Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines

INTERIM GUIDANCE

16 NOVEMBER 2020

World Health Organization

unicef
for every child

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Abbreviations

ACT	Access to COVID-19 Tools
AEFI	adverse events following immunization
AESI	adverse events of special interest
CDC	Centers for Disease Control
CEPI	Coalition for Epidemic Preparedness Innovations
CHAI	Clinton Health Access Initiative
CIOMS	Council for International Organizations of Medical Sciences
COVAX	the vaccine pillar of the ACT Accelerator
COVID-19	coronavirus disease 2019
CTC	controlled temperature chain
DNA	deoxyribonucleic acid
EIR	electronic immunization registry
EUL	Emergency Use Listing
FPL	focal point for logistics
FPV	focal point for vaccination
GACVS	Global Advisory Committee on Vaccine Safety
Gavi	The Vaccine Alliance
HMIS	health management information system
IA2030	Immunization Agenda 2030 (WHO)
ICC	inter-agency coordinating committee
ICU	intensive care unit
IFRC	International Federation of Red Cross and Red Crescent Societies
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IM	incident manager
IPC	infection prevention and control
KAP	knowledge, attitudes and practices
LMICs	low- and middle-income countries
MERS	Middle East Respiratory Syndrome
MMGH	MM Global Health
MoF	ministry of finance
MoH	ministry of health
NCC	national coordinating committee
NCL	national control laboratory
NDVP	national deployment and vaccination plan
NGO	non-governmental organization
NIP	national immunization programme
NITAG	national immunization technical advisory group
NRA	national regulatory authority

PCM	phase change material
PFM	public financing management
PHC	primary health care
PHEIC	public health emergency of international concern
PPE	personal protective equipment
RITAG	regional immunization technical advisory group
RMP	risk management plan
RNA	ribonucleic acid
SAGE	Strategic Advisory Group of Experts on Immunization (WHO)
SARI	severe acute respiratory infections
SARS	severe acute respiratory syndrome
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SDGs	Sustainable Development Goals
SOPs	standard operating procedures
SRA	stringent regulatory authorities
UCC	ultra-cold chain
UHC	universal health coverage
UNICEF	United Nations Children's Fund
VE	vaccine effectiveness
VIRAT	Vaccine Introduction Readiness Assessment Tool
VVM	vaccine vial monitor
VPD	vaccine-preventable disease
WHO	World Health Organization
WLA	WHO-Listed Authority

About this guide

KEY MESSAGES

- This document is intended to guide national governments in developing and updating their national deployment and vaccination plan (NDVP) for COVID-19 vaccines.
- The guidance is built upon existing documents and the core principles of the **WHO Strategic Advisory Group of Experts (SAGE) values framework for the allocation and prioritization of COVID-19 vaccination**, the **prioritization roadmap**, and the **Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility** and will be continually shaped by the vaccine-specific recommendations.
- Due to the current uncertain environment for COVID-19 vaccine development, the guidance is based upon key assumptions, best available at this time. There is a high likelihood that these assumptions will require updating over time due to the evolving situation and therefore should not be considered final. Future changes should be expected.
- This guidance document will be available on the WHO website and on the TechNet-21 website as a modular document and will be updated as new information becomes available.

Target audience

This guidance document is directed at national authorities who are responsible for managing deployment, implementation and monitoring of COVID-19 vaccines, as well as partners who provide the required support. As in most countries the establishment of a COVID-19 vaccine deployment and vaccination mechanism falls with the ministry of health (MoH), this guidance document is intended to support them as they develop the coordination mechanisms across all sectors of government and multistakeholders.

Objectives of the guidance document

This national deployment vaccination plan (NDVP) guidance document provides a framework that supports countries in:

- developing and updating their NDVP for the introduction of COVID-19 vaccines;
- designing strategies for the deployment, implementation and monitoring of the COVID-19 vaccine(s) in country;
- ensuring the plan and related financing is well aligned to other national COVID-19 recovery and response and support plans, and implementation is fully integrated into national governance mechanisms.

Organization and scope of the guidance document

This guidance document builds on existing immunization guidance documents on new vaccine introduction that have been developed previously by WHO through consultations with subject matter experts and is anchored around recent COVID-19 vaccine materials endorsed by the WHO SAGE *(1–4)*. This guidance document is a complement to and builds on similar elements in the COVID-19 Vaccine Introduction Readiness Assessment Tool (VIRAT) developed by WHO and UNICEF *(5)*.

This document will be available on the WHO and TechNet-21 websites as a modular document, that can be accessed by using key search words *(6)*. This format will make it possible to update the guidance document as and when new information is available.

This document consists of 13 chapters covering major areas key to enabling the successful deployment, implementation and monitoring of COVID-19 vaccines. Each chapter in the guidance document describes in detail the structure, processes and activities to be undertaken when preparing or updating NDVPs. Summaries of, and links to, the detailed guidance are provided in each chapter and will be updated regularly. A sample template has been developed to assist countries in developing and drafting their NDVP in Annex 1.

Role of WHO SAGE on immunization

The WHO SAGE has undertaken the following three-step process to provide guidance for overall programme strategy as well as vaccine-specific recommendations that form the basis of this guidance document.

1. **WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination:** this underpins the public health objectives and principles of vaccine prioritization for certain target populations during vaccine supply constraints *(7)*.
   - The framework articulates the overall goal of COVID-19 vaccine deployment and provides six core principles that should guide vaccine distribution: human well-being; global equity; reciprocity; equal respect; national equity; and legitimacy.
2. A **prioritization roadmap** to support countries in planning *(8)*.
   - The roadmap recommends public health strategies and target priority groups for different levels of vaccine availability and epidemiologic settings.
3. **Vaccine-specific recommendations:** once market-authorized vaccines become available, vaccine-specific recommendations will be issued. These recommendations will be updated as additional evidence of vaccine efficacy/effectiveness and safety, become available.

Key assumptions informing this guidance

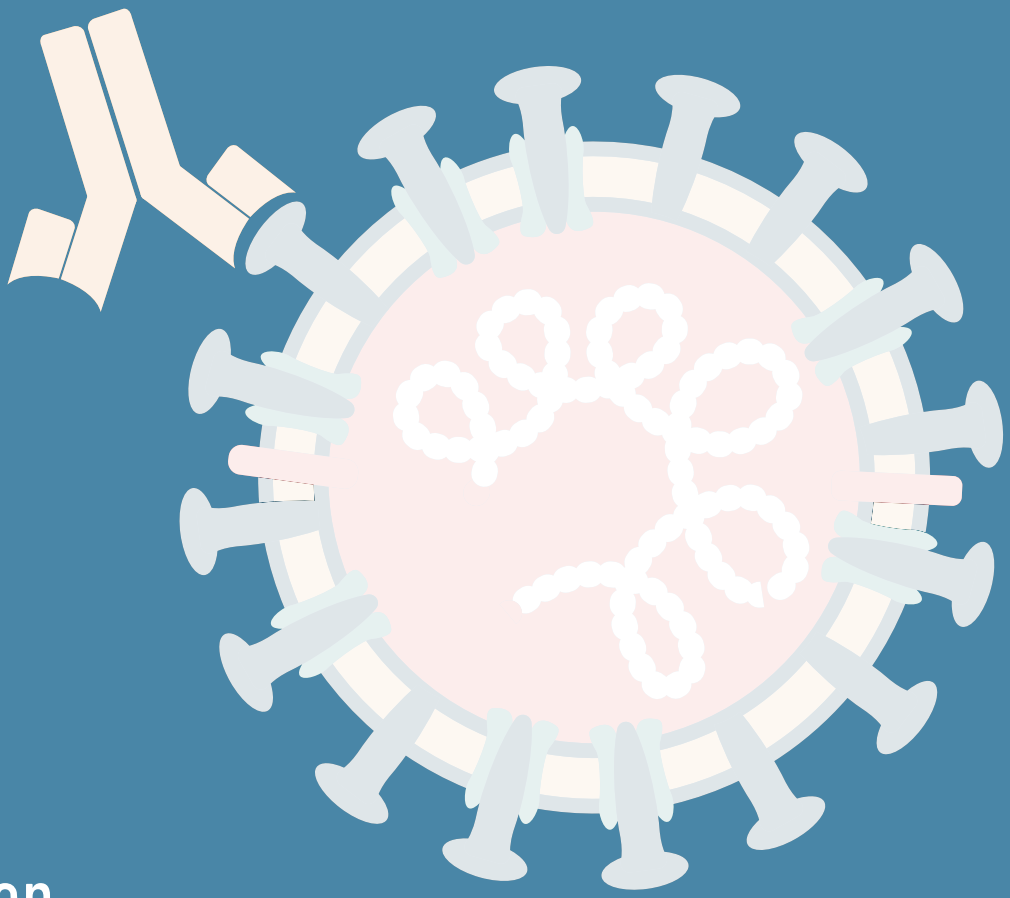
- Currently, more than 200 candidate vaccines are at some stage of clinical development *(9)*. The first Phase III trials began in July 2020 and the results for these first few candidates are expected at the end of 2020.
- The earliest use authorization of COVID-19 vaccines is expected at the end of 2020 or early 2021, with availability of shipment to countries soon thereafter.
- This guide is based on the WHO Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility to deliver at least 2 billion doses of approved vaccines by the end of 2021 *(10)*.
- Global recommendations for allocating vaccines between countries and for prioritizing groups for vaccination within each country must be complemented with information about the specific characteristics of the available vaccine or vaccines, the amount and pace of vaccine supply, and the current state of the epidemiology, clinical management, and economic and social impact of the disease and the pandemic.
- It is anticipated that most COVID-19 vaccines will require at least two doses for optimal immunogenicity. Storage and distribution temperature will likely be +2 °C to +8 °C for most vaccines but may require an ultra-cold chain of -20 °C to -80 °C storage for certain products. The COVID-19 vaccine products are likely to have varying vaccine characteristics and presentations and will require different administration techniques. Some products will not have vaccine vial monitors (VVM).
- The final vaccination strategy will be defined by the characteristics of vaccine products as they become available, so vaccination training and delivery strategies devised by countries will have to adjust accordingly. National immunization programmes (NIP) will need to devise non-traditional and novel immunization strategies for reaching priority target populations.

Constraints of this guidance document

At the time of the drafting this document, much remains unknown about the full characteristics of the COVID-19 vaccines that will receive authorization, and therefore, which vaccine products will be made available to which countries, and in what timeframe. Therefore, providing clear guidance in some sections is hindered. For example, specific data on the immune response in different age groups, pregnant women and people with underlying health conditions currently remains unknown. This makes it difficult to define exact target groups, and consequently, the precise vaccination strategies to reach them. Although this guidance has defined potential target populations based on the SAGE guidance documents and allocation framework, the final vaccination strategy will need to be defined by the characteristics of vaccine products as they become available *(7, 10)*. Tools that can support adaptation both to context and to vaccine characteristics, are needed to assist countries in preparing and scaling up capability.

Despite the absence of detailed information, COVID-19 vaccine product attributes, and general indications have been given to support countries in reflecting on potential needs for ultra-cold chain (UCC), human resource management and training of staff. Countries can already plan for or initiate many of the preparatory activities that will be required for COVID-19 vaccine introduction, regardless of the vaccine product ultimately received.

Once a vaccine, or vaccines, is closer to approval and more is understood about its properties, this guidance document will be updated.



1. Introduction

KEY MESSAGES

- On 30 January 2020, WHO declared COVID-19 – a severe acute respiratory syndrome (SARS) caused by a novel coronavirus – a public health emergency of international concern (PHEIC).
- The Access to COVID-19 Tools (ACT) Accelerator was launched in April 2020, at an event co-hosted by the Director-General of the World Health Organization, the President of France, the President of the European Commission, and the Bill & Melinda Gates Foundation. The ACT Accelerator brings together governments, scientists, businesses, civil society, and philanthropists and global health organizations (Bill & Melinda Gates Foundation, CEPI, FIND, Gavi, the Global Fund, Unitaid, Wellcome, WHO and the World Bank).
- COVAX, the vaccine pillar of the ACT Accelerator, is co-led by CEPI, Gavi and WHO, and will facilitate the equitable access and distribution of vaccines to protect people in all countries through the values framework endorsed by the WHO SAGE on immunization.
- There are multiple COVID-19 vaccines under development; countries should prepare for the possibility of introducing one or more COVID-19 vaccine product types.
- In developing their national strategies for the deployment of COVID-19 vaccines, countries should include activities to strengthen immunization, health services and health systems with collaboration across programmes. For countries to achieve timely and successful introduction of COVID-19 vaccines, a multisectoral collaboration, composed of high-level officials from concerned departments as well as major in-country partners will be required.

1.1 Objectives of this chapter

→ Provide countries with background information on COVID-19 disease, describe the current vaccine landscape and indicate where to find the most up-to-date information on vaccines in clinical development.

1.2 Background

On 30 January 2020, WHO declared the COVID-19 outbreak a PHEIC, WHO's highest level of urgency. On 11 March, WHO made the assessment that COVID-19 could be characterized as a pandemic. Globally, partners are working together on the response to mitigate the spread of disease – tracking the spread of disease, developing critical interventions, distributing vital medical supplies and supporting the development of therapeutics and multiple vaccines.

1.3 Coronavirus disease 2019

Coronaviruses are a large family of viruses that may cause illness in animals or humans. In humans, several coronaviruses are known to cause respiratory infections with symptoms ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and SARS. The most recently discovered coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), causes coronavirus disease 2019 (COVID-19). COVID-19 was unknown prior to the outbreak in Wuhan, China, in December 2019, but is now a pandemic affecting most countries globally.

The understanding of COVID-19 epidemiology continues to evolve and is rapidly changing. A description of the COVID-19 disease and what is currently understood of its transmission patterns can be found in **Annex 2.**

1.4 COVAX and COVID–19 vaccines

COVAX, the vaccines pillar of the ACT Accelerator, is co-led by CEPI, Gavi and WHO. This facility is supporting the research, development, manufacturing and negotiation of fair pricing for a wide range of COVID-19 vaccine candidates. COVAX will ensure all participating countries, regardless of income levels, will have equal access to these vaccines once they are developed and available. The aim is to have 2 billion doses of vaccine available by the end of 2021 (see Fig. 1.1).

WHO is working in collaboration with scientists, governments, businesses, civil society, philanthropists and global health organizations through the ACT Accelerator to expedite the pandemic response. When safety and efficacy data from clinical trials are sufficient to support the roll-out of vaccine products, COVAX will facilitate the equitable access and distribution of these vaccines to protect people in all countries *(11)*. The speed, breadth and magnitude of the effort to develop vaccines against COVID-19 is unprecedented.

Types of vaccines

WHO regularly updates a landscape analysis of COVID-19 vaccines in clinical development (https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines). The majority of the presently known vaccine candidates are expected to require two doses for optimal immunogenicity and efficacy.

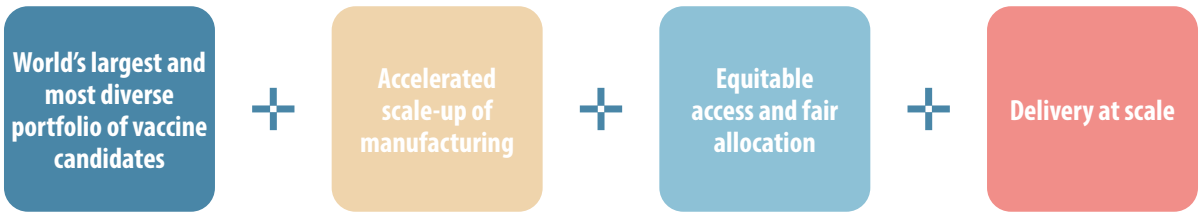


Fig. 1.1 COVAX – an end-to-end solution

All vaccines aim to expose the body to an antigen that will not cause disease but will provoke an immune response that can block or kill the virus if a person becomes infected. There are at least six vaccine technologies being tried against the coronavirus, and they rely on weakened or inactivated virus or viral particles (see Table 1.1).

Table 1.1 COVID-19 vaccines – a variety of approaches

Type of vaccine	Description	Pros	Cons	Example
Inactivated virus vaccines	An inactivated version of the target pathogen. The virus is detected by immune cells, but unable to cause disease.	Induces strong immune response	Requires lots of virus	Rabies
Live-attenuated	Consist of a living but weakened version of the target pathogen.	Same response as natural infection	Not recommended for pregnant women and immunocompromised individuals	Measles
Viral-vector vaccines (replicating and non-replicating)	A virus is genetically engineered or modified to contain antigens from the target pathogen. When the nucleic acid is inserted into human cells, they produce copies of the virus' protein, which stimulate a protective response from the host immune system.	Rapid development	Prior exposure to viral vector may reduce immunogenicity	Ebola
Nucleic-acid vaccines	RNA or DNA vaccines include a target pathogen protein that prompts an immune response. When the nucleic acid is inserted into human cells, RNA or DNA is then converted to antigens.	Strong cellular immunity, rapid development	Relatively low antibody response	None
Virus-like vaccine	Empty viral shells that are similar to the target pathogen, without genetic material. The viral shells stimulate a protective response from the host immune system.	Fast and relatively inexpensive	May be less immunogenic	HPV
Protein sub-unit vaccines	These vaccines use fragments of the target pathogen that is important for immunity.	May have fewer side effects than whole virus	May be poorly immunogenic, complex process	Hepatitis B

Notes: DNA – deoxyribonucleic acid; RNA – ribonucleic acid.

Vaccine landscape

There are several SARS-CoV-2 vaccine trial trackers with candidate-specific links to clinical trials registries, which facilitate finding details on trials and following their status, including the start and end dates for recruitment.[1,2] As of September 2020, nine CEPI-supported candidate vaccines are part of the COVAX initiative, with a further nine candidates under evaluation, and procurement conversations ongoing with additional manufacturers. Various vaccine candidates use different technology platforms and will likely

[1] London School of Hygiene & Tropical Medicine COVID-19 vaccine tracker (https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/).

[2] WHO Draft landscape of COVID-19 candidate vaccines (https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines).

have different characteristics, including immunogenicity, dosing schedules, safety profiles, cold chain requirements, and manufacturing time. These factors have implications for how each vaccine can be used and various scenarios should be considered when planning.

1.5 Considerations for COVID-19 vaccine introduction

1.5.1 Gender considerations for equitable, safe and effective COVID-19 vaccination

COVID-19 vaccination will be the world's first massively deployed public health intervention. In this, gender is a variable that will play out in different ways – biologically, behaviourally, and through influence and authority. Taken in combination, and at this time, it is not easy to predict the relative importance or impact of these factors. Evidence of differences is accumulating about immunological responses to COVID-19, exposure to risk, and acceptability, which may potentially affect vaccination strategies and equitable uptake of vaccine. Throughout the deployment and introduction of COVID-19 vaccines, a gender perspective needs to be incorporated into all activities in an "end-to-end" fashion to assure maximum success.

1.5.2 Health system strengthening, including strengthening immunization systems throughout the life course

The introduction of a new vaccine provides many opportunities as well as challenges to improve a country's overall immunization programme as well as its health services and health system. Many of the activities carried out to prepare, implement and monitor the introduction of COVID-19 vaccination will provide opportunities to improve the immunization programme and to identify best practices that could be applied to other health programmes and services. Activities that should be integrated into the national primary health care (PHC) operational framework include: microplanning, using an evidence-based decision-making process to govern the introduction of the COVID-19 vaccine; strengthening human resource management; training for new vaccine introduction; establishing new contact points for vaccination across the life course; ensuring traceability systems and technologies are leveraged to ensure the integrity and efficiency of supply chains, improving and expanding integrated project management and the supply chain; enhancing integrated disease surveillance and adverse events following immunization (AEFI) monitoring and reporting systems; and conducting integrated advocacy and communications activities to promote demand for vaccination as part of increasing overall demand and acceptability of all essential PHC services. Moreover, the most vulnerable include older populations, therefore building capacity for adult immunizations, including synergy of COVID-19 vaccine with influenza vaccination, will be important.

Experience has shown that the introduction of a new vaccine can have a significant impact – both positive and negative – on a country's health system. In recognition of this, the WHO SAGE endorsed six guiding principles for countries to follow in planning and implementing a new vaccine introduction while strengthening their overall immunization programme and health system *(2)*. It is anticipated that even in the course of COVID-19 vaccine deployment, elements of these core principles can be respected.

Furthermore, countries can also reference the WHO SAGE-endorsed document Immunization as an essential health service: guiding principles for immunization activities during the COVID-19 pandemic and other times of severe disruption which provides guiding principles for all countries to sustain their immunization activities *(12)*.

Guiding principles for optimal vaccine introduction into a national immunization programme and strengthening health systems

1. A strong country-led, evidence-based decision-making, planning and prioritization process that is accountable and coordinated with other components of the health system.
2. A well-performing or improving and responsive immunization programme.
3. Seizing the opportunity to achieve:
   - a well-trained and motivated health workforce;
   - quality education and communication about the new vaccine for the community;
   - functional cold storage, logistics and vaccine management systems;
   - safe immunization practices and monitoring and management of adverse events; and
   - high-quality monitoring and evaluation, including disease surveillance and immunization coverage monitoring.
4. Resource, performance and management accountability. Maximizing opportunities to deliver vaccines as integral components of comprehensive health promotion and disease prevention and control efforts so that vaccines are delivered as part of a package of effective, feasible and affordable interventions based on national contexts.
5. Sufficient allocation of human and financial resources to introduce the new vaccine and sustain its use without adversely affecting other programmes and services.
6. A safe and efficacious vaccine that is appropriate for local use and is available with an uninterrupted, sufficient supply.

1.6 Coordination with other health programmes or sectors

Introduction of a COVID-19 vaccination programme will require and allow opportunities to coordinate and collaborate across programmes, e.g. health emergencies, surveillance, PHC, noncommunicable diseases, programmes for health workers and older people, social services, training institutions, overall health service delivery platform and health system, etc. and different sectors, e.g. finance, social welfare, pension service, education, transport, energy etc. Establishing or strengthening coordination mechanisms between finance and health authorities to ensure COVID-19 vaccine introduction complements, rather than competes with, other COVID-19 response and recovery efforts is important *(13)*. Strengthening infectious disease surveillance systems will not only be critical in monitoring the introduction of the vaccine and the impact vaccines are having, but also for preparedness for future outbreaks. Given the rapid transmission characteristics of COVID-19 infection, innovative methods of disease surveillance and reporting will need to be considered, e.g. use of real-time monitoring, prioritization roadmap in the context of limited COVID-19 vaccine supplies.

The Immunization Agenda 2030 (IA2030) aims to align the activities of community, country, regional and global stakeholders to build effective partnerships both within and outside the health sector as part of efforts to achieve universal health coverage (UHC) and accelerate progress towards the 2030 Sustainable Development Goals (SDGs). IA2030 has seven strategic priority areas. The first strategic priority area, immunization programmes for PHC/UHC, is overarching, to ensure that the immunization programmes are an integral part of PHC services. Countries will need to have strong linkages between PHC services and immunization programmes, particularly for reaching the target population for the COVID-19 vaccines. Other IA2030 strategic priority areas stress the importance of PHC: commitment and demand; and life course and integration.

2. Regulatory preparedness

KEY MESSAGES

- The purpose of establishing appropriate and streamlined regulatory pathways during a public health emergency situation is to facilitate timely access to COVID-19 vaccines without compromising proper regulatory decision-making.
- Countries' national regulatory authorities (NRAs) are encouraged to develop and implement regulatory pathways to use a risk-based approach to assess the quality, safety and efficacy of vaccines.
- Countries will need to put in place emergency approval, and/or expedited fast-track regulatory pathways, and to have simulated these in advance to be sure they will work when needed.
- Recognition and/or reliance on the WHO prequalification programme, the decisions of stringent regulatory authorities (SRAs) and the use of the WHO Emergency Use Listing (EUL) are options available for NRAs.
- Due to the increased scale of cooperation required due to the large number of vaccines under development and the large number of countries who could benefit from such vaccines, WHO has developed product-specific roadmaps for regulatory collaboration during the scientific review of any vaccine submitted to WHO for assessment.
- Countries will need to provide import permits for medical products, based on a minimum number of documentation requirements, as quickly as possible.
- Vaccines procured from assured sources do not need to be tested again. Countries should release these vaccines to the immunization programme in the shortest possible time.
- The NRA, the NIP and other stakeholders should be able to implement vaccine vigilance plans to monitor the safety and effectiveness of the COVID-19 vaccine(s) in use.

2.1 Objectives of this chapter

→ Provide information for countries on current practices and options for regulatory preparedness that will ensure timely decision-making by NRAs during public health emergencies.

2.2 Establish emergency regulatory procedures

Adapting and implementing regulatory pathways and procedures that facilitate countries' preparedness for public health emergencies, such as the COVID-19 pandemic, should ideally be in place before the emergency occurs. Regulatory adaptation is critical during public health emergencies, hence NRAs are encouraged to modify a traditional, reactive control system into a proactive, risk-based approach to speed up the public's access to life-saving medical products. Establishing the legal aspects for procuring products not yet finalized could also be explored.

Emergency regulatory procedures for a COVID-19 vaccine should ensure:

- an expedited assessment of data and evidence that supports best regulatory decision-making on COVID-19 vaccine approval during the processes of registration and strain changes/variations and other post-approval changes. The expedited assessment could be based on reliance approaches to facilitate approval;
- provision of import permits in the shortest time possible; and
- expedited vaccine lot release for prompt administration of COVID-19 vaccine to target groups.

The established regulatory and administrative procedures should ensure proper information management, effective communication and cooperation among different branches of the NRA and relevant stakeholders, i.e. public health authorities – including national control laboratories (NCLs), customs authorities, procurement and deployment entities.

Communication and information-sharing systems should be established and implemented for all stakeholders. The NRA, NIP and other stakeholders should develop, or enhance, and implement vaccine vigilance plans to monitor the safety and effectiveness of the COVID-19 vaccine(s) in use.

2.2.1 Define pathways for emergency regulatory approval

Proper regulatory decision-making in a time-efficient manner could have an important impact in saving lives and mitigating the COVID-19 pandemic. NRAs are encouraged to develop and implement regulatory pathways to assess the quality, safety and efficacy of vaccines using a risk-based approach. A risk-based approach to evaluating COVID-19 vaccines should incorporate three elements:

- the severity and magnitude of the harm caused by the pandemic;
- the severity and magnitude of harm that would likely result if a vaccine is not made available to the public; and
- the likely impact (risk-benefit) of making a vaccine available to the public.

This regulatory function will play an ongoing role throughout the roll-out of the novel vaccine, requiring an intentional focus on understanding real-world safety and effectiveness.

As part of pandemic preparedness, emergency approval, and/or expedited fast-track regulatory pathways, with or without considering reduced data packages depending on available evidence, should be in place

and should have been simulated in advance to assure their functioning at the needed time. Recognition and/or reliance on the WHO prequalification/Emergency Use Listing (EUL) programme *(14, 15)*, the decisions of stringent regulatory authorities (SRA) or WHO-Listed Authority (WLA) *(16)*, are regulatory options available for NRAs. In addition, resources, i.e. human, financial and infrastructure, that enable emergency regulatory procedures to be developed and implemented should be made available to NRAs.

In the context of the current public health emergency, regulatory alignment and collaboration are some of the key components that will help to facilitate equitable access to safe and effective vaccines that meet international quality and manufacturing standards. A high degree of cooperation is anticipated to be required due to the large number of vaccines under development and the large number of countries which could benefit from such vaccines. To facilitate regulatory alignment and cooperation, WHO has developed product-specific roadmaps to assess whether candidate vaccines are safe and effective, and meet international quality and manufacturing standards *(17)*. The principles for strengthened collaboration post-introduction are also outlined in view of the heightened need for alignment in this area. Reliance approaches should also be considered for post-approval changes to facilitate the management of those changes as long as the sameness of product in different jurisdictions is maintained from the initial authorization (i.e. the vaccine assessed by the reference regulatory authority is essentially the same as the one submitted to the NRA using reliance).

If the regulatory system does not proactively establish the necessary processes and resources for timely vaccine assessment, relying on and/or recognizing the decisions of WHO (either prequalified or listed) and of other NRAs with stable formal approaches for the initial authorization and any post-approval changes might be the only possible tactic to provide timely access to COVID-19 vaccines.

The WHO Guidelines on regulatory preparedness for provision of marketing authorization of human pandemic influenza vaccines in non-vaccine-producing countries *(18)* provide such NRAs with guidance on:

- the regulatory pathways and evaluation processes for the provision of marketing authorization for pandemic influenza vaccines; and
- the general principles and basic necessary regulatory requirements for those processes which can be applied to the regulatory process for COVID-19 vaccines.

Experience with implementing the guidelines shows that translating them into national practice will require additional resources. Countries will need to prepare an implementation plan that identifies time, resources (human, financial human, infrastructure), methodology, and monitoring and evaluation mechanisms.

2.2.2 Facilitate import procedures

Importation of medical products should be done in accordance with national and regional legislation and should be enforced by the NRA as well as customs and other relevant authorities. Applicable procedures and formalities within and among the relevant authorities should facilitate rather than obstruct access to COVID-19 vaccines.

WHO Guidelines on import procedures for medical products provide details on legal responsibility, legal basis of control, required documentation, implementation by national authorities *(19)*.

Timely implementation of applicable procedures should be ensured by the regulatory authorities, and the NRA should be able to grant import permits expediently. Intermittent storage of the vaccine at the port(s) of entry is discouraged and immediate customs clearance should be facilitated where possible. All entities

relevant to import controls, including the NRA, the customs control authority, the NCLs and the port control authority, should coordinate their activities with the objective of enhancing and speeding up the importation and clearance of COVID-19 related medical products, including highlighting administrative processes that could delay customs clearance processes and addressing these bottlenecks ahead of time. If needed, exemptions to the required documentation for import control should be foreseen and initiated *(19)*. The regulatory coordinating body may also want to review previous import experiences for a new vaccine and integrate lessons learned and best practices into the country's action plan for importing COVID-19 vaccines.

It might not be possible to dispatch COVID-19 vaccines to a country until all the necessary authorizations are in place. This means that the product must have obtained a valid authorization/approval for use in humans issued by the concerned authority at national level, or that the approval process for the product has been initiated, and an import permit as per applicable national regulations sought.

2.2.3 Expedite lot release of COVID-19 vaccines

During the COVID-19 pandemic, the allocated COVID-19 vaccines should be released to the immunization programme in the shortest possible time without compromising safety.

Testing of vaccines requires sophisticated and complex analytical methods and equipment that should be managed by trained staff. WHO advises that vaccines procured from assured sources, e.g. WHO prequalified vaccines, vaccines listed as EUL, or vaccines approved by SRAs, are not tested again by receiving countries as they have been tested and released already by NRAs with stable, formal approaches for vaccine approval. If countries are required by law to review the summary lot protocols, vaccine release should be done quickly and through the review of the minimum documents as advised by WHO. Countries may also want to explore if there can be any law or exception granted in the case of emergency use of a vaccine with existing SRA approval.

For further reading please see the WHO Guidelines for independent lot release of vaccines by regulatory authorities *(20)*.

2.2.4 Traceability of vaccines in the context of the COVID-19 pandemic

As vaccines for prevention of COVID-19 become available, they will be distributed in exceptional circumstances, for example label and leaflet information, specifically expiration dates, may need to be updated after products have been released to national markets. Two-dimensional (2D) bar codes are already included on the secondary packaging of vaccines and medicines in many markets to facilitate traceability, and WHO recommends that this use case be applied for COVID-19 vaccines. Attempting to extend traceability technology to the vial level would only be optional (and to support well-planned operational research), if it does not compromise statutory information on the vial label. A WHO working position on labelling requirements of COVID-19 vaccines will be released separately.

For further reading please see the 21st WHO Regulatory update on COVID-19 published on 30 October 2020 and its Annex 1 for the WHO working position on bar codes, QR codes and vaccine vial monitors *(21)*.

Note: Since March 2020, WHO publishes regulatory updates on COVID-19 vaccines on a regular basis. These updates are prepared for NRAs, regional pharmaceutical advisors, regulatory networks and associated stakeholders to provide timely information around the development and regulatory approval of COVID-19 related diagnostics, treatments and vaccines. The regulatory updates on COVID-19 are accessible here *(21)*.

3. Planning and coordination

KEY MESSAGES

- Countries should use or adapt existing managerial and governance frameworks to oversee the planning, coordination and implementation of COVID-19 vaccination activities.
- Countries may establish a national coordinating committee (NCC) with multisectoral representation.
- Countries' national immunization technical advisory groups (NITAG) should provide evidence-based recommendations and policy guidance specifically related to COVID-19 vaccines, to facilitate fully informed decision-making by the government.
- Countries will need to establish a reporting and management structure to ensure smooth deployment, implementation and monitoring of COVID-19 vaccines. This structure should be coordinated by the incident management team and aligned with the COVID-19 strategic preparedness and response plan.

3.1 Objectives of this chapter

→ Advise countries on COVID-19 vaccine coordination mechanism to manage deployment and vaccination operations at all levels.

3.2 Establish or adapt a COVID–19 vaccine deployment and vaccination coordination mechanism

Introducing and deploying COVID-19 vaccines will require key national decisions to be made both prior to, and during, vaccine deployment. Ensuring a robust, accountable and transparent decision-making structure and process at country level is essential to protect national interests and to assure the public that deployment of the COVID-19 vaccine in the country is based on epidemiological need, assessed through rigorous scientific review and respects population safety.

WHO recommends that countries aim to use existing coordination mechanisms as much as possible that are fully integrated into the country's COVID-19 response structures. Countries may establish a COVID-19 national coordinating committee (NCC) for the successful planning, coordination and implementation of activities, which can be adapted from an existing oversight and management senior-level coordinating mechanism for the overall health sector. The coordination mechanism, or NCC, should be presided over by senior-level officials from the MoH, and have a multisectoral representation composed of senior-level officials from relevant ministries (e.g. social welfare, pension service, women's affairs, communications, finance, transport etc.), external partners, representatives from private sector providers and civil society organizations, with decision-making authority.

Some proposed responsibilities of the NCC include:

- reviewing global-level information related to COVID-19 vaccines and incorporating it into the planning and preparation for COVID-19 vaccine deployment at country level;
- considering the recommendation issued by the national immunization technical advisory group (NITAG) or the specific national COVID-19 vaccine technical advisory group;
- defining the deployment plan with clear functions, responsibilities and deadlines for different stakeholders. The plan needs to be aligned with the national COVID-19 preparedness and response plan, and include an estimate of costs to facilitate budget advocacy and resource allocation;
- establishing an operations process for coordination, information and communication;
- providing higher level authorities status reports as needed;
- communicating with partners and the media;
- ensuring integration with existing immunization programmes and coordination across programmes and different sectors embedding the vaccination programme into existing health system structures;
- coordinating and/or supporting the implementation of health services readiness and capacity assessments (at facility and community level) to identify bottlenecks and guide delivery of vaccines and other essential supplies; and
- monitoring progress using methods such as a dashboard with key indicators, readiness assessment tools, etc.

In some countries where, inter-agency coordinating committees (ICCs) exist, they play an important role in coordinating partner financing and activities, including the preparation of proposals for support for vaccine introductions and the subsequent roll-out and evaluation of the vaccine introduction.

It is essential that the individuals involved in the process of developing the NDVP understand their responsibilities, including the coordination structure under which they will function, to ensure the smooth deployment of the vaccine. The authorities and their management teams should include representatives from the MoH at the national, state/provincial and district/local levels, as well as appropriate representatives from other government offices, immunization partners, non-governmental organizations (NGOs), civil society and the private sector.

3.3 Activate the national immunization technical advisory group

Ideally, countries should already have a well-established and fully functional (NITAG) in place *(22)*. NITAGs are multidisciplinary groups of national experts responsible for providing independent, evidence-informed advice to policy-makers and programme managers on policy issues related to immunization and vaccines *(23)*. NITAGs should be able to review and contextualize the policy guidance issued by SAGE and the regional immunization technical advisory group (RITAG), taking into account country-specific data, national priorities and disease epidemiology. NITAGs should refine, revise and update their recommendations to national policy-makers regularly as new evidence becomes available. Most NITAGs were set up to make recommendations for childhood vaccinations. Given the nature of the pandemic and the different target groups, there may be a need for participation from additional experts, e.g. relevant health and social care worker associations such as medical or nursing academies/associations, geriatric medicine associations, where they exist, and occupational health associations, etc.

The chair, or core members, of the NITAG should be invited to participate in the national coordination mechanism to ensure adequate information flow between the planning, policy and implementation levels.

The NITAG, in its evidence-based, independent, advisory role, will provide transparency and credibility to the decision-making process and contribute to building public confidence in the vaccination programme. Some proposed responsibilities of the NITAG include:

- Reviewing recommendations from SAGE, the RITAG and/or other NITAGs.
- Periodic reviewing of country relevant data on the national/regional epidemiology and sero-epidemiology of COVID-19, including laboratory confirmed cases, hospitalization and deaths associated with COVID-19 and data on natural immunity.
- Advising the MoH on priority groups and vaccination strategies based on the evidence collected and available global and regional guidance, i.e. values framework.
- Updating the advice, and, in particular, issue vaccine-specific recommendations, as new information comes in on:
  - the characteristics of COVID-19 vaccines under development, including efficacy, immunogenicity and safety in different age and risk groups, effect of the vaccine on acquisition and transmission of infection, available supply of vaccine and vaccine supply forecasts, etc.;
  - COVID-19 vaccine-specific recommendations from SAGE and RITAGs; and
  - changes in the landscape of non-pharmacological interventions, COVID-19 diagnosis and treatment.
- Advising the MoH and the NIP manager on the best communication approaches regarding COVID-19 vaccine introduction, taking into account vaccine characteristics and public acceptance dynamics.

If the country does not have a NITAG, it should consider the establishment of a COVID-19 vaccine-specific technical advisory group to provide independent, evidence-based advice to the policy-makers, similar to the NITAG.

3.4 Establish a chain of reporting and management structure

Effective deployment of vaccines and vaccination will depend on the management of the planned activities and processes and the ability of the managers to make rapid decisions at all levels. See Fig. 3.1 for a graphic representation of how this could look at country level and may be adapted, as deemed appropriate in the country.

In addition, structures and processes to support decision-making should include individuals or designated offices that exist within the country, e.g. communicable disease, Expanded Programme on Immunization, cold chain and logistics: an incident manager (IM); a focal point for logistics (FPL); and a focal point for vaccination (FPV), who should be embedded in the national coordination mechanism. Table 3.1 shows the responsibilities of these focal points. Furthermore, each of these focal points or designated offices may appoint a technical working group either under them or for the six areas of work (planning and management, supply chain management, training and supervision, demand, vaccine safety, monitoring and evaluation) at all levels to support operations at all levels.

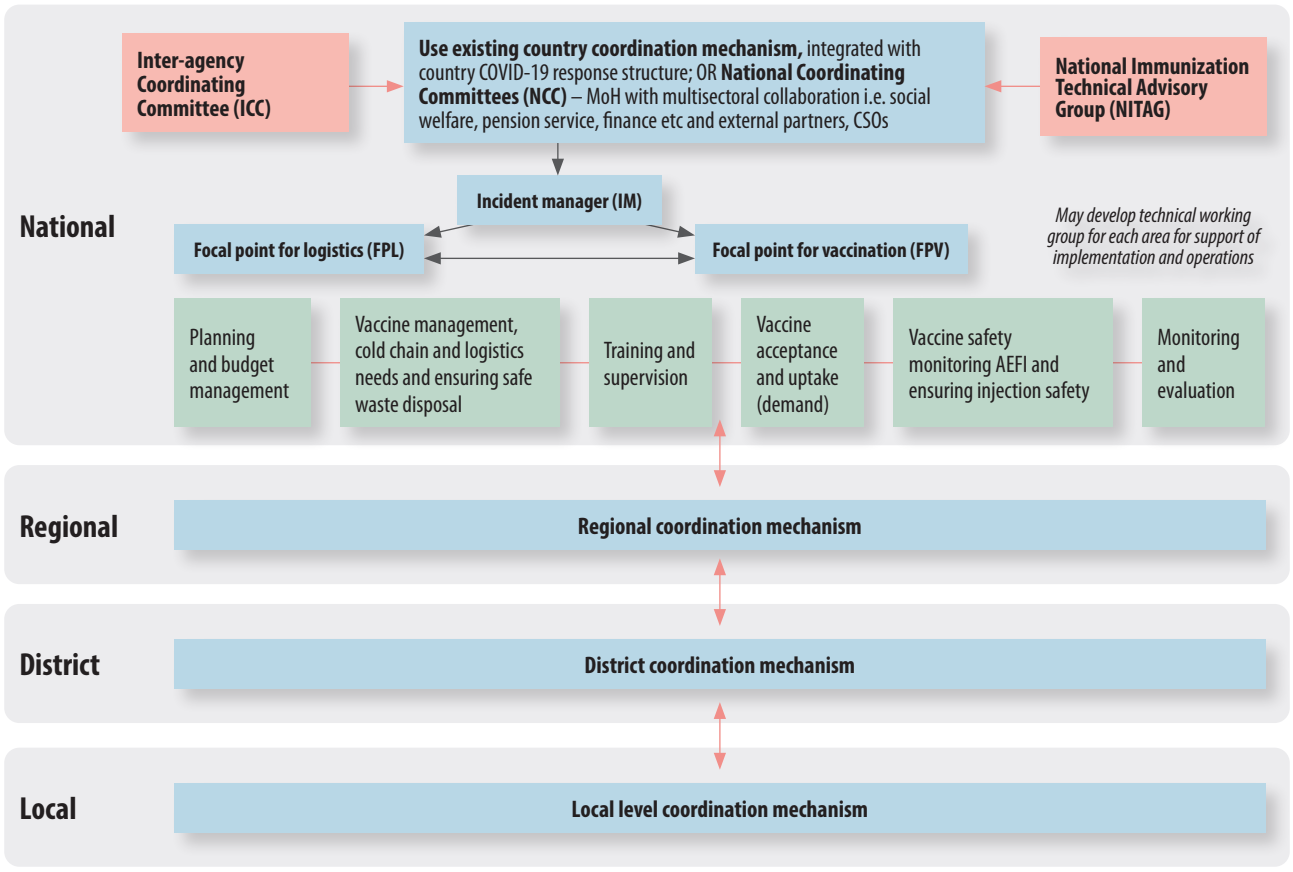


Fig. 3.1 Reporting and managing activities in support of vaccine deployment

Table 3.1 Chain of reporting and protocols for management structure

Offices	Reporting and control protocol (regional and district levels)
Incident manager (IM)	• Responsible for managing a country's overall pandemic response in coordination with the incident management team and emergencies collaboration. • Delegates responsibilities for deployment of vaccine and vaccination to the FPL and FPV. • In collaboration with the FPL and FPV, drafts the final report and outcomes on the deployment and vaccination activities.
Focal point for logistics (FPL)	• Responsible for deployment component of the NDVP. • Collects and organizes contact information for members of deployment committees, other key authorities and prepares a duty roster. • Proposes execution schedule covering shipments of vaccine and the mode of transport of each shipment. • Oversees process for forecasting, vaccine reception, storage, transport distribution and waste management. • Establishes processes for data collection, analysis, visualization and communication using management information systems, inventory management system and health facility service capacity assessments. • Drafts a standard format for information to be collected by each level. • Establishes process for monitoring and evaluating deployment activities.
Focal point for vaccination (FPV)	• Responsible for the vaccination component of the NDVP. • Collects and organizes contact information for members of deployment committees, other key authorities and prepares a duty roster. • Establishes processes for providing public information. • Establishes processes for data collection and information to display using a management information system. • Establishes a process for carrying out post-deployment surveillance and management of AEFI, monitoring and evaluating vaccination activities.

4. Costing and funding: ensuring funds reach the point of delivery

KEY MESSAGES

- Resources will be the core of the effort to deploy and use COVID-19 vaccines and should be estimated within available general government and MoH resources (domestic and external resources).
- As economic repercussions of COVID-19 impact government budgets, it is important that the COVID-19 vaccine strategy is an integral part of the general government response and reflected in budgets. It is also essential that the budget for COVID-19 vaccines does not replace budgets for other essential health services including the routine immunization budget.
- Financing arrangements for responding to short-term needs related to COVID-19 vaccination should minimize fragmentation within existing health financing arrangements and support strengthening of the foundations for longer term immunization strategies.
- Plans and related budgets will have to consider improvements and investments in the overall enabling environment (beyond direct service delivery considerations) to ensure implementation is well-coordinated, safe and efficient. Each component and stage of COVID-19 deployment and vaccination requires specific budget inputs and health systems adjustments.
- Leverage the COVID-19 national coordination mechanism to facilitate dialogue and alignment with the budget and planning departments of the MoH, MoF and the funding partners.

4.1 Objectives of this chapter

→ Provide guidance to countries to prepare a realistic budget to enable COVID-19 vaccine deployment and vaccination in respect of existing essential health services.

4.2 Identify budget inputs and the responsible budgetary units

Preparing national budgetary and financial management processes to ensure COVID-19 vaccine delivery requires multiple actions. Each activity specified in the deployment plan should be costed, leveraging the existing health system to maximize efficient spending. The careful budgeting of the plan is essential to secure funds for timely disbursement and delivery. Identifying entities or budget holders assigned the responsibility for overseeing, directly implementing or contracting out for the delivery of each function prepares for effective budgeting and subsequent implementation monitoring.

The budget planning and considerations should align and bear in mind the different phases of vaccine allocation to the country and identified target population, and be led by national health experts or NITAGs in wide consultation with stakeholders. The short-term budget should consider the initial allocation that covers the first 3% of the national population (health workers) and the next 17% of the population (older people and those with underlying health conditions). The medium-term budget should consider the incremental shipments to cover beyond the initial 20% (the additional priority populations). The 36-month budgetary horizon is practical as it is compliant with ministry of finance (MoF) medium-term budgetary and expenditure exercises. The budget proposals should be scenario-based and aligned with the strategies outlined in the plan.

A full list of necessary budgetary inputs over short and medium terms for COVID-19 vaccination, with some falling under the direct mandate of the immunization programmes, and others expected from the health system, could be prepared. This will help prepare a budget for immunization inputs and a budget for associated health systems improvements – the latter needing to be checked as available or planned by the planning department and communicated to the MoH planning department.

The process for identifying the "budget holder" (MoH, the national public health institute(s), the national centres for disease control, emergency response authorities, national guard/defence, health facilities and subnational government agencies) helps subsequently ensure investments are channelled smartly in a well-coordinated manner between fund holders and implementors. The mapping exercise helps identify the responsible budgetary units to be funded (including both central and subnational levels of government as relevant).

The health budget guidance note being prepared under the ACT-A Health Systems Connector provides more detailed guidance on the kinds of analyses needed at country level to ensure readiness.

4.3 Estimate funding needs (costing)

The NDVP needs to be costed to inform what additional resources are required to implement the plan, with a costing of COVID-19 vaccine-specific interventions and a costing of shared costs with existing health system delivery mechanisms (e.g. PPE for health workers will serve more than immunization activities). It is therefore recommended that the MoH work with the health planning department while costing the deployment plan. This coordination can help to identify existing health system functions (i.e. supply

chains, facilities, health workers, data systems, other inputs) that can be leveraged to deploy COVID-19 vaccination. Planning departments can facilitate this collaboration as a way to efficiently use system-wide resources and to minimize undue verticality.

Given the rapidly evolving environment, it is recommended that the plan and its costing be developed for a relatively short period (2 to 3 years possibly); to be revised annually in alignment with standard budgeting processes using the latest updates on vaccines and recommended strategies. It is important to evaluate immediate needs and short-term needs that will sustain, and position them within longer term investment frameworks. Part of the budget will need to be sustainably funded over the longer term and these budget items need to be identified. For example, when budgeting for training, short-term training can focus on COVID-19 vaccine deployment, which should then be gradually done in conjunction with the national immunization strategy and the health system strategic plan. This coordination can make sure training efforts mutually benefit from system strengthening and system financing. Similarly, handwashing stations may start as a short-term need for COVID-19 vaccination but should quickly be planned and budgeted as part of essential health services. This mechanism to assess costing, budgets and funding in collaboration with the rest of the system will support resource mobilization efforts; create opportunities for cross-programmatic efficiency; and ensure sustainable resources and effective investments.

The costing of delivery strategies (outreach, fixed site delivery, campaign or accelerated approaches) will each have different types of cost requirements.

4.4 Assess and align costed plan within available resources

The objective of budgeting is to have a ballpark figure of the additional cost on top of current routine immunization and health system spending, which respects the MoF's fiscal reality, and which is matched with available resources. The estimated cost of the existing routine immunization and health system costs that will be used for COVID-19 vaccine deployment should be included in the budget and provided by the MoH's planning department. The MoF will provide the resource envelope within which to cost the delivery of COVID-19 vaccines. Contacting the MoF is even more important in the current economic environment, where health resources are at risk of declining due to reduced general government revenues and increased socioeconomic costs. It is essential to support health system financing and efforts by the MoH to maintain the level of its budget.

Ultimately, the costing exercise will need to be mapped with mobilized resources: domestic resources from the MoF – COVID-19 response plan, MoH; and external funding from bilateral partners and multilateral agencies with Gavi, the World Bank Fast Track COVID Facility, and other multilateral development banks or international financing institutions. The roll-out of COVID-19 vaccines will only happen if resources have been estimated and mobilized appropriately. A tool will be made available to support countries to cost and track available resources.

It is important to plan and budget COVID-19 vaccine introduction while maintaining the budget for ongoing immunization activities (i.e. routine immunization under COVID-19). The estimated cost should include additional costs specific to COVID-19 vaccines, as well as an approximate estimate of ongoing routine immunization and health system costs that will be used for the deployment. This overall view is necessary for budget negotiations as it will bring a realistic ask to the negotiating table. The immunization programme working hand in hand with the MoH budget focal point and the MoF is critical for the symmetricity of information across all three parties. Another key aspect for consideration is the formulation of the supplementary budgetary envelope for immunization within existing budget classifications and structures. Where programme-based budgets are in place, it is recommended to add the additional

provisions to the existing programme structure, at subprogramme and activity level. This approach will facilitate integration in delivery systems and facilitate expenditure tracking, with minor adjustments to existing financial information systems (e.g. adding immunization expenditure-related codes to financial management information systems).

4.5 Assess need for changes in budgetary and public financial management processes

Historically, weaknesses and rigidities in public financing management (PFM) systems have constrained the effective planning and use of public funds in the health sector, often arising from rigid budget structures that in turn pose obstacles to spending. For example, when budgets are presented and disbursed by detailed line-items (e.g. for drugs, medical equipment, staff), they do not allow flexibility in terms of re-allocations across budget lines as needs evolve, and create complexities and inefficiencies in budget implementation by health service managers. In addition, PFM bottlenecks in many countries result in late transfers of funds, including for salaries, and low budget execution. Unless these bottlenecks are addressed, activities that are essential for vaccination will be at risk.

While COVID-19 vaccine deployment planning and budgeting cannot address these issues, it is nevertheless an opportunity to understand them and raise them with the MoH planning department, budget department and MoF. To make funding effective and contribute to the efficient delivery of the core activities needed for vaccination, many governments will need to adjust their budget structures and address other PFM bottlenecks that impede the flow of funds and the effectiveness of reporting at provider level. Some examples of the questions and related work needed to ensure budgetary/PFM readiness at country level are:

- **PFM bottleneck assessment:** Are fund holders able to effectively receive, manage and account for public resources to serve preparedness functions? If not, at which levels are the major bottlenecks (e.g. complex approval system, delays in disbursements, funds release by inputs)? How to address them to enable effective implementation, including in decentralized contexts?
- **Accountability and reporting for outputs:** Is the MoF implementing output-oriented budgeting including in the health sector? Are accountability mechanisms output-oriented? If not, how can performance monitoring frameworks be introduced to support effective monitoring of results, including for preparedness?

Potential areas of needed PFM change identified by this process could include conditional grants, improved fiscal accountability, expenditure tracking and frontline health worker fiscal decentralization.

5. Identification of target populations

KEY MESSAGES

- Countries are advised to base their decision-making on identification of target populations (e.g. health workers, older people and those with underlying health conditions) on the following resources:
  – The WHO SAGE values framework;
  – The WHO SAGE prioritization roadmap:
    - vaccine supply and availability
    - national context and epidemiologic setting.
  – The fair allocation mechanism for COVID-19 vaccines through the COVAX Facility.
- The decision-making process for identifying target populations should be led at country level by the NITAG or technical advisory groups, in wide consultation with stakeholders.
- It is important for countries to obtain accurate estimates of relevant target populations to facilitate allocation of resources, vaccine procurement, deployment planning and to measure vaccination coverage achievements.
  – Estimating relevant target populations is a complex and urgent activity in preparation for COVID-19 vaccine introduction and national planners will need to work with their national bureau of statistics to obtain these estimates.
- Striving for equity in vaccine access should be a guiding principle for all countries to adequately protect groups experiencing greater burden from COVID-19 disease.

5.1 Objectives of this chapter

➔ Provide guidance to countries to define their target populations and ensure equity in vaccine access.

5.2 Global allocation of COVID-19 vaccines

Built on the WHO Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility *(10)*, COVID-19 vaccine allocation is planned in two phases.

Phase 1: Allocated proportionally to all participating countries:

- Initially cover 3% of the national population. It is anticipated that this initial allocation will be for **health workers**.[1] By choosing to set a 3% benchmark, WHO wants to ensure that volumes meet the needs of well-resourced health systems while not penalizing countries with a lower proportion of health workers. If health workers make up less than 3% of the national population, additional doses can be used for the next priority group within the country.
- Incremental shipments to reach a further 17% of a country's population will follow. It is anticipated that this will likely be for **older people and individuals with underlying health conditions**.

Phase 2: Countries will receive doses to vaccinate populations beyond the initial 20% included in the first phase. Consideration may be given to a country's risk in establishing the pace at which it would receive additional volume of vaccines.

In addition, there should be plans for a "humanitarian buffer" to be made available to ensure that sufficient supplies of vaccine are available to attend to and manage humanitarian situations, deployments and other emergency related situations. This is envisaged to serve vulnerable populations, e.g. refugees and asylum seekers, and those dedicated to relieving their suffering.

5.3 Define and identify target populations

It is preferable that countries follow SAGE's policy recommendations and use available doses for target groups defined by SAGE, but national contexts and characteristics may be taken into consideration for the use of a vaccine within each country. The WHO Secretariat recognizes the right of each country to decide how the vaccine will be used within their territory, but it encourages countries to consider these recommendations and to be transparent about their decision-making processes and ultimate use of the vaccine. Countries will need to develop clear communication strategies explaining the selection of the priority groups and why certain groups are not receiving the vaccine.

The WHO SAGE values framework lists over 20 subgroup populations that, if prioritized, would advance one or more of the principles and objectives identified within the framework. Each country will need to consider the six guiding principles: **human well-being, global equity, reciprocity, equal respect, national equity and legitimacy,** to determine who should be allocated vaccines, and when. Following guidance on the SAGE prioritization roadmap and with the country-specific nuances in epidemiological

[1] Health workers are all people engaged in work actions whose primary intent is to improve health. This includes health service providers, such as doctors, nurses, midwives, public health professionals, technicians (laboratory, health, medical and non-medical), personal care workers, community health workers, healers and practitioners of traditional medicine. It also includes health management and support workers, such as cleaners, drivers, hospital administrators, district health managers and social workers, and other occupational groups in health-related activities. This group includes those who work in acute care facilities and in long-term care, public health, community-based care, social care and home care and other occupations in the health and social work sectors as defined by the International Standard Industrial Classification of All Economic Activities (ISIC), revision 4, section Q: Human health and social work activities (https://www.who.int/whr/2006/06_chap1_en.pdf?ua=1#:~:text=Health%20workers%20are%20people%20whose,up%20the%20global%20health%20workforce).

settings and different levels of vaccine availability, these priority groups will need to be further interpreted at a national level. This process should be led by national health experts or NITAGs in wide consultation with stakeholders.

In Phase 1, countries are advised to define their health workers, including in the private sector, who are at higher risk of COVID-19 infection than the general population due to the nature of their work, and more likely to be affected by COVID-19. Moreover, health workers infected with COVID-19 may contribute to health care-associated infection transmission of infection to their patients and people they care for, including those at high risk for developing severe COVID-19 disease and complications.

To ensure targeted use of COVID-19 vaccination of health workers in different settings (e.g. hospitals, long-term care facilities) *(24)* and to address potential uptake issues, national policies for health worker vaccination should outline: the classification of different health worker categories based on assessment of risk; the policy for vaccination for each category; and strategies for managing non-compliance of health workers.

In the latter part of Phase 1 countries are advised to define their older people by age-based risk specific to the country/region (specific age cut-off to be decided at the country level) and those with underlying health conditions who are at higher risk of serious health outcomes and mortality due to COVID-19.

5.4 Estimate size of targeted populations

Immunization programmes use population estimates to facilitate planning and vaccine procurement, as well as to measure coverage – the outcome of vaccination efforts. Existing vaccines have mostly well-defined targets, e.g. infants below the age of 1 year or girls under 15 years. COVID-19 vaccines, on the other hand, will target the global population but prioritize at-risk groups, and there will be an interest in monitoring progress in these groups separately. It is therefore important to obtain national estimates of the size of each of the following populations for the country, by any relevant administrative division such as states, provinces and districts (see Table 5.1).

5.5 Assure equity in distribution

The guiding principle of **global equity** is to ensure that all countries have fair access to vaccines, and to ensure that vaccine allocation takes into account the special epidemic risks and needs of all countries, particularly for low- and middle-income countries (LMICs). Although countries bear the primary responsibility for protecting and promoting the well-being and human rights of those living within their borders it is important that this national concern does not absolve nation states of obligations to people in other countries. The global community also has an obligation to address the human rights claim to vaccines of people living in countries who cannot, without assistance, meet their needs by, for example, reducing the obstacles to obtaining vaccines that confront countries with fewer resources and less geopolitical power. SARS-CoV-2 transmission knows no borders: as long as there is active transmission anywhere there will be a risk of transmission everywhere. The global community has to work together to contain the global pandemic. The recovery of national economies also depends on securing stable global supply chains and global markets and regularizing international travel, which will not be possible until the pandemic is contained globally. Hence the equitable allocation of vaccines globally is in the enlightened self-interest of all countries.

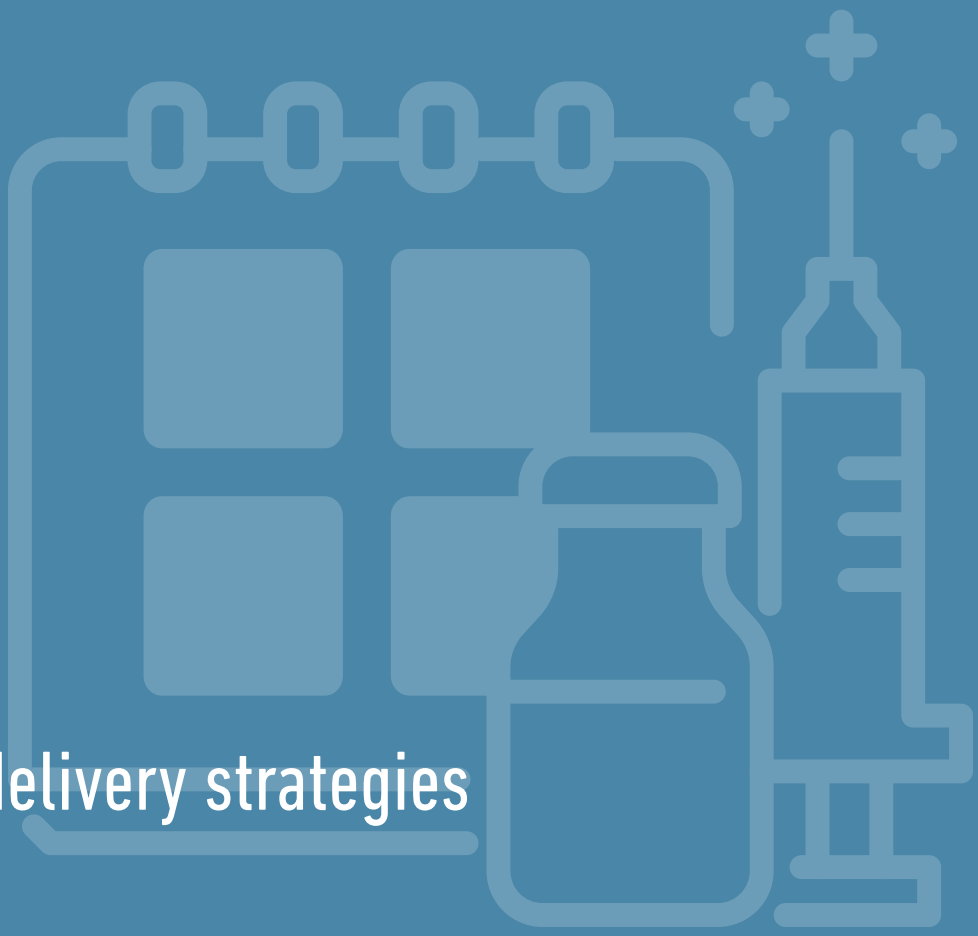
Table 5.1 Target population estimates

Target population	Definitions	Estimate size
Health workers (25)	All people engaged in actions whose primary intent is to enhance health (see footnote Section 5.2) For further clarification on defining health workers by risk groups (see interim guidance forthcoming from WHO and the International Labour Organization).	Might be available at national bureau of statistics, health worker registries, NGO registration bureaus. A global level estimate for the number of health workers is 3%, but large differences exist between countries. Countries should plan an enumeration exercise, for example, through the drafting of "beneficiary lists" at district level ahead of introduction.
Older people	Defined by age-based risk; will vary by country/region. Specific age interval to be decided at the country level by national health experts/NITAGs based on differential mortality by age.	Should be readily available at the national bureau of statistics *(26, 27)*.
Persons with underlying health conditions	Determined to be at significantly higher risk of severe disease or death (in countries where the relevant comorbidities can be equitably assessed across the population).	For those in long-term care facilities *(27)*. Some countries may have health surveys to inform these estimates *(28)*, but estimating these populations will be a complicated process. Additionally, countries should attempt to minimize double counting of patients, e.g. an older individual who has cancer in order to reduce the risk of overestimating the population.
Other targets groups: essential workers, social employment groups unable to social distance, age groups of high risk to transmit disease, border protection staff, travellers	Definition/characteristics to be decided at the country level by national health experts/NITAGs.	Data sources vary from census data to demographic and health household surveys. Some possible ways to estimate other groups include: • Essential workers: once defined in countries, estimates might be available from relevant administrations, (education, defence etc.). • Social employment groups unable to social distance: also would need to be defined; some estimates along broad occupational groups like hospitality may be available from national bureau of statistics. Estimates for specific groups like sex workers might also be available in surveys and studies. • Age groups at high risk of transmitting disease: age group estimates are readily available from national bureau of statistics. • Border protection staff: probably part of essential workers.

The guiding principle of **national equity** is to ensure that there is equitable access to vaccines, and that groups at increased risk of COVID-19, due to underlying societal, geographic or biomedical factors, benefit from vaccination.

Although everyone is affected by the COVID-19 pandemic, its impact is not shared equally. Some groups are experiencing serious illness and death at higher rates specifically associated with biological factors, e.g. those who are older or have underlying health conditions. Other groups are experiencing disproportionately greater health and other burdens because of societal factors, e.g. limitations of people living in poverty to practise physical distancing and experiencing barriers to accessing quality health care. Systemic disadvantage associated with racism and among other disadvantaged and marginalized groups, is also associated with disproportionate pandemic burden.

Promoting equity at national level requires addressing higher rates of COVID-19 related severe illness and mortality among such systematically disadvantaged or marginalized groups. Examples of specific considerations include but are not limited to gender, race, socioeconomic status, residents in long-term care facilities, those living in informal settlements or urban slums, sexual minorities, people living with disabilities, low-income migrant workers, refugees, internally displaced or nomadic persons, homeless persons, asylum seekers, marginalized ethnic groups, populations in conflict settings or those affected by humanitarian emergencies, and other hard-to-reach population groups. Countries will need to develop immunization delivery systems and the required infrastructure to ensure equitable access to COVID-19 vaccines for these vulnerable populations.



6. Vaccination delivery strategies

KEY MESSAGES

- National strategies for COVID-19 vaccination delivery will need to be tailored based on the vaccine characteristics, the risk-benefit assessment for different population groups, the amount and pace of vaccine supply, and be in line with countries' specific health systems and context.
- The final national vaccination strategy will be defined by the characteristics of vaccine products as they become available.
- Countries will need to collaborate with programmes and different sectors to leverage existing service delivery structures, and/or, for countries establishing a new delivery platform, consider scaling up other platforms delivering health services throughout the life course, to offer vaccination with COVID-19 vaccines.
- NIPs in countries will need to devise non-traditional and perhaps novel immunization strategies for reaching priority target populations.
- Countries will need to plan for, resource and implement infection prevention and control (IPC) and environmental measures when providing vaccination, including the use of PPE by health workers.

6.1 Objectives of this chapter

→ Provide countries with examples of strategies that can be used to deliver COVID-19 vaccine to different target populations.

6.2 Vaccination strategies

6.2.1 Define recommended immunization schedule

The precise details on the vaccine schedule and recommendations for administration will be defined once a COVID-19 vaccine product is registered for use.

6.2.2 Outline potential vaccine delivery strategies

The potential strategies used to deliver a vaccine will depend on the vaccine properties, vaccine availability and characteristics of the target population. Recognizing that few countries have adult immunization programmes, such as a seasonal influenza vaccine programme, innovation will be required to reach health workers and older adults *(29)*. Countries establishing a new delivery platform for COVID-19 vaccines will need to consider scaling up influenza vaccine delivery and/or other platforms delivering health services throughout the life course to use for administering COVID-19 vaccines. As discussed in Section 1.6, this will require collaboration across programmes, i.e. PHC, noncommunicable diseases; the overall health service delivery platforms within the health system; and across different sectors, e.g. finance, social welfare, pension service, education, transport, energy, in order to seek leverage on the vaccination strategies in the country.

Applicability of other vaccination experiences, such as hepatitis B vaccination for health workers, Ebola Virus Disease ring vaccination (i.e. identification of contacts and contacts of contacts), can be explored by countries for potential learning *(30)*. Countries may use fixed site settings close to the target population, to reduce travel time, minimize costs and consider logistics. Planning for target groups and the general public can include surveys, focus groups, community meetings and so forth to gather preferences on vaccine strategy and sites to maximize uptake.

Tools such as CAPACITI[1] are available to assist countries in deciding between strategies to determine the best one for their context *(31)*. In line with the recommendations for the target groups, potential delivery strategies and sites are shown in Table 6.1. Countries should have a robust vaccine safety monitoring and AEFI system in place. More detailed guidance for operational planning will be made available when vaccine-specific recommendations become available.

[1] https://decidehealth.world/index.php/en/capaciti

Table 6.1 Potential target groups and vaccination strategies

Target groups	Potential delivery strategy	Potential vaccination sites
Health workers	• Fixed sites	Primary health care facilities, hospitals, long-term care facilities, private clinics
Older people	• Fixed and outreach sites • Temporary/mobile clinics • Mass campaigns	Primary health care facilities, long-term care facilities, day care centres, community care centres, pharmacies, mobile teams for home visit and other public and private establishments, marketplace, parks, drive-through
Persons with underlying medical conditions	• Fixed sites and outreach sites • Temporary/mobile clinics	Primary health care facilities, outpatient clinics, hospitals, long-term care facilities, at workplaces, through mobile teams for those with underlying medical conditions confined at home, other public and private establishments
Other targets groups: essential workers, social employment groups unable to social distance, age groups of high risk to transmit disease, border protection staff, travellers	• Fixed site and outreach sites • Temporary/mobile clinics • Mass campaigns	Any of above plus special strategies, e.g. insecure areas (access negotiation, transit points vaccination teams), workplaces

6.2.3 Enforce infection prevention and control (IPC) measures

WHO recommends that IPC programmes should be in place at national and health care facility levels and should include an IPC focal point at each facility. Managers of immunization centres need to ensure adequate access to IPC supplies and equipment, e.g. PPE, masks, alcohol rub or handwashing stations with soap and clean water, to enable health workers to adhere to IPC measures during outreach activities. These preventative measures, intended for the health workforce, would include appropriate hand hygiene (handwashing or use of hand sanitizer), appropriate use of masks, ensuring there is no shared equipment or that adequate cleaning is occurring between recipients, and that the immunization centres are restricted to essential personnel and recipients.

Immunization activities should be undertaken in a clean and hygienic environment that facilitates practices related to the prevention and control of infections. This includes ensuring adequate physical distancing during immunization sessions and in waiting areas; this may be done by limiting the size of sessions and using open spaces where feasible, and changing the existing environment to allow for this.

Immunization sessions, irrespective of the vaccination strategies used, will need to adhere rigorously to best practices for IPC, both to protect health workers (against communicable diseases through needlestick injuries, or close contact), protecting the receivers of the vaccines, and their families and community around them against COVID-19. Most of the initial vaccine delivery scenarios prioritize vaccination for target populations who are at highest risk for COVID-19, therefore it is particularly important to be attentive with IPC precautions in order to avoid having the vaccination events inadvertently become transmission events for high-risk populations.

IPC programmes involve training in IPC measures, including standard precautions and risk assessments, knowing when and how to use PPE, and understanding modes of transmission of disease, including the COVID-19 virus. Where possible, the use of reusable PPE should be considered, as the potential waste

generated could overwhelm many existing facilities that are already struggling to safely manage and treat waste. Adhering to IPC would ensure the prevention of infections for health workers, the recipients of the vaccine and the community. However, it can also change the cost of conducting immunization outreach sessions considerably *(32)*. The IPC health care facility response assessment tool can help countries identify, prioritize and address the gaps in IPC capacity at health facility level.[1]

Further information on IPC measures as recommended by WHO can be found here: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications; https://www.who.int/infection-prevention/publications/core-components/en/

6.2.4 Integrate COVID–19 vaccination with other health interventions across the life course

COVID-19 vaccines will provide countries with opportunities to extend immunization services across the life course, and potentially improve integration of immunization with other health services. Therefore, in advance of a COVID-19 vaccine becoming available, countries should engage in multisectoral collaborations in an effort to provide comprehensive disease prevention approaches.

Integrated approaches can more comprehensively address populations' health needs, make efficient use of resources and improve collaboration between programmes, potentially leading to increased demand for services, which in turn can reduce morbidity and mortality. Depending on country policies, COVID-19 vaccination can be incorporated into other preventive care services, for example, for health workers and adults using platforms used for influenza vaccine programmes (including monitoring) for older people, as a part of their PHC visits, basic health check-up and community health campaigns; and for those with underlying conditions, COVID-19 vaccination can be added as a part of disease-specific follow up. The development of "delivery platforms" across the life course for immunization and other services, provides opportunities to integrate new vaccines and additional interventions more easily in the future *(33)*.

[1] https://www.who.int/teams/integrated-health-services/monitoring-health-services

7. Preparation of supply chain and management of health care waste

KEY MESSAGES

- Supply chain readiness is key to efficiently deploying COVID-19 vaccines to the target populations in line with defined vaccination strategies.
- Due to potential variations in storage temperature requirements of the different COVID-19 vaccine products, countries will need to compile information on the available cold chain capacity, including surge capacity from other government agencies and the private sector, to develop the vaccine deployment strategy and to mobilize resources to fill the gaps.
- Countries that will receive COVID-19 vaccine requiring ultra-cold storage (UCC) temperatures (e.g. -70 °C) are encouraged to explore practical solutions, such as commissioning logistic service providers to deploy the UCC equipment and facilitate vaccine transportation and reverse logistics.
- The first batches of COVID-19 vaccine supply may be limited, with a short shelf life and may not have vaccine vial monitors.
- A strengthened supply chain information system on stock management and distribution will be needed that includes monitoring and reporting of vaccine utilization and wastage rates to the COVAX Facility to guide appropriate allocation of subsequent supply.
- In addition to a robust mechanism to track COVID-19 vaccine distribution from the national store down to the service points to avoid risk of diversion and falsification, countries will need to ensure the security and safety of the vaccine storage facilities, preserve vaccine safety and integrity during transport, and the safety of all staff responsible for managing the supply and implementing the vaccination.

7.1 Objectives of this chapter

➔ Advise countries on the critical supply chain activities required to prepare for vaccine deployment and manage health care waste, and introduce countries to the tools and resources available.

7.2 Prepare supply chain for vaccine deployment

An effectively managed supply chain is crucial to the successful deployment of COVID-19 vaccines. Based on the current information shared by the manufacturers, it is assumed that most vaccines will be stored at +2 °C to +8 °C, with exceptions that some vaccines that would require ultra-cold chain (UCC) equipment (-70 °C) and either frozen phase change material (PCM)[1] or dry ice in lieu of traditional cold packs during transport. Prior to vaccine introduction, countries need to conduct careful assessments of the existing supply chain system to be able to identify and address gaps, such as in storage, distribution, temperature monitoring and tracking, tracing and reporting vaccine stocks. Where countries are unable to support all the additional capacity requirements, contracting private sector resources may be considered to address the capacity shortfall. Outsourcing of storage and transportation could also be a more efficient and cost-effective solution since the workload is transferred to supply chain experts with experience in managing lean and agile systems. If outsourcing is used as a solution, strict, independent monitoring procedures will be needed to guarantee vaccine quality, and the private sector companies should be involved in the planning phase for vaccine deployment.

Some vaccines are also being developed to become heat stable so that they could be administered under a controlled temperature chain (CTC), but it is uncertain if these vaccines will become part of the initial vaccine allocation. Once these vaccines are available, they will be managed and distributed according to the manufacturers' instructions and corresponding CTC guidance.

Key elements to ensure successful COVID-19 deployment operations are:

- coordinated deployment plan and standard operating procedures (SOPs) communicated to all levels of the supply chain managers;
- adequately trained, and sufficient quantity of supply chain and health staff;
- sufficient cold chain capacity, including surge capacity, and capacity for ongoing maintenance;
- efficient supply chain system and infrastructure;
- data recording and reporting mechanism for vaccines and cold chain equipment;
- robust oversight and data-driven management, including systems for monitoring adherence to cold chain practices; and
- secured resources from both internal and external sources.

The ACT-Accelerator collaboration is developing country guidance on supply, distribution and logistics, which will provide detailed guidance to support countries in preparing their supply chain for COVID-19 vaccine deployment, including practical options to address capacity gaps at different levels of the supply chain and safely manage health care waste. The document will specify the key supply chain activities to be implemented before, during and after the vaccine deployment period, including options for deploying cold chain equipment to guarantee sufficient capacity nationwide, and considering the different deployment scenarios based on the vaccine availability, target groups and vaccination strategy.

[1] Phase change materials (PCMs): a material, other than water, which changes state between solid and liquid or changes between two different solid crystallization states over a defined temperature range, absorbing or releasing heat during the phase change. This process is reversible and can be useful for thermal control in cold chain devices and products.

7.3 Strengthen supply chain human resource capacity

Managing the vaccine and other supplies to ensure successful and timely deployment is a complex task. All staff responsible for storing, handling, transporting and tracking the movement of the vaccines need to be properly briefed on the deployment plan and trained on the relevant guidelines, SOPs, including on IPC and proper management of PCM required for managing UCC equipment, prior to vaccine arrival. Tools for assessing human resource capacity for managing the supply chain can help identify gaps and ensure enough capacity is available to effectively carry out the deployment operations.

7.4 Assess vaccine, logistics and cold chain capacity needs

The global supply of vaccine will be limited, especially in the initial stages of vaccine deployment, and this may result in a number of shipments of small amounts of vaccine over time. Countries' deployment strategies should include conducting an urgent assessment (or re-assessment) of existing cold chain and supply chain capacity, and of available surge capacity, to ensure quality vaccine can be equitably delivered to the service points in the right place, at the right time and in the right quantity. Mapping of cold and dry storage facilities, including potential sources of additional capacity from private sector sources, estimating the relevant costs, and facilitating rental agreements, should be done in advance and any gaps should be addressed prior to vaccine arrival in country.

The following are pre-requisites to the development of appropriate deployment strategies:

- **Forecasting vaccine and logistics needs:** The Immunization Supply Chain Sizing Tool provides information on equipment, supply and budget requirements needed to support deployment and vaccination operations based on the size of the population to be vaccinated (see Section 4.3).
- **Assessing available storage capacity:** The Cold Chain Equipment Inventory and Gap Analysis Tool is useful in assessing vaccine volumes and corresponding cold chain capacity per catchment area.
- **Identifying surge capacity:** Assess and map available cold chain capacities according to the three temperature ranges (e.g. +2 °C to +8 °C, -20 °C, and -70 °C) for storing the different types of COVID-19 vaccines under development. Include all available cold chain equipment outside the immunization programme (e.g. pharmaceutical division, national reference laboratories, and private and business sectors) in the inventory and calculation of capacity.
- **Preparing a distribution plan:** Prepare a distribution plan for vaccines and ancillary supplies (such as syringes, safety boxes, vaccine carriers, cooling packs, markers, data collection forms, AEFI response kits and IPC/PPE) based on the target population and number of staff that will comprise the vaccination and monitoring teams (e.g. vaccinators, recorders, social mobilizers, supervisors and monitors).
- **Reinforcing supply and stock management:** Initially, the COVID-19 vaccine supply will be scarce, with short shelf life, and may not have VVM. Therefore, the monitoring and recording of cold chain equipment temperature, vaccines distribution, inventory and stock management, wastage rates should be done rigorously and efficiently throughout the supply chain.
- **Establishing a vaccine traceability system:** Establish a robust mechanism to ensure the traceability of the COVID-19 vaccines to avoid a risk of diversion and falsification of the vaccines.
- **Planning for the security of vaccines and concerned staff:** In the context of high demand but limited stocks, clear security arrangements must be in place to ensure the safety and integrity of COVID-19 vaccines and ancillary products throughout the supply chain. Develop a plan to safeguard the security of all concerned staff and all vaccine storage facilities, including during transit.

The tools have been updated to include items relevant to COVID-19. Supply chain managers are encouraged to familiarize themselves with the tools for scenario analysis and microplanning in order to be able to simulate the impact on human resources, logistics and budgets *(34)*. If capacity is inadequate, countries should consider practical options to address capacity gaps at the different levels of the supply chain. Countries are encouraged to be as thorough as possible in documenting the information collected. Countries eligible for partner support will need to submit this information as part of their application for vaccine allocation and support for deployment. Countries are encouraged to regularly check for the latest information about the vaccine that will be made available to them, and to revisit and adjust their plan accordingly.

7.5 Ensure supply chain system functionality

In any public health emergency such as COVID-19, countries should strive for a lean supply chain, distributing vaccines as quickly as possible to vaccination sites. This may include bypassing regional or district storage locations and holding very limited stock at a time, or more frequent delivery of vaccines to the storage points/sites.

In the context of COVID-19 vaccine deployment, the following will facilitate supply chain efficiency:

- staff are trained and can demonstrate ability to perform tasks according to standard protocols;
- policies, guidelines and SOPs are clearly written, updated based on vaccine profiles, and disseminated to concerned parties through a variety of channels, including mobile communication;
- operational tools, including those required for recording, reporting and monitoring are available and accessible;
- warehousing infrastructure is designed to ensure safe and smooth operations (receiving, storing, repacking, transporting and monitoring) during handling of vaccine and logistics;
- the cold chain inventory is updated, storage and transport capacity are adequate, equipment is functional and maintained, and systematic temperature monitoring is in place;
- sustained power supply, including backup generators, are available in the facilities;
- security measures are in place to prevent theft of vaccine during storage and transport;
- communication channels are clearly defined, including reporting requirements for issues needing urgent attention;
- a robust information management system, e.g. LMIS, is operational, and data are available to those in need;
- contingency and maintenance plans are clearly written and communicated to the responsible personnel;
- the operational budget is sufficient, secured and made available to supply chain or facility managers in good time;
- the role of the private sector is well documented, and oversight is provided to ensure adherence to standard operating procedures; and
- supply chain activities foster innovation and partnership.

7.6 Manage and track vaccines effectively

Given the COVID-19 pandemic context, some vaccines may not be prequalified at the time of the initial vaccine in-country delivery. They will be used under WHO's Emergency Use Listing (EUL) procedures *(14, 15, 35)*. It is possible that some vaccine profile characteristics, such as the VVM type and expiration date, will not be established by the time they are labelled for use. Most vaccines may come with date

of manufacture in lieu of the expiry date. Therefore, strict compliance with the standard protocols for storage, handling, supply distribution, transportation and logistics procedures and practices is critical throughout the deployment period. Countries should develop plans to ensure clear communication of these protocols and the distinction of the COVID-19 vaccine from previous antigens (e.g. manufacturers' date in lieu of expiry date, and guidance on management) to all relevant stakeholders to ensure that they are upheld across the supply chain. Proper recording and reporting of vaccine batches/lots will also be important for AEFI monitoring, batch/lot recall in case of serious AEFI, etc.

COVID-19 vaccines may come with a barcode and/or QR code attached on the secondary and tertiary packaging containers. The barcode facilitates efficient tracking of the vaccine and reduces the risk of falsified vaccine entering the supply chain. Some vaccine profile information, such as heat stability and shelf life, will be shared when it becomes available. The QR code may be used to rapidly inform countries and health workers on any new information. Countries should consider this possibility when developing guidance, conducting training, and strengthening their supply chain information management systems.

Where feasible, steps should be taken to improve the supply chain management system to facilitate track-and-trace capability and a plan to ensure security and authenticity of supply is critical. The WHO guidance on traceability contains information on the key considerations when establishing a traceability system for health products *(36)*.

Countries are will need to carefully monitor usage and wastage rates to report to the COVAX Facility, and to guide forecasting for the successive phases of the deployment and future management of COVID-19 vaccination.

7.7 Prepare for COVID-19 vaccine requiring ultra-cold chain (UCC) storage temperature

Countries receiving vaccine requiring UCC (-70 °C) should adjust their plan to ensure vaccine is safely stored, transported and managed up to the service points. To determine readiness to accept the vaccine requiring UCC, countries should demonstrate the following are in place prior to vaccine arrival:

- ☐ carefully mapped cold chain capacities (e.g. identified from both public and private sectors) both for vaccine storage and for dry ice production;
- ☐ UCC hub(s) established strategically at national level (if applicable, include subnational UCC hubs) according to the carefully planned vaccination strategies to reach the target groups – include plan for repositioning hubs as needed;
- ☐ installation of reliable continuous temperature monitoring system, especially in outsourced cold chain equipment;
- ☐ availability of appropriate technical support for installation and management of UCC equipment energy stations;
- ☐ availability of robust and sustained power supply and stand by generators in facilities housing UCC equipment;
- ☐ availability of specialized containers for transport such as Arktek+PCM[1] or dry ice and dry ice boxes;
- ☐ clear guidelines and SOPs on the use and maintenance of UCC, including deployment and re-positioning of UCC equipment and management of PCM;

[1] A modified version of the Arktek Passive Vaccine Storage Device uses PCMs rather than ice to maintain a cold environment; only device capable of keeping Ebola vaccines at -80 °C without power in remote areas for up to 6 days (https://www.intellectualventures.com/buzz/insights/ivs-global-good-fund-a-legacy-of-impact-invention).

- a communicated, disseminated and tested contingency plan; and
- all responsible personnel are trained and demonstrate ability to manage UCC according to SOPs and provided with appropriate PPE (e.g. cryogenic gloves)

COVID-19 vaccines with UCC (-70 °C) profile would pose several challenges for many LMICs, such as:

- lack of existing UCC equipment, including PCM and facilities to produce dry ice, within the health/immunization systems;
- huge investment cost considering the time-limited nature of the need for UCC capacity – many countries would seek to transition towards vaccines that can be stored at +2 °C to +8 °C; and
- complicated handling and distribution requirements, particularly where UCC products have limited stability (e.g. < 7 days) when stored at +2 °C to +8 °C.

Given these challenges, countries that would need UCC should explore practical solutions, such as utilizing established internal and/or external resources. One alternative is commissioning logistics service providers that can deploy the required UCC storage capacity and transportation, including facilitation of reverse logistics. In this case, the plan for UCC and vaccine deployment should be done jointly to ensure quality supplies reach the service points on time and in the right quantity. Before making this decision, countries should carefully weigh their options vis-à-vis the capacity of a third party to deliver within a short lead time (ideally < 3–4 months) versus the timeframe when more manageable vaccine products (e.g. vaccine that can be stored at +2 °C to +8 °C) can be made available. There could be other alternatives and in the context of COVID-19, the cost-competitive option is one that can demonstrate strong responsiveness to government's accountability and service delivery needs.

7.8 Manage reverse logistics

A strategy and SOPs for managing reverse logistics should be developed. In the context of COVID-19 vaccine, reverse logistics refers to the process of retrieving unused vaccine either to reallocate, to recall, or to dispose of. Since most vaccines will neither have VVM nor expiry date, any unused vials at the end of the campaign must be returned to the higher store level for proper management. It is critical to ensure all vaccine vials are duly accounted in all vaccine stores and service points.

7.9 Manage health care waste

Management of waste related to COVID-19 vaccination requires special attention, due to the infectious nature of the virus *(37–39)*. Proper waste management procedures are critical for the safety of health workers and the community *(40)*. Furthermore, if COVID-19 vaccines are delivered in a mass vaccination campaign strategy, the generation of health care waste will be amplified, due to the mandatory use of disposable and reusable materials and hazardous wastes, such as PPE, used by the vaccination teams.

To minimize risk to the communities, each vaccination team should practise on-site waste segregation and implement reverse logistics, where health care waste is taken back to the facility by the vaccination team to be disposed of properly along with other hazardous wastes.

A costed waste management plan must be developed with budget for training and employment of waste handlers, provision of waste containers and treatment technologies, and possible outsourcing to the private sector services for waste treatment and disposal. Countries should ensure that safe and

effective methods, including waste segregation, to manage and dispose of waste are in place prior to vaccine deployment. The WHO/UNICEF Water, sanitation, hygiene and waste for SARs-CoV2 guidance note provides a short description of key wastes measures for COVID-19 *(38)*.The waste management system should prioritize the use of best available technologies in accordance with the Stockholm Convention when possible *(41)*. WHO documents, Management of waste from injection activities at district level: a guide for district health managers *(42)* and Overview of technologies for treatment of infectious and sharp waste *(37)* provide tools needed to manage the treatment and disposal of used injection equipment. The UNICEF document, Appropriate disposal of immunization waste platform *(43)*, offers practical guidance to help districts or regions to cluster sites where the waste is generated with appropriate treatment and safe final disposal sites. The United Nations Environment Programme also published a report providing practical information, suggestions and guidelines on health care waste management given the restrictions and limitations imposed by the ongoing pandemic, including lack of human resources, technologies, equipment and funds *(44)*.

8. Human resource management and training

KEY MESSAGES

- Having sufficient human resources and equipping them with the right knowledge, skills and attitudes is an essential part of the introduction of COVID-19 vaccine.
- Even though several unknowns persist, countries can already identify their human resource needs, prepare a training plan, decide on their training modalities, and plan for supportive supervision.
- COVID-19 vaccine implementation can provide an opportunity to build on or scale-up innovative systems, such as digital tools, for training and supportive supervision.
- Intensified supportive supervisory visits are recommended for approximately the first 2 months following vaccine introduction.

8.1 Objectives of this chapter

➔ Advise countries on the steps involved in preparing a plan to adequately address the human resource requirements, including training and supervision, for the successful roll-out of COVID-19 vaccine.

8.2 Identify human resources needs

The successful introduction of COVID-19 vaccines requires having sufficient staff and providing them with high-quality training and performance support. The current pandemic has put a strain on the health workforce at large, therefore it is important to identify, and plan, needs and surge/redeployment strategies in a holistic manner, i.e. factoring in the entire health workforce needs including the prevention, diagnosis, treatment and care of COVID-19 patients, as well as maintenance of other essential health services.

COVID-19 vaccination may present several new challenges, including more complex handling and storage requirements, more complicated immunization schedules and the targeting of ages outside the routine immunization system. Planners must evaluate if the current immunization workforce will be sufficient in number to deliver the vaccines in line with the vaccination strategy or strategies agreed upon, or if additional staff need to be recruited or deployed from other departments within and outside of the health sector to the immunization programme. If surge staff are needed, planners need to decide what occupational groups can give vaccines. In some contexts, it may be necessary to consider a more diverse mix of skills, including associate health professionals, e.g. community/associate nurses, community health workers, pharma assistants, etc. It is also important to ensure there is sufficient capacity in the other occupational groups responsible for different aspects of vaccine delivery, such as community mobilizers, supply chain management personnel, etc.

Health workers recruited may require additional training and complementary performance support, including supervision and incentives if they do not have experience in vaccine delivery.

8.3 Design and plan trainings

The introduction of the COVID-19 vaccine will affect almost every aspect of the immunization system. Fortunately, many of the tasks are the same as with the introduction of any other new vaccine. At the same time, the presence of COVID-19 disease in the community means that traditional methods of training will not be appropriate.

A comprehensive curriculum with training materials addressing all aspects of COVID-19 vaccination will be available from WHO in two modalities: instructor-led and online learning. There are several steps that can be taken now to ensure that when the COVID-19 vaccine is available, relevant staff can be rapidly trained to implement vaccination.

To begin preparing their vaccinator workforce, countries can:

- ☐ designate a focal point responsible to coordinate with stakeholders for planning training and supervision at different levels;
- ☐ conduct a training needs assessment and identify the job categories that need to be trained, including not only vaccinators, but also individuals responsible for promoting the vaccine and clinical waste handlers;
- ☐ define the key competencies required by each category of personnel in order to deploy COVID-19 vaccine safely and correctly;

- determine the training modality for each job category;
- review available training materials at global level and determine adaptations needed, including translation; and
- identify the partners within and outside of the MoH, e.g. ministry of education, national training institutions such as nursing schools, and those at subnational, district and community level, that would help with training development and delivery.

8.4 Decide on training methods

Online, in-person and blended learning (combination of online and in-person) are the most common methods used to train staff. Due to travel limitations, and to respect current public health and social measures, many countries that used in-person training previously are now switching to online learning. Other considerations include staff experience and motivation with online learning, as well as support mechanisms available for trouble-shooting technical problems.

As countries determine the training modalities they will use, it is useful for them to consider the relative advantages of each modality. Annex 3 will assist with this decision-making. Additionally, countries could assess the training that has been conducted for health workers during the pandemic to support the design of their COVID-19 vaccine deployment training.

An alternative for staff that do not have access to online learning is in-person training of smaller groups using proper public health and social measures.

To maintain high-quality training for in-person training, countries should:

- limit the number of levels through which the training is rolled out, i.e. during cascade training, from national level to regional/provincial level, to district level, etc.;
- ensure the safety and health of staff being trained by equipping the facilities where trainings are held to enable hand hygiene and ability for staff to social distance;
- schedule the training in close coordination with the COVID-19 vaccine introduction – ideally no more than 2 or 3 weeks prior to the COVID-19 vaccine launch;
- consider ways to ensure that health workers being trained on general population vaccination have already received their COVID-19 immunization prior to training and vaccination activities;
- follow the training with supportive supervision to ensure that health workers correctly apply the new skills and procedures;
- use best practices of adult learning methods to ensure key points are understood and applied correctly in the job. These include small group discussions, demonstrations and skills practices;
- use mobile phone apps or text messages to share short videos or infographics to enhance learning; and
- involve experts from training institutes, universities, training units of the MoH and higher education as well as from other institutions to assist in designing and conducting training that uses effective teaching methods based on adult learning principles.

Procedures and mechanisms to monitor the quality of the training, especially at the service delivery levels, will need to be established. Administering pre- and post- knowledge, attitudes and practices (KAP) tests at all trainings is one commonly used method to do this. For particularly complex topics such as screening or data recording, the use of short videos can help ensure that the quality of the content is maintained across different levels of training.

8.5 Enhance supportive supervision

While existing supportive supervision activities can be used effectively to monitor the introduction of COVID-19 vaccine, intensified supportive supervisory visits are recommended for the first 2 months or so following the COVID-19 vaccine introduction. In addition, new supportive supervision instruments that specifically address the competencies required for the correct use of COVID-19 vaccine will need to be developed. Supportive supervision has been shown in several countries to significantly improve health worker performance and motivation. Supervisors can play an important role in the training process, including ensuring health workers have access to online learning materials, clarifying key points from online learning, developing and encouraging the use of job aids and other performance support tools, and conducting on-the-job training sessions for health workers. Countries are highly encouraged to identify indicators to assess the performance of health workers over time.

If supportive supervision is not currently being practised, or is conducted irregularly, the introduction of COVID-19 vaccine can provide an opportunity to establish such a system (refer to the Training for mid-level managers [MLM] module on supportive supervision) and to use innovative approaches such as digital tools for supportive supervision and self-assessment, as well as monitoring dashboards *(45)*. For the additional vehicles, electronic devices, training of supervisors, per diems for visits and transportation expenses that will be required, countries should look at harnessing existing capacity where possible, and ensuring that provision for these is included in the NDVP and budget.

8.6 Access key resources from WHO and other partners

WHO, in collaboration with immunization partners, will provide the following COVID-19 vaccine training materials for national and subnational level staff as well as for health workers:

- tools to quantify health worker requirements for vaccination;
- an online learning package, in the six official WHO languages, will be made available for online training of health workers and national focal points to prepare for COVID-19 vaccine introduction;
- materials for conducting classroom and blended learning activities such as slides, videos, etc.; and
- performance support materials such as job aids, checklists and summarized reference materials that can be used for post-training reference and support.

It important for countries to be ready to translate and adapt these global materials into the appropriate local languages and cultural contexts, if needed. A dedicated COVID-19 vaccine implementation site is planned that will include all training resources.

8.7 Prepare for unique scenarios

Additional specialized training may be needed if the COVID-19 vaccine product(s) require UCC, can be used in a CTC or use a novel delivery strategy. As more information becomes available on the vaccine product(s), WHO and global partners will prepare materials for these additional training needs as needed.

9. Vaccine acceptance and uptake (demand)

KEY MESSAGES

- Introducing any new vaccine – especially with new target populations, through potentially new delivery strategies – is challenging. Ensuring acceptance and uptake of COVID-19 vaccination at country level presents a unique set of difficulties but is key to successful reduction of transmission and containment of the pandemic.
- To ensure acceptance and uptake of COVID-19 vaccination countries will need to adopt an integrated approach that:
  - starts with listening to and understanding target populations, to generate behavioural and social data on the drivers of uptake and to design targeted strategies to respond;
  - builds a supportive and transparent information environment, and addresses misinformation through social listening and assessments that inform digital engagement initiatives;
  - builds trust and acceptance of the vaccines through engagement of communities by civil society organizations, particularly for vulnerable target populations;
  - provides health workers with the requisite knowledge of COVID-19 vaccines as first adopters, trusted influencers and vaccinators, giving them the skills to communicate effectively and persuasively with target populations and communities; and
  - prepares countries to respond to any reports of AEFI and have planning in place to mitigate any resulting crises of confidence.
- Striving for equity in vaccine access should be a guiding principle for all countries to adequately protect groups experiencing greater burden from COVID-19 disease.

9.1 Objectives of this chapter

- ➔ Advise countries on how to develop evidence-based demand planning for vaccine introduction.
- ➔ Support a data-driven approach to planning, implementing and evaluating demand strategies.
- ➔ Guide strategic communications activities that promote COVID-19 vaccination and manage expectations.
- ➔ Highlight how building trust and managing misinformation is key to achieving acceptance and uptake of COVID-19 vaccines.

This section covers the full range of strategies that are required to contribute to achieving high acceptance and uptake of COVID-19 vaccines. This includes communications, risk communications, community engagement, digital listening and the delivery of quality vaccination services. Local behavioural and social data should be used to inform the design and evaluation of targeted strategies. Aligning or integrating this work with similar existing vaccination uptake activities may offer broader benefits and facilitate efficient implementation.

To support implementation of these activities, any additional and specialized expertise in strategic communications and the behavioural and social sciences may be identified in dedicated agencies, research groups or in academia.

9.2 Initiate demand planning

The four strategic elements outlined in this chapter (Section 9.4) provide an overall framework for action, but success will depend on them being translated into time-bound operational plans. This in turn will require:

Securing high-level political support: Experience of the pandemic to date has shown the dangers of incoherent and sometimes conflicting and inaccurate messages. Planning without adequate buy-in from all stakeholders risks failure and wasted effort. It is essential to conduct national-level advocacy meetings with parliamentarians, medical and nursing associations, civil society networks, existing community engagement networks, relevant ministries, religious bodies/leaders, NGOs and donors to engage and involve various groups in planning and implementation, with particular emphasis on engaging local communities and acknowledging their voices at a national level.

Such engagement and involvement will create an enabling environment for vaccine introduction and for leveraging commitment and resources. Countries may want to commence now by mapping at all levels – community through to national – which key stakeholders have been critical champions or sceptics in the past and consider how they might be engaged. Some countries have found success with engaging with non-traditional stakeholders early and including them in the planning and trainings to gain their understanding and support for the vaccine.

Clarity, quality and dissemination: Plans only work if they are clear and accepted by those responsible for their implementation – avoiding overlap, duplication of effort and turf battles. Health systems are awash with advice from different sources of information on COVID-19; ensuring that the materials developed to increase demand are of the highest quality is critical. Plans should be informed by local data and outline tailored strategies, segmented per audience and per area of activity. Acceptance and uptake of vaccination can be supported through multiple types of activities, not only through the use of multiple communication

channels, including social and traditional media and two-way interpersonal communications essential for responding to concerns and broader community engagement.

Capacity building: Most countries already conduct the activities outlined in this chapter in some form but there are new aspects specifically related to COVID-19 vaccine. Countries should identify capacity building needs early in the process and ensure that they are fully integrated into training curricula for frontline health workers, social workers and community influencers and mobilizers. In addition to core skills and competencies associated with the role and responsibilities of each function, staff may also be trained in rapid data collection and use at a community level.

Use of data for planning, monitoring and evaluation: Demand planning needs to be informed by data on the full range of behavioural and social drivers of uptake. Data should be used to inform the selection, design and targeting of strategies and, furthermore, can guide the selection of measures that can also be used for tracking trends and assessing outcomes. A monitoring framework is an essential part of any demand plan, and measures established in early assessments should inform development of a framework for the monitoring and evaluation of the plan. Regular assessments of behavioural and social drivers, in accordance with the monitoring framework, will then guide any adjustments to strategies – to be responsive to any changes in the programme, the information environment, or in any other areas that may impact vaccination acceptance and uptake.

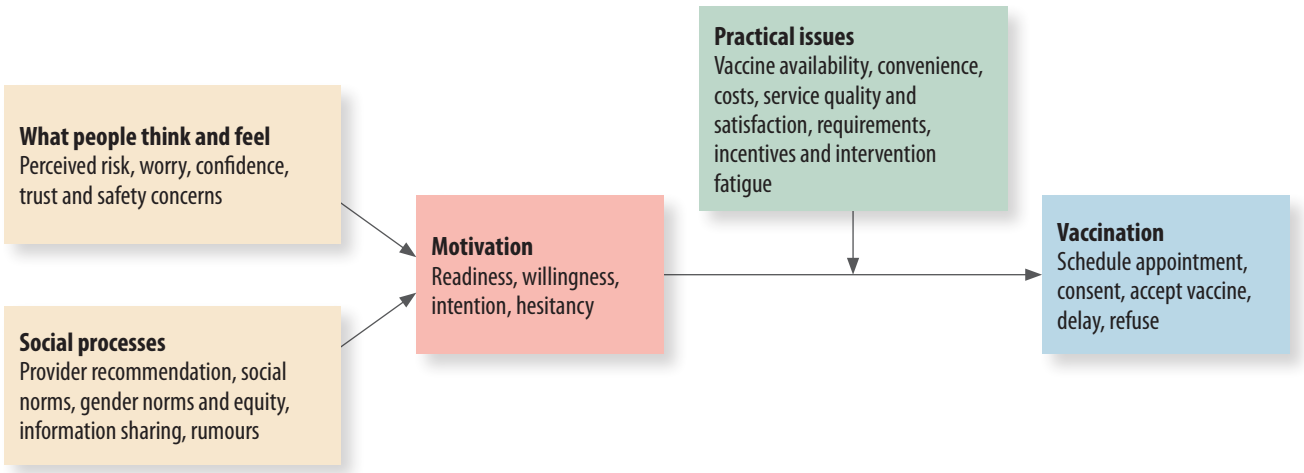
Integration with broader technical plans: For communication and community engagement activities to build demand successfully, they should be integrated in broader technical plans from the beginning, including needs assessment and microplanning. This will be important to build consensus and buy-in from key stakeholders, and to ensure rapid and effective crisis communications and rumour management. Demand work cannot operate as a separate pillar and therefore these connections should be identified and strengthened from the outset.

9.3 Understand and act on the drivers of vaccine acceptance and uptake

The drivers of vaccination are complex, context-specific and change over time. Regular and timely data collection, analysis and use of data on the behavioural and social drivers of vaccination uptake will inform evidence-based planning and contribute to the monitoring and evaluation of interventions. Such a systematic approach to planning will also offer insights that can potentially mitigate the negative effects of any service disruptions, system shocks and vaccine-related events.

In the context of COVID-19 vaccines, the gathering, analysis and use of behavioural and social data aims to understand the characteristics of priority target groups and related influences.

When carrying out surveys, assessments or other rapid data collection activities to understand the drivers of vaccination, it will be important to account for: what people think and feel about vaccines; the social processes that drive or inhibit vaccination; individual motivations (or hesitancy) to seek vaccination; and the practical factors that shape the seeking and experience of vaccination (outlined in the model of behavioural and social drivers) (see Fig. 9.1) *(46)*. Regular data gathering activities will be necessary as the introduction and roll-out of COVID-19 vaccines evolves and can also contribute more broadly to strategies to enhance uptake of all routine vaccines and the quality of PHC.



Source: The BeSD Expert Working Group. Based on: Brewer NT, Chapman GB, Rothman AJ, Leask J, Kempe A. Increasing vaccination: putting psychological science into action. Psychol Sci Public Interest. 2017;18(3):149-2017.

Fig. 9.1 Increasing vaccination model

9.4 Develop an integrated demand approach

The integrated approach for vaccination acceptance and uptake has four inter-related strategic elements:

1. Social listening, digital engagement and misinformation management

The novel SARS-Cov-2 virus has triggered rapid spread of misinformation – an "infodemic" – across social networks *(47)*. Vaccine-critical messaging has increased more than two-fold compared with pre-COVID-19 levels, with 4.5 billion views of content spreading vaccine misinformation in the United States alone between March and July 2020. The infodemic threatens to erode confidence in vaccination, which in turn could impact routine immunization programmes, complicate COVID-19 vaccine introduction and erode public trust in public health.

Management of vaccine misinformation at country level must be guided by an integrated strategy that links social listening and analysis with online and offline risk communication and community engagement. In addition to proactively sharing critical health information in a timely and accessible manner and tracking misinformation, a social listening strategy – starting soonest – should enable ongoing monitoring of vaccine-related conversations and identification of people's concerns. This should inform a range of strategies, e.g. advocacy campaigns, targeted communications, training and support for health workers to respond to questions, and interventions to share accurate information and "inoculate" audiences against misinformation.

2. Risk communication and community engagement

One of the most important lessons learned from past disease outbreaks is the central role of trust in enabling an effective outbreak response. First, risk communication and community engagement positions communities in an active role for the demand and acceptance of the COVID-19 vaccine by providing factual, timely and appropriately contextualized information about the COVID-19 vaccine. Second, community engagement is vital in any consideration of risk communication and positions communities as partners in the response by involving them in consultation and planning processes and providing mechanisms for feedback. Third, deployment of vaccines in a situation of limited supply creates the need for setting and gaining public acceptance for clear priorities.

Key considerations for supporting risk communication and community engagement activities to address vaccine hesitancy:

- listen to communities and gather social data to understand their concerns and beliefs, and address through timely and targeted communications and other strategies;
- use channels, including media and social media, to proactively share information about vaccination in general, the COVID-19 vaccine development process, key risks and challenges, to build public awareness of and trust in the development and roll-out process;
- through risk communications and community engagement, share information from trusted sources in local languages about eligibility and roll-out plans, details on populations that are initially prioritized for vaccination;
- partner with national and community civil society organizations, faith-based organizations, NGOs, etc., and include training of journalists as key advocates in the response;
- work with communities and religious and influential leaders, to dialogue and deliver messaging; community leaders can also be empowered with access to more detailed information on the vaccines and roll-out plans;
- engage local medical providers and ensure they support vaccination activities; and
- transparent and routine reporting on the progress and effectiveness of roll-out plans.

3. Empowering frontline health workers

Ensuring health workers have positive experiences as early beneficiaries of COVID-19 vaccine is essential, given their influential role as vaccinators, advocates and change agents in the community, including communication skills training to support them in dealing with rumours, misinformation, and vaccine hesitancy. As the first vaccine recipients and as vaccinators, health workers must be equipped with the technical capacity and confidence to deliver the vaccines and communicate and engage with the community. Health workers require capacity building in advance of the vaccine roll-out. They will need decision-making and job aids to support them in prioritizing eligible vaccine recipients, and tailored messaging to reach diverse community contexts. Building skills in listening, interpersonal communications and community dialogue will help to equip them to hold difficult conversations both in the face of demand from those not eligible to receive the vaccine in the first phases, and those who are hesitant about receiving the vaccine. Listening and collating early experiences, concerns, successes, etc. from health workers will help inform ongoing vaccine delivery.

Key objectives are to educate health workers on the COVID-19 vaccine; increase health worker uptake and satisfaction with the vaccine as early, priority recipients; and improve health workers' ability to communicate and engage with priority groups and caregivers and endorse COVID-19 vaccination.

Guiding principles and high-level actions to be taken at national and subnational levels to support health worker capacity to increase COVID-19 vaccine demand and uptake:

- Demand activities should initially focus on health workers and other high-risk groups (e.g. older adults) that have been prioritized by the country.
- Health workers (in addition to community members) are susceptible to misinformation and vaccine hesitancy *(48)*.

4. Crisis communications

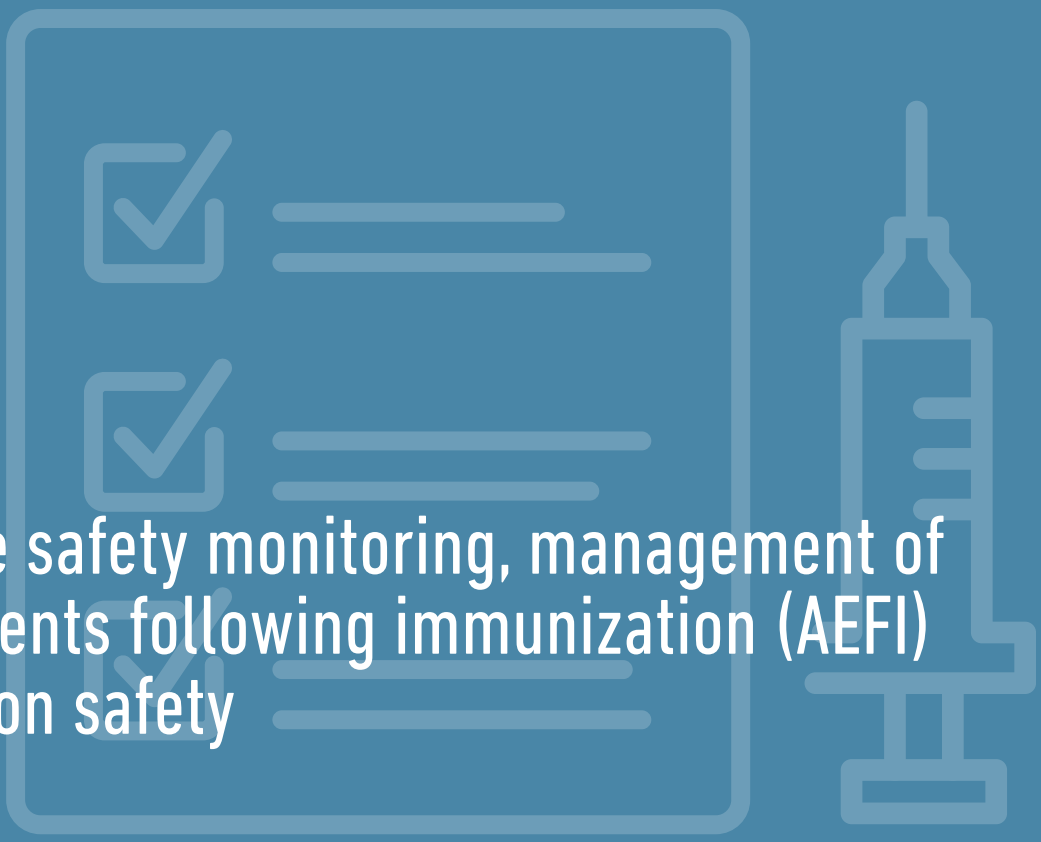
When a new vaccine is introduced, there will likely be public concerns regarding the safety of the vaccine and its possible side-effects. As a result, there may be negative rumours and sentiments about the vaccine, which could discourage some among the general public from being vaccinated. Effective community engagement and consultation in the early stages of planning will also help with mitigation of vaccine-related events.

Because of the scope of vaccination, adverse events are likely, whether related to the vaccine or not, and may be misattributed to the vaccine, suppressing vaccination uptake if not addressed swiftly and competently, with clear messages and actions. To prepare for this, regions and countries need to develop crisis communications plans that include actions to take before, during and after the crisis.

Crisis communication ensures that countries are prepared to respond first, fast and in a coordinated manner to any rumours and AEFI related to COVID-19 vaccination. Crisis communication management plans should be informed by social listening, community feedback and other relevant data and should be in place prior to deployment of the vaccine. Existing coordination mechanisms for planning and response to events should also be harnessed, so that in the case of an event, communications takes place rapidly, with transparency and empathy, and that there are not multiple conflicting voices.

A core team needs to be responsible for coordinating and managing crisis communication and for the following key functions:

- SOPs for managing crisis communication;
- development of content and guidance to detect and respond to rumours, misinformation and disinformation with a real-time rapid response, especially online;
- development and dissemination of key messages; ensuring that immunization programmes and stakeholders speak with one voice;
- training of media and spokespersons;
- social mobilization and communication activities; and
- communicating with affected population and other target audiences in case of AEFI.



10. Vaccine safety monitoring, management of adverse events following immunization (AEFI) and injection safety

KEY MESSAGES

- The vaccine safety monitoring of COVID-19 vaccines is unique and complex and requires specific attention by countries. COVID-19 vaccine development uses new technologies never previously licensed, against a novel target pathogen with many unknowns, in settings with varying capacities to identify, report, investigate, analyse, determine the cause of and respond to safety issues.
- Extraordinary national, regional and global efforts will be needed to ensure real-time monitoring, knowledge sharing and communication mechanisms are in place prior to COVID-19 vaccine introduction.
- The COVID-19 vaccines: safety surveillance manual in preparation for vaccine introduction developed by WHO, provides relevant preparedness guidance prior to, during and after COVID-19 vaccine introduction for global, regional and national staff of immunization programmes, regulatory authorities, partners and pharmacovigilance centres, as well as vaccine manufacturers and vaccine suppliers.
- In the context of the urgency and novelty of COVID-19 vaccination, countries will need to take additional steps to ensure injection safety. Providing training for vaccinators on the importance of injection safety at every step of the vaccination process will be key, as will ensuring adequate supplies of safe injection equipment.

10.1 Objectives of this chapter

- ➔ Explain the unique and different context in which vaccine pharmacovigilance will have to be implemented in the COVID-19 vaccine context.
- ➔ Highlight the need for countries to plan for adequate supplies to ensure injection safety.

10.2 Address vaccine safety and pharmacovigilance challenges

The global deployment and administration of many COVID-19 vaccines may involve multiple vaccine presentations, from different manufacturers, potentially being delivered through different vaccine delivery platforms simultaneously in a single country. As some of the potential vaccine products use new technologies never before licensed, against a novel target pathogen with many unknowns, in settings with varying capacities to identify, report, investigate, analyse, determine the cause of and respond to AEFI, the need to establish robust monitoring systems will be unprecedented.

This will require extraordinary national, regional and global efforts to ensure real-time monitoring, knowledge sharing and communication mechanisms to warrant that any safety concern can be identified early and investigated in a timely manner, safeguarding the health of target populations and, ultimately, maintain trust in the immunization programmes and the health systems.

10.3 Key vaccine pharmacovigilance considerations and the WHO COVID-19 vaccines safety surveillance manual

Fig. 10.1 AEFI surveillance cycle

The WHO, under the guidance of the Global Advisory Committee on Vaccine Safety, has developed the **COVID-19 vaccines safety surveillance manual** in preparation for vaccine introduction *(49)*. This document provides relevant preparedness guidance prior to, during and after COVID-19 vaccine introduction for global, regional and national staff of immunization programmes, regulatory authorities, partners, pharmacovigilance centres as well as vaccine manufacturers and vaccine suppliers. Guidance includes the specific approaches that countries must undertake to prepare for, and address, safety issues including the specific tools and methods to be used, and also the recommended forms and formats. It also outlines a pharmacovigilance preparedness checklist as part of the COVID-19 Vaccine Introduction Readiness Assessment Tool (VIRAT) and also describes the applicability of the Global Benchmarking Tool and the Vaccine Safety Blueprint 2.0 *(5)*.

The **COVID-19 vaccines safety surveillance manual** has been developed with separate modules addressing different vaccine safety and pharmacovigilance aspects. Each module is accompanied by

a slide set that could be used for training purposes. The brief synopsis below offers an overview of the overall contents; refer to the full manual for detailed information.

Vaccine safety monitoring will be a shared responsibility between the NIP, NRA and other stakeholders (e.g. disease surveillance). In addition to the general routine passive surveillance (spontaneous reporting) approaches of vaccine pharmacovigilance, in the COVID-19 context as a minimum, additional approaches should be considered by countries with mature pharmacovigilance systems during COVID-19 vaccine deployment. Vaccine pharmacovigilance systems should operate based on the types of vaccine platforms, different population profiles, different reports required, the need to anticipate new events, and addressing media concerns. Case-based AEFI reporting, with particular attention to the brand name of the vaccine and the manufacturer along with details such as batch numbers and documentation of dates, is important. These steps are necessary to gather more information on the safety of the vaccine in the field in addition to the information that is available in risk management plans (RMP) from the fast-track COVID-19 vaccine pre-licensure trials.

Prior to vaccine introduction, listing the various stakeholders, their roles and responsibilities in handling end-to-end COVID-19 vaccine safety issues will help to shorten the response time during a crisis and ensure that there is a harmonized approach to routine activities and managing a crisis and unexpected events.

For implementing RMPs, structures should be established, and strategies developed, including an oversight mechanism to ensure that the RMPs are in place and working. If needed, special studies and post-approval studies should be conducted. Manufacturers could be approached to provide guidance and support for such studies, and capacity building, as they will be best placed to have the necessary information on their products and their roll-out. Financing mechanisms for pharmacovigilance activities (training, reporting, investigation, data collection and transmission, causality assessment etc.) should be considered by the country during the planning stage and funds earmarked for this purpose. The involvement of the private sector and their roles in safety monitoring and reporting should also be established prior to vaccine roll-out.

The standard Council for International Organizations of Medical Sciences (CIOMS) WHO definitions for AEFI, including the cause-specific definitions and the practical implications of these, are identical for the COVID-19 context *(50)*. Unlike conventional vaccine pharmacovigilance systems, for COVID-19, it is important for countries to anticipate and prepare for adverse events of special interest (AESI). The AESI are a pre-defined list of AEFI that need to be specially evaluated given what is currently known about the safety risks of COVID-19 vaccines. Identification of background rates for such pre-defined events are important for AESI surveillance. This approach is novel to many immunization programmes and regulators. The operational and regulatory definitions for AESI have to be used in the local context and such events have to be confirmed through the Brighton Collaboration case definitions and followed up and evaluated by a group of experts.

Investigating serious AEFI and responding to AESI that are identified through different systems (passive and active surveillance) are essential, with important roles played by different stakeholders gathering key information during the process. Country capacities should be adequate and prepared for causality assessment for AEFI and specific specialized analyses for AESI. Feedback on findings of the investigation and causality assessment should be communicated to all stakeholders including the reporting health worker and the patient. Countries will need to use existing tools and adapt current global safety guidelines for both AEFI and AESI to the local context when responding to adverse events following COVID-19 vaccination. Maintaining quality surveillance in terms of timeliness and completeness for reporting, investigation, analyses and causality assessment is critical for decision-making and communication. There will be unique challenges when addressing deaths following COVID-19 vaccinations.

Countries should use recommended AEFI and AESI data collection tools and standardize the routing, timelines and activities to be done at various levels when processing the data and generating information for action. Electronic tools for data collection, collation, transmission and processing should be used whenever possible. For ensuring harmonization, identification of signals and rapid alerts, it is important to share national data in a standard database which can be accessed by relevant stakeholders such as the global database located in the WHO Programme for International Drug Monitoring *(51)*.

During COVID-19 vaccine introduction, there will be heightened public scrutiny on any adverse event that occurs. There will be a need to communicate better about "grey areas" and safety signals that get generated for which clear answers are not available yet. Communications approaches prepared beforehand should focus on what safety systems exist, what they do, and what their limitations are, so that when signals happen, communities will have been primed about how to interpret this information. Adequate priming is essential to building resilience against misinformation.

Communication is critical during COVID-19 vaccine introduction, keeping in mind the audience, the messages and the communication environment. Lack of timely information can have serious consequences on vaccine confidence, vaccine safety and risk communication. Health staff and other stakeholders should be trained in practical aspects such as addressing questions posed by the public, building trust, creating messages for communications, and addressing mainstream media and social media. It is important to learn from past experiences when safety communications went right or wrong to avoid making the same mistakes. The application of existing guidance from WHO – Vaccine safety events: managing the communications response – to the COVID-19 context can guide countries on the correct communication responses *(52)*.

10.4 Ensure safe vaccination delivery

In the COVID-19 context, the possibilities that newer vaccination technologies may be introduced combined with the need to vaccinate target populations that differ from those that immunization programmes are most familiar with, may further increase the risk of human error. Providing additional and refresher training for vaccinators on the importance of safe injection practices will be especially important to ensure vaccination safety.

Additional injections will also increase the quantities of safe injection supplies needed, such as auto-disable syringes and safety boxes. Budgeting for these additional supplies, including IPC measures, to ensure their timely availability is an important step in the planning process.

10.4.1 Safeguard injection safety

Injection safety is the safe handling of all injection equipment, routine monitoring of the availability and use of safe injection equipment, and correct disposal of contaminated injection equipment.

Sharps and, more specifically, needles are considered the most hazardous category of health care waste for health workers and the community at large if they are not properly handled and disposed of. Needle-stick injuries can easily occur and carry a high potential for infection, including hepatitis B and hepatitis C, human immunodeficiency virus and sepsis. To prevent risk of infection to the community and to health workers, the safe disposal of used needles and syringes is a critical component of any immunization programme. An adequate supply of safety boxes and their proper disposal must be assured. See Section 7.9 on managing health care waste.

Further details on injection safety are provided in the series Training for mid-level managers (MLM) module 3 on immunization safety *(53)* and in Immunization in Practice – a practical guide for health staff module 3 Ensuring safe injections *(54)*. WHO also provides an online training course on standard precautions for injection safety that could serve as a timely refresher for those administering injections in the context of COVID-19 *(55)*.

In addition to the traditional injection safety recommendations, in the context of COVID-19, vaccinators should perform hand hygiene after each recipient with soap and water or hand sanitizer containing 60–80% alcohol to prevent the spread of COVID-19.

11. Immunization monitoring systems

KEY MESSAGES

- There will be a strong and urgent demand for data on COVID-19 vaccination by in-country and international stakeholders. Countries should anticipate their data needs and strengthen information systems to be able to provide fast, frequent and accurate reporting.
- Obtaining estimates for each target population to be able to measure equitable coverage across different target populations is an important, complex and urgent activity that is required to prepare for COVID-19 vaccine introduction. National planners will need to work with their national bureau of statistics to obtain these estimates.
- Digital systems can help with several monitoring aspects: ideally, countries can use existing platforms and tools, but in some cases COVID-19 vaccine introduction may serve as a catalyst to introduce more efficient systems.
- Countries will need accessible and reliable home-based and provider-based, vaccination records for vaccine safety and effectiveness evaluations as well as for individual travel, professional and health purposes.

11.1 Objectives of this chapter

➔ Advise countries on how to identify data needs and strengthen information systems to monitor progress with COVID-19 vaccination.

11.2 Identify data needs and monitoring objectives

As COVID-19 vaccines are being introduced, there will likely be an intense demand for data by:

- public health decision-makers and other national and subnational authorities;
- the public, communities, civil society organizations, and the press;
- national, regional and global immunization partners, including donor organizations; and
- vaccine manufacturers and regulatory bodies, health researchers and academics.

To meet the key anticipated needs of these different stakeholders, country programmes should design a monitoring system for COVID-19 vaccines that is able to:

1. Measure equitable uptake and coverage over time by geography, population groups, and risk groups.
2. Monitor to what extent national policies to prioritize at-risk groups and settings (e.g. hospital and long-term care facilities) are effectively implemented.
3. Provide a personal vaccination record/certificate for any health, occupational, educational and travel purposes (as per national policies).
4. Ensure that the necessary records and documentation are in place for use in surveys, safety monitoring, disease surveillance and vaccine effectiveness studies.
5. Ensure that individuals can be monitored for the full course, in the likely case that a multidose schedule is required, to reduce the incidence of drop-outs.

The steps that need to be taken while designing a monitoring system are detailed below.

11.3 Define indicators to monitor progress

The main indicators to measure progress with COVID-19 vaccines are similar to any vaccine introduction:

- **Vaccine uptake:** The number or proportion of people vaccinated with a certain dose of the vaccine in a certain time period (e.g. during a month or year). If expressed as a percentage, an alternative term to be used is vaccination rate.
- **Vaccination coverage:** The vaccinated proportion of a target population, which is similar to uptake, but considers vaccination in previous time periods. Over time, coverage can be constructed by accounting for uptake in previous time periods (weeks, months, years), depending on the duration of protection of the vaccine. For the year of introduction (2021), uptake and coverage can be used interchangeably.

Uptake of COVID-19 vaccines can be represented as COV and should be tracked by dose as follows:

- **COV-1:** The number of people receiving a first dose of the vaccine, or the proportion of a target group that did so. For example: 50 000 doses of COV-1, corresponding to 5% of the total population;
- **COV-2, 3:** The number or proportion of people receiving a second or third dose of the vaccine, plus any booster doses if relevant for future recommended vaccination schedules;

- **COV-c:** In case multiple vaccine products with different dose requirements are used in a country, this indicator represents the number of people who received the last recommended dose for the respective vaccine product. The "c" denotes the dose that completes the schedule, which might be a first, second or third dose depending on the product that was used; and
- **Drop-out from COV-1 to COV-c:** The proportion of people who received at least one dose of a COVID-19 vaccine but did not receive the last dose in the schedule yet. Calculated as: (COV-1 – COV-c)/COV-1

Where feasible, vaccine uptake should be tracked or evaluated separately (disaggregated) according to each of the following dimensions shown in Table 11.1.

Table 11.1 Dimensions for disaggregating vaccine uptake and coverage

Disaggregation	Definition	Use
Vaccine product	By each vaccine product in use in a country	• Calculate uptake and coverage with a last recommended dose • Evaluate protection in a population, given differences in effectiveness • Evaluate vaccine safety issues that are specific to the different products in use
Geography (required)	By district, province, state etc.	• Monitor equitable distribution across regions in a country
Sex (required)	By sex of the vaccinated person	• Monitor equitable distribution by sex
Age group (required, at a minimum younger than 60, 60–69, 70–79, 80+)	By age group of the vaccinated person according to national policy for vaccine prioritization	• Age is a risk factor for severe COVID-19. Monitoring uptake among specific age groups is required to evaluate whether prioritization policies are implemented
Occupation (optional, where feasible)	By prioritized occupational group: definition/ characteristics to be decided at the country level by national health experts/NITAGs.	• Occupation is a risk factor for transmission of CoV-SARS-2, and country policies will need to ensure that essential frontline workers are protected first • Evaluate whether prioritization policies are implemented
Other risk factors (optional, where feasible)	Among people with co-morbidities or other risk factors for COVID-19 such as pregnancy	• Evaluate whether prioritization policies are implemented *Note:* this may not be feasible in all countries; foresee challenges disaggregating doses as well as establishing targets for these at-risk groups
Context (optional, where feasible)	In long-term care facilities, prisons, universities and schools	• Evaluate whether these strategies are implemented
Other equity dimensions (optional, where feasible)	By socioeconomic, ethnic, linguistic, religious, or any socially disadvantaged populations	• Monitor equitable distribution across different populations in a country *Note:* this may only be feasible to measure using surveys

11.4 Design a system to record, report, analyse and use vaccination data

Vaccine uptake of COVID-19 vaccines can be monitored through an "administrative system" or evaluated through household health (coverage) surveys. Both methods are complementary and have strengths and weaknesses.

- **Administrative reporting systems:** They are limited in the number of ways data can be disaggregated, and depend on reliable population estimates and accurate reporting, but can provide data in a more frequent and timely manner.
- **Coverage surveys:** Their quality depends on availability of reliable vaccination records (home-based vaccination cards or provider records) and are available in a less timely and less frequent manner but will offer more possibilities for disaggregate coverage evaluation and often produce higher quality estimates.

The remainder of this chapter will focus on administrative systems.

11.4.1 Aggregate or individual reporting

In general, countries use one of two systems to monitor their immunization programme as shown in Fig. 11.1.

- **Aggregate reporting system:** Administered doses are recorded, tallied along key dimensions and reported up the health system, often using a mix of digital and paper tools.
- **System based on access to individual immunization records:** Vaccination encounters are digitized and shared (possibly anonymized) between providers and public health authorities, such as electronic immunization registries (EIR).

EIR have many potential advantages, as they allow for much more granular and rich information. They can also make information available in a more timely manner, as there is no specific aggregation and reporting step needed. However, there are also challenges associated with the implementation and maintenance of such systems, and the urgency of COVID-19 vaccine introduction is such that most countries will have to rely on the reporting systems that are already in place.

Even where a national EIR is available, public health authorities need to establish if, and how, it can be used to monitor COVID-19 vaccination, depending on the system's flexibility and its users. For example: an EIR that is currently used by public health facilities or child clinics may not be easily extendable to hospitals, long-term care homes and private practitioners.

11.4.2 Distribute and use home-based records (personal vaccination records, vaccination cards or certificates)

Physical, paper-based personal records are needed both in aggregate and individual systems and should be updated to reflect COVID-19 vaccination status. They serve the following purposes:

- provide proof of vaccination for individual's travel, educational or occupational purposes;
- establish vaccination status in coverage surveys;
- provide vaccination information in case of an AEFI or in case of a positive COVID-19 test; and
- provide a useful vaccination card for adults and older adults to which COVID-19 vaccines and other recommended vaccines can be added and guidance on any doses required to complete vaccination course can be found.

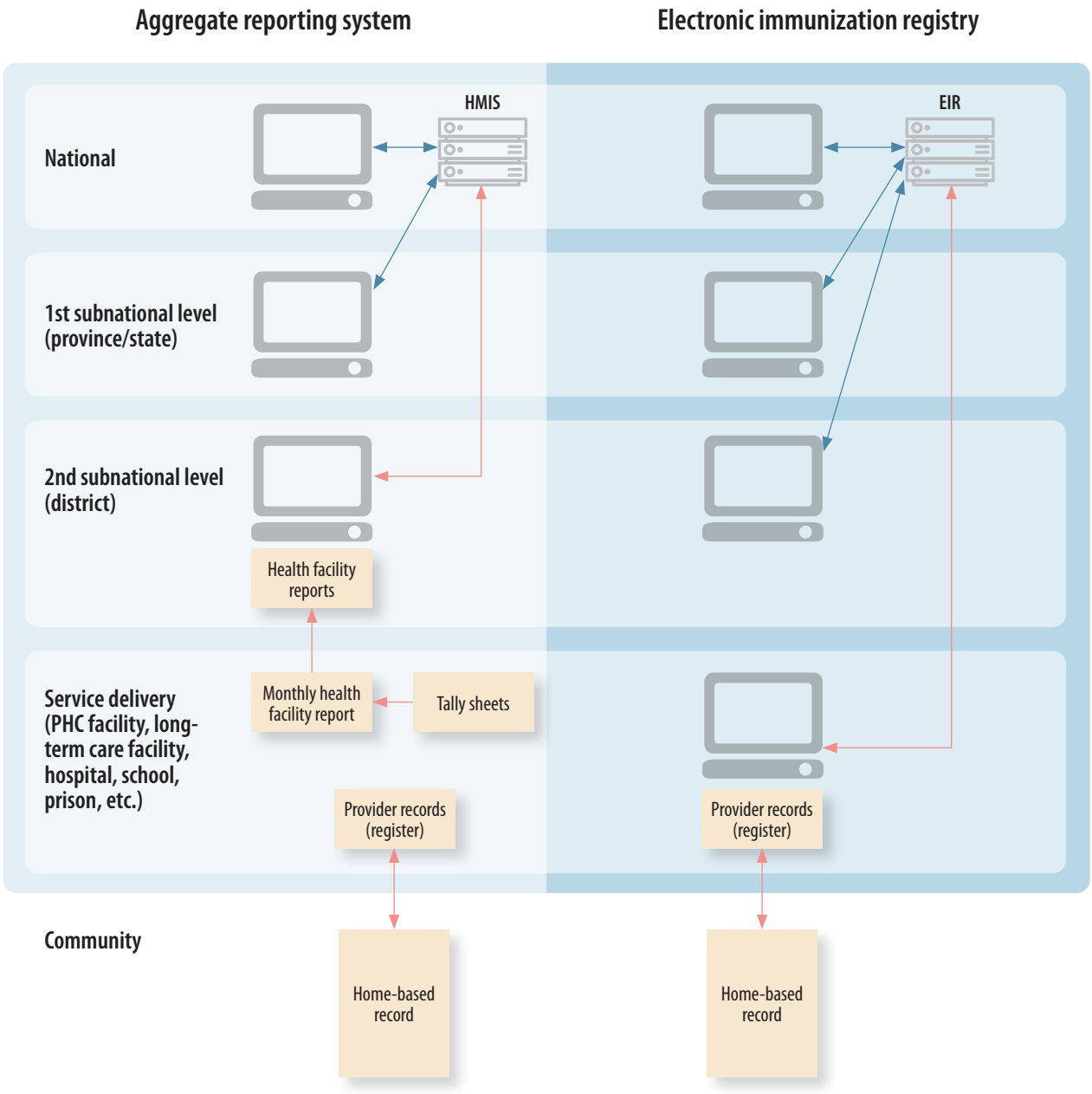


Fig. 11.1 Comparison of aggregate reporting system and an electronic immunization registry

The existing international vaccination certificate format[1] can serve as a guide to develop a COVID-19 vaccination card *(56)*. Existing childhood vaccination cards or child health booklets are less likely to present a good fit for this purpose. The vaccination card requires fields for the following information:

- personal information (names, identity document, birth date, address, sex, as relevant);
- different lines for each anticipated dose and booster. Yearly vaccinations would require plenty of lines or space on the card; and
- per line: the date of vaccination, vaccine product, the dose number, the batch or lot number, the name of the provider (vaccinator or institution) and space for a stamp or signature by the provider.

[1] A model for the international certificate of vaccination or prophylaxis is provided in annex 6 of the International Health Regulations (2005).

Falsification of certificates may become a problem, but mitigation strategies exist:

- vaccination cards could be printed on paper that is hard to copy – although adding or changing information on an existing card would still be possible;
- a unique identifier, such as a serial number, could be printed on each card; if copied on provider records that would make the falsification traceable; and
- electronic systems can issue digital certificates (e-vaccination cards) and provide ways to check the integrity of digital and physical records, for example using barcodes. Digital certificates can, for example, be sent by e-mail or text message and stored in the digital wallet of a phone.

11.4.3 Update facility-based records (provider records, vaccination registers, medical record systems)

Facility-based records are kept in the facility, hospital, long-term care facility, prison or doctor's office. They can be physical register books, provider-based digital medical record systems or an EIR, and they should be updated to reflect COVID-19 vaccination status. Provider records serve broadly the same purposes as personal vaccination records, but also enable providers to send reminders for second doses to patients, and to report data to public health authorities. They can also link vaccination data with other medical information, such as COVID-19 test results. Additional information captured in provider records is:

- contact information of the vaccinated person – needed to issue vaccination reminders, or in case a safety concern arises with any vaccine product or batch;
- any characteristics of the vaccinated person that are needed for data disaggregation (sex, age, occupational group, risk profile, etc.);
- COVID-19 lab test results; and
- any AEFI.

11.4.4 Update tally sheets and periodic reports (only for aggregation-based systems)

Tally sheets are used to count the number of vaccinations administered during a day, week, month, immunization session or campaign day. They should allow for the tallying of COVID-19 vaccinations by dimension of disaggregation mentioned above. Countries could develop specific tally sheets for specific COVID-19 target groups and strategies or use standard tally sheets but keep sheets separate for each strategy and group (such as health workers, social care workers, older populations, etc.). Doing so will simplify their design and use. Specific recommendations for tally sheets include:

- The header should contain information about the location, the targeted group, the vaccinator, the COVID-19 vaccine product used, and the applicable date or date range.
- Separate spaces (boxes) should be available for the different COVID-19 vaccine doses, and for any required dimension of disaggregation like sex and age range. Tally sheets become increasingly complex to use as more dimensions are introduced, which is why the number of dimensions to be included needs to be considered carefully.

Periodic reports are used to summarize the vaccinations administered along the same dimensions, together with vaccines used and other relevant information. The frequency of reporting and target reporting dates (deadlines) for COVID-19 vaccines should be established and well communicated. These reports are often prepared as a paper report at the service delivery level and entered as a digital report by a district administration into the national HMIS, with consolidated information and analytics. Many countries already have such systems. If not, applying alternative systems like an influenza uptake system to COVID-19 vaccine introduction can be considered.

11.4.5 Implement frequent assessments of capacities and readiness at health facility level

Against a rapidly evolving situation, many countries may face challenges in the availability of accurate and up-to-date data on the capacities of their health services (in terms of staff, supplies, safety measures, cold chain capacity) to deliver the COVID-19 vaccine(s) while simultaneously assuring continuity of routine vaccination programmes and other essential health services.

Data collection processes may need to be adapted and additional and more frequent efforts may be required to obtain regular reports from health facilities (e.g. primary care, hospitals, long-term care facilities). In such contexts, countries should consider implementing high frequency health facility assessments to track and monitor health service capacities and bottlenecks. Due to travel restrictions and safety measures, it may be necessary to contact health facilities and health workers directly by telephone to proactively obtain relevant reports. Where possible, data from the community health workforce and other service delivery platforms (e.g. home-based and long-term care) should be captured.

The WHO Harmonized health service capacity assessments in the context of the COVID-19 pandemic provides tools to support rapid and accurate assessments of the current and surge capacities of health facilities throughout the different phases of the pandemic *(57)*. The tools include a set of modules used to inform the prioritization of actions and decision-making at health facility, subnational and national levels. Countries may select different combinations of modules according to country context and the need for one-time or recurrent use throughout the pandemic.

11.4.6 Develop a COVID-19 vaccination dashboard

A COVID-19 vaccination dashboard could be developed to provide insights into a variety of programmatic aspects in addition to vaccination data, and to serve as a useful communication and visual tool. For example, the dashboard could show key performance indicators, bringing together data on:

- service availability and readiness (human resource capacity, cold chain and supply);
- vaccine uptake and coverage by geography, population groups, and risk groups, and over time series; and
- AEFI.

The vaccination component could also be part of a broader COVID-19 dashboard, that would include surveillance (cases and deaths). Designing a dashboard and thinking what information to include in it is also a useful exercise to help determine what data need to be collected.

12. COVID-19 surveillance

KEY MESSAGES

- While COVID-19 surveillance is currently ongoing in all countries, to enable public health authorities to reduce transmission of COVID-19, it will need to be adjusted after COVID-19 vaccines are introduced to understand the impact of vaccination.
- Countries can use the short-, medium- and long-term objectives of surveillance, as related to vaccination, to drive how their surveillance system is designed and what data are collected. In the short term, countries can assess the effectiveness and impact of the vaccine through high-quality sentinel site surveillance, ideally building on any influenza sentinel site surveillance system in place.
- National immunization staff will need to work with the national COVID-19 surveillance team to ensure the proper information is collected and findings are shared.

12.1 Objectives of this chapter

➔ Provide advice to countries on how current COVID-19 disease surveillance can be adapted to meet vaccination surveillance objectives.

12.2 Rationale, objectives and types of surveillance needed

The aim of national surveillance for COVID-19 is to enable public health authorities to reduce transmission of COVID-19, thereby limiting associated morbidity and mortality. Currently, the objectives of COVID-19 surveillance are to *(58)*:

- enable rapid detection, isolation, testing and management of cases;
- detect and contain clusters and outbreaks, especially among vulnerable populations;
- identify, follow-up and quarantine contacts;
- monitor trends in COVID-19 cases and deaths;
- guide the implementation and adjustment of targeted control measures, while enabling safe resumption of economic and social activities;
- evaluate the impact of the pandemic on health care systems and society;
- monitor longer term epidemiologic trends and evolution of COVID-19 virus; and
- contribute to the understanding of the co-circulation of COVID-19 virus, influenza and other respiratory viruses, and other pathogens.

As it relates to vaccination, surveillance will help to guide the implementation and adjustment of the vaccination programme and policies.

As COVID-19 vaccination is new, there are different objectives of disease surveillance as it relates to vaccination that apply in the short, medium and long term. Globally, given the numerous vaccines expected to be used by different countries, in addition to the surveillance being conducted to guide the outbreak response to COVID-19, countries should conduct some basic surveillance to help understand vaccine impact in their context. Data needed to support monitoring of vaccine impact should, as much as possible, leverage existing systems already in place for COVID-19 surveillance.

12.2.1 Define national or local surveillance objectives

Given the numerous vaccine candidates, the below will need to be adjusted based on the vaccine used in country and the characteristics of the future vaccine. Thus, what follows are broad ideas to help with future planning for surveillance implementation once a vaccine is introduced.

Determine the epidemiologic context to guide vaccine introduction

- This is a short-term objective due to the limited vaccine supply to guide vaccine introduction as outlined in the WHO SAGE roadmap for prioritizing uses of COVID-19 vaccines in the context of limited supply *(59)*.
- Based on surveillance data, countries should determine if they are having community transmission, sporadic cases or clusters of cases, and/or no cases, and use this information to guide phased vaccine introduction.

Understand vaccine effectiveness (VE) and impact of vaccination

- This is a short-term objective that could continue to the long term depending on the characteristics of the vaccine, e.g. if similar to influenza where yearly administration is needed or the virus evolves. Scientifically rigorous VE and vaccine impact studies (see Section 13.3) are not needed everywhere and should be done in those countries with interest and the capacity to do these, but basic monitoring of vaccination status of cases should be collected in all COVID-19 surveillance systems.
- High-quality surveillance needs to be conducted to be able to assess this objective. If this cannot be ensured, then the data generated from surveillance should not be considered definitive evidence of VE and vaccine impact.
- Ideally, this is best done through sentinel site surveillance, and can be efficiently added to influenza sentinel site surveillance (e.g. influenza-like illness, acute respiratory infection and SARI sites) by adding questions related to vaccination and COVID-19 testing. Other potential surveillance sentinel sites include acute febrile illness sentinel sites or COVID-19 diagnostic centres, but case definitions must be adhered to strictly and reliable high-quality data must be able to be collected on all cases. It is valuable to consider collecting data from a variety of sentinel sites that cover both outpatient and inpatient services to help understand the impact of the vaccine on the severity of disease.
- If a country does not have influenza sentinel site surveillance and is interested in starting surveillance, a COVID-19 sentinel site surveillance (joint influenza/COVID-19 where applicable) can be started by following the approach proposed in Global epidemiologic surveillance standards for influenza *(60)*. Alternatively, if a country is not interested in the mid-to long-term investment in modifying surveillance to monitor VE, targeted and time-limited research studies could be set up to answer the vaccine impact questions (see Section 13.3).
- The age group and target populations identified within the sentinel site need to be considered to ensure that surveillance covers those groups targeted by vaccination. Either the age group and/or risk group under sentinel site surveillance might need to be expanded, or additional sentinel sites might need to be added to achieve the objective.
- However, in some cases, understanding vaccine impact within specific subpopulations is best undertaken by designing a research study to ensure all needed information (e.g. type of job, duration of exposure, etc.) is acquired rather than building a surveillance system for this population specifically. For example, in the case of wanting to monitor vaccine impact among health workers, it will not be possible to get a sufficiently large sample size of health workers through sentinel surveillance to have meaningful results.
- Variables should be collected as listed in Section 12.3.
- Population denominator/catchment population of sentinel sites should be collected to calculate rates and allow for comparability across sites.

Understand long-term immunity, duration of immunity, and need for booster doses due to waning immunity

- This is a medium- to longer term objective and not every country will need to conduct surveillance to understand this.
- This can be achieved via a combination of influenza sentinel site surveillance and research studies.
- Countries that could consider conducting this type of surveillance include those with existing high-quality influenza surveillance platforms, with capacity to conduct such type of surveillance and funding support to pursue this.

Guide COVID-19 vaccination use to stop an outbreak

- This is a medium- to longer term objective.
- It is currently unknown if a future COVID-19 vaccine will be effective in stopping an outbreak, as this depends on the specifics of the vaccine (e.g. time to immunity, number of doses required for immunity, ability to act as post-exposure prophylaxis). For example, influenza vaccines are not used to stop influenza outbreaks, but measles vaccines are used to stop measles outbreaks.
- Given this unknown, research studies will need to be conducted to see if the future vaccines can stop an outbreak before surveillance is recommended to meet this objective.

12.3 Collect, report and use COVID-19 surveillance data

Recommended data elements critical for answering the objectives outlined above
In addition to the data elements already collected, countries are encouraged to collect the following data points. Some might already be part of surveillance but are repeated to highlight that these are vital to meeting the objectives:

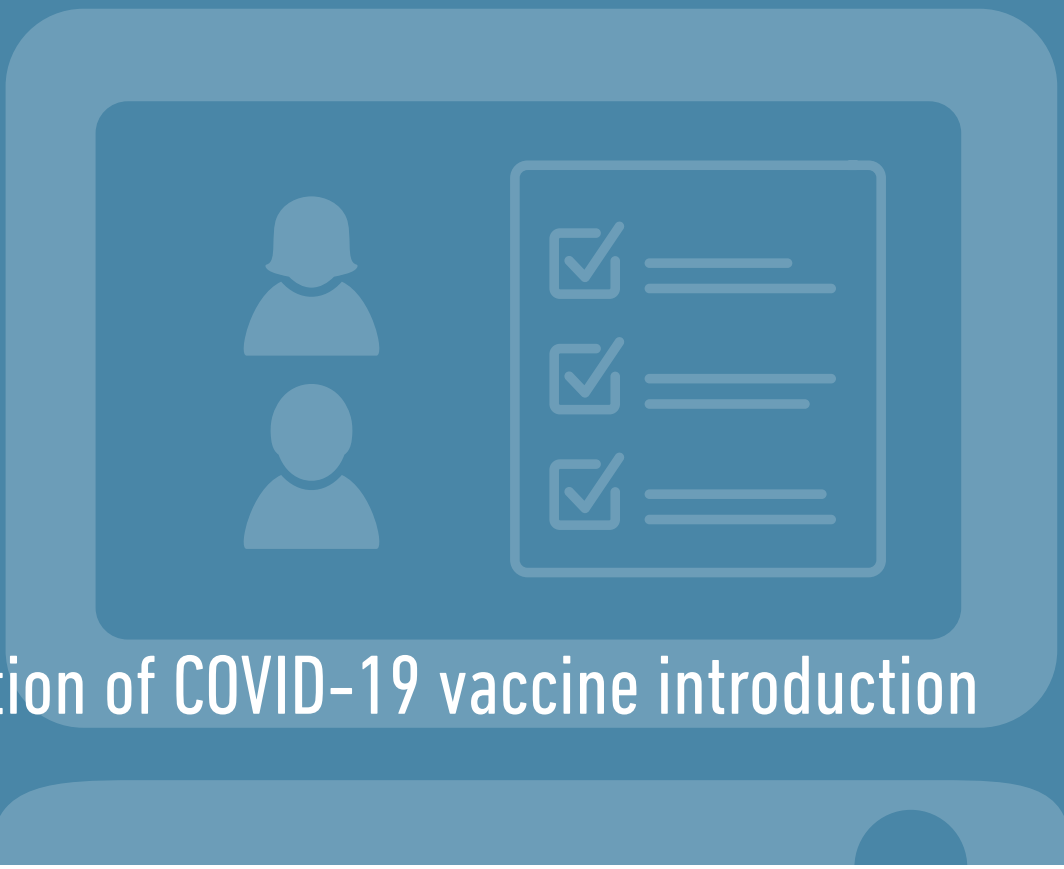
- age/date of birth;
- place of residence;
- sex;
- severity of disease hospitalization, intensive care unit (ICU) admission, oxygen requirement, ventilatory support, extracorporeal membrane oxygenation;
- COVID-19 treatments provided (e.g. dexamethasone, COVID-19 antibodies, remdesivir, etc.);
- co-morbidities;
- laboratory testing related data (type of test, test results, date of test);
- prior history of COVID-19 prior to this and date of last positive tests.
- Has the person received the COVID-19 vaccine (yes, no, unknown)?
- If yes, what are the brands/dates of vaccine (to be adapted based on number of doses needed)?

Case definitions, case investigation, specimen collection and laboratory testing should be in line with global and national surveillance guidance *(61)*.

Immunization programme staff should work with those conducting COVID-19 surveillance to ensure that surveillance is modified to meet the objectives that the country would like to achieve. This relationship is vital to ensure that data are used to drive vaccine-related decisions.

12.4 Address requested reporting requirements

As this is a global pandemic, WHO requests that all countries collecting surveillance data as they relate to vaccination, provide these case-based data to WHO to allow for a global perspective on VE and impact.



13. Evaluation of COVID-19 vaccine introduction

KEY MESSAGES

- One of the principal objectives of COVID-19 vaccines post-deployment monitoring activities is to be able to evaluate the programme implementation and vaccine performance in the population.
- Given the specificities and novelty of COVID-19 vaccines, evaluating their impact on the immunization programme will be critical to optimize vaccine deployment.
- Questions of vaccine effectiveness and impact after introduction into populations can be addressed by well-designed epidemiological studies, although pre-planning is needed to ensure the right data are collected at the time of vaccine introduction.
- Programmatic lessons learned will be useful for countries in planning for other emergency responses, and for other countries still introducing COVID-19 vaccines.

13.1 Objectives of this chapter

→ Advise countries on considerations in conducting a post-introduction evaluation following the introduction of COVID-19 vaccines to assess VE, impact and identify any improvements to the COVID-19 vaccination process.

13.2 Programmatic post-introduction evaluations of COVID-19 vaccines

Following new vaccine introduction into a routine immunization programme, the purpose of a post-introduction vaccine evaluation is to evaluate the impact of the vaccine introduction on the country's immunization programme and to rapidly identify problems needing correction as vaccination expands in country. The evaluation can not only lead to improvements in the implementation of the new vaccine and overall immunization programme but can also provide valuable lessons for other countries for future vaccine introductions.

In the context of COVID-19 vaccine introduction, the conduct of a classical post-introduction evaluation will likely require adaptation, where multiple COVID-19 vaccine products are introduced or where products are targeted at different population groups. Countries may possibly find value in carrying out small post-introduction evaluations after various introduction phases, e.g. a health worker specific evaluation, an older population evaluation, etc.

The utility and design of a post-introduction evaluation for COVID-19 vaccines will depend on vaccine-specific recommendations.

13.3 Vaccine effectiveness and impact

Confirmation of COVID-19 VE will be desired to verify performance in real-world populations and field conditions different from those enrolled in clinical trials. Moreover, the clinical trials will likely not answer all questions about VE for key secondary outcomes, such as among certain risk groups and against different levels of disease severity.

Various methodologies have been used to evaluate VE, including cohort studies, case-control studies and the so-called screening method. The method that is often used for evaluation of seasonal influenza VE due to its minimization of bias in the test-negative case-control design, in which cases and controls arise from the same population of persons seeking care for acute respiratory illness, the cases being those laboratory-confirmed for influenza and the controls being those who are negative *(62)*. Vaccination status is then compared between cases and controls. This method could also be appropriate for COVID-19 VE evaluations, using severe acute respiratory illness surveillance platforms, such as the Global Influenza Surveillance and Response System *(63)*. However, the test-negative case-control design might prove more challenging for COVID-19 vaccines, in which existing immunity and non-random deployment of vaccines based on risk criteria might introduce biases. Measuring the impact of COVID-19 vaccines in the population, that is the reduction in disease incidence, or reduction in disease severity or longevity, is also important. However, assessing the impact of COVID-19 vaccines is also likely to be challenging, given the lack of longitudinal baseline data and the evolving epidemiology of COVID-19 disease since the beginning of the pandemic.

Guidance on approaches to assessments of COVID-19 VE and impact, which address the unique issues related to this disease and the various vaccines, is forthcoming. Regardless of the approach, the data to be collected as part of surveillance and monitoring need to be considered ahead of vaccine introduction, as has been discussed in Chapters 11 and 12. Lastly, evaluations of VE and impact are important, but must be done with methodological rigour to yield accurate results. Erroneous results can lead to inappropriate public health action. Such evaluations are not necessarily required in all countries; at least a few well-executed evaluations, either in individual countries or several countries with similar populations and epidemiology, should be done in regions with similar demographic and epidemiologic characteristics to generate representative results.

13.4 Lessons learned

Documenting the lessons learned from deployment and vaccination operations will provide essential information about the effort for both the country itself, and for other countries introducing COVID-19 vaccines.

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Annex 1: Sample template of national deployment and vaccination plan for COVID-19 vaccines

Endorsement page

- ☐ Endorsement page with signatures on behalf of relevant government sectors.

Table of contents

Executive summary

- ☐ Purpose: the overarching goal for COVID-19 vaccines to save lives/mitigate the effects of the COVID-19 pandemic.
- ☐ Distribution of vaccines and ancillary items (country to communicate a timeframe for distribution of vaccines from port of entry to point of administration/vaccination).
- ☐ Summary of total doses distributed/needed (as information available); total target population and order of target population.
- ☐ Estimated date of introduction in country, consistent with country readiness assessment workplan.

1. Introduction

- ☐ Brief background of the country (geography, population size, health status).
- ☐ Burden of the targeted disease in the country, e.g. local data or regional or global estimates, economic estimates burden of disease.
- ☐ Lessons learned from influenza A H1N1 and other relevant activities.

2. Regulatory preparedness

- ☐ Brief description of regulatory requirements, importation and customs clearance procedures, and expected challenges or exemptions that may be required regarding importation and use of COVID-19 vaccines in the country.
- ☐ Outline of national regulatory pathways being put in place to expedite vaccine availability in country.

3. Planning and coordination of the vaccine introduction

- ☐ Brief section on COVID-19 coordination mechanism at country level and integrated efforts into the country's COVID-19 response structures.
- ☐ To include discussion on whether country has adapted existing national governance mechanism, or established national coordination and roles of advisory bodies in context to COVID-19 vaccine deployment and vaccination, e.g. NCC, NITAG and ICC.

4. Resources and funding (costing tool under development)

- ☐ Description of the costing, priority setting and funding process that will support the preparation of a realistic plan and final decisions with explanations.

- ☐ Additional costs for COVID-19 vaccine and valuation of the shared health system costs, with funding sources and amount.

5. Target populations and vaccination strategies

- ☐ Brief text on decision-making mechanism for order of priority (e.g. values framework, NITAG decision).
- ☐ Brief text on how each target group will be vaccinated.
- ☐ Vaccination strategies:

Target population (in order of priority)	Number of additional individuals to be vaccinated	Priority targeted delivery strategy for this population	Total cumulative % of vaccines as a percentage of population

- ☐ Please specify system adjustments required to build/strengthen the appropriate vaccination platform, including non-conventional vaccine delivery approaches to reach identified target groups (e.g. to reach people with comorbidities).
- ☐ Define whether country would be open to receiving -80 °C/-20 °C vaccine(s) with a short shelf life and, if so, what would be the required arrangements needed for delivery.
- ☐ Optimal schedule for vaccination, e.g. either for routine immunization or seasonal use, single- or two-dose administration, the optimal age for the first dose, minimum and maximum intervals between doses, interrupted schedule as information will be made available once COVID-19 vaccine product is registered for use.
- ☐ IPC measures, including adequate PPE to minimize exposure risk during immunization sessions.
- ☐ Opportunities for integrating COVID-19 vaccination with other health interventions across the life course.

6. Supply chain management and health care waste management

Supply chain management:

- ☐ Summary table of potential port(s) of entry, points of storage (stores), transportation capacity and cold chain capacity of in-country fallback facilities (categorized at +2 °C to +8 °C, -20 °C, and -60 °C to -80 °C storage temperatures) or link to other documents and platforms where this information is located.
- ☐ Description of distribution processes including identified gaps, challenges and solutions to complete vaccine deployment prior to vaccination start date.
- ☐ Summary of the volumes, doses and ancillary items to be distributed by areas/zones.
- ☐ Description of estimating cold chain and dry store capacity requirements, issues, challenges and solutions.
- ☐ Summary of the following requirements to support deployment and vaccination of target groups at different administrative levels prepared:
  - Cold chain strategy based on the different types of potential vaccines (mapping of in-country +2 °C to +8 °C and UCC, leveraging all national assets):
    - strategy for UCC and long-range equipment deployment, including need for joint investment/ external support, when applicable;

- investment required to establish UCC hub to reach 3% of the total population;
- capacity for dry ice production at UCC hub.

– Issues, requirements and challenges related to transportation of vaccines and supplies.
– Procedures for contractual agreements to prepare for vaccine introduction (e.g. vaccine warehousing, transport, waste management, cold chain capacity, etc.), where applicable.
– Supply chain data management: description of recording and reporting of vaccine stocks and usage; cold chain equipment functionality and temperature monitoring through existing information management systems.

Biohazard and immunization waste management:

☐ Current waste management capacity and practices, and their adequacy; changes needed to accommodate additional volume of wastage due to new vaccine, and plans for upgrading the waste management system.

7. Human resources management and training

☐ Summary table(s) of a national overview of human resources by category.

☐ Conclusion: statement on whether additional human resources (also staff for community mobilization, cold chain and supply chain management and other required support functions) are needed.

☐ Define training strategy building on lessons learned from other vaccines; ensure this is reflected in readiness checklist and in budget.

☐ Description of supportive supervision system.

8. Vaccine acceptance and uptake (demand)

☐ Coordination and planning: reactivate existing coordination mechanism(s) to discuss strategy and planning, and to develop a targeted, multicomponent and costed plan to achieve high acceptance and uptake.

☐ Description of plans to gather and use local data: behavioural and social data, digital listening and media monitoring, and other relevant sources to inform design and evaluation of interventions.

☐ Description of interventions across a range of key areas:
– National advocacy and stakeholder engagement.
– Communications and media engagement for public information, including key messages by target group.
– Risk communications and community engagement, and related social mobilization (includes preparedness for responding to vaccine-related events and AEFI).
– Engagement and capacity building of frontline health workers to support their role as vaccine recipients and as vaccinators.
– Misinformation management, including tracking and analysis from social listening.

9. Vaccine safety monitoring and management of AEFI and injection safety

☐ Description of key issues surrounding post-deployment surveillance for use of COVID-19 vaccines, requirements and challenges of AEFI management.

☐ Details on a national safety committee to support the evaluation of AEFI and AESI (with the participation of scientific societies, regulatory authorities and immunization programmes).

☐ Description of steps being taken to ensure injection safety.

☐ Line of reporting and roles and responsibilities of staff.

10. Immunization monitoring system

- ☐ Description of data needs and monitoring objectives including indicators to be used.
- ☐ Description of system to be used to record, report, analyse and use vaccination data and example of dashboard to be used to monitor COVID-19 vaccination.

11 Disease surveillance

- ☐ Detail if the current COVID-19 surveillance system will be modified to answer the country's vaccine-related objectives or if a new system will be put in place.
- ☐ Description of objectives that the country is interested in answering through modifying surveillance.
- ☐ Description of the type of surveillance that will be conducted. This should cover whether the vaccination data will be part of national surveillance or sentinel surveillance. If part of sentinel surveillance, details should be provided on number of sites, which age/risk groups are captured, etc.

12. Evaluate introduction of COVID-19 vaccines

- ☐ Indication of whether vaccine effectiveness and/or impact evaluations are planned; anticipated method to be used and in-country surveillance or other platforms that could support these evaluations; plans for technical support for such evaluations.
- ☐ Description of plans for post-introduction evaluations, including aspects of vaccine programme to be evaluated (e.g. importation, regulatory, supply/cold chain, wastage, coverage among total population and key risk groups, safety monitoring).
- ☐ Documenting lessons learned, a consultative exercise at national and subnational levels, involving different stakeholders.

Other annexes as determined by the country.

Annex 2: COVID-19 epidemiology

COVID-19 epidemiology

The epidemiology of COVID-19 is changing rapidly. As of 6 November 2020, there were more than 48 million cases and 1.2 million deaths globally. The most up-to-date case summaries can be found here: https://covid19.who.int/table

Transmission

The estimated incubation period is between 2 and 14 days with a median of 5 days. COVID-19 is primarily transmitted from person to person through respiratory droplets, from sneezing, coughing and talking *(64, 65)*. Transmission through aerosols has also been implicated as well as indirect transmission through contaminated fomites. Recent data suggest transmission of COVID-19 from those with mild to severe symptoms and also from those who are pre-symptomatic (prior to symptom onset) or asymptomatic (a person infected with SARS-CoV-2 that does not develop any symptoms *(66, 67)*. The onset and duration of viral shedding and the period of infectiousness for COVID-19 are not yet known with certainty.

COVID-19 illness

A wide range of symptoms for COVID-19 have been reported. These include fever or chills, cough, shortness of breath or difficulty in breathing, fatigue, headache, nasal congestion or runny nose, muscle or body aches, sore throat, new loss of smell or taste, rash on skin or discolouration of fingers or toes and diarrhoea. The majority of COVID-19 illnesses are mild, and most patients (approximately 80%) will recover without hospitalization. Data from several countries suggest that 14%–19% of cases are hospitalized and 3%–5% will develop severe disease that require ICU admission for complications such as respiratory failure, acute respiratory distress syndrome, sepsis and septic shock, thromboembolism, and/or multiorgan failure, including acute kidney injury and cardiac injury *(68)*.

The full range of COVID-19 disease, including long-term sequelae, is still to be fully understood and requires further research. Older age, smoking and underlying medical conditions such as cardiovascular disease, chronic respiratory or kidney disease, obesity, type 2 diabetes, solid organ transplantation and cancer, have been reported as risk factors for severe disease and death *(69–73)*. As more data become available, additional risk factors for severe COVID-19 may be identified.

Gender differences

Initial data demonstrate that men are more likely to suffer from severe COVID-19 than women. This is likely explained by a combination of factors including social, behavioural, genetic and hormonal factors, and differences in the biological pathways related to viral infection *(74)*. Men have a higher frequency of underlying conditions, including cardiovascular disease, and are more likely than women to smoke *(75–77)*. However, data from rapid gender assessment surveys suggest that women are particularly vulnerable to COVID-19. Women are more likely to be the caregivers and less likely to have access to health care and testing *(78)*. In addition, health care workers are particularly at risk of contracting COVID-19, and women make up 70% of health care workers globally, and 80% of nurses in most regions *(79)*. It is critical that efforts to address the pandemic should not jeopardize the fragile gains made for women in the workforce.

Special populations

Children: Clinical manifestations of COVID-19 are generally milder in children compared with adults. Relatively few cases of infants and young children confirmed with COVID-19 have been reported; of the few young children with COVID-19, most have had mild illness or remain asymptomatic. However, an acute presentation with a hyperinflammatory syndrome leading to multiorgan failure and shock has been described as multisystem inflammatory syndrome in children and adolescents temporally associated with COVID-19 *(80)*. Robust evidence associating underlying medical conditions with severe illness in children is still lacking.

Pregnant women: Pregnant women may be at increased risk for severe COVID-19 illness, including increased rates of hospitalizations, ICU care and mechanical ventilation, but not death. Additionally, pregnant women are more likely to experience preterm birth and their neonates are more likely to be admitted to a neonatal ICU *(81)*. During the postpartum period, mother and infant should have contact at birth regardless of COVID-19 status. A mother should not be separated from her infant unless too sick to care for her baby. From the available evidence, the benefits of breastfeeding substantially outweigh the risks of illness associated with COVID-19.

Older people: Older people and people with underlying medical conditions appear to develop serious illness more often than others. Also, case fatality rates are highest among older people. There is mounting evidence that suggests that the COVID-19 has disproportionately affected residents of long-term care facilities worldwide, with high rates of morbidity, mortality and substantial health care cost *(66, 82)*.

Annex 3: Training decision-making and planning tool

Choosing the right COVID-19 vaccine training delivery method

Global partners have developed two packages of training that you can use. One package is intended for in-person training at a health facility or other location. The second package is intended to be self-paced, which individuals can take when and where they need it. Use the training delivery method decision-maker (Table A3.1) to help you decide which method to use for different learners or modules. It is also possible to do a blend of distance learning and in-person training. The factors are colour coded to help you complete the tool that follows.

Table A3.1 Training delivery method decision-maker

✔	Digital learning (self-paced)	✔	Instructor-led learning (group)
	Unable/impractical to travel to central training location (venue, work location, etc.)		Can safely travel to central training location (venue, work location, etc.)
	Unable to meet in groups with mask-wearing *and* social distancing		Able to meet in groups with mask-wearing *and* social distancing
	Affordable access to a laptop computer, tablet or smartphone (required)		Fair to no access to laptop computer, tablet or smartphone
	Access to reliable internet or smartphone connection, either via live stream or download		Fair to no access to reliable internet connection
	Ability to learn in the available languages or translation can be done easily		Translation required

Planning workforce training

Use this table to plan training for the workforce under your responsibility. Consider all the factors listed above to determine your recommendation for the training delivery method for each category of workers. Add rows to this worksheet as needed. Based on your analysis, record your proposed training method for each group and identify local partners available to support training.

Table A3.2 Workforce training plan

Job title	Workforce training worksheet							
	District	Approximate number of workers	Able to meet safely in small groups	Internet access: (none, limited, satisfactory)	Mobile usage for work: (none, limited, satisfactory)	Local language translation required	Proposed training method (digital, instructor-led, blended)	Partners for training support
Health worker/vaccinator	A							
	B							
	C							
Communications/community engagement focal points	A							
	B							
	C							
Logistician								
Other specialist staff								
District level staff								
Provincial level staff								
National level staff								
Other (specify)								

You should now be able to determine the number and location of instructor-led trainings, as well as the number of staff who should take digital learning.

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