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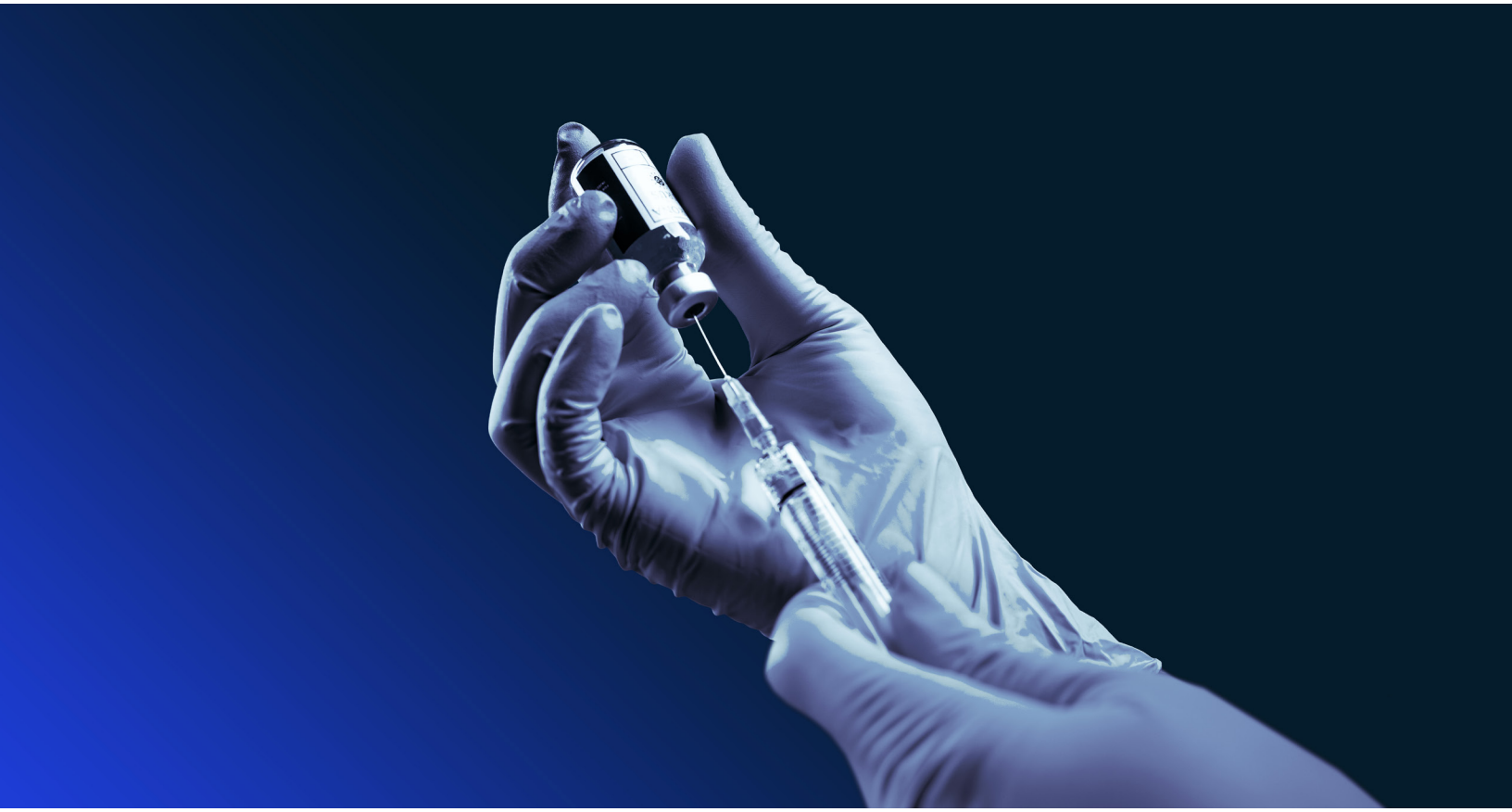
On pins and needles: How accessible and effective will COVID-19 vaccines be?

In this update, we track the progress of COVID-19 vaccines and therapeutics as new clinical data and virus variants emerge.

This article was a collaborative effort by the global Healthcare Systems & Services and Pharmaceutical & Medical Products Practices, including Gaurav Agrawal, Michael Conway, Jennifer Heller, Adam Sabow, and Gila Tolub.



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Since we shared our perspectives on COVID-19-vaccine development in July 2020, the pandemic has grown in proportion across most of Europe and North America, with more than a million new cases every two days, and more than 10,000 deaths per day. Even communities that managed to flatten the curve in the spring and summer of 2020 found themselves backsliding in the fall. The loss of lives and livelihoods has been devastating—and that isn't over yet—but there are some reasons to be cautiously optimistic about global recovery, not the least of which is the progress made to date on the pursuit of vaccines and other treatments for the novel coronavirus (SARS-CoV-2).

At least six vaccine manufacturers and two antibody-medicine manufacturers have shared preliminary results on the efficacy of their products—data that have outperformed the initial expectations of most experts. Already, the first vaccinations have been administered in more than 50 countries, including Brazil, Canada, China, India, Israel, Russia, the United Arab Emirates, the United Kingdom, most countries in western Europe, and the United States. Such progress has instilled hope in many that vaccines may, indeed, "save the world."

But while COVID-19 vaccines will almost certainly be one of the most critical tools for moving the world toward an epidemiological end to the pandemic, they will likely not be the only ones: diagnostics, antibody medicines, and other therapeutics will be important complements. A lot of work must also be done to ensure sufficient vaccination coverage for communities to reach herd immunity. "Sufficient" coverage would be between 60 and 70 percent of the population, although the figures are now possibly higher, given the emergence of new, more easily transmitted variants of SARS-CoV-2.[1]

In this article, we review the initial results from clinical trials of COVID-19 vaccines and explore several remaining uncertainties that are relevant to stakeholders across the globe: How many doses will we have and by when? How will the logistics work for distribution and administration? And, critically, will consumers agree to be vaccinated?

Initial data from clinical trials

COVID-19-vaccine candidates from BioNTech and Pfizer (in partnership) and from Moderna have demonstrated a rate of about 95 percent protection

While COVID-19 vaccines will be critical tools for an end to the pandemic, diagnostics, antibody medicines, and other therapeutics will be important complements.

[1] Summer E. Galloway et al., "Emergence of SARS-CoV-2 B.1.1.7 lineage—United States, December 29, 2020–January 12, 2021," *Morbidity and Mortality Weekly Report*, January 15, 2021, cdc.gov.

from infection with symptoms after two doses are administered several weeks apart.[2] Additionally, a vaccine candidate from AstraZeneca has demonstrated a range of efficacy that depends on the trial protocol: 90 percent for a half plus a full dose, 62 percent for two full doses, and 82 percent for two full doses with a longer interval between them.[3] Recent reports from Johnson & Johnson and Novavax have also been encouraging. Johnson & Johnson demonstrated that its single-dose vaccine confers 66 percent immunity against infection in a multiregion, multivariant data set, with 72 percent efficacy in the United States, 57 percent in South Africa, and 66 percent in Latin America. It also demonstrated 85 percent (28 days) and 100 percent (49 days) efficacy against severe disease.[4] A vaccine candidate from Novavax demonstrated efficacy of 89 percent in a UK trial and 49 percent in a South Africa trial[5] (Exhibit 1).

Specific ranges of efficacy vary among these vaccine candidates, but each has demonstrated an efficacy of at least 85 percent against severe disease.

This is all good news for several reasons: individuals will benefit from the health protection offered by the vaccine, the positive outcomes may encourage others to get vaccinated, and the proportion of the population required to reach herd immunity may be reduced.

Exhibit 1

These are the data available on Phase III trials for several vaccine candidates.

	Moderna	Pfizer/ BioNTech	AstraZeneca	Johnson & Johnson	Gamaleya National Center	Novavax
Technology	mRNA	mRNA	Viral vector	Viral vector	Viral vector	Protein subunit
Dose schedule	2 doses, 4 weeks apart	2 doses, 3 weeks apart	Varies by trial arm: • 2 full doses, 4 weeks apart • 1 half dose and 1 full dose, 12 weeks apart	1 dose	2 different doses (with different viral vectors), 3 weeks apart	2 doses, 3 weeks apart
Efficacy Symptomatic infection	94%	95%	70% across dosing regimens 90% for a half dose plus a full dose 62% for 2 full doses	66% overall and by region: US: 72% Latin America: 66% South Africa: 57%	92%	UK[1]: 89% South Africa[2]: 49% overall 60% in population that was HIV negative
Severe disease	100%	89%	100%	85% (28 days) 100% (49 days)	100%	100% (consistent across regions)
Thermostability	–20°C shipped/ stored for 6 months; 2–8°C for 30 days	–70°C shipped/ stored for 6 months; 2–8°C for 5 days	2–8°C for 6 months	2–8°C for 3 months; –20°C for 2 years	–18°C	4–8°C

[1]New variant B.1.1.7 was detected in more than 50% of confirmed positive cases.
[2]More than 90% of confirmed cases were B.1.351 variant.
Source: AstraZeneca; Bloomberg; clinicaltrials.gov; FDA; *Guardian*; J&J; Moderna; Novavax; Oxford University; Pfizer; WBUR

[2] "Pfizer vaccine efficacy could be a 'game changer,'" Cornell University, November 8, 2020, government.cornell.edu.
[3] "AZD1222 vaccine met primary efficacy endpoint in preventing COVID-19," AstraZeneca, November 23, 2020, astrazeneca.com.
[4] "Novavax COVID-19 vaccine demonstrates 89.3% efficacy in UK Phase 3 trial," Novavax, January 28, 2021, ir.novavax.com; "Johnson & Johnson announces single-shot Janssen COVID-19 vaccine candidate met primary endpoints in interim analysis of its Phase 3 ENSEMBLE trial," Johnson & Johnson, January 29, 2021, jnj.com
[5] 90 percent of the confirmed cases in the South Africa trial were attributed to the B.1.351 virus variant.

It's increasingly probable that multiple COVID-19 vaccines will be available in the coming months. Among others, CureVac, GlaxoSmithKline and Medicago (in partnership), and Inovio all have COVID-19-vaccine candidates in late-stage development (Exhibit 2). Several COVID-19-vaccine candidates from China, India, and Russia are also in late-stage development. For instance, in an interim analysis of data from a Phase III trial reported in *The Lancet*, the Sputnik V vaccine from the Gamaleya National Center of Epidemiology and Microbiology showed overall efficacy of 92 percent.[6]

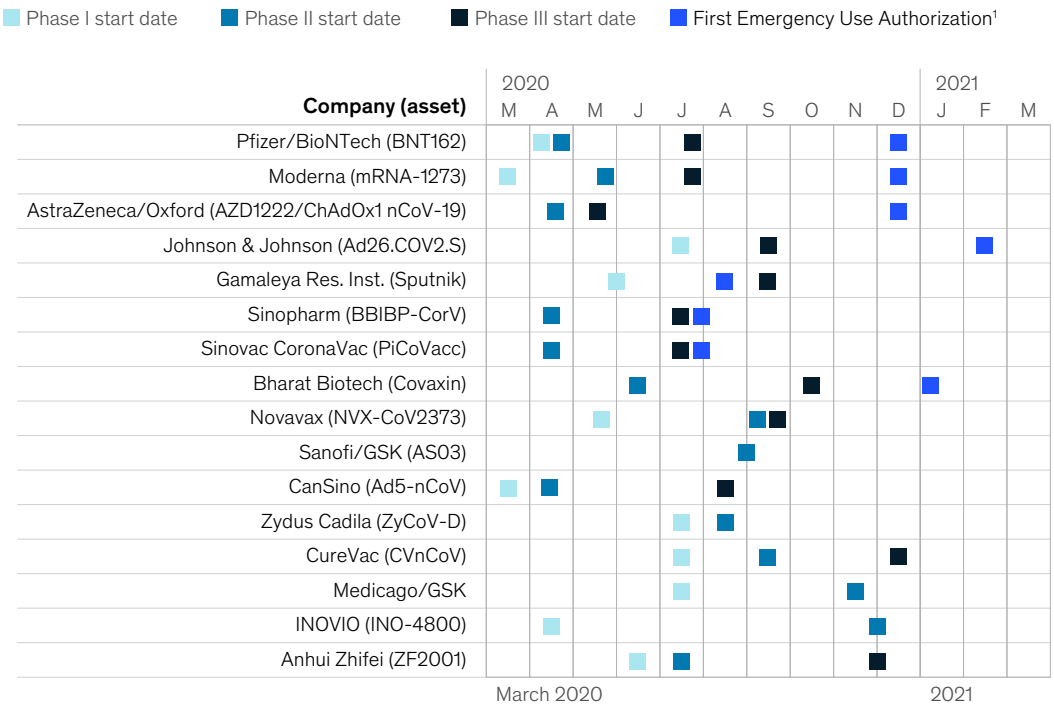
None of the leading COVID-19 vaccine candidates reported serious side effects during clinical trials, but additional safety data are being collected, as required by regulatory guidelines for licensure. For example, during the initial rollouts in the United Kingdom, the United States, and other markets of the COVID-19 vaccines from Moderna and Pfizer–BioNTech, there were some rare reports of anaphylaxis (2.1 cases per million and 6.2 cases per million, respectively, based on preliminary data), which led regulators to recommend that any person with a history of anaphylaxis related to food, a medicine, or a vaccine not receive the two COVID-19 vaccines.[7]

Additionally, it remains to be seen how long the protection from COVID-19 achieved by the vaccines will last. And because the trials haven't yet included children, it isn't known whether the efficacy will be comparable in those younger than the age of 18 years. More information will be revealed as the sample size grows and an increasingly diverse population is inoculated.

Exhibit 2

Multiple vaccines are authorized; additional candidates may receive Emergency Use Authorization in the first quarter of 2021.

Clinical-trial timelines for vaccine candidates



[1]The geography in which the first Emergency Use Authorization was granted varies by vaccine.
Source: BioCentury; clinicaltrials.gov; Milken Institute COVID-19 Treatment and Vaccine Tracker; press search

[6] Denis Y. Logunov et al., "Safety and efficacy of an rAd26 and rAd5 vector-based heterologous prime-boost COVID-19 vaccine: An interim analysis of a randomised controlled phase 3 trial in Russia," *Lancet*, February 2, 2021, thelancet.com.
[7] Alistair Smout, "UK issues anaphylaxis warning on Pfizer vaccine after adverse reactions," Reuters, December 9, 2020, reuters.com.

There has also been progress on the development of therapeutics for COVID-19. In November 2020, for instance, Eli Lilly's antibody medicine bamlanivimab was granted Emergency Use Authorization (EUA) by the US Food and Drug Administration. In clinical trials, it had demonstrated a 72 percent reduction in the rate of hospitalizations and emergency-department visits.[8] Additionally, Regeneron Pharmaceuticals submitted its antibody cocktail REGN-COV2 for EUA in October 2020. In trials, the therapy had demonstrated a tenfold reduction in viral load, on average, and a 57 percent reduction in COVID-19-related medical visits.[9] Those and other antibody medicines in development are part of a growing assortment of treatments and protocols related to COVID-19 that, collectively, could reduce mortality among hospitalized patients by between 18 and 30 percent.[10]

Additionally, it will be important to monitor the efficacy of vaccines and therapeutics against new variants of SARS-CoV-2 that have been identified in Brazil, South Africa, the United Kingdom, and other regions and that have in some geographies become the predominant strain. Multiple COVID-19 vaccines have demonstrated immune response to variant B.1.1.7, which was first identified in the United Kingdom. However, the B.1.351 variant, which was first identified in South Africa, has generated more concern in the scientific community; preliminary lab and clinical data across multiple vaccine candidates suggest that efficacy against this strain could be lower. Multiple vaccine manufacturers have reported preliminary data showing a severalfold reduction in antibody neutralization potency against the B.1.351 variant and relatively lower vaccine efficacy in trials taking place in South Africa—for example, 50 to 60 percent efficacy in South Africa trial data versus 70 to 90 percent efficacy in trial data in regions where B.1.351 is not predominant.[11]

This variant has also demonstrated evasion from the antibodies generated by natural infection (which are present in convalescent sera) and monoclonal-antibody therapies, suggesting the possibility of reinfection and limited effectiveness of the therapeutics currently available.[12]

Remaining uncertainties

It's becoming increasingly clear that COVID-19 vaccines will play a crucial role in controlling the pandemic.[13] As vaccines' role in saving the world expands, the baton passes from vaccine manufacturers to governments and local jurisdictions to assess what else will be required to move from having an approved vaccine to completing large-scale inoculation. Through research and conversations with healthcare experts in the field, McKinsey has identified several critical elements of an effective vaccination program as well as some of the remaining uncertainties associated with each[14] (Exhibit 3).

Specifically, vaccines and the mechanisms for administering them must include the following features:

— *Available.* Will there be enough of the vaccine to inoculate the world and reach herd immunity?

— *Administrable.* Who will get the vaccine first, and where will it be available?

— *Accessible.* How will the logistics of the vaccine be managed, particularly if it has complex, cold-chain requirements?

[8] "Lilly announces proof of concept data for neutralizing antibody LY-CoV555 in the COVID-19 outpatient setting," Eli Lilly, September 16, 2020, investor.lilly.com.
[9] "Regeneron's COVID-19 outpatient trial prospectively demonstrates that REGN-COV2 antibody cocktail significantly reduced virus levels and need for further medical attention," Regeneron Pharmaceuticals, October 28, 2020, investor.regeneron.com.
[10] Leora I. Horwitz et al., "Trends in COVID-19 risk-adjusted mortality rates," *Journal of Hospital Medicine*, October 23, 2020, journalofhospitalmedicine.com.
[11] "Moderna COVID-19 vaccine retains neutralizing activity against emerging variants first identified in the U.K. and the Republic of South Africa," Moderna, January 25, 2021, investors.modernatx.com; "Johnson & Johnson announces single-shot Janssen COVID-19 vaccine candidate met primary endpoints in interim analysis of its Phase 3 ENSEMBLE trial," January 29, 2021; "Novavax COVID-19 vaccine demonstrates 89.3% efficacy in UK Phase 3 trial," January 28, 2021.
[12] "SARS-CoV-2 501Y.V2 escapes neutralization by South African COVID-19 donor plasma," bioRxiv, January 18, 2021, biorxiv.org
[13] Sarun Charumilind, Matt Craven, Jessica Lamb, Adam Sabow, and Matt Wilson, "When will the COVID-19 pandemic end?," November 23, 2020, McKinsey.com.
[14] "The COVID-19 vaccines are here: What comes next?," December 9, 2021, McKinsey.com.

Exhibit 3

An effective COVID-19 immunization strategy addresses each component of vaccine adoption.

Key activities of vaccine adoption

Available	Administrable	Accessible	Acceptable	Affordable	Accountable
Vaccine is approved and in sufficient supply to reach the population.	Appropriate individuals can receive vaccination at convenient locations.	Vaccine is distributed and stored for use.	Consumers have accurate information they trust, and they choose to be vaccinated.	Costs of vaccine and administration are amenable to both payers (public/government and private) and consumers.	Patients receive full course of treatment, and monitoring is in place on postlaunch outcomes.
Technology portfolio and access	Population segmentation	Ordering	Public communications, messaging, and education	Funding	IT infrastructure and interoperability
Tech transfer and drug substance manufacturing	Vaccination dispensing strategy	Logistics, transport, and warehousing	Healthcare workforce education	Reimbursement strategy	Ongoing monitoring and reporting
Upstream/downstream sourcing and manufacturing					
Public-policy planning					

— *Acceptable.* Will consumers (especially those at highest risk of contracting a severe form of the disease) have trust and conviction to get vaccinated?

— *Accountable.* What would a closed-loop surveillance system look like to build more confidence in the long-term safety of the vaccine?

Questions about availability and capacity are front of mind for many who have been facing direct and indirect health risks and economic shock related to the COVID-19 pandemic. The foresight (and urgency) shown by the biopharmaceutical industry, major donors, multilateral organizations, and governments allowed innovators to scale up the manufacturing capacity for COVID-19-vaccine candidates even before much was known about their safety and efficacy. The potential outcomes of those at-risk investments are now beginning to come into focus.

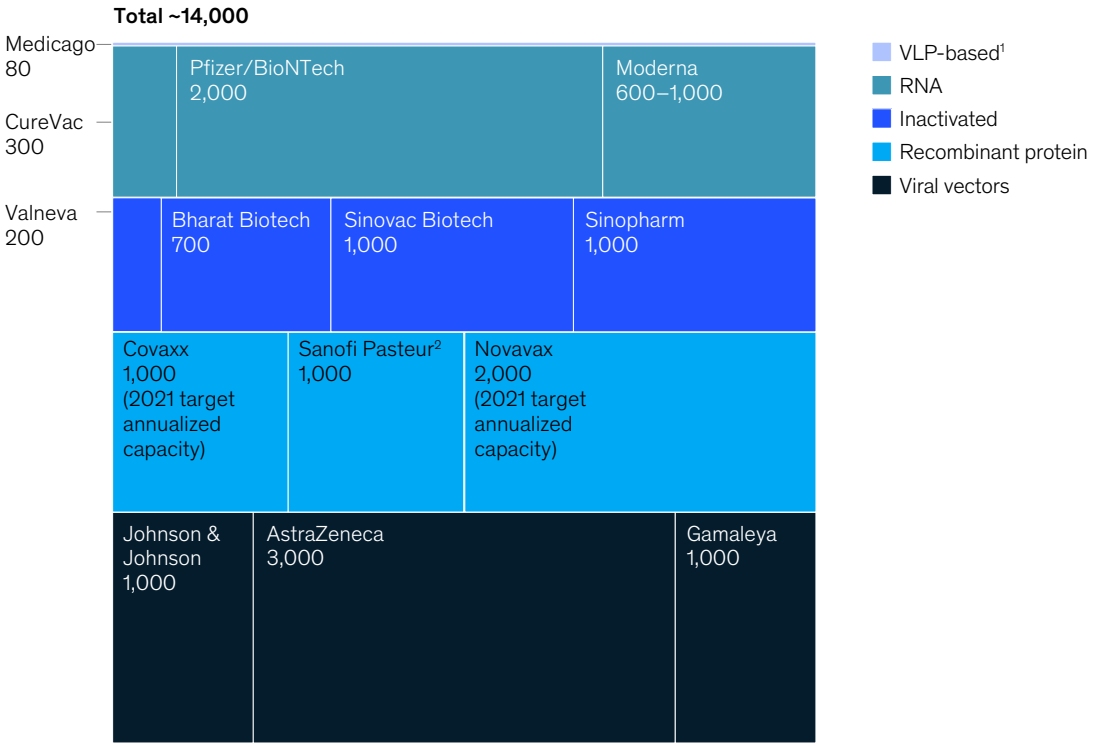
Will there be enough of the COVID-19 vaccines for the world?

If all COVID-19-vaccine innovators are successful in clinical trials, and if manufacturing commitments to scale up hold true, there may be enough capacity to vaccinate nearly 80 percent of the global population against COVID-19. According to manufacturers' public announcements, more than 14 billion doses' worth of capacity (including 2020 capacity) is planned for 2021 (Exhibit 4). Assuming that all innovators' vaccines are successful and require two doses (dosing remains uncertain for some of the vaccine candidates), full COVID-19-vaccine courses could be available for six billion individuals—approximately the size of the entire global adult population.

Exhibit 4

Public announcements indicate target global vaccine-manufacturing capacity of more than 14 billion doses by end of 2021.

Publicly announced vaccine-manufacturing capacity, million



[1]Virus-like particle.
[2]Target capacity announced prior to announced plan to launch new Phase II trial with improved antigen formulation.
Source: BioCentury; clinicaltrials.gov; Milken Institute; Nature; WHO

It may not be realistic to assume that every COVID-19-vaccine candidate will succeed. Some haven't made it through clinical trials to the level of EUA; others still need to collect more data for Biologics License Application reviews in the first and second quarters of 2021. The vaccine manufacturers' capacity estimates may also be over- or understated, depending on whether in-process or planned increases were reported.

Global scale-up of the manufacturing capacity for COVID-19 vaccines will likely occur over the course of 2021. The details are still emerging, but innovators' estimates suggest that manufacturing capacity will ramp up over the course of 2021. In the first half of 2021, the United States is likely to have around 500 million doses of the Johnson & Johnson, Moderna, and Pfizer–BioNTech vaccines, based on the reported delivery deadlines.[15]

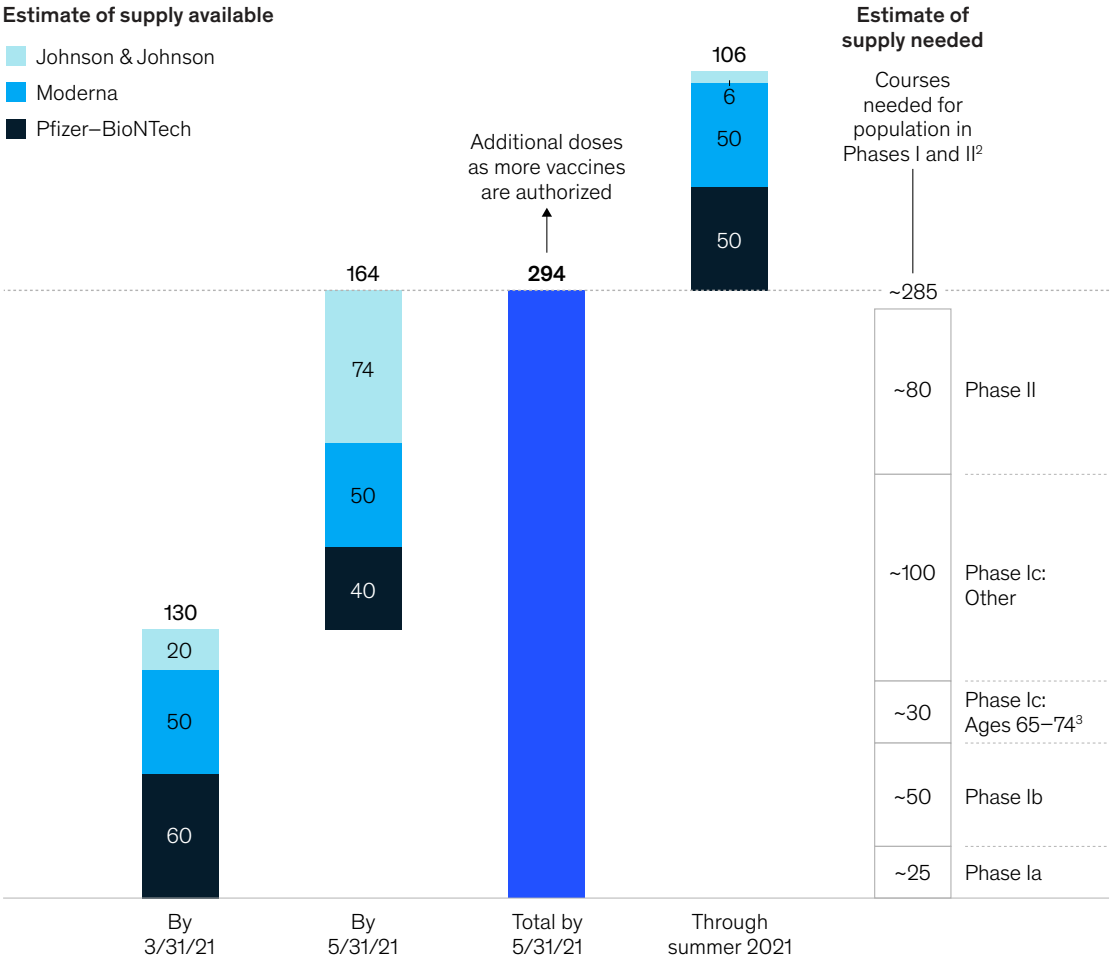
Given the contracted volume from those manufacturers, there will be sufficient vaccine doses available in the United States by the end of May for at least 300 million people—enough doses to immunize 100 percent of the adult population (Exhibit 5). AstraZeneca announced it will have enough capacity to produce 700 million doses of its COVID-19 vaccine for *global* distribution in the first quarter of 2021 and the remainder of its three billion doses later in the year.[16]

[15] Laurie McGinley and Christopher Rowland, "Merck will help make Johnson & Johnson coronavirus vaccine as rivals team up to help Biden accelerate shots," *Washington Post*, March 3, 2021, washingtonpost.com.
[16] "AstraZeneca will have enough COVID-19 vaccine for 200 million doses this year," Reuters, November 23, 2020, reuters.com.

Exhibit 5

Manufacturers have committed to deliver millions of COVID-19 vaccine doses in the United States.

Delivery commitments for vaccines with Emergency Use Authorization in the United States, millions of courses[1] (illustrative)



[1]Two doses needed per person per course for Pfizer–BioNTech, Moderna vaccines; one dose per person per course for Johnson & Johnson vaccine.
[2]According to CDC ACIP interim recommendations (December 22, 2020), will vary as individual states are making their own decisions (CDC Phase Ia = healthcare personnel, long-term care-facility residents; CDC Phase Ib = frontline essential workers, persons aged ≥75 years; CDC Phase Ic = persons aged 65–74 years; persons aged 16–64 years with high-risk medical conditions; essential workers not recommended for vaccination in Phase Ib); Phase II estimate based on 2019 census population estimate of persons aged ≥16, less population accounted for in CDC estimates of persons covered in Phase Ia–c; CDC and Operation Warp Speed vaccination guidelines may evolve over time.
[3]Phasing and distribution strategy may change based on recent statements from the US Department of Health and Human Services.
Source: Bloomberg; CDC; CNBC; Moderna; Pfizer; Reuters; US Department of Health and Human Services; *Wall Street Journal*

Depending on the success of COVID-19-vaccine candidates in late-stage development, the range of capacity scenarios may change. As mentioned previously, it's unlikely that all the vaccine candidates will be successful. Some developers have already experienced setbacks (for example, the need to reformulate vaccines for certain populations) during late stages that have delayed their vaccine-development timelines. But even if we assume that only a few candidates will succeed and see broad uptake (for example, those vaccines that are currently authorized for emergency use or under review by the EU European Medicines Agency and the US Food and Drug Administration), there would be capacity to manufacture between 5 billion and 6 billion doses in 2021—enough to inoculate approximately 40 percent of the global population.

Moreover, if we assume the ultimate success of all vaccines currently authorized or under review in at least one geography, there should be capacity to manufacture approximately 12 billion doses of COVID-19 vaccines by the end of 2021—enough to vaccinate 85 percent of the global population.

There may be sufficient manufacturing capacity for global COVID-19-vaccine coverage, but individual countries' contracted doses vary significantly. Most of the global capacity for COVID-19-vaccine manufacturing (more than seven billion doses) has been contracted and reserved by individual governments and institutions, although COVAX recently announced that it had arrangements in place to access nearly two billion doses of COVID-19-vaccine candidates on behalf of 190 participating economies (Exhibit 6). Country-specific agreements vary significantly, depending on the region and the relative size of population.[17]

In fact, it's possible that a significant number of countries—particularly those with wealthier economies—have contracted doses that exceed the needs of their populations. We haven't even accounted for the possibility that some countries won't vaccinate recovered patients or that not every targeted citizen will choose to receive a vaccination. Government leaders must consider how to manage the excess doses that will likely be available around the middle of 2021 to address the global challenge.

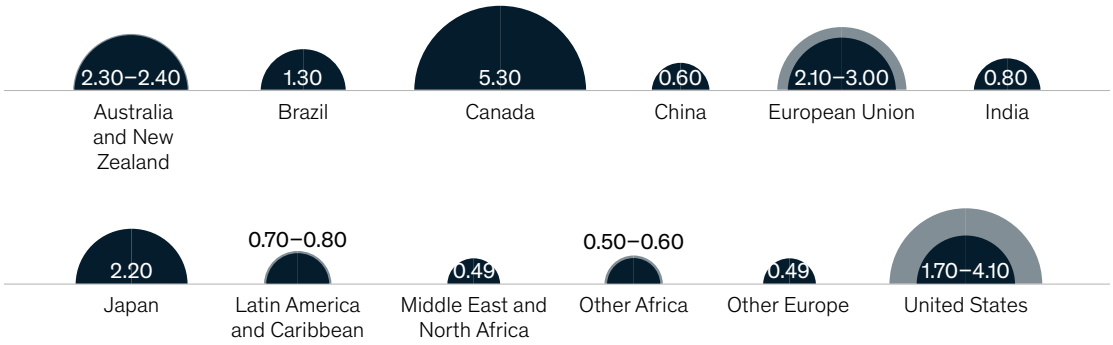
What other challenges remain?

Even as questions about COVID-19-vaccine availability and capacity become more clear, it will be critical in the coming months to monitor progress in other areas of vaccine development. Global attention is already shifting to the challenges associated with vaccine rollout and consumer adoption. Other underlying questions will also need to be addressed in the background, including those related to long-term safety, duration of protection, efficacy after the first dose of a multidose course (recent data show that some COVID-19 vaccines may be somewhat effective after only one dose[18]), impact of the

Exhibit 6

An overview of publicly announced supply contracts.

Course[1] per population ratio, publicly announced supply contracts, by region, nonexhaustive



[1]Calculation assumes 1 course equals 2 doses for all vaccines except Johnson & Johnson, for which 1 course = 1 dose.
Source: BBC; Bloomberg; *Economist*; FiercePharma; FOPH Switzerland; GlobalNews; Pharmaceutical Technology; Reuters; The Marker; UPI; company press releases

[17] Our research shows that, assuming that all vaccines require two doses, Africa, Latin America, and many Asia–Pacific countries have secured fewer than half a course of treatment per member of the population, while some countries have secured up to nearly five courses per individual.
[18] *FDA briefing document: Pfizer-BioNTech COVID-19 vaccine*, Vaccines and Related Biological Products Advisory Committee Meeting, December 10, 2020, fda.gov.

vaccine on transmission of the virus, and efficacy in specific patient populations, including the pediatric population. To reach the ideal vaccine profile—that is, a single dose with an impeccable record of long-term safety, extended duration of protection (ideally, five years or longer), and high efficacy against the disease—it will be critical for developers and other key stakeholders to make progress in several areas.

Realizing a pipeline of COVID-19 vaccines

The early success of the first few COVID-19-vaccine candidates is exciting, but the world will likely need additional, next-generation candidates in the pipeline to provide additional capacity. The vaccines that may become part of endemic vaccination in a country's schedule may need to optimize for the other parameters (for example, dosing and duration of protection) as much as—or perhaps more than—they do for efficacy.

Shifting the paradigm of COVID-19-vaccine development

It will become difficult to recruit patients for clinical trials of the next generation of COVID-19 vaccines once the current vaccines with EUA are rolled out. Even if COVID-19 vaccines aren't available for everyone immediately, some segments of the population are likely to wait a few weeks or months to get a vaccine that demonstrates 95 percent efficacy rather than enroll in a trial with a 25 to 50 percent chance of them receiving a placebo (or a 50 to 75 percent chance of them receiving a vaccine of uncertain efficacy).

For future COVID-19-vaccine candidates, ethics guidelines may also recommend a head-to-head comparison with existing vaccines, which would make clinical trials operationally challenging, requiring hundreds of thousands (if not millions) of patients to reach efficacy endpoints comparable to a vaccine with 95 percent efficacy. Regulators will need to think through that dilemma in short order and provide guidance in the absence of defined correlates of protection.

Monitoring and adapting to emergent SARS-CoV-2 variants

Key COVID-19-vaccine stakeholders will need to continue to monitor and adapt to the new SARS-CoV-2 variants emerging across the globe to respond effectively. COVID-19-vaccine manufacturers should continue to rapidly test (for example, in nonclinical assays and animal models) the effectiveness of their vaccines in provoking an immune response to new variants. Manufacturers have already announced new development plans in response to emerging variants. These include booster doses, new stand-alone vaccines matched to the new variants, and multivalent vaccines designed to confer immunity to multiple strains in one product.

For governments, health systems, and other stakeholders involved in immunization, the potential proliferation of vaccine products in response to new strains would create more complexity across the value chain (for instance, in procurement, administration, and manufacturing-capacity management).

Freeing up the production capacities and supply chains related to COVID-19 vaccines

Some COVID-19-vaccine manufacturers have aggressively partnered to ramp up their production capacities across geographies. Technology transfer at the required scale and in such a compressed time frame is complicated, and it's far from a done deal that it will work as intended. Governments, manufacturers, nongovernmental organizations, and others will need to deploy creative solutions to resolve issues or bottlenecks—for instance, by creating a knowledge-management infrastructure and applying digital tools and advanced analytics to technology transfers. Indeed, given the requirements of several of the COVID-19 vaccines, supply chains will likely present some challenges for manufacturers in low- and middle-income countries. The infrastructure may not allow for large-scale distribution of a vaccine that requires the long-term, complex, cold-chain storage required by some mRNA vaccines.

Addressing the uncertainties about COVID-19 vaccination

Even if the R&D and supply-chain challenges related to COVID-19 vaccines are resolved, the impact of the vaccines on the course of the pandemic is contingent upon equitable consumer access and adoption. Consumer-sentiment surveys in the United States show that around 100 million Americans don't sufficiently trust the vaccine-development process and are uncertain or ambivalent about getting vaccinated in the first six months following initial availability.[19] To put the world on a path to societal and economic recovery, it will be critical to have public- and private-sector support for at-scale COVID-19-vaccine adoption.[20]

There's clearly lots to cheer about when it comes to COVID-19-vaccine development, but there is just as much to ponder as the situation evolves. In the face of continuing ambiguity, it's important for all participants in the healthcare ecosystem to provide scientific and regulatory environments that will allow the further development of the vaccine pipeline; effective technology transfer, manufacturing, logistics, and distribution; and increased and equitable uptake by consumers. They all remain daunting challenges for the largest-ever public-health intervention in history.

[19] Aliza Apple, Tara Azimi, and Jenny Cordina, "COVID-19 vaccine: Are US consumers ready?," December 10, 2020, McKinsey.com.
[20] Tara Azimi, Michael Conway, Tom Latkovic, and Adam Sabow, "COVID-19 vaccines meet 100 million uncertain Americans," December 18, 2020, McKinsey.com.

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