

FROM BENCH TO BODY: HOW THE U.S. HEALTH CARE SYSTEM PLANS TO DISTRIBUTE COVID-19 VACCINES



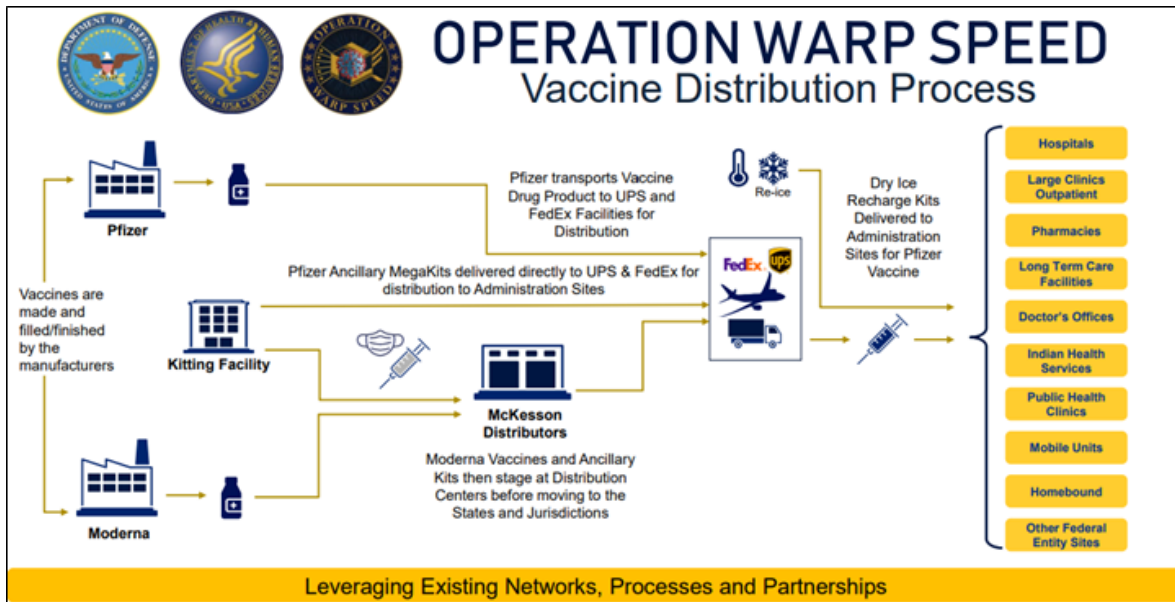
Overview

The COVID-19 pandemic sparked international concern about vulnerabilities in the global drug supply chain and disrupted the production of crucial pharmaceutical ingredients around the world. In a strained, but resilient market, two promising vaccine candidates boasting nearly 95% effectiveness rose to the top of various vaccine formulations. While vaccine manufacturers sought Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration for these vaccine candidates, the rest of the American health care system was preparing for vaccine deployment and mass immunization. On December 16, 2020, the Alliance for Health Policy hosted a webinar event titled “From Bench to Body: How the U.S. Health Care System Plans to Distribute COVID-19 Vaccines” to explore these issues. This briefing explored how our supply chain is responding to manufacturing goals for millions of doses and to swiftly deliver them to administration sites. Panelists illustrated the steps these stakeholders might take in the first 48 hours after an Emergency Use Authorization is approved. Key lessons and select questions and answers from this event have been highlighted in this resource.

Key Lessons

- Public concerns around the safety, effectiveness, and speed at which these vaccines were developed indicates that communication from scientific and governmental authorities to the public about the vaccines were lacking. In particular, transparent communication around the discovery and trial processes for the vaccines, as well as important evidence to support safety and efficacy, were not communicated well to the general public to build confidence. The vaccine development process was overseen by independent scientists at the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control (CDC). The independent group The Advisory Committee on Immunization Practices (ACIP) re-assessed safety and efficacy evidence for both vaccine candidates. Additionally, the vaccine manufacturers volunteered to participate in Vaccines and Related Biological Products Advisory Committee (VRBPAC) meetings, which were not a requirement for development or approval. The reported nearly 95% efficacy of the vaccines took the public and scientists by surprise. However, scientists leveraged existing data and previous experience with mRNA drugs that were not commercially licensed vaccines which aided in a timely response.
- States submitted their plans for vaccine deployment to the U.S. Department of Health and Human Services in October 2020. However, unless the public can be convinced to get vaccinated, the logistics plans that states have developed are null. **To combat vaccine hesitancy, health officials must first gain public confidence.** Currently, the average person does not know all of these details. So, officials need to make sure that this information reaches different populations. Women in particular are typically the family health decision makers, so it is important to focus on them. As well, thirty percent of health care workers are hesitant about receiving the vaccine. People of color are also concerned about taking this vaccine. **There is still much work to be done to reassure Indigenous, Black, and LatinX communities.**
- States have a registration process for providers who will administer COVID-19 vaccines to log those they vaccinate. Phase-1 distribution entails enrolling providers who will vaccinate healthcare workers. After

that, the goal is to enroll as many as providers as possible. ACIP and the CDC set population prioritization guidelines for the vaccine rollouts. There are three stages in Phase 1 — Phase 1A: Health care workers and long-term care recipients; Phase 1B: Essential workers; and Phase 1C: Individuals over 65 and those with chronic conditions. Most vaccine distribution agreements are with biopharmaceutical companies that will deploy the vaccine around the world at varying temperatures. Some distributors have the ability to ship and store the sensitive vaccines at freezing cold temperatures to keep them stable while traveling to local administration sites. Primary vaccine distribution for Pfizer travels from the manufacturer to pharmacies and hospitals, delivered in large containers of 1000 to 5000 doses or 10-days of vaccine administration. Vaccine distribution for the “last mile” includes boxes travelling from hospitals or pharmacies to acute care facilities with 5 to 500 doses or 24-hours of vaccine administration.



Source: Operation Warp Speed Vaccine Distribution Process Infographic. Available [here](#).

COVID-19 Vaccinations: Those most at risk get it first.

A tested, safe and effective vaccine will be available to all who want it, but supplies will be limited at first. Independent state and federal public health advisory committees have determined that the best way to fight COVID-19 is to start first with vaccinations for those most at risk, reaching more people as the vaccine supply increases from January to June. Keep practicing the 3W's—wear a mask, wait six feet apart, wash your hands—until everyone has a chance to vaccinate.

- Health care workers fighting COVID-19 & Long-Term Care**
Every health care worker at high risk for exposure to COVID-19—doctors, nurses, and all who interact and care for patients with COVID-19, including those who clean areas used by patients, and those giving vaccines to these workers.
Long-Term Care staff and residents—people in skilled nursing facilities and in adult, family and group homes.
- Adults at highest risk of severe illness and those at highest risk for exposure**
Adults with two or more chronic conditions that put them at risk of severe illness as defined by the CDC, including conditions like cancer, COPD, serious heart conditions, sickle cell disease and Type 2 diabetes, among others.
Adults at high risk of exposure including essential frontline workers (police, food processing, teachers), health care workers, and those living in prisons, homeless shelters, migrant and fishery housing with 2+ chronic conditions.
Those working in prisons, jails and homeless shelters (no chronic conditions requirement).
- Adults at high risk for exposure and at increased risk of severe illness**
Essential frontline workers, health care workers, and those living in prisons, homeless shelters or migrant and fishery housing.
Adults 65+
Adults under 65 with one chronic condition that puts them at risk of severe illness as defined by the CDC.
- Students and critical industry workers**
College and university students.
K-12 students when there is an approved vaccine for children.
Those employed in jobs that are critical to society and at lower risk of exposure.
- Everyone who wants a safe and effective COVID-19 vaccination**

Source: WakeMed, Raleigh, NC. December 2020. Available [here](#).

- Mass immunization against COVID-19 presents not only the challenge of initial uptake of the vaccine, but the hurdle of having patients return for their second dose to complete treatment 21 days +/- 12 hours from initial dosing for the Pfizer vaccine, or 28 days +/- 12 hours for the Moderna vaccine. Providers are encouraged to book first and second dose appointments prior to the patient receiving the first dose, similar to booking a “round-trip” airline ticket. Existing patient portals can be leveraged to schedule appointments and notify patients about appointment reminders. Existing call center, automatic voice-mail, text, and email reminder systems, in addition to physical appointment cards or immunization certificates, can all be leveraged to ensure patients return for their second dose. When inoculating staff, if everyone is vaccinated simultaneously, some individuals could develop symptoms severe enough that they would have to take a few days off. It is best to stagger vaccinations for staff to avoid this issue.

Questions & Answers

How can providers engage patients and teach their communities about vaccines, especially for communities of color who carry mistrust that stems from historical medical maltreatment?

"Some states are putting equity at the center of the distribution and have equity task forces to support culturally sensitive messaging. Nurses have taken it upon themselves to volunteer for the vaccine and do so while filmed to reassure patients. [It is] important to have colleagues and trusted people in communities show that it is okay. From a public perspective, transparency is going to be key, states and localities are working on this, it's not quite done yet, always challenging with tech, but we need these systems to work well, [and] need transparency around all of this so people are in the know." – Hemi Tewarson, MPH, J.D., Visiting Senior Policy Fellow, Duke-Margolis Center for Health Policy

Is there anything on the horizon in terms of pharmacy support of long-term care facilities?

"Walgreens Pharmacy has a location within five miles of 80% of the American population and has the infrastructure to carry-out vaccine deployment. Our goal is service 35,000 long-term care facilities by the week of December 21, 2020. We've been working with the Centers for Disease Control and Operation Warp Speed to work on deployment and will be sharing the responsibility for local administration with CVS Pharmacy. Pharmacists will go in to deliver vaccines in long-term and acute care facilities. The CDC has outlined a three-level plan to ensure that providers take care of older populations where COVID-19 risk is the highest like medically underserved areas, and to ensure there is as little vaccine dose waste as possible." – Edward J. Kaleta, Group Vice President, U.S. Government Relations, Walgreens

"We do not have mileage limitations outside of our pharmacy locations for vaccine distribution. We will be working with the CDC to measure our percentage of coverage in addition to the coverage provided by CVS." – Edward J. Kaleta, Group Vice President, U.S. Government Relations, Walgreens

What are longer term implications? mRNA concerns? Placebo concerns?

"Pfizer and Moderna did a great job of slowing down enrollment so they could diversify their population to include Black and Latinx communities; providing transparency around this is critical. For those communities, [there is a] lot of attention around racial justice and equity, people are looking for partnerships. Don't say 'you must get this,' and say, 'here is the information, here is why it's important.' We tend to swoop in to communities that don't traditionally get attention, and then wonder why they don't trust us. We need to continually explain that we went through the appropriate clinical processes." – Esther Krofah, MPP, Executive Director, FasterCures, a Center of the Milken Institute

"[The] FDA extended the two-month phase-3 follow-up guidelines, [and] continue to update guidance like allergic reactions. Is it going to change your DNA? No, it's not, it's going to give instructions to your DNA to your immune system." – Esther Krofah, MPP, Executive Director, FasterCures, a Center of the Milken Institute

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**Indicates expert was a speaker at the December 16, 2020 webinar event, "From Bench to Body: How the U.S. Health Care System Plans to Distribute COVID-19 Vaccine".*

Resources

"Supporting an Equitable Distribution of COVID-19 Vaccines: Key Themes, Strategies, and Challenges Across State and Territorial COVID-19 Vaccination Plans." Greene, K., Tewarson, H., Campbell, H. et al. Duke-Margolis Center for Health Policy. December 9, 2020. Available at <http://allh.us/EAg6>.

"Covid-19: Getting Ready for the Vaccines." Haislmaier, E. The Heritage Foundation. December 9, 2020. Available at <http://allh.us/fnJD>.

"COVID-19 Treatment and Vaccine Tracker." Milken Institute FasterCures. December 8, 2020. Available at <http://allh.us/c6wJ>.

“Coronavirus Vaccine Hesitancy in Black and Latinx Communities.” COVID Collaborative. November 23, 2020. Available at <http://allh.us/9HFb>.

“The Future of the COVID-19 Response: The New Administration, Vaccines, and the Health Care System.” Osterholm, M., Tewarson, H., Dallow, K. National Institute for Health Care Management (NIHCM). November 18, 2020. Available at <http://allh.us/g7tq>.

“Distributing a COVID-19 Vaccine Across the U.S. - A Look at Key Issues.” Michaud, J., Kates, J. Kaiser Family Foundation. October 20, 2020. Available at <http://allh.us/6vYR>.

“From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine.” U.S. Department of Health and Human Services. September 16, 2020. Available at <http://allh.us/mYUu>.

“Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry.” FDA Center for Biologics Evaluation and Research. June 30, 2020. Available at <http://allh.us/4bVj>.

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