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# COVID-19: Getting Ready for the Vaccines

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**KEY TAKEAWAYS**

Safe and effective COVID-19 vaccines may soon be available, thanks to private biomedical companies applying the latest science with federal government support.

State leaders now need to finish work on their vaccination plans and be ready to implement them.

Federal policymakers should take steps to support state efforts, including publicizing state vaccination plans.

Indications are that vaccines to immunize against COVID-19 will soon be available. Given that the virus first emerged little more than a year ago—and that in the past a new vaccine might have taken a decade to develop, test, and mass produce—that is an amazing achievement. But now that mass vaccination is on the horizon, state and federal policymakers need to quickly complete their preparations for the coming logistical challenges.

While the availability of vaccines will not put an end to COVID-19, it will mark a turning point in making COVID-19 a much more manageable, and far less socially disruptive, infection.[1]

## Private and Public Action towards the Vaccine

The imminent success of COVID vaccine development was the result of private biomedical companies

applying knowledge accumulated from years of leading-edge research to meet the new threat, complemented by the federal government facilitating and supporting their efforts.

For over two decades, scientists have been working to translate advances in genomics into the development of new and better vaccines, not only to counter viral pathogens but also to treat cancer and other diseases. Serendipitously, those efforts were approaching fruition just as COVID-19 emerged. Consequently, a number of biotech companies were well positioned to quickly shift to addressing the new threat.

Indeed, two of the COVID-19 vaccine candidates that have so far advanced the furthest in clinical trials—those developed by Moderna and BioNTech (in collaboration with Pfizer)—are prime examples. Both Moderna and BioNTech were founded to develop innovative therapies derived from insights into how "messenger RNA" (mRNA) could be used to trigger the body's immune responses.[2] Prior to the emergence of COVID-19, both companies were already engaged in far more difficult efforts to develop mRNA vaccines for cancers, and thus were well positioned to pivot to addressing the new threat posed by COVID-19.[3]

That base of knowledge and experience enabled researchers in those, and other companies, to develop and begin testing potential COVID-19 vaccines within only a few months—a timeline far shorter than for previous vaccine development that relied on older approaches and technologies.

Furthermore, the new technologies enable companies not only to develop vaccines faster but to also more rapidly mass produce them.[4]

The federal government responded to the challenge as well. Crucially, both biomedical companies and federal officials recognized early on that the key to speeding up the effort was to "parallel process" whenever and wherever possible, meaning processes that would normally take place sequentially were pursued simultaneously. For instance:

- A number of different companies simultaneously pursued a variety of different development strategies and technologies.
- The FDA issued detailed guidance for vaccine developers on the data and standards that the agency would need for evaluating candidate vaccines.
- Companies built out large-scale manufacturing capacity in advance.
- Both companies and the government contracted for necessary production supplies while vaccines were still in development.

This approach enabled companies and government officials to significantly shorten the time it normally takes to get a new vaccine to market.

In March, Congress appropriated substantial funding for the development and acquisition of COVID-19 vaccines and other counter-measures.[5] The Trump Administration subsequently launched its "Operation Warp Speed" initiative to coordinate the federal government's support of COVID-19 vaccine and therapeutic development. The Administration used the funding appropriated by Congress to provide grants for research and development and to purchase successful vaccines and related supplies such as vials and syringes.[6]

Particularly important was the federal government contracting in advance to purchase large quantities of vaccines if they proved to be safe and effective. Such pre-production purchase orders enabled vaccine makers to build out substantial manufacturing capacity in advance of clinical trials.[7]

## Meeting the Inoculation Challenge

With it now likely that several promising vaccines will soon be available, the focus is shifting from development and production to distribution. Those efforts are already well underway, but more remains to be done.

In recent months federal officials have leveraged the existing private-sector distribution system. Notably:

- In August federal officials exercised an option in the government's most recent (2016) contract with McKesson, a major drug wholesaler and distributor, to have that company manage the process of transporting COVID-19 vaccines and related supplies from manufacturers to the sites where vaccines will be administered.[8]

- In October federal officials entered into agreements with two major pharmacy chains—CVS and Walgreens—to offer long-term care facilities onsite administration of COVID-19 vaccines to residents and staff.[9]

- More broadly, the Centers for Disease Control and Prevention (CDC) has also entered into partnership agreements with major retail pharmacy chains and independent pharmacies to receive and administer COVID-19 vaccines.[10]

State and local health officials will also play crucial roles in implementing COVID-19 vaccination efforts. States, not the federal government, regulate

health professionals, medical facilities, and congregate living facilities for vulnerable populations such as the elderly, the developmentally disabled, the homeless, and migrant workers. State officials will also need to make decisions about numerous details, such as:

- Which ancillary health providers will be permitted to administer vaccines;
- Whether vaccinations will be offered at community centers, schools, or other designated places; and
- Whether mobile vaccination units will be deployed to reach specific populations.

To inform those efforts, federal officials engaged the National Academies of Sciences, Engineering, and Medicine to develop recommended vaccination priorities and strategies to guide planning by state and local public health officials.[11] The CDC also solicited from the states their plans for prioritizing and managing vaccinations.

Once vaccines become available, the focus will shift to how state and local health officials implement their vaccination plans. To prepare for that next phase, policymakers should now do the following:

- **Address any remaining gaps in their plans and infrastructure.** Some states' implementation plans are still "works in progress."[12] For example, a number of states are still working on their systems for registering and communicating with vaccinated patients.[13] Those systems are important because the vaccines will most likely require two shots, so providers will need to contact patients and schedule them to receive their second doses. Further, returning patients will need to receive the booster shot for the same vaccine that they originally received.
- **Better communicate state vaccination plans.** The CDC has posted executive summaries of the various state vaccination plans, but they are difficult to locate on the agency's website.[14] Researchers at the Kaiser Family Foundation obtained the full plans directly from almost all the states.[15] Federal officials should more prominently post the full state plans and update them as necessary.

- **Provide the general public with actionable information and guidance on vaccinations.** Much of the information in state plans addresses operational, logistical, and administrative issues that are relevant mainly to health care providers. However, what is most relevant to the general public is the who, where, and when of vaccinations in their areas. State officials should begin posting the population subsets that will be prioritized for vaccination as well as vaccination locations as arrangements with providers are confirmed, and update the information as they get confirmed schedules for the timing of vaccine shipments.

Congress should consider appropriating supplemental funding for state vaccination efforts. Providing widespread and rapid vaccination against COVID-19 will require additional personnel and resources. Congress should inquire as to whether additional, temporary, targeted funds are needed to support state efforts. These funds can be appropriated directly to the CDC, which already administers federal grants to states to support vaccinations and other public health initiatives.[16]

## Conclusion

Thanks to private biomedical companies applying the latest science, augmented by federal government support and partnerships, the goal of making safe and effective COVID-19 vaccines available is now within sight—and far sooner than almost anyone thought possible just a year ago.

As the focus shifts from developing effective vaccines to large-scale inoculation, policymakers at all levels of government should take helpful steps in this next phase of the response.

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## Endnotes

1. While a vaccine is an important step forward, it will not eliminate COVID-19 but rather give clinicians an essential tool for controlling and managing it, similar to how they control and manage other infectious diseases. There will still be a need for more and better screening tests to help guide people in resuming more normal activities. See, for example, Michael Mina, "How We Can Stop the Spread of COVID-19 By Christmas," *Time*, November 17, 2020, https://time.com/5912705/covid-19-stop-spread-christmas/ (accessed December 3, 2020). Researchers in industry and government will still need to collect and analyze data on long-term vaccine effectiveness, so as to determine whether and when people will need to get additional booster shots, as is sometimes the case with vaccines for other pathogens.
2. For a good overview, see Peter Loftus, Jared S. Hopkins, and Bojan Pancevski, "Moderna and Pfizer Are Reinventing Vaccines, Starting With Covid," *The Wall Street Journal*, November 17, 2020, https://www.wsj.com/articles/moderna-and-pfizer-are-reinventing-vaccines-starting-with-covid-11605638892 (accessed December 3, 2020).
3. More information on Moderna's portfolio of vaccines in development for cancer and other illnesses can be found at Moderna, https://www.modernatx.com/pipeline/modernas-mrna-clinical-trials-cmv-mma-zika-several-types-cancer-and-other-diseases (accessed December 3, 2020). Similar information on BioNTech's vaccine pipeline can be found at BioNTech, https://biontech.de/science/pipeline (accessed December 3, 2020).
4. See John R. Mascola and Anthony S. Fauci, "Novel Vaccine Technologies for the 21st Century," *Nature Reviews Immunology*, Vol. 20, 87–88 (2020), published November 11, 2019, https://doi.org/10.1038/s41577-019-0243-3 (accessed December 3, 2020). The authors note that "mRNA has the potential to be a rapid and flexible vaccine platform. Starting from gene sequence, mRNA vaccines can be produced in a few weeks, and clinical grade material can be rapidly produced." Similarly, Kathrin Jansen, Senior Vice President and Head of Vaccine Research and Development at Pfizer, commented that "[t]he mRNA platform is essentially fully synthetic. It's a defined molecule that can be made very, very quickly, so you don't need anything live—no live virus, no live cell culture, no eggs, no anything." Peter Loftus et. al., "Moderna and Pfizer Are Reinventing Vaccines, Starting With Covid."
5. Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Public Law No. 116–123, and Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law No. 116–136.
6. See U.S. Department of Health and Human Services, "Fact Sheet: Explaining Operation Warp Speed," November 30, 2020, https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html (accessed December 3, 2020).
7. See Edmund F. Haislmaier, "To Prepare for COVID-19 Vaccine, Let's Ensure Manufacturing Capacity Will Meet Demand," *The Daily Signal*, April 28, 2020, https://www.heritage.org/public-health/commentary/prepare-covid-19-vaccine-lets-ensure-manufacturing-capacity-will-meet; and Edmund F. Haislmaier, "A Week of Good News on Coronavirus Vaccines," *National Interest*, August 18, 2020, https://nationalinterest.org/blog/buzz/week-good-news-coronavirus-vaccines-167019 (accessed December 3, 2020).
8. U.S. Department of Health and Human Services, "Trump Administration Collaborates with McKesson for COVID-19 Vaccine Distribution," August 14, 2020, https://www.hhs.gov/about/news/2020/08/14/trump-administration-collaborates-mckesson-covid-19-vaccine-distribution.html (accessed December 3, 2020).
9. U.S. Centers for Disease Control and Prevention, "Understanding the Pharmacy Partnership for Long-Term Care Program," https://www.cdc.gov/vaccines/covid-19/long-term-care/pharmacy-partnerships.html (accessed December 3, 2020).
10. Sandra Levy, "Chains, Independents Partner with HHS to Distribute COVID-19 Vaccine," *Drug Store News*, November 12, 2020, https://drugstorenews.com/chains-independents-partner-hhs-distribute-covid-19-vaccine (accessed December 3, 2020).
11. National Academies of Sciences, Engineering, and Medicine, "Framework for Equitable Allocation of COVID-19 Vaccine," October 2, 2020, https://www.nap.edu/catalog/25917/framework-for-equitable-allocation-of-covid-19-vaccine (accessed December 3, 2020).
12. See Josh Michaud et al., "States Are Getting Ready to Distribute COVID-19 Vaccines. What Do Their Plans Tell Us So Far?," Kaiser Family Foundation, November 18, 2020, https://www.kff.org/coronavirus-covid-19/issue-brief/states-are-getting-ready-to-distribute-covid-19-vaccines-what-do-their-plans-tell-us-so-far/ (accessed December 3, 2020).
13. For instance, New Hampshire is the only state that does not already have a vaccine registry and the state is working to create one. Shawne K. Wickham, "New State Registry Will Track COVID-19 Vaccines," *New Hampshire Union Leader*, October 11, 2020, https://www.unionleader.com/news/health/coronavirus/new-state-registry-will-track-covid-19-vaccines/article_a329660c-ae2c-5f13-ae89-d374bf6bb860.html (accessed December 3, 2020).
14. U.S. Centers for Disease Control and Prevention, "COVID-19 Vaccination Program Operational Guidance," https://www.cdc.gov/vaccines/covid-19/covid19-vaccination-guidance.html (accessed December 3, 2020).
15. Michaud et. al. "States Are Getting Ready to Distribute COVID-19 Vaccines. What Do Their Plans Tell Us So Far?"
16. See Association of State and Territorial Health Officials and Association of Immunization Managers, letter to congressional leadership, October 15, 2020, https://www.astho.org/Federal-Government-Relations/Correspondence/ASTHO-AIM-Funds-for-Vaccination-Distribution-Letter/ (accessed December 3, 2020).