Special Report: COVID-19 Vaccine Allotment and Distribution

December 3, 2020

Recent advances in the race to develop a COVID-19 vaccine combined with the transition from a Trump to a Biden Administration have generated urgent questions about how and when a vaccine will be authorized and safely delivered to hundreds of millions of Americans. We understand how important the timing and prioritization of vaccine allotment and distribution is to you and your organization, so we have developed this Special Report providing the relevant details to ensure you have the most up-to-date information.

At the start of the effort to develop safe and effective vaccines for COVID-19, 50 companies positioned themselves with potential candidates for development. For easy reference, on the next page, we have provided a list of the frontrunners and details about their vaccine candidates. As of today, there are two vaccine candidates – from Pfizer and Moderna – that have applied to the FDA for Emergency Use Authorization (EUA). Both vaccines must be taken in two doses about a month apart.

Should those first two candidates be given the green light, approximately 40 million doses – enough for 20 million people – will be available in the U.S. by the end of 2020 with more doses to come in the first quarter of next year. and at least two others are expected to apply early next year.

While federal authorities, including the Centers for Disease Control and the U.S. military, have built a centralized allocation and distribution system, they are also providing guidance and coordination on administration to the State public health authorities, which will be responsible for administering the vaccine rollout and have final say on how to prioritize who gets the first doses of any coronavirus vaccines.

COVID-19 Vaccine Development – Current Frontrunners

Company	Type	Country	Development	Specifics
Pfizer BioNTech	mRNA	USA Germany	Phase III/EUA	• 95% effectiveness rate • Double dose • -70°C storage temp • $1.9 billion U.S. contract total projection: 1.3 billion doses worldwide by end of 2021 • FDA EUA decision expected after Dec. 10
Moderna NIH	mRNA	USA	Phase III/EUA	• 94.5% effectiveness rate • Double dose • -20°C storage temp for 6 months • FDA EUA decision expected after Dec. 17
Johnson & Johnson Beth Israel Lahey Health	Ad26 (viral)	USA	Phase III	• 99% effectiveness (early trial • Potentially single dose • -20°C storage temp for 6 months • $1 billion U.S. contract; $1 billion EU contract • Late Dec./early Jan. FDA EUA application expected
AstraZeneca University of Oxford	ChAd0x1 (viral)	UK Sweden	Phase II/III (combined)	• Strong immune response detected, esp. in older populations • 2-8°C stability • $1.2 billion U.S. contract (300 million doses) • Late Dec./early Jan. FDA EUA application expected
Novavax	Recombinant nano	USA	Phase II/III	• Effectiveness pending trial results • Double dose • $1.6 billion U.S. contract (100 million doses projected) • 2-8°C stability

Operation Warp Speed (OWS)

In a collaboration known as Operation Warp Speed (OWS), the U.S. government and the private sector have been working together toward the development and distribution of a COVID-19 vaccine to the American public. The federal agencies involved include the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense (DoD). Since July 2020, OWS has been led by COO General Gustave Perna, a four-star general and former commanding general of the United States Army Materiel Command, and Chief Advisor Moncef Slaoui, PhD, formerly of GlaxoSmithKline.

As part of this effort, U.S. Surgeon General Jerome Adams recently announced that the FDA hopes to quickly review and approve requests from two drug makers for emergency approval of their COVID-19 vaccines. Pfizer's submission for an Emergency Use Authorization (EUA) will be considered by the FDA on Tuesday, December 10, for the vaccine it developed with Germany's BioNTech. Moderna has submitted its own candidate for authorization, which is scheduled to be considered by the FDA on December 17. Internationally, the UK temporarily authorized Pfizer and BioNTech's COVID-19 vaccine on Wednesday, December 2, becoming the first country in the world to approve the Pfizer/BioNTech coronavirus vaccine and paving the way for mass vaccinations, which are expected to begin in earnest before the end of the year.

Distribution

Once a vaccine is approved, Gen. Perna anticipates distribution of allocated vaccine will be shipped to designated locations within 24-48 hours. In a recent press conference, Dr. Slaoui stated that due to investments the country made in scaling up and starting to stockpile manufacturing of the vaccines, he is confident that the program will be able to distribute enough vaccine to immunize 20 million people (40 million doses) in the US in December, and 30 million people (60 million doses) in January, and 50 million people (100 million doses) in February.

The prioritization of vaccine distribution is based on an October 2020 report from the National Academies of Sciences, Engineering, and Medicine (NASEM) focusing on high risk groups while ensuring that vaccine supplies are able to keep up with demand. NASEM's plan is currently being utilized by HHS, CDC, and DoD to inform a comprehensive centralized distribution effort for the vaccine.

The current distribution plan outlined by HHS envisions a centralized distribution mechanism utilizing CDC's 64 jurisdictions (50 states, six localities, and remaining territories and freely associated states), as well as Tribes and industry partners.

Each jurisdiction will operate off its own "micro-plan," which will determine the amount of vaccine delivered, timing of the delivery, and the method of distribution to individuals within relevant jurisdictions.

McKesson Corporation will serve as the centralized distributor for the vaccines. The delivery process requires secure health IT systems that can help scale up HHS's Vaccine Tracking System by assisting with incorporating new vaccine providers in each jurisdiction. This work is crucial as HHS and DoD have recently issued partnerships with an extensive network of pharmacy chains that cover nearly 60 percent of pharmacies throughout the CDC's jurisdictions. This network builds off of previous, targeted agreements with large pharmacy chains like CVS and Walgreens for facility-targeted administration of the vaccine when available.

First Allocation

U.S. officials will be deciding who receives the first coronavirus vaccines, a dicey political decision with life-or-death implications. Although public health experts broadly agree that groups at high risk – such as front-line health care workers and high-risk individuals such as those living in nursing homes – should be prioritized in any vaccination campaign, there will not be enough doses initially to treat all members of those groups.

The CDC's Advisory Committee on Immunization Practices (ACIP) held an emergency meeting on Tuesday, December 1, to recommend prioritizing front line health care providers and residents of long-term care facilities for a vaccine. The recommendations for this "phase 1a" passed by a vote of 13-1 and will be sent to CDC Director Redfield for review. If he approves, they will become official CDC guidance.

The recommendation defines *health care personnel* as paid and unpaid workers serving in health care settings who have direct patient contact, provide services to patients or patients' family members, or those who handle infectious materials.

Further, the definition of *long-term care facilities* could mean more than just skilled nursing and long-term care facilities would qualify – for example, medical congregate settings in prisons, homeless shelters, and group homes.

Essential workers, adults with high-risk medical conditions, and adults aged 65 years or older will have to wait for the second phase, which the ACIP has classified as "phase 1b," or later. ACIP is planning to discuss those groups later this month.

HHS Secretary Azar announced that once a COVID-19 vaccine is authorized by the FDA, allocations will be made to each State based on the total number of adults in the state – not based

on risk. Top officials from Operation Warp Speed announced they've already allocated 6.4 million doses of COVID-19 vaccines to states to be delivered immediately after approval. The CDC has indicated that after the initial distribution, there will likely only be 5 to 10 million doses available per week once a vaccine is authorized. That makes it likely that hospitals, and others in phase 1a, will have to prioritize certain subgroups among those allowed earliest access to the shots.

Despite the central planning, divisions are emerging among top U.S. officials over when the country's first COVID-19 vaccine will be available. Robert Redfield, the director of the CDC, and others have suggested vaccination of Americans could begin by the end of next week, December 11. However, Peter Marks, who heads the FDA's Center for Biologics Evaluation and Research – which is responsible for any such authorization – said that it may take several days or even "a few weeks" after the FDA Advisory Committee meeting before his office gives the vaccine a green light. Notably, FDA Commissioner Hahn was summoned to the White House this week to update the President directly on timing for consideration and approval of vaccine candidates.

It will take time. Because Pfizer and Moderna's vaccines must be taken in two doses about a month apart, the roughly 40 million doses that will be available by year's end is enough to immunize about 20 million people. For context, nationwide there are about 21 million healthcare workers; 3 million people living in long-term care facilities; 53 million senior citizens; about 87 million essential workers; and more than 100 million people with underlying medical conditions.

The State Plans

States will ultimately decide how to distribute vaccines according to their individual plans, which you can access here. ***States have until this Friday, December 4, to tell the federal government where they want their initial vaccine doses sent.*** Yesterday's vote by the ACIP is meant to help officials decide how to allocate the first doses that will arrive. There's a strong case for multiple populations to be at the front of the line, but limited vaccine supply means that Governors will ultimately have to make tough decisions about who to prioritize.

When asked about their allocation, some Governors, like Maine Governor Janet Mills, said they were getting one-third less than originally expected and much less than needed. Additionally, many states say they effectively lack the funding needed to administer the vaccine campaign. Alarmingly, according to GAO, officials in 38 states said they were concerned they won't have enough supplies, such as hypodermic needles and syringes, to distribute and administer coronavirus vaccines.

States are expected to receive $140 million more in December to design vaccine distribution plans and start updating the necessary information systems, but multiple states said they will need significantly more federal money to effectively distribute and administer these vaccines. In fact, according to a letter to Congressional leaders from groups that represent local health officials and immunization managers, states may need as much as $8.4 billion in extra funding.

Public Acceptance

While the prospect of effective vaccines has brought new hope to contain the spread of COVID-19, public distrust of inoculations runs high – though Americans' acceptance seems to be improving slightly. In a recent Gallup poll, just 58 percent of Americans said they planned to get a COVID-19 vaccine, up from 50 percent in September.

Incoming White House Chief of Staff Ron Klain said vaccine distribution also brings formidable logistical challenges. "Vaccines don't save lives, vaccinations safe lives," he told ABC. "The much bigger step is actually getting those vaccinations to the American people. That's hard."

Presidential Transition: The COVID-19 Advisory Board

In anticipation of its extensive and focused work to combat COVID-19, the Biden Transition Team assembled its COVID-19 Advisory Board, which includes scientific experts, former government officials, and others who will help guide the nascent Administration in its efforts to combat the virus. The Advisory Board's expertise will be called upon to make determinations about the appropriate actions to protect the public health, including ensuring adequate supply of personal protective equipment, distributing and administering vaccines, securing resources for health and other facilities for hardening against COVID-19, and other related issues.

In many cases, the transition to a Biden Administration will likely not affect the involvement of these groups, but rather how these groups coordinate with one another in the COVID-19 response. In certain cases, politically appointed leaders may change based on recommendations of the COVID Advisory Board.

President-Elect Biden is expected to announce his nominations soon for key Cabinet officials who will directly oversee COVID-19 efforts, including Secretaries of Health and Human Services and the Department of Defense.

Conclusion

The development, allotment, distribution, and administration of a COVID-19 vaccine is a massive undertaking unlike any other in history. There will very likely be additional changes, adjustments, and challenges in the months ahead. You can be confident your WSW team will continue tracking any developments – and their potential impact on your organization – in real-time.