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The risks and challenges of the global COVID-19-vaccine rollout

A realistic assessment of the heroic effort to administer billions of doses of COVID-19 vaccines to an agonized global population is necessary—the stakes could not be higher.

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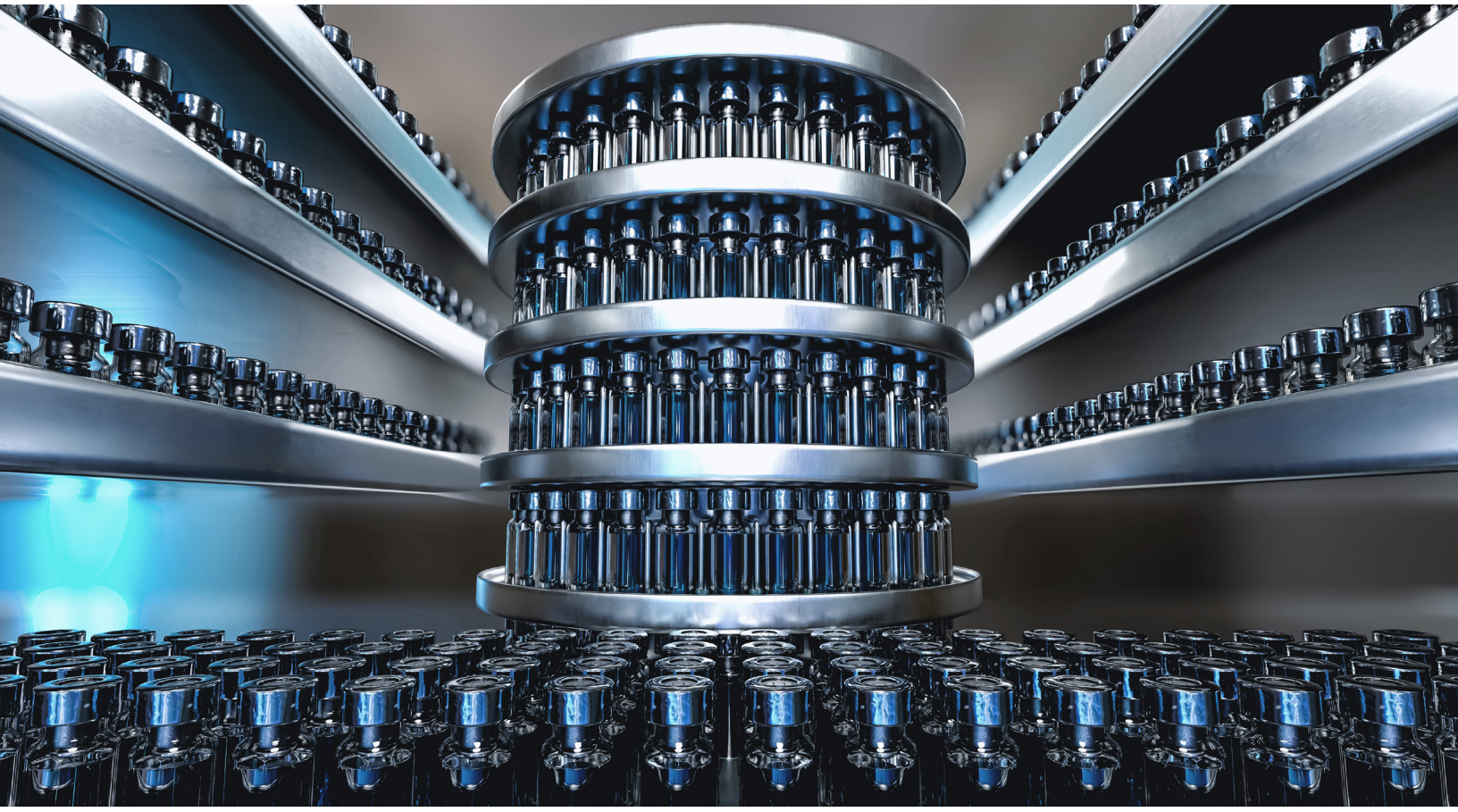

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The COVID-19 vaccines of the BioNTech and Pfizer partnership (Pfizer–BioNTech) and Moderna have received Emergency Use Authorization in Canada, the European Union, the United Kingdom, the United States, and other countries. Many frontline workers and priority population segments have received their first doses. Vaccines from AstraZeneca, Johnson & Johnson, and several other global manufacturers are also arriving (or are expected to arrive soon) and are being distributed for administration around the world. This monumental global effort has shattered the record for vaccine development: the fastest previous vaccine project, Merck's mumps vaccine, was four and a half years in development (1963–67).

In certain places, the COVID-19-vaccine effort has hit a few speed bumps; stockpiles have accumulated, and deployment to vulnerable countries and at-risk groups has been slower than expected. Nonetheless, experts have expressed confidence that safe and highly efficacious vaccines are reaching the market, and we are beginning to see "the light at the end of the tunnel" of this devastating pandemic. The epidemiological end to the COVID-19 pandemic seemed like an optimistic dream a few short months ago, but, with the development, approval, and rollout of several vaccines, it is now practically realizable in much of the world.

To arrive at the postpandemic era, in which populations experience herd immunity, vast numbers of dedicated individuals will need to continue working intensely in the months and years ahead. In this article, we consider elements of this enormous undertaking, the risks that are inherent, and potential means of further accelerating vaccination.

A common operating model of COVID-19-vaccine delivery, shown in Exhibit 1, demonstrates the complexity of the task at hand. Essentially, the exhibit is a qualitative risk map, showing the many stages of vaccine deployment and highlighting areas of potential failure as one party interacts with another. A breakdown at any point in the deployment process can set off a cascade, shutting down the entire system.

In the United States alone, hundreds of organizations play a role in vaccine deployment, adapting their operations to meet demands for volume, speed, and better technology. Suppliers, manufacturers, and regulators are collaborating to ramp up production of vaccines. Massive volumes handled, distributed, and stored through cold chains must adhere to safety regulations. Tens of thousands of transporters, vaccine handlers, medical and pharmacy staff, and frontline workers have required training on the specific characteristics of each manufacturer's distinct vaccines.

At the receiving end, vulnerable populations—especially in developing countries—could face added hurdles, including difficulty in reaching administrative sites, getting time off from work to receive doses, and arranging childcare for the same. Historical wariness of interacting with authorities can also be a barrier. A further issue is vaccine skepticism, affecting a certain segment of all populations, including the United States.

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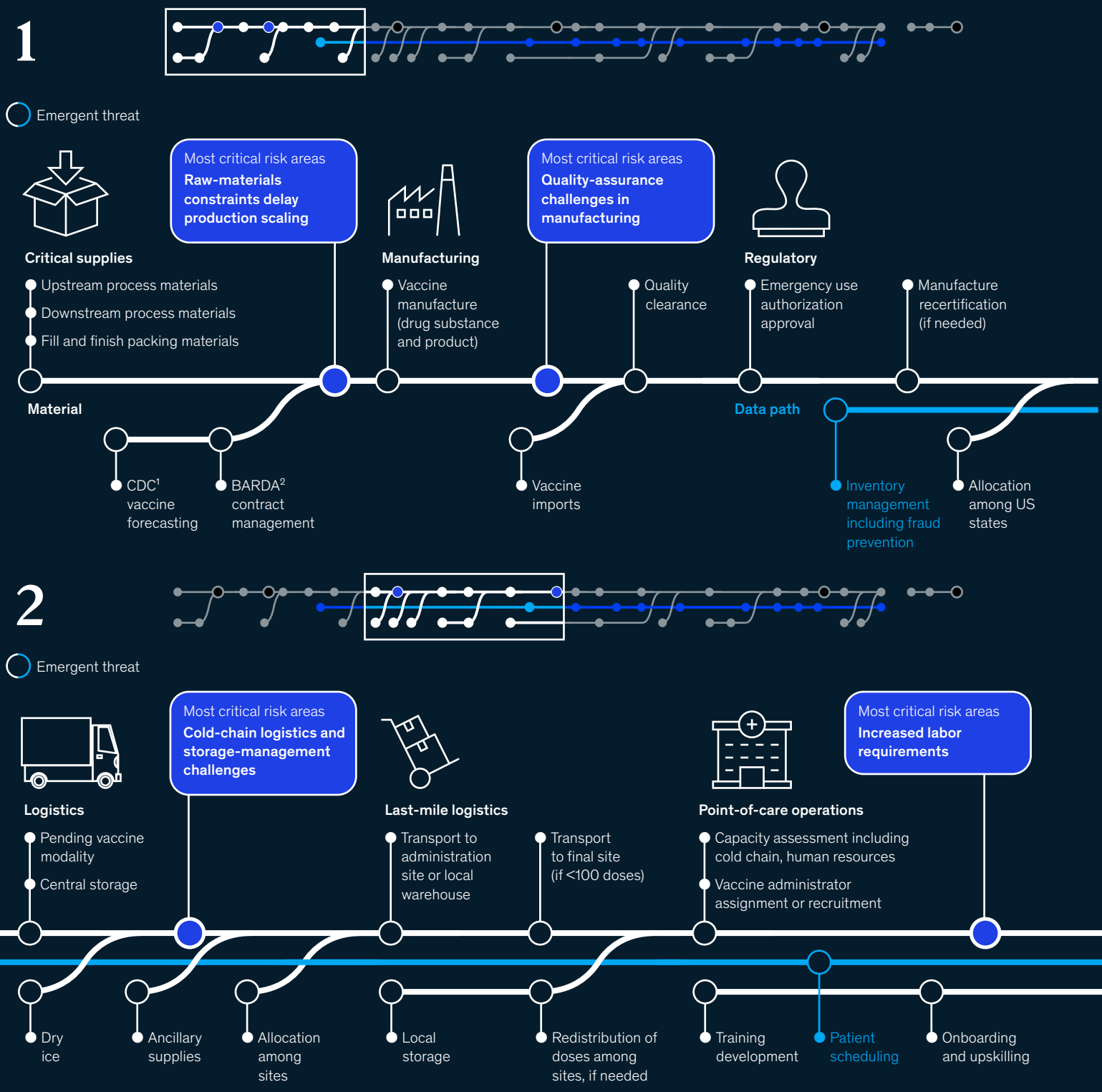
Exhibit 1

A map of the COVID-19 vaccine operating path can track data, locations, and risks for all stakeholders.

Common operating path for delivering COVID-19 vaccines (US example)



[1]Centers for Disease Control and Prevention. [2]Biomedical Advanced Research and Development Authority.
Source: CDC and US Food and Drug Administration literature; McKinsey analysis

Exhibit 1 (continued)

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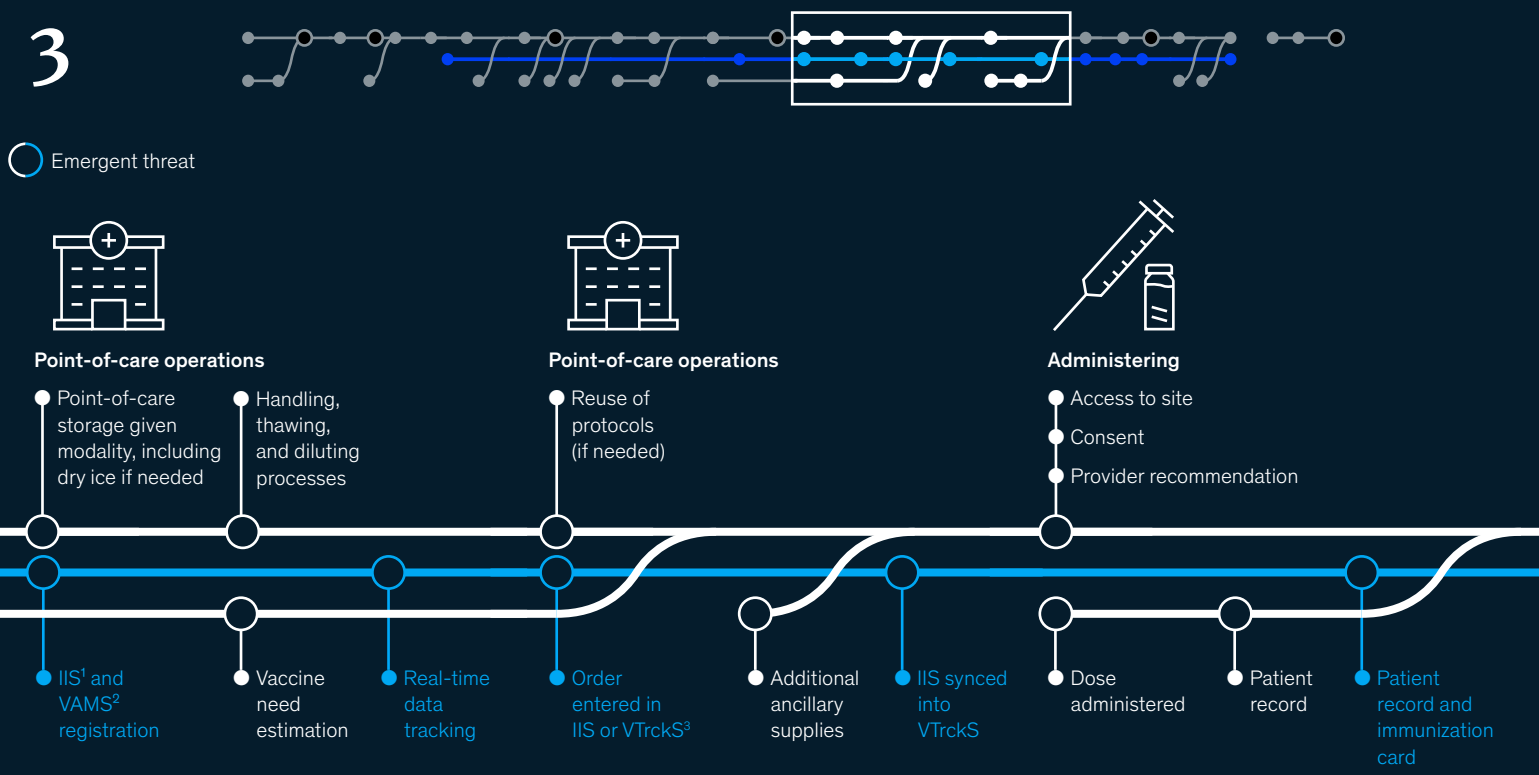
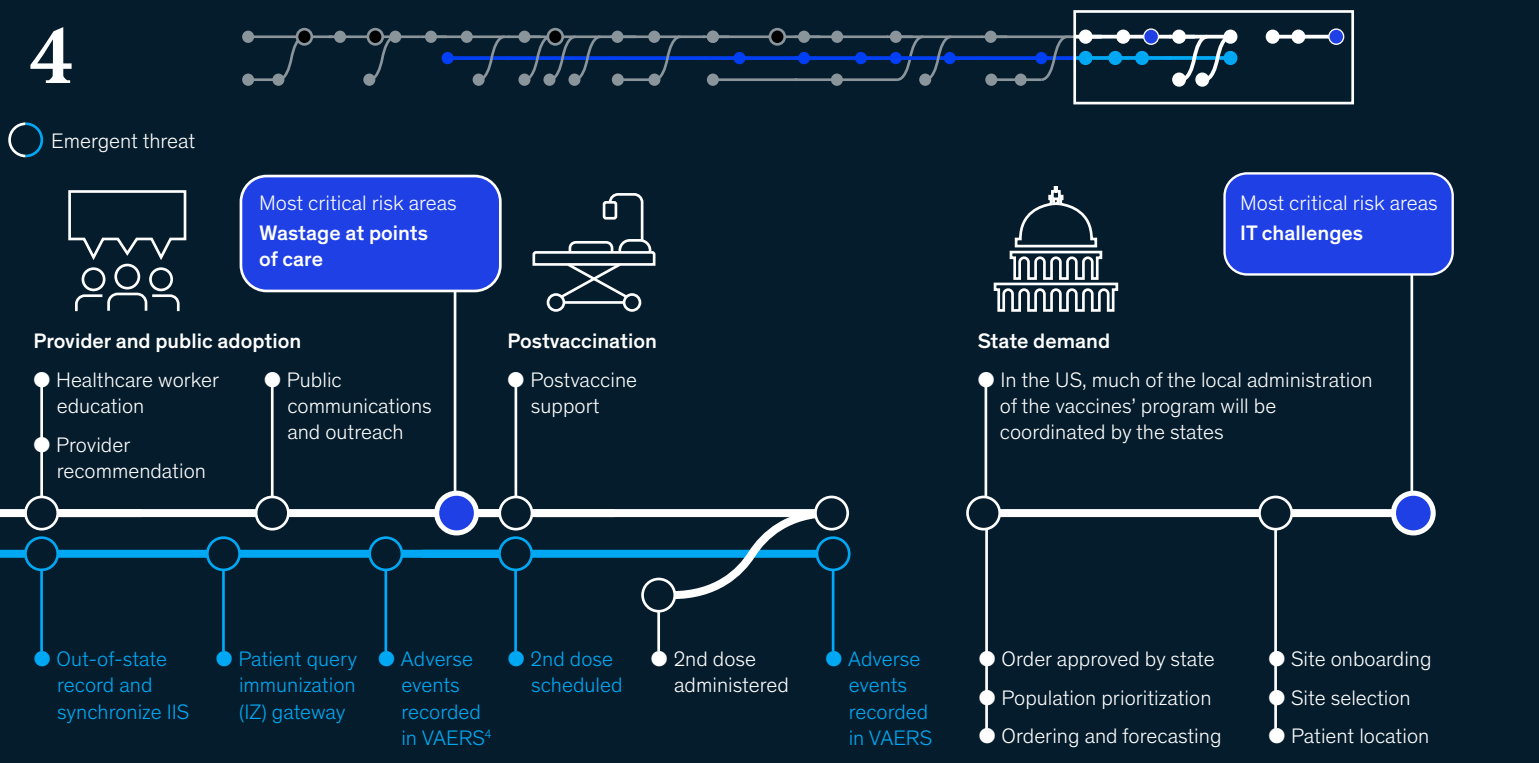




[1]Immunization information systems. [2]Vaccine Administration Management System. [3]Vaccine Tracking System. [4]Vaccine adverse event reporting system.
Source: CDC and US Food and Drug Administration literature; McKinsey analysis

In the United States and other countries with sufficient vaccine quantities and adoption, herd immunity by October 2021 is conceivable, but for that to happen, more than twice as many doses of COVID-19 vaccines will have to be administered each month as were administered during the 2009 H1N1 flu vaccine drive. Cumulatively, between 2.4 and 3.4 times as many doses (mainly because of the double-dose requirement) will be needed as are used for the annual flu vaccinations (Exhibit 2).

Scientists, doctors, other healthcare workers, clinical-trial participants, and regulators have been working intensely to develop, distribute, and administer the vaccines that will help end this pandemic. Their often-heroic efforts give cause for hope. An array of complex challenges are still before us, as production is ramped up and rollouts are planned and executed. A realistic risk assessment of vaccine deployment is needed, because future success cannot be taken for granted. Much needs to be done for the promise of COVID-19 vaccines to become a reality.

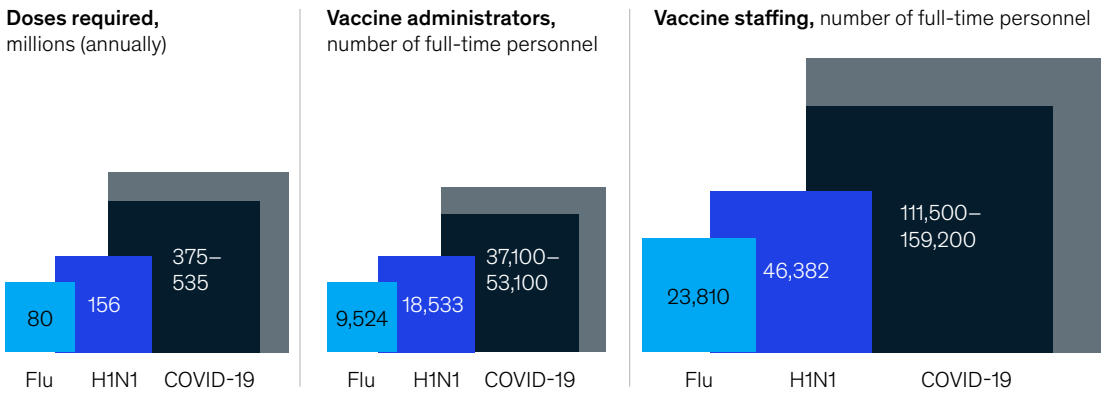
Critical emerging risks

The common operating model provides the details of end-to-end vaccine deployment. From this model, we have highlighted six possible areas of risk to the rapid delivery of COVID-19 vaccines in the United States and elsewhere. In a later section, we outline possible approaches to mitigating each of these risks, with practical steps for organizations that have a role in vaccine deployment.

Exhibit 2

To reach COVID-19 herd immunity, the United States will have to administer 2.4 to 3.4 times as many vaccine doses as it does during annual flu vaccinations.

Comparison of the annual flu and H1N1 flu vaccine drives with the proposed COVID-19 vaccine



Note: Full-time equivalent used in model represents a healthcare worker spending 140 hours per month vaccinating the population.
Source: Centers for Disease Control and Prevention literature; McKinsey analysis

Raw-materials constraints in production scaling

Scaling access to material inputs and boosting production levels can cause logistical, contractual, and even diplomatic challenges, requiring new forms of collaboration. Early indications suggest that there is sufficient global manufacturing capacity for syringes and fill-finish materials. The top two US manufacturers, for example, can produce 280 million vials per year, capable of holding up to 2.8 billion doses.[1] However, the suppliers of many niche chemical and biological vaccine components are scattered, and countries may compete for limited resources. At the same time, because vaccine manufacturers must load mRNA into lipid nanoparticles and purify the resulting therapeutic on a massive scale while following strict regulations, many vaccine manufacturers have sought highly specialized contract-manufacturing partners. Moderna, for example, has collaborated with Catalent and Lonza to produce its COVID-19 vaccine. Such partnerships will likely become increasingly necessary to meet global vaccine demand and will be a major determinant of the campaign's overall success.

Quality-assurance challenges in manufacturing

Generating yields while ensuring the safety and efficacy of each dose poses quality-assurance challenges. To produce a new class of vaccines—such as those based on mRNA or viral vectors—at an unprecedented scale (1.8 billion to 2.3 billion doses by mid-2021), manufacturers have required massive volumes of inputs, a larger technical workforce, and a much-expanded ecosystem of production facilities. At the same time, even while mass-scale production is ongoing, national regulators such as the US Food and Drug Administration continue to develop standards for these new therapeutics. Quality assurance in this context will remain vital.

Cold-chain logistics and storage-management challenges

In North America, manufacturers and distributors are planning to maintain cold-chain requirements for distribution and long-term storage of mRNA-based vaccines. Large amounts of dry ice may be needed at various locations before administration. Although the combined US–Canadian dry-ice manufacturing capacity of 30,000 to 35,000 tons annually will likely meet expected demand, supply chains may have to be strengthened in places to ensure that all areas are well served.[2] This is a particularly acute concern in developing countries with less access to cold storage and dry ice. At points of care, the current high demand for vaccine doses may mitigate initial storage concerns, but projected high-volume distribution later in 2021 could temporarily overtake vaccine consumption, putting greater emphasis on storage management.

Increased labor requirements

Complex protocols for handling and preparing COVID-19 vaccines, as well as the added precautionary observation period after patients are injected, have the potential to strain labor capacities or divert workers from other critical roles. Our estimates suggest that at a relatively streamlined vaccination site, one administrator could vaccinate seven to ten patients per hour with the help of two support staff. This rate is significantly slower and 3.5 times more labor intensive than that of the annual flu vaccination. According to the US Centers for Disease Control and Prevention (CDC), if retail pharmacies alone were tasked with public administration of the COVID-19 vaccine, 15 to 20 percent of their qualified workforce would need to be allocated to this full-time task.

[1] Corning and SiO2 Materials Science have capacity for 164 million and 120 million vials, respectively; each vial can hold five to ten doses, depending on the vaccine, per the US Department of Health & Human Services.

[2] "Compressed gas industry expects sufficient dry ice supply for COVID-19 vaccines in U.S. & Canada," Compressed Gas Association, November 9, 2020, cganet.com.

Wastage at points of care

Errors in storing, preparing, or scheduling administration of doses at points of care will have significant consequences. For example, failure to ensure that recipients attend their appointments will not only prevent individual immunity, it could also lead to product wastage, since all vaccine doses in multidose vials must be administered within a short window of time after the vial has been opened. Proper on-site storage conditions are also of critical importance. In 2014, the CDC's Vaccines for Children program estimated that hundreds of thousands of vaccine doses are thrown out each year as a result of improper refrigeration, at a cost of about $20 million. The current mRNA vaccines will pose a larger challenge for on-site storage because of the temperature requirements.[3]

IT challenges

IT systems, including vaccine-tracking systems (such as CDC's VTrckS) and immunization information systems (IIS), will be essential for allocating, distributing, recording, and monitoring the deployment of vaccines. In the United States, more than 50 uniquely designed IIS (for each state and territory) must interact with VTrckS. Ensuring that these can operate at unprecedented scale and are configured for a two-dose vaccine schedule has become a major software-development, data-hosting, and operational challenge. Additionally, it will remain vital that these systems protect patient privacy and are secure against cyberthreats, given the potential for hackers and criminals to cause damage. Cyberattacks have already occurred against COVID-19-vaccine developers and regulators.[4]

Collaborative approaches to help mitigate emerging risks

There are several possible approaches to help mitigate each of the six risks discussed, each with practical steps for organization to take across the common operating model.

Building resilient raw-materials supplies

— *Resilience planning.* Producers can partner with global suppliers of raw materials and ancillary-product manufacturers to create redundancies, where appropriate, across the supply chain. While manufacturers have established several new partnerships over the past six months, a greater diversity of global suppliers is needed to meet the unique demands of each vaccine seeking regulatory approval. Contracts could be negotiated with incentives for suppliers to invest early in scaling production and stockpiling goods. In addition, producers could reevaluate their own inventory management to reduce the risk of stock-outs of key raw materials.

A greater diversity of global suppliers is needed to meet the unique demands of each vaccine seeking regulatory approval.

[3] According to a survey of 18,000 adults from 15 countries conducted by Ipsos in October 2020, 64 percent of Americans and 73 percent in the overall sample want vaccination.

[4] Christopher Bing and Marisa Taylor, "China-backed hackers 'targeted COVID-19 vaccine firm Moderna,'" Reuters, July 30, 2020, reuters.com; Jack Stubbs, "Hackers steal Pfizer/BioNTech COVID-19 vaccine data in Europe, companies say," Reuters, December 9, 2020, reuters.com.

— *Collaboration between industry and government.* Ongoing industry engagement with government is essential for ramping-up production and maintaining high levels of production. In many instances, manufacturers and suppliers have worked closely with governments to manage national resource allocation. They can continue to collaborate over the economic and public-health implications of halting or outsourcing production of legacy products, as well as optimizing production lines for COVID-19 vaccines. At the same time, industry (including contract manufacturers) can work together with government to create technology-transfer timelines and devise new, creative means of bringing additional volumes to market and improving inventory management and last-mile distribution.

Scaling manufacturing within quality guidelines

— *Scale manufacturing in new and existing facilities.* As producers accelerate operations in new or existing manufacturing facilities, they could seek opportunities to ramp up capacity as quickly as possible. Various digital and analytics tools can help expand capacity and scale more quickly. Companies can also accelerate technology-transfer timelines, similar to what has been done in the last year. As an example, by conducting engineering runs, validation runs, and stability studies simultaneously, companies could both expand and speed up production.

— *Assure quality and yield in current facilities.* By continuing to coordinate with regulators, manufacturers and authorities can ensure that procedures and dosage quality meet both long-established and newly issued guidelines. Through close coordination and understanding, higher throughput can be attained, given the higher likelihood of meeting these quality standards. Likewise, stakeholders can collaborate to establish new standards for the production of vaccines that employ novel technology platforms (such as mRNA). Establishing best practices at the facilities furthest along in production can help to create a clear road map for new manufacturing facilities. This can enhance the speed of future production capacity and throughput while meeting necessary quality standards.

— *Establish predictable supplier plans.* Each manufacturing stakeholder can follow a clearly defined plan, with open communication to a manufacturing "control tower," where expert teams direct and prioritize efforts across functions. They can also conduct regular cross-functional risk reviews to ensure that quality is not compromised and involve regulators at systematic intervals to assess progress.

Optimizing the cold chain

— *Build redundancy into distribution.* Manufacturers, distributers, and local allocation teams can mitigate distribution risks by quickly identifying points of failure and creating redundancies at each stage. For example, in warehouses fitted with ultracold freezers, dry ice could be made available in case of power loss or machine malfunctions. Across distribution routes, sources of dry ice could be identified to restock coolers as necessary.

— *Leverage feedback loops.* Reporting systems could be set up to capture supply-chain disruption events as soon as they happen, with data used to refine best practices and procedures and avoid further losses.

— *Use point-of-care stock management.* If vaccine demand drops to levels where point-of-care stocks are not immediately consumed, vaccine inventories can be redistributed to locations with greater demand. Strategies to avoid overstockpiling must ensure maintenance of the cold chain to prevent risks to the receiving administration site. Where this is not possible, long-term storage by replenishing dry ice or prioritizing freezer capacity will be necessary.

Addressing labor shortages

— *Use several types of point-of-care facilities.* Many locations have begun to rely on hospitals and primary-care locations for vaccine administration, in addition to retail pharmacies. This will become increasingly necessary when the vaccines are deployed to the general public, to prevent shortages of vaccine administrators. If hospitals and primary-care locations are used to supplement vaccine administration at retail pharmacies, only 2 to 3 percent of the healthcare workforce may need to be diverted from their primary functions.[5]

— *Streamline administration across sites.* Deploying vaccines at larger, streamlined vaccination sites can be more efficient and improve patient safety, labor utilization, and speed of vaccination.

Reducing spoilage at points of care

— *Track and monitor spoilage at points of care.* Manufacturers and distributors can collaborate to establish the means to identify and trace instances of spoilage. They can learn from experience and refine guidance, training, certification, and allocation to optimize utilization of doses.

— *Pace first-dose allocation.* Especially with initial inventories, many authorities are directing allocations of first doses to populations and locations where the need is greatest and the confidence in the availability of second doses is high (such as healthcare professionals and vulnerable populations in nursing homes). As vaccines are made available to broader populations in greater numbers, pacing of first-dose allocation according to distribution schedules and available volumes will remain paramount.

— *Prioritize second doses.* Authorities can help ensure that the recommended two-dose course schedule for such vaccines as the Pfizer-BioNTech, Moderna, and AstraZeneca vaccines are duly completed. Many medical experts are warning that distribution should not be artificially expanded by diverting second-dose allotments to patients awaiting their first dose.

— *Establish recipient commitment.* Vaccine recipients could be asked to commit to second-dose appointments at their point of care before first-dose administration, improving the likelihood that second doses will not spoil.

— *Manage certification.* National and local government institutions can collaborate to ensure that vaccination certifications are withheld until recipients receive their second dose, further increasing the number of citizens who are fully vaccinated.

Meeting IT challenges

— *Balance IT upgrades and resilience.* Stakeholders should identify IT systems that can be relied upon in the deployment of COVID-19 vaccines and assess their ability to perform at scale. They can consider using a risk-based approach to balance the need to upgrade systems with associated risks. Transforming infrastructure and systems during a time of critical need can be highly disruptive even if beneficial in the long run (for example, moving systems to the cloud can cause some downtime in the short term but better reliability in the long term).

[5] Centers for Disease Control and Prevention; McKinsey analysis.

— *Share cyberthreat intelligence.* COVID-19-vaccine stakeholders should agree upon common requirements and processes for generating and sharing threat intelligence. Awareness of attacks on COVID-19-vaccine deployment will increase resilience to attacks and reduce the likelihood of attacks spreading in number and magnitude.

— *Establish means of demonstrating immunity.* Manufacturers and distributers can commission systems to track and verify that vaccine recipients have demonstrated immunity. This would build popular confidence in immunity by fostering a single national view of the current level of population immunity.[6] People will likely be very interested in having a recognizable and accepted means of proving that they have been vaccinated, especially if it will release them from travel limits and other pandemic-related restrictions.

Managing risks at the interface among organizations

Although none of the many organizations involved is solely responsible for managing vaccine deployment across the common operating model, the risks can be more fully addressed with increased stakeholder cooperation. To build this collaboration, working groups could meet to identify the various risks, assess their likelihood and potential impact, and determine whether certain risks are evolving and how urgently they should be addressed.

The groups could align on lead organizations to manage issues while building scenarios to test responses to emerging crises. The benefits in managing each of these risks could be demonstrated with compelling metrics and communications. At this point, clear roles, activities, and capabilities for risk management could be established, building accountability within and across relevant organizations. Most importantly, these steps can be undertaken by manufacturers, distributers, and governments, as COVID-19-vaccine rollouts commence, to facilitate widespread adoption and minimize the challenges associated with the vaccines' massive global deployment. By doing so, they will help ensure a more effective and efficient rollout of COVID-19 vaccines, paving the way for the epidemiological end to the devastating effects of the COVID-19 pandemic.

[6] For example, a national view of current immunity could include the number of positive antibody tests within a recent time period, positive antigen tests within a recent time period, or vaccines administered but immunity not confirmed.

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