

Immunization Newsletter

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Vaccine Development, Distribution, and Supply

Vaccine development is a prolonged and complex process, often lasting 10-15 years and, ideally, requiring combined involvement from the public and private sector. Vaccine are made using several different methods. They may contain live viruses that have been attenuated (weakened or altered so as to not cause illness), inactivated or killed organisms or viruses, inactivated toxins (for bacterial diseases where toxins generated by the bacteria and not the bacteria themselves, cause illness), or merely segments of the pathogen (this includes both sub-unit and conjugate vaccines)¹.

The vaccine development process goes through different research studies and prioritizes a vaccine's safety, followed by its efficacy. Studies are conducted in phases: the preclinical phase and phases I, II, III, and IV.²

- **Preclinical phase:** Experimental results on efficacy and tolerance in animal models support the vaccine's subsequent research in humans. Preclinical studies use tissue culture or cell culture systems and animal testing, which may be mice or monkeys, to assess the safety of the candidate vaccine and its immunogenic capacity, or ability to elicit an immune response.
- **Phase I:** Usually tests a new vaccine in an experimental stage in a small number of humans, generally fewer than 100 adults, with the aim of initially evaluating its safety and biological effects, including immunogenicity. This phase may include studies of doses and routes of administration.
- **Phase II:** Tests a vaccine that was considered safe in phase I and that requires a larger group of humans (usually between 200 and 500) to monitor safety. These trials also determine the efficacy of the vaccine. The goals of phase II trials are to study the candidate vaccine for its safety, immunogenicity, proposed doses, and method of administration.
- **Phase III:** Aims to assess safety and efficacy more fully in disease prevention and involves more volunteers participating in a properly controlled multicenter study. They can include hundreds to thousands of humans in one country or several countries. Phase III tests are randomized and double blind and involve the experimental vaccine that is tested against a placebo (the placebo can be a saline solution, a vaccine for another disease or some other substance). This is generally the step before approval of a vaccine.
- **Phase IV:** These are the studies that occur after the approval of a vaccine in one or more countries. These studies aim to assess how the vaccine works in the "real world." They are generally effectiveness studies and continue to monitor for adverse events.

The distribution and supply of vaccines depend on the licensure of national vaccine markets. Vaccines can be licensed directly in those countries that have highly developed regulatory authorities, while other countries rely on licensure in the manufacturing country, followed by reviews and approvals by the final country of use. In all cases, licensing includes approval of the manufacturing process and facilities; some countries also require assessments. The procurement of vaccines by United Nations (in the Region of the Americas, PAHO's Revolving Fund) agencies requires that the product has pre-qualification from the World Health Organization (WHO). This guarantees a reliable product quality standard for countries with less developed regulatory agencies and procurement is dependent on the vaccine having been previously licensed in the manufacturing country by an authority that is regarded as 'functional' by the WHO.

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What I Have Learned as an Immunization Advisor during the COVID-19 Pandemic...

By Marc Rondy, PAHO/WHO
Immunization Focal Point in Guatemala

2020 will remain an extraordinary year for everyone and especially for those of us who work in public health.

In my case, it is an especially extraordinary year in which I have been able to apply all my training and experience. An infectious diseases epidemiologist by training, I started working on vaccine-preventable diseases (VPDs) 15 years ago as part of my EPIET programme (European Programme for Intervention Epidemiology Training) in the Netherlands. At the end of those two years training, I returned to France where I joined EpiConcept, a company whose vision is to bring together the strength of European public health institutes in order to measure the impact and effectiveness of vaccines. We implemented multicentre platforms to study influenza, pneumococcal conjugate, pertussis, and human papillomavirus vaccines, among others. During that time, I was also deployed as an epidemiologist on several emergencies, including cholera in Haiti, meningitis in Niger and Ebola in Guinea.

I joined the Pan American Health Organization (PAHO) two years ago as an immunization advisor in Guatemala. Considering my experience and background in epidemiology and influenza, I was appointed as the surveillance focal point for COVID-19 to help strengthen Guatemala's good surveillance team that suffers from great understaffing.

This position as a focal point in surveillance put me in an interesting situation to support both the COVID-19 response and maintain VPD surveillance. Supporting COVID-19 surveillance encompasses periodic revision of surveillance guidelines (14 versions already!), including case definition and testing strategy, as well as the development and implementation of surveillance information systems, like Go.Data, data entry, data management, analysis and dashboard development, and modelling.

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¹ <https://www.historyofvaccines.org/content/articles/different-types-vaccines>
² Plotkin S et al. Vaccine Volume 35, Issue 33, 24 July 2017, Pages 4064-4071

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COVID-19 candidate vaccines and access

Various technologies and platforms are being used to develop the COVID-19 vaccines:

- **Nucleic acid (DNA, RNA) vaccines:** vaccines that use one or more of the coronavirus's own genes to provoke an immune response
- **Viral vector vaccines:** vaccines that use a virus – a non-replicating or replicating vector – to deliver coronavirus genes into cells and provoke an immune response
- **Protein-based vaccines:** vaccines that use a coronavirus protein or a protein fragment (protein sub-unit) to provoke an immune response
- **Whole-virus vaccines:** vaccines that use a weakened (attenuated) or inactivated version of the coronavirus to provoke an immune response

As of 28 August there are 33 COVID-19 candidate vaccines undergoing clinical evaluation, of these 8 are in phase III. Additionally, there are 143 candidate vaccines in the pre-clinical phase. The table below shows six candidate vaccines in phase III³.

Developer (country)	Sinovac (China)	Wuhan Institute of Biological Products/ Sinopharm (China)	Beijing Institute of Biological Products/ Sinopharm (China)	University of Oxford/ AstraZeneca (UK)	Moderna/NIAID (USA)	BioNTech/ Fosun Pharma/ Pfizer (USA)
Name of candidate vaccine	Sinovac vaccine	CNBG Wuhan	BBIBP-CorV	ChAdOx1-S	mRNA-1273	BNT162b
Platform	Inactivated	Inactivated	Inactivated	Non-replicating viral vector	RNA	RNA
Study design	Phase 3, double-blind randomized, 8,870 participants ≥ 18 years (healthcare professionals), 2 doses (0, 14 days), IM. Location: Brazil (collaboration with Butantan Institute). Primary completion date: 30/09/21	Phase 3, double-blind randomized, 15,000 participants ≥ 18 years, 2 doses (0, 14 days or 0, 21 days), IM. Location: United Arab Emirates. Primary completion date: 15/07/21	Phase 3, double-blind randomized, 15,000 participants ≥ 18 years, 2 doses (0, 14 days or 0, 21 days), IM. Location: United Arab Emirates. Primary completion date: 15/07/21	Phase 3, single-blind randomized, 10,260 participants 18-55 years, 1 dose, IM. Location: UK, Brazil (collaboration with Fiocruz-BioManguinhos), and USA. Primary completion date: 01/10/21	Phase 3, double-blind randomized, 30,000 participants 18-55 years, 2 doses (0, 28 days). Location: USA. Primary completion date: 27/10/22	Phase 3, triple-blind randomized, 28,481 participants 18-85 years, single or 2 doses (0, 28 days). Location: Argentina, Brazil, USA. Primary completion date: 16/04/21
Trial Number (link)	NCT04456595	ChiCTR2000034780	ChiCTR2000034780	ISRCTN89951424 NCT04516746 NCT04526990	NCT04470427	NCT04368728
Status	Recruiting	Recruiting	Recruiting	Recruiting	Recruiting	Recruiting

The COVID-19 Vaccine Global Access (COVAX) Facility represents a global multilateral collaboration intended to accelerate the development, production, and equitable access to COVID-19 vaccines when they become available. The COVAX Facility forms a key part of the COVAX pillar of the Access to COVID-19 Tools (ACT) accelerator, a ground-breaking global collaboration to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines. COVAX is co-led by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI), and WHO, working in partnership with developed and developing vaccine manufacturers. COVAX aims to accelerate the development and manufacturing of COVID-19 vaccines, and to guarantee fair and equitable access for every country in the world. PAHO's Revolving Fund has been working very closely with COVAX to ensure countries of the Region equitable access to the COVID-19 vaccine when it becomes available.⁴

Introduction of the COVID-19 vaccine in Latin America and the Caribbean

All countries must develop a COVID-19 vaccine introduction plan that should be based on previous experiences introducing new vaccines, as well as the experience using the influenza vaccine during the 2009 pandemic. The main objective of this planning is to implement massive COVID-19 vaccination campaigns to reduce severe morbidity and mortality. Countries in alignment with the NITAGs (National Immunization Technical Advisory Groups) will therefore need to define their priority groups for vaccination based on the epidemiology of the disease.⁵

The plan for the introduction of a new vaccine⁶ should contain several components, such as procurement and distribution logistics, cold chain, training of health personnel, supervision, monitoring, implementation of a reporting and investigation system for events supposedly attributable to vaccination or immunization (ESAVIs) and in the case of this vaccine, adverse events of special interest (AESIs), vaccine coverage monitoring, and subsequently, assessments of the impact and effectiveness of the vaccine.

It is important to highlight that vaccines are recognized to be one of the most cost-effective public health measures, however vaccine hesitancy was declared a top 10 global health risk by WHO in 2019. Human factors, such as understandings of disease, perceptions of risk, and social factors affecting access, are central to vaccination coverage. Therefore, general acceptance of these vaccines is extremely important. This acceptance, in turn, is not as simple as just making safe and effective vaccines available. It is a complex social effort that needs deep engagement around the human element.⁷ ■

³ For the most updated list of candidate COVID-19 vaccines, please visit: <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>

⁴ <https://www.who.int/news-room/detail/15-07-2020-more-than-150-countries-engaged-in-covid-19-vaccine-global-access-facility>

⁵ <https://iris.paho.org/handle/10665.2/52532>

⁶ <https://www.paho.org/immunization-toolkit/spanish/wp-content/uploads/2017/05/Introduccion-e-implementacion-de-nuevas-vacunas.pdf>

⁷ https://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2020/200709-The-Publics-Role-in-COVID-19-Vaccination.pdf

Summary of the Status of National Immunization Programs During the COVID-19 Pandemic

July 2020

Introduction

In December 2019, a novel coronavirus (SARS-CoV-2) was identified as the causal agent of a severe acute respiratory illness (COVID-19) in Wuhan, China.^{8,9} The virus spread to various countries, and on 11 March 2020 the World Health Organization (WHO) declared a pandemic.¹⁰

Both WHO and the Pan American Health Organization (PAHO) have recommended that uninterrupted vaccination be maintained as an essential health service.^{11,12} To this end, PAHO's Comprehensive Family Immunization (IM) unit, has worked assiduously with the countries of the Region to maintain sound national immunization programs on several fronts, such as the preparation of documents and guidelines for continuing vaccination in the context of COVID-19; monitoring the disease's impact on vaccination coverage; assessing the effects of the postponement of measles vaccination campaigns (Plurinational State of Bolivia, Colombia, Dominican Republic, Honduras, Paraguay) due to the pandemic; and strengthening seasonal influenza vaccination.

Work has also been carried out to monitor the functioning of immunization services and the main problems they face because of the pandemic. To date, five country surveys have been conducted; the first was sent out on 16 April, the last on 6 July. This document summarizes their main findings and developments.

Methods

The data presented in this publication were collected through a survey, sent every two weeks to IM focal points and advisors in the at PAHO country offices in the Region. The SurveyMonkey virtual platform was used and the data were analyzed with MS Excel tools. All the variables included in the survey were described using the appropriate univariate statistics. Categorical variables were described using proportions and percentages. Ordinal variables were described using the mean and median.

The responses in this report represent the opinions of survey participants, and do not represent reports officially sent or solicited by PAHO; the data should therefore be interpreted with caution.

Data and results

Since the first questionnaire on 16 April, five surveys have been sent to IM focal points and advisors in the countries. The response rate is shown in the table below:

Date of survey	Countries participating in the survey (Spanish- and Portuguese-speaking)	Countries participating in the survey (French- and English-speaking)	Total
16 April	13	3	16
4 May	16	14	30
20 May	16	17	33
3 June	16	23	39
6 July	16	22	38

The information presented in this summary represents responses from 38 countries and territories in the Region of the Americas received as of 3 July 2020 and collected in the fifth iteration of the survey. Of these 38 countries, 16 are in Latin America, while 22 are countries in the Caribbean, including Belize, Haiti, Guyana, and Suriname (**Figure 1**).

Lockdown status and supply of vaccination services

As the lockdowns in the countries of the Region have become less strict, regular vaccination services have increased. All respondents reported that vaccination services were open (**Figure 2**).

Demand for vaccination services

Although the supply of services has improved, the COVID-19 pandemic and

Figure 1. Countries Participating in the Survey

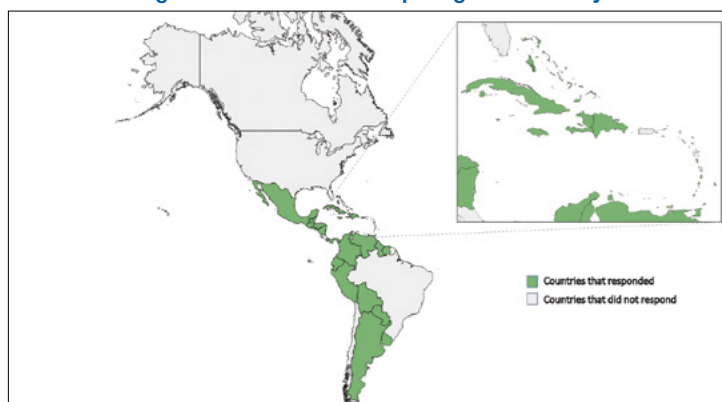
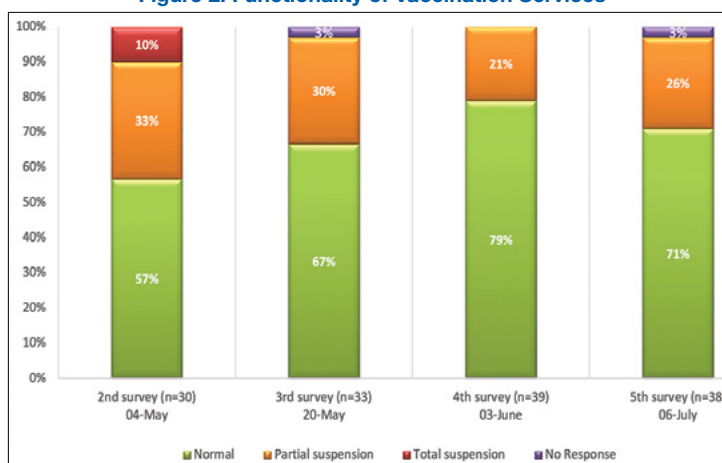
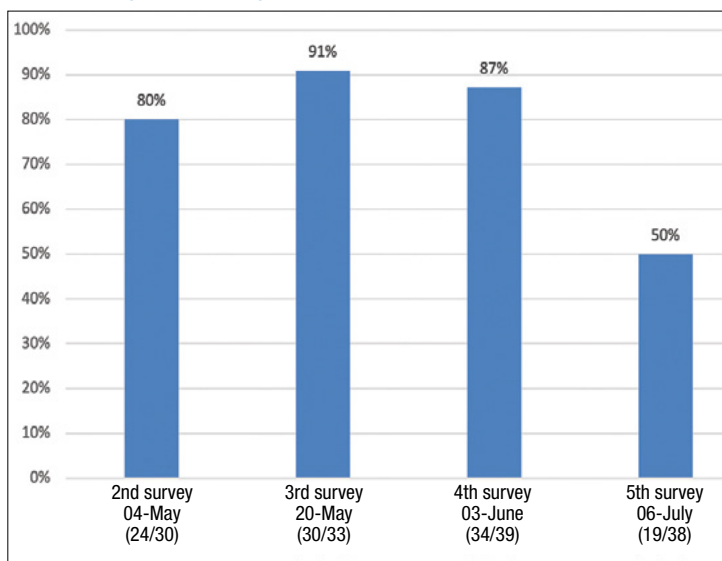


Figure 2. Functionality of Vaccination Services



containment policies in the countries of the Region have affected the demand for vaccination services (**Figure 3**). The main cause cited for decreased demand has been people's concern about the risk of exposure to COVID-19 if they seek vaccination services. Other causes include difficulties due to limitations in public transport, lockdowns, or physical distancing. These are consistent with the

Figure 3. Changes in Vaccination Demand over Time



⁸ Chan JF, Yuan S, Kok KH, To KK, Chu H, Yang J, et al. A familial cluster of pneumonia associated with the 2019 novel coronavirus indicating person-to-person transmission: a study of a family cluster. *Lancet*. 2020. 2. Novel, C. P. E. R. E. (2020).

⁹ The epidemiological characteristics of an outbreak of 2019 novel coronavirus diseases (COVID-19) in China. *Zhonghua liu xing bing xue za zhi= Zhonghua liuxingbingxue zazhi*, 41(2), 145. 3.

¹⁰ World Health Organization. WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020. Geneva: WHO; 2020. [Available at <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>]

¹¹ World Health Organization. Coronavirus disease (COVID-19) technical guidance: Maintaining Essential Health Services and Systems. Guiding principles for immunization activities during the COVID-19 pandemic. Geneva: WHO; 2020. [Available at <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/maintaining-essential-health-services-and-systems>].

¹² Pan American Health Organization. The immunization program in the context of the COVID-19 pandemic. Version 2 (24 April 2020). Available at: <https://www.paho.org/en/documents/immunization-program-context-covid-19-pandemic-version-2-24-april-2020>.

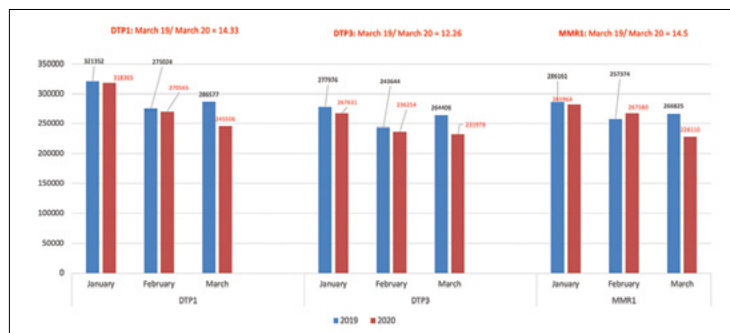
¹³ World Health Organization. Pulse Polls and regional data collection to get a sense of the spread and magnitude of immunization. Geneva: WHO; 2020. [Available at https://mcusercontent.com/96624bb47e6454ad3af81463d/files/d8d70eac-2d08-40bf-8ca1-a9f12d1e074b/1_D41_template_July2020.01.pdf].

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results of a similar survey conducted by WHO.¹³

Similarly, the number of doses of DTP1, DTP3, and MMR1 vaccines administered to children showed a decrease compared to the same period last year, particularly in March (Figure 4).

Figure 4. Comparison of Doses Administered, First Quarters of 2019 and 2020



Vaccination strategies

The countries of the Region have implemented various innovative strategies to continue vaccinating the population, including institutional drive-thru vaccination; mobile vaccination centers; vaccination in homes; vaccination with prior appointments or based on a person's gender or identity card number; vaccination in strategic locations; and follow-up vaccination using the electronic immunization registry (EIR). At the same time, countries have maintained social networking and digital media communication strategies to emphasize the importance of immunization during a pandemic to the population.



Credit: Karina Zambrana/PAHO

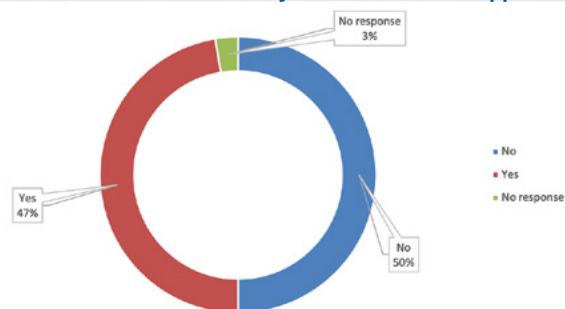
Delayed campaigns

PAHO has been closely monitoring the postponement of measles vaccination campaigns due to the COVID-19 pandemic in five countries (Plurinational State of Bolivia, Colombia, Dominican Republic, Honduras, and Paraguay). Brazil, Chile, and Mexico continue to study the possibility of resuming their campaigns by late 2020. Similarly, the Plurinational State of Bolivia and Colombia have delayed their yellow fever vaccination campaigns.

Supplies and syringes

Eighteen countries (47%) responded that they had encountered difficulties in the delivery of vaccines and supplies for national immunization programs (NIPs) (Figure 5). Of these 18 countries, 16 reported problems with vaccine delivery and five reported problems with other supplies such as syringes. Countries also indicated that these difficulties were due to the closure of international borders and to problems with international transportation (Figure 6).

Figure 5. Problems in the Delivery of Vaccines and Supplies



Surveillance of vaccine-preventable diseases

Seventeen countries have reported that epidemiological surveillance has been

affected by the pandemic. In most countries, this is due to the change in priorities, which have focused on SARS-CoV-2 cases. Countries also indicate that case reporting has decreased significantly.

Other factors hindering epidemiological surveillance include limited human resources, reduced field investigations and screenings for vaccine-preventable diseases (VPDs), as well as a halt in the shipment of samples for analysis (Figure 7).

As of the date of the fifth survey, six countries in the Region (Argentina, Brazil, Guatemala, Haiti, Mexico, and the Bolivarian Republic of Venezuela) were reporting outbreaks of VPDs, with some involving more than one disease.

Figure 6. Problems in the Delivery of Vaccines and Supplies

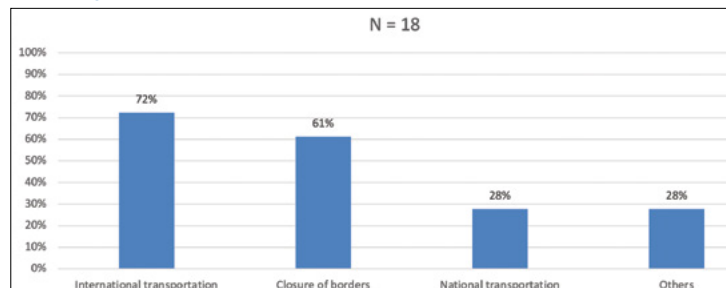
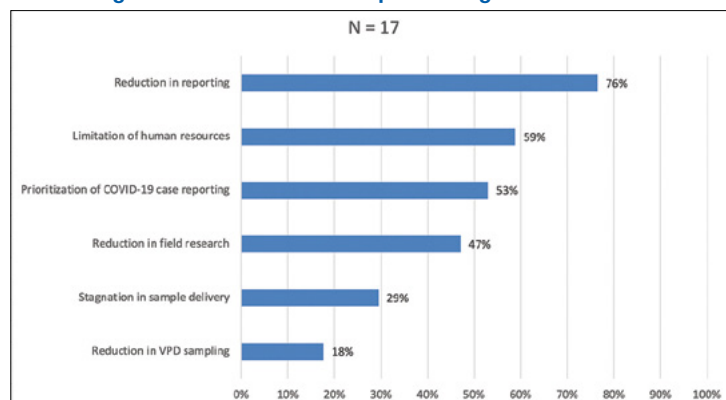


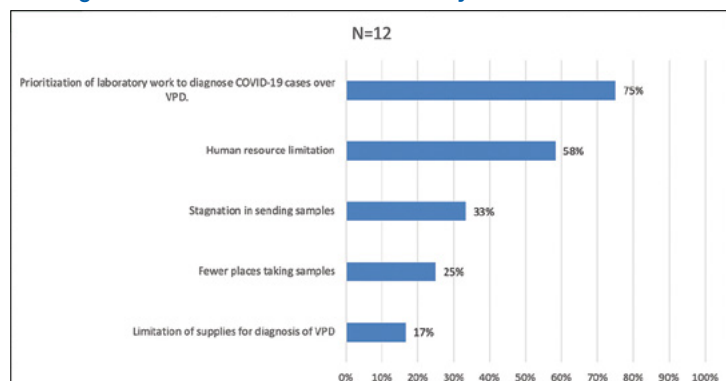
Figure 7. Problems in VPD Epidemiological Surveillance



Laboratories for the diagnosis of vaccine-preventable diseases

Of the 38 countries that responded to this survey, 12 emphasized that laboratory services and activities to support VPD surveillance have been affected. The main reason for this disruption, as with surveillance, has been the prioritization of work aimed at diagnosing COVID-19 cases (Figure 8).

Figure 8. Factors that Hinder Laboratory Surveillance of VPDs



Conclusion

The countries report that as lockdown policies have declined and relaxed, the supply of vaccination services has improved. Unfortunately, there has also been a decline in demand, with a consequent reduction in vaccination coverage and an increase in existing gaps.

Thus, it is important that countries continue to implement innovative measures and strategies to reach those who have not been vaccinated. This should be accompanied by plans and guidelines aimed at closing the gaps, including more initiatives in social communication. It is necessary to transmit messages to the population regarding the importance of immunization in keeping people healthy and protected from VPDs. ■

Guidelines to Plan for COVID-19 Vaccine Introduction

Version 1: 10 July 2020

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 25 million cases as of 31 August 2020. Approximately, more than 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 COVID-19 vaccines, 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.

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

1. Vaccination Objectives

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

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 considering 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.

2. Legal Bases

- 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 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 on defining 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 those with 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).

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.

COVID-19 VACCINATION cont. from page 5

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.
 - 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 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 inven-

tories 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.
- 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 vaccine safety 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.
- 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, polit-

COVID-19 VACCINATION cont. from page 6

ical 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.

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.
- 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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PAHO

RONDY cont. from page 1

While I have previously worked on various health emergencies, this one is unique in various aspects, impacting both on personal and professional levels:

1. Unlike other situations where I have worked as an epidemiologist, we all are vulnerable to COVID-19, either because we are at risk of severe infection or because our relatives are. Most of us know someone whom has suffered or died from a severe form of COVID-19. Working in a professionally stressful context with this extra vulnerability is challenging and maintaining healthy inter-personal relationships is key to avoid burnout.
2. So far, no sustainable solution to this outbreak has been found. In terms of pharmaceutical solutions, there are neither efficient cures nor vaccines yet. In terms of non-pharmaceutical approaches, while total lockdown has proven efficient in European and Asian settings, economical aspects make it difficult to implement in many Latin American countries and it can only be a transient solution. The current emergency is therefore going to last much longer than typical infectious disease emergencies.

The only efficient existing or planned solutions are directly related to my role as an immunization advisor:

- First stop, a mitigation approach: for the first time in Guatemala, influenza vaccination will be offered to everyone aged 60 years and above. This should help mitigate the burden of the



Marc Rondy.

2020-21 influenza season on the health care system.

- Secondly, monitor and manage expectations for a more sustainable solution: over 100 COVID-19 vaccines are currently in development, 33 are in clinical evaluation and eight vaccines are already in phase 3 (as of 28 August 2020).

To address this emergency response, supporting the immunization program is therefore a crucial aspect of my current and upcoming activities. While currently working on influenza vaccine order revisions, we need to plan for vaccination tactics

that are compatible with the COVID-19 context. But there is an additional and huge challenge: how to vaccinate adults over 60 years old against influenza in the community without putting them at risk of infecting themselves with SARS-CoV2? Luckily for us, we have the great advantage of being able to closely look at how our South American colleagues managed in March-April and learn lessons from their experience. In the meantime, and based on the A(H1N1)pdm09 vaccination campaign experiences, we will start planning for the COVID-19 massive vaccination campaign to be held...whenever that happens!

Combining my epidemiology and immunization skills is a very stimulating exercise as part of PAHO's support to the Guatemalan Ministry of Health. It is also a great opportunity to get better acquainted with the PAHO family and benefit from experience exchanges with colleagues from other national offices both in vaccination and surveillance.

Working with the amazing technical back up of both the IM and PHE/IHM units from WDC constitutes a great support that allows us to move forward, suggest, discuss, and come up with consensual advice.

I do believe that, despite the rough time that it is giving us, this emergency will make us stronger and more skilled as individual public health professionals, as well as an organization. 2020 will definitely remain a milestone in our personal and professional histories. ■