Guidance on development and implementation of a national deployment and vaccination plan

for vaccines against pandemic influenza and other respiratory viruses of pandemic potential

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Abbreviations

AEFI	adverse events following immunization
AESI	adverse events of special interest
CSO	civil society organization
EPI	Expanded Programme on Immunization (of National Immunization Programmes)
EUL	Emergency Use Listing
FBO	faith-based organization
HCW	healthcare worker
ICC	Inter-Agency Coordinating Committee
ICU	intensive care unit
IT	information technology
IDP	internally displaced person
IM	incident manager
IPC	infection prevention and control
KAP	knowledge, attitude and practice
LMICs	low- and middle-income countries
LMIS	logistics management information system
MCM	medical countermeasures
MoH	ministry of health
MIS	management information system
NCC	national coordinating committee
NDVP	national deployment and vaccination plan
NITAG	national immunization technical advisory group
NRA	national regulatory authority
PDS	post-deployment surveillance
PHC	primary health care
PHEIC	Public Health Emergency of International Concern
PIE	post-introduction evaluation
PPE	personal protective equipment
RITAG	Regional Immunization Technical Advisory Group
SAE	serious adverse event
SAGE	Strategic Advisory Group of Experts on Immunization
SARS-CoV-2	severe acute respiratory syndrome-coronavirus-2
SDG	Sustainable Development Goals
SOPs	standard operating procedures
SRA	stringent regulatory authority
TA	technical assistance
UCC	ultra-cold chain
UHC	universal health coverage
UNICEF	United Nations Children's Fund
VE	vaccine effectiveness
VPD	vaccine preventable disease
VVM	vaccine vial monitor
WHO	World Health Organization
WLA	WHO Listed Authority

Executive summary

Vaccines are powerful weapons in the fight against pandemic viruses as shown by responses to both the 2009 H1N1 influenza and the COVID-19 pandemics. However, planning for accessing, allocating and deploying vaccines in a pandemic situation is a complex endeavour, beset with multiple challenges at all levels – local, regional and global. The World Health Organization (WHO) and its partners have prepared this revised guidance document to assist countries update their national deployment and vaccination plans (NDVPs) by leveraging global learnings from past pandemic responses, including the recent COVID-19 vaccination effort. The development and testing of a NDVP would not only advance pandemic preparedness efforts but would also have benefits in terms of increasing national capabilities to manage other health emergencies which require emergency vaccination campaigns.

Throughout the NDVP development, testing and implementation cycle, countries are encouraged to adopt a multisectoral collaboration approach and seek alignment with wider health emergency preparedness plans including the respiratory pathogen pandemic preparedness plan and national action plans for health security.

This edition of WHO's NDVP guidance aims to support countries to plan and develop a range of processes and expertise in technical areas that are instrumental to a coherent, coordinated, equitable and efficient pandemic vaccine deployment effort. This guidance thus promotes:

- a NDVP development process that leverages all available national, regional and international expertise and support from multiple sectors;
- adoption of a wholistic, comprehensive and synergistic approach driven by public health goals and objectives which would help planning across all available medical countermeasures including vaccines; these public health goals can also guide broad quantification needs and allow strategic discussions on potential access mechanisms at national level;
- establishment of legal frameworks and regulatory mechanisms that support a rapid pandemic vaccine introduction and which are mindful of all available mechanisms that exist at regional and global level;
- the creation of planning and coordination structures, processes and tools that will allow engagement in and monitoring of relevant preparedness activities, as well as ensure efficient coordination and cooperation of operations at the time of the pandemic response;

- the design of processes and supporting structures which facilitate identification of key populations for vaccination;

- planning for different vaccination delivery strategies and related arrangements for supply chain management – including waste management and ensuring security of operations;

- assessment of human resources needs and the development of strategies to maintain a core cadre of trained staff, to augment the workforce during a pandemic situation and to ensure the health, well-being and safety of all staff engaged in pandemic vaccination activities;

- a continuous effort to nurture and maintain a trustful relationship with the public and other important stakeholders in order to support vaccine acceptance and demand; this will require a suite of activities aimed at identifying the drivers of vaccine acceptance and demand, risk communication and community engagement, infodemic management, science and knowledge translation and crisis communication;

- the strengthening of surveillance systems with different functions including ensuring real-time evaluation of pandemic vaccine safety and effectiveness;

- assessment of information and reporting systems to ensure that they support the timely dissemination of information from monitoring and evaluation activities and ultimately rapid, evidence-based decision-making throughout a pandemic;

- the use of simulation exercises to test the NDVP and the use of intra- and after-action reviews to monitor and evaluate a pandemic vaccination response;

- the preparation of a realistic budget, with clearly defined cost heads and a clear distinction between preparedness activities and response-related activities.

About this guide

Target audience

This guidance aims to support countries and stakeholders in developing preparedness and response plans for timely, effective and efficient national deployment and vaccination roll-out at the time of a pandemic caused by a respiratory virus, including pandemic influenza.

The following key stakeholders are expected to be involved in the development and implementation of national deployment and vaccination plans (NDVPs).

Stakeholder type	Potential roles
Government agencies	Preparation of the NDVP; political ownership; responsibility for consolidating vaccine requirements, evaluating options for implementing or expanding manufacturing of vaccines and supplies, budgetary allocations and regulatory preparedness for vaccine introduction; consultation with national and international experts; interministerial coordination; stakeholder and partner coordination; drafting of operational guidelines for vaccine rollout and governance and accountability frameworks; development and verification of micro plans; promotion of equitable vaccine distribution and fair allocation, and supportive supervision; AEFI management (including causality assessment); disease and vaccination coverage surveillance and reporting to WHO; oversight of programme reviews (including post-introduction evaluations) and reviews of lessons learned; implementation of corrective actions
National civil society organizations	Advocacy and community engagement to support uptake of pandemic vaccines; supporting planning and implementation of pandemic vaccination; provision of needs-based support to vaccination teams in areas with vaccine hesitancy; monitoring of field activities designed to pro-mote equitable allocation of vaccines
International partner organizations	Provision of technical assistance to support countries in drafting the NDVP, operational guidelines for vaccine roll-out and other operational activities; preparation of training materials; training of trainers; independent monitoring of field activities and providing related feedback to national and subnational levels; funding support
Private sector organizations	Expertise around R&D; support for cold chain and dry storage space; reporting of suspected cases of pandemic disease; community outreach and awareness generation; engagement with hesitant populations for vaccine acceptance

Objectives of the guidance document

This guidance document has the following objectives:

- to facilitate the development and implementation of a NDVP for preparedness and response to a pandemic caused by a respiratory virus, including pandemic influenza;
- to enable the development of national strategies for accessing pandemic vaccines;
- to provide a compilation of lessons learned from the COVID-19 and previous influenza pandemics; and
- to serve as a compendium of available guidance documents and tools relevant to preparedness and response activities in the area of emergency vaccination.

Organization and scope of the guidance document

The overarching purpose of the NDVP is to define strategies and plan operations for the deployment, timely roll-out and monitoring of pandemic vaccination. The NDVP serves as a single reference document for all stakeholders.

This guidance document comprises 16 chapters that address a given aspect of pandemic preparedness. Each chapter provides a list of key "take-home" messages and a list of resources. The guidance is designed to aid countries efficient deployment, implementation and monitoring of pandemic vaccines and help identify key preparedness activities that countries should engage in during the interpandemic period. The document also encloses a template to support countries in drafting their NDVP (Annex 1) as well a compilation of lessons learned from the COVID-19 pandemic (Annex 2).

The national deployment and vaccination plans are either standalone documents or are connected as parts of the national respiratory pathogen pandemic preparedness plan (WHO, 2023a).

Methodological approach to the development of the guidance document

This guidance draws on previous publications by WHO: the 2012 *Guidance on the development and implementation of an national deployment and vaccination plan for pandemic influenza vaccines* (WHO, 2012) and the *Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines – Interim Guidance 1 June 2021* (WHO, 2021a). A systematic effort was undertaken to search for and extract valuable insights and lessons from literature, with a specific focus on literature published after 2009. This year was selected as the starting point to ensure that it encompassed the period following the H1N1 2009/2010 pandemic. This also included the analysis

of the intra- and after-action reviews conducted throughout the COVID-19 pandemic. Regional workshops conducted in all WHO regions in 2023 through PIP supported activities, allowed the pilot-testing of provisions and further capturing of COVID-19 lessons learned. Inputs of experts from various organizations were gathered through a publicly open call. WHO technical teams assessed all recommendations, considering that this is an operational planning support guidance and not a normative, standard setting document.

1. Introduction

1.1. Objectives of this chapter

> To outline the key elements of a national deployment and vaccination plan (NDVP) and to provide an overview of lessons learned from past pandemics and recent technical developments which can contribute to the development an NDVP that is aligned with other health programmes and contributes to health system strengthening.

1.2. Overview of past pandemic vaccination efforts

The global response to the 2009 H1N1 influenza pandemic, and more recently to COVID-19, relied heavily on vaccines to reduce disease burden and to end the acute pandemic phase. However, both responses revealed significant gaps in preparedness such as inequitable, or delayed access to pandemic vaccines particularly in low resource countries; outdated or lack of information to inform pandemic preparedness and response plans that delayed activities; poor risk communication, community engagement and infodemic management; and inadequate logistics and cold chain capacity. Nevertheless, examples of good practice have emerged as a result of increased investment in pandemic preparedness and health systems strengthening activities, in particular in preparedness areas covered by the Pandemic Influenza Preparedness (PIP) framework (WHO, 2021b,c) and immunization systems strengthening activities among others.

Both pandemics have underscored the importance of global, national and local planning for improved access, allocation and deployment of pandemic vaccines. Having a current national deployment and vaccination plan (NDVP) was a requirement for countries to access vaccines through both the Pandemic Influenza A (H1N1) Vaccine Deployment Initiative (a donation-based mechanism) and COVAX (a pooled procurement approach used during the COVID-19 pandemic). This approach of requiring a NDVP to support vaccine deployment operations is likely to be employed in the event of a pandemic influenza, at which point the Pandemic Influenza Framework response mechanism would be activated and secured vaccines would be allocated to countries based on public health need.

1.3. Benefits of developing a NDVP

The primary purpose of developing a NDVP is to aid countries mount an efficient response to a pandemic and other health emergency. However, there are multiple benefits to be had from preparing a NDVP, some of which can have wider implications for health systems. These may be summarized as follows:

- Ensuring availability of a plan that is current and relevant for a pandemic response and which supports preparedness activities, keeps stakeholders cognizant and engaged in attaining preparedness goals and ready to work together in an event of a pandemic. It also encourages the continuous alignment of operational and strategic practices to evolving technological advancements.

- The mapping of different capacities, capabilities, gaps and potential resource avenues during the interpandemic period as part of NDVP development will strengthen core capacities.

- Developing or updating a NDVP sooner rather than later will utilize lessons learned and best practices from the COVID-19 pandemic while they are still vivid in everyone's memory. It will also be easier to advocate for sustained investment in infrastructure improvements that were made as part of the COVID-19 response.

- Alignment and integration of the NDVP with other pandemic preparedness and response plans will increase the effectiveness of other medical countermeasures and public health and social measures.

- Engagement in simulation exercises of different complexities and scenarios as part of the NDVP development process will help maintain preparedness and readiness for a potential pandemic response while fostering teamwork with clear roles and responsibilities.

- A current NDVP can be readily adapted for an emergency response to other serious outbreaks where emergency vaccination campaigns may be needed.

- Budgeting in advance for the estimated costs of various response elements and ensuring there are budget lines and mechanisms in place for the disbursements of funding will increase the timeliness of a pandemic response and avoid unnecessary delays in implementing operations.

- The process of developing a NDVP will build new or strengthen existing partnerships that will aid vaccine delivery activities. It will also foster strategic dialogues on national stockpiling needs (for those products that can be stockpiled) and identify potential avenues for securing access to pandemic products.

1.4. Process for developing or updating a NDVP

The development of an NDVP may be divided in four core phases – inception, development, adoption and continuous elaboration. These four stages are described in more detail in Table 1.

It is recommended that the NDVP is updated on a regular basis, developed in the interpandemic period, revised (i.e. tailored to clinical specificities) and activated (the response functions) during the alert and pandemic stages, and then reviewed and modified in alignment with the lessons learned after a pandemic.

Table 1. **NDVP development cycle**

Phase	Key activities	Examples of subactivities and outputs
Inception: Preparation and situation analysis	1. Establish a multidisciplinary planning committee 2. Raise awareness of committee members 3. Situation analysis to set plan's purpose, scope and outline 4. Develop workplan	• Situation analysis of country context, existing plans, capacity assessments, legal framework, and lessons learned from other pandemic responses and emergency vaccination campaigns • Stakeholder analysis • SWOT analysis • If needed, plan for prioritization of technical areas and creation of workstreams
Development: Developing or updating a plan	1. Draft, discuss and agree on plan contents 2. Consult stakeholders 3. Consolidate plan	• Writing, including costing and mapping of resources • Mapping roles of stakeholders and partner agencies
Adoption: Evaluating, finalizing and disseminating the plan	1. Test the plan by conducting simulation exercises 2. Review and evaluate the plan 3. Adjust plan accordingly and finalize content 4. Obtain final government approval 5. Disseminate plan	• Validation through simulation exercises (e.g. table-top) or other evaluation methods (e.g. group of independent experts) • Approval and formal endorsement • Publication
Continuous elaboration: Implementing, monitoring and continuously improving the plan	1. Embed preparedness in health system and multisectoral action 2. Conduct simulation exercises 3. Use indicator results to strengthen preparedness 4. Update plan at regular intervals during pandemic response, as well as after an event 5. Maintain advocacy, financing and coordination	• Assessment and identification of gaps • Integration of preparedness efforts into wider national planning activities (this activity should span the NDVP development cycle) • Conduct periodic reviews and updates of specific sections of the NDVP sections (to ensure that new information/priorities are acted upon)

1.5. Relationship between seasonal and pandemic influenza vaccination

In terms of implementing a pandemic response, the existence of a seasonal influenza vaccination programme has proven to be advantageous (WHO, 2022a, Porter et al., 2020). An analysis of the 2009 influenza A (H1N1) pandemic revealed that countries that had implemented seasonal influenza vaccination programmes were able to introduce the H1N1 pandemic influenza vaccine faster than those that did not (Porter et al., 2020). This was attributed to swifter regulatory approval of the pandemic vaccine and existing capacity and procedures for vaccinating adult populations. Furthermore, countries with established seasonal influenza vaccination programmes were better

placed to leverage the expertise of advisory committees when planning the specifics of a pandemic influenza vaccination campaign (e.g. determining the priority groups for vaccination) and already had mechanisms in place for monitoring vaccine safety.

A seasonal influenza programme can also be leveraged to continuously gather data that may inform a country's strategic national needs. The different drivers and variables that inform the burden of disease caused by the seasonal virus could inform assumptions for mathematical modelling that would help estimate medical countermeasures needs (such as vaccines, antivirals, PPEs) and consequently potential national stockpiling set-ups (for products that can be stockpiled).

Lastly, a seasonal influenza programme would facilitate the day-to-day "testing" of critical regulatory and delivery pathways, and a state of "readiness" for a pandemic vaccination response.

1.6. Vaccine technologies and their application in the event of a pandemic

The COVID-19 pandemic has been characterized by innovations in vaccine research and development. Ongoing studies are being conducted to develop seasonal influenza vaccines utilizing newer vaccine platforms. These studies also explore the possibility of creating a combination vaccine that targets both influenza and COVID-19 (Massare et al. 2021). Both traditional and mRNA-based vaccines are likely to be considered in a response to a pandemic influenza. The mRNA vaccine platforms offer the advantage of shorter initial synthesis timescales, as the vaccine's core can be synthesized from a DNA template within hours, in contrast to the days required for synthesizing virus antigen in eggs or mammalian cell lines. However, the regulatory procedures and timelines for product release remain similar to traditional vaccines. In the event of an influenza pandemic, existing production capacities for traditional seasonal vaccines can be quickly utilized by replacing the seasonal candidate vaccine virus (CVV) with the pandemic CVV through a process known as strain change. This enables the production of a vaccine in significantly shorter timelines compared to developing a completely new vaccine.

Expanding pandemic influenza vaccine production capacities would have a significant positive impact on the response to a pandemic, as it would help address the equity gap that often arises when the demand for vaccines exceeds the available supply. It is crucial to utilize all vaccine platforms to ensure the timely availability of an effective, safe, and high-quality pandemic vaccine. This requires global preparedness solutions that encompass various steps, starting with the identification of new pathogens through robust early detection and pathogen sharing mechanisms. Additionally, flexible supply chains for all necessary materials, robust and scalable manufacturing processes, improved methods for quantifying and obtaining optimal vaccine virus yields, as well as optimized regulatory pathways and inclusive access mechanisms guided by equity considerations, are all essential components of this preparedness.

The COVID-19 pandemic has prompted a "100-day response ambition" for the development and deployment of medical countermeasures that meet all the necessary safety, quality and efficacy

standards. The 2009 H1N1 vaccine development showcased that this was possible for a pandemic influenza vaccine (Rockman et al., 2022). NDVPs can help countries work towards this ambition during future pandemics by supporting a systematic approach to planning and testing the swift introduction of novel vaccines.

1.7. Pandemic vaccine introduction and the wider health system and national context: key considerations and challenges

1.7.1. Building and leveraging vaccination capacity

WHO's Strategic Advisory Group of Experts on Immunization (SAGE) values framework for the allocation and prioritization of COVID-19 vaccination stressed the importance of country ownership, evidence-based underpinnings, importance of enhancing programme capacities (e.g. cold chain) and capabilities (e.g. the availability, training and motivation of the health workforce), upholding high quality standards throughout the response, ensuring availability of resources (including the vaccine itself), and minimizing disruptions to other programmes and services as key considerations for guiding immunization activities (WHO, 2020a).

This framework and past experience highlight the importance in the pandemic period of leveraging the national capacities and capabilities that are already in place and in the interpandemic period of engaging, to the extent possible, in pandemic preparedness activities that also benefit and strengthen health systems in general. Given that it is likely that a pandemic respiratory virus will affect broad sectors of the population, there is also a need to ensure there is capacity to deliver both child and adult immunization services at the time of the pandemic. However, in developing a NDPV it must also be recognized that introducing a new pandemic vaccine comes with specific challenges. These can be product-specific (i.e. doses per person, doses per vial, route of administration, cold chain requirements, type of syringe required, shelf life, availability, and affordability) or system-based (e.g. availability of infrastructure and resources).

1.7.2. Gender and other equity considerations

Challenges related to vaccine introduction are often linked to inequities associated with a range of socioeconomic and population-related factors, such as but not limited to, living conditions and gender. The latter has both biological and behavioural bearings which can impact on access to services.

When tackling inequities, it is important to recognize that systemic inequities affect immunization when it comes to health-seeking behaviours – often referred to as "demand side", but also the provision of health services – or the "supply side". Therefore, it is important to take equity, diversity and inclusion into consideration throughout the entire vaccine deployment response. This includes maintaining a gender perspective across all planning areas.

Understanding of how social determinants of health, be they socioeconomic, geographical or cultural, influence health outcomes should underpin activities aimed at overcoming the barriers

which may prevent people from benefiting from health interventions, such as vaccines. For example, planning should consider the negative effects of certain gender roles, norms and relations which may impact vaccines access and demand among certain key populations.

1.7.3. Coordination with other health programmes and sectors

Pandemics and complex health emergency response efforts have revealed the importance of multilateral collaboration with a diverse set of actors and sectors. The need for collaboration between sectors is not limited to those more directly involved in health-oriented activities such as primary, secondary and tertiary healthcare services (including immunization services), disease surveillance, national medicines agencies and medical academic institutions but extends to other sectors whose activities impact on health-related outcomes such as financing, internal affairs, international cooperation, social services that take into consideration the needs of diverse population groups, education, transport and cross-border (points of arrival) services. All of these sectors, as well as relevant private sector stakeholders, need to be mapped and engaged in an appropriate fashion so that during the pandemic response they can contribute to the vaccination deployment effort and all available national assets and resources can be leveraged in an effective way.

Establishing and maintaining multisectoral coordination networks and mechanisms is thus an important component of the pandemic response and should be included in the NDVP. It is equally important to ensure that these mechanisms for coordination are aligned across all relevant national plans, including for example the national influenza (and other respiratory pathogens) pandemic preparedness and response plans. The respective roles and responsibilities of stakeholders in a pandemic vaccination deployment would need to be agreed and set out in a designated place (and this could be the NDVP), and ideally tested in simulation exercises designed to assess working assumptions and collaborations.

1.8. Key takeaways

Box 1: **Key messages**

- Throughout the NDVP development, testing and implementation cycle, countries should adopt a multisectoral collaborative approach and seek alignment with wider health emergency preparedness plans including the respiratory pathogen pandemic preparedness plan.
- Countries should include preparedness activities in their NDVP that will enable strengthening of immunization, health services and health systems.
- Countries with a routine seasonal influenza immunization programme may benefit in the event of a pandemic influenza by sustaining pandemic influenza vaccine production capacity; building public trust in the vaccine; testing elements of the vaccine deployment infrastructure; strengthening influenza surveillance mechanisms and strengthening National Regulatory Authorities and National Immunization Advisory Groups. Furthermore, establishing a seasonal influenza policy can also facilitate the decision-making process, identification and prioritization of key groups, and enhance vaccine acceptance.

Box 2: **Resources**

- IA2030 (2020). Immunization Agenda 2030: A Global Strategy to Leave No One Behind. Geneva: World Health Organization (https://www.who.int/publications/m/item/immunization-agenda-2030-a-global-strategy-to-leave-no-one-behind, accessed 31 May 2023).
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2. Setting medical countermeasures-related public health goals and objectives

2.1. Objectives of this chapter

> To provide recommendations on how to plan a comprehensive pandemic public health response considering all the medical countermeasures that may be available at the time.

2.2. Considerations related to the timing of vaccination within the wider pandemic response

While vaccines are less likely to be available at the start of pandemic, diagnostics and therapeutics might already have been deployed before vaccine introduction. There may be situations where for certain pathogens (e.g. for the seasonal influenza virus), available vaccines may provide cross-protective immunity until a safe, effective and strain-specific vaccine becomes available. This being said, there may also be pandemic situations where certain medical countermeasures (MCMs) may not be developed and approved for use (e.g. no therapeutics may be available). However, if and when, all these are in place, they should be leveraged to avoid over-reliance on one product that may also be in short supply at a given time, while appropriate public health and social measures (PHSMs) continue to be implemented.

2.3. Articulation of public health goals related to medical countermeasures

Public health goals guide a public health response, and are based on pandemic features, availability and characteristics of MCMs and effectiveness of PHSMs. Broadly they can be a combination of the objectives presented below in Table 2. As a planning tool, the framing of public health goals may help authorities to optimize the utilization of available MCMs in a pandemic situation and to quantify stockpiling needs in interpandemic periods. The listed goals and objectives are intentionally broad and are not limited to those where vaccination may contribute as a standalone intervention. The aim of introducing this type of broad-spectrum planning here is to stress the importance of a comprehensive, synergistic approach to pandemic response, where possible.

This chapter thus offers considerations and assumptions to guide MCM calculations. However, these can be further refined by employing more detailed scenarios (e.g. using more diverse epidemiological assumptions) and by including more detailed country specific data (e.g. estimated wastage rates).

Table 2: **Overview of types of public health goals and objectives**

Public health goal		Objectives	
Goal A	Reduce mortality	**A-1**	Treatment for all severe and critical cases
		A-2	Treatment for all mild and moderate cases
		A-3	Vaccine for all people in high-risk groups (e.g. obese, aged 65+ years, people with cardiovascular diseases, cancer, diabetes or chronic respiratory disease)
Goal B	Reduce morbidity	**B-1**	Vaccine to prevent the disease in young and otherwise healthy adults (people aged 20–65 years)
Goal C	Maintain critical services (healthcare workers and other essential workers)	**C-1**	Vaccinate healthcare workers
		C-2	Vaccinate people who work in essential services
Goal D	Limit disruption of economic and social functions	**D-1**	Vaccinate a specified percentage (X%) of the population
		D-2	Post-exposure quarantine and prophylaxis (vaccination or therapeutics, as applicable) of close contacts of a case
Goal E	Protect people in situations of vulnerability/ humanitarian setting	**E-1**	Vaccinate key populations in humanitarian settings (e.g. refugees, internally displaced persons)
Goal F	Prevent transmission (in all populations)	**F-1**	Vaccinate a large proportion of the population

2.4. Quantification of needs based on public health goals

The public health goals aid to inform ranges of likely quantitative needs for MCMs which can be calculated based on different assumptions. In the first instance, this type of exercise would generate general quantifications. These could be further enhanced by modelling efforts, also factoring in the impact of potential public health and social measures in the models. A country may choose to plan for different combinations of public health goals and objectives in accordance with its own circumstances and the potential pandemic characteristics and epidemiology. At the time of a pandemic, WHO SAGE recommendations will also be available to aid national planning. Each country should decide which public health goals are appropriate for its context.

Examples of how therapeutic treatments and vaccines could complement each other in terms of achieving specific public health goals and objectives are provided below. In each case, the rationale for the suggested approach is also provided, as well as possible assumed disease characteristics such as attack rates. These assumptions could be used to aid the quantification of needs estimates for these medical products. Note that the examples presented rely on 2009 H1N1 influenza data; when performing their own computations, countries should consider different scenarios, including with higher severity and different transmissibility features. It is important to note that the requirement for diagnostics and personal protective equipment (PPE) should also be factored into the estimations.

Goal A: Reduce mortality

- ***GOAL A-1: Treatment for severe and critical cases***

  Rationale and approach: If a treatment is available and administered to hospitalized patients, it is possible to reduce the proportion of people in need of sophisticated hospital attention (ICU and/or ventilation) and to reduce the risk of death.

  Assumptions: 24% of the population affected[1], out of which 4%[2] would be severe or critical cases.

- ***GOAL A-2: Treatment for mild and moderate cases***

  Rationale and approach: If a treatment is available and administered to people at the early stage of disease, it is possible to reduce the number of hospitalized cases.

  Assumptions: 24% of the population affected, out of which 96%[3] would experience mild or moderate disease.

- ***GOAL A-3. Vaccines for high-risk groups***

  Rationale and approach: There is no treatment, but a preventive vaccine can be administered to high-risk groups.

  Assumptions: Based on past pandemics, potential groups could include pregnant women[4], older persons, the immunocompromised and people with comorbidities such as obesity, cardiovascular diseases, cancer, diabetes or chronic respiratory disease. The high-risk groups listed here are to be considered only as examples, to illustrate a way of organizing an objective. It is important to remember that a pandemic may be caused by an atypical virus that may determine completely different risk-groups (e.g. there could be a situation in which older persons may have acquired prior immunity from earlier infections which would not necessarily put them in the highest risk group relative to other potentially high-risk groups).

Goal B: Reduce morbidity

- ***Vaccine to prevent the disease in young and otherwise healthy adults***

  Rationale and approach: There is a vaccine to prevent the disease in young and otherwise healthy adults (people aged 20–65 years).

Goal C: Maintain critical services (health and essential workers)

- ***Goal C-1: Vaccinate health workers***

  Rationale and approach: There is a vaccine to prevent infection and it can be administered to health workers.

  Assumptions: It should be assumed that in the event of a pandemic there will be a need for surge capacity, including allocating and diverting different categories of health workers

1. Based on the results of a meta-analysis that estimated the overall age-standardized incidence of 2009 pandemic influenza (Van Kerkhove et al. 2013).
2. The mid-range value of severe case rates (2–6%) reported by da Costa et al. (2020) and based on an analysis of data from the 2009 pandemic influenza.
3. The mid-range value of mild or asymptomatic case rates (94-98%) reported by da Costa et al. (2020) and based on analysis of data from the 2009 pandemic influenza.
4. The term 'woman' is intended to be inclusive of all those who identify as women and/or who give birth. While the majority of persons who are or can give birth are cisgender women (who were born and identify as female), our vision is also inclusive of the experiences of transgender men and other gender diverse people who have the reproductive capacity to give birth.

to different response areas which may place them at higher risk relative to their normal roles and duties.

- ***Goal C-2. Vaccinate people engaged in essential services***
  Rationale and approach: There is a vaccine to prevent infection and it can be given to all people providing essential services (e.g. police, teachers, transport, municipal workers, shopworkers).
  Assumption(s): People providing essential services comprise 2–5% of total population.

Goal D: Limit disruption of economic and social functions

- ***Goal D-1. Vaccinate X% of the total population***
  Rationale and approach: There is a vaccine conferring immunity to most vaccinees.
  Assumption(s): The vaccine prevents the spread of the disease in the population, provided at least X%[5] of the population is vaccinated in a given geographic area.

- ***Goal D-2. Post-exposure prophylaxis for contacts***
  Rationale and approach: There is no vaccine, but a drug reduces the virus shedding and can be given for post-exposure prophylaxis to the contacts of a case.
  Assumption(s): There are between two and four contacts per case[6]. The attack rate for the second wave will be the same as the first wave. However, in more detailed planning, countries should be mindful that historically the second wave differs from the first, and may cause a substantially higher number of cases than the first.

Goal E: Protect people in situations of vulnerability/humanitarian settings

- ***Goal E-1. Vaccinate refugees, asylum seekers, IDPs and other populations in situations of vulnerability***
  Rationale and approach: There is a vaccine to prevent infection and it can be administered to people in situations of vulnerability.
  Assumption(s): Vaccines can be deployed in certain settings.

Goal F: Prevent transmission (in all populations)

- ***Goal F-1. Vaccine for a high proportion of the population.***
  Rationale and approach: Vaccines are available to vaccinate the majority of a country's population. This approach also would reduce morbidity and mortality (including all-cause morbidity and mortality) as it would reduce the pressure on the healthcare system. It may further reduce the emergence of variants that are likely to evade the immune response and cause serious or severe disease.
  Assumption(s): Available vaccine is safe, effective, provides herd immunity and prevents transmission in all age groups.

5. This would be the herd immunity threshold.
6. This assumption regarding the range of contacts per case refers to influenza and is based on the findings of research studies that were conducted in four different countries: (a) Australia (Fielding et al., 2009), (b) Canada (Savage et al., 2011), (c) Germany (Poggensee et al., 2010) and (d) South Africa (Archer et al., 2012).

2.5. Key takeaways

Box 1: **Key messages**

- All applicable medical and public health and social measures should be used as part of the pandemic response, considering their effectiveness and synergistic effect.
- Flexibility in pandemic preparedness planning is essential and needs to be reflected when considering the need to adapt national public health goals at different points in the response. Using different assumptions (or scenarios) can facilitate a better understanding of potential ranges of needed medical countermeasures as well as 'triggers' of the rationale in changing strategies (e.g. depending on pandemic severity, risk groups, emerging evidence etc).
- For pandemic influenza planning, countries should consider estimating their needs for antivirals and potential pandemic vaccines by also leveraging available data from seasonal influenza vaccination efforts, but be mindful that a pandemic influenza may be substantially more severe than seasonal influenza.

3. Legal framework

3.1. Objectives of this chapter

> To recommend actions to identify and streamline the legal requirements governing the import, warehousing, packing, shipping and use of pandemic vaccines to ensure their timely introduction and deployment in a pandemic situation.

3.2. National laws applicable to the procurement and deployment of vaccines and related activities

National and international laws and regulations need to be considered if countries wish to avoid delays in accessing and rolling out vaccines in a pandemic situation. Lack of clarity on the mandates and prerogatives of authorities to institute vaccination requirements will also affect vaccine uptake and lead to erosion of public trust. Preparatory steps taken during the interpandemic period to ensure legal clarity can therefore avoid delays and further complications in the event of a pandemic.

Each country should have a national legal framework which makes provisions for the import and use of pandemic vaccines. However, it may be the case that not all the relevant laws are in place and/or there may be areas of overlap across existing legislation, with provision made in, for example, laws governing communicable diseases, public health laws and/or vaccination more broadly. The process of updating or amending legislation is often lengthy and therefore activities of this type are better suited to the interpandemic period. When preparing for a pandemic, it is important to map, list and monitor the legal and regulatory environment governing the use and deployment of a vaccine(s) in a pandemic scenario, as well as to identify all the necessary documentation, clarify timelines for obtaining the necessary approvals and maintain an up-to-date list of relevant focal persons.

Legal requirements may apply to the importing, warehousing, packaging, shipping and use of a pandemic vaccine, including waste management. Meeting these requirements and obtaining necessary approvals may require collaboration and exchanges with the legal offices across a range of appropriate agencies (e.g. national regulatory agency), government departments (e.g. ministry of health, customs/interior, airport administration and logistic services). When reviewing and planning legislation covering the importing of medical products, consideration should be given to the matter of import fees and whether there is a need to make legal provisions to waive these fees for donated goods.

As research and development, manufacturing and deployment of pandemic vaccines and other MCMs relies on global supply chains, consideration should also be given to national abilities (including legal considerations) to import or export raw materials that may be critical to the manufacture and supply of MCMs.

Prior to importation and regulatory approval of a pandemic vaccine, it is recommended that the relevant authorities consider different scenarios related to procuring or accessing the vaccine (or other medical countermeasures) and identify the responsible body for indemnification and liability issues, as well as any other legal limitations that may pose challenges depending on different vaccine access mechanisms. National legal provisions on providing compensation to patients who experience adverse events after vaccination should also be reviewed and mapped. In addition, a legal framework for "no fault compensation" may be needed and should be discussed by relevant national authorities.

3.3. Considerations on legal limitations

As part of their national preparedness planning, authorities may identify processes that would benefit from further streamlining, updating and alignment to enable emergency deployment operations.

Legislative challenges emerged during the COVID-19 pandemic, with one instance being the implementation of vaccine certificates that granted exemptions from quarantine for vaccinated individuals. A scoping review conducted in 2022 revealed that more than half of the articles examined legal, ethical, and policy concerns surrounding COVID-19 vaccine certificates, particularly their impact on health equity (Mithani et al., 2022). While technological advancements offer numerous advantages, they can also contribute to health disparities by excluding vulnerable populations with limited or no access to such technologies. This was evident in cases where online vaccine certificates required smartphone access. Therefore, as part of pandemic preparedness efforts, it is advisable to engage in national discussions and reach a consensus on the legal and societal approach to pandemic vaccination.

The legal provisions should also stipulate the duration for which potential approaches should be in effect and the criteria for establishing the temporality of interventions. All these aspects should be established in the interpandemic period, so that there is legal clarity and transparency during the pandemic on why certain approaches are being implemented.

3.4. Key takeaways

Box 1: **Key messages**

- Countries should use interpandemic periods to assess their legal frameworks and provisions for importing, warehousing, packaging, shipping, introducing and using the pandemic vaccine as well as for related waste management operations, to ensure timely deployment of pandemic vaccines.
- When reviewing these frameworks countries should consider the legal implications of different mechanisms for accessing pandemic vaccines and other medical countermeasures (e.g. direct purchasing, donations), as well as of introducing medicines that are still under investigation (e.g. the subject of a clinical trial).
- It is recommended to engage in a national dialogue and establish a consensus on the legal and societal approach to pandemic vaccination, considering the challenges posed by legislative issues and potential health inequities associated with these (e.g. the lack of access to technologies needed to introduce legal provisions).

4. Regulatory preparedness

4.1. Objectives of this chapter

> To support national regulatory agencies (NRAs) in their decision-making efforts by providing an overview of the latest developments and recommendations relating to regulatory preparedness

4.2. Map and establish regulatory procedures relevant for approving use of pandemic vaccines

The COVID-19 pandemic was an opportunity for NRAs to expedite regulatory pathways through rapid information sharing, enhanced communication and cooperation and access to evaluation reports among NRAs and WHO's prequalification programme when applicable. It also highlighted the need to quickly adapt to changes in product oversight (e.g. changes in product stability, shelf life extension).

4.2.1. Map existing regulatory processes and capacities in relation to international standards

Leveraging regulatory best practices undertaken during the COVID-19 pandemic, NRAs should continue to strengthen their analysis and decision-making processes, and serve as resources for other NRAs by increasing their maturity level, especially in countries that are aiming to host vaccine manufacturing capacities, as the manufacturing country's NRA will play an instrumental role in ensuring the rapid introduction of that vaccine. Countries should use the interpandemic period to advance regulatory capacities and capabilities that would enable analysis of adjustments in product presentation, expiration and authorised use with a constant view of ensuring products meet the highest standards of quality, safety and efficacy. Operational considerations to such changes should be mindful of the strength of the supply chain to accommodate the modifications safely.

The maturity level of a regulatory authority is based on WHO's 'Global Benchmarking Tool.' This tool assesses core regulatory functions, ranging from authorization procedures, testing practices, through to surveillance and pharmacovigilance, against more than 260 indicators (WHO, 2021d). Attaining maturity levels 3 and 4 is the first step towards the designation of a NRA as a "WHO-listed authority" (WLA)[7]. Currently, there is a transitional WLA list, which brings

7. The framework for evaluating and publicly designating regulatory authorities as WHO Listed Authorities (WLA) comprises i) policy on evaluating and publicly designating regulatory authorities as WHO listed authorities, ii) Interim Operational Guidance on evaluating and publicly designating regulatory authorities as WHO listed authorities, iii) Interim manual for the performance evaluation of regulatory authorities seeking the designation as WHO listed authorities and the iv) Global Benchmarking Tool (GBT) and Manual for benchmarking of the national regulatory system of medical products and formulation of institutional development plans.

together pre-existing lists of Stringent Regulatory Authorities for medicines, highly-performing regulatory authorities for vaccines, Regional Reference Authorities for medicines and vaccines in the Americas (designated by the WHO Regional Office for the Americas/Pan-American Health Organization), NRAs operating at maturity levels 3 and 4, and vaccine producing countries with functional regulatory authorities. Transitional WLAs are expected to transition to a permanent list of WLAs, upon successful completion of the "performance evaluation" exercise. The presence of a NRA on the permanent WLA list is intended to foster regulatory reliance on trusted agencies in the decision-making of regulatory authorities, the WHO Prequalification Programme and the procurement agencies.

Therefore, among the activities to set out to increase NRA regulatory preparedness , countries should map-out existing in-country and external regulatory processes, to identify high-priority needs to ensure regulatory preparedness, as well as middle-and longer-term objectives.

This mapping effort, as well as engagement in the global benchmarking process, would allow strengthening of regulatory systems, movement towards the highest level of maturity, increase the confidence in the decisions of the respective NRA, and essentially ensure availability and access to quality, safe and effective products.

4.2.2. Define pathways for emergency regulatory approval

In emergency situations, it is advised to adopt a risk-based approach that considers the severity and magnitude of the pandemic when evaluating products in conjunction with various regulatory pathways.

Table 3 lists the potential regulatory pathways that may be considered by NRAs towards approving a pandemic vaccine for use. One of them– the vaccine strain-change procedure, is particularly applicable for influenza and potentially COVID-19 vaccines. The most suitable regulatory pathway, at a given time, depends on the regulatory status of the vaccine itself, the source of supply and the respective pandemic phase.

Table 3: **Types of regulatory pathways for approving a pandemic vaccine**

Regulatory pathway	Example required documentation
Full review: The standard process which involves the evaluation of the full dossier for marketing authorization for vaccines that are new applications or previously licensed by NRAs other than a mature NRA.	• Modules 1 – 5 of the common technical document (CTD) dossier
Emergency Use Authorization: A tool to expedite the availability of medical products, including drugs and vaccines, during a public health emergency based upon the information available at the time. After a period when adequate data has been generated, the full application dossier should be provided for a full review and marketing authorization. A vaccine is given an emergency use authorization with a limited validity period and with certain conditions, mostly related to obtaining post-approval data such as AEFI and other safety, efficacy and quality data for further renewal (if required).	• Assessment and inspection reports of the producing country's NRA, mature NRA or Emergency Use Listing (EUL), if applicable • Evidence of quality (certificate of analysis or lot release) and Good Manufacturing Practice (GMP) certificate • Full available documentation necessary to demonstrate that vaccine quality, safety and efficacy are acceptable in the context of a public health emergency
Reliance: The process of relying on the assessments, inspections or decisions of other mature NRAs or WHO PQ to conduct abridged reviews.	• Certificate or evidence of the mature NRA's marketing authorization decision • Public assessment and inspection reports (if available) • Unredacted assessment reports of the mature NRA or WHO PQ • CTD dossier or documentation similar to that submitted to the mature NRA or WHO PQ
Recognition: The process of recognizing the WHO prequalification decision or the decision of a mature NRA with verification of the product sameness, but without further technical evaluation (verification review).	• Certificate or evidence of the mature NRA's marketing authorization decision • Public assessment and inspection reports (if available)
WHO CRP Apart from the regulatory procedures for authorization of pandemic or emergency use vaccines, reliance and recognition pathways can be applied through the WHO Collaborative Registration procedure for prequalified vaccines (PQ CRP) and vaccines approved by mature NRAs CRP, for an expedited assessment and approval. Both PQ CRP and mature NRA CRP can be used for suitable pandemic or emergency use vaccines as appropriate. When using the PQ CRP and mature NRA CRP, the importing/participating NRA will have access to the required documentation needed to apply reliance or recognition routes and accelerate the assessment and registration of vaccines in the country.	• An information-sharing agreement between WHO and the participating/importing NRA signed during the interpandemic or prepandemic phase • A consent form and an expression of interest to use the procedure are submitted to the WHO and the importing/participating NRA respectively by the manufacturer • Unredacted assessment and GMP inspection reports of the mature NRA or WHO Prequalification are provided to the importing/participating NRA. • The full CTD dossier similar to that submitted to the mature NRA or WHO PQ is submitted to the importing/participating NRA. • A Quality Information Summary validated by the mature NRA or WHO Prequalification is provided to the importing/participating NRA.

Regulatory pathway	Example required documentation
WHO EUL Is a risk-based procedure for assessing and listing unlicensed vaccines, therapeutics, and in vitro diagnostics with the aim of expediting the availability of these products to people affected by a public health emergency. The procedure is reserved for life threatening diseases with the potential to cause an outbreak, epidemic or pandemic and for which existing therapies are ineffective. It is therefore used to expedite availability of new vaccines for use in a public health emergency. These new vaccines would not have the full data required for prequalification and are therefore eligible for the emergency listing procedure. Under the EUL, manufacturers are requested to commit to apply for prequalification of the vaccine once all the data required for prequalification or licensure has been generated.	• Evidence of EUL • The WHO EUL assessment report should be provided to the importing NRA • Documentation similar to that submitted to WHO
Vaccine strain-change procedure: A procedure for addressing a strain or variant change in a licensed vaccine. Where it has been agreed (as defined in the approved NRA pandemic emergency procedures), the dossier of a pandemic preparedness vaccine may be evaluated in this way, following the criteria set out for a strain or variant change, as applicable for pandemic use.	• Specific documents as for a strain or variant change.

4.3. Facilitate import procedures

As mentioned in chapter 3, to ensure effective import procedures, it is crucial to regularly review and monitor the legal requirements. Furthermore, it is beneficial to keep track of potential costs that would arise during a pandemic response. Focal points responsible for coordination should engage in periodic preparedness activities to remain ready. Lessons learned from the COVID-19 experience should be utilized to identify bottlenecks and establish appropriate corrective actions.

Medical products, including vaccines, are usually imported with the supervision and participation of various actors such as NRAs, customs authorities, and port control authorities, among others. All participating agencies should coordinate their actions to improve and expedite clearance and imports.

In addition to planning for efficiency of import procedures for the finished medical countermeasures, countries should also consider having an approach in place to ensure that local manufacturers can import or export drug substances or active ingredients (e.g. adjuvant), at relevant port of entries.

A list of all necessary authorizations and documents needs to be compiled and made available to all stakeholders involved in import activities. Example documentation to facilitate import of vaccines is presented in Table 4. WHO EUL/prequalified vaccines or vaccines approved by WLAs should not require local testing prior to introduction in a country. However, some countries may require supporting documents for quality, safety and efficacy including GMP and certificate of lot release from NRA of origin country.

The recommended timeline for issuing an import permit should not be more than five working days.

Table 4: **Example documentation to facilitate import of vaccines**

- Summary protocols of manufacturing and control (or equivalent);
- Certificate of Analysis,
- Packing list (batch number, batch composition & expiration date);
- NRA lot release certificates;
- Certificate of Pharmaceutical Product (CPP);
- Proforma invoice; and
- Airway bills.

4.4. Expedite lot release of pandemic vaccines

Countries may, by law, require lot release testing of vaccines at national level, but are encouraged to waive the need for additional testing when vaccine is procured from assured sources (e.g. vaccines that have undergone WHO Prequalification/EUL assessment or approved by WLAs) through a rapid assessment of the minimum documentation advised by WHO (WHO, 2013), and ensure that the overall release time is maximum two days.

4.5. Traceability of vaccines in the context of a pandemic

Countries should maintain an up-to-date record of vaccine lots deployed at the national level, as well as trace how vaccine lots entering the country are distributed regardless of procurement route. Within the context of an unfolding pandemic, more information on the pandemic vaccines will become available and consequently require immediate tracking and updating of leaflets and labels (e.g., information on expiration dates, storage temperature).

To align with WHO recommendations, it is advisable to incorporate two-dimensional (2D) barcodes on the secondary packaging of medical products. Additionally, extending the use of 2D barcodes to the primary packaging, such as vials, should be considered without compromising any essential statutory information.

4.6. Regulatory considerations related to using vaccines under a research protocol

During the pandemic, it is anticipated that clinical trials will be conducted to assess new vaccines. To effectively lead or participate in these multicentre trials, it is crucial to establish a suitable regulatory framework that ensures compliance with ICH-GCP requirements. Previous pandemic and emergency responses demonstrated the success of research networks in enhancing the efficiency of trials through data sharing and conducting multi-site studies. Therefore, as a part of regulatory preparedness, countries should assess their national legal and regulatory frameworks, as well as other relevant capacities, to facilitate the conduct of clinical trials.

4.7. Key takeaways

Box 1: **Key messages**

- Countries should make use of interpandemic periods to establish a comprehensive regulatory framework which will ensure timely access to quality-assured medical products during health emergencies.
- Countries should introduce mechanisms to facilitate rapid exchange of regulatory relevant information at national and international level to avoid duplication of efforts and promote effective decision-making based on risk-benefit criteria. The public should be kept informed in a timely fashion, about any changes of the risk-benefit assessment.
- There should be clarity and transparency on conditions and relevant timeframes related to regulatory decisions made by respective NRAs.
- Countries should invest in advancing their regulatory maturity level and ensure that a variety of potential regulatory pathways are available so that at the time of the pandemic these can be quickly set into motion.
- The introduction of approved influenza, COVID-19 or any other vaccines that could require changes in composition would enable the national regulatory authorities' familiarity with licensing and importing through this pathway (strain-change).

Box 2: **Resources**

- WHO (2013). Guidelines for independent lot release of vaccines by regulatory authorities. In: WHO Expert Committee on Biological Standardization Sixty-first report. Annex 2. Geneva: World Health Organization (Technical Report Series, No. 978; https://www.who.int/publications/m/item/guidelines-for-independent-lot-release-of-vaccines-annex-2-trs-no-978, accessed 31 May 2023).
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5. Planning and coordination

5.1. Objectives of this chapter

> To enable a cooperation and coordination approach that would facilitate preparedness and response activities for deployment and vaccination operations at all levels.

5.2. Coordination with global, national, and local stakeholders

All available resources, capacities and capabilities at global, regional and domestic level should be leveraged throughout the pandemic preparedness and response.

To this end, in addition to planning for a structure that will be activated at the time of the pandemic, a national group should be established to monitor progress in preparedness activities, to keep abreast of latest international developments and best practices, take advantage of emerging resources and international support and adjust strategic directions that would benefit from debate and adoption in the interpandemic period.

This group should have a clear mandate and workplan and periodically report to the highest political level on progress and remaining gaps.

5.3. Coordination and preparedness activities within the context of wider emergency preparedness plans

The COVID-19 pandemic has alerted the world to the need for significant investments in the area of preparedness. The 2022 health emergency preparedness, response and resilience (HEPR) architecture defines three core principles to support engagement and activities in these areas (WHO, 2022c). These are:

- **Equity:** both between and within countries to ensure that no one is left behind and that populations living in vulnerable situations are protected;
- **Inclusiveness:** engagement and ownership from the whole of government and whole of society, taking a community-centred approach; and
- **Coherence:** reduce fragmentation and competition to maximize trust, agility, and evidence-informed decision-making.

HEPR lists five subsystems for health emergency preparedness, response and resilience. These are emergency coordination, collaborative surveillance, community protection, clinical care and access to countermeasures.

The NDVP spans capabilities captured in all these subsystems in particularly those around access to countermeasures, emergency coordination and community protection.

To ensure appropriate coordination throughout a pandemic or emergency response, the NDVPs should be coherent with other existing national strategic or operational plans, that may target other response areas but rely on the same coordination mechanisms. Therefore, the NDVPs can either be a standalone document, or can be incorporated or annexed into the wider respiratory pandemic preparedness and response plan and the National Action Planning for Health Security (NAPHS). Regardless of the approach, planning for all these documents should consider the opportunities for streamlining coordination and collaboration functions across the entire emergency planning and response mechanism.

5.4. Establish or adapt a pandemic vaccine deployment and vaccination coordination mechanism and leverage existing advisory groups

A coordinated response during a pandemic - one in which there is intersectoral collaboration, evidence-based decision-making as well as effective management and oversight – demands the existence of an efficient coordination mechanism. Countries are highly recommended to establish such as mechanism, preferably in the form of a national coordinating committee (NCC) which could leverage appropriate national structures. Such a committee would likely be comprised of a diverse set of stakeholders, including external partners, private sector and civil society, drafted in to complement or augment national and state capacities and capabilities.

Based on lessons learned during the COVID-19 response (WHO, 2021a), it is proposed that the key responsibilities of an NCC should include the following:

- Review and incorporate emerging global information on vaccines into the national vaccine deployment planning;
- Consider the recommendations issued by the national immunization technical advisory group (NITAG) or the specific national vaccine technical advisory group;
- Draft a vaccine deployment plan, detailing activities and functions, roles and responsibilities and timelines for different stakeholders (the vaccine deployment plan should be aligned with the national pandemic preparedness and response plan and include an assessment of the likely costs associated with its implementation);
- Review and set clear workflows for operations processes;

- Monitor real-time progress (using key indicators, dashboards and tracking tools) and report to authorities;
- Communicate with partners and the media; and
- Ensure existing systems (e.g. immunization, primary health-care, emergency services) are leveraged and operations are integrated into these structures.

Countries should decide whether a structure such as the NCC should also host a mechanism for accepting donations of medical countermeasures that may come through different channels. If this would be housed in a different structure, close coordination and collaboration should be ensured so that the products and deployed and tracked cohesively regardless of source.

5.5. Participation of the national immunization technical advisory group

The national immunization technical advisory groups (NITAGs) are key advisory groups that countries rely on to provide independent, expert, evidence-based advice on routine immunization and vaccine issues. NITAG membership should include senior professionals or representatives of governmental technical departments and research institutes, as well as individuals with expertise in epidemiology, paediatrics, gerontology or adult vaccination, vaccinology, infectious disease, laboratory testing, surveillance, risk communication, health economics, public health policy and monitoring.

In a pandemic scenario, an assessment of the current NITAG composition should be undertaken, to ensure that any gaps in expertise are quickly covered by inviting other experts to join the group. If a NITAG does not exist, countries should consider establishing an advisory group to provide the functions that would be undertaken by a NITAG. Functions of a NITAG would typically include collating and reviewing information available at the global level (through advice from WHO SAGE) or the regional level (through regional immunization technical advisory groups - RITAGs), and based on this information, translating, and continuously updating provisions through independent, transparent, competent and evidence-based decision-making process. This group would also be expected to review national emerging data on the progress of the pandemic[8] and information about any changes pertaining to the availability, efficiency and effectiveness of other medical countermeasures (e.g. therapeutics and diagnostics), and public health and social measures. In most settings, the remit of NITAGs also extends to providing advice on priority groups and vaccination strategies, and guidance on best communication approaches throughout the pandemic vaccine introduction and deployment process.

8. E.g. epidemiology and sero-epidemiology including laboratory-confirmed cases, hospitalization and deaths associated with the particular disease and data on natural immunity

In terms of pandemic vaccination, specific responsibilities of a NITAG would include:

- Review recommendations from WHO SAGE, RITAG and other NITAGs;
- Review country relevant data on disease epidemiology (e.g. numbers of laboratory confirmed cases, hospitalized cases and associated deaths, natural immunity);
- Advise the ministry of health on priority groups, vaccination strategies and best communication approaches regarding vaccine introduction;
- Issue vaccine-specific recommendations based on: characteristics of pandemic vaccines, including immunogenicity, efficacy and safety in different age and risk groups, available supply of vaccine and supply forecasts as well as changes in PHSM, diagnosis and treatment of cases

Countries should assess how to best support NITAG capacities and capabilities for example through the creation of a working group(s) that may prepare the materials/data for NITAG's review and advice.

5.6. Reporting and management structure

At the time of a pandemic, having in place an agreed management flow protocol – one which includes the chain of reporting - would help to clarify roles, responsibilities, processes, and information flows. Such a pandemic management flow protocol would need to consider any wider emergency response coordination structures such as the national Public Health Emergency Operation Center (PHEOC), as lines of communication and reporting will likely differ from routine programmatic work.

Over the past decade, there has been an evolution in the terminology used to characterize various functions within emergency response operations. For instance, the term "incident commander" was replaced with "incident manager", and chiefs of logistics or vaccination are now more likely to be referred to as "focal points". A more recent development establishes "pillar leads" as the persons responsible for different activities. As terminology will continue to evolve, Table 5 provides a list of specific functions that may be fulfilled by different persons in accordance with national decisions.

Table 5: **Examples of responsibilities for different functions throughout the pandemic vaccine deployment operations**

Function	Responsibilities
Overall coordination and management of response *(Incident manager)*	• Overall management of the national pandemic response. • Delegates responsibilities to relevant focal points or pillar leads. • Compiles the final report and outcomes on deployment and vaccination activities in collaboration with appropriate focal points and stakeholders.
Logistics deployment operations *(pillar lead/ focal point logistics and deployment operations)*	• Plans for the deployment activities (from vaccine/ancillaries arrival in country/ collection up to delivery point and subsequent movements) • Enlists contact information for members of deployment committees and other key authorities and prepares a duty roster • Plans shipments of vaccine/ancillaries, including mode of transport • Oversees vaccine/ancillaries forecasting, reception, storage, transport distribution and immunization waste management. • Establishes processes (and formats) for data collection, analysis, visualization and communication using management information system, inventory management and health facility service capacity assessments. • Establishes process for monitoring and evaluating deployment activities.
Vaccination activities *(pillar lead/ focal point vaccination operations)*	• Plans for the vaccination activities (e.g. vaccination strategies, monitors use/ administration, communication and safety monitoring) • Collects and organizes contact information for members of vaccination committees, and 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

5.7. Conducting simulation exercises to enable planning for the pandemic response

Countries are recommended to conduct simulation exercises as part of their pandemic preparedness planning and coordination efforts, including the development and/or updating of a NDVP. There are numerous resources that countries can utilize to assist with this aspect of preparedness planning, including the PIP Deploy table-top gaming exercise that touches on all components of the NDVP. In addition, several resources were developed for COVID-19 pandemic: of note are the two specific COVID-19 vaccine tabletop exercises which focus on: i) regulatory and safety issues and ii) vaccination strategy, supply chain and communications issues, respectively. It is recommended that simulation exercises involve all relevant stakeholders, including where possible providers (manufacturers) of vaccines.

5.8. Key takeaways

Box 1: Key messages

- Strong political leadership is key to the roll-out of successful vaccination campaigns.
- Pandemic vaccination rollout may be fast-tracked through enhanced coordination between national and sub-national level for identification of need for technical and financial support. In order to achieve this objective, it is crucial to define and clarify the coordination structures, their respective roles, responsibilities, and focal points.
- Countries should identify persons responsible for key activities, with clear terms of reference and accountability lines.
- In establishing relevant coordination and decision-making bodies, authorities should ensure gender balance and representation from women's groups and marginalized high-risk groups.

Box 2: Resources

- WHO (2021a). Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines: interim guidance, 1 June 2021. Geneva: World Health Organization (https://apps.who.int/iris/handle/10665/341564, accessed 31 May 2023).
- WHO (2022c). 10 proposals to build a safer world together – Strengthening the Global Architecture for Health Emergency Preparedness, Response and Resilience. Geneva: World Health Organization (https://www.who.int/publications/m/item/10-proposals-to-build-a-safer-world-together---strengthening-the-global-architecture-for-health-emergency-preparedness--response-andresilience--white-paper-for-consultation--june-2022, accessed 31 May 2023).
- WHO (2023a). Preparedness and Resilience for Emerging Threats (PRET). Module 1: Planning for respiratory pathogen pandemics. Geneva: World Health Organization (https://www.who.int/publications/m/item/preparedness-and-resilience-for-emerging-threats-module-1-planning-for-respiratory-pathogen-pandemics-version-1, accessed 31 May 2023).

6. Identification of key populations for vaccination

6.1. Objectives of this chapter

> To facilitate national decision-making processes for defining key populations for vaccination

6.2. Define and identify key populations

As pandemics are caused by novel viruses, emerging evidence will be considered by the WHO Strategic Advisory Group of Experts on Immunization (SAGE) to provide global guidance on recommended key groups for vaccination.

Country NITAGs are expected to review SAGE guidance in the national context, taking into consideration the broader public health goals, and if necessary, determine a prioritization approach within the determined key populations.

Due to the nature of pandemics, caused by new viruses, it is impossible to predict in advance which specific population subgroups should be targeted for vaccination during a future pandemic, as the details of the disease and vaccine are unknown. It is, however, possible to conduct some advance planning during interpandemic periods and to put in place the building blocks that will expedite the identification of key populations at the time of a pandemic. As a minimum, the prioritization criteria and process can be discussed and proposed; this would facilitate a transparent and rapid decision-making process when a pandemic occurs.

6.3. Criteria for identifying key populations

In the COVID-19 pandemic, WHO SAGE developed the values framework and roadmap for the allocation and prioritization of COVID-19 vaccination for key groups (WHO, 2020a). It articulates the overall goals for vaccination within the pandemic context, provides six core principles - *human well-being, equal respect, global equity, national equity, reciprocity, and legitimacy* - that should guide vaccine distribution and twelve objectives that further specify the six principles. This framework may serve as a blueprint that countries can leverage as part of the pandemic preparedness planning process for future pandemics.

6.4. Linkages to public health goals

Optimal selection of public health goals (chapter 2) is interlinked with the priority groups for vaccination. Public health goals encompass the planning for all medical countermeasures, including therapeutics, and involve considerations for adjusting public health and social measures as additional medical measures become accessible.

6.5. Sources of data to estimate size of key populations

The key populations for routine vaccinations, such as infants below 1 year of age, are generally well-established. However, vaccines targeting pandemic influenza and other respiratory diseases with pandemic potential are expected to involve a combination of key groups. Therefore, it is crucial for countries to have prompt access to national estimates for the different prioritized key population groups. Table 6 provides information on key populations targeted for vaccinations during previous pandemics, along with potential data sources that can be utilized to estimate the size of each population (WHO, 2021a). When determining priority groups, countries should be cautious about potential double counting since individuals may belong to multiple groups. For instance, a past pandemic experience in one country revealed that military healthcare workers (HCWs) were not considered in the HCW denominator but were counted as HCWs in the numerator when calculating the percentage of vaccinated HCWs. This resulted in the country reporting a vaccination rate exceeding 100% for HCWs. Existing methods for assessing influenza vaccination coverage in key groups could be utilized to inform pandemic preparedness efforts (WHO Regional Office for Europe, 2016).

It is important to give special considerations to the planning of offering vaccination to pregnant and lactating women within priority key groups. However, this decision should be based on the available evidence specific to each vaccine.

Table 6: **Example of key populations for past pandemics and potential sources of data to understand their size**

Key population	Definitions	Sources of data for the key populations
Health workers	Countries should decide the different categories of their relevant national health workers. WHO defines human resources for health/health workers/health workforce as all persons engaged in actions whose primary intent is to enhance health (WHO, 2006a).	National bureau of statistics, health worker registries, NGO registration bureaus. A global estimate for health workers is 3% of the population, but it varies across countries. Countries should plan an enumeration exercise (e.g. drafting "beneficiary lists" at district level prior to vaccine introduction)
Older people	Defined by age-based risk and will vary by country and region. Specific age interval to be decided at the country level by national health experts based on differential mortality by age.	National bureau of statistics, pension schemes

Key population	Definitions	Sources of data for the key populations
Persons with underlying health conditions	Determined to be at significantly higher risk of severe disease or death (these would need to be determined at the time of the pandemic depending on emerging evidence).	Existing disease registry programmes, residents in long-term care facilities, health surveys or published literature
Other key groups at significantly higher risk of severe disease or death or essential for maintaining health services (country-based)	Definition to be decided at the country level by national health experts. Groups in these categories may include public health professionals for outbreak preventions and control (who may not have been covered in the priority group of HCWs), essential workers, people working in certain occupations for example, mining, meat processing, factory workers (e.g. garment factories), and age groups at high risk of transmitting infection (e.g. young adults) etc.	Census data, national bureau of statistics, demographic and health household surveys, employer data for essential workers, group-specific surveys and studies (e.g. studies conducted among sex workers)
Sociodemographic groups in situations of vulnerability	Determined to be at significantly higher risk of severe disease or death (in countries where relevant). These could encompass: i) people living or working in detention facilities, incarcerated people, dormitories, informal settlements or urban slums, ii) people in dense urban neighbourhoods living on low-incomes, people experiencing homelessness, military personnel living in tight quarters, iii) disadvantaged populations (e.g. persecuted ethnic, racial, gender, and religious groups and sexual minorities), iv) people living with disabilities, v) migrant workers, refugees, internally displaced persons living on low-incomes, asylum seekers, populations in conflict settings or those affected by humanitarian emergencies, migrants living in vulnerable situations who are in irregular situations, vi) hard-to-reach population groups such as those in rural and remote areas.	UN Department of Economic and Social Affairs, International Migrant Stock 2020: Age, sex and destination; ILO Global Estimates on International Migrant Workers; UNHCR Refugee Statistics; Global Internal Displacement Database; IOM Global Data Portal

6.6. National allocation and prioritization considerations

In the event of a future global pandemic, countries will inevitably be required to make decisions about vaccine allocation and prioritization, especially when there is a shortage of vaccines. Principles and factors that countries may wish to bear in mind when considering what approach to adopt in order to support effective decision-making of this type in a pandemic situation are suggested below. This list is designed to assist countries in formulating a national strategy for vaccine allocation and prioritization, one which is aligned with appropriate public health goals and WHO SAGE advice and leverages lessons learned from the COVID-19 pandemic (WHO, 2022d):

- ***Human well-being:*** Prioritize populations at risk of severe disease and death and within a priority group, assess the impact of increasing the primary vaccination series coverage vs. increasing booster dose coverage for allocations.

- ***Epidemiological situation:*** Pandemic surveillance data can be used to identify geographical areas and populations at greater risk (e.g. areas and populations with high morbidity and mortality); these higher-risk areas and populations should be priorities for vaccine allocations.

- ***Equal respect and equity:*** Ensure equal opportunity for vaccination to underserved populations, ethnic groups, Indigenous People, women, persons in detention and living in institutional settings, stateless people, refugees, IDPs, asylum seekers and migrants living in vulnerable situations for vaccination.

- ***Reciprocity:*** Prioritize groups who bear significant additional risk of the pandemic disease to safeguard the welfare of others, including health and other essential workers as week as participants in pandemic-related research.

- ***Legitimacy:*** Employ best available scientific evidence, expertise, and engagement with relevant stakeholders for vaccine prioritization using transparent, accountable, unbiased processes, to engender deserved trust in prioritization decisions.

- ***Cultural and behavioural aspects:*** Countries may want to consider reallocation of vaccines from areas with significant vaccine hesitancy to other areas for faster vaccine utilization, especially for vaccines with short expiry dates. Meanwhile, social mobilization and community engagement activities should be intensified in such areas. Additionally, vaccination of key political and religious leaders, eminent doctors and other public personalities may instil community confidence and foster vaccine uptake and demand.

- ***Consider different additional parameters that may impact public health goals such as population density and geography:*** Countries may consider modelling group allocations of vaccines and other medical countermeasures based on different public health goals and context specificities. However, this type of decisions should be reconciled with other principles such as equity.

- ***Emerging evidence from research:*** As different vaccine products become available, countries should consider data on heterologous schedules for better protection of identified priority populations. Evidence on duration of protection accorded by natural infection should also be factored in for vaccine allocation in areas experiencing intense pandemic disease transmission.

6.7. Digital microplans and use of geospatial data for equitable access and delivery of pandemic influenza vaccines

Microplanning involves developing a detailed implementation roadmap for vaccination in the catchment area of a health care facility. A comprehensive microplanning roadmap should include components detailing service delivery, the management of human resources, demand generation and communications, cold chain and logistics, immunization waste management, and community engagement (WHO 2021a). Geospatial data and technologies, including geographic information systems (GIS) can support the planning and monitoring of service delivery at the local level. Using spatial data on population location, logistics and the surrounding environment, digital microplanning can ensure all populations are accounted for, identify equity gaps on access to care for different populations, and optimize planning for outreach activities to ensure equity and accessibility to services (Gachen, et al. 2021). Considering the cross-sectoral nature of data involved, investing in digital microplanning will potentially strengthen the health system and improve coordination across programmes, such as EPI, surveillance, primary healthcare, as well as strengthening community health systems.

6.8. Key Takeaways

Box 1: **Key messages**

- Countries should anticipate information needs for identifying key population groups for vaccination in the event of a pandemic.
- Countries should also anticipate what criteria will be used to guide decisions about vaccination allocation and prioritization, bearing in mind global guidance, NITAG recommendations and contextual characteristics.
- To ensure equity in vaccination allocation, national planning should consider disadvantaged and vulnerable populations as well as gender and intersecting inequalities that have traditionally hindered access to services and how to best handle the barriers faced by each group.
- Detailed microplanning on human resources, key beneficiaries, vaccine and logistics requirement, immunization waste management, communication and demand generation will contribute to better immunization coverages.

Box 2: **Resources**

- United Nations University International Institute for Global Health (2021). Guidance note and checklist for tracking gender-related barriers to equitable COVID-19 vaccine deployment. Kuala Lumpur: United Nations University International Institute for Global Health (https://www.undp.org/publications/guidance-note-and-checklist-tackling-gender-related-barriers-equitable-covid-19-vaccine-deployment, accessed 31 May 2023).
- WHO (2009). Strategic Advisory Group of Experts on Immunization.Report of the extraordinary meeting on the influenza A (H1N1) 2009 pandemic, 7 July 2009 [English and French]. *Weekly Epidemiological Record*, 84(30):301–304 (https://apps.who.int/iris/handle/10665/241386, accessed 31 May 2023).
- WHO (2020a). WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination. Geneva: World Health Organization (https://www.who.int/publications/i/item/who-sage-values-framework-for-the-allocation-and-prioritization-of-covid-19-vaccination, accessed 31 May 2023).
- WHO (2022d). WHO SAGE roadmap for prioritizing use of COVID-19 vaccines, Geneva: World Health Organization (https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccines-SAGE-Prioritization-2023.1, accessed 31 May 2023).
- WHO Regional Office for Europe (2016). Methods for assessing influenza vaccination coverage in target groups. Copenhagen: WHO Regional Office for Europe (https://apps.who.int/iris/handle/10665/345696, accessed 31 May 2023).

7. Vaccination delivery strategies

7.1. Objectives of this chapter

> To outline possible strategies and key planning considerations for delivering pandemic vaccines against influenza or other respiratory illnesses to key populations.

7.2. Vaccination strategies

The choice of appropriate strategies for vaccine delivery will be driven by a range of factors, including the properties of the vaccine itself (i.e. vaccine presentation, open vaccine vial policy, shelf life, cold chain requirements), its availability and suitability (i.e. whether there is vaccine that is suitable for specific priority groups only or is there one that can be used for wide age ranges) and the characteristics of the key populations (i.e. school going, working or older population, health workers or general population).

In-country experience gained through conducting other adult vaccination programmes and campaigns to reduce the burden of diseases such as seasonal influenza, hepatitis B (in health workers), measles, rubella and Japanese encephalitis can be used to inform pandemic planning, especially in regard to the location and timing of pandemic vaccination sessions, and human resources and training.

Countries are encouraged to engage with communities through various means such as surveys, focus group discussions, opinion polls and open meetings in order to increase acceptance and maximize pandemic vaccine uptake. Public engagement activities of this nature pay dividends in terms of providing a better understanding of attitudes to pandemic vaccination, in regard to, for example, preferred timing, strategy and private v/s public sector (see also Chapter 10). Countries should also consider vaccine delivery channels from a cost perspective, that is to say, whether the vaccine will be offered contra-cost or free-to-all, free to only certain populations like health and frontline workers and those on very low incomes who are not able to afford pay for their vaccinations.

7.2.1. Immunization schedule planning

Recommended immunization schedules for approved pandemic vaccines will be provided by WHO, based on the findings of clinical trials and the advice WHO SAGE. These recommendations will be offered at the time of the pandemic.

If multiple vaccine types are available, as was the case in the COVID-19 pandemic, NITAGs should review and recommend on their interchangeability in accordance with the WHO SAGE recommendations based on available scientific evidence (WHO, 2021f).

At the time of a pandemic, countries should consider and make specific provision in their vaccination schedules, based on WHO SAGE recommendations available at the time on, for

- interchangeability with other vaccine products (heterologous scheme); and
- co-administration with other vaccines.

Similarly, pandemic vaccination schedules should make allowance for the specific need and requirements of certain more medically vulnerable groups, such as:

- persons with prior infection or exposure
- persons with known infection of the respective pandemic virus
- immunocompromised persons
- pregnant women
- breastfeeding/lactating women.

7.2.2. Vaccine delivery strategies

Countries should identify a mix of vaccine delivery options and strategies to maximize vaccination uptake and coverages. Table 7 lists examples of such strategies.

Table 7: **Possible delivery strategies for different key groups**

Potential delivery strategy	Suggested vaccination sites	Key groups	Notes
Fixed site vaccination	Healthcare facilities including hospitals, private clinics and specialist clinics (e.g. antenatal clinics/ diabetes/ hypertension clinics)	Health workers, other frontline workers (e.g. police/army and similar forces), schoolchildren, university students, long-term care home residents, pregnant women, persons with comorbidities	Health data collected by diabetes/ hypertension and other specialist clinics may be used to identify persons with certain comorbidities
Outreach vaccination	Sites other than health facilities (e.g. community care centres, pharmacies, marketplaces, parks, stadia, drive throughs)	Older population, persons with underlying medical conditions and other disadvantaged groups including internally displaced populations, who may not have adequate access to fixed site vaccination and are at high risk of consequences if they are infected during the ongoing pandemic	Offers near-to-home vaccination when eligible beneficiaries are not mobile and unable to attend the nearest fixed site vaccination centre
Mobile clinics	Mobile vans/kiosks	Dispersed populations living in remote hard-to-reach areas, migrants, nomads, special populations working on construction sites/brick kilns/ agricultural fields and in other similar occupations	

Each of the above strategies has significant resource implications – both financial and human. It is essential therefore that countries put comprehensive micro plans in place to ensure optimal resource utilization. Planning of vaccine delivery at the local level will need to factor in the size of the key population groups, the number of trained vaccinators available and the number of vaccine doses required, allowing for a degree of vaccine wastage.

When choosing appropriate vaccine delivery strategies, countries will also need to be mindful of the characteristics of the pandemic vaccine (e.g. platform, routes of administration, storage and temperature requirements). As technological advancements will give way to different types of medical countermeasures and delivery support mechanisms, it will be important to periodically revisit planning in this area.

Countries should identify adequate human resources for the surge response well in advance, based on the planned numbers of vaccination sites that will be operationalized to reach out to the key populations.

Vaccine delivery strategies can benefit from targeted planning in the areas of registration of eligible beneficiaries, day-based schedules for vaccination, timing of sessions, logistics and set-up of vaccination sites, mobilization of beneficiaries and management of AEFIs, as detailed below:

- ***Registration of eligible beneficiaries:*** Countries should put in place mechanisms for facilitated registration of potential beneficiaries in certain population groups such as residents of retirement homes and health and essential service workers. Self-registration

for other priority populations could be facilitated either in advance or on-site. During the COVID-19 pandemic, many countries utilized various mobile apps or IT platforms to facilitate the advance registration of beneficiaries for vaccination. Advance registration is helpful for planning vaccine, logistics and human resources requirements, as well as for avoiding overcrowding at vaccination sites, which should be discouraged during a pandemic.

- ***Day-based schedules for pandemic vaccination:*** If the same health workers are expected to conduct routine immunization sessions, pandemic vaccination sessions should be planned on days other than those assigned for routine immunizations.

- ***Timing of vaccination sessions:*** While sessions may be planned during normal working hours, sessions should also be offered outside of these hours to ensure vaccination of working population, daily wage workers and similar populations.

- ***Vaccine and logistics for sessions:*** A checklist for vaccines and logistics should be prepared and sent to vaccination session sites as per existing vaccination guidelines. Adequate number of vaccine doses for the key beneficiaries should be made available in recommended cold chain conditions.

- ***Setting up a session site:*** An ideal fixed or outreach session site should have three demarcated rooms or areas:

  - a waiting room/area
  - a vaccination room
  - an observation room.

  All rooms or areas should be well ventilated and provide adequate physical distancing. Provision should be made to ensure access to all areas for the differently-abled. The vaccination room should offer an appropriate degree of privacy. In the planning stages, consideration should also be given to how to ensure site security for vaccines and other medical countermeasures, as well as for vaccinators and beneficiaries.

- ***Mobilization of beneficiaries:*** Eligible registered beneficiaries should be reminded of the date, time and venue for their vaccination through home visits and/or telephone calls by health workers or automated text messages sent via electronic registration systems. Vaccination teams should follow up eligible beneficiaries who have not reported to the session site, and encourage them to attend by leveraging support from local influencers, leaders or vaccine champions, as appropriate.

- ***Management of AEFIs:*** Vaccination teams should be equipped to deal with emergency management of adverse events following immunization, especially anaphylaxis. Suitable transport should be made available at the session sites for referral of such beneficiaries that require follow-up in an institutional setting.

7.3. Infection prevention and control measures

Infection prevention and control (IPC) is a key component of the pandemic response, more so in the initial phase of the pandemic when the vaccine availability is likely to be limited. It is also essential that appropriate IPC precautions are followed at vaccination sites to prevent the spread of the pandemic disease while providing vaccination services. This includes ensuring the availability of PPE in multiple sizes.

Training of all health workers on IPC, including understanding of the modes of transmission of the causative agent for the pandemic is critical. Regular refresher training should be conducted as new scientific information becomes available (see also Chapter 9). Countries should prepare a budgeted plan to cover the cost of activities to ensure strict adherence to IPC (see also Chapter 16).

7.4. Integration of vaccination with other health interventions

While learnings from adult vaccination campaigns conducted by the country will guide pandemic vaccine deployment in its initial phases, over time pandemic vaccination efforts may be de-escalated and merged with essential health services like routine immunization to ensure optimal utilization of human and financial resources. For example, vaccination of certain high-risk groups such as pregnant women and persons with certain comorbidities may be conducted through mechanisms such as ante-natal clinics or specialist clinics for the treatment of chronic conditions like diabetes and cardiovascular disease.

Some countries have successfully used their polio vaccination or SARI/ILI identification drives to find and enlist COVID-19 vaccine defaulters. Others resorted to door-to-door mobilization activities to search for and identify people, especially those in the higher-risk categories, who had not attended for vaccination against COVID-19. These identified individuals were later tracked and mobilized for vaccination.

7.5. Key takeaways

Box 1: Key messages

- Vaccination strategies against pandemic disease will be driven by key population and vaccine characteristics, availability of vaccines and disease epidemiology.
- Countries should leverage learnings from other adult vaccination programmes to devise locally relevant pandemic vaccination strategies for ensuring vaccine equity.
- Vaccine delivery strategies should be mindful of potential gender related and socioeconomic barriers, which may negatively impact vaccine enrolment/registration and follow-up for certain population groups.
- A mix of fixed site, mobile and outreach vaccination strategies may be deployed by countries to maximize reach to priority populations. Near to home and in-home vaccination could be considered for specific populations.
- Appropriate infection prevention and control strategies must be implemented at session sites to avoid spread of pandemic disease.
- Integration of pandemic vaccination with other ongoing health programmes may contribute to optimal utilization of available human and financial resources.

Box 2: Resources

- WHO (2021f). Interim recommendations for heterologous COVID-19 vaccine schedules, interim guidance, 16 December 2021. Geneva: World Health Organization (https://apps.who.int/iris/handle/10665/350635, accessed 31 May 2023).

8. Preparation of supply chain, management of waste and security of operations

8.1. Objectives of this chapter

> To provide advice relating to the strengthening of supply chain capacity in management of immunization/health care waste in preparation for pandemic vaccine deployment

8.2. Supply chain preparedness for pandemic vaccine deployment

Supply chain requirements for a pandemic vaccination depend on several factors including the size of key populations, vaccine characteristics (e.g. shelf life) and its mode of delivery (i.e. whether it is injectable or can be administered intranasally or in a patch), existing cold chain capacity, vaccine storage and transportation requirements (e.g. whether a vaccine requires special storage conditions), the quantities of vaccine available and vial presentation (single or multi-dose, liquid or freeze-dried).

As part of their NDVP, countries should make provision for the movement of vaccines and associated logistics operations from the point of manufacture (or importation), out to state, provincial or district distribution centres and finally to vaccine service delivery points. This provision should include any information and communication technologies that will be needed to track vaccines through the supply chain and associated logistics systems.

Countries should plan for movement of vaccines and associated logistics from the national to state/provincial and district levels, to the service delivery points. Specifications of information technologies and communication support will need to be developed for tracking cold-chain and logistic processes. Countries should develop costed supply chain plans, or update rate contracts with all suppliers and transportation firms in case the services are outsourced.

The completed supply chain plans should include estimates for each of the following:

- The number of vaccine doses and all ancillaries (factoring in wastage rates) to be shipped to each of the distribution points (including an estimate of the frequency of the shipments);

- The volume of electrical (deep freezers and ILRs) and non-electrical cold chain (cold boxes, vaccine carriers) space required and available at each point in the distribution network. When planning for this type of infrastructure, countries should also consider the stability of vaccines during transport; this is likely to be an important consideration in more remote and hard-to-reach areas that may rely on different modes of transport such as boats,

motorcycles or drones. Careful planning is also likely to be needed for locations that have less frequent flights or require a combination of transport means (e.g. plane and boat) before reaching the national point of entry (e.g. small island states);

- The capacity to generate cool/ice packs at each service delivery point;
- The number of anaphylaxis/ AEFI kits;
- The necessity and scale of stockpiling medical countermeasures or related supplies (e.g. syringes);
- The amount of medical waste generated during the event with plan for its safe disposal.

8.3. Strengthen supply chain human resource capacity

Trained human resources have the following key roles:

- Preparation of supply chain distribution plans
- Maintenance of cold chain equipment
- Packaging and re-packaging of vaccines, diluents and associated logistics for shipment to lower stores or session sites
- Monitoring of temperature of cold chain equipment and activate emergency plans in case of power failure or break-down of equipment
- Management of stocks in case of any reported AEFIs
- Tracking stock position, timely reorders, or relocation of supplies from stores where they are available
- Management of finances for key costed activities
- Maintaining records and reports
- Provide feedback for corrective actions

The capabilities of staff and managers responsible for storing, handling, transporting and tracking vaccines and associated logistics should be built on relevant guidelines, SOPs and standard forms & formats to ensure their effective functioning.

Countries may conduct table-top simulation exercises to assess the readiness of the system for emergency vaccine deployment.

8.4. Assess vaccine logistics and cold chain capacity needs

Most countries will likely receive their pandemic vaccines through international shipments, in which case supply will be largely dependent on global supply chains and often beyond the importing country's control.

Most routine immunization vaccines need to be stored at temperatures between +2°C and +8°C. Pandemic vaccines with similar cold chain requirements are easier to accommodate within the existing cold chain infrastructure and equipment. Additional cold chain space requirements for pandemic vaccines should be calculated based on the estimated number of beneficiaries and number of recommended vaccine doses per beneficiary, adjusted for an acceptable vaccine wastage rate.

However, for pandemic vaccines requiring ultra-cold chain (UCC), countries would need to rapidly augment cold chain capacities through procurement or partnership with the private sector and other stakeholders. As part of their supply chain planning process, countries are advised to map existing private and public sector partners to ensure rapid availability of cold chain capacity, as well as dry space, in the event it is needed.

8.5. Ensure supply chain system functionality

To ensure optimal supply chain functionality for a pandemic response, the following preparedness actions are recommended:

- Draft guidelines, SOPs and recording and reporting formats;
- Develop costed micro plans, with adequate budget allocation to programme managers at all levels;
- Forecast vaccine requirements, especially when multiple vaccine products are in use, and align with existing cold chain capacity;
- Ensure sustained power supply, including power backup at cold chain points;
- Organize regular training of key supply chain staff on topics such as guidelines, SOPs, forms and reporting formats, contingency planning and equipment maintenance;
- Ensure systematic temperature monitoring during transport and storage;
- Define communication channels, including reporting requirements for issues that need urgent attention;
- Facilitate visibility of information from supply chain management system to programme managers at all levels;

- Establish coordination between government departments such as the customs authority, NRA, the ministry of finance, and relevant local authorities (e.g. police and military); and
- Engage with existing and potential private sector providers.

8.6. Manage and track vaccines effectively (including UCC and reverse logistics)

It is prudent to keep the number of vaccines that are in transit at any one time to a minimum. This is best achieved by having an efficient tracking system in place; this not only helps to optimize the performance of the supply chains but also ensures vaccine availability at service delivery points and reduces wastage. The ability to track vaccines in transit is especially import for ultra-cold chain vaccines and vaccines with a short shelf life. To meet this challenge, countries should ensure the following prior to vaccine arrival:

- map ultra-cold chain capacities for vaccine storage and dry ice production;
- cold chain augmentation through equipment procurement or private sector partnership;
- availability of appropriate technical support for installation and management of UCC equipment;
- training of staff on SOPs and use of appropriate PPE;
- availability of sustained power supply and power back-up in facilities housing UCC equipment; availability of specialized containers or thermal shippers with dry ice for transport;
- clear guidelines and SOPs on the use and maintenance of UCC, including deployment and re-positioning of UCC equipment and management of phase change materials; and
- a documented and tested contingency plan with clear roles and responsibilities of key staff.

8.7. Management of healthcare waste

In the context of this guidance document, waste management refers to the process of safely collecting and disposing of hazardous waste material arising from vaccination activities (syringes, needles, vaccine vials).

Safe management and disposal of pandemic vaccination waste is critical to prevent spread of infection and protect health workers, the wider community and the environment. During a pandemic, there will be a surge in the volume of medical waste generated such that existing mechanisms for

disposal may not suffice. Countries are thus advised to include provision for managing increased volume of vaccination waste as part of their pandemic preparedness plans.

A waste management plan for a pandemic response should assess current waste management capacity, describe available methods for waste collection, transport, treatment and disposal, and outline a pandemic waste management strategy, covering the safe collection, transport and disposal of vaccine waste.

In this regard, the countries should conduct the following activities:

- estimate the expected volume of waste;
- identify and map waste disposal collection and transport capacities;
- identify facilities for storage and waste disposal methods (incineration, landfill, pressurized steam treatment);
- draft SOPs for segregation, collection and disposal of vaccination waste, with focus on the safety of health workers and the wider community;
- develop a costed waste management plan and map existing facilities for safe disposal of healthcare waste;
- prepare a logistics plan to identify the quantities of materials required for appropriate waste management, including safety boxes, waste collection bags and bins in accordance with the country's existing rules on biomedical waste management;
- train health staff on their role in ensuring appropriate management of immunization waste, including the risks associated with improper waste management and mechanism for reporting of incidents like needle stick injuries; and
- implement site waste segregation at the site of generation and its return to the waste collection point through reverse logistics

Countries should make every effort to ensure that their waste management strategies employ the best available technologies and are compliant with the Stockholm Convention for Collection, Segregation, Treatment and Safe Disposal of Healthcare Wastes (WHO, 2006b; WHO, 2019b).

8.8. Ensure security of operations

Countries should plan for ensuring the safety of the pandemic vaccines and security of healthcare staff during vaccine production, transit, storage and administration. Key communication messages on the vaccination plan and the rationale for prioritization of populations should be drafted and disseminated among communities.

8.9. Key takeaways

Box 1: Key messages

- Supply chain requirements for pandemic vaccine deployment are dynamic and optimization of the supply chain is critical to ensure efficient and timely roll-out.
- Countries need to ensure that all staff involved in the handling of vaccines and supply chain logistics are adequately trained and prepared to scale up operations in a pandemic.
- Countries should explore mechanisms such as public-private partnerships and collaboration with other key stakeholders ensure adequate supply chain surge capacity including related waste management.
- Safety of pandemic vaccines and health workers should be ensured, especially in the initial phase of the pandemic when vaccine supplies are limited, and vaccination is only available to priority populations.
- Vaccine management systems should be agile enough to accommodate and track multiple vaccine products, which may have different storage and transportation requirements and shelf life.
- Independent monitoring mechanisms should be put in place to identify gaps in the supply chain for corrective actions.

Box 2: Resources

- WHO (2006b). Management of waste from injection activities at the district level: guidelines for district health managers. Geneva: World Health Organization (https://apps.who.int/iris/handle/10665/43476, accessed 31 May 2023).
- WHO (2019b). Overview of technologies for the treatment of infectious and sharp waste from health care facilities, Geneva: World Health Organization (https://apps.who.int/iris/handle/10665/328146, accessed 31 May 2023).

9. Human resource management and training

9.1. Objectives of this chapter

> To assist countries in identifying and addressing the human resource requirements, including training and supervision, for the successful roll-out of pandemic vaccines.

9.2. Defining team roles, capabilities, and competencies

Having sufficient human resources with the appropriate skills will be key to the successful deployment of vaccines in a pandemic response. To this end, human resource managers involved in the pandemic response preparedness should prepare job descriptions for every function, clearly defining the chain of command, and the tasks and responsibilities for each category of staff. Staff should be given clear step-by-step instructions on how to perform the specific tasks assigned to them; this information could be provided through job aids or short videos. In addition, managers should discuss with each staff member what is expected of them, assess whether they have the skills and resources to perform their assigned tasks, and identify interventions that will improve staff performance. Simulation exercises are a useful way of identifying what skills individual staff members will need to improve their performance; such exercises also enable staff and managers to improve the performance of their expected roles in a collaborative environment.

9.3. Identify human resources needs

Mounting a pandemic response will likely place a considerable extra strain on health systems and their workforce. In addition to diagnosing and treating patients with pandemic disease, the health workers may be tasked with additional roles and responsibilities including disease prevention and education of the local community. Health staff engaged in pandemic vaccination will require training on vaccine storage, vaccination schedules, administration of vaccines, infection prevention and control, management of adverse events following immunization and advocacy with the community on issues related to key groups that are being offered vaccination on priority.

As far as possible, countries should ensure uninterrupted provision of essential maternal and child health services, including routine immunization. Gaps in workforce capacity to maintain these key services should be addressed systematically and promptly.

It is hence important to prepare a comprehensive, costed plan for human resource needs; this plan should include provision for surge vaccination support and capacity building requirements. Consideration should be given to how additional vaccinators may be recruited for rapid roll-out of pandemic vaccination. For instance, different types of health workers – such as community

pharmacists – may be leveraged to administer vaccines in accordance with the country's existing regulations. The involvement of community pharmacists in seasonal influenza vaccination campaigns and more recently in the COVID-19 response has proven beneficial in some countries.

In-country partners could be repurposed to support activities. Human resource planning should also make provision for lockdowns which will restrict the movement of human resources, as well as the movement of logistics staff involved in the handling and distribution of vaccines.

9.4. Design and plan training of health workers

Innovative training methods will be needed for rapidly upscaling the capacity of the health workforce, once a suitable pandemic vaccine becomes available. While facilitator-led training remains the ideal and may be conducted virtually or face-to-face, countries should consider using online self-paced training modules during the preparatory phase to deliver the necessary learnings to various categories of health staff. Countries should also consider the potential advantages of developing and employing short videos or infographics which can be shared over mobile phone apps to enhance learning. Whichever form of training is adopted, countries are advised to enlist the help of technical experts to assist in both the design of training materials and the delivery of training to ensure trainings are effective and based on adult learning principles.

Recommended actions pertaining to health workforce training during this time thus include:

- adapt available training materials to suit country requirements and context;
- identify different categories of staff vaccinators, cold chain handlers, social mobilizers, supervisors, data managers, waste handlers and logisticians, and prepare/update training materials as required;
- decide which training platforms and methods – face-to-face, virtual or hybrid/mixed – are most suitable for different settings and categories of staff;
- identify trainers from government or key partners at each level, and plan for orientation/ training of trainers;
- identify and designate a focal point for training activities;
- prepare tools for pre and post-test to assess the competency of each category of personnel trained.

Table 8 provides a decision matrix to assist human resource managers and supervisors select the most appropriate training modalities (face-to-face vs virtual) given various scenarios and settings.

Table 8: **Decision matrix to aide decisions on training modalities**

Virtual training	Face to face training
Intense transmission of pandemic disease	**Low** transmission of pandemic disease
Inadequate number of good trainers available	**Adequate** number of good trainers available
Large number of trainees	**Small** number of trainees
Unavailability of suitable training venue	Suitable training venue **available**
Variable PHSM implementation	**Good** PHSM implementation
Good internet connectivity and **availability** of personal devices	**Unreliable** internet connectivity and/ or **non-availability** of personal devices

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

- training is conducted by trained trainers in small batches;
- the training venue is well ventilated and suitable precautionary measures are in place to prevent infection of trainees and trainers;
- training is scheduled no more than 2 or 3 weeks prior to the pandemic vaccination launch, otherwise refresher training may be needed;
- health workers being trained have already received their pandemic vaccine prior to participating in training and vaccination activities;
- ensure key points are understood by trainees though the use of techniques such as group discussions, demonstrations and skills practices; and
- follow the training with supportive supervision to ensure that health workers correctly apply the new skills and procedures.

9.5. Plan for surge needs

As pandemic vaccine availability increases with time, countries will be able to offer vaccination services to additional priority groups. This will likely require on-boarding of additional health staff to operationalize additional vaccination session sites. Prior identification of additional technical human resources, supplementary microplanning and rapid training will be key to rapid scale-up of vaccination activities.

9.6. Key takeaways

Box 1: Key messages

- Availability of sufficient and adequately trained human resources is key to an efficient pandemic vaccination response.
- Countries should identify sources of surge staff well in advance of the launch of a pandemic vaccination campaign. A costed training plan for surge staff will also be needed to ensure timely roll-out of pandemic vaccination.
- Full advantage should be taken of range of options available for staff training, including online, face-to-face and blended learning approaches. Self-paced online learning can be used along with job-aids and short videos as a reference tool for refresher training.
- Supervision of training sessions for adherence to training guidelines will aid high-quality training sessions
- Mechanisms should be put in place to ensure the safety of the vaccine deployment workforce and gender considerations should be embedded in all related human resources planning.

Box 2: Resources

- WHO (2020b). COVID-19 vaccination training for health workers, OpenWHO [website]. Geneva: World Health Organization (https://openwho.org/courses/covid-19-vaccination-healthworkers-en, accessed on 31 May 2023).
- WHO (n.d.-b). COVID-19 Simulation exercise packages [webpage]. Geneva: World Health Organization (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/training/simulation-exercise, accessed 31 May 2023).

10. Vaccine acceptance and uptake (demand) – community protection

10.1. Objectives of this chapter

> To provide guidance on planning activities to foster acceptance and uptake of pandemic vaccines and community protection, such as risk communication and community engagement, infodemic management, science communication and public health and social measures communications, crisis communication.

10.2. Demand planning

In order to successfully introduce new medical countermeasures like vaccines, it is essential to consider the associated behavioural factors and employ effective communication approaches. This is crucial for establishing and preserving public trust, ensuring that key populations comprehend, accept, and act upon all pertinent preventive strategies and approaches.

Community engagement will be a priority activity both in the interpandemic phase and for the duration of a pandemic response. Steps that countries can take to foster community engagement and build public trust include:

- Transparent, timely, consistent and harmonized communication of evidence-based information by policymakers and programme managers which explains in an accessible way, how the research evidence led to particular recommendations.

- Availability of communication materials in appropriate places and/or online and via social media and in an appropriate language which are accessible and relevant to diverse populations groups. Dissemination of information should be proactive and consistent and, if applicable, public concerns should be addressed immediately and accurately.

- Collaboration and coordination with appropriate stakeholders and networks to facilitate diffusion, alignment and amplification of correct information and a more rapid identification of sources of mis and dis- information. Stakeholders in this process might include elected politicians, medical associations (including nurses, pharmacists, dentists and other health professionals), civil society and NGO networks, religious associations and their leaders, community engagement networks, labour association representatives as well as donors.

In a pandemic scenario, the successful operationalization of community engagement activities will be enhanced by:

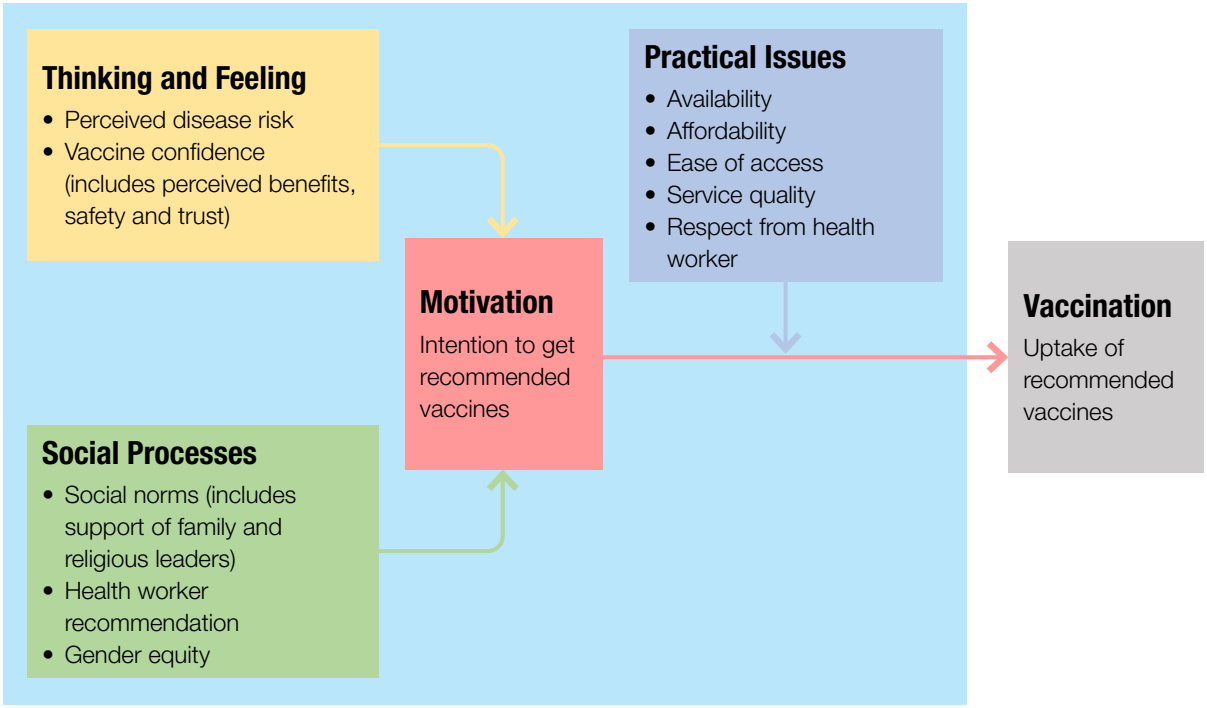
- high-level political support;
- understanding of how to engage with and enlist the support of stakeholders;
- developing plans that are informed by local data and rely on strategies adapted to the local context;
- ensuring capacity building needs and gaps are quickly identified;
- employing a data-driven approach to monitoring and evaluation; and
- an overarching effort to integrate all activities in the area of acceptance and demand into the pandemic response plan.

Frontline workers should be empowered to encourage key populations to attend for vaccination, as well as be equipped to engage in difficult conversations about vaccination (e.g. not being able to administer the vaccine to an individual that is not among a priority group). Frontline workers may be considered as another important group or "audience" for tailored messaging and engagement. Information should be provided in a way that addresses their questions, but at the same time is mindful of their likely limited time. To ensure all these are in place at the time of the pandemic response, skills in listening, interpersonal communication and community dialogue need to be built in the interpandemic period.

10.3. Drivers of vaccine acceptance and uptake

Preparedness and response activities should be underpinned by an understanding of the behavioural and social drivers of vaccination uptake. These may change over time and therefore need to be monitored continuously. The Behavioural and Social Drivers (BeSD) Framework – Figure 1, can be used to guide the overall approach to understanding these drivers, as well as to inform the design of surveys and/or interviews to enable data collection, analysis and the subsequent design of interventions. The BESD Framework facilitates an understanding of how people think and feel about a particular vaccine; the social processes that affect vaccination; the structural and social factors that can act as barriers to vaccination; the motivation (or hesitancy) to get vaccinated; and the practical enablers (or barriers) to getting vaccinated at the point of care.

Figure 1: **Behavioural and Social Drivers (BeSD) Framework**



The Behavioural and Social Drivers (BeSD) Framework Source: The BeSD working group. Based on Brewer et al. Psychol Sci Public interest. (2017)

10.4. Risk communication and community engagement (RCCE)

Risk communication and community engagement (RCCE) activities related to vaccination efforts are generally geared towards informing and engaging the public and in particular communities, including through traditional media channels (i.e. print media, television and radio), social media and community leaders. Populations should be informed about the risks and benefits of adherence/non-adherence to interventions such as vaccination, how it may affect their lives and how they can play an active role in generating demand and enhancing uptake of the pandemic vaccines. Fundamental to this effort – highlighted above – is the fostering of a trustful relationship, where communities can be meaningfully engaged in the pandemic response so that their unique needs and experiences are considered at all stages of the pandemic vaccine deployment process.

RCCE activities are supported by:

- Continuous engagement with communities to listen to, understand and systematically analyse community perspectives, in particular any emerging concerns and beliefs (which should be addressed appropriately through timely and tailored communication);

- Maximizing all communication channels to allow information on vaccination, including emerging topics of interest, to reach the widest possible audience;

- Ensuring accessibility of information by making it available in a variety of languages and by using messaging that is tailored to different populations (e.g. those that should be vaccinated first);

- Building partnerships with community groups and networks and leveraging those partnerships to develop appropriately tailored communications and messages that employ non-stigmatizing language; and

- Developing a communication plan to build and maintain public trust by providing clear and transparent information before, during and after vaccination.

10.5. Science and knowledge translation and public communication

The COVID-19 pandemic highlighted the critical importance of data-driven and evidence-informed decision-making – by policy-makers and the public – in all aspects of the pandemic response, including vaccination. However, for a range of reasons, people's actions were not always evidence-informed; sometimes key information was not accessible to the sectors of the population in a format that they understood or found relevant. Science translation is a relatively new discipline that aims to make scientific evidence accessible, understandable, relevant and actionable, both to the public and decision-makers, so that their actions and policies are evidence-informed. In a public health emergency, when there is so much uncertainty in a dynamic and evolving situation, an understanding that a rigorous process has been undertaken to ensure that a vaccine that is being offered is both safe and effective helps to reassure and build trust. But this understanding needs to be communicated through multiple sources, and in a way that the public and decision-makers understand – through direct engagement with decision-makers and scientists, through community leaders, through the media and through social media, and in a timely manner.

In the preparedness stage this area should also be captured in the wider communication plans.

10.6. Managing the infodemic

An "infodemic", defined by WHO as too much information including false or misleading information in digital and physical environments, is fuelled by recent technological advancements, and was very much a feature of the COVID-19 pandemic (WHO. n.d.-c). An information "overload" can lead to confusion and mistrust in health authorities, which in turn may lead to behaviours that can harm health, as segments of the population may delay acceptance of life-saving health interventions. Clarifying rumours and misinformation in a pandemic situation should be addressed by maintaining a very open flow of information at all stages of the vaccination campaign (before, during and after).

The negative impacts of an infodemic can be minimized by the systematic use of risk- and evidence-based analysis to establish good health practices, the results of which should be

promoted as widely as possible. In terms of managing an infodemic, this can be approached through four types of activities:

- listening to community concerns and questions
- promoting understanding of risk and health expert advice
- building resilience to misinformation
- engaging and empowering communities to take positive action.

Infodemic management can be particularly helpful in understanding and addressing community concerns around vaccination in online forums. Tools such as chatbots can be employed to respond to concerns and disseminate correct information and support pandemic vaccine acceptance and demand.

10.7. Public health and social measures

Public health and social measures (PHSMs) include a range of different activities that leverage non-pharmaceutical interventions to reduce the transmission of infectious diseases. Examples include mask wearing, maintaining physical distance, restricting public gatherings, introducing different measures in certain environment like schools and workplaces (e.g. modifying their hours and attendance flows), contact tracing, workplace closures, travel restrictions and quarantine requirements.

At the time of the start of a pandemic vaccination campaign it is highly likely that countries will have already introduced a series of PHSMs. However, although there is a social and economic case to be made for relaxing at least some of the more stringent measures once vaccination rates increase, countries should be mindful of the risks associated with relaxing restrictions too soon and consider maintaining the less stringent PHSMs so that there is no gap in protection of populations that may not be fully immunized.

Disease surveillance should guide the introduction, as well as the phasing out of potential intervention combinations in the safest way (see Chapter 13). Communities should be consulted when PHSM changes/adjustments are being considered.

10.8. Crisis communication

It is recommended that all elements of public engagement and communication be brought under an appropriate coordinated umbrella; this would not only increase the effectiveness of preparedness activities but also facilitate quick responses to public concerns on vaccine safety, reported adverse events following immunization and other related concerns during a pandemic.

To support the crisis communication management, and drawing on learnings from previous pandemics, the following activities should be considered:

- developing SOPs for managing crisis communication;
- adopting a multi-channel-oriented approach to managing the infodemic, including pre-empting, detecting and responding to rumours, mis-and dis-information in real-time;
- establishing communication pathways that meaningfully engage all stakeholders so that there is a unified message (as opposed to contradictory announcements);
- setting-up training mechanisms for different stakeholders (e.g. for media and spokespersons);
- strengthening engagement with communities and networks; and
- a well-defined approach to communicating vaccine safety issues to ensure transparency of reporting and analysis practices, in which relevant mechanisms are clearly explained.

10.9. Key takeaways

Box 1: **Key messages**

- Countries should put in place plans for conducting social mobilization and communication activities, and mechanisms for need based modifications as the pandemic progresses
- Capacity of health workers should be built during inter-pandemic period on inter-personal communication to equip these with the tools to build trust in vaccination and handle difficult conversations with those who may be reluctant to have a vaccine
- Communities should be apprised of the role of public health and social measures during the initial phase of the pandemic when medical countermeasures may be available in limited numbers
- Information should be disseminated proactively and consistently, and public concerns and queries should be addressed in a timely manner
- Gender and equity-related barriers to vaccine information and uptake should be anticipated and addressed (e.g. through tailored messages and accessing specific communication channels)
- Meaningful engagement with opinion leaders and key stakeholders should be fostered for enhancing vaccine acceptance amongst communities
- Countries should enable multi-channel approach to infodemic management to provide reliable evidence-based information to their communities

Box 2: **Resources**

- WHO (2021g). An ad hoc WHO technical consultation managing the COVID-19 infodemic: call for action, 7-8 April 2020. Geneva: World Health Organization (https://www.who.int/publications/i/item/9789240010314, accessed 31 May 2023).
- WHO (2021h). WHO competency framework: Building a response workforce to manage infodemics. Geneva: World Health Organization (https://www.who.int/publications/i/item/9789240035287, accessed 31 May 2023).
- WHO (2022e). WHO policy brief: COVID-19 infodemic management. Geneva: World Health Organization (https://www.who.int/publications/i/item/WHO-2019-nCoV-Policy_Brief-Infodemic-2022.1, accessed 31 May 2023).
- WHO (n.d.-c). Infodemic: Overview [webpage]. Geneva: World Health Organization (https://www.who.int/health-topics/infodemic#tab=tab_1, accessed 31 May 2023).

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

11.1. Objectives of this chapter

> To offer considerations on how countries could prepare to safely deliver pandemic vaccines minimizing the risk of adverse events following immunization (AEFI) and human errors during injection practices and implement vaccine pharmacovigilance to ensure vaccine safety prior to, during and after administration.

11.2. Address vaccine safety and pharmacovigilance challenges

A dynamic surveillance and monitoring system for adverse events following immunization (AEFIs) from the grassroots level to the national level as a part of the existing system is recommended in the context of varying country capacities and novel vaccines. This routine passive surveillance system should enable early identification, management, investigation, data analysis and causality assessment of AEFIs to safeguard population health and sustain community trust in immunization activities. Real-time monitoring and sharing of data with WHO is recommended to allow for pooling of data and identification of safety signals as outlined in the Global Manual of Surveillance of AEFI (WHO, 2016b).

The system should support capacity to investigate, analyse and manage any adverse event following immunization (AEFI) and adverse events of special interest (AESI) (depending on the context). This is especially relevant for new vaccines with limited post-marketing data.

11.3. Key vaccine pharmacovigilance considerations

As part of their pandemic preparedness planning, countries should ensure that there is at least a passive vaccine safety surveillance system in place and functioning adequately. Countries are encouraged to develop, if they have not done so already, active vaccine safety surveillance systems which are sufficiently flexible and capable of gathering and analysing large amounts of data from different subpopulations in a short period of time. These systems should be tested during the inter-pandemic period and adequately resourced (i.e. included in the pandemic preparedness budget) to ensure their operationality in a pandemic situation.

Particular attention should be paid to establishing mechanisms for the monitoring of adverse events of special interest (AESI), and a pre-defined list of events of interest based on emerging knowledge about the safety risks of pandemic vaccines should be compiled in time. Local background rates as well as operational and regulatory definitions for AESIs based on the Brighton Collaboration case definitions when available should be compiled (Brighton Collaboration, n.d.).

Findings from investigation and causality assessment for serious adverse events (SAEs) and monitoring of AESI should be shared with relevant stakeholders.

In addition to conducting their own vaccine safety monitoring programmes, countries are recommended to be on alert for information and recommendations provided by WHO's Global Advisory Committee on Vaccine Safety (GACVS). This committee is tasked with delivering independent, authoritative scientific advice on vaccine safety issues of global or regional concern which have the potential to affect national immunization programmes, both in the short- or long-term. In the COVID-19 pandemic, WHO, under the guidance of GACVS, has issued the *COVID-19 vaccines safety surveillance manual* (WHO, 2020c). During the COVID-19 pandemic, countries were recommended to adapt the principles presented in the manual as a preparedness guidance prior to, during and after the COVID-19 vaccine introduction.

Prior to introducing a novel vaccine, making a roster of relevant stakeholders (e.g. National Immunization Program (NIP), National Regulatory Authority (NRA)) and defining their roles and responsibilities and developing a crisis communication plan in addressing vaccine safety issues will allow countries to mount a rapid response during the crisis and facilitate a harmonized approach across stakeholders to handle unexpected events.

To ensure global collaboration and rapid identification of signals and alerts, countries are encouraged to share national data in a standardized format with the global safety database located in the WHO Programme for International Drug Monitoring (PIDM). WHO PIDM brings together more than 170 full members and associate members in the programme (as of October 2022) who submit reports of adverse reactions associated with medical products, including vaccines. WHO can offer assistance to help countries develop AEFI data collection tools (including electronic data collection, processing and management systems using mobile devices) best suited to their context.

Delayed information sharing on safety and AEFI can cause negative consequences on public confidence in the vaccine. Health staff and relevant stakeholders should be trained to effectively address questions posed by the public, build trust, send clear messages, and utilize mainstream media and social media (see also Chapter 10). Countries can apply the WHO guide on *Vaccine safety events: managing the communications response*, to effectively and accurately communicate such information to the public (WHO Regional Office for Europe, 2013).

11.4. Ensure safe vaccination delivery

During the interpandemic period, countries should continue to provide refresher training to vaccinators on all aspects of vaccine handling and administration to minimize the risk of immunization error-related reactions. WHO's Immunization in practice (WHO, 2015) provides a detailed guidance regarding safe injection practices, including:

- *Management of multidose vials (if applicable):* Use a different syringe to load each dose. Use a different needle for each vaccinee. Careful attention should be given to measuring correct volumes when vaccine reconstitution is necessary.

- *Injection equipment:* Use sterile injection equipment. Dispose of any needles that have been in contact with a non-sterile surface.

- *Packaging:* Inspect the integrity of the packaging. Discard the syringes and needles with packaging that has been perforated, broken or damaged as a result of exposure to moisture.

- *Batch numbers and expiry dates:* Look carefully at the product and its packaging; check batch numbers and expiry dates against documentation provided by distributors. Be alert to the possibility of falsified and substandard vaccines that have been detected in some supply chains during the COVID-19 pandemic.

- *Needle stick injury:* Take suitable precautions to prevent needle injuries. Recapping needles after injection is discouraged for this reason.

- *Collection and transport of safety boxes to disposal sites:* Make sure that safety boxes are properly sealed when full and before transportation. Do not reopen the safety box.

Vaccinators should be made aware of the need to exercise additional infection prevention and control precautions in the context of a pandemic. Furthermore, national pandemic response plans should anticipate the demand for safe injection supplies (e.g. auto-disable syringes, safety boxes) as well as face masks, hand sanitizers and other items of PPE and budget accordingly. Steps should also be taken to plan for the timely availability of injection supplies (WHO, 2021i).

11.5. Key takeaways

Box 1: **Key messages**

- Countries should ensure that there is a reliable passive AEFI surveillance system supported by active surveillance system during a pandemic for rapid data analysis to undertake evidence-based interventions.
- Data reported through these systems should capture key variables such as sex and age disaggregated data, pregnancy/lactating status, frequency, nature and severity of AEFIs.
- Budgets for pandemic vaccination should include safe injection supplies (e.g. auto-disable syringes, safety boxes), face masks, other appropriate PPE and hand sanitizers as well as training of staff on their use.

Box 2: **Resources**

- WHO (2015). Immunization in practice: a practical guide for health staff, 2015 update. Geneva: World Health Organization (https://apps.who.int/iris/handle/10665/193412, accessed 31 May 2023).
- WHO (2016b). Global manual on surveillance of adverse events following immunization, 2016 update. Geneva: World Health Organization (https://apps.who.int/iris/handle/10665/206144, accessed 31 May 2023).
- WHO (2019c). Causality assessment of an adverse event following immunization (AEFI): user manual for the revised WHO classification, second edition, 2019 update. Geneva: World Health Organization (https://www.who.int/publications/i/item/9789241516990, accessed 31 May 2023).
- WHO (2020c). COVID-19 vaccines: Safety surveillance manual. Geneva: World Health Organization (https://apps.who.int/iris/handle/10665/338400, accessed 31 May 2023).
- WHO Regional Office for Europe (2013). Vaccine safety events: managing the communications response: a guide for ministry of health EPI managers and health promotion units. Copenhagen: World Health Organization Regional Office for Europe (https://apps.who.int/iris/handle/10665/339860, accessed 31 May 2023).

12. Immunization monitoring systems

12.1. Objectives of this chapter

> To plan for comprehensive data collection, establish monitoring objectives, identify suitable indicators, and implement systems for recording, analysing, and evaluating immunization progress to make necessary corrections

12.2. Identify monitoring objectives and data needs

Timely management of information relating to immunization is essential to effective decision-making and to guide deployment and pandemic vaccination operations. In addition to ensuring that the necessary data collection systems are in place and primed to deal with the increases in data generated by a pandemic vaccination campaign, countries should also take steps to prepare their communication systems across all levels so that vaccination data are available to decision-makers in a timely manner throughout deployment and pandemic vaccination operations.

During a pandemic vaccine introduction, the following stakeholders will require data to inform programmatic actions:

- national and subnational authorities involved in decision-making process for public health;
- national, regional and global partners, donor agencies, vaccine manufacturers, regulatory authorities; and
- the public, civil society organizations, academia, and the media.

Countries should design and implement a vaccination data management and monitoring system that is able to cater to the information needs of a diverse set of stakeholders. Specifically, systems should be able to:

- track and evaluate vaccination coverage disaggregated by geography, populations, and groups at increased likelihood for infection and severe illness (e.g. healthcare workers, people aged over 65 years) including how this relates to the status of implementation of population prioritization for vaccination;
- issue a personal vaccination record and certificate for any health, occupational, educational and travel purposes in accordance with national policies;

- record and document necessary data for various purposes, including informing surveys, safety and effectiveness monitoring, aiding disease surveillance and vaccine effectiveness (VE) studies (please also see Chapter 13);

- track beneficiaries to ensure they complete their recommended vaccination and follow up drop-outs;

- to facilitate rapid analysis of vaccination progress to identify evidence-based course corrections;

- to provide information on staffing levels and human resources to manage the workforce more efficiently;

- to monitor vaccine stocks and inventories and avoid shortages (including data on the type and number vaccines shipped, received and administered (first and second dose), batch and lot numbers and expiration date; information on stocks and movements of ancillary equipment such as cold boxes, vaccine carriers and ice packs, syringes, safety boxes and PPE, should also be collected.

12.3. Define indicators to monitor progress

To monitor the progress of an introduced vaccine, the main indicators are as follows:

- ***Vaccine uptake:*** The number (or proportion) of beneficiaries vaccinated with a given dose (e.g. first or second, booster) of the vaccine within a certain time period. If the indicator is calculated and presented as a percentage, the term “vaccination rate” can be used as an alternative.

- ***Vaccination coverage:*** The proportion of beneficiaries that have been vaccinated with the pandemic vaccine in the key population since the start of the programme. This indicator may be reported as the proportion of beneficiaries that have been administered all due doses (i.e. the proportion fully vaccinated), or the proportion who have received the first dose (i.e. the proportion partially vaccinated) and/or the proportion who have dropped out between subsequent doses.

Vaccine uptake and vaccination coverage should be monitored in a disaggregated way. Examples of suggested disaggregation are presented (examples are presented in Table 9).

Table 9: **Dimensions for disaggregating vaccine uptake and coverage**

Disaggregation	Definition	Use
Vaccine product	By each vaccine product in use in a country	• To calculate uptake and coverage with a last recommended dose • To evaluate protection in a population, given differences in effectiveness • To evaluate vaccine safety issues that are specific to the different products in use
Geography (required)	By district, province, state etc.	• To monitor equitable distribution across regions in a country
Sex (required)	By sex of the vaccinated person	• To monitor equitable distribution by sex
Age group (required, at a minimum < 60, 60–69, 70–79-, 80+ years)	By age group of the vaccinated person according to national policy for vaccine prioritization	• To evaluate whether age prioritization policies are being implemented • Countries may consider disaggregating children in minimum age groups, as they may be one of the prioritized groups (but for different ages)
Occupation (optional, where feasible)	By prioritized occupational group, definition/ characteristics to be decided at the country level by national health experts/NITAGs	• To evaluate whether prioritization policies are implemented
Other risk factors (optional, where feasible)	By groups defined by the presence of existing co-morbidities or other risk factors (e.g. pregnancy)	• To evaluate whether prioritization policies are being implemented
Specific settings (optional, where feasible)	In long-term care facilities, prisons, universities and schools	• To evaluate whether prioritization policies are being implemented in all settings
Other equity dimensions (optional, where feasible)	By socioeconomic, ethnic, linguistic, religious, or any underserved populations	• To monitor equitable distribution across different populations in a country *Note:* this may only be feasible to measure using surveys
Disease severity	Coverage among those with severe disease who required hospitalization and/or died	• To monitor the protection against complications of the disease

12.4. Analysis, recording, reporting, analysing and using vaccination data

Countries can monitor and report pandemic vaccine uptake using either reported or estimated data. Both methods for generating national and disaggregated coverage estimates have their strengths and weaknesses and should be used to complement each other.

12.4.1. Administrative or reported coverage data

Administrative coverage is calculated as the number of doses administered to the target population, divided by the total estimated number of people in the target population. It is usually reported as aggregate data, and is dependent on the quality of the reporting of the number of vaccines administered from individual reporting sites and on the accuracy of the population denominators. It is available at regular intervals, usually every month but during the height of the pandemic it could be daily or weekly.

This type of administrative coverage data is usually available through existing systems set up to monitor immunization programmes, in particular through registries. There are two main types of administrative data systems that are usually employed to monitor immunization programmes:

- *Aggregated reporting systems.* These types of system rely on the recording and reporting of administered doses by the health system using a combination of digital and paper tools.

- *Reporting systems that capture individual immunization records.* Individual records are digitized and shared electronically (via electronic immunization registries (EIR)) between healthcare providers and public health authorities. Onward data sharing is conducted in a manner that is mindful of data protection considerations (e.g. can be done in an anonymized format). Data systems of this type offer a more detailed level of information, accessible in a timelier fashion.

In the interpandemic phase countries should consider improving their individual level vaccination reporting systems. Consideration should be given to which locations would be the most important to include in a nationwide immunization monitoring system, not only child clinics but also hospitals, long-term care homes and private practitioners. Furthermore, appropriate interconnectivities might be particularly helpful in a pandemic situation – e.g. linking the vaccine registry to other relevant registries – whether they are health-related or administrative.

12.4.2. Evaluated coverage data

Vaccine coverage rates can also be estimated through independent monitoring or periodic surveys. Surveys may be designed to provide a high level of disaggregated data (e.g. by age, gender and geographic location) and can generate accurate estimates, depending on the availability of reliable vaccination records.

Countries should monitor impact of pandemic vaccination activities on routine immunization coverage and optimize the planning and delivery strategies to ensure high coverages for both pandemic and routine immunization.

12.5. International indicators and reporting in the preparedness and response phases

WHO recommends that countries should share vaccination coverage reports for each pandemic vaccine introduced in the country on a periodic basis. These reports are collated into the health management information system (HMIS) from the service delivery level through a paper based or electronic system. Countries are encouraged to set-up dashboards for visualization of key data to identify gaps in vaccination coverages by geographies, age, gender and other relevant parameters. Such dashboards should guide programme managers to undertake necessary corrective actions for enhancing pandemic vaccination coverages.

12.6. Key takeaways

Box 1: **Key messages**

- Countries should design and implement a monitoring system for vaccination programmes, taking into account diverse perspectives of relevant stakeholders (e.g. national/subnational authorities, the public, civil society organizations).
- The main indicators for monitoring vaccination progress include vaccine uptake and vaccination coverage; both should be tracked in a disaggregated way by critical dimensions for the monitoring (e.g. geographic region, sex, age group).
- Countries need to recognize the characteristics of both types of main data sources for vaccine uptake – administrative system and health surveys – and to strategically plan how to leverage the strengths and complement weaknesses of each source type for effective monitoring of vaccine uptake.

Box 2: **Resources**

- WHO (2017b). WHO guidance for surveillance during an influenza pandemic, 2017 update. Geneva: World Health Organization (https://apps.who.int/iris/handle/10665/259886, accessed 31 May 2023).
- WHO (2022f). Public health surveillance for COVID-19: interim guidance. Geneva: World Health Organization (https://www.who.int/publications/i/item/WHO-2019-nCoV-SurveillanceGuidance-2022.2, accessed 31 May 2023).
- WHO/UNICEF (2021). Monitoring COVID-19 vaccination: Considerations for the collection and use of vaccination data. Geneva: World Health Organization (https://apps.who.int/iris/handle/10665/339993, accessed 31 May 2023).

13. Pandemic disease surveillance relevant for the vaccination campaign

13.1. Objectives of this chapter

> To provide advice to countries on implementation of pandemic disease surveillance and its adaptation to meet vaccination surveillance objectives in the context of an evolving pandemic.

13.2. Rationale, objectives and types of surveillance needed

Pandemic disease surveillance is key to understanding disease epidemiology and informing public health interventions for reducing disease transmission and associated morbidity and mortality. Countries are therefore encouraged to develop resilient surveillance systems for respiratory viruses of epidemic and pandemic potential that can be maintained, scaled-up, enhanced and/or leveraged during a pandemic (WHO, 2023b). Pandemic disease surveillance efforts should include genomic surveillance so that circulating variants can be rapidly identified and testing, treatment and vaccination strategies adapted accordingly.

More specifically, and in the context of developing a NDVP which is aligned with wider needs for and management of medical countermeasures in a pandemic scenario (see Chapter 2), public health surveillance systems are needed to provide data that will allow:

- rapid detection, isolation, testing and management of cases;
- Identification of populations at high risk of severe disease;
- monitoring of cases and deaths to identify clusters and outbreaks, establish linkages with hospitals and healthcare centres for hospitalization, if required;
- calibration of public health and social measures based on disease epidemiology;
- prioritization of populations for vaccination;
- assessing the impact of pandemic vaccination on infection and severe disease and death;
- identification of the need and periodicity for booster vaccine doses;

- as multiple vaccine products become available, identification of vaccines which have a greater impact on controlling serious and severe disease;

- monitoring longer term epidemiological trends, especially co-circulation with other similar viruses and pathogens.

Surveillance systems for respiratory viruses of epidemic and pandemic potential, including influenza, as well as associated investigations and studies, should be implemented as coordinated and collaborative systems and well-matched to specific priority objectives. For further guidance on developing pandemic disease surveillance programmes, please consult "Crafting the mosaic": A framework for resilient surveillance for respiratory viruses of epidemic and pandemic potential (WHO, 2023b). It should also be noted that wider pandemic preparedness plans are expected to contain an extended section on pandemic surveillance approaches (WHO, 2023b).

13.3. Pandemic surveillance data

Countries should put in place surveillance systems which use standard case definitions and case investigation protocols to collect the basic information from suspected cases to enable evidence-based public health actions. A suggested list of information that should be collected for each confirmed case includes the following data items:

- age/date of birth

- sex assigned at birth

- gender

- race or ethnic group

- clinical information (e.g. symptoms, date of onset, date of hospitalization)

- source of exposure (e.g. human contact/ laboratory/ livestock/ unknown)

- laboratory information (e.g. date of sample collection, test type: pcr/rdt and results)

- existing comorbidities

- place of residence

- history of recent travel

- date of onset of symptoms

- speed of disease progression (e.g. days from onset to symptoms peak)

- vaccination status (e.g. name of vaccine, number of doses, dates of doses, lot numbers of doses, serology test results (if performed))
- source of vaccination information (e.g. home based record/history/clinic record)
- severity of disease (e.g. mild symptoms/oxygen requirement/hospitalization/ ventilatory support/ other)
- outcome of illness (e.g. death/discharge/referral).

Additional information that could be collected by the surveillance system includes data on potential viral, bacterial and fungal co-infection, and an indication of whether testing for coinfections was sought and under what conditions.

Countries should ensure collection of relevant clinical specimen as per global and national surveillance guidelines for recommended standard laboratory testing.

Pandemic disease surveillance data requirements may change with the progression of the pandemic and should be guided by the vaccination programme requirements as well as what is needed to monitor the pandemic disease.

13.4. International reporting requirements

Countries are requested to share the collected pandemic disease surveillance data with WHO on a regular basis to facilitate understanding on vaccine effectiveness and impact on the pandemic at a global level.

13.5. Vaccine effectiveness and impact

While efficacy of the pandemic vaccines is determined through clinical trials, vaccine effectiveness under real-world conditions is key to understanding the performance of various vaccines in different age groups, individuals with specific characteristics and comorbidities, in different epidemiological and virological contexts (e.g. variants). Vaccine effectiveness evaluation will contribute to the evidence base which supports development of vaccination policy and strategies for an effective sustained pandemic response, in particular in the context of potential vaccine escape or understanding potential waning immunity.

Different study designs can be used for evaluating vaccine effectiveness in real-world settings. Existing sentinel surveillance for severe acute respiratory infection (SARI) or influenza-like-illness (ILI) surveillance may be leveraged to provide platforms and data for assessment of pandemic vaccine effectiveness. However, for sentinel surveillance to be used for this purpose, there must be adequate pandemic vaccine uptake in the population. Also, networks of countries may be required for data pooling to reach robust sample sizes. Impact evaluations aim to estimate the number of

events averted by the vaccination (incidence reduction, hospitalizations and death averted). Cost estimations can also be conducted to assess the cost-effectiveness of the vaccination.

13.6. Key takeaways

Box 1: Key messages

- Surveillance data for pandemic disease will enable public health authorities to adjust and guide vaccination activities, including defining priority populations, vaccine doses required, optimal interval between doses and need for booster doses, as well as need for hospital beds and curative services.
- Countries should devise disease pandemic surveillance or leverage existing influenza surveillance mechanism to collect key epidemiological virological, clinical and immunization data to inform evidence-based decision-making.
- Countries should explore different surveillance systems including sentinel, case based and community surveillance to generate evidence for programmatic actions.
- Pandemic disease surveillance teams should work in close coordination with immunization teams to ensure utilization of surveillance data for shaping vaccination activities.

Box 2: Resources

- WHO (2017b). WHO guidance for surveillance during an influenza pandemic, 2017 update. Geneva: World Health Organization (https://apps.who.int/iris/handle/10665/259886, accessed 31 May 2023).
- WHO (2017c). Evaluation of influenza vaccine effectiveness. A guide to the design and interpretation of observational studies. Geneva: World Health Organization (https://apps.who.int/iris/handle/10665/255203, accessed 31 May 2023).
- WHO (2022f). Public health surveillance for COVID-19: interim guidance. Geneva: World Health Organization (https://www.who.int/publications/i/item/WHO-2019-nCoV-SurveillanceGuidance-2022.2, accessed 31 May 2023).
- WHO (2023a). Preparedness and Resilience for Emerging Threats (PRET) Module 1: Planning for respiratory pathogen pandemics. Geneva: World Health Organization; 2023 (https://www.who.int/publications/m/item/preparedness-and-resilience-for-emerging-threats-module-1-planning-for-respiratory-pathogen-pandemics-version-1, accessed 31 May 2023).
- WHO (2023b). "Crafting the mosaic": A framework for resilient surveillance for respiratory viruses of epidemic and pandemic potential. Geneva: World Health Organization (https://apps.who.int/iris/handle/10665/366689, accessed 31 May 2023).
- WHO (2023c). Immunization analysis and insights: COVID-19 vaccine effectiveness [website]. Geneva: World Health Organization (https://www.who.int/teams/immunization-vaccines-and-biologicals/immunization-analysis-and-insights/surveillance/covid-19-vaccine-effectiveness-and-impact, accessed 31 May 2023).
- WHO (n.d.-d). Coronavirus disease (COVID-19) technical guidance: The Unity Studies: Early Investigation Protocols [website]. Geneva: World Health Organization (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/early-investigations, accessed 31 May 2023).
- WHO (n.d.-e). Global Influenza Programme: Influenza Investigations & Studies (Unity Studies) [website]. Geneva: World Health Organization (https://www.who.int/teams/global-influenza-programme/surveillance-and-monitoring/pandemic-influenza-special-investigations-studies-pss, accessed 31 May 2023).

14. Termination of pandemic vaccination deployment operations

14.1. Objectives of this chapter

> To offer guidance to countries in planning activities for terminating pandemic vaccination deployment and operations, including documentation of resources utilized and lessons learnt.

14.2. Termination of deployment and vaccination operations

Termination of activities is an official part of the deployment and vaccination activities, and it must be planned considering necessary steps and relevant stakeholders. Activities that typically need to occur during the during the termination phase include releasing surge staff to their original duty stations, returning unused resources to the stakeholders who provided them, and documenting lessons learned during the deployment. Following the official announcement of the end of a pandemic by WHO, the national public health authority should issue a statement confirming their intention to conclude their response operations. Resources used, best practices observed, and challenges faced should be documented to improve deployment activities for future pandemics.

14.2.1. Termination of vaccination activities

Following the release of the official statement of terminating response operations, responsible managers should:

- take stock of available vaccine and ancillary products in the management information system;
- recall excess stocks of vaccine and ancillary products and record their return in the management information system under appropriate conditions (reverse logistics)
  - *Note: The vaccines that were used for the respective pandemic may be useful for emerging outbreaks or if the virus shows seasonality (and the vaccines are still effective against the seasonal strain). Therefore a national assessment should be made on whether to keep the remaining vaccines or proceed to their safe disposal.*
- plan for how to handle unused or expired vaccine stocks;
- confirm that officials responsible for the waste disposal have properly completed their actions.

Managers who are responsible for tracking vaccine stocks should complete their allotted tasks in a timely manner; reports should include the number of unused vaccine doses and the quantities of ancillary supplies at each designated distribution point. Staff at distribution points can support this stock reconciliation effort by providing information on vaccine doses and other supplies received and utilized, which can then be compared with the number of vaccinated population.

14.2.2. Documentation of resources used

Data on the number of participating vaccination sites, number of vaccine doses received and administered, number and type of human resources deployed, communication and social mobilization activities conducted, activities outsourced through private contracts, and vaccine/logistics transportation can be collated from micro plans and local management information systems, assuming the pertinent information has been recorded before and during deployment and vaccination operations. Information sourced from partners and other stakeholders on their contribution should also be sought to prepare comprehensive reports.

14.2.3. The termination report

The termination report should document the technical, logistical and financial aspects of vaccine deployment operations and vaccination activities, including vaccination coverage for different key groups. Challenges faced and lessons learned should also be documented in the report, highlighting communication and operational strategies that proved successful at subnational levels (e.g. region, district). The report should describe how vaccines were approved for emergency use, procured and deployed nationwide, and how the plans for vaccine administration, including healthcare waste management were prepared and implemented. Learnings on AEFI reporting, management and causality assessment, including AESIs and their impact on the vaccination programme should be incorporated as well. The financial section should summarize the budgeted costs, the sources of funding (including domestic budget, multilateral/bilateral funding agencies and donors), the utilized and the unspent balance funds for further action. The ministry of health should review and endorse the national termination report.

14.3. Key takeaways

Box 1: **Key messages**

- Termination of activities is an official part of vaccine deployment and vaccination and typically include releasing surge staff to their original duty stations, returning resources to the stakeholders that originally provided them, and documenting lessons learned during the deployment.

15. Monitoring and evaluation of pandemic vaccination deployment and operations

15.1. Objectives of this chapter

> To describe the benefits of conducting intra-action and after-action evaluations and simulation exercises following a pandemic vaccine introduction and how these activities can assist countries plan, develop and update their NDVPs and contribute to pandemic preparedness and response planning

15.2. Intra-action and after-action reviews

As is recommended practice following the introduction of any new vaccine, countries are strongly encouraged to evaluate the impact of their pandemic vaccination programme. As part of this evaluation process, particular attention should be given to identifying barriers to access and other equity considerations that would need to be addressed in future vaccine roll-outs. Programmatic evaluations not only contribute to successful implementation of a vaccine introduction during a pandemic but also – through the sharing of good practice and lessons learned with other countries – to better pandemic preparedness going forward.

Drawing on the experience of the COVID-19 pandemic, WHO currently recommends two types of post-introduction evaluation (PIE) of a pandemic vaccination introduction (WHO, 2021j). The first, an intra-action review (IAR) should be conducted in the early post-introduction period (i.e. 2–6 months after the introduction) by a small group of experts. An IAR, sometimes termed a "mini-PIE", consists of a desk review of available routine monitoring data, followed by a discussion around a small number of pre-selected questions addressing key programmatic areas relevant to the country's vaccine introduction situation. The country may opt to supplement the IAR with vaccination site visits, observations of vaccination sessions or storage observations, and key informant interviews. As with a classical PIE, the IAR or mini-PIE aims to identify lessons learned and actionable results which can be implemented to improve the pandemic vaccine roll-out.

Countries may also choose to conduct a more detailed PIE to address key programmatic pandemic vaccine introduction activities at all levels of the immunization system including national, subnational and health facility levels. This type of evaluation should ideally be carried in the mid- to long-term post-introduction phase, i.e. 6–18 months after introduction. While WHO will provide normative guidance, including relevant tools and questionnaires, it is recommended that countries review and adapt the tools to their context. Alternatively, countries can adapt the generic WHO PIE tool that was designed to assist immunization managers evaluate the impact of the introduction of a new or underutilized vaccine into the existing, routine immunization system (WHO, 2010).

Results of the post-introduction evaluations should be referenced in the termination report (see Chapter 14) or the other way around (whichever activity takes place sooner).

15.3. Simulation exercises and regional workshops

Countries should aim to conduct simulation exercises in the interpandemic period to improve coordination between various stakeholders and to identify aspects of existing pandemic vaccine deployment plans that may require revision in the current context. These exercises have been described previously in Chapter 5 (see section 5.7).

WHO organizes periodic regional workshops to exchange best practices and lessons learned between different countries which also include simulation exercises. Countries attending these workshops should assess whether similar best practices could be introduced into their settings.

15.4. Key takeaways

Box 1: **Key messages**

- Evaluating the impact of introducing a new vaccine during and after a pandemic is critical to achieving a successful introduction and overall programmatic goals and to learning lessons which can be used to improve pandemic preparedness and response in the future.
- For vaccine post-introduction evaluation (PIE), WHO proposes two forms of evaluation – mini-PIE and full-PIE – as introduced in the COVID-19 vaccine post-introduction evaluation (cPIE) tool.
- Simulation exercises can help countries plan, develop and update their NDVP.

Box 2: **Resources**

- Ghiga I, Richardson R, Ropero Álvarez AM , Kato M, Naidoo D, Otsu S, Nguyen Thi P, Nguyen N, Nguyen T (2020). PIPDeploy: development and implementation of a gamified table top simulation exercise to strengthen national pandemic vaccine preparedness and readiness. Vaccine. 38(51):8082-8089
- WHO (2010). New vaccine post-introduction evaluation (PIE) tool. Geneva: World Health Organization (https://apps.who.int/iris/handle/10665/70436, accessed 31 May 2023).
- WHO (2021j). COVID-19 Exercise vaccine post-introduction evaluation (cPIE) guide: interim guidance, 25 Augusto 2021. Geneva: World Health Organization (https://apps.who.int/iris/handle/10665/344721, accessed 31 May 2023).
- WHO (2021k). COVID-19 Exercise Programme: Drills for vaccine deployment. Geneva: World Health Organization (https://www.afro.who.int/publications/covid-19-exercise-programme-drills-vaccine-deployment, accessed 31 May 2023).
- WHO (n.d.-b). COVID-19 Simulation exercise packages [webpage]. Geneva: World Health Organization (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/training/simulation-exercise, accessed 31 May 2023).

16. Costs and financing of pandemic vaccine deployment and vaccination

16.1. Objectives of this chapter

> To assist countries prepare a realistic budget for pandemic vaccine deployment and the scale-up of vaccination activities without compromising existing essential health services.

16.2. Cost drivers and funding needs

Countries need to identify and cost the activities that will be required to deliver a timely introduction of a pandemic vaccine(s). Costed workplans for key activities reflect the dual objective of causing minimal impact and disruption to ongoing essential health service provision. Health ministries and in country partners should work together on the costed workplan to ensure there is no duplication of effort. This coordination will also leverage the current strengths of each stakeholder to support the pandemic vaccination response. Engaging with manufacturers of vaccines and other medical countermeasures may be a helpful step, as this may provide a more detailed and accurate understanding of the potential costs associated with vaccination roll-out.

In the interpandemic period costing should distinguish between what are the:

i) preparedness activities to establish and maintain critical pandemic response functions in the area of pandemic products deployment and,

ii) estimated cost for activities to be introduced at the time of the pandemic response.

Separation of funding needs in this way would allow government departments to disburse or secure (maintain budget lines) the necessary financial resources, as well as bring clarity to national and international specialized agencies on needed technical support and investment. This may streamline engagement and avoid duplication of efforts. Budgetary planning should also be mindful of the potential overall budget for pandemic preparedness, response, recovery and business continuity.

Having a detailed budget for both preparedness and response NDVP related activities, would also facilitate a faster application for support to different international pandemic preparedness schemes and global funds.

Table 10: **Examples of different cost headings and their components**

Cost head	Components	Notes
Technical assistance for vaccine planning, coordination and rollout	**Key areas for technical assistance** 1) Regulatory processes 2) Cold chain and logistics assessment and planning 3) Pandemic disease surveillance 4) Costing and budgeting 5) Donor and partner coordination 6) Operational guidelines for vaccine rollout 7) Development of training materials, including job aids 8) Training of key health staff 9) Vaccine procurement and distribution 10) Programme implementation, supervision and monitoring	Includes in-country licensing of pandemic vaccine, cold chain assessment and augmentation, development of training materials and job aids, conducting and tracking training and supervision of field activities
Cold Chain	1) Additional cold chain equipment for augmentation of cold chain space 2) Data loggers, thermometers 3) Operational costs	Include cost of procurement, transportation, installation and maintenance
Vaccine and supply chain logistics	1) Vaccine doses (*difficult to estimate in the interpandemic period – but could be based on historic estimations*) 2) Ancillary equipment (e.g. jet injectors, syringes, safety boxes)	Include cost of transportation, storage
Safety and security	1) Personal protective equipment as per national recommendations 2) Security costs for vaccine transportation, storage and during vaccination sessions 3) Safe disposal of immunization waste 4) Monitoring of key processes	Include cost of segregation, transport, storage and disposal of immunization waste, including safety boxes and maintenance of incinerators. If outsourced, include cost for contracting service suppliers
Demand generation and community engagement	1) Technical assistance for situation analysis and development of communication strategy, including communication materials 2) Operational expenses including social listening, data collection, analysis and use of local behavioural and social data, social mobilization, crisis communications, operating social listening systems, rumour management, assessing behavioural data, risk communications and community engagement, mass media, and printing posters and banners	

Cost head	Components	Notes
Pandemic vaccination	1) Training of vaccinators, cold chain handlers and supervisors 2) Perdiem for vaccinators, supervisors and other key staff 3) Other costs, including transportation, communication infrastructure related 4) Vaccination waste management	Include operational costs for vaccination teams, cold chain handlers and supervisors; cost of segregation, transport, storage and disposal of vaccination waste
Monitoring and evaluation	1) Management of vaccination coverage data 2) Independent monitoring of service quality at session sites and coverage assessment through community monitoring 3) Post introduction evaluation of pandemic vaccination	Include cost of development of dashboards for visualization of data, training of data managers, building capacity in monitoring and evaluation activities and per diem/ transport expenses of independent monitors
Vaccine safety surveillance	1) Pandemic vaccine pharmacovigilance activities – Capacity building and operationalization of AEFI reporting, investigation, causality assessment and response 2) Sentinel site surveillance for AESIs 3) No fault compensation	Include operational cost for activities, including training, transportation, perdiem,
Sustain essential health services	1) Hiring of additional vaccinators and ancillary staff to minimize impact on essential health services 2) Training of staff on strategies like co-delivery of routine immunization services	Microplans to consider the injection load at sites with co-delivery of routine and pandemic vaccines

16.3. Sources of financing

16.3.1. Identify budget inputs

When drawing up a costed pandemic vaccine deployment plan, countries should make every effort to leverage the existing capacity and resources, while ensuring minimal impact on essential health services. Countries should aim to have a budget for a pandemic vaccine roll-out in place well in advance of a health emergency, so that the necessary funds can be secured and disbursed in a timely fashion in case of a pandemic. Identification of activities for implementation by the health system, development partners and contracting agencies along with timelines will ensure a smooth implementation with minimal duplication of activities.

It is expected that in the initial phases of a pandemic, vaccine supplies will be limited. Countries should therefore work with national experts and NITAGs to identify potential priority populations under the overall guidance of the SAGE values framework (see Chapter 2) and accordingly prepare

a budget which reflects a phased roll-out. The budget proposals should consider a range of scenarios, with varying rates of morbidity and mortality. Scenarios which anticipate high rates of mortality and morbidity, which will inevitably increase pressures on the existing health system, will require higher levels of resourcing if essential services are to be maintained.

16.3.2. Identify responsible budgetary units

Clear mapping of activities with corresponding budgetary heads within the ministry of health and among developmental partners or other stakeholders will allow clear allocation of funds and ensure accountability for implementation of the activities.

16.3.3. Assess and align costed plan within available resources

The list of budgetary requirements for the pandemic vaccination response compiled by the ministry of health should include incremental costs specific to pandemic vaccination, and submitted to the ministry of finance for allocation of resources. Resource allocation will be consequent upon available domestic resources (i.e. the resources set aside for the pandemic response by the national government), and eligibility for external funding from bilateral or multilateral agencies and other multilateral banks or international financing institutions.

A mechanism for in-country tracking of pandemic vaccination activities by funding source should be set up to ensure there is no (or perception) of misappropriation of funds.

16.3.4. Funding options for mobilizing additional resources

Countries could explore the possibility of securing additional resource allocation from the domestic budget through the ministry of finance by:

- preparing a realistic budget;
- leveraging existing health service delivery mechanism for pandemic vaccination;
- channelizing savings for pandemic vaccination,
- seeking support from development banks through grants, loans or restructuring of existing debts.

16.4. Key takeaways

Box 1: Key messages

- Timely availability of adequate financial resources is key to efficient implementation of pandemic vaccination and should be sourced from domestic funding as far as possible.
- The budgetary requirement may require adjustments as the pandemic evolves, and as more vaccine doses become available for the country.
- The WHO-UNICEF CVIC tool developed for COVID-19 vaccination could be utilized for countries for realistic planning of budgetary requirements.
- Countries should integrate budgetary requirements for pandemic vaccination in their domestic budgets as far as possible for sustained availability of resources.
- Joint response plans for pandemic vaccination response by national governments, developmental partners and other key stakeholders will ensure optimal utilization of resources without duplication of resources.

Box 2: Resources

- Saxenian H (2017). Immunization financing: a resource guide for advocates, policymakers, and program managers. Resource Guide by Results for Development Institute: Washington, DC (https://r4d.org/resources/immunization-financing-resource-guide-advocates-policymakers-program-managers/, accessed 31 May 2023).

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Annex 1: National Deployment and Vaccination Plan Template

Endorsement page

- Messages from representatives of relevant government departments (including signatures)

Table of contents

Executive summary

- Purpose: Countries should list potential purposes/ aims of the NDVP in accordance with the possible public health goals as described in section 2.3
- Scope: Depending on how the NDVP is articulated the scope should highlight the applicability of the NDVP – e.g. whether to pathogens of respiratory origins, or it also captures considerations that would allow for broader pathogens (emergency vaccinations planning)
- Summary of the responsible institutions and their broad role in both – preparedness and response activities
- Status of preparedness of the main areas covered by the NDVP
- Summary of identified prioritized preparedness activities and likely changes to the current NDVP at the time of the pandemic

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1. Introduction

- Country overview (geography, population, health profile)
- Risk categorization of the country based on outbreaks of other similar vaccine preventable diseases
- Public health infrastructure of the country, including human resources, health facilities, cold chain infrastructure and annual budgeted public health spending
- Lessons learnt from past pandemics (in particular COVID-19 pandemic), with focus on vaccination activities *(can also be placed under each chapter)*

2. Public health goals of the pandemic response and strategic approach to accessing MCMs

- Define public health goals of the pandemic response based on different pandemic scenarios
- Calculate ranges of potential needed vaccines and other MCMs based on identified public health goals
- Plan for integrated deployment of medical countermeasures including diagnostics, therapeutics and vaccines
- Highlight / set-out plans (or processes) of potential access mechanisms (strategies) in the event of different type of pandemics (e.g. influenza, respiratory disease X virus, etc)

3. Legal and regulatory preparedness

3.1. Legal provisions

- Map and list national laws applicable for procurement, deployment and vaccination activities (including responsible institutions)
- Identify legal limitations faced during past pandemics vaccination, and plan for their streamlining and alignment for rapid vaccine deployment and use
- Set-out different potential approaches to indemnification and liability management related to vaccine use that may arise in a pandemic situation
- Identify any areas where new legislation might be needed or amended

3.2. Regulatory preparedness

- Map and list the available national regulatory pathways to approve a vaccine use in a pandemic situation
- List regulatory requirements for emergency import, customs clearance, lot release etc.
- Review national regulatory requirements (incl. capacities and capabilities) to participate international clinical trials
- *Review lessons learned from recent pandemic experiences and list a work plan to address identified preparedness activities (this should be considered throughout all chapters)*

4. Planning and coordination for vaccine introduction

- Explain the existing governance and coordination mechanisms at national and sub-national level for emergency response coordination and new vaccine introduction, including mapping of functions such as coordination across different stakeholders, decision making,

management and oversight. Identify changes in governance and coordination mechanisms proposed based on learnings from recent pandemic and emergency responses

- Establish a committee/ structure/ working group that will be responsible for monitoring and advancing preparedness activities identified in the development of the NDVP and subsequent testing exercises

- Highlight the integration with the wider national pandemic preparedness plan & NHAP

- List (or link to) the roles of different national committees – e.g. NITAG, NRA and ICC

- Map partners and other stakeholders, followed by defining their non-overlapping roles and responsibilities for vaccination activities

- Create a flow (or figure) that would aid the understanding of the main activities (and triggers) of the different committees and partners throughout the different phases of the pandemic vaccination response

    - » This should be supported by other materials that would detail the mechanisms for ensuring accountability on actions required for deployment of pandemic vaccines, including responsibilities and timelines

- Explain the recording and reporting mechanisms for key data points, whether to be incorporated in HMIS or through a standalone MIS

5. Identification of key populations for vaccination

- Clarify the mechanism for prioritization of population groups for pandemic vaccination (SAGE values framework, NITAG recommendations or other) and guiding criteria that the mechanism should consider

    - » Considerations should be listed on strategies to address potential intra-national inequities

- Identify data sources to quantify all potential key groups

- Outline challenges in reaching potential priority populations

6. Vaccination delivery strategies

- List potential strategies for pandemic vaccination (including fixed sites, outreach sites, mobile clinics and others, based on population characteristics) and estimate resource needs for each strategy

- » Consider integration of pandemic vaccination with other health interventions like routine immunization, special clinics like antenatal clinics, diabetes or hypertension clinics etc.

- Identify key challenges expected in reaching high-risk populations and potential solutions, mindful of particular access barriers such groups may face, including by populations living in situations of vulnerability

- List infection prevention strategies to prevent disease transmission at vaccination session site

- Consider the role of potential emerging technologies (innovations) in aiding to overcome delivery challenges

7. Supply chain and healthcare waste management

- Review (or link to) existing cold chain and dry space capacities for transportation and storage at each level and set-out the approach to perform periodic assessments considering potential pandemic needs

  - » Map available cold chain resources against the potential priority populations, assess whether sufficient resources are available at each level
    - Assess supply chain augmentation needs, based on supply chain assessments (requirements are dynamic and depend upon the priority key populations), status of ultra-cold chain, and mechanisms for augmentation (in case the country considers approval for a vaccine that requires UCC)

- Description of vaccine and logistics supply process, including challenges and solutions for key operational gaps like storage space, special transportation needs etc.

- Review the suppliers contracts and commitments and stress-test capacities using different pandemic scenarios (e.g. what would happen if one supplier would be unable to continue delivering on key products) and consider potential continency plans to overcome such situations (compare potential needs of PPEs calculated in accordance with public health goals)

- List human resources required for management of cold chain, vaccines and logistics and need for surge support, if any

  - » Ensure there is clarity on roles to establish a training plan for cold chain handlers and managers

- Review status of power supply and actions required to ensure assured electricity supply

- Assess need for solar direct drives in special areas without assured electricity supply

- Ensure availability of a mechanism for supply chain data management, and mechanisms for need based interventions including shifting of cold chain equipment, vaccine and logistics supplies as required

- Review mechanisms and capacity for management of healthcare waste, whether existing mechanism would be able to sustain additional requirements arising from pandemic vaccine deployment

  - Set-up a logistics plan for appropriate waste management in accordance with national guidelines

  - Ensure there is clarity on roles to establish a training plan for handling healthcare waste, more specifically vaccination waste

- Plan for ensuring security of pandemic vaccines at different movement stages

- Map key partners and other stakeholders, and their role in supply chain and healthcare waste management

8. Human resource management and training

- Review availability and distribution of different categories of human resources, and plan for surge support with budget implications (including numbers by category and source for additional human resources), keeping in mind that essential health services should be minimally impacted

- Define terms of reference for each category of health staff

- Establish a potential training plan with platforms (whether online, face-to-face or hybrid), timelines, budget implications

  - Identify nodal person for training rollout and tracking

- Mapping and role of partners and other stakeholders

- Set-up provisions to ensure wellbeing and security of healthcare personnel

9. Vaccine acceptance and demand

- Draft (or link to) communication and social mobilization plan, outlining key activities and timelines, with persons/ stakeholders responsible for each activity

  - This should include a media engagement plan, including social media

- This should contain the identification of different networks to aide dissemination of information (and aide in developing of relevant information messages)

- Identify and enlist areas and populations with vaccine acceptance (hesitancy) issues in the past, and plan for engagement with such communities

- Identify mechanisms for identification of key community concerns through behavioural and social data, digital listening and media monitoring, and other relevant sources to plan interventions

  - This should make use of emerging tools for infodemic management

- Plan for capacity building of frontline health workers on inter-personal communication, community engagement and risk communication

- Mapping and role of partners and other stakeholders

10. Vaccine safety and management of adverse events following immunization

- Review current mechanism and status of reporting, investigation, causality assessment and classification and management of AEFIs as well as AESIs

- List (and establish if not available) national and sub-national committees, including their composition, role in review and classification of AEFI cases, and activity timelines

- Identify issues and gaps around AEFI surveillance for a new pandemic vaccine considering learnings from recent pandemic vaccine introduction

- Mapping and role of stakeholders and partners, if any

11. Immunization monitoring system

- Review data requirements and flows to enable real-time monitoring of vaccination campaign

  - Consider developing integrated reporting systems at all levels (if not available already) and creation of dashboards

  - Analyse how emergency-type vaccination reporting lines can be integrated into the existing mechanisms for recording, reporting, analysis and use of data for programmatic actions

  - Ensure the systems would allow tracking of operations and coverage for different vaccine products (in case these are different and also administered in different settings – both public and private)

- Identify sources of data, including reported coverages, independent monitoring and coverage surveys

- Review current availability of data managers, and how this would related to a pandemic situation when surge of staff might be needed – planning should be done for potential source of surge staff and training needs

- Establish indicators to assess progress in pandemic vaccination

- Ensure there are mechanisms of reporting pandemic vaccination coverage data to WHO and/or other partners (e.g. regional centres for disease control) to facilitate regional and global situation analysis

12. Pandemic surveillance relevant for the vaccination campaign

- Review existing surveillance systems for vaccine preventable diseases in the country and how these can be extended/ enhanced to be used in a pandemic situation

- Define key data points that will be collected to inform different decisions throughout the pandemic vaccination effort

- Ensure there is a mechanism to advise on standardised clinical specimen collection and mapping of accredited laboratories for specimen testing

- Plan for the type of surveillance that will be conducted at the time of the pandemic (sentinel site, case based or community surveillance). For sentinel surveillance, details on number of sites, age/risk groups should be mentioned

- Budget implications and source of funds for surveillance activities

- Ensure there is a mechanism of reporting surveillance data to WHO to understand disease epidemiology and vaccine effectiveness

13. Monitoring and evaluation of pandemic vaccination deployment and operations

- Plan for intra-action reviews and incorporating lessons learned for strengthening vaccination activities

- Define a timeline, mechanism and key areas for post-introduction evaluation

14. Cost and financing of pandemic vaccine deployment and vaccination

- Identify funding needs by preparedness and response activities using the different cost heads, with demarcation of various components under each head

- Identify funding sources for required budget, outlining the phase-wise budgetary requirements

- Mapping of potential donors and engage them at regular intervals – including in simulation exercises

- Establish a monitoring system for funding – in the preparedness stage this would be used to monitor funding and implementation of preparedness activities; this mechanism could also help support re-assessment of funding needs

Annex 2: Best practices and lessons learned from recent pandemics or emergency responses[9]

There are several enablers for efficient planning and coordination during a pandemic such as:

- *high political support which secured vaccination funding and enabled the coordination and cooperation of key multi-sectoral stakeholders involved in the vaccination process.*

- *close coordination with domestic and international partners and donors, as well as with bilateral governments which aided timely procurement of adequate vaccine supplies. Strong partner coordination was implemented through "One UN" and similar plans for technical assistance to national governments.*

- *establishment of governance and coordination structures (e.g. structures such as the National Task Force or Technical Working Group). Efficient planning and coordination committees also involved private sector providers, village health teams, and community leaders.*

- *regular meetings between national, provincial, and district level management groups which led to identification of technical assistance and financing needs at the subnational levels and enabled related (re)allocation of resources.*

- *private sector health providers which augmented resources for service delivery.*

- *district micro plans which enabled allocation of adequate resources, and improved service delivery.*

Public health goals drive a pandemic response and these should be informed by evidence on appropriate key groups and evolution of the pandemic as well as mindful of contextual specificities:

- *in a supply constraint environment, vaccine allocation approaches should also consider the availability of other medical countermeasures that could be used for different populations in synergy with the vaccines.*

- *a multi-faceted vaccination strategy should be informed also by past experiences of deploying other medical products in emergency situations, consider a whole-society approach, foresee enablers and barriers to implementing innovative technologies.*

9. Please see the Methodological Approach section in About this Guide for details on how these best practices were compiled.

- *rapid monitoring and feedback mechanisms enabled the COVID-19 vaccine redistribution at the global, regional, national, subnational and facility levels, promoted equitable vaccine access and minimized wastage.*

There are different regulatory approaches that can be employed at the time of a pandemic. However, to ensure a country has these type of options, investments should be made in strengthening NRAs.

- *the type of approaches governments adopted in past pandemics included: (a) Fast-tracking the regulatory approval process, especially in relation to vaccine manufacturers' indemnification requirements; (b) Issuing National Emergency Use Authorizations; (c) Selecting vaccines that met the cold chain capacity in their countries; (d) Authorizing vaccines using WHO's Emergency Use Listing (EUL), especially in countries without the necessary mature national regulatory structures to rapidly approve vaccine products; (e) Facilitating rapid custom clearance of vaccines upon arrival.*

Vaccine delivery strategies should:

- *be flexible and agile with a particular preoccupation for maintaining quality of services and using emerging evidence to re-adjust need-based strategies for enhancing vaccination coverage.*

- *contain provisions for hard-to-reach special populations such as refugees, internally displaced persons, and populations living in correctional facilities, military camps and homes for the aged as well as for those with mobility issues.*

- *plan for disruptions that may emerge due to potential pandemic travel restrictions.*

- *engage private facilities to enhance availability of vaccination sites.*

- *maintain operational outreach/mobile vaccination sites when dealing with delivering the 2nd dose of vaccine, especially for hard-to-reach areas.*

- *use ongoing public health programmes like polio vaccination campaigns, SARI/ ILI identification drives etc. to identify and mobilize key populations for vaccination.*

- *make use of integrated IT platforms to enable registration, tracking and provision of vaccination certificates to beneficiaries as well as track status of cold chain and vaccine availability at cold chain points.*

- *consider a combination of vaccine delivery strategies to attain equity driven goals, such as: (a) drones for vaccine delivery to access compromised areas; (b) mobile vans for sparsely populated areas; (b) newly set-up vaccination sites in diverse locations that may contain certain at-risk populations such as prisons, military health zones, mining sites, police camps and pandemic-specific treatment centres; (c) repurposing of existing distribution channels used for other vaccines; (d) a combination of different mobile and fixed vaccine delivery strategies at key sites such as pharmacies and markets to reach all population groups; (e) prioritize use of single-dose vaccines for mobile and hard-to-reach populations.*

Optimization of supply chain related operations was supported by:

- *timely preparation of guidelines and procedures to support operational, supply chain and waste management planning and dissemination of these plans with all relevant stakeholders including at district level.*

- *to the extent possible, selection of appropriate vaccines based on the cold chain requirements and vial size to enable appropriate storage and transport of vaccines.*

- *periodic nationwide assessments of cold chain storage capacities at all levels to identify potential needs for additional equipment.*

- *identifying potential funding sources in the event of rapid need for acquisition of ultra-cold chain equipment (UCC), refrigerated trucks, and other cold chain equipment as well as consumables such as fuel for vaccine deliveries.*

- *engaging in strategic partnerships with couriers including helicopters operators, airlines as well as security forces to plan for secure distribution in all potential vaccination areas.*

- *real-time monitoring of vaccine stocks to enable need-based redistribution of supplies between regions and health facilities and therefore reduce wastage of vaccines – this could be enabled by implementation of logistic management information systems to the service delivery points.*

- *Identification of potential private sector providers that could support various operations (e.g. waste management), in the event when public structures do not have sufficient capacity to undertake these operations.*

- *developing contingency plans to overcome potential lack of electricity supply at different administrative levels (e.g. as a result of high dependency on solar direct drive refrigerators).*

- *ensuring availability of training and appropriate participation (e.g. on cold chain, waste management).*

- *employing best practices in the event of vaccines that have short expiry dates, such as: (i) creating a governing body or mechanism to monitor the expiry and releases of batches and exercise recall functions when appropriate; (ii) rapid vaccination to ensure vaccines are utilized before their expiry; (iii) establishing stock monitoring and continuous communication system to facilitate the re-distribution of extra vaccine doses based on stock levels and demand; (iv) vaccinating the subsequent priority groups to minimize vaccine wastage when there was insufficient uptake from the main priority groups.*

A sufficient, trained and supported workforce can be achieved by:

- *ensuring a training plan that considers the needs of all staff and volunteers involved About thin vaccination activities, such as healthcare workers engaged in vaccine roll-out,*

community mobilization teams, vaccine supply and logistics managers, AEFI focal points responsible for monitoring vaccine safety.

- *conducting training via different modalities depending on the context, including face-to-face, on-the-job training, or through virtual environments to reach a wider group of target trainees.*
- *providing refresher and continuous training for vaccination staff, including those at call centres and healthcare workers implementing vaccine roll-out, to ensure they always have the most up-to-date and accurate information.*
- *implementing additional mass training and the training of trainers before national vaccination campaigns to ensure vaccination staff are adequately prepared at all levels.*
- *repurposing response personnel to support vaccination operations (based on different tasks – e.g. perform vaccination, support pre-registration, data entry and reporting) or by leveraging professionals from the private sector and non-governmental organisations.*
- *ensuring availability of training platforms that would allow rapid training in addition to in-person and cascaded training models.*
- *securing funds to provide relevant electronic devices to undertake needed training and create contingency plans to overcome barriers to delivering trainings (e.g. poor internet connectivity).*
- *creating a working plan that ensures adequate supportive supervision of the front-line health workers.*
- *conducting simulation exercises to maintain and test capabilities.*
- *enhancing the level of digital literacy in the community.*
- *enacting measures to ensure staff well-being and motivation by providing health insurance, creating a good working environment (e.g. by offering food boxes, air-conditioned cabins, and overall good ambience), remunerating staff for extra work hours, providing psychological support to health personnel to address stress and fatigue and mitigate the risks of programmatic errors.*

Vaccine acceptance and demand can be sustained by:

- *developing a communication and community engagement plan.*
- *ensuring regular communication by holding regular press briefings and organizing scientific discussions involving different groups, including academics, media professionals, and social media influencers, to promote transparency and accurate information is shared in a timely manner.*

- *holding regular meetings at the national, regional and district levels to facilitate dissemination of information to all key stakeholders.*

- *leveraging multisectoral and public-private partnerships in vaccination roll-out and campaign communications.*

- *ensuring political ownership for the vaccination campaign at the highest level, with Heads of State and other political leaders getting vaccinated in public and delivering regular public statements from the political leadership.*

- *creating plans to avoid vaccine hesitancy amongst health care workers as in the event of a pandemic they likely always be a priority target for vaccination.*

- *engaging religious, community and opinion leaders, including medical professionals to advocate for vaccination.*

- *ensuring proactive social listening and management of misinformation and disinformation. This would necessitate building specialised national capacities and capabilities for infodemic management.*

- *using hotlines and surveys to understand community perceptions and concerns around vaccination to promote acceptance and reduce hesitancy.*

- *creating a dashboard to provide real-time information to the public.*

- *using all media platforms including television clips, radio jingles and talk-shows, social and print media to track, gather and disseminate information.*

- *anticipate misconceptions that may arise from different potential legal requirements (e.g. during COVID-19 countries were required to sign "no fault compensation" agreements releasing the vaccine manufacturers from indemnification), short-life of vaccines, advice to use them past their expiry dates, vaccination of only predetermined groups.*

Vaccine safety monitoring, management of AEFI and injection safety is advanced by:

- *establishing a multi-disciplinary team at the national level and AEFI focal points at the subnational levels, standard operating procedures, and the use of digital tools for AEFI reporting and response.*

- *ensuring availability of a system (preferably electronic to enable real-time monitoring) for active surveillance and monitoring of Adverse Events of Special Interest.*

- *creating coordination processes between different relevant committees (e.g. between the AEFI committee and the National Communication Committee).*

- *training and retaining health workers and undertake sensitization of vaccine recipients and their relatives to report AEFI.*
- *deploying medical experts for on-site management of any serious AEFIs.*
- *providing free treatment in designated health facilities to persons that experienced SAEs and adapting insurance schemes (or creating short-term ones) to cover medical care for such cases.*
- *rapid updating of official relevant government websites with vaccine safety updates.*
- *ensuring appropriate funding for materials such as AEFI kits and AEFI reporting forms.*

Ensuring proficient data management by leveraging immunization monitoring systems through:

- QR codes to verify the vaccination status of individuals.
- affixing holograms on vaccination cards as an authentication mechanism.
- implementing a dedicated vaccination electronic registry.
- utilizing various IT platforms such as DHIS-2, Google Spreadsheet and other dashboards to conduct digitalized, real-time planning, analysis, monitoring and supervision of vaccine roll-out to identify and prioritize low-coverage areas.
- leveraging social media and chat groups on smartphone applications to coordinate and communicate coverage data to monitor vaccine roll-out.
- ensuring a paper-based system (e.g. vaccination registers, tally sheets, summary forms and vaccination cards) is available as a backup for vaccination sites where electronic systems may not be accessible.
- providing supportive supervision for digital systems and ensuring regular feedback regarding gaps in reporting.
- ensuring linkages of databases of cases and hospitalization to facilitate the measurement of vaccine effectiveness and impact.

Costing and financing of pandemic vaccine deployment and vaccination activities benefit from:

- establishing mechanisms to ensure monitoring of funds utilization.
- considering several potential resource mobilization strategies from domestic resources, grants or loans from the World Bank, international agencies, or from development partners.
- engaging in NDVP costing exercises in the inter-pandemic period to understand needs that may arise in different pandemic scenarios.

- establishing clear procedures to ensure swift funds release and disbursement to avoid low implementation levels and delays in payments – e.g. untimely remuneration of health workers.

- planning for potential disruptions in decision-making (e.g. due to election periods).


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