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Medical Intelligence Report

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Topic: Update on COVID-19 Vaccine Distribution

Overview

There are both practical and ethical issues surrounding the planning for distribution of a potential vaccine for COVID-19. Discussions are taking place in order to have a system ready once a vaccine has been proven to be efficacious and safe. Approval of a vaccine requires assessment of key factors, including safety, efficacy in preventing disease or reducing the severity of disease, and the duration of protection (Anderson et al., 2020). While the duration of the effect from a COVID-19 vaccine cannot be known for some time, manufacturers and researchers are close to having information on the efficacy of several potential vaccines.

> **As of November 4, there were 45 candidate vaccines being investigated in human clinical trials, and ten have progressed to Phase 3 trials, which is the final step before evaluation by government agencies such as the FDA.**

Effects of Differences between Manufacturers' Vaccines

Numerous different companies are in the process of developing vaccines for COVID-19. This is an advantage because it means that if one type is not effective there are others that will be available, but even if all of the proposed vaccines are shown to be effective differences are to be expected. The differences in the components of the vaccines may lead to variation in the safety and efficacy profiles across different population groups (Toner et al., 2020). In their framework for the allocation of COVID-19 vaccines, experts from John Hopkins University state,

> **The effectiveness of a vaccine can be defined by its ability to prevent infection, serious disease, and/or transmission. Some vaccines may be very effective at preventing disease but not as effective at blocking infection or further transmission.**

Due to changes in the immune system with age, vaccines often are less effective in older adults requiring higher doses to achieve an effective immune response. Additionally, each vaccine will have specific logistical and injection requirements.

These potential differences may mean that different vaccines are recommended for different groups or are used in different ways.

Effect of Limited Supplies of Vaccine

When a vaccine first becomes available, there will be limited amounts available due to manufacturing restraints so that only part of the entire population can be immunized. On an individual level, immunity is not conferred at the time of vaccination (Toner et al., 2020). Instead, immunity to the virus may not begin to emerge for up to two weeks after the first dose, and the peak immune response typically is achieved two to four weeks after the second dose with vaccines requiring two doses.

It may take as long as six to eight weeks for an individual to become "immune" after their first dose of vaccine.

Until full immunity is reached, breakthrough infections of the virus may occur among immunized or partially immunized individuals in the first 2 months after they have been vaccinated. Both because of the lag in immunity after vaccination and limited supplies early on, the impact of vaccination on community transmission is expected to also increase slowly over several years.

Researchers must determine how much vaccine is required to create a level of immunity that will block SARS-CoV-2 transmission (Anderson et al., 2020). Once this is known, policy makers will be able to define a threshold where sufficient amounts of vaccine are available for mass vaccination of the entire population and lift restrictions on who has priority for early immunization. Current estimates suggest that between 60% and 72% of a population will need to have immunity to SARS-CoV-2 in order to prevent transmission if a vaccine is 100% effective and provides lifelong immunity.

When calculated using a vaccine with 80% efficacy with lifelong immunity, the level of immunity required to prevent transmission in a population is between 75% and 90%.

If the vaccine provides shorter term immunity, repeated vaccination will be required. However, in the case of transient immunity, the percentage of the population that must be vaccinated in the first year is much larger than the percentage requiring vaccination once the transmission has been reduced and stabilized for a few years.

Priorities for Immunization

In most areas of the world, policy makers are reported to be prioritizing healthcare workers and individuals carrying out essential services for the first doses of vaccine. From there, officials must decide on their priority for mass vaccination.

Two endpoints that are often discussed while planning vaccine distribution are

- Priorities that minimize the number of deaths in a population, or the net mortality, per year
- Priorities that maximize the average number of years of life gained by an individual receiving the vaccine

In the course of these considerations, policy makers must weigh such factors as the number of life-years gained with adjustment for possible disability after illness or with advancing age and the impacts on society from the minimization of long-term disability from COVID-19 infection. The fatality rates of COVID-19 are the highest in individuals over the age of 70, and researchers at the Department of Infectious Disease Epidemiology at Imperial College in London, United Kingdom have calculated that focusing on those over the age of 70 would have the most effect on mortality from the virus (Anderson et al., 2020). This differs from the strategy employed for other vaccines, such as measles, where the young are most vulnerable and therefore targeted for vaccination.

Process of Federal Recommendations for the Use of Vaccines

The first step of the process for providing a vaccine to the population of the United States is review of the efficacy and safety by the FDA. The FDA can issue an Emergency Use Authorization (EUA) for COVID-19 vaccines or a full approval. In both scenarios, the efficacy and safety of the vaccine must be proven by the manufacturer based on clinical trials, but the amount of evidence that must be presented for an EUA is not as stringent as needed for full approval.

Use of Expanded Access Programs

There have also been discussions about using the FDA's expanded access programs (sometimes called Compassionate Use programs) to provide vaccine to the first groups of people (Branswell, 2020). The difference between EUA and expanded access means that the vaccine would not be available to the general public, and only those enrolled in the program could get the vaccine.

The main requirement that must be met for implementing expanded access is that "the patient must have a serious or immediately life-threatening disease or condition and have no comparable or satisfactory alternative therapy." The process has been streamlined so that it typically takes less than an hour to complete an expanded access application, and the FDA approves 99% of requests (McCarthy et al., 2020). Experts have suggested using expanded access programs in order to preserve the integrity of ongoing large-scale clinical trials while still allowing those at high risk for COVID-19 access to the vaccines.

Using the expanded access program would help ensure that there is an incentive for people to continue to participate in clinical trials rather than to try and access the vaccine on their own.

If a vaccine is granted an EUA, it is available for use by anyone who falls within the indications for use. Because state and local governments will be in charge of distribution early on, not everyone will have access to a vaccine, but knowing that they are available would be expected to reduce the number of people willing to enter clinical trials and potentially receive the placebo instead of the active vaccine. A similar problem occurred with clinical trials for convalescent plasma to treat COVID-19 after it was designated for EUA because potential volunteers were concerned about receiving the placebo rather than the active medication.

Additionally, if a vaccine is granted EUA status, there is a question of whether the people who were randomly assigned to receive a placebo in a clinical trial should be informed before the end of the trial. Once participants know they have not received the vaccine, researchers would no longer be able to compare the results from the two groups, leading to truncated data for the determination of efficacy. The types of questions that would be affected include whether the vaccines reduce the number of severe COVID-19 cases and if there is a difference in the efficacy in different subsets of the population, such as older individuals or people with racial or ethnic minority backgrounds. There may also be differences in the length of the efficacy between different vaccines that would be difficult to determine with truncated results. Several groups representing consumers in the general public supported the idea of using expanded access programs because it would allay rising concerns that political will instead of scientific evidence was driving the approval.

Use of an expanded access program would lead to an increase in the steps needed to receive the vaccine because it would still be considered an experimental treatment. This means that before being vaccinated, individuals would need to sign informed consent forms, which are lengthy and complicated. The forms allow for a discussion of risks and benefits of the treatment, but their use would slow down the process of distributing the vaccine. There would also be additional requirements to track safety data compared to use of a vaccine with an EUA.

Steps after FDA Acceptance

Once the FDA certifies that the vaccine is effective and safe by issuing an EUA or other type of approval, the Advisory Committee on Immunization Practices (ACIP) develops recommendations on the use of the vaccine (CDC-How CDC, 2020). The ACIP is a federal advisory committee made up of medical and public health experts that holds regular meetings about newly approved vaccines.

The ACIP will also review the data from the clinical trials, and then members of the group will vote on whether to recommend the vaccine and who should receive it.

Additionally, The National Academy of Sciences, Engineering, and Medicine (NAS), a society created by Congress in 1863 to provide independent, objective advice to the United States on matters related to science and technology, has released a document entitled “Framework for Equitable Allocation of a COVID-19 Vaccine” for adoption by the Department of Health and

Human Services (HHS), state, tribal, local, and territorial authorities (NAS, 2020). This publication will also be included in policy discussions.

The decision on who receives the vaccine includes decisions based on the clinical trial data so that those who are vaccinated receive a benefit and are safe. In some cases, vaccines have different levels of effect on different groups or lead to negative effects in certain people, such as children, the elderly, or people with other health conditions. The ACIP takes into consideration evidence from clinical trials that includes this information, and provides recommendations for use of the vaccine in individuals who would receive the most benefit, a distinction which becomes more imperative when supplies are limited. They also define priorities for which groups should be vaccinated first when supplies are limited as is expected in the near future for COVID-19 vaccines. The recommendations are then sent to the director of the CDC for review and approval before becoming official CDC policy.

Goals Stated by the ACIP when Supplies Are Limited

Early on, It is expected that supplies of vaccine will be limited compared to the number of doses needed to provide vaccination for the entire population due to the need to produce, package, and distribute the vaccine. With this in mind, the ACIP has already set up goals for recommending which groups should receive the available COVID-19 vaccine (CDC-How CDC, 2020).

The four goals set forth by the ACIP for COVID-19 distribution are to

- Decrease death and serious disease as much as possible
- Preserve functioning of society
- Reduce the extra burden the disease is having on people already facing disparities
- Increase the chance for everyone to enjoy health and well-being

To aid in the development of distribution plans, the ACIP has also identified some ethical principles to apply to the decision making process. The first is to minimize both deaths and severe illness. They also stress the need to mitigate the health inequities that already exist for certain populations. They suggest that there should be an effort to promote justice by treating affected groups and communities fairly. Additionally, barriers to vaccination should be identified and removed. Finally, officials should make the process transparent so that decisions are clear, understandable, and open for review with public participation in both the creation and review of processes.

With these ethical principles in mind the ACIP has made recommendations for groups to receive early vaccination for COVID-19. The recommendations were made after consideration of the public health data describing the location of outbreaks, who is most likely to become infected, who has been shown to have the most severe outcomes after infection, and how to aid in the continuation of necessary services for the rest of the population.

The four groups identified by the ACIP to for early vaccination with limited supplies are

- Healthcare personnel
- Workers in essential and critical industries
- People at high risk for severe COVID-19 illness due to underlying medical conditions
- People 65 years and older

The specific rationale for including healthcare workers in the first groups to be vaccinated are straightforward. People providing healthcare have a high risk of being exposed to and getting sick with COVID-19. Once infected, healthcare workers are also in a position where they could inadvertently spread COVID-19 to vulnerable patient groups.

Based on their definitions, the ACIP estimates there are approximately 21 million people that would be part of this group.

There are also certain occupations that are considered to be critical by the Cybersecurity and Infrastructure Security Agency. In additional to having roles essential to our country, doing their jobs often put this group in situations where viral transmission is more likely. Early vaccination of this group would both prevent transmission in a population that is more vulnerable as well as allow for the continuation of essential services.

The other two groups were selected for early vaccination because of an increased risk for severe outcomes from COVID-19, including hospitalization, intensive care, use of a ventilator, or death. Vaccination would ensure the health and safety of these populations.

Goals Stated by the NAS when Supplies Are Limited

The committee from the NAS has recommended a four phased approach based on evaluation of the currently available public health information that is focused on reducing morbidity and mortality caused by the transmission of SARS-CoV-2 (NAS, 2020).

The first phase (Phase 1a) of their plan covers approximately 5% of the United States population and includes front-line health workers (in hospitals, nursing homes, or providing home care); workers who provide healthcare-facility services such as transportation and environmental services who may also be exposed to bodily fluids or aerosols; and first responders.

The second part of Phase 1, Phase 1b, covers approximately 10% of the population and includes people of all ages with comorbid and underlying conditions (for example, cancer, serious heart conditions, and sickle cell disease) that put them at significantly higher risk of severe COVID-19 disease or death. Additionally, individuals over the age of 65 living in congregate or overcrowded settings including nursing homes, long-term care facilities, homeless shelters, group homes, prisons, or jails would be included in Phase 1b.

The second phase of the vaccination plan would cover approximately 30% to 35% of the of the population and includes K-12 teachers and school staff (including administrators, environmental services and maintenance workers, and bus drivers), child care workers, and critical workers who cannot avoid a high risk of exposure to COVID-19, such as workers in the food supply system and public transit. Other groups designated for Phase 2 include people and staff from homeless shelters, group homes for people with disabilities, and recovery programs; people and staff in prisons, jails, and detention centers; and all adults over the age of 65 not included in Phase 1.

Phase 3 covers approximately 40% to 45% of the population, including young adults (between 18 and 30 years), children, and workers in industries such as colleges and universities, hotels, banks, exercise facilities, and factories that are both important to the functioning of society and pose moderately high risk of exposure. The inclusion of children and young adults is due to the increased number of contacts these groups have, making them a reasonable target for preventing transmission lines even though they are at lower risk of poor outcomes after infection. Finally, Phase 4 includes everyone not previously vaccinated.

In addition to recommendations on the priority of vaccinating different groups in the United States, the NAS committee also included recommendations for other components of the vaccine program for HHS.

Other recommendations from the NAS committee:

- Expand the use of existing systems across all levels of government and provide the necessary resources (including funding items such as needles, syringes, and personal protective equipment for vaccinators) to ensure equitable allocation, distribution, and administration of COVID-19 vaccine.
- Secure vaccine storage, transport, and safe, efficient, and equitable vaccine distribution due to the potential ultra-cold requirements and a multidose vaccine regimen.
- Coordinate across agencies to provide and administer COVID-19 vaccine with no out-of-pocket costs for those being vaccinated, regardless of their social and economic resources or their employment, immigration, or insurance status.
- Create and appropriately fund a COVID-19 vaccination communication and community engagement program to support state and local authorities.
- Community-based organizations and other partner organizations, including hospitals, pharmacies, faith-based organizations, community centers, and schools and universities, can support community outreach and foster accountability.
- Employers and unions could support improved access by providing work-site clinics and by covering costs for employees.

Distribution Worldwide

Members of the public health community around the world are also stressing that the recommended strategy to both protect the most people and slow transmission should be applied on a world-wide scope. This would mean that the groups identified as the early recipients for the vaccine (Phase 1 and 2) across the world would be inoculated before those at lower risk (Phase 3 and 4) in the United States would receive the vaccine (Kupferschmidt, 2020b).

The World Health Organization (WHO) has set up a system to accelerate and equitably distribute vaccines called the COVID-19 Vaccines Global Access (COVAX) Facility (GAVI, 2020). The COVAX program includes research, development, and manufacturing in order to consolidate the costs of producing vaccines. While poorer countries would not be able to develop vaccines on their own and require aid in procuring doses for their population, the model was set up to benefit richer countries as well by splitting the cost of starting large-scale manufacture of vaccines before efficacy and safety information was available. By having the vaccine already manufactured before clinical trials are finished, the distribution can begin more quickly. However, if the vaccine ends up not being effective, the money used in production will have been wasted, making cost sharing attractive. Also if the vaccines invested in or pre-ordered do not end up being effective, countries would still have access to alternative vaccines through COVAX. In their report, the NAS recommends that the United States join the COVAX program. Based on their assessment, the country would both increase its chances of access to effective COVID-19 vaccines and regain a position of global health leadership (Branswell and Silverman, 2020).

Expected Number of Doses of Vaccine

Based on the estimated capacity reported by each company manufacturing vaccines, more than ten billion doses of the frontrunner candidates currently in clinical trials could be available by the end of 2021 though some experts feel that is an overly optimistic estimate (Callaway, 2020). Outside groups have estimated lower levels of production based on previous knowledge that range from one billion doses to four billion by the end of 2021. Many of the vaccines that are closest to approval for use require two doses, and the current population of the world is estimated to be around 7.8 billion.

On November 17, the chief executive of Pfizer, Dr. Albert Bourla, said the company can produce up to 50 million doses by the end of the year, and half of that supply will go to other countries (Thomas, 2020 and Robbins and Gelles, 2020).

> **Because the vaccine requires two doses, there will be enough Pfizer vaccine to fully inoculate 12.5 million Americans in 2020.**

The company had originally estimated that they could produce 100 million doses but fell behind due to setbacks from ordering new equipment and slower than expected delivery of raw materials. Paul Mango, deputy chief of staff for policy at the Department of Health and Human Services, stated that if several vaccines were authorized by the Food and Drug Administration in the next few months, he estimates that the United States might have “several hundred million” doses available by the end of March.

As of August 27, the United States had reportedly secured 800 million doses of at least six potential vaccines with an option to purchase one billion more doses for the approximately 330 million Americans. The United Kingdom had purchased 340 million doses, which corresponds to 5 doses for each citizen. Countries in the European Union are purchasing doses as a group. There has thus far been little transparency on the deals between manufacturers and different countries concerning number of doses or price of a dose. Further complicating the issue is that the United States and the United Kingdom both have sponsored the development of the vaccines, and it is not known if there were agreements based on this support for access to vaccines that arise.

Practical Considerations for Vaccine Distribution

While the federal government has provided some guidance on which groups should have priority while supplies of vaccine are limited, there are numerous other practical issues that need to be addressed. The vice president for pandemic response and recovery for the Association of State and Territorial Health Officials James Blumenstock stated that it is necessary to determine who is in charge of ordering supplies, signing up vaccine providers, training staff, and running the mass vaccination clinics and outreach campaigns (Simmons-Duffin and Huang, 2020). Systems will also be needed to track who has received an initial vaccine dose and to remind them to come back for their second dose.

Prioritizing Recipients

States will have to do their own process of prioritizing groups who will be first to be vaccinated (Branswell, 2020).

While the guidelines are established at a federal level, the process is carried out by state, local, and tribal governments.

State and local groups will make the final decisions on who is included based on their own priorities, and this process may become contentious. There is also concern that different policies in different areas may lead to differential access to vaccines and varying levels of control of the virus, which could impact neighboring jurisdictions (Michaud and Kates, 2020).

After the specific definitions of each group are determined, it will be necessary to also determine how people will be required to prove that they are part of a prioritized group. Individual doctor's offices would be able to identify individuals they have treated for the conditions, but they would likely not be able to administer the vaccine to large groups of people in an efficient manner. There are also individuals without access to a primary care provider that would not be able to access the vaccine in this way. Using vaccination clinics established specifically for efficient administration of the vaccine would allow for treatment of more people more quickly, but requiring documentation would put a stress on physician's offices and using the honor system could lead to abuse by some individuals.

Requirements for Pfizer's Vaccine

In the case of the vaccine from Pfizer, there are also complications with the transportation and storage of the vaccine (Branswell, 2020). The active ingredient in the vaccine, mRNA, is not very stable above freezing temperatures, and it must be transported and stored at -70° C, which is the temperature of dry ice. Most doctor's offices do not have refrigeration units that can store items at this temperature as typical freezers function at around -20° C. The company has designed special shipping boxes that contain dry ice and can maintain the correct temperature if opened twice a day for no more than a minute at time. However, the dry ice must be replenished as it evaporates and the time constraints for opening the boxes are not conducive to normal vaccination activities, suggesting that other storage options are necessary. Officials have also voiced concerns over if supplies of dry ice are sufficient to meet the increased demand.

Another complicating factor is that Pfizer is providing the vaccine in packages of around 1000 doses, and smaller orders are not available due to the configuration of the ultra-cold shipping containers. This type of packaging will be useful for large hospital institutions with access to freezers at -70° C, but could pose difficulties for other vaccination providers who need fewer doses and do not have special freezers. Once the vaccine is thawed, it can be stored in the refrigerator for up to 5 days, but it cannot be refrozen if a provider no longer needs it, causing concern for wasted doses.

Other vaccine developers, including Moderna, have made modifications to their vaccines that allow for storage at 4° C (the temperature of a typical refrigerator) and -20° C.

Other Areas of Concern

A shortage of custom made plastic bags used to produce virus in bioreactors has also been reported (Thomas, 2020). HHS has a $31 million contract with manufacturer Cytiva who makes the bags and other materials for vaccine production in the United States, but other countries are having problems accessing the supplies.

Providing sufficient numbers of needles, syringes, alcohol pads, and personal protection equipment for vaccinators is also necessary (HHS, 2020). HHS has "aimed to procure and assemble 6.6 million" kits for adults and children that would support the administration of up to 660 million doses of vaccine. The Biomedical Advanced Research and Development Authority of the HHS has put in orders for needles and syringes to "maximize the availability of needles and syringes toward the end of 2020." The Department of Defense has entered into agreements in coordination with HHS to increase needle and syringe capacity in the United States, and they report that some "will be available in time to support the COVID-19 vaccination in early 2021." HHS has also made agreements with factories to increase production of medical vials for packaging of the vaccine. To date, the federal government has obligated a total of more than $1.1 billion to purchase needles, syringes, vials and supply kits, and to expand the capacity to manufacture ancillary supplies and the fill-finish manufacturing capacity in the United States for COVID-19 vaccines and therapeutics.

Allocation of Vaccine

There are also concerns about how the amount of vaccine will be allocated to the different states, and how the state will allocate doses to local health departments and categories of providers (Bollyky and Emanuel, 2020). During the H1N1 pandemic, the vaccine in the United States was allocated based on population size. Experts suggest that, while this seems logical, using this method would not allow for coverage that would protect the most vulnerable.

Allocating vaccine based on population would not address the fact that the severity of the pandemic, the number of healthcare workers, and the proportion of people over 65 or with serious comorbidities is not evenly distributed across the country. For example, one out of five people living in Florida are over 65 while one in nine people in Alaska are over 65. Authorities must determine if Florida should receive a larger proportion of vaccine than Alaska or if areas of the country with larger outbreaks should be the first areas to get vaccine.

Experts from Johns Hopkins University stated that “Because the incidence and prevalence of SARS-CoV-2 will not be uniform across the country, distribution decisions may need to account for geographic variability” (Toner et al., 2020). They also present previous examples of how strategic deployment of vaccines can break chains of transmission.

Population-based distribution of a COVID-19 vaccine to states may not allow them to follow the prioritization plans they decide upon.

Distribution Plans

The CDC has stated that the advance planning that has been done will allow for vaccine to become available within a matter of days, rather than the typical months, after receiving authorization by the FDA (CDC Healthcare Professionals, 2020). The basic distribution plans are expected to build on existing vaccination plans that are used each year for other vaccines such as flu or shingles.

Federal Plans

HHS has signed a contract with the pharmaceutical distribution company McKesson, which is the company that distributed vaccine during 2009 H1N1 flu pandemic. (Schnirring, 2020). While McKesson will be responsible for shipping products and supplies to vaccine administration sites, the federal government is also planning on utilizing resources from the Department of Defense for logistical support. Experts have stated that distribution plans at the federal level seem to be going well, but plans at state and local levels are less clear due to limited specifics from both the manufacturers and the federal government. In the CDC playbook released to help with planning, the federal government has assured the states that it will procure and distribute the vaccine and any associated supplies (including needles, syringes, and limited masks and face shields) at no cost to providers (Cooper et al., 2020). However, once the vaccine and supplies are delivered to the state, they must implement their own plans.

Federal agreements have also been made with pharmacies across the United States to distribute free vaccines. The included pharmacies include major chain drug stores, grocery market pharmacies, and other chains so that about 3 out of 5 pharmacies in all 50 states are included in the network (Alonso-Zaldivar, 2020).

Distribution at pharmacies will not begin until after distribution to states for vaccination of the priority groups designated as part of the first phases of the vaccine program.

The CDC indicates that doses of vaccines purchased by the United States government will be available at no cost (CDC-FAQ, 2020). However, they stipulate that providers will be able to charge an administration fee for giving the shot. The fee is expected to be reimbursed by the individual's public or private insurance company or, for those who are uninsured, by the Health Resources and Services Administration's Provider Relief Fund.

Pfizer's Plans

Pfizer developed its vaccine outside of the federal program without accepting financial support and will bypass distribution by McKesson (Paris and Hopkins, 2020). The rationale for this plan is to speed transportation and avoid extra handling of the temperature sensitive product. The company has spent $2 billion on assembling a distribution network that is designed to move 7.6 million doses a day to airports. They have agreements with FedEx, UPS, and DHL for cargo space on 20 flights a day and truck service from the airport to vaccination centers. Based on their plans, the total delivery time is estimated to take three days from their distribution center to vaccination sites.

As of November 12, however, Pfizer had not been contacted by the federal government to inform them where the vaccine should be sent or who should get the first deliveries.

State and Local Plans

In preparation for vaccine distribution, the CDC has provided $200 million to the jurisdictions in the United States to help states and other communities prepare (CDC Newsroom, 2020). The specific amount of funds dispersed to each jurisdiction is based on the population of the region. However, the director of the CDC estimates that states will need $6 billion to distribute vaccines, and Association of State and Territorial Health Officials and the Association of Immunization Managers have written a formal letter to Congress outlining the need for $8.4 billion (Simmons-Duffin and Huang, 2020). The former director of the immunization program in Tennessee stated that the funds are needed for things such as staff, new computer systems, and people to use and maintain the new systems. In some cases, experienced staff from other health department areas will be reallocated to take advantage of their expertise, but their current roles at STD clinics and family planning organizations will still need to be filled by additional staff.

As mentioned above, while there are federal guidelines, each state or jurisdiction is in charge of formulating the details of the plan. The CDC has posted links to the preliminary plans for

coordinating vaccine response activities of each jurisdiction on their website. The most recent draft plans were uploaded on October 26.

https://www.cdc.gov/vaccines/covid-19/covid19-vaccination-guidance.html

The posted plans cover several topics about the local plans to distribute vaccinations. The first section outlines the phases of vaccine distribution, which are Phase 1 when supplies are limited; Phase 2, when there is expanded supply of vaccine; and Phase 3 when there is sufficient amounts of vaccine. There are also definitions of the critical populations that will receive vaccine in Phase 1, and outlines of methods of vaccination provider recruitment and enrollment. Because of the atypical storage methods for the Pfizer vaccine, there are also sections describing vaccine storage and handling, and how the states will monitor providers. Additionally, the vaccines that will be available first require two doses administered several weeks apart necessitating a system for reminding individuals when they need to return for the second dose. Specific plans for communication are also being required as well as monitoring the public for safety concerns as the vaccine is administered to a larger population and general program monitoring.

Example Plans

The **Maryland** state plan states that during Phase 1, when doses are limited, the vaccination efforts will focus on those at highest risk of developing complications from COVID-19 and those in critical workforce or infrastructure industries. They plan to work with state and local agencies to estimate the size of groups identified by the state and those listed in the ACIP recommendations. In order to recruit providers to administer the vaccine, the Maryland Health Department is currently recruiting and enrolling healthcare providers, local health departments, employee occupational health, and pharmacists who are in the health department's Immunization Information System (ImmuNet). The state plans to have specific vaccination sites for Phase 1, and people receiving the vaccine must be pre-registered using a program called PrepMod before they will be vaccinated. The PrepMod system is a preexisting system used for clinic management and appointment scheduling to conduct mass vaccinations. In Phase 2, orders from hospitals, local health departments, healthcare providers, and work sites will be tracked with an online tool as with previous vaccination efforts.

In the **North Dakota** plan, officials state that "It is likely that health care workers will be the first group recommended for vaccination." The state has also established an Advisory Committee on COVID-19 Vaccination Ethics to prioritize amongst federally recommended priority groups. Estimated numbers in each group will be compared to health care provider enrollment to determine allocations once vaccine is available. Some of the groups mentioned by the committee include those who are homebound, living in long term care facilities, custodial institutions (e.g. corrections and group homes), American Indians, and immigrant populations. Providers will be recruited through advertisements on various provider associations (North Dakota Medical, Pharmacy, Long Term Care, and Hospital), an immunization email list serv, and the North Dakota Department of Health website. The state is expecting to have problems with receiving the doses from the manufacturer because they are shipped in groups of 1,000 doses that are not useful for the smaller populations in rural areas and tribal areas in the state. Specifically, they mention that the CDC advises against redistribution of frozen vaccine, but they

foresee that it is unlikely that North Dakota will be able to fully meet the need of rural areas and tribes without repackaging some of the vaccine into smaller quantities. The state has a preexisting system that can be used for reminder and recall notifications for persons who received the initial dose of COVID-19 vaccine once the required time between doses has elapsed. The state also has acquired the PrepMod software for communication with vaccinated individuals.

The plan in **Ohio** states that officials have leveraged guidance provided by the NAS and advice from clinical leaders and the Ohio Department of Health's Bureau of Infectious Diseases. Based on that advice, vaccines will first be offered to high-risk healthcare workers, first responders, older adults in congregate settings, and people at significantly higher risk due to comorbid or underlying conditions. To recruit providers, the state has launched a registration tool that is open to all providers, including local health districts, hospitals, pharmacies, and nursing facilities. They also discuss that officials in Ohio are exploring several methods of notifying vaccine recipients of the need for second doses, in addition to the CDC recommended COVID-19 vaccination report cards. The processes being discussed include public communications emphasizing the importance of second-doses, direct outreach from the state (e.g., postcards, text messages), and calls or messages from provider to schedule and remind recipients about second doses.

Vaccination of People Who Have Recovered from COVID-19

At this time, it is not known how long immunity acquired from infection with SARS-CoV-2 lasts. It may be necessary for people who have recovered from COVID-19 to be vaccinated to improve the duration of the immune response. However, at this time since these are unknown quantities and because supplies of vaccine will be limited, it is not recommended that people who have recovered from COVID-19 be vaccinated (CDC-FAQ, 2020).

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