

# **Research Insights**

# The Economics of Vaccine Development and Supply: Responding to COVID-19 and Preparing for the Next Threat

### **Summary**

Once the depth and breadth of the COVID-19 pandemic was belatedly recognized, researchers across the world have moved at an unprecedented pace to advance more than 100 vaccine candidates. However, much of the infrastructure and funding needed to develop, produce, and distribute successful vaccine candidates has been pieced together reactively rather than through established emergency preparedness frameworks both nationally and globally. Delays in recognizing and responding to the threat of COVID-19, particularly in the United States, have resulted in lost lives and a battered economy. The International Monetary Fund estimates the world economy will face a \$12 trillion loss in 2020-2021 because of the pandemic,<sup>1</sup> implying a potential \$500 billion gain by accelerating vaccine development by a single month.

In the near-term, policymakers have focused on ensuring adequate incentives to develop and equitably distribute a safe and effective COVID-19 vaccine, but, as the threat of COVID-19 eventually recedes, policymakers need to consider strategies to ensure sufficient investment and interest in vaccine development, as well as surveillance and diagnostics, to respond to future infectious disease threats. This brief summarizes key points from a meeting convened by AcademyHealth in August 2020. Research and policy experts reviewed existing research on vaccine development, manufacturing, and distribution, including financing mechanisms to help ensure access to vaccines in developing countries. Additional research is needed to help policymakers understand what policies are needed to ensure global supply chains are up to the challenge of producing billions of doses of vaccines as efficiently as possible, as well as assess efforts during the COVID-19 pandemic to develop, manufacture, and distribute a vaccine both in the U.S. and globally.

### **Overview**

In theory, the United States, with its "top-notch scientists, modern hospitals and sprawling public health infrastructure," should have been among the "best prepared" nations in the world for the COVID-19 pandemic.<sup>2</sup> In reality, the U.S. has trailed the world in stemming the spread of the coronavirus, resulting in more than 6 million confirmed U.S. cases of COVID-19 and nearly 200,000 deaths by mid-September 2020—or 30 percent of all deaths worldwide while the U.S. accounts for 4 percent of the global population.<sup>3</sup>

The United States'—and the world's—best bet to halt the virus' deadly spread and restore economic stability is developing multiple safe and effective vaccines and ensuring equitable and swift allocation throughout the world. A key question for U.S. policymakers is

### **Genesis of this Brief:**

This brief is based on a meeting of policymakers and researchers that took place virtually on August 18, 2020. AcademyHealth convened the meeting as part of its Research Insights Project. Funding for the conference was made possible by Grant No. 5R13HS018888-09 from the U.S. Agency for Healthcare Research and Quality (AHRQ). The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the U.S. Department of Health and Human Services or AcademyHealth; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government. The Research Insights Project convenes invitational meetings, holds webinars, and produces reports and issue briefs to foster discussion of existing, relevant research evidence among policy audiences that need to implement health reform and develop new policy. Additional information and publications may be found on the project's website at http://www.academyhealth.org/about/programs/research-insights.

whether they can use the lessons of the current public health crisis to better prepare for future infectious disease outbreaks, especially related to vaccine development, production, and distribution.

In August 2020, AcademyHealth's Research Insights project convened a meeting of leading academic researchers and policy experts to discuss the current state of research on the economics of vaccine development and supply. The meeting's goal was to review the relevant evidence and recent experience around the economics of vaccine development and supply, including:

- What policies support a posture of readiness to rapidly respond to new threats across the spectrum of vaccine development, manufacturing, and distribution, both in the United States and globally?
- What policies and financing structures maintain incentives for vaccine development when demand falls between threats?
- How should vaccine development and manufacture be financed in a crisis to ensure equitable access globally?
- What policies promote equitable access to vaccines in the United States?

This brief summarizes the August meeting. Because the session was off the record, the brief conveys the general content of the meeting without attributing specific comments to particular participants. The discussion was informed by existing research though neither the discussion nor this brief incorporates a systematic review of the literature on vaccine development and supply. A bibliography of relevant, current literature is included at the end of the brief.

## **Fits and Starts of Preparedness**

Even before the 9/11 terrorist attacks and anthrax attacks in 2001, the United States had stepped up efforts to prepare for public health emergencies, especially global flu pandemics. Then, in the wake of 9/11, coupled with threats from emerging infectious diseases like the West Nile virus and the devastation of Hurricane Katrina in 2005, Congress passed multiple laws to shore up the nation's readiness not only for deliberate bioterror attacks but also naturally occurring public health emergencies.<sup>4</sup> One result was the creation in 2006 of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS) to coordinate the nation's preparedness for and response to health security threats. Along with working with HHS agencies, such as the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), to manage public health emergencies, ASPR oversees the Biomedical Advanced Research and Development Authority (BARDA). By supporting research and development of medical countermeasures, such as vaccines, drugs, and diagnostics, BARDA's mission is to protect the nation from

chemical, biological, radiological, and nuclear threats as well as emerging infectious diseases, including pandemic flu. $^5$ 

Notwithstanding the extensive preparedness infrastructure in place for almost 15 years, as one preparedness expert at the meeting said, "The whole field is characterized by repeated cycles of panic and neglect, and panic and neglect, and each time, we say never again, and then things happen again." Historically, there have been "two streams" of readiness related to vaccines—bioterrorism and pandemic flu, with little attention paid to other emerging infectious diseases, according to the expert. "Sadly, I would say that some of the problem we're facing now with COVID is because some of the people who focus a lot on bioterrorism could not imagine that Mother Nature could act as badly or worse than a bioterrorist and partly because this isn't flu. And, so it didn't conform to some people's mental model of what might happen, despite the fact that many groups have even warned that the next pandemic could be a novel coronavirus."

### **Vaccine Preparedness**

The 2009 H1N1 flu pandemic put vaccine preparedness in the spotlight. Unlike developing medical countermeasures for other infectious diseases, "we knew how to make flu vaccines and there were contracts in place" but still there were "glitches" in developing and distributing an H1N1 vaccine, according to the preparedness expert. Reviews of the H1N1 response concluded that instead of "one-bug, one-vaccine" approaches to developing medical countermeasures, much greater attention was needed on vaccine development platforms and platform technologies. More recently, the Ebola and Zika epidemics—both caused by viruses—tested and found global vaccine development efforts wanting.

For example, it took 5 years to get an Ebola vaccine licensed, while the only major pharmaceutical company working on a Zika vaccine stopped after BARDA cut funding for the project in 2017,<sup>6</sup> raising questions about the U.S. government's reliability as a partner, according to the preparedness expert. Moreover, during the H1N1 pandemic, the United States had "sewn up" up the market for vaccines, and "so early on in that outbreak, it was very difficult for any other countries to access vaccine," the expert said.

### **Policies to Support a Posture of Readiness**

To maintain a posture of readiness for the next threat, from a U.S. perspective, the structures are in place, but funding is needed now and well into future, both to start and then stay the course through the development of vaccines, according to the preparedness expert.

For example, in the case of COVID-19, BARDA waited for emergency supplemental funding before moving on vaccine development, which was "way too late, and vaccine developers didn't really

have a market signal that the U.S. government was interested in doing anything," the preparedness expert said, adding, "Even though vaccine development is progressing at unprecedented speed, I would argue that had we had a different posture of readiness and started vaccine development two months before we did, we would be in a very different position."

Other key elements of readiness include active surveillance and quickly developing and deploying diagnostic tests "not only to control an outbreak but to even figure out if you need to make a vaccine," according to the preparedness expert. Disinvestment at the CDC and FDA also hampered the U.S. response effort, due to reduced surveillance in other countries and a reduction in funds for regulatory science, which could have supported validation panels for diagnostic tests for COVID-19.

Much of the rest of the world, however, lacks even the structures for preparedness—and in the case of developing countries, the resources—to launch widescale vaccine development, production and distribution, leading to efforts to raise money from public and private sources to fund a global response. Perhaps, the most important lesson from the current crisis in preparing for future pandemics: "We shouldn't be passing the tin cup in the middle of a pandemic," the preparedness expert said.

# **Financing Vaccine Development**

Against a backdrop of missteps in responding to emerging infectious disease threats, the Coalition for Epidemic Preparedness Innovations (CEPI) was launched and funded by public, private, philanthropic, and civil society organizations in 2017 to accelerate development of vaccines against emerging infectious diseases and enable equitable access to vaccines during outbreaks. "We're not safe unless everybody is safe, and so we've got to talk about vaccines for the world, not just for the U.S., and we have to talk about vaccines for high-, middle- and low-income countries," the preparedness expert said.

Other than China and the United States, CEPI is the most prominent global funder of COVID-19 vaccine efforts. Along with the vaccine alliance known as Gavi and the World Health Organization, CEPI is leading the COVAX Facility,<sup>7</sup> which is the vaccines arm of the Access to COVID-19 Tools Accelerator, a global collaboration of almost 200 countries working to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines (see **About the COVAX Facility** for more information). COVAX currently has the world's largest and most diverse COVID-19 vaccine portfolio, including nine candidate vaccines, with another nine candidates under evaluation.<sup>8</sup> By supporting a diversified COVID-19 vaccine research portfolio, pooling negotiations with manufacturers, and investing in preinstalled vaccine production capacity, the COVAX Facility aims to deliver 2 billion vaccine doses by the end of 2021. Participating higher-income countries will self-finance, while lowerincome countries will be funded through donations to an advance market commitment for COVID-19 vaccines. Some COVAXparticipating higher-income countries are hedging their bets on having access to an effective vaccine by also contracting directly with manufacturers. The United States has declined to join the COVAX effort,<sup>9</sup> preferring instead to go it alone with Operation Warp Speed, which aims to deliver 300 million doses of a safe, effective vaccine for COVID-19 by January 2021.

# **About the COVAX Facility**

"Some countries have taken steps to protect their populations by directly securing supplies of vaccines. The risk attached to such bilateral transactions with single manufacturers is high as the probability of success for any vaccine in early stage development is low. Pooling demand with other countries through a joint mechanism vastly increases the probability of success for each country and global success in stamping out a disease which does not recognise borders. Through the COVID-19 Vaccines Global Access (COVAX) Facility, countries have the opportunity to benefit from a portfolio of vaccine candidates so that their populations can have early access to effective vaccines. For Governments that do not have bilateral agreements, the COVAX Facility offers a reliable supply of safe and efficacious vaccines. For Governments that are making deals with individual manufacturers to supply vaccines, joining the COVAX Facility provides an insurance policy."

- The COVAX Facility: Global Procurement for COVID-19 Vaccines

# **Ensuring Vaccine Manufacturing Capacity**

Given the perilous path of vaccine development and manufacturing, where every step of the process must be tested and certified, many experts believe pursuing as many vaccine candidates as possible is the best guarantee of success. As of early September 2020, more than 100 coronavirus vaccine candidates were under investigation worldwide, with 37 already in clinical trials on humans.<sup>10</sup>

If and when coronavirus vaccines receive regulatory approval, the next challenge will be manufacturing and distributing the vaccines at a scale never before attempted—potentially billions of doses. "People outside the field don't fully appreciate how different it is to manufacture vaccines versus produce a pill," according to an economist presenting at the meeting.

Understanding the global supply chain will be critical to quickly ramping up production and distribution of successful vaccine candidates. Along with the complicated manufacturing process of vaccines, each of those billions of doses will need a glass storage vial and a syringe to administer the vaccine. "Having lived through the

last few months, none of us would like to bet our lives on the supply chain working properly...If we can't make masks, how are we going to be sure we can make other things?" the economist said.

Typically, manufacturers wait until a vaccine completes successful clinical trials before installing production capacity-or the infrastructure to make the vaccine-which can take months to bring online. Instead, many leading economists believe the best way to quickly scale up vaccine research and development and production is through a combination of so-called push and pull financing approaches. An example of a push approach would be direct subsidies of research to identify vaccine candidates, while a pull approach helps guarantee a market for a successful vaccine by lining up buyers before a vaccine even exists. An example of a pull approach is an advance market commitment, which guarantees vaccine manufacturers sales at a fixed price in return for an effective vaccine.<sup>11</sup> The approach essentially pays manufacturers to preinstall and certify capacity to produce a vaccine once it clears regulatory hurdles, with payment for the actual vaccine close to marginal cost. If the vaccine candidate fails, buyers do not pay production costs. Such an approach avoids the lag between waiting until vaccines receive approval and then "letting the market figure it out," which could be a recipe for shortages and higher prices, the economist said (Exhibit 1).

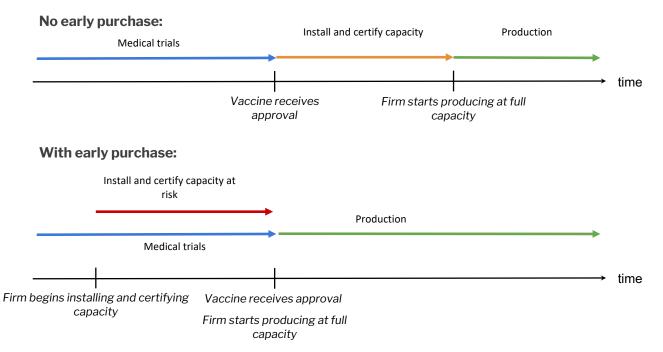
Including contractual safeguards to make sure manufacturers install enough capacity to produce and deliver the promised doses and then monitoring whether the specified capacity is actually getting built will be critical to producing a successful vaccine quickly. Otherwise, "if you're the manufacturer of the good vaccine, you say, oops, sorry, I don't have enough capacity," the economist said. "There's really nothing, anybody can do then—it's sort of like, oops, sorry, my aircraft carrier is late or my fighter jet is late. If you're late, you're still going to get your business probably."

# Allocating Access to Vaccines

Once effective vaccines are available, the global health ideal is to distribute vaccines by countries' health needs, independent of their wealth, according to another economist who studies approaches to equitably allocating vaccines both across and within countries. In practice, however, allocation is much trickier in a global collaboration that brings together high-, middle- and low-income countries, where to some degree wealthier countries subsidize poorer countries. Unless high-income countries receive enough value for participating, they may opt out, so linking their vaccine allocations to their investments and offering portfolio flexibility are important.

Gaining participation of high-income countries is critical because they bring bargaining power and investments in capacity that will remain available to produce more vaccine doses. "So even if the high-income countries get some of the first doses off the line or a proportional share relative to their investment, you still produce doses faster, which means you can distribute them more broadly faster," the economist said. For low-income countries funded through the advance market commitment, there is more discretion to set allocation rules, perhaps, conditioning allocation on countries taking basic precautionary measures and monitoring disease spread and severity.

Moreover, inherent risk and health outcomes vary both across and within countries, so there is a need for a transparent allocation formula managed by a scientific board that can parse emerging evidence on transmission and mortality rates and consider a number of factors in making allocations, including each country's intrinsic



### Exhibit 1. Vaccine investment timeline with and without early access

risk of severe disease, number of health care and other essential workers, size/scale of epidemic, and seasonal considerations.

Ideally, there will be multiple COVID-19 vaccines, and beyond vaccinating high-priority groups, countries may prefer different vaccines based on efficacy, availability and timing, and technology required to store and administer the vaccine. Some countries, in particular, may be unable to manage complex distribution chains, such as ensuring vaccines are maintained at temperatures as low as -80 degrees Celsius, known as "cold-chain" supply.

One approach might be creating a cross-country exchange, where countries could trade their guaranteed shares of different vaccines at rates determined by a centralized mechanism based on demand. "The last thing you want is for doses to go to waste," according to the economist. "If you end up allocating some doses of a technology that a country isn't in position to distribute, those might actually end up being wasted. But even more than that, if you have a system of trading, it enables countries to express their trade-offs and exchange so as to do better for themselves *and* for all at the same time."

An example of how such an exchange might work, according to the economist, is if a country tells the system that it values one vaccine at a particular time twice as much as some other vaccine at a different time. The exchange would then determine whether there are any value-creating trades that can be made. "And the nice thing is for transparency, if you clear the market in this way, you can actually publish all of the trade exchange rates that the market computed—you can do all of this without money and see that everyone's made better off," the economist said.

At least initially, all—or nearly all—countries will face vaccine scarcity, raising questions about fair and transparent ways to allocate vaccines within a country. Public health and ethical considerations point to prioritizing a number of different groups, such as front-line health and essential workers and high-risk groups, such as the elderly or low-income individuals. One possible approach would be using weighted lotteries.<sup>12</sup> Under such an approach, ethicists, doctors, epidemiologists, and policymakers would assign priority weights to different groups, with higher-priority individuals having a higher chance of receiving the vaccine.

### Promoting Equitable Vaccine Access in the U.S.

Vaccines serve a dual purpose—they save lives and they interrupt disease transmission, so the first question in designing policies to promote equitable access is to identify the objective, according to a physician researcher at the meeting. "Are we seeking to protect lives, in which case, our top priority should be the elderly and those with chronic conditions, who we know are more susceptible to illness and death," the physician researcher said. "Or is the objective to interrupt transmission, in which case, we would prioritize allocation of the vaccine for our front-line or essential workers or groups that we know may be super spreaders."

The second question flows from the first because "how we prioritize groups certainly has implications for equity, regardless of which objective ultimately becomes the priority," the physician researcher continued.

If the decision is to save lives and focus on the elderly, does that mean trying to protect all elderly or just those in nursing homes, who face a higher risk of transmission? Another consideration could be prioritizing nursing homes with a larger share of Medicaid patients or minority patients, which have been particularly hard hit by COVID-19 in some areas. Also, should nursing home staff be vaccinated? "How wide do the circles outward need to be, and then once you overlay the equity issues, it becomes even more difficult," the physician researcher said, adding that this is just one example of "the issues we have to figure out and deal with appropriately if we're going to avoid exacerbating existing inequities in this pandemic."

Other questions center on access to and demand for vaccines. Operation Warp Speed has already announced the vaccine will be free to U.S. providers, but will providers charge a fee to administer the vaccine? There are also questions about distribution networks and how to identify the most convenient and safe place for people to get the vaccine. During the HIN1 pandemic, for example, the vaccine was distributed through hospitals and doctors' offices and in some cases did not reach intended high-risk populations, according to the physician researcher.

Differences in people's demand for a COVID-19 vaccine also can impact equity, with a May 2020 Pew survey finding that Black Americans are less likely than white and Hispanic Americans to say they would get a vaccine.<sup>13</sup> A little over half of Black adults, or 54 percent, said they would get a vaccine if one were available, compared to 74 percent of both Hispanic and white adults.

The survey findings are unsurprising given the "historical legacies of mistrust" Black Americans have in the U.S. health care system, according to the physician researcher. That legacy dates back to slavery and more recently the Tuskegee experiments, which, under the auspices of the U.S. Public Health Service, knowingly withheld curative treatment from Black men infected with syphilis. "These legacies of discrimination and racism and horror still resonate,

certainly among the older generations of Black Americans," the physician researcher said, adding that efforts are needed "to acknowledge and address these issues and to ensure that the demand is where it needs to be in the Black community in the same way as it is for the other communities."

The physician researcher outlined the following five policies/issues that would help ensure equity in vaccine allocation now and during future threats:

- **Population information:** Gathering data by race, ethnicity, primary language, occupation, housing status, and other social and economic determinants of health. "We certainly were caught flat footed in the early days of the pandemic by not having this data, which would have helped us recognize certain populations were at higher risk and allowed us to intervene."
- Distribution networks: Identifying partners beyond traditional health care organizations, such as community health centers, and leveraging relationships with community-based organizations such as the United Way and Boys and Girls Clubs. Other approaches might include using mobile vans, pop-up sites, and other interventions to bring vaccination efforts to where people live rather than expecting them to go to a clinic or hospital.
- **Dedicated state and local funding:** Rebuilding weakened public health capacity in local communities, which requires funding to gather better information, build effective distribution networks, and deploy other interventions.
- Public campaigns to kickstart demand and overcome vaccine hesitancy: Identifying creative outreach opportunities targeting communities of color—for example, enlisting leaders like former First Lady Michelle Obama, who have strong credibility with the Black community, to raise awareness of the importance of vaccination.
- Transparent decision making: Ensuring allocation discussions are transparent, open, and allow optimal input.

"Fundamentally, an equity approach demands that we set aside notions of treating everyone the same or treating everyone equally, but instead, apply the concept of equity across all decision making and think about what is needed to prevent avoidable, unfair and remediable differences among groups of people, whether defined socially, culturally, geographically, or economically. That approach is core to the concept of equity," the physician researcher said.

### **Lessons Learned?**

In the eventual aftermath of the COVID-19 pandemic, only time and future threats will tell whether U.S. and global leaders have learned the importance of maintaining preparedness capacity from the worst public health crisis in a century. In the U.S., the public health emergency medical countermeasure enterprise was largely "disbanded in the last 3 years, it was not reconvened, and it was not used for COVID," with the federal government instead launching Operation Warp Speed, according to one participant. A key open question for the U.S. is whether in the "absence of national leadership," the nation must depend more on the "incredible brain trust in academia, in foundations, and the private sector" that has emerged to fill the vacuum.

Participants also stressed the importance of maintaining frameworks that allow global collaborations to continue pursuing advances in vaccine technologies, so we can better and more quickly mobilize to respond to new threats, with one saying, "We have to not let all this stuff fade....the estimated losses we're talking about are on order of \$12 trillion over a couple of years. And that means that if you hit a pandemic of a similar scale to this one, the benefits to accelerating a vaccine by a month are on the order of hundreds of billions of dollars." And despite ongoing questions about how to equitably share the costs and benefits of investing in capacity at risk to support global vaccine supply chains for production and distribution, early indications are that "the returns are really, really large."

Additional research can help policymakers understand what policies are needed to ensure global supply chains are up to the challenge of producing billions of doses of vaccines as efficiently as possible. Research also can assess efforts during the COVID-19 pandemic to develop, manufacture, and distribute a vaccine both in the U.S. and globally to help prepare for when—not if—the next pandemic unfolds. Possible areas of research focus include logistics and supply chain science, game theory to better understand and mitigate different country behaviors, social science research focused on achieving equity—all while advancing the vaccine platform/ basic science agenda. On the economic front, retrospective research to clearly estimate the economic losses and figure out which sectors were the biggest contributors to those losses could provide a better sense of vaccination priorities in a future pandemic

### **About the Author**

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### **Endnotes**

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