, configure and test equipment and software to perform web view of registration, lab results and dictated summaries for SRH and MCFM by May 2008.
3. The LRHN will purchase, setup, configure and test equipment and software between SRH/MCFM and Carolina Health Centers (CHC) for minimally defined scope (Web view/discrete data availability of registration, lab results and dictated summaries).

Service Area

The Lakelands Rural Health Network (LRHN) is a vertical network of health care providers located in a rural, economically depressed region of western South Carolina. LRHN was established in January 2004 and consists of a variety of partner organizations: a regional referral hospital, two Critical Access Hospitals (CAH), a Federally Qualified Health Center (FQHC) organization with nine medical practices, two Rural Health Clinics (RHC), a private health foundation, a family practice residency program, the local public health agency, and the South Carolina Office of Rural Health. LRHN's service area is Abbeville, Edgefield, Greenwood, Laurens, McCormick, and Saluda counties.

Network Members

Name of Tertiary Hospital for the CAH Network	**Location**	**Number of Beds**
Self Regional Healthcare	Greenwood, SC	421
Name of CAHs	**Location**	**Number of Beds**
Abbeville Area Medical Center	Abbeville, SC	25
Edgefield County Hospital	Edgefield, SC	25
Ancillary Providers	**Location**	**Provider Type**
Laurens County Health Care System	Laurens, SC	Acute care hospital
Carolina Health Centers 1. Calhoun Falls Family Practice 2. Lakelands Family Practice 3. Uptown Family Practice 4. The Children's Center 5. McCormick Family Practice 6. Saluda Family Practice 7. Ridge Spring Family Practice 8. Ware Shoals Family Practice	Calhoun Falls, SC Laurens, SC Greenwood, SC Greenwood, SC McCormick, SC Saluda,SC Ridge Springs, SC Ware Shoals, SC	FQHC " Family Practice " Family Practice " Family Practice " Pediatrics " Family Practice " Family Practice

		" Family Practice " Family Practice
Ware Shoals Center for Family Medicine	Ware Shoals, SC	Family Practice
Montgomery Center for Family Medicine	Greenwood, SC	Family Practice and Residency Program
Riley Family Practice	Saluda, SC	RHC
Due West Family Medicine	Abbeville, SC	RHC
Family Healthcare Center	Laurens, SC	Family Practice
Family Health Care	Greenwood, SC	Family Practice

# Annual Common Patient encounters expected between CAH-HIT Network Providers	250,000 (Shared Service Area)
# Total Network Provider FTEs	77.5 FTE

Equipment/Vendors or Collaborative Partners

CareEvolution Inc. —Vik Kheterpal software for Health Information Exchange
Self Regional Healthcare—Patrick Stewart—housing LRHN hardware and building of adapters to client sites and security around LRHN database.

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NAME OF NETWORK
Middle Tennessee Rural Health Information Network (MTRHIN)

Name of Grantee
Tennessee Department of Health, Office of Rural Health

Principal Investigator/Project Manager Angie Allen
Address 425 5th Ave North Nashville, TN 37247
Phone (615) 741-5226
Fax (615) 253-2100
E-mail angie.allen@state.tn.us

Project Purpose
MTRHIN will support the two-way sharing of electronic medical information among three Critical Access

Hospitals, (Trousdale Medical Center, Macon County General Hospital, and Riverview Regional Medical Center South) an FQHC (United Neighborhood Health Care) and their tertiary provider (Sumner Regional Medical Center). HIE software will enable these sites and other local providers to share patient information generated in different systems to enhance patient care. The project will be constructed in a fashion that will allow for expansion beyond the pilot participants.

Outcome Measures/Expectations

1. Implement an effective health information exchange network among the participating CAHs and the area rural community providers.
2. Develop a system that provides quality patient health information exchange to support patient transfers and consultations from the rural hospitals and referring physicians to the designated tertiary care facility.
3. Expand the project scope beyond the end of the pilot period to support other regions of the state, to include linkage with existing HIEs along with the Tennessee Department of Health Department Clinic sites and other existing telehealth projects.
4. Participate in the State's eHealth initiatives and work closely with the Governors eHealth Advisory Council to ensure compliance and compatibility with the State's master roadmap for promoting electronic health data sharing in Tennessee.

Service Area

The hospitals and their patients reflect the variety of Tennessee's regions and geography from Appalachia to the Cumberland Plateau to the upper Mississippi Delta. Health care in the outlying rural areas of the network is limited primarily to small critical access and primary care hospitals and clinics. Often patients must travel miles to larger facilities for routine tests and treatments provided by facilities in metropolitan areas. Health disparities impact this population, with high rates of diabetes, asthma, hypertension, cancer and black lung among subpopulations.

The majority of the counties in the service area have also been designated as federal shortage areas in terms of mental health services, dental care, medical professionals and medically underserved geographical areas and populations in general.

Network Members

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Sumner Regional Medical Ctr / Tertiary Care Ctr	Sumner	555 Hartsville Pike	Gallatin	TN	37066
Contact	**Phone**		**Email**		
Bruce James, CEO	(615) 328-5519		bruce.james@sumner.org		

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Macon County General Hospital/CAH	Macon	204 Medical Drive	LaFayette	TN	37083

Contact	Phone	Email
Dennis Wolford, Administrator	(615) 666-2147	dwolford@mcgh.net

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Riverview Regional Medical Center-South/CAH	Smith	130 Lebanon Hwy	Carthage	TN	37030
Contact	**Phone**		**Email**		
Scott Tongate, Assistant Administrator	(615) 735-5240		scott.tongate@sumner.org		

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Riverview Regional Medical Center North/CAH	Smith	158 Hospital Drive	Carthage	TN	37030
Contact	**Phone**		**Email**		
Edward Sanford, Administrator	(615) 735-5250		chip.sanford@sumner.org		

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
United Neighborhood Health Care / FQHC	Trousdale	100 Damascus	Hartsville	TN	37074
Contact	**Phone**		**Email**		
Mary Bufwack, CEO	(615) 228-8902		maryunhs@aol.com		

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Trousdale Medical Center	Trousdale	500 Church Street	Hartsville	TN	37074

Contact	Phone	Email
Bill Mize, Administrator	(615) 328-6704	Mizeb@sumner.org

Equipment/Vendors or Collaborative Partners
The Community Health Network is in the process of completing a Request for Quote (RFQ) for the acquisition of Health Information Exchange (HIE) software. This RFQ will be sent to a select list of HIE vendors. The RFQ responses will then be used to select two HIE vendor finalists for site visits and/or onsite demos with the goal of signing a purchase contract in June, 2008.

The Tennessee Department of Health has formed a coalition of partners to work on this project. These partners include the State of Tennessee eHealth Initiative, the Community Health Network (CHN), the State of Tennessee Office of Information Resources, the Tennessee Hospital Association, the Vanderbilt University Center for Better Health, and Qsource (Tennessee's designated CMS Quality Improvement Organization).

In conjunction with this project, the State of Tennessee has contracted with the Community Health Network (CHN) to purchase, install and host a health information exchange (HIE) solution for sending and receiving electronic health data between the target systems below:

Meditech- used by Sumner Regional, Trousdale and Riverview hospitals
CPSI Healthcare Information and Patient Care System – used by Macon County General Hospital
QS Technologies Patient Tracking Billing System – used by the Tennessee Department of Health
NextGen Ambulatory System – used by CHN (Community Health Network) member clinics

In addition, CHN will be working with the State of Tennessee for providing high speed broadband access to the participating healthcare providers that will include utilization of funds from a FCC Telehealth grant.

.

NAME OF NETWORK
FLEX CAH HIT Network Implementation (Improving Texas Rural Community Healthcare Through HIT Implementation)

Name of Grantee
Texas Office of Rural Community Affairs

Principal Investigator - Theresa Cruz (ORCA)
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Organizational Website www.orca.state.tx.us
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Project Manager –
Kathy Mechler (Texas A&M Health Science Center-Rural and Community Health Institute)
Address 3833 Texas Avenue –Ste 150 Bryan, Texas 77802
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Project Purpose The goal of this project is to improve health care delivery and quality of life through HIT

implementation in two rural communities as a demonstration model for all rural Texas communities. The objectives are to improve the safety, quality, efficiency and effectiveness of health care delivery through implementation of health information technology. The project is intended to connect health information within each individual community and to their tertiary care facility in Amarillo, Texas. Additionally, the project intends to improve access to healthcare services through the use of telemedicine.

Outcome Measures/Expectations

1. **Disease Management Indicators**

The ability to collect and measure the disease specific measures for diabetes and heart disease as indicated below (a & b) will only be possible once the clinical information system is installed in each community. Baseline findings from these measures will be obtained at the time of clinical information system implementation (Phase 2, Month 5) and monitored throughout the grant period.

a. Diabetes: Average patient HbA1c at or below the American Diabetes Association and Physician Consortium for Performance Improvement Measurement Set goal of 7.0%. **Per Patient** – Trend of HbA1C values over 12 months. **Per Patient Population - Numerator:** Number of Patients with one or more HbA1C tests. **Denominator:** All patients diagnosed with diabetes. The study will also provide the opportunity to evaluate the distribution of HbA1c values by range: <6.0, 6.0-6.9%, 7.0-7.9%, 8.0-8.9%, 9.0-9.9% ≥10%

b. Cardiovascular: Average patient LDL at or below 100. Measurement standards established by the American College of Cardiology, American Heart Association and the Physician consortium for Performance Improvement will be utilized. **Per Patient** – Trend of LDL values over 12 months. **Per Patient Population – Numerator:** Number of patients who received at least one lipid profile to include LDL. **Denominator:** All patients with cardiovascular disease. The study will also provide the opportunity to evaluate the distribution of LDL values by range: ≥160, 130-159, 100-129,<100.

1. **Patient Safety Indicator**

The ability to collect and measure the ***decubitus ulcer patient safety indicator*** will continue to be monitored and evaluated through the use of administrative data utilizing the AHRQ algorithms currently available through the rural data warehouse.

a. Decubitus Ulcer: Cases of decubitus ulcer per 1,000 discharges with a length of stay of 4 or more days. **Numerator:** Discharges with ICD-9-CM code of decubitus ulcer in any secondary diagnosis field among cases meeting the inclusion and exclusion rules for the denominator. **Denominator:** All medical and surgical discharges 18 years and older defined by specific DRGs. **Exclusions:** Length of stay of less than 5 days, ICD-9-CM code of decubitus ulcer in the principle diagnosis field or in a secondary diagnosis field if present on admission, MDC 9, 14, ICD-9-CM diagnosis of hemiplegia, paraplegia, or quadriplegis, spina bifida, debridement or pedicle grants before or on the same day as the major operating room procedure, admission from a long-term care facility or transferred from an acute care facility.

3. Inpatient Quality Indicator

Pneumonia: The ability to collect and **measure the pneumonia inpatient quality indicator** will continue to be monitored and evaluated through the use of administrative data utilizing the AHRQ Pneumonia mortality rate algorithms as currently available through the rural data warehouse. Baseline data for this measure is provided. Pneumonia mortality will be measured utilizing mortality in discharges with a principle diagnosis code of pneumonia. **Numerator:** Number of deaths among cases meeting the inclusion and exclusion rules for the denominator. **Denominator:** All discharges, age 18 years and older, with a principal diagnosis of pneumonia. **Exclusions:** Missing discharge disposition, transferring to another short-term hospital, MDC 14, 15.

4. Effectiveness and Efficiency Indicator
Medication Errors: Currently data collected regarding medication errors that ultimately impact the effectiveness and efficiency of medical care in both Collingsworth and Friona is a paper-based system. Through the implementation of a community-wide patient information system, medication error is expected to be reduced and the efficiency of treatment enhanced through information sharing throughout the continuum. Medication errors will be measured by evaluating the number of medication errors monthly. **Numerator:** Number of medication or dispensing errors per month. **Denominator:** Number of medications dispensed per month.

Service Area This project intends to impact the two frontier communities of Wellington and Friona, Texas located in the Texas panhandle. Both of these community hospitals and local providers offer limited specialty care, forcing local residents to drive more than 70 miles from one community and more than 100 miles from the other to access specialty care in Amarillo.

Network Members

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Texas Tech University /Telemedicine	Lubbock	3601 4th St STOP 9416	Lubbock	TX	79430
Contact	**Phone**		**Email**		
Debbie Voyles	806.743.4440		Debbie.voyles@ttuhsc.edu		

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Northwest Texas Health System / Tertiary Hosp	Potter	1501 S. Coulter	Amarillo	TX	79106
Contact	**Phone**		**Email**		
Michael Smith	806.351.6608		michael.smith@nwths.com		

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Collingsworth General Hospital/CAH	Collingsworth	1015 15th St	Wellington	TX	79095
Contact	**Phone**		**Email**		
Mike Easley Or	806.277.0176		mikeeasley@austin.rr.com		

Candy Powell	806.447.2521	CandyPowell@collingsworthgeneral.net

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Parmer County Hospital/CAH	Friona	1307 Cleveland St	Friona	TX	79035
Contact	**Phone**		**Email**		
Mike Easley Or Lance Gatlin	806.277.0176 806.250.2754		mikeeasley@austin.rr.com lgatlin@trhta.net		

Equipment/Vendors or Collaborative Partners:

OPUS is the selected vendor for this project.
Contact: Chris Mountzouris
VP, Marketing & Business Development
Opus Healthcare Solutions, Inc.
12301 Research Blvd., Bldg. IV, Suite 200
Austin, TX 78759

Toll Free: 800.676.3371
Phone: 512.336.4410
Fax: 512.336.4799
Email: cmountzouris@opushealthcare.com
Web: www.opushealthcare.com

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NAME OF NETWORK
Virginia Acute Stroke Telehealth Network (VAST)

Name of Grantee
Virginia Department of Health, Office of Minority Health and Public Health Policy
Principal Investigator/Project Manager
Cynthia Barrigan, Executive Director, Virginia Telehealth Network
Address PO Box 2356 Centreville, Virginia 20122
Phone 703-802-4878
Fax 1-888-205-0114
Organizational Website www.ehealthvirginia.org
E-mail cbarrigan@ehealthvirginia.org

Project Purpose

Virginia's incidence and mortality rates for stroke are among the highest in the nation – a vexing problem for the State's health care providers. The Institute of Medicine of the National Academy of Science and the American Stroke Association has concluded that the fragmentation of stroke systems of care contributes to the magnitude of this health problem—especially in rural and underserved communities.

The American Stroke Association, a division of the American Heart Association, says that a community's stroke system of care must include certain fundamental components ((*Stroke.* 2005; 36:690.) http://stroke.ahajournals.org/cgi/content/full/36/3/690):

- Primary prevention
- Community education
- Notification and response of emergency medical services
- Acute stroke treatment
- Subacute stroke treatment and secondary prevention
- Rehabilitation
- Continuous Quality Improvement Initiatives

The lack of focused health information technologies (HIT) that enable health information exchange (HIE) and the delivery of remote telehealth/telemedicine services (TH/TM) are partially responsible for serious disruptions in continuity of care as stroke patients move from one level of care and care provider to another throughout Virginia's health care system. Further, the lack of integrated HIT capabilities that enable the rapid and efficient transfer of patient data and digital images impedes the timely diagnosis and treatment of stroke victims.

The purpose of the Virginia Acute Stroke Telehealth Network (VAST) is to design, development, test and evaluate a model stroke network across the Central Shenandoah Region. HIT will be implemented at Bath Community Hospital—a critical access hospital-- and its supporting hospitals as part of a regional stroke quality improvement initiative. The intent of this project is to examine the first four components of the stroke continuum of care—Prevention, Community Education, EMS Notification and Acute Treatment—and introduce HIT solutions--along with other interventions-- to strengthen , improve and more tightly integrate these components of the stroke systems of care. It is envisioned that this model would be considered for state-wide adoption.

Primary Objectives

- Increase awareness of stroke signs and symptoms and best practices in stroke care.
- Improve the stroke EMS response.
- Accelerate time to diagnosis and treatment of acute stroke

Outcome Measures/Expectations

Prevention/Community Education

- Develop and implement a centralized stroke website for Virginia (virginiastrokenetwork.org) that patient/providers can use to access information on national and state-level stroke initiatives, stroke policy, best practices, VAST, and receive on-line stroke education and training.

EMS Notification and Response

- Develop a Stroke EMS Plan for the Region
- Develop electronic stroke training materials and standardized protocols.
- Implement a web-based learning management system.
- Deliver on-line stroke training to EMS providers.

Acute Treatment

- Deploy critical tele-stroke infrastructure which includes: the RP-7 Remote Presence System to facilitate remote neurology stroke consults; the implementation of PACS and integrated tele-radiology solutions to enable the digital capture, transfer, archiving and on-going sharing of CT scans for rapid interpretation across the network; and improvements to the existing CPSI electronic medical record system for enhanced medical documentation of stroke in the Emergency Department.

Service Area

The service area for the project spans the entire Central Shenandoah Valley---- with a special emphasis on Bath County which is a designated Medically Underserved Area (MUA). The Central Shenandoah Valley Region is located in the middle of the historic and scenic Shenandoah Valley in west-central Virginia. It has a land area of 3,439 square miles; the Region is home to some 246,400 persons. Geographically, the Region is the largest health planning district in the state.

The Region is comprised of five counties (Augusta, Bath, Highland, Rockbridge and Rockingham); five independent cities (Buena Vista, Harrisonburg, Lexington, Staunton, and Waynesboro); and eleven towns (Bridgewater, Broadway, Craigsville, Dayton, Elkton, Glasgow, Goshen, Grottoes, Monterey, Mt. Crawford and Timberville).

According to the U.S. Census, Bath County's population is approximately 4,814. Persons over age 65 make up 19.4% of the county as compared to 11.4% of the State's population. The median household income in Bath County (2000) was $38,145 as compared to the State median of $51,103.

Network Members

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Bath Community Hospital / Critical Access Hospital	Bath	P O Drawer Z	Hot Springs	VA	24445
Contact	**Phone**		**Email**		
Debbie Lipes, CEO	540-839-7059		bcchdl@bcchospital.org		

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Rockingham Memorial Hospital-Community Hospital	Rockingham	235 Cantrell Avenue	Harrisonburg	VA	22801
Contact	**Phone**		**Email**		
Dr. Dennis Carroll, Chief Medical Officer	540-433-4100		dcarroll@rhcc.com		

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Augusta Medical Center	Augusta	78 Medical Center Drive	Fishersville	VA	22939
Contact	**Phone**		**Email**		
Dr. Fred Castello, Chief Medical Officer	540-332-4251		fcastello@augustamed.com		

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
University of Virginia / Tertiary Care Academic Medical Center.	Albemarle	1215 Lee Street	Charlottesville	VA	22908
Contact	**Phone**		**Email**		
Dr. Nina Solenski	**434-924-8374**		NJS2J@virginia.edu		

Organization Name / Provider Type	County/ Parish	Address	City,	State	Zip Code
Central Shenandoah EMS Council / EMS	Augusta	2312 West Beverly Street	Staunton	VA	24401
Contact	**Phone**		**Email**		
Dr. Asher Brand, Medical Director	540-886-3676		Asher.Brand@gmail.com		

Equipment/Vendors or Collaborative Partners

Vendors

- **InTouch Health**: RP-7 Remote Presence System: Uses a mobile robot with live untethered video-teleconferencing capability and allows a stroke neurologist to immediately initiate an assessment from any location using a remote control joystick to pilot the robot in the remote environment without assistance from the remote community ED.

- **Computer Programs and Systems, Inc (CPSI):** Electronic Forms Module: Replaces paper-based patient data and care forms with user-defined electronic ones. Displayed and completed on-line using Microsoft's Internet Explorer, the module's forms are easy to use and can be customized to meet such

needs as ED triage, trauma, assessments, modality worksheets, consent for treatment, information release requests, transfers, etc.

- **PACS Vendors being evaluated include DR Systems, CPSI and Carestream.**

Collaborative Partners

- American Heart Association (Mid-Atlantic Affiliate)
- Edward Via Virginia College of Osteopathic Medicine (VCOM)
- Virginia Department of Health - Division of Chronic Disease & Control
- Virginia Department of Health – Office of Minority Health and Public Health Policy
- Virginia Health Quality Center
- Virginia Stroke Systems of Care Collaborative
- Virginia Telehealth Network
- Winchester Medical Center - Valley Health

NAME OF NETWORK
Western Washington Rural Health Care Collaborative (WWRHCC)

Name of Grantee
Washington State Department of Health, Office of Community and Rural Health

Principal Investigator/Project Manager
Elizabeth Floersheim

Address PO Box 55451 Seattle, WA
Phone 206-769-5871
Fax 206-881-7730
Organizational Website wwrhcc.org E-mail efloersheim@msn.com

Project Purpose
WWRHCC proposes to develop a network for Health Information Exchange among three CAHs and their community partners. The rural pilot sites, Jefferson Healthcare (Port Townsend), Whidbey General (Coupeville), and Morton General (Morton), serve areas with combined rural populations totaling almost 100,000 people. These CAHs were chosen due to the variety of local clinics/services they operate – i.e., Rural Health Clinics, home health, diabetes education, etc. – and also because each currently operates a different patient information system. WWRHCC has identified Harborview Medical Center as the project's tertiary referral partner, which as the State's only Level I trauma referral destination, is important to CAHs statewide.

Outcome Measures/Expectations
This HIT project will develop a universal data exchange/interfacing capability on multiple levels, expressed in the project's goals:
I. Develop a seamless patient information exchange capability among local rural providers for each CAH participant.
II. Develop a seamless patient information exchange capability between the CAH participants.
III. Develop a seamless information exchange capability to support rural trauma and inpatient consultations and transfers to Harborview Medical Center.
IV. After the grant project period, support the expansion of the project's HIT system to other WWRHCC members, and to other rural hospitals statewide.

Service Area
Each of the three HIT CAHs serves a rural community/service area that is itself unique within Western Washington. Jefferson Healthcare is located in Port Townsend, at the northwest area of the Olympic Peninsula. Forks Community Hospital is located in Forks and serves western Clallam and southwestern Jefferson counties. Forks Community Hospital is the most far northwestern hospital in the contiguous US. Forks is located the heart of the Olympic Peninsula, between the Olympic Mountains and the Pacific Ocean beaches. Morton General Hospital is located in Morton and serves the rugged, densely forested area between Mt. Rainier and Mt. St. Helens. Harborview Medical Center located in Seattle is the only Level I Trauma Center in the State of Washington.
Counties involved include Jefferson, Clallam, Lewis and King.

Network Members
Note - please identify provider types as Tertiary Care Center, Critical Access Hospital (CAH), Medicare Certified Rural Health Clinic (RHC), Federally Qualified Health Centers (FQHC), Home Health Agency (HHA), Public Health Department, Emergency Medical Service (EMS), Family Practice Group/Practitioner, Private Practice Physicians, Nursing facilities, Pharmacy or other appropriate provider type. If the entity is receiving funds from the CAHHIT grant it is appropriate to list them as a Network

Organization Name /
Provider Type County/
Parish Address City, State Zip Code
Western Washington Rural Health Care Collaborative/
PO Box 55451 Seattle WA 98155-0451
Elizabeth Floersheim 206-769-5871

Organization Name County/
Parish Address City, State Zip Code
Jefferson Healthcare/ Jefferson
834 Sheridan Avenue Port Townsend WA 98368-2443
Contact Phone Email
Roger Harrison 3
60-385-2200 ext 3392

Organization Name County/
Parish Address City, State Zip Code
Forks Community Hospital Clallam
300 Bogachiel Way Forks WA 98331
Andrea Perkins-Pepper
360-374-6271

Organization Name County/
Parish Address City, State Zip Code
Morton General Hospital/ Lewis 521 Adams Street Morton WA 98356
Contact Phone Email
Stephen Morton
360-496-5112

Organization Name County/
Parish Address City, State Zip Code
Harborview Medical Center/ King University of WA
Box 357110 Seattle WA 98195
David Chou

Equipment/Vendors or Collaborative Partners
Operating systems being used at by the CAHs: Meditech (Client Server and Magic) and Healthland (Dairyland).

Health Information Exchange – Orion Health

Equipment-Servers: HP and Dell. We are considering Omnicell Automatic Dispensing Devises.

Clinics: Clallam Bay Medical Clinic. 74 Bogachiel, Clallam Bay, WA 98326 , Fork's Women's Clinic, 231 Lupine Way, Forks, WA 98331, 530 Bogachiel Way, Forks, WA 98331 and West End Outreach, 551 Bogachiel Way, Forks 98331 and 601 Bogachiel Way (Adult Day Treatment), Forks, WA 98331 and Oak Street Center (Chemical Dependency) 109 Oak Street, Port Angeles, WA. 98362.
Forks Community Hospital also operates a Long Term Care Facility and an ambulance service.

NAME OF NETWORK
RWHC Information Technology Network

Name of Grantee
Board of Regents of the University of Wisconsin System

Principal Investigator/Project Manager
Louis Wenzlow

Address 880 Independence Lane Sauk City, WI 53583
Phone 608.644.3237
Fax 608.643.4936
Organizational Website rwhc.com
E-mail lwenzlow@rwhc.com

Project Purpose
The Wisconsin CAH network is working to implement a collaborative electronic health record (EHR) environment (initially consisting of a hospital information system and a physician practice EMR system) that is shared by multiple critical access hospitals from a common datacenter and supported by a pooled staff. The Rural Wisconsin Health Cooperative Information Technology Network (RWHC ITN) is the non profit consortium organization that operates the collaborative EHR environment. CEOs of participant hospitals serve as the ITN Board of Directors; and project leaders from each ITN participant hospital work with ITN staff to align collaborative efforts with facility needs. The RWHC ITN's mission is "to provide community hospitals and their affiliates with health information technology (HIT) applications and support services that promote high quality, cost effective healthcare."

Outcome Measures/Expectations
Primary ITN goals include: to drive improvements to patient safety and the quality of care and service; increase secure access to healthcare information; increase healthcare cost effectiveness, and eventually provide all Wisconsin CAHs with an integrated, cost-effective option to meet their EHR needs.

In working to achieve its goals, the RWHC ITN will provide the following services and benefits:

- Advanced clinical systems such as E-MAR, medication verification through barcoding, inpatient charting, CPOE, physician practice EMR with e-prescribing, and an EHR web portal
- Data exchange capabilities between shared system participants
- Reduced datacenter, hardware, software, implementation, support, and operating costs due to group volume purchasing and a shared data center model

- Improved support quality with a shared HIT staff

Service Area

The initial network participants are located in south central and western Wisconsin, including in Sauk, Dane, Monroe, Vernon, Grant, and Lafayette counties, which are parts of Wisconsin's second and third congressional districts. Each of the 4 network participant facilities are located in areas designated as "rural" or "exceptionally rural" per USDA rurality scoring.

Network Members

Organization Name	Address	City,	State	Zip Code
RWHC Information Technology Network	880 Independence Lane	Sauk City	WI	53583
Contact	**Phone**	**Email**		
Louis Wenzlow	608.644.3237	lwenzlow@rwhc.com		

Organization Name	Address	City,	State	Zip Code
St Joseph's Community Health Services	400 Water Avenue	Hillsboro	WI	54634
Contact	**Phone**	**Email**		
Donavan Decot	608.489.8177	ddecot@stjhealthcare.org		

Organization Name	Address	City,	State	Zip Code
Tomah Memorial Hospital	321 Butts Avenue	Tomah	WI	54660
Contact	**Phone**	**Email**		
LaVonne Smith	123.123.1234	ljsmith@tomahhospital.org		

Organization Name	Address	City,	State	Zip Code
Boscobel Area Health Care	205 Parker Street	Boscobel	WI	53805
Contact	**Phone**	**Email**		
Toni Brown	608.375.4112	tbrown@boscobelhealth.com		

Organization Name	Address	City,	State	Zip Code
Memorial Hospital of Lafayette County	800 Clay Street	Darlington	WI	53530
Contact	**Phone**	**Email**		
Kevin Glass	608.776.4466	kevin.glass@monroeclinic.org		

Equipment/Vendors or Collaborative Partners
Healthcare Management Systems – HMS, a CCHIT certified inpatient system vendor, will be providing the hardware, software (including advanced clinical systems such as E-MAR, medication verification through barcoding, inpatient charting, CPOE, an EHR web portal, as well as data exchange functionality), and related implementation services for the project.

Medinotes – Medinotes will be providing the physician practice EMR and related implementation services for the project.

PhaseWare – PhaseWare will be providing the web-enabled helpdesk software for the project.

RWHC – RWHC (to be distinguished from RWHC ITN), a collaborative organization of 32 non-profit Wisconsin hospitals, provided the early planning and startup resources for RWHC ITN; and will be providing ITN shared staffing services.

WORH – The Wisconsin Office of Rural Health has also provided early planning and startup resources for RWHC ITN and serves as a key collaborative partner.

FCC Pilot Program – The FCC Pilot Program will be providing 85% of eligible costs relating to the project telecommunications aspects.

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CASE#	Requestor	SUBJECT	REFTO	DATE DUE	FINAL DATE DUE
10-003	Rose Santos	Request a copy of HHSH250200900022C0001 & HHSH250200900022C	Contracts	10/13/2009	11/03/2009
10-025	Hollie Bennett	Request all Financial audits for Rock Hill SC 2003 - 2009	OFM Audits	10/27/2009	11/18/2009
10-035	Dr. Bob Phillips	Updated NHSC data	BCRS	11/03/2009	11/25/2009
10-047	Hal Stern	Request 2008 UDS data	BPHC	11/13/2009	12/07/2009

10-038	Steven Garmisa	Request copies of each expert's Curriculum Vitae	HSB	11/05/2009	11/30/2009
09-330	Daniel Krivit	Request document related to 2005/2006 approved application by HRSA to CHC	grants, fyi BPHC	09/28/2009	10/20/2009
09-314	Jenny Small	Correspondece regarding ferderal coordiniating council for comparative effectivness research with government agencies and pharmaceutical companies from 1/2009 to present	BCRS, BPHC, HAB, HSB, MCHB, Exec.Sec,, OPR, Rural Health, BHPr	09/11/2009	10/02/2009
09-305	Jenny Small	Correspondece regarding ferderal coordiniating council for comparative effectivness research with government agencies and pharmaceutical companies from 1/2009 to present	Exec. Sec, HAB, BCRS, BPHC,BHPr, MCHB, OPR Rural Health	09/04/2009	09/28/2009
09-309	Daniel Krivit	Request for records relating to CHC	grants, bphc	09/10/2009	10/01/2009
09-278	Daniel Schwartz	Appeal of records	FOIA		08/21/2009
09-222	Mr. Brad Wright T	Request FQHC grant applications and UDS reports	BPHC, grants	06/16/2009	07/16/2009
09-245	Karen I. Kaiser	Appeal on HRSA 09-092	FOIA	07/08/2009	07/29/2009
09-270	Margaret Willner	Appeal request all records from 2007 to present for HRSA and IOM	FOIA	08/06/2009	08/27/2009

Integrated Information & Communication Technology

Integrating electronic health record systems, secondary databases and protocols at the point of care for administrative, clinical, care management, financial and information systems purposes establishes an electronic delivery of care system that

- Supports patient self-management, evidenced-based clinical decision-making, efficient practice design, and the improvement of the health status of communities and populations.
- Enhances the safety, efficiency, effectiveness, and timeliness of care.
- Provides patient access to health information and support, as well as their health record.
- Assures that all patients receive high quality care.
- Ensures that clinical information infrastructure is integrated with the business information systems.
- Supports rapid response in emergency situations.

Information & Clinical Technology Grants

HRSA is currently supporting six Integrated Information and Communication Technology grantees in reinventing and substantially enhancing primary and preventive care in the health center delivery system through:

- Development of a robust information and communication technology infrastructure that supports the Health Disparities Collaborative Care Model and leads to a seamless delivery system.
- Establishment of networked information and communication technology systems that maximize economies of scale.
- Dissemination of and support for the spread of the information and communication technology infrastructure to all health centers within State or regional marketplaces.

These projects built on and expanded efforts of health centers and health center networks that manage a select number of chronic conditions through the Health Disparities Collaborative so that their approaches could be applied to all conditions and all health center patients across their delivery systems.

Capitalizing on innovations in chronic care management, electronic patient registries, and performance improvements, the program aligned information system goals and objectives to focus on patient and clinical care, specifically the implementation and dissemination of a clinical information system or "electronic health record" supportive of Health Disparities Collaborative care model objectives.

Projects supported the move to a clinical information system through an integrated system with common architecture providing the best clinical and administrative solution the clinical information system marketplace, eliminating both disparate clinical database sources and the fragmentation of clinical data and information.

Grant awards ranged from $450,000 to $750,000 per budget period, with project periods as long as 4 years.

Beginning in 2006, the Integrated Information and Communication Technology grantees are working to install electronic health records in approximately 60 health centers with 300 sites. Statewide efforts are taking place in Maine, Oregon and West Virginia. Marketplace efforts are taking place in Florida, Illinois and North Carolina.

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Integrated Information & Communication Technology Grant Projects

Health Choice Network, Inc.
Miami, Florida

- **Technology: Electronic Health Record; Practice Management System**
- **Community: rural/urban**
- **Members: 11 community health centers, 86 sites**
- **Integration: horizontal**
- **Service Area: (Counties) Pinellas, Pasco , Charlotte , Lee, Hendry, Broward, Miami-Dade**
- **HIPAA Compliance: (In place) Privacy Policy and Procedures, Training, HIPAA Compliance Officer, IT Infrastructure/Security Policy and Procedures, Electronic Transactions/Code sets, HIPAA Clearinghouse Compliant**
- **Network Stats: 205,000 users, 916,000 encounters**
- **Total Providers in Network: Medical: 431.5; Mental Health Substance Abuse 44.75; Oral Health: 97; Pharmacy: 32**

Alliance of Chicago Community Health Services, Inc.
Chicago, Illinois

- **Technology: Electronic Health Record**
- **Community: urban**
- **Members: four community health centers, 23 sites**
- **Integration: horizontal**
- **Service Area: (County): Cook**
- **HIPAA Compliance: (In place) Privacy Policy and Procedures, Training, HIPAA Compliance Officer, IT Infrastructure/Security Policy and Procedures, Electronic Transactions/Code sets**
- **Network Stats: 69,505 users, 305,349 encounters**
- **Total Providers in Network: Medical: 131.1; Mental Health Substance Abuse 80.4; Oral Health: 5.6**

Collaborative Network for Northern New England (CONNECT)
Augusta , Maine

- **Technology: Electronic Health Record; Practice Management System; Disease Registry**
- **Community: rural**
- **Members: six community health centers with 21 sites**
- **Integration: horizontal**
- **Service Area: (Counties) Aroostook, Cumberland, Hancock, Penobscot, Oxford, Washington, York, Canada**
- **HIPAA Compliance: (In place) Privacy Policy and Procedures, Training, HIPAA Compliance Officer, IT Infrastructure/Security Policy and Procedures, Electronic Transactions/Code sets, HIPAA Clearinghouse Compliant**
- **Network Stats: 51,269 users, 210,729 encounters**
- **Total Providers in Network: Medical: 79.74; Mental Health Substance Abuse 9.49; Oral Health: 12.45**

Community Partners HealthNet, Inc.

Snow Hill, North Carolina

- Technology: Electronic Health Record; Practice Management System
- Community: rural
- Members: five community health centers, 30 sites
- Integration: horizontal
- Service Area: (Counties) Bladen, Duplin, Wayne, Brunswick, Pender, Sampson, Robeson, Columbus, Cumberland , Harnett, Johnston , Green, Wilson, Pitt
- HIPAA Compliance: (In place) Privacy Policy and Procedures, Training, HIPAA Compliance Officer, IT Infrastructure/Security Policy and Procedures, Electronic Transactions/Code sets, HIPAA Clearinghouse Compliant
- Network Stats: 65,000 users, 300,000 encounters
- Total Providers in Network: Medical: 120.55; Mental Health Substance Abuse 3.5; Oral Health: 22.26; Pharmacy: 5.5

Oregon Community Health Information Network
Portland, Oregon

- Technology: Electronic Health Record; Practice Management System
- Community: rural/urban
- Members: 15 community health centers, 80 sites
- Integration: horizontal
- Service Area: (Counties) Multnomah, Clackamas, Tillamook, Jefferson, Benton, Jackson, Yamhill, Klamath, Washington, Douglas, King (WA), Santa Cruz (CA)
- HIPAA Compliance: (In place) Privacy Policy and Procedures (in review), Training, HIPAA Compliance Officer, IT Infrastructure/Security Policy and Procedures, Electronic Transactions/Code sets, HIPAA Clearinghouse Compliant
- Network Stats: 278,221 users, 1,706,958 encounters
- Total Providers in Network: Medical: 184.8; Mental Health Substance Abuse 37.22; Oral Health: 30.3; Pharmacy: 19

West Virginia Primary Care Network (WVPCN), Inc.
Huntington , West Virginia

- Technology: Electronic Health Record, General Ledger
- Community: rural/urban (Statewide)
- Members: 22 community health centers, 70 sites
- Integration: horizontal
- Service Area: (Counties) Kanawha, Webster, Clay, Raleigh , Monongalia, Lincoln , Morgan, Greenbrier, Pocahontas, Pendleton, Preston, Ritchie, Roane, Upshur, Taylor , McDowell, Cabell, Wayne , Wirt, Putnam, Gilmer, Monroe
- HIPAA Compliance: (In place) Privacy Policy and Procedures, Training (ongoing), HIPAA Compliance Officer, IT Infrastructure/Security Policy and Procedures, Electronic Transactions/Code sets, HIPAA Clearinghouse Compliant
- Network Stats: 185,160 users, 607,400 encounters
- Total Providers in Network: Medical: 342; Mental Health Substance Abuse 3.25; Oral Health: 11.5; Pharmacy: 4.75

community partners.

Outcome Measures/Expectations
The Illinois PHIN project will demonstrate the following:

1. cost efficient, nondisruptive integration of the selected electronic medical record software into a hospital's existing best of breed information system
2. feasibility of user adaptation of an ambulatory electronic medical record system for use in the inpatient setting
3. implementation of an easily scalable health information exchange that will be available to project participants and their partners
4. on-going expansion of health information exchange users to include small area networks of all critical access hospitals in the state and their local health care partners

Service Area
The two critical access hospitals are located in southwestern Illinois. Washington County Hospital is 55 miles east of St. Louis, Missouri and Salem Township Hospital is 96 miles east of St. Louis. Washington County has a population of slightly more than 15,000 (27/square mile), and Marion County, home of Salem Township Hospital, has a population of nearly 42,000 (73/square mile). Both counties have economic bases comprised of light manufacturing, agriculture, and tourism. The referral hospital, SSM St. Mary's Good Samaritan, is located in Mount Vernon in Jefferson County, population of approximately 40,000 (70/square mile). Mount Vernon is 26 miles from Salem and 31 miles from Nashville.

Network Members

Organization Name / Provider Type	**County/ Parish**	**Address**	**City,**	**State**	**Zip Code**
Salem Township Hospital / Critical Access Hospital	Marion	1201 Ricker Drive	Salem	IL	62881
Contact	**Phone**		**Email**		
Richelle Rennegarbe, CEO	618-548-3194 x 8186		rrennegarbe@salemtownhosp.org		

Organization Name / Provider Type	**County/ Parish**	**Address**	**City,**	**State**	**Zip Code**
Washington County Hospital /Critical Access Hospital	Washington	705 S. Grand Ave.	Nashville	IL	62263
Contact	**Phone**		**Email**		
Nancy Newby, CEO	618-327-2200		nnewby@washingtoncountyhospital.org		

HRSA CORE MEASURES
HRSA QUALITY MEASUREMENT PRINCIPLES

Quality performance measures, when selected, are intended to be used for continuous improvement by HRSA grantees, Bureau and Office Programs, and by HRSA as an Agency.

- Data will be used by project officers, Bureaus, Offices and HRSA, to assess, compare and interpret performance; to identify benchmarks and best practices; to communicate the impact HRSA is having on the delivery of care to the populations that it serves and to implement HRSA level quality improvement strategies and technical assistance.
- Whenever results are shared it will be done in the context of the work HRSA does as an Agency.

HRSA will identify a core set of measures that target crosscutting issues important to HRSA grantees and populations.

- Measures will be nationally endorsed when appropriate starting with clinical measures most relevant for safety net populations cared for through HRSA clinical programs.

Data from Core Measures will be collected and interpreted at the program level and utilized for further analysis and improvement strategies at the HRSA level.

- Data from Bureaus and Offices will allow HRSA to track trends in quality performance and create benchmarks.
- Performance feedback directly to grantees will be given at the Bureau and Offices program level.

When new quality measures are sought, programs will draw from the HRSA pool of standardized core measures when appropriate to their programs and populations, and will align their data collection requirements to use the exact national data specifications.

If programs require data beyond that available from national or HRSA level measures, programs will be encouraged to expand the measures to capture more safety net specific quality data (Core+).

- This ensures that programs will be able to track evidence-based care that is more rigorous and/or data dimensions that are specific to our safety net populations, program priorities and legislative mandates, while still providing HRSA level data.

When National measures are inadequate or do not exist, HRSA programs will collaborate together, and when appropriate with other external and national partners, to identify measures that more adequately capture the intensity of services or special care needs of HRSA safety net populations.

Where current HRSA program measures are similar but NOT in alignment with Core Measures, efforts will begin to either align, retire or otherwise communicate why the measures are purposely different, with a deadline for action by June of 2010. In situations where different program measures are essential, every effort will be made to structure data to also be used at the HRSA level.

- Agency-wide alignment of subset of Core Measures by 2010
- Alignment will decrease burden to dual funded grantees

HRSA Core Measures will be maintained and updated as appropriate.

- Keeping with current practice standards, data collection requirements and guidelines.

HRSA Quality Measurement Principles
HRSA CORE MEASURES

Background

HRSA is the access agency for the DHHS serving 20 million individuals across every territory and state via an array of direct and indirect service grants to improve health coverage and care for under and uninsured vulnerable populations. HRSA envisions optimal health for all, supported by a health care system that assures access to high quality, patient centered, comprehensive and culturally competent care. HRSA programs include block grants to states and community-based delivery systems, and support for health care delivery infrastructure, education and training and a variety of other special health services capacity building projects; all managed by 6 different HRSA Bureaus and 14 Offices.

In response to a nationwide movement to measure quality performance using nationally endorsed performance measures, HRSA implemented an agency level quality measurement and performance improvement project that started with clinical quality measures for HRSA's health service delivery programs. The agency level clinical initiative includes a Core Clinical Measures Set approved by HRSA senior leadership in December of 2006 which addresses priority health conditions of HRSA safety-net populations, cover all life cycles, are amenable for quality improvement, and were selected for their relevance to HRSA programs.

This initiative underscores HRSA's commitment to performance measurement for quality improvement and begins to measure and demonstrate the quality of care across the agency as a whole—a capstone to the program specific quality measures now in use by many HRSA programs. The Core Measures initiative intends to create performance measures alignment across HRSA programs to allow data aggregation, comparisons, benchmarking and to capture stories about quality care for HRSA populations. The initiative will measure performance along the continuum of care and services of HRSA funded programs and will begin with an important set of clinical measures. Informed by a cross agency working group, work with national measures developers, and the results of a Core Measures feasibility study, this initial measures set begins to address clinical measures alignment across HRSA clinical programs. Implementation of the initial HRSA Core Measures will allow for critical national comparisons using National Quality Forum (NQF), Ambulatory Care Quality Alliance (AQA), and other national quality measures.

For decades, HRSA has been an innovative leader in quality care, performance measurement, and implementation of quality improvement strategies that address a broad variety of special challenges and the needs of safety net populations. Using measures to document the performance and impact of HRSA funded programs aligns with the increasing focus on assessing value present in the broader health care arena. Payers, congress and patients want key information about the value of the care and services that are being funded and delivered.

Elements that improve the quality of care are embedded in most HRSA programs. In addition to guideline development, technical assistance and the tracking of program performance measures

and reports, HRSA employs a number of different strategies to ensure high quality accessible care. Strategies include developing the evidence base regarding effective care to HRSA target populations, and implementing systematic approaches and support for collaborative learning that accelerates knowledge sharing and quality improvement across large communities of practice. These strategies have helped to define what constitutes high quality practice and the critical elements necessary to achieve effective care and improved health outcomes for safety net populations in ways that can be practically implemented by the providers serving the targeted populations. This information is also useful to the wider practice community, particularly those caring for comparable or similar populations. For example, as a result of quality reporting and improvement efforts, health center prenatal programs now demonstrate lower rates of low birth weight than national averages, with less racial disparities than for similar mothers in other prenatal care settings.

HRSA has also collaborated with the Institute for Healthcare Improvement (IHI) for over a decade and supported hundreds of learning collaborative teams across the country that have documented performance improvements and gained proficiency with sophisticated quality improvement models while positively impacting diverse groups of safety net organizations and populations. The learning collaboratives continually test quality performance measures and generate new knowledge about effective approaches to service improvements in resource constrained settings (e.g. increased medication adherence or cervical cancer screening rates among HIV populations).

Through its programs, HRSA has developed a comprehensive understanding of the performance challenges of safety net populations and providers that operate in complex systems and low resource environments. This knowledge and experience about quality and performance measurement has led us to a balanced approach such that the results of performance measurement are carefully and thoughtfully interpreted and often balanced with multifaceted strategies addressing quality improvement and technical assistance.

Based on lessons learned through some of the quality activities noted above, the following concepts are incorporated into the HRSA Core Measure principles:

1. Development and use of quality indicators is a new "science". The value of particular measures developed for one purpose may not be appropriate for other uses. Testing and validating measures to assure they do what is intended in their use is a key activity currently built into national measures consensus activities (NQF) as measures mature and are refined and/or retired and replaced by better measures.

2. Aggregation of numbers, populations, and subpopulations is a complex science that must be handled carefully and with transparency to capture the correct information. HRSA programs, populations and service priorities are very diverse. HRSA will continue to invest considerable expertise to determine the types of measures that will be most useful to implement across programs and the types of messages we will be able to create as a result of the measures we capture. HRSA will continue to approach these alignment and aggregation decisions in a thoughtful collaborative manner and share progress and lessons learned.

3. Quality performance measures are not designed to measure adherence to clinical care guidelines and are intended to be a gross indicator of levels of care based on measuring an action or activity that has a known impact or a relationship to quality outcomes. Performance measures are not intended to reflect every aspect of service or treatment for a particular condition because there are many other activities involved in creating the desired quality outcome that are not captured in the measure.

4. Many nationally endorsed clinical quality performance measures are designed to measure activities or processes that reflect care in managed care settings and hospital based practices and critical aspects of care for HRSA target populations may not be captured. The performance results generated by HRSA programs will be interpreted in the context of the programs and populations that we serve, and improvement strategies will likely come from experience of similar organizations, populations and systems of care.

5. HRSA has special expertise related to care for safety net populations with high disease burdens, lower incomes, lack of insurance, higher transience rates, and that are highly vulnerable to the effects of fragmented healthcare delivery systems. Some of the evidence base to support improvements and quality outcomes for our special populations has been developed through our programs. HRSA is committed to adding to the national dialogue and measures development process and will continue work on an enhanced set of quality indicators that adequately address these aspects of care.

Given the importance of performance measures as a method for assessing quality, these Quality Measurement Principles for HRSA Core Measures incorporate the above lessons and create a path for the use of current national measures and the development of new "disparity sensitive" performance measures when such are called for by HRSA Populations and programs.

HRSA CORE MEASURES
HRSA QUALITY MEASUREMENT PRINCIPLES

1) Quality performance measures, when selected, are intended to be used for continuous improvement by HRSA grantees, Bureau and Office Programs, and by HRSA as an Agency.

Discussion: Quality performance measurement is not an end in itself, it is a means for improving care for all of the populations that HRSA serves. As such, when selected, measures should be used to track and improve quality of care. Whenever quality performance results are shared it will be done in the context of the work HRSA does as an Agency.

In addition, the data will be used by project officers, Bureaus, Offices, and HRSA, to assess, compare and interpret performance, and identify benchmarks and best practices. Finally, the data will be used to communicate the impact HRSA is having on the delivery of care to the populations that it serves, and to implement HRSA level quality improvement strategies and technical assistance.

2) HRSA will identify a core set of measures that target crosscutting issues important to HRSA grantees and populations.

Discussion: The Core Measures development process identifies nationally endorsed measures, whenever appropriate and aligned with program priorities, starting with clinical measures that are most relevant for safety net populations cared for through HRSA clinical programs. This core set will continue to expand, through an inclusive consensus process, to include other appropriate measures that capture the crosscutting scope of HRSA services. Core Measures will be recommended by the Clinical Core Measurement System (CCMS) workgroup for approval by the HRSA Healthcare Quality Council (HHQC).

3) Data from Core Measures will be collected and interpreted at the program level and utilized for further analysis and improvement strategies at the HRSA level.

Discussion: Core Measure data will allow HRSA to track trends in quality performance for its funded programs and to create HRSA level benchmarks. When HRSA Bureaus and Offices elect to utilize a core measure, they will incorporate them into their program reporting tools and provide program level aggregated data to HRSA. Although quality improvement technical assistance may be available at the HRSA level, feedback on performance to individual grantees will continue to occur through the Bureau and Office programs.

4) When new quality measures are sought, programs will draw from the HRSA pool of standardized Core Measures when appropriate to their programs and populations, and will align their data collection requirements to use the exact national data specifications.

Discussion: Standardization makes an effective quality measurement system feasible for the nation. A high level of alignment is necessary for data aggregation, benchmarking and comparisons. If a program determines the need for a measure in an area that has already been addressed by a Core Measure, using the specific data sources and inclusion criteria that are incorporated into the Core Measures will ensure that HRSA programs are in full alignment with national measures and with each other. Use of the data sources and codes included in national measures will minimize the grantee reporting burden, especially when reporting tools and formats also evolve from the measure data.

5) If programs require data beyond that available from national or HRSA Level measures, programs will be encouraged to expand the measures to capture more safety net specific quality data (Core+).

Discussion: The purpose of this principle is to assure that HRSA and its programs can participate in the national alignment process and the national quality conversation; and continue to track evidence-based care that is more rigorous and/or data dimensions that are specific to our safety net populations, program priorities and legislative mandates. When thoughtfully constructed, "Core +" measures will have the capacity to capture more sensitive safety net quality information and also allow comparison with others when useful.

6) When National measures are inadequate or do not exist , HRSA programs will collaborate together, and when appropriate with other external and national partners, to identify measures that more adequately capture the intensity of services or special care needs of HRSA safety net populations.

Discussion: HRSA programs are designed to address the special challenges of the healthcare safety net and grantees often serve particular populations with very specific clinical objectives. National measures may be insufficient to assess the types of services needed to achieve the desired outcome improvements; in such cases HRSA programs will demand measures not yet vetted or standardized.

Through early collaboration on issues important to our programs, HRSA will play a leadership role in developing, testing and collaborating on the adoption of new measures. This agency level Core Measures collaboration will result in more "disparity sensitive" measures for the healthcare safety net from which benchmarks can be developed and tracked. This process will highlight HRSA's approach to addressing health disparities and it will promote continuous quality improvement in areas important to HRSA grantees and populations.

7) Where current HRSA program measures are similar but NOT in alignment with Core Measures, efforts will begin to either align, retire or otherwise communicate why the measures are purposely different, with a deadline for action by June of 2010. In situations where different program measures are essential, every effort will be made to structure data to also be used at the HRSA level.

Discussion: Implementing this principle will result in agency-wide alignment of a subset of Core Measures by 2010 and result in tangible benefits for dual funded grantees and HRSA as a whole.

8) HRSA Core Measures will be maintained and updated as appropriate.
Discussion: HRSA will update and maintain the measures in keeping with current practice standards, data collection requirements and guidelines. Core Measures and updates will be recommended by the CCMS workgroup and approved by HHQC.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Health Resources and Services Administration EHR READINESS CHECKLIST	FOR HRSA USE ONLY			
	Grantee Name			
	Grantee Name		Application Tracking #	
	Project #		Project Type	
	Project Title			

1. Why are you purchasing a certified EHR or enhancing your current system?
(Please check one)

[ ] Move from paper system to electronic
[ ] Reimbursement purposes, e.g., Medicare and Medicaid incentive payments
[ ] Clinical technology to achieve workflow efficiencies
[ ] Primarily as a technology to enable quality care improvement goals

2. Do you have organizational wide commitment from:
(Check all that apply)

[ ] Leadership (CEO, COO, CMO, CFO)
[ ] Board Members
[ ] All Providers
[ ] IT Staff
[ ] Support Staff
[ ] Other; please identify:_____

3. Has your center identified business and clinical goals for adopting a certified EHR system?
[ ] Yes [ ] No

4. Has your center identified a clinical champion and other staff to oversee the readiness process?
[ ] Yes [ ] No

5. Have you used the EHR Selection Guidelines for Health Centers developed by HRSA to select the functionality for your EHR?
[ ] Yes [ ] No

6. Have you considered the ongoing expenses required for a certified EHR system?
[ ] Yes [ ] No

7. Are all key staff members willing to use computers in their daily work?
[ ] Yes [ ] No

8. Do you have IT staff or access to a Health Center Controlled Network or IT consultant to provide support for troubleshooting your current and proposed IT/HIT infrastructure?
[ ] Yes [ ] No

9. Do the exam rooms in your center have networked computers?
[ ] Yes [ ] No

10. Does your center have a broadband/high speed internet connection?
[ ] Yes [ ] No

Electronic Health Records: Selection Guidelines for Health Centers

December 2008 version

In consultation with health center clinicians and Chief Medical Officers, the Selection guidelines have been fully reviewed and updated.

Highlights of the newly revised December 2008 version include:

- Enhanced vendor section with information on CCHIT certification
- Newly created sections on Children's Health and Pregnancy Care
- Enhanced Clinical Practice Guidelines specifying guidelines in areas covered by the Health Disparities Collaboratives
- Added detail in the reporting section including UDS reporting

Electronic Health Records: Selection Guidelines help health centers evaluate electronic health records (EHR) products and develop requests for proposals (RFP) or requests for information (RFI).

The downloadable Word document, written in RFI format, enables health centers to gather detailed information from EHR vendors about their products.

The Guidelines

- Borrow from the Health Level 7 (HL7) EHR functional model, the industry standard,
- Were developed in consultation with HIT staffers and clinicians from health centers, and
- Are tailored for health centers.

How to Use EHR Selection Guidelines

- Add to or subtract from the relatively comprehensive list of features in the Guidelines to make sure the EHR you select meets your needs.
- Gather detailed information from vendors as you consider EHR products.
- Specify EHR needs to vendors as part of an RFP. Products will meet the guidelines to varying degrees.
- Evaluate vendor proposals and products to make informed purchasing decisions.
- In addition, you should verify that products you are considering purchasing are also certified by the Certification Commission for Health Information Technology (CCHIT). The EHR Selection Guidelines address the specific needs of health centers and complement, but do not replace CCHIT certification.

Feedback

Do you have comments or questions about the guideline? Have you used them? Please let us know your experience by emailing us at healthit@hrsa.gov. The guidelines are a living document and will be updated periodically as the environment changes or at least annually.

Integrated Information & Communication Technology

HRSA is currently supporting six Integrated Information and Communication Technology grantees to ultilize HIT to reinvent and substantially enhance primary and preventive care in the health center delivery system.

Integrating electronic health record systems, secondary databases and protocols at the point of care for administrative, clinical, care management, financial and information systems purposes establishes an electronic delivery of care system that:

- Supports patient self-management, evidenced-based clinical decision-making, efficient practice design, and the improvement of the health status of communities and populations.
- Enhances the safety, efficiency, effectiveness, and timeliness of care.
- Provides patient access to health information and support, as well as their health record.
- Assures that all patients receive high quality care.
- Ensures that clinical information infrastructure is integrated with the business information systems.
- Supports rapid response in emergency situations.

Information & Clinical Technology Grants

The grants that HRSA is supporting have three primary objectives:

- Development of a robust information and communication technology infrastructure that supports the Health Disparities Collaborative Care Model and leads to a seamless delivery system.

- Establishment of networked information and communication technology systems that maximize economies of scale.
- Dissemination of and support for the spread of the information and communication technology infrastructure to all health centers within State or regional marketplaces.

These projects built on and expanded efforts of health centers and health center networks that manage a select number of chronic conditions through the Health Disparities Collaborative so that their approaches could be applied to all conditions and all health center patients across their delivery systems.

Capitalizing on innovations in chronic care management, electronic patient registries, and performance improvements, the program aligned information system goals and objectives to focus on patient and clinical care, specifically the implementation and dissemination of a clinical information system or "electronic health record" supportive of Health Disparities Collaborative care model objectives.

Projects supported the move to a clinical information system through an integrated system with common architecture providing the best clinical and administrative solution the clinical information system marketplace, eliminating both disparate clinical database sources and the fragmentation of clinical data and information.

Grant awards ranged from $450,000 to $750,000 per budget period, with project periods as long as 4 years.

Beginning in 2006, the Integrated Information and Communication Technology grantees are working to install electronic health records in approximately 60 health centers with 300 sites. Statewide efforts are taking place in Maine, Oregon and West Virginia. Marketplace efforts are taking place in Florida, Illinois and North Carolina.

Integrated Information & Communication Technology Grant Projects

Health Choice Network, Inc.
Miami, Florida

- **Technology: Electronic Health Record; Practice Management System**
- **Community: rural/urban**
- **Members: 11 community health centers, 86 sites**
- **Integration: horizontal**
- **Service Area: (Counties) Pinellas, Pasco , Charlotte , Lee, Hendry, Broward, Miami-Dade**
- **HIPAA Compliance: (In place) Privacy Policy and Procedures, Training, HIPAA Compliance Officer, IT Infrastructure/Security Policy and Procedures, Electronic Transactions/Code sets, HIPAA Clearinghouse Compliant**
- **Network Stats: 205,000 users, 916,000 encounters**
- **Total Providers in Network: Medical: 431.5; Mental Health Substance Abuse 44.75; Oral Health: 97; Pharmacy: 32**

Alliance of Chicago Community Health Services, Inc.
Chicago, Illinois

- **Technology: Electronic Health Record**
- **Community: urban**
- **Members: four community health centers, 23 sites**
- **Integration: horizontal**
- **Service Area: (County): Cook**
- **HIPAA Compliance: (In place) Privacy Policy and Procedures, Training, HIPAA Compliance Officer, IT Infrastructure/Security Policy and Procedures, Electronic Transactions/Code sets**
- **Network Stats: 69,505 users, 305,349 encounters**
- **Total Providers in Network: Medical: 131.1; Mental Health Substance Abuse 80.4; Oral Health: 5.6**

Collaborative Network for Northern New England (CONNECT)
Augusta , Maine

- **Technology: Electronic Health Record; Practice Management System; Disease Registry**
- **Community: rural**
- **Members: six community health centers with 21 sites**
- **Integration: horizontal**
- **Service Area: (Counties) Aroostook, Cumberland, Hancock, Penobscot, Oxford, Washington, York, Canada**
- **HIPAA Compliance: (In place) Privacy Policy and Procedures, Training, HIPAA Compliance Officer, IT Infrastructure/Security Policy and Procedures, Electronic Transactions/Code sets, HIPAA Clearinghouse Compliant**
- **Network Stats: 51,269 users, 210,729 encounters**
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- **Service Area: (Counties) Multnomah, Clackamas, Tillamook, Jefferson, Benton, Jackson, Yamhill, Klamath, Washington, Douglas, King (WA), Santa Cruz (CA)**
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- **Technology: Electronic Health Record, General Ledger**
- **Community: rural/urban (Statewide)**
- **Members: 22 community health centers, 70 sites**
- **Integration: horizontal**
- **Service Area: (Counties) Kanawha, Webster, Clay, Raleigh , Monongalia, Lincoln , Morgan, Greenbrier, Pocahontas, Pendleton, Preston, Ritchie, Roane, Upshur, Taylor , McDowell, Cabell, Wayne , Wirt, Putnam, Gilmer, Monroe**
- **HIPAA Compliance: (In place) Privacy Policy and Procedures, Training (ongoing), HIPAA Compliance Officer, IT Infrastructure/Security Policy and Procedures, Electronic Transactions/Code sets, HIPAA Clearinghouse Compliant**
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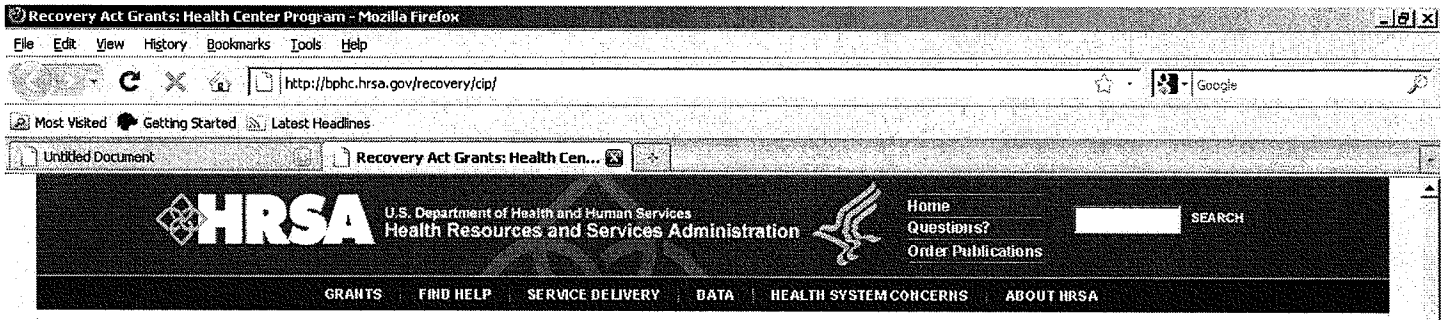

The Health Center Program: Recovery Act Grants

Contact/Questions:
BPHCRecovery@hrsa.gov

Recovery Home
Health Centers Quarterly Reporting
Facility Investment Program
Capital Improvement Program
Increased Demand for Services

HHS.gov/Recovery
Overview
Plans & Reports
Grants & Contracts
Announcements
Community Health Centers

Capital Improvement Program (CIP)

Announcements

Capital Improvement Program (CIP)
Awarded June 29, 2009

CIP Project Type	Number of CIP Projects	Amount Awarded
Construction Projects	411	$221,599,361
Alteration/Repair/Renovation Projects	1,153	$318,238,474
IT/Equipment-Only Projects	490	$136,059,253
Health Information Technology Projects	176	$31,551,085
Electronic Health Record (EHR) Projects (Overall)	384	$144,072,086
EHR Projects with New EHRs	*295*	*$119,243,808*
EHR Projects with Upgraded/Expanded EHRs	*89*	*$24,828,278*
Totals	**2,614**	**$851,520,259**

Capital Improvement Program Guidance(PDF - 305 KB)

CIP Award Press Release

Read Remarks by First Lady Michelle Obama

Health Center Recovery Act Funding by State and Grantee

CIP Post-Award Technical Assistance

• GENERAL RESOURCES

CIP Post-Award Technical Assistance Presentation(PPT - 1 MB)

CIP Post-Award Frequently Asked Questions(PDF - 128 KB) (Updated 7/29/09)

Resolving Conditions on Capital Improvement Program Awards(PDF - 117 KB)

• BLANK FORMS AND TEMPLATES

Blank CIP Electronic Health Record Checklist(DOC - 34 KB)

Blank CIP Environmental Information and Documentation Checklist(DOC - 142 KB)

Sample Notice of Federal Interest (PDF - 13 KB)

Owner Statement of Agreement Template (PDF - 7 KB)

• FACT SHEETS

FAQ: Draft Environmental Assessments

FAQ: Force Account Labor

FAQ: Procurement Standards

• NATIONAL HISTORIC PRESERVATION ACT REQUIREMENTS

Notice of Delegation for Grantee Historic Preservation Consultation(PDF - 25 KB)

Section 106 Historic Preservation Fact Sheet(PDF - 787 KB)

• NATIONAL ENVIRONMENTAL POLICY ACT REQUIREMENTS

Programmatic Environmental Assessment Alteration/Repair/Renovation of Existing Medical Center Facilities(PDF - 377 KB)

Recovery Act Funding

$500 million to

- support new health center sites and service areas,
- increase services at existing sites, and
- support spikes in uninsured populations.

$1.5 billion to

- support construction, renovation and equipment (incliuding IT) in approved health centers.

Awarded Programs

Increased Demand for Services:

- 1,128 awards

Capital Improvement Program:

- 2,614 projects
- $851 million total

New Access Points:

- 126 awards
- $155 million total

Finding of No Significant Impact (FONSI) for Alteration/Repair/Renovation of Existing Medical Center Facilities(PDF - 43 KB)

Finding of No Significant Impact for Expansion of Existing Medical Center Facilities (Nationwide) (PDF - 45 KB)

Finding of No Significant Impact for Expansion of Existing Medical Center Facilities (Nationwide) (DOC - 56 KB)

Programmatic Environmental Assessment Expansion of Existing Medical Center Facilities (Nationwide) (PDF - 328 KB)

Programmatic Environmental Assessment Expansion of Existing Medical Center Facilities (Nationwide) (DOC - 1.31 MB)

Application Technical Assistance

Frequently Asked Questions(PDF - 428 KB) updated 05/28/09

Summary of CIP Resources(PDF - 30 KB)

Projecting FTEs for Your CIP Projects(PDF - 74 KB)

Technical Assistance Conference Calls

Overview	Slides(PPT - 3 MB)	Replay: 1-866-453-4973 Passcode: 65795
Alterations & Construction	Slides(PPT - 8 MB)	Replay: 1-800-860-4708 Passcode: 26478
Electronic Health Records (EHR) Readiness	Slides(PPT - 4 MB)	Replay: 1-800-860-4708 Passcode: 26478
Equipment	Slides(PPT - 2.5 MB)	Replay: 1-800-570-8796 Passcode: 75698
Recovery Act New Start Grantees		Replay: 1-800-925-5459 Passcode: 85649

If you need help accessing information in different file formats such as PDF, Word, PPT, see Instructions for Downloading Viewers and Players.

Done

Ryan White HIV/AIDS Program - HIV/AIDS Bureau (HAB)

Overview of HAB Core Clinical Performance Measures- Monitoring the Quality of Care

http://hab.hrsa.gov/special/habmeasures.htm#performance1

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Measures

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HAART		pdf 46KB
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PCP Prophylaxis		pdf 45KB

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Hepatitis B Vaccination	pdf 53KB
Hepatitis C Screening	pdf 51KB
HIV Risk Counseling	pdf 45KB
Lipid Screening	pdf 51KB
Oral Exam	pdf 53KB
Syphilis Screening	pdf 51KB
TB Screening	pdf 73KB

GROUP 3 MEASURES (New April 2009)

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Gonorrhea Screening	pdf 66KB
Hepatitis B Screening	pdf 64KB
Hepatitis/HIV Alcohol Counseling	pdf 62KB
Influenza Vaccination	pdf 62KB
MAC Prophylaxis	pdf 66KB
Mental Health Screening	pdf 66KB
Pneumococcal Vaccination	pdf 66KB
Substance Use Screening	pdf 66KB
Tobacco Cessation Counseling	pdf 66KB
Toxoplasma Screening	pdf 63KB

TOP

Technical Assistance

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10. Why aren't performance measures for case management or other supportive services included in the HAB core performance measures?
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20. Hepatitis B vaccination is a one-time series for immunization. How will this be monitored over time?
21. In regards to Hepatitis B immunization, should patients with isolated anti-HBc be included or excluded in the denominator?
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24. Since toxoplasmosis affects only those clients with CD4 counts < 50 cells/mm^3, why does it apply to all clients?
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26. Why does the substance use measure only focus on newly enrolled clients?
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HRSA Clinical Quality Performance Measures
A Commitment to Quality Improvement in the Safety Net

HRSA has begun implementation of a Clinical Quality Core Measure Set of 12 performance measures as part of a larger clinical quality measurement and improvement initiative. This initiative underscores HRSA's commitment to quality improvement and begins to measure and demonstrate the quality of care across the agency as a whole—a capstone to the program specific quality measures now in use by many HRSA programs. The new initiative not only aligns clinical performance measures across the HRSA's clinical service delivery programs, but also makes them consistent with national quality measures endorsed by the National Quality Forum (NQF), AQA and other national quality organizations.

The Clinical Core Measures Set was approved by HRSA senior leadership in December of 2006 and is available for use by HRSA programs. Some of the measures have already been incorporated into program grant guidance including those for health information systems and rural quality improvement; they are also featured in revisions to the Consolidated Community Health Centers program reporting tool. To help HRSA plan for technical assistance support, data analysis and quality performance reporting, the measures will be tested during performance review site visits and through feasibility study testing during the summer and fall of 2007.

The core measures address priority health conditions of HRSA safety-net populations, cover all life cycles, are amenable for quality improvement, and were selected for their relevance to HRSA programs. To reflect HRSAs' important role in population and community health, the core measure set includes screening for colon, breast and cervical cancer screening; cancers which disproportionately affect HRSA populations and for which early detection and care can significantly decrease mortality and improve 5 year survival.

In addition the HRSA set includes measures for prenatal HIV screening, access to prenatal care, and appropriate immunizations by life cycle. Chronic disease management performance measures are included for diabetes and hypertension. Additional Clinical Core measures are planned in the areas of mental health, oral health, asthma, obesity and smoking. Quality measures for patient safety, patient satisfaction and health literacy/communication are also being considered.

The attached list of measures is supported by a more extensive document of measure specifications. Questions about the measures can be directed to Dr Deborah Willis-Fillinger in HRSAs' Center for Quality at DWillis-Fillinger@HRSA.Gov or 301-443-6614.

HRSA Clinical Performance Measure Subset
May 19, 2008

PREVENTION

PRENATAL

FIRST TRIMESTER CARE

Percentage of pregnant women beginning prenatal care in the first trimester

Numerator: Number of patients who began prenatal care in the first trimester.

Denominator: Number of patients who entered prenatal care during the measurement year.

HIV PERINATAL PREVENTION

HIV SCREEN- PREGNANT WOMEN

Percentage of patients who were screened for HIV infection during the first or second prenatal care visit

Numerator: Number of patients who were screened for HIV infection during the first or second prenatal care visit

Denominator: All patients seen for 2 prenatal visits during the measurement year.

CANCER

BREAST CANCER

Percentage of women 40-69 years of age who had a mammogram

Numerator: One or more mammograms during the measurement year or the year prior to the measurement year.

Denominator: All female patients aged 42 to 52 and 53 to 69 years of age at the beginning of the measurement year or year prior to the measurement year.

OR

CERVICAL CANCER

Percentage of women 21-64 years of age who received one or more Pap tests

Numerator: One or more Pap tests during the measurement year or the two years prior to the measurement year.

Denominator: All female patients age 24-64 years of age during the measurement year

OR

COLORECTAL CANCER

Percentage of adults 50-80 years of age who had an appropriate screening for colorectal cancer.

Numerator: One or more screenings for colorectal cancer.

Denominator: All patients age 51-80 years during the measurement year.

IMMUNIZATIONS

AGE APPROPRIATE IMMUNIZATIONS

Percentage of patients with appropriate immunizations documented according to age & risk group. (or as per ACIP and/or NVAC guidelines)*

CHILDREN

Percentage of children 2 years of age with appropriate immunizations.

Numerator: Number of children who have received 4xDTaP/DT, 3xIPV, 1xMMR, 3xHiB, 3xHepB, 1xVZV, and 4x PCV vaccines by their second birthday.

Denominator: All children who turn two years of age during the measurement year.

OR

ADULT

Percentage of patients 50-64 years and 65 and above who have received influenza vaccine.

Numerator: Number of patients who received influenza vaccination from September through February of the year prior to the measurement period.

Denominator: All patients *50-64 years and 65 and above* at the beginning of the one-year measurement period.

OR

GERIATRICS

Percentage of patients ≥ 65 years of age who have ever received pneumococcal vaccine.

Numerator: Number of patients who have ever received pneumococcal vaccine.

Denominator: All patients 65 years and older in the measurement year.

OR

HIV/AIDS

Percentage of patients with HIV infection who completed the vaccinations series for Hepatitis B.

Numerator: Number of patients with HIV/AIDS who were vaccinated for Hepatitis B (vaccine Bx3 vaccinations)

Denominator: All patients with HIV/AIDS in the measurement year who are documented to be susceptible to Hepatitis B virus or have an unknown Hep B status.

CHRONIC DISEASE MANAGEMENT

DIABETES

HbA1c CONTROL

Percentage of adult patients with type 1 or 2 diabetes, with most recent hemoglobin A1c (HbA1c) greater than 9% (poor control).

Numerator: Number of adult patients whose most recent hemoglobin A1c level during the measurement year is greater than 9 %.

Denominator: Number of adult patients 18-75 years of age as of December 31 of the measurement year with a diagnosis of type 1 or 2 diabetes.

CARDIOVASCULAR -HYPERTENSION

CARDIOVASCULAR- HYPERTENSION

Percentage of adult patients, 18 years and older, with diagnosed hypertension (HTN) whose blood pressure (BP) was less than 140/90 (adequate control).

Numerator: Patients with last systolic blood pressure measurement less than 140 mm Hg and diastolic blood pressure less than 90 mm Hg during the measurement year.

Denominator: All patients ≥ 18 years of age as of December 31 of the measurement year with diagnosis of hypertension (HTN).

HHS News Release

FOR IMMEDIATE RELEASE
Tuesday, September 29, 2009

Contact: HHS Press Office
(202) 690-6343

Secretary Sebelius Releases $27.8 Million in Recovery Act Funds to Expand the Use of Health Information Technology

HHS Secretary Kathleen Sebelius today announced awards totaling $27.8 million to health center-controlled networks and large multi-site health centers to implement electronic health records (EHR) and other health information technology (HIT) innovations. The funds are part of the $2 billion allotted to HHS' Health Resources and Services Administration (HRSA) under the American Recovery and Reinvestment Act of 2009 (ARRA) to expand health care services to low-income and uninsured individuals through its health center program.

"The increased use of health information technology is a key focus of our reform efforts because it will help to improve the safety and quality of health care generally while also cutting waste out of the system," said Secretary Sebelius.

"These funds to expand and upgrade electronic health records systems will make a huge difference for health centers struggling to provide health care to the growing number of people in need," said HRSA Administrator Mary *Wakefield*, Ph.D., R.N.

"Broad use of health information technology has the potential to improve health care quality, prevent medical errors, and increase the efficiency of care provision," added David Blumenthal, National Coordinator for Health Information Technology. "This program supports the Department's overall efforts to assist physicians and hospitals in adopting and becoming meaningful users of health information technology."

Eighteen grants totaling more than $22.6 million will support EHR implementation. Grants totaling more than $2.6 million will help four grantees implement a variety of HIT innovations, including the creation of health information exchanges among different providers and the incorporation of HIT at dental delivery sites. Another five grants totaling over $2.5 million will help health centers devise plans to use existing EHRs to improve patient health outcomes.

HRSA received $2 billion through the Recovery Act to expand health care services to low-income and uninsured individuals through its health center program. To date, more than $1.3 billion of these funds have been awarded to community-based organizations across the country. HRSA-supported health centers treated 17 million patients in 2008, 40 percent of whom have no health insurance.

In addition, HRSA received $500 million in Recovery Act workforce funds—$300 million to expand the National Health Service Corps (NHSC) and another $200 million for other health care workforce programs. The NHSC funds will pay for student loan repayments for primary care medical, dental, and mental health clinicians who will practice for a minimum of two years in NHSC sites that treat underserved and uninsured people. Recently, awards totaling $33 million—part of the $200 million total—were announced to expand the training of health care professionals.

The list of grant recipients follows:

Electronic Health Record Implementation Initiative Grants, FY 2009

Organization	*City*	*State*	*Amount*
Clinica Sierra Vista	Bakersfield	Calif.	$1,865,625
Colorado Coalition for the Homeless	Denver	Colo.	$1,865,625
Community Integrated Services Network of Pennsylvania	Wormleysburg	Pa.	$1,400,001

Family Health Centers of San Diego, Inc.	San Diego	Calif.	$1,865,625
Greene County Health Care, Inc.	Snowhill	N.C.	$1,865,625
Hawaii Primary Care Association	Honolulu	Hawaii	$750,000
Illinois Primary Care Association	Springfield	Ill.	$750,000
Michigan Primary Care Association	Lansing	Mich.	$1,863,409
Near North Health Service Corporation	Chicago	Ill.	$746,671
Neighborhood Health Care Network	Saint Paul	Minn.	$832,768
Total:			**$13,805,349**

High Impact - Electronic Health Record Implementation Initiative Grants, FY 2009

Organization	*City*	*State*	*Amount*
Alaska Primary Care Association, Inc.	Anchorage	Alaska	$750,000
Coastal Family Health Center, Inc.	Biloxi	Miss.	$1,369,546
Community Health Centers of Arkansas	North Little Rock	Ark.	$458,003
Dena' Nena' Henash dba Tanana Chiefs Conference	Fairbanks	Alaska	$1,373,240
Georgia Association for Primary Health Care	Decatur	Ga.	$1,400,000
INConcertCare, Inc.	Urbandale	Iowa	$1,371,125
OCHIN	Portland	Ore.	$1,400,000
Whatley Health Services, Inc.	Tuscaloosa	Ala.	$750,000
Total:			**$8,871,914**

Health Information Technology Innovation Initiative Grants, FY 2009

Organization	*City*	*State*	*Award*
Alta Med Health Services Corporation	Los Angeles	Calif.	$746,250
Blackstone Valley Community Health Care	Pawtucket	R.I.	$746,250
Health Choice Network, Inc.	Miami	Fla.	$555,000
Southbridge Medical Advisory Council, Inc.	Wilmington	Del.	$555,262
Total:			**$2,602,762**

Electronic Health Record Quality Improvement Grants, FY 2009

Organization	*City*	*State*	*Award*
Colorado Community Managed Care Network	Denver	Colo.	$250,000
Community Health Center	Middletown	Conn.	$400,000
El Rio Santa Cruz Neighborhood Health Center	Tucson	Ariz.	$621,874
The Institute for Family Health	New York	N.Y.	$615,706
OCHIN	Portland	Ore.	$621,875
Total:			**$2,509,455**

###

The Health Resources and Services Administration (HRSA), part of the U. S. Department of Health and Human Services, is the primary Federal agency for improving access to health care services for people who are uninsured, isolated, or medically vulnerable. For more information about HRSA and its programs, visit www.hrsa.gov.

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FTS-BPHC (US)

Moderator: Beth Tchinski
May 7, 2009
2:00 pm CT

Coordinator: Good afternoon and thank everyone for holding.

At this time we'd like to welcome everyone to today's teleconference and remind participants that your lines have been placed on listen-only mode. Until the question and answer session of today's program. At that time if you wish to ask a question you may press star 1 on your touchtone phone.

Once again that will be star 1 for any questions. I would also like to inform all participants that today's call is being recorded. If you have any objections to this you would disconnect at this time.

It is now my pleasure to turn the call over to your main speaker today Mr. Jim Macrae.

Thank you sir you may begin.

Jim Macrae: Great thank you very much. Good afternoon, good morning for those who are way out west. I hope you are all having a great day. And for those of you who have been with us on every call, welcome back and for those of you who are new to the call. Welcome.

Today's call is focused on the whole opportunity under the Capital Improvement Program for electronic health records and health information technology systems, no?

Beth Tchinski: Focusing more on HIT Tomorrow.

Jim Macrae: HIT tomorrow sorry. They haven't clearly prepped me well enough but anyway.

All right let me start all over, hi, good morning, good afternoon. Hope you all are doing well. We're going to talk about EHRs today, all joking aside. It's great to be here, we really do see this as an incredible opportunity to really push forward the whole health center program with this Capital Improvement Program.

There are some incredible opportunities that health centers have whether that's in the construction area. To do alteration repair renovation, to do things around IT/equipment, HIT and then for today's call around certified electronic health records.

Today's focus is going to be on electronic health records. And we have a number of different folks who are here to participate in today's call. I'll have them go through and introduce themselves as they speak in turn.

But I just wanted to begin with the fact this is going to be the major opportunity for health centers around electronic health records under the Capital Improvement Program. Many folks have asked well are there going to be additional opportunities for health centers to compete for or be able to purchase EHRs?

This is the main opportunity to be able to do that. There have been some competitions out there for health center control networks as well as larger health centers. But this is the main opportunity for individual health centers to come in and purchase EHRs.

We have been working with our colleagues in the Office of the National Coordinator. As well as our colleagues in our own Office of Health Information Technology to develop a guidance that we think really is in alignment with where we are going as a department.

Where we're headed as a country in terms of electronic health records. And so we really see this as a first key step for health centers to move forward in this direction under the Recovery Act.

And we also have been working with our colleagues in CMS. And want to make sure that whatever we do and whatever we support. Is in alignment with where they are headed with respect to both Medicaid and Medicare payments. And the whole issue of "Meaningful Use" we will talk about that a little bit later in the call.

But basically the intent is that this is the first as I understand it major investment in electronic health records for health centers. And we hope it will build the foundation for the subsequent money that may be available. Either through the Health Center Networks Funding that we will do to our Office of Health Information Technology, the ONC.

And then ultimately to support health centers as they move into the whole reimbursement around Medicaid and Medicare for Meaningful Use. And then ultimately, you know, what becomes a disincentive at some point if you do not have an electronic health record.

I don't want to however minimize the complications with EHRs. And we have many folks around here who know it much better than I do. But this is not something to just jump into or think of it as a plug and play type of situation.

This really has some fundamental impacts on health center operations and you really have to be ready to be able to implement this. Because this is not just an electronic or technological change. Is it a fundamental change in your operations both in terms of basic practice as well as cultural practices? As well as just how you do your work.

And it's not just for the front line providers it really does impact the entire practice. So for those of you who have been thinking about it, we definitely want you to continue to think about it.

But also realize this is not just something that's going to be an easy switch on switch off or switch off switch on type of project. This really is something that will take some thought and some work to get there.

And it's not just the technology that's the to be honest probably the easy part. The harder part really is getting to a place where you feel comfortable with it. Making sure the system meets your needs and really being clear about what those needs are.

In addition which makes it even more complicated is there are a number of different people out there who are offering different options. And may say that they can meet all of your needs and will be able to do it immediately.

We would strongly encourage you to talk to others who have utilized those services to get their perspectives and feedback. Because those are your best I think people to talk to. Other health centers that have either worked with that particular company, to really get their feedback in terms of what their experience has been.

In addition as you know we've made a significant investment over the last several years in our Health Center Control Network. They are an incredible resource and where they are located and where they are available.

We would definitely encourage you to contact them and explore the possibility of either continuing our expanding your work with them. Or if you have not to explore the opportunities to actually work with them as you implement your EHR.

So for me the bottom line behind all of this is not just to have an EHR but to actually use it for quality improvement. As you know we implemented our new UDS measures this year which for those who have EHRs. It's much easier to be able to track and utilize for the most part but not perfectly.

But where we really hope to be able to get it is where we are able to collect this data and information on all of our patients in an electronic format. Because that will make it ultimately easier for us to be able to report the impacts.

But most importantly be able to improve the quality of care that's provided. And really identify what are some of the best practices out there. What can people learn from each other and what can we do as a whole community to improve and really push the ball forward on quality.

So to me that's really the promise of EHRs is not only to be electronic but to really improve the quality of care that we provide. And ultimately improve the lives and the health outcomes. And really working to eliminate disparities among our patients and our communities in terms of their health.

So with that I will turn it over to Beth Tchinski bit close in terms of your last name I apologize. Beth is new to our staff but has jumped right in and will be sharing with us, sort of the basics around the EHR application aspect. And with that I'll turn it over to Beth. So thank you.

Beth Tchinski: Good afternoon.

Beth Tchinski here to review some points specific to the Certified Electronic Health Records Project within the Capital Improvement Program.

And before I get started I would like to remind everyone that these slides are available online at the (specific) Recovery website. So you can go on there and download those, print them off and follow along.

The first few slides give a general broad overview of the Capital Improvement Program as a whole. It is an $850 million one time budget project and the big reminder we would like to throw out to everyone is that this is a one time award.

So any projects you begin at the end of the project period after two years if they require further maintenance, further staffing. Anything you would like to do, you are responsible for those costs.

The applications are due on June 2nd and we are expecting the NGAs to go out on July 1st if I'm correct. And application is through the Electronic Handbook.

Moving onto Slide 4 the different types of eligible projects are alteration, repair, renovation and construction projects. Which were covered in detail in a teleconference yesterday. And those slides are available online and also the recordings are available online. If they are not there now they will be available shortly.

IT equipment and health information technology purchases will be touched on in tomorrow's call and those slides. I'm sorry that call is from 2:30 to 4:00 and those slides will be available tomorrow.

As far as ineligible CIP costs specific to electronic health records. The kind of health records that are not certified by an organization recognized by the Secretary of Health and Human Services is not authorized.

Currently the only organization that is authorized is the Credentialing Commission for Health Information Technologies. All EHRs funded through this at this time. Non-certified EHRs cannot be listed under the guise of other equipment on the application. And costs incurred prior to February 17th are not authorized at all.

It is important to differentiate the differences between the electronic health records and the health information technology health records. The certified EHRs are computer software that providers use to track all aspects of patient care.

Whereas the health information technology includes hardware software and other innovative technology related licenses. Intellectual property upgrades and packaged solutions that help the different systems talk to each other. And that being the EHRs in the health information technology systems as well as any other systems may be the accounting systems that are used. Registries and what not.

The implementation and readiness software infrastructure and clinical facilities, data center infrastructures and implementation staffing are allowable costs.

If EHRs staffing and maintenance costs are funded with this grant. Keep in mind that you need to be able to provide for these resources after the grant has ended if you would like to retain them.

And throughout the slides you will see that pretty much everywhere is referred to as a certified EHR. And we really want to hit that point home that it has to be certified by CCHIT.

At this time we can't look at anything that is in the process of becoming certified because it is not guaranteed that it will be by the time the implementation is to occur.

Allowable use of the funds for the certified EHRs are software computer based training, infrastructure facility costs, hardware. Data infrastructure costs, (unintelligible) physical securities, power upgrades and implementation staff.

As far as the health information technologies the tele-health related equipment. Registries, electronic prescribing, enhancements necessary to interface between HIT and EHR and other electronic systems.

And also dental and oral health will fall under the health information technology. As opposed to the electronic healthcare system, excuse me electronic health records.

EHR purchases refer to the entire package include planning, implementation and associated costs with the certified systems. Equipment purchases for existing systems should be proposed as equipment projects within the EHB application.

And certified EHR systems can be single site multi site or organization wide. Thinking about how to encourage to learn from others who have used certified EHRs. And we do remind you that up to 2% of the Capital Improvement Project's budget can be used for implementation and technical assistance.

The grantees are part of a host of funded networks they should work with their network to enhance the existing systems. If installation of this system requires construction or renovation. A separate project should be proposed for the construction or renovation projects and then EHR as its own separate project.

The purchase of licenses for current EHR systems are only allowed if those systems that are already in place are certified by CCHIT. And again that is the Certification Commission for Health Information Technology and is available at http://www.cchit.org.

And again, if you look at the website you will see where there are different approved EHRs by years. But any of the EHRs listed on that website are certified and approved for use by the CIP funds.

So you must be able to demonstrate readiness by completing the EHR readiness checklist that is within the EHB. And certify if you can demonstrate immediate readiness. Or if you will be able to purchase a certified EHR once readiness is achieved at the end of the two year period.

As far as the EHR planning and readiness process. You need to be able to identify goals for the EHR projects creative strategic plan that guides the certified EHR procurement and identifies key milestones to achieving meaningful use.

Included are completed feasibility analysis include a completed comprehensive organization readiness assessment. A completed comprehensive staff skills assessment. Assess an inventory current resources as far as staff, hardware, software goes.

Outline an implementation strategy for the EHR project that will achieve meaningful use. Inventory, all additional hardware software and staff expertise needed to implement the EHR.

Identify a multi-disciplinary committee to oversee the readiness due diligence selection and implementation of the certified EHR project. Identify a plan to adjust the decrease in productivity during training and implementation. And develop a plan to protect patient's health information.

And this is a long list of things that need to be done for the planning and readiness process. It is in depth but if you visit the website http://www.hrsa.gov/healthit/ there's a lot of good information on that website. That will help you in this process because we do realize that it can be rather daunting.

Some caveats are associated with implementing the EHRs. They cannot supplant HRSA funds that have been allocated for a certified EHR related activities. So no double dipping for the funds.

Purchase of EHR systems that are not certified by an organization recognized by the Secretary of HHS are not allowed. That brings us back to CCHIT they currently are the only recognized body.

Grantees may not add a new site as part of this certified EHR only project. Any sites that you do plan on implementing the EHRs at must already be within your scope of projects.

Grantees must demonstrate readiness to purchase the certified EHR system prior to spending the Capital Improvement Funds. And if readiness gaps do exist grantees will need to certify that a certified EHR purchase will occur once readiness is achieved within the two year period.

On the next page this is just a screenshot of the EHB EHR readiness checklist that is included within the guidance. As far as any procurements that occur standard procurement principals apply and you must comply with 45CFR Part 74.34 and 92.32.

Furthermore if vendors have any hand in writing adjusting or providing technical assistance to the grant rating system they cannot be awarded any grants associated with these funds.

And if the budget project obligates money beyond 25% of the combined budget for all projects. Or beyond $250,000 a change in scope will need to be reviewed and possibly changed.

As part of the EHB application there is an environmental information checklist. We don't anticipate any EID issues but completion of this checklist is required by NFI for all projects including the EHR projects.

For budget justification EHR HIT specific on Form 424C line items. Line one which is administrative and legal expense. Refers to personnel costs, travel of staff for training, sub-contracts and justifications. Pre-implementation and readiness costs as well as support and maintenance in any consultation and technical assistance cost.

And line one there is further it describes Line 1 requirements further on Page 21 of the guidance. Line 10 which is EHR acquisition and implementation costs that means software costs, infrastructure clinical facility costs and data center infrastructure costs.

There is a long laundry list there I won't read them but just keep in mind that all of these are included. But when including them as part of your EHR project. This is for implementing an overall EHR project, if you are buying hardware to implement with your current EHR that you already have at your site. Those should be submitted as equipment only purchases.

Then as far as project impact and recording project the number of providers that will be using the certified EHR. Project the number of patients that will actually have an electronic health record. And as far as the impact of the funds go number of new and approved sites.

Number of health center jobs created in a team. Number of construction related jobs created, completion status including percent complete. And actual versus projected budget information as far as uses of Capital Improvement Grant Funds go.

And this should comply with any other reporting requirements that are within the Act. And with that I will turn it back over to Jim. Thank you.

Jim Macrae: Great I think at this point I am turning it over to our colleagues in the Office of Health Information Technology. To just I think share some of their expertise and knowledge about what are the things that you need to be thinking about in terms of readiness. And I believe (Johanna Barraza-Cannon) is going to be speaking so I'll turn it over to (Johanna). Thank you.

(Johanna Barraza-Cannon): Good afternoon everyone. I am with the Office of Health Information Technology and I'm here with some of my colleagues from OHIT who you will also hear from this afternoon.

We're very excited to be working with the Bureau of Primary Health Care on this opportunity. We think it is a tremendous opportunity for health centers to continue to adopt electronic health records.

So our goal for today is to talk a little bit about some of the work that we've been doing over the past years. With primarily the networks of health centers which many of you should be familiar with.

And we're going to talk a little bit about the tools that we've created that we hope you'll use as you start to work on your submissions. And these tools are not new tools and they will not be going away.

So we just want to make sure that you are aware that they're there and know that you'll be able to use them now and in the future.

So we're going to talk a little bit about things that you should be considering as you're doing this guidance. And then things to consider as you move forward.

So with that I'll just start by telling you that the goals for HIT at HRSA are really multiple. We have over the last few years worked to improve quality of care, reduce health disparities, increase efficiency in care delivery systems. Increase patient safety, decrease medical errors and eliminate the digital divide.

The reason that we wanted to touch on these goals is because we wanted you to know that these purchases are not intended to just purchase a software license and then the project is done.

The way the point of doing this and investing in HIT is to be able to use these tools to improve care and patient outcomes. And so we really want folks to be able to focus on that. This is a very complicated process but it's also a very rewarding process.

We feel that you will be able to achieve so much in terms of improving patient and population health through the use of electronic health records and HIT.

So what is HIT and electronic health records? I think most everyone is familiar with this and we describe what is allowable in the guidance. But just to make a couple of distinctions.

One is the distinction between HIT and electronic health records. For our purposes an electronic health record is defined in the guidance and it's what many of you are familiar with. It's the record that a medical provider would use to keep track of your care as opposed to a paper record.

But we contrast that with health information technology which is all of this other technologies that are available to improve care such as a personal health record. Or a tele-health or tele-pharmacy or electronic prescribing. Those are some of the other technologies that are included under the definition of Health Information Technology.

The other distinction that we want to make is the distinction between information technology and health information technology. And the primary distinction there is between a practice management system and an electronic health record.

Practice management system while it is related to an electronic health record or should be. Is information technology and not necessarily health information technology.

And that's not to say that this guidance cannot be used for practice management systems it can. And there will be more about that discussed tomorrow. But it's to make the distinction between some of these terms that we tend to throw around.

So with that I'll talk a little bit about the process of implementation and purchasing. And using this system so that we can try to set the stage for what you will be looking at as you purchase and implement EHRs hopefully.

So in terms of implementation and we put some slides out there they're with the other slides for this presentation. We're not going to go through them each one; we have a lot of slides and a lot of background material.

But you will find some additional slides if you look online that will provide additional guidance. And also all of the websites that we'll cite are in the slides so that you will be able to find them at a later time.

So the first thing we want to talk about is the cycle of HIT implementation. And yes there is a cycle that's got a start and a stop. It really is a dynamic process.

So the first point of this cycle is planning and figuring out where you are. Figuring out what problems you are trying to solve with your HIT purchase and your EHR purchase.

Figuring out whether or not you are ready which is a tremendous step. And the readiness steps that we outline in the guidance. Are really just a drop in the bucket in terms of what we've seen with our successful EHR implementations.

Readiness is really a way to not just figure out where you are but to set the strategy as you implement. So it is a very important step.

The next step is really implementation. Some people think of this as pushing the button and turning on the system. But really implementation is a whole host of activities in addition to, you know, quote unquote "the go live date."

So for implementation we're really talking about the testing process the training process. You know, having physicians buy into this system being able to adopt across your system and use it.

The last one is really related to in terms of the cycle as the evaluation and being able to figure out where you are and what you do next. Because you may get to the point where you adopted a particular system. But then you decide that in order to really use that system you need to think about disease registries. Or you need to think about how you an interface with other providers.

And so there's the evaluation of what you've done and then you move into planning again in terms of planning. Where do we want to go now, do we want to do upgrades, do we want to do interfaces? Do we want to bring on new participants? So it really is this cycle of work that takes place.

I want to talk a little bit more about the needs assessments and the readiness assessments. Just to point out to you that in your slides that are on the web. Slide 23 includes a number of readiness tools. And also to talk a little bit here about making a decision to purchase and implement.

There it is a very complex process; we are definitely here to help you. Not just with the funding but with the technical assistance. But it's something that you really need to go into carefully.

And so we highly recommend that people take a look at the readiness tools that we've laid out here. And (Christie) will talk in a little bit about some of the other websites where you can find additional tools. But again the readiness assessment is what really lays the groundwork for the rest of it.

To talk a little bit about certifications that seems to be a favorite buzzword around here next to meaningful use. But certification, you know, we talked a little bit about CCHIT many folks have noticed that CCHIT is not mentioned specifically in the Recovery Act.

We think that there will be other certifying bodies but at this point CCHIT is what we have. So we provided the website for you to be able to see which systems are CCHIT certified and for now that is what is allowable.

But we also want to point out that CCHIT is the floor it's not the ceiling. CCHIT talks about inter-operability it talks about HL7 it talks about the basic framework that you need for health record.

It does not talk about functionality or whether it's a practical system for you as a health center. What we've found over the years is that health centers have very unique needs compared to the rest of the population.

The health centers that we've worked with to do the EHR implementation are mission driven. They're very interested in doing population (health); they're very interested in being able to (sort) by panels of patients. They're very interested in being able to report on UDS in an easy way.

So there are very specific needs that health centers have and we also have some links on our slides to functional specifications for EHR purchase. Where you'll be able to see if a set of requirements that you could give to a vendor and say, "Can you do all of these things?" Because these are the things that we need as health centers.

So it can be a very helpful tool, so you'll be able to find the websites that are there in the slides also.

Just to give you a couple of tips before I move onto our network model. In terms of purchasing we get the question, well just tell me which system to buy? And first of all we don't do that, we're vendor neutral but also, you know, there is no gold standard at this point. If there was I'm sure the (hype) after the Recovery Act would have recognized that and we would all be using it.

But at this point different systems meet different needs. And so that's why it's very important to conduct due diligence and to conduct a very careful selection process.

It's very important to go into the purchasing process knowing what you want and knowing what you need and asking the vendor to provide that. If you ask a vendor what they have they will give you want they have and it may or may not meet your needs.

So it's very important to go through the acquisition costs very carefully. Some of the things that you should consider when you're doing that is thinking about your workflow. Thinking about where you have issues, thinking about the population that you serve. Thinking about the particular needs of your center.

So some of those functions that you may think about could include a problem list, medications, clinical decisions report. Do we look for medication errors, do we interface with labs or x-ray? We want to interface with our practice management system. You know, do we want to think about referrals and preventive care and billing?

So those are all issues to think about. One caution I will put out there is that everyone has the need for a practice management system. Some of those are in better shape than other practice management systems. Some of those are more up to date than other ones. And you may be getting pressure to purchase a practice management system that has a corresponding electronic health record.

Those types of decisions need the same kind of considerations as any other EHR purchase. You need to make sure that any EHR is going to meet your needs whether or not it will, you know, interface with your practice management system automatically or not. So that's just something to be aware of.

We're going to talk a little bit about our networks and I'm going to pass the microphone to (Susan Lumsden) who is the Director of our division for HIT State and Community Assistance. Just to reiterate some of the messages that Jim gave you about the network. So here is (Susan).

(Susan Lumsden): Thank you (Johanna). I would like to just add one more thing that (Johanna) said about careful due diligence as you're going through your acquisition process.

A lot of vendors will tell you that they have experience working with health centers. They're the health centers number one vendor of choice. You need to take that a step further and go talk to the health centers, attend user groups' implementation teams of the vendors. They may not have an national health center implementation team. That would be nice but they may be very local.

So where the vendor may have experience implementing in the health center up in Maine they may not have it down where you are.

So with that I am going to talk a little bit about the networks. The health center control networks. The concept is probably about 10, 15 years old; they arose back in the 90s out the health centers need to operate more efficiently. By working together to form a business structure to really maximize the purchasing power of their limited dollars by sharing the cost of services.

The majority of our networks, there is about 56 of them we fund about 76 projects. Some of them have more than one project. The majority of the networks are heavily engaged in quality improvements. And technology due to the skill sets and the equipment background required to efficiently deploy and manage the sophisticated technology in health center members.

First I recommend health centers participate in networks when adopting HIT or any other expensive venture. But like Jim said the health centers really have to make that decision on their own. Networks are good for some health centers; they may not be the right choice for everyone.

But there's a couple of options health centers can choose from. They can adopt HIT on their own; they can join an existing network. They can form a network on their own or they can purchase the service from an existing network.

In March 2008 the California Healthcare Foundation came out with a report of findings from a study. Comparing safety net providers implementation of EHRs (free) networks versus stand alone implementations.

The report really came to the conclusion that EHR networks may be more suitable for midsized or small organizations without strong technical or quality infrastructures.

Or for health centers that cannot divert a substantial amount of time from clinical operation and technical resources to EHR implementation. And networks maybe good for those with an interest in working with and learning from other clinics and health centers that have already adopted EHR system.

Or organizations that want to implement disease management or QI programs predicated upon their EHR system.

Again networks are, you have to really do due diligence with joining a network just like you would choosing a vendor. Flexibility, going it alone there's a lot more flexibility when you go it alone you can make your own decisions versus joining the network.

The time educating your board on the value of networks is certainly none if you go it alone it's much more when you join the network. The level and depth of IT experience is much less if you go it alone, it's much more when you join the network.

The leverage with the vendor is less when you go it alone it's more when you join or do it through a network. And using data to improve quality and reduce cost to correct errors. That's probably less when you go it alone or when you go through a network.

In terms of stable and secure hosting facilities, those are expensive when you go it alone. It is more efficient and more stable when you go through a network. Disaster recovery capacity is less when you go it alone and more capacity when you go through a network.

Again I think it requires due diligence we do have a list of our networks with the contact information and also the EHR vendors that they have. And we will give that to our contacts at (unintelligible) and they will post that sometime next week.

And again you probably don't need that for your application. But over the next couple of years as you implement your systems those are good resources to have.

I'm going to turn it over to (Christie) to talk a little bit more about some other resources that are available.

(Christie Brown): Good afternoon everyone. This is (Christie Brown) with the Officer of Health Information Technology. I'm going to cover some technical assistance tools that we have out there that can help you in getting your applications and throughout your process of your implementation of your EHR.

We have an HIT technical assistance center through our office that provides support to grantees. There's several different phases of PA that we have. We have one to many which is a lot of the PA that we do we have the HRSA health IT community. Where you do need a log in to access the community but it is where we post various HIT materials that are relevant to safety net providers.

We post the functional requirements there are our webinars. There are separate communities that are developed based upon rural health and if you're a small health center a large health center. There's also discussion boards within the community where you can link up possibly with others. Who may have the same product that you are looking at to have a discussion about what's working and what's not working.

There is a log in required and on the slides that you can download there is the process for going about and getting a log in. We also have the health IT adoption toolbox which was developed probably about a year and a half ago. It went public in November 2008.

The toolbox is a compilation of tools and resources basically from A to Z in your implementation. From what is health IT all the way through to sustaining it and evaluating it and pushing the envelope to more advanced HIT topics.

It is in a Q&A format within separate modules and each module and each question has tools and resources that are tried and true. They've been used by health centers who have gone down this path before you. They've been used by networks or that there are readiness assessments that have been done specifically for health centers and safety net providers.

And we strongly encourage you to download and use those tools to be able to assist you in your implementation and your readiness factors of your EHR.

We currently as I said have the health IT adoption toolbox. We also have upcoming toolboxes so for those of you who are in a rural area. We have a rural health toolbox coming out for HIT.

If you're interested in tele-health there's one coming out on tele-health. And there's also one coming out on kids and HIT. What do I need to know specific to children for HIT?

We also have additional modules on network development. So those of you out there that may want to be forming your own network to do this. There will be a module coming out on how do I form a network?

As well as pushing the envelope for personal health records and quality through HIT. Is a separate module that will be coming out to help you use your EHR through quality improvement as well.

The toolbox is in, as I said in specific modules those are listed on the slides that you can download as well. We also have what we call our webinars which we hold monthly on various HIT topics. I'm sure most of you have seen the emails that come out monthly.

Those webinars are recorded and posted to the HRSA Health IT Community. Again you do need a password for that one but it is relatively very easy to get if you do not have one.

Some webinars that we have had in the past are HIT 101, Important Factors to Consider Once When Selecting an EHR System. Financing HIT, Readiness Assessments for HIT, Using EHR to Drive Quality Improvement.

And those that I listed off are ones that we strongly encourage you to listen to and download those slides so you can be ready to implement your EHR. And some of them may help you with your application as well.

Some upcoming webinars we have also are HIT and Sustainability for Rural Settings. Coming up this month Due Diligence so those of you who will be selecting a vendor we will have a webinar in June on due diligence. What is it, why do I need to do it, how important is it?

And in July we will also have Disaster Recovery Plans for HIT which kind of go hand in hand with I'm sure your other disaster recovery plans. So and we actually had a network had to implement their disaster recovery plan for a water main break recently. So it's not just hurricanes and tornadoes and things.

We are also sponsoring several HIT workshops across the country between June and September 2009. There are going to be several on EHR implementation and the workshops are going to provide you hands on assistance.

You will be able to bring your application with you, you readiness assessment things that you've already completed with you. And there will be a team there that will be able to help walk through with you on the steps you need to take in crafting your implementation plans. And again more lessons learned on what's worked and what hasn't worked.

Those announcements will be coming out to all HRSA grantees as they become available. They are completely across country and I believe there are about 12 that we are sponsoring.

So last thing I want to mention is that we are also here to support our HRSA colleagues and our CIP colleagues as well as the grantees. So feel free to contact us at any time. Our general email address is on our last slide there.

So email us, call us, we work with CIP very closely and your project officers very closely so you can feel free to ask them a question. And they will punt it down to us and we will get on the phone with you and your project officer and we'll figure it out. With that I go...

Woman: Thank you. I'll quickly walk us through some of the (unintelligible) aspects of the application but given that this is our third call. Many of you may be able to walk through us, you know, do this presentation so I'll point you really to the highlights in the interest of time.

Again the first slide, Slide 41 just gives you the overall architecture of this application. You know that there's an overall proposal which you can have multiple projects. The projects that we'll focus on today are the certified EHR type of projects.

So there is a proposal cover page the only important note is that the proposal cover page is the overlay. That does not have to be completed first so if you have someone in your organization who is going to be filling out all of that for the overall project. You can go in ahead and go ahead and start your individual project.

Also if you have multiple projects instruction and the like you can have individual people going on and working on each of those. And you can begin working on your certified EHR projects.

The only caveat to that and I'll mention it again at the end when we get to sites. Is that if your, you can't propose a new site with the EHR project. You must work within sites that you've already, either within your scope that are impending a changing scope request. Or that you suppose there is alteration renovation repair project or a construction project.

So if you are going to do, if you're proposing some work through ARR or construction go ahead put those sites in to start those project elements. So that you have the opportunity to select those as a site that you would like to propose EHR components to as well. So that's the only caveat but it shouldn't stop you otherwise.

Moving along to Slide 43 again you will be able to propose multiple projects so you want to go in and select a project. You have the drop down box it will allow you to select EHR projects. You select one and continue to fill out all of the application components related to that.

Moving onto Slide 45 is just the confirmation page that you will get. Let's focus on Slide 46 which is the status page. Again the nice benefit of using EHB to do this application is that it will provide you some prompts to let you know where you are in the status with all of the elements associated with an EHR project.

Once all of those are complete only then can you submit that project. So you can go back to this page to see if you've completed all of the necessary elements.

Moving onto Slide 47 is when you get into the project specific information. So when you begin to propose an EHR specific project you'll have all of the standard sections that apply to all of the projects. So site information who is managing your project, contact information and the like.

The real specific instance here for EHR is the EHR system readiness components. And that's what I'd like to focus on for the next few slides.

Slide 48 shows you the elements that are specific to EHR system readiness. It begins with a certification of yes or no are you purchasing an EHR system and by virtue of doing this project you probably are.

And then you go ahead and certify yes you are immediately ready to move forward. Or yes you will only begin to begin your project or purchase your EHR system once you met all of the readiness checklist requirements.

Speaking of the readiness checklist below you'll see the document that you can download from the hyperlink there. Complete the application complete the readiness checklist and upload it and attach it. And then you have completed that.

The next slide just shows you a picture of the readiness checklist and we've gone through that so we'll not spend any time on that at this point.

The next element that you have to complete for this EHR project is the project impact. And this is where you identify the direct impacts of your projects as Beth alluded to at the beginning.

Now because we have leveraged some of the architecture throughout the system there maybe some things that don't seem very intuitive. So if you look under direct impact you see the total square feet improved or increased. And you may be wondering well by virtue of getting an EHR how do they do that?

It's functionality that's across projects, so for this here as it is it requires a field, just feel free to go ahead and put zero for the improvement in the square footage.

And then you will propose the number of FTEs and the number of patients served. So providers that will be using your system as well as patients that will be served participating in the EHR system.

And then you'll go down and complete the FTE types in the projected FTE table as well.

As part of your EHR project you can elect to get equipment necessary for the EHR project. Slide 51 and 52 focus on this, Slide 51 shows you if you add an equipment item and if you want to make any updates or deletions you can do so there.

Slide 52 shows you the drop down menu of the types of equipment that you can choose. Really given the guidance that we've had earlier in the session today. Again this is a standard pick list from across the applications so it shows clinical, non-clinical and HIT/EHR.

For 90% of the projects and the equipment that you're buying related to this. I think for the most part they all fall under HIT/EHR. So as you're trying to decide which equipment type to select that's probably the one that you're going to want to select as you go through this system.

Moving on the next piece of information you have to complete for this project is the project budget. Again as we described in earlier sessions. The project budget they have the total cost for the project each element of the project as well as the allocated costs.

So if you're leveraging or allowable costs if you're leveraging other funds you fill out the first column and the second column. And then the final column calculates automatically through the virtue of the system and you get a total at the end generated by the system.

Again if you're leveraging the next Slide 54 if you're leveraging other funds to complete your project. You would just note them there.

Moving onto Slide 55 the budget justification. Again like all of the other projects this is a free form where you will upload and attach your budget justification for your EHR project.

Slide 56 and we'll spend a moment talking about the site. As we said before the only time you can propose new sites if for alteration renovation and repair projects. Or for construction projects.

However, the only way to access those new sites in the EHR project is by as you look on the slide you see add a new site. Well you can't add a new site however you have to click to add new site button to access the sites that you added per the construction or ARR project.

That's one opportunity to select those sites. As well as you can pick from sites in your existing scope. And this slide doesn't show the third alternative which we've kind of added recently based upon your feedback; is you

can also add for your EHR project any sites that you have within, you have submitted change in scope requests for. This will allow you to tag those as well.

Again with and the next slide just shows you Slide 57 shows you when you click add a site. In this particular example no one has, they had not started an ARR construction project. But if you had identified a new site they would show up here and you'd select those to move forward.

In terms of selecting again you can select EHR for one site for multiple sites or organizational lines. You'll have to when you get all of your sites in a list there the radio button you'll have to select each site that you would like the EHR to apply to. And click save and continue.

In terms of Slide 59 again leveraging this same architecture across you'll be prompted to add a site and or other requirements.

But again because we don't have the opportunity to add a site here you just ignore that and hit save and continue. And move on for both the add site checklist and the other requirements because there are not other requirements for this list.

You just go down to the bottom and you'll see there's a note that says you're not required to complete this. So you just go down to the bottom and save and continue. One item that you are required is the EID checklist that is important as I mentioned at the beginning of the presentation.

So again you'll want to download that document, complete the document and upload and attach it. And then the only other caveat is there is that opportunity again leveraging the entire system. Is the schematics and that's again you will be prompted that you are not required to complete that.

So you'll hit save and continue and that will take you to the end of the EHR related project. And you'll go ahead and submit that and it will go into your overall query. All of the data and information on the budget and some of the impacts will roll up to the proposal coverage sheet at the beginning.

And again remember it's important that you're authorizing an official is assigned. Because they're the only person that will be able to submit it to HRSA. And again as you're working on this, remember save often as you can. If you're inactive in the system for more than 30 minutes you will get kicked out and may lose your work. And lastly the health and resources slide that you're very familiar with at this point.

Jim Macrae: All right thank you (Suma) I think at this point we'll open it up for questions because we are sure that you have quite a few. So operator please let's get the questions started.

Coordinator: Thank you.

At this time if anybody does have any questions please press star 1 on your touchtone phone. Again for any questions please press star 1 on your touchtone phone.

Please unmute your phone and record your name so that we may announce you clearly. Again that will be star 1 for questions. Your first question will come from (Victoria Derek) your line is open.

(Victoria Derek): Yes hi I'm sorry if this is a repetitive question but the speakers although very good spoke very quickly. We are wanting to purchase a process management system as well as an EHR system. So my understanding is that the practice management system should be purchased through an HIT project?

Jim Macrae: It's actually an IT project it's practice management.

(Victoria Derek): Okay so practice management is an IT not an HIT?

Jim Macrae: That's correct.

(Victoria Derek): Okay and then, you know, one of the things that we would like to do is to be able to perhaps purchase laptops or additional computers in our exam rooms. So does that also go into IT?

Woman: If you are purchasing a certified EHR system you can propose all that as related to that system within yours.

(Victoria Derek): Okay so yes because we would be using the EHR either through a laptop or a computer. And that goes in the EHR.

Woman: If there someone who does already have their certified system placed then they would, additional laptops or something would be purchased as equipment. That would only be as separate.

(Victoria Derek): Okay thank you very much.

Coordinator: Your next question will come from (Andrea Bender) your line is open.

(Andrea Bender): Hello I have a question to confirm that you had said that licenses are allowable are an allowable cost. We currently have EHR and we implemented one department but we had to stop because we couldn't afford to continue with the license fees of all the other, we have 10 other docs to get online.

And we just want to make sure that license fees even though we already have our EHR product and it is certified. If we can put licensing fees as an allowable cost?

Woman: Yes licenses are allowable however you need to make sure that the systems they are being applied to is certified by CCHIT.

(Andrea Bender): Okay now with that, my question about that is. I looked on the website for CCHIT and does it have to be 2008 certified, 2000 because they have a bunch of different years listed.

Woman: Any year.

Woman: Any year is fine.

(Andrea Bender): Any year is fine okay those are my questions thank you.

Jim Macrae: Thank you. And I forgot to mention at the beginning just in the interest of trying to get through as many questions as possible. If you could limit it to one or two that would be great. Because we want to try to reach as many people as we can. So thank you very much.

Coordinator: Okay your next question will come from (Brent Far) your line is open. (Brent) please check your mute key and pick up the headset if using a speaker phone. Okay we'll go onto the next one, your next one will come from (Nicole) from the Clinica Del Corina your line is open.

(Nicole): Hi we have a question about on Slide 13 when you addressed the project budget obligates money beyond 25%. Could you explain that and particularly what scope are you referring to? Hello?

Jim Macrae: Oh I'm sorry go ahead.

Woman: That was just to refer kind of to some, in that slide just some general requirements. So if you budget, you know, and you're planning implementation. And you send in the application and then later on during the project period you might have to shift costs between different cost categories.

That's just the standard requirement for any of the grants through HRSA anyway. So I guess it wasn't quite clear on that slide. It was just an additional requirement we wanted to remind you of after you already have the grant.

(Nicole): So basically so I understand it, if we change how we allocate so instead of going towards the HIT or the EHR if it went towards renovation we would have to come up with a justification for that?

Jim Macrae: Yes if it was 25% or $250,000 whichever is less that's...

(Nicole): Whatever is less okay?

Jim Macrae: And I think though the point behind this was in particular just to reemphasize that, you know, while EHRs are one thing they still follow the overall grant rules in terms of how you do contracts. How you do procurements all those different pieces and also what change in scope. So we apologize if that created confusion we just wanted to...

(Nicole): Okay thanks. My second question is about dental which on one of the earlier slides you said would fall under HIT? Which is the third wave of funding correct?

Jim Macrae: Yes that's correct. Well it's under HIT it's actually...

Woman: It's one of the category types within the Capital Improvement Program.

(Nicole): It is okay.

Woman: It is yes.

Woman: And the call for that one is tomorrow?

Beth Tchinski: Yes we can discuss more about exactly what fits with an equipment or HIT tomorrow.

(Nicole): Okay.

Coordinator: Okay your next question would then come from (Jean Therion) your line is open.

(Jean Therion): Thank you.

I've heard that, my question is very similar to the last question. But I have to admit I'm still confused. We have a practice management system and we're going to be covering the practice management as well as the EHR IT within the two year period.

I'm going to be buying additional computers and achieving readiness over the first six moths and then doing a conversion probably in the second year of the two year period. Do I have three separate projects then?

Because I'm going to be buying computers right now with my existing practice management. And then go eventually going to an EHR which this is another part of my question. We're considering being hosted by a local hospital on their software which is certified?

Woman: As long as you're working towards ultimately implementing the certified EHR system the hardware and any other costs that are going towards that. You can include that in the EHR project type.

(Jean Therion): Okay great so I don't have to separate it out into those other two categories?

Woman: No.

(Jean Therion): Thank you.

Coordinator: Your next question will come from (Craig) your line is open.

(Craig): Hi we've been using EHR for a few years now and we're finding that our hardware is not living up to the needs of the upgraded software system. So we need to do upgrades. Upgrading the server hardware the clients' laptops and their nurses and providers and the wireless network.

What category would that be best under, the EHR or the equipment?

Woman: If you're buying only the equipment then that would be posed as an equipment only IT project. As long as it's also stuff that can be for supporting a certified system that you have.

(Craig): Yes ours is certified.

Woman: Okay then yes. That would be equipment.

(Craig): Thank you.

Coordinator: Okay and as a reminder to ask a question you may press star 1 on your touchtone phone. If your question has already been answered you may press star 2 to withdraw your question. Again that's star 1 to ask a question star 2 to withdraw a question.

You next question will come from (Arty Store) your line is open.

(Arty Store): Thank you. Good afternoon.

There was no discussion about consortium groups. I was curious if there's been any discussion about the ability of consortia or partnership to apply? Thank you.

Jim Macrae: Well actually for this particular announcement the money will go directly to individual health centers. However if you would like to come together in terms of a proposal we would encourage you to do that. But that's not, you know, one of the options that will be available under this.

Under the Health Center Control Network there are opportunities for groups of health centers to come together. But for this particular opportunity that Capital Improvement Program that will just go to individual centers.

Woman: Can I just add one other thing. Individual centers certainly want to apply for funding. And then turn that funding over to their network or as a group. That's an allowable cost too.

Coordinator: Okay your next question will come from a (Jim Davis) your line is open.

(Jim Davis): Hopefully not a duplicate question but if the system that we are desiring to purchase is a combined package for practice management and EHR. Can it just be an EHR application?

Jim Macrae: Yes it can be.

(Jim Davis): Thank you.

Coordinator: Okay your next question will come from a (Jody Abjus) your line is open.

(Jody Abjus): Hi am I on?

(Jim Davis): You are on.

(Jody Abjus): Oh sorry, my question is related to the EHB if we have multiple users entering and adding and uploading. It seems like we have different EHB tracking numbers. So I just want to confirm then when we're all finished if the AO goes in, you know, does let's say final checks and hits submit. It's all going to feed up to that correct tracking number?

Woman: Yes it will as we mentioned in one of the earlier calls. The first person who accesses the application gets the role of creator. But then everyone who is assigned to that as the appropriate role for the organization. They can go in and work on the application and all of the application pieces you will see it will roll up to the proposal level.

But the entire application and proposal cannot be submitted by anyone other than the authorizing official. But yes each of the, you know, applications components that you work for by project will then roll up appropriately to the proposal level.

(Jody Abjus): Okay great.

Jim Macrae: Should only be one number.

Woman: Yes the tracking number is applied to the application or the general proposal not all of the sub-projects. So all of the sub-projects are tied to that one application tracking number.

(Jody Abjus): Okay, okay great thank you.

Woman: Sure.

Coordinator: Okay your next question will come from (Robert Fineberg) your line is open.

(Roberta Fineberg): It's (Roberta Fineberg) thank you.

Coordinator: My apologies.

(Roberta Fineberg): We have two questions on the retained jobs and the created jobs. If we're not creating a job and we're just retaining the people we have. Because we're doing and EHR project how close should we fill that out?

Woman: You can put zero in any of those fields. But I do want to say to you that they can only be jobs that are being directly supportive of the CIP project. So it could be someone, you know, who is kind of implementing the actual EHR.

(Roberta Fineberg): Okay and in our budget we are putting several months of temporary staff as we get through the transition. Those would be temporary new jobs for six months or four months or we haven't figured that out yet. Maybe we putt hose as jobs created?

Jim Macrae: Yes.

Woman: Yes. If they are supported with the CIP.

(Roberta Fineberg): And then my last and we'll move on is the projected number of users with an EHR as a result of this project. Of course we have our user targets for our parent grant. How should we handle that question?

Jim Macrae: That's a great question, you know, there's the specific thing about patients that will now be covered under the EHR and we're asking you to project that. The second part is as a result of this CIP project whether it's an EHR or any other project.

Will you be able to serve any additional new patients if really you will not be able to, you may put zero in there. Because we anticipate that that may happen. But for others, you know, in particular for construction projects, alteration repair renovation.

Because you've been able to build a new facility or been able to create some efficiencies or streamlining if processes, as a result you may be able to see new patients. You should include that. But if your overall number is your overall number just report that as a regular UDS. Only as a result of the CIP any additional patients from that regular number would you include.

(Roberta Fineberg): So that's very helpful in relation to that, since we all know that the actual implementation will result in hopefully a short term decline in revenues as we implement. Are there any guidelines for what percentage of lost revenue related to the cost of the actual product that we should use in our budget?

Woman: No there aren't estimates of productivity loss by product. I mean part of why we gave you the resources that we provided today is that there are resources to help you avoid productivity loss and minimize productivity loss. There are webinars and tools in the HIT adoption tool kit. But we don't have a product by product description partly because that is not product dependent.

(Roberta Fineberg): Are there any general guidelines across products, how much anticipated, how many less users and how much anticipated loss of revenue?

Woman: No I mean someone; two people using the same product could have completely different productivity losses.

(Roberta Fineberg): Okay.

Woman: You know, going back again to readiness. How you prepare for the implementation is going to, you know, it's going to really impact your productivity loss and that's for any products that you use.

(Roberta Fineberg): Okay thank you very much.

Coordinator: Okay your next question will come from a I believe it's (Darren) your line is open.

(Darren): Hello we are fortunate that we have had our city build us a new facility. Which we should be moving into in August. We have an existing facility which we are going to be closing. Changing the scope and opening the new facility.

The new facility is much larger and we were looking at ways of funding, getting in the IT infrastructure that we need there. And the computers and implementing EHR in the new facility.

But I'm trying to make sure that we can do that or with this grant. Because it seems like you got working here that says "grantees may not add a new site that isn't part of something that has to do with the same application."

Woman: You can do that, what you need to do before you start your project on the EHR specific project. Is go in and submit a change in scope and as I mentioned the kind of third option around sites for your EHRs.

Once you've submitted your change in scope and once you've submitted from your side it's been submitted to HRSA. It will be populated into that third option about pending change in scope requests. So you'll be able to pull down that newly proposed site at for your EHR project.

(Darren): Okay so I have to have that done before I can propose the project?

Jim Macrae: Well let me just ask a question. We're doing this on the fly, so I apologize; we're doing it in front of you. But you're not going to move in until August is that correct?

(Darren): That's correct the building will not be open, they're constructing it currently.

Jim Macrae: How far in advanced can people submit changes scope request? Can they?

Woman: They can submit a change in scope if essentially knowing that once the grant award approving it is issued that they will be able to have demonstrate that the site is operational within 120 days.

Jim Macrae: Okay.

Woman: So it's essentially four to five months.

(Darren): Okay.

Woman: Is sort of what I would say is the outside of the limits of change in scope.

Jim Macrae: Okay sounds like that would work.

(Darren): Okay.

Jim Macrae: And do it before you submit your application.

(Darren): And the application we have to do before the 22nd of June.

Jim Macrae: Yes that's correct.

(Darren): Thank you.

Jim Macrae: You're welcome.

Coordinator: Okay your next question will come from (Mike Ladier) your line is open.

(Mike Ladier): Yes hi thanks. This has to do with some questions health centers have asked me who are already in process of selecting or purchasing EHRs. And the situation is around they may have signed a contract at this point.

Maybe they signed the contract before 2.17 but haven't actually paid. So if the expenses are actually paid after 2.17 is that allowable under this guidance with what would be the first question?

Woman: That would be considered an obligation, they're already signed a contract. So might not have changed hands.

(Mike Ladier): So that would mean it would not be covered?

Woman: That would not be covered.

(Mike Ladier): Okay and then are there restrictions about canceling contracts and signing a new one?

Jim Macrae: No.

Woman: That has been brought up before.

Jim Macrae: No you may cancel it, you know, it depends on what the penalties and other things are that people may do. But again, you know, I think it goes back to whether that's what your contractor would like to do.

If there are any penalties and if they sign a new contract, you know, does it meet the requirements in terms of certification and all those different pieces. But that is a possibility that folks have asked us about.

(Mike Ladier): Okay so that would be allowable and they have to look at it and make sure it's, you know, workable from their end. But then it would be an allowable expense if they were to do that?

Jim Macrae: That's correct but I would just caution them that, you know, nothing is guaranteed until they get the grant award. So I just, I don't want to have anybody cancel contracts without, you know, there is some risk associated with this.

(Mike Ladier): I understand okay thank you very much.

Woman: Also keeping in mind that, you know, any contracts that are awarded using these funds have to follow the procurement regulations that's mentioned earlier too.

Jim Macrae: And we do plan to add a Q&A response to reference to this because this has come up a couple of different times. Not just for EHRs but also with equipment and some other purchases that people have asked questions about. So we'll get something out on our website.

And for those of you who have not had the opportunity I encourage you to visit our website. This is my plug, we have slides from the various presentations, audio rebroadcasts of the different calls that we've had.

In addition we have a set of frequently asked questions which I think are close to 100 at this point. And we also have resources that will be available to help people with EHRs construction repair renovation all the different aspects.

So if you haven't had the chance please visit our website, that's my plug for information. We'll take the next question.

Coordinator: Your next question will come from (Meredith Edwards) your line is open.

(Meredith Edwards): Yes sir, I have two questions. And the first question is we're relocating our administrative office to expand our kid net (unintelligible) behavior and dental services. Where administrative services were, where we were using, you know, having for those services. So could you tell me if that would be covered the administrative side?

Woman: Yes you can propose any HR project for your administrative site.

Woman: But you'd need to add the site if it's not on the appointed scope of projects. You need to make sure that the EHB system recognizes that location as an administrative only location.

(Meredith Edwards): Okay and the other question is he addressed this when we were first on the conference but I'm still not clear on it. Is this is the main round for EHR and the next one that's going to come out, did you say it was going to be limited to networks or would, you know, a stand alone facility be able to apply for it?

Jim Macrae: Right now the thinking is that the money will be available to networks and large health centers. Meaning 30 or more sites.

(Meredith Edwards): Okay.

Jim Macrae: And actually (competition) has been held and are closed at this point. So this really is the opportunity for focus to be able to purchase EHRs.

(Meredith Edwards): Okay thank you sir.

Coordinator: Okay your next question will come from (Mary Crooks) your line is open.

(Mary Crooks): Hi this is (Mary Crooks) I have a question; I looked on the website earlier. And I couldn't find the slides for today, are they up currently?

Jim Macrae: We believe so if they are not we will check right after the call. We think they are up.

Woman: They should have been posted right before the call started. So we apologize for not giving you a little more time to download those.

Jim Macrae: We had a little problem getting them up on our website today so we apologize. A technical glitch not HR related but technical. Sorry about that.

Coordinator: Okay your next question comes from (Renee) your line is open.

(Renee): Hi yes currently we have a certified EHR and we want to upgrade to the new CHC version so that way our process management and our EHR are in the same system. The upgrade costs for that include a little bit of hardware but most of it is for training. Where would this fall as a project? Would it be under the EHR project or would it be under IT? The HIT?

Woman: That would fall within the EHR, you know, if you're upgrading your system and the software and the training that's associated with it.

(Renee): Okay and then we are also looking at; we're upgrading our x-ray system with an interface to go into our EHR. Would that also be under the EHR project? And that would include some equipment as well.

Woman: I think we were, I think it's on page, in the appendix, appendix I where it lists the examples of different costs and we have set enhancements necessary to interface between systems and EHR. It's categorized in HIT.

(Renee): That category is in HIT. Okay so the interface will be in HIT?

Jim Macrae: That may be something that if you could send in an email to our BPHCrecovery@HRSA.gov as a specific question we can get back to you. You know, on these real specific ones we know that sometimes it's a little complicated so just to understand it a little bit better. If you want to send that question in we'll get back to you on that one.

(Renee): Okay thank you very much.

Woman: Could you please specify if this is all part of this same project if the interface is part of the upgrade to the new EHR?

(Renee): No it's separate.

Jim Macrae: Okay that's great well we'll get back to you on that if you could shoot us an email.

(Renee): Okay thank you.

Jim Macrae: Sure thank you.

Coordinator: Once again to ask a question that will be star 1 on the touchtone phone and star 2 to withdraw your question.

Your next question will come from a (Susan Amberson) your line is open.

(Susan Amberson): Hi I just had a question that related to I believe earlier in the call. You had said that it was an allowable situation for individual health centers who are members of a health center controlled network. To utilize some of the money through the CHR HIT funding to turn that over to the network. Or to support some of those network costs is that correct?

Woman: Yes.

(Susan Amberson): Okay and then my question my more specific question about that is. So within, if an individual health center were going to do that but they had other capital projects that they were going to do.

They would just use that as an individual project. And that all of the allowable costs that you were talking about in your Form 424C line items would be applicable?

Jim Macrae: Maybe say just a little bit more about that, just so we can answer your question. Or this maybe one where we need to follow up with you on it.

(Susan Amberson): Okay I'm just looking at what items specifically they're thinking about equipment and hardware costs. So this might be more appropriate for tomorrow but if there were other costs that they would be doing.

Basically there's no difference I guess is my question between if they are using the funding for these costs. Are there individual health center or if because they're part of a network they're using those for network based cost?

Woman: If it's part of an EHR project you just have to determine where you're going to allocate those funds. If it goes to the network to pay for, you know, servers or additional costs. And you had indicated it probably would all be under EHR.

(Susan Amberson): Okay great. All right thank you.

Woman: And that would probably be a sub-contract with them, versus buying equipment directly.

Woman: And the other thing too a caveat too is if it's a funded network. The funds for the CIT can't duplicate the funds that they already have for the EHR project from HRSA. So you're requesting to be complimentary as to what's already within the scope of that network.

(Susan Amberson): Okay all right that makes sense.

Woman: Your network they'll know.

Woman: And I just want to say one thing in terms of the reporting for the Recovery Act the prime grantees so the health center would need to make sure they still do a report on the funds that go to the networks.

(Susan Amberson): Okay all right. Great well that makes sense thank you.

Coordinator: Okay your next question will come from (Brian Keaton) your line is open.

(Brian Keaton): Yes I've got a question if you choose to go the route of an ASP with a hosted model. Where you then have the software licensing infrastructure, data center, backup disaster services those type of things wrapped into a pre-user per month charge. Is there a way to capitalize portions of that ASP charge as opposed to having it all in operating expense?

Jim Macrae: I think we may have to explore that one a little bit more in terms of what's the possibility. My initial reaction is probably not, but we'll need to just explore that a little bit more. And I think that would be one of those questions if you could sent it into us.

(Brian Keaton): It would seem that doing that would defeat the intent to be able to have people cooperate and work with networks or work with vendor provided solutions. As opposed to hosting the systems themselves.

Jim Macrae: Well and maybe we don't maybe I'm just not, I'll say it for myself understanding more clearly exactly what it is that you're proposing?

Woman: It sounds like what you're asking is some allocation of expenses, you know, yes the ASP model with a network is a very good approach. But I think you're asking like how you put things on the 424 so if you just email that in we can...

Jim Macrae: Maybe we could do it under the EHR umbrella or?

Woman: Yes we probably need to know what your question is.

Jim Macrae: Okay.

Woman: Okay because not all of the networks, you know, do the ASP model and I think you need to think about all of the associated costs. Because I think you're thinking more about the ongoing costs that would be associated with an ASP model.

But, you know, I think you should send it in but it maybe that some of the costs that, I don't know where you are in terms of your implementation.

But even when you go with ASP model there are still other costs besides, you know, the daily connection with the ASP. You would still have to think about, you know, hardware and licenses.

Because even with the ASP model they're providing really the support so if you could break out the costs that you want for support, versus the costs that you'll think you'll have to do, you know, initially and then ongoing.

(Brian Keaton): Thanks.

Jim Macrae: Thank you.

Coordinator: Your next question will come from (Carol Mars) your line is open. Okay she's dropped out of the queue. Your next question will then come from (Melissa Glass) your line is open.

(Melissa Glass): Hi I have two questions. And while I do I want to let you know that your slides were available online. And my first question is the 2% of the 2% that is to be used for collaboration purposes. Do they have to be with other HRSA funded health centers?

Jim Macrae: Actually I'm sorry it's 2% for technical assistance is available.

(Melissa Glass): Okay technical assistance.

Jim Macrae: Yes and that's just basically a strong strong strong encouragement for health centers if they're thinking about an EHR to include the aspects of technical assistance to help support the implementation.

(Melissa Glass): Okay I think I read that incorrectly then. And then second this is actually similar to the question before. But if we're looking at having off site data storage as part of the disaster recovery program. Is it possible to have those support service fees included in the two year period of the grant that it covers?

Woman: If you're talking in terms of, you know, when you I mean in terms of just the time period of using the funds. They should be obligated within the two years of the project period.

(Melissa Glass): So it's okay to include support services in part of the application?

Woman: Yes and I think our colleagues from (unintelligible) were saying that that's covered in IT related project costs. So not in the HR so you would want to fill it under your IT project.

(Melissa Glass): Okay thank you.

Jim Macrae: Again realize that it's only two years so...

Woman: Right you would be committed to continue in that but during that period of time.

(Melissa Glass): Okay.

Jim Macrae: Right.

(Melissa Glass): Thank you.

Coordinator: And your next question will come from (Darcy Dunyonciver) your line is open.

(Darcy Dunyonciver): Yes hi there. I have a question about allowable staff costs. I know on page 7 of the guidance it says very clearly that these grant sums cannot be used to support direct service providers. We have providers that are on our EHR project kind of management team, where they're using some of their

((AUDIO BREAK))

Time that providers would spend being trained and so we're wondering if that those would be allowable provider costs?

Jim Macrae: So in terms of the first aspect anything administrative yes you can include that and we would encourage you actually to include that as part of what you're submitting as part of your application.

In terms of the training aspect to be honest we hadn't actually thought of that one. So that's a good question and we'll have to get back to you on that in terms of what the answer is.

(Darcy Dunyonciver): Okay that sounds great thank you.

Jim Macrae: Sure I think we have time for two more questions.

Coordinator: Okay your next question would then come from (Christopher Peters) your line is open.

(Christopher Peters): This is involved to a prior question. We're rolling out EHR clinic by clinic, we've got nine clinics. We've got several coming up in June are the cost of those roll outs allowable under this?

Woman: The first question is how are you doing the roll out. I mean are you, you know, a unique individual entity or are you part of a network or I mean with this planning that you're doing under what project scope was it previously included? Or was this just something you were self funding in terms of implementation?

(Christopher Peters): Yes we were self funding, we are part of a network. In terms of where our product is coming from, but we're still funding through our, I mean all of those clinics are within our same corporation.

Woman: Do you have an agreement with the network, are you a network member?

(Christopher Peters): Yes.

Woman: Roll out with the clinics?

(Christopher Peters): Yes.

Woman: So these are included under a previous scope for a network grant?

(Christopher Peters): No.

Woman: More than likely those costs you would just coordinate with your network most likely. If those are like increased staff costs or increased licenses.

(Christopher Peters): This is licensing fees to the network yes.

Woman: I would want to look more closely at this, this particular case, because one of the things we want to be careful is that we do provide other grants. Does your network have a HRSA grant?

(Christopher Peters): No.

Woman: Your network has no HRSA funds?

(Christopher Peters): Oh the network does but we don't have any OHIT money in the corporation in within the CHC.

Woman: But your network was the recipient of the grant?

(Christopher Peters): Yes.

Woman: My question is was the implementation to these new sites part of that scope?

(Christopher Peters): No.

Woman: I think it would be more helpful if you could also email that question in and we can kind of research it a little bit more and then get back to you with a concrete answer.

(Christopher Peters): Okay thank you.

Woman: To say that as we review the applications we are going to be looking to make sure that there is no overlap between the network scope and, you know, these implementations. So if a network receives funds to do an implementation and your health center was one of those implementations. We would not then fund you to do the same implementation.

(Christopher Peters): Right that I understand.

Jim Macrae: Okay.

Woman: I just want to emphasize too that I think you mentioned that you wanted to start doing this in June?

(Christopher Peters): Well that's our next scheduled roll out.

Woman: Okay and just to be aware of the whole being a pre-award cost and that, you know, you would need to make sure it meets the readiness standards and all that. That when you are proposing that.

(Christopher Peters): Okay but costs between February and July will be allowable under certain circumstances?

Woman: Yes depending, you know, your final notice of grant award. And there are, you know, certain things we need to look at before we can say if it's okay.

(Christopher Peters): Understood thank you.

Jim Macrae: Right I think we have time for one last question.

Coordinator: Okay then your last question will come from a (Mandy Reed) your line is open.

(Mandy Reed): My question has actually been asked before but I really need some clarification on this.

Jim Macrae: Sure.

(Mandy Reed): We are we have already started implementation of an integrated practice management EHR system. We have signed a contract we have incurred some costs. We do have remaining costs left can we apply for funding under this?

Jim Macrae: Unfortunately the answer to that is no because you've already signed the contract. And as a concept of an obligation to pay those costs however, if, you know, there is a way to sever that contract or cancel that contract and you then enter into a new contract there maybe the opportunity.

But again as the folks before had said there are risks associated with it and it needs to meet the certification standards, needs to meet the basic requirements of statute. But the unfortunate answer is no if you've already signed the contract and have begun obligating we cannot pay for costs before February 17th.

(Mandy Reed): Okay all right that's what I thought I understood I just wanted to make sure thank you.

Jim Macrae: Sure sure. Well at this point I just really want to thank everybody for participating in this call especially our colleagues here at HRSA for helping answer many questions.

We know you will likely have other questions so please please send those in, we will get back to you in addition we will be posting additional frequently asked questions as well as the slide information so you can take a look at that.

In addition we have resources available both on the programmatic side as well as on the grant side, as well as on the systems side. So people can utilize that. We want to do everything in our power to make this the best opportunity that you can take advantage of and provide you the support.

And if there are things that you need, you know, please send in your question or comment into BPHCRecovery@HRSA.gov. Is that right?

I hope so; I should know it by heart by now.

Research on the Comparative Effectiveness of Medical Treatments

DECEMBER 2007

A CBO PAPER

CONGRESS OF THE UNITED STATES
CONGRESSIONAL BUDGET OFFICE

A

CBO

PAPER

Research on the Comparative Effectiveness of Medical Treatments: Issues and Options for an Expanded Federal Role

December 2007

The Congress of the United States ■ Congressional Budget Office

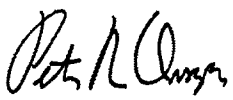
Preface

Rising costs for health care represent a central challenge both for the federal government and the private sector, but opportunities may exist to constrain costs in both sectors without adverse health consequences. Perhaps the most compelling evidence of those opportunities involves the significant geographic differences in spending on health care within the United States, which do not, on average, translate into higher life expectancy or substantial improvements in other health statistics in the higher-spending regions. At the same time, only a limited amount of evidence is available about which treatments work best for which patients and whether the added benefits of more-effective but more-expensive services are sufficient to warrant their added costs. Together, those findings suggest that generating better information about the costs and benefits of different treatment options—through research on the comparative effectiveness of those options—could help reduce health care spending without adversely affecting health overall.

This Congressional Budget Office (CBO) paper—prepared at the request of the Chairmen of the Senate Budget and Finance Committees—examines options for expanding federal support for research on comparative effectiveness. It reviews the current state of such research in both the public and private sectors and discusses several mechanisms for organizing and funding additional research efforts. It also discusses the different types of research that could be pursued and their likely benefits and costs. Finally, it considers the potential effects that such research could have on health care spending and the difficult steps that public and private insurers would probably have to take to achieve substantial savings on the basis of that research—in particular, changing the financial incentives for doctors and patients to reflect that information. In accordance with CBO's mandate to provide objective, impartial analysis, this paper contains no recommendations.

Philip Ellis of CBO's Health and Human Resources Division prepared the paper, with valuable contributions from Colin Baker and Morgan Hanger. The analysis benefited from comments by Dr. Alan Garber, Henry J. Kaiser Professor of Medicine at Stanford University, and Dr. Sean Tunis of the Center for Medical Technology Policy. (The assistance of external reviewers implies no responsibility for the final product, which rests solely with CBO.)

John Skeen edited the paper, and Maureen Costantino prepared it for publication and designed the cover. Lenny Skutnik printed the initial copies, Linda Schimmel handled the print distribution, and Simone Thomas prepared the electronic version for CBO's Web site (www.cbo.gov).



Peter R. Orszag
Director

December 2007

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Research on the Comparative Effectiveness of Medical Treatments

Summary and Introduction

Over the past 30 years, federal spending on Medicare and Medicaid has roughly tripled as a share of gross domestic product (GDP), rising from about 1.3 percent in 1975 to about 4 percent in 2007. According to the Congressional Budget Office's (CBO's) projections, under current policies such spending will reach about 12 percent of GDP by 2050—but substantial uncertainty surrounds that estimate.[1] If costs per enrollee continued growing over the next four decades as quickly as they have grown over the past four—about 2.5 percentage points faster than per capita GDP—then federal spending on those programs would reach about 17 percent of the economy. If, instead, costs per enrollee did not exceed the growth of GDP, those federal costs would reach about 6 percent of GDP in 2050 solely because of demographic changes (see Figure 1). As those figures indicate, the rate at which health care costs grow relative to income is the most important determinant of the country's long-term fiscal balance; it exerts a significantly larger influence on the budget over the long term than other commonly cited factors, such as the aging of the population or the coming retirement of the baby-boom generation.[2]

Rising health care costs represent a challenge not only for the federal government but also for private payers. Indeed, trends in both sectors reflect many of the same underlying forces—including the development and spread of new and more-expensive medical technologies—so controlling those federal costs over the long term will be difficult without addressing the forces that are also causing private costs for health care to rise. Total health care spending, which consumed about 8 percent of the U.S. economy in 1975, currently accounts for about 16 percent of GDP, and that share is projected to reach nearly 20 percent by 2016. About half of overall health spending in the United States is now publicly financed, and half is privately financed.

A variety of evidence suggests that opportunities exist to constrain health care costs both in the public programs and in the rest of the health system without adverse health consequences. Perhaps the most compelling evidence of those opportunities involves the substantial geographic differences in spending on health care—both among countries and within the United States—which do not translate into higher life expectancy or measured improvements in other health statistics in the higher-spending regions. For example, Medicare's costs per beneficiary vary significantly among different regions of the country, but much of the variation cannot be explained by differences in the population, and the higher-spending regions perform no better on available measures of average health outcomes than the lower-spending regions do.

Furthermore, hard evidence is often unavailable about which treatments work best for which patients and whether the added benefits of more-effective but more-expensive services are sufficient to warrant their added costs—yet the current health system tends to adopt more-expensive treatments even in the absence of rigorous assessments of their impact. Indeed, the extent of the variation in treatments may be greatest when evidence about their relative effectiveness is lacking. Together, those findings suggest that better information about the costs, risks, and benefits of different treatment options,

1. Congressional Budget Office, *The Long-Term Outlook for Health Care Spending* (November 2007). The estimates of federal spending reflect Medicare's costs net of the premiums that enrollees pay and other offsetting receipts; the program's gross costs are about 15 percent higher than its net costs.

2. For additional discussion, see Congressional Budget Office, *The Long-Term Budget Outlook* (December 2007).

less definitive results—and therefore might have a smaller impact on medical practice. Clinical trials could be more persuasive but also more time-consuming, and there is probably a limit to how many comparative trials could be undertaken effectively at any given time. If privacy concerns could be addressed, having more health records available in electronic form would facilitate the use of such data for research.

- Studies might need to compare not only broadly different treatment options—such as surgery versus drug therapy—but also different approaches to the same basic treatment—such as different levels of follow-up care after surgery. Studies that included an analysis of cost-effectiveness would probably have a larger impact than ones that compared only clinical effectiveness, because they would highlight cases where more-expensive treatments or approaches provided added benefits that were modest compared with their added costs (at least for some types of patients).

- To affect medical treatment and reduce health care spending in a meaningful way, the results of comparative effectiveness analyses would not only have to be persuasive but also would have to be used in ways that changed the behavior of doctors, other health professionals, and patients. For example, the higher-value care identified by comparative effectiveness research could be promoted in the health system through financial incentives—the payments doctors receive or the cost sharing that patients face. Making substantial changes in payment policies or coverage rules under the Medicare program to reflect information on comparative effectiveness would almost certainly require legislation.

- Making such substantial changes in the delivery of health care could prove difficult and controversial for a number of reasons. To inform new systems of incentives—designed to discourage the use of more costly treatments that provided little or no added benefits—the results of effectiveness studies would have to be sufficiently robust to minimize the risk of overlooking subgroups of patients who could benefit greatly from a treatment. Even with an expanded evidence base, some patients and providers might object to the use of such incentives, and keeping pace with new treatments and procedures would be an ongoing challenge.

- Generating additional information about comparative effectiveness and making corresponding changes in incentives would seem likely to reduce health care spending over time—potentially to a significant degree. The precise impact, however, depends on several factors and is difficult to predict. Given the time necessary to conduct the research, to alter incentives in a manner reflecting the results, and to affect behavior through those changes, any potential for substantial cost savings from new research would probably take a decade or more to materialize. Even so, generating additional information comparing treatments would tend to reduce federal health spending somewhat in the near term—but that effect may not be large enough to offset the full costs of conducting the research over that same time period.

The Current State of Comparative Effectiveness Research

In weighing options to expand and reorganize research efforts, it is useful to define what comparative effectiveness research means and to consider the arguments for an expanded federal role in conducting such research. Related issues include the reasons why the current stock of research on comparative effectiveness is limited and why treatments and procedures can gain wide use even when evidence about their relative effectiveness is lacking. Reviewing past and current research efforts—by private and public organizations in the United States and by other countries—also sheds light on several issues and challenges likely to arise in any future U.S. efforts. To the extent that past and current efforts are seen as inadequate, careful consideration of those shortcomings would inform the choice of an organizational approach and funding mechanism for new federal activities.

What Is Comparative Effectiveness?

As applied in the health care sector, an analysis of comparative effectiveness is simply a rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients. Such a study may compare similar treatments, such as competing drugs, or it may analyze very different approaches, such as surgery and drug therapy. The analysis may focus only on the relative medical benefits and risks of each option, or it may also weigh both the costs and the benefits of those options. In some cases, a given treatment may prove to be more effective clinically or more cost-effective for a broad range of patients, but fre-

- One recent trial found that older, relatively inexpensive drugs for treating high blood pressure (known as diuretics) were more effective in preventing cardiovascular disease in patients age 55 or older than commonly used newer drugs known as angiotensin-converting enzyme inhibitors and calcium channel blockers.[7]

- Another trial compared the effects of surgery to reduce lung volume for patients suffering from emphysema—a treatment that had anecdotal support but lacked hard evidence about its effectiveness—with standard medical therapy for that disease. For many patients, lung surgery increased their risk of death slightly and did not improve their functional status, but for patients with certain types of lung problems and a limited capacity for exercise, the surgery yielded small net improvements in their quality of life (though not in their survival rates).[8]

- A trial of two statin drugs, which was sponsored by the maker of one of those drugs, found that its competitor's product was more effective both at lowering cholesterol levels and at reducing the risk of mortality—illustrating the point that comparative trials can be risky for manufacturers to conduct.[9]

- Recent studies have found that magnetic resonance imaging combined with mammography is more effective than mammography alone in detecting breast cancer for women with certain genetic markers that indicate a substantial increased risk of contracting that disease; the impact of that difference on survival rates, however, could not be measured.[10]

The range of findings that those studies yielded highlights several characteristics of research on comparative effectiveness. First, studies can examine not only treatments for health problems but also different procedures to screen for the presence of a disease. Second, the findings may have broad applicability or may pertain only to a very specific subset of patients and may also vary in the outcomes considered—such as effects on mortality or other measures of health gains.

Third, studies are often based on clinical trials, in which eligible patients are randomly assigned to the treatments under review—but there are several other methods available to compare treatments, each with its own strengths and weaknesses. Clinical trials can yield persuasive findings but can also be relatively costly and time-consuming to conduct. In particular, a trial designed to determine whether two treatments differ in their effectiveness may require a large number of enrollees to be followed for an extended period in order to generate results that are statistically significant. Less expensive approaches include systematic reviews of the evidence about treatment options, which are essentially meta-analyses of all available studies, and studies that use medical claims data, which can be used to follow large groups of patients who have already received different treatments. The impact of systematic reviews can be limited, however, by the fact that they simply reflect existing evidence, and studies using claims data can be subject to bias because the treatments are not randomly assigned to comparable patients.

The studies cited above focus on relative clinical effects, and not cost-effectiveness. For reasons discussed below, gauging cost-effectiveness as well as clinical effectiveness is sometimes controversial, and some observers believe that the two considerations are in separate fields. But cost-effectiveness analysis appears to be well within the scope of research on comparative effectiveness—and

7. Officers and Coordinators for the ALLHAT (Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial) Collaborative Research Group, "Major Outcomes in High-Risk Hypertensive Patients Randomized to Angiotensin-Converting Enzyme Inhibitor or Calcium Channel Blocker vs. Diuretic," *Journal of the American Medical Association*, vol. 288, no. 23 (December 18, 2002), pp. 2981–2997.

8. National Emphysema Treatment Trial Research Group, "A Randomized Trial Comparing Lung-Volume-Reduction Surgery with Medical Therapy for Severe Emphysema," *The New England Journal of Medicine*, vol. 348, no. 21 (May 22, 2003), pp. 2059–2073.

9. Christopher P. Cannon and others, "Intensive Versus Moderate Lipid Lowering with Statins After Acute Coronary Syndromes," *The New England Journal of Medicine*. vol. 350, no. 15 (April 8, 2004), pp. 1495–1504. Note that this study was undertaken in response to a similar one financed by the manufacturer of the other drug, which also showed that drug to be superior at lowering cholesterol levels but did not address mortality risks.

10. Ellen Warner and others, "Surveillance of BRCA1 and BRCA2 Mutation Carriers with Magnetic Resonance Imaging, Ultrasound, Mammography, and Clinical Breast Examination." *Journal of the American Medical Association*, vol. 292, no. 11 (September 15, 2004), pp. 1317–1325; and Mieke Kriege and others, "Efficacy of MRI and Mammography for Breast-Cancer Screening in Women with a Familial History or Genetic Predisposition," *The New England Journal of Medicine*, vol. 351, no. 5 (July 29, 2004), pp. 427–437.

Box 1.

Continued

in 2004 that evaluates health care services. Discussions about the use of comparative effectiveness in those countries sometimes focuses on their review processes for prescription drugs, but their efforts generally encompass all forms of acute medical care. (For all the attention they receive, drug costs represent less than 15 percent of health care spending in the United States—so research that focused only on medications would miss the vast majority of services and would not be able to compare drug therapy with surgical procedures or other interventions.)

Although those countries all have government-run health care systems, they have taken different approaches regarding the placement of and funding for their assessment bodies. In the United Kingdom and Australia, the agencies are part of the government's health departments; France and Canada have established independent not-for-profit organizations; and Germany has taken a mixed approach (the Institute for Quality and Efficiency is independent, but the technology assessment agency is an arm of the health ministry). Financing arrangements vary correspondingly: Funding in the United Kingdom and Australia comes from their health departments, whereas Germany's independent institute is funded by a levy on inpatient and outpatient health care services (which are mainly reimbursed by the country's regional health insurance funds), and the French agency gets its funding from a combination of taxes on promotional spending by drug companies, government subsidies, and accreditation fees. Health ministries in Australia, Canada, France, and Germany also help fund clinical trials and other forms of primary research, but total spending related to comparative effectiveness in those countries is also difficult to estimate.

Given the interest that has developed in many countries, it is not surprising that several international organizations have become involved in comparative effectiveness research. The best known may be the Cochrane Collaboration—a nonprofit organization that has a network of volunteers who conduct systematic reviews of treatments. Many of its activities are organized through centers located around the world, including one in the United States. Founded in 1993, the Cochrane Collaboration maintains an accessible database that now contains more than 4,500 reviews; its limited funding comes primarily from subscription fees for its quarterly journal. Any new or expanded U.S. entity that would organize and fund research on comparative effectiveness would probably draw upon Cochrane's findings and the results of research conducted in other countries (to the extent such research was applicable to U.S. patients).

More generally, the relative cost-effectiveness of treatment options is clear when a less expensive treatment yields comparable or superior health gains. In other cases, however, determining whether the additional medical benefits of a more expensive treatment warrant their added costs is complex. Typically, the benefits of different treatments are summarized as an increase in life expectancy or, more commonly, as an increase in quality-adjusted life years (QALYs) to account for effects on morbidity as well as mortality. That calculation reflects estimates of how much people value improving their health or avoiding various side effects, which are combined to create a single metric. By convention, cost-effectiveness analyses report results as the cost per QALY gained, so a lower dollar amount indicates a more cost-effective service. If that metric is used to determine whether specific health procedures are covered by an insurance program, choosing a cost-effectiveness threshold can be a controversial endeavor—but that need not be the manner in which such research is applied.

Research in the Private Sector

In the United States, most of the formal research that is done to examine the effects of drugs or medical devices is

insurance programs—which collectively account for about 40 percent of all health care spending—have not sought to make extensive use of it. In particular, the Medicare program has made only limited use of comparative effectiveness data in making decisions about which treatments to cover and how much to pay for them. It stands to reason that the limited demand for such research from such a prominent payer has constrained the supply correspondingly. Conversely, increasing the amount of credible and objective research that was available could facilitate moving Medicare toward what former program administrator Mark McClellan has called a "fee-for-value" system rather than a fee-for-service one. (Options to incorporate research findings into Medicare's coverage and payment policies, along with the issues they raise, are discussed in the final section.)

Past and Current Federal Efforts

In the United States, the federal government has a rather long but somewhat checkered history of involvement in comparative effectiveness research and related efforts. Federal efforts date at least to the late 1970s and the short-lived National Center for Health Care Technology. Established in 1978 as part of the Department of Health, Education, and Welfare, it was given a broad mandate to conduct and promote research on health care technology, and it included an advisory board appointed by the Secretary to assist in setting research priorities. The center sponsored or cosponsored major evaluations of coronary artery bypass graft surgery, dental radiology, and cesarean delivery and made about 75 recommendations to the Medicare program about coverage. The center ceased operations at the end of 1981, however, reflecting changes in priorities for the new Administration and the Congress as well as opposition from some provider and industry groups.[16]

In that same period, the Office of Technology Assessment (OTA) was created as an advisory agency to the Congress, covering a broad set of issues, including health care. Given the agency's focus on evaluating technologies, much of its work would now be called research on comparative effectiveness; over the years, it studied a variety of health care topics, including the costs and benefits of screening tests for several diseases. OTA also produced an extensive review and analysis of the issues involved in and options for improving evidence about the clinical effectiveness and cost-effectiveness of medical treatments.[17] For a variety of reasons, however—having little to do with its health care studies specifically but instead reflecting broader questions about the agency's role—OTA was eliminated in 1995.

More recently, the Agency for Health Care Research and Quality (AHRQ) has been the most prominent federal agency supporting various types of research on the comparative effectiveness of medical treatments. Established in 1989 as the Agency for Health Care Policy and Research, AHRQ is an arm of the Department of Health and Human Services (HHS).[18] It currently has a staff of about 300 and an annual budget of over $300 million, which primarily funds research grants to and contracts with universities and other research organizations covering a wide range of topics in health services.

AHRQ has undertaken a number of initiatives related to comparative effectiveness. One such step—initially taken in collaboration with the American Medical Association and America's Health Insurance Plans, a coalition of insurance companies—has been the creation of a national clearinghouse for treatment guidelines, which are designed to summarize the available medical evidence on the appropriate treatments for various conditions. AHRQ has also endorsed about a dozen evidence-based practice centers around the country. Generally affiliated with a university, those centers analyze and synthesize existing evidence about treatments and technologies. Although many studies sponsored by AHRQ have examined only the relative clinical benefits of different treatments, some have also analyzed their cost-effectiveness. Research on comparative effectiveness has accounted for only a modest portion of AHRQ's budget, though.

As with other agencies examining the effectiveness of medical treatments or evaluating medical technologies, support for AHRQ has varied over time. In the mid-1990s, controversies arose after an agency-sponsored research team concluded that there was insufficient

16. See Seymour Perry, "The Brief Life of the National Center for Health Care Technology," *The New England Journal of Medicine*, vol. 307, no. 17 (October 21, 1982), pp. 1095–1100.

17. See Office of Technology Assessment, *Identifying Health Technologies that Work: Searching for Evidence*, OTA-H-608 (September 1994).

18. Prior to AHRQ's establishment as a separate agency, some of its functions were carried out by the National Center for Health Services Research within HHS.

stents to drug therapy mentioned above. Indeed, over the past 30 years, some of the most influential clinical trials have been supported by and conducted in the VA health system, including the first major trials that demonstrated the value of bypass surgery over medical therapy for some forms of coronary artery disease as well as head-to-head studies of drugs that treat prostate enlargement. Another source is the National Institutes of Health (NIH), part of HHS, which is the leading federal sponsor of medical research—primarily in the form of clinical trials. Although comparative effectiveness is not a focus of that research, over the years NIH has sponsored a number of trials that compare treatments directly.

The Centers for Medicare and Medicaid Services (CMS) has helped to sponsor a limited amount of research on comparative effectiveness (for example, it covered the medical costs of the study of lung-volume-reduction surgery). When making decisions about what services are covered, however, CMS generally considers only whether devices and procedures are clinically effective. It has sponsored some studies comparing the effectiveness of different treatments but has done so largely to determine whether to establish separate payment rates for similar treatments. For example, CMS is currently cosponsoring a trial with NIH that may eventually compare the effects of daily dialysis for kidney patients with the conventional treatment of dialysis three times per week.[20] If daily dialysis proves more effective for certain patients, CMS could modify its payment policy to cover the additional costs of more frequent treatment for those patients.

Estimating the total amount that is spent in the United States each year on research that compares the effectiveness of medical treatments is difficult. According to one recent analysis, the federal government spent about $1.5 billion in 2005 on all health services research, a broader category that includes some of the work on comparative effectiveness but also encompasses many other types of studies.[21] For example, that total included AHRQ's entire budget of roughly $300 million, whereas the funding devoted to the agency's effective health care program has been $15 million per year. At the same time, that aggregate figure may not include all federal funding for comparative trials or other efforts that are outside the traditional scope of health services research.

Estimating private expenditures is even more challenging. Although drug and device manufacturers spend billions of dollars each year on clinical trials aimed at demonstrating the safety and efficacy of new products, the vast majority of those efforts contribute to comparisons of treatments only indirectly. Data are simply not available on how much is spent by private organizations such a health plans, medical specialty societies, and technology assessment centers to compare medical treatments and procedures. Nevertheless, one recent study estimated that less that $2 billion is spent annually on comparative effectiveness research in this country—and even that rough estimate is subject to uncertainty.[22]

The Consequences of Limited Information

Whether the cause is limited supply or limited demand, the relative scarcity of rigorous data about comparative effectiveness has several effects. First and foremost, it means that decisions about what treatments to use often depend on anecdotal evidence, conjecture, and the experience and judgment of the individual physicians involved. In many cases, that basis may be sufficient; as some observers have noted, it is not necessary to conduct a randomized trial to determine whether to use a parachute when jumping out of an airplane. But if the benefits of a treatment—or risks of not providing it—are less obvious, the lack of hard data makes determining the appropriate choice of treatment difficult. Although estimates vary, some experts believe that less than half of all medical care is based on or supported by adequate evidence about its effectiveness.[23]

Evidence about treatments' effectiveness remains limited even though the number of rigorous studies has grown substantially in recent decades. To illustrate that point, one study simply examined the number of articles that were published each year in peer-reviewed medical journals that reported results from randomized trials.[24]

20. Initially, the study sought to test the feasibility of randomly assigning conventional or daily dialysis to a representative sample of patients.

21. AcademyHealth, *Placement, Coordination, and Funding of Health Services Research within the Federal Government* (September 2005), available at www.academyhealth.org/publications/placementreport.pdf.

22. See Institute of Medicine, *Learning What Works Best: The Nation's Need for Evidence on Comparative Effectiveness in Health Care* (September 2007), p. 8, available at www.iom.edu/ebm-effectiveness.

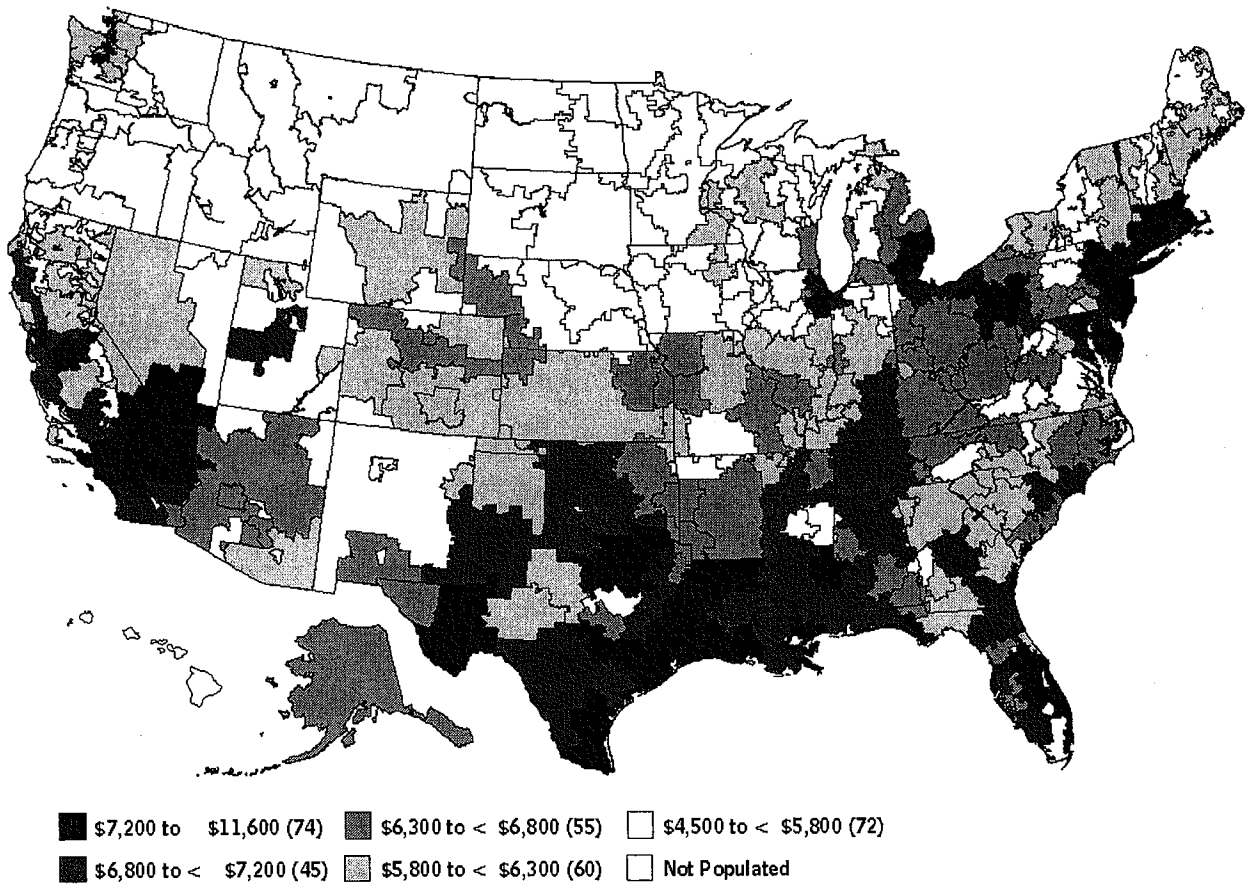
23. Institute of Medicine, *Learning What Works Best*, p. 2.

24. Mark R. Chassin, "Is Health Care Ready for Six Sigma Quality?"

Figure 2.

Medicare Spending per Capita in the United States, by Hospital Referral Region, 2003

(Percent)



Source: *The Dartmouth Atlas of Health Care.*

Note: Numbers in parentheses refer to the number of hospital referral regions with per capita spending in each interval.

(see Figure 3). And there appears to be even more variation in the rates of back surgery—a treatment whose benefits have been the subject of substantial questions. Determining what share of any geographic variation in the use of procedures is due to differences in the treatments that doctors recommend and what share is due to differences in underlying illness rates is challenging, however, so the comparison of procedures may be sensitive to the manner in which the differences in illness rates are estimated.[29]

The implications of the observed variations in treatments and spending depend importantly on their relationship to health outcomes. If life expectancy and other measures were better in the areas with higher spending, that result would imply that increased spending in the low-cost areas would yield health benefits. One recent and well-

29. The data used in Figure 3 were adjusted to account for differences in illness rates among areas using data on five conditions, one of which was hip fracture. In the unadjusted data, the variation in knee and hip replacements is somewhat larger than the variation in hip fracture surgery—and variation in back surgery rates is larger still—but the differences are not as substantial. Whether the adjusted results were affected by including hip fracture rates both as an adjustment factor and in the comparison of procedures is not clear. Whether the prevalence of other diseases is correlated with the prevalence of those five conditions is also uncertain.

designed study examined differences in hospital spending in Florida and found that areas with higher spending had lower mortality rates among Medicare patients who were treated in the emergency room for a heart attack.[30] Using data on Medicare enrollees nationwide, however, another study found that higher-spending regions did not, on average, have lower mortality rates than the lower-spending regions, even after adjustments to control for differing illness rates among patients and regions.[31] That study also found that higher spending did not slow the rate at which the elderly developed functional limitations (reflecting their ability to take care of themselves). Although more research is needed about the impact that differences in spending have on patients' morbidity and quality of life, perhaps using more-extensive measures of health outcomes, those findings suggest that spending in the high-cost areas could be reduced without adverse effects on the overall health of residents in those areas.

How much could spending be reduced? Some estimates of the potential savings from reducing the variations in treatments are quite large, although questions remain about what mechanisms could achieve those savings and what the effects on health would be. The Dartmouth researchers have suggested that Medicare spending—and perhaps all health spending in the country—could be cut by about 30 percent if the more conservative practice styles used in the lowest-spending one-fifth of the country could be adopted nationwide.[32] While they note the need for more research about the specific steps needed to reduce spending levels without harming health, their analysis indicates that the added spending is not contributing to better health outcomes. Other studies suggest that overall health might not suffer in the process of changing practice patterns but that patients who would benefit most from more-expensive treatments might be made worse off as a result, while patients who would do better with treatments that were less expensive would gain.[33]

Other studies of geographic variation indicate that there may be room to reduce spending without harming health in both high-use and low-use areas of the country. One older study, for example, had independent panels of doctors conduct after-the-fact reviews of the medical charts of Medicare enrollees who had had certain surgeries.[34] In areas with high use of the procedures, the study found that the share of surgeries that was clinically appropriate ranged from about 35 percent to about 70 percent; the remainder were either clinically inappropriate or of equivocal value. In low-use areas, the share considered appropriate ranged from about 40 percent to about 80 percent. In other words, the share of procedures deemed appropriate was slightly higher in the low-use areas, but that share was well below 100 percent in both high-use and low-use areas.

Options for Organizing and Funding New Federal Research Efforts

The approach that is taken for organizing and funding any increased federal efforts to support research on comparative effectiveness could play an important role in determining their impact. Some approaches would seek to insulate those efforts from political pressure by setting up an organization at "arm's length" from the government and by providing a dedicated source of financing. Many of the options that have been proposed seek to coordinate and centralize existing activities through one entity—which would tend to give any conclusions it reached more weight—but developing several competing sources of information about comparative effectiveness could also have value.

30. Joseph J. Doyle, Jr., "Returns to Local-Area Health Care Spending: Using Health Shocks to Patients Far From Home," NBER Working Paper 13301 (National Bureau of Economic Research, August 2007).

31. Elliott S. Fisher and others, "The Implications of Regional Variations in Medicare Spending, Part 2: Health Outcomes and Satisfaction with Care," *Annals of Internal Medicine*, vol. 138, no. 4 (February 18, 2003), pp. 288–298.

32. Elliott Fisher, "More Care is Not Better Care," *Expert Voices*, Issue 7 (National Institute for Health Care Management, January 2005), available at www.nihcm.org/publications/expert_voices.

33. Amitabh Chandra and Douglas O. Staiger, "Productivity Spillovers in Health Care: Evidence from the Treatment of Heart Attacks," *Journal of Political Economy*, vol. 115, no. 1 (February 2007), pp. 103–140.

34. Mark R. Chassin and others, "Does Inappropriate Use Explain Geographic Variations in the Use of Health Care Services? A Study of Three Procedures," *Journal of the American Medical Association*, vol. 258, no. 18 (November 13, 1987), pp. 2533–2537. The procedures studied were coronary angiography (which generally involves inserting a tube and special dyes into the heart to see how well blood flows through it), carotid endarterectomy (in which plaque is removed from the main artery that goes to the brain), and gastrointestinal endoscopy (in which a flexible tube with a small camera mounted on it is inserted into the intestines).

were funding either to consider changes in the levels of spending or to adjust any funding formula to keep dedicated resources in line with spending trends—which could also provide a vehicle for pressure from interest groups. Nevertheless, automatic or dedicated funding mechanisms would tend to limit the influence of political pressure to some extent. But such mechanisms also would raise questions about how the entity set its priorities and allocated resources—and how it would be held accountable for those decisions. A nongovernmental organization might be able to act more quickly than a federal agency, but that speed could come at the expense of transparency.

Under any option, an advisory board (or governing council) could be established to serve several functions: providing guidance to the entity and establishing priorities for its research projects; creating an independent process for reviewing and possibly approving the findings that resulted from that research; and serving as a channel for interested parties to participate. For example, the board could include representatives of major federal health programs, private insurers, health care providers, advocacy groups for patients, and drug and device makers—as well as members of the general public and disinterested policy experts. Alternatively or in addition to including various stakeholders, a regular process could be established for getting input from interested parties. An example of that type of structure is the U.S. Preventive Services Task Force (see Box 2).

In designing such an oversight group, a number of issues would arise. The types of participants on any board and the manner in which members were chosen and replaced would have to be determined carefully to avoid giving one perspective undue influence. Similarly, conflict-of-interest rules governing the entity's staff would probably be needed. Trade-offs could exist between the extent to which many views and interests were represented and the ability of the council or board to make timely decisions or to reach consensus on contentious issues. Whether any oversight group was involved in reviewing or approving the results of research projects or focused instead on which projects to initiate and what those reviews entailed would also affect the entity's staffing requirements and the types of expertise that board members needed.

Another organizational issue is whether to establish a single or highly centralized entity or, instead, to design a more loosely coordinated system encompassing several distinct centers to produce independent analyses. Many of the options that have been proposed seek to centralize research activities through one entity—partly to address concerns about the lack of coordination among current U.S. efforts. An advantage of that centralized approach is that it would tend to give more weight to any conclusions reached. At the same time, that potential for having a greater impact could also lead the organization to adopt findings that were watered down to reach consensus; even if the entity did not have a formal approval process and instead simply released any results of approved projects, a single agency might be more reluctant to pursue research into more contentious questions. A decentralized approach could give individual research centers more latitude and encourage more competing perspectives to emerge. However, a more pluralistic approach could also involve some redundant efforts and, if it yielded any conflicting findings, would leave users with the task of reconciling the results.

An additional consideration—particularly if a new entity was created—would involve start-up costs and other implementation challenges. If funds were directed through an existing federal agency, some ongoing costs for additional staffing would be incurred, but the basic support infrastructure would largely exist already. By contrast, establishing a new agency or public–private partnership could require a greater effort before research could begin. At the same time, a quasi-governmental organization or public–private partnership could have more flexibility to develop and maintain its staff than a new or existing federal agency would have. Creating a new source of revenues (such as a tax on health insurance premiums) to help fund research on comparative effectiveness would also involve time and administrative costs.

Among existing organizations, their relative strengths and weaknesses could affect which one was best suited for new research efforts. NIH has extensive experience overseeing clinical trials but may not see research on comparative effectiveness as central to its mission of expanding the frontiers of biological and medical knowledge. AHRQ has substantial expertise in many areas of comparative effectiveness but has limited experience managing trials, and some observers have raised concerns about the impact that significantly expanded research about comparative effectiveness might have on that agency's other research endeavors. For its part, the Institute of Medicine is widely respected but does not have an extensive organizational capacity to conduct or oversee primary research,

Box 2.

Continued

The task force has presented its recommendations in a periodic series of reports, the most recent of which covers about 60 specific services. Those services are now given a letter grade, as follows:

- A, for services that are strongly recommended on the basis of solid evidence that the benefits of improved outcomes outweigh the risks of harm;
- B, for services that are recommended on the basis of reasonable evidence of net benefits;
- C, for services with no recommendation because the balance of benefits and risks is too close;
- D, for services that should not be routinely provided because the evidence indicates the services are ineffective or that the risks outweigh the benefits; and
- I, for services that do not have sufficient evidence on which to base a recommendation.

Initially, when formulating recommendations, the task force did not take into account the costs of providing preventive services or their cost-effectiveness.[2] According to one recent summary, however, the task force now "considers the total economic costs that result from providing a preventive service, both to individuals and to society, in making recommendations, but costs are not the first priority."[3] Although some immunizations against a disease have been shown to reduce total spending on health care, many other preventive services appear to increase spending on net—either because of the costs of providing those services to large segments of the population (only some of whom will be found to have the disease) or because the overall effects on treatment costs are modest. Analyses of cost-effectiveness would shed light on how the health benefits of preventive services compared with those increases in spending.

2. See Somnath Saha and others, "The Art and Science of Incorporating Cost-Effectiveness in Evidence-Based Recommendations for Clinical Preventive Services," *American Journal of Preventive Medicine*, vol. 20, no. 3 (April 2001), pp. 36–43.
3. Russell P. Harris and others, "Current Methods of the U.S. Preventive Services Task Force," *American Journal of Preventive Medicine*, vol. 20, no. 3 (April 2001), pp. 21–35.

ing the interests of drug and device manufacturers and of providers of health services.

Options for Comparing the Effectiveness of Treatments

The appropriate organizational form for any new or expanded federal entity, along with the mechanism and level of funding, may depend in large part on what activities it would carry out. For example, analyzing existing data would require a different set of skills, and would cost less, than overseeing new clinical trials that compared different treatments. In addition to setting priorities among the various methods of research, a new or expanded entity would have to define the scope of its analyses—both the types of comparisons it would commission and the questions that analyses would address. In particular, would the organization focus only on trying to determine which treatments conferred the greatest medical benefits, or would it also assess which treatments were most cost-effective? Whatever approach was taken, the manner in which the results were communicated to doctors, patients, and health insurers could play an important role in determining the impact on medical practice.

Methods of Research

Federal efforts to assess different treatment options could be pursued in a variety of ways. Options range from synthesizing existing research—a process known as a systematic review—to conducting new studies using data that are already available to funding new head-to-head clinical trials. Although those options are not mutually exclu-

Table 2.

Cost-Effectiveness of Different Screening Methods for Colorectal Cancer

(Dollars)

Screening Method	Lowest	Highest
Colonoscopy		
Every 5 Years	17,316	36,612
Every 10 Years	10,633	26,693
Fecal Occult Blood Testing		
Annually	4,643	25,860
Every 3 Years	2,942	10,861
Sigmoidoscopy		
Annually	1,391 [a]	1,391 [a]
Every 3 Years	16,318	20,727
Every 5 Years	14,384 [b]	42,310

Source: Congressional Budget Office based on Medicare Payment Advisory Commission, *Review and Analysis of Cost-Effectiveness Analyses for Two Medicare-Covered Services* (prepared by the Institute for Clinical Research and Health Policy Studies, New England Medical Center, June 2006), available at www.medpac.org.

Note: The cost-effectiveness ratio is the estimated cost per one-year increase in quality-adjusted years of life expectancy, in comparison with the result of no screening.

a. Only one study was available for analysis.

b. One study found that screening every five years yielded lower costs and better health outcomes than no screening.

diseases, limiting the potential usefulness of the findings. In addition, the implication of the review—that older drugs for diabetes should be tried first—was already the protocol recommended by the American Diabetes Association. Thus, although the review was relatively inexpensive to conduct and may well have been worth its costs, its contribution was also limited.

In some cases, the existing evidence may permit more clear-cut determinations, but many systematic reviews are inconclusive—so views differ about their overall contribution. Britain's National Institute for Clinical Excellence (NICE) relies solely on systematic reviews of available studies. It has nonetheless been able to analyze many different treatments on the basis of their cost-effectiveness and to develop an extensive set of clinical guidelines and recommendations about using medical technologies.[41] Whether that record indicates the greater strength of the evidence on the reviewed treatments or a greater willingness on NICE's part to draw conclusions from that evidence is not clear. Typically, though, systematic reviews find that the available evidence is not adequate to address many important questions, so the primary value of such reviews may lie in clearly identifying the gaps in knowledge that should be the subject of future research.

Analyses of Claims Records. A somewhat more challenging approach than reviewing existing studies would be to fund new analyses comparing medical treatments using existing sources of data, such as health insurance claims records. An advantage of that approach is that it could provide new information to help resolve uncertainties about treatments at relatively low cost—using data on patients that had already been treated.

A central difficulty in such studies, however, is accounting for the differences in patients' health status that play a role in determining which treatment they get—which can make simple comparisons misleading. Insurance claims typically do not include any information about health status. Yet patients with more severe heart disease, for example, are more likely to receive invasive and expensive surgical procedures such as an angioplasty or a bypass operation. The greater severity of their condition may also make them more likely to have a subsequent heart attack and more likely to die. As a result, a comparison with patients receiving less aggressive treatments—who are probably not as sick, on average, to begin with—could understate the benefits of more aggressive treatments. In other settings, patients receiving more aggressive treatments may be healthier, so even well-designed observational studies can generate misleading findings regarding the benefits of those treatments. Studies of

41. To estimate cost-effectiveness, NICE generally combines the results of such reviews with its own models of the impact of different treatment options on the use of health services and health care spending.

Medical Registries. Another option that could supplement or help improve analyses of claims data would be to establish medical registries, which generally track patients who have a particular disease or who have received a specific treatment. Registries collect additional information that is typically not contained in claims records, such as measures of health status or test results. In the United States, a number of registries—established or managed by various entities, including medical specialty societies and product manufacturers—have been used to help determine the clinical effectiveness or cost-effectiveness of various products and services.[45] Some health plans establish registries of their enrollees, although a centrally managed registry would have the advantage of being able to track patients if they moved or changed health plans.

Data from medical registries could help improve claims-based analyses both by allowing a broader set of outcomes to be measured and by providing information to control for differences among patients getting different treatments, including the severity of their illness. But a number of challenges and trade-offs would exist. One issue would be how to recruit patients and their providers to participate in and provide information to the registries and to retain them over time. Voluntary participation might be easy to implement but could introduce bias into analyses if patients choosing to participate differed in important ways from patients who had opted out. Some form of mandatory participation could avoid that problem but might raise objections from participants. Registries focused on specific treatments could also be subject to bias if those patients differed systematically from patients who did not receive those treatments—a problem that could be addressed by including a comparison group in the registries. Another trade-off concerns the data elements to collect; a more extensive list would permit richer analyses but would raise the burden of participation. More-extensive registries and registries involving more patients would also be more expensive to operate, although the annual costs of maintaining a typical registry are probably on the order of several million dollars.

The establishment of registries could affect medical practice in various ways. For example, CMS recently instituted a policy of "coverage with evidence development" for Medicare, to address treatments with potentially promising but uncertain medical benefits. Under that policy, Medicare now covers the costs of implantable cardioverter-defibrillators for a broader set of heart conditions than had previously been eligible—but only if those new patients are included in a registry that is supposed to track their progress.[46] If CMS would otherwise have decided not to cover that treatment for those patients, then the new policy means an increase in spending in the near term, but it also allows broader access to that technology in order to help generate the kind of evidence needed to reach a conclusion about its value. The registry may also help ensure, through its documentation requirements, that all patients meet the medical criteria required for Medicare coverage. Another example comes from Sweden, where a registry of patients undergoing hip replacement surgery has been used to provide periodic feedback to doctors about their surgical techniques and to track which specific models of artificial hip have the lowest rates of complications. That effort is credited with reducing health costs by avoiding repeat operations to fix faulty or poorly installed hips.[47]

Randomized Controlled Trials. The method of research that would probably yield the most-definitive results involves randomized controlled trials to compare treatments head to head, but that approach would also be the most expensive and would take the longest to conduct. The main advantage of random assignment is that it usually ensures that any differences in outcomes reflect true differences among treatments and not confounding differences among patients (such as their health status or other factors that are more difficult to observe). But detecting differences that are statistically significant—that is, unlikely to have arisen simply by chance—can require a substantial number of patients to participate, and in some cases, they must be followed for several years. Total costs for conducting an extensive trial can exceed

45. For more information, see Richard E. Gliklich and Nancy A. Dreyer, eds., *Registries for Evaluating Patient Outcomes: A User's Guide*, AHRQ Publication No. 07-EHC001-1 (Rockville, Md.: Agency for Healthcare Research and Quality, April 2007).

46. See Sean R. Tunis and Steven D. Pearson, "Coverage for Promising Technologies: Medicare's 'Coverage with Evidence Development,'" *Health Affairs*, vol. 25, no. 5 (September/October 2006), pp. 1218–1230. An implantable cardioverter-defibrillator (ICD) is a device designed to quickly detect a life-threatening rapid heartbeat and to deliver an electric shock that converts the rhythm back to normal. Apparently, CMS has not yet implemented the longitudinal registry for ICD patients.

47. See Henrik Malchau and others, "The Swedish Total Hip Replacement Register," *The Journal of Bone and Joint Surgery*, vol. 84, no. 11 (November 2002), pp. S2–S20.

feasibly be conducted at any given time. One is getting a sufficient number of patients to participate to allow valid statistical comparisons of treatment outcomes. For medical conditions that are common, that may not be a substantial challenge, but the difficulty increases the more narrowly the target population is defined—just because fewer patients meet the criteria for participation in the trial. Ethical issues can also arise if one set of participants is assigned a treatment that is generally considered less effective, although such concerns may be less likely to arise when significant uncertainty exists in the medical community about the relative benefits of different treatments. In light of those constraints, significantly expanding comparative effectiveness research is likely to require a combination of randomized trials and other research methods.

Modeling. Another approach that has been suggested—as an alternative or supplement to clinical trials—is the use of computer models to simulate the effects of treatments on different populations of patients. While many well-designed models exist, perhaps the most prominent one is known as Archimedes; its development has been led by Dr. David Eddy with the support of the Kaiser Permanente health plan.[53] One benefit of that approach is that, once such a model is developed, it can be used to answer questions about effectiveness at relatively low cost. Indeed, that approach can even have advantages over analyses of claims data, electronic health records, or medical registries: If the model can accurately predict the effects of a new treatment, waiting for those treatments to be used and then tracking their effects on actual patients over time can be avoided in some cases.

Achieving that objective may be quite difficult, however, and a particular obstacle is that models rich enough to simulate real-world medical care may not be transparent enough to generate confidence in or acceptance of their results. Archimedes, for example, is a highly complex model that seeks to capture not only the behavior of doctors and patients but also many of the biological processes of the human body. Tests of the model have shown that under certain conditions, it is able to predict the results of trials with high accuracy. In those tests, a set of trials is examined—and usually, about half of them are used to calibrate the model, while the rest are used to test its predictions. It is not clear, however, how well the model would do when starting with a less extensive evidence base, so its primary contribution might be to fill in some gaps between existing trial results and to permit modest extensions of completed trials at relatively low cost. For more ambitious efforts, it would not be possible to tell whether the model's predictions proved correct or incorrect until after the treatment in question had been used and analyzed via the other methods described above.

The Scope and Focus of Analyses and the Dissemination of Results

In addition to determining what types of research to conduct, any organization sponsoring research on comparative effectiveness would have to make a number of decisions about the scope and focus of that research—or policymakers might decide to set parameters for those decisions. One important question is whether federally sponsored research would seek to assess both the relative clinical benefits and the cost-effectiveness of treatments. A second is what balance to strike between evaluating treatments already being used widely and examining new treatments that seemed likely to become common—and more generally, how to keep up with the rapid pace of technological development in health care. Another issue is whether and to what extent the research would compare the performance of different providers or types of providers (such as high-volume and low-volume hospitals). Last but not least is the issue of how to communicate results to doctors, patients, and other interested parties.

Clinical Effectiveness or Cost-Effectiveness? There are arguments both for and against having federally sponsored research on comparative effectiveness consider cost-effectiveness as well as clinical effectiveness. Those arguments involve the practical steps needed to do the analysis and the ultimate effects of the research.

One practical reason a federal entity might not seek to assess which treatment was most cost-effective for a given type of patient is that the answer to that question might vary by health plan. Health insurance plans have different cost structures and may pay different prices for the same services, so there is an argument for giving insurers (and other interested parties) more information about the relative benefits of different treatments and letting those parties calculate which one was most cost-effective. Indeed, the prices of the inputs involved are often subject to

53. See David M. Eddy, "Linking Electronic Medical Records to Large-Scale Simulation Models: Can We Put Rapid Learning on Turbo?" *Health Affairs*, Web Exclusive (January 26, 2007), pp. w125–w136.

could estimate cost-effectiveness ratios and rank treatment options on that basis.

Other Questions of Scope and Focus. In addition to choosing which methods of research to pursue and whether to consider cost-effectiveness, a new or expanded agency would need to consider several other questions of scope and focus as well. Would it make recommendations about coverage of treatments as well? On which treatments would it focus attention, and how would it set those priorities? Would it compare different ways of providing a given treatment or concentrate on assessing broadly different options? Would it also try to assess doctors and other providers in terms of their effectiveness? And should it take explicit steps to expand the capacity for comparative research or anticipate that supply would grow to meet demand?

The question is whether the new or expanded federal entity would make recommendations about which treatments should be covered by insurance—either generally or for public programs—is related to but separate from the issue of whether to assess cost-effectiveness. Some observers have suggested that a U.S. entity focusing on comparative effectiveness should steer clear of making such recommendations because they would be controversial in themselves and because they might be seen as tainting findings about relative medical benefits. As a practical matter, furthermore, the entity would not have to make formal recommendations in order for its research to affect the use of medical care, as long as its findings on clinical effectiveness or cost-effectiveness were considered credible by doctors and other health professionals and could be easily used by insurers and other parties.

A more pressing issue is how a new or expanded entity would choose the specific treatments on which to focus its attention. Selecting broad areas of treatment (such as cardiovascular disease) might be relatively easy, but tradeoffs could arise between focusing on specific treatments that were widespread, expensive, and had uncertain benefits or, instead, on emerging treatments and technologies that promised to be expensive and might be adopted widely but had not yet become common practice. In the former case, data might be more readily available, but changing ingrained practice patterns might be difficult (short of producing evidence of actual harm). In the latter case, analyses might be more difficult to conduct given the limited claims data that would be available, while generating new data via clinical trials would take several years and thus might not be timely. A related question is how frequently to reassess treatments or variations on them; according to one study, systematic reviews typically require revision after about five years.[55]

An additional issue is whether to expand the scope and structure of comparisons so that they analyzed degrees of service use within a given treatment approach, not just broadly different approaches. As noted above, the literature on geographic variations in health care indicates that overall surgery rates do not vary systematically or in a manner that is strongly correlated with the variation in total Medicare spending. Rather, spending differences reflect more intensive use of hospital and physician services (as well as more use of ancillary services like tests). Therefore, future studies might need to examine different approaches to providing the same basic treatment, such as the extent of follow-up care provided or the frequency of using tests and imaging services—in addition to the "either/or" question of whether a given type of imaging or test was informative. Such analysis could also be applied to structured programs of care coordination or disease management, in order to assess their impact on health and their cost-effectiveness.

Another question is whether assessments would be limited to procedures and treatments or would also seek to evaluate the performance of individual doctors. In particular, the data from medical records that were used to compare the effectiveness of different treatments for a given type of patient could also be used to analyze the quality with which doctors provided each treatment. The potential gains from such analysis would include identifying doctors who delivered high-quality care and encouraging doctors who were not performing as well to improve—and doing both on the basis of objective evidence. At the same time, concerns could arise that evaluating doctors would detract from the focus on identifying effective procedures. Further, controlling for differences among patients that could affect the ratings of numerous individual doctors could be even more challenging than controlling for differences in patients when comparing a small set of treatments. Although such an approach could

55. See Karen J. Shojania and others, "How Quickly Do Systematic Reviews Go Out of Date? A Survival Analysis," *Annals of Internal Medicine*, vol. 147, no. 4 (August 21, 2007), pp. 224–233.

additional information and revised incentives would tend to reduce spending for health care below currently projected levels, potentially to a substantial degree.

Currently, Medicare is effectively precluded from taking costs into account when making decisions about coverage and would probably need new legal authority to adjust payments to providers or cost-sharing requirements for enrollees to encourage the use of more cost-effective care. For their part, private insurers might not face legal barriers to limiting coverage of or altering payments for treatments that were shown to be less effective but still might be reluctant to do so if Medicare did not alter its own policies regarding coverage and payment. Thus, beyond conducting the analyses themselves, many difficult steps would probably need to be taken before spending on comparative effectiveness research translated into substantial savings for federal programs and the health care system. Even so, additional information comparing treatments would tend to reduce federal health spending in the near term—but probably not by enough to offset the full costs of conducting that research over the same period.

The Potential for Savings on Health Care

Predicting the impact that research on comparative effectiveness could have on health care spending is difficult because it is hard to know what that research will show. In some cases, the research could provide clearer evidence than exists today that the benefits of an expensive treatment outweighed the costs—in which case spending on such treatments could increase. Some observers have therefore suggested that comparative effectiveness research could also cause spending to increase on treatments already considered effective but not used as extensively as recommended protocols indicate.[60] By itself, however, new research on comparative effectiveness seems unlikely to increase the use of services that are already deemed effective, for two reasons. First, that research is unlikely to focus on such cases—instead, it would presumably target treatments of uncertain value. Second, even if it did address those types of care, an additional finding of effectiveness would be unlikely to have much impact on the use of already-recommended services without corresponding changes in the incentives to use them.

Although spending increases in some areas would be possible, current incentives already favor the adoption and spread of more-expensive treatments, so new research that found those treatments to be more effective or more cost-effective would probably increase their use only modestly. As a general rule, the fee-for-service reimbursement system by which health care is primarily financed in the United States—especially but not exclusively in Medicare—typically provides financial incentives for doctors and hospitals to adopt new treatments and procedures broadly even if hard evidence about their effectiveness is not available. For their part, insured individuals generally face only a portion of the costs of their care and, consequently, have only limited financial incentives to seek a lower-cost treatment. Although private health insurers have incentives to limit the use of ineffective care, they are currently constrained both by a lack of information and by public concerns about overly aggressive management (as was evident in a recent "backlash" against managed care plans).

Conversely, credible and well-designed studies that found that more-expensive treatments and approaches to care yielded little or no additional health benefits would have a greater potential to affect health care spending. Moreover, the evidence that additional spending and use of services in some parts of the country is not producing better health suggests that additional comparative research would be more likely to question than to support the value of more-expensive services. Research that affected the demand for treatments would also affect their supply; in particular, if the developers of new medical products and procedures had to demonstrate their value more clearly, those parties would not only have incentives to produce more evidence but also would be encouraged to focus their developmental efforts on approaches that were more clinically effective or more cost-effective. Over the long term, therefore, generating additional objective information about the relative costs and benefits of treatments seems much more likely to reduce total health care spending than to raise it—particularly if public and private insurers incorporated the findings into their coverage and payment policies.

Getting to the point at which additional research on comparative effectiveness could have a noticeable impact on health care spending would take several years. In addi-

60. One recent study found that patients typically received about half of recommended services, whether for preventive care, treatment of acute conditions, or treatment of chronic conditions. See Elizabeth A. McGlynn and others, "The Quality of Health Care Delivered to Adults in the United States," *The New England Journal of Medicine*, vol. 348, no. 26 (June 26, 2003), pp. 2635–2645.

to all types of patients that were considered—so that subgroups of patients who could benefit greatly from a treatment might be overlooked. And as discussed above, having research studies keep pace with the development of new technologies would be an ongoing challenge. Consequently, any new incentive systems would probably be applied only in areas of care where the evidence was convincing.

Making such changes would also generate some new costs for insurers. Some administrative costs would be incurred to monitor whether patients met the medical criteria for which a given treatment had been proved effective or cost-effective. An exception or appeals process might also be needed to permit case-by-case reviews, and negotiating more complex reimbursement arrangements with providers would entail some costs. Those costs would probably be small in comparison to the change in health spending, given that insurers already monitor the use of treatments to ensure that they are medically necessary and generally have appeals processes in place. In addition, providing stronger incentives for patients and providers to use effective care would probably increase the use of services that are already deemed effective. The types of effective care that studies find are underprovided, however, tend to be relatively inexpensive screening and monitoring services for chronic health problems.

The steps that private insurers took could both affect public spending and be affected by public programs' responses to additional information about comparative effectiveness. To the extent that changes instituted by private insurers affected doctors' methods, there would probably be some "spillover" benefits for public programs. However, private insurers might be more reluctant to pursue such approaches aggressively, at least in the short term, if public insurance programs were not adopting similar methods.

Medicare. To reduce spending substantially under Medicare on the basis of comparative effectiveness research would probably require additional legislative authority to allow the program to consider relative benefits and costs in a more extensive way and to modify the financial incentives facing doctors and enrollees accordingly. Under current law, Medicare does not have clear authority to take costs into account when making decisions about what treatments are covered and has made only limited use of information about relative clinical effectiveness. Federal law does not explicitly prohibit Medicare from considering costs, but the Medicare statute provides that the program will pay for items or services if they are deemed "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[64] A regulation was proposed in 1989 that would have included cost-effectiveness as a factor in determining whether a treatment was reasonable and necessary, but that proposed regulation generated considerable opposition and was eventually withdrawn.[65]

Most recently, Medicare officials sought to clarify the definition of "reasonable and necessary" for the purpose of determining whether a new treatment or procedure would be covered. In 2000, they issued a "notice of intent" to publish a proposed rule on that topic.[66] Under the concept outlined in that notice, Medicare would generally require new treatments to provide "added value," which was defined in the following way:

- A "breakthrough" technology (one conferring substantially more benefits than existing treatments) would be covered without regard to its cost.
- A new item or service that had some medical benefits would be covered regardless of its cost if no other medically beneficial alternative was available or if the alternative treatment used a different "clinical modality." (That term was not defined precisely, but drug therapy and surgery would clearly be treated as different modalities.)
- An item or service equivalent in its benefits to a similar currently covered service (using the same modality) would be covered only if its costs were comparable to or lower than the cost of the currently covered service.

64. See section 1862(a)(1)(A) of the Social Security Act.

65. See Peter J. Neumann and others, "Medicare and Cost-Effectiveness Analysis," *The New England Journal of Medicine*, vol. 353, no. 14 (October 6, 2005), pp. 1516–1522.

66. Health Care Financing Administration, "Criteria for Making Coverage Decisions," *Federal Register*, vol. 65, no. 95 (May 16, 2000), pp. 31124–31129.

If changes in law were made, Medicare could use information about comparative effectiveness to promote the use of more-effective care. It could, for example, choose not to cover treatments that were less effective or less cost-effective or it could exclude extremely inefficient providers from participating in the program—just as private insurers may do today. Alternatively, Medicare could tie its payments to providers to the cost of the most effective or most efficient treatment. If that payment was less than the cost of providing a more expensive service, then doctors and hospitals would probably elect not to provide it—so the change in Medicare's payment policy could have the same practical effect as a coverage decision. Even so, patients and providers might object more strongly to a decision not to cover a treatment than they would to a change in Medicare's payment for it. Alternatively, enrollees could be required to pay for the additional costs of less effective procedures (although the impact on patients' incentives and their use of care would depend on whether and to what extent they had supplemental insurance coverage that paid some or all of Medicare's cost-sharing requirements).

More modest steps that Medicare could take would include smaller-scale financial inducements to doctors and patients to encourage the use of cost-effective care. Doctors and hospitals could receive bonuses for practicing effective care or reductions in their payments for using less effective treatments (although the evidence to date about the effect of such pay-for-performance initiatives on health care spending is somewhat mixed).[70] Likewise, enrollees could be asked to pay only a portion of the additional costs of less efficient procedures. Or Medicare could simply provide information to doctors and their patients about their patterns of practice, which would create some pressure for doctors to use more-efficient approaches and could encourage patients to select more-efficient doctors. Adopting more modest measures to incorporate the findings of comparative effectiveness research, however, would probably yield smaller savings for the program.

Medicaid. As for Medicaid, state officials generally determine what specific services are covered—subject to broad federal requirements—and are reimbursed by the federal government for a portion of the reported costs using formulas specified in law. Because enrollees have low income, options for adjusting cost-sharing requirements to encourage the use of cost-effective care may be limited. Furthermore, a substantial portion of Medicaid spending pays for long-term care services such as nursing home care for elderly and disabled enrollees, which may be less amenable to comparative effectiveness research. At the same time, most of the poor mothers and children enrolled in the program receive their care through a private health insurance plan under contract to Medicaid, so spending for them would be directly affected by any changes that private insurers made. Another portion of Medicaid spending goes to cover cost-sharing requirements and payments of premiums for enrollees who are also on Medicare, so the impact on that spending would depend largely on what the Medicare program did.

An additional issue in applying the results of comparative effectiveness studies in Medicaid relates to the sharing of program costs between the federal and state governments. Federal matching rates under Medicaid currently range across states from 50 percent up to about 75 percent, and, by CBO's estimates, the federal government now covers 57 percent of the reported costs of health services provided by that program across the nation as a whole. At least in principle, those financing arrangements reduce the incentives for state Medicaid officials to limit coverage of less effective services—because, on net, states would face only a portion of those costs currently and would see only a portion of the savings that resulted from a programmatic change. Some coordination between state and federal officials might therefore be required to incorporate the results of comparative effectiveness research.

At the same time, many states recognize the growing fiscal burden posed by Medicaid costs, and several of them have already expressed interest in comparative effectiveness research. For example, more than a dozen state Medicaid programs are involved in a project (affiliated with the Oregon Health and Sciences University) assessing evidence about the relative safety and effectiveness of competing drugs in the same class. Similarly, the state of Washington has recently initiated a program to provide independent assessments of health technologies; a committee of physicians and other providers will review that evidence and make decisions about what treatments will be covered under the state's Medicaid program and other state-run health care programs. Oregon tried a broadly similar approach in its Medicaid program the 1990s (although controversies about the ranking of medical ser-

70. See Congressional Research Service, *Pay-for-Performance in Health Care*, CRS Report RL33713 (December 12, 2006).

impact that the resulting research would have on federal spending for health care would have to come primarily from changes such research induced in doctors' patterns of practice or patients' choices of treatments. Those changes—encouraged in some cases by private health insurers—would primarily affect private health spending, but some changes in treatment patterns would also be likely for enrollees in public programs because doctors tend to treat their patients in a similar manner regardless of their source of insurance.

To a lesser extent, some federal savings might also occur through changes in coverage that could be implemented under current law (although CBO did not make explicit assumptions about what those changes would be). For example, if research on comparative effectiveness determined that a service covered by Medicare did not confer any health benefits for certain types of patients or involved risks that outweighed the expected benefits, under its current coverage policies CMS would have clear authority to decide not to cover that service for those patients.

As discussed, evaluating the precise effect of new research is difficult because it is hard to know which studies will be undertaken and what they will find, but CBO estimates that such research would probably reduce spending for health care somewhat. Any impact of a given research study is likely to be felt over many years, so the change in spending in any given year would reflect the cumulative effects of past studies. Little evidence is available with which to estimate the precise magnitudes of the annual effects, although one comprehensive review of the issue indicated that additional information about the effectiveness of treatment options could "succeed in improving health care while paying for its own research-related costs through targeted health system cost reductions."[72] In estimating the effects of section 904, CBO assumed that the annual federal savings on health care would eventually reach a point at which they roughly equaled the annual outlays for research on comparative effectiveness—a process that would take about a decade.

Under H.R. 3162, budget authority for the Center for Comparative Effectiveness Research would be $1.1 billion over the 2008–2012 period and $2.9 billion over the 2008–2017 period. Because spending those funds would take some time, CBO estimates that outlays would amount to about $600 million over five years and $2.4 billion over 10 years. Direct spending by the federal government—mostly for Medicare and Medicaid—would be reduced by $0.1 billion over the 2008–2012 period and $1.3 billion over the 2008–2017 period. (Those amounts would constitute a very small fraction of cumulative federal outlays for those programs—less than one one-hundredth of 1 percent.) Thus, the net effect of enacting section 904 would be to increase federal direct spending by $0.5 billion over five years and $1.1 billion over 10 years, CBO estimates.

The impact on total spending on health care in the United States would be about five times as large as the effect on federal outlays, CBO estimates. Some of that effect would be seen in lower costs for providing health insurance to workers—costs that are excluded from income and payroll taxes. In turn, some of those savings on private insurance premiums would go to increase the taxable compensation of workers; by itself, that change would lead to a small increase in expected federal revenues. At the same time, the new fees on health insurance that would be used to finance the research would generate corresponding increases in health care costs for workers, which would tend to reduce taxable compensation modestly. Overall, those indirect effects of section 904 on revenues would be small.

72. Office of Technology Assessment, *Identifying Health Technologies that Work: Searching for Evidence*, p. 6.

FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH

REPORT TO THE PRESIDENT AND THE CONGRESS

JUNE 30, 2009

US DEPARTMENT OF HEALTH AND HUMAN SERVICES

Federal Coordinating Council for Comparative Effectiveness Research

Report to the President and the Congress

June 30, 2009

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EXECUTIVE SUMMARY

Across the United States, clinicians and patients confront important health care decisions without adequate information. What is the best pain management regimen for disabling arthritis in an elderly African-American woman with heart disease? For neurologically impaired children with special health care needs, what care coordination approach is most effective at preventing hospital readmissions? What treatments are most beneficial for patients with depression who have other medical illnesses? Can physicians tailor therapy to specific groups of patients using their history or special diagnostic tests? What interventions work best to prevent obesity or tobacco use? Unfortunately, the answer to these types of comparative, patient-centered questions in health care is often, "We don't really know."

Thousands of health care decisions are made daily; patient-centered comparative effectiveness research focuses on filling gaps in evidence needed by clinicians and patients to make informed decisions. Physicians and other clinicians see patients every day with common ailments, and they sometimes are unsure of the best treatment because limited or no evidence comparing treatment options for the condition exists. As a result, patients seen by different clinicians may get different treatments and unknowingly be receiving less effective care. Patients and their caregivers search in vain on the Internet or elsewhere for evidence to help guide their decisions. They often fail to find this information either because it does not exist or because it has never been collected and synthesized to inform patients and/or their caregivers in patient-friendly language. When they do find information, it may be informed by marketing objectives, not the best evidence.[1]

Due to astonishing achievements in biomedical science, clinicians and patients often have a plethora of choices when making decisions about diagnosis, treatment, and prevention, but it is frequently unclear which therapeutic choice works best for whom, when, and in what circumstances. The purpose of comparative effectiveness research (CER) is to provide information that helps clinicians and patients choose which option best fits an individual patient's needs and preferences. It also can inform the health choices of those Americans who cannot or choose not to access the health care system.[2] Clinicians and patients need to know not only that a treatment works on average but also which interventions work best for specific types of patients (e.g. the elderly, racial and ethnic minorities). Policy makers and public health professionals need to know what approaches work to address the prevention needs of those Americans who do not access health care. This information is essential to translating new discoveries into better health outcomes for Americans, accelerating the application of beneficial innovations, and delivering the right treatment to the right patient at the right time.

Examples of successful CER include summaries of evidence from the Agency for Healthcare Research and Quality (AHRQ) on numerous conditions, such as prostate cancer and osteoporosis, as well as the National Institutes of Health (NIH) diabetes prevention trial that demonstrated lifestyle change was superior to metformin and placebo in preventing onset of type 2 diabetes. Additionally, the Veterans Affairs (VA) COURAGE trial demonstrated that patients treated with optimal medical therapy alone did just as well as patients who received percutaneous coronary intervention plus medical therapy in preventing heart attack and death. These exemplars show the power of CER to inform patient and clinician decisions and improve health outcomes.

Patients increasingly and appropriately want to take responsibility for their care. Therefore we have a responsibility to provide comparative information to enable informed decision-making. This patient-

[1] Lee TH, Brennan TA. N Engl J Med. 2002;346:529-531.
[2] Green LA, et al. N Engl J Med. 2001; 344:2021-5.

Flavin, Tom (HRSA)

From: Conway, Patrick H (OS)
Sent: Monday, June 29, 2009 5:35 PM
To: OS - FCC_Members
Subject: fyi
Attachments: FCC CER final report-6-29-09.pdf

The final FCC report was released today and is attached in pdf format. We also briefed the Hill and it went well. Thanks.

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centered, pragmatic, "real world" research is a fundamental requirement for improving care for all Americans.

Comparative effectiveness differs from efficacy research because it is ultimately applicable to real-world needs and decisions faced by patients, clinicians, and other decision makers. In efficacy research, such as a drug trial for the U.S. Food and Drug Administration (FDA) approval, the question is typically whether the treatment is efficacious under ideal, rather than real-world, settings. The results of such studies are therefore not necessarily generalizable to any given patient or situation. But what patients and clinicians often need to know in practice is which treatment is the best choice for a particular patient. In this way, comparative effectiveness is much more patient-centered. Comparative effectiveness has even been called patient-centered health research or patient-centered outcomes research to illustrate its focus on patient needs.

The American Recovery and Reinvestment Act (ARRA) provided $1.1 billion for comparative effectiveness research. The Act allocated $400 million to the Office of the Secretary in the U.S. Department of Health and Human Services (HHS), $400 million to the National Institutes of Health (NIH), and $300 million to the HHS Agency for Healthcare Research and Quality. It also established the Federal Coordinating Council for Comparative Effectiveness Research (the Council) to foster optimum coordination of CER conducted or supported by Federal departments and agencies. Furthermore, the legislation indicated that "the Council shall submit to the President and the Congress a report containing information describing current Federal activities on comparative effectiveness research and recommendations for such research conducted or supported from funds made available for allotment by the Secretary for comparative effectiveness research in this Act" by June 30, 2009.

Transparent, Open Process Seeking Public Input

From the outset, the Council recognized the importance of establishing a transparent, collaborative process for making recommendations and sought the input of the American people on this important topic. The Council held three public listening sessions, two in the District of Columbia and one in Chicago. The Council also received comments for two months on its public Web site. Importantly, the open process allowed the Council to hear from hundreds of diverse stakeholders who represent views across the spectrum. Many patients expressed their need for this type of research; one of the most emotional and moving testimonies came from the mother of a child with a seizure disorder in Chicago who had struggled to find the best treatment for her child. A physician from the American Board of Orthopedics summarized many physicians' testimony by saying, "developing high quality, objective information will improve informed patient choice, shared decision-making, and the clinical effectiveness of physician treatment recommendations." The Council heard repeatedly at the listening sessions that the Federal Government must use this investment to lay the foundation for informing decisions and improving the quality of health care. In addition, the Council posted interim working documents for feedback, including the definition of CER, the prioritization criteria, and the strategic framework, and modified these based on the feedback. Comments from the listening sessions and via the Web site significantly influenced Council discussion and decisions. Indeed, this entire report is influenced by the public input—and Appendix A elaborates on the key themes that ran through the public comments.

Vision

The Council's vision for the investment in comparative effectiveness research focuses on laying the foundation for this type of research to develop and prosper so it can inform decisions by patients and clinicians. This research is critical to transforming our health care system to deliver higher quality and more value to all Americans. The Council specifically focused on recommendations for use of the

Office of Secretary (OS) funds to fill high priority gaps that were less likely to be funded by other organizations and therefore represent unique opportunities for these funds.

Early in the process, the Council set the following objectives consistent with ARRA:

1. Develop a definition, establish prioritization criteria, create a strategic framework, and identify priorities that lay the foundation for CER.

2. Foster optimum coordination of comparative effectiveness research conducted or supported by relevant Federal departments.

3. Formulate recommendations for investing the $400 million appropriated to the HHS Office of Secretary as part of this Report to Congress.

Definition and Criteria
The Council first established a definition, building on previous definitions, for comparative effectiveness research:

> Comparative effectiveness research is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in "real world" settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.
>
> - To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations and sub-groups.
> - Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, diagnostic testing, behavioral change, and delivery system strategies.
> - This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness and actively disseminate the results.

The Council needed explicit criteria to make recommendations for priorities. Therefore, the Council's second step was to establish minimum threshold criteria that must be met and prioritization criteria.

Minimum Threshold Criteria (i.e. must meet these to be considered):

- Included within statutory limits of Recovery Act and the Council's definition of CER
- Potential to inform decision-making by patients, clinicians, or other stakeholders
- Responsiveness to expressed needs of patients, clinicians, or other stakeholders
- Feasibility of research topic (including time necessary for research)

The prioritization criteria for scientifically meritorious research and investments are:

- Potential impact (based on prevalence of condition, burden of disease, variability in outcomes, costs, potential for increased patient benefit or decreased harm)

- Potential to evaluate comparative effectiveness in diverse populations and patient sub-groups and engage communities in research
- Uncertainty within the clinical and public health communities regarding management decisions and variability in practice
- Addresses need or gap unlikely to be addressed through other organizations
- Potential for multiplicative effect (e.g. lays foundation for future CER such as data infrastructure and methods development and training, or generates additional investment outside government)

Importance of Priority Populations and Patient Sub-Groups
One important consideration for comparative effectiveness research is addressing the needs of priority populations and sub-groups, i.e., those often underrepresented in research. The priority populations specifically include, but are not limited to, racial and ethnic minorities, persons with disabilities, children, the elderly, and patients with multiple chronic conditions. These groups have been traditionally under-represented in medical research.

In addition, comparative effectiveness should complement the trend in medicine to develop personalized medicine—the ability to customize a drug and dose based on individual patient and disease characteristics. One of the advantages of large comparative effectiveness studies is the power to investigate effects at the sub-group level that often cannot be determined in a randomized trial. This power needs to be harnessed so personalized medicine and comparative effectiveness complement each other.

Strategic Framework
After completing the draft definition and criteria for prioritization of potential CER investments, the Council recognized the need to develop a strategic framework for CER activity and investments to categorize current activity, identify gaps, and inform decisions on high-priority recommendations. This framework represents a comprehensive, coordinated approach to CER priorities. It is intended to support immediate decisions for investment in CER priorities and to provide a comprehensive foundation for longer-term strategic decisions on CER priorities and the related infrastructure. At the framework's core is responsiveness to expressed needs for comparative effectiveness research to inform health care decision-making by patients, clinicians, and others in the clinical and public health communities.

Types of CER investments and activities can be grouped into four major categories:

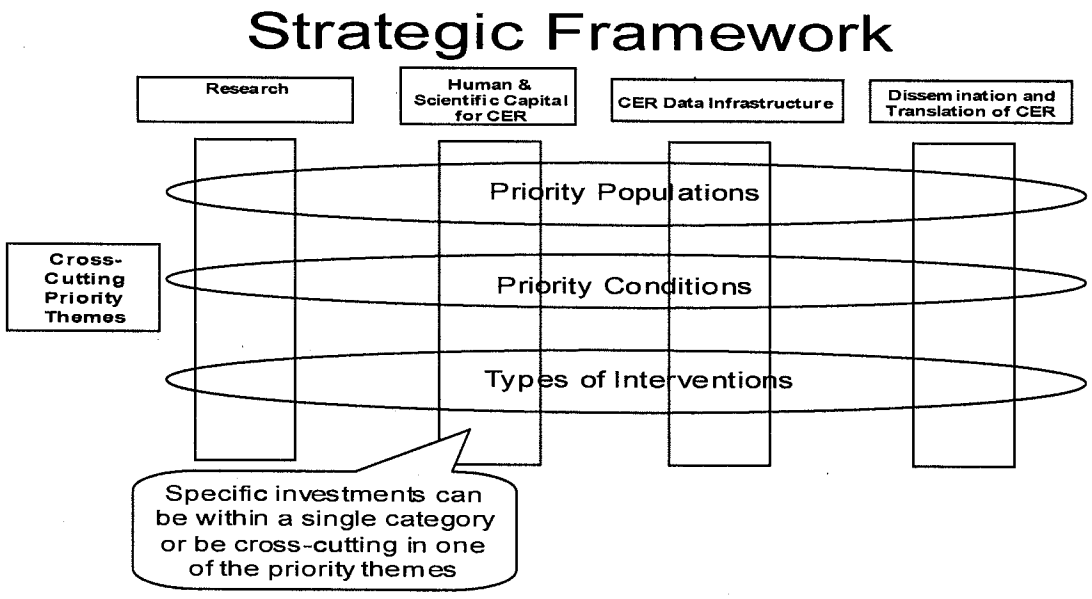
- **Research** (e.g., comparing medicines for a specific condition or discharge process A to discharge process B for readmissions)
- **Human and Scientific Capital** (e.g., training new researchers to conduct CER, developing CER methodology)
- **CER Data Infrastructure** (e.g., developing a distributed practice-based data network, longitudinal linked administrative or Electronic Health Record (EHR) databases, or patient registries)
- **Dissemination and Translation of CER** (e.g., building tools and methods to disseminate CER findings to clinicians and patients and translate CER into practice)

Furthermore, investments or activities related to a specific theme can cut across one or more categories and may include research, human and scientific capital, CER data infrastructure, and/or translation and adoption. These themes could include:

- **Conditions** (e.g., cancer, heart failure)
- **Patient populations** (e.g., elderly, minorities, children, persons with disabilities)
- **Type of intervention** (e.g., devices, behavioral change, delivery system)

Together, these activities and themes make up the "CER Strategic Framework" (Figure A)

Figure A



CER Inventory and Priority-Setting Process

The Council also conducted an inventory of CER and data infrastructure to help identify gaps in the current CER landscape. Maintaining that inventory and ongoing evaluation of government and private sector (where possible) CER investments and programs across these activities and themes is critical to this framework's value for decision-making. The first draft Federal Government inventory of CER and data infrastructure is included in this report, but it is critical to note that evaluation of current activities and the identification of gaps in order to inform priority-setting must be iterative and continue in the future.

As noted above, the Council's priority-setting process was informed by public input, and that input had a substantial influence on how the Council formulated its framework and priorities for CER. CER is an important mechanism to improve health and continued public input is vital for agenda setting.

Priority Recommendations

In developing its recommendations for how to invest the OS ARRA funding of $400 million, the Council sought to respond to patient and physician needs for CER, to balance achieving near-term results with building longer-term opportunities, and to capture the unique value that the Secretary's ARRA funds could play in filling gaps and building the foundation for future CER. The Council recommended that, among the four major activities and three cross-cutting themes in the CER

framework, the primary investment for this funding should be data infrastructure. Data infrastructure could include linking current data sources to enable answering CER questions, development of distributed electronic data networks and patient registries, and partnerships with the private sector.

Secondary areas of investment are dissemination and translation of CER findings, priority populations, and priority types of interventions. The priority populations identified that could be the focus of cross-cutting themes were racial and ethnic minorities, persons with disabilities, persons with multiple chronic conditions (including co-existing mental illness), the elderly, and children. CER will be an important tool to inform decisions for these populations and reduce health disparities. High-priority interventions for OS to consider supporting include medical and assistive devices, procedures/surgery, behavioral change, prevention, and delivery systems. For example, behavioral change and prevention have the potential to decrease obesity, decrease smoking rates, increase adherence to medical therapies, and improve many other factors that determine health. Delivery system interventions, such as comparing different discharge and transitions of care processes on hospital readmissions, community-based care models, or testing the effect of different medical home models on health have substantial potential to drive better health outcomes for patients.

The OS funds may also play a supporting role in research and human and scientific capital. Because the Council anticipates that AHRQ, NIH, and VA will likely continue to play a major role in these essential activities for the CER enterprise, OS funding would likely only fill gaps in these areas.

Longer-Term Outlook and Next Steps
This report and an Institute of Medicine report funded by the Department will inform the priority-setting process for CER-related funding. The most immediate next step will be the development of a specific plan, to be submitted by July 30, 2009, from the Secretary of Health and Human Services for the combined $1.1 billion of ARRA CER funding. In addition, an annual report from the Council is required under the ARRA legislation.

It will be important for this funding both to accomplish short-term successes and to build the foundation for future CER. The CER activity and investments should be coordinated across the Federal Government and avoid duplicative effort. In addition, the funding should complement and link to activities and funding in the private sector to maximize the benefits to the American people.

Clinicians, patients, and other stakeholders greatly need comparative effectiveness research to inform health care decisions. One private citizen unaffiliated with any health care group summarized, "It is more important than ever to engage in robust research on what treatments work and what do not. Doing so empowers doctors and patients, and helps make our practice of medicine more evidence-based."

This is a unique opportunity to invest in the fundamental building blocks for transformation of health care in the United States to improve the quality and value of health care for all Americans. Physicians and patients deserve the best patient-centered evidence on what works, so Americans can have the highest quality care and achieve the best possible outcomes.

I. INTRODUCTION

The American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. 111-5, made available to the Department of Health and Human Services $1.1 billion for comparative effectiveness research (CER). Of this amount, $300 million was allocated to the Agency for Healthcare Research and Quality (AHRQ), $400 million to the National Institutes of Health (NIH), and $400 million was allocated to the Office of the Secretary (OS) for disbursement.

These and all Federal agencies distributing ARRA funds must do so in accordance with all nondiscrimination and equal opportunity statutes, regulations, and Executive Orders that apply to the distribution of funds under the Recovery Act. Agencies that grant funds also must ensure that their recipients comply with Title VI of the Civil Rights Act of 1964 (prohibiting race, color, and national origin discrimination), Section 504 of the Rehabilitation Act of 1973 (prohibiting disability discrimination), Title IX of the Education Amendments of 1972 (prohibiting sex discrimination in education and training programs), the Age Discrimination Act of 1975 (prohibiting age discrimination in the provision of services), and a variety of program-specific statues with nondiscrimination requirements.[3]

ARRA provides further guidance on how funds appropriated to the Office of the Secretary are to be allocated:

> ... the funding appropriated in this paragraph shall be used to accelerate the development and dissemination of research assessing the comparative effectiveness of health care treatments and strategies, through efforts that: (1) conduct, support, or synthesize research that compares the clinical outcomes, effectiveness, and appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, disorders, and other health conditions; and (2) encourage the development and use of clinical registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data.

Section 804 of ARRA authorizes the establishment of the Federal Coordinating Council for Comparative Effectiveness Research (the Council). The Council is composed of senior Federal officials with responsibility for health-related programs. Most of the members are physicians and many have research expertise. The members represent not only the Department of Health and Human Services but also the Department of Veterans Affairs and the Department of Defense. Members of the Council come from a broad range of backgrounds, including the Office of Minority Health, the Office on Disability, community health centers, mental health, HIV and other infectious diseases, prevention, and others. The Council's purpose is to coordinate comparative effectiveness research and related health services research across the Federal Government with the intent of reducing duplication and encouraging the complementary use of resources. The Council is also charged with advising the President and Congress on strategies to address the infrastructure needs for CER within the Federal Government and organizational expenditures for CER by relevant Federal Departments and agencies.

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[3] Memorandum from the Acting Assistant Attorney General for Civil Rights. 4 March 2009

The 15-member Council was announced by HHS via website on March 19, 2009, and has been meeting regularly since then.[4] One of the Council's responsibilities is to submit to the President and Congress an initial report describing current Federal activities on comparative effectiveness research and recommendations for CER conducted or otherwise supported from the $400 million made available for CER to be allocated by the Secretary. This report meets that requirement.

Rationale for Comparative Effectiveness Research

When patients ask clinicians about the evidence supporting one treatment choice, diagnostic plan, or prevention modality over another, the answer too often is that the evidence is unclear. Even when evidence exists, it is often from a trial that may not apply to the specific patient and/or situation under consideration, such as an elderly African-American woman with multiple comorbidities. When specific evidence is lacking, clinicians have to rely on their clinical experience to make the best treatment decisions possible. Nevertheless, these decisions can result in less than optimal, and sometimes inappropriate, treatment choices.

Due largely to government and scientific leadership accompanied by astonishing achievements in biomedical science, clinicians and patients often have a plethora of choices when making decisions about diagnosis, treatment, and prevention. Total investment in health services research, which includes CER, accounts for only 1.5 percent of medical research expenditures.[5] The Recovery Act greatly increased funding for CER and the prominence and important of such research. The purpose of CER is to provide information that helps clinicians and patients choose which option best fits an individual patient's needs and preferences. The amazing biomedical discoveries made in the United States to date can now support CER to routinely compare commonly used therapies or test which interventions work best for particular patients. This information is essential to translate new discoveries into better health outcomes for Americans.[6] We must generate this knowledge to be able to deliver the right treatment to the right patient at the right time. Patients increasingly and appropriately want to take responsibility for their care; therefore, we have an obligation to provide the comparative information that enables informed decisions.

No standardized Federal definition of comparative effectiveness research existed prior to the Council's definition. However, several government entities had developed individual definitions for CER. For example, the Congressional Budget Office has described comparative effectiveness research as "rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients." The Institute of Medicine refers to comparative effectiveness as "the extent to which a specific intervention, procedure, regimen, or service does what it is intended to do when it is used under real world circumstances." The Council's definition builds on these concepts and highlights key aspects of the ARRA CER provisions. The Council defined CER broadly, asserting that it is patient-centered, "real world" research that can help patients, clinicians, and other decision makers

[4] See Appendix D for Council membership.
[5] Moses III H, Dorsey EK, Matheson DHM, et al. Financial Anatomy of Biomedical Research. JAMA 2005; 294:1333-42
[6] Dougherty, D, Conway PH. The "3 T's" Roadmap to Transform U.S. Health Care: The "How" of High Quality Care. JAMA. 2008 May 21;299(19):2319-21

assess the relative benefits and harms of strategies to prevent, diagnose, treat, manage, or monitor health conditions and the systems in which they are made.[7] This definition will form the foundation of the common Federal definition.

The Department of Health and Human Services' ARRA appropriation for CER is a significant investment. CER and activities that support CER have been undertaken by a wide range of stakeholders both inside and outside the public sector. However, despite diverse activities across the Federal Government,[8] funds exclusively appropriated for CER have until now been funded under authorized by section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 for the Agency for Healthcare Research and Quality, which the Agency makes available for projects through its Effective Health Care Program. Since 2005, Congress has appropriated a total of $125 million for the program, including $50 million for comparative effectiveness in FY 2009.

The ARRA funding reflects the heightened interest in CER among the nation's clinicians, patients, policy makers and researchers and broader recognition of its potential to improve outcomes that matter to patients, including morbidity, mortality, and quality of life. CER has the ability to assess these very patient-centered outcomes in a comprehensive way. Furthermore, patients increasingly play an active role in their health care and expect to be active participants in decisions about their health care. These interests are rooted in the strong desire for better evidence upon which to make clinical and other health-related decisions at a time of heightened focus on the quality and variability of care delivered.

A health system guided by better information about "what works" would have benefits for all who have a stake in the nation's health system. Consumers and patients would develop more confidence that the increasingly complex array of treatments and interventions could be tailored to meet their individual needs; health professionals would have more certainty that their clinical decisions were evidence-based and serving patients well. Consequences of the lack of such information include wide geographic variations in treatments typically received for specific conditions and, with these variations, sizeable differences in related health care spending not accompanied by proportional differences in outcomes.

Noted medical author Dr. Atul Gawande recently summarized this issue, "In situations where the right thing to do is well established, physicians from high- and low-cost cities make the same decisions. But in cases where the science is more unclear, some physicians pursue the maximum possible amount of testing and procedures; some pursue the minimum. And what kind of doctor they are depends on where they came from. In case after uncertain case, more was not necessarily better... We will need to do in-depth research on what makes the best systems successful... and disseminate what we learn. Congress has provided vital funding for research that compares the effectiveness of different treatments, and this should help reduce uncertainty about which treatments are best. But we also need to fund research that compares the effectiveness of different systems of care—to reduce our uncertainty about which systems work best for communities. These are empirical, not ideological, questions."[9] This variation in care

[7] See Chapter 3 for the Council's definition of CER.
[8] See Chapter 6 for a comprehensive listing of CER activities across the Federal Government.
[9] Atul Gawande. "The Cost Conundrum." The New Yorker. June 1, 2009.

documented by Wennberg[10], Fisher[11] and others, means that Americans in one part of the country who are seeing particular clinicians may get vastly different care with potentially worse outcomes than Americans somewhere else. The health system can no longer produce highly variable results and tolerate low quality and inefficiency. The care delivered should be based on evidence and best practices, not on which physician a patient was referred to or where a patient lives. The Council believes that bringing to bear careful research across the continuum of care, from prevention, to diagnosis, to treatment, to delivery systems, will yield improved care for both individuals and for populations.

Current Comparative Effectiveness Research Landscape

In order to inform recommendations for comparative effectiveness research, the Council conducted an inventory of current CER activity. Section 6 summarizes CER activity in the Department of Health and Human Services, the Department of Veterans Affairs and the Department of Defense. Several examples of these activities are discussed below.

AHRQ has an established CER program as described above. As an example, an AHRQ Comparative Effectiveness Review in 2008 examined treatments for localized prostate cancer. There are a number of treatment options available for prostate cancer, each with its own potential for risks and benefits, so it is important that men understand what is known about the effectiveness of these treatments. Key findings from the report included:

- There is a lack of comparative studies across major modalities of treatment (e.g. surgery, radiation, watchful waiting).
- There were no randomized trials evaluating cryotherapy, laparascopic or robotic prostatectomy, primary androgen deprivation therapy, high-intensity focused ultrasound (HIFU), proton beam therapy, and intensity modulated radiation therapy (IMRT). While these therapies have become increasingly of interest for men considering treatments for prostate cancer, it is impossible to evaluate whether these therapies are more or less effective than other options.
- Of men who had surgery, those undergoing a radical prostatectomy were less likely to experience urinary incontinence and other complications if the operation was done by an experienced surgeon in a hospital that does many of the procedures.

NIH has funded numerous comparative trials with huge implications for the practice of medicine. For example, the Diabetes Prevention Program was a major multicenter trial to evaluate the comparative effectiveness of intensive lifestyle changes (diet and exercise), a pill for diabetes (Metformin), or a placebo in preventing the onset of type 2 diabetes in adults with pre-diabetes. This landmark trial found that while both lifestyle changes and Metformin reduced the risk of developing diabetes compared to a placebo, lifestyle changes were significantly more effective than Metformin. This effect was seen in men and women, and in all ethnic groups. With the increasing incidence of pre-diabetes in this country, the results of this trial were critical in informing patients and physicians about prevention strategies for diabetes. Similarly, the BARI

[10] Wennberg J, Gittelsohn A. Small area variations in health care delivery. Science. 1973; 182:1102-8.
[11] Fisher ES, Wennberg J. Health Care Quality, Geographic Variations, and the Challenge of Supply-Sensitive Care Perspectives in Biology and Medicine. 2003; 46(1): 69-79

2D trial compared optimal medical management with revascularization for preventing premature death in Type 2 diabetes and found medical management to deliver equivalent outcomes.[12]

VA also has a very strong history of conducting CER. For example, the COURAGE trial, published in 2007, compared the effectiveness of percutaneous coronary intervention (PCI, or angioplasty) plus optimal medical therapy with optimal medical therapy alone in the prevention of heart attack or death in veteran patients with stable heart disease. The results showed that patients treated with optimal medical therapy alone did just as well as patients who received PCI plus medical therapy. This trial can inform patients and clinicians about the most efficient use of PCI in patients with stable angina.

In addition to Federal activities, state level, private sector, and non-profit sector CER efforts are currently underway across the country.[13,14] For example, 14 states participate in the Drug Effectiveness Review Project (DERP), based at the Center for Evidence-Based Policy (EPC) at the Oregon Health & Science University. The project is a collaboration between the Oregon EPC and the Oregon Center for Evidence-Based Policy. Together, they produce evidence-based reviews of the comparative effectiveness and safety of drugs in many drug classes, and then make this information publicly available.

Large insurers and health organizations such as Aetna, CIGNA, UnitedHealthcare, and Humana have developed the capacity to conduct evidence reviews in-house. These payers may also commission external studies from entities such as the Blue Cross and Blue Shield Association Technology Evaluation Center, which has been conducting evidence-based technology assessments for more than thirty years. Pharmaceutical, biotechnology, and medical device companies may sponsor studies that share some of the attributes of CER. In the non-profit sector, organizations synthesize and publicize CER, rather than generating new evidence. For example, Consumers Union relies on DERP reports to provide information for its *Best Buy Drugs* Web site.

Although there are a number of institutions, both public and private, involved in CER, a number of challenges remain unaddressed. Much of the CER underway is fragmented, and not aligned with a common set of priorities or definition of what constitutes CER. Databases and patient registries that are invaluable for comparative effectiveness analysis are similarly fragmented and often limited in numbers of patients or of variable or unknown data quality. Some resources, such as privately maintained claims databases and Medicare claims data, are difficult for researchers to access due to licensing and cost issues. Furthermore, there are a number of gaps in the content of the research being conducted. Studies often do not include participants of sub-groups, such as racial minorities or people with disabilities, and generally focus on therapeutics at the expense of other types of interventions (e.g., devices or the delivery system). Many effective interventions for improving health are likely to involve prevention and community

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[12] BARI 2D study group et al. N Engl J Med. 2009; 360(24):2570-2.

13 Academy Health. A First look at the Volume and Cost of Comparative Effectiveness Research in the United States. Available at: http://www.academyhealth.org/files/FileDownloads/AH_Monograph_09FINAL7.pdf. Accessed June 17, 2009.

[14] The following paragraphs draw on information contained in an environmental scan prepared by the Lewin Group for the Federal Coordinating Council on Comparative Effectiveness Research.

intervention, but these areas are currently understudied. CER should identify interventions that yield the most health improvement and represent the best value wherever and however the interventions are delivered.

The OS ARRA funds are a unique opportunity to address some of these gaps. The following box summarizes gaps in CER landscape:

Major Gaps in CER Landscape

- **Coordination across the CER framework**
  - Substantial CER assets exist across the Federal Government, but coordination is necessary to capture their full value
- **Research**
  - Many comparative, patient-centered research questions remain unanswered
- **Human and Scientific Capital**
  - CER methods development needed
  - Limited trained researchers for conducting CER
- **CER Data Infrastructure**
  - Fragmented data
  - Data sources limited in terms of clinical robustness of data and longitudinal data capture
  - Data capture and feedback loop at point of care often lacking
- **Dissemination and Translation of CER**
  - Suboptimal dissemination and translation of CER findings to patients and clinicians
  - Limited linkages between CER findings and directly improving patient outcomes
- **Priority populations**
  - Limited information on many priority populations and sub-groups
- **Priority Interventions**
  - Less information on certain comparative interventions such as behavioral change, procedures, devices, delivery system strategies, and prevention

Opportunity Provided by ARRA Funds

Within this context of national and international activity, the ARRA CER funds offer an extraordinary opportunity to complement ongoing research in the public and private sectors by establishing a solid infrastructure for future CER. Such investments could include development of data and methods, training of researchers who could accelerate the conduct of future studies, and rapid dissemination of results to patients and clinicians. For example, enhancing existing data resources and learning better how to maximize their utility could expand the types of questions addressed as well as identify high-impact opportunities for research. In addition, ARRA's investment in CER coincides with expected increases in the adoption of health information technology to improve health care quality and safety. That technology also offers the promise of including care delivery in the conduct of research (what some have termed a "learning health care system") and offering a platform for rapid dissemination of results to the

point of care to inform physician and patient decisions.[15] The field of CER is not entirely new, but increased availability of clinical electronic data resulting from diffusion of information technology demands improved methods and a cadre of researchers ready to take advantage of these expanding data resources.

As CER becomes a more integrated resource for health care decision-making, we must assure public trust by ensuring the privacy and security of health information and by maintaining access to appropriate care options. CER should not be used as a sole criterion for denying or awarding care or as justification for making care choices based on cost without consideration of effectiveness, safety, and convenience for an individual patient. CER has the potential to offer tremendous benefits to Americans so long as we apply its conclusions appropriately and protect the individual health information that informs it.

The Council believes that there is much to be learned about how research results can be incorporated into the everyday practice of medicine and inform consumer health care choices. The Council's hope is that ARRA funding has the potential to form a firm base for the Federal Government's future investments in CER and lay the foundation for a productive CER enterprise that improves care for all Americans.

II. VISION AND COUNCIL OBJECTIVES

Comparative effectiveness research has the potential to catalyze a patient-centered transformation of the U.S. health care system. By equipping patients and clinicians with the information needed to make joint medical decisions, and by optimizing the system in which the patient/clinician team makes these decisions, CER can improve the quality, safety, and value of care delivered while increasing patient satisfaction.[16] By passing ARRA, Congress recognized this vision and the need for CER, and also highlighted the need for an unbiased, cross-functional Council to "foster optimum coordination" of the Federal Government's CER efforts.

Given the Council's distinct role and the unprecedented resources available to the Secretary, the Council has a unique opportunity to begin working toward this vision for CER. The Council sees the following as potential accomplishments at the end of the ARRA funding period:

1. Establishment of a process for CER priority-setting that maximizes the value of Federal investments in CER through responsiveness to patient and other stakeholder needs, transparency, and effective coordination.

2. Development of a robust, foundational infrastructure for CER.

3. Implementation of a strategy to support rapid, systematic dissemination of CER results to empower patients, clinicians, and other stakeholders to make more informed decisions and increase the quality of care.

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[15] Conway PH, Clancy C. Transformation of Health Care at the Front Line. JAMA. 2009 Feb 18;301(7):763-5.
[16] Naik AD, Peterson LA. The Neglected Purpose of Comparative Effectiveness Research. NEJM. 2009 May 7; 360(19):1929-31.

To accomplish this vision, the Council outlined three specific, near-term objectives that build on those established in ARRA:

1. Develop a definition, establish prioritization criteria, create a strategic framework, and identify priorities that lay the foundation for CER.

2. Foster optimum coordination of comparative effectiveness research conducted or supported by relevant Federal departments.

3. Formulate recommendations for investing the $400 million appropriated to the HHS Office of Secretary as part of this Report to Congress.

III. COMPARATIVE EFFECTIVENESS RESEARCH DEFINITION AND CRITERIA

One of the first activities of the Council was to build on previous definitions of comparative effectiveness research, including IOM, CBO, and others, to develop a definition of comparative effectiveness research for the Council. After much discussion and sharing with the public for feedback, the Council established the following definition.

Definition

Comparative effectiveness research is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in "real world" settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.

- *To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations and sub-groups.*
- *Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, diagnostic testing, behavioral change, and delivery system strategies.*
- *This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness and actively disseminate the results.*

The definition above is not meant to exclude randomized trials; however, these trials would need comparator arms other than placebo and be representative of populations seen in "real world" practice.

Once a definition was established, the Council drafted threshold criteria for consideration and prioritization criteria for comparative effectiveness research and related investment. These criteria were posted on a public Web site, feedback was received, and modifications were made. The following are the current Council criteria.

Prioritization Criteria for Comparative Effectiveness Research Related Investments

Minimum Threshold Criteria (i.e. must meet these to be considered):

- Included within statutory limits of Recovery Act and FCC definition of CER
- Potential to inform decision-making by patients, clinicians, or other stakeholders
- Responsiveness to expressed needs of patients, clinicians, or other stakeholders
- Feasibility of research topic (including time necessary for research)

The prioritization criteria for scientifically meritorious research and investments are:

- Potential impact (based on prevalence of condition, burden of disease, variability in outcomes, costs, potential for increased patient benefit or decreased harm)
- Potential to evaluate comparative effectiveness in diverse populations and patient sub-groups and engage communities in research
- Uncertainty within the clinical and public health communities regarding management decisions and variability in practice
- Addresses need or gap unlikely to be addressed through other organizations
- Potential for multiplicative effect (e.g. lays foundation for future CER such as data infrastructure and methods development and training, or generates additional investment outside government)

This definition and criteria guided the Council as it considered potential priority recommendations for the OS funds and will guide AHRQ and NIH in allocating their CER funds.

IV. IMPORTANCE OF PRIORITY POPULATIONS AND SUB-GROUP ANALYSIS

As the United States has grown in its diversity, there has remained a persistent under-representation of women, the elderly, persons with disabilities, and racial and ethnic minorities in clinical and other research studies. While the NIH has a policy of inclusion of women and racial and ethnic minorities in all NIH-funded clinical trials,[17] the majority of research conducted in the U.S. does not require the inclusion of these and other priority populations. The lack of adequate representation of important patient populations in many research studies presents a major challenge in applying the results of these studies to important populations and sub-groups. In recognition of this fact, the ARRA legislation notes that "research conducted with funds appropriated shall be consistent with Departmental policies related to the inclusion of women and minorities." This criterion is critically important for ensuring that information gained from comparative effectiveness research improves the quality of care for all Americans.

[17] http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

Indeed, focused attention is needed on priority populations,[18] including racial and ethnic minorities, individuals with disabilities, children, persons with multiple chronic conditions, and the elderly, not only because of their under-representation in current research but also because of the increased disease burden and health disparities faced by these sub-groups.

The following sections highlight some of the challenges facing our health system as it relates to priority populations. Disparities in health care and health outcomes for these populations persist, affecting an ever-increasing proportion of residents of the United States. Also outlined are some of the research challenges that exist for priority populations, followed by recommendations to address these issues.

Growth in Priority Populations

Priority populations not only account for a large proportion of current health services utilization, but their numbers are growing; their need for health care services will likewise continue to grow. The most recent U.S. Census Bureau data reveal that over 100 million people living in the United States belong to a racial or ethnic minority group; this equates to 34 percent of the total U.S. population, and these minorities will likely become the majority of the U.S. population within 30 years.[19] Similarly, the number of elderly Americans is growing, with that segment of the population expected to increase from 35 million today to 71 million by 2030— or nearly 20 percent of the overall U.S. population. The population over the age of 85 is projected to grow from 5.3 million today to 21 million by 2050.

Health Disparities

A number of important reports have highlighted disparate disease prevalence, progression, and health outcomes for racial and ethnic minorities, elderly Americans, individuals with disabilities people of low socioeconomic status, people with mental illness, and others.[20,21] In this context, health disparities are defined as significant gaps or differences in the overall rate of disease incidence, prevalence, morbidity, mortality, or survival rates in the priority population as compared to the health status of the general population.[22] For example, African-American women are 34 percent more likely to die from breast cancer, even though they are diagnosed with the disease 10 percent less frequently than white women; Hispanics in the U.S. are 50 percent more likely than whites to suffer from diabetes; and the incidence of diabetes among

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[18] Priority populations are defined in Sec. 901 of the Healthcare Research Act of 1999, S. 580.
[19] U.S. Census Bureau. Minority Population Tops 100 Million: Press Release. Available at: http://www.census.gov/Press-Release/www/releases/archives/population/010048.html. Accessed April 1, 2009.

[20] Report of the Secretary's Task Force on Black and Minority Health. U.S. Department of Health and Human Services. 1985.

[21] Brown ER et al. Racial and Ethnic Disparities in Access to Health Insurance and Health Care. UCLA Center for Health Policy Research and the Henry J Kaiser Family Foundation. 2000.

[22] Minority Health and Health Disparities Research and Education Act of 2000. Public Law 106-525. November 20, 2008.

Native Americans is more than twice that for whites. Elderly Americans also face particular health challenges, from greater susceptibility to multiple chronic conditions to a lower likelihood of obtaining preventive treatments, including mammograms and immunizations. In addition, approximately 42 percent of individuals over the age of 65 report a functional limitation.[23]

Persons with Disabilities

According to the 2007 Institute of Medicine report *The Future of Disability in America,* from 40 to 54 million people in the United States have disabilities. These numbers will grow considerably in coming decades as baby boomers age and as new medical interventions extend the lives of young persons with significant impairments who would once otherwise have died. Although rates are lower in children, disability prevalence is rising at younger ages. According to figures from the National Health Interview Survey, childhood disability has risen by 350 percent during the last 40 years, with the largest increase occurring during the past decade.

Across the lifespan, disabilities are clinically and functionally heterogeneous, encompassing diverse cognitive, sensory, physical, and mental health impairments. Traditionally patients with disabilities have been excluded from clinical trials, yet they have the same risk for diseases as non-disabled persons. Future clinical trials should exclude persons with disabilities only if there are clear and compelling reasons to do so.

Comparative effectiveness research relating to persons with disabilities is important in a number of areas.

First, research would be beneficial about the most effective interventions to prevent or mitigate disability and the disabling effects of chronic diseases. All research including comparative effectiveness research relating to disability should include outcome measures that address functional abilities, people's abilities to participate in daily activities, and quality of life. This is critical as the world's population is growing older at a very fast pace and this has serious implications due to expected increasing rates of chronic conditions. Moreover, with the advances in science and technology, lifespan has increased considerably; this is also true for persons with disabilities.

Second, future comparative effectiveness research should look into community-based models of care for persons with disabilities. Following the Supreme Court *Olmstead v. L.C. ex rel. Zimring, 527 U.S. 581 (1999) Decision*, traditionally institutionalized individuals with disabilities or those at risk of being placed in institutions are increasingly being cared for in their own homes and/or communities. Underscored by the *Olmstead Decision* states now have to consider civil rights when developing their programs. Effective care coordination/care management is critical to help persons with disabilities live independently in their communities with added years of quality life. Care coordination/care management is even more important for those individuals with multiple chronic conditions, which are often associated with certain levels of disability. While care

[23] Federal Interagency Forum on Aging-Related Statistics. Older Americans 2008: Key Indicators of Well Being. Federal Interagency Forum on Aging-Related Statistics. Washington, DC: U.S. Government Printing Office. March 2008

coordination/care management is the current state-of-the-art, it is still considered to be in its early stage. This represents a major opportunity for building the infrastructure to support future CER studies. In addition, because the definition of care coordination varies according to settings and models of care, its effectiveness has not been clearly established, particularly as it relates to the role support services play and how better integration of health and support services can lead to improved health outcomes for persons with disabilities and reduced health care costs for our nation.

Third, persons with disabilities are at increased risk for developing secondary conditions that are associated with their primary disabling condition. For example, without preventive measures, individuals with spinal cord injuries may acquire a number of adverse health conditions, including cardiovascular disease, genitourinary tract disorders, depression, obesity, and pressure sores. Comparative effectiveness studies should determine which interventions are most likely to prevent secondary conditions or ameliorate their consequences.

Fourth, studies should investigate the comparative effectiveness of rehabilitation interventions to restore or maintain functioning or minimize its loss. For example, much more research is needed to identify effective speech-language, physical, and occupational therapy interventions. This research could include a comparison of conventional treatments to newer interventions or a comparison of various systems of care. More research is also required about various assistive devices, medical equipment, and technologies, including technologies addressing sensory deficits, communication impairments, and physical and motor limitations.

Fifth, comparative effectiveness studies of therapeutic and preventive interventions need to address explicitly the needs of children with disabilities and be sensitive to the developmental stage of the child. For many children with disabilities and complex health care needs, the transitions through adolescence and into adulthood are complicated by the absence of comprehensive care programs that fully address their needs. Comparative effectiveness studies should examine different care models to determine which ones offer the best care coordination and generate the greatest patient and family satisfaction and health outcomes.

Other underrepresented populations

Children represent another group that can benefit tremendously from comparative effectiveness research. Evidence cannot simply be extrapolated from adults to the pediatric population. There is a dearth of information to inform decisions by children and their families, especially since outcomes, such as quality of life and functioning, are often more subtle. In addition, comparative preventive interventions (e.g. for obesity) will often have the most long-term effects if started in the pediatric population.

At the other end of the continuum, the elderly represent another group for which there exists little information about best care practices. As our population ages, knowledge about the best and most effective treatments for this group will become essential. Other important areas of focus for the elderly include home health care strategies and optimal approaches to delivery of care within nursing facilities.

Veterans and service members often have many conditions for which CER could be informative. They have a number of special considerations in deployment-related illness such as post traumatic stress disorder, traumatic brain injury, exposures, infectious diseases, disabilities and others. CER provides a vital opportunity to glean additional information necessary for clinicians to make informed decisions about particular veterans needs and information to assist veterans in their participation in care decisions.

Finally, research to compare the effectiveness of prevention strategies, treatments, diagnostics, and care delivery for patients with multiple chronic conditions is essential. Again, as our population ages, patients increasingly have several comorbidities which may impact their response to treatment. The majority of clinical research to date excludes such patients, so the applicability of "standard" treatments to this population is unclear. A physician advising a 45-year-old woman with asthma and HIV about treatment for breast cancer simply does not have the evidence necessary to factor her comorbidities into her patient's treatment decision. By utilizing varied and robust research methodologies, CER affords the opportunity to target treatments and other interventions to improve the quality of life and overall health of this important group of patients.

Personalized Medicine and Patient Sub-groups

The need to identify and address the needs of emerging patient sub-groups, and indeed the very concept of sub-categories of conditions to which medical products are applied, is expected to change and grow as our understanding of genomics and molecular medicine increases and becomes an integral part of health care. Better understanding of an individual's genomic and other individual biological characteristics will enable us to recognize and respond to human variability with a new degree of specificity. Understanding biological differences at the molecular level promises a significant leap in our ability to use and develop medical technologies more effectively, targeting interventions at more defined groups of individuals with greater precision. This potential, sometimes referred to as personalized medicine, has strong bearing on comparative effectiveness research.[24] Many drugs prescribed in the United States today are effective in fewer than 60 percent of treated patients. This is not a fault of the drugs, but reflects the variability of metabolism or other factors from person to person.[25]

Unfortunately, it remains common medical practice to follow a trial-and-error approach in selecting medical interventions for patients to achieve a satisfactory therapeutic outcome. In the case of breast cancer, for example, while chemotherapy can be an important positive treatment for some patients, we have few tools today to successfully predict which patients will benefit– and the result is that many women who are treated with chemotherapy today are receiving treatments that may not be effective for their condition.

Personalized medicine aims to make medical care more precise and effective. Increased understanding of our individual genomic profiles and other individual biological characteristics

[24] Willard HW: Organization, Variation and Expression of the Human Genome as a Foundation of Genomic and Personalized Medicine. In *Genomic and Personalized Medicine. Volume 1.* Edited by Willard HW and Ginsburg GS. London: Academic Press; 2009:4-21.
[25] Spear BB, Heath-Chiozzi M, Huff J. Trends Mol Med. 2001 May; 7(5):201-4.

will enable us both to use more effectively the therapies we have now and to identify significant areas where research and development of new products may be needed. Pharmacogenomics, the use of genetic information or other biomarkers to assist in accurate medical therapy decision-making, is expected to be a hallmark of this approach.

CER can be an important partner in helping to bring about this new level of medical effectiveness, personalization, and innovation. At the same time that CER is being used to identify which interventions and strategies work best on average, it can also help to identify different responses by different groups of patients. In some cases, different existing therapies may be identified as most effective for specific sub-groups. In other cases, CER may help to identify significant sub-groups for whom effective therapies do not yet exist. CER may also help steer research efforts toward the development of products and strategies for areas of significant need.

Research Challenges

Multiple research challenges exist for priority populations. Examples include a need for increased diversity in research populations, expanded data sources for evidence-based studies in diverse populations, enhanced collection of racial and ethnic health data, a better understanding of the effectiveness of interventions in the context of comorbidities, and a greater focus on implementation research.

Generalizations that result from comparative effectiveness research that fail to consider sub-groups and individual differences may have limited applicability. Currently there are gaps in knowledge about whether specific treatment strategies work across different sub-groups under a variety of circumstances. Recognizing that there might be variations in the effectiveness of specific interventions in the elderly, racial and ethnic minorities, individuals with disabilities, and other priority populations is key to designing evidence-based strategies to successfully improve the quality of care that is delivered. Infrastructure investments that capture priority populations and patient sub-groups will be critical to overcoming these challenges.

Strategies to Strengthen Comparative Effectiveness Research for Priority Populations

In light of the aforementioned challenges, comparative effectiveness research presents an opportunity to be more inclusive of minorities, the elderly, persons with disabilities, and other priority populations. This feature of CER is especially true in the context of conducting specific studies that take into account health conditions and linguistic and cultural attributes in order to develop the most appropriate and effective interventions.

Investments in CER can be used to address the needs of priority populations by doing the following:

Evaluating and identifying interventions that are tailored for priority populations. To explore which interventions are most effective for addressing the needs of priority populations, specific studies are needed to look at interventions that target diseases with a high prevalence in racial and ethnic minority communities, the elderly, and individuals with disabilities. These

studies may need to simultaneously address several diseases/conditions, or assess combinations of interventions (e.g., behavioral and physical treatments/interventions) that are most effective in promoting desired outcomes for these populations. Studies examining care delivery interventions tailored for priority populations are also needed in order to ensure that care is delivered to these individuals through effective approaches that are targeted to their needs. To ensure effective communication with the priority populations both in conducting the research and implementing its results, investigators should ensure that those language and communication services are available for those with limited English proficiency or disabilities.

Creating and enhancing potential databases looking at interventions in priority populations. Successfully examining and evaluating a range of interventions that are effective for priority populations will require a broad range of potential data sources and infrastructure investments. In addition to traditional patient registries and systematic reviews, the inclusion of distributed data networks that utilize community-based infrastructure, such as Federally Qualified Health Centers, will be an important asset in broadening the tools to evaluate effectiveness in various priority populations. CER studies should routinely perform and report sub-group analyses to examine possible differences in effectiveness for important racial and ethnic groups, and should over-sample such groups whenever there is existing evidence to suggest differences in effects or outcomes in any priority population. Standardized reporting and analysis of priority population sub-groups will also permit pooling of research results across studies to explore sub-group differences.

In addition, efforts should be made to build capacity and infrastructure within traditionally underserved racial/ethnic communities to allow for standardization of data collection and to enable the seamless integration of such data with larger databases/systems currently in use by the research community. This will allow for more accurate downstream comparisons to pre-existing and future majority data sets, producing more comprehensive and reliable CER study results.

Finally, this infrastructure for CER in priority populations is particularly important for developing and implementing Clinical Preventive Services Guidelines and recommendations for the U.S. Preventive Services Task Force. According to the IOM, CER data on priority populations is often unavailable for developing guidelines, and what information is available is often insufficient for making conclusions on how to treat priority populations.

Increasing the number of community-based studies, including community-based participatory research (CBPR) studies. CBPR is defined as a collaborative research approach in which communities and researchers are equally involved in the design and conduct of research that is conducted in their communities. Successful and effective CBPR studies result in the development of research tools, strategies, and interventions that are effective in creating sustainable and positive behavior changes and outcomes among priority populations within communities. Because CBPR studies are conducted with substantial input from the community, interventions are typically tailored to fit the needs and characteristics of the community. Furthermore, communities become "owners" of the research, which results in sustainable research outcomes.

Increasing cultural competency. Understanding the linguistic, cultural, social, and environmental attributes of priority populations is essential in designing interventions and promoting strategies that are effective in addressing the needs of these populations. Specifically, doing so allows for the development of culturally and linguistically appropriate interventions. For example, an obesity/diabetes intervention involving diet and/or physical activity would require an understanding and assessment of the populations' cultural attributes (e.g., food preferences), social attributes (e.g., competing family and work demands), and environmental attributes (e.g., access to 'healthy' foods and safe walkways) that support or inhibit adhering to a diet and/or physical activity intervention.

Building workforce capacity. Racial/ethnic minorities, individuals with disabilities, and women are underrepresented in the research and medical communities. The lack of a diverse and linguistically competent scientific workforce adds to disparities in research development, service delivery, and quality of care. Initial CER investments in workforce capacity could create opportunities to engage researchers and providers from diverse backgrounds. For example, 90 percent of minority physicians educated at Historically Black Medical Colleges live and serve in minority communities. Hispanic-Serving Institutions (HSIs) also play a major role in educating Hispanics researchers. Approximately 49 percent of all Hispanic students attend an HSI. A special focus on priority populations could provide an avenue for engaging Historically Black Colleges and Universities and HSIs in the conduct of CER among priority populations.

Developing and implementing outreach strategies to various racial, ethnic, and health disparity populations for participation in research protocols. In order to strengthen CER, effective outreach strategies must be developed and implemented that will increase the participation of priority populations in clinical research protocols. Developing appropriate strategies to reach out to various priority communities requires an understanding of the history of these populations in research and the identification and recruitment of trusted community members who can champion the research benefits and inform communities about risks. Community health workers can be important partners in addressing and advocating for the needs and concerns of priority populations. In addition, clinicians and providers will need to be educated on the benefits and implications of CER and the utilization of evidence-based interventions.

Dissemination, translation and adoption of research results is one of the biggest challenges within comparative effectiveness research, particularly as applied to priority populations, but also as applied to the population as a whole. The young science of implementation research focuses on the acceleration of translation of evidence into everyday care, and affords an opportunity to build a more coordinated approach to improving the quality of health care of priority populations. This is not a one-way transfer of knowledge. Racial and ethnic minorities, persons with disabilities, children, and the elderly, can offer insights into how best to engage their communities. Active listening and thoughtful planning of the dissemination process can create better health outcomes for all Americans.

Making CER investments that are responsive to the needs of priority populations and sub-groups is critical to ensuring that the benefits of CER reach those with the greatest needs. Such

investments, however, can also benefit the population as a whole by validating new strategies and approaches for comparative research and implementation.

V. STRATEGIC FRAMEWORK FOR CER

There are countless opportunities for action and investment in CER. Many Federal, state, and private institutions are already involved in CER and have made choices about which of these activities and investments to pursue. After completing the draft definition and criteria for prioritization of potential CER investments, the Council recognized the need to develop a strategic framework for CER activity and investments to categorize current activity, identify gaps, and inform decisions on high-priority recommendations.

This framework represents a comprehensive, coordinated approach to CER priorities. It is intended to support immediate decisions for investment in CER priorities and to provide a comprehensive foundation for longer-term strategic decisions on CER priorities and the related infrastructure. At the framework's core is responsiveness to expressed needs for comparative effectiveness research to inform health care decision-making by patients, clinicians, and others in the clinical and public health communities. The framework will be supported by detailed inventories of Federal CER activities and research/data infrastructure, and a priority-setting approach. This organizing framework fosters consideration of the balance of activities and priority themes, focuses on the most pressing needs expressed by patients and clinicians, and allows for identifying and addressing gaps in the current landscape of CER.

CER activities and investments made by the government or other institutions can be grouped into four major Core Categories:

- **Research** includes activities or investments in primary research or meta-analysis. Organizations involved in this group of activities may be funding research, conducting research themselves, or helping to establish a common set of research priorities to create momentum around the most critical research topics.

- **Human and Scientific Capital** includes activities or investments that enhance the United States' capacity for CER by expanding and strengthening relevant research skills or by advancing CER approaches and methodologies. Organizations involved in this group of activities may be directly involved in training and workforce development, developing new CER methods, validating results of CER, or driving consensus on valid approaches to CER.

- **CER Data Infrastructure** includes activities or investments that develop, build, or maintain data infrastructure, systems, or tools. These investments could include the creation of new research data sets and repositories, aggregation of existing data sources, development of new tools to query and analyze existing data sets, or creation of standards for new data collection.

• **Dissemination and Translation of CER** includes activities or investments that disseminate CER findings and put them into practice. Activities and investments range from dissemination and distribution of CER information to improving processes and outcomes in health care and public health delivery systems through CER translation and adoption.

Table 1
Example Activities in Each Major Category

Activity	Examples
Research	Comparing outcomes of treatments or care delivery for a specific condition
Human & Scientific Capital	Training new researchers to conduct CER or developing CER methodology and standards
CER Data Infrastructure	Developing a distributed practice-based data network, linked administrative or EHR databases, or patient registries
Dissemination and Translation of CER	Building tools and methods to disseminate findings and translate CER into practice to improve health outcomes for patients

Furthermore, investments or activities focused on a specific priority theme can cut across these categories. The potential themes include:

•**Conditions.** Organizing investments and activities around a condition or disease state is common in research and reflects the organization of medical practice. Focusing on a single disease state across all four major categories of activity (e.g., funding primary CER in oncology, developing new methodologies for CER in palliative care settings, expanding the Surveillance, Epidemiology, and End Result database (SEER), and partnering with an academic cancer center to pilot CER implementation strategies) could result in significantly improved patient-centered outcomes in that disease area.

•**Patient populations.** While clinical research is relevant to the patient population it is designed to address, it often provides little information relevant to patient groups not typically enrolled in clinical studies. In private-sector-funded trials, this often includes the elderly, racial and ethnic minorities, children, and persons with disabilities. The NIH, however, already requires that all publicly funded trials include appropriate numbers of women and racial and ethnic minorities. Cross-cutting activities and investments that facilitate studies responsive to the needs of these populations can ensure that all Americans benefit from CER.

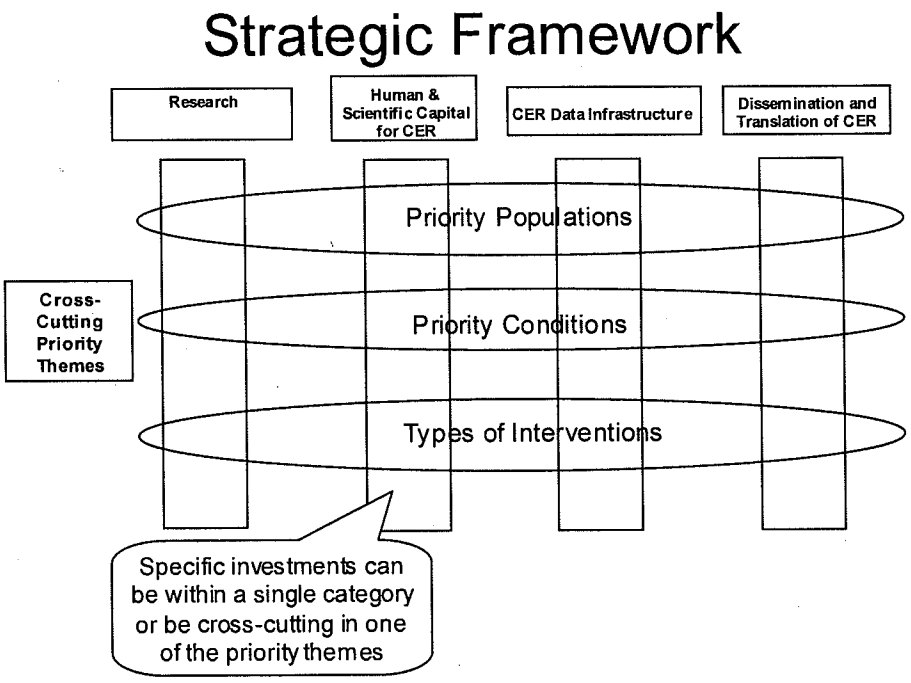
•**Type of intervention.** Several potential areas of focus emerge from studying interventions by type. In defining CER, the Council specifically included the following types of interventions: medications, medical and assistive devices, procedures, behavioral change, diagnostic testing, and delivery system strategies. Each of these has unique opportunities for coordinated investment in data infrastructure, research, building

research capacity, and translation. In addition, one could focus on interventions at a stage of the disease (i.e., prevention, diagnosis, treatment, and management).

Together, these activities and themes make up the CER strategic framework (Figure 1).

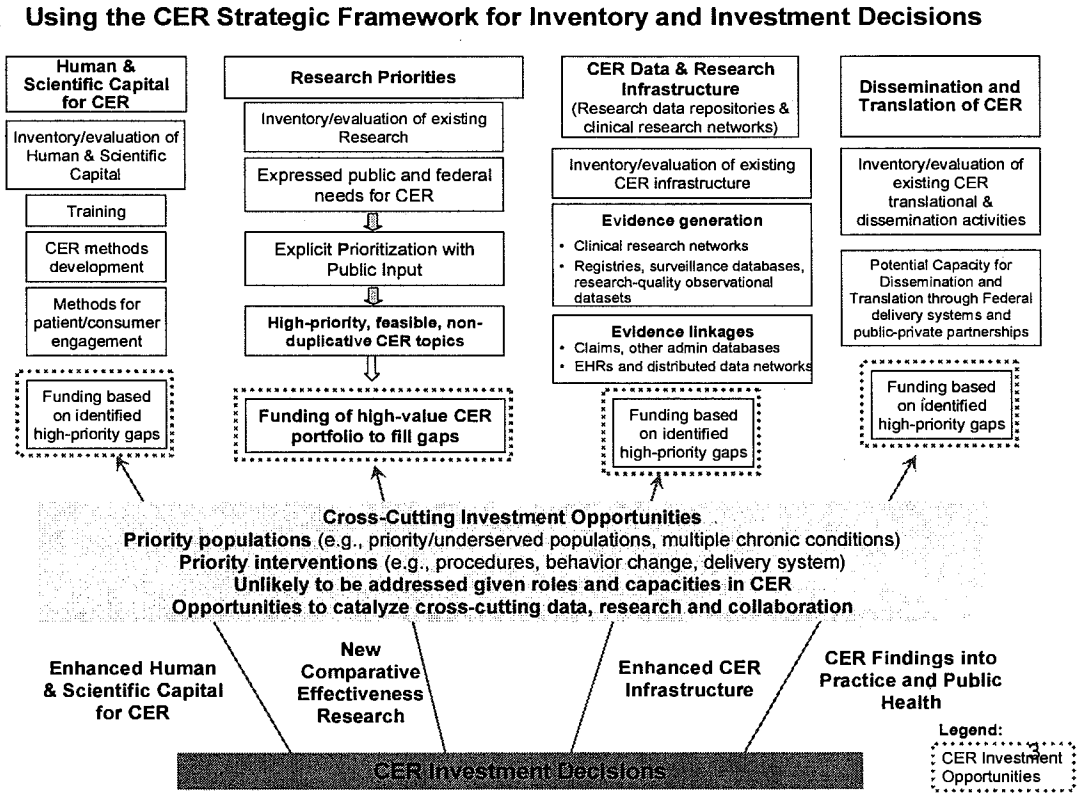
Agencies or organizations that are engaged in CER will often make investments in one group of activities or across multiple groups within a cross-cutting theme. The pattern of activity and investment for a single organization highlights its strategy. For example, a medical information database company may concentrate its CER activities in data infrastructure, whereas the National Cancer Institute is involved in multiple types of activities with a focus on cancer. When patterns of activity for the most critical agencies and organizations involved in CER are viewed in aggregate, the CER framework reveals gaps in CER activities and investments. These gaps are potential areas of opportunity and impact for the Secretary's ARRA funds. As such, the framework is useful for determining what investments are appropriate for ARRA funds and for future Federal investments in CER, as well as for codifying the ongoing activities of Federal agencies involved in comparative effectiveness research.

Figure 1



Creating and maintaining an inventory summarizing current and past Federal efforts across the CER framework is critical to its value in decision-making. This inventory of Federally-sponsored CER activities will also be a critical component of future Council annual reports. This process of inventory-taking, gap analysis, and establishing priorities for investment should be iterative. The process for developing the inventory and aligning findings from that process with CER investment decisions is outlined in Figure 2.

Figure 2



Overall, the CER framework is a useful strategic and analytic tool to help organize ongoing CER activities of Federal agencies, to facilitate development of a strategy for the Secretary's ARRA investments, and to continually monitor progress in CER across the different dimensions of the framework.

VI. CURRENT CER INVENTORY AND CER DATA INFRASTRUCTURE

The following CER inventory and data infrastructure was collected for the first time and on a very short timeline. The counts of CER studies are based primarily on electronically accessible sources, informed in part by interviews of senior agency staff. Attributes of the research reported here (study designs, types of interventions studied, etc.) were determined from study summaries or abstracts rather than inspection of full-text reports of these studies.

As described below, providing a high-confidence estimate of the number of Federally-funded CER studies underway for a given fiscal year is not currently feasible. Prospective identification of CER studies using keywords or other "tagging" in one or more readily searchable electronic databases would enable tracking of completed and ongoing CER. Therefore, this preliminary inventory is informed by a convenience sample and should be viewed as a rough estimate of what will be an iterative process going forward.

Although ARRA is the first coordinated Federal CER effort, several Federal agencies have been conducting comparative effectiveness research and maintaining data and infrastructure for CER. Most of this activity has been conducted independently within the given agency. The agencies most active in CER include AHRQ, NIH, and the Veterans Health Administration (VHA). But many other agencies conduct or have resources related to CER to a lesser degree, such as comparative effectiveness research studies, related data infrastructure, or the potential to be effector arms for research dissemination and translation. Finally, it is important to note that this inventory does not include CER conducted by private or not-for-profit organizations.

CER Inventory

Table 2 provides information about the numbers of studies for these agencies. There is no standard, systematic means of reporting on CER studies and funding across Federal agencies. It is not possible at this time to estimate the total number of primary or secondary CER studies conducted by the Federal Government. Other than AHRQ, by virtue of its dedicated Effective Health Care Program, agencies have limited ability to track CER studies and spending, reflecting that CER is a relatively new field of inquiry, has no standard definition, and is not "tagged" or readily searchable in biomedical or health services research databases. AHRQ tracks its funding and number of studies by fiscal year. Funding for CER studies for AHRQ ranges from 12 million to 35 million per fiscal year since FY 2006, with 12-18 studies funded per year. Estimates for the number of CER studies and funding for DoD and VHA are approximations per year rather than specific numbers for particular years. For example, DoD estimates its funding to be approximately $125,000 to $500,000 per year for 5-10 studies per year; the VHA estimates are 50 million to 70 million per year for 40-50 studies per year.

As part of its large portfolio of biomedical research, the CER funded by NIH makes that agency the single largest sponsor of primary comparative effectiveness research. These studies are difficult to identify, however, as they are not "tagged" or otherwise readily searchable as CER in such databases as ClinicalTrials.gov or CRISP (Computer Retrieval of Information on Scientific Projects, a database of biomedical research funded by NIH).

For purposes of this pilot inventory, a keyword search of ClinicalTrials.gov yielded an initial set of 1,800 NIH-funded trials during the years 2006-2009 that were candidates for CER. Subsequently, in cooperation with NIH, a sample set of 463 NIH CER studies for 2008 was identified, starting with a new searching process under development by NIH to track CER studies and spending.[26]

[26] NIH recently developed an initial process involving a keyword searching software algorithm based on consensus among several experts regarding which studies from among those funded by NIH qualify as CER. NIH applied this algorithm to all studies funded by NIH in 2008, which yielded more than 800 studies with a score above a certain threshold—tagging them as potential CER. Inspection of all of the records of all of these studies in CRISP by staff supporting the Coordinating Council identified the set of 443 that appeared to qualify as CER. This set of 443 does not necessarily represent the full set of CER studies funded by NIH in 2008.

Table 2: Estimated CER Grant/Study Counts FY 2006 – FY 2009[1]

Agency	CER Grants/Studies FY2006-FY 2009 (YTD)
AHRQ	144
DoD	25
VHA	96
NIH[2]	463

[1]As of June 2009, based on review of agency/department websites and agency/department generated lists

[2]NIH is in process of cataloging CER. This primarily represents FY 2008.

CER studies conducted or sponsored by VHA and DoD often focus on the particular populations they serve. These include CER studies involving patient groups that fall within designated U.S. priority populations (e.g., the elderly, racial and ethnic minorities, patients with multiple chronic conditions, persons with disabilities).

The main findings from analyses of Federal CER for fiscal years 2006-2009 include the following:

- In this initial compilation, the inventory of CER that could be confirmed independently for those agencies that perform or sponsor it was generally comparable to the inventory as described in interviews with agency staff. The main exception was NIH, where the volume of CER is acknowledged to be large yet remains to be quantified.
- Other than that for AHRQ, agency budgets for CER are not well defined. Agency staff typically described rough percentages of total research budgets or approximate ranges of annual expenditures on CER, but generally could not cite budget amounts allocated to CER (e.g., by Federal fiscal year).
- Excluding AHRQ, which could cite studies in its Effective Health Care program as at least a core set of CER, agency staff could not specify the number of CER studies conducted per year or other period. Three main factors account for this. First, there has not been a standard definition of CER. Second, while agencies may have a sense of expenditures or relative emphasis of CER, individual studies are typically not titled, given keywords, or otherwise "tagged" in a manner for identification as CER. Third, the time frame for CER study counts is not standardized; some agencies provided counts in terms of studies underway during a given year, others provided counts of studies initiated in a given year. Thus, providing a high-confidence estimate of the number of Federally-funded CER studies underway for a given fiscal year is currently not feasible. Clear identification of CER studies, particularly prospectively, would better enable tracking of completed and ongoing CER.
- Combined Federal CER is broadly distributed across study types (i.e., primary versus secondary studies). The volume of primary CER sponsored by NIH, particularly Randomized Controlled Trials (RCTs) and other trials, accounts for the largest general type of CER.
- The greatest concentrations of Federal CER are systematic reviews by AHRQ, RCTs by NIH, and RCTs by VHA (Table 3).

- Most AHRQ CER comprises secondary research (i.e., systematic reviews and other syntheses) and VHA supports secondary research through its Evidence-based Synthesis Program. Otherwise there is little emphasis on secondary research. Moreover, mathematical modeling is infrequently used in Federal CER (Table 3).
- Most primary research is done through RCTs (Table 3).
- Without careful inspection on a trial-by-trial basis, reliable detection of "practical" (or "pragmatic") trials among the primary CER studies is not possible. As a group, the VHA trials appear to have more such "practical" characteristics than trials sponsored by other agencies.
- Relative to the RCT volume from NIH and VHA, the use of observational analyses, including those involving large patient-level databases, is relatively infrequent.
- The locus of research varies by agency. All CER funded by VHA and most by DoD is intramural. Most CER funded by AHRQ is extramural. Although NIH conducts some intramural primary research, most CER is done extramurally.
- The interventions studied most often in Federal CER are pharmacologic, which account for the majority of the interventions studied by AHRQ and NIH. These are followed by studies of the health care delivery system, led by VHA, and behavioral interventions (which are often compared to pharmacologic interventions), led by NIH and VHA (Table 4).
- Roughly 86 percent of the CER studies in this sample across agencies focus on at least one priority disease/condition. The leading categories among these are depression and other mental health disorders, substance abuse, cardiovascular disease, and diabetes (Appendix C).
- The distribution of priority diseases/conditions studied by DoD and VHA largely reflects the respective populations they serve. For DoD, they are cancer, functional limitations and disability, and depression and other mental health disorders. For VHA, they are cardiovascular disease, and depression and other mental health disorders (Appendix C).

Table 3: Estimated Types of CER by Agency/Department

Study Type[1]	AHRQ	NIH[2]	DoD	VHA	Total
Primary Research					
Randomized Controlled Trial	11%	79%	0%	77%	60%
Practical/Pragmatic Controlled Trial[3]	3%	1%	16%	1%	2%
Other Non-Randomized Controlled Trial	2%	2%	32%	0%	3%
Observational Study (natural experiment)	1%	2%	0%	4%	2%
Observational Study (Prospective/Registry)	4%	3%	16%	6%	4%
Observational Study (Retrospective)	9%	5%	6%	4%	6%
Secondary Research					
Systematic Review	58%	0%	13%	0%	14%
Meta-Analysis	3%	0%	0%	0%	1%
Mathematical Model	4%	3%	3%	3%	3%
Research Training	n/a[4]	0%	13%	0%	1%
Other Capacity Building	n/a[4]	0%	0%	1%	0%
Other	2%	2%	0%	3%	2%

[1] Some studies include more than one study design, totals may not equal 100% due to rounding.
[2] NIH 2008 (based on sample of 443 studies) plus NIH multi-year (based on 30 studies across years).
[3] Rough estimate given no standard definition for pragmatic trial.
[4] AHRQ has been heavily involved in development of human and scientific capital for CER. It provides career development (K) grants for CER as well as a T and R grant for CER capability building. It also has funded numerous methodology studies for CER. These will be more fully quantified in the completed inventory.

Table 4: Estimated Types of Interventions Included in Studies

Study Intervention Type[1]	AHRQ	NIH[2]	DoD	VHA	Total
Pharmacologic Treatment	35%	68%	24%	10%	34%
Biologic Treatment	1%	1%	10%	4%	4%
Alternative Medicine	2%		8%	1%	2%
Medical Device/Equipment	17%	6%	0%	7%	11%
Surgical Procedure	11%		3%	9%	9%
Behavioral Intervention	11%	24%	11%	24%	16%
Public Health Intervention	2%	1%	17%	3%	3%
Delivery System	11%		19%	41%	20%
Other	10%		8%	1%	2%

[1] Some studies include multiple types of interventions and may not total 100% due to rounding
[2] NIH multi-year. Will need to be updated once inventory based on types of NIH interventions is complete.

The involvement of priority populations in CER sponsored by Federal agencies is varied. While several studies do not explicitly focus on a priority population, investigators sometimes report on analyses of one or more specific sub-groups:

- About half of CER studies across these Federal agencies involve a priority population, with nearly 60 percent of VHA studies doing so. Many studies focus on more than one population group. In part consistent with their respective missions, the agencies exhibit different distributions of emphasis on priority populations.
- Among those studies that do involve priority populations, those involving patients requiring chronic care, and those who are elderly are the most common. While no studies specifically indicate a focus on low-income groups, such individuals often comprise some of the patients studied, including the elderly, those with multiple chronic conditions, and minority groups.
- Studies vary as to whether there is sufficient representation of one or more priority groups in the study population to enable sub-group analysis, even if the study does not focus on a priority population as a principal objective. Particularly at AHRQ, in cases where studies do not have as their primary focus a priority population, sufficient numbers of members of priority groups may not be present for sub-group analyses, especially in the case of systematic reviews.
- Future iterations of the inventory will need to drill down on the representation of priority populations in studies.

CER Data Infrastructure

Substantial Federal and private sector infrastructures exist that could be used to identify potential CER priorities, to support the conduct and improve the productivity of CER, and to enable the translation of research findings into actionable information. However, the current infrastructure for CER is fragmented, and it is not coordinated or mobilized in a way that would enable providing coherent and targeted support for CER.

Patient-level Databases and Databases to Support Researchers

Federal agencies support or have access to substantial patient- and person-level databases that could support CER. Additional databases in the private sector can also deliver specialized content for CER. For example, these Federal and private sector databases can support or enable:

- Analyses preparatory to CER, such as.:
    - Disease prevalence and burden to help determine priority areas for comparative effectiveness research.
    - Utilization and distribution (e.g., geographic) of alternative interventions to help identify variations in practice and candidate interventions for CER.

    - Patient characteristics, socioeconomic attributes, comorbidities, and so forth, to determine the availability of certain patient populations for clinical trials, registries, and other person-level studies.
- Observational studies and retrospective data analysis (e.g., mining data from natural experiments).
- Support for prospective studies, including efficient development of registries and objective collection of treatment detail.

Important considerations for investing in and applying patient/person level databases to CER include:

- Potential to link to other databases that enrich the person/patient view, such as databases containing socioeconomic characteristics of individuals and mortality information (e.g., the Social Security Deathmaster or the CDC National Death Index).
- Potential to link databases that contain clinical information to those with transactional information (e.g., linking claims databases that have chemotherapy detail on cancer patients to electronic health records or registries for the same patients that have clinical data such as cancer stage, histology, and patient status).
- Research readiness of the databases (e.g., requiring minimal time on the part of the researcher to learn database attributes and develop special programs for data clean-up and access).
- Requirement to maintain security and privacy for any personally identifiable health information.

Appendix C lists some key patient-level databases with potential applications for CER. Among the ones available through Federal agencies are the major administrative databases maintained by CMS, the medical records databases at VHA, targeted databases maintained by AHRQ and NIH focused on service areas (e.g., HCUP on hospital-based care), and the NIH's SEER cancer registry.

Key private sector databases for CER include large administrative databases with longitudinal health care detail on millions of patients, and consolidated databases on EHRs. To the extent that these repositories can be linked (for which many have the potential), they can be highly valuable assets for CER, particularly because they account for commercially insured populations that are not captured in Federal and state databases.

In supporting research activities, the following Federal data infrastructure assets can speed communication among researchers and expedite identification of researchers with special skills:

- AHRQ: the DEcIDE Network, the CERTs (Centers for Education & Research on Therapeutics), and group of EPCs (Evidence-Based Practice Centers).
- NIH Clinical Translational Research Awards (CTSAs) recipients.
- CDC: Evaluation of Genomic Applications in Practice and Prevention (EGAPP) workgroup.
- HRSA research networks: Pediatric Research in Office Settings (PROS) and Emergency Medical Services for Children (EMSC) groups, among others

- SAMHSA: National Child Traumatic Stress Network
- VA Research Center of Excellence

Other databases for supporting researchers include:

- ClinicalTrials.gov (Federally and privately supported clinical trials).
- MEDLINE/PubMed (biomedical journal literature), HSRProj (Health Services Research Projects in Progress).
- CRISP (biomedical research funded by NIH, including clinical trials and other studies).
- Disease-oriented databases, surveys and Web sites, including the Longitudinal Studies on Aging (NCHS and NIA) and the Cardiovascular Health Study (NHLBI).
- Survey of Mental Health Organizations, General Hospitals Mental Health Services, and Managed Care Organizations (SAMHSA).
- Numerous CDC disease and research data assets and sites, including the NCHS surveillance systems, cancer registries, and vaccine registries.

None of these databases with actual or potential applications in CER were developed for the explicit purpose of comparative effectiveness research. Furthermore, they generally have not been organized or indexed to enable searching for CER. For example, careful record-by-record inspection of such research study databases as ClinicalTrials.gov and CRISP is required to identify CER. In order to assess current gaps and support translation and adoption of CER findings efficiently, these databases would require "tagging" of records or related searching functions that would enable accurate identification of CER.[27]

Dissemination and Translation Infrastructure

A few agencies, notably AHRQ, VHA, NIH, and SAMHSA, have capacities to translate CER into actionable information for practitioners, patients, and other target audiences. The VHA's capabilities for translation and adoption are inherent in its integration of research and patient care at VHA treatment centers. Additional agencies also have capabilities for disseminating information to segments of consumers and practitioners. All of these agencies have the potential to influence adoption of CER findings.

There are, however, minimal formal mechanisms to disseminate and translate CER from research agencies such as AHRQ and NIH into the delivery system side of HHS (e.g., HRSA, IHS, SAMHSA, CMS QIO's). In addition, given the current expansion of CER and the increased emphasis on achieving impact from its findings, the current dissemination and translation capacity of the relevant agencies involved in CER is likely to be insufficient for achieving CER's potential.

Some of the key elements that can be leveraged in a comprehensive and articulated CER dissemination and translation strategy are outlined below.

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[27] In MEDLINE, for example, indexing tags for particular "publication types," such as Randomized Controlled Trial, Clinical Trial, Phase III, Meta-Analysis, and Review, would readily enable searching for journal articles that report such studies.

- AHRQ
  - CER methods guides, tools, and resources made available via the AHRQ Web site, Web conferences, public service announcements, advertising campaigns, online audio guides available to public, and other means for informing consumers, clinicians, and policymakers.
  - The John M. Eisenberg Clinical Decisions and Communications Science Center, which focuses on translation of research to various target audiences.
  - AHRQ Publications Clearinghouse.
  - AHRQ dissemination partnerships, including with health professional societies, patient advocate groups, and non-profit organizations focused on particular diseases/conditions.
  - Effective Health Care Program Stakeholder Group, which helps to identify important information gaps, ensure transparency, and provide feedback on reports.

- CDC
  - Information to monitor the adoption of CER recommendations and to track the effects from changes in clinical practices and policies on the following process and outcomes measures: clinical management of specific conditions, including the use of medications and other specific services, and intermediate health-related outcomes, such as test results; incidence and prevalence of specific conditions; personal behaviors, health status, and functioning; and births and deaths.
  - Public use data from NCHS surveys available through the CDC/NCHS Web site and internal confidential data available for researchers through the NCHS Research Data Centers.
  - NCHS/CDC reports, including Data Briefs and E-Stats, and other analyses available through the Web site, and articles in the peer-reviewed literature.
  - Dissemination by and with collaborators, including sponsors of specific data collection and analysis.

- DoD
  - Searchable publication libraries, including the Military Health System Publication Search.
  - DeployMed Research Link, which informs Service members, researchers, health care providers, military leaders, and others about DoD and other Federally funded medical research related to deployments since 1990.

- NIH
  - Clinical and Translational Science Awards (CTSAs), which are NIH-funded academic centers that translate research into practice.
  - Nation Cancer Institute's Physician Data Query, an online database that summarizes study results in prevention, screening and management of cancer in versions appropriate for physicians and for patients.
  - Research databases, including MEDLINE/PubMed, HSRProj, CRISP, and ClinicalTrials.gov.

- Public health campaigns, such as Red Dress (women's heart health) and Small Steps Big Rewards (weight loss).
- NIH Consensus Development Conference program, which summarizes knowledge about a variety of clinical and public health interventions.

- VHA
  - QUERI (Quality Enhancement Research Initiative) program for enhancing the uptake of evidence within VHA.
  - Periodic research summaries and issues briefs for senior VHA clinical and policy leaders, and related research results disseminated to researchers.
  - CME programs for nurses and other health professionals that incorporate recent research findings.
  - Print and online patient education tools, including the MyHealthE Vet Web site, for dissemination to patients.
  - Point-of-service decision-support tools and reminders to clinicians within the VHA EHR system guiding practice toward the most effective treatment, including a Web portal for clinicians to access clinical practice guidelines.

- SAMHSA
  - National Registry of Evidence-based Programs and Practices (NREPP) and the Technical Assistance Centers can serve as translation vehicles. NREPP is a searchable online registry of approximately 140 mental health and substance abuse interventions and targeted outcomes; it provides quality of research and "readiness for dissemination" ratings.
  - The Addiction Technology Transfer Center (ATTC) Network is comprised of 14 Regional Centers and a national office which facilitates alliances among providers, administrators, and recovery and treatment communities, and connects them to the latest research and information through activities such as skills training, academic education, online and distance education, conferences, workshops, and publications.
  - The National Centers for the Application of Prevention Technologies (CAPT) work to bring research to practice by assisting States/Jurisdictions and community-based organizations in the application of the latest evidence-based knowledge to their substance abuse prevention programs, practices, and policies.
  - The SAMHSA Health Information Network (SHIN) provides a one-stop, quick access point that connects the behavioral health workforce and the general public with the latest information on the prevention and treatment of mental and substance abuse disorders.

- FDA
  - Web site provides news and other information to physicians and consumers on drugs, biologics, and devices.

- Office of Public Health and Science (OPHS)
  - Comprises 12 core public health offices and the Commissioned Corps, some of whom work with population and community-based networks to disseminate health information (e.g., Office of Disease Prevention and Health Promotion, Office of

Minority Health (OMH), Office on Women's Health). OMH, for example, has cooperative agreements and other partnerships to disseminate research findings (though not CER to date) to minority populations.

- Office of the National Coordinator for Health Information Technology (ONC)
  - Efforts to develop and implement a nationwide, interoperable health information technology infrastructure could provide a means for incorporating CER into decision-support systems for clinicians and other applications in health care.

- HRSA
  - Among multiple dissemination vehicles, the AIDS Education and Training Centers Program and the Ryan White HIV/AIDS Program support a network of 11 regional centers and more than 130 associated sites that conduct targeted, multidisciplinary education and training programs for health care providers treating people living with HIV/AIDS.
  - HRSA's Maternal and Child Health Bureau disseminates information using cooperative agreements with professional organizations and academic institutions, and funds grants for continuing education to academic centers across the country, specifically for the purpose of translating research into practice.

There is virtually no capacity to track the impact of CER dissemination, translation, and adoption activities. As a result, this limits the ability to measure the impact of CER and to conduct research on effective approaches. Claims databases could be one resource for tracking changes in practice over time and their impact.

Human and Scientific Capital

The future workforce engaged in CER should include experts from a wide array of disciplines, including biostatistics, epidemiology, mathematics, economics, and ethics. To date, however, there has been little focus on human and scientific capital infrastructure for CER. The principal exception is the close affiliation of certain AHRQ activities involving academic centers and other organizations, including the DEcIDE network, CERTs, EPCs, the Eisenberg Center, and various awards to researchers. AHRQ funding of DEcIDE network members and EPCs supports research trainees at those organizations. AHRQ also provides career development (K) grants focusing on generation of new scientific evidence and analytic tools that enable the prioritization of evidence-based services and goals for patients with multiple comorbidities.[28] In addition, AHRQ has sponsored other scientific and methodological activities, including development of methods guides, training seminars, and related events (e.g., at AcademyHealth and other professional conferences), and various workshops and support materials on MEPS, HCUP, and other data sets.

NIH provides significant training opportunities that could incorporate CER, including support for medical students interested in research, clinical fellowships, workshops for researchers, training grants, and consensus conferences. The CTSA program at NIH provides translational development support at academic and other research centers, some of which addresses evidence-

[28] http://grants.nih.gov/grants/guide/notice-files/NOT-HS-08-004.html.

based medicine approaches, if not CER in particular. The NIH K30 Clinical Research Curriculum Awards support training in design of clinical research projects, hypothesis development, biostatistics, epidemiology, disease mechanisms, medical technology, human genetics, and the legal, ethical, and regulatory issues related to clinical research.[29]

Although DoD has an extensive training and professional education infrastructure, it does not focus on CER.

A small number of training programs at academic centers focus on areas that address methodologies and study designs related to CER. Among these are the Clinical Research Training (CREST) program at Boston University, which provides training in clinical research that includes epidemiology, clinical epidemiology, health services research, biobehavioral research, and translational research,[30] and the Duke Clinical Research Training Program, which provides training in quantitative and methodological principles of clinical research, including research design, research management, medical genomics, and statistical analysis.[31]

Several agencies draw on the considerable scientific and methodological expertise resident in the FDA, but there is little emphasis on comparative effectiveness research at that agency. These informal links to scientific expertise could be formalized; also, specific CER expertise could be housed in selected agencies with an expectation of a cross-agency role. FDA expertise would be of exceptional value in, for example, understanding the respective merits of alternative study designs for assessing efficacy vs. effectiveness and for collecting and assessing adverse event data, strengths and limitations of using surrogate endpoints and other biomarkers in CER, incorporation of genomics and other aspects of personalized medicine into CER. Phase III and phase IV studies could also generate evidence on comparative effectiveness, as well as on other scientific and methodological aspects of CER.

Despite the promise of "practical" or "pragmatic" trials for CER, methodological gaps and threats to internal and external validity remain. Real world trials must deal with confounders, including confounding by indication and presence of comorbidities, selection bias, and other factors that impede the assessment of cause and effect. Focused research to improve the validity of practical trials and interpretation of their findings could enhance the use of these study designs.

Further development of mathematical modeling approaches and retrospective data analysis capabilities would also provide alternative means of analyzing comparative effectiveness, as well as generating viable research hypotheses and providing input for designing primary and secondary CER.

Gaps in the Current CER Landscape and Investment Opportunities

The inventories of CER and CER data and research infrastructure reveal gaps and other challenges for achieving the potential of comparative effectiveness research.

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[29] http://grants.nih.gov/training/K30.htm.
[30] http://www.bumc.bu.edu/clinepi/crest/general-info/
[31] http://crtp.mc.duke.edu/content.asp?page=about

Coordination across the CER framework: Substantial CER assets exist across the Federal Government, but coordination is necessary to capture their full value. Several challenges exist in achieving this:

- Prior to this report, there was no standardized Federal definition for CER; aligning organizations around this definition will be necessary for identifying, cataloging, and disseminating CER in a coordinated manner
- Difficulty in setting national CER priorities.
- Structural barriers that limit collaborations among agencies.
- Limited coordination with private sector CER efforts. This includes lack of integration of existing data sets across payers, suboptimal development of CER data infrastructure, an inability to track populations and treatments across payers, and suboptimal translation and adoption of CER findings.
- Unrealized benefits of stakeholder involvement. Greater involvement of stakeholders (e.g., patient advocates, health professionals, researchers, technology manufacturers, payers) in CER processes can help to achieve the goals of CER, including more informed priority setting, input on certain aspects of study design (e.g., identification of important subgroups and patient-centered outcomes), and identification of target audiences for CER and strategies to reach them.

Research: Despite the comparative effectiveness research to date, there are many unanswered questions.

- Those who sponsor and design clinical trials continue to face challenges in tradeoffs between internal validity of CER for causal effects of interventions on outcomes and external validity of CER to heterogeneous patient groups and routine health care settings.
- Increased emphasis on well-conducted pragmatic trials could increase acceptance of CER findings.
- May research questions for important clinical health care decisions remain unanswered

Human and scientific capital: Due in part to the increasing interest in comparative effectiveness research, continued investment in human and scientific capital for the field is needed.

- Greater investment is needed in developing education and training programs to support the development of professional talent, the development of methods for linking and using databases for CER, the development of new methodologies for pragmatic trials, effective translation and adoption of CER findings into practice, modeling approaches for CER, and evaluation of the impact of CER
- More methods work is needed to advance the state-of-the-art for pragmatic trials and to provide training for using these study designs.
- Recent growth in training for the related fields of health technology assessment, outcomes research, and health economics, among others, has helped to yield a cohort of researchers who are well-positioned to become more expert in CER, along with

educational curricula and materials that can be adapted for training in comparative effectiveness research.

CER Data Infrastructure: The scope and scale of CER requires data infrastructure that may outstrip current capabilities.

- Current data sources are fragmented and limited in terms of clinical robustness and longitudinal data capture.
- An evolving inventory of CER data infrastructure is needed to track the capacity of this infrastructure and provide a basis for its further development; this inventory should include observational databases, registries, claims and other administrative data, pharmacy and laboratory data, adverse events registries, EHR networks, and other health information technology.
- In addition to one or more inventories, greater understanding is needed regarding the strengths and limitations of these data sources, and areas for their further development. An example of a relevant resource is the 2007 *Registries for Evaluating Patient Outcomes: A User's Guide*, produced by the AHRQ's DEcIDE Research Center.
- Investment in linking such data sources is more likely to be realized by establishing clear information policies and technical standards, standardized terminology, improved platform capability, novel search algorithms, mechanisms to maintain patient privacy, and controls to access data, and by reducing and coordinating data processing times.[32]
- There are few searchable electronic inventories or related databases of CER and CER infrastructure. While sources like ClinicalTrials.gov, CRISP, MEDLINE, and HSRProj contain information about completed and ongoing CER, but they are not presently configured or linked to serve the needs of CER.
- Absence of an inventory of CER limits the ability to assess the magnitude and nature of the current portfolio of completed and ongoing CER, to identify CER on particular topics, and to inform priority-setting for CER.
- A comprehensive inventory of CER infrastructure would improve the ability to conduct CER and to allocate resources to develop the national capacity to conduct CER.

CER Dissemination and Translation: Many findings to date from CER have not yet been fully integrated into clinical practice or made accessible to patients in easy-to-understand language.

- Certain effective dissemination avenues are in place, including among some of the agencies engaged in CER. Except for AHRQ, however, these agencies are not yet oriented to CER and do not adequately extend beyond dissemination alone to translation and adoption of CER into practice.
- Tools and mechanisms to support clinicians and patients in incorporating available CER information are lacking. This information needs to be delivered to the front line of care where health decisions are made and results measured.

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[32] See, for example: Diamond CC, Mostashari F, Shirky C. Collecting and sharing data for population health: a new paradigm. Health Aff (Millwood) 2009;28(2):454-66.

Priority populations and other sub-groups: At present, the agencies have largely separate approaches to addressing these groups. A better-coordinated Federal approach is needed to address priority populations and priority conditions, including sub-groups with multiple chronic conditions.

- Greater attention on designing studies with sufficient power to discern treatment effects and other impacts of interventions among patient sub-groups (e.g. accounting for heterogeneity of treatment effects) will better serve clinical decision-making, enabling more individualized, patient-specific care.
- Improved partnerships with Federal grantees serving priority populations, such as Community Health Centers, will enhance their engagement with CER.
- Improved access to and utilization of Federally sponsored databases that include priority populations can significantly enhance the inclusion of sub-groups into CER.

Types of interventions: To date, CER has been disproportionately focused on pharmacologic treatments rather than the full spectrum of intervention types. This likely derives in part because of the relative emphases of the research agendas of agencies that sponsor CER and the focus of the private sector is primarily on new drugs and biologics. The emphasis on pharmacologic treatments has meant fewer resources for other interventions, including behavioral, procedures, prevention, and delivery system interventions, that can have major impacts on health outcomes.

VII. PRIORITY-SETTING PROCESS

The Council actively sought public input throughout this process, and this input significantly influenced all Council decisions. To help guide the Council's deliberations on the definition, framework, and priorities for comparative effectiveness research, the Council held three listening sessions and solicited additional public comments online. The Council heard from over 300 stakeholders representing health care associations; consumer, community, and advocacy organizations; academia and think tanks; patients; providers; hospitals and hospital systems; payers; pharmaceutical companies; foundations, public health entities; and private sector companies engaged in the health care field. One U.S. Senator also submitted comments.

Several respondents honed in directly on the reason why investments in CER are important. One person, for example, said that CER is crucial to reforming the practice of medicine to increase the quality, safety, value, and effectiveness of what providers bring to patients on a daily basis. Other respondents addressed a wide range of interrelated issues, including priorities for the research agenda, collaboration, infrastructure development, research methodology, transparency, care delivery, cost, and knowledge transfer. Many patients expressed their need for this type of research; one of the most emotional and moving testimonies came from the mother of a child with a seizure disorder in Chicago who had struggled to find the best treatment for her child. A physician from the American Board of Orthopedics summarized many physicians' testimony by saying, "developing high quality, objective information will improve informed patient choice, shared decision-making, and the clinical effectiveness of physician treatment recommendations."

The public input has been extremely valuable in informing the Council's deliberations, and many of the major thematic threads that run thought the public comments are reflected in the strategic framework, focus, and recommendations for priorities for OS CER funds. Details about what the public had to say are contained in Appendix A.

The Council also conducted a first draft inventory of CER and data infrastructure (outlined above) to help identify gaps in the current CER landscape. For the Office of Secretary funding recommendations, the Council proceeded through structured deliberations informed by public input, developed an inventory of current activities, established prioritization criteria and a strategic framework, and discussed the unique role for OS funds to fill gaps and build the foundation for future CER. In the future, the Council should continually and actively engage stakeholders inside and outside the government, including patients, providers, payers, employers, industry, academia, and others. This critical component of the priority-setting process could take the form of even more active participation by external stakeholders in the future.

VIII. PRIORITY RECOMMENDATIONS FOR OFFICE OF SECRETARY CER FUNDS

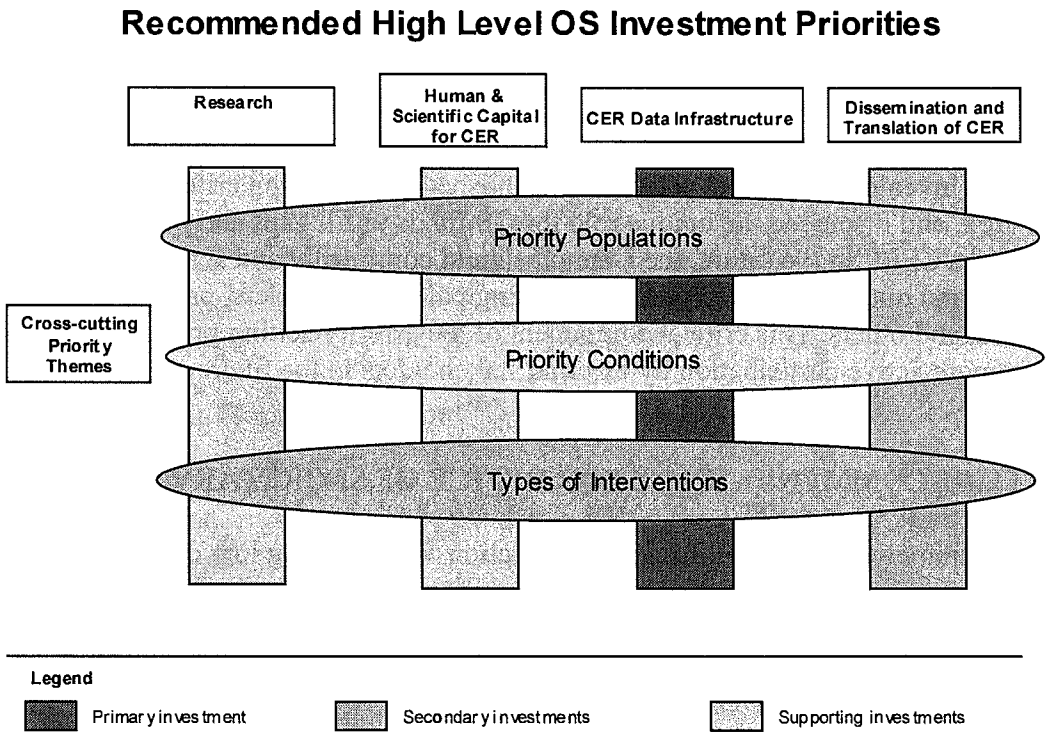
Using the strategic framework for CER discussed in Section V, and taking into consideration the unique role that OS funds can play in addressing high priority gaps, the Council developed a recommended high-level investment strategy for the use of the OS ARRA funds. The strategy has three different levels of priority recommendations for OS fund investments in the Core Activities and Cross-cutting Priority Themes in the CER framework (Figure 3).

- **Primary investment.** This area of investment should represent a large portion of the OS funds. It best fulfills the full range of prioritization criteria and requires scaled investment in order to be successful. The Council recommends that CER Data Infrastructure be the primary investment.

- **Secondary investments.** These areas should also receive significant investment. They are as critical to success in CER as the primary focus, but individually may require a smaller amount of funding to be successful. The Council recommends that Dissemination and Translation of CER, Priority Populations, and Priority Types of Intervention be secondary investments.

- **Supporting investments.** These areas should not be the major focus of OS funding as they do not fulfill the prioritization criteria as well as primary and secondary investments, but some funding may be necessary to support and enable investments in higher priority areas and fill identified gaps. The Council recommends that Human and Scientific Capital, Research, and Conditions receive supporting investments. It is important to note that these recommendations pertain only to OS funds; AHRQ, NIH, and VA have a history of significant investments in Research, Human and Scientific Capital, and Conditions.

Figure 3



The Council believes that this strategy and distribution of investments will best position the Secretary to:

- Respond to patient and physician demand for CER.
- Balance achieving near-term results with building longer-term opportunities.
- Capture the distinctive value of the Secretary's ARRA funds.

While it is the responsibility of the Office of the Secretary to operationalize this strategy, the Council's rationale for these recommendations is designed to help guide the Secretary in making specific investment decisions. The Council based its rationale for each level of investment in the strategy on the prioritization criteria described above, as well as representative examples of investment in each area proposed through the public comment process and by Federal agencies.

Primary investment

CER data infrastructure development is the most distinctive opportunity for OS ARRA funding. It requires a large, up-front infusion of capital to be successful that is unlikely to come from any source other than OS ARRA funds, making it ideal for this funding mechanism. It has broad potential impact, with the ability for resulting research to address conditions and populations captured in the primary data. Given the absence of comprehensive databases and data evaluation