

COVID-19 Vaccination Plan for the Veterans Health Administration



VA

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of Veterans Affairs

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Record of Changes

Date	Description of change	Page of section	Posted by
10/15/2020	Release of version 1.0		
12/14/2020	Release of version 2.0 to reflect EUA for initial vaccine	Executive Summary Overview and updates to all content.	

COVID-19 Vaccination Plan for the Veterans Health Administration

Executive Summary

Nine months into the 2020 COVID-19 Pandemic, the United States is averaging more than 200,000 new cases of COVID-19 disease and about 2,400 deaths caused by SARS-CoV-2 per day. As of December 13, 2020, there have been 296,818 total COVID-19 related deaths in the United States. New therapies and disease management strategies 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 temporarily. Significant surges in late fall led to all-time high rates of SARS-CoV-2 cases and COVID-19 related deaths per day, and hospitals and intensive care units in multiple areas of the country reached capacity. The pandemic has significantly affected the US economy, with lower-income and minority populations bearing the brunt of both financial and medical hardship. A return to normalcy, or the new norm, will occur when the US has safe, accessible, and highly efficacious treatment, preventive medication, or a vaccine that provides immunity to SARS-CoV-2 for an extended period.

Operation Warp Speed (OWS), a Department of Human & Health Services (HHS) team, has been working to produce and deliver 300 million doses of safe and effective vaccines to the US 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, 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) has led planning for data collection and vaccine distribution with state jurisdictions, VHA, and other Federal agencies. There are four large-scale Phase II/III vaccine trials underway in the US and the first two vaccine candidates entered Phase III trials in July 2020. The US 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, which is the first COVID-19 vaccine to be authorized for use in the US, on December 11, 2020, and the CDC's Advisory Committee on Immunization Practices (ACIP) and CDC discussed and provided recommendations for use December 12 and 13th.

The *VHA COVID-19 Vaccination Plan* that follows provides guidance on key aspects of a successful vaccination program for products that have, or will have received FDA EUA, including management of vaccination while initial supply is limited, and later when robust supply of vaccine is expected; and navigating specific storage and handling constraints. The Plan addresses

vaccinations for Veterans, staff, and if applicable, caregivers, State Veteran Homes, and other federal partners (e.g., Department of Homeland Security). 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 OWS, and plans for education, communications, and tabletop exercises. This document serves as interim guidance for VHA on how to plan and operationalize a vaccination in response to the COVID-19 pandemic and will be updated periodically as new information becomes available.

Overview

The U.S. Government Secretary of Health and Human Services (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 December 13, 2020, there were 15,932,116 cases of SARS-CoV-2 in the United States and 296,818 total deaths attributable to COVID-19;¹ in VA, there were 129,979 cases, and 5,542 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} Given that Veterans are older on average and have more chronic conditions than non-Veterans, a higher case fatality rate among Veterans is expected.

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 Rentsch and colleagues⁶ found that the death rate from COVID-19 did not differ by race among VA patients when controlling for chronic conditions. Higher than expected mortality among racial and ethnic minorities has been 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.^{5,7}

Multiple vaccines are being studied to prevent spread of SARS-CoV-2 and severe disease and death from COVID-19; the Pfizer-BioNTech COVID-19 vaccine is the first COVID-19 to be authorized for use in the US. It is expected that additional vaccines will be approved in the following weeks and months, initially in limited quantities and eventually in quantities sufficient for a large-scale vaccination program.

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 employees, including contract employees, volunteers, and trainees) and high-risk Veteran patients especially during limited vaccine supply; drug distribution focusing on cold chain management; data transmission and interfaces for procuring and recording vaccination activities; and tabletop exercise designed for facility-level planning. In addition, vaccination for VHA caregivers, State Veteran Homes, and Federal partners is covered in the event that these services are provided. This plan is not intended to provide final guidance and will be updated as dictated by changes in ACIP, CDC, and FDA guidance.

Purpose

This plan outlines VHA activities for COVID-19 vaccination in the United States, Puerto Rico, and U.S. territories where VHA provides health care to enrolled Veterans. VHA will conduct activities necessary to make vaccine available to protect Veterans and staff 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 has been developed in partnership with other federal agencies including CDC with a focus on planning that is ethical, evidence-based, equitable, transparent, and aimed at maximizing benefits of COVID-19 vaccination.

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 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. VHA medical facilities must prepare for early limited and targeted vaccination, followed by large scale vaccination and communication plans 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 to develop processes for procuring and distributing vaccine
- Review ACIP and CDC COVID-19 vaccine recommendations and apply CDC prioritization framework to VHA
- Provide guidance on use of Personal Protective Equipment (PPE) for vaccine administration
- Provide guidance for the provision of vaccines to State Veteran Homes
- Provide guidance for the provision of vaccines to employees of other agencies
- Order vaccine for VHA 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 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
- Consider state requirements for reporting vaccine administration, supply and wastage
- 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

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 if necessary

Planning Assumptions and Considerations

VHA Operations Relevant to COVID-19 Vaccination

VHA operations will continue to use nonpharmaceutical interventions (NPIs) after vaccine candidates against SARS-CoV-2 receive emergency use authorization. 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
 - 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 staff (including volunteers and trainees) and Veterans regularly receiving care at VHA facilities. (State Veteran Veterans Homes not included).
 - VHA should plan 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, and Federal Partner staff, if so directed by the Secretary of Veterans Affairs.
 - 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 6.4 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 in 2021.
- Healthcare workers (HCWs) and highest-risk VHA beneficiaries may be prioritized for early COVID-19 vaccination.
- Many persons who desire vaccination may face delays in vaccination due to limited initial quantities or distribution limitations.
- Many persons may be hesitant to receive COVID-19 vaccines because of general vaccine hesitancy or due to specific concerns related to COVID-19 vaccine, or to avoid personal risk of SARS-CoV-2 infection associated with presenting to a VHA facility for vaccination.
- For Veterans considered unable to give informed consent, VHA will determine process to provide COVID-19 vaccine information and to receive consent for COVID-19 vaccination from the Veterans' decision maker, such as the Veterans' Health Care Power of Attorney.

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.

- Cold chain storage and handling requirements for each COVID-19 vaccine product may vary 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 should develop strategies to ensure the correct match of COVID-19 vaccine products and dosing intervals. For some COVID-19 vaccines, two doses separated by either 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.
- Some COVID-19 vaccine products will require reconstitution, diluent or adjuvant before administration.

- Some COVID-19 vaccines will have relatively short time intervals between timing of thawing and dilution to time of use.
- Some COVID-19 vaccines will be supplied in multi-dose vials.

VHA COVID-19 Vaccine Allocation

The initial vaccine candidates for SARS-CoV-2 are expected to be limited. VHA will distribute a national risk stratification plan for facilities to use in their local vaccine plans. 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 may 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 assisted living facilities
 - Patients 65 years and older
 - Patients with high-risk medical conditions for COVID-19
- 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.
- VHA should plan for high-demand and low-demand scenarios, ramping up and decreasing administration as a function of supply.
- VHA will plan for COVID-19 allocations for State Veterans' Homes staff and Veterans, family caregivers enrolled in VA's Program of Comprehensive Assistance for Family Caregivers, and Federal Partner staff if vaccination of these populations is directed by the Secretary of Veterans Affairs. It is expected that these groups will otherwise be offered vaccine by their state jurisdictional public health authority.

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 will share more information about reimbursement claims for administration fees as it becomes available.
- CDC will use its centralized distribution contract to fulfill orders for most COVID-19 vaccine products as approved by jurisdiction immunization programs. Some vaccine products,

such as those with ultra-cold temperature requirements, may be shipped directly from the manufacturer.

- Ultra-cold vaccine will be shipped from the manufacturer in containers packed with dry ice. Coolers should be repacked with dry ice within 24 hours of receipt of shipment (day 0) and repacked again every 5 days to maintain temperature. On or before day 30, vaccine should be moved into the refrigerator, stored at 2° to 8°C, and used within 5 days (120 hours). This is current as of 12/13/20 and may change if directed by the manufacturer.
- COVID-19 vaccination providers will be required to report COVID-19 vaccine inventory.
- Vaccine orders will be approved and transmitted in CDC's Vaccine Tracking System (VTrckS).
- Vaccine (and adjuvant, if required) will be shipped to sites after order approval by the vaccination program, if supply is available. 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 will be 100 doses per order for most vaccines. Minimum order size for the Pfizer direct-ship vaccine is 975 doses. CDC and manufacturers will provide more detail as it becomes available.
- VHA will be allowed to redistribute vaccines while maintaining the cold chain.
 - With the challenge of meeting cold chain requirements for frozen or ultra-cold vaccines, VHA should be judicious in use of redistribution and limit redistribution to refrigerated vaccines only.
- 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 evaluate data connections to report VHA COVID-19 vaccination supply information to CDC's Vaccine Finder.
- VHA will evaluate the functionality of CDC's Vaccine Administration Management System (VAMS) which CDC will make available to sites that need assistance in patient registration and scheduling, clinic flow, supply management, patient record management, and reporting.
- VHA will evaluate other CDC data and informatics tools to link internally developed VHA data collection and reporting tools to CDC for supply and administration data transmission.
- VHA will develop internal reporting solutions to monitor the VHA COVID-19 vaccination program and evaluate solutions to present data on VHA's COVID-19 vaccination program to the general public.

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 vaccination provider enrollment, COVID-19 vaccine ordering, COVID-19 vaccine storage, handling, administration (i.e., reconstitution, adjuvant use, administration techniques), safety monitoring and reporting, promotion of other preventive strategies and behaviors will be available in a variety of formats.

Strategic Stakeholder Communications:

- Provide awareness and information and 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 misperceptions about the COVID-19 vaccination plan and vaccines.

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 have 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 Vaccine Adverse Event Reporting System (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.

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

VHA COVID-19 Vaccination Planning and Actions

12-14-2020

Purpose

The purpose of this document 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.

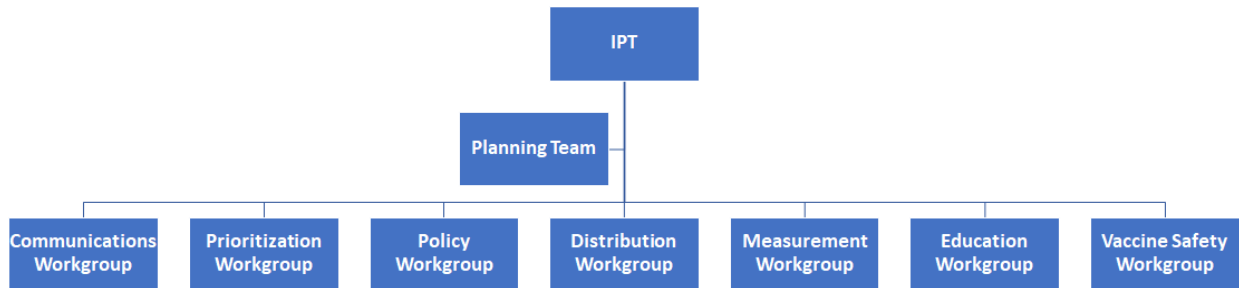
Concept of Operations

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 reviewed lessons learned from past experiences, including the 2009 H1N1 pandemic response and vaccination campaign. CDC and ACIP frameworks were reviewed, and workgroups present findings and proposals based on CDC COVID-19 vaccine planning and risk stratification recommendations. The IPT carefully considers the feasibility and acceptability of all proposals for VHA, accounting 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 disproportionately affected racial and ethnic minority populations receive dedicated outreach efforts and ready access to vaccine.

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

Direction, Control, and Coordination

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

- Veterans Integrated Service Network (VISN) – VISN Network Directors and Chief Medical Officers: regional (VISN) operational and clinical leaders representing 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 community providers
- National Center for Ethics in Healthcare – 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, 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

12-14-2020

Purpose

The purpose of this document 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 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, communications 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.
 - 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.

The Workgroup developed external relationships with communications experts at the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (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
 - How-to Guide
 - Key Messages
 - Placemat
 - Fact Sheets – Planning
 - Veteran Listening Sessions Leadership Update
 - Risk Stratification
 - Vaccine Safety Monitoring
 - Response to Query
 - All Sites Waiting
 - Slotted Future Sites
 - Slotted Initial Sites
 - COVID-19 Web Resource Links
 - Employee COVID-19 Vaccine Awareness Toolkit
 - 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

- Flu/COVID-19 Vaccine Comparison Infographic for Non-Clinical Staff
- Veteran COVID-19 Vaccine Awareness Toolkit
 - 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
 - Spanish Language Resources
 - Elevator Speech
- National Planning Toolkit
 - How-to Guide
 - News Release
 - VAntage Point Blog
 - My HealtheVet Newsletter
 - VSO Brief Slide Deck
 - VetResources
- 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 – Risk Stratification

VHA COVID-19 Vaccination Planning and Actions

12-14-2020

Purpose

The purpose of this document 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. Reviewed past experiences in VHA relevant to COVID-19 vaccination.
3. Reviewed existing frameworks for COVID-19 and other vaccine risk stratification, including the National Academies of Sciences, Engineering, and Medicine and the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (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. Reviewed 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. Reviewed 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 World Health Organization (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. Member(s) of the workgroup attends 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 will finalize recommendations after CDC guidance is finalized.
 - i. As of 12/14/2020, CDC has finalized guidance on phase 1a. Phases 1b and 1c have been discussed but not voted on or finalized by ACIP or CDC, so

VHA guidance beyond phase 1a remains in draft and is marked as such in the table below in grey.

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.
 - a. The group convened biweekly meetings of high-risk stakeholders within VHA to review and discuss proposed approaches. The stakeholder group includes 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.
 - b. The group presents and discusses updates and draft frameworks with the IPT.
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 Emergency Use Authorization (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 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
 - 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.

Risk Stratification Table (grey sections remain in draft)

CDC-VA	Healthcare Personnel*	Veterans	Comments	
A- 1a	CLC/SCID unit staff	Veterans residing in VA CLC/SCID	<p><i>Staff members not listed, including those who travel between units, should be offered vaccine with the group or unit most resembling their risk profile</i></p>	
A- 1b	Emergency Department, EMS			
A- 1c	COVID ICU staff			
A- 1d	COVID non-ICU inpatient staff			
A- 1e	Other staff providing face-to-face care and services for COVID patients			
A- 1f	Staff in other congregate living settings	Veterans residing in other nursing facilities without access to vaccine; Veterans residing in other VA residential/congregate settings	<p>*For vaccines where rate of anticipated side effects in high, it is recommended that 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 vaccine. Under this scenario, offering vaccine to any HCP would be appropriate, rather than offering sequentially by risk.</p> <p>**this should comprise the smallest number of staff that are needed to continue operations, rather than all persons who hold a particular job or role, with intent of keeping the health care system functioning to care for Veterans and keep staff safe.</p>	
A- 2a	Core staff critical to function of the hospital and the COVID response (e.g. logistics, facilities operations, police, food services, occupational health, environmental engineering, limited executive or leadership roles)**	<div style="border: 1px solid black; padding: 10px; background-color: #E0E0E0;"> <p>ACIP (CDC) Phases 1a = Blue (HCP, LTCF) 1b = Green (Essential Workers) 1c = Brown (65 and older; high-risk conditions)</p> </div>		
A- 2b	Inpatient staff, non-COVID units			
A- 2c	Staff performing high risk procedures (non-COVID, pre-screened)			
A- 3a	Hemodialysis staff			
A- 3b	Oncology/chemotherapy unit staff			
A- 4a	Homeless Outreach staff			
A- 4b	Staff with frequent contact with Veterans who have not been pre-screened for COVID symptoms (screeners, drivers, etc.)			
A- 4c	Outpatient direct care/contact (pre-screened, non-COVID)			
<p>The section below is in draft pending ACIP and CDC recommendations on Phase 1b and 1c vaccination</p>				
B-1a	<p>All other staff (staff who do not interact with patients/Veterans and who are not critical to day-to-day operations)</p>		<p>Homeless Veterans; Hemodialysis patients; Solid Organ Transplant patients or patients who are listed for transplant; and Chemotherapy patients Specifically – Veterans receiving chemotherapy in a clinic/hospital setting</p>	<p><i>Open for Essential Workers</i></p>
C-1a		Veterans age 85+	<p>Outreach efforts for these groups should emphasize patients with <u>CDC high-risk conditions</u> and members of <u>high-risk racial or ethnic minority groups.</u></p>	
C- 1b		Veterans age 75+		
C- 1c		Veterans age 65+		
D- 1a		Veterans age 50+		
D- 1b		Veterans age <50:		

VA Population Enumeration

Please refer to the Appendix for VHA's population enumeration by state.

Category	Number	%	State level data
Staff			
Department of Veterans Affairs (Total)	4,688 418,461		Attachment A
Veterans Health Administration (Total)	373,435 369,596		"
HCP	247,239 248,161		"
Essential	41,259 41,302		"
Others	84,937 60,133		"
Volunteers	61,420		Attachment A
Trainees	124,190 Unchanged		Not available
Veterans			
Enrolled Veterans (total)	10,068,322 10,029,567		Attachment A
≥65	4,988,832 4,966,696	49.3%	"
African American	1,380,936 1,378,360	13.7%	"
Hispanic	595,875 597,508	5.9%	"
Veterans Receiving Care	5,821,113 5,790,509	-	Attachment A
≥65	3,063,682 3,028,246	52.2%	"
African American	1,022,986 1,022,386	17.6% 17,6	"
Hispanic	397,162 399,437	6.8% 6,9	"
Veterans in State Veteran Homes	19,275		August 2020 ADC
Fourth MISSION - Non Veteran	9208		Initial Submission
Fourth MISSION - Veteran	132		Initial Submission
High Risk Medical Conditions			Attachment A
Cancer	544,149 527,067	9.3% 9,1	"
Chronic Kidney Disease	339,435 332,207	5.8% 5,7	"

COPD	439,287 434,237	7.5% 7,5	“
Asthma	157,918 160,524	2.7% 2.7%	“
Obesity (BMI of 30 or greater)	2,278,608 2,269,776	39.1% 39.2	“
Cardiovascular disease	2,709,759 2,698,997	46.6% 46.6	“
Sickle cell disease	2,998 3083	0.1% 0.5	“
Type 2 diabetes mellitus	1,556,431 1,544,159	26.7% 26.7	“
Homeless Veterans	242,297 222,283		Attachment A
Community Living Centers (CLC)	17,456		
Nursing Home	19,954	0.1%	Attachment A
Other congregate settings	2279 2284	0.04%	
Rural	1,992,232 1,978,305	34.2%	Attachment A
Spinal Cord Injury/Diseases			

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 Program Office provides representation for the high-risk stakeholder meetings. The Risk Stratification Workgroup will communicate through those 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. Outlines 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 to ensure that each high-risk group, among the many that are high-risk and high priority for a COVID vaccine, has adequate representation and that the needs of each group are carefully considered.
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.

Appendix D – Vaccine Policies and Clinical Guidance

VHA COVID-19 Vaccination Planning and Actions

12-14-2020

Purpose

The purpose of this document is to outline best practices for the Vaccine Policies and Clinical Guidance Workgroup for COVID-19 Vaccination in VHA.

The overarching goal is to coordinate approval and implementation of VHA policies and clinical guidance for COVID-19 vaccination and vaccine campaigns for Veterans and staff.

Scope

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

1. Reviews guidance from the VHA COVID-19 Risk Stratification workgroup.
2. Reviews and understands existing vaccine guidance in VHA and past relevant guidance including that issued for 2009 H1N1 influenza vaccine.
3. Drafts guidance and policy 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 exists to draft policies and guidance to support implementation of the COVID-19 Vaccination plan in VHA.

The workgroup:

1. 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.
2. Reviewed existing vaccine guidance in VHA, and past relevant guidance including that issued for 2009 H1N1 influenza vaccine.
3. Drafts memoranda, guidance, and policy 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 is responsible for drafting 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:
 - a. Administration of vaccines
 - b. Documentation of administration and Reporting Requirements
 - c. Use of specific Electronic Health Records
 - d. Scheduling of Vaccine Visits
 - e. Use of Risk Stratification Guidance
 - f. General distribution plans
 - g. Required training and education

- b) As vaccine supply increases and vaccination efforts shift to a larger scale, group will draft a more durable policy to support COVID-19 vaccination, such as a VHA Directive.
- c) The COVID-19 Vaccination Project Team, including the policies and distribution workgroups, developed 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. See Appendix O for a description of the tabletop exercise.
- 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 and policy from the 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 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 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.
- 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 policy, guidance, and assisting in communication of guidance and policy.

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 policy.
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 actionable guidance and policy must be based on the risk stratification framework as developed by ACIP and tailored for VHA.

Appendix E – Metrics and Informatics

VHA COVID-19 Vaccination Planning and Actions

12-14-2020

Purpose

The purpose of this document 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, vaccination rates for Veterans and staff and to develop capabilities to report vaccine administration and supply data to the Centers for Disease control and Prevention (CDC) and all internal VHA 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 exists to identify 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. VSSC tool developed to help VISNs and facilities to 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, or both when appointments for second vaccine doses are due.
 - ii. Patient reminders, alerts or texts may be generated through the My HealtheVet 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 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 xxx date and is available for national, VISN and facility use.
 - 1. Metrics include vaccine administration detail by location (national, VISN, facility), and demographics including age and gender.
 - 2. A COVID-19 Second Dose tracking report is also in development
- 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.
 - 1. CVX codes were added to immunization file 11/19/2020
 - 2. A national clinical reminder dialog for COVID-19 Vaccination was released 11/23/2020 and is mandatory for use across VHA
 - 3. Reminder for second dose incorporated in the reminder dialog
 - ii. Vaccine data will be populated in the VistA Immunization File and VA's Corporate Data Warehouse.
 - b. Determine VHA's capacity for documenting vaccine administration for VHA staff.
 - i. VHA evaluated and determined it would modify an existing electronic record keeping system, Occupational Health Record System (OHRS) 2.0, to document COVID vaccine doses administered to VHA staff and prompt with reminders when 2nd doses of vaccine are due.

1. VHA issued an operational memo in October 2020 requiring OHRS 2.0 be used for employee COVID-19 vaccine administration documentation throughout the enterprise.
 2. OHRS 2.0 team built a COVID-19 Vaccine sub module on the OHRS 2.0 platform which went live on 12/10/2020.
 3. This OHRS 2.0 sub module will allow documentation of doses of COVID-19 vaccine administered to employees
 4. The OHRS 2.0 team developed functionality to send Outlook email reminders for 2nd dose appointments
 5. OHRS 2.0 recorded, on-demand training is available on TMS for OHRS 2.0 new users and OHRS 2.0 current users
 6. 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.
 7. 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
 8. 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 follow 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 has 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. Coordinated 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 Emergency Use Authorization (EUA), the workgroup will determine if there are any additional required reporting elements for the vaccine and incorporate the collection and transmission of data to CDC.
 6. Evaluates VA use of Operation Warp Speed (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
 7. 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.
 8. 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

12-14-2020

Purpose

The purpose of this document is to outline best practices for distribution of COVID-19 vaccine to VA facilities for the purpose of immunizing both patients and employees. The overarching goal is to develop a distribution and storage plan for COVID-19 vaccines at VA facilities based on the Centers for Disease Control (CDC) framework for distribution of the vaccine.

Scope

The Distribution Workgroup will be responsible for developing a plan for distribution and storage of COVID-19 vaccine and related supplies based on VA's risk stratification framework and the VA allocation issued by the CDC and delivered to VA facilities by the CDC's authorized distributor.

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. 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 starting in September 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 to its initial 37 sites with ultra-cold freezer capacity. Pro-rata allocation was based on the number of health care personnel at each VA facility.
2. Communicates with VA and VHA leadership.
 - a. Relays distribution information to the VA 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. 2 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 COVID-19 vaccine workgroups (Communications, Metrics and Informatics, Risk Stratification and Vaccine Safety) to inform them of the distribution plan so they can incorporate it into their workstreams.
 - i. Communications: COVID-19 vaccine Frequently Asked Questions, PowerPoint presentations and placemat included information on vaccine distribution, focusing on when 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 staff were used to determine pro-rata allocation to initial VHA facilities.
 - iv. Vaccine Safety: weekly communication between Distribution and Vaccine Safety workgroup leadership to ensure
 - v. Education: Distribution team leads worked with the education group to develop content for storage and handling training specific for both the Pfizer -70C and the Moderna -20C 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 Vaccine Tracking System (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 VPOP and VTrckS training, received access to VPOP and VTrckS and successfully placed initial orders on 12/4/2020.
 - 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.
 1. A distribution plan for the -70C vaccine product was developed and released to the field on 12/14/2020.
 2. A distribution plan for the -20C product was developed and released to the field on 12/21/2020.
 3. A limited redistribution plan for the -20C vaccine product was developed and released to the field on 12/21/2020.
 - 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. -70C 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 -70C 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 -20C 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. Collaborated 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 tabletop exercise was release to VHA VISNs and facilities in October and was mandatory for completion; sites were requested to certify completion by October 30, 2020. See Appendix N for a description of the tabletop exercise.
- 5. Reviewed requirements for a vaccine approved under an Emergency Use Authorization (EUA)
 - a. Upon authorization of the -70C 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 -70C vaccine to VHA sites in coordination with VHA operations. Each VISN designated two facilities per VISN to receive initial shipments of -70C 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. -70C 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.
- 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 and 12/21/2020 (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

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) will be responsible for directing and coordinating all purchasing activities and ensuring a detailed distribution plan is developed and followed at VAMCs. They will coordinate the ordering, storage and distribution using the CDC's Distribution COVID-19 vaccine framework and ensure appropriate implementation at all VAMCs. VHA PBM will coordinate 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 COVID19 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 COVID19 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 used 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 was used, in conjunction with input from VHA Operations, VISNs and facilities, to determine initial sites to receive -70C product for high-throughput vaccination to Phase 1a individuals.

The storage and distribution plan for the -70C vaccines was shared across COVID-19 vaccine workgroups and distributed to VISN and facility-based pharmacy staff handling vaccine product after EUA approval by the FDA was finalized 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, nursing and providers. The COVID-19 Vaccine Distribution workgroup coordinated communications efforts with the COVID-19 Vaccine Risk Stratification, Education, Safety and Communications workgroups. A key deliverable was the development of a VHA mandatory Talent Management System (TMS) training for vaccinators and handlers which included information on COVID-19 vaccine distribution, storage and handling specific to the -70C vaccine product.

Appendix G – Vaccine Safety

VHA COVID-19 Vaccination Planning and Actions

12-14-2020

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 monitor 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 adverse events (AEs) through the VA Adverse Drug Event Reporting System (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 Vaccine Adverse Event Reporting System (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. Provide a Vaccine AE Reporting Frequently Asked Question 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 Emergency Use Authorization (EUA).

Organization and Assignment of Responsibilities

1. Lead: VA Center for Medication Safety (VAMedSAFE) and VA Adverse Drug Event Reporting System (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 (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 COVID19 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 (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 Adverse Drug Event Reporting System (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 the VA Adverse Drug Event Reporting System (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 will work 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 will 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 will monitor 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, the CDC and the FDA.

Summary of active surveillance results will be 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

12-14-2020

Purpose

The purpose of this document 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 the CDC's 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 Talent Management System (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.

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:
 - a) Vaccine and ancillary kit storage and handling
 - b) Proper vaccine administration techniques
 - c) Patient education requirements
 - d) Prompting second dose reminders
 - e) Documentation/Data reporting requirements including informatics tools that need to be used for data collection
 - f) Process for reporting vaccine usage, waste, and spillage
 - g) Process of reporting vaccine adverse events
 - xiii. Vaccinator training materials and associated training requirements will be disseminated through several VHA clinical communications modalities.
 - xiv. 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 Emergency Use Authorization (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

12-14-2020

Purpose

The purpose of this document 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 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.

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 coordinate with CDC, Federal Partner and jurisdictional vaccination leads to develop a plan for vaccine allocation 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 -70C 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 -70C 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 -70C vaccine product.
 - b. VHA Caribbean was identified as a ship-to site and VISN8 identified VHA Caribbean as an initial VHA site to receive -70C 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 -20C vaccine product
 - b. VA Pacific Islands ship-to locations will place vaccine orders with VA Pharmacy Benefits Management (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 -20C vaccine product to 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 -20C vaccine.
 - b. Due to its conventional freezer capacity, VHA designated Anchorage VA as an initial site to receive -20C 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 -20C 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

12-14-2020

Purpose

The purpose of this document is to outline a plan to support VHA's COVID-19 Vaccination program if VA is granted significant quantities of vaccine to provide COVID-19 vaccination for State Veterans' Homes residents and staff. This plan will be implemented if State Veterans Homes request VA assistance through the Federal Emergency Management Agency. If VA receives a request for assistance, the Secretary of Veterans Affairs 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 the Secretary of Veterans Affairs.
2. When requests are approved, VHA will:
 1. Identify the number of staff serving the State Veterans' Home who will need vaccine.
 2. 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.
 1. VHA communicated this approach to CDC's Federal Entities team who notified CDC's jurisdictional team in October 2020.
 2. VHA's national office of Geriatrics & Extended Care communicated this approach to the National Association of State Veterans Homes (NASVH) in October 2020.
 3. 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.
 4. 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 State Veterans' Home staff and residents.

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, 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 of Veterans

VHA COVID-19 Vaccination Planning and Actions

12-14-2020

Purpose

The purpose of this document 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 should be offered COVID-19 vaccination through a Humanitarian/4th Mission assignment. If caregivers are offered vaccination under a 4th mission assignment, it will be in accordance with their level of risk based on VHA's COVID-19 Vaccine Risk Stratification Framework. VHA will need to determine whether its allocation of COVID-19 vaccine is sufficient to pursue immunization of caregivers, or if additional vaccine doses should be requested from CDC.

Scope

VHA will:

1. Review and accept the assignment to provide COVID-19 vaccination to PCAFC Family Caregivers as directed by the Secretary of Veterans Affairs.
2. Ensure adequate vaccine allocation to cover vaccination to Family Caregivers in the PCAFC; VHA may need to request additional COVID-19 vaccine supply, if available, from Health and Human Services (HHS)/CDC.
3. Identify when caregivers may be offered COVID-19 vaccination in accordance with VHA's and/or CDC's COVID-19 vaccine risk stratification framework.
4. Identify the number of family caregivers enrolled in VA's Program of Comprehensive Assistance for Family Caregivers
5. Develop a plan to provide COVID-19 vaccination to Family Caregivers enrolled in VA's PCAFC.
6. Develop a plan to collect data on vaccine administration, supply and wastage and transmit these data to states and/or CDC.

Concept of Operations

VHA will:

1. Identify the number of Family Caregivers enrolled in VA's PCAFC.
2. Request additional COVID-19 vaccine allocation from HHS/CDC for this Humanitarian Mission assignment.
 - a. COVID-19 vaccination for Family Caregivers will be contingent upon VHA receiving an additional allocation sufficient to vaccinate the PCAFC Family Caregiver population.
3. 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. VHA health care personnel and Veterans living in long-term care facilities will be offered vaccination first when initial supply is limited. Family Caregivers may be offered vaccination after these initial groups are vaccinated according to their risk, based on risk criteria used as the foundation for VHA's framework as well as from CDC allocation recommendations.
 - b. Vaccination may occur in VHA immunization clinics or by directly delivering vaccine in the community, such as via mobile vaccination clinics.
 - 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 Family Caregivers vaccination campaign.
4. Develop plans to collect data on vaccine administration, supply, and wastage.
 - 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 Family Caregivers enrolled in VA's PCAFC.

Organization and Assignment of Responsibilities

1. VA, VISNs and VHA medical centers will review assignments and make plans for Humanitarian/4th Mission outreach to offer 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 distribution, storage, 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 via guidance and policy from the COVID-19 Vaccination Project Team. 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

12-14-2020

Purpose

The purpose of this document 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 the Secretary of Veterans Affairs.
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.
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 identify state reporting requirements as applicable. 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 a Memorandum of Understanding and states as applicable.
 - 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 prioritization 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. 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 and Staff

VHA COVID-19 Vaccination Planning and Actions

12-14-2020

Purpose

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

Scope

VHA:

1. Developed a risk stratification framework for COVID-19 vaccination of VA staff based upon VHA's Risk Stratification Plan for COVID-19 vaccination.
2. Assessed VA employee enumerations by state, VISN and facility, including subgroups of health care and essential personnel.
3. Provides 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. Developed solutions for collection and reporting of employee vaccination administration data to CDC according to CDC data reporting requirements.

Concept of Operations

VHA:

1. Identified numbers of VA and VHA employees, including VHA health care personnel and essential personnel by state, VISN and VA medical center.
2. Outlined highest risk groups for initial vaccination to assist with planning of facility employee vaccination campaigns when vaccine supply is limited, including:
 - a. Health care personnel (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. Developed 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 Occupational Recordkeeping System (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 and email reminders in OHRS 2.0 to track and remind employees due for second doses of vaccine.
 - 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. Developed plans to collect data on vaccine administration, supply, and wastage.
 - a. VHA identified 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. VHA has made OHRS 2.0 the required 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 Talent Management System (TMS) in November 2020.
 - i. Completion of TMS training is mandatory for users of the OHRS 2.0 system.
 - e. VHA identified processes for reporting vaccine data to CDC.
 - i. The national Veterans Data Integration & Federation (VDIF) solution will transmit OHRS 2.0 vaccine administration data to CDC every 24 hours per CDC requirements.
 - f. VHA identified internal 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

12-14-2020

Purpose

The purpose of this document is to describe tabletop exercises to support preparedness for COVID-19 vaccination in VA medical centers and clinics.

Scope

VHA:

1. Developed 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. Maximized transparency by ensuring the most up-to-date information and preliminary planning assumptions are made available with the tabletop exercises.
3. Distributed tabletop exercises to the field and encourage responses in order to identify gaps and challenges to vaccine deployment.

Concept of Operations

VHA:

1. Developed 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 prioritization.
 - 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. Maximized transparency by ensuring the most up-to-date information and preliminary planning assumptions were made available with the tabletop exercises.
 - a. Including 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. Included a draft risk stratification framework
 - i. Included draft guidance on rationale and framework 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 developed tabletops which the VHA Central Office distributed to VISN leadership.
2. VISN leadership determined which facility groups should participate to maximize preparedness and brought 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 were coordinated by the VISN leadership team.
2. VAMC Level: Direction, control, and coordination activities at the facility level occurred in the Executive Leadership Team and Incident Command. The facility reviewed 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 occurred in the Program Office Executive Leadership Team.

Communications

The COVID-19 Vaccination Project Team communicated 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

12-14-2020

Purpose

The purpose of this document is to outline a plan for VHA to implement outreach efforts directed toward at-risk racial and ethnic minority populations in order 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 Healthcare 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 solicited 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, 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.
- 3. VHA collaborated with CDC and OWS Federal Partner COVID-19 Communications teams to coordinate and leverage strategies and materials designed for minority reach.
 - a. VHA collaborated 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 reach will be made available to support VHA's COVID-19 communications approach where relevant and appropriate for Veteran minority audiences.
- 4. VHA collaborated with its VISN and VA facility Public Affairs Officers in order 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. In order 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 heterogeneous 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 collaborated 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.

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

12-14-2020

Purpose

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

Scope

VHA:

1. Identified 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. Will develop a collection of targeted outreach materials to best inform and encourage rural Veterans regarding COVID-19 vaccination options and locations.
3. Consider alternative methods of direct and indirect outreach to inform Veterans and promote vaccination.
4. Leverage expertise of VA's Office of Rural Health, National Center for Ethics in Healthcare 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. Identified 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 Veterans 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. Developed 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. Developed 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 plans 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. Consider 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.

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.