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ad hoc TAG Meeting November 2020

**Sixth ad hoc Meeting of PAHO's Technical Advisory Group
(TAG) on Vaccine-preventable Diseases**

**United States of America (virtual meeting)
16 November 2020**

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Introduction

PAHO's Technical Advisory Group (TAG) on Vaccine-preventable Diseases held its sixth ad-hoc virtual meeting on 16 November 2020, to follow-up on the last ad-hoc virtual meeting held 3 months prior on the COVID-19 pandemic. The specific objectives of the meeting were to provide an epidemiological update on COVID-19 and its impact on national immunization programs (NIPs) in the Americas; review recommendations from WHO's Strategic Advisory Group of Experts (SAGE) on immunization regarding the value framework and roadmap for prioritizing the use of COVID-19 vaccines in the context of limited supply; update participants on the progress made through planning components for the introduction of COVID-19 vaccines; and discuss key priority activities to support countries in the Region.

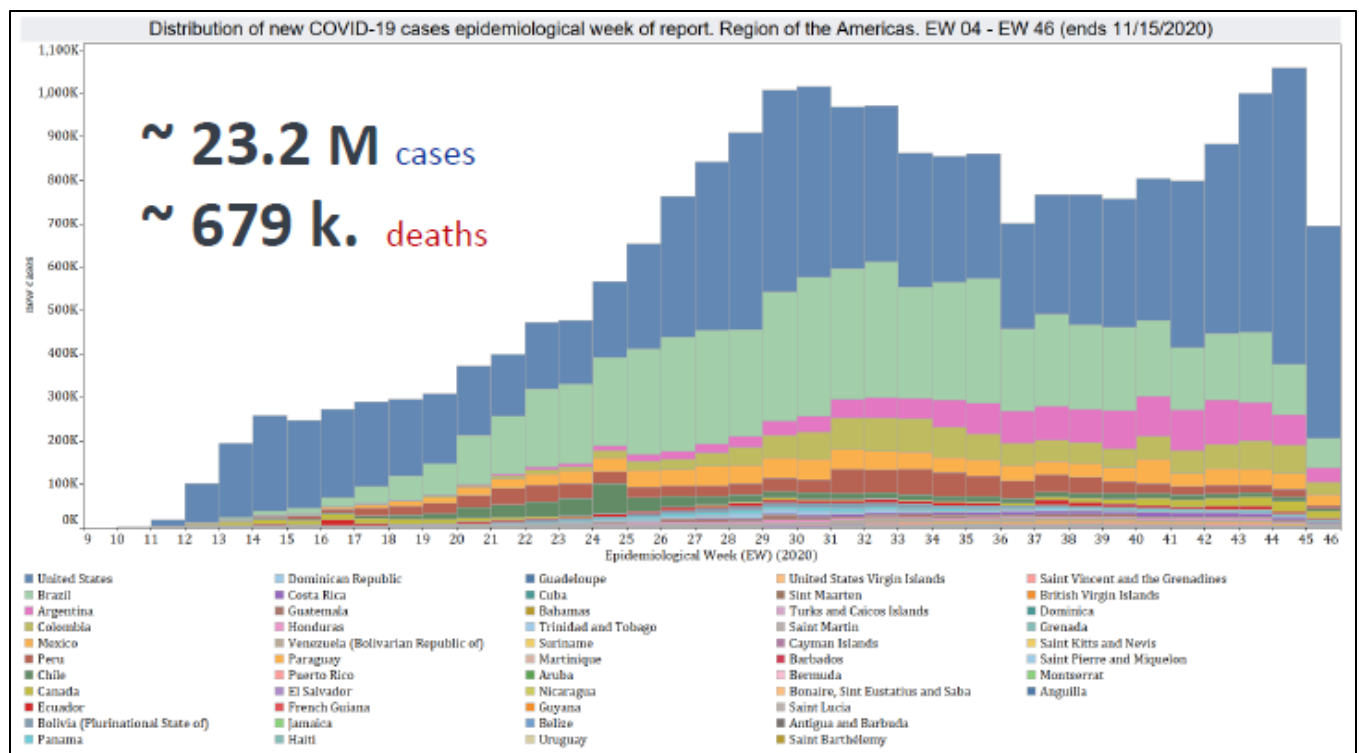
Dr. Andres de Francisco, Director of PAHO's Department of Family, Health Promotion, and Life Course (FPL), opened the meeting by welcoming participants and sharing that the COVID-19 pandemic represents one of humanity's greatest challenges and that an orderly and adequate response is required from all countries and health institutions to defeat it. He reiterated his appreciation to the TAG's commitment on vaccine-preventable diseases. Dr. Peter Figueroa, Chair of the TAG, followed by adding his welcome to the TAG members, participants, and especially thanking SAGE Chair Alejandro Cravioto for his presence and the PAHO team for organizing the meeting.

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COVID-19 Epidemiological Situation Update

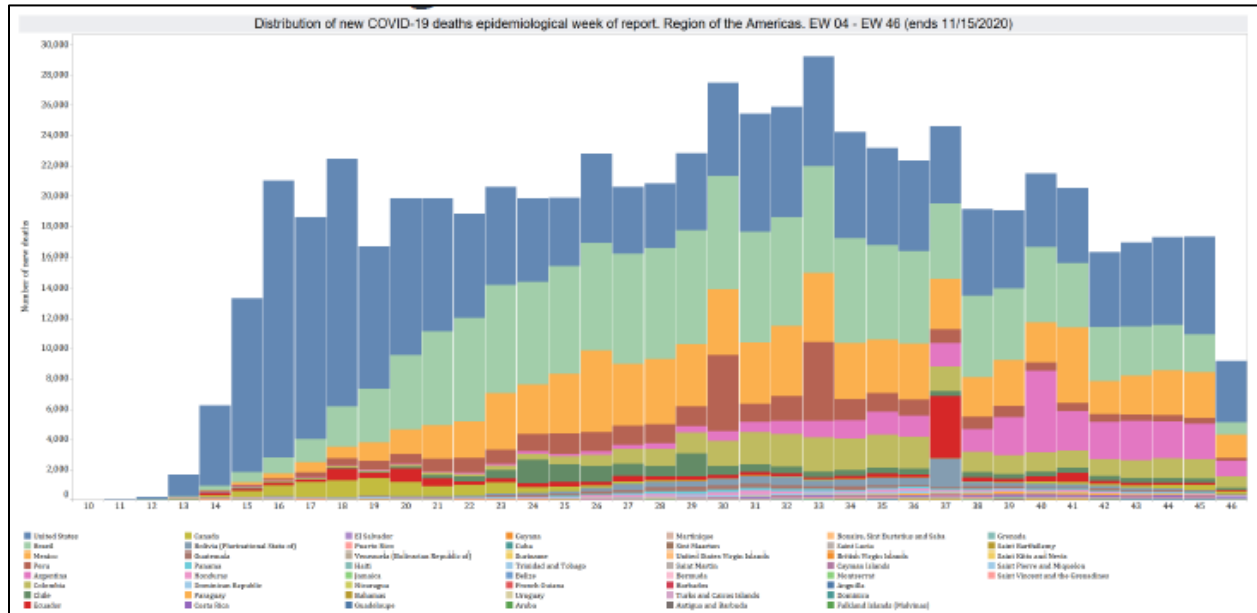
On 20 January 2020, the first COVID-19 case in the Americas was confirmed in the United States. To date, COVID-19 has reached all 54 Member States and territories of the Americas, with 23.2 million confirmed cases and 679,000 deaths. Since the start of the pandemic, the United States and Brazil have reported the highest number of cases and deaths, as well as the highest incidence and mortality rates. During epidemiological week 45, cases in the Americas accelerated due mostly to increases in the United States.

Figure 1. Epidemiological Curve of COVID-19 Cases, by Epidemiological Week and Country, Data as of 15 November 2020



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Figure 2. Epidemiological Curve of COVID-related Deaths, by Epidemiological Week and Country, Data as of 15 November 2020



In the subregion of North America, Canada, the United States, and Mexico have reported an increasing trend in their respective 7-day cumulative incidence rate (**Figure 3**).

Figure 3. Number of COVID-19 Cases and 7-day Incidence Rate in the North American Sub-region, 1 March to 22 November 2020

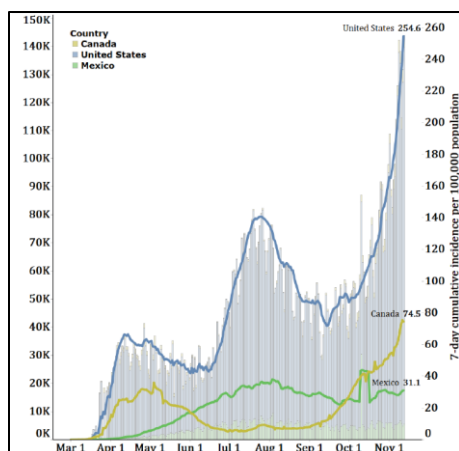
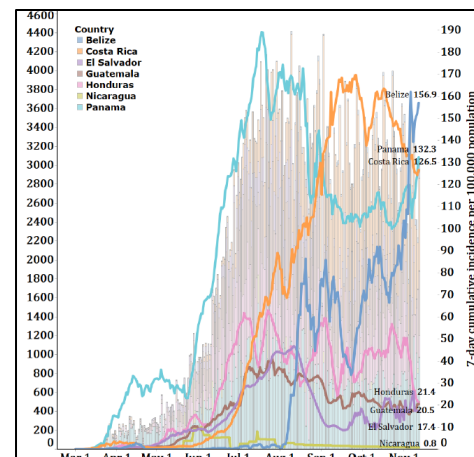


Figure 4. Number of COVID-19 Cases and 7-day Incidence Rate in the Central American Sub-region, 1 March to 22 November 2020



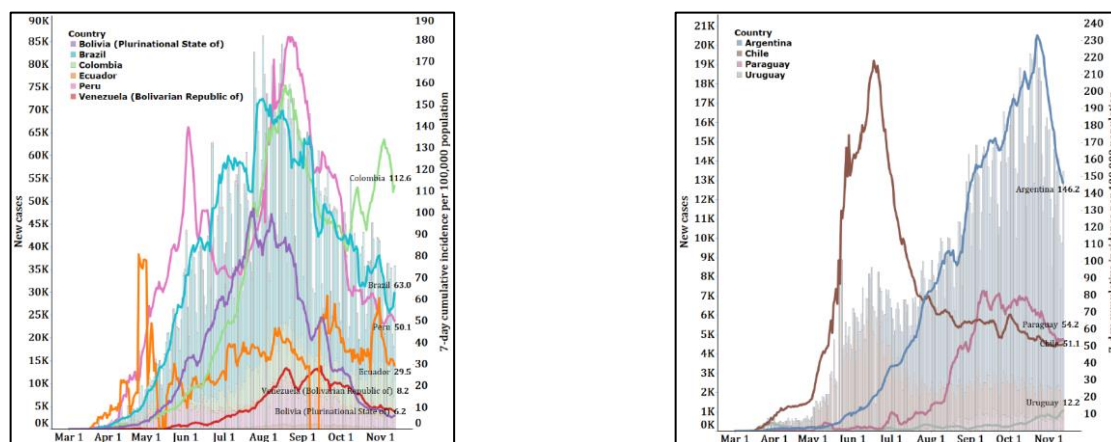
In the Central American sub-region, Panama and Belize continue with their increasing trend in 7-day incidence rate (**Figure 4**). While Costa Rica has been on a downward trend during the past

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weeks, there was a slight increase in the 7-day incidence during epidemiological week 45. To date, these countries have not reported important variations in the 7-day incidence rate since epidemiological week 44. Nonetheless, these trends should be interpreted with caution because surveillance and notification systems have been impacted by the hurricane, and the reported totals are not up to date. All seven countries in the central American Region were affected by hurricane Eta (especially Honduras, Guatemala, and Nicaragua), and the risk of infection with COVID-19 and other transmissible diseases is high because of pre-existing vulnerabilities.

In the Andean sub-region, most countries reported a decreasing trend in the 7-day incidence rate. The exception is Brazil, which saw a slight increase compared with epidemiological week 44. At the subnational level, many provinces in Ecuador reported a three to ten-fold increase in cases in the past two weeks. With regards to deaths, many departments in Colombia reported a doubling of the number of deaths in the past two weeks. In the Southern Cone, Argentina continues to report a sharp decrease in the 7-day incidence rate since epidemiological week 42. Uruguay reported a large increase in its 7-day incidence per 100,000 population (8 cases per 100,000 during epidemiological week 44). Chile and Paraguay reported decreasing trends over the last few weeks (**Figure 5**).

Figure 5. Number of COVID-19 Cases and 7-day Incidence Rate in the Andean Sub-region and Southern Cone, 1 March to 22 November 2020

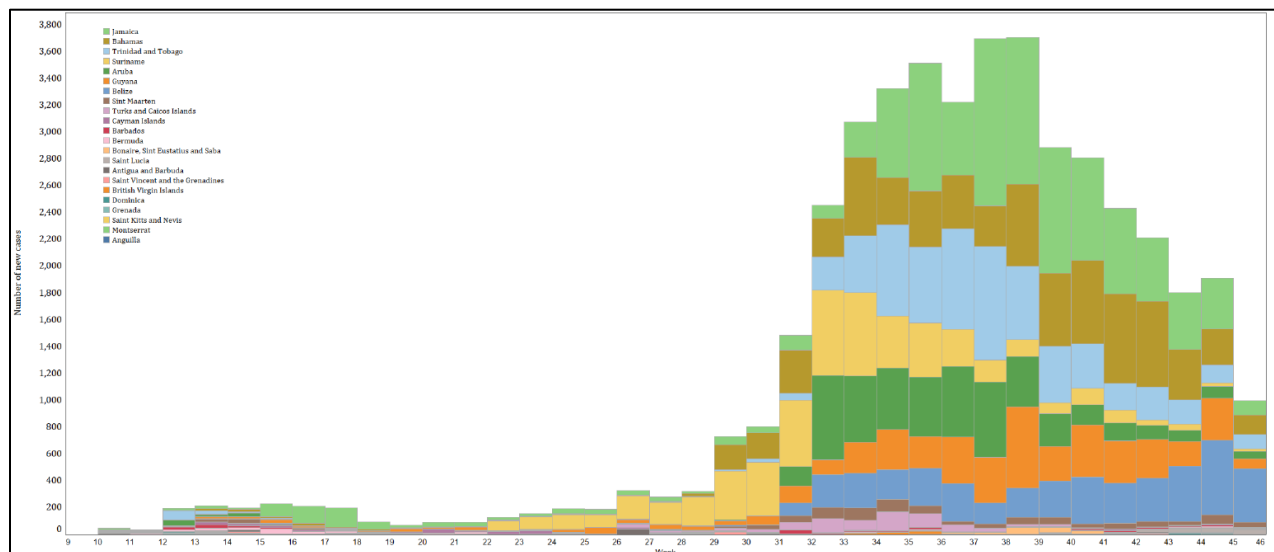
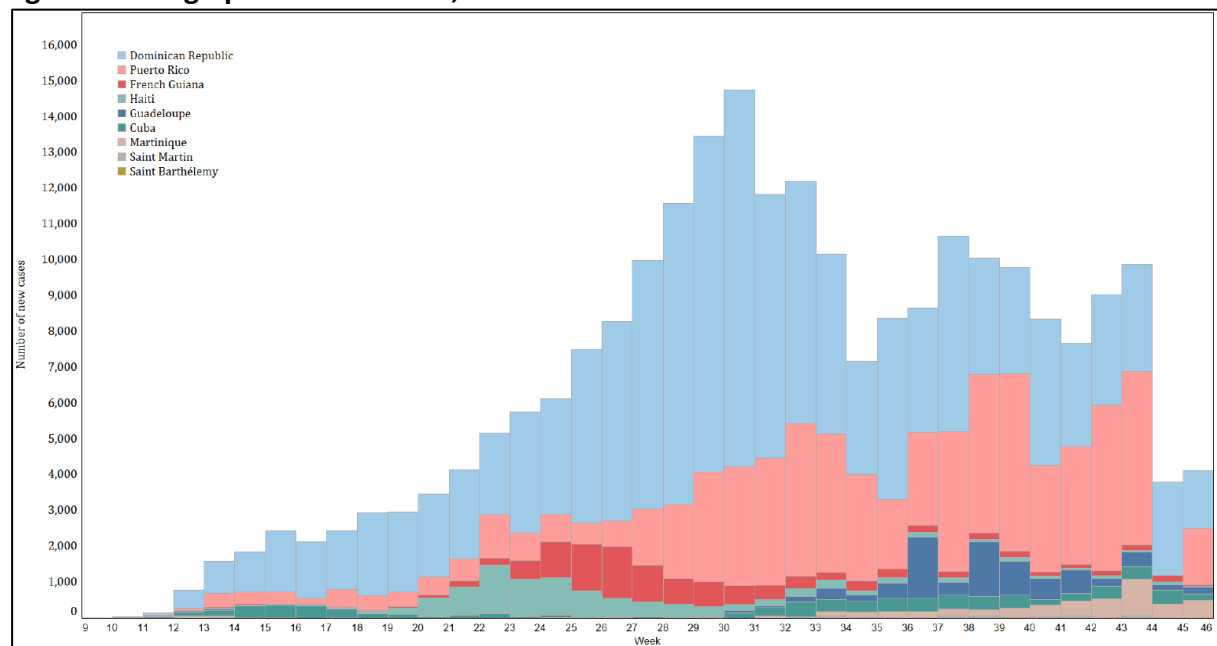


In the Latin Caribbean islands, the weekly number of cases are higher compared to the cases reported during epidemiological week 44. However, Puerto Rico did not report data during epidemiological week 44. Cases in Martinique decreased since the peak in epidemiological week 43, but the number was slightly higher this week than the previous week. In the non-Latin Caribbean and Atlantic Ocean sub-region, the weekly number of cases increased during epidemiological week 45, after recording a sustained decrease in the previous five weeks. The Falkland Islands and Grenada updated their transmission category from “no cases” to “sporadic

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cases.” Saint Lucia updated its classification to “clusters of cases” after the recent and sustained increase in cases (**Figure 6**).

Figure 6. Number of COVID-19 Cases and 7-day Incidence Rate in the Latin Caribbean Sub-region and Anglophone Caribbean, 1 March to 22 November 2020



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Risk of Severe COVID-19 due to Underlying Health Conditions in the Americas

Persons living with underlying health conditions are at increased and high risk of severe COVID-19, and therefore it is necessary to develop shielding strategies aimed at this population.^{1,2,3,4} PAHO, in collaboration with the London School of Hygiene and Tropical Medicine (LSHTM), conducted an adaptation of the tool/model to produce estimates that better respond to the needs of the countries of the Americas. Originally, the model developed and published by LSHTM uses data from the Global Burden of Disease (GBD) 2017 for eleven conditions by sex and five-year age groups.¹ The regional version of the model includes 14 conditions, as hypertension, smoking of 25 or more daily cigarettes, and severe obesity (IMC \geq 40) are included. This model considers the population at increased risk of severe COVID-19 as those with at least one underlying health condition based on public health agencies guidelines (WHO, CDC and PAHO/PHE), and at high risk as those that would require hospitalization if infected.^{2,3,4}

The objective of the COVID-19 and comorbidities model is to estimate the population at increased and high risk of severe COVID-19 due to underlying health conditions. Its purpose is to identify at-risk groups, guide vaccination planning, inform the design of possible shielding strategies (self-isolation, asking support from close contacts to deliver food and/or medical supplies, etc.), and support the planning of the management of chronic conditions.

When applying the PAHO/LSHTM model to estimate the population at increased risk of severe COVID-19, 24% of the population of the Americas (250 million persons) was found to be at increased risk of severe COVID-19, meaning that they have at least one underlying condition (**Figure 7**). For Latin America, this value is 22% and for the non-Latin Caribbean, 29%. In the countries of the Region of the Americas where these scenarios were calculated, the proportion of population with at least one underlying condition (at increased risk) varies between 18% in Honduras and 33% in Chile (**Figure 8**).

It is important to note that a large part of this at-risk population is of working age (15-64 years) and is not exclusive to persons 65 years old and over. For example, in the Latin America and Caribbean sub-region, more than 103 million of a total of 145 million people who are at increased risk, are of working age (**Figure 8**).

¹ Clark A, Jit M, Warren-Gash C, Guthrie B, Wang HH, Mercer SW, Sanderson C, McKee M, Troeger C, Ong KL, Checchi F. Global, regional, and national estimates of the population at increased risk of severe COVID-19 due to underlying health conditions in 2020: a modelling study. *The Lancet Global Health*. 2020 Jun 15. Available at: <https://rb.gy/zggzaa>

² WHO guidance on COVID-19 and NCDs, 2020. Available at: <https://rb.gy/8rcqsj>

³ Public Health England (PHE) definition of individuals at increased risk of severe COVID-19 illness. Available at: <https://rb.gy/dlkczc>

⁴ CDC guidance on individuals at higher risk of severe COVID-19 disease. Available at: <https://rb.gy/lwbqlw>



Figure 7. Distribution of Population by Number of Underlying Health Conditions and at Increased Risk in Select Countries of the Americas

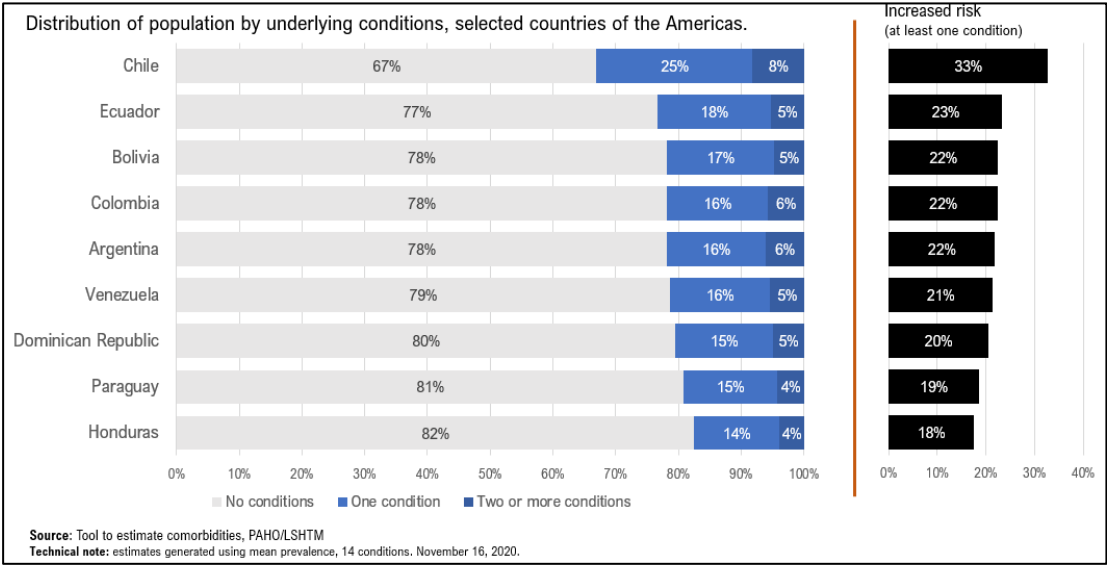
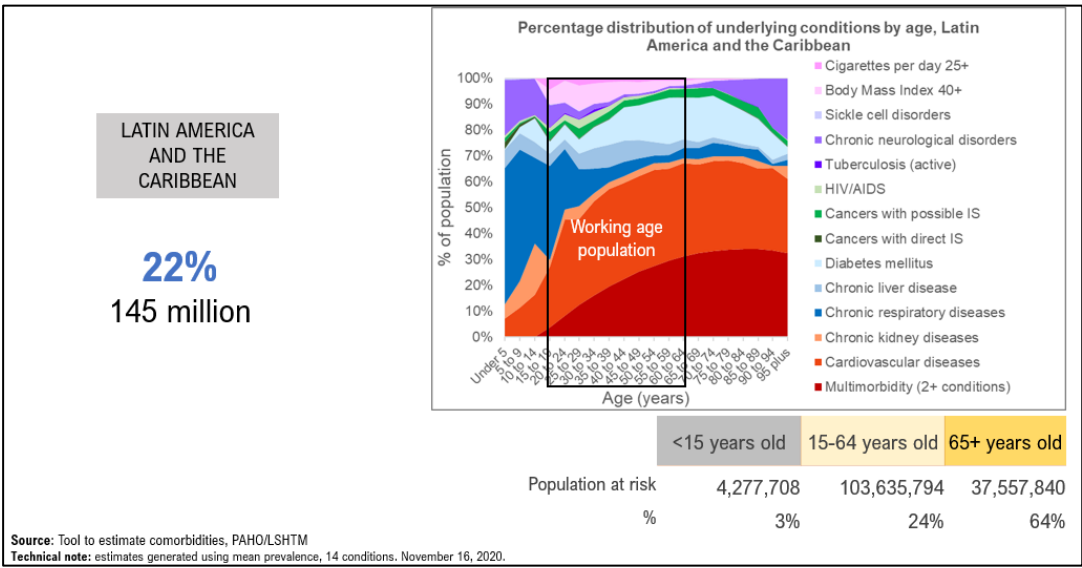


Figure 8. Percentage Distribution of Underlying Conditions by Age in Latin America and the Caribbean



In addition to adapting the tool and model to the reality of the Region, PAHO has systematized the process of supporting the countries in producing their estimates. PAHO's technical team works in conjunction with the national technical areas related to noncommunicable diseases, immunization, and emergencies, which are involved in the COVID-19 response. This collaborative work has provided the identification of national/local data sources needed to produce the estimates of population at risk for severe COVID-19. The technical cooperation process with the

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countries essentially has three phases: i) identification of data sources; ii) training on the management of the tool; and iii) use of data for action supporting the planning of activities related to the acquisition/allocation of vaccines, management of people with noncommunicable diseases, and shielding strategies directed to the at-risk population. Currently, PAHO is in the process of collaborating with ten countries of the Americas.⁵

Considerations:

- People living with underlying health conditions are at higher risk for severe COVID-19.
- Shielding strategies are necessary to protect this population at risk.
- It is important to identify how many and who are most at risk for severe COVID-19 to define and plan vaccine procurement and distribution strategies.
- PAHO has developed tools to support countries on the production of their estimates using, whenever possible, national/sub-national data that represent the local/national reality.
- A quarter of the Americas' population is dealing with a dangerous combination: chronic diseases and COVID-19. Most of this population is of working age (15-64), and not only 65 years of age and older.

⁵ Ten countries: Argentina (National, Cordoba, Jujuy), Bolivia, Colombia, Ecuador, Guyana, Honduras, Mexico, Peru, Dominican Republic, and Venezuela.

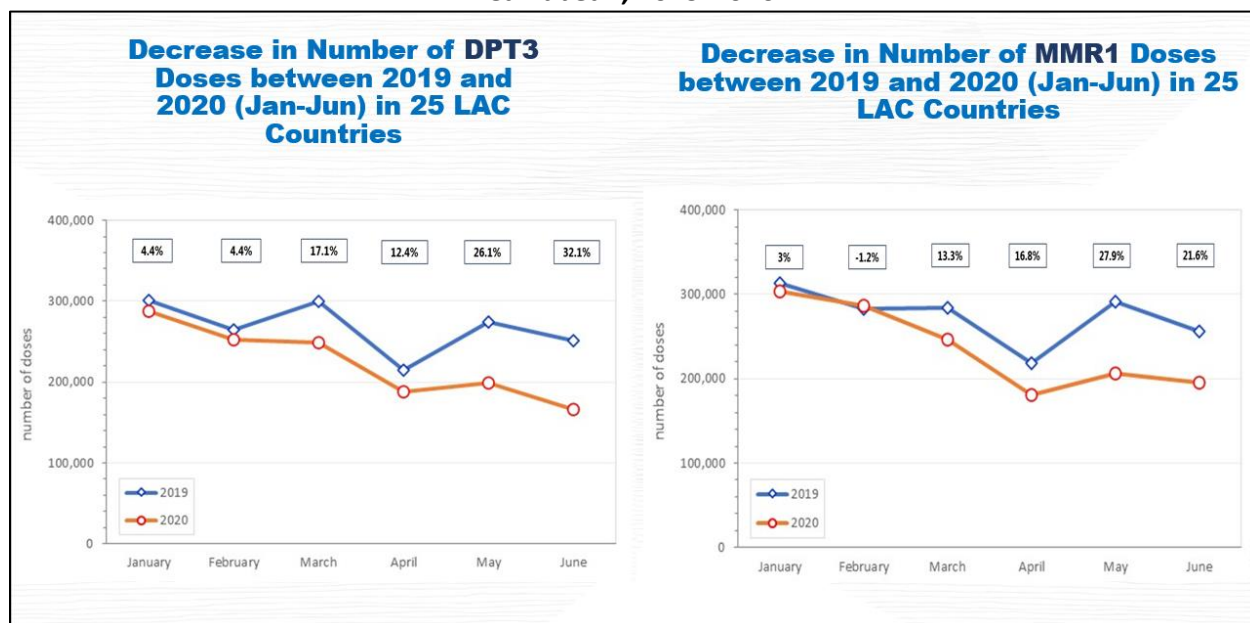
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Addressing the Impact of the COVID-19 Pandemic on National Immunization Programs

In the past several years, Latin America has faced a decline in coverage with the third dose of the diphtheria, tetanus, pertussis vaccine (DTP3) among infants less than 1 year old. From 2010 to 2019, coverage for the Region decreased 10 percentage points from 95% to 85%, with a 6-percentage point decrease between 2016 and 2019. These decreases have resulted in more than 2.1 million unvaccinated children in 2019. During recent years, countries with the largest cohorts of children, such as Brazil representing 20% of the cohort under one year old, and Mexico representing 15.3% of the cohort, have reported a decrease in their DTP3 vaccination coverage, impacting the entire DTP3 coverage in the Region. However, countries with smaller cohorts of children, such as Haiti and Suriname, have also reported similar percentage point decreases in the last decade.

Since the WHO declared COVID-19 a pandemic on 11 March 2020, PAHO's Comprehensive Family Immunization (IM) unit has monitored the impact of the pandemic on vaccination coverage comparing 2020 with 2019's coverage, confirming a plummet in the number of DTP3 and MMR1 doses applied from March to June 2020, illustrated in Figure 9.

Figure 9. Decrease in DTP3 and MMR1 Doses Administered in Latin America and the Caribbean, 2019-2020



Source: Reports from 23 countries with subnational data for 2019 and 2020. Data received as of 31 June 2020.

Since April, PAHO has conducted a total of six country surveys in the Region, to monitor the operation of immunization services and to design a response plan based on needs expressed. The results of these surveys show that the functionality of vaccine services had increased in normalcy

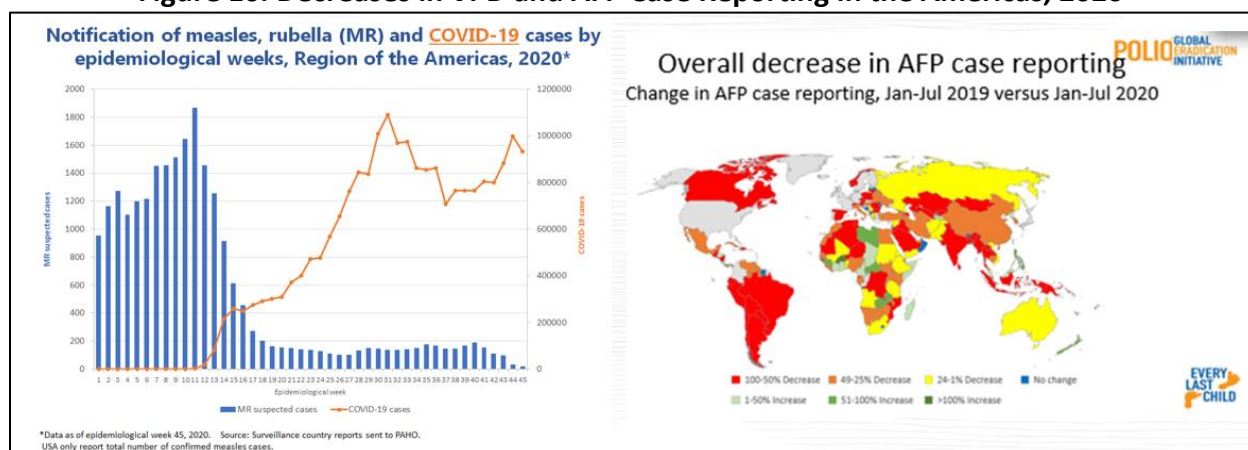
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from May to August 2020, with partially or totally suspended services decreasing from 43% to 16%. The same decreasing trend was observed regarding the impact of vaccination demand, with 80% of the demand affected in May to being 51% affected by August. The main reasons for persons abstaining from getting vaccinated included limited public transportation, lockdowns, physical distancing policies, as well as user concerns about the risk of exposure to COVID-19 if they visited a vaccination service.

Between the months of March and August 2020, five vaccine-preventable disease (VPD) campaigns had been postponed in Bolivia, Colombia, Honduras, Dominican Republic, and Paraguay. PAHO has continued to support countries in developing their micro-planning and has been closely monitoring the effects of these postponed campaigns, as well as the best time to resume them.

VPD surveillance was impacted substantially by COVID-19 control interventions, in the sense that as COVID-19 cases increased, suspected measles and rubella cases decreased due to a dramatic shift in attention to COVID-19. The decrease in acute flaccid paralysis (AFP) case reporting was also substantial when compared to 2019 (**Figure 10**). The main reasons reported for difficulties in VPD surveillance systems included limited human resources, prioritization in the notification of COVID-19 cases over other VPDs, and decreased notification.

Figure 10. Decreases in VPD and AFP Case Reporting in the Americas, 2020



Countries in the Region have worked to close vaccination coverage gaps by implementing and strengthening various innovative immunization strategies to continue vaccinating the population, including vaccinating in strategic locations, such as in closed schools, cars, homes, and in the community: adapting vaccination centers; diversifying appointment systems, such as vaccinating with prior appointments or based on a person's gender or identity card number; and following-up vaccination using electronic immunization registries (EIRs). Developing new communication strategies, plans and channels have also been prioritized to face current

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challenges related to misinformation and disinformation, growing vaccine hesitancy and anti-vaccine movements, as well as the politicization of the pandemic.

PAHO's technical assistance to Member States during these months includes the development of various technical and communication documents, organizing technical meetings, as well as meetings with countries, and monitoring immunization polls, monthly immunization coverage and subnational coverage.

Considerations

Countries should:

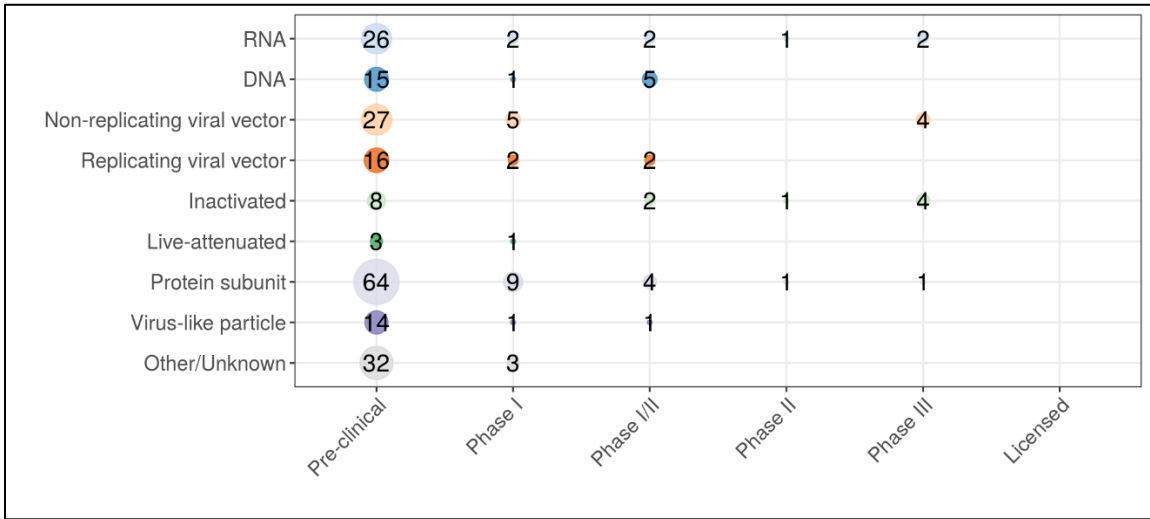
- Advocate to maintain immunization as an essential health service under safe conditions.
- Deliver immunization through coordination and collaboration with other health programs to ensure effective and efficient services.
- Integrate vaccination campaigns and catch-up activities with other primary health care activities across the life course, following the decision-making Framework: Implementation of Mass Vaccination Campaigns in the Context of COVID-19.
- Innovate strategies for VPD surveillance, laboratory support, and information systems.
- Sensitize health care workers on managing immunization sessions, using personal protective equipment (PPE), and supporting communities to increase routine vaccination demand.
- Instill public confidence and preserve trust in vaccines.



Development Status of COVID-19 Candidate Vaccines

There are currently 164 COVID-19 vaccine candidates in pre-clinical evaluation and 48 in clinical evaluation in various stages of development around the world, with a wide range of vaccine technologies, as shown in Figure 11 below.

Figure 11. Candidate COVID-19 Vaccine Technologies



Source: https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/

The preliminary phase two results of candidate vaccines currently undergoing phase three clinical trials have shown good safety profiles, high immunogenicity levels (~90%+) for two doses, and both humoral and cellular responses. Large-scale ongoing phase three clinical trials are required to evaluate whether immunogenicity levels translate into efficacy and protection against disease and infection, as well as safety in large numbers of study subjects. Additionally, the duration of protection and waning of antibodies over time are being assessed in these long-term phase three clinical trials. Considering the positive safety results from phase two trials, most of the ongoing phase three clinical trials have included the elderly, individuals with co-morbidities, adolescents, and previously infected individuals. However, to date, no trial has enrolled children or pregnant women.

Considering the target product profile (TPP) for COVID-19 vaccine candidates, the primary endpoint of interest is COVID-19 (i.e. symptomatic SARS-CoV2 infection), with minimally accepted efficacy of 50%. Trials have been designed as event-based trials, with interim analysis planned when a given number of events occurs. Most ongoing trials have set the number of events at 60-90 and at 150-160 for analyses.

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These vaccines could receive emergency use authorization (EUA) by regulatory agencies (USA: FDA, EU: EMA, UK: MHRA, national regulatory agencies in selected countries, WHO: PQ) if efficacy and safety results are demonstrated in preliminary analyses.

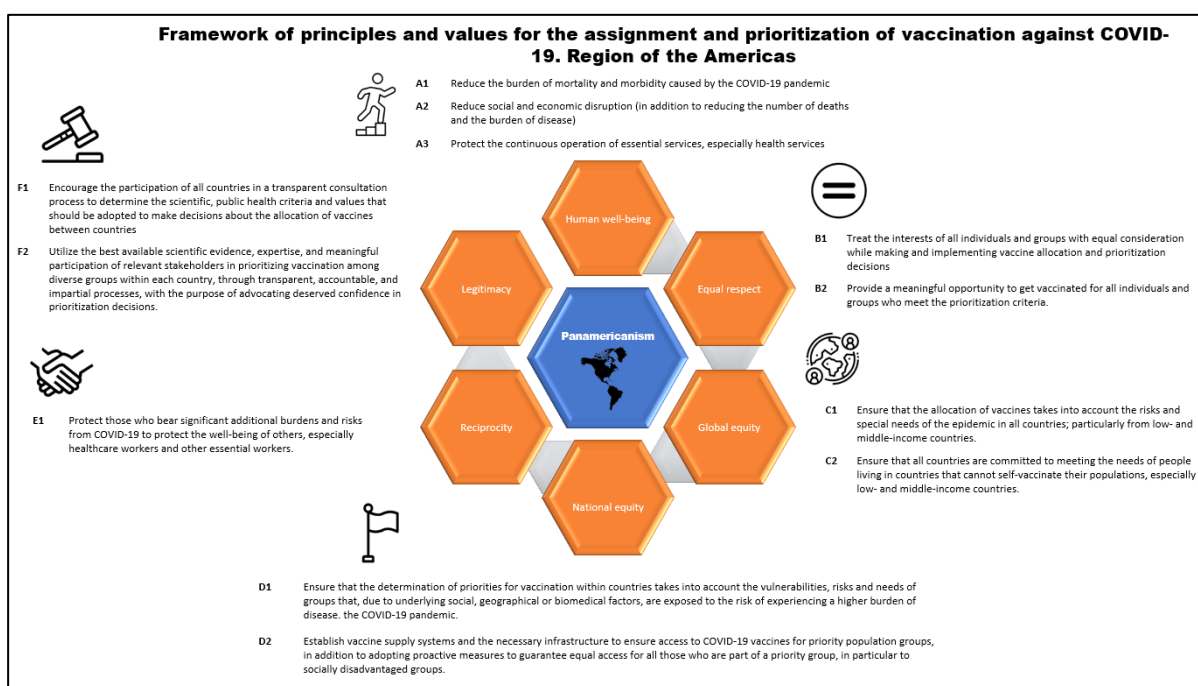
In November 2020, preliminary analysis of phase three clinical trials of vaccine candidates from Pfizer BioNTech, Gamaleya, Moderna, and Astra Zeneca were presented by press releases. Sinovac has indicated that preliminary results will be available in mid-December. Additional vaccine candidates in phase three clinical trials include Janssen, Novavax, Cansino, Sinopharm, and Bharat Biotech, which may also have interim analyses shortly.

All ongoing phase three clinical trials must continue in order to complete analyses of efficacy and safety, evaluate efficacy against other study endpoints, and assess the duration of immunogenicity and protection over time.

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SAGE Recommendations: Values Framework and Prioritization Roadmap Planning and Micro-planning for COVID-19 Vaccination

It is essential to determine the population to be vaccinated in the initial phases, guided by scientific knowledge, epidemiological environment of the pandemic, supply scenario, but also by equity and Pan-Americanism, two fundamental PAHO/WHO principles that have guided the health policies of the Region for 118 years. These principles are aligned with the Framework of Principles and Values proposed by WHO's Strategic Advisory Group of Experts (SAGE) on immunization and the principles for equitable access and fair allocation of products against COVID-19 formulations for the ACT Accelerator COVAX Mechanism. These principles and values should be the framework that guides the definition of the population to be vaccinated, in phases, as more doses of the vaccine(s) become available.



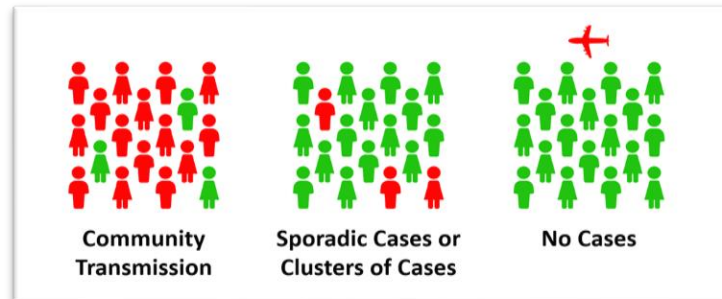
Over the years, the countries of the Region have built strong national immunization programs and gained significant experience from the implementation of large and successful vaccination campaigns, placing the Region in a privileged position to ensure the successful introduction of COVID-19 vaccines.

National health authorities, with support from their national immunization technical advisory groups (NITAGs), should advance in finalizing national plans to introduce the COVID-19 vaccine(s), determining both the populations to be vaccinated by phases and the required

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budget. Operational levels should also advance in developing the basic aspects of micro-planning, such as:

a) Characterizing districts and/or communities according to the epidemiological scenario:



b) Characterizing districts and/or communities according to the following vulnerability criteria:

- Population density (pop/km²)
 - Multidimensional poverty index for Latin America (MPI-LA)
 - Presence of ethnic minorities and Afro-descendant populations
 - Informal economy (percentage)
 - Proportion of unemployed population
 - Presence of migrants or refugees
 - Proportion of population with two or more pre-existing health conditions
- c) Preparing the census and mapping of at-risk populations**
- d) Identifying concentrated at-risk populations**
- e) Determining requirements for vaccines, syringes, and supplies**
- f) Identifying difficult-to-reach populations**
- g) Updating the inventory of cold chain equipment**
- h) Determining human resource requirements (vaccinators, registers)**
- i) Coordinating training by components at all levels**
- j) Developing schedule of activities with logistics and transport**
- k) Identifying and involving community leaders**
- l) Determining the best local promotion and communication strategies**
- m) Organizing supervision, monitoring, and evaluation**
- n) Organizing management of waste related to COVID-19 vaccination**

As information becomes available about the specific characteristics of licensed vaccines, or supply scenarios change, the prioritization of the population to be vaccinated should be reviewed.

However, decision-making must always follow a process summarized in the following three steps:

- **Step 1:** Apply the SAGE values framework, which is aligned with PAHO/WHO principles

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- **Step 2:** Apply the roadmap for prioritizing the populations to be vaccinated, which considers: a) the epidemiological scenario; b) vulnerability criteria; and c) the supply scenario
- **Step 3:** Develop specific recommendations for each vaccine, which will be known once the vaccines authorized in the market are available. Public health policies, plans/micro-plans, strategies, and guidelines should be reviewed considering these recommendations, and strategic recommendations should be defined, if necessary

Countries will find significant similarities between vaccination against other diseases (measles, rubella, polio, influenza, yellow fever, H1N1) and COVID-19 vaccination, all while having to face substantive differences in the planning, micro-planning, and implementation of COVID-19 vaccination.

Similarities and differences between other SIAS and COVID-19 vaccination campaigns		
	Others SIAS (Measles/Rubella/Polio/Influenza/YF/H1N1)	COVID-19 vaccination
Values, principles	• Equity, Panamericanism	• Human well-being, equal respect, global equity, national equity, reciprocity, legitimacy
Target population	• Susceptible cohorts + Epi scenario	• Values + Principles + Epi Scenario+ Vulnerability
Epidemiological scenario	• No cases / sporadic cases or outbreaks (measles, YF)	• Pandemic (high morbidity & mortality)
Vaccine characteristics	• Known	• Unknown (number of doses per vial, diluent, dose, cold chain requirements, product packaging etc)
Planning & microplanning	• 6 to 12 months	• Short time for planning & microplanning
Supply	• Adequate and timely supply	• Limited supply, various type of vaccines can be used at the same in the same country
ESAVI	• Known	• Unknown
Advocacy, social mobilization, communication	• Long-standing experience • Hesitancy • Antivaccine movement	• Unknown degree of vaccine acceptance • Infodemia • Hesitancy • Antivaccine movement

Considerations

- Countries should declare COVID-19 vaccines a public good that will provide protection and well-being to all communities in the Region; allow a progressive return to human, social, family and work activities; and help address the unprecedented uncertainty generated by the pandemic and its economic impact.
- Countries and their NITAGs should adopt SAGE's values framework and the prioritization roadmap to define priority groups for COVID-19 vaccination in the context of limited vaccine supply and different epidemiologic scenarios.
 - During stage I, countries should define health workers at high to very high risk of acquiring and transmitting infection, as well as the age of the older population.

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- During stage II, countries should use relevant local and regional epidemiological data to identify co-morbidities associated with different levels of risk from COVID-19, as well as sociodemographic groups at significantly higher risk of severe disease and death.
- Countries should develop COVID-19 vaccine introduction plans based on the guidelines from PAHO's COVID-19 vaccine introduction document from July 2020⁶, and WHO's Guidance on Developing a National Deployment and Vaccination Plan for COVID-19 Vaccines, published on 16 November 2020.⁷
- Community engagement and effective communication are essential to the success of COVID-19 vaccine programs and reinforce establishing a transparent process based on shared values, using the best available scientific evidence and engaging with affected parties.

⁶ PAHO's Guidelines to Plan for COVID-19 Vaccine Introduction, available at <https://iris.paho.org/handle/10665.2/52532>

⁷ WHO's Guidance on Developing a National Deployment and Vaccination Plan for COVID-19 Vaccines, available at: https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccine_deployment-2020.1

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Cold Chain

As several COVID-19 vaccines are preparing to become available to the public, PAHO has been assisting countries in analyzing whether their capacity to receive, store, and distribute a COVID-19 vaccine can be accommodated, given the current cold chain and logistical challenges to transport vaccines to multiple sites, while assuring that vaccine temperatures are maintained. Estimating sufficient ice-pack-making capacity or access to a facility that can provide ice packs is a concern, as well as the countries' capacities to safely collect and dispose of contaminated medical injection equipment and personal protective equipment (PPE).

PAHO started conducting virtual workshops to highlight these concerns and has recommended for all countries to update their cold chain equipment and transport inventories. Countries should also assess their cold chain information systems to ensure that information can flow up and down the system for best decision-making. Concomitantly, all managers should develop a budget to support all operations. PAHO's immunization program is also completing work on operational guidelines to facilitate the planning and execution of cold and supply chain operations.

The availability of genetically produced vaccines, using a platform based on mRNA technology, is important to all countries. These vaccines will require vaccine storage temperature of -70° to -80°C , special cold chain equipment capable of maintaining these temperatures during all operations, and handling of vaccines from being stored to being transported to each health service or facility for administration to the population. The ultra-low temperature (ULT) equipment required for this type of vaccine has never been used in current immunization cold chain infrastructures, requiring for countries that have established agreements to purchase mRNA-based vaccines to purchase the ULT freezers and adequate cold chain containers to transport these vaccines, not to mention the required ice packs (phase change materials [PMC]). Considering that the current ULT equipment has a very short hold over time, electrical generators should be made available to provide emergency electricity in the case of a power outage. The ministries of health should develop training materials on the use of this new cold chain equipment, as well as provide PPE to workers who need to handle vaccines at these ultra-low temperatures, ice packs, or dry ice. This is also true for all health services that will store the mRNA vaccines for more than five days⁸.

Considerations:

Countries should:

- Update the cold chain equipment inventory.
- Estimate storage and distribution capacities for COVID-19 vaccines.

⁸ As of mid-November 2020, there is limited information on the exact number of days that a genetically manufactured COVID-19 vaccine can be safely used without being stored at -70° to -80°C . One manufacturer has indicated that the number of days that their COVID vaccine can be safely stored from 2° to 8°C is five days. Other COVID-19 vaccines that may be made available will require vaccine storage temperatures like current vaccines routinely used in immunization programs.

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- Estimate transportation types and capacities required to deliver vaccines and injection supplies to all distribution points.
- Estimate capacities for safe collection, transportation, and final disposal of waste generated by vaccinations.
- Evaluate logistical operations to support different immunization strategies.
- Evaluate capacities of information systems to track storage, distribution, temperature monitoring, and inventory control.
- Calculate the budget required to implement different activities.

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Information Systems

The objective of this chapter is to advise countries on how to identify their data needs and strengthen their information systems to adequately monitor COVID-19 vaccine introduction. Given that there will be a strong and urgent demand for data on COVID-19 vaccination by country and international stakeholders, countries should anticipate their data needs and strengthen information systems to be able to provide fast, frequent, and accurate reporting, taking into consideration the following four stages of the introduction process: planning, implementation, monitoring, and evaluation as seen in the figure below:

Figure 12. Scope Information System for COVID-19 Vaccine Introduction



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

- Analyze the trends of COVID-19 vaccination coverage according to the variables of person, time, geography or place, and characteristics of the biological to take specific actions when necessary.
- Monitor the equitable application of COVID-19 vaccines, that is, the extent to which national policies are effectively implemented to prioritize at-risk groups.
- Ensure that the necessary forms and documentations are adapted and available to record doses of the administered vaccine in a timely manner.
- Facilitate the availability of information for analysis and use in decision-making, such as impact evaluation, vaccine effectiveness, potential epidemiological studies, surveys, surveillance of AESIs and ESAVIs, among others.
- Provide a personal vaccination record document, such as a vaccination card or proof for the vaccinated population, for occupational, educational, and/or travel purposes.

The main indicators to measure progress with COVID-19 vaccines are like any other vaccine and include:

- Access (application of the first vaccine dose)
- Number of people vaccinated according to number of doses
- Coverage (application of the complete schedule)
- Drop-out rate between first and second or more doses
- Reasons for rejecting vaccination

Each of these indicators should be disaggregated by variables of 1) person: age, gender, occupation, comorbidities, other equity dimension - socioeconomic, ethnic, linguistic, religious, or any socially disadvantaged population; 2) place: place of residency and place of vaccination by district, province, state, etc.; 3) time: date of vaccination and vaccine product (name of the vaccine, producer, platform, and batch).

Obtaining estimates for each target population to measure equitable coverage across different target populations is an important, complex, and urgent activity that is required to successfully prepare for COVID-19 vaccine introduction. Sources of the denominators could be:

- Population by age: national censuses, World Bank population or United Nations population (<https://population.un.org/wpp/>)
- Occupation: national censuses defined by country
- People with co-morbidities: health and chronic disease surveys conducted by the country or the global burden of disease (<http://www.healthdata.org/gbd>)
- Micro-planning data at the local level: These data should be disaggregated by location to the lowest possible level.

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Periodic meetings should be held with supervisory teams at all levels to monitor the progress of vaccination to analyze the strengths and weaknesses and corrective measures needed to achieve the proposed goal. Countries should define performance standardized information analysis routinely, as well as schedules for the flow of information on COVID-19 vaccination.

Each country should adapt their systems to record, report, analyze, and use vaccination data for COVID-19. Guidelines should be developed at national levels to ensure modification of the country's registration instruments, regardless of whether they are individualized, aggregated, on paper, electronic, or both.

Regarding the use of paper, countries should develop daily, weekly, and monthly tally sheets for specific COVID-19 target groups and strategies, or use standard tally sheets, but keep sheets separate for each strategy and group (such as health workers, social care workers, older populations, etc.). Doing so will simplify their design and use. The header for tally sheets should contain information about the location, targeted group, vaccinator, COVID-19 vaccine product used, and applicable date or date range. Separate spaces (boxes) should be available for different COVID-19 vaccine doses, and for any required dimension of disaggregation, like sex and age range.

Regarding electronic systems, while electronic individual records have potential advantages, such as allowing more detailed and timely information, implementing, and maintaining such systems can be challenging. This needs to be considered when introducing one of these systems. In cases where electronic systems are available, it is important to ensure their timely adaptation for collection of information, reports, and respective tests.

Considerations

- There will be a strong and urgent demand for data on COVID-19 vaccination by countries and international stakeholders.
- Countries should anticipate their data needs and strengthen information systems to be able to provide fast, frequent, and accurate reporting.
- Countries can use existing platforms and tools, but in some cases COVID-19 vaccine introduction may serve as a catalyst to introduce more efficient systems.
- Countries will need accessible and reliable home-based and clinic vaccination records for vaccine safety and effectiveness evaluations, as well as for individual travel, professional, and health purposes.

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Vaccine Safety

At the global level there are two main mechanisms for reporting adverse events supposedly attributable to vaccination or immunization (ESAVI) to WHO: The first mechanism is reporting aggregated data from the immunization programs of each country annually through the PAHO/WHO-UNICEF Joint Reporting Form (JRF). Part of the required data includes responding to a few questions pertaining to the number and severity of ESAVI cases and the existence of national committees for ESAVI analysis and classification. This information, however, is basic and does not allow PAHO to conduct comprehensive analyses of ESAVI characteristics, preventing the possibility of identifying challenges at the regional level. The second mechanism is reporting ESAVI from national regulatory authorities (NRA) through the Vigiflow channel sending Individual Case Safety Reports (ICSR) to the Uppsala Monitoring Center (WHO Collaborating Center for a Global Safety Database). This global database (Vigibase) allows all countries to browse and view data on suspected side effects from various medicinal products (also known as suspected adverse drug reactions (ADRs)). However, this mechanism does not allow immunization programs to access information from Vigibase and reports are more related with ADRs than ESAVI classification. Therefore, none of the current global mechanisms allow PAHO to do timely and comprehensive analyses of the ESAVI situation in the Region.

At the regional level, PAHO has had successful experiences supporting ESAVI monitoring between 2002 and 2016, including several national workshops for vaccine safety trainings and regional workshops for ESAVI surveillance for new vaccine introductions, like the H1N1 vaccine between 2009 and 2010 and the yellow fever vaccine in 2012, as well as a WHO global vaccine safety multi-country collaboration between 2014 and 2016 for the measles, mumps, and rubella (MMR) vaccine.

Passive ESAVI surveillance, on the other hand, has been carried out differently in each country in Latin America and the Caribbean. Some countries only carry out surveillance during national vaccination campaigns or when serious events have been reported during routine immunization program. In general, the coordination between immunization and pharmacovigilance has been limited to sporadic serious events.

Since 2018, PAHO's Comprehensive Family Immunization Unit (IM) has started to pave the road towards designing a regional ESAVI surveillance system, updating its 2002 Regional Manual for ESAVI Surveillance, which was adapted from the 2016 WHO Global Manual after three meetings with experts from PAHO, CDC, WHO, Argentina, Colombia, Chile, Peru, Mexico, and the United States. Recently, PAHO has also participated in the WHO Global Advisory Committee for Vaccine Safety (GACVS) Working Groups for launching a Global Manual for Vaccine Safety for COVID-19 Vaccines. Most of the global recommendations from this Global Manual will be reflected in PAHO strategies for implementing a regional ESAVI surveillance system as part of the PAHO regional plan for COVID-19 vaccine introduction.

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Within the context of various potential challenges surrounding the introduction of COVID-19 vaccines, there is a proposal to implement a regional ESAVI surveillance system in the Americas, with the goal of achieving a sensitive, timely, standardized, reliable, and integrated regional surveillance system. This system will include co-participation from all actors involved in vaccine safety to maintain vaccine confidence and acceptance in the Americas. The purpose of this regional surveillance is to contribute to the early detection and classification of serious ESAVIs and ESAVI risk signals, to generate a rapid and appropriate response at national and regional levels. The specific objectives of the surveillance system are to:

- Obtain and analyze information in real time for decision-making, identify different types of ESAVIs: a) vaccine-product-related reaction, b) vaccine-quality-defect reaction, c) immunization-error-related reaction, d) immunization-anxiety-related reaction and e) coincidental event with temporal association to vaccination.
- Design and implement a regional vaccine safety surveillance system through intensified passive surveillance, active surveillance, and special studies related to COVID-19 vaccine introduction.
- Coordinate actions with PAHO's Revolving Fund for ESAVIs linked to quality defects of COVID-19 vaccines.
- Build and maintain vaccine confidence and acceptance through systematic regional feedback to the countries.

To address these challenges and to accomplish the goal, purpose, and objectives, PAHO has convened five working groups with experts from PAHO, CDC, and countries to develop five strategies with their respective products. Some relevant products include:

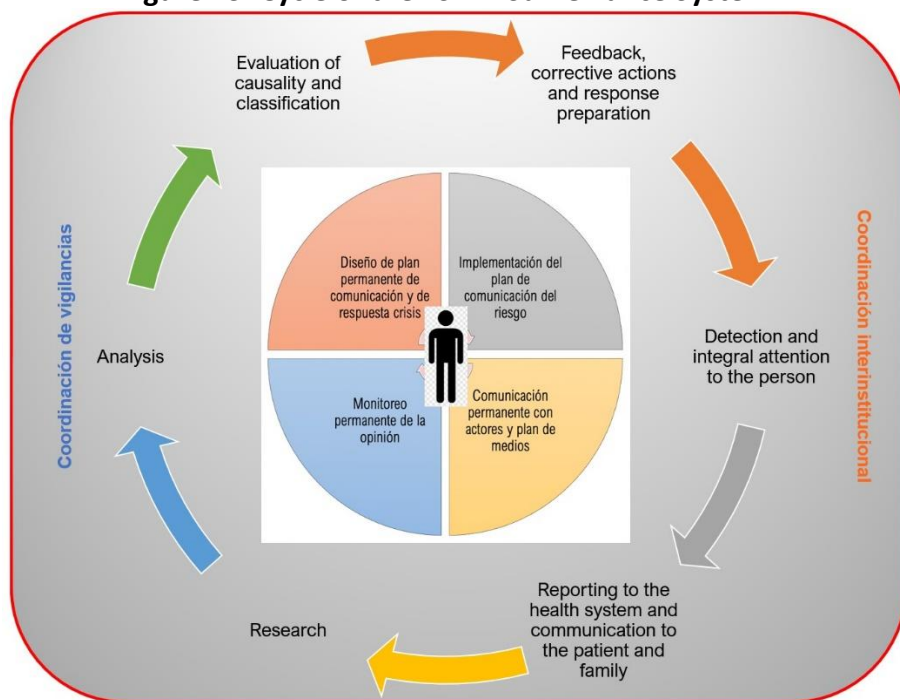
- Implement and monitor regulatory mechanisms for COVID-19 vaccine introduction:
 - Develop a dashboard for monitoring the risk of vaccines, the progression of clinical trials, and the safety profiles of the different COVID-19 vaccine platforms.
 - Define the activities and/or procedures for integrating reports of serious adverse events, suspected unexpected adverse reactions (SUSARs), or ESAVI in clinical trials with activities that monitor vaccine safety.
- Develop standard operating procedures (SOPs) for the regional surveillance system.
 - Conduct and consolidate results from the regional survey for decision-making.
 - Document SOPs of regional ESAVI surveillance.
 - Define a model and project for a regional notification system for ESAVI surveillance (including business rules, architecture, evaluation of digital tools, among others).
- Strengthen national capacities in the surveillance of ESAVIs or adverse events of special interest (AESIs) in the COVID-19 context.
 - Prepare a virtual course for the ESAVI surveillance manual.
 - Prepare an ESAVI surveillance training strategy to strengthen national capacities (investigation, causality assessment, etc.).

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- Define the functional model of the sentinel network of active surveillance for the safety of COVID-19 vaccines, as well as ESAVI/AESI research protocols.
 - Identify the standard protocol for a sentinel network aimed at active ESAVI/AESI surveillance and a research protocol for cohort event monitoring for high risk groups that will be vaccinated.
- Establish a regional committee for vaccine safety with support from Strategic Alliances and the Strategy for Communication during ESAVI-related Crisis.
 - Deploy PAHO social communication materials related to ESAVI risk.
 - Prepare webinars, videos, frequently asked question (FAQ) documents, workshops for risk-related social communication, among others.

The regional reporting system will be established after analyzing results from a regional survey assessing that a certain level of system maturity has been reached. ESAVI notification will be transferred from the local level to the national level. Once the entire ESAVI surveillance cycle has been completed at the national level – detection, notification, investigation, analysis, and causality assessment – case-based data will be transferred to the regional level.

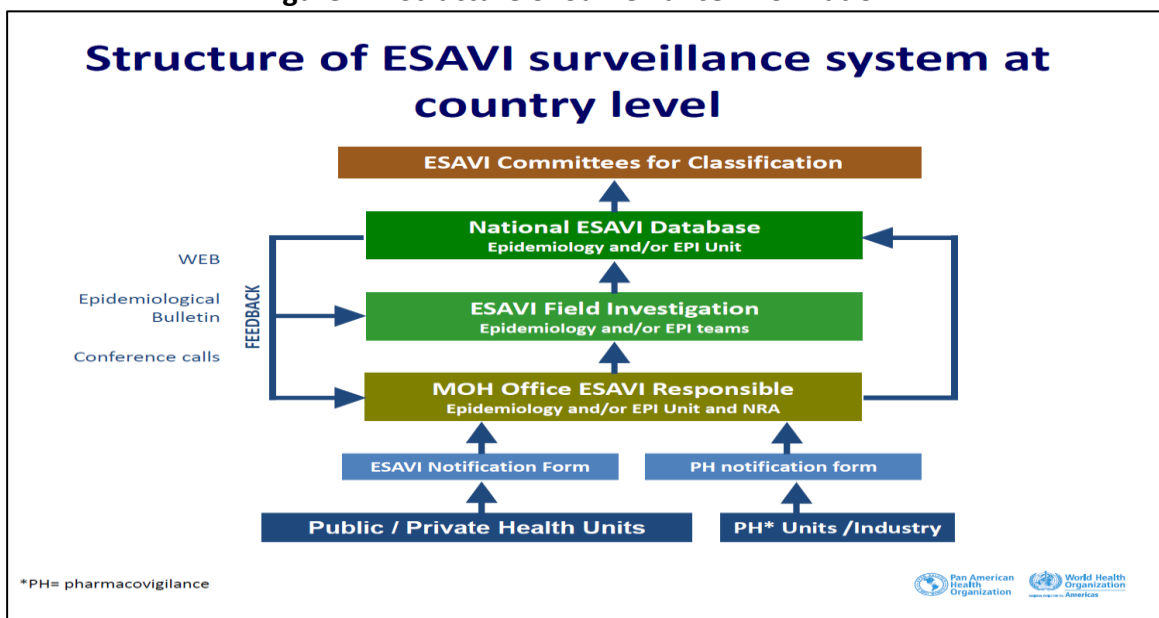
Figure 13: Cycle of the ESAVI Surveillance System





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Figure 14: Structure of Surveillance Information



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Communication Demand and Generation

Following 2019 TAG recommendations,⁹ PAHO began work on an immunization communication strategy to guide regional work and support Member States. In consultation with EPI managers from select countries and other stakeholders, it was determined that such a strategy should be adaptable to reflect the diversity of the Americas; go beyond offering just information and appeal to emotions; employ segmented communications, understanding that “one size fits all” approaches have limited success; create constant dialogue rather than waiting for emergencies or campaigns to communicate; and be proactive to stay ahead of resistance. A strategy was thus developed with those characteristics to meet three objectives: empower the community to seek vaccination; empower health care workers to promote immunization; and sensitize decision-makers and influencers and leverage their support in favor of vaccination.

The enabling factors were identified as promoting the benefits of vaccines, maintaining or increasing trust, and stopping myths and misinformation. In the context of the COVID-19 pandemic, PAHO communications on immunization continue in the original framework, but have since been adapted to consider additional challenges related to the infodemic, including mis- and disinformation; growing vaccine hesitancy and anti-vaccine movements; the politicization of the pandemic, including around COVID-19 vaccines; and other issues.

PAHO’s goals for communications to support the introduction of COVID-19 vaccines include successfully planning and implementing risk and crisis communication around the introduction of COVID-19 vaccines in the Region of the Americas; promoting community engagement to generate demand for COVID-19 vaccines while maintaining credibility and trust in national routine immunization programs; and positioning PAHO as a regional leader and trusted source in immunization technical cooperation, in collaboration with relevant stakeholders, including media and vaccine champions.

Considerations:

- Populations should be informed about COVID-19 vaccines, including prioritization processes to determine who receives vaccines in initial phases.
- Efforts should be made to build trust and create demand for vaccination.
- Efforts should be made for infodemic management and risk communications planning.

⁹ Recommendations from July 2019’s TAG meeting:

- TAG urges PAHO to develop a regional strategy for vaccine access, acceptance and demand, and support countries in identifying social and behavioral determinants of vaccination and addressing barriers to vaccination.
- Countries should use theory-based approaches to identify local barriers and drivers to vaccination, and use these insights to develop tailored, evidence-based interventions to reach vaccination coverage goals, evaluate their impact, and share their findings with other countries.
- Countries should strengthen their preparedness and response to vaccine safety events, which have the potential to erode trust in vaccine safety and in the health authorities delivering them.

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Monitoring and Reporting Country Readiness for the Introduction of COVID-19 Vaccines

As part of technical assistance for planning the introduction of COVID-19 vaccines, WHO and UNICEF developed an assessment tool called the Vaccine Introduction Readiness Assessment Tool (VIRAT), which is a checklist that aims to provide a planning roadmap to prepare for the introduction of COVID-19 vaccines; allow countries to self-monitor their readiness progress against key milestones; and support countries to identify technical cooperation needs.

The checklist includes nine components:

1. **Planning and Coordination:** Develops the working groups and coordinating bodies that will ensure understanding and adherence to delivery timelines.
2. **Resources and Funding:** Estimates human and operational resource needs and identifies potential sources of funding, as well as mechanisms for disbursement to operational levels.
3. **Regulatory:** Confirms the regulatory pathway for licensing COVID-19 vaccines in country and secures necessary approvals/waivers for import.
4. **Service Delivery:** Establishes the priority target populations and develops traditional and non-traditional strategies to best reach them.
5. **Training and Supervision:** Identifies training needs, develops materials/platforms, deploys to target groups; and establishes supervision model.
6. **Surveillance and Monitoring:** Develops or adapts surveillance mechanisms (coverage, AEFIs) for COVID-19, updating data collection tools as needed.
7. **Vaccine Logistics and Cold Chain:** Assesses and plans for logistical needs, such as the cold chain, distribution, and security, from port of entry to service delivery points.
8. **Safety and Surveillance:** Ensures that sufficient capacity for vaccine safety surveillance is in place.
9. **Advocacy, Mobilization, and Communications:** Designs and implements communications, social mobilization, and engagement strategies to generate confidence, trust, and demand for COVID-19 vaccines.

As part of the work in progress, PAHO's Comprehensive Family Immunization Unit (IM) and the Revolving Fund have developed a regional dashboard, allowing countries to monitor VIRAT implementation in the Region, with eight countries having already submitted the VIRAT; monitor the development of the National Deployment Vaccination Plan (NDVP); and generate COVID-19 vaccine demand forecast for countries participating in the Revolving Fund.

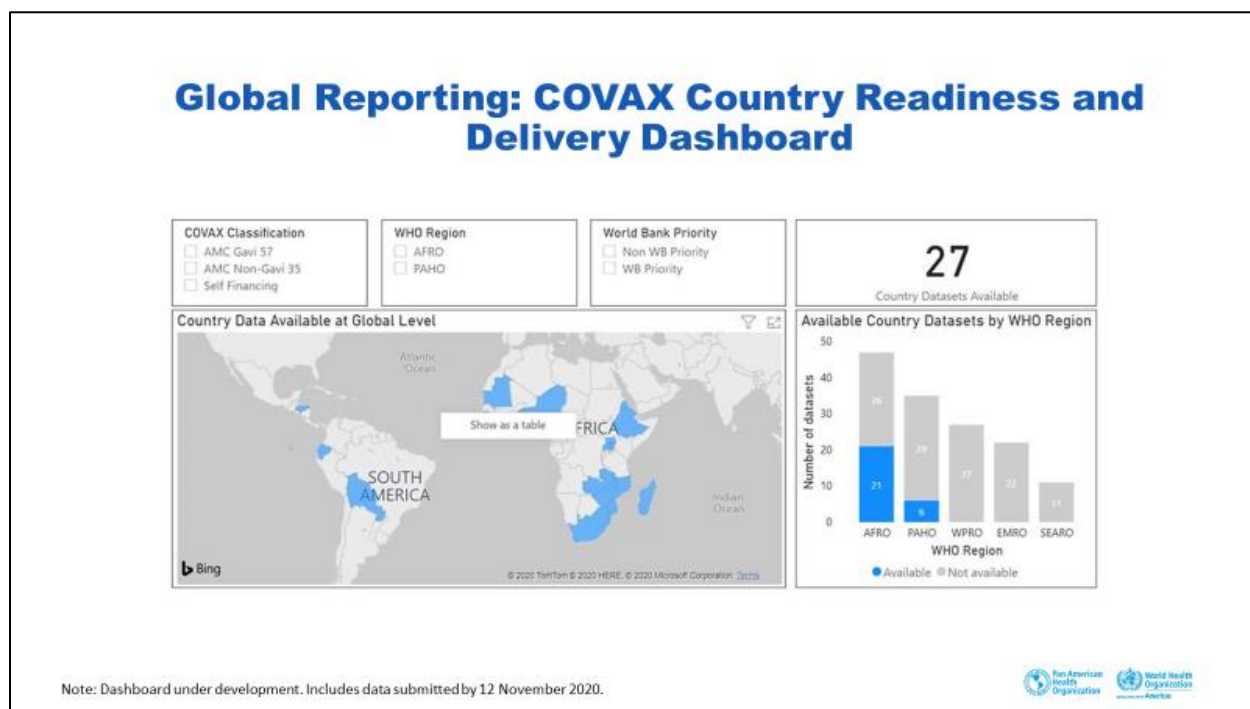
PAHO encourages countries to use the VIRAT tool to self-assess their readiness and share it with PAHO. The World Bank has also developed its own Vaccine Readiness Assessment Framework called VRAF. However, WHO and the World Bank are working to merge VIRAT and VRAF into one



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tool that can be used for all countries and partners to harmonize requirements, identify gaps, and provide technical cooperation tailored to country needs.

PAHO highlights the importance of supporting countries to develop “One Country Deployment and Vaccination Plan” that partners can rally around and use for assessing country readiness, as well as applying to the COVAX Facility and World Bank financing.



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Progress Made in COVID-19 Vaccine Access for Latin American and Caribbean Countries

To date, regional solidarity has led to an unprecedented level of participation from countries in Latin America and the Caribbean (LAC) in the COVAX Facility, with 27 self-financing¹⁰ countries and territories signing commitment agreements (against 95 self-financing countries globally – representing 33% of the projected global procurement volume). Despite the financial implications for national budgets, most of the 27 self-financing countries have already met the Facility's financial requirements, representing allocation of more than \$1 billion as down payments and financial guarantees. Additionally, the ten countries (out of a total of 92 globally) in the Region eligible for Advance Market Commitment (AMC) support have been initiating the process of submitting applications to the Facility.

PAHO estimates that for a typical country in the LAC, the initial cost burden of the new COVID-19 vaccine is likely to be 12 times more than the annual national immunization budget. Just to acquire the vaccine for 20% of their total population (for those considered at highest risk) in 2021, countries in the Region will need to invest three times their current annual immunization budgets. To this end, the affordability of the future COVID-19 vaccines will be critical. Given public sector investments in Research and Development by global partners, such as the Coalition for Epidemic Preparedness Innovations (CEPI) and developed countries, PAHO continues to advocate for flat prices¹¹, minimal returns, sustainable financing, leveraging existing systems, and consolidated demand forecasting to improve access and affordability.

Under the COVAX Facility, PAHO's Revolving Fund and UNICEF's Supply Division mechanisms are recognized as the main procurement agents, having issued a joint Request for Proposal (RFP) to vaccine manufacturers on 12 November 2020. PAHO is preparing to procure COVID-19 vaccines on behalf of all PAHO interested Member States as part of its technical cooperation and country preparedness initiatives for introducing COVID-19 vaccines.

¹⁰ Number does not include Canada.

¹¹ A pricing structure where a supplier charges a single fixed price for a specific product for all customers.

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Recommendations

- TAG notes the ongoing pandemic and the significant toll that it is taking and emphasizes the importance of non-pharmaceutical measures in reducing the transmission of COVID-19.
- TAG notes the critical importance of more effectively communicating how the force of infection that comes with surges or increased waves of infections results in increased case severity and mortality.
- TAG appreciates the work of both PAHO's team and national teams and encourages the continuation of efforts to improve vaccination coverage and increase the demand for vaccines, as well as efforts to improve the surveillance of communicable diseases relevant to vaccination.
- TAG notes the analysis on estimating the populations most at risk due to underlying conditions and sees the value of these estimates for COVID-19 response, as well as for allocation of the vaccine. It would be useful to explore which of the underlying conditions are most predictive of poor health outcomes, so that the prioritization and allocation of vaccines can be refined, where possible.
- TAG supports the adoption of the WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination and the Roadmap for Prioritizing Population Groups for Vaccines against COVID-19 and urges their use to guide country planning and decision-making.
- TAG encourages countries and stresses the need for them to begin their planning using the values framework and prioritization roadmap, and to involve the NITAGs and all stakeholders in a transparent process to plan for the administration of COVID-19 vaccines. It is important to engage all stakeholders and the public in a dialogue to build confidence in COVID-19 vaccines and those protecting against other diseases.
- TAG supports vaccinating health workers, the elderly, and adults with comorbidities as a priority to reduce morbidity and mortality due to SARS-CoV-2 infection.
- TAG stresses the importance of careful micro-planning, considering the specific characteristics of the COVID-19 vaccines that are available for use, with special attention to all aspects of the cold chain, logistics, and information systems (electronic or paper), including the provision of a vaccination registry to vaccinated persons.
- TAG notes the need to strengthen national capacities for ESAVI surveillance in relation to COVID-19 and other vaccines and supports the establishment of a regional ESAVI surveillance system.
- TAG recommends preparing special studies to monitor cohorts of vaccinated persons to determine the safety and duration of protection from COVID-19 vaccines. TAG also supports the establishment of a regional committee for COVID-19 vaccine safety.
- TAG emphasizes the critical role of communication, including social media and the identification and use of both national influencers and personalities, as well as regional

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champions and ambassadors, in promoting COVID-19 immunization once vaccines are available.

- TAG notes that the VIRAT tool is useful to monitor country preparedness and preparation of national vaccination plans, and TAG strongly supports the integration of the VIRAT tool and the World Bank's Vaccine Readiness Framework (VRAF) tool into one tool for monitoring country readiness and facilitating the preparation of national vaccine plans.
- TAG appreciates the critical role of PAHO's Revolving Fund and the COVAX Facility and supports the lowest price most favored customer clauses in the agreements. TAG is in support of the measures and efforts to ensure global equitable allocation of the vaccines at fair pricing.
- TAG notes that it is important for PAHO to track and monitor the characteristics of vaccines as they become available and work diligently towards obtaining the best solutions for countries.
- TAG stresses the importance of having sufficient human resources in place and training sufficient personnel to prepare for the introduction of COVID-19 vaccines, as well as to ensure that routine vaccination programs continue to be provided.
- TAG urges PAHO to continue monitoring the progress countries are making on their vaccine introduction plans.
- TAG recommends that PAHO monitor the efficacy and safety data on ongoing COVID-19 vaccine candidates that are in clinical trials to make specific regional recommendations regarding strategies and vaccination policy.
- Considering the possibility that both the influenza and COVID-19 vaccines have similar at-risk and target populations, TAG recommends countries use their established influenza immunization infrastructure to prepare for the introduction of COVID-19 vaccines.

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