

# Vaccines Aren't the End of the Fight, but the End of the Beginning

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Governments cannot let the most vulnerable be the least protected again. Countries, regions, and states can still get the rollout right through science, hard work, and vigilance.

The pivotal Phase III trials of COVID-19 vaccine candidates are nearing the first results, and hopes are rising that the end of the worst pandemic in a century may be approaching. These understandable hopes must be tempered by the complexities of defeating this virus. Countries are still only months into a very long fight.

Even with a highly successful vaccine rollout—the *bull* case—the public will still be wearing masks, maintaining distance, and avoiding crowds for many months after regulatory authorization. In fact, the public will likely be taking these precautions into the second half of 2021 or longer. Testing, tracing, and continuing efforts to reduce the severity of the disease with therapeutics will also remain crucial. If the rollout is less successful—the *base* and *bear* cases—such interventions could stay in place for 15 more months or longer. (See the sidebar "The Bull, Base, and Bear Cases.")

The rollout needs to happen both efficiently and equitably. We will have failed if vaccines disproportionately flow to wealthy nations and individuals at the expense of nations with low or midrange per capita income and marginalized communities. Governments cannot repeat the mistakes made during the early days of the pandemic, when the most vulnerable were the least protected from the virus. Countries, regions, and states still have time to get this right through science, hard work, and vigilance.

For public health officials, who have been on the frontlines all year, the work enters the next crucial phase. In countries that have contained the virus, winning the health endgame will cement trust and legitimacy, creating a platform on which to build economic recovery. For countries that have struggled with their public health response, this phase is the opportunity to flip the script and restore faith in the government.



### The Bull, Base, and Bear Cases

Amid uncertainty and complexity, scenario exercises offer a window into the future. The purpose of scenarios is less to predict the future than to prepare for it and incorporate variability into planning. Our three vaccine rollout scenarios, tailored for the US but applicable more broadly, range from bullish to bearish and highlight the need for agility and resilience. Low- and middle-income countries are likely to face a longer timeline for recovery.

**The Bull Case.** In this scenario, all the puzzle pieces fall into place. Several highly effective vaccines receive emergency-use authorization in late 2020. Highly effective therapeutics mitigate disease severity during the vaccine ramp up. The vaccine rollout across the supply chain is effective and well coordinated. The public and private sectors partner to create and execute a thoughtful, clear, and trustworthy communication and administration plan. The plan provides for the right number of administration

sites with the right storage and handling capacity, in the right communities, with the right operating hours, and with the right staff. Under this best-case scenario, the pandemic would persist for less than another year; the number of infections would gradually decrease, and the virus would be under control before the end of the third quarter of 2021.

The Base Case. The puzzle pieces fall into place but with less speed, precision, and coordination. Two vaccines are authorized for use by the end of 2020, but they are slightly less effective. Therapeutics are only moderately effective and face broad distribution challenges. Vaccine manufacturing is effective, but delays in the last mile and a limited number of vaccine administration sites constrain vaccination volumes. The information campaign does not fully address the public's underlying skepticism, especially among high-risk groups, worsening existing disparities. The ongoing release of safety and efficacy data that demon-

strates the effectiveness of the vaccines slowly alleviates those concerns. The good-but-not-great rollout delays defeating the pandemic by about six months, until the first quarter of 2022.

The Bear Case. Little proceeds as planned. A single vaccine receives emergency-use authorization in 2020. It is moderately effective, but the rollout is largely inefficient, including manufacturing, distribution, and administration. Health officials do not approve therapeutics other than remdesivir and dexamethasone. Last-mile challenges generate waste. Poor communication and record keeping lead to many individuals missing their second dose. A second vaccine is authorized for use but not until mid-2021. In the meantime, subsequent waves of cases emerge, and the pandemic persists for two more years.

#### Where the World Stands

The response to the coronavirus is proceeding in three phases—flatten, fight, and future. The world is still in the early stages of the fight phase, which began when nations restarted activity to end the flatten (or lockdown) phase.

Rolling out vaccines and improving therapeutics will help us accelerate the fight, while crush-and-contain strategies and smart government policies will help manage further impact. (See Exhibit 1.)

Ten novel COVID-19 vaccine candidates have entered Phase III clinical trials across the globe less than nine months after the sequencing of the virus genome. Many more are close behind. The US Food and Drug Administration (FDA) and the European Medicines Agency could grant emergency-use authorizations as soon as November 2020. The Chinese and Russian governments have already approved five vaccines for emergency use.

These authorizations start the clock on the hard work of rolling out vaccines to a global population in an orderly and scientific sequence that prioritizes protecting the health vulnerable and those who have a high risk of exposure. What happens in low-income nations matters for humanitarian and practical reasons. In an interconnected world of global trade and tourism, fully restoring a country's economic, social, and public health depends on a global recovery that includes all nations.

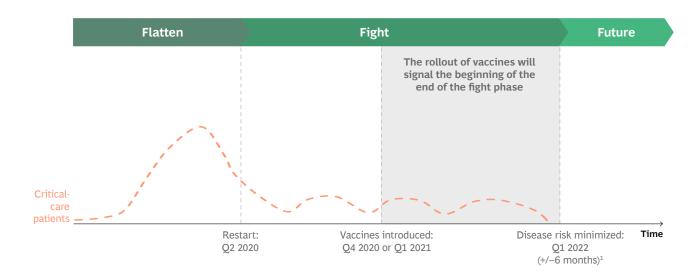
Likewise, the rollout of vaccines requires the near-flawless execution of an interconnected chain of processes. Because of the vagaries of manufacturing vaccines, there is a saying in the scientific community that "the process is the product." In the case of COVID-19 vaccines, this aphorism extends to every aspect of the rollout: distribution, the supply of glass vials and syringes, ultracold storage, public education and outreach, record keeping and follow-up, and safety and efficacy monitoring.

Four known vaccine "unknowns"—availability, effectiveness, safety, and uptake—will determine how swiftly this happens.

**Availability.** The foundational question concerning availability is how long will it take to manufacture, distribute, and administer enough doses to protect a global population of almost 8 billion people.

Our best-case analysis suggests that 2 billion to 3 billion people will remain unprotected by the end of 2021, even if all ten current Phase III trial vaccines receive approval and if manufacturers ramp up distribution quickly and utilize 100% of their capacity. (See Exhibit 2.) Even if the vaccination of all 2 billion children is delayed until more safety data is available, a shortfall is almost certain.

### Exhibit 1 - Vaccines Are Another Tool for the Fight Phase

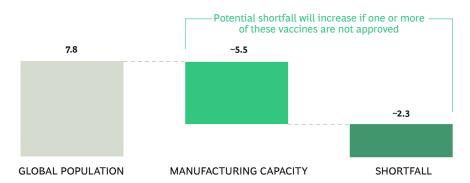


Source: BCG analysis.

<sup>1</sup>Estimated time frame for a safe and effective vaccine to be developed, manufactured, and delivered on a wide scale to minimize disease risk.

### Exhibit 2 - The Best Case Still Leaves a Large Vaccine Shortfall by the End of 2021

Projected global supply by year-end 2021 for Phase III candidates (billions)1



Sources: Company press releases; New York Times; Wall Street Journal; BCG analysis.

Note: Capacity estimates assume all ten Phase III vaccines from the following organizations will receive authorization: AstraZeneca, CanSinoBio, the Gamaleya National Center of Epidemiology and Microbiology, Johnson & Johnson, Moderna, Novavax, Pfizer, SinoPharm (two vaccines), and Sinovac Biotech.

<sup>1</sup>Projection includes options for additional purchases beyond the original agreement. Manufacturing and prebooked dose quantities have been halved for vaccines requiring two doses. Production quantities for vaccines developed in China and Russia were estimated on the basis of press reports.

Most of the shortfall will impact people in countries with low or midrange per capita income that can least afford an extended public health and economic crisis. That is in part because wealthy countries have prebooked billions of doses of promising vaccine candidates. For example, Canada, the European Union, Japan, the UK, and the US will have more than two-and-a-half times the supply they need if all the candidates receive approval, accounting for the fact that all but one of the vaccines require two shots. (See Exhibit 3.) China and Russia are subsidizing five homegrown vaccines, which account for half of the candidates that are in Phase III trials worldwide.

Low-income countries are dependent on the success of the COVID-19 Vaccine Global Access Facility (or the Covax Facility), a global coalition led by the World Health Organization and two public-private alliances. The Covax Facility's mission is to distribute enough vaccines to cover 20% of the population in participating countries by the end of 2021, with rich nations subsidizing vaccinations for 92 low- and middle-income countries. It has commitments from 84 wealthy nations, including China but excluding the US.

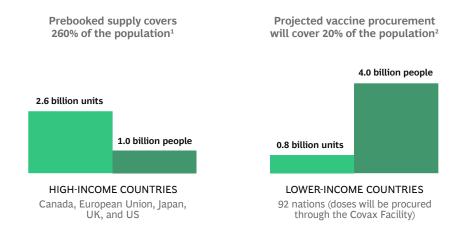
Europe and the US will likely redistribute excess capacity to emerging markets if most of their late-stage trials are approved. But that is cold comfort to public health officials in nations in desperate need now.

Manufacturing billions of doses is rivaled in complexity by the distribution, storage, and administration challenges. Two of the leading vaccine candidates require doses to be stored at ultracold temperatures at or below  $-20^{\circ}$ C. These ultracold requirements create supply chain challenges, limit where vaccines can be distributed (especially in emerging markets), and increase the risk of spoilage. Of the leading vaccine candidates, only one is being considered for a single-dose regimen; all others require a booster shot three or four weeks apart. Annual boosters may also be required.

Government advisory bodies are finalizing allocation and prioritization recommendations for the vaccines. In the best case, these decisions will be free of controversy and political pressure. The reality is that vaccines will initially be a scarce resource, and they may or may not be deployed to maximize public health. The rollout of the antiviral drug remdesivir in the US, which initially excluded states with high caseloads, should be a cautionary tale.

There are optimistic signs that stakeholders understand these dynamics. More than a dozen pharmaceutical companies along with the Bill & Melinda Gates Foundation recently pledged to ensure "global access to diagnostics, therapeutics, and vaccines."

## Exhibit 3 - Wealthy Nations Have 13 Times the Per Capita Vaccine Coverage as Lower-Income Countries



Sources: Company press releases; New York Times; Wall Street Journal; Covax Facility; BCG analysis.

<sup>1</sup>Prebooked data is not exhaustive. Prebooked quantities for AstraZeneca, Johnson & Johnson, Moderna, Novavax, and Pfizer were estimated using information available in company filings. Units have also been halved for candidates requiring two doses. Prebooked estimates for late-stage vaccines in China and Russia were unavailable.

<sup>2</sup>Based on the stated objectives of the Covax Facility.

**Effectiveness.** The effectiveness of a vaccine is often compressed into a single number—the percentage of disease reduction among the vaccinated population—and then rated on the basis of it being higher or lower than 50%. That number, which is the FDA's threshold for the first generation of vaccines, is important. Vaccines with effectiveness ratings that are above but close to 50% require a greater number of people to be vaccinated, which lengthens the amount of time that people will need to continue modifying their behavior until herd immunity is reached.

While that number is critical, there are several other important characteristics of vaccine effectiveness: How effective is the vaccine among various populations, including children and those over the age of 65? How durable is the immunity? And how does the efficacy impact the need to continue taking other measures, such as wearing a mask and practicing social distancing? Does immunity prevent transmission of the virus or simply prevent the disease? (In other words, can vaccinated individuals still pass along the virus?) Finally, how effective will the second generation of vaccines be? The answers will influence both the availability and the uptake of vaccines and the overall complexity and timing of reaching herd immunity.

**Safety.** Phase III trials lasting several months and with tens of thousands of participants help ensure that the vaccines are safe. The pauses of the Phase III trials show that the system is working. But given their relatively short length and small populations, these trials cannot fully anticipate rare safety issues that will arise in populations of hundreds of millions of people or the vaccines' long-term impacts. Ongoing pharmacovigilance will greatly influence the success of vaccine programs and provide evidence of the duration of protection.

**Uptake.** A vaccine is only as effective as the communication strategies and policies meant to engender trust in its safety and efficacy. These strategies and policies must address concerns that the approval process was rushed, and they must respond to preexisting antivaccine sentiment in many markets and communities. In a recent poll, for example, only 27% of US registered voters said that they would get the COVID-19 vaccine as soon as it became available. In August, 37% of respondents to a global survey "strongly agreed" that they would get a vaccine once one is available. Persuading the unwilling, the skeptics, and the unaware may be the biggest challenge of all.

### A Public Sector Agenda

Countries need massive, unified mobilization analogous to a wartime effort to roll out vaccines and therapeutics while simultaneously maintaining the daily fight using masks, distancing, virus monitoring, and other interventions. Experts, businesses, and civil society must all be drafted to the cause. The challenges will be staggering, and so will the range of capabilities needed to address them. Unity must be the watchword.

From the perspective of certain countries, this approach may sound fantastical, but it is possible. Australia created the National Cabinet (consisting of the prime minister and all state premiers, regardless of their party affiliation) that helped ensure a consistent national approach to defeat both the first and second waves of the coronavirus. It is not too late for other governments to find the same alignment and drive. For all involved in the effort in the private and public sectors, it will likely be among the most important societal contribution of their lives.

**Coordination and Stakeholder Management.** Every day that is lost to the fight against the virus adds to the death toll and delays the return of livelihood and life. The whole of government must mobilize—from national policymakers to community health organizations. The success of execution will be determined by the day-by-day decisions, conversations, compromises, and overall willingness to abandon the not-invented-here and not-my-problem syndromes that can torpedo well-meaning initiatives.

There cannot be effective coordination without data sharing and transparency across states, regions, and countries. That is the only way to learn quickly, disseminate best practices, and make midcourse adjustments. Officials need to treat the vaccine rollout as the life-or-death issue that it is for all citizens, but especially the vulnerable.

This desire for speed must be balanced by an assessment of public health impact. The perception that vaccine development has been rushed will likely feed into the reluctance to be vaccinated. People's reservations and reluctance can be overcome with smart public health policy and execution.

Thoughtful, Strategic Communication. Leaders will also be fighting an information and communication war. Clear, consistent messages won't be enough. Public sector leaders will need to play offense and defense. On the one hand, they should be encouraging vaccination through traditional and social media, applying behavioral insights to influence the public, and reaching immigrants, undocumented workers, and communities of color through trusted intermediaries. Without thoughtful, targeted campaigns, communities with low testing levels and high rates of infection are also likely to have low vaccination levels, amplifying the health disparity these communities face. On the other hand, leaders will need to respond quickly and with finesse to fears and conspiracy theories, tracking social media sentiment and intervening if necessary to get control.

**Vaccine Administration Logistics and Data Management.** Governments that excelled at testing, tracing, and isolation relied on digital capabilities and robust operating models. The success of logistics management and the tracking of dose administration and vaccine status will all rely on those same capabilities. Governments must be able to track and account for their vaccine stocks and rapidly respond to shortages. They also need to be able to track who has been vaccinated, and individuals need to be able to demonstrate their vaccine status. Governments without digital service platforms need to build or license one.

Domestic and Global Equity. As we've noted in prior publications, COVID-19 has exposed fundamental inequities in exposure risk and health care outcomes. Collectively, government failed many marginalized communities in testing, tracing, and other nonpharmaceutical interventions during the height of the pandemic. These inequities need to be addressed within countries and globally. It's necessary but insufficient for states to have a vaccine campaign aimed at specific communities and for nations to make a financial commitment to the Covax Facility. If societies are serious about eradicating the virus, they need to make eliminating the inequities it exposed a top and animating priority of all stakeholders.

Vaccine authorization will not be the end of the fight phase, but vaccines ought to give people confidence that the fight can be won. Researchers and manufacturers will continue their mission of developing and improving vaccines and therapeutics. It's time for governments and society to fulfill the potential that vaccines offer and to fix the societal weaknesses that the virus worsened. If you are involved in this fight, it is your life's work.

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