Division of Immunization, Office of Epidemiology

Virginia Department of Health

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Introduction

During Special Session I of the 2020 General Assembly, HB5005, Item 299#1c, was passed by the General Assembly and signed by the Governor requiring the Virginia Department of Health (VDH) to convene a work group to (i) evaluate the methods by which vaccines and other medications necessary to treat or prevent the spread of COVID-19 are made available to the public; (ii) identify and develop a plan to implement specific actions necessary to ensure such vaccines and other medications are equitably distributed in the Commonwealth to ensure all residents of the Commonwealth are able to access such vaccines and other medications; and (iii) make recommendations for any statutory, regulatory, or budgetary actions necessary to implement such plan. The bill requires that the work group include the Commonwealth's Chief Diversity, Equity, and Inclusion Officer and representatives of the Office of Health Equity at VDH, the Department of Emergency Management, and such other stakeholders as the department shall deem appropriate and which may be an existing work group or other entity previously convened for a related purpose. Finally, the bill requires VDH to make an initial report on its activities and any findings to the Chairs of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by December 1, 2020, and shall report monthly thereafter.

Background

In March 2020, the Commonwealth of Virginia established a unified command system to manage the state-level response to COVID-19. In June 2020, the Vaccine Unit was formed under the Public Health Surveillance and Guidance Workgroup to conduct planning and coordination of COVID-19 vaccination. In August 2020, the Vaccine Unit established a COVID-19 <u>Vaccine Advisory Workgroup</u>, made up of a diverse group of stakeholders, to provide ongoing input regarding vaccination planning and communications using a health equity lens. This past fall, VDH developed Virginia's COVID-19 vaccination plan, which was exercised with partner state agencies. This plan continues to be updated in collaboration with local health districts, the Virginia Emergency Support Team, and the COVID-19 Vaccine Advisory Workgroup as more information becomes available. The most current information, including the plan, is available at https://www.vdh.virginia.gov/immunization/covid19vaccine/.

Findings

COVID-19 Vaccines Available in the United States

As of December 31, 2020, the U.S. Food and Drug Administration (FDA) had issued emergency use authorizations (EUAs) for two COVID-19 vaccines. Pfizer-BioNTech submitted its application, including trial data, to the FDA requesting emergency use authorization (EUA) on November 20, 2020, and the FDA granted the EUA on December 11, 2020. On November 30, 2020, Moderna submitted its application, including trial data, to the FDA requesting EUA, and the FDA granted it on December 18, 2020.

Vaccine Allocation

The Centers of Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) and the National Academies of Sciences, Engineering, and Medicine have published guidance on populations of focus for COVID-19 vaccination and equitable access to

COVID-19 vaccination in the United States. ACIP reviews 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.

ACIP voted on December 1, 2020 to formally recommend that COVID-19 vaccine be distributed during Phase 1 in three timeframes: Phase 1a, 1b, and 1c. ACIP recommended that during Phase 1a, COVID-19 vaccine be allocated to healthcare personnel (HCP) and long-term care facility (LTCF) residents. ACIP recommended that among LTCF groups, vaccine first be allocated to skilled nursing facilities, then to assisted living facilities, then to residential care communities, then to intermediate care facilities for individuals with developmental disabilities, and then to state veterans homes.

ACIP ethical principles for allocating initial supplies of COVID-19 vaccine, namely to maximize benefits and minimize harms, promote justice, and mitigate health inequities, support this decision. LTCF residents, because of their age, high rates of underlying medical conditions, and congregate living situation, are at high risk for infection and severe illness from COVID-19. As of November 15, 2020, approximately 500,000 COVID-19 cases and 70,000 associated deaths had been reported among residents of skilled nursing facilities in the United States. As of December 1, 2020, approximately 245,000 COVID-19 cases and 858 COVID-19-associated deaths had been reported among U.S. HCP. Early protection of HCP is critical to preserve capacity to care for patients with COVID-19 and other illnesses.

In response, the Virginia Disaster Medical Advisory Committee (VDMAC) and the Virginia Unified Command voted to adopt ACIP recommendations in Virginia. <u>The Virginia Disaster</u> <u>Medical Advisory Committee (VDMAC) provided guidance</u> on how to prioritize vaccine within subgroups of healthcare providers. However, they stressed the importance of not missing opportunities to vaccinate HCP out of strict adherence to prioritized groupings, with the goal of administering vaccine in Virginia as quickly as possible. Vaccine is being allocated to HCP who are public-/patient-facing and not able to perform their duties remotely. The Virginia Department of Health (VDH) estimates that there are more than 500,000 HCP and LTCF residents in Virginia.

On December 20, 2020, the Centers for Disease and Prevention <u>Advisory Committee on</u> <u>Immunization Practices (ACIP)</u> recommended that in Phase 1b nationally, vaccine should be offered to people \geq 75 years of age and to frontline essential workers (non-health care workers). In Phase 1c, vaccine should be offered to people 65–74 years of age, people 16–64 years of age with high-risk medical conditions, and essential workers not recommended for vaccination in Phase 1b.

On January 12, 2021, the U.S. Department of Health and Human Services issued new guidance to states recommending they open vaccine availability to all people ages 65 and older and to those under 65 with high-risk medical conditions. At the same time, the Department indicated that it would reverse its policy of holding back half of the federal vaccine supply for second doses, thereby significantly increasing deliveries to states. On the basis of this guidance, Governor Northam announced on January 14, 2021, that Virginia would update the Phase 1b eligibility criteria as recommended.

Almost immediately thereafter, federal officials acknowledged that the allocation change had already occurred in December 2020, and there was no remaining second-dose reserve to be released. This left approximately half of Virginia's population in Phase 1a or Phase 1b, with no increase in supply.

Vaccine Distribution

The majority of LTCF residents and staff in Virginia elected to receive vaccinations from CVS and Walgreens' teams onsite through CDC's Federal LTCF Pharmacy Partnership. VDH notified CDC on December 10, 2020 that it was activating Part A of the contract as of December 14, 2020 and allocated Pfizer vaccine for that purpose.

The first shipment of vaccines from Pfizer-BioNTech (Pfizer) were received in Virginia on December 14, 2020. The Pfizer-BioNTech vaccine requires ultracold storage (negative 70 degrees Celsius) and was distributed to geographically diverse health care systems with ultracold storage capacity. They were provided for HCP. Healthcare systems and local health departments are now holding vaccination clinics, utilizing both Pfizer and Moderna vaccine, for healthcare personnel across the state. Local health districts are developing plans to ensure opportunities for non-hospital healthcare personnel to get a COVID-19 vaccine. Together with healthcare systems, they are making plans to hold vaccination clinics for providers in their areas. Local health districts are reaching out to practices to engage them in this process. Opportunities for vaccination will continue to increase.

CVS and Walgreens began onsite vaccination in skilled nursing facilities on December 28, 2020. Part B of the CDC's Federal LTCF Pharmacy Partnership provides for vaccination in assisted living facilities, continuing care retirement communities, personal care homes, residential care, adult family home, adult foster home, intellectual or developmental disabilities, HUD 202, and Veteran's homes. On December 31, 2020, VDH notified CDC that it was activating Part B of the contract as of January 4, 2021 and allocated Pfizer vaccine doses for that purpose. CVS and Walgreens began contacting facilities to schedule clinics and initiated facilities covered by Part B in January 2021.

COVID-19 vaccines are allocated to the Commonwealth by the federal government on a weekly basis. The amount of vaccine and the timing of when Virginia will receive it will depend on the capabilities of the manufacturers to produce the vaccine safely, but it has been approximately 105,000 first doses per week for several weeks. When first doses are shipped, the U.S. Government sets aside doses for second dose allocation. They are allocated at the appropriate interval in addition to vaccine allocated for people to receive their first dose.

VDH established a <u>dashboard</u> on its website to keep people apprised of the number of vaccine doses distributed in Virginia and the number of doses administered. It is updated daily. As of December 31, 2020, a total of 388,100 doses of COVID-19 vaccine had been distributed from the two manufacturers to 110 sites in Virginia, including healthcare facilities and local health departments, and 64,882 people had been reported to VDH as receiving a vaccination. The number of doses of vaccine administered shown on the vaccine dashboard will always lag behind the actual number of doses administered. Providers must record vaccinations into the Virginia Immunization Information System (VIIS), and there is a delay between the recording and availability of this information. VIIS is a confidential, secure registry containing vaccine information provided by participating providers to individuals of all ages.

On January 21, 2021, President Biden released the <u>National Strategy for the COVID-19</u> <u>Response and Pandemic Preparedness</u>, which included the expectation of a 16% increase in the federal allocation of vaccines to states. This is expected to mean approximately 122,000 weekly first doses for Virginia, instead of the current 105,000. Supply is not expected to significantly increase again until March 2021.

There are simply not enough doses available yet for everyone who is eligible to receive them. Virginia is not likely to catch up to the demand for Phase 1b until March or April. On January 27, 2021, VDH expanded the Virginia Vaccine Summary Dashboard to provide greater transparency about the status of doses that have been received and administered. Dedicated teams worked to reduce the backlog of data entry from vaccine providers, clarify the status of doses sent to CVS and Walgreens, align the timing of Virginia's data submissions to the CDC with those of other states, and identify excess vaccine supply in one location that could be quickly redistributed to be administered. As a result, Virginia now ranks 12th among all states in per capita vaccinations, and 18th for percent of available doses administered. As of January 31, 2021, more than 87% of all available first doses had been administered.

Virginia's dashboard does not include vaccine allocations to employees of the Department of Defense, certain other federal agencies, and the Indian Health Service because those doses are administered by those agencies directly. VDH is working with federal partners to obtain more detail about those efforts, with the goal of adding more information to the dashboard.

Allocation Strategy

During the first several weeks of vaccine distribution in December 2020 and January 2021, there were more doses available than vaccinators who had the ability and capacity to administer them. As a result, VDH distributed Virginia's allocation of vaccine to nearly any vaccinator who had an immediate plan to use it. This included many hospitals, which already had the necessary staff and infrastructure, and who employed a significant portion of individuals eligible to be vaccinated in Phase 1a. While many hospitals made quick use of all doses, some wound up with far more doses than they needed (based in part on how many 1a individuals actually chose to get the vaccine, and in part on a mistaken belief that part of the supply had to be reserved for second doses).

In mid-January, as additional vaccinators became available, VDH reached the point of approximately three times the demand for doses from vaccinators as Virginia actually received from the federal government. This required an allocation strategy based on limited resources instead of the previous approach of filling every valid order. Doses are now allocated to local health districts based on population, with the expectation that each district leverages any available combination of vaccinators. This may include the district's own staff, hospitals and health systems, pharmacies, individual providers, Medical Reserve Corps volunteers, and Virginia National Guard members when deployed.

Although this allocation strategy is intended to provide for local flexibility, it became clear that some statewide consistency was needed. On January 27, 2021, Governor Northam announced that local health districts should use roughly half of available doses for people age 65 and older. The other half should be used for frontline essential workers; people who are at increased risk of severe illness, <u>as identified by the CDC</u>; and people in correctional facilities, homeless shelters, and migrant labor camps. Local health districts should use the order of priority for frontline essential workers in the <u>Phase 1b details</u>.

Access to Information and Pre-Registration

Currently, individuals who are eligible for vaccination must pre-register with the local health districts where they live (if eligibility is based on age or medical condition) or work (if eligibility is based on occupation). VDH has directed each local health district to ensure that information about the current phase of vaccinations is clearly available on their homepage, and that a pre-registration form and phone number are provided. Still, it is sometimes difficult for individuals–particularly those without internet access–to understand and navigate the appropriate pre-registration process.

On January 27, 2021, Governor Northam announced that VDH will soon dramatically increase the capacity of its statewide call center (877-ASK-VDH-3) to improve access to information and help individuals pre-register. A statewide pre-registration form will soon replace the ones on each local health district's website.

Registration and Scheduling

Once individuals pre-register, local health districts invite them to register for individual vaccination clinics through an appointment system. The selection of individuals to invite for each clinic is based on prioritization of eligibility groups and operational efficiency. It is critical to make these selections with an equity lens, and to evaluate whether otherwise objective selection criteria may have results in disparate impact on underserved populations. The interagency Health Equity Work Group and VDH's Office of Health Equity are assisting with these issues, and have recently been elevated to a more prominent role in the command structure of Virginia's pandemic response.

Ongoing Efforts

At the beginning of February, a survey (N = 34) was administered to the local health districts, exploring how they are currently addressing and plan to address equitable COVID-19 vaccine outreach to their communities. The majority of respondents indicated that they are aware of and have deep connections with the vulnerable populations in their region. Local health districts are extensively using available data (e.g., from Community Health Assessments) to identify vulnerable populations, and they welcome any additional data that the state could provide. VDH is currently working with the Commonwealth's Chief Data Officer to provide such data by adding missing vaccine-related race/ethnicity data. Local health districts shared various existing practices used to address equity, including establishing Health Equity Teams; forming partnerships with community partners (e.g., NAACP); and utilizing media outreach (e.g., via Spanish-language radio stations). Furthermore, nearly half (n = 16) of the responding local health districts indicated that they currently have community health workers who engage with vulnerable populations, with nearly 90% (n = 14) of those respondents adding that the district is using and/or has plans to use those CHWs to reach out to vulnerable populations regarding COVID-19 vaccination. Slightly more than 90% of all responding local health districts (n = 31)also stated that, if funding were available, they would hire more CHWs for this purpose.

Statutory, Regulatory, or Budgetary Actions

The COVID-19 vaccine landscape is complex and evolving. These complexities include the likely need for a two-dose series; vaccine products not being interchangeable; varying presentations and efficacy and adverse event profiles in different populations; varying cold-chain requirements; unknown ability to administer to children and pregnant women; the need for

socially distanced vaccination practices; communication and education; and distrust of public health among some high-risk groups. In order to ensure a successful mass vaccination campaign once vaccines become available, VDH will require funding to support the purchase of equipment and ancillary supplies and also will require funding for information management staffing, support for local health districts, warehousing and shipping, and a statewide communications campaign. For instance, in the aforementioned survey, The Governor has included language in his budget to support expected COVID-19 vaccine expenditures through June 2022. Furthermore, House Bill 2333 and Senate Bill 1445, which have passed both houses during the 2021 General Assembly session, seek in part to address the data gap that exists around race/ethnicity reporting by making it a requirement to capture this info for all individuals vaccinated for COVID-19.

Conclusions

The COVID-19 vaccination response is complex and will continue to evolve. VDH continues to update its planning on new information and expects continued adaptation as new vaccines are introduced and other considerations arise. VDH will continue to publish new information on its external <u>COVID-19 vaccine website</u> as it becomes available.