



**Strategic considerations
in preparing for deployment of
COVID-19 vaccine and vaccination
in the WHO European Region**

9 October 2020

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Contents

Introduction	2
Scope and purpose	2
Key strategic considerations	2
Broad considerations	2
Country-specific considerations.....	3
a. Management structure, advocacy and resources	3
b. Evidence-informed and ethical values-based national vaccination strategy	3
c. Legal and regulatory framework facilitating vaccine deployment	4
d. Immunization service delivery modalities	4
e. Vaccine and supply chain management	5
f. Human resources and security	5
g. Vaccination data and information management.....	6
h. Vaccine safety monitoring	6
i. Safe injections and waste management	7
j. Demand generation, community engagement and communication.....	7

Acknowledgements

This document was developed by the WHO Regional Office for Europe Working Group on COVID-19 Vaccination, which engages a broad group of stakeholders including experts from the United States Centers for Disease Control and Prevention, the European Centre for Disease Prevention and Control, the Europe and Central Asia Regional Office and the Supply Division of the United Nations Children’s Fund, representatives of national public health agencies, regulatory authorities and academia. WHO also gratefully acknowledges the valuable guidance and contributions of the European Technical Advisory Group of Experts (ETAGE).

Introduction

Emergence of the novel coronavirus (SARS-CoV-2) quickly led to a rapidly spreading outbreak of COVID-19 throughout the world. On 30 January 2020, WHO declared COVID-19 a public health emergency of international concern (PHEIC) and on 11 March 2020, the outbreak was described as a pandemic. As of 15 September, more than 29 million cases and over 925 000 deaths have been reported globally. While non-pharmaceutical interventions have slowed the pace of the spread of COVID-19, it is widely recognized that development and rapid deployment of one or more vaccines against COVID-19 will be essential to contain the pandemic, protect health care systems, save lives and help restore global economies. As COVID-19 vaccines become available, factors such as global demand and manufacturing capacity and health systems capacity to deliver them will influence equitable access as well as rational and effective use of the vaccines.

Scope and purpose

This document outlines the key strategic considerations for ministries of health, their agencies, national immunization technical advisory groups/committees and relevant public and private sector authorities in the WHO European Region in preparing for deployment of COVID-19 vaccine and vaccination in their countries. The objective is to allow Member States to identify and address any critical gaps for effective deployment of COVID-19 vaccines.

As new scientific evidence and information related to COVID-19 vaccines become available, a detailed operational guidance and related tools for vaccination and deployment of COVID vaccines in countries will follow.

Key strategic considerations

The recently established Access to COVID-19 Tools (ACT) Accelerator, an unprecedented global collaboration to accelerate the development, production and equitable access to COVID-19 vaccines, aims to make available 2 billion doses of vaccine by the end of 2021. Independent advisory mechanisms (the global Strategic Advisory Group of Experts on immunization (SAGE) and the European Technical Advisory Group of Experts on immunization (ETAGE)) will provide further guidance on COVID-19 vaccination policy following a review of the available scientific evidence.

Broad considerations

Availability of and access to COVID-19 vaccines are expected to be limited during the initial stages following licensing due to insufficient manufacturing capacity and unprecedented demand. Therefore, it will be important that every country has fair and equitable access to vaccines and that they allocate them equitably based on evidence-informed decisions. As availability of one or more COVID-19 vaccines improves, every country will have to adjust their national vaccination strategy accordingly. Collaborative efforts amongst relevant national stakeholders and partners will be essential to address any country-specific challenges.

Country-specific considerations

While specific characteristics of the vaccines are still unknown, there are immediate actions that countries can take to prepare for vaccination and deployment of COVID-19 vaccines.

A national preparedness plan for vaccination and deployment of COVID-19 vaccines should address the following programmatic areas (not an exhaustive list):

- a. highest-level advocacy, policy dialogue, partner engagement and resource mobilization;
- b. evidence-informed and ethical values-based national vaccination strategy;
- c. legal and regulatory framework facilitating vaccine deployment;
- d. immunization service delivery modalities;
- e. vaccine and supply chain management;
- f. human resources and security;
- g. vaccination data and information management;
- h. vaccine safety monitoring;
- i. injection safety and waste management;
- j. demand generation, community engagement and communication.

The broad characteristics of the above programmatic areas and suggested considerations are outlined below.

a. Management structure, advocacy and resources

A fit-for-purpose governance structure at both strategic (policy) and operational levels will play a critical role in achieving the national COVID-19 vaccination objectives. Implementation of the national vaccination strategy will require intersectorial approach, collaboration and partnerships with relevant governmental and non-governmental entities. While providing high-level policy direction, this structure will obtain required political commitment and support mobilizing adequate resources.

Consider:

- operationalizing a governance structure (strategic and operational; national and subnational levels) with technical experts from each of the programmatic areas – preferably within the national emergency operational mechanism for COVID-19 pandemic response;
- ensuring participation of relevant institutions, organizations and advisory bodies that have a role in vaccination and deployment in the country.

b. Evidence-informed and ethical values-based national vaccination strategy

National immunization technical advisory mechanisms (groups/committees) will play a critical role in translating global and regional policies and guidance into national vaccination strategies. As additional evidence and knowledge on COVID-19 vaccines and their characteristics become available, each country's National Immunization Technical Advisory Group (NITAG) or its equivalent national committees will need to review and adapt the global and regional policy

recommendations and address ethical issues relating to the allocation and prioritization of COVID-19 vaccines.

NITAGs may consider:

- reviewing available evidence regularly to define, re-assess and adapt periodically the national COVID-19 vaccination objectives, strategies, estimation of target vaccination groups, coverage targets and priorities;
- requesting, in consultation with the Ministry of Health, suitable modeling exercises, such as vaccine interventions effectiveness, to inform national policies.

c. Legal and regulatory framework facilitating vaccine deployment

Novel vaccine platforms and limited data during the pre-licensure stage will require optimizing national regulatory processes and procedures to ensure rapid access to and safe deployment of COVID-19 vaccines. Provisions to accept donations of vaccines and ancillary products should be within the scope of national regulations for medicines, vaccines and other health products.

Consider:

- optimize regulatory pathways for licensing the use of a new vaccine(s) under emergency conditions, including accelerated licensure and lot release of COVID-19 vaccine(s) based on recognition of the decisions or reliance of the expertise of supporting NRAs;
 - o consider expedited marketing authorization through the WHO collaborative procedure for prequalified vaccines and/or Emergency use listing, as appropriate;
 - o establish fast-track procedures based on regulatory alignment, advanced communication and collaboration with global and regional regulatory networks;
- defining procedures to manage potential vaccine safety liabilities, including provision of support and care if any vaccine recipient develops a serious reaction.

d. Immunization service delivery modalities

As COVID-19 vaccine availability improves, more population groups will be targeted for COVID-19 vaccination. In addition to the increased workload and resources required, reaching out to some target groups may present challenges to the health systems and may easily outstretch the capacity of the existing immunization system.

Consider:

- identifying or devising appropriate platform(s) and service delivery mechanisms to deliver COVID-19 vaccines to target population groups as per the national vaccination strategy with minimal disruptions to the routine immunization services, which may require;
 - o reviewing the scope and capacity of existing immunization service delivery platforms (i.e. facility-based or outreach immunization services for routine and influenza vaccines);

- establishing or adapting appropriate vaccination service delivery modalities (such as mobile teams, at homes for the elderly, pharmacies, educational institutes, workplace, supermarkets, or drive-through);
- developing, reviewing and updating detailed micro-plan that identifies target population groups and their sizes (provision for regular updating and listing of target populations should be in place), resources to conduct vaccination sessions (human resources, equipment, supplies, transport) and plans for capacity building and performance monitoring.

e. Vaccine and supply chain management

It is envisaged that appropriate administrative and funding provisions will be made by countries to secure access to COVID-19 vaccines and consumables. The safe delivery of vaccines will require adequate vaccine management and supply chain logistics based on the final product profile of available vaccines (presentations and formulations, stability and temperature characteristics, storage and transport volumes). A national system to track and trace the vaccine products and their lots would be essential to handle multiple vaccine products, manage vaccine supply for subsequent doses, contribute to vaccine safety monitoring and manage eventual product recalls.

Consider:

- establishing early communication with potential vaccine suppliers to get access to product profile data and plan for appropriate infrastructure and procedures for storage, transportation and delivery;
- evaluating, based on the vaccine product characteristics, the national and sub-national level vaccine storage, transportation, delivery and handling system and address any identified gaps, which may include;
 - considering surge capacity for vaccine storage and transportation and, contingency plans to expand existing capacities of distribution systems;
 - reviewing, updating (as needed) and disseminating the “standard operating procedures” for all aspects of vaccine and supply management.
- planning for management of immunization supplies (syringes, needles, sharps collection devices, personal protection equipment, cold boxes, vaccine carriers, coolant-packs, anaphylaxis management kits, vaccination cards, communications materials).

f. Human resources and security

Adequate deployment of COVID-19 vaccines and rapid vaccination of the target populations will require adequate skilled, trained, motivated and supported health care professionals. In addition, it is essential that any risk of COVID-19 transmission during the vaccination sessions either to the vaccinators or the recipients is mitigated in line with the national infection prevention policies.

Consider:

- assessing the existing human resources and developing a contingency plan to minimize the impact of any expected shortages including a robust training plan for personnel involved in COVID-19 vaccination, including development of training materials with simple visual aids;
- implementing COVID-19 infection prevention and control measures (safety and security of personnel, infrastructure, facilities, equipment, inventories) at all vaccine distribution and delivery sites.

g. Vaccination data and information management

Effective national implementation of COVID-19 vaccination will depend on the ability to access, receive and share information rapidly between managers and staff at all levels. To enable comprehensive decision-making, information from different data sources linked to COVID-19 such as local epidemiology, vaccination preparedness, performance and coverage monitoring, vaccine and supply management, vaccine safety and immunization waste management should be collected, analysed and disseminated. The real-time monitoring of uptake, safety and effectiveness of COVID-19 vaccines would benefit from use of electronic information platforms, however, alternatively, appropriate paper-based or partially digitized systems could also be used.

Consider:

- defining essential data and indicators needed to monitor immunization performance, standardizing the reporting formats and establishing information flow and procedures for all levels;
- reviewing the existing national information management systems and determining their usability for COVID-19 vaccination data management including any additional needs;
- identifying and performing required modifications, ahead of time, in the existing data collection and monitoring platforms, or developing a dedicated system, based on defined standard requirements, if no such system exists.

h. Vaccine safety monitoring

COVID-19 vaccines will be novel and potentially use novel platforms, which were not previously used in any licensed vaccine. Licensure for use will be based on available safety information from the clinical trial data and thus, rare vaccine reactions and reactions unique to specific populations may not be identified before the vaccines are used in large populations. National surveillance systems should be capable of identifying both known vaccine reactions (identified during clinical trials) and new and rare adverse events (or signals). Also, identifying, investigating and assessing causality of any adverse events following immunization (AEFI) will be important to support corrective actions and maintain public trust in immunization.

Consider:

- ensuring regulatory provisions are in place for manufacturers to implement risk management plans and report COVID-19 vaccine safety data;

- strengthening mechanisms to detect, review and respond to vaccine safety events, including by
 - o enhancing passive vaccine pharmacovigilance activities (AEFI reporting, investigation, causality assessment, risk communication and response) by updating and/or developing guidelines, procedures and tools;
- establishing mechanisms, where possible, for active surveillance of adverse events of special interest (AESI) to measure background rates and undertake research to test hypotheses;
- establishing mechanisms for real-time assessment and sharing of vaccine safety data through global and regional platforms.

i. Safe injections and waste management

COVID-19 vaccines will require injection devices to administer the doses. The scale of the vaccination response will require large amounts of syringes to administer vaccine doses (and possibly reconstitution syringes) and equipment for safe collection and disposal of generated waste. By following the existing WHO recommendations on the use of safety-engineered injection devices, auto-disable syringes for the delivery of vaccines and reuse prevention syringes for the reconstitution of vaccines including proper management of waste, countries can ensure that the injections and associated waste do not pose threats to vaccine recipients, healthcare providers, communities, and the environment.

Consider:

- planning, for procurement of injection equipment and waste management supplies, based on the information on the vaccine product profile;
- assessing existing infrastructure and planning for safe collection, storage and disposal of used injection equipment, vaccine vials, and other hazardous medical wastes with special considerations for non-fixed service delivery sites.

j. Demand generation, community engagement and communication

Public acceptance and utilization of COVID-19 vaccines will be essential to control coronavirus transmission. Several behavioural insights surveys have shown widespread hesitancy or resistance towards any future COVID-19 vaccine. Rapid development of multiple candidate vaccines and limited initial supply including prioritization of access all create a unique context that could lead to public resistance to implemented policies and distrust in COVID-19 vaccines in general and authorities. The unprecedented abundance of information and misinformation circulating during the pandemic can also impact the public response.

Consider:

- conducting social research to identify the public's risk perceptions, decision-making factors and the barriers and drivers for accepting and utilizing COVID-19 vaccination;

- drawing on evidence related to trust in health authorities, vaccine hesitancy and perceptions of COVID-19 to shape relevant vaccine safety event communication and risk communication and community engagement (RCCE) strategies and plans;
- coordinating communications across national and subnational levels as well as public and private sectors and engaging relevant stakeholders.

The WHO Regional Office for Europe

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WHO/EURO:2020-1148-40894-55356

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