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COVID-19 Vaccination Plan for the Veterans Health Administration



VA

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Record of Changes

Date	Description of change	Page of section	Posted by
10/15/2020	Release of version 1.0	N/A	N/A
12/14/2020	Release of version 2.0 to reflect EUA for initial vaccine	Executive Summary Overview and updates to all content.	N/A
12/28/2020	Release of version 2.1 to reflect EUA for initial vaccine	Executive Summary Overview, Risk Stratification, and updates to all content. Appendix C: Expanded to include published Risk Stratification Framework Sections Added: » Acronyms	N/A
03/31/2021	Draft of version 3.0 to reflect EUA for third vaccine	Executive Summary Overview, Risk Stratification, and updates to all content.	N/A
06/30/2021	Completion of draft version 3.0, addition of Appendices Q, R, S	117+	N/A
07/2/2021	Completion of version 3.0	N/A	N/A

COVID-19 Vaccination Plan for the Veterans Health Administration

Executive Summary: On June 23, 2021, the United States surpassed 600,000 COVID-19 related deaths. Disease management strategies initially lowered mortality from COVID-19, and the use of non-pharmaceutical interventions (NPI) such as physical distancing, face covering use, self-quarantine when sick, and good hand hygiene lowered new infection rates. Significant surges in the fall and winter from 2020 moving in to 2021 led to high rates of SARS-CoV-2 cases and COVID-19 related deaths per day. Hospitals and intensive care units in multiple areas of the country reached capacity. The pandemic significantly affected the U.S. economy, with lower-income and minority populations bearing the brunt of both financial and medical hardship. A return to normalcy, or the new norm, began to occur in May 2021 when the U.S. had fully vaccinated more than 131 million persons with a COVID-19 vaccine.

The Countermeasures Acceleration Group (formerly known as Operation Warp Speed), a Department of Human & Health Services (HHS) and Department of Defense (DoD) cooperative effort, worked to produce and deliver 300 million doses of safe and effective vaccines to the U.S. population with initial doses available in December 2020. The normal timeline for vaccine development was significantly compressed through a series of process streamlines, new partnerships in the pharmaceutical industry, and significant Federal funding for both development and guaranteed vaccine purchase.

At the beginning of September 2020, the Veterans Health Administration (VHA) chartered a team to plan for the availability of a COVID-19 vaccine as early as October 2020. The Centers for Disease Control & Prevention (CDC) led planning for data collection and vaccine distribution with states, jurisdictions, VA, and other Federal agencies. There were four large-scale Phase II/III vaccine trials underway in the U.S. and the first two vaccine candidates had entered Phase III trials in July 2020. The U.S. Food and Drug Administration (FDA) held a *Vaccines and Related Biological Products Advisory Committee Meeting* on October 22, 2020 to discuss development, authorization and/or licensure of vaccines to prevent COVID-19 and requirements to apply for emergency use authorization (EUA) including efficacy and safety criteria from clinical trials; vaccine safety monitoring and evaluation before and after authorization; and review of chemistry, manufacturing and controls.

The FDA issued an EUA for the Pfizer-BioNTech COVID-19 vaccine, the first COVID-19 vaccine to be authorized for use in the U.S., on December 11, 2020. The Advisory Committee on Immunization Practices (ACIP) and CDC provided interim recommendations for use of the Pfizer-BioNTech COVID-19 vaccine on December 13, 2020, with a full Morbidity and Mortality Weekly Report (MMWR) published on December 18, 2020. On December 18, 2020, FDA issued an EUA for the Moderna COVID-19 vaccine, the second to be authorized in the U.S. ACIP and CDC published their guidance on use of the Moderna COVID-19 vaccine in the CDC's Morbidity and Mortality Weekly Report (MMWR) on December 20, 2020. ACIP also updated their guidance on risk stratification for groups who should be offered COVID-19 vaccination when vaccine supply was limited. On February 27, 2021, FDA issued an EUA for the Janssen COVID-19 vaccine, the third to be authorized in the U.S. ACIP and CDC published their guidance on use of the Janssen COVID-19 vaccine in the CDC's Morbidity and Mortality Weekly Report (MMWR) on March 2, 2021.

The *VHA COVID-19 Vaccination Plan* that follows provides guidance on key aspects of a successful vaccination program for products that have, or will receive, FDA EUA or licensure. Such guidance includes management of vaccination both while supply is limited and when there is robust supply of vaccine, as well as navigation of specific storage and handling constraints. The plan addresses vaccination of Veterans, VA staff, caregivers, staff and residents of State Veteran Homes, other federal partners (e.g., Department of Homeland Security), and all other individuals eligible under SAVE LIVES Act authority. Guidance includes a risk stratification scheme for identifying population(s) at highest risk in order to plan vaccine distribution, vaccine safety monitoring and vaccination reporting as required by CDC and HHS, as well as plans

for education, communications and tabletop exercises. This document served as interim guidance for VHA on how to plan and operationalize a vaccination campaign in response to the COVID-19 pandemic. This document also includes best practices and lessons learned from VHA's 2020-2021 COVID-19 vaccination campaign that may inform future enterprise-wide vaccination efforts.

Overview

The U.S. Government Secretary of HHS declared a public health emergency (PHE) on January 31, 2020, in response to the novel coronavirus disease (COVID-19). The World Health Organization (WHO) declared a global pandemic on March 11, 2020. A pandemic, as defined by the WHO, is a worldwide spread of a new disease occurring over a wide geographic area and affecting an exceptionally high proportion of the population. SARS-CoV-2, the virus that causes COVID-19 disease, has higher rates of infection, hospitalization, and death than influenza. As of July 1, 2021, there were 33,496,454 cases of SARS-CoV-2 in the United States and 602,401 total deaths attributable to COVID-19;¹ in VA, there were 266,197 cases, and 12,466 known deaths.²

SARS-CoV-2 infection may be asymptomatic or cause COVID-19 disease with a range of symptoms from mild to severe. Risk of severe disease and death is higher with increasing age and with comorbid conditions, such as cancer, chronic kidney disease, chronic obstructive pulmonary disease (COPD), solid organ transplant, obesity (body mass index [BMI] of 30 or higher), serious heart condition (e.g., heart failure, coronary artery disease, cardiomyopathies), sickle cell disease and Type 2 diabetes mellitus.^{3,4}

Members of specific racial and ethnic minority populations, including Black or African-American, Hispanic or Latino, and American Indian or Alaska Native, have borne a disproportionate share of COVID illness and death in the United States.⁵ Higher than expected mortality among racial and ethnic minorities was attributed to broader social inequities resulting in higher burden of chronic disease and a greater likelihood of both living in high population density neighborhoods and serving as essential workers, resulting in greater exposure to COVID-19.^{5,6}

Scope of the Guidance

This guidance addresses multiple aspects of vaccine planning including: risk stratification of COVID-19 vaccine administration for VA staff (defined as VA employees, contract employees, volunteers, and trainees) and high-risk Veteran patients during limited vaccine supply; drug distribution focusing on cold chain management; data transmission and interfaces for procuring and recording vaccination activities; and the VHA's tabletop exercise that was designed for facility-level planning prior to vaccine availability. In addition, this guidance addresses vaccination for VHA caregivers, State Veteran Homes, federal partners, and other individuals covered under the SAVE LIVES Act authority. This plan was intended to provide interim guidance and was updated with changes in ACIP, CDC, and FDA guidance.

1 Centers for Disease Control and Prevention. CDC COVID Data Tracker. Accessed 7/1/2021 at: https://covid.cdc.gov/covid-data-tracker/#cases_casesinlast7days

2 US Department of Veterans Affairs. Department of Veterans Affairs COVID-19 National Summary. Accessed 7/1/2021 at: <https://www.accesstocare.va.gov/Healthcare/COVID19NationalSummary>

3 Centers for Disease Control and Prevention. People with Certain Medical Conditions. Accessed 9/26/2020 at: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

4 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 9/26/2020 at: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/evidence-table.html>

5 Centers for Disease Control and Prevention. Health Equity Considerations and Racial and Ethnic Minority Groups. Accessed 9/26/2020 at: <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html>

6 Centers for Disease Control and Prevention. COVID-19 Hospitalization and Death by Race/Ethnicity. Accessed 9/26/2020 at: <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html>

Purpose

This plan outlines VHA activities for COVID-19 vaccination in the United States, Puerto Rico, U.S. territories and Manila, Philippines, where VHA provides health care to enrolled Veterans. VHA will conduct activities necessary to make vaccine available to protect Veterans, staff, federal partners, caregivers and individuals covered under SAVE LIVES Act authority from SARS-CoV-2 infection, and severe disease and death from COVID-19, while maximizing safety related to the vaccine and administration. VHA's COVID-19 vaccination plan was developed in partnership with other federal agencies, including CDC.

Guiding Principles

A successful vaccination program for SARS-CoV-2 in VHA is founded on three guiding principles:

1. The primary goal of the VHA COVID-19 vaccination plan is to lower the risk of infection, severe disease and death from COVID-19, and spread of SARS-CoV-2.
2. Safety of staff and Veterans is the highest priority.
3. Vaccine risk stratification, distribution, and accessibility should be fair, evidence-based, equitable, transparent, and aimed at maximizing benefits of COVID-19 vaccination.

All actions implemented by VHA should be anchored on these principles. The goal of this plan is to prepare VHA medical facilities for early, limited, and targeted vaccination, followed by large scale vaccination. Communication plans should be developed locally, based on national guidance, to ensure Veterans and staff are able to access vaccine and actively participate in VHA's COVID-19 vaccination program.

VHA COVID-19 Vaccination Program Goals

The guiding principles for the VA COVID-19 vaccination plan are supported by three operational goals:

1. Develop and implement a plan to procure, distribute, and administer COVID-19 vaccine for Veterans and VA staff.
2. Develop a population-based risk stratification plan for COVID-19 vaccine administration and implement as required by vaccine supply limitations.
3. Implement solutions to track and report vaccine supply, administration, course completion, safety, and outcomes for internal and external stakeholders.

Tabletop exercises were designed to address each of these goals through a series of operational scenarios at medical centers and community-based clinics. COVID-19 vaccination services through the Care in the Community Network will be determined when vaccine is more widely available.

Roles and Responsibilities

National responsibilities include inter-federal agency collaborations; enterprise-wide standardization for efficiency; ethics; equity; oversight; and assessment of established metrics and outcomes. VISN and Facility leadership are responsible for development and successful implementation of a plan to provide and document administration of vaccine.

National Level Roles and Responsibilities

- » Collaborate with CDC and HHS to develop processes for procuring and distributing vaccine
- » Review ACIP and CDC COVID-19 vaccine recommendations and apply CDC risk stratification framework to VHA
- » Provide guidance on use of Personal Protective Equipment (PPE) for vaccine administration

- » Order vaccine for VA staff and beneficiaries and others as required
- » Gather input and feedback from staff, Veterans, caregivers, and other key stakeholders to inform the development of tailored communication products and targeted educational programs, tools, and resources
- » Create and distribute national communications through the VHA Public Affairs Officer network
 - Educate staff and Veterans about COVID-19 vaccines
 - Initiate outreach to priority groups
 - Provide information on accessing vaccine to Veterans and staff
 - Engage in targeted outreach for second dose/series completion
 - Communicate about vaccine plans, distribution, and supply to VHA staff, enrolled Veterans, federal entities, external partners, and key stakeholders
- » Report vaccine administrative and supply data to CDC, per CDC requirements
- » Establish and report on metrics for the COVID-19 vaccination program
- » Develop national guidance, procedures, and coordination on provision of COVID-19 vaccination services or training to State Veteran Homes, if necessary
- » Develop national guidance, procedures, interagency agreements, and coordination of the provision of COVID-19 vaccination services to employees of other federal agencies, if necessary
- » Develop national guidance, procedures, and coordination of the provision of COVID-19 vaccination services to caregivers of Veterans, if necessary
- » Develop national guidance and procedures on the provision of COVID-19 vaccination services to persons covered by the SAVE LIVES Act authority, including adolescents, if necessary
- » Provide guidance, procedures, and coordination on the reimbursable fund and the COVID-19 reimbursement processes for respective Mission Assignments (MA) and/or Inter-Agency Agreements (IAA) to VISNs

VISN and Facility Roles and Responsibilities

- » Conduct a tabletop exercise to plan for vaccine deployment and administration
- » Assign vaccine coordinators to lead local vaccination planning and implementation
- » Train VHA staff on proper vaccine storage, handling, and administration
- » Provide appropriate PPE to VHA staff for vaccine administration
- » Report vaccine safety through the Vaccine Adverse Event Reporting System (VAERS) via established VA safety data reporting mechanisms
- » Distribute COVID-19 vaccine and ancillary supplies from centralized location to clinics, drive-throughs, and other point-of-care vaccination locations, as vaccine handling constraints allow
- » Communicate and coordinate vaccination services, data collection, and reporting with State Immunization Programs if needed and authorized
- » Develop and implement plans to provide vaccine to State Veteran Homes if necessary, in coordination with national plans and policies
- » Develop and implement plans to provide vaccine to employees of other Federal Agencies as necessary in coordination with national plans and policies
- » Develop plan to administer vaccine to family caregivers enrolled in VA's Program of Comprehensive Assistance for Family Caregivers
- » Develop plan to administer COVID-19 vaccine persons covered by the SAVE LIVES Act authority, including adolescents
- » Develop plan to capture, account and report reimbursables to VHA, and if applicable, in accordance with published VHA Office of Finance, Financial Management and Accounting System ALERTS

Planning Assumptions and Considerations

VHA Operations Relevant to COVID-19 Vaccination

VHA operations will continue to use NPIs after vaccine candidates against SARS-CoV-2 receive emergency use authorization per guidance from the CDC and VHA. Some of the NPIs limit the number of Veterans and staff at VA facilities and must be accounted for in planning mass vaccination strategies. NPIs covered in VHA guidance include:

- » Routine virtual and telephonic outpatient care
- » Staff on maximal telework
- » VHA facility measures to limit the spread of SARS-CoV-2:
 - Limiting number of persons present in each facility
 - Separating persons suspected of having infection from those who are uninfected
 - Maximizing virtual care
 - Requiring source control via face covering or masking for all persons in VHA facilities, regardless of vaccination status, until further guidance is available on modification of source control mitigation measures post-vaccination
 - Requiring eye protection for healthcare personnel
 - Following CDC and VHA-recommended infection control and prevention measures
 - Encouraging and facilitating distancing
- » COVID-19 vaccines may be delivered in newly expanded settings such as mobile units or drive through clinics, in new locations separate from existing screening and triage locations, and in collaboration with other federal and state programs.

As clinical trials data continues to become available on COVID-19 vaccine candidates, FDA and CDC will review these data and make decisions for vaccine authorization and/or licensure as well as recommendations for use. PPE will continue to be required for all contact with suspected and confirmed cases of COVID-19 disease regardless of vaccination status. This requirement will remain in effect until CDC guidance on vaccinated populations and PPE use changes.

Vaccine Recipient Considerations

There are several important considerations related to demand/supply and limited vaccine knowledge to include in the planning process.

- » Allocation for VA will cover VHA workforce and VHA beneficiaries.
 - VA's vaccine allocation will cover VHA staff (including volunteers and trainees) and enrolled Veterans eligible for care at VHA facilities. (State Veteran Veterans Homes not included).
 - VHA has planned for scenarios in which only workforce or only beneficiaries would be included in vaccine allocation.
 - VHA will consider scenarios for COVID-19 vaccination of State Veterans' Homes staff and Veterans, family caregivers enrolled in VA's Program of Comprehensive Assistance for Family Caregivers, federal Partner staff, and persons covered by the SAVE LIVES Act authority, if so directed by VHA leadership.
 - VHA employs approximately 400,000 persons with 247,190 healthcare providers and 44,724 additional essential employees.
 - VHA serves approximately 9 million Veteran beneficiaries with 5.8 million receiving healthcare from VHA.
- » Limited COVID-19 vaccine doses will be available by the end of 2020, with COVID-19 vaccine supply increasing substantially throughout 2021.
- » Health care personnel (HCPs) and highest-risk VHA beneficiaries have been prioritized for early COVID-19 vaccination.

- » Many persons who desire vaccination may face delays in vaccination due to limited initial quantities or distribution limitations.
- » Persons may be hesitant to receive COVID-19 vaccines because of general vaccine hesitancy or due to specific concerns related to COVID-19 vaccine, concerns about safety and efficacy of COVID-19 vaccines, or to avoid personal risk of SARS-CoV-2 infection associated with presenting to a VHA facility for vaccination.
- » Oral informed consent must be obtained before administering a COVID-19 vaccine. Written informed consent is not required for adults 18 and older, although for vaccination of persons 12-17 years of age, written consent from the parent or legal guardian and adolescent assent is required.
- » For vaccines authorized under EUA, the EUA fact sheet must be provided, and any questions answered before administering the vaccine. For Veterans who lack decision-making capacity, informed consent should be obtained from the surrogate as authorized in VHA Handbook 1004.01.

COVID-19 Vaccine Candidate Characteristics

Initially available COVID-19 vaccines may receive biologic licensing but will first be made available for use under an EUA issued by the FDA.⁷

- » Cold chain storage and handling requirements for each COVID-19 vaccine product varies from refrigerated (2° to 8°C) to frozen (-15°C to -25°C) to ultra-cold (-60° to -80°C) temperatures, and ongoing stability testing may impact these requirements.
- » Facilities will develop strategies to ensure correct intervals between COVID-19 vaccine products. For two of the current COVID-19 vaccine products, two doses separated by 21 or 28 days will be needed, and second-dose reminders for patients will be necessary. Both doses will need to be the same vaccine and manufacturer unless there are exceptional circumstances that necessitate 2nd dose from a different manufacturer from the first dose. One of the COVID-19 vaccines requires refrigerated storage only and is a one-dose vaccine.
- » Some COVID-19 vaccine products require reconstitution before administration.
- » Some COVID-19 vaccines have relatively short time intervals between timing of thawing and dilution to time of use.
- » COVID-19 vaccines will be supplied in multi-dose vials.

VHA COVID-19 Vaccine Allocation

The COVID-19 vaccines that were submitted for Emergency Use Authorization from the FDA were anticipated to be initially limited in supply. VHA will distribute a national risk stratification plan, which will be updated based on the updates issued by ACIP, for facilities to use in their local vaccine plans (Appendix C). Several key points are highlighted below:

- » VHA will follow recommendations of CDC and ACIP, including recommendations about risk stratification groups for initial COVID-19 vaccination. Populations of focus for initial COVID-19 vaccination include:
 - Critical workforce providing health care and maintaining essential functions of society (see <https://www.cisa.gov/identifying-critical-infrastructure-during-covid-19>)
 - Staff and residents in long-term care and residential treatment settings
 - Persons aged ≥75 years and frontline essential workers
 - Persons aged 65–74 years, persons aged 16–64 years with high-risk medical conditions, and other essential workers
 - Patients with high-risk medical conditions for COVID-19

⁷ US Food and Drug Administration. Emergency Use Authorization for Vaccines to Prevent COVID-19. Accessed 12/2/2020 at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19>

- VA will branch from CDC guidance for selected populations that have both high-risk medical conditions and a related ongoing exposure risk.
 - » Allocation of COVID-19 vaccine will be based on multiple factors, including:
 - COVID-19 vaccine production and availability
 - Vaccine-specific information, including safety, storage, handling, and specific populations for use
 - Ability of sites to handle constraints of cold chain requirements, handling, and minimum order quantities
 - Number of persons at each site that are in groups recommended by ACIP and CDC for initial vaccination
- VHA should anticipate that allocations may be adjusted based on supply and demand.

COVID-19 Vaccine Distribution, Monitoring and Reporting Requirements

Guidance from CDC provides several assumptions about vaccine distribution, VHA requirements for reporting vaccine use and wastage, and ongoing monitoring requirements:

- » COVID-19 vaccine and ancillary supplies will be procured and distributed by the federal government at no cost to COVID-19 vaccination providers. CDC has provided information regarding reimbursement claims for providers' administration fees (see <https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html>).
- » CDC will use its centralized distribution contract to fulfill orders for some COVID-19 vaccine products. Some vaccine products, such as those with ultra-cold temperature requirements, may be shipped directly from the manufacturer.
- » The Pfizer BioNTech COVID-19 ultra-cold vaccine will be shipped from the manufacturer in containers packed with dry ice. Preferably, once received the vial cartons should be immediately stored in an ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F) until the expiration date printed on the label. Alternatively, vials may be stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks. Vials must be kept frozen and protected from light until ready to use. Vials stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks may be returned one time to the recommended storage condition of -80°C to -60°C (-112°F to -76°F). Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks. Furthermore, undiluted vaccine vials may be stored at 2° to 8°C (36° to 46°F) for up to 1 month, or until manufacturer labelled expiration date, whichever is shorter. Once thawed, vials should not be refrozen to any temperature. Total cumulative time the vials are stored in a -25° to -15°C (-13° to 5°F) freezer and refrigerator should not exceed 45 days.
- » Moderna COVID-19 frozen vaccine will be centrally distributed by CDC in a minimum order quantity of 100 doses. Upon receipt it can be stored in a refrigerator for up to 30 days or in a freezer at -25°C to -15°C (target temperature of -20°C) until the manufacturer labelled expiration date or for a maximum of six months.
- » Janssen (Johnson & Johnson) COVID-19 refrigerated vaccine will be centrally distributed by CDC in a minimum order quantity of 100 doses. Upon receipt it can be stored in a refrigerator until its expiration date.
- » As additional vaccine storage and redistribution options become available from manufacturers, VHA will align with manufacturer guidance.
- » COVID-19 vaccination providers will be required to report COVID-19 vaccine inventory to CDC.
- » Vaccine orders will be approved and transmitted in CDC's Vaccine Tracking System (VTrckS).
- » Vaccine will be shipped to sites after orders are placed. Ancillary supply kits and diluent (if required) may ship separately from the vaccine due to different cold chain requirements, but shipment will be timed to arrive with, or before the vaccine.
- » Minimum order size for CDC centrally distributed vaccines such as the Moderna COVID-19 vaccine will be 100 doses per order for most vaccines. Minimum order size for the Pfizer-BioNTech COVID-19 direct-ship vaccine is 450 doses. Minimum order size for Janssen-Johnson & Johnson COVID-19 centrally distributed vaccine is 100 doses.
- » As additional vaccine quantity presentations become available from manufacturers, VHA will order supply based on

expected future demand.

- » VHA will allow limited redistribution of vaccines, per CDC guidelines, manufacturer guidance and approved VHA redistribution plans to ensure cold chain requirements are met during transport to maintain the stability and integrity of vaccine product.
 - With the challenge of meeting cold chain requirements for frozen or ultra-cold vaccines, VHA will be judicious in use of redistribution.
 - Refrigerated vaccine redistribution must also follow VHA's redistribution plan for refrigerated COVID-19 vaccine. Redistribution plans within or between Veterans Integrated Service Networks (VISNs) or outside of VA will need approval by the VISN Pharmacy Executive (VPE).
- » VHA will report CDC-defined data elements related to vaccine administration daily (i.e., every 24 hours). CDC has provided information on these data elements to VHA.
- » VHA will continue to evaluate data connections to report VHA COVID-19 vaccination supply information to CDC.
- » VHA has developed internal VHA data collection and reporting tools to link with CDC data and informatics tools to transmit supply and administration data.
- » VHA has developed internal reporting solutions to monitor the VHA COVID-19 vaccination program and to present data on VHA's COVID-19 vaccination program to the general public.
- » For additional COVID-19 vaccines authorized under FDA EUA, or for COVID-19 vaccines approved under a Biologics License Application, VHA will plan for distribution and redistribution of vaccine and reporting of vaccine administration to CDC per CDC requirements.

Communications and Education related to VHA's COVID-19 Vaccination Program

VHA COVID-19 vaccination communications will consist of both operational and strategic stakeholder engagement communications products.

Operational Communications: Communications with stakeholders about the required business activities to implement the program.

- » Communication and educational materials, including those about COVID-19 vaccine ordering, COVID-19 vaccine storage, handling, administration (i.e., reconstitution and administration techniques), safety monitoring and reporting, and promotion of other preventive strategies will be available in a variety of formats.

Strategic Stakeholder Communications:

- » Communication resources are designed to provide awareness and information as well as incorporate change management messaging.
- » VHA develops communication resources for key audiences. These resources are both internal and external. Internal-facing products are available on a VHA SharePoint site and external-facing products are available on a public-facing website.
 - The SharePoint site (<https://dvagov.sharepoint.com/sites/vhacovidvaccine>) is an internal resource not available to the public.
 - The external-facing site (www.va.gov/covid-19-vaccine) is an external resource available to the public and created for Veterans.
- » Products are developed specific to Veteran and staff and other identified target audiences.
- » VHA uses existing Veteran and employee communication channels to disseminate tailored messaging for these populations.
- » In addition to its primary role in creating stakeholder engagement communication products that incorporate change

management principles, the Communications Workgroup communicates internally to other workgroups in order to provide support and consultation, as well as receive key messaging topics for product development. More specifically, communications include information gathered from stakeholder listening sessions, including messaging focused toward persons in racial and ethnic groups at higher risk from COVID-19.

- » Communications address stakeholder needs and concerns, including, but not limited to:
 - Vaccine acceptance and hesitancy.
 - Vaccine safety and efficacy.
 - Logistics and foundational principles of phased implementation, explaining rationale for stratification of certain groups when vaccine supply is limited, as well as safe vaccine administration and need for monitoring.
 - Vaccine uptake and coverage as an element of the overall strategy for reducing risk of SARS-CoV-2 infection and the risk of severe COVID-19.
 - Addressing misinformation about the COVID-19 vaccination plan and vaccines.
- » For additional COVID-19 vaccines authorized under FDA EUA, or for COVID-19 vaccines approved under a Biologics License Application, VHA will develop strategic communications plans and products for internal and external audiences.

COVID-19 Vaccine Safety

The FDA announced that all vaccine candidates approved under EUA will meet efficacy and safety requirements. FDA requires a median of two months of follow up from the second vaccine dose for COVID-19 vaccine clinical trial participants. Vaccine manufacturers reported a focus on recruitment of trial participants over the age of 65 as well as of racial and ethnic minorities. Inclusion of these populations will provide useful safety and efficacy data to inform CDC vaccine use recommendations. VHA has a long history of tracking post-approval adverse events to FDA-approved medications. There are several assumptions related to VHA's role in vaccine safety:

- » Clinically important adverse events following any vaccination should be reported to the VAERS through VA Adverse Drug Event Reporting System (VA ADERS).
- » VHA personnel who receive vaccine from VHA will report adverse events to the local VHA facility Occupational Health program from which they received vaccine.
- » Adverse events will also be monitored through electronic health record (EHR)- and claims-based systems (e.g., Vaccine Safety Datalink).
- » Additional vaccine safety monitoring may be required under an EUA from the FDA.
- » VA will follow guidance from FDA and CDC about COVID-19 vaccine administration if safety concerns are identified post-authorization
- » For additional COVID-19 vaccines authorized under FDA EUA, or for COVID-19 vaccines approved under a Biologics License Application, VHA will plan for safety monitoring of adverse events for each vaccine product.

Other VHA COVID-19 Vaccination Efforts

VHA will plan for COVID-19 allocation, administration and distribution for other populations based on VHA leadership approval. These populations may be vaccinated through a 4th mission request, federal partnership interagency agreement, or through other arrangements. VHA may offer vaccination services for populations such as: State Veterans' Homes staff and Veterans, family caregivers enrolled in VA's Program of Comprehensive Assistance for Family Caregivers, and federal partner employees.


Acronyms

- » ACIP - Advisory Committee on Immunization Practices
- » AE - Adverse Events
- » API - Application Program Interface
- » BMI - Body Mass Index
- » CBOC – Community Based Outpatient Clinics
- » CDC - Centers for Disease Control & Prevention
- » CLC - Community Living Centers
- » CCN - Community Care Network
- » COPD - Chronic Obstructive Pulmonary Disease
- » CVEBs - Community Veteran Engagement Boards
- » DHS - Department of Homeland Security
- » EHR - Electronic Health Record
- » EUA - Emergency Use Authorization
- » FAQs - Frequently Asked Questions
- » FDA - US Food and Drug Administration
- » HCP – Health Care Personnel
- » HHS - Department of Human & Health Services
- » IPT - Integrated Project Team
- » ISA - Information Security Agreement
- » LEAF - Light Electronic Action Framework
- » MOA - Memorandum of Agreement
- » NASVH - National Association of State Veterans Homes
- » NPI - Non-Pharmaceutical Interventions
- » OCONUS - Outside of Continental United States
- » OHRS - Occupational Health Record System
- » OWS - Operation Warp Speed
- » PBM - Pharmacy Benefits Management
- » PCAFC - Program of Comprehensive Assistance for Family Caregivers
- » PHE - Public Health Emergency
- » PL&O - Procurement and Logistics Office
- » POA&M - Plan of Action and Milestones
- » PPE - Personal Protective Equipment
- » SME - Subject Matter Expert
- » TMS - Talent Management System
- » USAPI - U.S. Affiliated Pacific Islands
- » VA ADERS - VA Adverse Drug Event Reporting System
- » VAERS - Vaccine Adverse Event Reporting System
- » VAMC - Veterans Affairs Medical Center
- » VAMS - Vaccine Administration Management System

- » VDIF - Veterans Data Integration and Federation
- » VEO - Veterans Experience Office
- » VHA - Veterans Health Administration
- » VISN - Veterans Integrated Service Network
- » VTrckS - Vaccine Tracking System
- » WHO - World Health Organization

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Appendix A – COVID-19 Integrated Project Team (IPT)

VHA COVID-19 Vaccination Planning and Actions

7-2-2021

Purpose

The purpose of this appendix is to outline best practices for the VHA COVID-19 Vaccination Project National Integrated Project Team (IPT). The IPT is comprised of cross-functional stakeholders from across VHA including those with clinical and operational expertise. The overarching goal is to provide national guidance on the overall strategy for COVID-19 vaccination for VHA and to advise the COVID-19 vaccine workgroups on the feasibility and acceptability of their plans. The IPT will give operational and strategic feedback to ensure that VHA is ready to distribute COVID-19 vaccine as soon as a product is approved and becomes available for use.

Scope

The Integrated Project Team:

1. Has broad representation including national VHA clinical leaders in preventive medicine, pharmacy, nursing, primary care, medicine subspecialties, informatics, performance measurement, safety and quality, ethics, equity, and VHA leadership from facilities in rural and urban settings.
2. Provides input into the needs of a diverse range of stakeholders for COVID-19 vaccination in VHA.
3. Solicits and incorporates Veteran feedback.
4. Reviews products of the workgroups and provide guidance on the feasibility and acceptability of implementation in VHA's integrated health system.

Concept of Operations

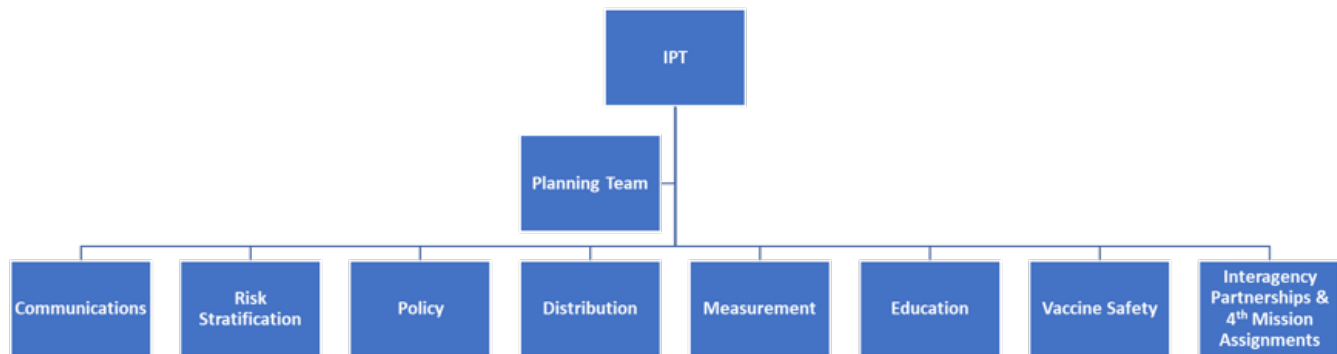
The Integrated Project Team began meeting regularly in September 2020 to discuss needs of Veterans, staff, and VHA with respect to COVID-19 vaccine. The group is responsible for review and approval of critical products and plans from all workgroups. Additionally, this group is responsible for bringing concerns forward for the workgroup to address. These concerns may originate from the IPT, VHA staff, Veterans, or other internal or external stakeholder groups. This group is vital in discussing feasibility and acceptability of COVID-19 vaccine workgroup plans and activities.

This group reviews lessons learned from past experiences, including the 2009 H1N1 pandemic response and vaccination campaign. The IPT reviews CDC and ACIP frameworks for COVID-19 vaccination, and workgroups present plans based on CDC COVID-19 vaccine planning and recommendations. The IPT carefully considers the feasibility and acceptability of all proposals for VHA, accounting for equity and ethical principles in its deliberations, and advises on communication and implementation plans. The group will ensure that principles of equity are a focus of COVID-19 vaccination activities, including measures to ensure that racial and ethnic minority populations disproportionately impacted by COVID-19 receive dedicated outreach efforts and ready access to vaccine.

The group will meet through April 2021.

Organization and Assignment of Responsibilities

1. Sponsor: VHA Patient Care Services
2. Lead Office: VHA National Center for Health Promotion and Disease Prevention



VHA COVID-19 Vaccination Plan Project Organizational Structure: Full text description can be found in [Appendix T](#)

Direction, Control, and Coordination

This group is an internal VHA advisory group, communicating with VHA COVID-19 vaccination planning team workgroups described in the appendices of this plan. The IPT includes the following representatives:

- » Veterans Integrated Service Network (VISN) – VISN Network Directors and Chief Medical Officers: Regional operational and clinical leaders represent a range of geographic locations, facility complexities, and rural and urban settings
- » Veterans Affairs Medical Center (VAMC) – VAMC Directors, Chiefs of Staff and lead COVID-19 Clinicians: Local facility operational and clinical leaders from a variety of geographic locations and facility complexities, including those with COVID-19 clinical leadership roles
- » VHA Central Office Program Offices – National VHA clinical and operational leadership and subject matter experts in Preventive Medicine, Infectious Diseases, Geriatrics, Health Informatics, Primary Care, Rural Health, Health Equity, Medicine subspecialties, Research, and Performance Measurement
- » Labor and Management Relations – National VHA experts on labor-management cooperation
- » Workforce Management and Consulting – National VHA leaders in developing and administering workforce practices including strategic human capital planning, diversity and inclusion, and operations and administration
- » Office of Community Care – National VHA Office coordinating care for Veterans through regional contractors (TRI-West, Humana, HealthNet, etc) and community providers
- » National Center for Ethics in Health Care – VHA’s authoritative resource for addressing complex ethical issues in patient care, health care management, and research
- » Employee and Occupational Health – national VHA experts for employee and occupational health policy and programs; responsible for aligning healthcare occupational health in the Federal sector with national standards
- » National Center for Patient Safety – national VA office focused on the reduction and prevention of inadvertent harm to patients as a result of their care
- » Office of Nursing Services – national VHA experts for nursing policy and practice
- » Patient Care Services – national VHA office dedicated to ensuring the full continuum of health care including prevention, rehabilitative care, pharmacy services, and recovery

Review and feedback on COVID-19 workgroup plans and products occurs during IPT meetings. The IPT functions under the leadership of the VHA National Center for Health Promotion and Disease Prevention.

Communications

The IPT is responsible for recommending revisions or adjustments of workgroup plans and products to the COVID-19 vaccine workgroups. IPT members are responsible for bringing forward concerns from staff and Veterans about the COVID-19 vaccination plan for the IPT to address.

Critical partners for the IPT are the VHA COVID-19 vaccine workgroups. IPT members are expected to represent stakeholder groups including, but not limited to, Veterans and VHA staff.



Appendix B – Communications

VHA COVID-19 Vaccination Planning and Actions

7-2-2021

Purpose

The purpose of this appendix is to outline a phased approach for the Communications Workgroup for COVID-19 vaccination in VHA. The phased approach addresses the two stages of vaccination implementation: the initial limited supply stage and the subsequent general implementation stage, when large supplies of vaccine are available. The overarching goal is to build strategic stakeholder engagement and communications products to provide awareness and information about the COVID-19 vaccination program and incorporate change management messaging.

The Communications Workgroup communicates internally to other workgroups to provide support and consultation, as well as receive key messaging topics for product development. More specifically, the Communications Workgroup gathers information from stakeholder listening sessions, including sessions with persons in racial and ethnic groups at higher risk from COVID-19. Communications products address stakeholder needs and concerns, including, but not limited to:

- » Vaccine acceptance and hesitancy
- » Vaccine safety and efficacy
- » Logistics and foundational principles of phased implementation, explaining rationale for stratification of certain groups when vaccine supply is limited, as well as safe vaccine administration and need for monitoring
- » Vaccine uptake and coverage as an element of the overall strategy for reducing risk of SARS-CoV-2 infection, the risk of severe COVID-19, and reducing harms to society if essential workers (including health care personnel) are unable to work.
- » Addressing misperceptions about the COVID-19 vaccination plan and vaccines

Scope

The VHA COVID-19 Vaccine Communications Workgroup:

1. Is responsible for a comprehensive communications approach that develops key messages on COVID-19 vaccination for Veteran and VA employee audiences using input from stakeholders.
2. Applies culturally and linguistically appropriate communication approaches designed to support health literacy and enhance COVID-19 vaccine awareness, understanding, acceptance and uptake among critical populations, including racial and ethnic minority populations disproportionately affected by COVID-19.
3. Uses multiple channels of communication to reach target audiences.
4. Anticipates, elicits, and addresses specific concerns and questions as they arise from all stakeholders and audiences.
5. Coordinates with all VA offices and organizations as well as other federal agencies to ensure unified messaging.
 - a. The Workgroup established a communications workstream to include experts from VHA Communications, VHA National Center for Health Promotion and Disease Prevention, Patient Care Services and Community Care in communications strategies and product development.
 - b. The Workgroup coordinates efforts with the following internal VA partners: VHA Communications, VA Office of Information Technology, and VHA's Office of Research and Development.
 - c. The Workgroup developed external relationships with communications experts at the CDC, the FDA, Department of Defense, Office of Warp Speed and other federal agencies to ensure unified, consistent messaging.

Concept of Operations

The VHA COVID-19 Vaccine Communications Workgroup is responsible for communications products that provide awareness and information about VHA's COVID-19 Vaccination program and incorporate change management messaging.

Communication products target the following stakeholders:

- » External to VA
 - Veterans
 - Veteran Service Organizations (VSOs)
 - Congress
 - Federal partners
 - Media
 - Community Providers
- » Internal to VA
 - Employees
 - Volunteers
 - Trainees

Communications Activities and Products include:

- » Development of a Communications Playbook with products to date including:
 - COVID-19 Vaccine Planning Overview Toolkit including how-to guide, key messages, placemat, fact sheets, and response to query.
 - Employee COVID-19 Vaccine Awareness Toolkit including how-to guide, six essential questions for the COVID-19 vaccine, frequently asked questions, elevator speech, facility director message to staff, employee town hall slide deck, risk stratification fact sheet, vaccine safety monitoring fact sheet, flu/COVID-19 vaccine comparison infographic for health care personnel and non-clinical staff.
 - Veteran COVID-19 Vaccine Awareness Toolkit including how-to guide, elevator speech, Veteran town hall slide deck, frequently asked questions, knowledge management system/call center scripts, social media, risk stratification fact sheet, flu/COVID-19 vaccine comparison infographic for Veterans, clinical call center script, source photographs, and Spanish language resources.
 - National Planning Toolkit including how-to guide, news release, Vantage Point blog, MyHealthVet newsletter, VSO brief slide deck, VetResources.
 - Early Distribution Employee COVID-19 Vaccine Toolkit including how-to guide, elevator speech, key messages, employee town hall slide deck, Executive In Charge message, facility director messages for initial and future sites, slotted internal newsletter, slotted facility director message regarding vaccine hesitancy, employee fact sheet, next steps after receiving COVID-19 vaccination, vaccine storage and handling fact sheet, Emergency Use Authorization process and Operation fact sheet, posters and flyers, vaccination stickers.
 - Early Distribution Veteran COVID-19 Vaccine Toolkit including how-to guide, elevator speech, key messages, Veteran town hall slide deck, local slotted news release for initial sites, Veteran eligibility letter, Veteran frequently asked questions, non-clinical phone script for knowledge management system, COVID-19 vaccination scheduler script, interactive voice response phone tree script, local slotted news release for distribution plan release, next steps after receiving COVID-19 vaccination, social media, local slotted web feature story, vaccination stickers.
 - Early Distribution National Toolkit including how-to guide, news releases (initial sites, VA begins vaccinations, Vaccine plan released, Moderna), executive in charge message, Vantage Point blog for initial limited supply, MyHealthVet initial limited supply
 - Government Partner Toolkit (Products from FDA, CDC) including government partner communication material links Emergency Use Authorization fact sheets for Vaccines, what to expect at vaccination
- » Collaboration with the Veterans Experience Office to conduct interviews and listening sessions with diverse Veteran

groups regarding COVID-19 vaccine

- » Collaboration with VHA Office of Health Equity
- » Communication with VHA Research Office
- » Weekly workstream meetings with VA Communications experts to review comprehensive communications approach and T-Minus Schedule
- » Weekly meeting with CDC communications experts

Organization and Assignment of Responsibilities

1. Lead: VHA National Center for Health Promotion and Disease Prevention
2. Co-Lead: VHA Stakeholder Engagement Team

Direction, Control, and Coordination

This group is responsible for direction, control, and coordination of strategic stakeholder engagement products related to COVID-19 vaccination across VHA. Specifically, the group provides information and awareness to stakeholders about COVID-19 vaccination and incorporates change management messaging to assist stakeholders in understanding key information about the new vaccines, as well as process for approving and disseminating vaccine.

Direction, control, and coordination activities at the Communications Workgroup level occur during weekly meetings. The Workgroup coordinates planning, drafting, and delivery of stakeholder engagement communication products using change management language about COVID-19 vaccine in VHA.

Communications

The Communications workgroup is responsible for recommending an approach to dissemination of communications products in a timely manner to support COVID-19 vaccination of staff and Veterans. Prior to the approval of a COVID-19 vaccine, the Communications workgroup will develop key messages about VHA's process and plan for COVID-19 vaccination that will be shared with VHA leaders, staff and Veterans in order to provide transparency to VHA's planning process for COVID-19 vaccination. These communications may occur through a variety of modalities, including SharePoint (internal for VHA staff), publicly available web sites, press releases, articles, and social media posts.

Critical partners for the Communications workgroup are the VHA COVID-19 Vaccination Workgroups, particularly the Risk Stratification and Education workgroups.



Appendix C – Stratification

VHA COVID-19 Vaccination Planning and Actions

7-2-2021

Purpose

The purpose of this appendix is to outline best practices for the Risk Stratification Workgroup for COVID-19 vaccination in VHA.

The overarching goal is coordinated review, approval, and implementation of a risk stratification framework for COVID-19 vaccination among Veterans and staff that is equitable, evidence-based, fair, transparent, and adaptable to changing conditions of vaccine availability.

Scope

The COVID-19 Vaccine Risk Stratification workgroup:

1. Includes subject matter experts relevant to vaccine risk stratification.
2. Reviews past experiences in VHA relevant to COVID-19 vaccination.
3. Reviews existing frameworks for COVID-19 and other vaccine risk stratification, including the National Academies of Sciences, Engineering, and Medicine and the ACIP and CDC models.
4. Reviews data relevant to populations in VHA that are high risk or high priority for COVID-19 vaccination.
5. Reviews CDC and ACIP guidance to determine implementation in VHA.
6. Engages stakeholders representing high-risk VHA beneficiaries in regular meetings for discussion, input and feedback.
7. Considers allocation/risk stratification schemes based on several potential scenarios including different initial amounts of vaccine availability.
8. Considers each potential framework in the context of fairness, ethics, evidence, equity, and transparency while maximizing benefits of COVID-19 vaccination to Veterans, staff, and the general population.
9. Communicates rationale for risk stratification to major stakeholders and prepare summaries for use in external communications.

Concept of Operations

The Risk Stratification Workgroup ensures that the framework for COVID-19 vaccine distribution in VHA is fair, evidence-based, equitable and transparent while maximizing benefits of COVID-19 vaccination to Veterans and staff.

The workgroup:

1. Includes subject matter experts (SMEs) relevant to vaccine risk stratification:
 - a. Representatives with expertise in Infectious Diseases, Equity, Ethics, and Pharmacy Benefits Management
2. Reviews past experiences in VHA relevant to COVID-19 vaccination.
 - a. The group began with a review of past experiences in VHA that are most relevant to COVID-19 vaccination planning, including but not limited to:
 - i. 2009 H1N1 planning and response for VHA.
 - ii. Hepatitis C risk stratification and treatment planning in VHA.
 - iii. COVID-19 experience to date in VHA, including Remdesivir risk stratification
3. Reviews existing frameworks for COVID-19 and other vaccine risk stratification, including:
 - a. Ethical and practical frameworks from non-governmental organizations, including the National Academies of Sciences, Engineering and Medicine, the Johns Hopkins Bloomberg School of Public Health, and the WHO
 - b. Framework from ACIP
 - c. Prior CDC pandemic vaccination plans, such as for pandemic influenza

- d. VHA 2009 H1N1 vaccination plan
4. Reviews data relevant to populations in VHA that are high risk or high priority for COVID-19 vaccination:
 - a. Conditions that place individuals at high risk for severe infection from SARS-CoV-2
 - b. Conditions, characteristics or situations that may place individuals at higher risk for acquiring SARS-CoV-2 infection, including race and ethnicity
 - c. Criteria for defining high risk groups and high-priority groups for vaccination, such as frontline healthcare personnel
 - d. Sizes of workforce and Veteran enrolled populations within VHA
 - e. Additional data, such as on safety or efficacy of vaccine, in the context of potential impact on risk stratification
 - f. How criteria such as personal risk of acquiring infection, risk of severe morbidity and mortality, risk of negative societal impact, and risk of transmitting infection to others weigh in determining which persons should be invited for vaccination first
 - g. How additional vulnerabilities, such as living in group settings, being a member of a racial and ethnic group at increased risk for SARS-CoV-2 infection and/or mortality from COVID-19, and limited access to healthcare and vaccination services, should be weighed when creating a framework for risk stratification
 - h. How additional factors, such as feasibility of distribution, should be considered when planning risk stratification
 - i. How various populations were represented in vaccine trials, data on vaccine efficacy and safety, gaps in data, and how recommendations based on that data were formed by FDA and CDC.
 5. Reviews recommendations of CDC and CDC's ACIP to determine how to best implement these recommendations for VHA.
 - a. Members of the workgroup attend all ACIP meetings, and updates from ACIP and other new evidence or information is reviewed with the work group in weekly meetings.
 - b. Following each discussion, and after issue of recommendations from the CDC and ACIP, the workgroup discusses application to the VHA population.
 - c. The Risk Stratification Workgroup drafted a framework based on CDC and ACIP recommendations, internal discussion, Veteran feedback, and high-risk stakeholder input outlining which groups within VHA will be offered vaccine first.
 - d. The workgroup finalized initial recommendations after CDC their guidance.
 - i. Phase 1a includes healthcare personnel and residents in long term care facilities and was approved by ACIP 12/1/2020. ACIP voted on Phases 1b and 1c on 12/20/2020 following initiation of vaccination at some sites. 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. Phases of allocation are expected to overlap and CDC highlighted the need for local considerations and flexibility.
 - ii. Following ACIP's recommendations and updates, the Risk Stratification Group updated VHA's phases 1b and 1c recommendations
 6. Engages stakeholders representing high-risk VHA beneficiaries in regular meetings for discussion, input, and feedback, and solicit and incorporate Veteran feedback on draft vaccine risk stratification frameworks in advance of its publication.
 - a. The group convened biweekly meetings of high-risk stakeholders within VHA to review and discuss proposed approaches. The stakeholder group included representatives of patients with high risk conditions, persons at high risk for exposure to infection, and healthcare personnel, and including both clinical and non-clinical service lines within VHA.

7. Considers allocation/risk stratification schemes based on several potential scenarios including different initial amounts of vaccine availability, and feasibility.
 - a. Collaborated on development of outreach tool for Veterans at highest risk related to COVID-19.
8. Considers each potential framework in the context of fairness, basis in evidence, equity, and transparency while maximizing benefits of COVID-19 vaccination to Veterans and staff, and to the general population.
 - a. Reviews frameworks including discussion led by subject matter experts in ethics and health equity.
 - b. Ensures that disparities in SARS-CoV-2 infection and access to care are addressed, including disproportionate burden of SARS-CoV-2 infection on specific racial and ethnic groups.
9. As vaccines are authorized under EUA for specific groups and CDC publishes recommendations for use of the vaccine in those groups, incorporates this recommendation in risk stratification framework.
10. Communicates rationale for risk stratification to major stakeholders (internal, external and government partners) and prepares summaries for stakeholders and the communications team for external communications.
 - a. Drafts key messages for communications products to the field, including clinical and nonclinical audiences, to explain the rationale for and logistics of the risk stratification plan.
 - b. Drafted the following document detailing instructions for use and ethical and evidence-based rationale, including
 - i. Instructions to include all staff, rather than just the units listed, and how to use the risk framework to compare and place staff member by risk grouping. Explanation was provided on the location/service-based risk groupings, and how staff not listed should be stratified based on locality-specific roles including care of or proximity to patients with SARS-CoV-2.
 - ii. Ethical review prepared by the National Center for Ethics in Health Care (see Attachment A)
 - iii. Evidence review based on current evidence on populations at high risk from COVID-19.
 - iv. Description of current finalized and draft ACIP and CDC guidance.
 - v. When vaccine supply exceeds demand for the VHA patient and staff population, this risk stratification approach will no longer be used.

Organization and Assignment of Responsibilities

1. Lead: VHA National Center for Health Promotion and Disease Prevention
2. Co-Lead: VHA Office of Health Equity

Direction, Control, and Coordination

1. This group is primarily responsible for determining how the ACIP risk stratification and allocation framework for COVID-19 vaccine will be best implemented in VHA.
2. VISN Level: Direction, control, and coordination activities at the VISN level occur via guidance and policy from the Risk Stratification group in concert with the Policy group. This is communicated via email in addition to presentations on national leadership meetings and on daily office hours and vaccine coordinator calls. The Risk Stratification Workgroup communicates with this group primarily through vaccine coordinators.
3. VAMC Level: Direction, control, and coordination activities at the facility level occur in the facility's Executive Leadership Team and Incident Command in coordination with local and VISN vaccine coordinator(s). The facility will review the risk stratification framework, guidance, and policy and pursue outreach and planning for vaccination of Veterans and staff based on this guidance. The Risk Stratification Workgroup communicates with this group primarily through vaccine coordinators.
4. VHA Program Offices: Direction, control, and coordination activities at the Program Office level occur in the Program Office Executive Leadership Team. The Risk Stratification Workgroup will communicate through meetings and

through national calls.

5. Risk Stratification Workgroup: Direction, control, and coordination activities at the workgroup level occurs during weekly meetings. The workgroup provides coordination in drafting a risk stratification framework and assists in communication of that framework.

Communications

The workgroup will communicate the process, background, constraints, and risk categories used to determine risk stratification framework for VHA.

1. This is communicated internally to VHA COVID-19 vaccine workgroups and the IPT.
2. Summaries are provided to the communications team to assist in presenting this rationale to Veterans, VHA healthcare personnel, VHA staff, and other audiences, and to develop outreach messaging to high-risk vulnerable populations.
3. The workgroup assists the COVID-19 Vaccine Education workgroup in developing educational materials, including specific messaging for high-risk groups.
4. Workgroup members or delegates present the risk stratification framework and rationale for that framework on national calls.

Critical partners:

1. The VHA COVID-19 Vaccine Communications and Education workgroups are critical partners in ensuring transparency and maximizing understanding and trust throughout the vaccine campaign in VHA.
2. VHA experts representing high-risk stakeholders are vital partners.
3. The VHA COVID-19 Vaccine Distribution workgroup and the VHA COVID-19 Vaccine Risk Stratification workgroup work closely together. Distribution limitations may affect risk stratification and such schemes significantly affect distribution needs and planning.
4. The VHA COVID-19 Vaccine Policy workgroup is an important partner in creating actionable guidance and policy based on the risk stratification framework as developed by ACIP and tailored for VHA.
5. CDC and ACIP COVID-19 vaccine recommendations form the foundation of VHA's risk stratification guidance. CDC and CDC's ACIP recommendations for risk stratification are expected to be finalized following FDA authorization of a COVID-19 vaccine. After ACIP votes and approves each phase of a risk stratification framework, these recommendations will be reviewed by CDC's Director and published as official CDC policy, then adapted for VHA use.

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 the general principles outlined in this framework rather than creating separate guidance for each site, with the understanding that it will need flexibility and customization for local conditions, populations, and storage and handling constraints.

CDC guidance comprises broad categories to maximize feasibility across 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 recommends including persons who are 65 and older, persons with high risk conditions as defined by CDC, and other essential workers. It is expected that phases will overlap. 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, group 1c was further stratified by risk, 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.

Risk Stratification Table version 2.0

Key: ACIP (CDC) Phases

(+) = 1a: HCP, LTCF

(++) = 1b: Essential Workers, 75 and older

(+++) = 1c: 65-74; high-risk conditions

CDC-VA	Staff	Veterans
A- 1a	CLC/SCID unit staff (+)	Veterans residing in VA CLC/SCID
A- 1b	Emergency Department, EMT (+)	N/A
A- 1c	COVID-19 ICU staff (+)	N/A
A- 1d	COVID-19 non-ICU inpatient staff (+)	N/A
A- 1e	Other staff providing face-to-face care and services for COVID-19 patients (+)	N/A
A- 1f	Staff in other congregate living settings (+)	Veterans residing in other long term/congregate settings without access to COVID-19 vaccine.

CDC-VA	Staff	Veterans
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, infection control, environmental engineering, limited executive or leadership roles) *(+)	N/A
A- 2b	Inpatient staff, non-COVID-19 units (+)	N/A
A- 2c	Staff performing high risk procedures (non-COVID-19, pre-screened) (+)	N/A
A- 3a	Hemodialysis staff (+)	N/A
A- 3b	Oncology/chemotherapy unit staff (+)	N/A
A- 4a	Homeless Outreach staff (+)	N/A
A- 4b	Staff with frequent contact with Veterans who have not been pre-screened for COVID-19 symptoms (screeners, drivers, etc.) (+)	N/A
A- 4c	Outpatient direct care/contact (pre-screened, non-COVID-19) (+)	N/A
A- 4d	Other health care personnel and staff ** (+)	N/A
B- 1a	N/A	<ul style="list-style-type: none"> » Veterans age 75+ » Homeless Veterans, Hemodialysis patients, Solid Organ Transplant patients, patients listed for transplant, and Chemotherapy patients (chemotherapy in a clinic/hospital setting), or Veterans with spinal cord injuries and disorders (+++) » Frontline Essential Workers as defined by CDC
C- 1a	Other VA services, non-health care (+++)	<ul style="list-style-type: none"> » Veterans age 65-74 (+++) » Other Essential Workers, as defined by CDC (+++)
C- 1b	Other VA services, non-health care (+++)	<ul style="list-style-type: none"> » Veterans younger than 65 with high-risk conditions as defined by CDC (+++) » Other Essential Workers, as defined by CDC (+++)

Comments

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.

**Front line cemetery workers and Veterans in care who are non-VA HCP may be offered vaccine during “A” as they are CDC 1a essential workers.

Population Enumeration

Employees

Category	Estimated Population Size	%
Department of Veterans Affairs (Total)	418,688	N/A
Veterans Health Administration (Total)	373,435	N/A
HCP (VHA)	247,239	N/A
Essential (VHA)	41,259	N/A
Others (VHA)	84,937	N/A
Volunteers	61,420	N/A
Trainees	124,190	N/A

Veterans

Enrolled Veterans

Category	Estimated Population Size	%
Enrolled Veterans (total)	10,075,834	N/A
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

Category	Estimated Population Size	%
Veterans Receiving Care (total)	5,821,113	N/A
>65	3,063,682	52.6%
African American	1,022,986	17.6%
Hispanic	397,162	6.8%

High Risk Medical Conditions

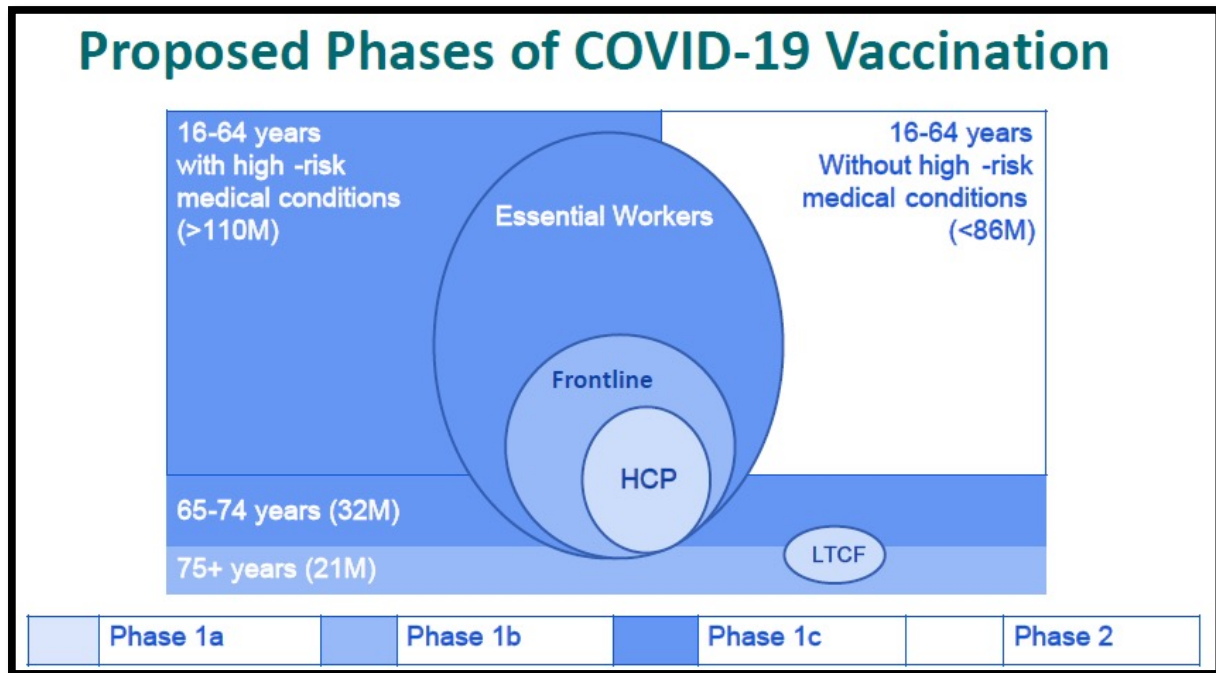
Category	Estimated Population Size	%
Cancer	544,149	9.3%
Chronic Kidney Disease	339,435	5.8%
COPD	439,287	7.5%
Obesity (BMI of 30 or greater)	2,278,608	39.1%
Cardiovascular disease	2,709,759	46.6%
Sickle cell disease	2,998	0.1%
Type 2 diabetes mellitus	1,556,431	26.7%

Other Categories

Category	Estimated Population Size	%
Veterans in State Veteran Homes	19,275	N/A
Fourth MISSION - Non-Veteran	9208	N/A
Fourth MISSION - Veteran	132	N/A
Homeless	242,297	N/A
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)	N/A

ACIP/CDC Phases of Vaccination

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



Proposed Phases of COVID-19 Vaccination: Full text description can be found in [Appendix T](#)

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 and was approved by ACIP 12/1/2020. ACIP voted on Phases 1b and 1c on 12/20/2020 following initiation of vaccination at some sites. 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. Phases of allocation are expected to overlap, and CDC highlighted the need for local considerations and flexibility:

“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. **A flexible approach to allocation will facilitate efficient management and ensure that COVID-19 vaccine is administered equitably and without delay.**”

CDC guidance is available at:

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

Additional interim considerations for phased implementation of COVID-19 vaccines are available at <https://www.cdc.gov/vaccines/covid-19/initial-populations.html> and <https://www.cdc.gov/vaccines/covid-19/phased-implementation.html>.

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/coronavirus/2019-ncov/vaccines/recommendations-process.html>

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 1c.

At that time, they defined “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, and those who work in the education sector (teachers and support staff members) as well as child care workers”.

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

Following this, on January 13, 2021, CDC gave more specific definitions and an expanded list of frontline and non-frontline essential workers in Phase 1b and Phase 1c. <https://www.cdc.gov/vaccines/covid-19/categories-essential-workers.html>

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.

The above 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.

Within healthcare facilities, for each subset of staff 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 health care personnel depending on their role and location. CDC definition of health care personnel is here <https://www.cdc.gov/infectioncontrol/guidelines/healthcare-personnel/appendix/terminology.html> and includes:

“all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP may include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, students and trainees, contractual staff not employed by the health care facility, and persons (e.g., clerical, dietary, environmental services, laundry, security, maintenance, engineering and facilities

management, administrative, billing, and volunteer personnel) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted among from HCP and patients.”

Additionally, 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. A subset of these staff may be offered vaccine as part of A-2a to ensure continued hospital operations, but many would be offered vaccine in A-4d, which is the last group in Phase 1a and which is expected to overlap with Phase 1b.

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 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 locally is not sufficient to offer vaccine to all persons in a phase, CDC noted that sub prioritization may be needed, and local decisions may be made on how to best to approach subgroups within a phase. Use of the Veteran Outreach Tool allows sub-stratification by presence of one or multiple high-risk conditions as defined by CDC. Veterans may be further stratified based on presence of 5+ high-risk conditions, 4+ high-risk conditions, and onward.

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 the general principles of 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-curtailling 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 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 outreach to a particular area means offering vaccine to persons from different risk groups.

For the first dose in the vaccine series, reasonable attempts should be made to reach those at highest risk but it is not expected that COVID-19 vaccines be held if there is delay in returning calls and mailings for scheduling; it is reasonable to continue movement through priority groups.

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, scheduling vaccination could start with persons 85 and older if there is insufficient vaccine for all persons 75 and older. Further stratification by [high risk conditions, as defined by CDC](#) can also be done using the Veterans Outreach tool, which will allow sorting by number of high-risk conditions. Tools have been provided as an aid but it is not required that sites follow a specific model or order for sub-stratification. Given the scale of COVID-19 vaccination in VA, it is important to ensure that risk stratification does not create a barrier to maximizing the number of Veterans offered and scheduled for vaccination.

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, and potentially to lower risk to colleagues and patients.

Assignments, Infection Control and Personal Protective Equipment after 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** – on January 13, CDC updated guidance indicating that persons working in administration of Veterans Affairs should be offered vaccination as part of Phase 1c. <https://www.cdc.gov/vaccines/>

[covid-19/categories-essential-workers.html](https://www.cdc.gov/covid-19/categories-essential-workers.html)

- » **Health Care Personnel working virtually or offsite** – some health care personnel working virtually may be offered vaccine to keep a minimum core of staff for ongoing care of Veterans. This may include staff who may be needed to provide face-to-face care either locally or via deployment (i.e. surge capacity). This could also include staff supporting the COVID-19 response, such as intensive care unit physicians providing supervision virtually to support an area with surging COVID-19 cases. Additionally, some services are necessary for continued care of Veterans, such as VA Consolidated Mail Outpatient Pharmacy (CMOP). Staff not falling into these roles would still be considered essential personnel as of CDC January 13 updates to the essential workers list and would be eligible for vaccination within Phase 1c.
- » **Staff working outside a medical center** – on January 13, CDC updated guidance indicating that persons working in administration of Veterans Affairs should be offered vaccination as part of Phase 1c. <https://www.cdc.gov/vaccines/covid-19/categories-essential-workers.html>. A small subset who are critical to continued safe provision of Veteran care or to the COVID-19 response may be offered vaccine earlier.

* definition of close contact should follow CDC definitions.

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. Such considerations will be based on a number of factors including whether the individuals being considered for COVID-19 vaccination are similar to those on whom safety and efficacy of the vaccine has been demonstrated, whether targeting the COVID-19 vaccine to these individuals or groups will better stop the spread of the virus, and what methods for vaccine administration are most practical. 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-2 to 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-2 and 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 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).

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[Link back to Risk Stratification Table version 2.0](#)

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.

[Link back to Risk Stratification Table version 2.0](#)

Ethical Principle	Essential Workers (non-health-care)(~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	<ul style="list-style-type: none"> » Workers unable to work from home (increased 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	<ul style="list-style-type: none"> » Racial and ethnic minority groups disproportionately represented in many essential industries » ~1/4 of essential workers live in low-income families 	<ul style="list-style-type: none"> » Increased prevalence of some medical conditions in race/ethnic minority groups & persons in rural areas » Diagnosis of medical conditions requires access to healthcare 	<ul style="list-style-type: none"> » Highest incidence and mortality in congregate living » Racial and ethnic minority groups under-represented among adults ≥ 65

McClung M, et al. The Advisory Committee on Immunization Practices’ Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020 | MMWR (cdc.gov) <https://www.cdc.gov/mmwr/volumes/69/wr/mm6947e3.htm>

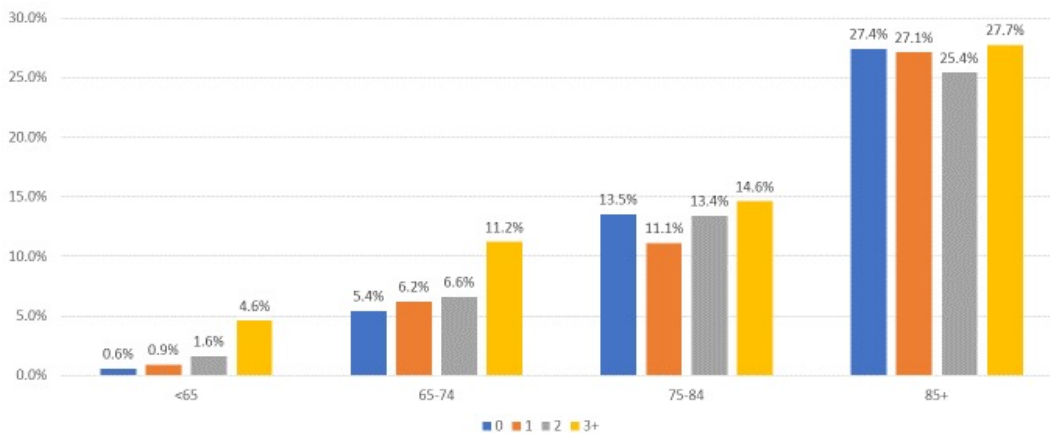
Age

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.

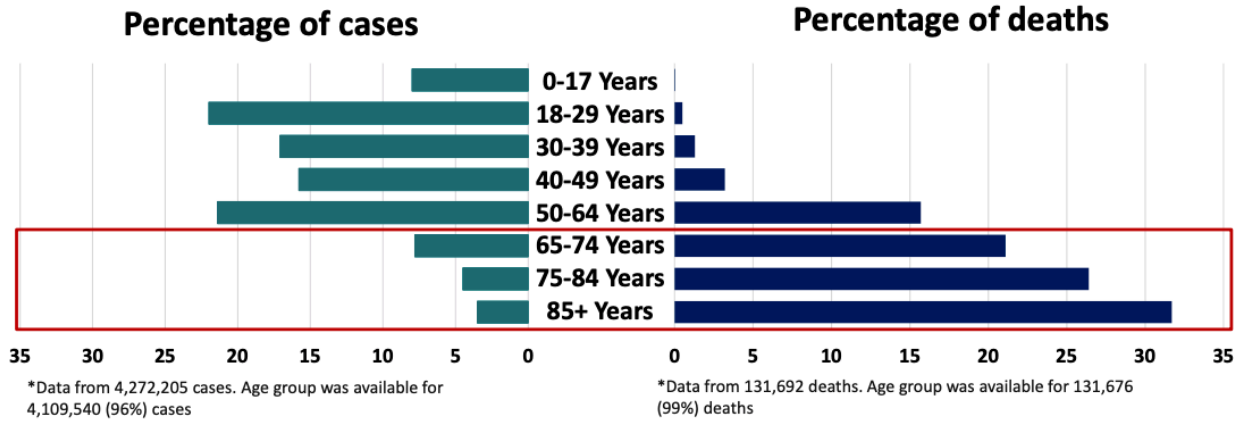
Mortality Rate among COVID Veteran Cases by Age and # of Comorbidities through 8/27/20



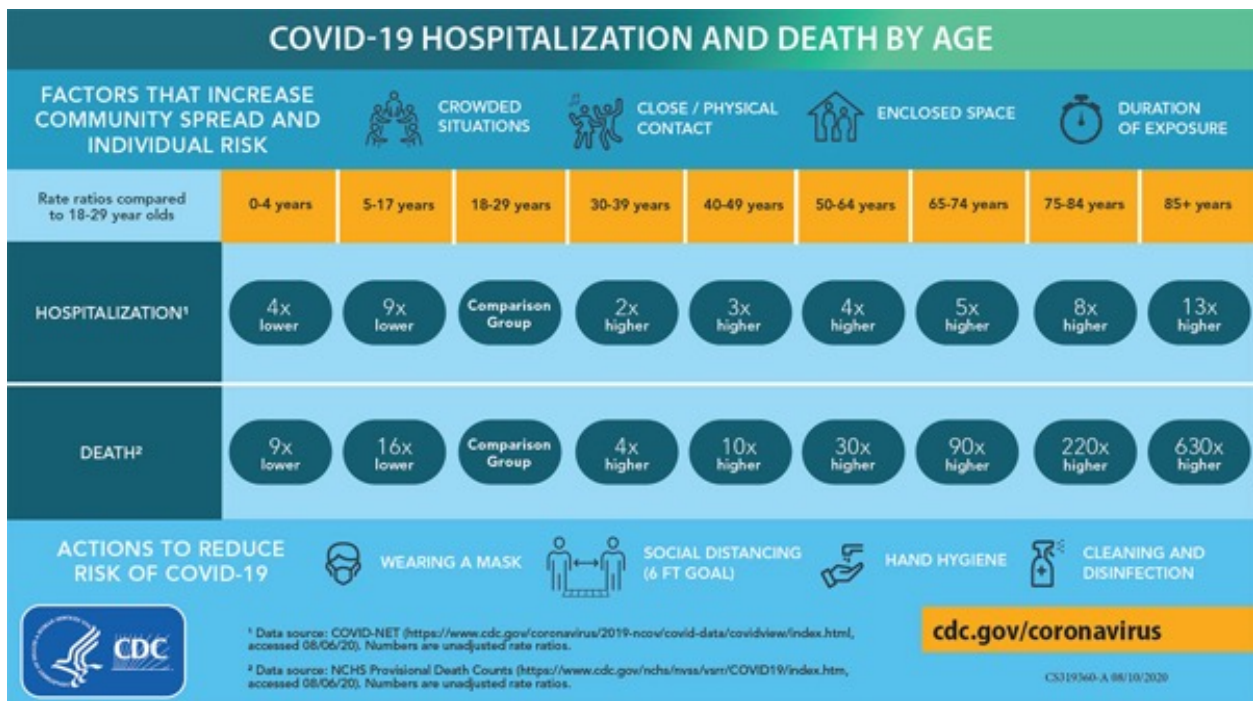
Comorbidities: BMI>=30, asthma, diabetes, CKD, IHD, stroke, COPD

Mortality Rate among COVID Veteran Cases by Age and # of Comorbidities through 8/27/20: Full text description can be found in [Appendix T](#)

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



In the United States, adults aged 65 years or older represent 16% of COVID-19 cases, but nearly 80% of COVID-19 deaths: Full text description can be found in [Appendix T](#). Source: [ACIP 8/26 Meeting, McClung](#)



COVID-19 Hospitalization and Death by Age: Full text description can be found in [Appendix T](#). Accessed Nov 9, 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.

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[Link back to Risk Stratification Table version 2.0](#)

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 are 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.

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[Link back to Risk Stratification Table version 2.0](#)

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.

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[Link back to Risk Stratification Table version 2.0](#)

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.

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[Link back to Risk Stratification Table version 2.0](#)

Veterans with Spinal Cord Injuries and Disorders

Most persons with spinal cord injuries and disorders (SCI/D) are at high risk for respiratory complications because their respiratory muscles are typically weak and their ability to cough is impaired, resulting in less effective clearance of pulmonary secretions. In addition, there are autonomic changes that result in an imbalanced parasympathetic drive resulting in bronchospasm and increased secretions. As a result, morbidity and mortality from respiratory-related

illnesses are higher than in the general population. Respiratory conditions are a leading cause of complications and death following SCI/D. Other respiratory infections, such as influenza, result in significantly higher rates of complications and death; for example, persons with SCI/D who contract influenza or pneumonia are 37 times more likely to die from influenza or pneumonia complications than comparable persons from the general population.

Data that are currently available indicate that COVID-19 infections result in higher mortality rates as well. Following the first few months of the pandemic, Burns and colleagues described a 2.4 times higher mortality rate from COVID-19 infections for Veterans with SCI/D than the general Veteran population even though there is a similar proportion of individuals age 65 years or greater in both groups. The most recent VA data demonstrate this increased mortality rate in Veterans with SCI/D. Although the initial concern was for Veterans with SCI/D in institutional care settings (e.g., inpatient care, VA Community Living Centers (CLCs), and community nursing homes), VA data indicate that approximately half of the deaths (59%) that have occurred in Veterans with SCI/D with COVID-19, have been in individuals living independently in the community. There are several reasons why Veterans with SCI/D living in the community are also at high risk for COVID-19 infections, complications, and death. Due to paralysis and decreased hand function, a large proportion of people with SCI/D need assistance and have one or more caregivers for activities of daily living, bladder and bowel care. In general, Veterans with SCI/D are sicker and require care in inpatient and outpatient settings at a higher rate than most other Veteran cohorts. Veterans with paralysis and limited hand function have additional challenges with precautions and prevention strategies such as managing masks independently and effectively washing their hands.

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[Link back to Risk Stratification Table version 2.0](#)

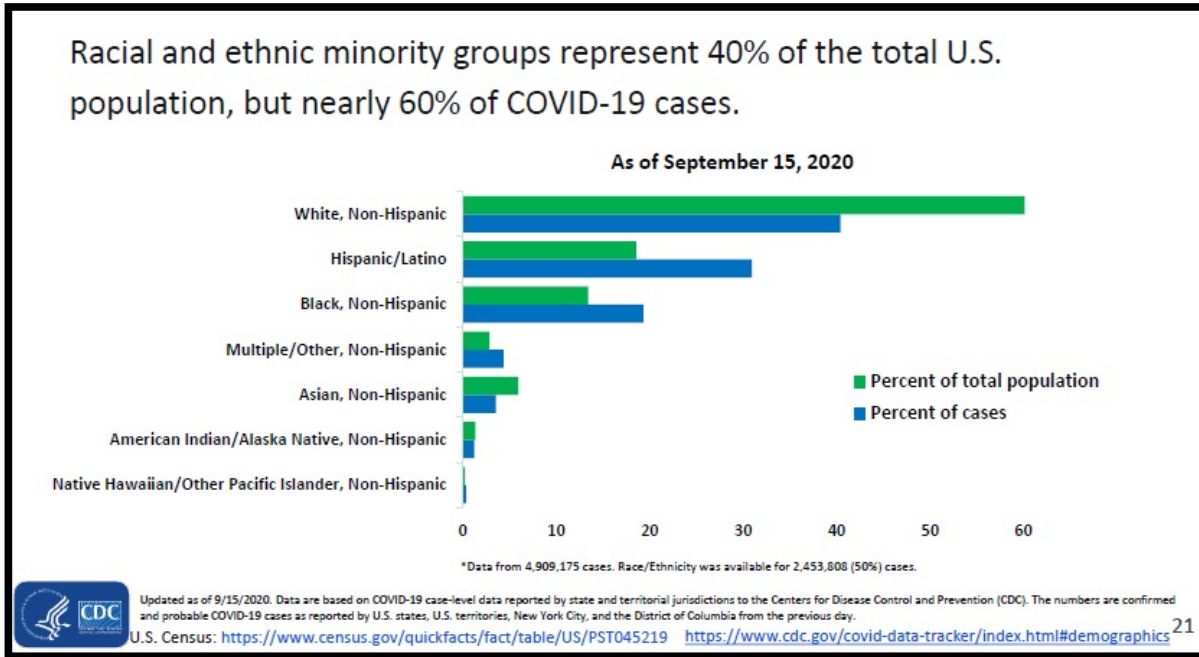
Race and Ethnicity

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.

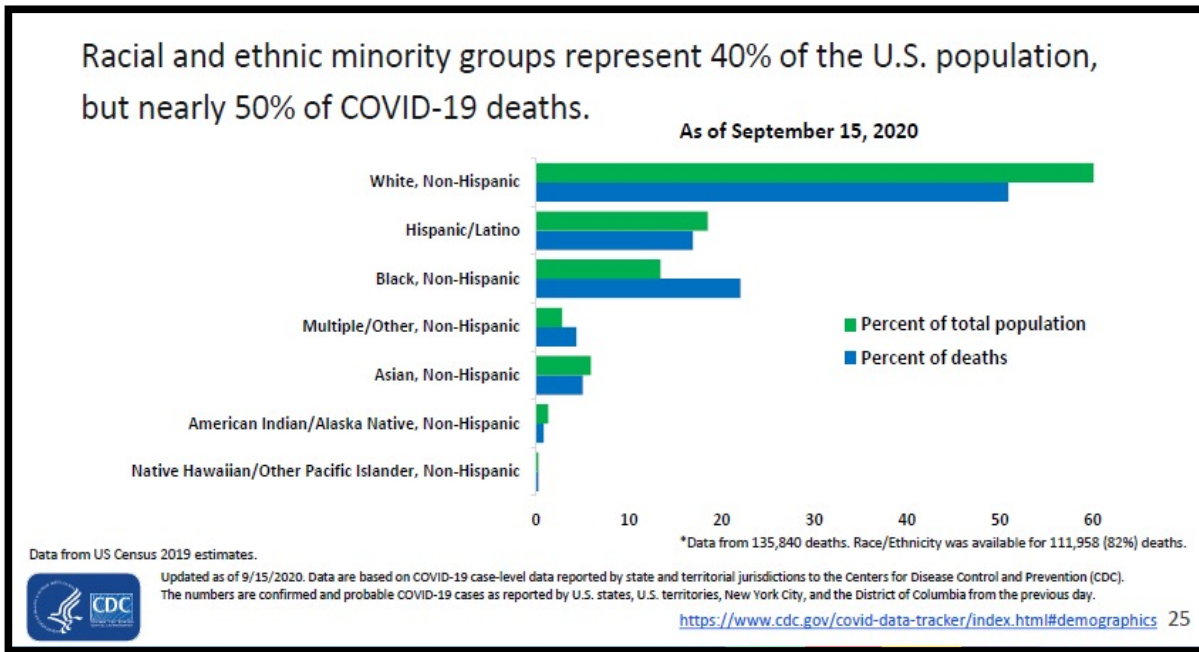
Racial and ethnic minorities make up 40% of the population but about 50% of the COVID-19 deaths. In the United States, there are about 25% more COVID-19 deaths in racial and ethnic minorities than there should be based on population size, and the mortality differences indicates that the burden of COVID-19 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.



Racial and ethnic minority groups represent 40% of the total U.S. population, but nearly 60% of COVID-19 cases: Full text description can be found in [Appendix T](#).



Racial and ethnic minority groups represent 40% of the U.S. population, but nearly 50% of COVID-19 deaths: Full text description can be found in [Appendix T](#).

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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.

Note that the CDC [high-risk conditions](#) list may change as evidence is reviewed. Both the highest evidence and limited evidence may be considered as part of Phase 1c (VA “C”). VA guidance follows CDC because this is the best available evidence regarding conditions raising COVID-19 associated risk. However, VA recognizes that there are conditions that may elevate COVID-related risk that may not be recognized or represented in the medical literature, particularly if the condition is uncommon. Flexibility and clinical decision making are recommended particularly as vaccine supply increases.

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.

Conditions of Special Import to Veterans

Note that there are many conditions of special interest to Veterans served by VHA which elevate risk related to COVID-19.

For example, many conditions associated with exposure to Agent-Orange have strong evidence supporting increased risk from COVID-19. These conditions include several types of cancer (Chronic B Cell Leukemia, Hodgkin’s Disease, Non-Hodgkin’s Lymphoma, Multiple Myeloma, Prostate Cancer, Respiratory Cancers, and Soft Tissue Sarcomas), and other

conditions such as Ischemic Heart Disease and Diabetes Mellitus Type 2. Additional conditions, such as Parkinson's Disease, may fall within the group of conditions with limited evidence for increased risk related to COVID-19 (neurologic conditions, such as dementia).

[Veterans' Diseases Associated with Agent Orange - Public Health \(va.gov\)](#)

Appendix D – Vaccine Policies and Clinical Guidance

VHA COVID-19 Vaccination Planning and Actions

7-2-2021

Purpose

The purpose of this appendix is to outline the scope and operations of the Vaccine Policies and Clinical Guidance Workgroup for COVID-19 Vaccination in VHA.

The overarching goal is to coordinate approval and implementation of VHA clinical and operational guidance for COVID-19 vaccine campaigns for Veterans, VA staff, and other populations such as federal partner staff and individuals covered by SAVE LIVES Act authority.

Scope

The VHA COVID-19 Vaccine Policies and Clinical Guidance workgroup:

1. Reviews and understands existing vaccine guidance in VHA and past relevant guidance including that issued for 2009 H1N1 influenza vaccine.
2. Reviews guidance from the VHA COVID-19 Risk Stratification workgroup.
3. Drafts memoranda and guidance to facilitate implementation of the COVID-19 vaccination plan across VHA.
4. Considers how policy will help critical populations, such as rural Veterans and racial and ethnic minority populations disproportionately affected by SARS-CoV-2 infections, access vaccine.

Concept of Operations

The Vaccine Policies and Clinical Guidance workgroup drafts clinical and operational guidance to support implementation of the COVID-19 Vaccination plan in VHA.

The workgroup:

1. Reviews existing vaccine guidance in VHA, and past relevant guidance including that issued for 2009 H1N1 influenza vaccine.
2. Reviews guidance from the VHA COVID-19 Risk Stratification workgroup.
 - a. Reviews risk stratification framework for VHA to determine what policy and guidance is needed to aid implementation.
3. Drafts memoranda and guidance to facilitate implementation of the COVID-19 Vaccination plan in VHA.
 - a. For the initial phase of vaccination, where a limited amount of vaccine is expected and types of available vaccines may change to include multiple manufactures, this group will draft policy that can be updated efficiently to reflect these changes.
 - i. Initial vaccination planning for VHA includes memos and supporting detailed guidance and will be updated as conditions in the field, availability of vaccine, or other factors shift. Initial memos and guidance include instruction around:
 01. Administration of vaccines
 02. Documentation of administration and Reporting Requirements
 03. Use of specific Electronic Health Record decision support and documentation tools
 04. Scheduling of Vaccine Visits
 05. Use of Risk Stratification Guidance
 06. General distribution plans
 07. Required training and education
 - b. As vaccine supply increases, vaccination efforts shift to a larger scale, and COVID-19 vaccines are licensed by the

FDA, VHA subject matter experts will consider drafting a durable policy to support COVID-19 vaccination, such as a VHA Directive.

4. Considers how policy will help critical populations, including rural Veterans and racial and ethnic minority populations disproportionately affected by SARS-CoV-2, access vaccine.

Organization and Assignment of Responsibilities

1. Lead: VHA Clinical Operations for Specialty Care Services
2. Co-Lead: VHA National Center for Health Promotion and Disease Prevention

Direction, Control, and Coordination

This group is primarily responsible for drafting policy and guidance to support implementation of the COVID-19 vaccination plan in VHA.

1. VISN Level: Direction, control, and coordination activities at the VISN level occur via guidance drafted by the national Policy group. This is communicated via email and presentations to national leadership. The COVID-19 Vaccine Policies and Clinical Guidance workgroup is responsible for direct communications to VISN vaccine coordinators.
2. VAMC Level: Direction, control, and coordination activities at the facility level occurs in the Executive Leadership Team and Incident Command and through vaccine coordinators. The COVID-19 Vaccine Policies and Clinical Guidance workgroup is responsible for direct communications to VAMC vaccine coordinators.
3. Program Offices: Direction, control, and coordination activities at the Program Office level occur in the Program Office Executive Leadership Team. The COVID-19 Vaccine Policies and Clinical Guidance workgroup is not responsible for direct communications to Program Office leadership. Communications to program office leadership will occur through presentations made by other members of the COVID-19 vaccine planning team.
4. COVID-19 Vaccine Policies and Clinical Guidance workgroup: Direction, control, and coordination activities at the workgroup level occur during weekly meetings. The workgroup provides coordination in drafting VHA guidance and assisting in communication of guidance to key stakeholders.

Communications

The workgroup communicates VHA policy and guidance to relevant VHA audiences.

1. Key messages are communicated internally to COVID-19 vaccine workgroups and the IPT.
2. Key messages are provided to the COVID-19 Vaccine Communications workgroup to assist in communicating COVID-19 vaccine guidance and policy across VHA.
3. The workgroup assists the COVID-19 Vaccine Education workgroup in the development of educational materials for VHA staff and Veterans who are covered in VHA policy and guidance.
4. Workgroup members present changes in policy and guidance on VHA national calls.

Critical partners:

1. All COVID-19 vaccine workgroups must participate in review of guidance as relevant to their area of expertise.
2. The COVID-19 Vaccine Communications and Education groups are critical partners in maximizing uptake and implementation across VHA.
3. The COVID-19 Risk Stratification workgroup is a critical partner, as VHA risk stratification guidance will be based on the initial allocation framework developed by ACIP.



Appendix E – Metrics and Informatics

VHA COVID-19 Vaccination Planning and Actions

7-2-2021

Purpose

The purpose of this appendix is to outline best practices for the Metrics and Informatics Workgroup for COVID-19 Vaccination in VHA.

The overarching goal is to coordinate development of key metrics for tracking of COVID-19 vaccine supply, distribution, and vaccination rates for Veterans and staff as well as to develop capabilities to report vaccine administration and supply data to the CDC, internal, and external VA stakeholders.

Scope

The COVID-19 Vaccine Metrics and Informatics workgroup:

1. Develops informatics solutions for VHA's electronic medical record that will facilitate identification of and communications with risk stratified persons in need of COVID-19 vaccination.
2. Develops informatics solutions that support documentation and data capture of COVID-19 vaccinations in VHA's electronic health record.
3. Reviews and follows vaccine administration and supply reporting requirements from CDC.
4. Identifies solutions to document and report vaccine inventory and wastage daily to CDC.

Concept of Operations

The COVID-19 Vaccine Metrics and Informatics workgroup identifies informatics solutions to support COVID-19 vaccine administration to staff and Veterans, reporting of key vaccine administration metrics for VHA operational purposes, and developing solutions to report required vaccine data to CDC.

The workgroup:

1. Develops informatics solutions for VHA's electronic medical record that facilitate identification of and communications with persons at highest risk and in need of COVID-19 vaccination.
 - a. Develops tools, dashboards and/or reporting portals that will identify staff and patients who should be offered COVID-19 vaccine at each phase of the vaccination program.
 - i. VHA Support Service Center (VSSC) tool developed to help VISNs and facilities identify Veteran patients by conditions that may elevate risk associated with COVID-19 including age, comorbidities, gender, race and ethnicity, so that they can be invited for vaccination.
 - ii. SharePoint-based tools to identify and pre-register high-risk staff for COVID-19 vaccination were developed by VISN8 and VISN21. Information about these best practices were disseminated to other VISNs. VISNs interested in developing a similar tool could contact VISN8 and VISN21 points of contact to receive assistance.
 - b. Determines VHA's mechanism of notifying patients about second doses of vaccine.
 - i. VHA will create appointments for 2nd doses of vaccine using its VistA scheduling package. VHA will notify patients by letter, phone call, VEText, or other modalities when appointments for second vaccine doses are due.
 - ii. Patient reminders, alerts or texts may be generated through the My HealthVet patient health portal or other VA supported text apps (i.e., Annie app).
 - iii. VHA informatics solution will notify staff when their 2nd doses of vaccine are due. Employees due for second doses will be visible through Occupational Health Recordkeeping System (OHRs) 2.0.
 - c. Develops vaccine reporting and analytic tools for VHA operational purposes
 - i. VHA will develop requirements for dashboards or other reporting tools to allow for vaccine administration and supply data visualization for operational purposes.

- ii. Evaluates informatics solutions to track whether critical populations, including persons at high-risk for severe infection or persons who may be at higher risk for getting infection, such as members of racial and ethnic minority populations, are being reached for vaccination.
 - iii. VHA developed a Power BI dashboard to include Veteran and Employee vaccination metrics. This Power BI dashboard was released on December 18, 2020 and is available for VHA national, VISN and facility use.
 - 01. Metrics include vaccine administration detail by location (national, VISN, facility), and demographics including age and gender.
 - 02. The COVID-19 CPRS Clinical Reminder also provides for first and second dose tracking and reminders.
2. Develops informatics solutions that support documentation and data capture of COVID-19 vaccinations in VHA's electronic health record.
- a. Determines VHA's baseline capacity for documenting vaccine administration for Veteran beneficiaries.
 - i. VHA developed a national decision prompt for COVID-19 vaccination for its patient electronic medical record, CPRS, that will provide prompts tailored for high-risk priority populations, prompt for 2nd doses when due, and provide standard documentation and data capture for COVID vaccine doses given to Veteran patients.
 - 01. CVX codes were added to immunization file 11/19/2020
 - 02. A national clinical reminder dialog for COVID-19 Vaccination was released 11/23/2020 and is mandatory for use across VHA
 - 03. Reminder for second dose incorporated in the reminder dialog
 - ii. Similar functionality was developed for the Cerner electronic health record in use at some VHA facilities.
 - iii. Vaccine data will be populated in the VistA Immunization File and VA's Corporate Data Warehouse.
 - b. Determines VHA's capacity for documenting vaccine administration for VHA staff.
 - i. VHA evaluated and determined it would modify an existing electronic record keeping system, OHRS 2.0, to document COVID vaccine doses administered to VHA staff.
 - 01. VHA issued an operational memo in October 2020 requiring OHRS 2.0 be used for employee COVID-19 vaccine administration documentation throughout the enterprise.
 - 02. OHRS 2.0 team built a COVID-19 Vaccine sub module on the OHRS 2.0 platform which went live on 12/10/2020.
 - 03. This OHRS 2.0 sub module will allow documentation of doses of COVID-19 vaccine administered to employees.
 - 04. OHRS 2.0 recorded, on-demand training is available on TMS for OHRS 2.0 new users and OHRS 2.0 current users
 - 05. A total of 7000 OHRS 2.0 licenses were obtained to support role-based access for non-Employee Occupational Health Staff administering COVID-19 vaccines to employees who need OHRS 2.0 access for vaccine documentation.
 - 06. OHRS 2.0 will provide additional OHRS 2.0 technical support and help desk support to field questions from the 7000 OHRS 2.0 licensees, including EOH users and role-based access users
 - 07. The role-based users will have OHRS 2.0 access for approximately 6 months to support the surge of COVID-19 vaccinations for staff. After VHA determines that there is no longer need for surge access to OHRS 2.0, the role-based users' access will be discontinued.
3. Reviews and follows vaccine administration and supply reporting requirements from CDC.
- a. VHA reviewed requirements, capabilities and resources to determine an appropriate integration platform to transmit core vaccine data elements to CDC on vaccines administered to VHA beneficiaries.
 - b. VHA identified the Veterans Data Integration and Federation (VDIF) solution as the platform to transmit VHA

vaccine administration data to the CDC Clearing House

- i. VDIF allows for reporting CDC-defined core data elements to CDC within 24 hours of vaccine administration
 - ii. VHA developed a connection between OHRS 2.0 and VDIF to transmit core vaccine data elements to VDIF for reporting of CDC-defined core data elements from administered to VHA staff to CDC within 24 hours of administration
 - iii. For patient vaccine administration data, VDIF will transmit vaccine administration data from VistA and Cerner.
 - iv. The preferred connection modality is an Application Program Interface (API) that is currently being tested by VA and CDC.
 - v. VDIF production go-live: 12/16/2020
 - vi. VHA planned for and tested manual transmission of vaccine administration data as an interim solution until API go-live. Manual data transmission is covered under the VA-CDC Memorandum of Agreement (MOA) which was fully executed on 11/18/2020
 - vii. VA Office of Information Technology determined that a separate MOA/Information Security Agreement (ISA) was needed for the API between VA VDIF and CDC
 - viii. Plan of Action and Milestones (POA&M) will be established as an interim agreement until MOA/ISA executed.
4. Coordinates review by VHA Office of General Counsel, Privacy Office, and others if needed of a provider agreement with CDC. This agreement will need VA signature for VA to receive vaccine.
 - a. This review was successfully conducted, and the VA-CDC MOA was fully executed and sent to CDC on 11/18/2020.
 5. If a vaccine is approved under an EUA, determines if there are any additional required reporting elements for the vaccine and incorporate the collection and transmission of data to CDC.
 6. Reviews publicly available reporting platforms that display VA COVID-19 vaccination administration data
 7. Evaluates VA use of OWS's Tiberius platform, a COVID-19 vaccine distribution planning, tracking, modeling, and analysis application that provides flexible, real-time, data-backed processes so users of all types can make data-driven decisions.
 - a. VHA staff received Tiberius access on 12/2/2020
 - b. VHA staff used Tiberius for access to weekly VHA COVID-19 vaccine allocations and for allocation transfers to federal entities, states, and jurisdictions
 8. Evaluates and identifies data solutions for recording and transmission of vaccine administration data from VA to federal partners or State Veterans Homes whose employees and/or Veteran patients receive vaccination services from VA.
 - a. This will be accomplished by assigning an indicator in the medical record to record that the individual is being vaccinated as a federal partner employee or State Veteran Home patient.
 - b. This data will be de-identified and aggregated in a summary report provided to the federal or state partner.
 9. Identifies solutions to document and report vaccine inventory and wastage daily to CDC.
 - a. Vaccine information will be collected at each local VA facility to determine a vaccine utilization rate so that adequate supply can be distributed. This will include daily supply on hand, daily doses administered and wasted doses.
 - b. Vaccine information will be aggregated for all sites to calculate national VA daily inventory totals, doses administered, and wastage.

Organization and Assignment of Responsibilities

1. Lead: VHA Office of Population Health
2. Co-Lead: VHA Health Informatics

Direction, Control, and Coordination

This group is primarily an internal advisory group, communicating with VHA COVID-19 vaccination workgroups described in these annexes.

1. VISN Level: Direction, control, and coordination activities at the VISN level occur via communications from national VHA operational leadership. The Metrics and Informatics workgroup communicates key initiatives to VHA operational leadership in addition to presentations on national leadership meetings upon request. This workgroup provides updates for the office hours and vaccine coordinator teams.
2. VAMC Level: Direction, control, and coordination activities at the facility level will occur in the Executive Leadership Team and Incident Command. The Metrics and Informatics workgroup will communicate key initiatives to VHA operational leadership in addition to presentations on national leadership meetings upon request. This workgroup provides updates for the office hours and vaccine coordinator teams.
3. VHA Program Offices: Direction, control, and coordination activities at the Program Office level occur in the Program Office Executive Leadership Team. The Metrics and Informatics workgroup communicates key initiatives to VHA program office leadership in addition to presentations on national leadership meetings upon request. This workgroup is not responsible for direct communications to program office leadership.
4. Workgroup: Direction, control, and coordination activities at the Workgroup level occur during weekly meetings. The group functions under the leadership of VHA Office of Population Health and VHA Health Informatics.

Communications

The workgroup will communicate:

1. Availability of COVID vaccine metrics and informatics solutions for VHA staff and leadership to relevant audiences and education materials and related training on use of these solutions.
2. Key initiatives to COVID-19 vaccine workgroups and the IPT. Outlines will be provided to the communications team to assist in communicating the available COVID-19 metrics and informatics solutions across VHA.
3. VHA informatics solutions for staff and beneficiary vaccine data reporting to CDC.

Communications will occur via:

1. Outlines provided to the COVID-19 Vaccine Communications workgroup to assist in communicating the available COVID-19 metrics and informatics solutions across VHA.
2. Presentations on national calls to review changes in functionality and development and availability of new tools.
3. Updates and presentations on office hours and vaccine coordinator calls.

Critical partners:

1. The COVID-19 Vaccine Communications and Education groups are critical partners in maximizing uptake and implementation of metrics and informatics solutions within VHA.
2. VHA Health Informatics, VA Office of Information Technology, VHA Office Applied Performance and Improvement, and other VHA Program Offices are key partners in disseminating information about national vaccine metrics and informatics solutions to users, quality management leaders, and national and VISN operational leadership.



Appendix F – Distribution

VHA COVID-19 Vaccination Planning and Actions

7-2-2021

Purpose

The purpose of this appendix is to outline best practices for distribution of COVID-19 vaccine to VHA facilities for the purpose of immunizing patients, employees, and other populations such as federal partner staff. The overarching goal is to develop a distribution and storage plan for COVID-19 vaccines at VHA facilities based on the CDC framework for distribution of the vaccine.

Scope

The Distribution Workgroup is responsible for developing and refining plans for distribution and storage of COVID-19 vaccines and related supplies based on VA's risk stratification framework and the VA allocation issued by the CDC and delivered to VHA facilities by the CDC's authorized distributors.

The Distribution Group:

1. Communicates with CDC regarding all aspects of COVID-19 vaccine distribution.
2. Communicates with VA and VHA leadership.
3. Plans ordering, distribution and storage of vaccine.
4. Collaborates in development of a tabletop exercise and supporting materials.
5. Reviews requirements for a vaccine authorized under EUA.
6. Tracks and monitors COVID-19 vaccines at each VHA facility.

Concept of Operations

The Distribution workgroup:

1. Communicates with CDC regarding all aspects of COVID 19 vaccine distribution.
 - a. Weekly meetings were held from September through December 2020 with CDC's Federal Entities COVID-19 vaccine team and leaders from VHA's COVID-19 planning team to coordinate COVID-19 vaccine plans. Topics included VA's population enumerations for employees and Veteran patients; informatics solutions; Outside of Continental United States (OCONUS) vaccine allocation and distribution; and strategies for distribution, allocation, and administration of specific vaccine products.
 - b. Based on HHS's pro-rata allocation strategy, VHA's initial allocation also followed a pro-rata allocation strategy to distribute vaccine.
2. Communicates with VA and VHA leadership.
 - a. Relays distribution information to the VHA COVID-19 working groups.
 - i. Minutes of COVID-19 vaccine distribution workgroup meetings were sent to the COVID-19 working group and verbal updates given at least weekly to the team.
 - ii. Weekly meetings were held with senior VHA leadership starting in October 2020 to discuss distribution plans and to ensure distribution plans were coordinated with VHA operations.
 - iii. Two briefings were given to VA leadership, one in October 2020 to the VA Acting Deputy Secretary and one in November 2020 to the VA Chief of Staff and Acting Deputy Secretary, which included information on VHA's distribution strategy and plan.
 - b. Works with other COVID-19 vaccine workgroups (Communications, Metrics and Informatics, Risk Stratification and Vaccine Safety) to inform them of the distribution plans so they can incorporate the information into their workstreams.
 - i. Communications: COVID-19 vaccine Frequently Asked Questions (FAQs), PowerPoint presentations, and

placemat included information on vaccine distribution, focusing on initial distribution when vaccine supply will be limited.

- ii. Metrics & Informatics: Distribution team members worked with Informatics colleagues to include vaccine supply information on a Power BI dashboard for internal reporting of vaccine administration and supply.
 - iii. Risk Stratification: for VHA's initial allocation, the population enumeration for VHA employees and Veteran patients in care was used to determine pro-rata allocation to VHA facilities.
 - iv. Vaccine Safety: weekly communication between Distribution and Vaccine Safety workgroup leadership to ensure alignment of objectives.
 - v. Education: Distribution team leads worked with the education group to develop content for storage and handling trainings specific for the Pfizer -70°C, Moderna -20°C, and Janssen -2° to 8°C products.
- c. Provides COVID-19 vaccine supply information to VA Leadership.
3. Plans ordering, distribution and storage of vaccine.
- a. Developed a system for VA Pharmacy Benefits Management (PBM) to place a centralized order through the CDC's VTrckS. Three PBM staff were identified as national leads to receive order requests from individual VHA facilities and place centralized orders that included quantities for individual VHA ship-to sites. These staff completed CDC Vaccine Provider Ordering Portal (VPOP) and VTrckS training, received access to VPOP and VTrckS and successfully placed initial orders in December 2020 and subsequent weekly orders.
 - b. Works with Pharmacy leadership at the VISN and Facility level to:
 - i. Prepare them for the needs of COVID-19 vaccine distribution.
 - ii. Operationalize distribution of COVID-19 vaccine upon release.
 - 01. A distribution plan for the -70°C vaccine product was developed and released to the field on 12/14/2020 (updated 5/20/2021).
 - 02. A distribution plan for the -20°C product was developed and released to the field on 12/21/2020 (updated 4/19/2021).
 - 03. A limited redistribution plan for the -70°C vaccine product was developed and released to the field on 12/14/2020 (updated 5/26/2021).
 - 04. A limited redistribution plan for the -20°C vaccine product was developed and released to the field on 12/21/2020 (updated 5/13/2021).
 - 05. In February 2021, PBM allowed sites to order Pfizer BioNTech and Moderna vaccines at the same station for administration if a written safety plan was in place to ensure correct vaccine storage, handling and administration procedures were followed for each vaccine product.
 - 06. Distribution and redistribution plans for the -2° to 8°C product were developed and released to the field on 3/3/2021 (updated 4/1/2021 and 5/19/2021, respectively).
 - 07. Additional edits to distribution and redistribution plans will be developed and released to the field based on manufacturers' changes in guidance.
 - iii. Ensure a feedback loop regarding internal distribution within facility and facility alignments.
 - c. Works with VHA Procurement and Logistics Office (PL&O) leadership at the national level to assure that all ancillary supplies or pertinent storage needs are available at facilities, especially as relevant to vaccine cold-chain requirements for storage and handling.
 - i. -70°C vaccine product cold-chain handling requirements, including appropriate freezer storage, temperature monitoring, and dry ice replenishment when necessary for storage in the thermal shipper, are included in the -70°C distribution plan. This plan also includes instructions on reporting and responding to temperature excursions should they occur.

- ii. P&LO acquired ultra-cold and conventional cold freezers via a centralized purchase for necessary expansion where needed for VISN locations with high-throughput vaccination capacity to ensure that at 2 least sites per VISN had ultra-cold storage capacity. Additional sites per VISN were identified for conventional freezer purchases to store -20°C vaccine product. A total of 36 ultra-cold freezers and approximately 153 conventional cold freezers were purchased and distributed to VHA facilities from mid-November to mid-January.
 - iii. P&LO also worked with PBM to develop recommendations for extra medical grade refrigerators and refrigerated transport containers so that the field could purchase in order to be prepared for the storage and redistribution of COVID-19 vaccine products.
4. Collaborates in development of a tabletop exercise and supporting materials to assist VISNs and VA medical facilities in planning for COVID-19 vaccination campaigns for VA staff and Veteran patients. The mandatory tabletop exercise was released to VHA VISNs and facilities in October and sites were requested to certify completion by October 30, 2020. See Appendix N for a description of the tabletop exercise.
5. Reviews requirements for a vaccine authorized under EUA.
- a. Upon authorization of the -70°C vaccine under an Emergency Use Authorization (EUA), the Distribution workgroup reviewed the EUA product specifications, CDC's recommendations for use of the vaccine and CDC's recommendations for initial vaccine allocation in Phase 1a for individuals at highest risk.
 - b. Developed plan for distribution and allocation of -70°C vaccine to VHA sites in coordination with VHA operations. Each VISN designated two facilities per VISN to receive initial shipments of -70°C product based on the availability of an ultra-cold freezer for product storage and high-throughput capacity for employee and Veteran vaccination and based on their capacity to vaccinate individuals in Phase 1a.
 - c. -70°C vaccine orders were submitted by individual VHA ship-to sites. Orders were coordinated at the national level by PBM and reviewed with VHA senior leadership. Initial orders for VHA were placed centrally on 12/4/2020.
 - d. Upon authorization of -20°C vaccine, the workgroup reviewed the EUA product specifications and developed a plan for distribution and allocation of vaccine to VHA sites in coordination with VHA operations. Each VISN selected facilities to receive shipments of -20°C product based on the availability of a freezer for product storage.
 - e. Upon authorization of -2° to 8°C refrigerated vaccine, the workgroup reviewed the EUA product specifications and developed a plan for distribution and allocation of vaccine to VHA sites in coordination with VHA operations. Each VISN selected facilities to receive shipments of refrigerated vaccine product based on the availability of a refrigerator for product storage.
6. Tracks and monitors COVID-19 vaccines at each facility.
- a. Collaborated with COVID-19 vaccine metrics and informatics workgroup on tracking and monitoring.
 - i. PBM distributed guidance to VISN and facility pharmacists on 12/14/2020, 12/21/2020, and 3/3/2021 (in conjunction with the distribution plans for each specific product) outlining the process for reporting vaccine and ancillary kit receipt, vaccine supply, inventory, wastage, and spillage for required daily national reporting to CDC
 - ii. PBM national staff obtained access to VPOP for submission of supply, inventory, wastage, and spillage data to CDC according to CDC requirements
 - iii. PBM collaborated with Metrics & Informatics to ensure that vaccine supply and inventory data was included in the VHA Power BI reporting dashboard on COVID-19 vaccination
 - iv. PBM developed a process for sites to report quantities and dates of on-hand vaccine inventory expiration to VA Central Office in May 2021.

Organization and Assignment of Responsibilities

1. Lead: VHA Pharmacy Benefits Management
2. Co-Lead: VHA National Procurement & Logistics Office

Direction, Control, and Coordination

VHA Pharmacy Benefits Management (PBM) is responsible for directing and coordinating all purchasing activities and ensuring detailed distribution plans are developed and followed at VAMCs. They coordinate the ordering, storage and distribution using the CDC's Distribution COVID-19 vaccine framework and ensure appropriate implementation at all VAMCs. VHA PBM coordinates with VHA Procurement & Logistics to ensure that ancillary supplies and storage are optimal for the COVID-19 vaccines.

1. VHA PBM is responsible for:
 - a. Placing the centralized order for COVID-19 vaccines through the CDC's Vaccine Tracking System (VTrckS).
 - b. Ensuring purchased COVID-19 vaccines from the manufacturer are received by VHA facility pharmacies.
 - c. Ensuring that the number of doses from each multi-dose vial is accounted for and tracking is set up for purchased vaccines and distribution throughout the facility.
 - d. Evaluating and planning for cold- and ultra-cold shipping, storage and handling requirements for COVID-19 vaccines.
 - e. Ensuring that a feedback loop is developed and followed by VHA facility pharmacy leadership to account for internal distribution of COVID-19 vaccines.
 - f. Developing a finalized plan to track and monitor all COVID-19 vaccines at each VHA facility.
2. VHA Procurement & Logistics Office (P&LO) is responsible for:
 - a. Ensuring ancillary supplies not included in ancillary supply kits provided by the U.S. Government are purchased and distributed appropriately for preparation, handling and administration of specific COVID-19 vaccines.
 - b. Assisting with storage as needed once specific vaccines are identified. P&LO may also support safe movement of assets, such as movement of ultra-cold freezers from one station to another if necessary, for COVID-19 vaccine operations.
3. VISN Level: Direction, control, and coordination activities at the VISN level occur in the Office of VISN Pharmacy Executives. The VISN ensures that all VAMC pharmacies in their VISN are following the plans put forth by the Distribution lead.
4. VAMC Level: Direction, control, and coordination activities at the facility level occur in the Executive Leadership Team and Incident Command for accepting purchases. Ensuring optimization of Distribution and tracking plans will be overseen by the Chief of Pharmacy. The facility provides coordination through their COVID-19 vaccine committee and COVID-19 vaccine coordinator between pharmacy for storage and handling, logistics, occupational health, nursing, and other disciplines needed for COVID-19 vaccination operations.
5. Program Offices: Direction, control, and coordination activities at the Program Office level occur within the Executive Leadership Team.
6. COVID-19 Vaccine Distribution Workgroup: Direction, control, and coordination activities at the Workgroup level occurred in the initial phase continue and throughout the distribution process. The Workgroup provides coordination as a primary group to ensure distribution is optimal and a tracking system is in place.

Communications

The COVID-19 Vaccine Distribution workgroup uses the framework adapted by the COVID-19 Vaccine Risk Stratification workgroup, along with guidance and policy from the COVID-19 Vaccine Policy workgroup, to inform distribution needs and processes. The VHA risk stratification framework and accompanying population enumeration is used, in conjunction with input from VHA Operations, VISNs and facilities, to determine initial sites to receive product for distribution to VHA facilities.

The storage and distribution plans for the -70°C, -20°C and -2° to 8°C vaccines were shared across COVID-19 vaccine workgroups and distributed to VISN and facility-based pharmacy staff handling vaccine product after EUA issuance by the FDA and prior to vaccine administration efforts. The COVID-19 Vaccine Distribution workgroup worked with the COVID-19 Vaccine Communications and Education workgroups to ensure that VHA leadership and field staff understood processes by which vaccines will be ordered, distributed, and tracked. Critical recipients of this information included VISNs, facilities, pharmacists, nurses, and providers. The COVID-19 Vaccine Distribution workgroup coordinated communications efforts with the COVID-19 Vaccine Risk Stratification, Education, Safety and Communications workgroups. Key deliverables were VHA mandatory Talent Management System (TMS) training for vaccinators and handlers which included information on COVID-19 vaccine distribution, storage, and handling specific to each vaccine product.



Appendix G – Vaccine Safety

VHA COVID-19 Vaccination Planning and Actions

7-2-2021

Purpose

The purpose of the COVID-19 Vaccine Safety Workgroup is to outline best practices for reporting, tracking and monitoring COVID-19 vaccine adverse events through the VA Vaccine Safety Surveillance program.

The overarching goal is to develop a comprehensive Passive and Active COVID-19 vaccine safety surveillance program for Veteran patients and employees.

Scope

The COVID-19 Vaccine Safety Workgroup will be responsible for ensuring a plan is implemented for reporting, tracking, and monitoring adverse events associated with COVID-19 vaccines.

The Workgroup:

1. Tracks and monitors reported adverse events (AEs) related to vaccine.
2. Works with VHA Office of Employee Occupational Health on employee AE tracking.
3. Supports the active surveillance system developed by VAMedSAFE.
4. Ensures that summary of COVID-19 vaccine AEs are reported internally within VHA.

Concept of Operations

The COVID-19 Vaccine Safety Group:

1. Tracks and monitors voluntary reported AEs through VA ADERS, VA's Passive Surveillance program.
 - a. The VA ADERS staff tracks and benchmarks sites to ensure draft reports are completed and submitted to VAERS.
 - b. The VA ADERS staff provides training to facility staff identified by the VAMCs to ensure that COVID-19 vaccine AEs that occur in inpatient and extended care settings will be promptly identified, reported, and submitted to VA ADERS and the VAERS system.
 - c. The Vaccine Safety Group worked with the VHA Office of Employee Occupational Health to develop a process for tracking, monitoring, and ensuring AEs occurring in staff are promptly and adequately reported in VA through VA ADERS and to the VAERS system.
2. Works with the VHA Office of Employee Occupational Health to potentially track and monitor suspected AEs in staff (e.g., COVID-19 Vaccine Monitoring Form given to staff at time of vaccination).
3. Provides a Vaccine AE Reporting FAQ document.
4. Supports the Active Surveillance System developed by VAMedSAFE to monitor, track, and assess COVID-19 AEs in the high risk and general Veteran patient population.
5. Ensures that a summary of COVID-19 AEs is reported to the other COVID-19 Vaccine Workgroups, subject matter experts, and other audiences.
6. Follows any conditions for use and safety and monitoring requirements for the vaccine product if a vaccine is approved under an EUA.

Organization and Assignment of Responsibilities

1. Lead: VA Center for Medication Safety (VAMedSAFE) and (VA ADERS Program)
 - a. The VA Director, Center for Medication Safety oversees all vaccine safety surveillance for VA and helps run the Active Surveillance program.
 - b. The Program Manager of VA ADERS oversees the Passive Surveillance program and helps run the actual day to day

efforts of the VA ADERS program.

- c. The VAMedSAFE Senior Biostatistician runs the Vaccine Safety Active Surveillance program.
- d. VAMedSAFE pharmacovigilance staff work in the VA ADERS program and serve as reviewers. They validate AEs through the real time chart review for suspected AEs identified as part of the Active Surveillance program.
- e. VAMedSAFE Programmers are responsible for data extraction and assisting in running specific programs for portions of the Active Surveillance system.

Direction, Control, and Coordination

1. The VA Director for VAMedSAFE oversees the COVID-19 vaccine safety surveillance program in coordination with the Program Manager for VADERS and Senior Biostatistician.
2. The VA Center for Medication Safety conducts vaccine safety surveillance (Passive and Active Surveillance) for the Department of Veterans Affairs. COVID-19 vaccines are added to this longstanding vaccine safety surveillance program's current activities.
3. The VHA Office of Employee Occupational Health oversees the reporting of COVID-19 AEs for employees.
4. VAMedSAFE staff, specifically the Director of VAMedSAFE and Program Manager for VA ADERS, work with the VHA Office of Employee Occupational Health to ensure AEs are reported in a timely fashion, tracked and submitted to VA ADERS and VAERS. VAMedSAFE along with the Vaccine Safety Workgroup worked with the Office of Occupational Health to develop and implement a program to actively query employees about potential AEs.
5. The VA Center for Medication Safety has tactical and operational control for the COVID-19 vaccine safety program including responsibility for overseeing the entire Passive Surveillance and Active Surveillance Program. This has fallen under the purview of VAMedSAFE for the last decade and COVID-19 vaccines will be added to the armamentarium.
6. The VHA Office of Employee Occupational Health is responsible for ensuring vaccine AEs are reported or ensure that VAMedSAFE has the capability to track, monitor and ensure AEs are addressed and reported to VA ADERS and the VAERS system.
7. VISN Level: Direction, control, and coordination activities at the VISN level occur in the VISN Pharmacy Executive Office. The VISNs have coordination oversight of the VAMC AE reporting for all COVID-19 vaccine AEs into VA ADERS/VAERS and the responsibility to work with VAMedSAFE to review benchmarking and summary reports at VISN level Pharmacy and Therapeutics/Medication Safety meetings.
8. VAMC Level: Direction, control, and coordination activities at the facility level occur in the Executive Leadership Team and Incident Command - Chief of Pharmacy or Designee. The facility works with VA ADERS staff to provide instruction and coordination as a reporting facility to follow-up and observe patients for COVID-19 vaccine AEs and subsequently report all AEs to the VA electronic health record as an observed event. VA facility staff ensure all AEs/observed events are then reported into the VA ADERS and the VAERS system for all patients. VA facility staff respond to VA ADERS staff related to benchmarking for vaccine AE reporting and submission to VAERS.
9. Program Offices: Direction, control, and coordination activities at the Program Office level occur in the Executive Leadership Team. The Program Office provides coordination as subject matter experts to educate health care staff on AE reporting for all COVID-19 vaccine AEs into the patient EHR as per local policy and VA ADERS.
10. COVID-19 Vaccine Safety Workgroup: Direction, control, and coordination activities at the Workgroup level occur in the initial phase and intermittently throughout the vaccine process. The Workgroup level provides coordination as a primary group to ensure vaccine surveillance is optimal for VHA employees and as needed for patients.

Communications


The COVID-19 Vaccine Safety workgroup works closely with the COVID-19 Vaccine Communications and Education workgroups to inform VHA staff about best practices in vaccine safety monitoring and reporting. Communication tools include a summary of COVID-19 AE reports and a summary of signals or risks identified through active surveillance. The COVID-19 Vaccine Safety workgroup monitors input from the field regarding safety and adverse events related to vaccine and will have a process to quickly and effectively inform VHA leadership and field staff if a change in process related to a safety concern is needed.

A COVID-19 Vaccine Safety Fact Sheet was developed collaboratively by the Vaccine Safety and Communications workgroups. This was completed and distributed on the internal VHA COVID-19 SharePoint communications toolkit in November 2020.

Summary voluntary COVID-19 AE reports will be communicated to the COVID-19 Vaccine workgroups, VHA Infectious Disease Subject Matter Experts, VHA Office of Employee Occupational Health, CDC, and FDA.

Summary of passive and active surveillance results is shared with the Vaccine Safety Technical Subgroup of ACIP, which includes leadership members from FDA and CDC. Results will also be shared with the Office of Research and Development investigators as needed for further investigation/study of potential long-term safety outcomes.

Critical partners include: VHA Office of Employee Occupational Health and the following COVID-19 Vaccine workgroups: Metrics and Informatics, Risk Stratification, and Communications.



Appendix H – Education

VHA COVID-19 Vaccination Planning and Actions

7-2-2021

Purpose

The purpose of this appendix is to outline an educational plan to support the COVID-19 Vaccination program in VHA.

The overarching goal is to develop and/or distribute educational material for staff, Veterans, and caregivers, with content developed in coordination with other workgroups and federal agencies and distributed in concert with the Communications workgroup.

[COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations V2.0 Dated October 29, 2020](#) indicates that CDC will develop and share a variety of clinical educational and training resources for healthcare professionals related to COVID-19 vaccine(s). In addition, other materials will be available as regulatory authorization or approval from the FDA for each vaccine candidate is acquired. Each manufacturer will develop education and training resources for its individual vaccine candidate. VHA will make these resources available to Veteran patients and staff as appropriate. Content requiring tailoring to meet our patient population will be developed using these authoritative sources of information once materials are available for public use. In addition, content from the FDA, CDC, and each vaccine manufacturer will inform staff training programs for staff handling and distributing the vaccine as well as staff who will be administering each specific vaccine. These training programs will be entered into VHA's TMS to track training completion.

Additional resources, including [COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals](#) released by the CDC on November 24, 2020 and the [Vaccine Storage and Handling Toolkit with COVID-19 Addendum](#), were shared with VHA clinical staff in preparation for vaccine distribution and administration.

Scope

The COVID-19 Vaccine Education workgroup:

1. In collaboration with communications, creates and distributes educational material for staff and Veterans.
2. Coordinates with workgroups and stakeholders to develop Veteran educational materials and messaging.
3. Coordinates with workgroups and stakeholders to develop training materials for providers and staff.
4. Develops educational strategies and disseminates information regarding vaccines authorized under EUA.

Concept of Operations

The COVID-19 Vaccine Education workgroup:

1. In collaboration with communications, creates and distributes tailored educational material for staff and Veterans.
 - a. Staff education includes:
 - i. Employee Health related COVID-19 vaccine information (such as EUA Fact Sheets)
 - ii. High-risk groups for severe disease from COVID-19
 - iii. High-risk groups for acquiring COVID-19
 - iv. General COVID-19 vaccine information
 - v. Potential benefits of vaccine
 - vi. Limitations of vaccine
 - vii. Rationale for stratification of some groups before others when vaccine supply is limited
 - viii. How to access vaccine
 - ix. Monitoring of persons who are vaccinated
 - x. Information to support educating Veterans and caregivers about the COVID-19 vaccine
 - xi. Training and tools to support patient-centered conversations to address vaccine hesitancy and support vaccine

acceptance.

xii. Vaccinator training, including:

01. Vaccine and ancillary kit storage and handling
02. Proper vaccine administration techniques
03. Patient education requirements
04. Prompting second dose reminders
05. Documentation/Data reporting requirements including informatics tools that need to be used for data collection
06. Process for reporting vaccine usage, waste, and spillage
07. Process of reporting vaccine adverse events

- A. Vaccinator training materials and associated training requirements will be disseminated through several VHA clinical communications modalities.
- B. Completion of training will be monitored at local, VISN and/or national levels through TMS.

b. Veteran education will include:

- i. High-risk groups for severe disease from COVID-19
- ii. High-risk groups for acquiring COVID-19
- iii. General COVID-19 vaccine information
- iv. Potential benefits of vaccine
- v. Limitations of vaccine
- vi. Rationale for stratification of some groups before others when vaccine supply is limited
- vii. How to access the vaccine
- viii. Monitoring of persons who are vaccinated

c. This should include specific messaging geared toward:

- i. Persons who may have limited access to vaccine
- ii. Racial and ethnic minority populations disproportionately affected by COVID-19
- iii. Other underserved populations
- iv. Persons or groups who are vaccine-hesitant
- v. Special populations served by the VA who may be at high risk based on other risk factors and may be lower on the risk stratification framework

2. Coordinates with COVID-19 Vaccine workgroups and other key stakeholders:

- a. Content and need for educational materials
- b. Targeted messaging to critical or difficult-to-reach populations

3. In collaboration with the COVID-19 Vaccine Distribution workgroup, develops training materials for those staff who will be ordering, storing, handling, and distributing the COVID-19 vaccine:

- a. Proper handling, storage, and vaccine administration
- b. Process for ordering/reordering vaccine
- c. Receiving vaccine shipments
- d. Distributing vaccine
- e. Documenting usage and waste of vaccine
- f. Reporting adverse events

4. For vaccines authorized under an EUA:

- a. VA develops educational strategy to ensure that VHA staff have access to fact sheets and conditions of use for staff and Veterans.
- b. VA disseminates educational requirements of an EUA to staff and Veterans, including requirements for distribution of EUA fact sheets to providers and vaccine recipients.
- c. VA disseminates links to the EUA fact sheets for specific vaccine products. The fact sheets will be available on the FDA and CDC websites.

Organization and Assignment of Responsibilities

Lead: Veterans Health Education and Information Program, VHA National Center for Health Promotion and Disease Prevention

Direction, Control, and Coordination

This group is primarily responsible for creating educational material for staff and Veterans, with content in coordination with other workgroups, and distribution in concert with the Communications workgroup.

1. VISN Level: Direction, control, and coordination activities at the VISN level are coordinated with the Communications team. Communications may be via email, presentations to VISN leadership, or via other trainings. This group provides direct communications to VISN leadership in collaboration with or with facilitation by the Communications team. The VISN vaccine coordinator may also be involved in the dissemination of education and training materials.
2. VAMC Level: Direction, control, and coordination activities at the facility level occur in the Executive Leadership Team and Incident Command. Outreach and products for these teams is coordinated with the COVID-19 Vaccine Communications workgroup. Communications may be via email, presentations to leadership, or other trainings. The facility reviews educational materials for Veterans and staff and aids in distribution. The facility vaccine coordinator may also be involved in the dissemination of education and training materials.
3. VHA Program Offices: Direction, control, and coordination activities at the Program Office level occur in the Program Office Executive Leadership Team. The Program Office may provide input on educational needs of specific patient groups or of field staff. This group may provide and present educational materials to Program Office leadership in collaboration with the Communications workgroup.
4. COVID-19 Education Workgroup: Direction, control, and coordination activities at the Workgroup level occur during regular meetings. The Workgroup creates educational materials for staff, Veterans, and addresses educational needs regarding COVID-19 vaccine across VHA and assists in communication of those educational materials.

Communications

The COVID-19 Vaccine Education workgroup, in collaboration with the COVID-19 Vaccine Communications workgroup, communicates directly with VHA staff and Veterans in order to educate on COVID-19 and COVID-19 vaccine. The COVID-19 Vaccine Education workgroup works closely with other COVID-19 Vaccine workgroups including Risk Stratification, Policy, Distribution, Metrics and Informatics, and Vaccine Safety to determine educational information that should be tailored to VHA staff or Veteran audiences.

Appendix I – Outside of Continental United States COVID-19 Vaccination

VHA COVID-19 Vaccination Planning and Actions

7-2-2021

Purpose

The purpose of this appendix is to outline a plan to support VHA's COVID-19 Vaccination program in the VA facilities and clinics located outside of the continental United States (OCONUS). OCONUS VA locations include Puerto Rico; Hawaii; Alaska; Manila, Philippines; Guam; American Samoa; and Saipan.

Scope

VHA will:

1. Identify the number of VHA staff and VHA Veterans actively receiving care for COVID-19 vaccination by OCONUS jurisdiction, including enumeration for populations prioritized for vaccination.
2. Communicate VHA's population enumerations to CDC.
3. Coordinate with CDC and HHS to obtain sufficient COVID-19 vaccine allocation for VHA staff and VHA Veterans actively receiving care either via centralized order placed by VHA for a VA ship-to location, or via a jurisdictional allocation that includes vaccine sufficient for VHA employees and Veteran patients.
4. Identify CDC requirements and data systems for COVID-19 vaccine data reporting administration, supply, and wastage in VA OCONUS locations.
5. Identify and implement informatics solutions to transmit COVID-19 vaccine data on administration, supply, and wastage to CDC.
6. Collaborate with CDC, HHS and OCONUS COVID-19 vaccine jurisdictional leads, if needed, on vaccine allocation, distribution, administration, and data reporting for VA OCONUS staff and Veterans receiving health care.

Concept of Operations

VHA will:

1. Identify the number of VHA staff and VHA Veterans actively receiving care, include those prioritized for COVID-19 vaccination, by OCONUS jurisdiction. VHA communicated these population enumerations to the CDC Federal Entities team in October 2020.
 - a. Priority groups and definitions will be identified through CDC and/or VA guidance on risk stratification of COVID-19 vaccine.
 - b. VHA provided to CDC in October 2020 its population enumeration for OCONUS VHA locations for the following:
 - i. VHA staff, including enumerations for VHA staff who are health care personnel and essential personnel
 - ii. VHA enrollees, including those at highest risk due to age and other comorbidities
2. For the Manila, Philippines, VA health care location, VHA will coordinate vaccine allocation and administration of COVID vaccine with the jurisdiction and/or Federal partners with employees in Manila.
 - a. VA will evaluate its ship-to capacity to determine whether VA can ship COVID-19 vaccine to Manila, Philippines.
 - b. VA will coordinate with CDC, Federal Partner and jurisdictional vaccination leads to develop a plan for vaccine allocation, delivery, and administration of staff and enrolled Veterans at the VA Manila clinic.
3. For VA U.S. Affiliated Pacific Islands (USAPI) health care locations in Saipan, Guam, and American Samoa:
 - a. Due to shipping constraints for the -70°C vaccine product, and smaller numbers of VHA staff and patients at this location that were not sufficient to use the 975-dose minimum shipment of the -70°C product, VHA will coordinate with CDC to include VHA's initial vaccine allocation for high-risk Veterans and health care personnel in USAPI jurisdictional vaccine allocations.
 - b. VHA Saipan, Guam, and American Samoa staff will work with COVID-19 Vaccine jurisdictional points of contact regarding vaccination administration services for VHA staff and Veterans.

- i. At some USAPI locations, VHA staff may administer COVID-19 vaccine to its employees and Veterans.
 - ii. At other USAPI locations, VHA staff and Veterans may be vaccinated by the jurisdiction.
 - iii. The staff or program administering vaccine will be responsible for CDC data reporting on administration, supply, and wastage per CDC data requirements.
4. For VA's Puerto Rico Health Care System (VA Caribbean Health Care System):
 - a. VHA Caribbean Health Care System has an ultra-cold freezer on station that can store -70°C vaccine product.
 - b. VHA Caribbean was identified as a ship-to site and VISN 8 identified VHA Caribbean as an initial VHA site to receive -70°C vaccine product via direct ship from the manufacturer.
 - c. VHA Caribbean will place vaccine orders with PBM and will administer and report on vaccine administration, supply, and wastage per national VA reporting requirements.
5. For VA's Hawaii health care location, VA Pacific Islands:
 - a. VHA determined conventional freezer capacity is available on station for VA Pacific Islands and can receive an initial shipment of -20°C vaccine product.
 - b. VA Pacific Islands ship-to locations will place vaccine orders with VA PBM who will place orders centrally for VHA.
 - c. VA Pacific Islands will receive, store, and administer vaccine and use national VA informatics tools to document vaccine administration, supply, and wastage per national VA reporting requirements.
 - d. VA Pacific Islands may be able to redistribute -20°C vaccine product to Community Based Outpatient Clinics (CBOCs) per approved VHA redistribution plans.
6. For VA's Alaska health care location, Alaska VA:
 - a. VHA identified Anchorage VA as a ship-to site. Anchorage VA has conventional freezer capacity to store the -20°C vaccine.
 - b. Due to its conventional freezer capacity, VHA designated Anchorage VA as an initial site to receive -20°C vaccine product.
 - c. Anchorage VA will place vaccine orders with PBM, will receive, store, and administer vaccine, and report on vaccine administration, supply, and wastage per national VA reporting requirements.
 - d. Anchorage VA may be able to redistribute -20°C vaccine product to CBOCs per approved VHA redistribution plans.

Organization and Assignment of Responsibilities

1. The VHA COVID-19 Vaccination Project Team will provide national coordination and guidance to VISNs and OCONUS VHA medical facilities on communicating and coordinating distribution, storage, and administration of VA's COVID-19 vaccine allocation at OCONUS VA facilities.
2. The VISNs and/or OCONUS VA facilities will identify points of contact to communicate and coordinate vaccine distribution and administration with the national COVID-19 vaccination program team.


Direction, Control, and Coordination

1. VISN Level: Direction, control, and coordination activities at the VISN level will be coordinated within the VISN and its VHA medical centers with national guidance from VHA's COVID-19 vaccination Distribution, Metrics, and Safety workgroups. Communications may be via email, presentations to VISN leadership, or other trainings.
2. VAMC Level: Direction, control, and coordination activities at the facility level will occur in the Executive Leadership Team and Incident Command. OCONUS VAMCs will coordinate vaccination distribution and administration activities with jurisdictional staff when necessary through the VAMC point of contact for COVID-19 vaccination. Communications may be via email, phone, or presentation.
3. VHA Program Offices: Direction, control, and coordination activities at the Program Office level will occur in the

Program Office Executive Leadership Team. The Program Office may provide input to national guidance for VISNs and facilities' COVID-19 activities as relevant to the Program Offices' scope of expertise.

Communications

COVID-19 vaccination points of contact at VISNs and OCONUS VHA medical centers will communicate with the national COVID-19 vaccine team and with jurisdictional COVID-19 vaccine points of contact about VHA population enumerations for staff and enrollees, vaccine distribution, and vaccine administration. Additional communications may be needed within VHA to ensure VISN and national coordination, tracking, and reporting of vaccine administration, supply, and wastage.



Appendix J – State Veterans’ Home COVID-19 Vaccination

VHA COVID-19 Vaccination Planning and Actions

7-2-2021

Purpose

The purpose of this appendix is to outline a plan to support VHA's COVID-19 Vaccination program if State Veterans Homes request VA assistance through the Federal Emergency Management Agency and VA is granted significant quantities of vaccine to provide COVID-19 vaccination for State Veterans' Homes residents and staff. If VA receives a request for assistance, VHA leadership will review and decide whether to accept this responsibility through a Humanitarian/4th mission assignment.

State Veterans Homes serve a population of Veterans and staff who are high risk for acquiring, transmitting, and having severe disease from SARS-CoV-2.

Scope

VHA will:

1. Review and determine whether to accept the assignment to provide COVID-19 vaccination in response to a formal mission assignment from the state or jurisdiction. States or jurisdictions may request vaccination services, provision of vaccination product, or both, for SVH staff and Veterans. Acceptance of an assignment will be determined by VHA leadership.
2. When requests are approved, VHA will:
 - a. Identify the number of staff serving the State Veterans' Home who will need vaccine.
 - b. Identify the number of Veterans in the care of State Veterans' Homes who will need vaccine.
3. Develop a plan to provide COVID-19 vaccination to staff and Veterans working and residing in State Veterans' Homes.
4. Develop a plan to collect data on vaccine administration, supply, and wastage and transmit these data to states and/or CDC.
5. In October and November 2020, VHA coordinated with CDC and HHS to determine that states and jurisdictions had primary responsibility for planning vaccination for SVH staff and residents, including vaccine allocation and administration through enrollment in CDC's COVID-19 vaccination pharmacy partnership program that provides on-site vaccination services in long-term care facilities.
 - a. VHA communicated this approach to CDC's Federal Entities team who notified CDC's jurisdictional team in October 2020.
 - b. VHA's national office of Geriatrics & Extended Care communicated this approach to the National Association of State Veterans Homes (NASVH) in October 2020.
 - c. VHA also communicated this approach to Operation Warp Speed leadership. VHA subsequently announced this approach to CDC's jurisdictional team on a national coordinating call in November 2020.
 - d. VHA remains available to assist states who request assistance with COVID-19 vaccination of their SVH staff and patients.

Concept of Operations

If a Humanitarian/4th mission SVH COVID-19 vaccination assignment is received and accepted by VA, VHA will:

1. Identify the number of staff serving State Veterans' Homes that are requesting assistance with vaccine.
 - a. VA will request reports from these State Veterans' Homes on number of staff, including those who are in priority groups for vaccination if feasible.
2. Identify the number of Veterans who need vaccine and are in the care of State Veterans' Homes that are requesting assistance with vaccinating Veterans.

- a. VA will request reports from individual SVHs on number of Veterans in need of COVID-19 vaccine including those who are in priority groups for vaccination.
- 3. Develop a plan to provide COVID-19 vaccine to staff and Veterans working and residing in State Veterans' Homes that request assistance with vaccine.
 - a. A vaccination plan will be developed in collaboration with VA Central Office, VISNs and VA medical centers and State Veterans Homes.
 - i. Vaccination may occur in VHA immunization clinics or by directly delivering vaccine to sites of care, such as via mobile vaccination clinics or VHA staff who travel to State Veterans' Homes to provide vaccination services.
 - ii. Vaccination services will include first and second doses of COVID-19 vaccine as appropriate to the specific vaccine product.
 - b. The VHA COVID-19 Vaccination Project Team will provide supporting materials including guidance, communication, and education products, to support this vaccination campaign.
- 4. Develop plans to collect data on vaccine administration, supply, and wastage.
 - a. VHA will identify state and CDC vaccine reporting requirements and determine whether VHA needs to report data to state registries or directly to CDC.
 - b. VHA will identify solutions for reporting vaccine data to states and/or CDC.
 - c. VHA will identify internal solutions for tracking, monitoring, and reporting vaccination of

Organization and Assignment of Responsibilities

- 1. VISNs and VA medical centers will review assignments and make plans for Humanitarian/4th Mission outreach.
- 2. The VHA COVID-19 Vaccination Project Team will provide supporting guidance on logistics of distribution, storage, and handling, as well as communication and education resources as outlined elsewhere in this Vaccination Plan.

Direction, Control, and Coordination

- 1. VISN Level: Direction, control, and coordination activities at the VISN level will occur at the direction of VISN leadership in VISNs where State Veterans Homes have requested or accepted COVID-19 vaccination services from VHA. VISN leadership will provide coordination of the operation of vaccination services as well as maintain oversight for data collection and monitoring of State Veterans Homes staff and/or Veterans in alignment with VHA national guidance on COVID-19 vaccine operations.
- 2. VAMC Level: Direction, control, and coordination activities at the facility level will occur in the Executive Leadership Team and Incident Command. The facility will review the risk stratification framework, guidance, and policy and begin outreach and planning for vaccination of State Veterans Home Veterans and/or staff based on this guidance.
- 3. Program Offices: Direction, control, and coordination activities at the Program Office level will occur in the Program Office Executive Leadership Team.

Communications

The COVID-19 Vaccine Project Team will communicate VHA policy and guidance about vaccination of State Veterans Home staff and/or Veterans to relevant VHA audiences.

Appendix K – COVID-19 Vaccination for Caregivers for Veterans

VHA COVID-19 Vaccination Planning and Actions

7-2-2021

Purpose

The purpose of this appendix is to outline a plan to support the COVID-19 Vaccination program if VA is granted significant quantities of vaccine to provide COVID-19 vaccination to caregivers of Veterans enrolled in VA's Program of Comprehensive Assistance for Family Caregivers (PCAFC). VA's PCAFC serves caregivers of Veterans who may be at high risk for severe disease from SARS-CoV-2 infection. A Veteran in the PCAFC may have one Primary Caregiver and up to two Secondary Caregivers. These caregivers are identified as Family Caregivers in the PCAFC.

This plan will be activated if VA and VHA leadership determine that caregivers will be offered COVID-19 vaccination through legislative authorities. If caregivers are offered COVID-19 vaccination, they will be encouraged to receive COVID-19 vaccination in coordination with, or at the same time as, the vaccination for their Veteran.

Scope

VHA will:

1. Review the need for and legal authority to provide COVID-19 vaccination to PCAFC Family Caregivers.
2. Identify the process by which caregivers may be offered COVID-19 vaccination in coordination with their Veteran, whose opportunity for COVID-19 vaccination will be determined by VHA's COVID-19 vaccine risk stratification framework.
3. Identify the number of Primary and Secondary family caregivers enrolled in VA's Program of Comprehensive Assistance for Family Caregivers
4. Develop a plan to provide COVID-19 vaccination to Family Caregivers enrolled in VA's PCAFC.
5. Develop a plan to collect data on vaccine administration for COVID-19 vaccinations given to Primary and Secondary Caregivers.

Concept of Operations

VHA will:

1. Identify the number of Family Caregivers enrolled in VA's PCAFC.
2. Develop a plan to administer COVID-19 vaccination to Family Caregivers enrolled in VA's PCAFC.
 - a. Family Caregiver vaccination will occur in accordance the risk tier determined by VHA's COVID-19 vaccine risk stratification framework.
 - b. Vaccination services will include first and second doses of COVID-19 vaccine as appropriate to the specific vaccine product.
 - c. The VHA COVID-19 Vaccination Project Team and the VA Caregivers Support Program Office will provide supporting materials, including guidance to facilities on how to implement caregiver vaccination and communication and education products to support this Family Caregivers vaccination campaign.
3. Develop plans to collect data on vaccine administration for caregivers.
 - a. VHA will use VA-CDC data connections to send required vaccine administration, supply and wastage data from vaccine administered to Family Caregivers to CDC.
 - b. VHA will identify internal solutions for tracking, monitoring and reporting vaccination of Primary and Secondary Family Caregivers enrolled in VA's PCAFC.

Organization and Assignment of Responsibilities


1. VA, VISNs and VHA medical centers will review guidance and make plans for COVID-19 vaccination to Family Caregivers enrolled in VA's PCAFC.
2. VA Caregiver Support Program Office will provide expertise to inform the plan and operations of COVID-19 vaccination services for Family Caregivers enrolled in VA's PCAFC.
3. The VHA COVID-19 Vaccination Project Team will provide supporting guidance on logistics of administration, documentation and reporting of administration data for internal operational reports and to CDC as well as communication and education resources as outlined elsewhere in this Vaccination Plan.

Direction, Control, and Coordination

1. VISN Level: Direction, control, and coordination activities at the VISN level will occur via guidance and policy from the COVID-19 Vaccination Project Team and the VA National Caregiver Support Program Office. The VISN will lead the coordination, data capture and monitoring of vaccination of caregivers.
2. VAMC Level: Direction, control, and coordination activities at the facility level will occur in the Executive Leadership Team and Incident Command. The facility will review the risk stratification framework, guidance, and policy and begin outreach and planning for vaccination of Family Caregivers.
3. Program Offices: Direction, control, and coordination activities at the Program Office level will occur in the Program Office Executive Leadership Team.

Communications

1. Key messages will be provided to VISN and facility leadership, VHA staff, and Family Caregivers to assist in communicating VHA's COVID-19 vaccine guidance and operations for COVID-19 vaccination of caregivers.
2. Information and educational materials on COVID-19 vaccines will be provided to support vaccination of Family Caregivers.



Appendix L – COVID-19 Vaccination for Federal Partners

VHA COVID-19 Vaccination Planning and Actions

7-2-2021

Purpose

The purpose of this appendix is to outline a plan to support the COVID-19 Vaccination program when VA provides COVID-19 vaccination for federal partners.

Scope

VHA will:

1. Accept the assignment to provide COVID-19 vaccination to federal partner employees as directed by VHA leadership.
2. Identify the number of federal partner employees who will need COVID-19 vaccination services.
3. Develop a plan to vaccinate federal partner staff.
4. Develop plans for collection and reporting of data to CDC, states and/or federal partners.
5. Vaccinate federal partner employees in accordance with an established Memorandum of Agreement between VA and CDC (VA-CDC MOA).
6. Collaborate with federal partners to establish interagency agreements that delineate the scope of services provided and address issues related to privacy and reimbursement.

Concept of Operations

VHA will:

1. Identify the number of federal partner staff needing COVID-19 vaccination.
 - a. VA will receive reports from federal partners on number of staff by location in need of immunization.
 - b. VA or the federal partner will communicate the federal partner population enumeration to CDC and request an increase in VA's allocation sufficient to vaccinate federal partner staff.
2. Develop a plan to vaccinate federal partner staff needing immunization.
 - a. This plan will establish a mechanism for registering federal partner employees in VHA's electronic medical record.
 - b. Vaccination may occur at selected VHA sites of care in immunization clinics. Other options that may be considered are directly delivering vaccine to the site of care, such as via mobile vaccination clinic or VHA staff who travel to federal partner sites to provide vaccination services.
 - c. Vaccination services will include first and second doses of COVID-19 vaccine as appropriate to the specific vaccine product.
 - d. The VHA COVID-19 Vaccination Project Team will provide supporting materials including guidance and communication and education products to support this vaccination campaign.
3. Develop plans to collect data on vaccine administration, supply, and wastage.
 - a. VHA will follow CDC vaccine reporting requirements.
 - b. VHA will report CDC-required data elements for federal partner staff by the same mechanism used to report VHA data. VHA will report de-identified, aggregated federal partner employee vaccine data to federal partners as established in interagency agreements.
 - c. VHA will use an indicator in the electronic medical record to track, monitor and report vaccination of federal partner staff.

Organization and Assignment of Responsibilities


1. VHA, VISNs and VA medical centers will review assignments and make plans for vaccination of federal partner staff.
2. The VHA COVID-19 Vaccination Project Team will provide supporting guidance on logistics of distribution, storage, handling, as well as communication and education resources as outlined elsewhere in this Vaccination Plan. Additional members of the VHA COVID-19 Vaccination Project Team will be assigned to work specifically on efforts related to federal partner vaccination.

Direction, Control, and Coordination

1. VISN Level: Direction, control, and coordination activities at the VISN level will occur via guidance and policy from the COVID-19 Vaccination Project Team on vaccination of federal partner staff. This will be communicated via email and presentations to VISN leadership.
2. VAMC Level: Direction, control, and coordination activities at the facility level will occur in the Executive Leadership Team and Incident Command. The facility will review VA's COVID-19 vaccine risk stratification framework guidance; identify federal partner staff that are prioritized for vaccination based on their occupation; and begin outreach and planning for vaccination of federal partner staff based on this guidance.
3. VHA Finance Office will review Interagency Agreements (IAAs) and Memorandums of Understanding (MOUs) and if applicable, publish appropriate guidance and/or financial alerts to VISNs and stations in order to maximize reimbursable fund in accordance with the IAA/MOU.
4. Program Offices: Direction, control, and coordination activities at the Program Office level will occur in the Program Office Executive Leadership Team.

Communications

1. Key messages and informational materials will be provided to VISN and facility leaders and VHA staff to support COVID-19 vaccination of federal partner staff.
2. VHA will provide approved communications and educational materials on COVID-19 vaccines to federal partners to support vaccination of their employees.



Appendix M – COVID-19 Vaccination for VA Employees

VHA COVID-19 Vaccination Planning and Actions

7-2-2021

Purpose

The purpose of this appendix is to outline a plan to support the COVID-19 Vaccination program for VA employees.

Scope

VHA will:

1. Develop a risk stratification framework for COVID-19 vaccination of VA employees, including VHA clinical and administrative staff, Veterans Benefits Administration staff, National Cemetery Administration staff, and Department of Veterans Affairs staff, based upon VHA's Risk Stratification Plan for COVID-19 vaccination.
2. Assess VA employee enumerations by state, VISN and facility, including subgroups of health care and essential personnel.
3. Provide guidance and training materials to VISNs and VA facilities to support planning and implementation of COVID-19 vaccination, including second dose reminders and administration as indicated for specific vaccine products.
4. Develop solutions for collection and reporting of employee vaccination administration data to CDC according to CDC data reporting requirements.

Concept of Operations

VHA will:

1. Identify numbers of VA and VHA employees, including VHA health care personnel and VHA essential personnel by state, VISN and VA medical center.
2. Outline highest risk groups for initial vaccination to assist with planning of facility employee vaccination campaigns when vaccine supply is limited, including:
 - a. HCP who are prioritized for initial vaccination. HCPs are those who have the potential for direct or indirect exposure to infectious materials that put them at risk of acquiring SARS-CoV-2. Examples include staff who care for COVID-positive hospitalized patients and staff working in Emergency Department settings.
3. Develop tools and resources to prepare VHA facilities for employee vaccination.
 - a. VA drafted a tabletop exercise to assist VISNs and facilities in planning their COVID-19 employee vaccine operations. See Appendix N for information on VHA's COVID-19 vaccination tabletop exercise.
 - b. VHA will use the OHRS 2.0 solution to document COVID-19 vaccine doses administered to VHA employees. OHRS 2.0 will be also used to track employees due for second doses of vaccine when applicable for specific vaccine products.
 - i. VHA will utilize dashboards
 - ii. VHA will also use tools to pre-register and schedule employees for vaccination, including MS Bookings, Secure SharePoint portals, and the Light Electronic Action Framework (LEAF) web application.
 - c. Vaccination may occur in VHA immunization clinics or by directly delivering vaccines to the site of care, such as via mobile vaccination services to medical center work units (Intensive Care Units, inpatient wards).
 - i. Vaccination services will include first and second doses of COVID-19 vaccine as appropriate to the specific vaccine product.
 - ii. The VHA COVID-19 Vaccination Project Team will provide supporting materials including guidance and both communication and education products to support this vaccination campaign.
 - iii. Best practices from current influenza vaccination campaigns, such as drive-through vaccination clinics and vaccination clinics that ensure physical distancing and use of PPE, may be adapted for COVID-19 vaccination of VA employees.

- iv. Staggering vaccination of staff by unit was recommended as a best practice given the known reactogenicity of the -70C vaccine. Post-vaccination reactions may cause employees to miss work after vaccination due to symptoms that limit employee ability to perform work duties.
4. Develop plans to collect data on vaccine administration, supply, and wastage.
 - a. Identify an electronic record keeping system, OHRS 2.0, and built the capability to document CDC-required data elements for COVID-19 vaccine doses administered to VA employees.
 - b. OHRS 2.0 will include a link to submit adverse events post-vaccination to the VA Adverse Events Drug Reporting System.
 - c. Require OHRS 2.0 enterprise-wide employee documentation system for COVID-19 vaccination doses administered to VA employees.
 - d. OHRS 2.0 training for new and current users was developed and posted to VA's TMS in November 2020.
 - i. Completion of TMS training is mandatory for users of the OHRS 2.0 system.
 - e. Identify processes for reporting vaccine data to CDC.
 - i. The national VDIF solution will transmit OHRS 2.0 vaccine administration data to CDC every 24 hours per CDC requirements.
 - f. Identify solutions for tracking, monitoring, and reporting COVID-19 vaccination of VA staff.
 - i. A Power BI dashboard will display OHRS 2.0 vaccine administration data for internal VHA reporting and operational purposes.

Organization and Assignment of Responsibilities


1. VHA, VISNs and VA medical centers will review assignments and make plans for vaccination of VA staff.
 - a. VHA developed a tabletop exercise, frequently asked questions, OHRS 2.0 training, and supporting materials to assist VISNs and facilities in their planning efforts.
2. The VHA COVID-19 Vaccination Project Team provides supporting guidance on logistics of distribution, storage, handling, informatics tools, reporting requirements, as well as employee communication and education resources as outlined elsewhere in this Vaccination Plan.

Direction, Control, and Coordination

1. VISN Level: Direction, control, and coordination activities at the VISN level is coordinated by the VISN leadership team.
2. VAMC Level: Direction, control, and coordination activities at the facility level occur in the Executive Leadership Team and Incident Command.
3. VHA Program Offices: Direction, control, and coordination activities at the Program Office level occur in the Program Office Executive Leadership Team.

Communications

The COVID-19 Vaccination Project Team, and especially the Communications and Education workgroups, will provide key messages and information to support COVID-19 vaccination of VA employees. Key messages tailored specifically for VHA employees include a description of VA's planning process; VHA's risk stratification approach; and information on vaccine efficacy and safety specific to each FDA-authorized vaccine product.



Appendix N – COVID-19 Tabletop Exercises

VHA COVID-19 Vaccination Planning and Actions

7-2-2021

Purpose

The purpose of this appendix is to describe tabletop exercises that VAMCs, VISNs and VHACO Program Offices will conduct to support preparedness for COVID-19 vaccination in VA medical centers and clinics.

Scope

VHA will:

1. Develop tabletop exercises to distribute across VA to assist in planning a flexible and efficient response for when COVID-19 vaccine becomes available and vaccination of staff and Veterans begins.
2. Maximize transparency by ensuring the most up-to-date information and preliminary planning assumptions are made available with the tabletop exercises.
3. Distribute tabletop exercises to the field and encourage responses in order to identify gaps and challenges to vaccine deployment.

Concept of Operations

VHA will:

1. Develop a tabletop exercise and distributed across VA to assist in planning a flexible and efficient response for when COVID-19 vaccine becomes available and vaccination of staff and Veterans begins.
 - a. Exercises were mandatory for completion by all VHA facilities and completion was certified in a national portal by October 30, 2020.
 - b. Key objectives were:
 - i. Addressing how sites will coordinate ordering, storage, handling, and organization of COVID-19 vaccine for immunization.
 - ii. Considering how sites will prioritize based on both number of doses available and VHA's draft framework for risk stratification.
 - iii. Planning for how sites will coordinate administration of COVID-19 vaccine, leverage existing flu immunization practices, and what new practices, clinics or sites will be needed.
 - iv. Anticipating how sites will coordinate documentation of vaccine given in accordance with CDC data reporting requirements, as well as wastage and spillage.
 - v. Planning communication to and scheduling of immunization for priority groups/tiers among staff and Veterans
 - vi. Developing plans for targeted communications to high-risk populations, underserved or difficult-to-reach Veterans, and Veterans in racial and ethnic groups that may be disproportionately affected by the COVID-19 pandemic.
2. Maximize transparency by ensuring the most up-to-date information and preliminary planning assumptions were made available with the tabletop exercises.
 - a. The exercise included current best information on which vaccines are expected to be authorized or approved and specific information on expected challenges related to:
 - i. Cold-chain storage and handling.
 - ii. Multi-dose vaccine vials.
 - iii. limited dose availability
 - b. The exercise included a draft risk stratification framework.
 - i. This framework referenced draft guidance on rationale for considering how to prioritize among the highest

- priority groups of staff and Veterans.
- c. Tabletops were accompanied by resource room contact information for questions, concerns, and ideas.
 - i. The resource room is an email address to which VHA staff can submit questions about COVID-19 vaccination. The resource room is staffed by members of the COVID-19 Vaccination Project Team. Responses are provided to the staff member to assist with planning and operations.
 - ii. The resource room email address (VHACOVIDRR@va.gov) is internal to VHA and not available to the general public.
 - d. In December 2020, a summary best practices document developed from lessons learned in the tabletop exercise was added to the COVID-19 Vaccine SharePoint site to allow sharing of best ideas and plans that will help other vaccine teams maximize preparedness.
 - i. The SharePoint site (<https://dvagov.sharepoint.com/sites/vhacovidvaccine>) is internal to VHA and not available to the general public.

Organization and Assignment of Responsibilities

1. The COVID-19 Vaccination Project Team will develop tabletops which the VHA Central Office will distribute to VISN leadership.
2. VISN leadership will determine which facility groups should participate to maximize preparedness and incorporate questions and ideas developed from the tabletops back to the COVID-19 Vaccine Project Team via the resource room and via daily vaccine coordinator and office hours calls.

Direction, Control, and Coordination

1. VISN Level: Direction, control, and coordination activities at the VISN level will be coordinated by the VISN leadership team.
2. VAMC Level: Direction, control, and coordination activities at the facility level will occur in the Executive Leadership Team and Incident Command. The facility will review the Tabletop Exercise and supporting materials, such as a draft risk stratification list and draft population enumeration, to assist with completion of the Tabletop Exercise.
3. VHA Program Offices: Direction, control, and coordination activities at the Program Office level will occur in the Program Office Executive Leadership Team.

Communications

The COVID-19 Vaccination Project Team will communicate the purpose and timeline of the tabletop exercise via a memo accompanying the exercise when distributed to VISN and facility leadership.

Appendix O – Outreach to Racial and Ethnic Minority Populations

VHA COVID-19 Vaccination Planning and Actions

7-2-2021

Purpose

The purpose of this appendix is to outline a plan for VHA to implement outreach efforts directed toward racial and ethnic minority populations to promote equitable administration of vaccine to all Veterans.

Scope

VHA:

1. Identifies concerns of Veterans from racial and ethnic minority groups about administration of vaccine. Concerns will be identified from listening sessions with Veterans, VHA staff experience and expertise, data, and findings from qualitative and quantitative evaluation on minority vaccine communication needs during the current and past pandemics, and general knowledge of health equity principles.
2. If necessary, solicits further responses from Veterans belonging to a racial or ethnic minority population regarding COVID-19 vaccination.
3. Develops a diverse collection of tailored digital and print publications to inform Veterans of the benefits and risks of COVID-19 vaccination and support informed decision-making by addressing identified concerns.
4. Considers alternative methods of direct and indirect outreach to inform Veterans and promote sharing of vaccination information.
5. Leverages expertise of VA's Office of Health Equity and National Center for Ethics in Health Care by including representatives from these offices on the Risk Stratification Workgroup and Integrated Project Team.
6. Reviews Veteran vaccination rates for flu and other vaccines by race and ethnicity in order to identify existing disparities that should be considered in COVID-19 vaccination approaches to minority Veterans.
7. Reviews results of surveys and findings from CDC's COVID-19 vaccine communications workstreams that may inform vaccine hesitancy, vaccine confidence, and communications needs among individuals of racial and ethnic minority groups.

Concept of Operations

VHA:

1. Identifies concerns of racial and ethnic minority populations with respect to administration of vaccine.
 - a. VHA leaders with expertise and experience in minority Veteran outreach gave guidance and input on COVID-19 vaccine approaches and development of materials to support communications to minority Veterans. VHA also leveraged general knowledge of health equity principles.
 - b. In order to best understand precisely what concerns might affect equitable administration of the vaccine, or lead to disparate rates of vaccination across various populations, VHA reviewed sources of information:
 - i. Veterans from those population groups, especially through the review of past listening sessions on COVID-19 and other topics, surveys, and other outreach efforts
 - ii. Experiential knowledge of its staff, especially those with relevant backgrounds in working with racial and ethnic minority populations
 - iii. General principles and concerns of health equity, detailed more comprehensively by the VHA's Office of Health Equity
2. VHA will solicit further responses from Veterans belonging to a racial or ethnic minority population regarding COVID-19 vaccination.
 - a. The Veterans Experience Office (VEO) conducted Veteran listening sessions between October 13 and 19, 2020.
 - b. VEO interviewed 4 groups and 19 individual Veterans and received qualitative data responses from participants.

Participants were from a range of geographical locations, gender, and age. 30% of participants were Black or African American, 7% were Native Hawaiian or other Pacific Islander, 7% were Hispanic or Latino, 4% were American Indian or Alaska Native, and 4% were Asian.

- c. Key themes identified by the participants include the need for meaningful, trusted, and science-based information; access to vaccine at VA clinics, not just at main facilities; and trusted sources of information including primary care providers, other members of the VA health care team, and other trusted Veterans.
 - d. Several communications channels were identified: mailings, newspaper articles, call centers, email, social media, churches, local media outlets, retirement councils, and Transition Offices on military bases.
 - e. VHA will leverage the data obtained from these listening sessions to inform the modality and content of COVID-19 communications to best target minority Veterans. A key strategy will be to use the VA care provider team, a trusted source of information, to provide information and recommendations about COVID-19 vaccine to minority Veterans.
 - f. Additional listening sessions may be scheduled if more input from minority Veterans is needed or desired.
3. VHA will collaborate with CDC and OWS Federal Partner COVID-19 Communications teams to coordinate and leverage strategies and materials designed for minority outreach.
 - a. VHA will collaborate with the CDC COVID-19 Vaccine Communications team and Operation Warp Speed strategic communications through weekly calls and via email.
 - b. CDC's COVID-19 vaccine communications will use a national approach to reach minorities with targeted messaging via purchased advertising on TV, radio, social media, web sites, and other communications and channels. Minority Veterans will be reached through these national approaches.
 - c. CDC communications materials designed for minority outreach will be made available to support VHA's COVID-19 communications approach where relevant and appropriate for Veteran minority audiences.
 4. VHA will collaborate with its VISN and VA facility Public Affairs Officers to identify outreach strategies for COVID-19 vaccine communications to minority Veterans. Approaches that will be used in local minority Veteran communications efforts include:
 - a. Local facility Veterans Service Organizations engagements
 - b. Local VA facility town halls
 - c. Local Director engagement through VAMC Veterans Advisory Councils
 - d. Local Congressional Offices
 - e. Working with local town, city and state Veteran offices and programs
 - f. Working with Community Veteran Engagement Boards (CVEBs)
 - g. Local outreach events
 - h. Local churches
 - i. Local social media videos and stories shared by Veterans
 5. To support national and local VHA minority communications efforts, VHA will develop a diverse collection of digital and print publications that keep Veterans informed of the benefits and risks of COVID-19 vaccination and help them decide whether to receive COVID-19 vaccination.
 - a. In creating an outreach campaign directed toward racial and ethnic minority populations, the campaign will include materials and messaging as heterogenous as the spectrum of populations itself. Broadly, VHA must seek to establish trust both in VHA and the vaccine itself, but different messages will resonate most strongly within different populations. Here, VHA must ensure that the right messages are delivered by the right messengers through the proper media in order to most effectively inform and support Veterans.
 6. VHA will collaborate with leaders from Veterans Service Organizations (VSOs) to solicit feedback on approaches to communicate with Veterans of racial and ethnic minorities.

- a. A COVID-19 vaccine briefing was given to VSO Communications leads on November 20, 2020. VSO Communicators gave feedback on VHA's COVID-19 vaccine communications campaign after the briefing. Print materials were provided to VSO Communicators for dissemination to VSO members.
- b. VHA will provide VSO leaders with additional access to digital and print publications and materials as these materials are developed that can be disseminated by national and local VSO leaders to Veterans.
- c. VHA will continue to engage VSO leaders and communicators with updates and discussion about VHA's COVID-19 vaccination efforts for racial and ethnic minorities.

Organization and Assignment of Responsibilities


1. The VHA COVID-19 Vaccine Project Team, specifically the Communications workgroup, will provide national coordination and guidance to VISNs and VHA medical facilities on implementing outreach efforts for at-risk racial and ethnic minority populations to promote equitable administration of vaccine to all Veterans.
2. VISNs and VHA facilities will implement national guidance and strategies aimed at equitable vaccination of racial and ethnic minority Veterans.

Direction, Control, and Coordination

1. VISN Level: Direction, control, and coordination activities at the VISN level will be coordinated within the VISN and its VHA medical centers with national guidance from VHA's COVID-19 Integrated Project Team. Communications may be via email, presentations to VISN leadership, or other trainings.
2. VAMC Level: Direction, control, and coordination activities at the facility level will occur in the Executive Leadership Team and Incident Command. VAMCs will coordinate activities through the VAMC point of contact for COVID-19 vaccination. Communications may be via email, phone, or presentation.
3. VHA Program Offices: Direction, control, and coordination activities at the Program Office level will occur in the Program Office Executive Leadership Team. The Program Office may provide input to national guidance for VISNs and facilities' COVID-19 activities as relevant to the Program Offices' scope of expertise.

Communications

The Communications workgroup will be responsible for recommending an approach to develop and disseminate tailored messaging and other communication strategies aimed at increasing confidence among Veterans of racial and ethnic minority groups to make an informed decision about COVID-19 vaccination.



Appendix P – Outreach to Rural Populations

VHA COVID-19 Vaccination Planning and Actions

7-2-2021

Purpose

The purpose of this appendix is to outline a plan for VHA to implement outreach efforts directed toward at-risk rural Veteran populations to promote equitable administration of vaccine to all Veterans.

Scope

VHA:

1. Identifies logistical challenges and concerns among rural populations about administration of vaccine. Identified concerns, strategies and approaches specific to rural Veteran and staff outreach from VISN and facility leaders serving rural and highly rural Veteran populations, leaders from the VA National Office of Rural Health, and VHA staff with experience and expertise in working with Veterans in rural locations.
2. Develops a collection of targeted outreach materials to best inform and encourage rural Veterans regarding COVID-19 vaccination options and locations.
3. Considers alternative methods of direct and indirect outreach to inform Veterans and promote vaccination.
4. Leverages expertise of VA's Office of Rural Health, National Center for Ethics in Health Care and leaders from VISNs and VHA facilities serving rural Veterans by including representatives from these groups on the Integrated Project Team, Risk Stratification Workgroup and obtaining input via individual consultation as needed.

Concept of Operations

VHA:

1. Identifies logistical challenges and concerns among rural populations with respect to administration of vaccine from sources including VHA staff expertise and previously solicited responses from Veterans.
 - a. VHA reviewed available data to best understand the underlying factors driving rural Veterans' health decisions, and how those might impact the likelihood of COVID-19 vaccination in this population.
 - i. VHA reviewed ultra-cold storage capacity, conventional cold storage capacity, refrigerator capacity, and population enumerations for staff and Veterans for larger facilities that were potential sites for receipt of initial -70C and -20C vaccine shipments that will serve as vaccine administration hubs.
 - ii. VHA determined average and maximum drive times from hub VHA facilities to smaller VHA facilities and CBOCs in rural areas.
 - iii. VHA identified locations without ultra-cold storage capacity but with conventional cold storage capacity and ship-to status as first sites to receive -20C vaccine product, including many smaller facilities serving rural Veterans.
 - iv. VHA solicited and considered experiential knowledge of VHA staff and leaders working in facilities serving rural Veteran and leaders with national roles in the VHA Office of Rural Health.
 - v. Information previously volunteered by rural Veterans in past listening sessions, surveys, and other outreach efforts was considered.
 - vi. VHA considered COVID-19 vaccination options through the Care in the Community Network of providers that extend reach to Veterans living in rural locations.
2. Develops a collection of strategies and targeted outreach materials that can inform and encourage rural Veterans regarding vaccination.
 - a. The unique challenges and concerns associated with COVID-19 vaccination for rural populations deserves a tailored campaign. VHA's goals are to establish trust both in VHA and the vaccine as well as demonstrate the ease and accessibility of vaccination for potentially underserved rural communities.

- b. Listening sessions that featured rural Veterans identified preferred communication approaches, including their perceptions regarding messages and messengers that would engender trust and confidence in vaccines.
 - i. Communications materials were developed for use by local facility leaders to communicate VHA's process for vaccine planning, initial distribution and risk stratification. These materials can be used in targeted outreach efforts at the local level to rural Veteran audiences.
 - c. Evaluation of modalities preferred by rural Veterans indicated that U.S. Postal Service mailings are an effective form of communication.
 - i. A template letter to Veterans describing COVID-19 vaccine availability and options at the local facility was developed by the VHA COVID-19 Communications team and posted on the COVID-19 Vaccine SharePoint site (internal web site not available to the public). This letter may be adapted and used by local VA facilities in their outreach to rural Veterans. The letter may be tailored to risk groups recommended for vaccination when adequate supply of vaccine is available.
3. Develops approaches to ensuring equitable access to COVID-19 vaccination services for rural Veterans and staff.
- a. VHA's strategy for initial vaccination of Phase 1a populations, health care personnel and residents of long-term care facility settings in VHA, includes the following:
 - i. For Phase 1a staff who are able to travel to VHA facilities who receive the initial shipment of -70C vaccine product, travel to these VHA facility vaccine hubs may be an option for health care personnel, especially those working in high-risk settings such as urgent care or Emergency Department locations. Since -70C product redistribution options are limited by its cold-chain storage requirements, staff travel to VHA facilities offering -70C product vaccination services will be offered as an option in some rural areas.
 - ii. VHA planned to distribute its first allocations of -20C vaccine product to smaller and rural VHA facilities with secure conventional cold capacity and/or refrigerator storage capacity.
 - iii. This strategy allows for safe storage of -20C product at facilities and clinics serving rural Veterans and staff, avoiding potential vaccine wastage or spoilage during redistribution.
 - iv. In addition, the 100-dose minimum order quantity of the -20C product allows for smaller orders compared to the 975-dose minimum quantity of the -70C product. These smaller orders allow for tailoring of orders to facilities and clinics serving staff and Veteran rural populations smaller than the 975-dose minimum of the -70C product and ensures that vaccine supply does not exceed the population enumeration for those locations.
 - b. VHA facilities may also redistribute -20C product further to smaller clinics, based on redistribution guidance for COVID-19 vaccine products according to manufacturer and CDC specifications for transport of COVID-19 vaccines.
 - i. Any redistribution efforts will need to follow chain of custody, cold chain requirements, and safe handling and transport of vaccine.
 - ii. Redistribution guidance will be specific to the storage and handling specifications for each authorized COVID-19 vaccine product.
 - c. VHA will plan to offer COVID-19 vaccination services to Veterans through VA's Community Care Network (CCN)
 - i. For initial vaccination efforts, rural Veterans who desire COVID-19 vaccination but do not have access to vaccine at a CBOC or facility close to their residence may be authorized, on a case-by-case basis, for CCN COVID-19 vaccine administration at a CCN provider offering COVID-19 vaccination close to their home.
 - ii. In Phase 2, pharmacy providers that are part of VA's CCN may receive direct allocations of COVID-19 vaccines from the Federal government as a part of CDC's Pharmacy partnership program.
 - iii. VA will plan to explore the provision of a COVID-19 vaccination benefit through the CCN to Veterans when these pharmacy and other community vaccination options become available.
 - iv. Data from COVID-19 vaccine doses administered through the CCN may be available to VHA through a direct connection between the CCN partners and VHA or may be entered as a historical vaccination into the Vista

electronic medical record if written documentation is available.

4. Considers alternative methods of direct and indirect outreach to inform rural Veterans and promote vaccination.
 - a. For some rural populations, direct publication and distribution of information via U.S. mail is preferred by Veterans. Additional modalities for communication include VA website information, the My HealthVet online patient portal, phone call, and social media. These channels may be used to communicate vaccine information as well as availability of vaccine at local VA medical centers.
 - b. VHA facilities serving rural Veterans may also engage and collaborate with local media, community leaders, and other institutions trusted by rural Veterans to leverage synergies and improve effectiveness of rural outreach efforts.
 - c. VHA facilities may also consider targeted communication campaigns that feature communication messages, messengers and modalities shown to be successful at reaching rural Veterans.
 - d. Veterans living in rural areas may also choose to be vaccinated when eligible through a state or jurisdictional COVID-19 vaccine partner if vaccine is offered at a site convenient to them.

Organization and Assignment of Responsibilities


1. The VHA COVID-19 Vaccine Integrated Project Team will provide national coordination, communications materials, and guidance to VISNs and VHA medical facilities on implementing outreach efforts and vaccination services for Veterans in rural areas to promote equitable access of vaccine to rural Veterans.
2. VA medical centers will implement national guidance for vaccine allocation and distribution aimed at equitable access to vaccination of Veterans and staff in rural areas.

Direction, Control, and Coordination

1. VISN Level: Direction, control, and coordination activities at the VISN level will be coordinated within the VISN and its VHA medical centers with national guidance from VHA's COVID-19 Integrated Project Team. Communications may be via email, presentations to VISN leadership, or other trainings.
2. VAMC Level: Direction, control, and coordination activities at the facility level will occur in the Executive Leadership Team and Incident Command. VAMCs will coordinate activities through the VAMC point of contact for COVID-19 vaccination. Communications may be via email, phone, or presentation.
3. VHA Program Offices: Direction, control, and coordination activities at the Program Office level will occur in the Program Office Executive Leadership Team. The Program Office may provide input to national guidance for VISNs and facilities' COVID-19 activities as relevant to the Program Offices' scope of expertise.

Communications

The Communications workgroup will be responsible for recommending an approach to develop and disseminate of tailored messaging and strategies to promote vaccine access and confidence to make an informed vaccination decision among rural Veterans and staff.



Appendix Q – Mass Vaccination

VHA COVID-19 Vaccination Planning and Actions

7-2-2021

Purpose

The purpose of this appendix is to outline a plan for VHA to implement mass vaccination events for high-volume, high-throughput COVID-19 vaccination.

Scope

VHA will:

1. Identify locations and populations in need of mass vaccination for COVID-19, including VHA staff and Veterans receiving VA health care.
2. Identify opportunities for partnership with non-VA mass vaccination efforts for the general population led by entities such as the Federal Emergency Management Administration (FEMA)
3. Identify opportunities for partnership through 4th mission requests from states and jurisdictions for mass vaccination assistance.
4. Develop a mass vaccination plan that includes staffing, logistics, and other resources needed for both internal and external efforts.

Concept of Operations

VHA will:

1. Develop a plan to identify VHA staff, both paid and volunteer such as trainees, to participate and assist in mass vaccination events.
2. Identify 4th mission requests for mass vaccination assistance to states and jurisdictions and will identify the level of support VHA can provide to assist such as clinical and administrative staff or technical assistance.
3. Identify FEMA mass vaccination efforts where VHA can provide assistance in the form of clinical and/or administrative assistance or technical assistance.
4. Identify best practices for mass vaccination and plan for dissemination throughout VHA.
5. Identify and draft a plan for the use of mobile assets such as Mobile Vet Centers that may be used for mass vaccination events.

Organization and Assignment of Responsibilities

VHA leaders from VA Central Office, VISNs and facilities, and the VHA COVID-19 vaccine planning team will draft mass vaccination plans and identify best practices.

Direction, Control, and Coordination

1. VISN Level: Direction, control, and coordination activities at the VISN level will be coordinated within the VISN and its VHA medical centers with national guidance from VHA's COVID-19 vaccine planning team or from VHA Central Office leadership. Communications may be via email, presentations to VISN leadership, or other trainings.
2. VAMC Level: Direction, control, and coordination activities at the facility level will occur in the Executive Leadership Team and Incident Command. VAMCs will coordinate activities through the VAMC point of contact for COVID-19 vaccination. Communications may be via email, phone, or presentation.
3. VHA Program Offices: Direction, control, and coordination activities at the Program Office level will occur in the Program Office Executive Leadership Team. The Program Office may provide input to national guidance for VISNs and facilities' COVID-19 activities as relevant to the Program Offices' scope of expertise.

Communications

The Communications workgroup will be responsible for recommending an approach to develop and disseminate of tailored messaging and strategies to promote mass vaccination to Veterans receiving health care and VHA staff.

Appendix R – Vaccination of Individuals under SAVE LIVES Act

VHA COVID-19 Vaccination Planning and Actions

7-2-2021

Purpose

The purpose of this appendix is to outline a plan for VHA to identify allocation, registration, and processes for COVID-19 vaccine administration for individuals eligible for COVID-19 vaccination from Veterans Health Administration based on the Strengthening and Amplifying Vaccination Efforts to Locally Immunize All veterans and Every Spouse Act (SAVE LIVES Act), Public Law No.117-4.

Scope

VHA will:

1. Estimate the number of individuals eligible for COVID-19 vaccination under the SAVE LIVES Act.
2. Identify mechanisms for individuals eligible for COVID-19 vaccination under the SAVE LIVES Act to request and schedule vaccination.
3. Plan for the logistics of how individuals eligible under SAVE LIVES may indicate interest and receive COVID-19 vaccine administration services from VHA.

Concept of Operations

VHA will:

1. Estimate the number of individuals eligible for COVID-19 vaccination under the SAVE LIVES Act, including Veterans, spouses, caregivers, and Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMP VA) recipients.
2. Identify and request vaccine allocation, if needed, from the Department of Health and Human Services sufficient for vaccination of individuals eligible under the SAVE LIVES Act.
3. Identify mechanisms for registration of individuals eligible for COVID-19 vaccination under the SAVE LIVES Act for the purposes of creating a record for documentation of COVID-19 vaccine administration.
4. Identify mechanisms for individuals eligible under SAVE LIVES Act to indicate interest in and schedule COVID-19 vaccination at VHA facilities and clinics.
5. Once allocation is available, determine how and when SAVE LIVES individuals may receive COVID-19 vaccination through VHA COVID-19 vaccination efforts in VHA facilities.
6. Record information on vaccine administration required by CDC in CPRS, VHA's electronic medical record.
7. Communicate to Veterans living outside of the U.S. how they may receive reimbursement through the Foreign Medical Program for a COVID-19 vaccine received in a foreign country.
8. Develop guidance and procedures for COVID-19 vaccine administration for adolescents 12-17 years old who identify as Veteran caregivers. Guidance will include clinical preparedness for vaccine administration, post-administration monitoring and evaluation and treatment of adverse events; registration of adolescents; training for vaccinators and handlers; and procedures for written informed consent from the parent or legal guardian as well as adolescent assent prior to vaccination.

Organization and Assignment of Responsibilities

VHA leaders from VA Central Office, VA Office of Information Technology, VISNs and facilities, and the VHA COVID-19 vaccine planning team will identify and plan for COVID-19 vaccination of individuals eligible for COVID-19 vaccination under the SAVE LIVES Act.

Direction, Control, and Coordination

1. VISN Level: Direction, control, and coordination activities at the VISN level will be coordinated within the VISN and its VHA medical centers with national guidance from VHA's COVID-19 vaccine planning team or from VHA Central Office leadership. Communications may be via email, presentations to VISN leadership, or other trainings.
2. VAMC Level: Direction, control, and coordination activities at the facility level will occur in the Executive Leadership Team and Incident Command. VAMCs will coordinate activities through the VAMC point of contact for COVID-19 vaccination. Communications may be via email, phone, or presentation.
3. VHA Program Offices: Direction, control, and coordination activities at the Program Office level will occur in the Program Office Executive Leadership Team. The Program Office may provide input to national guidance for VISNs and facilities' COVID-19 activities as relevant to the Program Offices' scope of expertise.

Communications

The Communications workgroup will be responsible for recommending an approach to develop and disseminate tailored messaging and strategies to outline when and how individuals eligible for COVID-19 vaccination from VA under the SAVE LIVES Act may indicate interest and receive COVID-19 vaccination.

Appendix S – Accomplishments, Lessons Learned & Best Practices

VHA COVID-19 Vaccination Planning and Actions

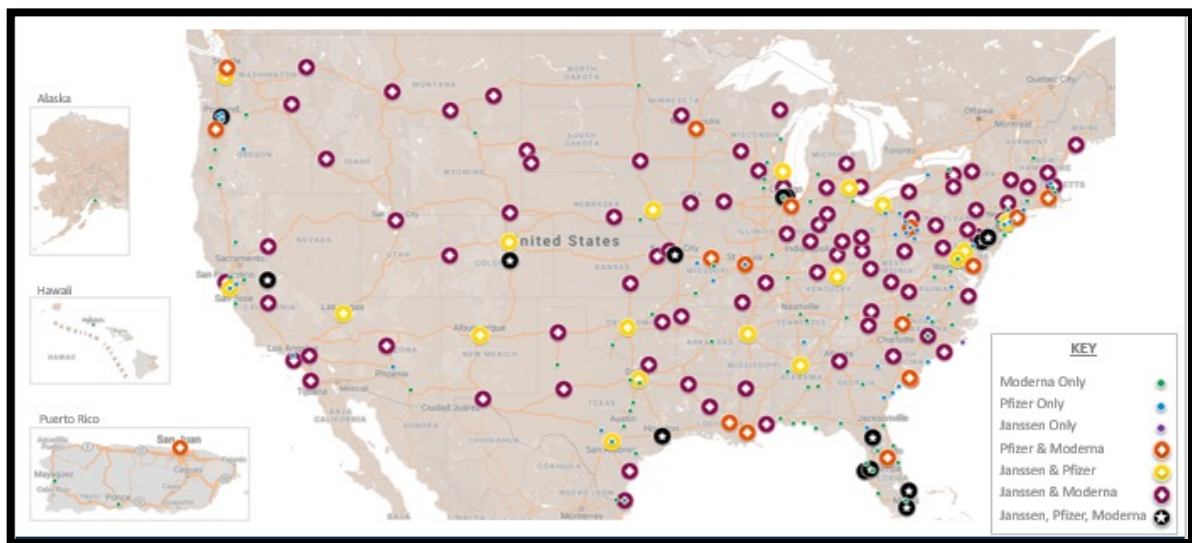
7-2-2021

Purpose

The purpose of this appendix is to detail lessons learned and best practices identified thus far through the VHA's COVID-19 Vaccine delivery efforts.

VHA COVID-19 Vaccine Campaign Accomplishments

1. VA successfully initiated COVID-19 vaccinations at 37 sites with the Pfizer-BioNTech (Pfizer) vaccine during the week of December 14, 2020 and expanded to an additional 15 Pfizer and 123 Moderna sites during the week of December 21, 2020. VA built upon initial lessons learned to continue expansion of vaccination with some VA sites now able to administer two different COVID-19 vaccine products safely on-site. VA currently administers COVID-19 vaccinations at more than 251 sites across the United States with additional vaccinations occurring through mass vaccination and mobile efforts.



VHA locations offering COVID-19 vaccinations as of March 2, 2021: Full text description can be found in [Appendix I](#).

2. To equitably and ethically allocate vaccine when supply is limited, VA developed a COVID-19 vaccination risk stratification framework based on the Centers for Disease Control and Prevention (CDC) guidelines for phased vaccination using the following risk-based criteria: risk of acquiring infection; risk of transmitting disease; risk of severe illness and death; and risk of harm to society (if essential workers, including health care personnel, are unable to work).
3. VA's COVID-19 vaccination campaign led to over 2.8 million persons being fully vaccinated against COVID-19 as of May 19, 2021. This number includes over 2.5 million Veterans and over 291,000 VA employees fully vaccinated.
4. VA partnered with other federal agencies to vaccinate their employees prioritized for COVID-19 vaccination. VA established a Memorandum of Understanding (MOU) and associated Interagency Agreement (7600A and 7600B forms) with each federal agency pursuant to the authority of the Economy Act, 31 U.S.C. § 1535, which authorizes federal agencies to provide services or supplies to other federal agencies on a reimbursable basis. As of May 10, 2021, VA had vaccinated 27,916 federal partner employees, primarily Department of Homeland Security (DHS) personnel in mission-critical, location-dependent positions.

Best Practices and Lessons Learned

The following information provides details of key drivers, strategies, and tactical actions for VHA's COVID-19 vaccination roll-out.

1. Frequent communication and coordination with VHA senior leadership; regional and local operations; and clinical staff. Efforts included:
 - a. Identification of VISN and facility COVID-19 Vaccine Coordinators.
 - b. Daily Office Hours and Vaccine Coordinators calls.
 - c. Summaries and training on new national tools for documentation and data transmission.
 - d. Presentations for operations and clinical leadership and staff.
 - e. National required training for vaccinators and handlers.
2. Development of tools to reach Veterans, employees and stakeholders with comprehensive and easy-to-understand information on the Why, Where and How that people can and should be vaccinated. VHA developed multiple tools including:
 - a. Guides for Vaccine Coordinators based on the CDC Vaccination Program Interim Playbook 2.0. and the accompanying Annex: Considerations for Increasing COVID-19 Vaccination: Reaching and Increasing Uptake in Priority Populations – V 1.0; (January 2021).
 - b. A national SharePoint repository of meeting recordings; presentations; guidance and policies; and a Q&A Resource Room.
 - c. Targeted outreach guides for Veterans, employees, media, and congressional delegations.
 - d. Minority-specific toolkits for African American, Latino, Asian, Pacific Islander and American Indian Alaska Native Veteran populations.
 - e. Translations of multiple communications products into Spanish and Tagalog.
 - f. Professionally designed materials such as template posters and flyers.
 - g. Messages for posting on all major social media networks.
 - h. Tailored messages and communication resources that are designed to address vaccine hesitancy by confronting misinformation and promoting vaccine confidence
 - i. Change management strategies and best practices for facilities.
3. National sharing of best practices and national solutions for scheduling, inventory management, administration, documentation, and data transmission, including:
 - a. Development of online tool to track Veteran interest in receiving the vaccine.
 - b. Identification and dissemination of potential failure points and mitigation strategies for each COVID-19 vaccine product.
 - c. Development of outreach tool for facilities to identify Veterans in each prioritization phase.
 - d. Mandatory tabletop exercise issued in October 2020, completed by all sites.
 - e. Collaboration between VHA, Microsoft, and VA's Office of Information and Technology to create an online appointment scheduling application.
 - f. National sharing of best practices on weekly coordinator calls and in other forums.
4. To ensure safe transportation of vaccine, VA developed national COVID-19 redistribution guidance. This guidance allowed VA to improve access to available vaccines while ensuring vaccine product integrity. VA used multiple strategies to reach remote sites and to enhance safe access to COVID-19 vaccines for Veterans, including the transport of vaccine using fixed-wing planes to reach Veterans at two sites in rural Montana:
 - a. <https://www.va.gov/opa/pressrel/pressrelease.cfm?id=5610>

- b. <https://blogs.va.gov/VAntage/84499/veterans-rural-montana-receive-covid-19-vaccine-via-airplane-delivery/>
5. VA used Mobile Vet Centers (MVCs) to allow for COVID-19 vaccination outside of VA Medical Centers. VA developed an overview document outlining key points and simple setup for a vaccination clinic using Mobile Vet Center as a hub. The VA overview document highlighted vaccine transportation constraints and monitoring requirements, safety including recognition and management of anaphylaxis, and examples for managing clinic flow in a mobile drive-through center.
 6. The COVID-19 Vaccine Communications Team had a strategic plan to develop products that directly address vaccine hesitancy, promote vaccine confidence and acceptance, and ultimately increase the percentage of Veterans who get fully vaccinated. The team developed content with the input from VA's Minority Outreach Working Group and other Veterans, and in consultation with VA clinician leaders who specialize in health equity, women's health, evidence-based risk communication, and clinician-patient communication strategies. The team also leveraged CDC's Vaccinate with Confidence resources and materials to identify, develop and disseminate communication tools and resources that were tailored to Veteran populations, including women Veterans and Veterans from minority communities. Products include:
 - a. Multiple banners featuring Asian and African-American men and women.
 - b. A message from the VHA Chief Medical Officer, Dr. Kameron Matthews, emphasizing her own personal experience addressing vaccine hesitancy as an African-American woman, family member, and physician leader.
 - c. A minority high-risk Brochure and a COVID-19 vaccine trials demographics slide deck featuring the percentage of minorities involved in trials and photos of a diverse group of minorities being vaccinated.
 - d. Fact sheet on racial and ethnic minority health – Debunking COVID-19 Vaccine Myths
 - e. Fact sheet – Women's Health Debunking Vaccine Myths
 - f. Frequently Asked Questions – Women's Health and COVID-19 Vaccine
 - g. News story – Older Black Veterans Outpace Whites in COVID-19 Vaccination at VA
 - h. National Shot of Hope Poster featuring a picture and quotes from a VA Nurse and Veteran who grew up in Tuskegee, AL.
 - i. A -myth-debunking Infographic.
 - j. Fact sheet – Communication Strategies to help Clinicians Accept the COVID-19 Vaccine
 - k. An online VHA Employee Education System training module for clinicians to support use of communication strategies that promote Veteran confidence and acceptance.
 - l. A Moving to Vaccine Acceptance tool for VA clinicians that features Veteran-centered communication strategies that promote empathy, address misinformation, and foster enhanced Veteran understanding trust and vaccine confidence.
 - m. A Moving to Vaccine Acceptance – Minority and Special Populations Edition tool to assist VA clinicians to address specific sources of misinformation and mistrust.
 - n. Clinical Conversations about the Janssen COVID-19 Vaccine script for vaccinators emphasizing strategies to address misinformation and promote confidence in the vaccine.
 7. Best practices in outreach to minority Veterans include:
 - a. Central Alabama Health Care System (CAHCS): Sharing Stories of Acceptance: CAHCS shared the story of Cheryl Owens, a nurse leader from the Tuskegee community, who received the vaccine and shared her enthusiasm for and confidence in COVID-19 vaccines in local communications and on a National Public Radio broadcast. Central Alabama reported over 190 minority Veterans attended a walk-in clinic in Tuskegee shortly after the story was aired.
 - b. VA Connecticut Health Care System (CT HCS): VA CT HCS partnered with Dr. Saad Omer, a well-known Yale equity researcher, to identify evidence-based strategies for conducting outreach to minority Veterans and monitoring

hesitancy/acceptance among these groups. CT HCS collaborated with local Veterans Service Organizations (VSOs) to share information and plans to reach out to community faith leaders to engage in 2-way communication and collaborative events.

8. Best practices in establishing and implementing federal partnerships include:
 - a. A generic Memorandum of Understanding and Interagency Agreement was established by VA and shared with other federal agencies for agency-specific modifications that were needed.
 - b. The cost of vaccination procedures is determined by VHA Office of Finance.
 - c. Federal partners should not be billed for vaccination of their employees who are also Veterans enrolled in VA care.
 - d. Billing procedures should be determined by the VHA Office of Finance and established at the outset with each federal partner.
 - e. The best strategy for documenting vaccination of federal partner employees was to register them as patients in the Enrollment System/VistA with eligibility code of "Other Federal Agency" and document their vaccination in VA's electronic health record.
 - f. Registration procedures and training should be established with VHA HEC Member Services Enrollment Standardization Office (ESO).
 - g. In many cases, advanced registration of federal partner employees was optimal and required the federal partner to send information in advance.
 - i. Advance registration was coordinated nationally with Member Services and completed through a batch or bulk registration process.
 - ii. The following elements were required to register a federal employee in the Enrollment System/VistA: first name, last name, social security number, date of birth, gender, address, best contact information.
 01. Ideally, best contact information was a cell phone number that may be used for text messaging.
 02. Residential address should be used.
 - h. VA established with federal partners that VA may use text messages to schedule federal partner employees. This required each federal partner employees to endorse the following statement: SMS ACKNOWLEDGEMENT: I acknowledge that I may receive health information in text messages from the Department of Veterans Affairs (VA) to assist with coordinating/scheduling an appointment at a VA facility. I understand text messages are unencrypted. Message and data rates may apply.
 - i. An unsecured link (e.g., Microsoft Bookings) should not be used for scheduling. Use of such a mechanism can result in the link being shared with individuals not vetted for vaccination. It is also prudent to set up a system whereby VAMCs contact federal partner employees to schedule appointments, otherwise phone systems can be inundated.
 - j. A representative from VA's National Data Systems team must coordinate with a federal partner representative about how data transfer will occur from one agency to another.
 - k. A national interagency data team consisting of subject matter experts was needed to communicate with the respective data teams of other federal partners. The following should be managed by the interagency data team:
 - i. Data specifications: data elements and required format for registration to occur
 - ii. Remediation of any data issues that are discovered upon data transfer
 - iii. Collaborating with the larger COVID-19 Vaccine Data Team to ensure accurate data capture and remediation of issues.
 - iv. Establishing a reporting structure and cadence to provide to federal partners.
 - v. Developing interagency reporting tools guidance for facilities, as necessary.
 - vi. Documentation of data processes and changes to data processes.
 - l. The establishment of data requirements and systems was crucial to tracking vaccination of federal partner

employees and reporting to internal and external stakeholders. The interagency data team worked in conjunction with the interagency project team to:

- i. Collaborate with the VHA COVID-19 Vaccine Metrics and Informatics Team to ensure consistent reporting of data to Federal Partners and CDS
 - ii. Utilize technical expertise in SQL, Excel, Power BI, or other programs to appropriately obtain and analyze data regarding patient registration and vaccination administration.
 - iii. Collaborate with VHA Support Service Center to visually display data in the form of dashboards to allow VHA leadership to adequately determine supply needs across the enterprise.
 - iv. Understand and explore vaccination workflows at facility sites to optimize efficiency for local operations including but not limited to scheduling and documentation in CPRS.
 - v. Represent VHA as a subject matter expert in discussions with federal partners related to information flow, security of data, and patient privacy concerns during data transfer.
 - vi. Establish communications and partnerships with federal partners to minimize redundant processes and maintain situational awareness of upcoming changes or milestones.
- m. Data requirements or specifications must be established at the outset and adhered to throughout the effort. If federal partner provides data that does not meet the established requirements, it must be sent back to them for remediation early and often.
- n. A Standard Operating Procedure should be established for use by facility-based VA staff
- o. A representative from the VA Privacy Office was needed to work with the national program office leads overseeing the interagency work to develop any necessary privacy guidance for the VA facilities and the federal partner.
- p. Each VA facility should designate an interagency point of contact for their facility.
- q. In order to determine where federal partner employees can be vaccinated, the starting point should be VA's list of Sta3n stations to include the Sta3n number, facility name, and facility address. This is very important because it will allow for more accurate tracking of vaccination data. While the starting point is Sta3n stations, ultimately facilities may choose to provide vaccinations at the division level (Sta6a). This should be vetted through the Healthcare Operations Center before it is shared with a federal partner.
9. Best practices in metrics reporting and informatics include:
- a. Ensuring consistent messaging was disseminated to clinical, clerical, and informatics staff. It was important to deliver timely, consistent messaging between Office of Veterans Access to Care (OVAC), Nursing, and Informatics staff so that they had knowledge about the COVID-19 vaccine documentation tools and process.
 - b. Involving VISN and facility leadership in monitoring the process, and correction of errors, as soon as possible.
 - c. Giving VISN and facility staff tools and clear instructions for the components for which they were responsible.
 - d. Use of auto-fill or drop down data entry selection to pre-populate and standardize data for parsing. Manual forms should not be used for data entry to be inputted later into electronic systems.
 - e. Delineating decision-making authority for various lanes of effort or major areas of scope and review often when scope is modified.
 - f. Communicating throughout multiple levels of the organization, as well as to VHA Central Office leadership, particularly about changes in clinical and administrative processes.
 - g. Aligning the documentation of the vaccine as closely to already existing documentation of other vaccines as possible to make the process easier for the end user.
 - h. Building the clinical decision support tool (clinical reminder in CPRS) with the flexibility to document one of multiple COVID-19 vaccines with different schedules
 - i. Allowing the reminder dialog template to be used in other formats for flexibility of the processes in any given

facility.

- i. E.g. The portion of the reminder dialog template that captures “historical/prior” vaccination given outside the VA could be pulled out and included in an immunization note or separate note for staff not administering the vaccine to update the patient’s record.
- j. Holding multiple office hours sessions to both update informatics and clinical staff and be available for technical and clinical questions.
- k. Having a centralized source of enterprise data.
- l. Bringing in sufficient project management resources based on scope and technical skills/requirements.

Appendix T – Graphic and Chart Full Text Descriptions

VHA COVID-19 Vaccination Planning and Actions

7-2-2021

VHA COVID-19 Vaccination Plan Project Organizational Structure

Organization structure:

- » IPT
 - Planning Team
 - Communications
 - Risk Stratification
 - Policy
 - Distribution
 - Measurement
 - Education
 - Vaccine Safety
 - Interagency Partnerships & 4th Mission Assignments

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Proposed Phases of COVID-19 Vaccination

- » Phase 1a:
 - Essential Workers:
 - 16-64 years with high-risk medical conditions (>110 M)
 - 65-74 years (32 M)
 - Frontline:
 - 75+ years (21 M)
- » Phase 1b:
 - Essential Workers:
 - 16-64 years with high-risk medical conditions (>110 M)
 - 65-74 years (32 M)
 - Frontline:
 - 75+ years (21 M)
- » Phase 1c:
 - 16-64 years without high-risk medical conditions (<86 M)
 - Essential Workers:
 - 65-74 years (32 M)
 - Frontline:
 - 75+ years (21 M)
 - HCP:
 - LTCF
- » Phase 2

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Mortality Rate Among COVID Veteran Cases by Age and # of Comorbidities Through 8/27/20

Comorbidities: BMI \geq 30, asthma, diabetes, CKD, IHD, stroke, COPD

- » Age < 65
 - 0 comorbidities: 0.6%
 - 1 comorbidity: 0.9%
 - 2 comorbidities: 1.6%
 - 3+ comorbidities: 4.6%
- » Age 65-74
 - 0 comorbidities: 5.4%
 - 1 comorbidity: 6.2%
 - 2 comorbidities: 6.6%
 - 3+ comorbidities: 11.2%
- » Age 75-84
 - 0 comorbidities: 13.5%
 - 1 comorbidity: 11.1%
 - 2 comorbidities: 13.4%
 - 3+ comorbidities: 14.6%
- » Age 85+
 - 0 comorbidities: 27.4%
 - 1 comorbidity: 27.1%
 - 2 comorbidities: 25.4%
 - 3+ comorbidities: 27.7%

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

- » 0-17 years
 - Percentage of cases: ~8%
 - Percentage of deaths: <1%
- » 18-29 years
 - Percentage of cases: ~22%
 - Percentage of deaths: <1%
- » 30-39 years
 - Percentage of cases: ~17%
 - Percentage of deaths: ~2%
- » 40-49 years
 - Percentage of cases: ~16%
 - Percentage of deaths: ~3%

- » 50-64 years
 - Percentage of cases: ~21%
 - Percentage of deaths: ~15%
- » 65-74 years
 - Percentage of cases: ~8%
 - Percentage of deaths: ~21%
- » 75-84 years
 - Percentage of cases: ~4%
 - Percentage of deaths: ~26%
- » 85+ years
 - Percentage of cases: ~4%
 - Percentage of deaths: ~32%

Percentage of cases data from 4,272,205 cases. Age group was available for 4,109,540 (96%) cases.

Percentage of deaths data from 131,692 deaths. Age group was available for 131,676 (99%) deaths.

Updated as of 8/24/20. Data are based on COVID-19 case-level data reported by state and territorial jurisdictions to the Centers for Disease Control and Prevention (CDC). The numbers are confirmed and probable COVID-19 cases as reported by U.S. states, U.S. territories, New York City, and the District of Columbia from the previous day.

<https://www.cdc.gov/covid-data-tracker/index.html#demographics>

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COVID-19 Hospitalization and Death by Age

Factors that increase community spread and individual risk:

- » Crowded situations
- » Close/physical contact
- » Enclosed space
- » Duration of exposure

Rate ratios compared to 18-29 year olds	0-4 years	5-17 years	18-29 years	30-39 years	40-49 years	50-64 years	65-74 years	75-84 years	85+ years
Hospitalization	4x lower	9x lower	Comparison Group	2x higher	3x higher	4x higher	5x higher	8x higher	13x higher
Death	9x lower	16x lower	Comparison Group	4x higher	10x higher	30x higher	90x higher	220x higher	630x higher

Actions to reduce risk of COVID-19:

- » Wearing a mask
- » Social distancing (6 ft goal)

- » Hand hygiene
- » Cleaning and disinfection

Hospitalization data source: COVID-NET (<https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>, accessed 08/06/20). Numbers are unadjusted rate ratios.

Death data source: NCHS Provisional Death Counts (<https://www.cdc.gov/nchs/nvss/vsrr/COVID19/index.htm>, accessed 08/06/20). Numbers are unadjusted rate ratios.

[cdc.gov/coronavirus](https://www.cdc.gov/coronavirus)

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Racial and ethnic minority groups represent 40% of the total U.S. population, but nearly 60% of COVID-19 cases

As of September 15, 2020:

- » White, Non-Hispanic:
 - Percent of total population: ~60%
 - Percent of cases: ~40%
- » Hispanic/Latino:
 - Percent of total population: ~18%
 - Percent of cases: ~30%
- » Black, Non-Hispanic
 - Percent of total population: ~13%
 - Percent of cases: ~20%
- » Multiple/Other, Non-Hispanic
 - Percent of total population: ~3%
 - Percent of cases: ~4%
- » Asian, Non-Hispanic
 - Percent of total population: ~6%
 - Percent of cases: ~3%
- » American Indian/Alaska Native, Non-Hispanic
 - Percent of total population: ~1%
 - Percent of cases: ~1%
- » Native Hawaiian/Other Pacific Islander, Non-Hispanic
 - Percent of total population: <1%
 - Percent of cases: <1%

Data from 4,909,175 cases. Race/Ethnicity was available for 2,453,808 (50%) cases.

Updated as of 9/15/2020. Data are based on COVID-19 case-level data reported by state and territorial jurisdictions to the Centers for Disease Control and Prevention (CDC). The numbers are confirmed and probable COVID-19 cases as reported by U.S. states, U.S. territories, New York City, and the District of Columbia from the previous day.

U.S. Census:

<https://www.census.gov/quickfacts/fact/table/US/PST045219>

<https://www.cdc.gov/covid-data-tracker/index.html#demographics>

[Link to return to source image](#)

Racial and ethnic minority groups represent 40% of the U.S. population, but nearly 50% of COVID-19 deaths

As of September 15, 2020:

- » White, Non-Hispanic:
 - Percent of total population: ~60%
 - Percent of deaths: ~50%
- » Hispanic/Latino:
 - Percent of total population: ~18%
 - Percent of deaths: ~17%
- » Black, Non-Hispanic
 - Percent of total population: ~13%
 - Percent of deaths: ~22%
- » Multiple/Other, Non-Hispanic
 - Percent of total population: ~3%
 - Percent of deaths: ~4%
- » Asian, Non-Hispanic
 - Percent of total population: ~6%
 - Percent of deaths: ~5%
- » American Indian/Alaska Native, Non-Hispanic
 - Percent of total population: ~1%
 - Percent of deaths: ~1%
- » Native Hawaiian/Other Pacific Islander, Non-Hispanic
 - Percent of total population: <1%
 - Percent of deaths: <1%

Data from 135,840 deaths. Race/Ethnicity was available for 111,958 (82%) deaths.

Data from US Census 2019 estimates.

Updated as of 9/15/2020. Data are based on COVID-19 case-level data reported by state and territorial jurisdictions to the Centers for Disease Control and Prevention (CDC). The numbers are confirmed and probable COVID-19 cases as reported by U.S. states, U.S. territories, New York City, and the District of Columbia from the previous day.

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VHA locations offering COVID-19 vaccination as of March 2, 2021

The key to this map is as follows:

- » Moderna only
- » Pfizer Only
- » Janssen Only
- » Pfizer & Moderna
- » Janssen & Pfizer
- » Janssen & Moderna
- » Janssen, Pfizer, Moderna

However, the map does not provide exact details regarding where to find the various vaccination locations, and some of the marks on the map are very close to state lines and difficult to discern which state they fall in. With this in mind, the following list provides a rough estimate of which vaccines can be obtained in each state or U.S. territory:

- | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none">» Alabama<ul style="list-style-type: none">• Janssen, Pfizer, Moderna» Alaska<ul style="list-style-type: none">• Moderna» Arizona<ul style="list-style-type: none">• Janssen, Pfizer, Moderna» Arkansas<ul style="list-style-type: none">• Janssen, Moderna» California<ul style="list-style-type: none">• Janssen, Pfizer, Moderna» Colorado<ul style="list-style-type: none">• Janssen, Pfizer, Moderna» Connecticut<ul style="list-style-type: none">• Janssen, Pfizer, Moderna» Delaware<ul style="list-style-type: none">• Janssen, Pfizer, Moderna» Florida<ul style="list-style-type: none">• Janssen, Pfizer, Moderna» Georgia<ul style="list-style-type: none">• Janssen, Pfizer, Moderna» Hawaii<ul style="list-style-type: none">• Moderna» Idaho<ul style="list-style-type: none">• Janssen, Moderna» Illinois<ul style="list-style-type: none">• Janssen, Pfizer, Moderna» Indiana<ul style="list-style-type: none">• Janssen, Pfizer, Moderna | <ul style="list-style-type: none">» Iowa<ul style="list-style-type: none">• Janssen, Pfizer, Moderna» Kansas<ul style="list-style-type: none">• Janssen, Pfizer, Moderna» Kentucky<ul style="list-style-type: none">• Janssen, Pfizer, Moderna» Louisiana<ul style="list-style-type: none">• Janssen, Pfizer, Moderna» Maine<ul style="list-style-type: none">• Janssen, Moderna» Maryland<ul style="list-style-type: none">• Janssen, Pfizer, Moderna» Massachusetts<ul style="list-style-type: none">• Janssen, Pfizer, Moderna» Michigan<ul style="list-style-type: none">• Janssen, Pfizer, Moderna» Minnesota<ul style="list-style-type: none">• Janssen, Pfizer, Moderna» Mississippi<ul style="list-style-type: none">• Janssen, Moderna» Missouri<ul style="list-style-type: none">• Janssen, Pfizer, Moderna» Montana<ul style="list-style-type: none">• Janssen, Moderna» Nebraska<ul style="list-style-type: none">• Janssen, Pfizer, Moderna» Nevada<ul style="list-style-type: none">• Janssen, Pfizer, Moderna |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

- » New Hampshire
 - Janssen, Moderna
- » New Jersey
 - Janssen, Pfizer, Moderna
- » New Mexico
 - Janssen, Pfizer, Moderna
- » New York
 - Janssen, Pfizer, Moderna
- » North Carolina
 - Janssen, Pfizer, Moderna
- » North Dakota
 - Moderna
- » Ohio
 - Janssen, Pfizer, Moderna
- » Oklahoma
 - Janssen, Pfizer, Moderna
- » Oregon
 - Janssen, Pfizer, Moderna
- » Pennsylvania
 - Janssen, Pfizer, Moderna
- » Rhode Island
 - Janssen, Pfizer, Moderna
- » South Carolina
 - Janssen, Pfizer, Moderna
- » South Dakota
 - Janssen, Moderna
- » Tennessee
 - Janssen, Pfizer, Moderna
- » Texas
 - Janssen, Pfizer, Moderna
- » Utah
 - Janssen, Moderna
- » Vermont
 - Janssen, Moderna
- » Virginia
 - Janssen, Pfizer, Moderna
- » Washington
 - Janssen, Pfizer, Moderna
- » West Virginia
 - Janssen, Moderna
- » Wisconsin
 - Janssen, Pfizer, Moderna
- » Wyoming
 - Moderna

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