U.S. Department of Veterans Affairs

Veterans Health Administration
VHA FOIA Office (105HIG)
810 Vermont Avenue NW
Washington, DC 20420

In Reply Refer To: **FOIA Request 21-05085-F**

07/06/2021

Sean Dunagan
Judicial Watch, Inc.
400 Scott Avenue
Fort Collins, CO, 80521

Dear Sean Dunagan:

This letter is the initial agency decision to your April 14, 2021, request under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, submitted to the Department of Veterans Affairs (VA), Veterans Health Administration (VHA) Central Office FOIA Office requesting the following records:

1. Any and all reports regarding, concerning, or related to any adverse reaction to any COVID-19 vaccine administered at any Department of Veterans Affairs medical facility. This request includes, but is not limited to, any such reports transmitted to the Vaccine Adverse Events Reporting System (VAERS).
2. Any and all policies, regulations, or other guidance documents regarding, concerning, or related to the reporting and/or tracking of adverse reactions to COVID-19 vaccines.

(Date Range for Record Search: From 1/1/2021 To 4/19/2021).

Referral:

As indicated in their April 15, 2021 letter, the VA FOIA Service referred your request to VHA Central Office FOIA Office for further processing and direct response to you under the FOIA tracking number of 21-05085-F. As stating in our April 16, 2021 letter acknowledging receipt, VHA FOIA Central Office FOIA received your request on April 15, 2021 under the above mentioned FOIA tracking number.

Fee Waiver:

On your April 15, 2021 request you had requested a fee waiver for search and duplication fees. 38 C.F.R. § 1.561(b)(7)) indicates that News Media request is not subject to search fees or review fees. News Media requests are subject to duplication fees after the first 100 pages. There are no duplication fees as this request is being sent electronically. Therefore, there are no fees assessed for this request. Please be advised, we reserve the right to assess fees as appropriate under the FOIA on any and all future FOIA requests.

Clarification:

Per my email to you on April 19, 2021; you were advised that clarification/further information was needed in order to be able to process your request. Specifically, a date range of when you are seeking the records was needed. On the same day, you responded to the request for clarification (date range needed) advising you are seeking the records January 01, 2021 to present (April 19, 2021).

Search:

Pharmacy Benefit Management (PBM) conducted a search for documents responsive to your request. The search was conducted by utilizing the search criteria of VA Adverse Drug Events Reporting System (VA-ADERS), COVID Vaccine guidance in Pharmacy Benefit Management databases and the VAERS database for the time period of January 01, 2021 to April 19, 2021.

Determination:

With respect to the portion of your request for: **"any such reports transmitted to the Vaccine Adverse Events Reporting System (VAERS),"** a search for this data has concluded. However, upon review, I have concluded the requested dataset must be withheld in its entirety under the disclosure protections of FOIA exemption 3, 5 U.S.C. § 552(b)(3) and FOIA exemption 6, 5 U.S.C.552(b)(6) as patient level data. Reports to the VA-ADERS are single entry/single patient reports.

FOIA Exemption 3, 5 U.S.C. § 552 (b)(3) specifically exempts from disclosure all information that another Federal statute protects from disclosure under FOIA. The applicable statute is 38 U.S.C. § 5701 which prohibits the disclosure of all files, reports, records, and other documents and papers that pertain to any claim filed under any laws administered by VA, as well as the names and home addresses of present or former members of the Armed Forces and their dependents (which includes VA beneficiaries and applicants for VA benefits). The requested patient-level data falls under the protections of 38 U.S.C. § 5701. Consequently, I am denying your request for this information under FOIA Exemption 3, 5 U.S.C. § 552 (b)(3).

Additionally, FOIA Exemption 6 permits VA to withhold a document or information within a document if disclosure of the information would constitute a clearly unwarranted invasion of a living individual's personal privacy. Stated another way, VA may withhold information under FOIA Exemption 6 where disclosure of the information, either by itself or in conjunction with other information available to either the public or the FOIA requester, would result in an unwarranted invasion of an individual's personal privacy without contributing significantly to the public's understanding of the activities of the federal government.

As patient-level statistical data, the individual to whom the data pertains has a significant privacy interest in its disclosure. We are unable to de-identify the patient-level statistical data you are requesting to a level that would prevent the re-identification of the individual to whom it pertains and to whose identity I am protecting under FOIA exemption 6.

Please note, Pharmacy Benefit Management (PBM) advised that VA adverse drug reporting to include all COVID-19 vaccine reactions are reported to the Food and Drug Administration (FDA) and the Center for Disease Control (CDC) via their FDA/CDC VAERS database. PBM advised that VAERS Data is available publicly on the Health and Human Services website at: VAERS - Data (hhs.gov).

For the remaining portions of your request, specifically:

- "Any and all policies, regulations, or other guidance documents regarding, concerning, or related to the reporting and/or tracking of adverse reactions to COVID-19 vaccines" and

- "Any and all policies, regulations, or other guidance documents regarding, concerning, or related to the reporting and/or tracking of adverse reactions to COVID-19 vaccines."

three (3) documents, totaling seventy-five pages, were determined to be responsive to your request.

My review of these documents revealed that they contained information that falls within the disclosure protections of FOIA Exemption 6, 5 U.S.C. § 552(b)(6). FOIA Exemption 6 permits VA to withhold a document or information contained within a document if disclosure of the information would constitute a clearly unwarranted invasion of a living individual's personal privacy. Stated another way, VA may withhold information under FOIA Exemption 6 where disclosure of the information, either by itself or in conjunction with other information available to either the public or the FOIA requester, would result in an unwarranted invasion of an individual's personal privacy without contributing significantly to the public's understanding of the activities of the federal government.

Specifically, the information I am withholding, as indicated on the enclosed documents, under FOIA Exemption 6 consists of: images of employee signature(s) and email address(es) as the individuals associated with this information have a personal privacy interest in it.

In United States Department of Justice v. Reporters committee for Freedom of the Press, 489 U.S. 749 (1989), we must determine if a privacy interest is involved, and determine if disclosure of the requested information would serve the public interest, and balance the personal privacy interest against the public interest. In evaluating the public interest in a given case, we must focus on the nature of the requested document and its relationship to the public interest generally. We must consider whether disclosure of the requested document, or portions thereof that have been withheld, would "open agency action to the light of public scrutiny" rather than focus on the particular purpose for which the document is being requested. See Reporters Committee, 489, U.S. at 772.

FOIA Exemption 6 "broadly exempts disclosure of all information that 'applies to a particular individual.'" *Schoenman v. FBI*, 575 F. Supp. 2d 136, 159 (D.D.C. 2008) (*quoting U.S. Dep't of State v. Washington Post Co.*, 456 U.S. 595, 602, 102 S. Ct. 1957 (1982)). As shown in *Reporters Comm. for Freedom of Press*, 489 U.S. 749, 775, 109 S. Ct. 1468, 103 L. Ed. 2d 774 (1989); *Bibles v. Or. Natural Desert Ass'n*, 519 U.S. 355, 355-56, 117 S. Ct. 795, 136 L. Ed. 2d 825 (1997) "Identifying relevant public interest as extent to which disclosure of the information sought would shed light on an agency's performance of its statutory duties or otherwise let citizens know what their government is up to." Releasing email addresses does not "open the agency action to the light of public scrutiny" or add to the public's understanding of agency operations (*Reporter's Committee*, 489 U.S. at 772.) Instead, the release of this information can lead to unwanted contact.

Regarding the withholding of signature/images of signatures, employees also have a personal privacy interest in their signature. Release of this information, especially in a public forum, could lead to fraudulent use/copying of their signature. See Wilson v. U.S. Air Force, No. 08-324, 2009 WL 4782120, at *4 (E.D. Ky. Dec. 9, 2009) finding: "signatures, personal phone numbers, personal email addresses, and government email addresses were properly redacted."

The coverage of FOIA Exemption 6 is absolute unless the FOIA requester can demonstrate a countervailing public interest in the requested information by demonstrating that the individual is in a position to provide the requested information to members of the general public and that the information requested contributes significantly to the public's understanding of the activities of the Federal government. Additionally, the requester must demonstrate how the public's need to understand the information significantly outweighs the privacy interest of the person to whom the information pertains. Upon consideration of the materials provided, I have not been able to identify a countervailing public interest of sufficient magnitude to outweigh the privacy interest in this case. The individuals associated with this information have a personal privacy interest in information that outweighs any public interest served by disclosure of their identities under FOIA. Consequently, I am denying your request for this information under FOIA Exemption 6, 5 U.S.C. § 552 (b)(6).

If you disagree with my determination to withhold the information under FOIA Exemption 3 and 6, please be advised you may appeal to:

Office of the General Counsel (024)
Department of Veterans Affairs
810 Vermont Avenue, N.W.
Washington, D.C. 20420
Email: ogcfoiaappeals@va.gov

If you should choose to file an appeal, your appeal must be postmarked or electronically transmitted no later than ninety (90) calendar days from the date of this

letter. Please include a copy of this letter with your written appeal and clearly state why you disagree with the determinations set forth in this response.

You may also seek assistance and/or dispute resolution services for any other aspect of your FOIA request, excluding the release determination, from VHA's FOIA Public Liaison and or Office of Government Information Services (OGIS) as provided below:

VHA FOIA Public Liaison:
Email Address: vhafoia2@va.gov
Phone Number: (877) 461-5038

Office of Government Information Services (OGIS)
Email: ogis@nara.gov
Fax: (202) 741-5769
Mailing address:
Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road
College Park, MD 20740-6001

Thank you for your interest in VA. If you have any further questions, please feel free to contact me at (785) 230-8430 or via email at stacy.ekis@va.gov.

Sincerely,

Stacy Ekis
VHA FOIA Officer

Enclosure:

Department of Veterans Affairs

Memorandum

Date: December 23, 2020

From: Assistant Under Secretary for Health for Operations (15)

Subj: Updated: Department of Veterans Affairs (VA) Guidance on COVID-19 Vaccine

To: Veterans Integrated Service Network (VISN) Directors (10N1-23)
VISN Chief Medical Officers
VISN Chief Nurse Officers
Medical Center Directors (00)

1. The purpose of this memorandum is to provide guidance on the U.S. Food and Drug Administration (FDA) authorized use of COVID-19 vaccines under an Emergency Use Authorization (EUA) for the prevention of SARS-CoV-2 infection and COVID-19 disease, and the Centers for Disease Control and Prevention (CDC) published recommendations for use. The guidance in this memorandum will provide information on the storage, handling, distribution, reporting, administration and training for each vaccine. In some cases, this information will be the same regardless of the vaccine (e.g. risk stratification, reporting), and in others, updated logistics, clinical protocols, trainings, and other guidance will be provided through the SharePoint sites below as vaccines are approved.

2. **National Distribution**:

   a. VA will be allocated a specific number of doses of each authorized vaccine. Given that these amounts are not anticipated to be sufficient to vaccinate all patients and staff initially, VA will follow the risk stratification framework included in Attachment A. Phase 1a is approved and final. Phases 1b and 1c are draft and will be finalized after CDC issues recommendations. The VA risk stratification framework can be also be accessed on the VA COVID-19 vaccine sharepoint at: https://dvagov.sharepoint.com/sites/vhacovidvaccine/SitePages/Vaccine-Policies-and-Clinical-Guidance.aspx. As the supply of vaccine increases, this framework will be implemented in the stages indicated. It is expected that VHA should have sufficient supply to offer vaccine to all who are interested in COVID-19 vaccination over the coming months.

   b. Distribution of vaccine to sites that have previously identified capacity to receive, store and administer the COVID-19 vaccine will be coordinated by VHA Pharmacy Benefits Management (PBM). Site distribution will be based on total allocation for VA, the number of employees and patients in the risk categories and orders previously placed and coordinated by PBM. Each site eligible for vaccine delivery will be given an individual site

allocation, and orders may only be placed at quantities at or below that allocation level. Orders from the field can be placed at the following link [https://dvagov.sharepoint.com/sites/VHAPBM/VA_MedSAFE/App/SitePages/COVID-Vaccine.aspx].

c. Both first and second doses of vaccine must be from the **same** manufacturer product and should be received in the **same** clinic location.

3. **Logistics and Scheduling:**

a. Logistics of vaccine delivery, storage, and dosing requirements for each authorized vaccine will be posted on the PBM Sharepoint: https://dvagov.sharepoint.com/sites/VHAPBM/VA_MedSAFE/App/SitePages/COVID-Vaccine.aspx

b. Appointments for second dose vaccination will be made at time of administration of the 1st dose. An immunization card must be provided with date, make and lot # of vaccine given and when 2nd dose is due, and will be provided in the ancillary supply kits supplied with each vaccine.

4. **Reporting:**

a. Administration data for COVID-19 vaccines must be reported electronically to CDC within twenty-four hours of administration. ***The reporting of required data elements will occur via national data extraction and transmission***. This will **require** that all facilities use the national COVID-19 vaccine clinical reminder dialog or dialog group for documentation of vaccines administered to Veteran patients and use the Occupational Health Recordkeeping System (OHRS) 2.0 for documentation of vaccines administered to VA employees.

i. Patients: The national clinical reminder dialog or dialog group for COVID-19 vaccines **must** be completed for **all** Veteran vaccinations (both outpatients and inpatients). Information on the National COVID-19 Clinical Reminder is posted here: COVID-19 Immunization Reminder page

ii. Staff: OHRS 2.0 for documentation of vaccines administered to VA employees. OHRS 2.0 will send the employee a reminder through Outlook mail for those requiring a second dose, but will not schedule the employee for a follow-up visit. Sites must develop a process for this per the guidance in the Assistant Under Secretary for Health for Operations (AUSHO) Memorandum: *Scheduling COVID-19 Employee Vaccination*, released on December 11, 2020. More

information on OHRS 2.0 is available through the AUSHO Memorandum *Coronavirus Disease 2019 (COVID-19) Vaccine Documentation Requirement for Veterans Health Administration (VHA) Employees and Health Care Personnel in the Occupational Health Recordkeeping System 2.0*, released on November 16, 2020 and information is posted on the OHRS 2.0 Training Home Page.

1. *NOTE: All COVID-19 vaccine Memos are posted here: https://dvagov.sharepoint.com/sites/vhacovidvaccine/SitePages/Vaccine-Policies-and-Clinical-Guidance.aspx*

iii. Supply and wastage must be reported to CDC daily. Documentation of vaccine supply, wastage spillage, and safety information will occur through PBM. More information is available here: https://dvagov.sharepoint.com/sites/VHAPBM/VA_MedSAFE/App/SitePages/COVID-Vaccine.aspx

iv. COVID-19 vaccine safety surveillance and enhanced Vaccine Adverse Event Reporting System (VAERS) reporting using the National Healthcare Safety Network (NHSN) sites will continue to be coordinated through PBM. More information is available here: https://dvagov.sharepoint.com/sites/VHAPBM/VA_MedSAFE/App/SitePages/COVID-Vaccine.aspx

5. **Administration:**

a. Please refer to AUSHO Memorandum: *VA COVID-19 Vaccine Administration for Vaccinators*, released on December 11, 2020, for specific guidance and procedures for eligible healthcare professionals (RNs, APRNs, PAs, LPN/LVNs, MDs, DOs, Pharmacists, and any already authorized Unlicensed Assistive Personnel, or UAPs) who may vaccinate adults for COVID-19.

i. NOTE: All COVID-19 vaccine Memos are posted here: https://dvagov.sharepoint.com/sites/vhacovidvaccine/SitePages/Vaccine-Policies-and-Clinical-Guidance.aspx

b. For sites currently using standing orders for vaccine administration, the sites may proceed with standing orders for vaccination by eligible staff.

c. Please refer to AUSHO Memo: *Updated COVID-19 Vaccination Documentation for Vaccinators* released on December 23, 2020 for specific guidance on documentation of vaccine administration in order to maintain

throughput and preserve personal protective equipment. An acceptable alternative would be for a second person to document vaccination at the point of care, as long as the following requirements are met:

i. The system supports a process with scribes and/or addendums. OHRS 2.0 does not currently have that functionality, but CPRS and CERNER do allow this.

ii. The person documenting vaccination is trained in proper documentation in the appropriate system (CPRS/CERNER) and is able to consistently meet all documentation needs as required by CDC.

iii. The person administering the vaccine is the responsible party for documentation and must review and sign the documentation before the end of the vaccinator's shift.

6. **Training and Education Materials:**

   a. Information regarding the mandatory training requirements for staff handling and administering the vaccine is located here: Training Link

   b. The COVID-19 Vaccine SharePoint Site provides a host of resources, including operational toolkits for planning, education and training materials, and scientific research. This site includes a Communications Toolkit providing products including frequently asked questions (FAQ) that have been approved for use to communicate and educate both internal and external audiences. Please check back regularly as the content is likely to change frequently as new information emerges.

7. Questions can be submitted to the COVID-19 Resource Room or send an email to (b)(6) @va.gov.

(b)(6)

Renee Oshinski

Attachment

Interim Guidance on Risk-Stratification for COVID-19 Vaccination in VHA

Version 1.1

Interim Risk-Stratification for COVID-19 Vaccination in VHA

VHA's recommendations on risk stratification, also called prioritization, are based on guidance from the independent Advisory Committee on Immunization Practices (ACIP), the Center for Disease Control and Prevention (CDC). This guidance is intended to maximize benefits of COVID-19 vaccine to Veterans and staff when initial supply is limited and help guide outreach and scheduling when supply is robust and larger scale vaccination becomes possible.

It is expected that VA sites will follow this general framework rather than creating separate guidance for each site, with the understanding that it will need customization to reflect local conditions and staff roles, and that flexibility may be needed initially when utilizing vaccines with time-sensitive storage and handling constraints.

CDC guidance comprises broad categories to maximize feasibility across all state and federal jurisdictions. The first groups to be offered vaccine COVID-19 (CDC phase 1a) include healthcare personnel and persons residing and working in long term care facilities, For healthcare personnel, this is based on risk of SARS-CoV-2 infection, risk of transmitting SARS-CoV-2 infection to patients, and public health and infrastructure risk if they are unable to work. Residents in long term care facilities are also among the first to be offered COVID-19 vaccine because they are at heightened risk of morbidity and mortality during the COVID-19 pandemic.

Following Phase 1a vaccination, ACIP voted on December 20, 2020 to offer vaccine to persons 75 years and older and persons who are essential frontline workers as Phase 1b. For Phase 1c, ACIP recommended including persons who are 65 and older, persons with high risk conditions as defined by CDC, and other essential workers. These recommendations were published as official CDC guidance on December 21, 2020 at:
https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e2.htm?s_cid=mm695152e2_x

While the population of enrolled Veterans who are essential workers is not known, more than half of our Veterans are aged 65 and older, and a large proportion of our Veterans have at least one high-risk condition. Because the number of Veterans expected to be offered COVID-19 vaccine during Phase 1 is so high, this group was further stratified by risk categories, to aid sites across VA in an ethical and equitable approach to offering COVID-19 vaccine. With our team of subject matter experts, including ethics, health equity, infectious diseases, infection prevention and control, preventive medicine, occupational health, pharmacy, public health, metrics and measurement, we reviewed risks to specific groups of staff and Veterans associated with COVID-19, and existing evidence and recommendations, to determine which groups should be offered COVID-19 vaccine first within broader categories, in order to maximize benefits to staff and Veterans.
Based on frameworks from the National Academies of Science, Engineering and Medicine (NASEM) (https://www.nationalacademies.org/our-work/a-framework-for-equitable-allocation-of-vaccine-for-the-novel-coronavirus) and discussions of the Advisory Committee on Immunization Practices (ACIP) for CDC (https://www.cdc.gov/vaccines/acip/meetings/index.html) we considered multiple contributors to overall risk, including:

- Risk of acquiring SARS-CoV-2 infection
- Risk of severe morbidity and mortality
- Risk of negative societal impact (risk of harm to society if that person is unable to work)
- Risk of transmitting SARS-CoV-2 infection to others

Note, these risk criteria are not listed in order of weight or importance.

Interim Risk Stratification Table Version 1.1

<table>
<tr><th>CDC-VA</th><th>Staff</th><th colspan="3">Veterans</th><th>Comments</th></tr>
<tr><td>A- 1a</td><td>CLC/SCID unit staff</td><td colspan="3">Veterans residing in VA CLC/SCID</td><td rowspan="20">Staff members not listed, including those who travel between units, should be offered COVID-19 vaccine with the group or unit most resembling their risk profile

For COVID-19 vaccines where rate of anticipated systemic side effects is high according to the applicable EUA fact sheet and/or CDC guidance, it is recommended that COVID-19 vaccination is staggered, so that the number of personnel in each unit receiving vaccine at a given time is low. This will limit absences related to response to the COVID-19 vaccine. Under this scenario, offering COVID-19 vaccine to any HCP would be appropriate, rather than offering sequentially by risk.

*this should comprise the smallest number of staff needed to continue operations, rather than all persons who hold a particular job or role, with intent of keeping the health care system functioning to care for Veterans and keep staff safe.</td></tr>
<tr><td>A- 1b</td><td>Emergency Department, EMT</td><td colspan="3" rowspan="3"></td></tr>
<tr><td>A- 1c</td><td>COVID-19 ICU staff</td></tr>
<tr><td>A- 1d</td><td>COVID-19 non-ICU inpatient staff</td></tr>
<tr><td>A- 1e</td><td>Other staff providing face-to-face care and services for COVID-19 patients</td><td colspan="3"></td></tr>
<tr><td>A- 1f</td><td>Staff in other congregate living settings</td><td colspan="3">Veterans residing in other long term/congregate settings without access to COVID-19 vaccine.</td></tr>
<tr><td>A- 2a</td><td>Core staff critical to function of the hospital and the COVID-19 response (e.g., logistics, facilities operations, police, food services, occupational health, infection control, environmental engineering, limited executive or leadership roles) *</td><td colspan="3" rowspan="11">ACIP (CDC) Phases
1a = Blue
(HCP, LTCF)
1b = Green
(Essential Workers, 75 and older)
1c = Brown
(65-74; high-risk conditions)</td></tr>
<tr><td>A- 2b</td><td>Inpatient staff, non-COVID-19 units</td></tr>
<tr><td>A- 2c</td><td>Staff performing high risk procedures (non-COVID-19, pre-screened)</td></tr>
<tr><td>A- 3a</td><td>Hemodialysis staff</td></tr>
<tr><td>A- 3b</td><td>Oncology/chemotherapy unit staff</td></tr>
<tr><td>A- 4a</td><td>Homeless Outreach staff</td></tr>
<tr><td>A- 4b</td><td>Staff with frequent contact with Veterans who have not been pre-screened for COVID-19 symptoms (screeners, drivers, etc.)</td></tr>
<tr><td>A- 4c</td><td>Outpatient direct care/contact (pre-screened, non-COVID-19)</td></tr>
<tr><td>A- 4d</td><td>Other health care personnel and staff</td></tr>
<tr><td>B- 1a</td><td></td><td>Veterans age 75+</td><td>Homeless Veterans, Hemodialysis patients, Solid Organ Transplant patients or patients who are listed for transplant, and Chemotherapy patients (receiving chemotherapy in a clinic/hospital setting)</td><td>Frontline Essential Workers as defined by CDC</td></tr>
<tr><td>C- 1a</td><td rowspan="3">Other VA services, non-health care</td><td colspan="2">Veterans age 65-74</td><td rowspan="2">Other Essential Workers, as defined by CDC</td></tr>
<tr><td>C- 1b</td><td colspan="2">Veterans younger than 65 with high-risk conditions as defined by CDC</td></tr>
<tr><td>C- 1c</td><td colspan="3">Veterans younger than 65</td></tr>
</table>

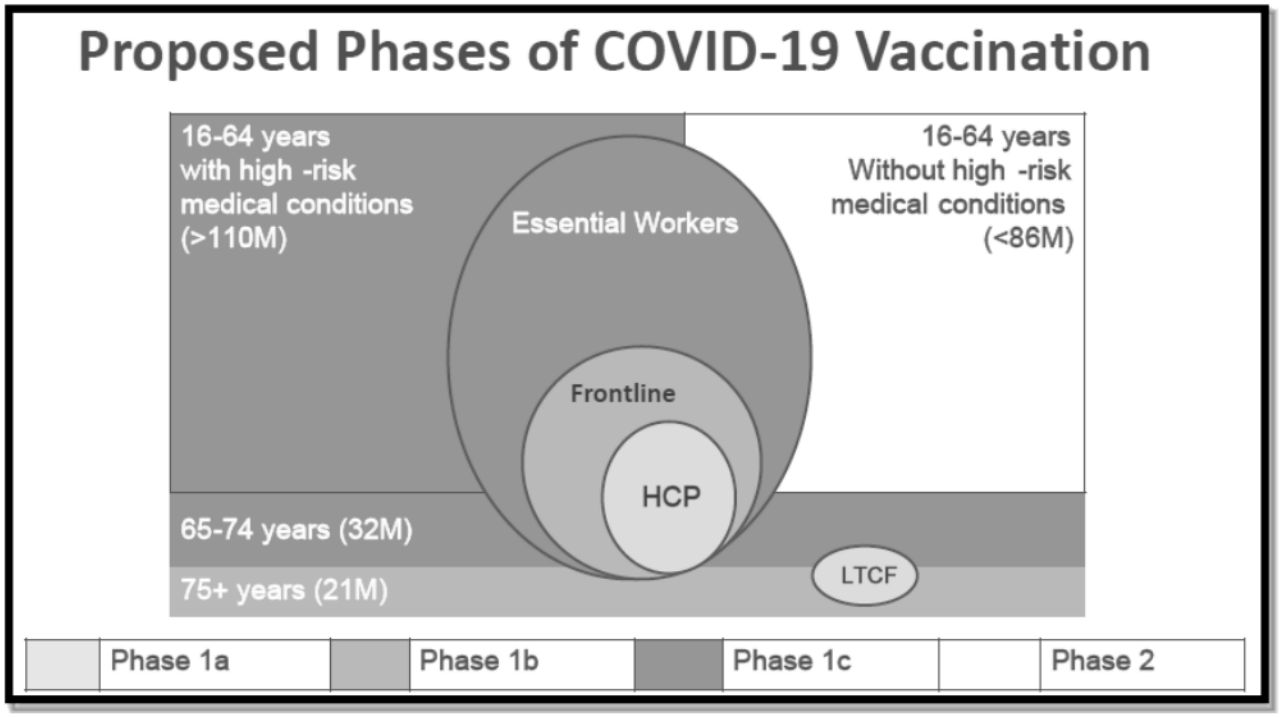
Appendix A: Population Enumeration

Note: this list does NOT contain all conditions that may be on the list of high-risk conditions as defined by CDC. This is because that list is being continually updated. This list may help guide planning, but should not be considered a recommendation for which groups to invite for vaccination. The high-risk conditions as defined by CDC should be used to guide invitation for vaccination.

Category	Estimated Population Size	%
Employees		
Department of Veterans Affairs (Total)	418,688	
Veterans Health Administration (Total)	373,435	
HCP	247,239	
Essential	41,259	
Others	84,937	
Volunteers	61,420	
Trainees	124,190	
Veterans		
Enrolled Veterans (total)	10,075,834	
Age 85 and older	832,973	8%
Age 75-84	1,483,666	15%
Age 65-74	2,675,315	27%
≥65	4,991,954	50%
Veterans Receiving Care	5,821,113	-
≥65	3,063,682	52.6%
High Risk Medical Conditions Please use the CDC high-risk conditions list for vaccination decisions.		
Cancer	544,149	9.3%
Chronic Kidney Disease	339,435	5.8%
COPD	439,287	7.5%
Obesity (BMI of 30 or greater)	2,278,608	39.1%
Cardiovascular disease	2,709,759	46.6%
Sickle cell disease	2,998	0.1%
Type 2 diabetes mellitus	1,556,431	26.7%
Homeless	242,297	
Nursing Home	9998	0.1%
Other congregate settings	2279	0.04%
Rural	1,992,232	34.2%
Veterans with disability (100%)	847,580	14.5%
Veterans with significant disabilities	291,348	5.0%
Home based primary care	144,447	2.5%

Appendix B: ACIP/CDC Phases of Vaccination

This graphic is from the 12/20/20 meeting of the independent Advisory Committee on Immunization Practice (ACIP).



CDC recommends offering vaccine in phases when supply of vaccine is limited initially.

Phase 1a includes healthcare personnel and residents in long term care facilities, was approved by ACIP 12/1/2020, and is now official CDC guidance. ACIP voted on Phases 1b and 1c on 12/20/2020. Phase 1b includes adults 75 and older and frontline essential workers, and Phase 1c includes adults 65-74 and adults 16-64 with high-risk medical conditions. Phases 1b and 1c were published as official CDC guidance on December 22, 2020, available at: **https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e2.htm?s_cid=mm695152e2_x**

Frontline Essential Workers:

ACIP classified the following non–health care essential workers as frontline workers:

- first responders (e.g., firefighters and police officers)
- corrections officers
- food and agricultural workers
- U.S. Postal Service workers
- manufacturing workers
- grocery store workers, public transit workers
- those who work in the education sector (teachers and support staff members)
- childcare workers

Other Essential Workers: Essential worker sectors recommended for vaccination in Phase 1c include those in transportation and logistics, water and wastewater, food service, shelter and

housing (e.g., construction), finance (e.g., bank tellers), information technology and communications, energy, legal, media, public safety (e.g., engineers), and public health workers

https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e2.htm?s_cid=mm695152e2_x

https://www.cdc.gov/mmwr/volumes/69/wr/mm6949e1.htm?s_cid=mm6949e1_w

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-20/02-COVID-Dooling.pdf

CDC uses Cybersecurity & Infrastructure Security Agency definitions for essential workers and noted that this comprises about 87 million persons in the United States.

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-20/02-COVID-Dooling.pdf

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations-process.html

Appendix C: Differences between CDC and VHA guidance

VHA guidance closely follows guidance from CDC with a few branch points that are in keeping with the general CDC framework.

- CDC guidance states: "State and local health authorities will need to take local COVID-19 epidemiology and demand for vaccine into account when deciding to proceed to the next phase or to sub prioritize within an allocation phase if necessary." https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e2.htm?s_cid=mm695152e2_x

1. The first exception is that VHA includes a small subgroup of Veterans that may be younger than age 75 in Phase 1b, because they fall into several categories of risk.
   - This includes Veterans who are homeless, Veterans with Solid Organ Transplant, with particular emphasis on the peri-transplant period, and Veterans who are treated with hemodialysis or chemotherapy in a hospital or clinic setting.
   - These groups are not only at elevated risk for morbidity or mortality from COVID-19 disease, but also have an additional exposure/transmission risk, which is of particular importance during surges of SARS-CoV-2 infection.
     - For homeless Veterans, there is increased risk of needing to be in congregate living settings/shelters, particularly during the upcoming winter months.
     - For Veterans receiving in-facility chemotherapy or hemodialysis, they will be present in a hospital or clinic setting, generally shared with other high risk Veterans, on a regular basis, which means increased risk of exposure to infection or of passing it to others who are also at high risk.
     - For Veterans in the peri-transplant period for solid organ transplant, there is not only a very high morbidity and mortality associated with COVID-19 disease, but there is also a planned period of profound immunosuppression and hospitalization in the post-transplant period. Ideally, this group would be offered COVID-19 in the pre-transplant period, when immune response to vaccine might be greatest, and prior to planned hospitalization, surgery, and intensive care unit stay.
2. The second branch-point is a sub-stratification in CDC Phase 1c.
   - CDC Phase 1c includes persons who are 65 and older, and persons with high-risk conditions. VHA sub-stratifies this into persons 65 and older, followed by younger persons with a high-risk condition.
     - Note that in
     - Evidence specific to our Veteran population suggests that age has a greater influence on COVID-19-related mortality than even presence of multiple high-risk conditions
     - A very large proportion of the Veterans served in VA have high-risk conditions and/or are aged 65 or older, making CDC Phase 1c a very large population

CDC guidance is available here:

https://www.cdc.gov/mmwr/volumes/69/wr/mm6949e1.htm?s_cid=mm6949e1_w

https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e2.htm?s_cid=mm695152e2_x

Appendix D: Using the risk-stratification (prioritization) table

Using the risk-stratification framework: Groups of staff not specified

Note: risk stratification assumes sites are following infection control guidance on personal protective equipment and screening measures.

This table includes only categories of staff and units with predictable exposure risks across VA; others, such as food service workers, environmental management, IT, radiology and engineering, are not specifically assigned because exposure and risk patterns varies significantly from site to site.

It is expected that all staff will be accounted for in your local COVID-19 vaccine plan. Because of variation in assignments and movement patterns from site to site, local determination must be made based on local patterns of movement and exposure.

For each subset of staff that are not directly mentioned in this framework, the three major risk-based criteria that form the basis for prioritizing healthcare personnel vaccination should be compared to those of the units listed (risk of acquiring SARS-CoV-2 infection, risk of transmitting SARS-CoV-2 infection to others, and societal/hospital impact if unable to work). Staff members should be offered vaccine along with the group or unit most resembling their risk profile. For example, Home Based Primary Care providers who care for COVID-19 patients may fall under "Other staff providing face-to-face care for COVID-19 patients"; those who perform high risk procedures in the home but do not care for COVID-19 patients may fall under "Staff performing high risk procedures"; and those who perform general outpatient care of patients without COVID would fall under "Outpatient direct care". Similarly, food service workers may be offered vaccine along with the COVID+ units if they spend significant time interacting with patients in that setting. See additional examples at the end of this section.

Staff who do not interact with patients at all may be considered essential personnel depending on their role. Some staff may also be considered to be "core staff critical to the function of the hospital and the COVID-19 response" even if their role is virtual, but caution must be taken to ensure that front line staff at highest risk for exposure to COVID-19 are at the forefront, and this exception should be used judiciously. See additional examples at end of this section.

Using the priority framework: Progressing through phases

The intent of the framework is to collaborate in the public health response to the COVID-19 pandemic and follow the national COVID-19 vaccine framework per CDC guidance to maximize benefit when vaccine quantities are limited. It is important to note that CDC recommends local flexibility in determining when to progress from one phase to the next: "State and local health authorities will need to take local COVID-19 epidemiology and demand for vaccine into account when deciding to proceed to the next phase or to sub prioritize within an allocation phase if necessary."
https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e2.htm?s_cid=mm695152e2_x
It is expected that there will be some overlap between phases as vaccine is offered.

Using the priority framework: Age stratification and Risk stratification

The relative effects of comorbid 'high-risk' conditions on overall COVID-19 risk are attenuated in older age groups (because of the high level of risk associated with increasing age). The role of high-risk conditions as defined by CDC and membership in certain high-risk racial or ethnic

minority groups becomes increasingly important in younger age groups, as overall risk decreases. The expectation is that VA will have ample availability of COVID-19 vaccine within Phase 1c, and it is for this reason that risk groups are addressed as a priority for outreach but are not tightly stratified.

If vaccine supply remains limited during phase 1c, use of the Veteran Outreach Tool allows sub-stratification by number of high-risk conditions as defined by CDC. Veterans may be further stratified based on presence of 5+ high-risk conditions, 4+ high-risk conditions.

Outreach and education to ensure that we communicate with and promote access for Veterans in high-risk racial and ethnic minority groups and Veterans with high-risk medical conditions must be a focus of COVID-19 vaccination planning at all sites.

Using the risk-stratification framework: Flexibility of the framework

- **Flexibility for Staff**
  As above, it is expected that this framework will be followed to ensure that benefits to staff and Veterans are maximized during periods of limited vaccine supply and that vaccine is offered in a way that is ethical and equitable. However, local flexibility is needed in assigning staff not specifically mentioned, as noted under “Groups of staff not specified”. Additionally, significant flexibility may be needed for feasibility of use with vaccine products requiring ultra-cold storage methods. While it is expected that general principles of this framework will be followed, it is possible that additional staff or Veterans who are not in the highest risk groups may need to be included in several scenarios, including if: interest in initial vaccine is low (i.e., vaccine hesitancy); there are cancellations among scheduled staff or Veterans and a waitlist must be utilized to avoid wasting vaccine; or significant side effects from vaccine are expected (e.g., it may be preferable not to vaccinate entire units of staff simultaneously if potentially work-curtailing side effect from vaccination are common, as this would jeopardize ability to work, and potentially affect safety of other staff and Veterans).

- **Flexibility for Veterans**
  It is expected that this framework will be followed when offering COVID-19 vaccine to Veterans to ensure equitable vaccination across VA. While it is expected that general principles of this framework will be followed, it is possible that additional staff or Veterans who are not in the highest risk groups may need to be included in several scenarios, including if: interest in initial vaccine is low (i.e., vaccine hesitancy); there are cancellations among scheduled staff or Veterans and a waitlist must be utilized to avoid wasting vaccine; or significant side effects from vaccine are expected (e.g., it may be preferable not to vaccinate entire units of staff simultaneously if potentially work-curtailing side effect from vaccination are common, as this would jeopardize ability to work, and potentially affect safety of other staff and Veterans).
  For the first dose in the vaccine series, it is not expected that COVID-19 vaccines be held if there is delay among Veterans in the highest risk groups in returning calls and mailings for scheduling, and it is reasonable to continue on to next priority groups as long as reasonable attempts have been made to reach and schedule Veterans in the higher risk group.

Using the priority framework: sub-stratification
If vaccine supply does not cover the size of a population group in the risk stratification table, consider further stratifying by age, as risk rises significantly with increased age. For example, could start with persons 85 and older if there is insufficient vaccine for all persons 75 and older. Can further stratify by high risk conditions, as defined by CDC, by using the Veterans Outreach tool, which will allow sorting by number of high-risk conditions.

Using the priority framework: staff and Veterans who opt out for the first vaccine
For staff and Veterans who opt out of receiving the first COVID-19 vaccine but are in a priority group to vaccinate early, they should still be eligible to receive COVID-19 vaccine later even if unwilling or unable to receive COVID-19 vaccine initially, unless they have changed jobs/roles and no longer meet criteria for prioritization. These staff and/or Veterans should be considered and scheduled along with whichever priority group is prioritized for COVID-19 vaccine at the time they 'opt in' but should not be allowed to take the place of another Veteran that has already been scheduled for COVID-19 vaccination. There is possibility of delays in scheduling due to high demand or limited quantity of COVID-19 vaccine.

Using the priority framework: COVID-19 vaccine requirements.
Being in a high priority group for COVID-19 vaccination means that COVID-19 vaccine should be offered. ***However, COVID-19 vaccination will not be required while a vaccine is available under an Emergency Use Authorization.*** Many healthcare personnel are at risk for SARS-CoV-2 infection, and may also transmit SARS-CoV-2 to others, including patients who may be at high-risk for severe COVID-19 disease if they become infected. For this reason, healthcare personnel will be encouraged to get vaccinated to lower risks to themselves, colleagues, and their patients.

Assignments and Personal Protective Equipment: Decision to accept or refuse COVID-19 vaccine

Veterans and staff should continue to follow infection control recommendations regardless of COVID-19 vaccination status, including masking for source control and distancing. Staff should not be assigned differently based on their decision to accept or decline vaccine, as this may create incentives to either receive or decline vaccination.

Additional Examples:

There is some degree of risk associated with any in-person work during the COVID-19 pandemic and the goal is to eventually offer COVID-19 vaccine to all staff. While supply of COVID-19 vaccine is limited, it must first be offered to those with highest risk of exposure to COVID-19 in the workplace, those caring for the most vulnerable patients, and those critical to continued ability to maintain operations, care for Veterans, and keep staff safe. This list is not inclusive of all occupations and is meant to provide examples to guide decision making at the facility level.

CLC – to start with a unit listed, it is expected that all staff performing roles on this unit where they will be interacting closely with Veterans and other unit staff will be offered vaccination with

the unit. This may include, for example, nurses, physicians, technicians drawing blood, other unit-based personnel.

Food Services –personnel should be prioritized based on with whom they interact, which determines their risk of COVID exposure in the workplace. If frequent close contact* with COVID-positive patients is expected, it may be most appropriate to offer those staff vaccine along with staff in those units. If they do not enter rooms on those units, it may be more appropriate to offer vaccine with non-COVID inpatient or outpatient staff, depending on pattern of service.

Environmental Management Services –should be considered similarly to food services, based on units in which service is provided.

Nursing staff who work in multiple units – nursing staff working across multiple units should be offered vaccine with the highest risk unit in which they are assigned.

Scheduling staff – when to offer vaccine to scheduling staff will depend on the environment in which they work. If they have direct contact with Veterans, they should be assigned according to whether that includes close contact with COVID positive, unscreened, or pre-screened Veterans.

Van Drivers – van drivers interacting with Veterans who have been pre-screened as with hospital entry may be considered at similar risk to outpatient non-COVID clinics, provided they have the same personal protective equipment (PPE). If Veterans have not been pre-screened, it would be most reasonable to consider them along with persons who interact with Veterans who have not been pre-screened.

Entry Screeners – entry screeners for hospitals and clinics may have close contact with persons who have not been pre-screened for COVID signs and symptoms.

Vaccination Providers – risk should be considered based on screening processes and likelihood of close contact with persons who are COVID positive, in comparison to units listed.

Anesthesiology – risk should be considered based on whether services are performed on COVID-positive patients (similar risk to COVID ICU personnel), pre-screened patients only (risk similar to those performing high-risk procedures) or include roles such as functioning on a cross-cutting code team (risk similar to the staff in the highest-risk unit that the code team serves).

Gastroenterology – this is an example of a specialty where some may be performing high risk procedures, some on COVID-positive patients (similar risk to COVID unit personnel), some on pre-screened patients (similar risk to those performing high risk procedures) while others may provide virtual care only (offered vaccine after it has been offered to staff providing in-person care). Risk stratification should align with services provided.

Home Based Primary Care – risk will depend on whether care is provided for COVID-positive patients, whether high-risk procedures are performed, and on symptom screening processes.

Support staff on site, no patient contact –staff will need to be considered based on risk. Limited personnel may be considered as critical to operations, while most would be offered vaccine after all Veteran/patient-facing staff have been offered.

VA Central Office Employees – these staff are expected to be offered vaccine after healthcare personnel, with limited exceptions for those persons critical to maintain operations or critical to the COVID response.

Staff working virtually – these staff would be considered after staff providing in-person care. There may be limited exceptions to keep a minimum core of staff for ongoing care of Veterans.

* definition of close contact should follow CDC definitions.

Appendix E: Ethical Justifications for COVID-19 Vaccine Allocation in a Situation of Scarcity

VHA's National Center for Ethics in Health Care

When allocating a scarce health care resource, such as a vaccine, VA health care leaders and experts must develop an ethically justifiable plan or framework for how to allocate the resource. When vaccines against SARS-Cov-2, the virus that causes COVID-19, first become available, there will be a limited supply of doses, requiring a fair plan to determine who will receive the vaccine first. If we only have 100 doses of a vaccine, and 1000 people need to be vaccinated, selecting who should receive the vaccine will depend on several factors. Are the individuals being considered for COVID-19 vaccination similar to those on whom safety and efficacy of the vaccine has been demonstrated? Will targeting the COVID-19 vaccine to these individuals or groups better stop the spread of the virus? What are practical methods for vaccine administration? Unfortunately, there are many unknowns related to COVID-19 that challenge the ability to unequivocally predict which vaccine allocation framework will provide the most benefit and avoid the most harm to individuals and society. However, VA has developed an ethically defensible approach to vaccine allocation that has been informed by a wide range of subject matter experts.

In the very early phase of vaccine availability, the goal will be to select only individuals meeting certain scientific and ethical criteria to vaccinate so that benefit to Veterans and VA staff is maximized, and everyone is treated with equal respect. As more vaccine becomes available, the goal will be to expand outreach so that the greatest number of Veterans and VA staff will be vaccinated to achieve community immunity (also referred to as "herd immunity") from COVID-19. Below, we expand on the ethical justifications for the VA's proposed allocation plan. This includes maximizing benefit to Veterans, treating people with equal concern (meaning attributing the same worth to all individuals regardless of their vaccine allocation priority), and addressing health inequities as they relate to vaccination.

Maximizing benefit

The ethical principle of utility involves seeking the greatest good for the greatest number of people—that is, maximizing benefit to society. Assuming that an FDA authorized or licensed vaccine mounts a sufficient immune response against the SARS-CoV-2 virus, three categories of benefit may be achieved: (1) sparing infection, illness, and death from COVID-19 in vaccinated individuals; (2) not spreading the virus; and (3) allowing vaccinated individuals to continue serving as essential workers. In the early phase of COVID-19 vaccine deployment, when there is more demand than supply, benefit is maximized by vaccinating individuals for whom all three categories of benefit can be achieved. Because COVID-19 spreads fastest in areas where there are people in close quarters and harms are greatest for those who are vulnerable to becoming seriously ill (e.g., elderly people with multiple medical conditions), prioritizing health care workers who care for such individuals will mitigate the spread of the virus to the patients in their care. COVID-19 vaccination would thus begin with the staff of community living centers (CLCs) and spinal cord injury and disorder (SCID) facilities, followed by vaccinating patients in these facilities. This is justified because the patients there are at higher risk of contracting COVID-19 and suffering severe or fatal outcomes. In a modeling study from

CDC, vaccinating staff first was likely to more effectively halt viral contagion in such facilities. This is because staff interact with a greater number of individuals and can more easily spread the virus, especially when infected with SARS-CoV-2 but showing no symptoms of COVID-19. Also, staff (being generally younger and healthier) may more effectively mount an immune response as a result of receiving the COVID-19 vaccine.

The categories of persons allocated to receive the vaccine next represent evaluations, in decreasing order of priority, of which VA staff and Veterans are most likely to transmit SARS-CoV-2to others, be removed from critical professional functions, and/or are most at risk of contracting SARS-CoV-2 and suffering serious or fatal illness. The latter (individuals at highest risk of suffering serious or fatal illness) are those with advancing age and presence of comorbid conditions such as asthma, kidney disease, diabetes, high blood pressure, and obesity. As more becomes known about COVID-19, adjustments may be made to these allocation phases to achieve maximum benefit to the most people from the vaccine allocation framework.

It is important that Veterans and VA staff maintain trust in VA's plan for COVID-19 vaccine allocation. Allocation decisions should be based on the principles outlined here and not on arbitrary factors or individual favoritism or perceived social worth. For example, if COVID-19 vaccine is dispatched to a CLC facility and all CLC staff with direct patient contact are eligible to be vaccinated, all such staff should have an equal opportunity to be selected for vaccination, rather than using an ad hoc process. Effectively informing COVID-19 vaccine-eligible individuals of the risks and benefits of the candidate vaccine and establishing a fair and transparent process for selecting which individuals to vaccinate is essential. All communication should be truthful and respectful to earn, secure, and maintain trust in the COVID-19 vaccination program.

Independent of the COVID-19 vaccine allocation protocol, vaccine acceptance will be critical for any vaccine program because to achieve community immunity, most VA Veterans and staff will need to be vaccinated against COVID-19. A recommended approach is to provide tailored education to individuals on both the benefits (both to them individually and to society) and burdens of and concerns with accepting the vaccine and to appeal to altruism and solidarity in achieving vaccine acceptance. Special efforts are necessary to minimize the number of vaccine non-adopters, a term encompassing individual hesitant to accept vaccine (due to lack of information, misinformation, or emotional ambivalence) as well as individuals refusing vaccine (Su et al., 2020). Wilson and Wiysonge (2020) demonstrated a correlation between misinformation spread through false news outlets and social media and vaccine non-adoption. This underscores the importance of effective messaging and education.

There are limits to what is justifiable in the interest of maximizing societal benefit. For example, quarantine of individuals who test positive for COVID-19 has been voluntary to date. However, as stated in VHA's *Ethics Guidance for Pandemics,* 2020, "individual liberties may be limited to prevent harm to others; public health measures are established on this basis." Because individual liberty is highly valued, the notion of using the least restrictive means is critical in promoting COVID-19 vaccine acceptance among Veterans and VA staff. Mandating vaccination either when COVID-19 vaccines are first released or later is a matter for discussion; no decision has been made thus far. A COVID-19 vaccine mandate might be justified if a proven safe and effective vaccine is the least restrictive means to prevent serious harm to others and no alternative is available. This evokes the concept of proportionality, which involves weighing risks, benefits, and alternatives.

Criteria to mandate COVID-19 vaccine will not likely be met in the early vaccination program, since COVID-19 vaccines will initially only be available under emergency use authorization (EUA). An EUA is a mechanism through which the U.S. Food and Drug Administration (FDA) may facilitate the availability and use of certain unapproved medical countermeasures, including vaccines, during public health emergencies. Under an EUA, FDA may allow the use of an unapproved medical product, or unapproved uses of approved medical products, in an emergency when certain statutory criteria have been met. FDA has stated that, for a COVID-19 vaccine for which there is adequate manufacturing information, FDA may issue an EUA if FDA determines that the vaccine's benefits outweigh its risks based on data from at least one well-designed Phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner. EUA criteria include that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition, that the known and potential benefits of the vaccine outweigh its known and potential risks, and there are no adequate, approved, and available alternatives (FDA, 2017).

Treating people with equal concern

Fairness does not require treating everyone exactly alike. For example, an elderly individual residing in a CLC rightly warrants getting vaccinated earlier than a younger, healthy person living at home because the elderly individual's risk of serious illness and death is greater. This does not mean that the elderly individual is considered more valuable, rather, he or she has greater need to be protected from the virus. Fairness in this context involves giving opportunity of access based on need. Every individual, however, is equally valued and thus should be treated with equal concern. Discharging this ethical duty involves providing consistent, respectful, and accurate communication to earn, secure, and maintain Veterans' and VA staff's trust in the COVID-19 vaccination program.

This duty to show equal concern and respect for all persons likewise disallows deprioritizing older adults for COVID-19 vaccine allocation on a utilitarian basis. For example, some have reasoned that because the mortality rate from COVID-19 is five times higher for individuals 80 years of age and older and that such individuals have limited remaining life years left, this would justify allocating resources to younger individuals with better prognoses and more years of life to enjoy. However, Veterans are older on average than the general population (over 50% of Veterans in VA care are 65 years and older) and denying older Veterans priority access to a potentially lifesaving or disease-sparing vaccine is inconsistent with VA values. Instead, VA's COVID-19 vaccine allocation plan *prioritizes* older Veterans because of their vulnerability to the disease. This is based on an assessment of their need (i.e., sparing disease and contagion) and equal regard for their worth.

Addressing health inequities

National U.S. data show that COVID-19 has disproportionately affected persons of color (Kopel et al. 2020). This is attributed to social injustices that create a higher disease burden and shorter lifespan in this population (Ajilore & Thames 2020). Geronimus (1992) attributed this partly to the concept of "weathering," that lifelong exposure to the stresses of racial disparity and injustice manifests in greater physical and psychological disease burden and less ready access to quality health care and health-related resources. In addition, persons of color are more likely to work and live in settings with higher exposure to SARS-CoV-2. That is, merely being Black or Hispanic or Native American does not cause one to more easily contract SARS-CoV-2. Rather,

the lifetime social disadvantages experienced by persons of color make them more likely to have health problems that predispose them to contract SARS-CoV-2and more often suffer serious or fatal outcomes. Thus, these individuals, along with others who are at risk for suffering serious or fatal illness due to the presence of comorbidities, will be prioritized for COVID-19 vaccine per the allocation plan as a consequence of risk factors.

There is widespread consensus that more must be done to rectify health disparities upstream through improved access to quality education, preventive health care, economic and job opportunities, safe housing and healthy food, reduced exposure to crime and violence, and public safety (CDC, n.d.). The VA plays a role here in its provision of high-quality health care to Veterans. Another way to address health disparities is to reach out effectively to communities of color and others who have been socially disadvantaged to engage them in the vaccination process. Active efforts must be made to address concerns about vaccine safety and fairness in the allocation process. Outreach efforts should engage community champions to ensure that communications are culturally congruent and transparent and remove access obstacles that might thwart individuals who are eligible for vaccine from getting it.

Other duties to address health inequities include ensuring that individuals with disabilities have unimpeded access to vaccine when they are eligible as per the allocation plan. This involves anticipating and removing access barriers by accommodating persons who are blind or have low vision, deaf, or hard of hearing, and cognitively or physically impaired, in communications and logistics for vaccine administration. For example, messaging should be available in plain language and in multiple formats, such as audio, large print, and captioning, and websites or health alerts should provide accessible information.

SUMMARY

Ensuring trust in vaccine allocation decisions requires using objective criteria to justify these decisions with a clear explanation of their ethical basis and applying criteria equally across settings. These ethical criteria are described above. The procedural principles undergirding VA's COVID-19 vaccine allocation framework include fairness, transparency, and reliance on best-available scientific evidence. This requires communication that is tailored to specific groups, consistent, respectful, and accurate to earn, secure, and maintain the trust of VA staff and Veterans under their care.

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Appendix F: Evidence Review and Rationale

Healthcare Personnel

Healthcare Personnel are prioritized for vaccination based on risk of acquiring infection, risk of passing infection to others, and risk of harm to society and hospital operations if unable to work.

Among those with status available, healthcare personnel status represented 6% of infections documented in COVID-NET from March 1–May 31, 2020 (Kambhampati). Seroprevalence studies among healthcare personnel have shown high rates, comparable to areas that have had a high burden of SARS-CoV-2 infection.

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Moscola J, Sembajwe G, Jarrett M, et al. Prevalence of SARS-CoV-2 Antibodies in Health Care Personnel in the New York City Area. *JAMA*. 2020;324(9):893–895. doi:10.1001/jama.2020.14765. Accessed 9 Nov 2020 at https://jamanetwork.com/journals/jama/article-abstract/2769322

Persons residing in nursing facilities

Persons residing in nursing care, including CLC and SCI within VA, have borne a profoundly disproportionate burden of infections, morbidity, and mortality throughout the pandemic. As of November 9, 2020, CMS reported 281,110 confirmed nursing home cases and 63,617 confirmed deaths (CMS). In the US, 9,913,553 cases were reported as of the same date, and 237,037 deaths (CDC). This represents at least 2.8% of infections and 26.8% of deaths in the United States, even though <1% of the United States population resides in nursing care (see note).

In modeling studies presented by the data, analytics, and Modeling task for the Advisory Committee on Immunization Practices for CDC on August 26 2020, a model of vaccinating nursing home healthcare personnel versus nursing home residents showed greater reductions in both infections and deaths when personnel received vaccine (Slayton), which offers support to vaccinating staff in nursing homes first.

Note: In 2016, there were an estimated 286,300 current participants enrolled in adult day services centers, 1,347,600 current residents in nursing homes, (National Center for health statistics) At the end of December 2016, the US population was 324,310,011 (United States Census Bureau).

Centers for Medicare and Medicaid Services. COVID-19 Nursing Home Data. Accessed 9 Nov 2020 at https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg/

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Slayton, Rachel B. Modeling Allocation Strategies for the Initial SARS-CoV-2 Vaccine Supply. Presented for the Advisory committee on Immunization practices 26 August 2020. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-08/COVID-06-Slayton.pdf

Essential Workers

According to CDC, "workers in essential and critical industries are considered part of America's critical infrastructure, as defined by the Cybersecurity & Infrastructure Security Agency. Current data show that many of these workers are at increased risk for getting SARS-CoV-2 (the virus causing COVID-19). Early vaccine access is critical not only to protect them but also to maintain the essential services they provide U.S. communities." In the November 2020 meeting of the Advisory Committee on Immunization Practices, a proposal was made that offering vaccine to this group is supported by the balance of science, ethics, and ability to implement.

Ethical Principle	Essential Workers (non-healthcare) (~87 million)	Adults with high-risk medical conditions (>100 Million)	Adults age ≥65 years (53 Million)
Maximize benefits and minimize harms	Preserves services essential to the COVID-19 response and overall functioning of society "Multiplier effect"	Reduces morbidity and mortality in persons with high burden of COVID-19 disease and death	Reduces morbidity and mortality in persons with highest burden of COVID-19 hospitalization and death
Promote justice	-Workers unable to work from home (↑exposure risk) -Promotes access to vaccine and may reduce barriers for workers with low vaccine uptake	Will require focused outreach to those with limited or no access to healthcare	Will require focused outreach to those who experience barriers to access healthcare
Mitigate Health inequities	-Racial and ethnic minority groups disproportionately represented in many essential industries -~1/4 of essential workers live in low-income families	Increased prevalence of some medical conditions in race/ethnic minority groups & persons in rural areas -Diagnosis of medical conditions requires access to healthcare	-Highest incidence and mortality in congregate living --Racial and ethnic minority groups under-represented among adults ≥65

McClung N, Chamberland M, Kinlaw K, et al. The Advisory Committee on Immunization Practices' Ethical Principles for Allocation of Initial Supplies of COVID-19 Vaccine — United States, 2020. MMWR Morb Mortal Wkly Rep. ePub: 23 November 2020. DOI: http://dx.doi.org/10.15585/mmwr.mm6947e3external icon

On December 20, 2020, ACIP separated essential workers into “frontline” and “other”, with “frontline essential workers” falling into Phase 1b, and others falling into Phase 1b.

Frontline Essential Workers:

ACIP classified the following non–health care essential workers as frontline workers:

- first responders (e.g., firefighters and police officers)
- corrections officers
- food and agricultural workers
- U.S. Postal Service workers
- manufacturing workers
- grocery store workers, public transit workers
- those who work in the education sector (teachers and support staff members)
- childcare workers

Other Essential Workers: Essential worker sectors recommended for vaccination in Phase 1c include those in transportation and logistics, water and wastewater, food service, shelter and housing (e.g., construction), finance (e.g., bank tellers), information technology and communications, energy, legal, media, public safety (e.g., engineers), and public health workers

https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e2.htm?s_cid=mm695152e2_x

Work Group assessment: Ethics

Ethical Principle	Essential Workers (non-healthcare) (~87 million)	Adults with high -risk medical conditions (>100 Million)	Adults age ⩾65 years (53 Million)
Maximize benefits & minimize harms	+++	++	+++
Promote justice	+++	++	++
Mitigate health inequities	+++	+	+

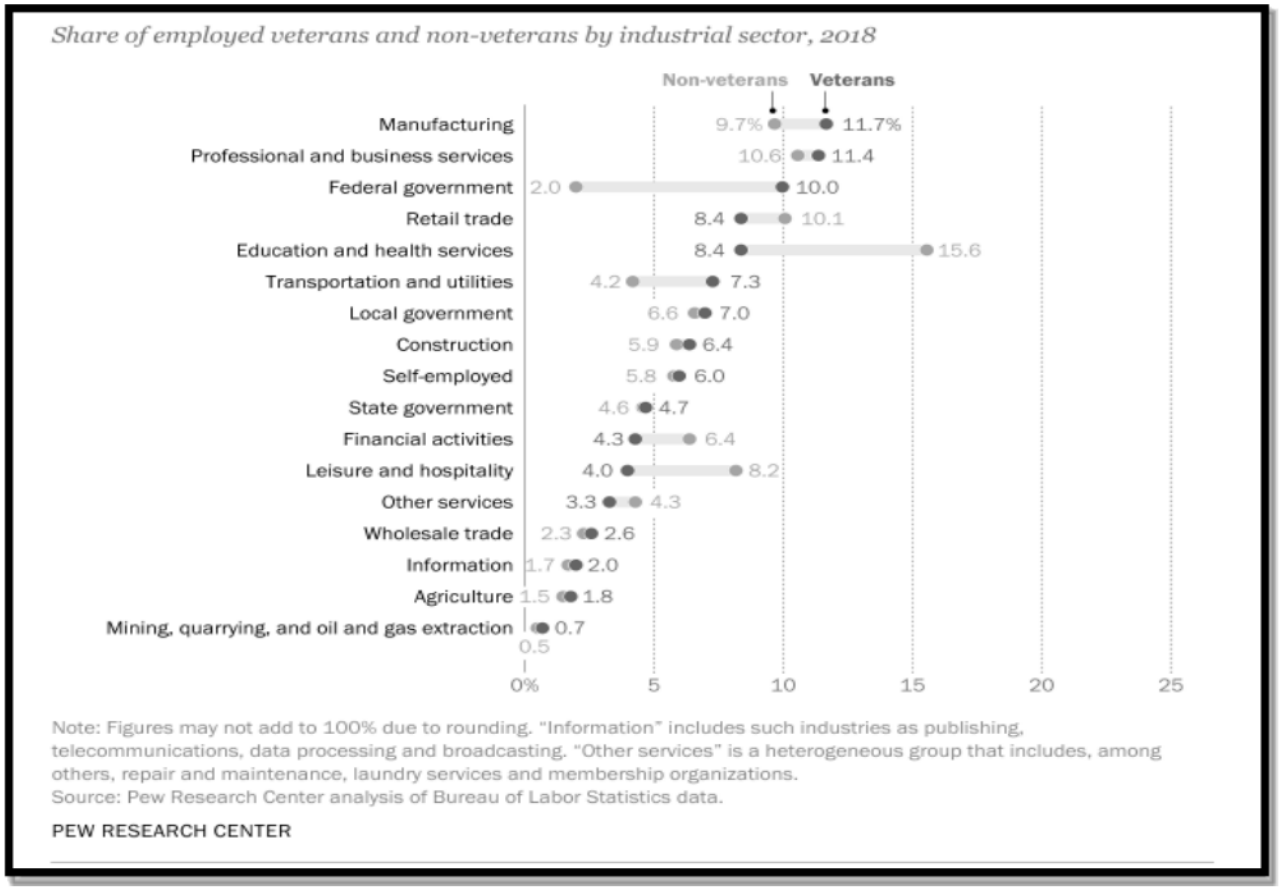
Work Group assessment: Overall

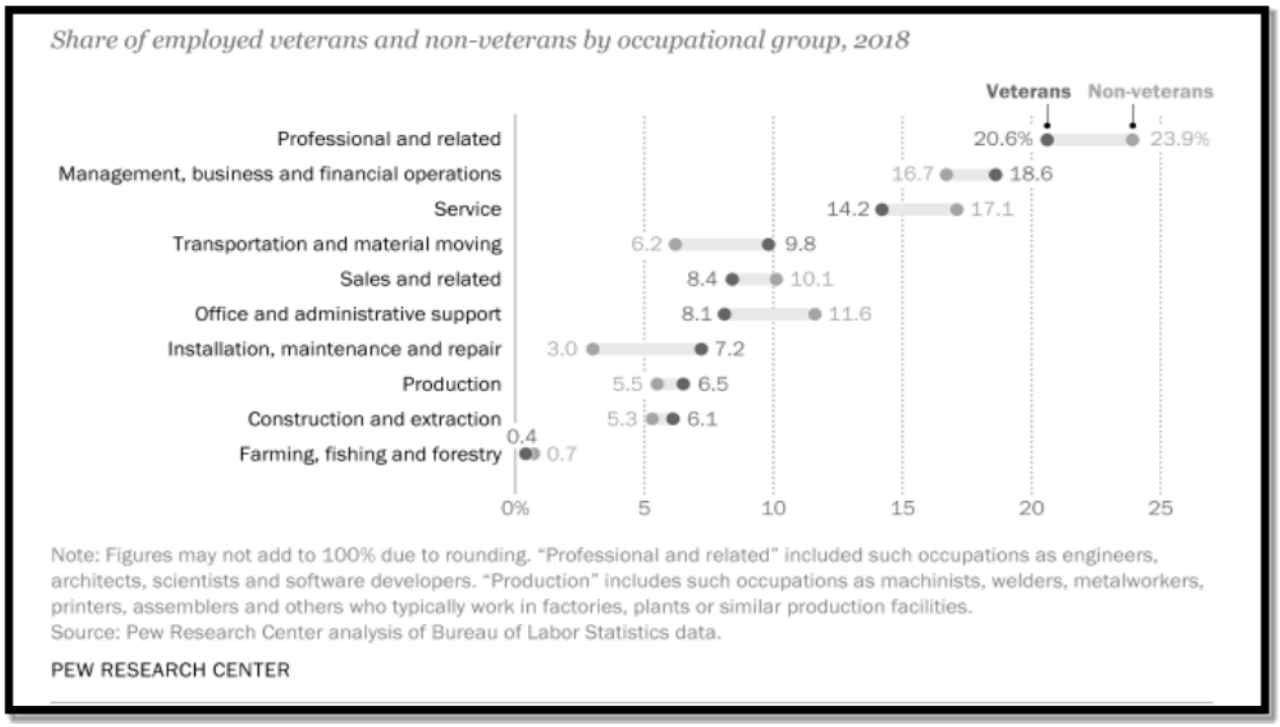
	Essential Workers (non-healthcare) (~87 million)	Adults with high -risk medical conditions (>100 Million)	Adults age ⩾65 years (53 Million)
Science	+++	+++	+++
Implementation	++	++	+++
Ethics	+++	+	+

Dooling, K. Phased Allocation of COVID-19 Vaccines. Advisory Committee on Immunization Practices COVID 19 Vaccine Work Group. ACIP Meeting 23 November 2020. Accessed 27 Nov 2020 at https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-11/COVID-04-Dooling.pdf

Centers for Disease Control and Prevention. How CDC Is Making COVID-19 Vaccine Recommendations. Accessed 27 Nov 2020 at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations-process.html

While the exact numbers of enrolled Veterans who are essential workers is not known, there is some data on employment among Veterans in the United States. Noting that this includes data on Veterans not enrolled in VA care, a 2019 Pew Research Center report noted that, among Veterans, 8.4% were in education and health services, 7.3% in transportation and utilities, 1.8% in agriculture, 4.3% in financial activities, 2.0% in information, and 6.4% in construction.





DeSilver, Drew. How Veterans and non-Veterans fare in the U.S. job market. Pew Research Center. 17 September 2019. https://www.pewresearch.org/fact-tank/2019/09/17/how-veterans-and-non-veterans-fare-in-the-u-s-job-market/

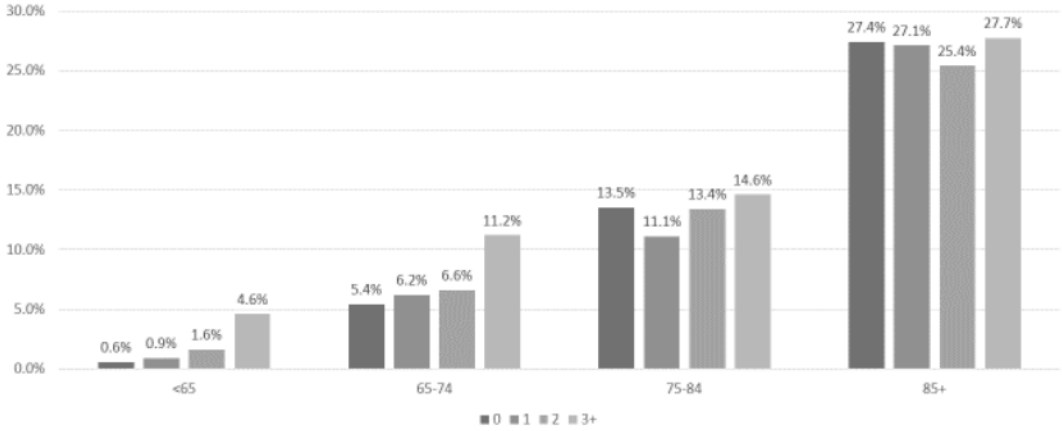
Age

Age has a profound effect on morbidity and mortality related to COVID-19. The Centers for Disease Control and Prevention report that, when compared to persons aged 18-29, hospitalizations are 5 times higher and mortality is 90 times higher in persons aged 65-74; 8 times higher and 220 times higher, respectively, in persons aged 75-84; and 13 times higher and 360 times higher, respectively, in persons aged 85 and older.

On review of COVID-19-associated mortality among Veterans in VHA, age was found to have a stronger association with excess mortality than other high-risk conditions or combination of multiple conditions (see figure below). Among Veterans, increasing age appears to be a much more significant risk factor even than having several high-risk conditions. Additionally, among persons aged 75 and older, having one or several high-risk conditions did not appear to significantly alter that risk.

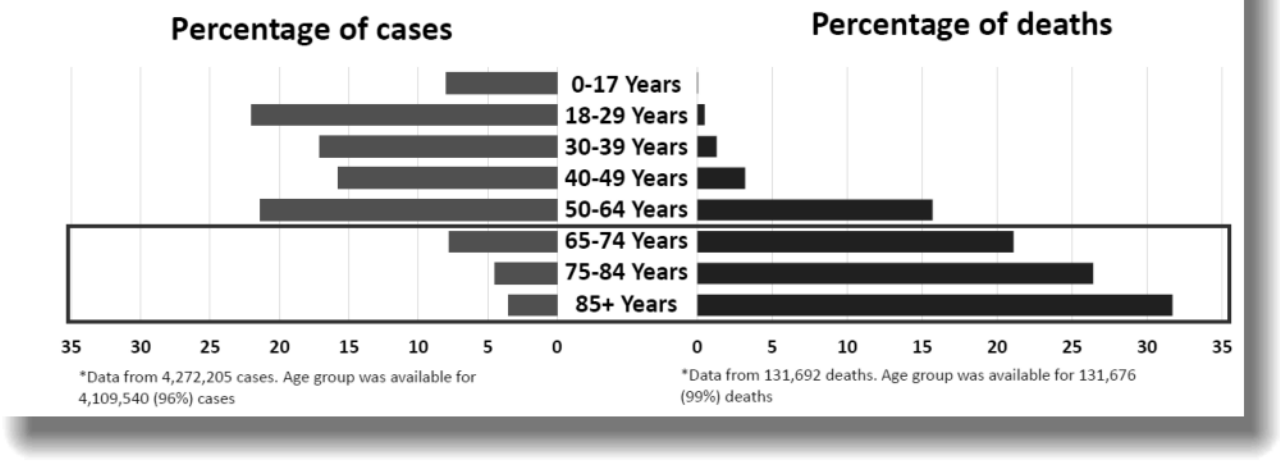
If vaccine supply does not cover the size of a population group in the stratification table, consider further stratifying by age, as risk increases significantly with increased age. For example, could start with persons 85 and older if there is insufficient vaccine for all persons 75 and older.

Mortality Rate among COVID Veteran Cases by Age and # of Comorbidities through 8/27/20

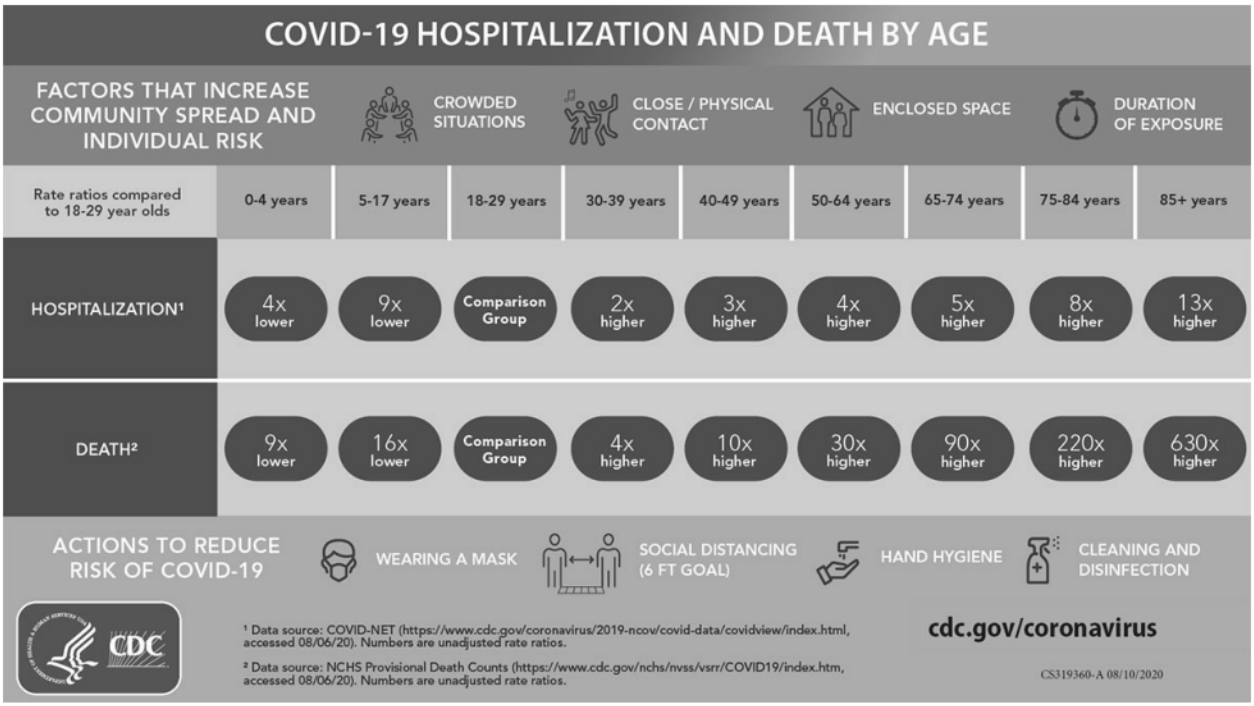


Comorbidities: BMI>=30, asthma, diabetes, CKD, IHD, stroke, COPD

In the United States, adults aged 65 years or older represent 16% of COVID-19 cases, but nearly 80% of COVID-19 deaths



Source: ACIP 8/26 Meeting, McClung



Centers for Disease Control and Prevention. COVID-19 Hospitalization and Death by Age. Accessed 9 November 2020 at https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-age.html

Veterans on Hemodialysis

Chronic kidney disease is considered a high-risk condition for severe disease from COVID-19 by the Centers for Disease Control and Prevention with similar magnitude of risk to other high-risk conditions. There is less data specific to hemodialysis. However, data from small studies reveals that mortality rates from COVID-19 may be as high as 14.9-30% among hemodialysis patients.

In addition to high risk of severe disease, morbidity and mortality, persons receiving hemodialysis in a facility or center need to be physically present in a healthcare setting several times per week, which means they are at increased risk of acquiring and passing on infection to others who are also at high risk from COVID-19.

It is because of this “triple-risk” that Veterans requiring in-person hemodialysis are stratified among Veterans who should be offered vaccine early: risk of severe disease, morbidity and mortality from COVID-19; risk of acquiring infection; and risk of transmitting infection.

Shimada N, Shimada H, Itaya Y, Tomino Y. Novel coronavirus disease in patients with end-stage kidney disease. Ther Apher Dial. 2020 Oct 11. doi: 10.1111/1744-9987.13599. Epub ahead of print. Accessed 9 November 2020 at. https://onlinelibrary.wiley.com/doi/10.1111/1744-9987.13599

Goicoechea M, et al. COVID-19: clinical course and outcomes of 36 hemodialysis patients in Spain, Kidney International. Accessed 9 November 2020 at https://www.sciencedirect.com/science/article/pii/S0085253820305093?via%3Dihub

Trujilo H, et al. SARS-CoV-2 infection in hospitalized patients with kidney disease. Kidney Int Rep. Accessed 9 November 2020 at https://doi.org/10.1016/j.ekir.2020.04.02

Keller N, et al. Impact of first-wave corona virus disease 2019 infection in patients on haemodialysis in Alsace: The observational COVIDAL study. Neprol Dial Transplant. Accessed 9 November 2020 at https://doi.org/10.1093/ndt/gfaa170

D'Marco L, et al. Coronavirus disease 2019 in chronic kidney disease. Clin Kidney J. 2020 Jul 16;13(3):297-306. doi: 10.1093/ckj/sfaa104. PMID: 32699615; Accessed 9 November 2020 at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7367105/

Ma Y, et al. 2019. novel coronavirus disease in hemodialysis (HD) patients: report from one HD center in Wuhan, China. medRxiv 2020; Accessed 9 November 2020 at https://www.medrxiv.org/content/10.1101/2020.02.24.20027201v3

Veterans with a Solid Organ Transplant or who are listed for transplant

Although it is likely that risk differs by timing relevant to transplant (i.e., likely highest closer to time of transplant), and also differs based on type of transplant, data on solid organ transplantation overall shows increased mortality related to COVID-19 when compared to the general population. In a July review in Transplant Infectious Disease, Moosayi et al found that “excluding studies, in which their data about expired patients were not clear in detail, the mortality rate was 18/79 (22.8%), 3/21 (14.3%), 2/10 (20.0%), and 1/6 (16.7%) among patients with kidney, liver, heart, and lung transplantations, respectively”.

In addition to having a high-risk condition, the peri-transplant populations is likely to undergo hospitalization and have frequent medical visits including planned surgery and intensive care unit stay during a period of immune suppression, which increases risk.

When considering magnitude of risk, it is likely highest for those nearer to transplant and those with frequent contact with the healthcare system (i.e. in the peri-transplant period). Because immunologic response to vaccine may be attenuated post-transplant because of immune-suppression, patients listed for transplant are also included, as the ideal timing for offering vaccine would be in the pre-transplant period.

Outreach to this group should emphasize those in the peri-transplant period.

Moosavi, S et al. “COVID-19 clinical manifestations and treatment strategies among solid-organ recipients: a systematic review of cases.” *Transplant infectious disease : an official journal of the Transplantation Society*, e13427. 24 Jul. 2020, doi:10.1111/tid.13427 Accessed 18 November 2020 at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7404594/pdf/TID-9999-e13427.pdf
Ketcham, S.W., et al., Coronavirus Disease-2019 in Heart Transplant Recipients in Southeastern Michigan: A Case Series. Journal of Cardiac Failure, 2020.

Akalin, E., et al., Covid-19 and Kidney Transplantation. New England Journal of Medicine, 2020. Accessed 10 November 2020 at https://www.nejm.org/doi/full/10.1056/NEJMc2011117

Latif, F., et al., Characteristics and Outcomes of Recipients of Heart Transplant With Coronavirus Disease 2019. JAMA Cardiology, 2020. Accessed 10 November 2020 at https://jamanetwork.com/journals/jamacardiology/fullarticle/2766123

Fernández-Ruiz, M., et al., COVID-19 in solid organ transplant recipients: A single-center case series from Spain. American Journal of Transplantation, 2020. 20(7): p. 1849-1858. Accessed 10 November 2020 at https://onlinelibrary.wiley.com/doi/full/10.1111/ajt.15929

Travi, G., et al., Clinical outcome in solid organ transplant recipients with COVID-19: A single-center experience. American Journal of Transplantation, 2020. Accessed 10 November 2020 at https://onlinelibrary.wiley.com/doi/10.1111/ajt.16069

Tschopp, J., et al., First experience of SARS-CoV-2 infections in solid organ transplant recipients in the Swiss Transplant Cohort Study. American Journal of Transplantation, 2020. Accessed 10 November 2020 at https://pubmed.ncbi.nlm.nih.gov/32412159/

Veterans on Chemotherapy (in person, facility-based)

According to the Centers for Disease Control and Prevention, having current cancer increases risk of severe illness from COVID-19, but it is not known at this time whether a history of cancer increases that risk.

The data on cancer and COVID-19 risk are mixed and limited by heterogeneity of cancer types and prognoses.

It is not clear what role immunosuppression plays in COVID-19 risk. Rather, the rationale for placing Veterans receiving in-person, facility-based chemotherapy is that, in addition to having cancer, they must be physically present in a healthcare setting on a regular basis, generally for prolonged periods of time and often in a communal setting. This means that this group is not only at elevated risk for morbidity and mortality from COVID-19, but also for acquiring and passing on infection.

It is because of this “triple-risk” that Veterans requiring in-person chemotherapy are stratified among Veterans who should be offered vaccine early: risk of severe disease, morbidity and mortality from COVID-19; risk of acquiring infection; and risk of transmitting infection.

Centers for Disease control and prevention. People with Certain Medical Conditions. Accessed 9 Nov 2020 at https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html#cancer

Centers for Disease control and prevention. Evidence used to update the list of underlying medical conditions that increase a person’s risk of severe illness from COVID-19. Accessed 9 Nov 2020 at https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/evidence-table.html

Fung M, Babik JM. COVID-19 in Immunocompromised Hosts: What We Know So Far. 27 June 2020. Clin Infect Dis. 2020; Accessed 9 Nov 2020 at https://pubmed.ncbi.nlm.nih.gov/32592461/

Liang W, et al. Cancer patients in SARS-CoV-2 infection: a nationwide analysis in China. Lancet Oncol. Accessed 9 Nov 2020 https://pubmed.ncbi.nlm.nih.gov/32066541/

Robilotti, EV, et al. Determinants of COVID-19 disease severity in patients with cancer. Nature Medicine. 2020. 26(8): p. 1218-1223. Accessed 9 Nov 2020 https://pubmed.ncbi.nlm.nih.gov/32581323/

Zhang H et al. Outcomes of novel coronavirus disease 2019 (COVID-19) infection in 107 patients with cancer from Wuhan, China. Cancer. https://pubmed.ncbi.nlm.nih.gov/32573776/

Veterans Experiencing Homelessness

There is very limited data available on the impacts of the COVID-19 pandemic on homeless persons, and demographic data including homelessness and housing is not always available for hospitalized patients. However, homeless persons are more likely to have underlying high-risk conditions and fall into older age groups. Additionally, and particularly during the winter months, persons experiencing homelessness are at high risk of needing housing in congregate living settings.

This group was included among Veterans who should be offered vaccine early because of the likelihood of being in a congregate setting, in addition to likely elevated risk of morbidity and mortality from COVID-19.

Veterans who are currently in, or are likely to be in, congregate living such as a shelter, should be prioritized for outreach.

Centers for Disease Control and Prevention. People Experiencing Homelessness. Accessed 4 December 2020 at: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/homelessness.html

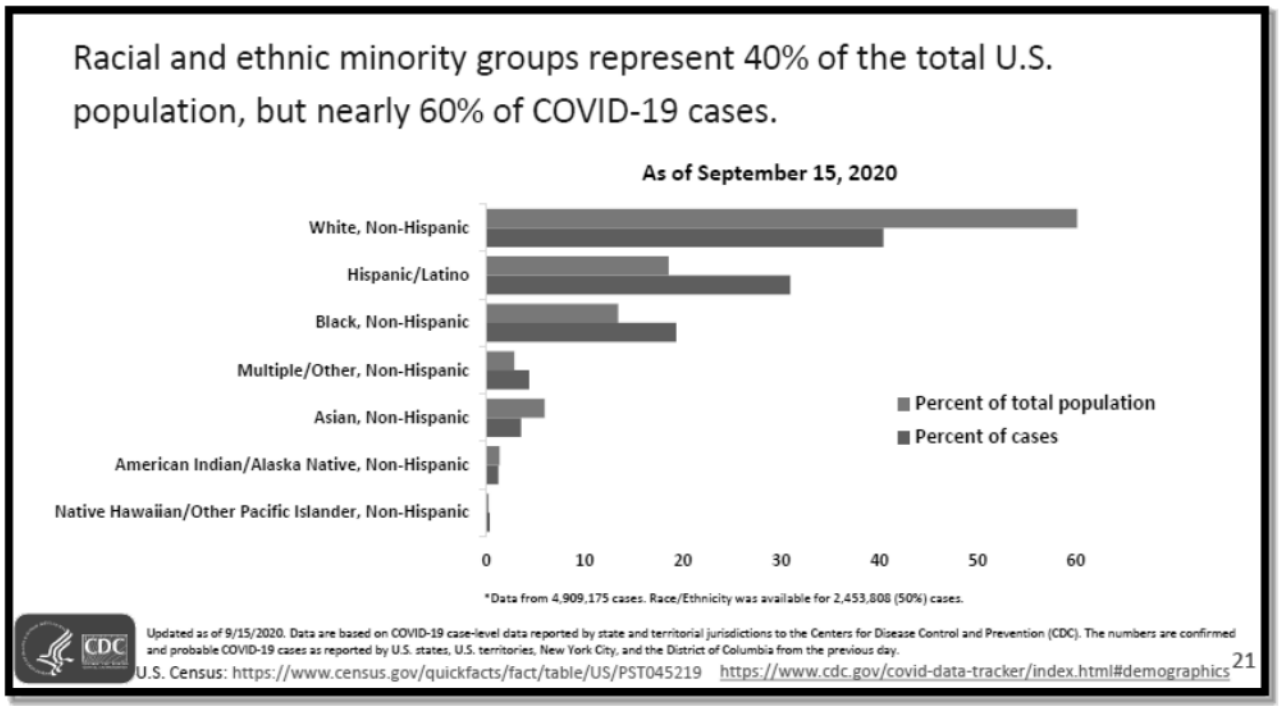
Perri, M et al. COVID-19 and people experiencing homelessness: challenges and mitigation strategies. Canadian Medical Association Journal. 29 June 2020. Accessed 9 Nov 2020 at https://www.cmaj.ca/content/192/26/E716

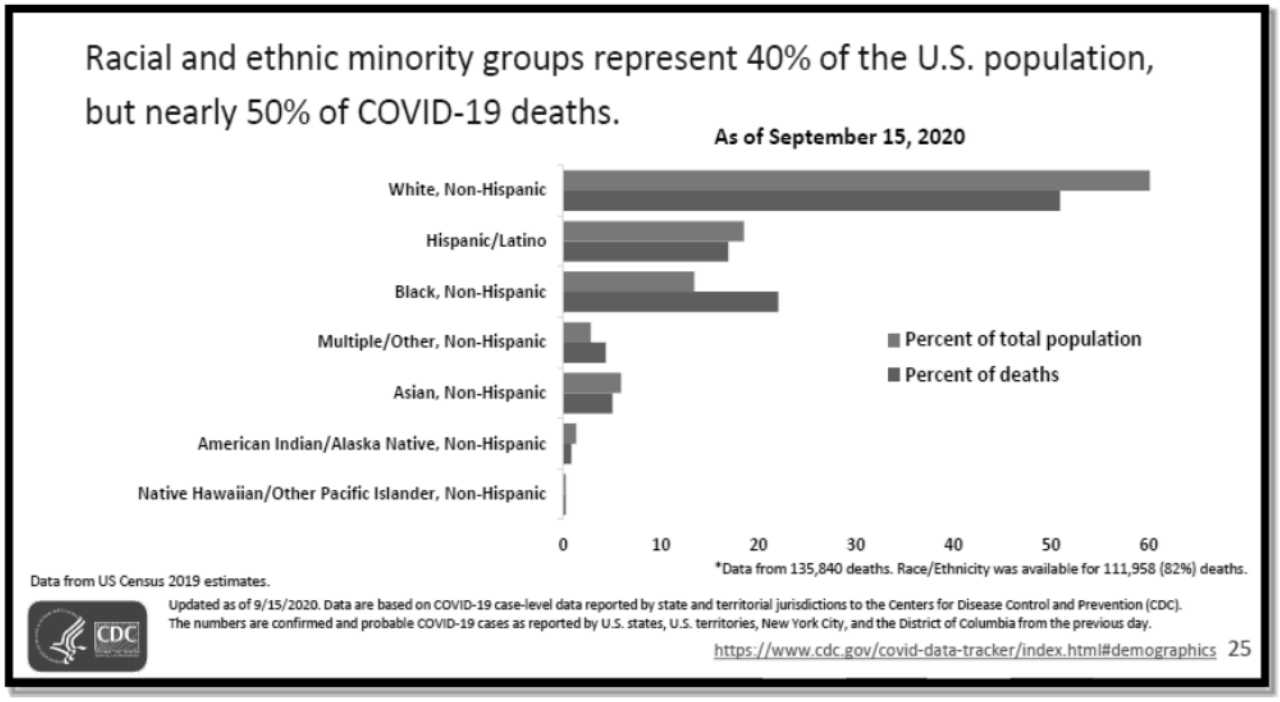
Race and Ethnicity

Certain racial and ethnic minorities are at higher risk for acquiring SARS-CoV-2 infection and for severe outcomes from COVID-19. The disproportionate burden of COVID-19 on racial and ethnic minorities has been well described and is thought to be multifactorial.

Racial and ethnic minorities make up 40% of the population but about 50% of the COVID-19 deaths. In the United States, there are about 25% more COVID-19 deaths in racial and ethnic minorities than there should be based on population size, and the mortality differences indicates that the burden of COVID-19 on these communities cannot be adequately explained by overdiagnosis bias. For some groups, risks associated with COVID-19 are comparable to risks for persons with a high-risk condition, so it is important that this be a focus of outreach and education.

The consideration of race and ethnicity and of health equity was cross-cutting in the deliberations of the Advisory Committee on Immunization Practices and in the deliberations in VHA, where our team included representation from the National Center for Ethics in Health Care and the Office of Health Equity. It is thought that much of the elevated risk relates to factors such as medical conditions and presence in the essential workforce. Over-representation of racial and ethnic minorities and persons of lower socioeconomic status among essential workers was one factor in the prioritization of essential workers by ACIP. In VHA the decision was made additionally to hold listening sessions and include focused communications to promote equitable access to COVID-19 vaccine.





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Price-Haygood EG, Burton J, Fort D, Seoane L. Hospitalization and Mortality among Black Patients and White Patients with Covid-19. N Engl J Med 2020. Accessed 9 Nov 2020 at https://doi.org/10.1056/nejmsa2011686.

Millet GA, Jones AT, Benkeser D, et al. Assessing Differential Impacts of COVID-19 on Black Communities. Ann Epidemiol. 2020;47:37-44. Accessed 9 Nov 2020 at https://doi.org/10.1016/j.annepidem.2020.05.003.

Killerby ME, Link-Gelles R, Haight SC, et al. Characteristics Associated with Hospitalization Among Patients with COVID-19 — Metropolitan Atlanta, Georgia, March–April 2020. MMWR Morb Mortal Wkly Rep. ePub: 17 June 2020. Accessed 9 Nov 2020 at http://dx.doi.org/10.15585/mmwr.mm6925e1 .

Stokes EK, Zambrano LD, Anderson KN, et al. Coronavirus Disease 2019 Case Surveillance — United States, January 22–May 30, 2020. MMWR Morb Mortal Wkly Rep 2020;69:759–765. Accessed 9 Nov 2020 at http://dx.doi.org/10.15585/mmwr.mm6924e2.

Gold JA, Wong KK, Szablewski CM, et al. Characteristics and Clinical Outcomes of Adult Patients Hospitalized with COVID-19 — Georgia, March 2020. MMWR Morb Mortal Wkly Rep 2020;69:545–550. Accessed 9 Nov 2020 at http://dx.doi.org/10.15585/mmwr.mm6918e1.

Veterans younger than age 75

While the relative effects of comorbid 'high-risk' conditions on overall COVID-19 risk are attenuated in older age groups and other very high risk populations, the role of CDC high-risk conditions and membership in certain high-risk racial or ethnic minority groups becomes increasingly important in younger age groups, as overall risk decreases. It is predicted that VA will have ample availability of vaccine by Phase 1c, and it is for this reason that risk groups are addressed as a priority for outreach but are not tightly stratified.

Outreach and education to ensure that we are reaching Veterans in high-risk racial and ethnic minority groups and Veterans with high-risk medical conditions must be a focus of COVID-19 vaccination planning at all sites. While these groups are categorized together based on similar risks of morbidity and mortality due to COVID-19, the needs of each group are distinct and targeted communications are vital.

Appendix G: Workgroup Members

Lisa Backus, MD, PhD
Acting Chief Consultant Health Solutions
Deputy Chief Consultant, Measurement and Reporting
VHA Population Health Services

Gio Baracco, MD
VISN 8 Infectious Disease Lead
Chief, Infectious Disease Section
Hospital Epidemiologist and Medical Director, Infection Prevention and Control
Miami VA Healthcare System

Pamela Belperio, BCPS, AAHIVP
National Public Health Clinical Pharmacy Specialist
VHA Population Health Services

Sophia Califano, MD, MPH
Deputy Chief Consultant, Preventive Medicine
VHA National Center for Health Promotion and Disease Prevention

Marla Clifton, MSN, RN, CIC
Clinical Programs Coordinator
VHA National Infectious Diseases Service

Jacqueline Cook, MD
Medical Advisor
VHA Office of OSH and GEMS Programs

Kathleen DeRoos, APRN, MSN
Healthcare Associated Infection (HAI) Clinical Program Coordinator
Infection Prevention & Control
VHA National Infectious Diseases Service

Ajay Dhawan, MD
National Director of Medicine
VHA Specialty Care Services

Kelly Echevarria, PharmD
National Clinical Pharmacy Program Manager
VHA Pharmacy Benefits Management

Jane Kim, MD, MPH
Chief Consultant, Preventive Medicine
VHA National Center for Health Promotion and Disease Prevention

Steven Kralovic, MD
Deputy Director
VHA National Infectious Diseases Service

Ernest Moy MD, MPH
Executive Director
VHA Office of Health Equity

Leonard Pogach, MD, MBA
National Program Director
VHA Office of Diabetes and Endocrinology

Gary Roselle, MD
Director
VHA National Infectious Diseases Service

Anita Tarzian, PhD, RN
Deputy Executive Director
VHA National Center for Ethics in Health Care

Patricia Wallace, MSN, RN
Senior Clinical Advisor
VHA Office of Healthcare Transformation

Jennifer Zacher, PharmD
Deputy Chief Consultant
VHA Pharmacy Benefits Management

Department of Veterans Affairs

Memorandum

Date: December 16, 2020

From: Assistant Under Secretary for Health for Operations (15)

Subj: Department of Veterans Affairs (VA) Guidance on COVID-19 Vaccine

To: Veterans Integrated Service Network (VISN) Directors (10N1-23)
VISN Chief Medical Officers
VISN Chief Nurse Officers
Medical Center Directors (00)

1. The purpose of this memorandum is to provide guidance on the U.S. Food and Drug Administration (FDA) authorized use of COVID-19 vaccines under an Emergency Use Authorization (EUA) for the prevention of SARS-CoV-2 infection and COVID-19 disease, and the Centers for Disease Control and Prevention (CDC) published recommendations for use. The guidance in this memorandum will provide information on the storage, handling, distribution, reporting, administration and training for each vaccine. In some cases, this information will be the same regardless of the vaccine (e.g. risk stratification, reporting), and in others, updated logistics, clinical protocols, trainings, and other guidance will be provided through the SharePoint sites below as vaccines are approved.

2. **National Distribution**:

   a. VA will be allocated a specific number of doses of each authorized vaccine. Given that these amounts are not anticipated to be sufficient to vaccinate all patients and staff initially, VA will follow the risk stratification framework included in Attachment A. Phase 1a is approved and final. Phases 1b and 1c are draft and will be finalized after CDC issues recommendations. The VA risk stratification framework can be also be accessed on the VA COVID-19 vaccine SharePoint at the following link: https://dvagov.sharepoint.com/sites/vhacovidvaccine/SitePages/Vaccine-Policies-and-Clinical-Guidance.aspx. As the supply of vaccine increases, this framework will be implemented in the stages indicated. It is expected that Veterans Health Administration (VHA) should have sufficient supply to offer vaccine to all who are interested in COVID-19 vaccination over the coming months.

   b. Distribution of vaccine to sites that have previously identified capacity to receive, store and administer the COVID-19 vaccine will be coordinated by VHA Pharmacy Benefits Management (PBM). Site distribution will be based on total allocation for VA, the number of employees and patients in the risk categories and orders previously placed and coordinated by PBM.

Each site eligible for vaccine delivery will be given an individual site allocation, and orders may only be placed at quantities at or below that allocation level. Orders from the field can be placed at the following link [https://dvagov.sharepoint.com/sites/VHAPBM/VA_MedSAFE/App/SitePages/COVID-Vaccine.aspx].

c. Both first and second doses of vaccine must be from the **same** manufacturer product and should be received in the **same** clinic location.

3. **Logistics and Scheduling:**

   a. Logistics of vaccine delivery, storage, and dosing requirements for each authorized vaccine will be posted on the PBM Sharepoint: https://dvagov.sharepoint.com/sites/VHAPBM/VA_MedSAFE/App/SitePages/COVID-Vaccine.aspx

   b. Appointments for second dose vaccination will be made at time of administration of the 1st dose. An immunization card must be provided with date, make and lot # of vaccine given and when 2nd dose is due, and will be provided in the ancillary supply kits supplied with each vaccine.

4. **Reporting:**

   a. Administration data for COVID-19 vaccines must be reported electronically to CDC within twenty-four hours of administration. ***The reporting of required data elements will occur via national data extraction and transmission***. This will **require** that all facilities use the national COVID-19 vaccine clinical reminder for documentation of vaccines administered to Veteran patients and use the Occupational Health Recordkeeping System (OHRS) 2.0 for documentation of vaccines administered to VA employees.

      i. **Patients**: The national clinical reminder for COVID-19 vaccines **must** be completed for **all** Veteran vaccinations (both outpatients and inpatients). Information on the National COVID-19 Clinical Reminder is posted here: COVID-19 Immunization Reminder page

      ii. **Staff**: OHRS 2.0 for documentation of vaccines administered to VA employees. OHRS 2.0 will send the employee a reminder through Outlook mail for those requiring a second dose, but will not schedule the employee for a follow-up visit. Sites must develop a process for this per the guidance in the Assistant Under Secretary for Health for Operations (AUSHO) Memorandum: *Scheduling COVID-19 Employee Vaccination*, released on December 11, 2020. More information on OHRS 2.0 is available through the AUSHO

Memorandum *Coronavirus Disease 2019 (COVID-19) Vaccine Documentation Requirement for Veterans Health Administration (VHA) Employees and Health Care Personnel in the Occupational Health Recordkeeping System 2.0*, released on November 16, 2020 and information is posted on the OHRS 2.0 Training Home Page.

***NOTE**: All COVID-19 vaccine memorandums are posted here: https://dvagov.sharepoint.com/sites/vhacovidvaccine/SitePages/Vaccine-Policies-and-Clinical-Guidance.aspx*

iii. Supply and wastage must be reported to CDC daily. Documentation of vaccine supply, wastage spillage, and safety information will occur through PBM. More information is available here: https://dvagov.sharepoint.com/sites/VHAPBM/VA_MedSAFE/App/SitePages/COVID-Vaccine.aspx

iv. COVID-19 vaccine safety surveillance and enhanced Vaccine Adverse Event Reporting System (VAERS) reporting using the National Healthcare Safety Network (NHSN) sites will continue to be coordinated through PBM. More information is available here: https://dvagov.sharepoint.com/sites/VHAPBM/VA_MedSAFE/App/SitePages/COVID-Vaccine.aspx

5. **Administration:**

a. Please refer to AUSHO Memorandum: *VA COVID-19 Vaccine Administration for Vaccinators*, released on December 11, 2020, for specific guidance and procedures for eligible healthcare professionals (RNs, APRNs, PAs, LPN/LVNs, MDs, DOs, Pharmacists, and any already authorized Unlicensed Assistive Personnel, or UAPs) who may vaccinate adults for COVID-19.

***NOTE**: All COVID-19 vaccine memorandums are posted here: https://dvagov.sharepoint.com/sites/vhacovidvaccine/SitePages/Vaccine-Policies-and-Clinical-Guidance.aspx*

b. For sites currently using standing orders for vaccine administration, the sites may proceed with standing orders for vaccination by eligible staff.

c. Please refer to AUSHO memorandum: *COVID-19 Vaccination Documentation for Vaccinators* released on December 11, 2020 for specific guidance for on documentation of vaccine administration in order to

maintain throughput and preserve personal protective equipment. An acceptable alternative would be for a second person to document vaccination at the point of care, as long as the following requirements are met:

i. The system supports a process with scribes and/or addendums. OHRS 2.0 does not currently have that functionality, but CPRS and CERNER do allow this.

ii. The person documenting vaccination is trained in proper documentation in the appropriate system (CPRS/CERNER) and is able to consistently meet all documentation needs as required by CDC.

iii. The person administering the vaccine is the responsible party for documentation and must review and co-sign the documentation ***before the end of the vaccinator's shift.***

6. **Training and Education Materials:**

a. Information regarding the mandatory training requirements for staff handling and administering the vaccine is located here: Training Link

b. The COVID-19 Vaccine SharePoint Site provides a host of resources, including operational toolkits for planning, education and training materials, and scientific research. This site includes a Communications Toolkit providing products including frequently asked questions (FAQ) that have been approved for use to communicate and educate both internal and external audiences. Please check back regularly as the content is likely to change frequently as new information emerges.

7. Questions can be submitted to the COVID-19 Resource Room or send an email to (b)(6) @va.gov.

(b)(6)

for Renee Oshinski

Attachment

Risk-Stratification for COVID-19 Vaccination in VHA

Risk-Stratification for COVID-19 Vaccination in VHA

VHA's recommendations on risk stratification, also called prioritization, are based on guidance from the independent Advisory Committee on Immunization Practices (ACIP), the Center for Disease Control and Prevention (CDC). This guidance is intended to maximize benefits of COVID-19 vaccine to Veterans and staff when initial supply is limited and help guide outreach and scheduling when supply is robust and larger scale vaccination becomes possible.

It is expected that VA sites will follow this general framework rather than creating separate guidance for each site, with the understanding that it will need customization to reflect local conditions and staff roles, and that flexibility may be needed initially when utilizing vaccines with time-sensitive storage and handling constraints.

CDC guidance comprises broad categories to maximize feasibility across all state and federal jurisdictions. The first groups to be offered COVID-19 vaccine (CDC phase 1a) include healthcare personnel and persons residing and working in long term care facilities. For healthcare personnel, this is based on risk of SARS-CoV-2 infection, risk of transmitting SARS-CoV-2 infection to patients, and public health and infrastructure risk if they are unable to work. Residents in long term care facilities will also be among the first to be offered COVID-19 vaccine because those persons have been shown to be at heightened risk of morbidity and mortality during the COVID-19 pandemic.

ACIP has not yet voted on recommendations for Phases 1b and 1c; based on most recent discussions, it is likely that COVID-19 vaccine will next be offered to essential workers (phase 1b), followed by persons 65 and older, and persons with high risk conditions (phase 1c). Phases 1b and 1c recommendations in VA will be expected to follow CDC guidance, so remain in draft at this time.

While the population of enrolled Veterans who are essential workers is not known, more than half of our Veterans are aged 65 and older, and a large proportion of our Veterans have at least one high-risk condition. Because the number of Veterans expected to be offered COVID-19 vaccine during Phase 1 is so high, this group was further stratified by risk categories, to aid sites across VA in an ethical and equitable approach to offering COVID-19 vaccine. With our team of subject matter experts, including ethics, health equity, infectious diseases, infection prevention and control, preventive medicine, occupational health, pharmacy, public health, metrics and measurement, we reviewed risks to specific groups of staff and Veterans associated with COVID-19, and existing evidence and recommendations, to determine which groups should be offered COVID-19 vaccine first within those broader categories, in order to maximize benefits to staff and Veterans.
Based on frameworks from the National Academies of Science, Engineering and Medicine (NASEM) (https://www.nationalacademies.org/our-work/a-framework-for-equitable-allocation-of-vaccine-for-the-novel-coronavirus) and discussions of the Advisory Committee on Immunization Practices (ACIP) (https://www.cdc.gov/vaccines/acip/meetings/index.html) we considered multiple contributors to overall risk, including:

- Risk of acquiring SARS-CoV-2 infection
- Risk of severe morbidity and mortality
- Risk of negative societal impact (risk of harm to society if that person is unable to work)
- Risk of transmitting SARS-CoV-2 infection to others

Note, these risk criteria are not listed in order of weight or importance.

Risk Stratification Table (grey sections remain in draft)

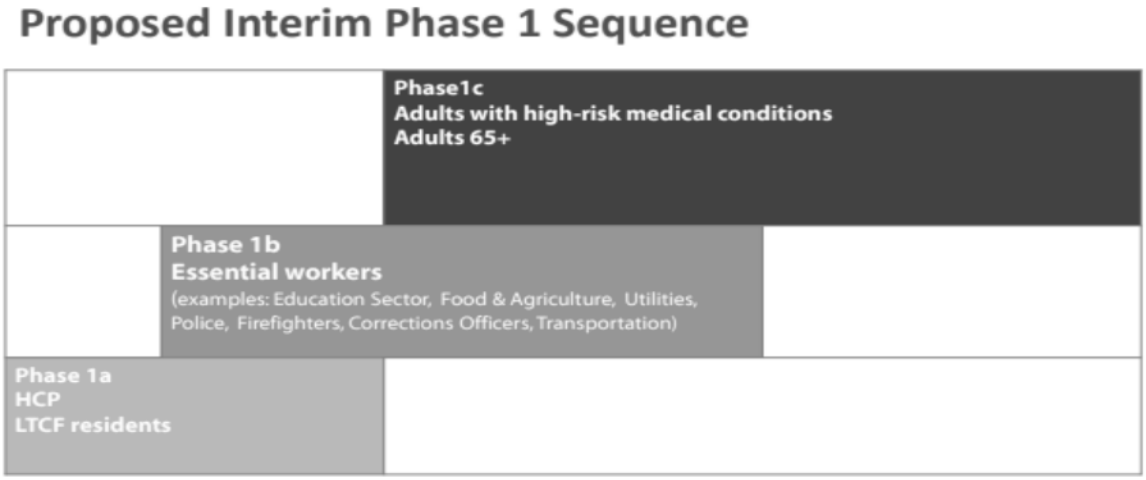
CDC-VA	Healthcare Personnel*	Veterans	Comments
A- 1a	CLC/SCID unit staff	Veterans residing in VA CLC/SCID	***Staff members not listed, including those who travel between units, should be offered COVID-19 vaccine with the group or unit most resembling their risk profile*** ***For COVID-19 vaccines where rate of anticipated systemic side effects is high according to the applicable EUA fact sheet and/or CDC guidance, it is recommended that COVID-19 vaccination is staggered, so that the number of personnel in each unit receiving vaccine at a given time is low. This will limit absences related to response to the COVID-19 vaccine. Under this scenario, offering COVID-19 vaccine to any HCP would be appropriate, rather than offering sequentially by risk.** ****this should comprise the smallest number of staff who are needed to continue operations, rather than all persons who hold a particular job or role, with intent of keeping the health care system functioning to care for Veterans and keep staff safe.**
A- 1b	Emergency Department, EMS		
A- 1c	COVID-19 ICU staff		
A- 1d	COVID-19 non-ICU inpatient staff		
A- 1e	Other staff providing face-to-face care and services for COVID-19 patients		
A- 1f	Staff in other congregate living settings	Veterans residing in other nursing facilities without access to COVID-19 vaccine; Veterans residing in other VA residential/congregate settings	
A- 2a	Core staff critical to function of the hospital and the COVID-19 response (e.g., logistics, facilities operations, police, food services, occupational health, environmental engineering, limited executive or leadership roles)**	**ACIP (CDC) Phases** **1a = Blue** **(HCP, LTCF)** 1b = Green (Essential Workers) 1c = Brown (65 and older; high-risk conditions)	
A- 2b	Inpatient staff, non-COVID-19 units		
A- 2c	Staff performing high risk procedures (non-COVID-19, pre-screened)		
A- 3a	Hemodialysis staff		
A- 3b	Oncology/chemotherapy unit staff		
A- 4a	Homeless Outreach staff		
A- 4b	Staff with frequent contact with Veterans who have not been pre-screened for COVID-19 symptoms (screeners, drivers, etc.)		
A- 4c	Outpatient direct care/contact (pre-screened, non-COVID-19)		
The section below is in draft pending ACIP and CDC recommendations on Phase 1b and 1c vaccination			
B-1a	All other staff	Homeless Veterans; Hemodialysis patients; Solid Organ Transplant patients or patients who are listed for transplant; and Chemotherapy patients Specifically – Veterans receiving chemotherapy in a clinic/hospital setting	*Open for Essential Workers*
C-1a		Veterans age 85+	Outreach efforts for these groups should emphasize patients with CDC high-risk conditions and members of high-risk racial or ethnic minority groups.
C- 1b		Veterans age 75+	
C- 1c		Veterans age 65+	
D- 1a		Veterans age 50+	
D- 1b		Veterans age <50:	

Appendix A: Population Enumeration

Category	Estimated Population Size	%
Employees		
Department of Veterans Affairs (Total)	418,688	
Veterans Health Administration (Total)	373,435	
HCP	247,239	
Essential	41,259	
Others	84,937	
Volunteers	61,420	
Trainees	124,190	
Veterans		
Enrolled Veterans (total)	10,075,834	
Age 85 and older	832,973	8%
Age 75-84	1,483,666	15%
Age 65-74	2,675,315	27%
≥65	4,991,954	50%
African American	1,380,936	13.7%
Hispanic	595,875	5.9%
Veterans Receiving Care	5,821,113	-
≥65	3,063,682	52.6%
African American	1,022,986	17.6%
Hispanic	397,162	6.8%
Veterans in State Veteran Homes	19,275	
Fourth MISSION - Non-Veteran	9208	
Fourth MISSION - Veteran	132	
High Risk Medical Conditions		
Cancer	544,149	9.3%
Chronic Kidney Disease	339,435	5.8%
COPD	439,287	7.5%
Obesity (BMI of 30 or greater)	2,278,608	39.1%
Cardiovascular disease	2,709,759	46.6%
Sickle cell disease	2,998	0.1%
Type 2 diabetes mellitus	1,556,431	26.7%
Homeless	242,297	
Nursing Home	9998	0.1%
Other congregate settings	2279	0.04%
Rural	1,992,232	34.2%
Veterans with disability (100%)	847,580	14.5%
Veterans with significant disabilities	291,348	5.0%
Home based primary care	144,447	2.5%
Caregivers	35,117 (2020) 43,500 (2021)	

Appendix B: ACIP/CDC Phases of Vaccination

This graphic is from the 11/23/20 meeting of the Advisory Committee on Immunization Practices and is up to date as of 12/12/2020. ***Phase 1a has passed a vote and is now official CDC guidance, while Phases 1b and 1c remain in draft as of 12/14/2020.***
https://www.cdc.gov/mmwr/volumes/69/wr/mm6949e1.htm?s_cid=mm6949e1_w



https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-11/COVID-04-Dooling.pdf

According to CDC, they will use Cybersecurity & Infrastructure Security Agency definitions for essential workers. CDC noted that this comprises about 87 million persons in the United States. It is not known how many of our Veterans would be considered Essential Workers

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations-process.html

Appendix C: Using the risk-stratification (prioritization) table

Using the risk-stratification framework: Groups of staff not specified

Note: risk stratification depends on following infection control guidance on personal protective equipment and screening measures.

This table includes only categories of staff and units with predictable exposure risks across VA; others, such as food service workers, environmental management, IT, radiology and engineering, are not specifically assigned because exposure and risk patterns varies significantly from site to site. More information will be forthcoming regarding COVID-19 vaccination of staff who do not work in clinical roles, such as administrative staff who work virtually and VA Central Office staff.

It is expected that all staff will be included in COVID-19 vaccine planning. Because of variation in assignments and movement patterns from site to site, local determination must be made based on local patterns of movement and exposure.

For each subset of staff that are not directly mentioned in this framework, the four major risk-based criteria that form the basis for prioritizing healthcare personnel vaccination should be compared to those of the units listed (risk of acquiring SARS-CoV-2 infection, risk of transmitting SARS-CoV-2 infection to others, risk of severe morbidity and mortality, and societal/hospital impact if unable to work). Staff members should be offered vaccine along with the group or unit most resembling their risk profile. For example, Home Based Primary Care providers who care for COVID-19 patients may fall under “Other staff providing face-to-face care for COVID-19 patients”; those who perform high risk procedures in the home but do not care for COVID-19 patients may fall under “Staff performing high risk procedures”; and those who perform general outpatient care of patients without COVID would fall under “Outpatient direct care”. Similarly, food service workers may be offered vaccine along with the COVID+ units if they spend significant time interacting with patients in that setting. Staff who do not interact with patients at all may be assigned with “all other staff” depending on work-related risk profile. See additional examples at end of this section.

Using the priority framework: Age stratification and Risk stratification

The relative effects of comorbid ‘high-risk’ conditions on overall COVID-19 risk are attenuated in older age groups because of the high level of risk associated with increasing age. The role of high-risk conditions as defined by CDC and membership in certain high-risk racial or ethnic minority groups becomes increasingly important in younger age groups, as overall risk decreases. The expectation is that VA will have ample availability of COVID-19 vaccine by Phase 1c, and it is for this reason that risk groups are addressed as a priority for outreach but are not tightly stratified.

Outreach and education to ensure that we are reaching Veterans in high-risk racial and ethnic minority groups and Veterans with high-risk medical conditions must be a focus of COVID-19 vaccination planning at all sites. While these groups are categorized together based on similar risks of morbidity and mortality due to COVID-19, the needs of each group are distinct and targeted communications are vital.

Using the risk-stratification framework: Flexibility of the framework

- **Flexibility for Staff**
  As above, it is expected that this framework will be followed to ensure that benefits to staff and Veterans are maximized during periods of limited vaccine supply and that vaccine is offered in a way that is ethical and equitable. However, local flexibility is needed in assigning staff not specifically mentioned, as noted under "Groups of staff not specified". Additionally, significant flexibility may be needed for feasibility of use with vaccine products requiring ultra-cold storage methods. While it is expected that general principles of this framework will be followed, it is possible that additional staff or Veterans who are not in the highest risk groups may need to be included in several scenarios, including if: interest in initial vaccine is low (i.e., vaccine hesitancy); there are cancellations among scheduled staff or Veterans and a waitlist must be utilized to avoid wasting vaccine; or significant side effects from vaccine are expected (e.g., it may be preferable not to vaccinate entire units of staff simultaneously if potentially work-curtailing side effect from vaccination are common, as this would jeopardize ability to work, and potentially affect safety of other staff and Veterans).

- **Flexibility for Veterans**
  It is expected that this framework will be followed when offering COVID-19 vaccine to Veterans to ensure equitable vaccination across VA.
  For the first dose in the vaccine series, it is not expected that COVID-19 vaccines be held if there is delay among Veterans in the highest risk groups in returning calls and mailings for scheduling, and it is reasonable to continue on to next priority groups as long as reasonable attempts have been made to reach and schedule Veterans in the higher risk group.

Using the priority framework: staff and Veterans who opt out for the first vaccine
For staff and Veterans who opt out of receiving the first COVID-19 vaccine but are in a priority group to vaccinate early, they should still be eligible to receive COVID-19 vaccine later even if unwilling or unable to receive COVID-19 vaccine initially, unless they have changed jobs/roles and no longer meet criteria for prioritization. These staff and/or Veterans should be considered and scheduled along with whichever priority group is prioritized for COVID-19 vaccine at the time they 'opt in' but should not be allowed to take the place of another Veteran that has already been scheduled for COVID-19 vaccination. There is possibility of delays in scheduling due to high demand or limited quantity of COVID-19 vaccine.

Using the priority framework: COVID-19 vaccine requirements.
Being in a high priority group for COVID-19 vaccination means that COVID-19 vaccine should be offered. ***However, COVID-19 vaccination will not be required while a vaccine is available under an Emergency Use Authorization.*** Many healthcare personnel are at risk for SARS-CoV-2 infection and may also transmit SARS-CoV-2 to others, including patients who may be at high-risk for severe COVID-19 disease if they become infected. For this reason, healthcare personnel will be encouraged to get vaccinated to lower risks to themselves, colleagues, and their patients.

Assignments and Personal Protective Equipment: Decision to accept or refuse COVID-19 vaccine

Veterans and staff should continue to follow infection control recommendations regardless of COVID-19 vaccination status, including masking for source control and distancing. Staff should not be assigned differently based on their decision to accept or decline vaccine, as this may create incentives to either receive or decline vaccination.

Additional Examples:

There is some degree of risk associated with any in-person work during the COVID-19 pandemic and the goal is to eventually offer COVID-19 vaccine to all staff. While supply of COVID-19 vaccine is limited, it must first be offered to those with highest risk of exposure to COVID-19 in the workplace, those caring for the most vulnerable patients, and those critical to continued ability to maintain operations, care for Veterans, and keep staff safe. This list is not inclusive of all occupations and is meant to provide examples to guide decision making at the facility level.

Community Living Centers (CLCs) – to start with a unit listed, it is expected that all staff performing roles on this unit where they will be interacting closely with Veterans and other unit staff will be offered vaccination with the unit. This may include, for example, nurses, physicians, technicians drawing blood, other unit-based personnel.

Food Services –personnel should be prioritized based on with whom they interact, which determines their risk of COVID exposure in the workplace. If frequent close contact* with COVID-positive patients is expected, it may be most appropriate to offer those staff vaccine along with staff in those units. If they do not enter rooms on those units, it may be more appropriate to offer vaccine with non-COVID inpatient or outpatient staff, depending on pattern of service.

Environmental Management Services –should be considered similarly to food services, based on units in which service is provided.

Nursing staff who work in multiple units – nursing staff working across multiple units should be offered vaccine with the highest risk unit in which they are assigned.

Scheduling staff – when to offer vaccine to scheduling staff will depend on the environment in which they work. If they have direct contact with Veterans, they should be assigned according to whether that includes close contact with COVID positive, unscreened, or pre-screened Veterans.

Van Drivers – van drivers interacting with Veterans who have been pre-screened as with hospital entry may be considered at similar risk to outpatient non-COVID clinics, provided they have the same personal protective equipment (PPE). If Veterans have not been pre-screened, it would be most reasonable to consider them along with persons who interact with Veterans who have not been pre-screened.

Entry Screeners – entry screeners for hospitals and clinics may have close contact with persons who have not been pre-screened for COVID signs and symptoms.

Vaccination Providers – risk for should be considered based on screening processes and likelihood of close contact with persons who are COVID positive, in comparison to units listed.

Anesthesiology – risk should be considered based on whether services are performed on COVID-positive patients (similar risk to COVID ICU personnel), pre-screened patients only (risk

similar to those performing high-risk procedures) or include roles such as functioning on a cross-cutting code team (risk similar to the staff in the highest-risk unit that the code team serves).

Gastroenterology – this is an example of a specialty where some may be performing high risk procedures, some on COVID-positive patients (similar risk to COVID unit personnel), some on pre-screened patients (similar risk to those performing high risk procedures) while others may provide virtual care only (offered vaccine after it has been offered to staff providing in-person care). Risk stratification should align with services provided.

Home Based Primary Care – risk will depend on whether care is provided for COVID-positive patients, whether high-risk procedures are performed, and on symptom screening processes.

Support staff on site, no patient contact –staff will need to be considered based on risk. Limited personnel may be considered as critical to operations, while most would be offered vaccine after all Veteran/patient-facing staff have been offered.

VA Central Office Employees – these staff are expected to be offered vaccine after healthcare personnel, with limited exceptions for those persons critical to maintain operations or critical to the COVID response.

Staff working virtually – these staff would be considered after staff providing in-person care. There may be limited exceptions to keep a minimum core of staff for ongoing care of Veterans.

* definition of close contact should follow CDC definitions.

Appendix D: Ethical Justifications for COVID-19 Vaccine Allocation in a Situation of Scarcity

VHA's National Center for Ethics in Health Care

When allocating a scarce health care resource, such as a vaccine, VA health care leaders and experts must develop an ethically justifiable plan or framework for how to allocate the resource. When vaccines against SARS-Cov-2, the virus that causes COVID-19, first become available, there will be a limited supply of doses, requiring a fair plan to determine who will receive the vaccine first. If we only have 100 doses of a vaccine, and 1000 people need to be vaccinated, selecting who should receive the vaccine will depend on several factors. Are the individuals being considered for COVID-19 vaccination similar to those on whom safety and efficacy of the vaccine has been demonstrated? Will targeting the COVID-19 vaccine to these individuals or groups better stop the spread of the virus? What are practical methods for vaccine administration? Unfortunately, there are many unknowns related to COVID-19 that challenge the ability to unequivocally predict which vaccine allocation framework will provide the most benefit and avoid the most harm to individuals and society. However, VA has developed an ethically defensible approach to vaccine allocation that has been informed by a wide range of subject matter experts.

In the very early phase of vaccine availability, the goal will be to select only individuals meeting certain scientific and ethical criteria to vaccinate so that benefit to Veterans and VA staff is maximized, and everyone is treated with equal respect. As more vaccine becomes available, the goal will be to expand outreach so that the greatest number of Veterans and VA staff will be vaccinated to achieve community immunity (also referred to as "herd immunity") from COVID-19. Below, we expand on the ethical justifications for the VA's proposed allocation plan. This includes maximizing benefit to Veterans, treating people with equal concern (meaning attributing the same worth to all individuals regardless of their vaccine allocation priority), and addressing health inequities as they relate to vaccination.

Maximizing benefit

The ethical principle of utility involves seeking the greatest good for the greatest number of people—that is, maximizing benefit to society. Assuming that an FDA authorized or licensed vaccine mounts a sufficient immune response against the SARS-CoV-2 virus, three categories of benefit may be achieved: (1) sparing infection, illness, and death from COVID-19 in vaccinated individuals; (2) not spreading the virus; and (3) allowing vaccinated individuals to continue serving as essential workers. In the early phase of COVID-19 vaccine deployment, when there is more demand than supply, benefit is maximized by vaccinating individuals for whom all three categories of benefit can be achieved. Because COVID-19 spreads fastest in areas where there are people in close quarters and harms are greatest for those who are vulnerable to becoming seriously ill (e.g., elderly people with multiple medical conditions), prioritizing health care workers who care for such individuals will mitigate the spread of the virus to the patients in their care. COVID-19 vaccination would thus begin with the staff of community living centers (CLCs) and spinal cord injury and disorder (SCID) facilities, followed by vaccinating patients in these facilities. This is justified because the patients there are at higher risk of contracting COVID-19 and suffering severe or fatal outcomes. In a modeling study from

CDC, vaccinating staff first was likely to more effectively halt viral contagion in such facilities. This is because staff interact with a greater number of individuals and can more easily spread the virus, especially when infected with SARS-CoV-2 but showing no symptoms of COVID-19. Also, staff (being generally younger and healthier) may more effectively mount an immune response as a result of receiving the COVID-19 vaccine.

The categories of persons allocated to receive the vaccine next represent evaluations, in decreasing order of priority, of which VA staff and Veterans are most likely to transmit SARS-CoV-2to others, be removed from critical professional functions, and/or are most at risk of contracting SARS-CoV-2 and suffering serious or fatal illness. The latter (individuals at highest risk of suffering serious or fatal illness) are those with advancing age and presence of comorbid conditions such as asthma, kidney disease, diabetes, high blood pressure, and obesity. As more becomes known about COVID-19, adjustments may be made to these allocation phases to achieve maximum benefit to the most people from the vaccine allocation framework.

It is important that Veterans and VA staff maintain trust in VA's plan for COVID-19 vaccine allocation. Allocation decisions should be based on the principles outlined here and not on arbitrary factors or individual favoritism or perceived social worth. For example, if COVID-19 vaccine is dispatched to a CLC facility and all CLC staff with direct patient contact are eligible to be vaccinated, all such staff should have an equal opportunity to be selected for vaccination, rather than using an ad hoc process. Effectively informing COVID-19 vaccine-eligible individuals of the risks and benefits of the candidate vaccine and establishing a fair and transparent process for selecting which individuals to vaccinate is essential. All communication should be truthful and respectful to earn, secure, and maintain trust in the COVID-19 vaccination program.

Independent of the COVID-19 vaccine allocation protocol, vaccine acceptance will be critical for any vaccine program because to achieve community immunity, most VA Veterans and staff will need to be vaccinated against COVID-19. A recommended approach is to provide tailored education to individuals on both the benefits (both to them individually and to society) and burdens of and concerns with accepting the vaccine and to appeal to altruism and solidarity in achieving vaccine acceptance. Special efforts are necessary to minimize the number of vaccine non-adopters, a term encompassing individuals hesitant to accept vaccine (due to lack of information, misinformation, or emotional ambivalence) as well as individuals refusing vaccine (Su et al., 2020). Wilson and Wiysonge (2020) demonstrated a correlation between misinformation spread through false news outlets and social media and vaccine non-adoption. This underscores the importance of effective messaging and education.

There are limits to what is justifiable in the interest of maximizing societal benefit. For example, quarantine of individuals who test positive for COVID-19 has been voluntary to date. However, as stated in VHA's *Ethics Guidance for Pandemics,* 2020, "individual liberties may be limited to prevent harm to others; public health measures are established on this basis." Because individual liberty is highly valued, the notion of using the least restrictive means is critical in promoting COVID-19 vaccine acceptance among Veterans and VA staff. Mandating vaccination either when COVID-19 vaccines are first released or later is a matter for discussion; no decision has been made thus far. A COVID-19 vaccine mandate might be justified if a proven safe and effective vaccine is the least restrictive means to prevent serious harm to others and no alternative is available. This evokes the concept of proportionality, which involves weighing risks, benefits, and alternatives.

Criteria to mandate COVID-19 vaccine will not likely be met in the early vaccination program, since COVID-19 vaccines will initially only be available under emergency use authorization (EUA). An EUA is a mechanism through which the U.S. Food and Drug Administration (FDA) may facilitate the availability and use of certain unapproved medical countermeasures, including vaccines, during public health emergencies. Under an EUA, FDA may allow the use of an unapproved medical product, or unapproved uses of approved medical products, in an emergency when certain statutory criteria have been met. FDA has stated that, for a COVID-19 vaccine for which there is adequate manufacturing information, FDA may issue an EUA if FDA determines that the vaccine's benefits outweigh its risks based on data from at least one well-designed Phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner. EUA criteria include that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition, that the known and potential benefits of the vaccine outweigh its known and potential risks, and there are no adequate, approved, and available alternatives (FDA, 2017).

Treating people with equal concern

Fairness does not require treating everyone exactly alike. For example, an elderly individual residing in a CLC rightly warrants getting vaccinated earlier than a younger, healthy person living at home because the elderly individual's risk of serious illness and death is greater. This does not mean that the elderly individual is considered more valuable, rather, he or she has greater need to be protected from the virus. Fairness in this context involves giving opportunity of access based on need. Every individual, however, is equally valued and thus should be treated with equal concern. Discharging this ethical duty involves providing consistent, respectful, and accurate communication to earn, secure, and maintain Veterans' and VA staff's trust in the COVID-19 vaccination program.

This duty to show equal concern and respect for all persons likewise disallows deprioritizing older adults for COVID-19 vaccine allocation on a utilitarian basis. For example, some have reasoned that because the mortality rate from COVID-19 is five times higher for individuals 80 years of age and older and that such individuals have limited remaining life years left, this would justify allocating resources to younger individuals with better prognoses and more years of life to enjoy. However, Veterans are older on average than the general population (over 50% of Veterans in VA care are 65 years and older) and denying older Veterans priority access to a potentially lifesaving or disease-sparing vaccine is inconsistent with VA values. Instead, VA's COVID-19 vaccine allocation plan *prioritizes* older Veterans because of their vulnerability to the disease. This is based on an assessment of their need (i.e., sparing disease and contagion) and equal regard for their worth.

Addressing health inequities

National U.S. data show that COVID-19 has disproportionately affected persons of color (Kopel et al. 2020). This is attributed to social injustices that create a higher disease burden and shorter lifespan in this population (Ajilore & Thames 2020). Geronimus (1992) attributed this partly to the concept of "weathering," that lifelong exposure to the stresses of racial disparity and injustice manifests in greater physical and psychological disease burden and less ready access to quality health care and health-related resources. In addition, persons of color are more likely to work and live in settings with higher exposure to SARS-CoV-2. That is, merely being Black or Hispanic or Native American does not cause one to more easily contract SARS-CoV-2. Rather,

the lifetime social disadvantages experienced by persons of color make them more likely to have health problems that predispose them to contract SARS-CoV-2and more often suffer serious or fatal outcomes. Thus, these individuals, along with others who are at risk for suffering serious or fatal illness due to the presence of comorbidities, will be prioritized for COVID-19 vaccine per the allocation plan as a consequence of risk factors.

There is widespread consensus that more must be done to rectify health disparities upstream through improved access to quality education, preventive health care, economic and job opportunities, safe housing and healthy food, reduced exposure to crime and violence, and public safety (CDC, n.d.). The VA plays a role here in its provision of high-quality health care to Veterans. Another way to address health disparities is to reach out effectively to communities of color and others who have been socially disadvantaged to engage them in the vaccination process. Active efforts must be made to address concerns about vaccine safety and fairness in the allocation process. Outreach efforts should engage community champions to ensure that communications are culturally congruent and transparent and remove access obstacles that might thwart individuals who are eligible for vaccine from getting it.

Other duties to address health inequities include ensuring that individuals with disabilities have unimpeded access to vaccine when they are eligible as per the allocation plan. This involves anticipating and removing access barriers by accommodating persons who are blind or have low vision, deaf, or hard of hearing, and cognitively or physically impaired, in communications and logistics for vaccine administration. For example, messaging should be available in plain language and in multiple formats, such as audio, large print, and captioning, and websites or health alerts should provide accessible information.

SUMMARY

Ensuring trust in vaccine allocation decisions requires using objective criteria to justify these decisions with a clear explanation of their ethical basis and applying criteria equally across settings. These ethical criteria are described above. The procedural principles undergirding VA's COVID-19 vaccine allocation framework include fairness, transparency, and reliance on best-available scientific evidence. This requires communication that is tailored to specific groups, consistent, respectful, and accurate to earn, secure, and maintain the trust of VA staff and Veterans under their care.

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Evidence Review and Rationale

Healthcare Personnel

Healthcare Personnel are prioritized for vaccination based on risk of acquiring infection, risk of passing infection to others, and risk of harm to society and hospital operations if unable to work.

Among those with status available, healthcare personnel status represented 6% of infections documented in COVID-NET from March 1–May 31, 2020 (Kambhampati). Seroprevalence studies among healthcare personnel have shown high rates, comparable to areas that have had a high burden of SARS-CoV-2 infection.

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Persons residing in nursing facilities

Persons residing in nursing care, including CLC and Spinal Cord Injury (SCI) centers within VA, have borne a profoundly disproportionate burden of infections, morbidity, and mortality throughout the pandemic. As of November 9, 2020, CMS reported 281,110 confirmed nursing home cases and 63,617 confirmed deaths (CMS). In the US, 9,913,553 cases were reported as of the same date, and 237,037 deaths (CDC). This represents at least 2.8% of infections and 26.8% of deaths in the United States, even though <1% of the United States population resides in nursing care (see note).

In modeling studies presented by the data, analytics, and modeling task for the Advisory Committee on Immunization Practices for CDC on August 26 2020, a model of vaccinating nursing home healthcare personnel versus nursing home residents showed greater reductions in both infections and deaths when personnel received vaccine (Slayton), which offers support to vaccinating staff in nursing homes first.

Note: In 2016, there were an estimated 286,300 current participants enrolled in adult day services centers, 1,347,600 current residents in nursing homes, (National Center for health statistics) At the end of December 2016, the US population was 324,310,011 (United States Census Bureau).

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Slayton, Rachel B. Modeling Allocation Strategies for the Initial SARS-CoV-2 Vaccine Supply. Presented for the Advisory committee on Immunization practices 26 August 2020. https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-08/COVID-06-Slayton.pdf

Essential Workers

According to CDC, “workers in essential and critical industries are considered part of America’s critical infrastructure, as defined by the Cybersecurity & Infrastructure Security Agency. Current data show that many of these workers are at increased risk for getting SARS-CoV-2 (the virus causing COVID-19). Early vaccine access is critical not only to protect them but also to maintain the essential services they provide U.S. communities.” In the November 2020 meeting of the Advisory Committee on Immunization Practices, a proposal was made that offering immunization to this group prior to offering vaccine to persons 65 and older, and with high risk medical conditions (except for those in long term care facilities) was supported by the balance of science, ethics, and ability to implement.

Ethical Principle	Essential Workers (non-healthcare) (~87 million)	Adults with high-risk medical conditions (>100 Million)	Adults age ≥65 years (53 Million)
Maximize benefits and minimize harms	Preserves services essential to the COVID-19 response and overall functioning of society “Multiplier effect”	Reduces morbidity and mortality in persons with high burden of COVID-19 disease and death	Reduces morbidity and mortality in persons with highest burden of COVID-19 hospitalization and death
Promote justice	-Workers unable to work from home (↑exposure risk) -Promotes access to vaccine and may reduce barriers for workers with low vaccine uptake	Will require focused outreach to those with limited or no access to healthcare	Will require focused outreach to those who experience barriers to access healthcare
Mitigate Health inequities	-Racial and ethnic minority groups disproportionately represented in many essential industries -~1/4 of essential workers live in low-income families	Increased prevalence of some medical conditions in race/ethnic minority groups & persons in rural areas -Diagnosis of medical conditions requires access to healthcare	-Highest incidence and mortality in congregate living --Racial and ethnic minority groups under-represented among adults ≥65

McClung N, Chamberland M, Kinlaw K, et al. The Advisory Committee on Immunization Practices' Ethical Principles for Allocation of Initial Supplies of COVID-19 Vaccine — United States, 2020. MMWR Morb Mortal Wkly Rep. ePub: 23 November 2020. DOI: http://dx.doi.org/10.15585/mmwr.mm6947e3external icon

Work Group assessment: Ethics

Ethical Principle	Essential Workers (non-healthcare) (~87 million)	Adults with high -risk medical conditions (>100 Million)	Adults age ⩾65 years (53 Million)
Maximize benefits & minimize harms	+++	++	+++
Promote justice	+++	++	++
Mitigate health inequities	+++	+	+

Work Group assessment: Overall

	Essential Workers (non-healthcare) (~87 million)	Adults with high -risk medical conditions (>100 Million)	Adults age ⩾65 years (53 Million)
Science	+++	+++	+++
Implementation	++	++	+++
Ethics	+++	+	+

Dooling, K. Phased Allocation of COVID-19 Vaccines. Advisory Committee on Immunization Practices COVID 19 Vaccine Work Group. ACIP Meeting 23 November 2020. Accessed 27 Nov 2020 at https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-11/COVID-04-Dooling.pdf

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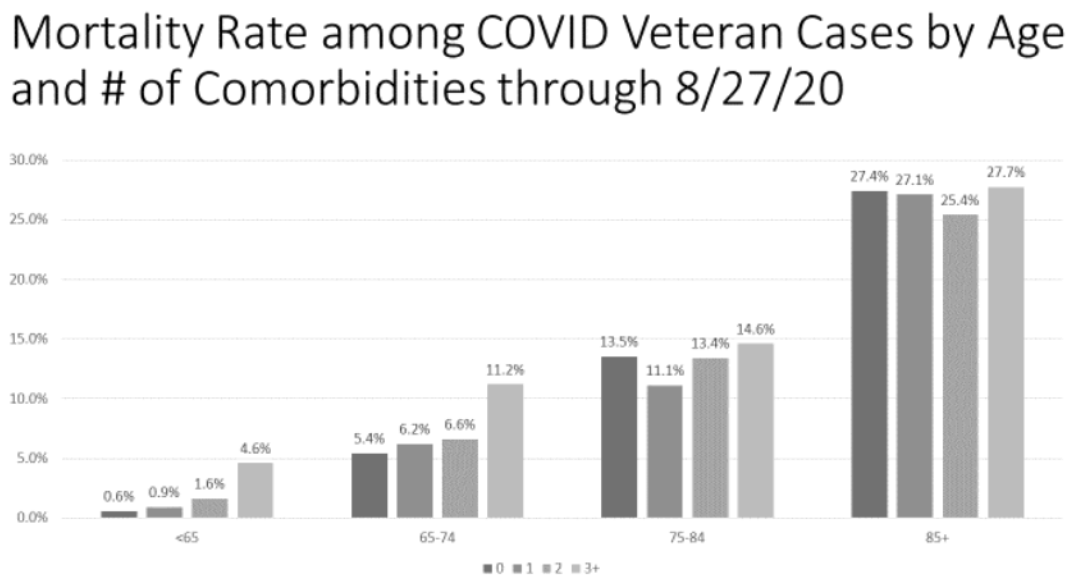
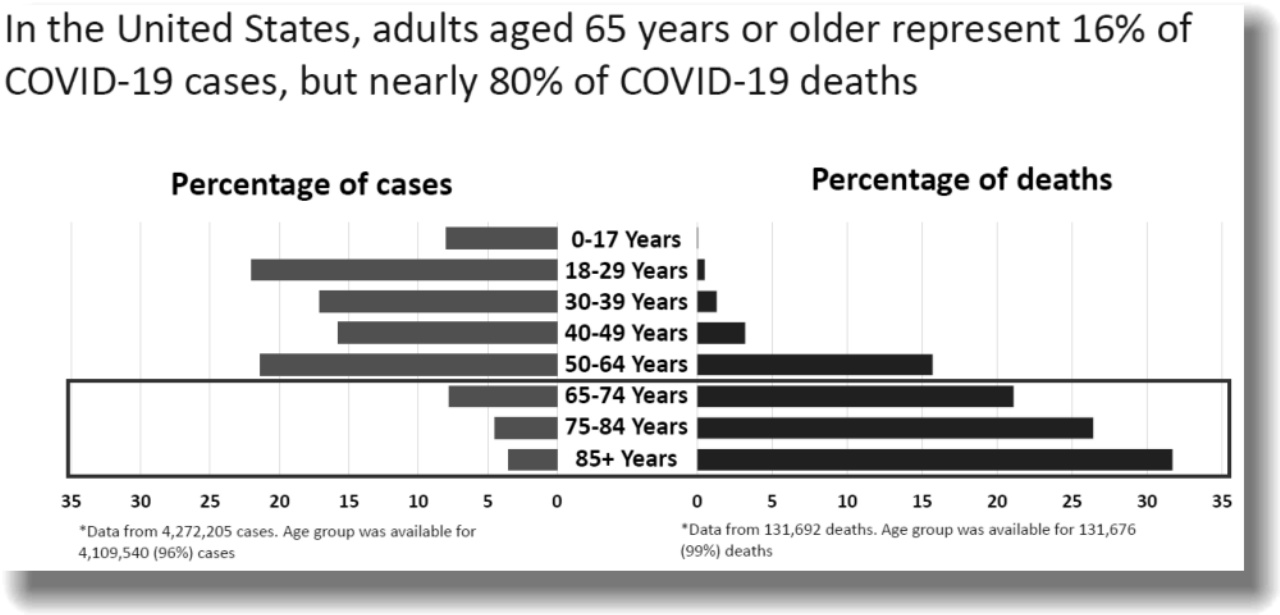
Age

Age has a profound effect on morbidity and mortality related to COVID-19. The Centers for Disease Control and Prevention report that, when compared to persons aged 18-29, hospitalizations are 5 times higher and mortality is 90 times higher in persons aged 65-74; 8 times higher and 220 times higher, respectively, in persons aged 75-84; and 13 times higher and 360 times higher, respectively, in persons aged 85 and older.

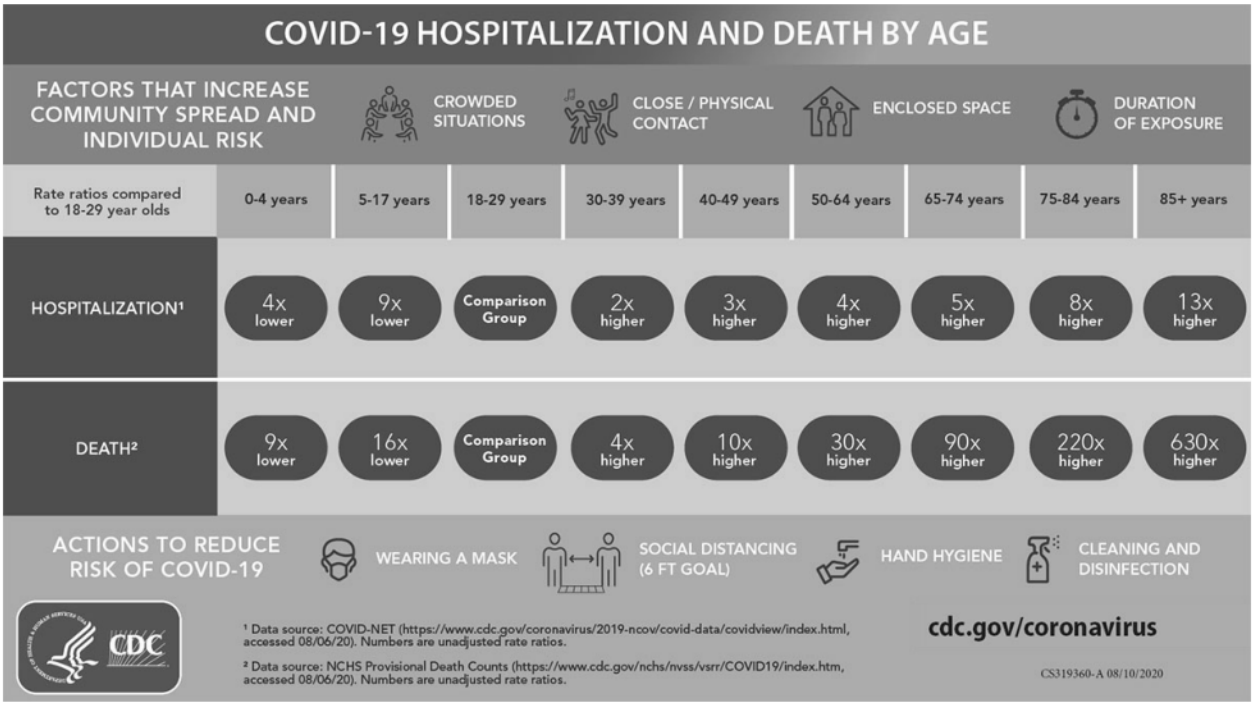
On review of COVID-19-associated mortality among Veterans in VHA, age was found to have a stronger association with excess mortality than other high-risk conditions or combination of multiple conditions (see figure below). Among Veterans, increasing age appears to be a much more significant risk factor even than having several high-risk conditions. Additionally, among persons aged 75 and older, having one or several high-risk conditions did not appear to significantly alter that risk.



Comorbidities: BMI>=30, asthma, diabetes, CKD, IHD, stroke, COPD



Source: ACIP 8/26 Meeting, McClung



Centers for Disease Control and Prevention. COVID-19 Hospitalization and Death by Age. Accessed 9 November 2020 at https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-age.html

Veterans on Hemodialysis

Chronic kidney disease is considered a high-risk condition for severe disease from COVID-19 by the Centers for Disease Control and Prevention with similar magnitude of risk to other high-risk conditions. There is less data specific to hemodialysis. However, data from small studies reveals that mortality rates from COVID-19 may be as high as 14.9-30% among hemodialysis patients.
In addition to high risk of severe disease, morbidity and mortality, persons receiving hemodialysis in a facility or center need to be physically present in a healthcare setting several times per week, which means they are at increased risk of acquiring and passing on infection to others who are also at high risk from COVID-19.

Shimada N, Shimada H, Itaya Y, Tomino Y. Novel coronavirus disease in patients with end-stage kidney disease. Ther Apher Dial. 2020 Oct 11. doi: 10.1111/1744-9987.13599. Epub ahead of print. Accessed 9 November 2020 at. https://onlinelibrary.wiley.com/doi/10.1111/1744-9987.13599

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Trujilo H, et al. SARS-CoV-2 infection in hospitalized patients with kidney disease. Kidney Int Rep. Accessed 9 November 2020 at https://doi.org/10.1016/j.ekir.2020.04.02

Keller N, et al. Impact of first-wave corona virus disease 2019 infection in patients on haemodialysis in Alsace: The observational COVIDAL study. Neprol Dial Transplant. Accessed 9 November 2020 at https://doi.org/10.1093/ndt/gfaa170

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Ma Y, et al. 2019. novel coronavirus disease in hemodialysis (HD) patients: report from one HD center in Wuhan, China. medRxiv 2020; Accessed 9 November 2020 at https://www.medrxiv.org/content/10.1101/2020.02.24.20027201v3

Veterans with a Solid Organ Transplant or who are listed for transplant

Although it is likely that risk differs by timing relevant to transplant (i.e., likely highest closer to time of transplant), data on solid organ transplantation overall shows increased mortality related to COVID-19 when compared to the general population. In a July review in Transplant Infectious Disease, Moosayi et al found that “excluding studies, in which their data about expired patients were not clear in detail, the mortality rate was 18/79 (22.8%), 3/21 (14.3%), 2/10 (20.0%), and 1/6 (16.7%) among patients with kidney, liver, heart, and lung transplantations, respectively”.
In addition to having a high-risk condition, the peri-transplant populations is likely to undergo hospitalization and have frequent medical visits, which increases exposure risk.
When considering magnitude of risk, it is likely highest for those nearer to transplant and those with frequent contact with the healthcare system (i.e. in the peri-transplant period). Because

immunologic response to vaccine may be less post-transplant because of immune-suppression, patients listed for transplant are also included here, and the ideal timing for offering vaccine would be in the pre-transplant period.

Moosavi, S et al. “COVID-19 clinical manifestations and treatment strategies among solid-organ recipients: a systematic review of cases.” *Transplant infectious disease: an official journal of the Transplantation Society*, e13427. 24 Jul. 2020, doi:10.1111/tid.13427 Accessed 18 November 2020 at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7404594/pdf/TID-9999-e13427.pdf
Ketcham, S.W., et al., Coronavirus Disease-2019 in Heart Transplant Recipients in Southeastern Michigan: A Case Series. Journal of Cardiac Failure, 2020.

Akalin, E., et al., Covid-19 and Kidney Transplantation. New England Journal of Medicine, 2020. Accessed 10 November 2020 at https://www.nejm.org/doi/full/10.1056/NEJMc2011117

Latif, F., et al., Characteristics and Outcomes of Recipients of Heart Transplant With Coronavirus Disease 2019. JAMA Cardiology, 2020. Accessed 10 November 2020 at https://jamanetwork.com/journals/jamacardiology/fullarticle/2766123

Fernández-Ruiz, M., et al., COVID-19 in solid organ transplant recipients: A single-center case series from Spain. American Journal of Transplantation, 2020. 20(7): p. 1849-1858. Accessed 10 November 2020 at https://onlinelibrary.wiley.com/doi/full/10.1111/ajt.15929

Travi, G., et al., Clinical outcome in solid organ transplant recipients with COVID-19: A single-center experience. American Journal of Transplantation, 2020. Accessed 10 November 2020 at https://onlinelibrary.wiley.com/doi/10.1111/ajt.16069

Tschopp, J., et al., First experience of SARS-CoV-2 infections in solid organ transplant recipients in the Swiss Transplant Cohort Study. American Journal of Transplantation, 2020. Accessed 10 November 2020 at https://pubmed.ncbi.nlm.nih.gov/32412159/

Veterans on Chemotherapy (in person, facility-based)

According to the Centers for Disease Control and Prevention, having current cancer increases risk of severe illness from COVID-19, but it is not known at this time whether a history of cancer increases that risk.

The data on cancer and COVID-19 risk are mixed and limited by heterogeneity of cancer types and prognoses.

It is not clear what role immunosuppression plays in COVID-19 risk. Rather, the rationale for placing Veterans receiving in-person, facility-based chemotherapy is that they must be physically present in a healthcare setting on a regular basis, generally for prolonged periods of time and often in a communal setting. This means that this group is not only at elevated risk for morbidity and mortality from COVID-19, but also for acquiring and passing on infection.

Centers for Disease control and prevention. People with Certain Medical Conditions. Accessed 9 Nov 2020 at https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html#cancer

Centers for Disease control and prevention. Evidence used to update the list of underlying medical conditions that increase a person’s risk of severe illness from COVID-19. Accessed 9 Nov 2020 at https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/evidence-table.html

Fung M, Babik JM. COVID-19 in Immunocompromised Hosts: What We Know So Far. 27 June 2020. Clin Infect Dis. 2020; Accessed 9 Nov 2020 at https://pubmed.ncbi.nlm.nih.gov/32592461/

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Robilotti, EV, et al. Determinants of COVID-19 disease severity in patients with cancer. Nature Medicine. 2020. 26(8): p. 1218-1223. Accessed 9 Nov 2020 https://pubmed.ncbi.nlm.nih.gov/32581323/

Zhang H et al. Outcomes of novel coronavirus disease 2019 (COVID-19) infection in 107 patients with cancer from Wuhan, China. Cancer. https://pubmed.ncbi.nlm.nih.gov/32573776/

Veterans Experiencing Homelessness

There is very limited data available on the impacts of the COVID-19 pandemic on homeless persons, and demographic data including homelessness and housing is not always available for hospitalized patients. However, homeless persons are more likely to have underlying high-risk conditions and fall into older age groups. Additionally, and particularly during the winter months, persons experiencing homelessness are at high risk of needing housing in congregate living settings.

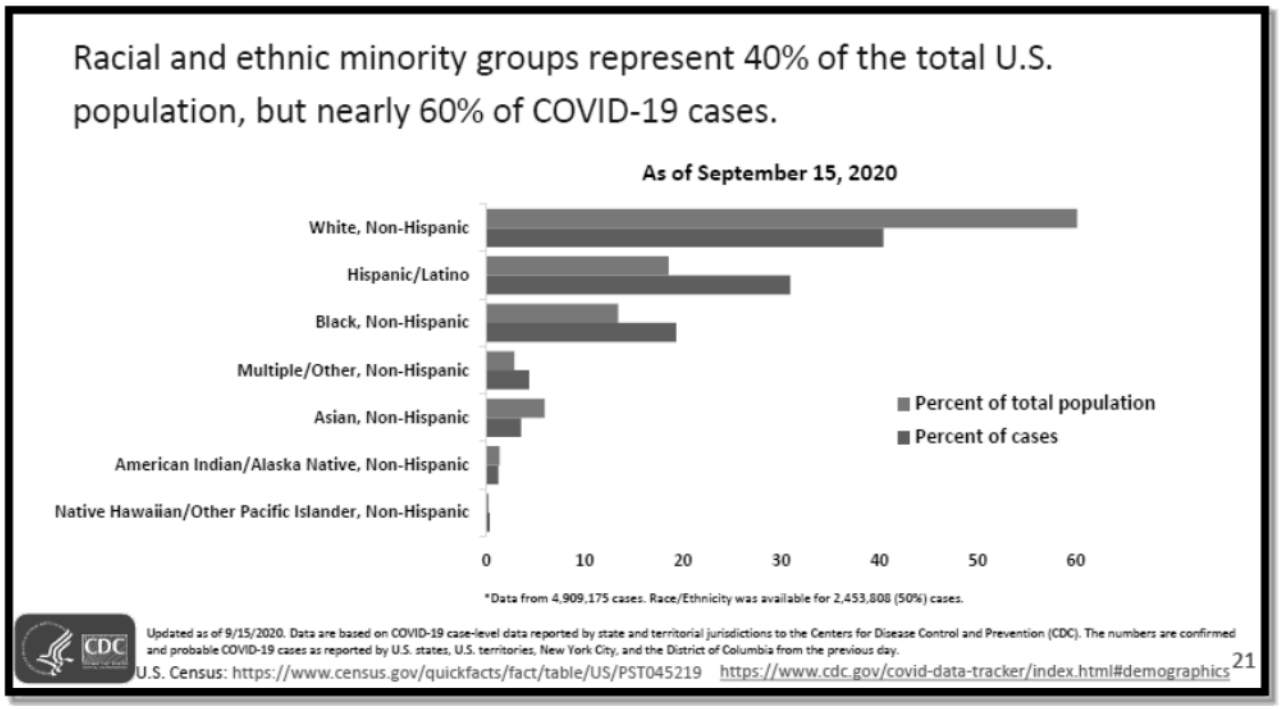
Centers for Disease Control and Prevention. People Experiencing Homelessness. Accessed 4 December 2020 at: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/homelessness.html

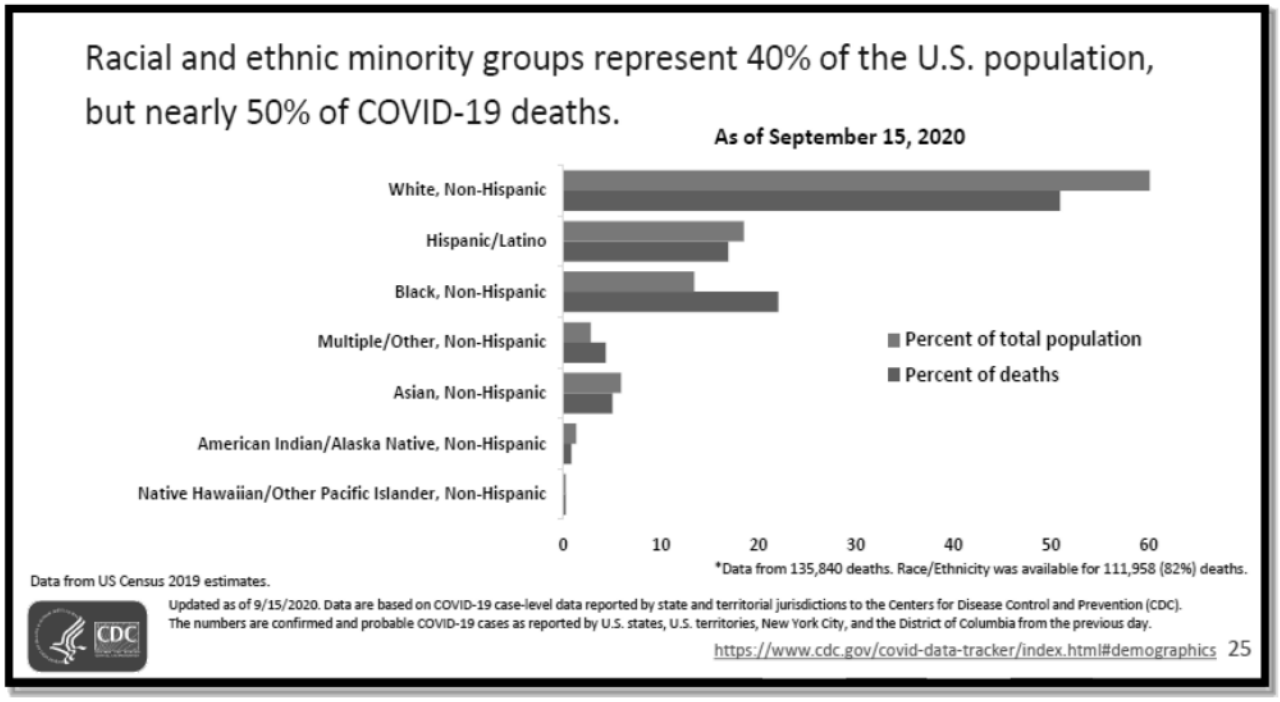
Perri, M et al. COVID-19 and people experiencing homelessness: challenges and mitigation strategies. Canadian Medical Association Journal. 29 June 2020. Accessed 9 Nov 2020 at https://www.cmaj.ca/content/192/26/E716

Race and Ethnicity

Certain racial and ethnic minorities are at higher risk for acquiring SARS-CoV-2 infection and for severe outcomes from COVID-19. The disproportionate burden of COVID-19 on racial and ethnic minorities has been well described and is thought to be multifactorial.

Racial and ethnic minorities make up 40% of the population but about 50% of the COVID-19 deaths. In the United States, there are about 25% more COVID-19 deaths in racial and ethnic minorities than there should be based on population size, and the mortality differences indicates that the burden of COVID-19 on these communities cannot be adequately explained by overdiagnosis bias. For some groups, risks associated with COVID-19 are comparable to risks for persons with a high-risk condition, so it is important that this be a focus of outreach and education.





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Price-Haygood EG, Burton J, Fort D, Seoane L. Hospitalization and Mortality among Black Patients and White Patients with Covid-19. N Engl J Med 2020. Accessed 9 Nov 2020 at https://doi.org/10.1056/nejmsa2011686.

Millet GA, Jones AT, Benkeser D, et al. Assessing Differential Impacts of COVID-19 on Black Communities. Ann Epidemiol. 2020;47:37-44. Accessed 9 Nov 2020 at https://doi.org/10.1016/j.annepidem.2020.05.003.

Killerby ME, Link-Gelles R, Haight SC, et al. Characteristics Associated with Hospitalization Among Patients with COVID-19 — Metropolitan Atlanta, Georgia, March–April 2020. MMWR Morb Mortal Wkly Rep. ePub: 17 June 2020. Accessed 9 Nov 2020 at http://dx.doi.org/10.15585/mmwr.mm6925e1 .

Stokes EK, Zambrano LD, Anderson KN, et al. Coronavirus Disease 2019 Case Surveillance — United States, January 22–May 30, 2020. MMWR Morb Mortal Wkly Rep 2020;69:759–765. Accessed 9 Nov 2020 at http://dx.doi.org/10.15585/mmwr.mm6924e2.

Gold JA, Wong KK, Szablewski CM, et al. Characteristics and Clinical Outcomes of Adult Patients Hospitalized with COVID-19 — Georgia, March 2020. MMWR Morb Mortal Wkly Rep 2020;69:545–550. Accessed 9 Nov 2020 at http://dx.doi.org/10.15585/mmwr.mm6918e1.

Veterans younger than age 75

While the relative effects of comorbid 'high-risk' conditions on overall COVID-19 risk are attenuated in older age groups and other very high risk populations, the role of CDC high-risk conditions and membership in certain high-risk racial or ethnic minority groups becomes increasingly important in younger age groups, as overall risk decreases. It is predicted that VA will have ample availability of vaccine by Phase 1c, and it is for this reason that risk groups are addressed as a priority for outreach but are not tightly stratified.

Outreach and education to ensure that we are reaching Veterans in high-risk racial and ethnic minority groups and Veterans with high-risk medical conditions must be a focus of COVID-19 vaccination planning at all sites. While these groups are categorized together based on similar risks of morbidity and mortality due to COVID-19, the needs of each group are distinct and targeted communications are vital.

Appendix F: Workgroup Members

Lisa Backus, MD, PhD
Acting Chief Consultant Health Solutions
Deputy Chief Consultant, Measurement and Reporting
VHA Population Health Services

Gio Baracco, MD
VISN 8 Infectious Disease Lead
Chief, Infectious Disease Section
Hospital Epidemiologist and Medical Director, Infection Prevention and Control
Miami VA Healthcare System

Pamela Belperio, BCPS, AAHIVP
National Public Health Clinical Pharmacy Specialist
VHA Population Health Services

Sophia Califano, MD, MPH
Deputy Chief Consultant, Preventive Medicine
VHA National Center for Health Promotion and Disease Prevention

Marla Clifton, MSN, RN, CIC
Clinical Programs Coordinator
VHA National Infectious Diseases Service

Jacqueline Cook, MD
Medical Advisor
VHA Office of OSH and GEMS Programs

Kathleen DeRoos, APRN, MSN
Healthcare Associated Infection (HAI) Clinical Program Coordinator
Infection Prevention & Control
VHA National Infectious Diseases Service

Ajay Dhawan, MD
National Director of Medicine
VHA Specialty Care Services

Kelly Echevarria, PharmD
National Clinical Pharmacy Program Manager
VHA Pharmacy Benefits Management

Jane Kim, MD, MPH
Chief Consultant, Preventive Medicine
VHA National Center for Health Promotion and Disease Prevention

Steven Kralovic, MD
Deputy Director
VHA National Infectious Diseases Service

Ernest Moy MD, MPH
Executive Director
VHA Office of Health Equity

Leonard Pogach, MD, MBA
National Program Director
VHA Office of Diabetes and Endocrinology

Gary Roselle, MD
Director
VHA National Infectious Diseases Service

Anita Tarzian, PhD, RN
Deputy Executive Director
VHA National Center for Ethics in Health Care

Patricia Wallace, MSN, RN
Senior Clinical Advisor
VHA Office of Healthcare Transformation

Jennifer Zacher, PharmD
Deputy Chief Consultant
VHA Pharmacy Benefits Management

Vaccine Adverse Event Reporting

VA Center for Medication Safety (VAMedSAFE)April 29, 2021

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Veterans Health Administration

Vaccine AE Reports

Product	Reports	All AE's /10,000 Doses	Anaphylaxis/10,000 Doses	Sent to VAERS
J&J (2)	585	TBD	TBD	583 (99.7%)
Moderna (48)	17687	63.1	0.171	17653 (99.8%)
Pfizer (44)	7208	30.1	0.184	7188 (99.7%)
Grand total	25480	48.9	0.181	25424 (99.8%)

Vaccine AE Reports – Serious/Non-Serious (Unvalidated Information per Reporter Completed AE Template)

	Reports
Serious*	895
Non-Serious	24585
Grand total	25480

*Events where Death, hospitalization, and/or Life-Threatening Event is marked as an outcome

VA ADERS – CV AESI Reports

Symptom	J&J	MODERNA	PFIZER
CARDIAC ARREST	0	15	5
CEREBROVASCULAR ACCIDENT	5	21	10
DEEP VEIN THROMBOSIS	4	9	2
MYOCARDIAL INFARCTION	0	7	3
PULMONARY EMBOLISM	3	9	7

VA ADERS – TIME TO EVENT (MEDIAN DAYS-RANGE)

Symptom	J&J	MODERNA	PFIZER
CARDIAC ARREST	0	3 (1-34)	1 (1-11)
CEREBROVASCULAR ACCIDENT	19 (0-40)	4.5 (0-47)	1 (0-18)
DEEP VEIN THROMBOSIS	12 (3-24)	11 (2-59)	15 (9-21)
MYOCARDIAL INFARCTION	0	5 (0-80)	0 (0-6)
PULMONARY EMOLISM	9 (4-24)	6 (3-20)	9 (1-30)

VA ADERS – CV AESI Reports Breakdown by Employee/Veteran

Symptom	J&J		MODERNA		PFIZER	
	EMP	VET	EMP	VET	EMP	VET
CARDIAC ARREST	0	0	0	15	0	5
CEREBROVASCULAR ACCIDENT	0	5	5	16	0	10
DEEP VEIN THROMBOSIS	0	4	4	5	1	1
MYOCARDIAL INFARCTION	0	0	2	5	0	3
PULMONARY EMBOLISM	0	3	2	7	0	7

VA ADERS – Other AESI Reports

Symptom	J&J	MODERNA	PFIZER
EMBOLISM	1	0	0
EMBOLISM VENOUS	0	2	1
THROMBOCYTOPENIA	0	9	3
THROMBOSIS	5	5	3
VENOUS THROMBOSIS	0	1	0

VA ADERS – TIME TO EVENT (MEDIAN DAYS-RANGE)

Symptom	J&J	MODERNA	PFIZER
EMBOLISM	7	0	0
EMBOLISM VENOUS	0	4 (2-6)	50
THROMBOCYTOPENIA	0	5 (0-20)	1 (0-2)
THROMBOSIS	12 (10-40)	10 (0-41)	22 (9-67)
VENOUS THROMBOSIS	0	1	0

VA ADERS – Other AESI Reports Breakdown by Employee/Veteran

Symptom	J&J		MODERNA		PFIZER	
	EMP	VET	EMP	VET	EMP	VET
EMBOLISM	0	1	0	0	0	0
EMBOLISM VENOUS	0	0	0	2	0	1
THROMBOCYTOPENIA	0	0	4	5	1	2
THROMBOSIS	0	5	1	4	1	2
VENOUS THROMBOSIS	0	0	0	1	0	0

AEs – Top 10 by MedDRA Preferred Term