# COVID-19 Mass Vaccination Campaigns: A Global Guide

*Prepared by Members of The Open Group Healthcare Forum and Jason S. Lee PhD, Healthcare Forum Director*


**THE OPEN GROUP GUIDE**

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Comments relating to the material contained in this document may be submitted to:

The Open Group, Apex Plaza, Forbury Road, Reading, Berkshire, RG1 1AX, United Kingdom

or by electronic mail to:

j.lee@opengroup.org

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# Preface

### The Open Group

The Open Group is a global consortium that enables the achievement of business objectives through technology standards. Our diverse membership of more than 800 organizations includes customers, systems and solutions suppliers, tools vendors, integrators, academics, and consultants across multiple industries.

The mission of The Open Group is to drive the creation of Boundaryless Information Flow™ achieved by:

- Working with customers to capture, understand, and address current and emerging requirements, establish policies, and share best practices
- Working with suppliers, consortia, and standards bodies to develop consensus and facilitate interoperability, to evolve and integrate specifications and open source technologies
- Offering a comprehensive set of services to enhance the operational efficiency of consortia
- Developing and operating the industry's premier certification service and encouraging procurement of certified products

Further information on The Open Group is available at www.opengroup.org.

The Open Group publishes a wide range of technical documentation, most of which is focused on development of Standards and Guides, but which also includes white papers, technical studies, certification and testing documentation, and business titles. Full details and a catalog are available at www.opengroup.org/library.

### The Open Group Healthcare Forum

The Healthcare Forum, a Forum of The Open Group, is a global community in which participants share a professional interest in the architecture of healthcare enterprises. Members work for large, international organizations as well as smaller companies. They live in countries with healthcare systems as diverse as those in India, Scandinavia, the Philippines, Germany, Australia, the US, the UK, Canada, and elsewhere. The global span of Forum membership brings value to its work.

The Forum has published several papers which are available free-of-charge from The Open Group Library. In 2019, it became the worldwide steward of the Federated Health Information Model (FHIM). The FHIM is a complex but elegantly designed framework (including information and terminology modeling) to help enable widespread health information exchange. It is applicable at all levels: local, regional, and global.

The FHIM was developed by the US Government and its contractors, within the now defunct Federal Health Architecture (FHA) Program. The FHIM was supported by over 20 Federal

Agencies and was organizationally located within the Office of the National Coordinator for Health Information Technology (ONC). By the time The Open Group became the new FHIM Steward, over $5 million and 200,000 person hours had been spent building and using the FHIM, primarily within the US Department of Veterans Affairs (VA) and Department of Defense (DoD).

The FHIM is an integrated model composed of health and healthcare-related content explicitly aligned with industry information models and standards. The FHIM addresses two persistent gaps:

- The "too many standards" problem in healthcare
- Data inconsistencies within and between standards

The FHIM supports the exchange of meaningful, interoperable information, quickly, accurately, and consistently, for the betterment of patient care.

The FHIM Profile Builder™ tool (also known as the FPB™ tool) is an open source tool managed by The Open Group that responds to the need to produce standards-based API profiles that can be easily reused to promote widespread interoperability. The FPB tool can automate profile building, rendering the use of APIs, such as Fast Healthcare Interoperability Resources (FHIR), functional without special effort, as required by legislation (in the US) and the exigencies of typical clinical practice settings.

In other work, the Healthcare Forum has developed a comprehensive, 12-step framework, or Healthcare Enterprise Reference Architecture (the O-HERA™ framework), designed to help users identify and deliver solutions to a wide range of business problems that healthcare enterprises experience or wish to guard against.[1]

The O-HERA framework is rooted in deep knowledge of:

- Health services provider and supplier industries, including the political, technical, and socio-cultural contexts in which they operate
- The barriers and benefits to using Healthcare Information Technology (HIT) to solve business problems
- Best practices and lessons learned from using Enterprise Architecture methods to create efficiencies in industries as diverse as communications, financial services, and defense

In its current work, the Healthcare Forum is using the O-HERA framework to guide its development of a specific implementation: a globally-relevant Hospital Reference Architecture. This work is undertaken in collaboration with Dutch Colleagues at NICTIZ, which has been developing the ZiRA hospital architecture, for and with hospitals and medical centers in The Netherlands, for about 10 years.

For more information on the Healthcare Forum, see www.opengroup.org/healthcare.

[1] For more information about the O-HERA framework, see www.opengroup.org/library/s182.

## This Document

This document is The Open Group Global Guide to COVID-19 Mass Vaccination Campaigns. It is consistent with the first mission statement of The Open Group: "[w]orking with customers to capture, understand, and address current and emerging requirements, establish policies, and share best practices". It was developed and is maintained by The Open Group Healthcare Forum, under the direction of Jason S. Lee, PhD.

## Abstract

Countries around the world are beginning, or planning to begin, to implement their mass vaccination campaigns to gain control of the COVID-19 pandemic that has torn across the globe for the past year.

## Vaccine History

In 1796, Edward Jenner invented the first vaccine administered through injection, thus establishing the basis for protection against smallpox, the most dreadful scourge in the history of humankind. When it was finally eradicated worldwide in 1979, smallpox had killed 300-500 million people in the 20th century alone.[2] Since Jenner, many vaccines have been discovered and used to protect against infectious diseases in children and adults. And although millions continue to die and suffer from vaccine-preventable infectious diseases worldwide, it is recognized that the public health benefit of vaccination is second only to the availability of clean water and sanitation.[3]

Over the years, much has been learned about designing mass vaccination plans and implementing mass vaccination campaigns throughout the world. In the 21st century, we know so much more about how to protect large populations from infectious diseases. Still, never has the world confronted a public health effort equal in scale or scope to the one it now faces in response to the COVID-19 pandemic.

[2] Mummified evidence of smallpox has been traced to 3,000 years ago. See https://en.wikipedia.org/wiki/Vaccination, accessed December 23, 2020.
[3] It should be noted that vaccine hesitancy – also known as anti-vax – has existed throughout the history of vaccine availability.

# Trademarks

# Acknowledgements

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# 1 Introduction

## 1.1 Objective

The objective of this document is to provide a practical, fact-based synthesis of best practices associated with successful mass vaccination campaigns for the purpose of controlling the COVID-19 pandemic. It identifies and describes the main architectural themes and key requirements – the strategies and capabilities – that are common to successful mass vaccination campaigns.

## 1.2 Overview

This document discusses the pillars of successful vaccination campaigns globally. It is not tailored to a single country or region, but rather is designed to be broadly useful. The information provided here is grounded in scientific evidence and best practices.

Although the scope of this document is global, it focuses on national, regional, and local applications. Its approach is to balance the need for enough information without providing details that are relevant to one or a few countries, but not to many others. A country-specific campaign must build out its own detailed requirements – based on the strategies and capabilities discussed here – that will help to ensure its successful implementation. Mass vaccination campaigns must evolve with changing circumstances, but the major themes discussed in this document serve as stable guideposts for architecting mass vaccination campaign responses.

This document will be updated as necessary. The most recent version is available in The Open Group Library at www.opengroup/library.

### 1.2.1 Intended Audience

This document is intended for national, regional, and local authorities who are responsible for managing the organization, operation, and monitoring of COVID-19 mass vaccination campaigns. It is also written for campaign partners whose work must be coordinated and collaborative to ensure success in controlling the pandemic.

### 1.2.2 Intended Use

The intended use of this document is to provide the reader with a reference model for how to plan, conduct, monitor, and manage a mass vaccination campaign. It can be used as a standalone guide or as additional guidance with existing plans.

### 1.2.3 Background

In the final month of 2019 a new coronavirus, designated as Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2), was detected in Wuhan, China, a city of 11 million. On January

11, 2020, its genetic sequence was published.[4] At the end of January, the World Health Organization (WHO) declared COVID-19 "a public health emergency of international concern". Just five weeks later, on March 11, 2020, WHO declared the COVID-19 infectious disease outbreak a global pandemic.[5]

Surging infection rates observed worldwide in early 2020 triggered urgent vaccine development efforts that involved 80 companies and institutes in 19 countries by April. Countries responded with lockdowns and widely varied adoption of behavioral efforts to contain the spread of the disease. Though important, these responses had limited success, leading to roller coaster episodes of surges, diminished surges, and resurgent record-breaking incidents of disease and death. Economies have been dealt crushing blows and people and livelihoods have suffered greatly. By the end of 2020, worldwide reported cases numbered 83.8 million and 1.8 million people had perished as a direct result of the virus.[6] By the end of the first month of 2021, cases swelled to over 100 million and deaths to over 2 million.[7]

The end of 2020 also brought hope. The first COVID-19 vaccine tested in a large clinical trial was developed and approved in record-breaking time for emergency use in the UK on December 2, 2020. Within two weeks, the US authorized two vaccines for emergency use.[8] Soon thereafter, other countries approved vaccines for emergency use.[9]

Soon after the first vaccines were approved, both pre-negotiated contracts between countries and manufacturers as well as manufacturers' pre-production of vaccine supply and packaging made it possible to start worldwide distribution of COVID-19 vaccine before the end of 2020, largely to rich nations.[10]

Yet, just weeks after vaccine distribution rollouts began, countries experienced difficulties and challenges. Many times, goals were not met. Expectations were diminished. Public attitudes and trust suffered.[11] Indeed, at the rate of early vaccination efforts, projections of herd immunity extended into years, and grave concerns were raised about the continued devastation of human lives and countries' economies.

In the early stages of rollout, problems getting vaccine into arms related less to vaccine supply than to underfunded, insufficiently coordinated, and logistically complex rollout of mass vaccination campaigns.[12]

[4] Refer to: SARS-CoV-2: An Emerging Coronavirus that Causes a Global Threat (see Reference Documents); accessed January 13, 2021.
[5] Refer to: WHO Declares COVID-19 a Pandemic (see Reference Documents); accessed January 13, 2021.
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[9] AstraZeneca's COVID-19 vaccine was approved for emergency supply in the UK and the first doses were released on December 30, 2020. Refer to: AstraZeneca's COVID-19 Vaccine Authorized for Emergency Supply in the UK (see Reference Documents); accessed January 28, 2021.
[10] Acquisition and distribution of vaccine for low and middle-income countries is orchestrated by the COVAX Facility, a joint international effort funded by dozens of countries (including high-income countries) and philanthropic organizations, intended to ensure the just and equitable distribution of vaccine throughout the world.
[11] Exceptions were observed in small countries with protected borders.
[12] This is not to say that vaccine supply is not and will not continue to be a major gating factor, however.

# 2 Strategy Planning

Successful COVID-19 mass vaccination campaigns require comprehensive *strategy planning* focused on the following key factors: identifying jurisdictions, which have the power to exercise authority; collaboration among public and private partners; definitions of critical populations and decisions about their vaccination priority; selection of vaccination sites, which must be safe, accessible, and capable of meeting demand; a phased approach determined by vaccine supply and population needs; vaccination communications, to instil vaccine trust and counter vaccination hesitancy; and vaccination monitoring and management.[13]

## 2.1 Jurisdiction

A country's lead authority with ultimate responsibility for developing and implementing a mass vaccination campaign is its national government. A national government, in turn, designates other entities – typically starting with the Ministry of Health or equivalent organization – and gives them jurisdiction or authority to plan and orchestrate collaboration among public and private sector partners to ensure successful implementation of a mass vaccination campaign.

Throughout this document, we refer to entities that exercise authority in the development and execution of mass vaccination campaigns as *jurisdictions*, regardless of the level of their authority (national, regional, local, etc.).

### 2.1.1 Rules, Roles, and Responsibilities

Jurisdictions establish *rules* that set key parameters for mass vaccination campaigns. How will vaccination campaigns be funded? What allocation directives will be decided? What vaccine priority groups will be established? Will vaccination be provided on an opt-in, opt-out, or mandatory basis? Who will pay for vaccines and vaccination? What scope of practice, licensure, and certification requirements should determine who can provide vaccines? How will vaccination settings be selected? What rules will be established to ensure safety at vaccine sites? What requirements will ensure the ability to respond to adverse drug reactions? How will liability issues be decided? What data must be collected, using what platform(s), and by whom? What personal privacy rules will apply?

Public and private partners must adopt clearly defined *roles* and associated *responsibilities* that link them together in end-to-end supply chains. Mass vaccination campaign logistics require constant monitoring and agile modification to meet schedule demands and ensure coordination among partners. Consider, for example, the distribution of vaccines (a focus of Chapter 3). Direct transportation from manufacturer to provider may be possible in some situations, but more often jurisdictions will need to utilize centralized distribution hubs with transportation partners who can safely and dependably transport vaccines to vaccination settings. Other roles and responsibilities – related to distribution, vaccine provision, data monitoring, and research

[13] Early in 2020, countries began developing COVID-19 mass vaccination campaigns based on knowledge and experience gained from decades of prior vaccination campaigns. It is widely recognized that controlling the COVID-19 pandemic will require a global response at a significantly larger scale than any previous response to outbreaks of infectious diseases, including MERS, SARS, Swine flu, and Ebola.

competencies – must be assigned and adopted by competent public and private partners who should reasonably be held accountable for ensuring these capabilities are met as part of successful vaccination campaigns.

## 2.2 Collaboration

Effective collaboration among diverse mass vaccination campaign partners is of paramount importance for success in gaining control over COVID-19. The highest level of political and administrative ownership, commitment, and support needs to be sustained for successful rollout and implementation.

According to the World Economic Forum (WEF): "the sum of many individual actions will not add up to a sufficient response. Only coordinated action … at exceptional scale and speed … can potentially mitigate the risk and impact of this unprecedented crisis.[14]

Collaborating partners should include members with expertise in infectious disease, immunization preparedness planning, legal affairs, media/public affairs, crisis and emergency risk communication, and many other capabilities. Table 1 is a partial list of collaborator types.

**Table 1: Types of Collaborators**

| | | |
|---|---|---|
| Emergency management agencies | International health organizations | Non-governmental organizations |
| Healthcare coalitions | Immunization coalitions | Local health departments |
| Health systems and hospitals | General medical practices | Community health centers |
| Rural health clinics | Pharmacies | Correctional facilities (jails) |
| Large employers | Health insurance issuers and plans | Education agencies and providers |
| Long-term care facilities (including nursing homes/skilled nursing facilities, assisted living facilities, intermediate care facilities for individuals with intellectual and developmental disabilities, and independent/retirement communities | Religious leaders and institutions | Social influencers (especially for vulnerable subgroups whose members don't trust vaccine safety) |
| Community representatives | Entities involved in COVID-19 testing centers | |

[14] Refer to: COVID Action Platform (see Referenced Documents); accessed December 22, 2020.

## 2.3 Critical Populations

Jurisdictions must identify the risk profiles and estimated size of critical populations to be among the first to receive vaccination. High-risk critical populations include:

- Critical infrastructure workforce at high risk of contracting the disease; notably, healthcare workers who have direct contact with COVID-19 patients
- Elderly persons at high risk for severe COVID-19 illness (e.g., residents of nursing homes and long-term care facilities)
- Non-elderly persons with underlying medical conditions that put them at high risk
- People at increased risk of getting or transmitting the disease due to crowded housing conditions – including members of minority groups, incarcerated persons, homeless people – and people who work in dense educational or occupational settings
- People with limited access to healthcare services due to geographic isolation, disability, or lack of health insurance

## 2.4 Vaccination Sites

The determination of approved sites for mass vaccination campaigns is dependent on the existing infrastructure of a country, region, or locale. Every inoculation should occur at an approved site, based on jurisdictions' established standards of safety and efficiency. Vaccination sites should provide an accessible, dependable, and simplified scheduling system. They should allow for the maximum number of people to be vaccinated while maintaining social distancing and other infection control procedures. They must have appropriate equipment to manage serious adverse events that may occur.

Common vaccination settings include, but are not limited to:

- Hospitals and health systems
- General practitioner, primary care, and similar accessible ambulatory care settings
- Commercial partners, such a pharmacy chains
- Mass vaccination settings, such as sports stadiums, convention centers, and large public arenas
- Mobile vaccination clinics
- Large employers
- Nursing homes and long-term care facilities
- Community health centers

To optimize program efficiency, jurisdictions should estimate vaccine administrative capacity, defined as the maximum achievable vaccination services that can be delivered regardless of demand. They must plan to step up operations to keep pace with greater supply and demand as vaccine availability increases and an ever larger percentage of a country's population is eligible for vaccination.

## 2.5 Vaccination Providers

Mass vaccination campaigns must enroll a workforce of trained and competent vaccination providers to work in accessible vaccination settings. Preparation of training materials and establishing credentialing and licensing requirements are key to the vaccination provider recruitment process. Core educational and training materials are provided by designated jurisdictional entities and each manufacturer provides such materials for its approved vaccine. This training information must be updated as needed.

Provider enrollment is performed at the appropriate jurisdictional level. Jurisdictions may identify detailed conditions specified in provider agreements that must be followed to meet enrollment requirements. Depending on the country and context, a jurisdiction that determines conditions for provider enrollment may take legal action if a provider is not in full compliance with requirements.

Jurisdictions that enroll providers should establish and track compliance with enrollment requirements, verify provider credentials, and onboard providers to the program's monitoring system (see Chapter 4).

## 2.6 Phased Approach

Planning for vaccine distribution is challenging amid rapidly changing conditions. For example, countries do not grant legal authorization for vaccine use at the same time. Moreover, the type(s) and amount of vaccine supply varies from country to country and time to time. Planning must be flexible but also specific. COVID-19 vaccine supply is limited at the start of most campaigns; thus, doses are allocated in phases and to the highest priority populations first. Vaccine supply generally increases quickly following initial rollout, which will enable expansion to additional critical populations and ultimately to the general population.

Recommendations for who will gain access to vaccination, and when, could change after vaccines become available, depending on multiple factors, including the speed of vaccination rollout, vaccine supply, vaccine characteristics (number of doses required), disease epidemiology, and local community factors. Complicated gating factors that slow down the rate of vaccination may be replaced by less complicated rules; for example, rather than vaccinating only elderly persons with high-risk profiles in the earliest phase, jurisdictions may choose to vaccinate all people over 65, without distinction.

Vaccine characteristics (safety, efficacy, storage temperature, supply, dosing requirements, and more) must be considered as decisions are made about which priority groups are offered vaccination initially. Vaccination campaign rollout is typically considered in three phases.

### 2.6.1 Phase 1: Limited Supply

In the initial phase, jurisdictions concentrate efforts on reaching priority populations. They communicate strategies that maximize vaccination coverage, meet cold chain requirements, and satisfy monitoring requirements for tracking vaccine supply, uptake, outcomes, and pharmacovigilance surveillance.

Uncertainty about the type of vaccine products available, number of doses allocated, storage and handling requirements, and administration can be especially keen during Phase 1 and can play an important role throughout implementation of a mass vaccination campaign. Planning must be as

specific as possible, but also agile. Planners should anticipate and be prepared for likely deviations.

### 2.6.2 Phase 2: Increased Supply

During this phase, jurisdictions expand access to vaccination for lower priority populations and plan for the expected surge in vaccine supply to cover the general population in Phase 3. This requires a great deal of operational development and maturity. Jurisdictions need to build out infrastructure and workforce requirements; supplies; engagement, collaboration, and coordination of partners; monitoring capabilities; and appropriate messaging to encourage and administer vaccination of the general population.

### 2.6.3 Phase 3: Sufficient Supply

Jurisdictions make vaccination widely available to the general population in Phase 3. They monitor and analyze all key program functions and outcomes and ensure continuous improvement and equitable access to vaccination. A key activity required in all phases – but particularly critical in this phase – is to implement targeted communication strategies to increase uptake among vaccine-hesitant members of priority populations as well as those in the general population.

## 2.7 Vaccination Communications

Successful COVID-19 mass vaccination campaigns include vaccination communications[15] planning and execution that ensures coordinated and consistent messaging from trusted sources. Messaging must be cast at appropriate literacy levels to reach targeted communities, especially those in which people are most reluctant to get vaccinated. Planners need to understand the reasons for vaccine hesitancy and lack of vaccine confidence and address underlying issues directly and with empathy. Vaccine communications should also address the broader pandemic context by emphasizing the need to maintain preventive behaviors post-vaccination, until COVID-19 is under control.

### 2.7.1 Coordinated and Consistent Top-Line Messaging

Evidence from the behavioral and social sciences supports a number of goals and practices that should guide vaccination communication planning. There is no one-size-fits-all approach, but there are top-line goals common to effective and successful communication efforts. Messages should be accurate, transparent, and truthful. Vaccination benefits and risks should be neither exaggerated nor minimized. Clear explanation of the individual and collective benefits of vaccination should be part of top-line communication programs.

While not strictly a communication issue, conveying choice architecture by asking people to opt out rather than opt into vaccination (thereby preserving personal autonomy), where possible, can make a huge difference in the percentage of a population vaccinated.

It is important to build agility and rapid message modification into communication efforts in response to evolving environments of vaccination campaigns, emerging pandemic and vaccine information, and shifts in public sentiment.

[15] Refer to: COVID-19 Vaccination Communication (see Referenced Documents); accessed January 13, 2021.

### 2.7.2 Trusted Sources

Key to building support for mass vaccination campaigns is the involvement of national, regional, and local community advocates in communication outreach. Partners involved in communication planning should strive to engage such local advocates as trusted healthcare providers, religious leaders, beloved civic personalities, and social influencers to spread the word to invoke confidence and trust. The importance of building advocacy is to mitigate vaccine hesitancy.

### 2.7.3 Address Vaccine Hesitancy

It is incumbent on communication planners to develop a deep understanding of the underlying reasons for vaccine hesitancy. They should strive to get feedback from those who are reluctant to get vaccinated, and they should respond appropriately. Only when concerns, motivations, values, and information needs associated with vaccine hesitancy are understood, is it possible to develop effective messaging. If the issue is misinformation, top-line counter messages should be developed. Messaging should be tailored to a community's values and priorities. Communication planners may find that personal narratives and short videos are an effective means to counter vaccine hesitancy.

Whatever the underlying cause of vaccine hesitancy, it is important to remember that effective communication goes beyond providing accurate content. Messaging should elicit positive emotions. It should avoid over-activating fear and overly directive framing. The use of empathy helps avoids alienation. See Table 2 for examples of targeted and well-tailored vaccination messages.

Note: Some examples reflect the authors' national "embeddedness", such as "avoid language of requirement and mandate". This might be legal in some countries.

**Table 2: Targeted and Tailored Vaccination Messages**[16]

| |
|---|
| Partner with a wide range of trusted information sources: co-design and co-dissmeninate messages with community partners. |
| Establish COVID-19 vaccination as an accepted social norm (e.g., through "I got the shot" stickers or sharing vaccine intention through social media). |
| Consider behavioral nudges for vaccination (e.g., favoring opt-out *versus* opt-in, making receiving vaccination convenient) while respecting decision autonomy. |
| Avoid language of requirement and mandate. |
| Convey a message of unity and bipartisanship in vaccination and avoid language that sows divisions or conveys judgment. |
| Ensure that all messages are accurate, transparent, and truthful; avoid exaggerating the benefits or minimizing the risks of vaccination; be clear that the vaccine is not an instant fix or a "silver bullet". |
| Incorporate the values and beliefs of the target audience, such as protecting the community or caring for those at higher risk. |

[16] Source: COVID-19 Vaccination Communication, National Institutes of Health; see Referenced Documents.

| |
|---|
| Induce positive emotions and avoid communication (including non-verbal) that heightens negative emotions, such as fear or shame. |
| Use simple graphics, images, personal experience narratives, “edutainment”, or short videos to creatively distill vaccine information. |

# 3 Capability Planning

Mass vaccination planning is not "once and done". Jurisdictions must remain vigilant; continuously modifying, refining, and improving their campaigns. Agility is key. Local, regional, national, and global rollout experiences should inform jurisdictions' continuous improvement programs. Success in gaining control over the COVID-19 pandemic depends on key factors already discussed in this document: engagement among leaders at all levels of jurisdiction, effective coordination among campaign partners, commitment to fully funding campaigns, and other strategy planning elements discussed in Chapter 2.

In this chapter we focus on the capabilities required to move from the world "as it is" – caught in the devastating jaws of a once-in-a-century public health crisis – to the world "as it will be" – freed from the ravages of surging COVID-19 infections and deaths.

In the development and deployment of capabilities, a key ingredient for success is the ability to expand functions, operations, processes, and activities based on the workforce and other infrastructure resources that already exist (or can rapidly be built) where people live.

Jurisdictions should work with partners to help ensure that allocation, ordering, and distribution capabilities operate as planned. When barriers arise, which is inevitable, predetermined solutions should be rapidly deployed to avoid unnecessary bottlenecks and slowdowns. Preventable delays in vaccination rollout should be avoided because they can have a deleterious effect on the public's health, expectations, attitudes (especially vaccine hesitancy), and behavior.

## 3.1 Allocation

Allocating vaccines may seem straightforward. Who should receive the vaccine and when? How many doses will be sent and where? However, vaccine allocation is a complex process that requires constant assessment of supply and demand across multiple jurisdictions and settings. Capacity and capability standards must be met in order to allocate and administer available vaccine.

The sheer magnitude of the job of allocating vaccine to the world's population is daunting. To the extent possible, jurisdictions throughout the world will directly allocate vaccine to existing settings with significant vaccine administrative capacity and certified capability. Service contracts should be established with settings approved to administer vaccine.

Vaccine will also be allocated to large mobile mass vaccination centers that can ferry thousands of people through each day. Germany, to take just one example, recently converted an empty trade fair hall, two airport terminals, a concert arena, a velodrome, and an ice rink into mass vaccination centers. In addition to ensuring sufficient staffing and security protections, "the biggest challenge will be succeeding in getting the right people at the right time at the right vaccination center".[17]

[17] Refer to: Berlin Plans Six Vast COVID-19 Vaccination Centers Handling 4,000 People a Day (see Referenced Documents); accessed January 11, 2021.

As discussed in Chapter 2, jurisdictions typically determine vaccination priority based on expert evaluations of health risk. But the complex logistics of getting vaccine into the arms of priority group members, and only those members before vaccinating lower priority groups, can result in unintended bottlenecks and even an undermining of public confidence if significantly more vaccines are distributed than administered.

Consider the situation in which frontline healthcare workers are placed in the highest priority group, vaccine is allocated and distributed to hospitals, frontline workers are vaccinated, and large stores of vaccine remain available. In such cases, specific plans are needed for redistributing "surplus" doses so others can receive them before they expire and are wasted.

In this scenario, which is not uncommon, what allocation rules govern redistribution? Allocation decision-makers must judge when to require redistribution from population subgroups that may not receive vaccination in time to lower-priority but more easily reached population subgroups. These are not easy decisions. However, avoidable vaccine wastage in the face of surging COVID-19 cases and deaths is unconscionable. Such situations may lead to public mistrust of mass vaccination campaigns that let vaccine go to waste in the face of great demand for it.

## 3.2 Ordering

High-income countries that have negotiated contracts with manufacturers for pre-ordered vaccine typically request doses from a centralized distributor via an ordering portal. Jurisdictions that establish or already use a monitoring system may integrate with such an ordering portal.

Medium and low-income countries typically order COVID-19 vaccine from the COVAX Facility,[18] a global risk-sharing mechanism for pooled procurement and equitable distribution of COVID-19 vaccines coordinated by Gavi: The Vaccine Alliance; the WHO; and the Coalition for Epidemic Preparedness Innovations (CEPI). COVAX has created the world's largest and most diverse portfolio of vaccines to maximize chances of successfully developing multiple types of COVID-19 vaccines and to manufacture them in the quantities needed to end the pandemic worldwide. COVAX secures vaccine by consolidating demand, uses its purchasing power to negotiate price, and streamlines distribution throughout the world.

By the end of 2020, 190 countries (about half of which are high-income countries and half of which are middle to low-income countries) were participating in COVAX. High-income countries that have no bilateral deals with manufacturers can order vaccine through the COVAX Facility by participating via self-financing arrangements. Middle to low-income countries can order vaccine through the COVAX portal regardless of ability to pay. Rollout starts in early 2021. Gavi estimates that 2 billion doses will have been secured by the COVAX Facility by the end of the year.[19]

## 3.3 Distribution

We know from past endemic/pandemic responses that the tendency has been to under-appreciate the significance of the vaccine distribution process. We assume that "once vaccines are approved and paid for, vaccine delivery is the easy part, and they can somehow magically appear in

[18] For more information, see https://www.gavi.org/covax-facility; accessed January 3, 2021.
[19] A number of high-income countries contribute financial support to COVAX, which provides the only global solution to the pandemic because it ensures that people from all corners of the world can get vaccine.

people's arms".[20] Policy, funding, and planning authorities tend to give too little attention to breaks in the supply chain, which are inevitable. As a result, they neglect to anticipate risks and do not organize rapid solutions that can minimize delays. Inadequacies observed during past campaigns – related to transportation, storage and handling, and track and trace capabilities, for example – require close attention in the preparation and rollout of mass vaccination campaigns to control COVID-19. Appendix A reproduces a six-graph representation of the risks and challenges of the global COVID-19 vaccine rollout across the entire supply chain. It provides a valuable view into the complexity of the supply chain as well as the highest risk areas for rupture.

### 3.3.1 Transportation

Jurisdictions should work with their transportation partners to ensure vaccine transit is conducted in accordance with standards for effective, efficient, safe, and secure product delivery. Where possible and practical, shipping and tracking data should be collected using GPS-enabled devices and information systems that produce reliable and valid data. The number of steps from vaccine manufacturer to vaccination administrator should be minimized to reduce risk of error, including breaks in the cold chain. When vaccine is redistributed from a first administration site to another – from a hospital to a public health clinic, or from one mass vaccination setting to another – additional oversight and enhanced storage and handling practices are needed.

Transportation of vaccine "kits" should include ancillary supplies needed to administer vaccine. This includes, but is not limited to, needles, syringes, alcohol pads and swabs, rubber gloves, and other personal protective equipment to protect personnel administering the vaccine. Basic vaccination record cards are also part of ancillary kits. Vaccine administration should not be slowed down by lack of ancillary materials.

### 3.3.2 Storage and Handling

Three elements are required to safeguard vaccine storage and handling: well-trained staff, dependable temperature monitoring equipment, and accurate vaccine inventory management. To minimize vaccine loss and limit risk of administering vaccine with reduced effectiveness, local jurisdictions should work with all vaccination sites to ensure they follow appropriate vaccine storage and handling procedures, including the ability to meet cold chain requirements.

### 3.3.3 Track and Trace

As noted, every vaccine shipping container or storage unit should include a precise and dependable temperature monitoring device and GPS location technology. Should a vaccine temperature excursion occur, in which COVID-19 vaccine is exposed to temperature outside its prescribed range, all vaccine should be removed from use. The monitoring system (discussed in Chapter 4) should be used to manage all inventory.

[20] Refer to: Don't Repeat the Mistakes of Past Vaccine Distribution Effort (see Referenced Documents); accessed December 30, 2020.

# 4 Monitoring Systems

The backbone of modern mass immunization campaigns is the technology infrastructure used to collect, organize, store, share, and analyze data for the common good. Absent these capabilities, mass vaccination campaigns would devolve into highly chaotic, inefficient, and largely ineffective efforts to control the worldwide scourge of the COVID-19 pandemic.

All countries need to build digital platforms for planning, implementing, monitoring, and evaluating their COVID-19 mass vaccination campaigns. These systems should allow end-to-end monitoring, registration of beneficiaries, facilities planning, scheduling vaccination appointments, and planning the vaccination process. Monitoring systems are used to track vaccine-related information (e.g., utilization, wastage, and coverage) on a real-time basis at national, regional, and local levels.

The three main types of information collected by campaigns are:

1. **Supply chain data**, needed to track and monitor the vaccine as it moves from point A (manufacturer) to point B (peoples' arms)
2. **Vaccination administrative data**, such as vaccine type, vaccination date, scheduling information, age, gender, and other characteristics of vaccinated persons, and key demographic information about those not vaccinated
3. **Research data**, including information needed for clinical, public health, epidemiology, program improvement, and policy studies

Jurisdictions may use an existing immunization information system, vaccine registry, or other IT architecture developed to enable monitoring for public health purposes. Perhaps somewhat ironically, these monitoring systems may be more developed in low-income countries than in high-income countries, because low-income countries have had more experience responding to infectious disease outbreaks.

Mass vaccination campaigns should build their monitoring systems on existing IT infrastructure to the extent possible. Capability gaps and unmet needs can be addressed using new, agile solutions.[21]

## 4.1 Supply Chain Data

Managing vaccination supply chains requires continuous scrutiny of information about vaccine allocation, ordering, shipping, tracking, handling, receiving, vaccine storage, and cold chain integrity. Collaboration with partners, a key requirement for successful mass vaccination campaigns, depends on the availability of data, the ability to share information safely and

[21] For one example where this is happening, consider the collaboration between a large technology company (such as Microsoft®) and partners (Accenture, Avande, EY, and Mazik Global) to build and launch new platforms for COVID-19 vaccine management to assist public health agencies and healthcare providers. Refer to: Microsoft Deploys COVID-19 Vaccine Management Platform (see Referenced Documents); accessed January 6, 2021.

securely, and data analytics. Dependable and streamlined monitoring systems enable these capabilities (see Appendix A).

## 4.2 Vaccination Administrative Data

Basic information about the type of vaccine that is administered to an individual includes the name of the vaccine manufacturer, the number of the lot (batch) from which it was made, and its expiration date.

Information collected about the person vaccinated varies according to privacy regulations in effect (some of which may be relaxed during a pandemic).[22] The collection of basic demographic data includes age, gender, ethnicity, risk category, and area or region of residence.

Claims and payment data may be collected, depending on the funding mechanisms set up in different countries.

Vaccination scheduling is an important capability for mass vaccination campaigns. Some means of communication, often connected to the monitoring system, is necessary to make an appointment to receive vaccination. Often, appointments are made online or by phone.

To encourage people to receive a second dose (if applicable), a follow-up appointment is scheduled at the time of the first vaccination. Information may be generated and given to individuals on a vaccination card or appointment reminder. Scheduling information may be kept online and instructions are provided to persons vaccinated so they can access it in a confidential and secure manner. Where permitted, second dose reminders can be delivered to individuals who provide personal information, such as a phone number, email, or physical address.

Immunization providers should be trained to watch for and recognize adverse drug events, such as allergic reactions, in patients. This data can be helpful for pharmacovigilance studies (discussed in Section 4.3) and for studying the biology of infectious disease.

Jurisdictions that enroll or contract with vaccination providers should ensure they have the capability to document and report required data. Administrative data typically is collected and submitted to higher, centralized monitoring authorities.

## 4.3 Research/Analytics Data

Monitoring systems that provide administrative and supply chain data provide important information for use in research on disease epidemiology, pharmacovigilance surveillance and post licensure clinical trials, biology of infectious disease, and improving mass vaccination campaigns. But additional data is needed, often person-level data that is only available in clinical documentation stored in electronic medical or health records. Some countries have created a digital infrastructure grounded in common, shared data standards that enable interoperability, or the ability to exchange data in a meaningful way. Others have not. In those countries, the ability to conduct the research discussed here may be handicapped. The healthcare systems in those

[22] Countries vary with respect to security and privacy rules. Consistent with those rules, all precautions should be taken to collect and safely store only necessary and relevant data.

countries depend on methods – which are at different stages of development – to render data from different vendor platforms sharable and meaningful.[23]

COVID-19 pharmacovigilance studies are critical because they provide evidence-based data on the efficacy and safety of vaccines in mass populations that were previously tested only in clinical trials. They provide information on adverse drug events. And, importantly, they also provide information on vaccine effectiveness against new strains of the virus.

[23] The Open Group Healthcare Forum has written about these issues in several publications available free-of-charge from The Open Group Library at: https://publications.opengroup.org/catalogsearch/result/?q=healthcare+interoperability.

# 5 Non-Pharmaceutical Protections During Campaigns

It is unrealistic to expect that mass vaccination campaigns will eradicate the SARS-CoV-2 virus. Only smallpox has been eradicated globally, as declared by the WHO in 1980.[24] As with influenza and its mutating viruses, protecting ourselves from coronaviruses is likely to become part of our annual public health plans.

## 5.1 Precautions After Vaccination

After getting a COVID-19 vaccine, people will still need to take precautions. A 95% effectiveness rating means that 1 out of 20 people will remain unprotected from exposure to the virus after vaccination. Populations will need to continue to observe precautions – mask wearing, social distancing, and frequent handwashing – until herd immunity is reached and more is learned about how long natural and vaccine-produced immunity lasts.

## 5.2 Rapid Testing

Testing for COVID-19, followed by isolation of positive cases, contract tracing, and mandatory quarantine for exposed persons who test positive, are practices that should remain in effect. The need for low-cost, self-administered, rapid COVID-19 testing remains significant and will continue after countries have successfully controlled COVID-19 through their mass vaccination campaigns.

## 5.3 Metabolic Health

Obesity, diabetes, inactivity, insulin resistance, and other impairments associated with poor metabolic health are closely linked to severe cases of COVID-19. Public health experts talk about the dual pandemics of obesity and COVID-19 and the negative impact they have on each other. Thus, life-style practices (healthy nutrition and exercise) and medical treatments that decrease metabolic syndrome will increase individuals' ability to fight against severe effects of COVID-19.

[24] Refer to: https://en.wikipedia.org/wiki/Smallpox; accessed January 22, 2021.

# 6 Graphic Relationship Between the O-HERA Framework and This Document

The Open Group Healthcare Forum has developed a Healthcare Enterprise Reference Architecture – the O-HERA framework – based on the well-known Plan-Build-Run framework.[25] The information presented in this document can easily be overlaid upon the O-HERA framework, which may be useful for further work, as briefly discussed Chapter 7.

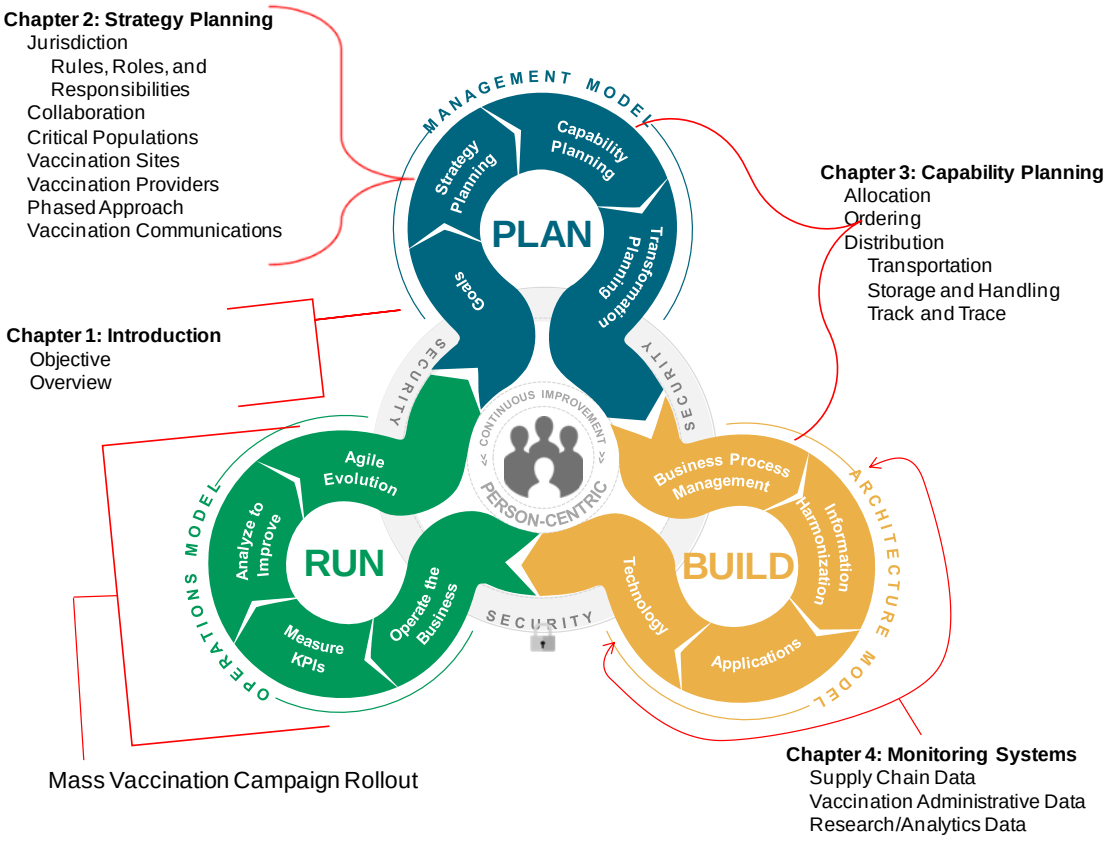


**Figure 1: The O-HERA Framework and This Document**

[25] Refer to The Open Group Healthcare Enterprise Reference Architecture (HERA) (see Referenced Documents).

# 7 Conclusion

In this short document we have identified the main, fact-based pillars of successful mass vaccination campaigns to control the COVID-19 pandemic. Countries around the world are fighting the same enemy. How they design and implement their campaigns will vary greatly in specifics, but the structure and architecture should address the main pillars identified in this document.

Enterprise Architects have an immense opportunity to work with jurisdictions, authorities, and partners to help them coordinate, collaborate, and effectively and efficiently solve strategy, capability, and monitoring system problems that arise in the development and rollout of COVID-19 mass vaccination campaigns.

Solutions will not be once-and-done. With ingenuity and effort, the field of Enterprise Architecture can help to improve the way the world responds to deadly epidemics and pandemics as far into the future as the eye can see and the mind can imagine.

# A Vaccine Supply Chain by McKinsey & Company

The graphics presented in this appendix are taken from the McKinsey & Company article entitled: The Risks and Challenges of the Global COVID-19 Vaccine Rollout, January 26, 2021. The full article can be accessed at:

https://www.mckinsey.com/business-functions/risk/our-insights/the-risks-and-challenges-of-the-global-covid-19-vaccine-rollout?cid=other-eml-alt-mip-mck&hdpid=44fd1a35-4fc9-4d03-aeaa-52bf680bbb89&hctky=2337410&hlkid=b47afc7058c742118e656c25426c4180

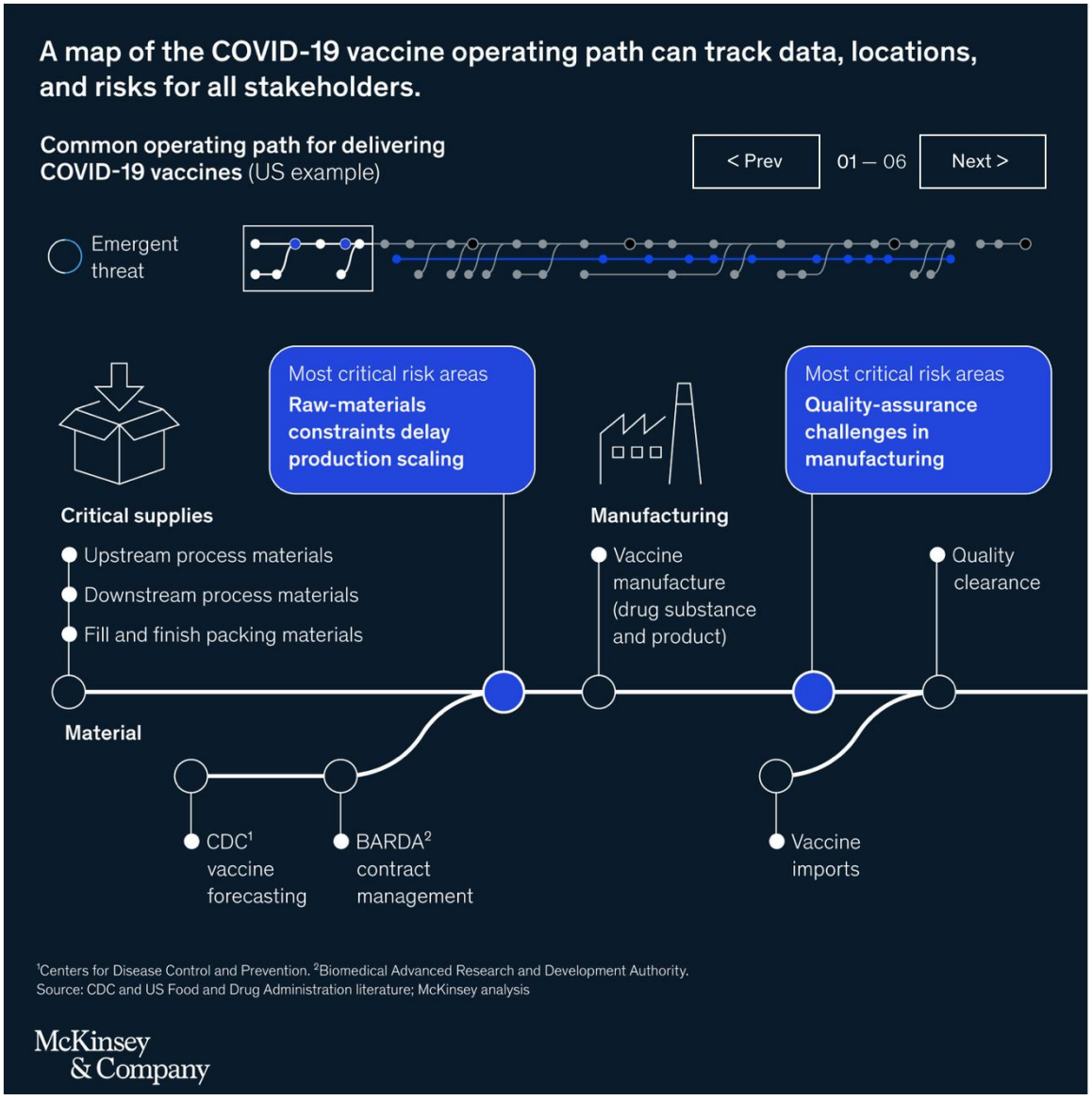


**Figure 2: Vaccine Supply Chain – Manufacture to Post-Vaccination (1 of 6)**

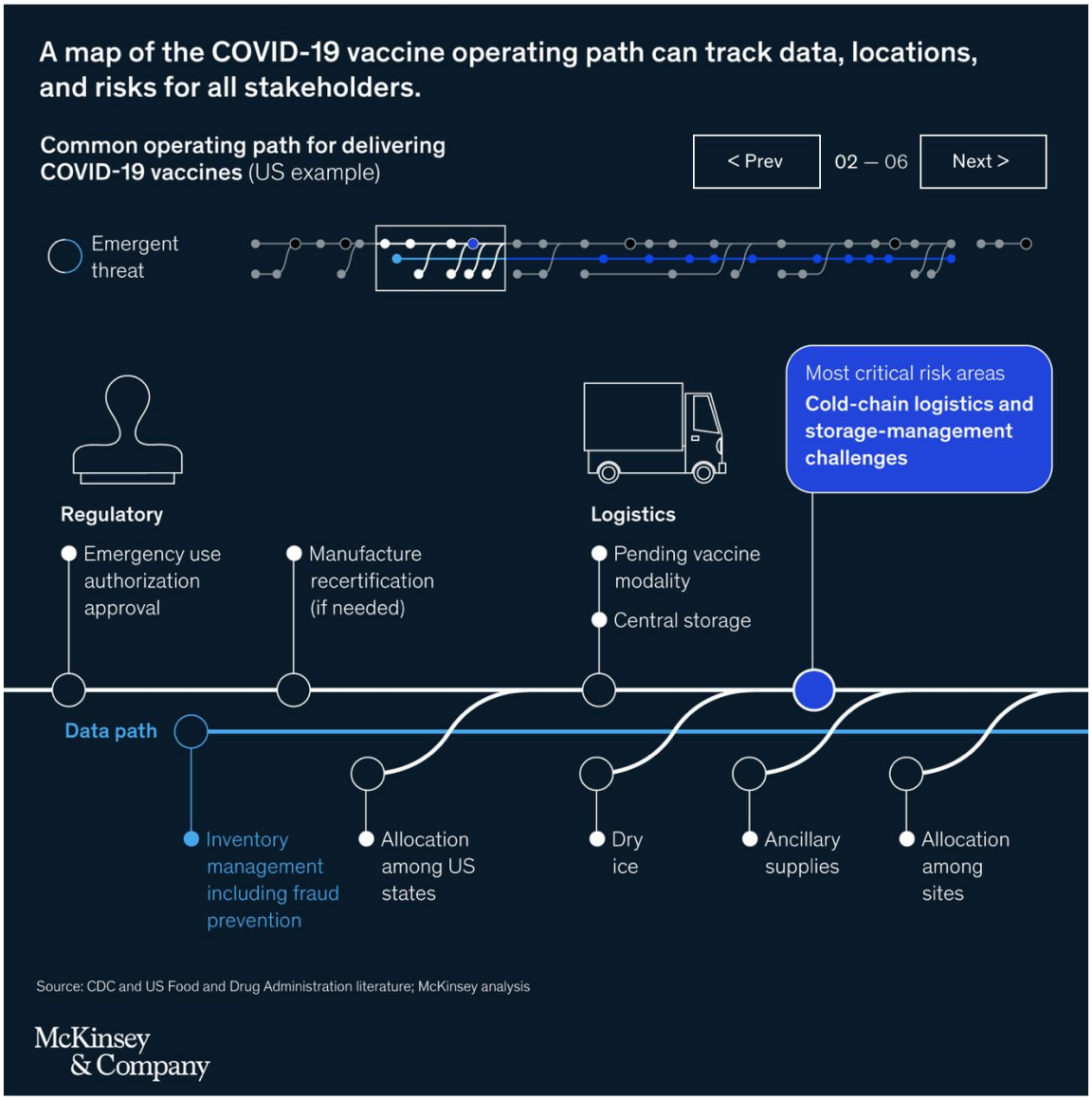


**Figure 3: Vaccine Supply Chain – Manufacture to Post-Vaccination (2 of 6)**

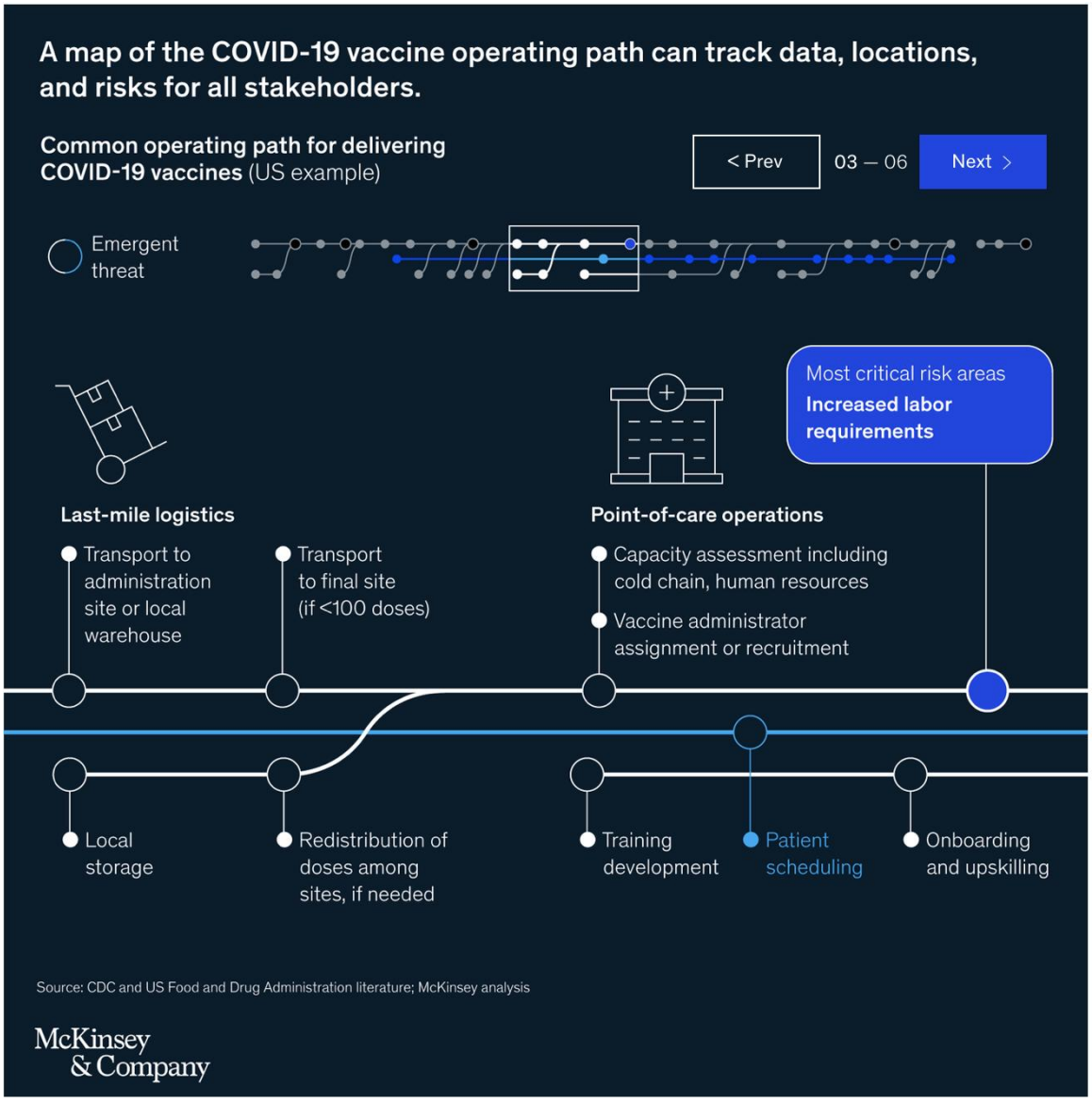


**Figure 4: Vaccine Supply Chain – Manufacture to Post-Vaccination (3 of 6)**

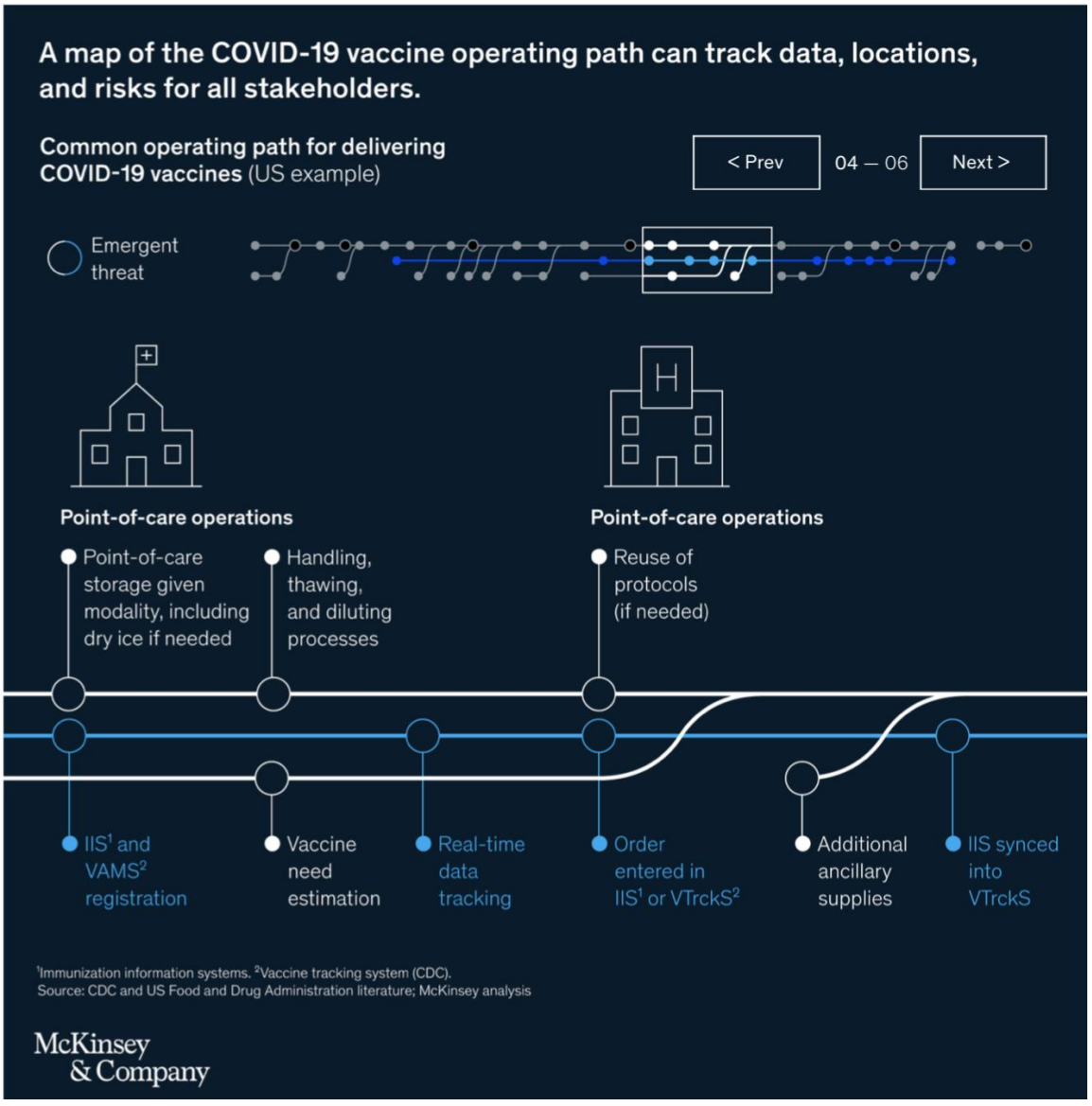


**Figure 5: Vaccine Supply Chain – Manufacture to Post-Vaccination (4 of 6)**

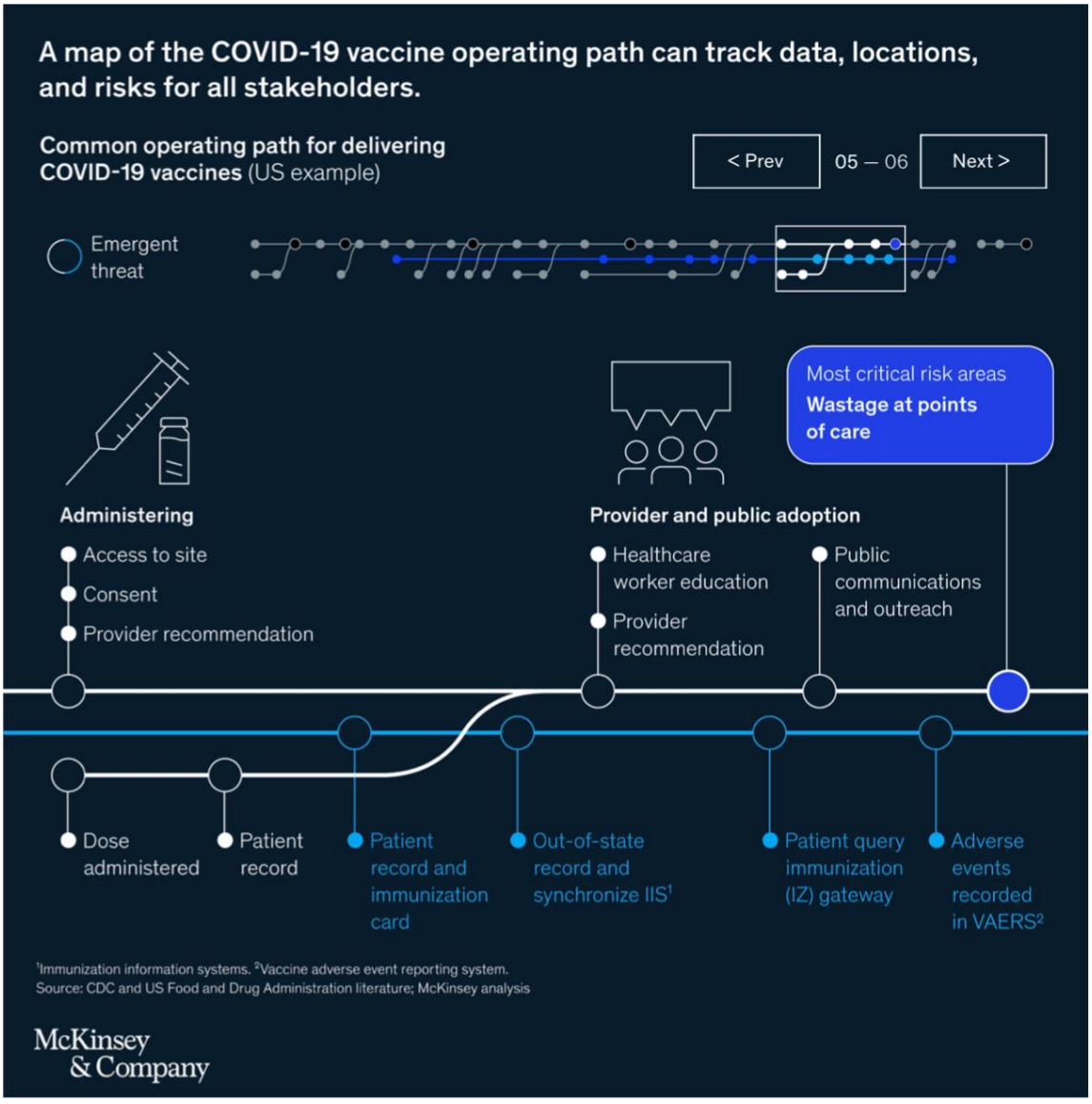


**Figure 6: Vaccine Supply Chain – Manufacture to Post-Vaccination (5 of 6)**

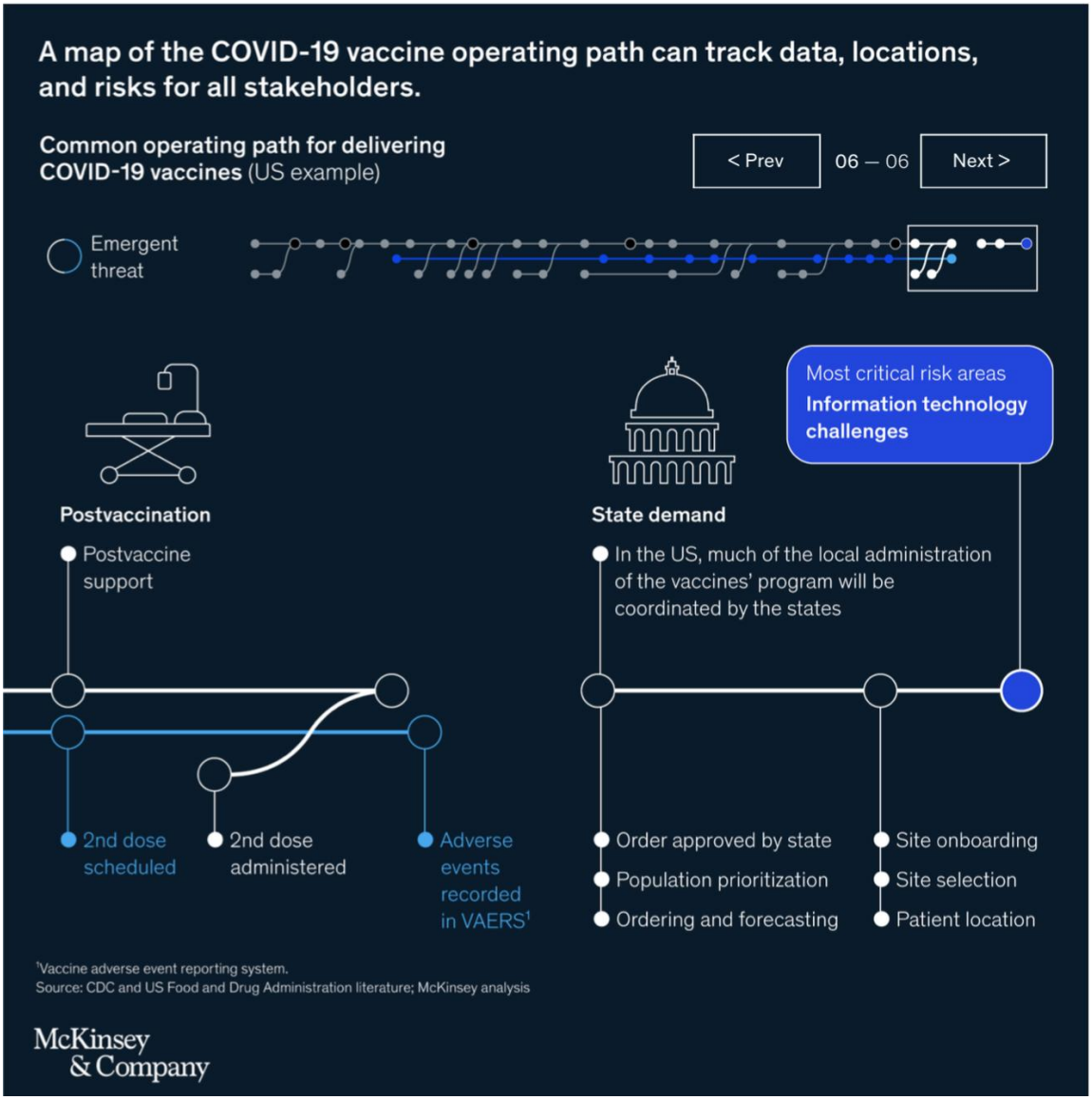


**Figure 7: Vaccine Supply Chain – Manufacture to Post-Vaccination (6 of 6)**

# Acronyms & Abbreviations

| | |
|---|---|
| ADE | Adverse Drug Event |
| CDC | Centers for Disease Control and Prevention |
| CEPI | Coalition for Epidemic Preparedness Innovations |
| COVAX | COVID-19 Vaccines Global Access |
| COVID-19 | Corona (CO) Virus (VI) Disease (D) – 19 (2019, year of discovery) |
| CSSE | Center for Systems Science and Engineering |
| DoD | Department of Defense (US) |
| EHR | Electronic Health Record |
| FHA | Federal Health Architecture |
| FHIM | Federated Health Information Model |
| FHIR | Fast Healthcare Interoperability Resources |
| GPS | Global Positioning System |
| HDL | High-Density Lipoprotein |
| HIT | Healthcare Information Technology |
| IIS | Immunization Information System |
| JHU | John Hopkins University of Medicine |
| NHS | National Health Service (UK) |
| NPR | National Public Radio (US) |
| O-HERA | Open Healthcare Enterprise Reference Architecture |
| ONC | Office of the National Coordinator for Health Information Technology (US) |
| RDT | Rapid Diagnostic Testing |
| SARS | Severe Acute Respiratory Syndrome |
| VA | Department of Veterans Affairs (US) |
| WEF | World Economic Forum |
| WHO | World Health Organization |

# Glossary

Adverse Drug Event (ADE)
: An injury resulting from medical intervention related to a drug. This includes medication errors, adverse drug reactions, allergic reactions, and overdoses. ADEs can happen anywhere: in hospitals, long-term care settings, and outpatient settings.

Ancillary Materials
: Vaccine kits may include any of the following materials needed to administer vaccine: needles, syringes, alcohol prep pads, surgical masks, face shields, vaccination record cards, sharps containers, gloves, bandages, or gowns.

Capability
: An ability that an organization, person, or system possesses.

Centralized Monitoring Authority
: An authorized organization that has the ability to accumulate and aggregate immunization information from other data collection authorities.

Cold Chain
: A temperature-controlled supply chain. An unbroken cold chain is an uninterrupted series of refrigerated production, storage, and distribution activities, along with associated equipment and logistics, which maintain quality via a desired low-temperature range.

Coronavirus
: Coronaviruses are a large group of viruses that have crown-like thorns on their surface. The Latin word for crown is '*coronam*".

COVAX Facility
: COVID-19 Vaccines Global Access, abbreviated as COVAX, is a global initiative aimed at equitable access to COVID-19 vaccines led by the Global Alliance for Vaccines and Immunization, WHO, CEPI, and others.

COVID-19
: 'Co' stands for 'Corona', 'VI' stands for 'Virus', 'D' stands for 'Disease', and '19' indicates the year in which it was discovered.

Enterprise Architecture
: Concerned with the structures and behaviors of a business, especially business roles and processes that create and use business data. It has been defined as: "a well-defined practice for conducting enterprise analysis, design, planning, and implementation, using a comprehensive approach at all times, for the successful development and execution of strategy. Enterprise Architecture applies architecture principles and practices to guide organizations through the business, information, process, and technology changes necessary to execute their strategies."

Epidemic
: An outbreak of a disease that affects a large number of individuals within a population, community, or region at the same time, but is less widespread than a pandemic.

Global Positioning System (GPS)
: A navigational system using satellite signals to fix the location of a radio receiver on or above the earth's surface.

Herd Immunity
: A situation in which a sufficient proportion of a population is immune to an infectious disease (through vaccination and/or prior illness) to make its spread from person to person unlikely. Even individuals not vaccinated (such as newborns and those with chronic illnesses) are offered some protection because the disease has little opportunity to spread within the community. Herd immunity to viruses that cause respiratory tract infection is usually acquired by high levels of vaccination in a population. Experts have estimated that many people (60-8%) would need to be vaccinated to achieve herd immunity to COVID-19. When herd immunity is reached, everyone within the community is protected, even if some people lack protection themselves. Vaccination rates to achieve herd immunity vary by disease.

Immunization Registry, or Immunization Information System (IIS)
: A confidential, population-based, computerized information system that attempts to collect vaccination data about all persons within a geographic area. Information can be shared one way or bidirectional, meaning you can both upload immunization information and download it from the registry. An electronic health record connected to an immunization registry can add significant value by saving effort and time. An Electronic Health Record (EHR) with built-in vaccine tracking, inventory management capabilities, and barcode scanning of vaccines can dramatically improve efficiency. If a jurisdiction allows connecting a registry data with EHR data at the person level, it can provide timely access to complete and relevant immunization data for use by patients, schools, healthcare providers, and researchers.

Infectious Disease
: A disease (such as influenza, malaria, meningitis, rabies, or tetanus) caused by the entrance into the body of pathogenic agents or microorganisms (such as bacteria, viruses, protozoans, or fungi) which grow and multiple there.

Jurisdiction
: The official power or extent of power or authority to make decisions and judgments. Jurisdiction often, but not always, implies legal authority. The entity that is given jurisdiction is sometimes referred to as a jurisdiction. Jurisdictional authority is held by entities at many different levels in a political hierarchy or organizational complex.

Metabolic Health
: Having ideal levels of blood sugar, triglycerides, High-Density Lipoprotein (HDL) cholesterol, blood pressure, and waist circumference, without using medications. These factors directly relate to a person's risk of heart disease, diabetes, and stroke. They are related to life style as well as diet.

Monitoring System
: Used for controlling the technology used by a company or project (including hardware, networks and communications, operating systems or applications, among others) in order to analyze their operation and performance and to detect and alert about possible errors.

Pandemic — An outbreak of a disease that occurs over a wide geographic area (such as multiple countries or continents) and typically affects a significant proportion of the population.

Pharmacovigilance, or Pharmacovigilance Surveillance (also known as Drug Safety) — The pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products.

Population — A large group of people with a common defining characteristic (e.g., residents of a specific location). In practice, a "population" is often a "subpopulation", such as people age 65 and older who are high-risk due to pre-existing health conditions.

Portal — A website or webpage providing access or links to other sites; for instance, access to scheduling information or test results.

Rapid Diagnostic Testing (RDT) — A medical test that is quick and easy to perform for preliminary or emergency screening and for use in medical facilities with limited resources. They provide same-day results within two hours, typically in approximately 20 minutes.

SARS-CoV-2 — Severe acute respiratory syndrome coronavirus-2 is the novel virus that causes the COVID-19 disease. Because the virus was new when it was first detected in Wuhan, China in December 2019, humans had not built up antibodies to protect against it.

Strategy — A summary formal description of the enterprise (e.g., COVID-19 mass vaccination campaigns) providing an organizing framework for operational and change activity, and an executive-level, long-term view for direction setting.

Supply Chain — The sequence of processes involved in the production and distribution of a commodity.

Vaccine Administrative Capacity — The maximum achievable vaccination services that can be delivered regardless of demand.

Vaccine Efficacy — The percentage reduction of disease in a vaccinated group, using the most favorable conditions. It is best measured using double-blind, randomized, clinical controlled trials. Vaccine effectiveness refers to how well a vaccine works in a population, whereas vaccine efficacy shows how well a vaccine works in certain, often controlled, conditions.

Vaccine Hesitancy — A reluctance or refusal to be vaccinated or to have children vaccinated against contagious disease. The term encompasses outright refusal to vaccinate, delaying vaccines, accepting vaccines but remaining uncertain about their use, or using certain vaccines but not others. Vaccine hesitancy often results in disease outbreaks and deaths from vaccine-preventable disease.

# Index