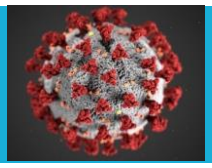
VIRGINIA EMERGENCY SUPPORT TEAM

WORKING DRAFT – PRELIMINARY AND SUBJECT TO CHANGE

COVID-19 VACCINATION PLAN

Version 1.1
October 2020

VDH VIRGINIA DEPARTMENT OF HEALTH



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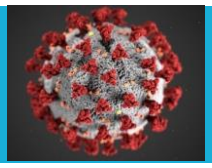

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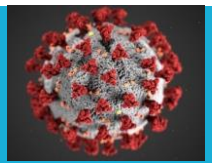

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A. COVID-19 Vaccination Campaign Guidance for Local Health Districts

B. Local Health District Tool for Identification of Critical Personnel for Early Vaccination

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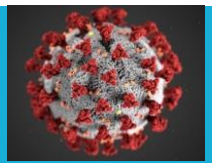

Record of Changes

Date of original version: September 22, 2020

Date Reviewed	Change Number	Date of Change	Description of Change	Name of Author
9/23/20	1	9/25/20	Clarified definition and roles/responsibilities of "jurisdictions" throughout	Planning Section based on State Epidemiologist review
10/1/20	2	10/1/20	Added limited information available regarding direct allocation to federal government entities and commercial pharmacies	Planning Section

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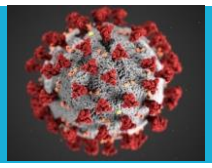

I. Planning Assumptions

A. COVID-19 Vaccine

- Limited COVID-19 vaccine doses may be available by early November 2020, but assuming a safe, effective vaccine(s) is developed, COVID-19 vaccine supply will increase substantially in 2021.
- Initially available COVID-19 vaccines will either be approved as licensed vaccines or authorized for use under an Emergency Use Authorization (EUA) issued by the U.S. Food and Drug Administration (FDA).
- Cold chain storage and handling requirements for each COVID-19 vaccine product will vary from refrigerated (2° to 8°C) to frozen (-20°C) to ultra-cold (-60º to -80ºC) temperatures, and ongoing stability testing may impact these requirements. *Note: These temperatures are based on information available as of August 26, 2020. Updated information will be provided as it becomes available.*
- Strategies are necessary to ensure the correct match of COVID-19 vaccine products and dosing intervals. For most vaccines, two doses of COVID-19 vaccine, separated by either >21 or >28 days, will be needed for immunity, and second-dose reminders for patients will be necessary. Both doses will need to match each other (i.e., be the same vaccine product).
- Some COVID-19 vaccine products will likely require reconstitution with diluent or adjuvant at the point of administration.

B. COVID-19 Vaccine Allocation

- The federal government will issue guidance on groups to prioritize for initial COVID-19 vaccination; populations of focus for initial COVID-19 vaccination will likely be:
  - Critical workforce that provides healthcare and maintains 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
- Allocation of COVID-19 vaccine to jurisdictions will be based on multiple factors, including:
  - Populations recommended by the Advisory Committee on Immunization Practices (with input from the National Academies of Science, Engineering and Medicine)
  - Current local spread/prevalence of COVID-19
  - COVID-19 vaccine production and availability
- Allocations may shift during the response based on supply, demand, and risk.
- Plans are needed for high-demand and low-demand scenarios.

C. COVID-19 Provider Outreach and Enrollment

- To receive and administer COVID-19 vaccine and ancillary supplies, vaccination providers must enroll in the United States Government (USG) COVID-19 vaccination program, coordinated through the VDH Division of Immunization, by signing and agreeing to conditions outlined in the *COVID-19 Vaccination Program Provider Agreement*.

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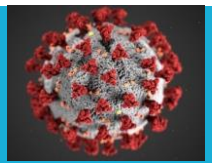


- CDC will make this agreement available to the VDH Division of Immunization for use in conducting outreach and enrolling vaccination providers. Jurisdictions will be required to maintain these agreements on file for a minimum of three years. Agreements can be paper or electronic.
- Some multijurisdictional vaccination providers (e.g., select large drugstore chains, Indian Health Service [IHS], and other federal providers) will enroll directly with CDC to order and receive COVID-19 vaccine. These direct partners will be required to report vaccine supply and uptake information back to each respective jurisdiction. CDC will share additional information when available on these procedures to ensure jurisdictions have full visibility for planning and documentation purposes.
- Routine immunization programs will continue.
- VDH will partner with commercial entities to reach the initial populations of focus. VDH currently has agreements for dispensing of vaccine and medications with large chain, small grocery store chain, and independent community commercial pharmacies such as Walgreens, Food City, and other stores. These existing relationships can be leveraged to expand vaccine availability.

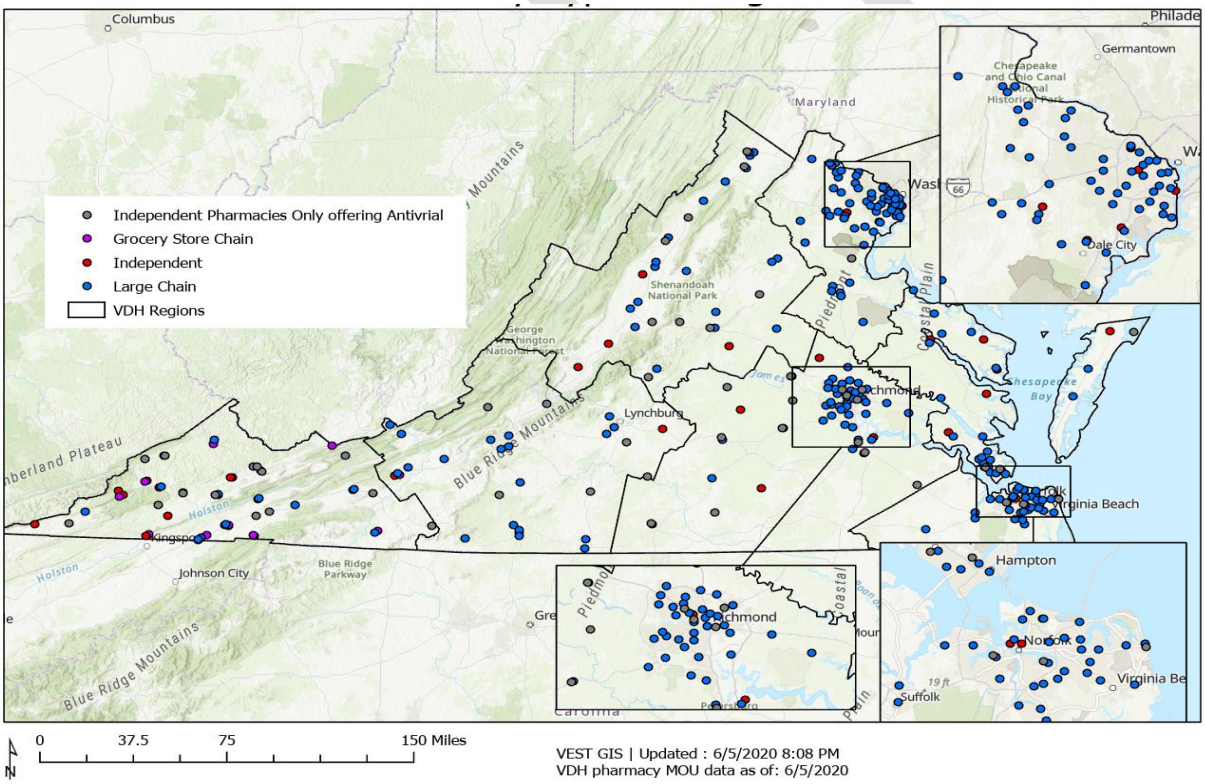
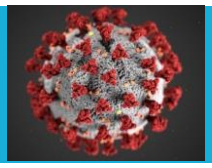


Figure 1: Locations of pharmacies with existing agreements with VDH

- CDC has provided a COVID-19 Vaccination Program Provider Agreement, a COVID-19 Vaccination Program Provider Profile Form, and a Supplemental COVID-19 Vaccine Redistribution Agreement. These documents must be used by VDH to begin enrolling facilities and organizations as COVID-



19 vaccination providers. VDH has developed an online COVID-19 Vaccine Provider Intent Form to facilitate this process.

- The CDC COVID-19 Vaccination Program Provider Agreement (section A of form) specifies the conditions of participation for vaccination provider organizations and their constituent facilities in the U.S. COVID-19 vaccination program. COVID-19 vaccine products will be available only to organizations that sign and agree to the conditions of this agreement. The agreement is between CDC and the organization and must be used by awardees to enroll COVID-19 vaccination provider organizations in the program. A signed CDC COVID-19 Vaccination Program Provider Agreement is required for any organization to receive delivery of any COVID-19 vaccine from CDC's distributor or a COVID-19 vaccine manufacturer. The CDC COVID-19 Vaccination Program Provider Agreement is also applicable for government-affiliated providers at any level (local, state, territorial, and federal) to receive COVID-19 vaccine.
    - The medical (or equivalent role) and chief executive officer(s) (or chief fiduciary) signing this agreement must be the individuals who will be held accountable for and responsible for compliance with the conditions outlined in the agreement. The language, format, or order of this agreement may not be edited by any person, including an awardee. However, CDC may update the agreement language, as necessary.
    - Failure of any enrolled COVID-19 vaccination provider organization or vaccination location under its authority to meet the conditions of the agreement may impact whether COVID-19 vaccine product orders are fulfilled and may result in legal action by the federal government.
- The CDC COVID-19 Vaccination Program Provider Profile Form (section B of form) outlines key minimum data elements required by CDC to be collected from every vaccination provider location receiving COVID-19 vaccine and constituent products, such as receiving site address information, practice type, and patient population size and volume. These data elements must be collected, compiled, and reported to CDC by awardees for every location where patients will be vaccinated, whether the location receives directly shipped or redistributed COVID-19 vaccine. The vaccine coordinator listed on this form is the individual who will be responsible for receiving vaccine shipments, monitoring storage unit temperatures, managing inventory, etc. This form must be fully completed, and the medical/pharmacy director or vaccine coordinator must provide signature attesting to the ability of any listed COVID-19 vaccine storage units to maintain required temperature ranges. The language, format, or CDC-required data elements included in this form may not be edited by any person, including VDH; however, VDH may add other provider profile variables beyond those listed on this form or use an VDH-developed supplemental form to collect information, as needed, for internal awardee planning purposes.
    - When an enrolled provider (e.g., local health department) takes vaccine off-site to a temporary location for a one-day vaccination clinic, it is not necessary to complete a provider agreement for that location. The provider - on Section B - should have indicated that a temporary/off-site setting would be used for vaccine administration. However, if an enrolled provider is taking vaccine repeatedly to a particular location, then a Section B is needed for that location.

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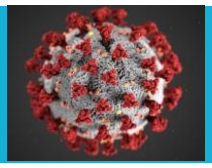

- The CDC Supplemental COVID-19 Vaccine Redistribution Agreement outlines conditions for any potential redistribution (a.k.a. secondary distribution) of COVID-19 vaccine beyond the organization locations identified as primary CDC ship-to locations. This redistribution process may be used when providers will utilize fewer than the minimum number of doses which can be direct-shipped, and when maintenance of the cold chain can be assured. The language, format, or order of this agreement may not be edited by any person, including VDH, though CDC may update the agreement language, as necessary.
    - VDH will only furnish this form to those organizations that they approve to redistribute COVID-19 vaccine. For each location receiving redistributed COVID-19 vaccine, constituent products, and ancillary supplies, a fully completed CDC COVID-19 Vaccination Program Provider Agreement and CDC COVID-19 Vaccination Program Provider Profile form must also be completed, and the medical/pharmacy director or vaccine coordinator must provide signature attesting to the ability of any listed COVID-19 vaccine storage units to maintain required temperature ranges. CDC does not pay for or reimburse VDH, COVID-19 vaccination provider organizations, facilities, or other entities for any redistribution beyond the initial designated primary CDC ship-to location, or for any vaccine-specific portable refrigerators and/or qualified containers and pack-outs.
- VDH responsibilities:
    - Validate the professional licensure information for each prescriber (e.g., MD, DO, RPh/PharmD, NP, PA) listed in Section B.
    - Submit to CDC COVID-19 vaccination provider enrollment data twice a week (i.e., Monday and Thursday by 9:00pm EST), including all data elements described above.
    - Forms may be completed electronically and incorporated into the immunization information system (IIS) or other system used for enrollment.
    - As a component of the enrollment process, VDH must instruct enrolled COVID-19 vaccination providers on how to report temperature excursions as well as any unused, spoiled, expired, or wasted vaccine or adjuvant doses.
    - Awardees must maintain records of COVID-19 vaccine and constituent products redistributed beyond the primary COVID-19 vaccination provider locations, even if redistribution is conducted by third-party vendor(s) or COVID-19 vaccination providers, and report this information to CDC, as requested.

To be determined:

- Specific multijurisdictional providers to be served directly by CDC
- Jurisdiction responsibility/involvement concerning multijurisdictional provider training
- Provider reimbursement for administration fees, etc. VDH has had preliminary discussion with a Pharmacy Benefits Manager (PBM) and is preparing to stand up a system if the federal government does not provide a tool/funding (similar to what was put in place for testing). CDC has mentioned direct engagement with large pharmacy chains; there may be a need for a PBM to focus on smaller pharmacies.

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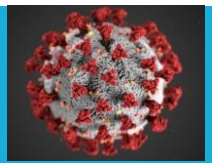

- Specific tasks for the COVID-19 Vaccine External Advisory Workgroup, Virginia Disaster Medical Advisory Committee, Board of Health, etc. in allocation determinations.

D. COVID-19 Vaccine Ordering and Distribution

- COVID-19 vaccine and ancillary supplies will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers. CDC will share more information about reimbursement claims for administration fees as it becomes available.
- CDC will use its current 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, will be shipped directly from the manufacturer.
- VDH-enrolled COVID-19 vaccination providers will follow VDH's vaccine ordering procedures.
- COVID-19 vaccination providers will be required to report ongoing COVID-19 vaccine inventory.
- Vaccine orders will be approved and transmitted in CDC's Vaccine Tracking System (VTrckS) by the VDH Division of Immunization for vaccination providers VDH enrolls.
- Vaccine (and adjuvant, if required) will be shipped to provider sites within 24 hours of order approval by the VDH immunization program if supply is available. Ancillary supply kits and diluent (if required) will ship separately from the vaccine due to different cold chain requirements, but the shipment will be timed to arrive with or before the vaccine.
- Ancillary supply kits will include needles, syringes, alcohol prep pads, COVID-19 vaccination record cards for each vaccine recipient, and a minimal supply of personal protective equipment (PPE), including surgical masks and face shields, for vaccinators.
    - Each kit will include supplies needed to administer 100 doses of vaccine.
    - For COVID-19 vaccines that require reconstitution with diluent or mixing adjuvant at the point of administration, these ancillary supply kits will include additional necessary syringes, needles, and other supplies for this purpose.
    - Sharps containers, gloves, bandages, and other supplies will not be included.
- Plans are needed for additional PPE and depend on vaccination site needs.
    - Unified Command has approved a funding request to support PPE for public health vaccination efforts. This PPE will be provided to local health districts through the existing PPE distribution model.

To be determined:

- Frequency requirement for provider-level COVID-19 vaccine inventory reporting
- Vaccine disposal/recovery procedures

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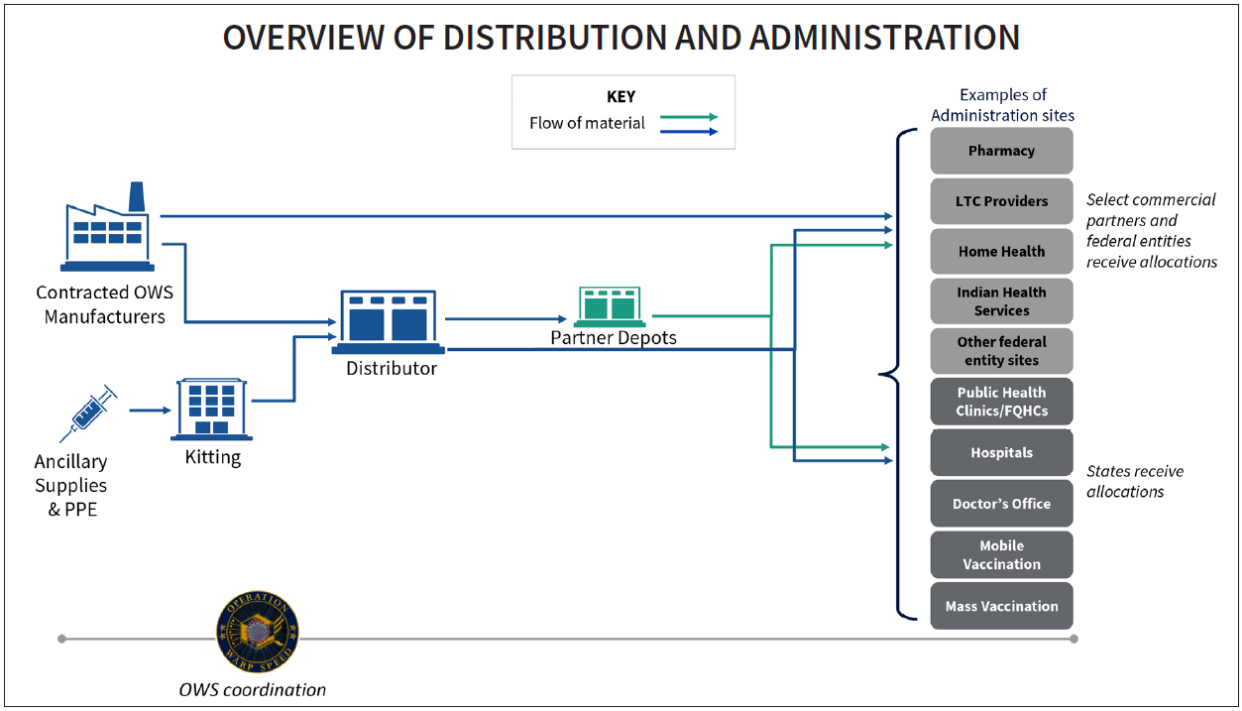
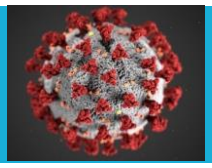


Figure 2: CDC/OWS Overview of Distribution and Administration

E. COVID-19 Vaccine Administration Data Reporting

- VDH will be required to report CDC-defined data elements related to vaccine administration daily (i.e., every 24 hours). CDC will provide information on these data elements to jurisdictions.
- All vaccination providers may be required to report and maintain their COVID-19 vaccination information on CDC's Vaccine Finder.
- CDC's Vaccine Administration Management System (VAMS) will be available to VDH/provider sites that need assistance in patient registration and scheduling, clinic flow, supply management, patient record management, and reporting.
- CDC has prioritized jurisdiction onboarding to the Immunization (IZ) Gateway* to allow Immunization Information Systems (IISs) to receive data directly from national providers, nontraditional vaccination providers, and VAMS, as well as to report vaccine administration data to CDC.
- Data Use Agreements (DUAs) will be required for data sharing via the IZ Gateway and other methods of vaccine administration data sharing with CDC and will be coordinated by each jurisdiction's immunization program.

** The IZ Gateway is a portfolio of project components that share a common IT infrastructure. The IZ Gateway aims to rapidly onboard IISs to support readiness for COVID-19 vaccine response through data exchange, both among IIS and between IIS and federal providers, mass vaccination*



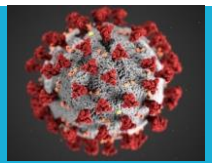
reporting, and consumer access tools. The IZ Gateway aims to increase the availability and volume of complete and accurate immunization data stored within IIS and available to providers and consumers regardless of their jurisdictional boundaries.

F. Communication

- CDC will develop communication resources for jurisdictions to use with key audiences. These resources will be available on a public-facing website currently under development, but VDH and the Joint Information Center (JIC) will need to tailor messaging and resources specific to special populations.
- CDC will work with national organizations to disseminate key messages.
- VDH will work with stakeholders across the state to develop and disseminate targeted key messages.
- Communication and educational materials about COVID-19 vaccination provider enrollment, COVID-19 vaccine ordering, COVID-19 vaccine storage, handling, administration (i.e., reconstitution, adjuvant use, administration techniques), etc. will be available in a variety of formats.
- When vaccine supply is available for expanded groups among the general population, a national COVID- 19 vaccine finder will be available on the public-facing CDC Vaccine Finder webpage.
- A screening tool on the CDC website will help individuals determine their own eligibility for COVID-19 vaccine and direct them to the Vaccine Finder.

G. COVID-19 Vaccine Safety

- Clinically important adverse events following any vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).
- 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 the EUA.
- The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of covered countermeasures identified in and administered or used under a PREP Act declaration. The CICP also may provide benefits to certain survivors of individuals who die as a direct result of the administration or use of such covered countermeasures. The PREP Act declaration for medical countermeasures against COVID-19 states that the covered countermeasures are:
    - Any antiviral, any other drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine, used:
        - To treat, diagnose, cure, prevent, mitigate, or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or
        - To limit the harm that COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, might otherwise cause; or



- Any device used in the administration of any such product, and all components and constituent materials of any such product.

- Covered countermeasures must be "qualified pandemic or epidemic products," or "security countermeasures," or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the Federal Food, Drug, and Cosmetic Act (FD&C Act), and the Public Health Service Act, or a respiratory protective device approved by National Institute for Occupational Safety and Health (NIOSH) under 42 CFR part 84, or any successor regulations, that the Secretary of the Department of Health and Human Services determines to be a priority for use during a public health emergency declared under section 319 of the Public Health Service Act. For more information about the CICP, visit the program's website at www.hrsa.gov/cicp, email cicp@hrsa.gov, or call 1-855-266-CICP (1-855-266-2427).

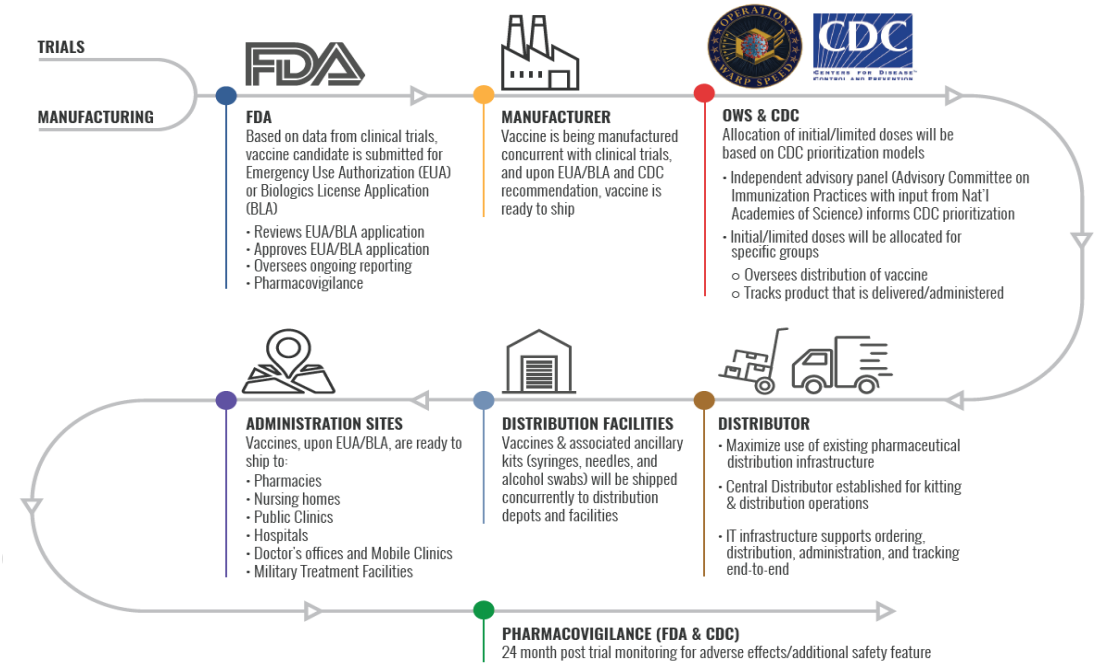
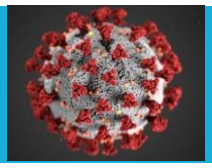


Figure 3: Operation Warp Speed Vaccine Distribution Process



II. Organization and Assignment of Responsibilities

A. Unified Command System

- In March 2020, the Commonwealth of Virginia established a Unified Command System to manage the state-level response to COVID-19.
- The current incident objectives, as determined by the Unified Command, include:
    - **Testing**: Further develop and implement a sustainable infrastructure that supports public health and private sector SARS-CoV-2 testing strategies.
    - **Surveillance and Investigation**: Continue to conduct surveillance, case investigation and contact tracing to contain the spread of SARS-CoV-2.
    - **Community Mitigation:** Based on review of public health data, continue to evaluate the need for implementation of community mitigation strategies (e.g. face coverings, physical distancing, etc.) in communities experiencing moderate-substantial community transmission. Continue to provide public health consultation on plans to implement risk mitigation strategies in community settings.
    - **Behavioral and Mental Health**: Develop and support strategies that mitigate the impact of stressors on the public and healthcare providers/first responders (i.e. deteriorating health of self, loved one, or patients; job loss; disruption in daily activities).
    - **Medical Surge**: Continue to support and refine medical surge plans in collaboration with hospitals, long-term care facilities, correctional facilities and other congregate settings.
    - **Medical Countermeasures**: Develop a plan and prepare for the statewide distribution of and dispensing of COVID-19 vaccines (and /or other medical countermeasures, e.g. antivirals).
    - **Resource Management**: Maintain and adapt strategies to ensure supplies of goods and services can meet an evolving demand environment. (i.e. new community spread or a second wave). Commence stockpiling of PPE, laboratory testing equipment, vaccination ancillary supplies and/or other medical goods for future response.
    - **Public Communications:** Develop and implement appropriate communications and media campaign strategies to inform the response of partners and the general public (i.e. provider training, business planning, getting tested, wearing a mask/social distancing, and vaccination).
    - **Operational Flexibility**: Be prepared to respond simultaneously to additional threats to include hurricanes and other weather related events in the SARS-CoV-2 environment.
    - **Recovery**: Return economic, employment and business activities to a healthy state and restore and improve health and social services capabilities and networks to promote the resilience, independence, health (including behavioral health), and well-being of the whole community.

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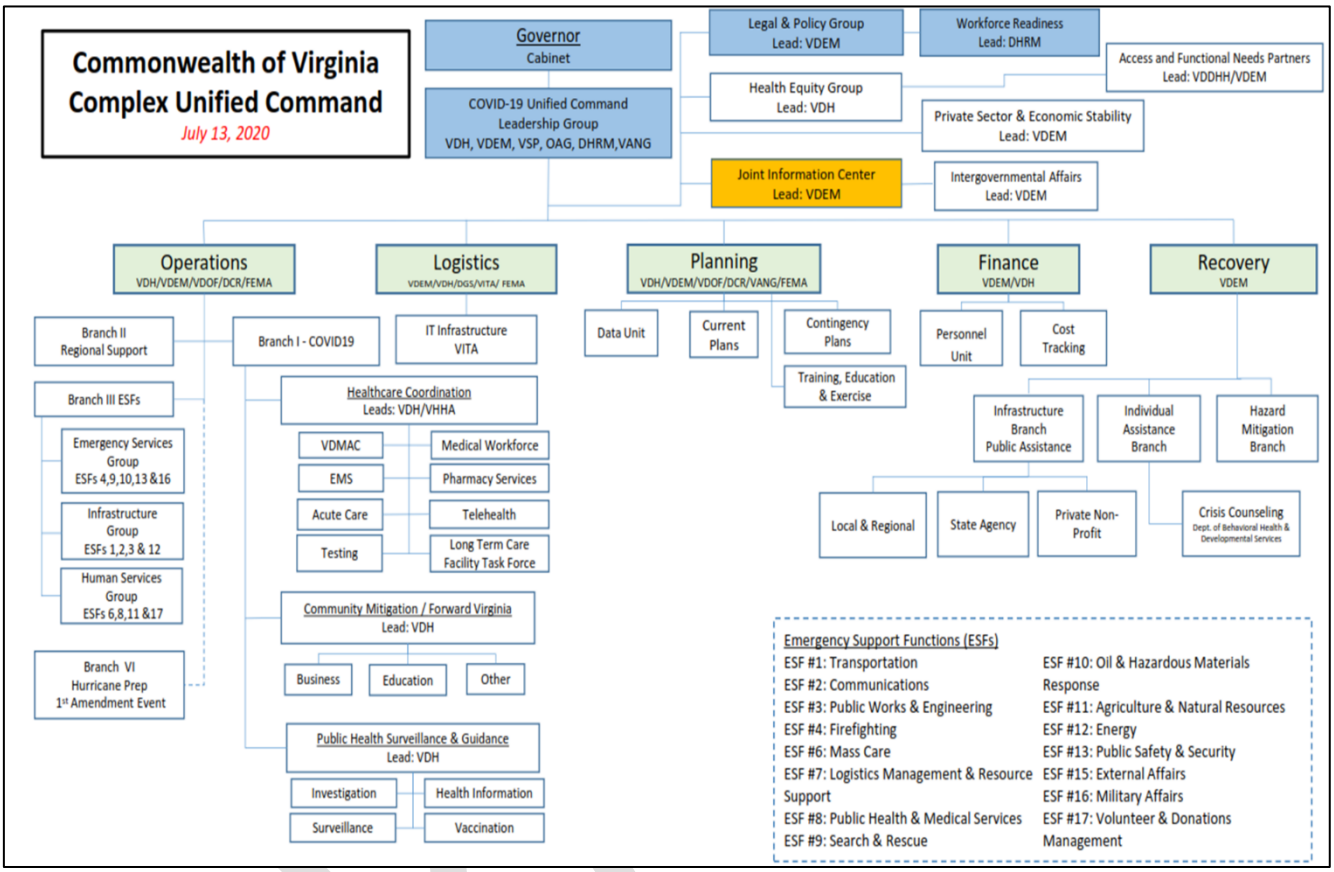
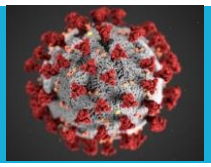


Figure 4: Commonwealth of Virginia COVID-19 Unified Command Structure

- A Vaccine Unit was formed under the Public Health Surveillance and Guidance Workgroup of the Commonwealth's unified command structure in June 2020 to conduct internal planning and coordination. This unit includes representatives from the immunization program, preparedness program, emergency management agency, healthcare preparedness program, media/public affairs, and emergency risk communications to develop plans and coordinate activities.



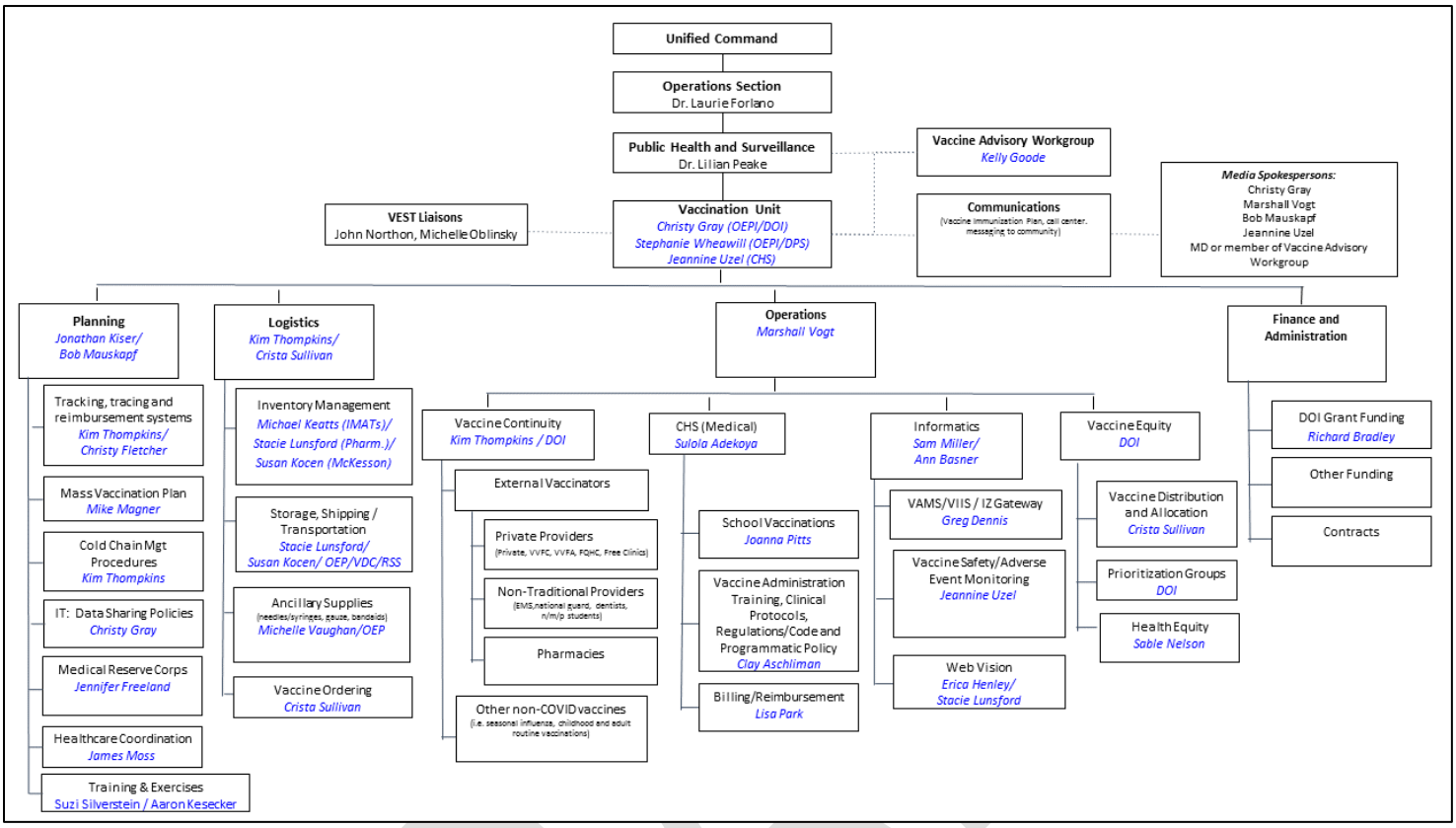
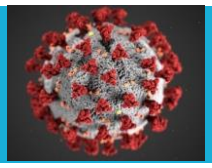


Figure 5: Commonwealth of Virginia COVID-19 Unified Command Structure, Vaccine Unit

- A COVID-19 Vaccine Advisory Workgroup was established in August 2020. The purpose of the Advisory Workgroup is to provide key stakeholder input to vaccine plans and to provide input on vaccine priority groups, vaccine equity, and other related issues. The Advisory Workgroup consists of:
    - Community members with expertise in care and access issues for critical populations to enhance the development of plans, reach of activities, and risk/crisis response communication messaging and delivery.
    - Representatives from key vaccination providers for groups identified by CDC as being at increased risk of severe COVID-19 and others likely to be prioritized for initial vaccination.
    - Representatives from other sectors within the community, such as health systems, pharmacies, long-term care/assisted living facilities, business, education, corrections, religious, tribal, and racial and ethnic minority-serving organizations, etc.

B. State and Local Public Health Coordination

The Virginia Department of Health consists of 33 local health districts, with each health district supporting one or more local jurisdictions. These local health districts report to the State Health Commissioner



through the Deputy Commissioner for Community Health Services. Additionally, there are two health districts (Fairfax and Arlington) that are locally funded and operated, and not part of VDH. They are, however, closely affiliated with VDH and perform certain state mandated services to include public health emergency preparedness, response, and recovery. VDH has included federal funding for public health emergency personnel in these locally administered districts.

Virginia's local health districts work closely with the localities that they support and include local health departments for those jurisdictions. In addition to serving as stand-alone plans, local health district emergency preparedness, response and recovery plans support their local Emergency Operations Plans (EOPs) and the VDH Emergency Preparedness Response and Recovery Plan and its annexes.

For preparedness and response purposes, the VDH has further organized the 35 health districts into five regions. Each region has a regional team consisting of an Emergency Coordinator, an Epidemiologist, and a Public Information Officer. These teams provide technical assistance to the districts and augment district staffing as necessary during times of emergency.

C. Preparedness Gap Analysis

The Vaccine Unit conducted a gap analysis of existing plans, personnel, supplies, equipment, storage, transportation, and other requirements.

- **Equipment:** The Vaccine Unit estimates a total of $2,493,535 will be required to support the purchase of equipment such as vaccine refrigerators and freezers, temperature data loggers, thermometers, and portable units to support vaccine transportation.
- **Ancillary Supplies:** The Vaccine Unit estimates a total of $3,367,598 will be required to support purchase of ancillary supplies such as syringes, needles, alcohol prep pads, band-aids, sharps containers, emergency medical kits, and dry ice.
- **Information Management Staffing:** The Vaccine Unit estimates a total of $399,000 will be required to support additional staffing for the VDH Office of Information Management. These three temporary, contract positions will be responsible for developing and maintaining multiple ".net" applications in support of the messaging team.
- **Pharmacy Benefits Administrator:** The Vaccine Unit estimates a total of $39,952,000 will be required for a pharmacy benefits administrator to manage claims for uninsured and underinsured Virginians as well as provide payment to pharmacists and other community providers for administering vaccines.
- **Mass Vaccination Support for Local Health Districts:** The Vaccine Unit estimates a total of $71,041,125 will be required to support local health districts with establishing and operating mass vaccination clinics. This funding will support the hiring of temporary, contract positions (both medical and non-medical), travel costs, facility rental costs, printing, signage, translation services, and other associated costs of operating these clinics to ensure Virginians have access to vaccine in their communities.

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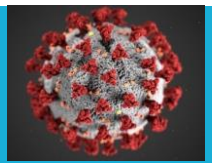


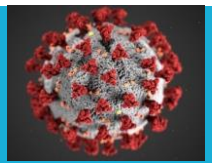
- **Warehousing and Shipping:** The Vaccine Unit estimates a total of $700,000 will be required to support warehousing and shipping of ancillary supplies as well as modifications to the DGS warehouse to ensure efficient operations and meet Board of Pharmacy requirements for medical equipment storage.
- **Communications Campaign:** The Vaccine Unit estimates a total of $3,000,000 will be required to support a public education campaign to enhance vaccine coverage rates. The public education campaign will include television, social media, radio, websites, billboards, etc. as well as targeted outreach to clinicians, vulnerable populations, and other key groups.
- **Planning Gaps:** The Vaccine Unit identified the need for Districts to update existing Point of Dispensing (POD) and Closed POD (CPOD) plans to account for the planning assumptions listed in Section I of this document and to comply with CDC guidelines for safe vaccination during COVID-19, Forward Virginia reopening guidelines, and COVID-19 Vaccination Scenarios for Jurisdictional Planning—Phase 1, Q4 2020.
- **Education Seminar and Tabletop Exercises:** VDH will conduct an educational seminar and tabletop exercise (TTX) with state agency partners and state leadership to test and refine preliminary plans.

D. Tribal Communities

Although CDC is working directly with the Indian Health Service (IHS) at the federal level, plans have not been finalized. It is important that VDH include tribal leaders and tribal organizations in their planning efforts. While IHS may provide vaccination services to the populations they serve, plans are currently in development regarding vaccine distribution to tribal health facilities, including urban facilities, that are not officially connected to IHS. Those facilities may need to work through VDH local health districts to receive vaccine. It is also critical that local health districts reach out to any non-federally recognized tribes in their area to ensure they have access to vaccination services, since these groups will likely not be served by IHS.

E. Roles and Responsibilities

- **Vaccine Unit – Public Health Surveillance and Guidance Group**
  - Oversee all vaccination efforts in collaboration with local health districts and Unified Command/VEST partners
  - Serve as primary liaison with CDC/ASPR/HHS
  - Secure available quantities of vaccine for priority groups
  - Ensure equitable distribution of vaccine to providers serving priority groups
  - Ensure vaccine is distributed to pre-identified providers
  - Support local health districts with facilitation of clinics/PODs for priority groups including vulnerable populations
  - Continue to work with community partners, healthcare providers, targeted populations, local health districts, and immunization coalitions to promote and enhance vaccination levels for seasonal influenza and other vaccine-preventable diseases



  - Keep the healthcare and public health community up-to-date on anticipated vaccine availability
  - Mobilize response partners and prepare to activate plans for receiving, distributing, and administering vaccines
  - Accelerate training for vaccination and vaccine monitoring for public health staff and for partners responsible for vaccinating priority groups
  - Modify plans as needed to account for updated interim recommendations on priority groups, projected vaccines, and timelines for availability
  - Monitor and investigate adverse events
- **VDH Office of Epidemiology – Division of Immunization**
  - Serve as the lead for all VDH COVID-19 vaccination operations
  - Manage vaccine tracking and ordering systems
  - Manage provider enrollment in COVID-19 vaccination program, and monitor execution of Provider Agreements
  - Monitor providers request for vaccine and transmit orders in the CDC's Vaccine Tracking System (VTrckS)
  - Provide periodic data and reports as required
  - Monitor vaccine safety and efficacy; report vaccine adverse events to the CDC/FDA Vaccine Adverse Event Reporting System (VAERS)
- **VDH Office of Epidemiology - Division of Pharmacy Services**
  - Identify all vaccine and ancillary supply storage requirements, to include cold-chain storage
  - Procure storage space for vaccine and supplies, ensuring all storage locations comply with Board of Pharmacy Requirements
  - Coordinate with Unified Command Logistics for purchase or contracting of all required supplies and spaces
- **VDH Office of Emergency Preparedness**
  - Provide vaccination campaign planning support
  - Estimate and submit funding requests to support campaign efforts
  - Conduct Situation Reporting throughout the campaign to support decision-making efforts
  - Help coordinate Health District vaccination efforts
  - Identify priority group members among state-level emergency responders
  - Support the deployment of members of the agency's Medical Reserve Corps (MRC) in assisting with Points of Dispensing operations
  - Develop training to support safe vaccine storage and handling, to include dry ice handling
  - Serve as the Virginia Liaison Officer between the VEST and CDC/ASPR/HHS and FEMA
  - Coordinate and liaise with the Virginia Hospital and Healthcare Association (VHHA) and regional healthcare coalitions

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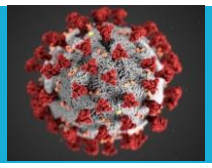

- **VDH Office of Community Health Services**
  - Provide vaccination safety guidelines and policies
  - Provide vaccinator education, training, and certification requirements
  - Help coordinate Health District vaccination efforts
- **VDH Office of Communications**
  - Provide communications and messaging support to each phase of the vaccination campaign
  - Coordinate messaging strategy with Unified Command Joint Information Center (JIC), and Regional and Health District Public Information Officers
- **VDH Office of Procurement and General Services**
  - Provide procurement and contracting support to Vaccine Unit and local health districts
- **Local Health Districts**
  - Assist with recruitment and referral of local vaccine providers into the COVID-19 Vaccination Program
  - Identify priority groups and group members within the District, and develop plans for prioritized vaccination of these group members during Phase I of the campaign
  - Develop and execute strategies for mass vaccination of priority groups and the general population during Phase II, with special emphasis on underserved and underrepresented population groups
  - Compile list of qualified staff that can administer vaccine or otherwise assist with vaccination efforts (site set up, data entry, etc.)
  - Compile list of volunteers from other agencies/organizations within their districts that can assist with vaccination efforts
  - Identify additional vaccine storage capacity
  - Review and update standard operating procedures and plans for mass vaccination clinics
  - Ensure accurate data reporting on vaccine supply, vaccine recipients, and other data as required
  - Mobilize response partners and prepare to activate plans for receiving, distributing, and administering vaccines
  - Verify that plans, agreements, systems, and supplies are in place to reach priority groups
  - Update existing Point of Dispensing (POD) and Closed POD (CPOD) plans to account for the planning assumptions listed in Section I of this document and to comply with CDC guidelines for safe vaccination during COVID-19, Forward Virginia reopening guidelines, and COVID-19 Vaccination Scenarios for Jurisdictional Planning—Phase 1, Q4 2020
  - Ensure district staff participating in COVID-19 vaccination clinics are trained
  - Conduct vaccination clinics
  - Conduct outreach to hard-to-reach populations to promote and provide vaccination

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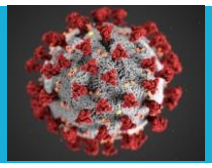

- **VDH Office of Family Health Services**
  - Provide staffing support to the Receipt, Store, and Stage (RSS) site as outlined in the RSS Field Operations Guide to support distribution of ancillary supplies, as needed.
- **VDH Office of Health Equity / Health Equity Working Group**
  - Develop/modify Health Equity Guidebook to provide guidance related to providing culturally appropriate community vaccination services in a manner that is inclusive of elevated-risk individuals and communities
  - Ensure decisions are made with a health equity lens
  - Provide data to ensure vulnerable populations are reached
- **Virginia Department of Emergency Management (VDEM)**
  - Coordinate Virginia Emergency Support Team (VEST) activities
  - Provide logistical support through Disaster Logistics
  - Provide GIS support to assist with identifying critical populations and facilities
  - Liaise with VDH Office of Communications to ensure consistent state-wide messaging and media campaign via the Joint Information Center (JIC)
  - Process requests for assistance from localities through Chief Regional Coordinators
- **Virginia State Police (VSP)**
  - Provide security and traffic control, as needed, to local PODs
- **Virginia Department of General Services (DGS)**
  - Provide facility space to store and distribute ancillary supplies, as needed
- **Virginia National Guard**
  - Provide back-up security support to VSP, as needed
  - Provide transportation and communication assets, as needed
  - Provide non-medical support to points of dispensing (logistical support, equipment, staffing, etc.)
- **Virginia Department of Medical Assistance Services**
  - Establish systems and procedures for reimbursement of healthcare providers administering vaccine, if needed
- **Virginia Department of Health Professions**
  - Support VDH with communication to healthcare providers
  - Develop emergency regulations, as required
  - Ensure Board of Pharmacy, Board of Medicine, and other Boards are kept informed and regulations are adhered to
- **Virginia Department of Corrections**
  - Plan for the vaccination of correctional facility staff and inmates (refer to Closed POD plan)
- **Virginia Department of Social Services**
  - Plan for vaccination of adult daycare, assisted living facilities, and other facilities regulated by VDSS, in coordination with Local Health Districts.
- **Virginia Department of Education**

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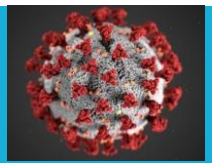

    - Plan for vaccination of school staff and students, in coordination with Local Health Districts.
- **State Council of Higher Education for Virginia**
    - Plan for vaccination in institutions of higher education, in coordination with Local Health Districts.
- **Virginia Department of Behavioral Health & Developmental Services**
    - Plan for vaccination of behavioral health hospitals and facilities and other facilities regulated by DBHDS, in coordination with Local Health Districts.
- **Private providers (hospitals, healthcare systems, nursing homes, doctors offices, pharmacies, etc.)**
    - Enroll intent to provide COVID-19 vaccine with VDH
    - Sign CDC COVID-19 Vaccination Program Provider Agreement
    - Complete CDC COVID-19 Vaccination Program Provider Profile Form
    - Complete any required training
    - Activate PODs to vaccinate target staff, residents, and/or patients
    - Administer vaccines to population once widely available
    - Leverage existing corporate relationships/partnerships to provide vaccination support to one another

III. Campaign Strategy

A. Summary

Immunization with a safe and effective COVID-19 vaccine is a critical component of the United States strategy to reduce COVID-19-related illnesses, hospitalizations, and deaths and to help restore societal functioning. The goal of the U.S. government is to have enough COVID-19 vaccine for all people in the United States who wish to be vaccinated. Early in the COVID-19 Vaccination Program, there may be a limited supply of COVID-19 vaccine, and vaccination efforts may focus on those critical to the response, providing direct care, and maintaining societal function, as well as those at highest risk for developing severe illness from COVID-19.

B. Key Objectives

In order to ensure Virginians are adequately protected from COVID-19, the Virginia Department of Health and the Commonwealth's Unified Command will:

- Ensure equitable vaccination access to vaccination services.
- Monitor COVID-19 vaccine uptake and coverage in critical populations and enhance strategies to reach populations with low vaccination uptake or coverage.
- Partner with commercial and private entities to ensure COVID-19 vaccine and vaccination services are widely available.
- Monitor supply and repositioning of refrigerated vaccine products to minimize vaccine wastage

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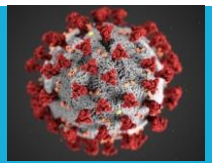

- Establish information systems that can track and report vaccine doses from receipt through distribution and dispensing, and that can track individual patient immunization data.
- Identify critical populations that must receive the initial vaccine doses while vaccine is still in limited supply and establish plans to immunize these populations as soon as the vaccine is available.
- Communicate effectively to all Virginians, across all demographics, abilities, and languages, to promote uptake of vaccine and counter anti-vaccination narratives.
- Partner with the private healthcare sector to maximize the number of vaccine providers in the community to ensure maximum opportunity for vaccinations.
- Focus public health vaccination efforts on people with limited access to vaccination services, including underserved communities, people underinsured or without health insurance, individuals with disabilities, homeless populations, etc.

C. Campaign Phases

Due to changing vaccine supply levels at various points during the COVID-19 Vaccination Program, planning needs to be flexible but as specific as possible to accommodate a variety of scenarios. A key point to consider is that vaccine supply will be limited at the beginning of the program, so the allocation of doses must focus on vaccination providers and settings for vaccination of limited critical populations as well as outreach to these populations. The vaccine supply is projected to increase quickly over the following months, allowing vaccination efforts to be expanded to additional critical populations and the general public. It is important to note that recommendations on the various population groups to receive initial doses of vaccine could change after vaccine is available, depending on each vaccine's characteristics, vaccine supply, disease epidemiology, and local community factors.

Final decisions are being made by CDC about use of initially available supplies of COVID-19 vaccines. These decisions will be partially informed by the proven efficacy of the vaccines coming out of Phase 3 trials, but populations of focus for initial COVID-19 vaccination may include:

- Healthcare personnel likely to be exposed to or treat people with COVID-19.
- People at increased risk for severe illness from COVID-19, including those with underlying medical conditions and people 65 years of age and older
- Other essential workers

This plan will be carried out in three phases:

- **Phase I: Limited doses of vaccine available**
  - This phase will involve a highly targeted campaign to immunize critical infrastructure workforce and persons with the highest risk of severe illness.
  - Most vaccination events in this phase will be Closed Point of Dispensing (CPOD) events for specific groups.

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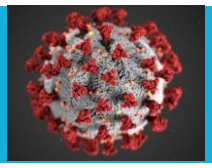
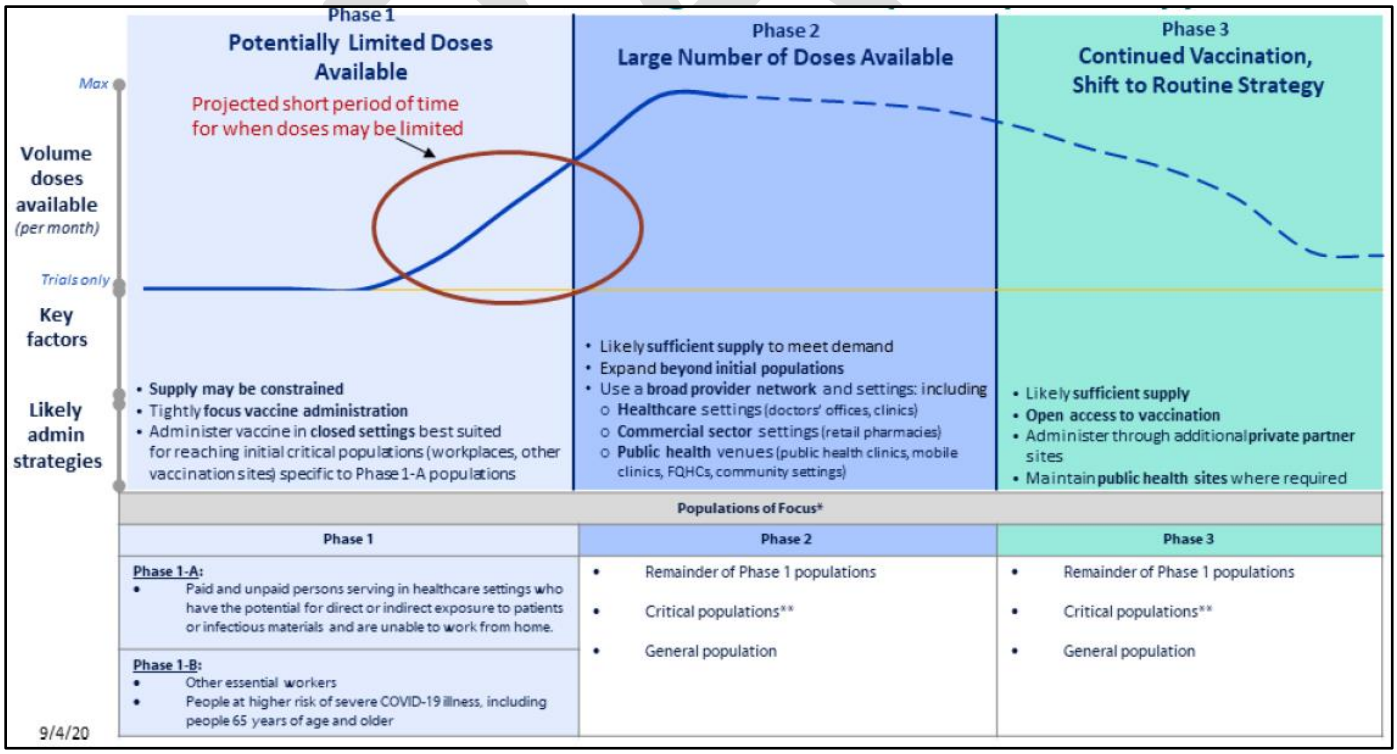


- Public communications during this phase will emphasize the need to prioritize limited supplies for critical populations while assuring the general public that additional supplies of the vaccine will be on the way soon.

- **Phase II: Sufficient supply to meet demand**
  - This phase marks the transition from vaccinating critical populations to vaccinating the general public.
  - Administration through commercial and private sector partners will occur during this phase.
  - Large open/community PODs and mobile vaccination events will occur during this phase.
  - Public Health focused events on underserved and hard to reach populations will also take place during this phase.
  - Public Health messaging will encourage all Virginians to get vaccinated, counter anti-vaccine narratives, and include appropriate targeted messaging campaigns for specific demographics (i.e., race, ethnicity, age groups, etc.).

- **Phase III: Sufficient supply of vaccine doses for entire population (surplus of doses)**
  - The public health vaccination effort will ramp down.
  - Vaccine will continue to be available in the private sector.
  - Annual booster vaccinations for SARS-COV-2 may be required.



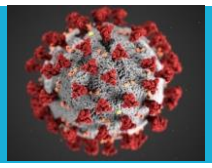


Figure 6: CDC Anticipated Vaccine Distribution Phases

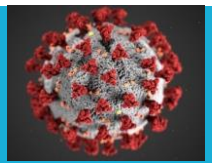
D. Seasonal Influenza

Annual influenza vaccination is recommended for all persons age 6 months and older to decrease morbidity and mortality caused by influenza. Healthcare providers should consult current influenza vaccine recommendations for guidance around the timing of administration and use of specific vaccines. During the COVID-19 pandemic, reducing the overall burden of respiratory illnesses is important to protect vulnerable populations at risk for severe illness, the healthcare system, and other critical infrastructure. Thus, healthcare providers should use every opportunity during the influenza vaccination season to administer influenza vaccines to all eligible persons, including:

- *Essential workers*: Healthcare personnel, including nursing home, long-term care facility, and pharmacy staff, and other critical infrastructure workforce
- *Persons at increased risk for severe illness from COVID-19*: Including older adults (risk of severe illness increases with age), residents in a nursing home or long-term care facility, persons of all ages with certain underlying medical conditions. Severe illness from COVID-19 has been observed to disproportionately affect members of certain racial/ethnic minority groups
- *Persons at high risk for influenza complications*: Including infants and young children, children with neurologic conditions, pregnant women, adults age 65 years and older, and other persons with certain underlying medical conditions

Routine vaccination should be deferred for persons with suspected or confirmed COVID-19, regardless of symptoms, until criteria have been met for them to discontinue isolation. While mild illness is not a contraindication to vaccination, vaccination visits for these individuals should be postponed to avoid exposing healthcare personnel and other patients to the virus that causes COVID-19. When scheduling or confirming appointments for vaccination, patients should be instructed to notify the provider's office in advance if they currently have or develop any symptoms of COVID-19.

Vaccination in the medical home is ideal to ensure that patients receive other preventive services that may have been deferred during the COVID-19 pandemic. However, vaccination at locations outside the medical home may help increase access to vaccines in some populations or situations, particularly when the patient does not have a primary care provider or when care in the medical home is not available or feasible. Regardless of vaccination location, best practices for storage and handling of vaccines and vaccine administration should be followed. In addition, information on administered vaccines should be documented (e.g., through the state-based immunization information system [IIS], patient's electronic medical record, client-held paper immunization records) so that providers have accurate and timely information on their patients' vaccination status and to ensure continuity of care in the setting of COVID-19-related disruptions to routine medical services.



IV. Vaccine Information Systems & Reporting Requirements

A. Vaccine Information Systems

1. CDC's Vaccine Administration Management System (VAMS):
    a. During the early phase of the COVID-19 immunization campaign, Health Districts (and private providers) will order and track delivery of their vaccine using VAMS.
    b. VAMS is a secure, online tool to manage vaccine administration from the time the vaccine arrives at a clinic through vaccine administration.
    c. VAMS is free for public-health-approved clinics and can be used on computers, tablets, and other mobile devices.
    d. VAMS is not a smartphone app, and no installation or download is required for this web-based platform.
    e. VAMS will be able to share near real-time data with IISs through the Immunization (IZ) Gateway. Healthcare providers will be able to query data for electronic health records (EHRs) from the IIS.
    f. Data access will be protected and secure, with the VDH Division of Immunization (DOI) establishing who has access to its data.
    g. VAMS will allow real-time or near-real-time data on early COVID-19 vaccination in mass vaccination clinics to CDC.
    h. VAMS Modules:
        i. DOI Module
            1. DOI sets up "Employers" and "Clinics"
            2. "Employers" are those organizations that hire persons in the Tier 1 categories (i.e., critical healthcare or infrastructure workers) – this may be a hospital or an electric utility company – whatever the DOI deems to be critical infrastructure.
            3. Health Districts should work with DOI and ESF-8 partners to determine the list of employers that will be included for vaccination during Phase I, and enter those employer organizations in VAMS.
            4. DOI decides which "clinics" will be designated to receive and dispense vaccine. "Clinics" can be any location or entity that can dispense vaccine – Health Department clinics, Open and Closed PODs, local pharmacies, etc.
        ii. Employer Module
            1. Once an employer organization has been identified as a Tier 1 organization, they will manually enter (or upload a list of) all their employees.
            2. Employers will only enter the following data fields: Employee's first name, last name, and email address.
            3. Employees will enter additional data in the "Patient Module" in a later step.

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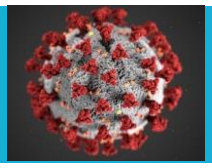

iii. Clinic Module
    1. After DOI has created the clinic modules for Virginia, individual points of contact from those clinics can set up their clinics in VAMS.
    2. VAMS Clinic Module functions include:
        a. Register/Activate Clinic
        b. Manage Vaccine Inventory
        c. Set-Up Clinic Schedule
        d. View Patients
        e. Complete Electronic forms
        f. Log Vaccinations
        g. Enter vaccine wastage transactions (as needed to maintain accurate inventory counts)
        h. Other admin functions
    3. A vaccine clinic can be set up as a daily operation (for example, M-F, 8a to 5p, with appointment slots throughout the day) or may a single day POD event, or even a Mobile Clinic.
    4. All events are "Appointment Only," requiring Patients to register for appointment slots in VAMS.

iv. Patient Module
    1. In order to become a "patient," the individual must first be entered into VAMS by their employer (which has been designated by DOI as a critical healthcare or infrastructure agency or organization).
    2. The patient will need to finish setting up their account by clicking on a link in an email invitation, and then adding a password to their account, then entering additional personal and medical information into VAMS.
    3. Once the patient has completed their account set-up, they can search for nearby vaccine clinics with open appointments and register for an open appointment.
    4. The patient will also need to read and sign the consent forms prior to the clinic.

2. Vaccine Tracking System (VTrckS):
    a. Health Districts and enrolled providers will submit vaccine requests to the VDH Division of Immunization using the system to be established.
    b. VDH Division of Immunizations will prioritize and submit vaccine orders to CDC using VTrckS.
    c. CDC's Centralized Distribution center will process the order requests and deliver vaccine directly to the vaccine provider address.

3. Virginia Electronic Registration for Immunization Programs (VERIP) System:

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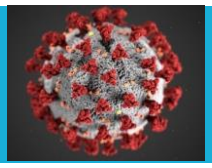

a. VERIP is a web-based registration system for the Division of Immunization.
b. Providers must complete registration in VERIP before access to VIIS (Virginia Immunization Information System) is granted. Local Health Districts already have access to VIIS.
c. All VIIS Organizations are required to register in VERIP and sign the security agreements. Registrations are renewed annually.
d. Each VERIP registration must have at least one individual who will be the VERIP User for the organization. The VERIP User is the main point-of-contact on the registration and responsible for ensuring the organization's registration is updated annually
e. The VIIS Administrator is the primary contact for those using VIIS at an organization. The Administrator must be added to the registration and will receive an email from VERIP which will contain the VDH security agreements that must be signed electronically.
f. The VIIS Administrator is expected to keep track of the following:
    i. Staff using VIIS have been properly trained to access the registry
    ii. Reset passwords for users.
    iii. Reactivate and inactivate VIIS user accounts.
    iv. Be able to train internal staff or schedule training with a VIIS Trainer.
g. The COVID-19 Vaccine Provider Intent Form will be housed in VERIP with the ability for providers who already have an account to complete their form in the system and connect it to their account. Providers who do not have an account will be able to complete the form without an account.
h. The COVID-19 Vaccination Program Provider Agreement, and COVID-19 Vaccination Program Provider Profile Form will also be housed in VERIP. Providers will need an account to complete the Agreement and Form.

4. Virginia Immunization Information System (VIIS):
    a. VIIS is Virginia's immunization information system (IIS) or immunization registry.
    b. VIIS is a free statewide registry system that combines immunization histories for a person of all ages from both the public and the private sector into a definitive record.
    c. The goal of VIIS is to support individuals, families, and clinicians in making the best health decisions by providing a statewide, readily accessible, and reliable immunization information system.
    d. It is important that all COVID-19 vaccines administered are entered into VIIS. This serves two purposes:
        i. This will allow providers to make better-informed decisions on treating their patients. It can indicate to other providers that the person has already received the vaccine. VIIS will also indicate which vaccine was given first in the series and when it is time to give the second vaccine.
        ii. Public health can use the aggregate data to see the distribution of vaccine throughout the Commonwealth. This data can look at the number of doses, by

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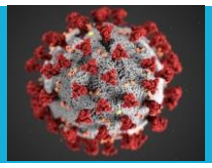

provider type, by geography, by patient age, race, or ethnicity. This data can help find gaps in coverage which can inform outreach efforts

B. Vaccine Recipient Information Reporting

1. Detailed records must be collected and retained for all vaccine recipients to including:
    a. Patient's full legal name, date of birth, address, contact information
    b. The Priority Group that the patient belongs to
    c. Vaccine administered (including vaccine type, lot number, and dosage)
    d. Date and location the vaccine was administered
    e. Name of the provider that administered the vaccine

2. In the early phase of the vaccination campaign, LHDs and other vaccine providers will enter all vaccine recipient data in VAMS.
    a. Later in the campaign (upon instruction from VDH DOI), LHDs will use WebVISION, VDH's clinic management information system for LHDs, to report all vaccines administered by the LHD, regardless of whether the event occurs at the LHD or an off-site clinic event.
    b. VAMS will provide data into VIIS via the IZ Gateway.
    c. WebVision will interface directly with VIIS to seamlessly transmit data from LHDs to CDC.
    d. Note that VAMS will track both the vaccine delivered to the provider and the doses provided, allowing on-hand dose numbers to be reported back to CDC. VTrckS and VIIS do not communicate with each other to provide real-time on-hand dose numbers. CDC has indicated that provider inventory will need to be reported by VDH but has not determined the frequency or method of reporting. Future CDC guidance is expected.
    e. Some COVID-19 vaccines will require a two-dose series. The vaccines will NOT be interchangeable. It will be extremely important to ensure recipients receive their second dose of the correct vaccine at the correct time interval (which will vary depending on the type of vaccine). Detailed patient record keeping will be needed, along with a patient notification/call-back plan to follow up with second doses.

C. Inventory Management and Tracking System (IMATS)

- IMATS will <u>not</u> be used to order and track COVID-19 vaccine.
- IMATS will likely be used to ship state-procured ancillary supplies and equipment to Health Districts, Regional Healthcare Coalitions, Hospitals, and other facilities
- Health Districts and Healthcare Coalitions should ensure that all delivery addresses and point of contact (POC) information are correct for all sites that will likely receive shipments of supplies and equipment.

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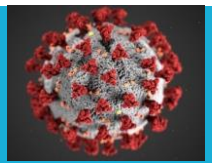

V. Vaccine Priority Groups

CDC's Advisory Committee on Immunization Practices (ACIP), the National Institutes of Health, and the National Academies of Sciences, Engineering, and Medicine (NASEM) are working to determine populations of focus for COVID-19 vaccination and ensure equity in access to COVID-19 vaccination availability across the United States. CDC has established an ACIP work group to review evidence on COVID-19 epidemiology and burden as well as COVID-19 vaccine safety, vaccine efficacy, evidence quality, and implementation issues to inform recommendations for COVID-19 vaccination policy. A key policy goal is to determine critical populations for COVID-19 vaccination, including those groups identified to receive the first available doses of COVID-19 vaccine when supply is expected to be limited.

After a period of potentially limited vaccine supply, supply will likely increase quickly, allowing vaccination efforts to be expanded to include additional critical populations as well as the general public. Jurisdictions should develop plans to ensure equitable access to vaccination for each of the critical populations identified below.

A. Identifying and Estimating Critical Populations

The first step in planning is to identify and estimate the critical populations within a jurisdiction. These populations (listed in no particular order) may include but are not limited to:

- **Critical infrastructure workforce**
  - Healthcare personnel (i.e., paid and unpaid personnel working in healthcare settings, which may include vaccinators, pharmacy staff, ancillary staff, school nurses, and EMS personnel)
  - Other essential workers (see additional guidance from the Cybersecurity and Infrastructure Security Agency [CISA])
  - Note: The critical infrastructure workforce varies by jurisdiction. Each jurisdiction must decide which groups to focus on when vaccine supply is limited by determining key sectors that may be within their populations (e.g., port-related workers in coastal jurisdictions)
- **People at increased risk for severe COVID-19 illness**
  - LTCF residents (i.e., nursing home, assisted living, independent living facility residents)
  - People with underlying medical conditions that are risk factors for severe COVID-19 illness
  - People 65 years of age and older
- **People at increased risk of acquiring or transmitting COVID-19**
  - People from racial and ethnic minority groups
  - People from tribal communities
  - People who are incarcerated/detained in correctional facilities
  - People experiencing homelessness/living in shelters
  - People attending colleges/universities

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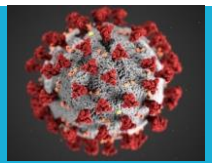

  - People who work in educational settings (e.g., early learning centers, schools, and colleges/universities)
  - People living and working in other congregate settings
- **People with limited access to routine vaccination services**
  - People living in rural communities
  - People with disabilities
  - People who are under- or uninsured

B. Estimating Population Groups for Initial COVID-19 Vaccine Distribution during Phase 1

In the event that Virginia's allocation during Phase 1 is insufficient to vaccinate all those included in the initial populations of focus, it is important for the Virginia Unified Command to identify and estimate the subset groups (i.e., Phase 1-A, Phase 1-B) within these initial populations of focus to determine who will receive the first available doses of COVID-19 vaccine. The Virginia Unified Command will review current ACIP work group considerations for assistance in identifying, prioritizing, and estimating Phase 1 sub-population groups.

Considerations for Phase 1 subset groups may include, for example:

- Phase 1-A: Paid and unpaid people serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials and are unable to work from home.
- Phase 1-B: People who play a key role in keeping essential functions of society running and cannot socially distance in the workplace (e.g., healthcare personnel not included in Phase I-A, emergency and law enforcement personnel not included in Phase 1-A, food packaging and distribution workers, teachers/school staff, childcare providers), and people at increased risk for severe COVID-19 illness, including people 65 years of age or older.

There may be insufficient COVID-19 vaccine supply initially to vaccinate all those who fall into the Phase 1-A subset, so the Virginia Unified Command should plan for additional subsets within that group. Phase 1-B and Phase 2 planning may also benefit from identifying subsets of population groups if there is high demand for vaccine. The U.S. Department of Labor's Occupational Safety and Health Administration has information on classifying workers at risk (low to very high based on position within an organization) for exposure to SARS-CoV-2. This information could prove helpful in determining subsets of critical populations for vaccination.

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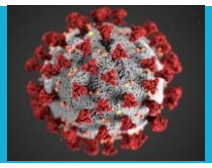

VI. Vaccine Provider Recruitment and Enrollment

An adequate network of trained, technically competent COVID-19 vaccination providers in accessible settings is critical to COVID-19 Vaccination Program success. For this reason, COVID-19 vaccination provider recruitment and enrollment may be the most critical activity conducted before vaccine becomes available. Early planning efforts will focus on engaging those vaccination providers and services that can rapidly vaccinate initial populations of focus (see Section IV: Vaccine Priority Groups) as soon as a COVID-19 vaccine is available in Phase 1. Concurrent and subsequent planning will include measures for recruiting and enrolling enough providers to vaccinate additional critical populations and eventually the general population when sufficient vaccine supply is available (Phases 2 and 3).

A. Vaccine Provider Recruitment

VDH will reach out to potential COVID-19 vaccine providers through letters from the State Health Commissioner and targeted recruitment efforts at the state and local levels. All providers/settings, especially those enrolled for Phase 1, must be able to meet the reporting requirements discussed in Section IX: COVID-19 Vaccine Administration Documentation and Reporting and Section XI: COVID-19 Requirements for Immunization Information Systems or Other External Systems. VDH will partner with the private sector and with local hospitals or health systems to provide COVID-19 vaccination in the closest proximity possible to the initial populations of focus. Types of provider groups that will be targeted include, but are not limited to:

- Large hospitals and health systems
- Commercial partners* (e.g., pharmacies)
- Long Term Care Facilities
- Correctional Facilities
- Mobile vaccination providers
- Occupational health settings for large employers
- Community Health Centers (including Federally Qualified Health Centers and Rural Health Centers)
- Free-Standing Emergency Departments and Walk-in Clinics
- Doctor's Offices
- College and University Student Health Clinics
- Specialty clinics, including dialysis centers
- Emergency Medical Services (EMS) Medical Directors
- In-home care providers

*CDC is working to engage large pharmacy partners to assist with on-site vaccination in LTCFs. These partners have existing distribution and administration infrastructure (including cold chain) and relationships with some LTCFs to provide medication and, in some cases, vaccination services (e.g.,

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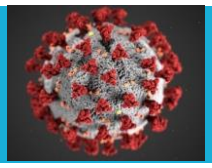

seasonal influenza) for staff and residents in LTCFs; this may reduce burden on jurisdictional health departments. CDC will ensure jurisdictions have visibility on this work with large pharmacy partners.

B. Vaccine Provider Enrollment

To receive/administer COVID-19 vaccine, constituent products, and ancillary supplies, vaccination provider facilities/organizations must enroll in the federal COVID-19 Vaccination Program, by means of the Virginia Electronic Registration for Immunization Programs (VERIP) System. (See Section IV.3.) This will include local health districts. As local health districts have a vital role to play in the success of this vaccination campaign, DOI will work with local health districts to identify POD options, locations, and populations of vaccination for that district. Enrolled COVID-19 vaccination providers must be credentialed/licensed in the jurisdiction where vaccination takes place, and sign and agree to the conditions in the CDC COVID-19 Vaccination Program Provider Agreement. These conditions are detailed in the agreement itself:

1. Administer COVID-19 vaccine in accordance with ACIP recommendations. (*Note: ACIP will review data on the safety and efficacy of each available COVID-19 vaccine and vote on recommendations for use.*)
2. Within 24 hours of administering a dose of COVID-19 vaccine and adjuvant (if applicable), record in the vaccine recipient's record and report required information to the relevant state, local, or territorial public health authority. (*See CDC IIS Data Requirements for COVID-19 Vaccine Monitoring*). The provider must maintain the vaccine administration records for at least 3 years following vaccination, or longer if required by state, local, or territorial law. These records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law.
3. Not sell or seek reimbursement for COVID-19 Vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies provided by the federal government.
4. Administer COVID-19 vaccine regardless of the vaccine recipient's ability to pay.
5. Provide an Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as applicable, to each vaccine recipient/parent/legal representative prior to vaccination.
6. Comply with CDC requirements for vaccine management, including storage and handling, temperature monitoring at all times, complying with jurisdiction's instructions for dealing with temperature excursions, and monitoring expiration dates. Providers must keep all records related to COVID-19 vaccine management for a minimum of 3 years, or longer if required by law.
7. Report COVID-19 vaccines and adjuvants that were unused, spoiled, expired, or wasted as required by the jurisdiction's immunization program.
8. Comply with federal instruction regarding disposal of unused COVID-19 vaccine and adjuvant.
9. Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).
10. Provide a completed COVID-19 vaccination record card to every vaccine recipient/parent/legal representative.

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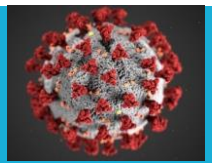

11. Comply with the U.S. Food and Drug Administration's requirements, including EUA-related requirements, if applicable. Providers must also administer COVID-19 vaccine in compliance with all applicable state and territorial vaccine laws.

Failure of any enrolled COVID-19 vaccination provider organization or vaccination location under its authority to meet the conditions of the agreement may impact whether COVID-19 vaccine product orders are fulfilled and may result in legal action by the federal government.

Enrolled COVID-19 vaccination providers must also fully complete the *CDC COVID-19 Vaccination Provider Profile form* for each location where COVID-19 vaccine will be administered. The profile form collects the following variables for each location:

- Address and contact information
- Days and hours of operation
- Vaccination provider type (e.g., medical practice, pharmacy, LTCF)
- Settings where vaccine will be administered (e.g., hospital, university, temporary or off-site clinic)
- Number of patients/clients served
- Influenza vaccination capacity during the peak week of the prior (2019–2020) influenza season
- Populations served (e.g., pediatric, adult, military, pregnant women)
- Current IIS reporting status
- Vaccine storage unit capacity in volume and ability to maintain required temperatures

The profile form includes a field where the brand/model/type of storage unit is to be listed, requiring an attestation from the medical/pharmacy director or vaccine coordinator that each unit will maintain the relevant required temperatures (i.e., refrigerated [2°C to 8°C], frozen [-15° to -25°C], ultra-cold [-60° to -80°C]. VDH may request photos of vaccine storage units for confirmation, if deemed necessary.

VDH will provide additional supplemental guidance on the form submission process.

*Note: A **vaccine coordinator** is the POC for receiving vaccine shipments, monitoring storage unit temperatures, managing vaccine inventory, etc. Immunization programs should encourage enrolled facilities/organizations to designate a vaccine coordinator role at each location as well as a back-up vaccine coordinator.*

The VDH Division of Immunization will:

- Ensure provider agreement, profile form, and redistribution agreement (if applicable) are thoroughly and accurately completed by each enrolled provider, retained on file for a minimum of 3 years, and made available to CDC upon request
- Verify COVID-19 vaccination providers (prescribers only, e.g., MD, DO, RPh, NP, PA) have active, valid licensure/credentials to possess and administer vaccine.
- Onboard COVID-19 vaccination providers to the jurisdiction's IIS or other external system using an expedited process.

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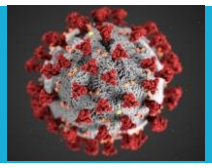

- Enter ship-to site information for each enrolled COVID-19 vaccination provider location in the Vaccine Tracking System (VTrckS) via direct upload or extensible XML information set (ExIS).
- Report COVID-19 vaccination provider enrollment data electronically to CDC twice a week (i.e., Monday and Thursday by 9:00pm EST), using CDC-provided Comma Separated Values (CSV) template to report via a Security Access Management Services (SAMS)–authenticated mechanism. CDC will monitor provider enrollment progress (see Section 15: COVID-19 Vaccination Program Monitoring).
- Ensure that all COVID-19 vaccination providers have been trained appropriately and have the appropriate equipment at their location to manage any serious adverse events. (Note: For new vaccination providers and nontraditional provider settings, it will be helpful to furnish vaccination clinic planning guidance to ensure optimum staffing, layout, supplies, and infection control procedures are in place.)

C. COVID-19 Vaccination Provider Training

Training of COVID-19 vaccination providers is vital to ensure the success of the COVID-19 Vaccination Program. VDH requires the following training for VDH vaccinators (included paid and volunteer staff):

- Cardiopulmonary resuscitation (CPR) and basic life support (BLS), responding to anaphylaxis, syncope, and knowledgeable about reporting any needlestick injury.
- Infection control practices
- How and where to document vaccines administered
- Vaccine storage, handling, preparation, and administration for the vaccine(s) being offered, using manufacturer instructions for the vaccine and CDC and Advisory Committee on Immunization Practices (ACIP) guidance found in:
    - CDC's Vaccine Storage and Handling Toolkit (for all staff that transport or manage vaccine storage and handling)
    - Vaccine Administration Recommendations and Guidelines
- Training should include an observation component. Validate staff knowledge of and skills in vaccine administration with a skills checklist
- You Call the Shots training programs about specific vaccines

Additionally, all COVID-19 vaccination providers (including public health and private sector providers) must understand the following:

- ACIP COVID-19 vaccine recommendations, when available
- How to order and receive COVID-19 vaccine
- COVID-19 vaccine storage and handling (including transport requirements)
- How to administer vaccine, including reconstitution, use of adjuvants, appropriate needle size, anatomic sites for vaccine administration, avoiding shoulder injury with vaccine administration, etc.
- How to document and report vaccine administration via the VIIS and/or VAMS
- How to manage vaccine inventory, including accessing and managing product expiration dates
- How to report vaccine inventory

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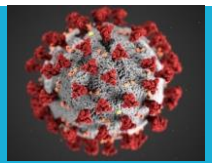

- How to manage temperature excursions
- How to document and report vaccine wastage/spoilage
- Procedures for reporting moderate and severe adverse events as well as vaccine administration errors to VAERS
- Providing EUA fact sheets or VISs to vaccine recipients
- How to submit facility information for COVID-19 vaccination clinics to CDC's VaccineFinder (particularly for pharmacies or other high-volume vaccination providers/settings)

D. Select Commercial and Federal Partners

Some multijurisdictional vaccination providers (e.g., select large drugstore chains) will enroll directly with CDC to order and receive COVID-19 vaccine.

Additionally, VDH is awaiting detailed guidance regarding anticipated direct allocation to the Department of Defense (DOD) and other federal government agencies. It is expected that DOD enlisted personnel, their dependents, and contractors who are eligible to receive DoD/VHA benefits will be served by the federal government. CDC is coordinating with other federal entities likely to receive direct allocation, including the Department of State, Bureau of Prisons, Veterans Health Administration and Indian Health Service.

CDC will notify VDH of any entities receiving direct allocations within the Commonwealth. These direct partners will be required to report vaccine supply and uptake information to VDH. VDH and local health districts will partner with commercial entities that are enrolled directly with CDC to reach certain populations. These providers may be particularly helpful in conducting PODs as well as vaccinating LTCF residents and staff. Health insurance issuers and plans may also assist in informing their enrollees about vaccination efforts.

VII. COVID-19 Vaccination Clinics and Community Events Guidance

A. Site Selection Considerations

Sites that were previously designated for Points of Dispensing (POD) may need to be reconsidered in light of COVID-19 social distancing recommendations to prevent the spread. Alternate sites may include:

- Outdoor/drive-thru venues (weather permitting)
- Indoor venues with sufficient space for increased social distancing
- Any site used should comply with the Americans with Disabilities Act and Section 504 of the Rehabilitation Act of 1973, and be suitable for all potential clients
- Other non-traditional vaccination settings:
    - Homeless shelters
    - Senior Centers
    - Food Pantries
    - Schools (K-12, Colleges, Universities, and other institutes of higher education)

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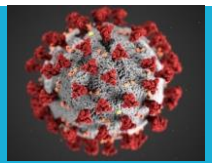

B. Modifications to Existing Closed POD Plans

Previous vaccination clinic plans will need to be modified to ensure the safe administration of vaccines in a COVID-19 environment. Such modifications will include:

- Staffing adjustments
- Registration/Pre-Registration processes
- POD layout adjustments
- Training adjustments
- PPE requirements
- Supplies and equipment
- Patient data collection and reporting processes

C. Infection Control

It is important to consider infection control measures that are currently necessary when conducting COVID-19 vaccination clinics:

- Providing specific appointment times or other strategies to manage patient flow and avoid crowding and long lines.
- Ensuring sufficient staff and resources to help move patients through the clinic flow as quickly as possible.
- Limiting the overall number of clinic attendees at any given time, particularly for people at higher risk for severe illness from COVID-19.
- Setting up a unidirectional site flow with signs, ropes, or other measures to direct site traffic and ensure physical distancing between patients.
- When feasible, arranging a separate vaccination area or separate hours for people at increased risk for severe illness from COVID-19, such as older adults and people with underlying medical conditions.
- Making available a point of contact for any reasonable accommodation needs for people with disabilities.
- Ensuring vaccination locations are accessible to individuals with disabilities consistent with disability rights statutes such as the Americans with Disabilities Act and Section 504 of the Rehabilitation Act of 1973.
- Selecting a space large enough to ensure a minimum distance of 6 feet between patients in line or in waiting areas for vaccination, between vaccination stations, and in post vaccination monitoring areas. Note: ACIP recommends that providers consider observing patients for 15 minutes after vaccination to decrease the risk for injury should they faint. For mobile or drive-through vaccination clinics, it is important to assess parking to accommodate vaccine recipients as they wait after vaccination.

See plan appendices for Local Health Districts and Closed Point of Dispensing partners for detailed guidance on these topics.

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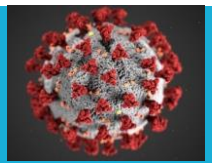

D. Personnel Support for Vaccination Efforts

VDH Central Office intends to support local health districts with staffing requirements by providing funding support to hire temporary, contract positions (both medical and non-medical), and assist with travel and facility rental costs, printing, signage, translation services, and other associated costs as needed.

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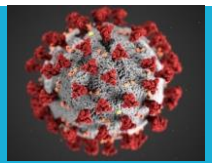


VIII. Phase I COVID-19 Vaccine Planning Scenarios

The planning scenarios described below will be used to develop operation plans for early COVID-19 vaccination when vaccine supply may be constrained. The scenarios describe potential COVID-19 vaccine requirements, early supply estimates after vaccine product approvals, and populations that may be recommended for vaccination during this early period. These scenarios are designed to support state and local, federal, and partner planning, but they are still considered hypothetical. The COVID-19 vaccine landscape is evolving and uncertain, and these scenarios may change as more information is available.

Planners should assume that by January 2021 significantly more COVID-19 vaccine will be available for distribution and plans will need to evolve to address additional vaccine availability. Please refer to COVID-19 vaccine planning assumptions and additional guidance from CDC.

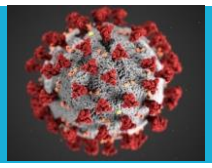
Scenario 1: Vaccine A demonstrates sufficient efficacy/safety for EUA in 2020

Availability Assumptions

Candidate	Vaccine availability by			Notes
	End of Oct 2020	End of Nov 2020	End of Dec 2020	
Vaccine A	~2M doses	10–20M doses	20–30M doses	Ultra-cold (-70 °C), for large sites only

Distribution, Storage, Handling, and Administration Assumptions

Vaccine A	
SHIPMENT *3 separately acquired components (mixed on site)* 1. Vaccine • Direct to site from manufacturer (on dry ice) • Multidose vials (5 doses/vial) 2. Diluent • Direct to site from USG (at room temperature) 3. Ancillary supply kits • Direct to site from USG (at room temperature)	**ON-SITE VACCINE STORAGE** *Frozen (-70 °C ± 10 °C)* • Must be used/recharged within 10 days • Storage in shipping container OK (replenish dry ice as needed) *Thawed but NOT reconstituted (2–8 °C)* • Must use within 24-48 hours *Reconstituted (room temperature)* • Must use within 6 hours
ORDERS *Large quantities, to large administration sites only* • Minimum order: ~1000 doses • Maximum order: ~5,000 doses	**ADMINISTRATION** *2-dose series (21 days between doses)* • On-site mixing required; reconstitute with diluent just prior to administration • Administer by intramuscular (IM) injection
PRIORITIZED POPULATIONS AND ANTICIPATED VACCINE ADMINISTRATION SITES *Health care professionals (incl. LTCF staff)* – public health closed temporary mass vaccination clinics + potential for mobile clinics *Essential workers (specifics TBA)* – public health closed temporary mass vaccination clinics + potential for mobile clinics *National Security populations* – public health closed temporary mass vaccination clinics + DoD sites *LTCF residents & staff* – potential for mobile clinics to facilities	



Additional considerations for Scenario 1:

- VDH Central Office and administration sites (local health districts and private providers) should plan for real-time shipment of doses.
- Administration sites (during Phase 1) will not be required to store vaccine products beyond the period of time Vaccine A can be stored in the ultra-cold shipment box.
- Vaccine will be free of cost, but administration fees may not be reimbursable while a vaccine product is administered under an EUA.
- Given the challenging storage, handling, and administration requirements, early vaccination should focus on administration sites that can reach prioritized populations with as much throughput as possible.
- Stability testing is ongoing for Vaccine A; the storage and handling requirements presented here may shift. The requirements in these scenarios are likely the strictest set of requirements for which planning is needed.
- VDH and local health districts will partner with the private sector and with local hospital systems to provide vaccine in the closest proximity to the prioritized populations as possible, given the limitations with the product. For example, Vaccine A may be administered through mobile clinics if multiple mobile clinics are planned over a short period of time to ensure high enough throughput.

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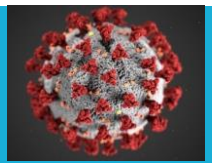


Scenario 2: Vaccine B demonstrates sufficient efficacy/safety for EUA in 2020

Availability Assumptions

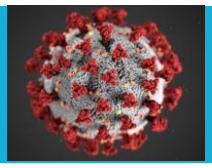
Candidate	Vaccine availability by			Notes
	End of Oct 2020	End of Nov 2020	End of Dec 2020	
Vaccine B	~1M doses	~10M doses	~15M doses	Central distro capacity required (-20 °C)

Distribution, Storage, Handling, and Administration Assumptions

Vaccine B	
SHIPMENT ***2 separately shipped components*** 1. Vaccine • To central distributor (at -20 °C) • Multidose vials (10 doses/vial) 2. Ancillary supply kits • Direct to site from USG (at room temperature)	**ON-SITE VACCINE STORAGE** ***Frozen (-20 °C)*** • Storage in shipping container OK (replenish dry ice as needed) ***Refrigerated (2–8 °C)*** • Must use within 7-14 days ***Room temperature*** • Must use within 6 hours
ORDERS ***Central distribution capacity required*** • Required by Dec 2020 • Maintained at -20 °C	**ADMINISTRATION** ***2-dose series (28 days between doses)*** • No on-site mixing required • Administer by intramuscular (IM) injection
PRIORITIZED POPULATIONS AND ANTICIPATED VACCINE ADMINISTRATION SITES ***Health care professionals (incl. LTCF staff)*** – health care clinics + health care occupational health clinics + public health closed temporary mass vaccination clinics + mobile clinics ***Essential workers (specifics TBA)*** – hospital occupational health + hospital clinics + public health closed temporary mass vaccination clinics ***National Security populations*** – DoD + closed temporary mass vaccination clinics + mobile clinics ***LTCF residents & staff*** – commercial pharmacy partners + mobile clinics	

Additional considerations for Scenario 2:

- VDH Central Office and administration sites (local health districts and private providers) should plan for real-time shipment of doses.
- Administration sites (during Phase 1) will not be required to store vaccine products beyond the period of time Vaccine B can be stored at 2–8 °C for up to 7-14 days.
- Vaccine will be free of cost. If vaccine product is administered under an EUA, administration fees may not be reimbursable from insurance. A person cannot be denied administration of the vaccine if they cannot pay the administration fee.
- Given the challenging storage, handling, and administration requirements, early vaccination should focus on administration sites that can reach prioritized populations with as much throughput as possible.
- Stability testing is ongoing for Vaccine B; the storage and handling requirements presented here may shift. The requirements in these scenarios are likely the strictest set of requirements for which planning is needed.
- Jurisdictions should consider partnering with the private sector and with local hospital systems to provide vaccine in closest proximity to the prioritized populations as possible, given the limitations with the product.



IX. COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management

A. Allocation

The federal government will determine the amount of COVID-19 vaccine designated for Virginia. The VDH Division of Immunization (DOI) will then be responsible for managing and approving orders from enrolled providers in Virginia using this allotment. The amount allotted will change over time, which may be based on critical populations recommended for vaccination by ACIP (with input from NASEM), COVID-19 vaccine production and availability, and overall population.

Federal agencies and additional commercial partners will also receive allocations directly from CDC once larger volumes of vaccine are available. CDC is currently developing procedures to ensure that jurisdictions and tribes have full visibility of COVID-19 vaccine supply and vaccination activities among these entities located within their boundaries.

The VDH DOI will develop allocation methods for critical populations identified by CDC in early- and limited-supply scenarios. VDH DOI will prioritize COVID-19 vaccine order allowances among vaccination providers based on the critical populations the vaccination providers serve. Allotments of doses to vaccination providers within Virginia will be based on:

- CDC guidance and requirements
- ACIP recommendations (when available)
- Estimated number of doses allocated to Virginia and timing of availability
- Populations served by vaccination providers and geographic location to ensure distribution throughout the Virginia
- Vaccination provider site vaccine storage and handling capacity
- Minimizing the potential for wastage of vaccine, constituent products, and ancillary supplies
- Other local factors

B. Vaccine Ordering

COVID-19 vaccination providers enrolled in VIIS and with signed CDC COVID-19 vaccine provider agreements will order vaccine through VAMS or through VIIS. See Section IV for more information on those systems. VDH DOI will ensure that the orders are uploaded to VTrckS. (Note, VDH DOI is still working out the details with the VDH Office of Information Management (OIM) on how this will happen. This may require a manual upload, or an automatic pull, depending on how the system is established. The key point is that VDH DOI will review the orders and prioritize approval based on the factors described in Paragraph A, above.)

The minimum order size and increment for centrally distributed vaccines will be 100 doses per order; though early in the response, some ultra-cold (-60°C to -80°C) vaccine (if authorized for use or approved)

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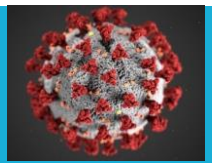

may be shipped directly from the manufacturer in larger quantities. CDC will share more information on these shipments as it becomes available.

C. Ancillary Supplies

Ancillary supplies will be packaged in kits and will be ordered in amounts to match vaccine orders in VTrckS. The order for vaccine will automatically trigger the shipment of diluent and the associated kit. Each kit will contain supplies to administer 100 doses of vaccine, including:

- Needles, 105 per kit (various sizes for the population served by the ordering vaccination provider)
- Syringes, 105 per kit
- Alcohol prep pads, 210 per kit
- 4 surgical masks and 2 face shields for vaccinators, per kit
- COVID-19 vaccination record cards for vaccine recipients, 100 per kit

For COVID-19 vaccines that require reconstitution with diluent or mixing with adjuvant at the point of administration, mixing kits with syringes, needles, and other needed supplies will also be included. Ancillary supply kits will not include sharps containers, gloves, and bandages. Additional personal protective equipment (PPE) may be needed depending on vaccination provider site needs.

VDH also plans to purchase a significant amount of supplies to support the vaccination effort. These supplies include, but are not limited to syringes, needles (to include smaller gauge needles), alcohol prep pads, band-aids, sharps containers, emergency medical kits (including epinephrine), and dry ice.

D. Equipment

VDH will coordinate with Unified Command Logistics and Local Health Districts to support the purchase of equipment to support the vaccine campaign. This equipment may include vaccine refrigerators and freezers, temperature data loggers, thermometers, and portable units to support vaccine transportation and other equipment as necessary.

E. Warehousing and Shipping

CDC is planning to ship vaccines and ancillary supply kits directly to administration sites (private providers and local health departments) at no cost to the states. However, VDH is planning to provide warehouse space for ancillary supplies purchased by VDH to support the vaccine campaign. As needed, these items will be shipped to local health departments and other vaccine providers using contract shipping agencies.

F. Distribution

COVID-19 vaccines and ancillary supplies will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers. CDC will use its centralized distribution contract to fulfill orders for most vaccine products and associated ancillary supplies. Some vaccine products, such as

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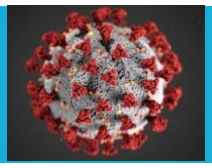

those with ultra-cold temperature requirements, will be shipped directly from the manufacturer to the vaccination provider site.

It is essential that accurate and complete shipping information (e.g., shipment address, provider contact information, shipping hours) be entered in VTrckS for all vaccine shipments to enrolled vaccination providers. This includes local health districts (similar to the Virginia Vaccines for Children program).

COVID-19 vaccine (and diluent or adjuvant, if required) will be shipped to vaccination provider sites within 48 hours of order approval by VDH DOI. Because of cold chain requirements, ancillary supply kits (and diluent, if applicable) will ship separately from vaccine but should arrive before or on the same day as vaccine.

The federally contracted vaccine distributor uses validated shipping procedures to maintain COVID-19 vaccine cold chain and minimize the likelihood of vaccine loss or damage during shipment. Once a vaccine product has been shipped to a COVID-19 vaccination provider site, the federal government will neither redistribute the product nor take financial responsibility for its redistribution. (See Section X: COVID-19 Vaccine Storage and Handling for more information.)

G. Redistribution

Redistribution of vaccine after delivery should be avoided through careful planning prior to delivery. However, there may be circumstances where COVID-19 vaccine needs to be redistributed beyond the identified primary CDC ship-to sites (i.e., for orders smaller than the minimum order size or for large organizations whose vaccine is shipped to a central depot and requires redistribution to additional clinic locations). In these instances, vaccination provider organizations/facilities, third-party vendors, and other vaccination providers may be granted permission to redistribute COVID-19 vaccine, if validated cold-chain procedures are in place in accordance with the manufacturer's instructions and CDC's guidance on COVID-19 vaccine storage and handling. These entities must sign and agree to conditions in the CDC COVID-19 Vaccine Redistribution Agreement for the sending facility/organization and have a fully completed and signed CDC COVID-19 Vaccination Provider Agreement and Profile form for each receiving location. CDC strongly advises that redistribution be limited to refrigerated vaccines only.

Note: Movement of small quantities of vaccine from local health departments to local offsite or mobile clinic events do not count as "redistribution." However, health departments need to ensure cold chain management of vaccines according to the manufacturers recommendations, and in accordance with CDC's Vaccine Storage and Handling Toolkit. See section X for more information.

H. Inventory Management

COVID-19 vaccination providers will be required to report inventory of COVID-19 vaccines, and jurisdictions must ensure this inventory information is submitted with each order. If Webvision is being used by local health districts, DOI can submit vaccine inventory on behalf of the local health districts.

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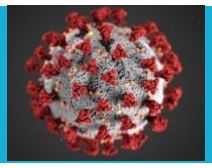

It is anticipated COVID-19 vaccines will initially be authorized under an EUA. Vaccines authorized under an EUA will contain slight variations from approved Food and Drug Administration (FDA) products, including:

- **Expiration Date**: The vaccine vials and cartons will not contain a printed expiration date. Expiration dates may be updated based on vaccine stability studies occurring simultaneously with COVID-19 vaccine distribution and administration. Current expiration dates by vaccine lots for all authorized COVID-19 vaccines will be posted on a US Department of Health and Human Services (HHS) website (weblink pending), accessible to all COVID-19 vaccination providers. To ensure that information systems continue to work as expected, CDC has worked with FDA and the manufacturers to include a two-dimensional (2D) barcode on the vaccine vial (if possible) and carton (required) labels that includes a National Drug Code (NDC), lot number, and a placeholder expiration date of 12/31/9999 to be read by a scanner. The placeholder 12/31/9999 expiration date is not visible on the vaccine packaging nor found anywhere else; it is only to facilitate information system compatibility. CDC is developing "beyond use date" (BUD) tracker labels to assist clinicians with tracking expiration dates at the point of vaccine administration. The label templates will be available on the CDC website.
- **Manufactured Date**: A manufactured date will be on the packaging and should not be used as the expiration date when documenting vaccine administration. This date is provided to help with managing stock rotations; however, expiration dates should also be considered (see above) as using manufactured date alone could have some limitations.
- **2D Barcode**: The 2D barcode available on the vaccine carton (also on the vials for some vaccines) will include NDC, lot number, and a placeholder expiration date of 12/31/9999.
- **QR Code**: Each vaccine manufacturer will include a Quick Response (QR) code on the vaccine carton for accessing FDA-authorized, vaccine product-specific EUA fact sheets for COVID-19 vaccination providers and COVID-19 vaccine recipients.

A list of authorized COVID-19 vaccine products with corresponding EUA fact sheets for healthcare providers and vaccine recipients, and up-to-date expiration information by vaccine lot will be available on an HHS website.

I. COVID-19 Vaccine Recovery

Details of COVID-19 vaccine recovery are still being finalized and will be communicated when available.

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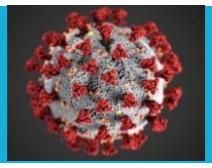

X. COVID-19 Vaccine Storage and Handling

COVID-19 vaccine products are temperature-sensitive and must be stored and handled correctly to ensure efficacy and maximize shelf life. Proper storage and handling practices are critical to minimize vaccine loss and limit risk of administering COVID-19 vaccine with reduced effectiveness. VDH will provide guidelines and assistance to COVID-19 vaccination providers to ensure appropriate vaccine storage and handling procedures are established and followed.

It is expected that cold chain storage and handling requirements for COVID-19 vaccine products will vary in temperature from refrigerated (2°C to 8°C) to frozen (-15 to -25°C) to ultra-cold (-60°C to -80°C in the freezer or within the dry ice shipping container in which product was received). Ongoing stability testing may impact these requirements. Note: These temperatures are based on information available as of 9/04/2020. Updated information will be provided as it becomes available.

For a reliable cold chain, three elements must be in place:

- Well-trained staff
- Reliable storage and temperature monitoring equipment
- Accurate vaccine inventory management

The cold chain begins at the COVID-19 vaccine manufacturing plant, includes delivery to and storage at the COVID-19 vaccination provider site, and ends with administration of COVID-19 vaccine to a person. Jurisdictions and vaccination providers are responsible for maintaining vaccine quality from the time a shipment arrives at a vaccination provider site until the dose is administered. To minimize opportunities for breaks in the cold chain, most COVID-19 vaccine will be delivered from CDC's centralized distributor directly to the location where the vaccine will be stored and administered, although some vaccine may be delivered to secondary depots for redistribution. Certain COVID-19 vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer to the vaccination provider site. If redistributing vaccine, jurisdictions must adhere to all cold chain requirements and should limit transport of frozen or ultra-cold vaccine products. A COVID-19 vaccine redistribution policy and procedure for Virginia is being drafted. All redistributions will need to be reported to DOI using this procedure.

An addendum to the Vaccine Storage and Handling Toolkit that specifically addresses COVID-19 vaccines is currently being developed in addition to other training materials.

A. Satellite, Temporary, and Off-Site Clinic Storage and Handling Considerations

Satellite, temporary, or off-site clinics in collaboration with community or mobile vaccinators may assist LHDs in providing equitable access for COVID-19 vaccination. However, these situations require additional oversight and enhanced storage and handling practices, including:

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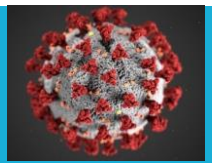

- The quantity of COVID-19 vaccine transported to a satellite, temporary, or off-site COVID-19 vaccination clinic should be based on the anticipated number of COVID-19 vaccine recipients and the ability of the vaccination provider to store, handle, and transport the vaccine appropriately. This is essential to minimizing the potential for vaccine wastage and spoilage.
- COVID-19 vaccines may be transported—not shipped—to a satellite, temporary, or off-site COVID-19 vaccination clinic setting using vaccine transportation procedures outlined in the upcoming COVID-19 addendum to CDC's Vaccine Storage and Handling Toolkit. The procedures will include transporting vaccines to and from the provider site at appropriate temperatures, using appropriate equipment, as well as monitoring and documenting temperatures.
- Upon arrival at the COVID-19 vaccination clinic site, vaccines must be stored correctly to maintain appropriate temperature throughout the clinic day.
- Temperature data must be reviewed and documented according to guidance in the upcoming COVID-19 addendum to CDC's Vaccine Storage and Handling Toolkit.
- At the end of the clinic day, temperature data must be assessed prior to returning vaccine to fixed storage units to prevent administration of vaccines that may have been compromised.
- As with all vaccines, if COVID-19 vaccines are exposed to temperature excursions at any time, the temperature excursion should be documented and reported according to the jurisdiction immunization program's procedures. The vaccines that were exposed to out-of-range temperatures must be labeled "do not use" and stored at the required temperature until further information on usability can be gathered or further instruction on disposition or recovery is received.

XI. COVID-19 Vaccination Second-Dose Reminders

For most COVID-19 vaccine products, two doses of vaccine, separated by 21 or 28 days, will be needed. Because different COVID-19 vaccine products will not be interchangeable, a vaccine recipient's second dose must be from the same manufacturer as their first dose. Second-dose reminders for vaccine recipients will be critical to ensure compliance with vaccine dosing intervals and achieve optimal vaccine effectiveness. COVID-19 vaccination providers should make every attempt to schedule a patient's second-dose appointment when they get their first dose.

COVID-19 vaccination record cards will be provided as part of vaccine ancillary kits. Vaccination providers are required to complete these cards with accurate vaccine information (i.e., vaccine manufacturer, lot number, date of first dose administration, and second dose due date), and give them to each patient who receives vaccine to ensure a basic vaccination record is provided. Vaccination providers should encourage vaccine recipients to keep the card in case the IIS or other system is not available when they return for their second dose. The card provides room for a written reminder for a second-dose appointment. If vaccine recipients have a smartphone, they may consider documenting their vaccine administration with a photo of their vaccination record and entering the date the next vaccine dose is due on their electronic calendar.

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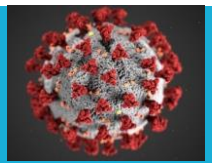

Redundant methods and systems should be used to remind vaccine recipients about their need for second doses. VDH will assess current practices for patient reminder/recall in existing healthcare provider organizations, and work with occupational health providers and partners to consider the most appropriate and effective method of issuing second-dose reminders. The VIIS has a reminder/recall functionality allowing providers to print out a list of people who are due or template letters, and/or VDH could call or text reminders on behalf of the provider.

Many pharmacies and healthcare systems have their own systems for patient notifications and reminders, some using functionality within their electronic health record (EHR) systems. Jurisdictions may consider exploring the use of automated patient phone calls ("robocalls"), emails, and SMS text message-based systems. Health plans may also help to notify their enrollees about second doses based on claims information.

XII. Training and Exercises

- VDH, in collaboration with VDEM, will host a seminar and tabletop exercise for VEST partners in October 2020. A table-top in a box will also be developed to assist local health districts.
- Training products are in development and will be posted to TRAIN Virginia for easy access.
- A strategy to conduct the required skills assessment (of contractors and volunteers) without adding the task to district nurses is in development.
- POD Training taught in 2018 and 2019 as a Train-the-trainer is being made into online modules.
- Training/Job Aids are being developed for vaccine cold chain management.
- Each year, VDH local health districts conduct mass vaccination exercises with seasonal influenza vaccine. These exercises will be conducted this year and used as an opportunity to test mass vaccination plans taking into consideration the CDC Vaccination Guidance during a Pandemic.

XIII. COVID-19 Vaccination Program Communication

Starting before COVID-19 vaccines are available, clear, effective communication will be essential to implementing a successful COVID-19 Vaccination Program. Building vaccine confidence broadly and among groups anticipated to receive early vaccination, as well as dispelling vaccine misinformation, are critical to ensure vaccine uptake.

A successful COVID-19 Vaccination Program will have lasting effects on the nation's immunization system and overall vaccination efforts in the future. VDH will follow and build upon the CDC's recently developed Vaccinate with Confidence framework to develop and implement timely, evolving plans as the foundation for their overall COVID-19 vaccination communication efforts.

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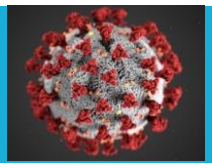

A. Message Coordination

VDH will coordinate communication efforts at the state level with the Governor's Office, the Joint Information Center, and the COVID-19 Vaccine Advisory Workgroup. Local health departments will coordinate local messaging efforts with their local jurisdictions' public information officers. Coordination of messaging will ensure a unified message and approach, while reaching a broader audience.

B. Communication Objectives

- Educate the public about the development, safety reviews, authorization, distribution, and provision of COVID-19 vaccines, including that the situation is continually evolving as more information becomes available.
- Ensure public confidence in the approval or authorization process, safety, and efficacy of COVID-19 vaccines.
- Help the public to understand key differences in FDA emergency use authorization and FDA approval (i.e., licensure).
- Engage in dialogue with internal and external partners to understand their key considerations and needs related to COVID-19 vaccine program implementation.
- Ensure active, timely, accessible, and effective public health and safety messaging along with outreach to key state/local partners and the public.
- Work with community leaders who are trusted by the communities they serve and/or represent to provide messages about COVID-19 vaccines.
- Provide guidance to local health departments, clinicians, and other hosts of COVID-19 vaccination provider locations.
- Track and monitor public receptiveness to COVID-19 vaccination messaging.

C. Key Audiences

Messaging will be tailored for each audience to ensure communication is effective.

- Healthcare personnel (i.e., organizations and clinicians who will receive information about receiving and administering vaccine)
- Health insurance issuers and plans (coverage for vaccine, in-network providers)
- Employers
- Government and community partners and stakeholders
- Public/consumers
    - Essential workers
    - Those in groups at risk for severe outcomes from COVID-19 infection
    - Those in groups at increased risk of acquiring or transmitting COVID-19
    - Those with limited access to vaccination services

D. Broad Communication Planning Phases

Messaging will be timely and applicable for the current phase of the COVID-19 Vaccination Program.

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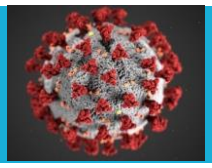

- Before vaccine is available
- Vaccine is available in limited supply for certain populations of early focus (Phase 1)
- Vaccine is increasing and available for other critical populations and the general public (Phase 2)
- Vaccine is widely available (Phase 3)

E. Communication Activities

- Communicate early about the safety of vaccines in general and have easily accessible, public health information to address myths, questions, and concerns.
- Keep the public, public health partners, and healthcare providers well-informed about COVID-19 vaccine(s) development, recommendations, and public health's efforts.
- Engage and use a wide range of partners, collaborations, and communication and news media channels to achieve communication goals, understanding that channel preferences and credible sources vary among audiences and people at higher risk for severe illness and critical populations, and channels vary in their capacity to achieve different communication objectives.
- Communicate proactively whenever possible, anticipating issues and forecasting possible problems before they reach broad awareness.
- Ensure that communications meet the requirements of the Americans with Disabilities Act, the Rehabilitation Act, the Patient Protection and Affordable Care Act, the Plain Language Act, and other applicable disability rights laws for accessibility.
- Use information and education campaigns to extend reach and increase visibility of vaccine recommendations and resources.
- Work closely with partner agencies, representatives of local communities with critical populations, and intermediaries to achieve consensus on actions, consistency in messages, and coordinated communication activities.
- Communicate transparently about COVID-19 vaccine risks and recommendations, immunization recommendations, public health recommendations, and prevention measures.

F. Messaging Considerations

Public health messages and products will be tailored for each audience and developed with consideration for health equity, using plain language that is easily understood. Information will be presented in culturally responsive language and available in languages that represent the communities. Information efforts will address all people inclusively, with respect, using non-stigmatizing, bias-free language. Insufficient consideration of culture in developing materials may unintentionally result in misinformation, errors, confusion, or loss of credibility. When developing/utilizing materials, public information officers should check for the following:

- Are there words, phrases, or images that could be offensive to or stereotypical of the cultural or religious traditions, practices, or beliefs of the intended audience?
- Are there words, phrases, or images that may be confusing, misleading, or have a different meaning for the intended audience (e.g., if abstract images are used, will the audience interpret them as intended)?

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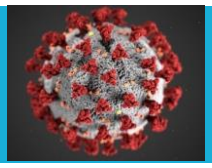

- Are there images that do not reflect the look or lifestyle of the intended audience or the places where they live, work, or worship?
- Are there health recommendations that may be inappropriate or prohibited for the social, economic, cultural, or religious context of the intended audience?
- Are any toll-free numbers or reference web pages in the message in the language of the intended audience?

These considerations and any others that emerge during message development and deployment will be reviewed again when material is translated.

G. Communication Channels

Even perfectly developed messages and materials will provide no benefit if they are not received by the intended audience. Virginia will use feedback mechanisms such as a web page or e-mail accounts to allow the audience to express concerns, ask questions, and request assistance. This feedback will be used to improve messaging efforts.

H. Partners and Trusted Sources

Working to engage and empower partners is critical to reinforcing COVID-19 vaccination messages. Efforts with partners and trusted sources should be integrated into other channels in addition to programmatic and community engagement efforts. These partners include:

- State and local government
- Employers
- Healthcare providers (including federally funded safety net and in-home care providers)
- Health insurance issuers and plans
- Educators
- Unions and professional organizations
- Organizations serving minority populations and people with disabilities
- Community and faith-based groups

I. Crisis and Risk Communication

Crisis and emergency risk communication (CERC) is the application of evidence-based principles to effectively communicate during emergencies. These principles are used by public health professionals and public information officers to provide information that helps people, stakeholders, and entire communities make the best possible decisions for themselves and their loved ones. CERC recognizes that during emergencies, we work under impossible time constraints and must accept the imperfect nature of our choices.

CERC principles include:

- Be First
- Be Right

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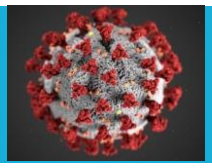


- Be Credible
- Express Empathy
- Show Respect

Messaging before, during, and after COVID-19 vaccine is available will help communities understand the importance of vaccination as well as the benefits and risks. Communicating what is currently known, regularly updating this information, and continuing dialogue with media and other partners throughout the vaccine distribution and administration process is essential to establish and maintain trust and credibility.

J. CDC and World Health Organization (WHO) Communication Resources

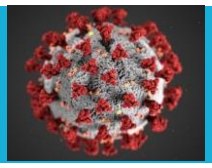
- CDC's COVID-19 Communication Resources: https://www.cdc.gov/coronavirus/2019-ncov/communication/
- CDC's COVID-19 One-Stop Shop Toolkits: https://www.cdc.gov/coronavirus/2019-ncov/communication/toolkits/index.html
- COVID-19 Communications Plan for Select Non-Healthcare Critical Infrastructure Employers https://www.cdc.gov/coronavirus/2019-ncov/community/communication-plan.html
- CDC's CERC manual: https://emergency.cdc.gov/cerc/manual/index.asp
- The WHO guide for communications planning: https://www.euro.who.int/__data/assets/pdf_file/0007/187171/Vaccine-Safety-Events-managing-the-communications-response-final.pdf

XIV. Regulatory Considerations for COVID-19 Vaccination

A. Public Readiness and Emergency Preparedness (PREP) Act

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of the Department of Health and Human Services (Secretary) to issue a declaration (PREP Act declaration) that provides immunity from liability (except for willful misconduct) for claims of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined by the Secretary to constitute a present, or credible risk of a future public health emergency to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures. A PREP Act declaration is specifically for the purpose of providing immunity from liability, and is different from, and not dependent on, other emergency declarations.

On August 19, 2020, the U.S. Department of Health and Human Services (HHS) issued a third amendment to the Declaration under the PREP Act to increase access to lifesaving childhood vaccines and decrease the risk of vaccine-preventable disease outbreaks as children across the United States return to daycare, preschool and school.



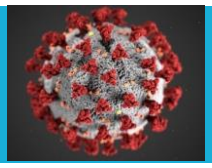
The amendment authorizes State-licensed pharmacists (and pharmacy interns acting under their supervision to administer vaccines, if the pharmacy intern is licensed or registered by his or her State board of pharmacy) to order and administer vaccines to individuals ages three through 18 years, subject to several requirements:

- The vaccine must be approved or licensed by the Food and Drug Administration (FDA).
- The vaccination must be ordered and administered according to the CDC's Advisory Committee on Immunization Practices (ACIP) immunization schedules.
- The licensed pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.
- The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period.
- The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine.
- The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregivers accompanying the children of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate.

On September 9, 2020, additional guidance was released which authorizes state-licensed pharmacists to order and administer, and state-licensed or registered pharmacy interns acting under the supervision of the qualified pharmacist to administer, COVID-19 vaccinations to persons ages 3 or older, subject to certain requirements.

To qualify as "covered persons" under 42 U.S.C. § 247d-6d((i)(8)(B) when administering COVID-19 vaccines authorized or licensed by the U.S. Food and Drug Administration (FDA) to persons ages 3 or older, state-licensed pharmacists and pharmacy interns licensed or registered by their state board of pharmacy must satisfy the following requirements:

- The vaccine must be FDA-authorized or FDA-licensed.

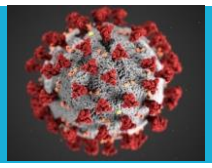


- The vaccination must be ordered and administered according to the Advisory Committee on Immunization Practices' (ACIP) COVID-19 vaccine recommendation.
- The licensed pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE.
- The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic CPR.
- The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each state licensing period.
- The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including reviewing the vaccine registry or other vaccination records prior to administering a vaccine.
- The licensed pharmacist must, if the patient is 18 years of age or younger, inform the patient and the adult caregiver accompanying the patient of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate.
- The licensed pharmacist and the licensed or registered pharmacy intern must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID-19 vaccine(s).

The authorization preempts any state and local laws that prohibit or effectively prohibits those who satisfy these requirements from ordering or administering COVID-19 vaccines as set forth above. The authorization does not preempt state and local laws that permit additional individuals to administer COVID-19 vaccines to additional persons.

B. Emergency Use Authorization (EUA) Fact Sheets

The EUA authority allows FDA to authorize either (a) the use of an unapproved medical product (e.g., drug, vaccine, or diagnostic device) or (b) the unapproved use of an approved medical product during an emergency based on certain criteria. The EUA will outline how the COVID-19 vaccine should be used and any conditions that must be met to use the vaccine. FDA will coordinate with CDC to confirm these "conditions of authorization." Vaccine conditions of authorization are expected to include distribution requirements, reporting requirements, and safety and monitoring requirements. The EUA will be authorized for a specific time period to meet response needs (i.e., for the duration of the COVID-19 pandemic). Additional information on EUAs, including guidance and frequently asked questions, is located on the FDA website at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.



Product-specific EUA fact sheet for COVID-19 vaccination providers will be made available that will include information on the specific vaccine product and instructions for its use. An EUA fact sheet for vaccine recipients will also be developed, and both will likely be made available on the FDA website and through the CDC website. Jurisdictions should ensure providers know where to find both the provider and recipient fact sheets, have read and understand them, and are clear on the requirement to provide the recipient fact sheet to each client/patient prior to administering vaccine.

C. Vaccine Information Statements (VIS)

VISs are required only if a vaccine is added to the Vaccine Injury Table. Optional VISs may be produced, but only after a vaccine has been licensed (e.g., such as with zoster vaccines). Plans for developing a VIS for COVID-19 vaccine are not known at this time but will be communicated as additional information becomes available. Additional information on VISs is located at: https://www.cdc.gov/vaccines/hcp/vis/current-vis.html.

XV. COVID-19 Vaccine Safety Monitoring

An "adverse event following immunization" is an adverse health problem or condition that happens after vaccination (i.e., a temporally associated event). It might be truly caused by the vaccine or it might be purely coincidental and not related to vaccination.

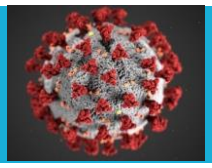
CDC continuously monitors the safety of vaccines given to children and adults in the United States. VAERS (Vaccine Adverse Event Reporting System), co-administered by CDC and FDA, is the national frontline monitoring system for vaccine safety.

A. Vaccine Adverse Event Reporting System

Healthcare providers should report clinically important adverse events following COVID-19 vaccination to VAERS. VAERS is a national early warning system to detect possible safety problems with vaccines. Anyone—a doctor, nurse, pharmacist, or any member of the general public—can submit a report to VAERS. VAERS is not designed to detect whether a vaccine caused an adverse event, but it can identify "signals" that might indicate possible safety problems requiring additional investigation. The main goals of VAERS are to:

- Detect new, unusual, or rare adverse events that happen after vaccination
- Monitor for increases in known side effects
- Identify potential patient risk factors for particular types of health problems related to vaccines
- Assess the safety of newly licensed vaccines
- Detect unexpected or unusual patterns in adverse event reports

Per the CDC COVID-19 Vaccination Program Provider Agreement, COVID-19 vaccination providers are required to report adverse events following COVID-19 vaccination and should report clinically important



adverse events even if they are not sure if the vaccination caused the event. Vaccine manufacturers are required to report to VAERS all adverse events that come to their attention. VAERS data-sharing agreements with Department of Defense and IHS healthcare facilities are being coordinated through the federal government. VDH will ensure that COVID-19 vaccination providers it enrolls understand the procedures for reporting adverse events to VAERS. More information on submitting a VAERS report electronically can be found at https://vaers.hhs.gov/reportevent.html.

B. Vaccine Safety Datalink

The Vaccine Safety Datalink (VSD) is a collaboration between CDC's Immunization Safety Office and nine healthcare organizations. This active surveillance system monitors electronic health data on vaccination and medical illnesses diagnosed in various healthcare settings and conducts vaccine safety studies based on questions or concerns raised from medical literature and VAERS reports. VSD information can be found at https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html

C. Clinical Immunization Safety Assessment Project

CDC's Clinical Immunization Safety Assessment Project is a national network of vaccine safety experts from CDC's Immunization Safety Office and seven medical research centers. This project conducts clinical research and assesses complex adverse events following vaccination. See https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/ for more information. Healthcare providers can request a consultation for a complex vaccine safety issue with an individual patient at CISAeval@cdc.gov.

XVI. COVID-19 Vaccination Program Monitoring

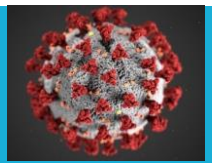
Continuous monitoring for situational awareness throughout the COVID-19 Vaccination Program is crucial for a successful outcome. Prior to receiving COVID-19 vaccine, jurisdictions should establish procedures for monitoring various critical program planning and implementation elements, including performance targets, resources, staffing, and activities.

A. CDC Dashboards

To provide situational awareness for jurisdictions and the general public throughout the COVID-19 vaccination response, CDC will have two dashboards available. The Weekly Flu Vaccination Dashboard will include weekly estimates of influenza vaccination for adults, children, and pregnant women (when approved for these groups) using existing (National Immunization Survey [NIS]-Flu) and new (IQVIA) data sources. Data and estimates from additional sources will be added, as available.

The COVID-19 Vaccination Response Dashboard will include:

- Data for planning (e.g., estimates of critical population categories, number and attributes of healthcare providers and facilities)



- Implementation data (e.g., number of enrolled COVID-19 vaccination providers, COVID-19 vaccine supply and distribution, COVID-19 vaccine administration locations)
- COVID-19 vaccine administration data

The COVID-19 Vaccination Response Dashboard will be implemented in stages based on data availability and shareability. Both dashboards will include a view tailored for jurisdictions, available through SAMS, and a view for the general public on CDC's website.

B. Resources

VDH and local health districts will regularly monitor their resources to avoid unexpected obstacles to the progress of their COVID-19 Vaccination Programs.

Staffing

Having enough adequately trained staff with current situational awareness is key to a successful COVID-19 vaccination program. Specialized expertise is required, and it is important to have backups in each specialty area to guard against interruption of activities because of illness or other personal situations. For example, if staff are supporting temporary or off-site COVID-19 vaccination clinics, the hours are likely to be long and physically taxing. Managers and supervisors need to regularly check in with and support assigned staff's wellness and overall resilience to perform the assigned tasks.

Inventory

Important activities during the COVID-19 vaccination program might be halted if certain supplies are depleted without replenishment. LHDs should develop lists and track inventory for various program components (e.g., temporary/off-site clinics, vaccination provider enrollment and training, vaccine management). Regular monitoring of such records will foster early prompts to order and replenish supplies and ensure availability as needed. For example, jurisdictions will need to project and monitor use of PPE throughout the response and have ordering and procurement protocols in place for securing additional supplies.

C. Messaging

CDC will provide timely messaging throughout the COVID-19 vaccination response via all-jurisdiction calls, regular e-mail communication, and website updates. The VDH Health Information Unit, in coordination with the Virginia Joint Information Center, will monitor both CDC and local-level messaging to inform their communications efforts. Variations in messaging can create confusion and hamper the effective implementation of the vaccination program. Messaging must be clear, current, and received as intended by the audience. Monitoring social media can be helpful in assessing message delivery and reception and dispelling inaccurate information.

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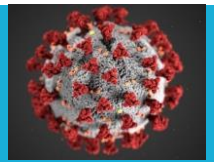
Attachment 1: Vaccine Planning Timeline

	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	*Assigned to*
Establish Vaccination Unit within the Virginia Unified Command under Public Health and Surveillance and Guidance Work Group										*Unified Command*
Establish an external Vaccine Advisory Workgroup										*Vaccination Unit*
Develop a budget for COVID-19 needs including ancillary supplies, staff, equipment, communications campaign										*Vaccination Unit*
Review data from COVID-19 trials provided through the Food and Drug Administration, Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) and post-survellience monitoring regarding the safety and efficacy of COVID-19 vaccine candidates										*Vaccine Advisory Workgroup*
Identify, estimate and locate critical populations										*Vaccination Unit*
Identify and help establish partnerships with trusted community organizations in order to facilitate communication channels, methods for rapidly disseminating information and ensuring that critical populations have access to the vaccination										*Vaccine Advisory Workgroup*
Establish and maintain points of contact (POCs) for specific organizations within the community who may serve as partner and trusted sources within the community and critical population groups										*Vaccine Advisory Workgroup*
Develop strategies to reach critical populations to administer vaccine and identify any barriers needed to overcome to reach critical populations										*Vaccine Advisory Workgroup / Vaccination Unit*
Identify communications vendor and develop and implement robust communications plan										*Vaccination Unit*
Vet messaging of COVID-19 vaccine to the population, including identifying key audiences, effective communication activities, and messaging considerations such as risk/crisis response communication messaging and delivery										*Vaccine Advisory Workgroup*



Conduct table top exercise of mass COVID-19 vaccination response to inform vaccination planning										*Vaccination Unit*
Identify vaccine providers and vaccine administration capacity for the providers										*Vaccine Advisory Workgroup / Vaccination Unit*
Define and develop required training and reporting expected of COVID-19 vaccine providers										*Vaccine Advisory Workgroup / Vaccination Unit*
Develop a vaccination plan based on the CDC playbook and incorporates CDC feedback										*Vaccination Unit*
Identify barriers (PPE, reimbursement of administration fees) for providers and strategies to mitigate as possible										*Vaccine Advisory Workgroup*
Develop and implement a process for vaccine allocation and distribution										*Vaccination Unit*
Develop and implement a process for vaccine inventory and ordering										*Vaccination Unit*
Provide training to vaccine providers for vaccine storage and handling (for all expected temperatures)										*Vaccination Unit*
Develop and implement a process for vaccine tracking (administration, wastage)										*Vaccination Unit*
Develop and implement a process for vaccine redistribution tracking										*Vaccination Unit*
Develop and implement a process to disseminate vaccine doses administered data (CDC, State, Local)										*Vaccination Unit*
Ensure capacity for data exchange, security, storage, and reporting										*Vaccination Unit*

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