

# COVID-19

## **Guidelines to Plan for COVID-19 Vaccine Introduction Version 1: 10 July 2020**

**Document developed by the Comprehensive Family Immunization Unit of the Family, Health Promotion and Life Course Department (FPL/IM) in the Pan American Health Organization (PAHO)**

### **Background**

COVID-19 is an infectious disease caused by a novel coronavirus that recently emerged (SARS-CoV-2). The COVID-19 pandemic was declared by the World Health Organization (WHO) on 11 March 2020, the first non-influenza pandemic to affect more than 200 countries, with more than 10 million cases to date. Approximately, half of these cases have been reported in the Region of the Americas. The world hopes to soon have COVID-19 vaccines as one of the most cost-effective measures to control the pandemic and lessen the health, economic, and social impacts.

While progress is being made in the development and production of vaccines against COVID-19, countries must simultaneously advance in planning to introduce this new vaccine and identify key components to strengthen as preparation for vaccination against this pandemic. Gained experiences in the Region of the Americas with vaccination against the H1N1 influenza pandemic in 2009, annual vaccination against seasonal influenza, vaccination campaigns against measles and rubella, polio and yellow fever, among others, should be used to develop national COVID-19 vaccination plans.

Among the main challenges expected for COVID-19 vaccination are timely, equitable, and sufficient access to vaccines, technical and logistical aspects, such as the development of vaccines with new technologies, definition of priority groups, number of doses to administer for adequate protection, as well as vaccine safety and effectiveness. Additionally, other programmatic challenges can be evident related to cold chain needs and creating demand for vaccination, among others. However, with the information currently available and with the assumption that vaccines will be available in the countries of the Region starting in 2021, it is important to start preparing the infrastructure and key components to introduce the vaccine in all countries, prioritizing components in which progress can be made.

The objective of this document is to provide guidelines to national immunization programs (NIPs) for the development of their respective COVID-19 vaccination plans. It is important to involve National Immunization Technical Advisory Groups (NITAGs) in the development of these national plans. It is also important to consider recommendations previously issued by PAHO/WHO on security measures for health care workers and the rest of the population regarding COVID-19.

**This document will be updated as new evidence becomes available.**

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The following text details various components to consider when developing national COVID-19 vaccination plans:

Technical Components	Operational Components
Definition of vaccination objectives	Organization and coordination
Legal bases	Planning and micro-planning
Technical recommendations	Cold and supply chain
Definition of target groups and goals	Information system
COVID-19 vaccines	Safe vaccination
National Regulatory Authorities	Monitoring, supervision, and evaluation
Vaccine access and distribution	Communication, information, and social mobilization
	Human resources
	Training
	Operational research
	Waste management
	Closure of campaign
	Budget and timeline

## 1. Vaccination Objectives

Countries should set COVID-19 vaccination targets, considering the epidemiological situation, highest risk populations, and vaccine access. The lack of opportunity in vaccine availability will make it necessary to prioritize and vaccinate in phases following the following objectives:

- **Protect the integrity of the health care system and infrastructure for the continuity of essential services:** Vaccinate health workers at all levels of care and other essential services established in the country.
- **Reduce severe morbidity and mortality associated to COVID-19 by protecting populations at greatest risk:** Vaccinate groups at greatest risk according to epidemiological situation.
- **Reduce transmission of infection in the community and generate herd immunity.** Expanding vaccination to other groups will be done based on increases in vaccine availability in the country.

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## 2. Legal Basis

- Review laws, resolutions, and decrees linked to decision-making, vaccine introduction, acquisitions, and public health emergencies, among others.

## 3. Technical Recommendations

The country will make the decision to introduce the new vaccine, considering technical, programmatic, social, and economic criteria. For technical aspects, countries will rely on the recommendations from advisory groups at the global, regional, and national levels.

The main immunization advisory groups are the following:

- Global: Strategic Advisory Group of Experts (SAGE) on immunization
- Global: Global Advisory Committee on Vaccine Safety (GACVS)
- Regional: Technical Advisory Group (TAG) on Vaccine-preventable Diseases
- National: National Immunization Technical Advisory Groups (NITAGs) and ethics committees

Recommendations from different technical advisory groups to define target populations to be vaccinated will be based on available evidence, which will consider vaccine characteristics (safety, immunogenicity, efficacy, and duration of protection), at-risk groups (older adults and chronic diseases), and other conditions, such as pregnant women. Similarly, recommendations on the number of necessary doses, co-administration with other vaccines, and events to monitor, will depend on the available evidence and will be continuously updated.

## 4. Definition of Target Groups and Goals

Guided by technical recommendations from advisory groups, countries should develop technical guidelines that define:

- Priority groups to vaccinate
- Vaccination goals at national, sub-national, and local levels

For reference, WHO population estimates for risk groups (health personnel [3%], older adults, and people with chronic diseases [20%]) should be included. The countries have various information sources that can be used to calculate these risk populations: national censuses, national plans for seasonal influenza vaccination (that include different risk groups), lists of public and private sector health personnel, prevalence surveys of chronic diseases, among others.

## 5. COVID-19 Vaccines

- Describe the characteristics of WHO-prequalified COVID-19 vaccines and those approved by national regulatory authorities (NRAs) like the United States Food Drug Administration (FDA) or the European Medicines Agency (EMA).

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## 6. National Regulatory Authorities (NRAs)

- Review legal and regulatory aspects that apply to purchased and donated vaccines.
- Review processes and documentation required to import, license, and register vaccine at the national level.
- Review importation and approval processes for a vaccine in emergency situations.

## 7. Access and Distribution of the Vaccine

- Estimate preliminary needs for vaccines (consider scenarios for schedules with one and two doses), syringes, and supplies, using data from national vaccination plans for different risk groups.
- Forecast demand of vaccine through PAHO's Revolving Fund.
- Review processes related to accepting donations through WHO or other institutions or agencies.

## 8. Organization and Coordination

- Apply and strengthen inter-institutional and multi-sectorial coordination mechanisms.
- Describe the organization and coordination of the vaccination campaign.
- Define the organizational structure: national and sub-national, political, technical, and emergency committees, defining roles and responsibilities.
- In coordination with the ministry of education, determine role of teachers, universities, etc.
- In coordination with the ministry of labor, determine role of employers, public and private sector, essential worker sectors, etc.
- Ensure coordination with local governments (governors, mayors, secretaries of health).
- Coordinate participation from institutions or advisory bodies: NITAGs, NRAs, professional associations, scientific associations, NGOs, ministry of finance, ministry of transportation, ministry of tourism, airports, civil organizations, churches, community representatives, armed forces, etc.
- Organize operational committees for vaccine administration.

## 9. Planning and Micro-planning

- Define target population to be vaccinated according to objectives and priority groups at the national, departmental, district or municipal, neighborhood or community levels, etc.
- Define denominators by referring to estimations from population censuses, civil registries, influenza vaccination plans, registries and studies of chronic disease prevalence, diabetes support groups, hypertension and other chronic pathologies, censuses or lists of public and private health workers, essential workers, etc.
- Analyze the capacity of vaccination services (human resources, cold chain storage capacity and conditions, availability of personal protective equipment [PPE], etc.).
- Define campaign phases according to vaccine availability.

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- Describe strategies and tactics for vaccination based on phases, priority groups and schedule, including:
  - i. Specific workshops for each previously identified risk group
  - ii. Institutional vaccination
  - iii. Vaccination in special places: pharmacies, supermarkets, banks, work centers, etc.
  - iv. Mobile vaccination
  - v. Drive-thru vaccination (self-service)
  - vi. Vaccination by appointment
  - vii. House-to-house vaccination
  - viii. Vaccination at border points
- Adapt vaccination services according to the local COVID-19 transmission situation.
- Define personnel needs, roles, and responsibilities at the local level.
- Determine number of vaccination teams or brigades and supervisors required.
- Estimate requirements for vaccines, considering loss factor, syringes, and supplies (safety boxes, vaccine thermoses, boxes, cold packs, bags, sheets/registry booklets, PPE, masks, soap, sanitizing gel) at national and subnational levels.

## 10. Supply and Cold Chain

- Define basic functions and responsibilities of the logistics manager.
- Determine basic data for the logistics plan and supply chain.
- Describe the characteristics of the different vaccines and syringes required.
- Review the inventory of storage capacity for the cold chain at all management levels.
- Determine cold chain requirements, gaps, and challenges.
- Expand, as needed, the cold chain (equipment and supplies) to guarantee capacity to include vaccine at all management levels.
- Update contingency plans for vaccine storage.
- Develop a distribution plan down to the local level; adapt needs of vaccines, syringes, and safety boxes to planning of stages or phases according to vaccine availability.
- Schedule transportation of vaccines and other supplies at all levels.
- Implement monitoring systems for vaccine distribution and conduct inventories using logistics information software integrated into existing systems and technology development (barcodes, electronic tracking, etc.).
- Define indicators to evaluate the supply chain from the international to the national level and from the national to the local level (7 days after arrival in the country).

## 11. Information System

- Design information system to evaluate coverage to the most detailed level possible (neighborhood, neighborhood, community).
- Update electronic immunization registries, vaccination card by risk group, and standardization of data reporting.

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- Apply technologies that facilitate data collection in real time and guide the implementation of these technologies during public health emergencies.
- Establish alliances with ministries of information and communication technologies.
- Establish procedures, with information flows and periodicity from the local to the national levels.
- Conduct analysis and monitoring of vaccination coverage by risk groups; use digital and georeferencing platforms, as well as those to identify inequities.

## 12. Safe Vaccination

### **Surveillance of Events Supposedly Attributable to Vaccination or Immunization (ESAVIs)**

- Convene national committee on safe vaccination with participation from scientific societies, national regulatory authorities, the immunization program, and ESAVI national classification sub-committee.
- Strengthen or implement surveillance of ESAVIs and Adverse Events of Special Interest (AESIs).
- Prepare surveillance of potential expected AESIs to establish incidence rates, prior to introduction of the COVID-19 vaccine.
- Define requirements to strengthen intensified passive surveillance and active surveillance (sentinel hospital network).
- Participate in the regional ESAVI surveillance system with case reporting from local to national and regional levels.
- Prepare a risk communication and crisis plan.

### **Safe injection**

- Develop safe injection guidelines in all three aspects (those vaccinated, health personnel and environment) in the context of the pandemic.

## 13. Monitoring, Supervision, and Evaluation

- Convene a committee responsible for the monitoring, supervision, and evaluation of the campaign:
  - Implement a room for situation analysis and monitoring
  - Review updated data on doses administered by district/municipality, health establishments, and communities disaggregated by prioritized population group
  - Review of demographic information
  - Design a dashboard to monitor coverage and other tracing indicators of immunization implementation at each stage
- Define criteria and indicators of high-quality campaigns (effectiveness, homogeneity, opportunity, and efficiency).
- Design a digital and manual vaccinometer as a mechanism that allows the local level to identify the fulfillment of daily and weekly goals, resume or re-adapt strategies and programming, and identify the lags of the target population that has not been vaccinated.
- Establish supervision and monitoring mechanisms at all management levels.

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- Develop supervision guide, form supervising team by level and schedule.
- Evaluate vaccine introduction plan for each phase at all levels of the health system.
- Evaluate reasons why people are not being vaccinated, including different sources of information, surveys, focal groups, etc.
- Develop checklist to monitor and evaluate the implementation of introduction plan.

## 14. Communication, Information and Social Mobilization

Define a demand strategy for COVID-19 vaccination that includes increasing knowledge, raising awareness, and increasing the population's confidence in vaccination. Likewise, coordinate with all strategic partners (civil society, political and community leaders, NGOs, etc.) so that they contribute to a positive dialogue on vaccination and the COVID-19 vaccine.

Identify spokespersons, chains of command and types of messages; articulate collaboration with the media; monitor use of social networks, including rumor analysis and management; monitoring international, national, and local media, among others.

### Specific activities

- Design a communication campaign to generate vaccine confidence and demand (define phases, messages, media, and social networks).
- Define a strategy for social mobilization and community engagement (involving community leaders), to create and maintain demand for the COVID-19 vaccine and routine vaccination (scientific societies, and opinion leaders).
- Define a crisis management plan including a communication strategy with messages designed to respond to specific scenarios and provide tools and adequate training for key spokespersons.
- Describe what is needed to establish fluid communication among institutions and agencies in support of the deployment and implementation of vaccination, and anticipate challenges.
- Ensure coordination with partners to promote consistency of messages.
- Work with media to train, inform and encourage responsible reports on vaccination.
- Identify the needs to build population trust and demand for the COVID-19 vaccine.
- Develop materials for different audiences, advocacy packages for local authorities, governors, strategic allies, community leaders, media, among others, taking into account interculturality.
- Validate materials with the various audiences through consultations, focus groups, and other mechanisms.
- Conduct meetings with the media and opinion leaders for advocacy and coordination.
- Conduct surveys and opinion polls on the vaccine in specific groups and population at-large.
- Monitor media and social media platforms with a focus on vaccine information.
- Evaluate communication strategies and any other interventions implemented to increase vaccination coverage and acceptance.

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## 15. Human Resources

- Evaluate human resources needed to execute, manage, and coordinate supervision, information registry, and COVID-19 vaccination activities.
- Determine availability of human resources and existing needs at each level of care to execute vaccination in a short period of time.
- Map educational institutions to train health professionals, public and private, that may be potential sources of human resource supply.

## 16. Training

- Determine the type of training required for different audiences, virtual platforms, and mechanisms for supervision, evaluation, accreditation, and monitoring.
- Establish training content, including national technical guidelines for COVID-19 vaccination, vaccinator manuals, supervisor manuals, administration and surveillance techniques, ESAVI and AESI reporting, and operational implementation.
- Develop training materials for use in different virtual platforms.
- Develop national training plan.
- Define timeline.

## 17. Operational Research

- Define agenda for operational research based on the information available in the NIP (based on identifying knowledge and information gaps to guide interventions to help reach vaccination goals).
- Coordinate with universities and research institutions to carry out operational research on implementation, including the social and behavioral determinants of vaccination, attitudes, knowledge, and practices, among others, related to COVID-19 vaccination.
- Consider utilizing existing sentinel surveillance platforms for respiratory viruses (SARINET/REVELAC-i) to evaluate the effectiveness and impact of the COVID-19 vaccine. Note that COVID-19 and influenza surveillance are currently integrated.

## 18. Waste Management

- Review the national norms on waste management.
- Establish solid waste management guidelines: a) estimation of volumes of waste; b) management and institutional disposal routes; c) extramural management and disposal routes; d) coordination with processing units and local health authorities; and e) methods of waste disposal.

## 19. Closure of Campaign

- Officially declare the closure of the vaccination campaign.
- Evaluate campaign based on high quality criteria and established indicators.



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- Present a report on the campaign results to the authorities, including coverage by age group and sex, homogeneity of coverage, risk group, summary of mild, moderate, and severe adverse events reported and investigated, summary of epidemiological surveillance indicators, lessons learned, and good practices.
- Present results from operational research and studies on the effectiveness and impact of vaccination.
- Describe the investment highlighting national and external resources.

## 20. Budget

- Describe the budget by component.
- Determine available funds and assess gaps by component to identify financing sources.
- Mobilize resources from national and external sources.

## 21. Timeline

- Describe the period planned to execute the main activities by component and define roles and responsibilities.

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