

COVID-19

ad hoc TAG Meeting August 2020

**Fifth ad hoc Meeting of the Technical Advisory Group (TAG)
on Vaccine-preventable Diseases**

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Introduction

Dr. Jarbas Barbosa opened the meeting by thanking participants for their presence and remarked the importance of the Pan American Health Organization's (PAHO) Technical Advisory Group (TAG) on Vaccine-preventable Diseases support in reviewing the situation of immunization programs and preparing for COVID-19 vaccination. The meeting aimed to update TAG members on the epidemiological situation of COVID-19 in the Americas, its impact on the immunization programs to date, and the actions taken by PAHO to ensure that immunization services across the Region are maintained as essential health services. Moreover, an update was provided on PAHO's efforts to facilitate equitable access to COVID-19 vaccines to countries of the Region and preparation for vaccine introduction. TAG Chair Peter Figueroa recognized the countries' tremendous efforts in responding to the COVID-19 pandemic and maintaining immunization activities where possible. He also acknowledged the difficulties that PAHO has faced in the past months and commended the team for continuing technical cooperation despite numerous challenges and uncertainties.

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Immunization Programs in the Region of the Americas in the Context of COVID-19

COVID-19 is a communicable disease caused by the novel coronavirus SARS-CoV-2. The COVID-19 pandemic was declared by the World Health Organization (WHO) on 11 March 2020, and to date more than 31 million cases and 967,000 deaths have been reported worldwide¹. Approximately, more than half of these cases (N~15,800,000) and deaths (N~534,000) have been reported in the Region of the Americas.

In response to the COVID-19 pandemic, both WHO and PAHO have recommended that vaccination be maintained as an essential health service. To this end, PAHO's Comprehensive Family Immunization (IM) unit (Family, Health Promotion, and Life Course Department [FPL]), has worked with the countries of the Region to maintain sound national immunization programs (NIPs) on several fronts, such as the preparation of documents and guidelines to continue vaccination activities in the context of COVID-19, monitoring the disease's impact on vaccination coverage, monitoring the effects of postponing measles vaccination campaigns due to the pandemic, and strengthening vaccination against seasonal influenza.

PAHO has also monitored the operation of immunization services across the Region and the main challenges faced due to the pandemic. To date, PAHO has conducted five country surveys; the first one was sent out to countries of Latin America and the Caribbean (LAC) on 16 April and the last one on 30 June 2020. An online survey was sent every two weeks to IM focal points and advisors in the PAHO country offices in the Region. The responses represent the opinions of survey participants and do not represent official reports to PAHO. Thus, the findings should be interpreted with caution. Following each survey, IM systematically updated its technical cooperation agenda to prioritize and address the identified needs of LAC countries. We summarize hereafter the information from 38 countries and territories in the Region received as of 6 July 2020 and collected in the fifth iteration of the survey. Of these 38 countries, 16 were Latin American and 22 Caribbean countries including Belize, Haiti, Guyana, and Suriname (Figure 1).

¹ WHO. COVID-19 Dashboard. Available at: <https://covid19.who.int/>

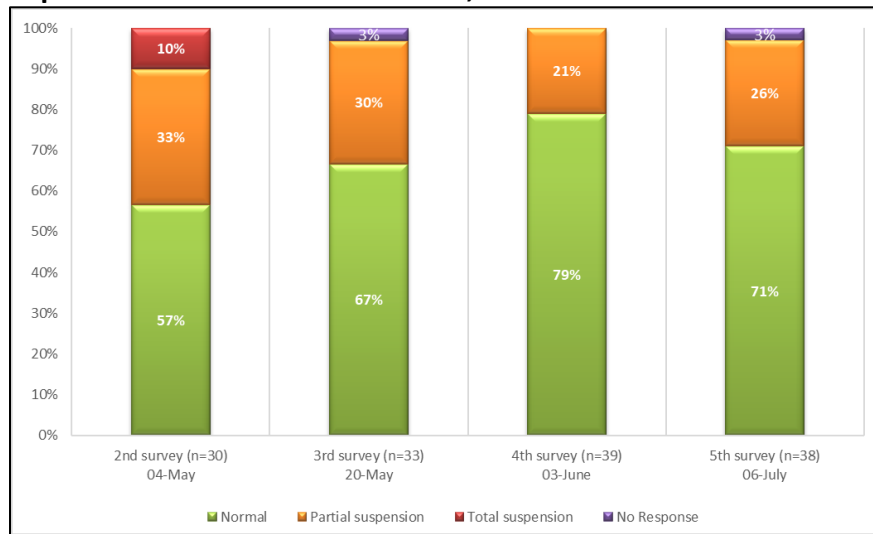
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Figure 1. Country Participation in the Survey on Pandemic Impact on Immunization services, July 2020



Source: Poll on national immunization programs in the context of COVID-19 to focal points and country immunization advisors in PAHO country offices.

Figure 2. Operation of Vaccination Services, Latin America and the Caribbean, 2020



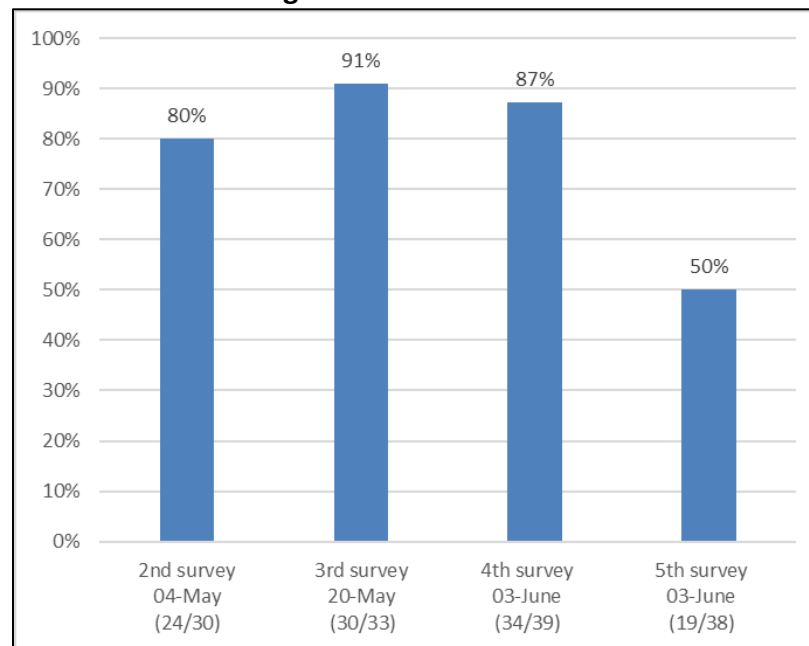
Source: Poll on national immunization programs in the context of COVID-19 to focal points and country immunization advisors in PAHO country offices.

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As the restriction of movement² in the LAC Region has become less strict, the operation of routine vaccination services has resumed or increased. All respondents reported that vaccination services were open (Figure 2). IM is currently working with LAC countries to map coverage at the municipality level to further identify gaps.

Although service supply has improved, the COVID-19 pandemic and 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 when seeking vaccination services. Other causes have included difficulties due to limitations in public transportation, lockdowns, or physical distancing. These are consistent with the results of a similar survey conducted by WHO. Consequently, 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 3. Perceived Changes in Demand for Vaccination Services during the COVID-19 Pandemic

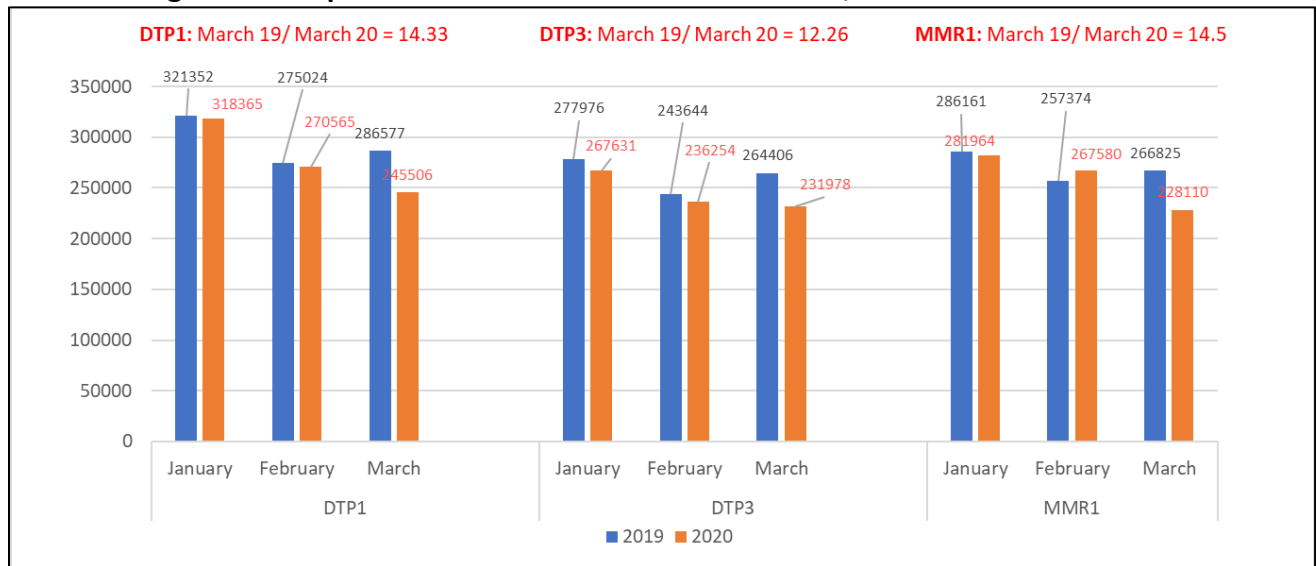


Source: Poll on national immunization programs in the context of COVID-19 to focal points and country immunization advisors in PAHO country offices.

² Restriction of movement in the Region includes: Restriction or prohibition on the entry of foreigner travelers, border closure and controls, border controls, restriction or closure of public space and mass gatherings, among others.

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Figure 4. Comparison of Vaccine Doses Administered, Jan-Mar 2019-2020



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

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 appointment 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.

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

Eighteen countries (47%) responded that they had encountered difficulties in the delivery of vaccines and supplies for the NIP. Sixteen of these 18 countries 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.

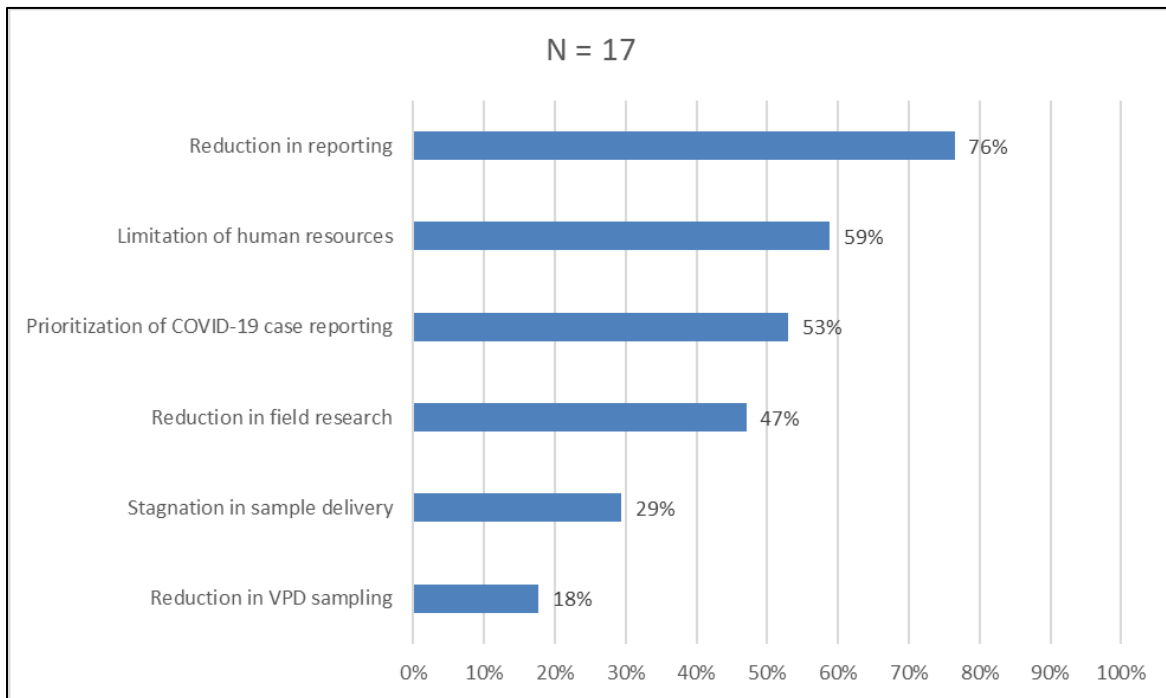
Seventeen countries reported that epidemiological surveillance of vaccine-preventable diseases (VPDs) had been affected by the pandemic. In most countries, this came because of the shift in priorities, redirecting attention and resources to COVID-19 surveillance and outbreak response. Countries also indicated that VPD case reporting overall had decreased significantly. Other factors hindering epidemiological surveillance included limited human resources, reduced field

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investigations and screenings for VPDs, as well as a halt in the shipment of samples for analysis (Figure 5).

Of the 38 countries that responded to this survey, 12 (32%) emphasized that laboratory services and activities to support VPD surveillance had been affected. The main reason for this disruption, as for epidemiological surveillance, had been the prioritization of laboratory resources for COVID-19 diagnosis (Figure 6).

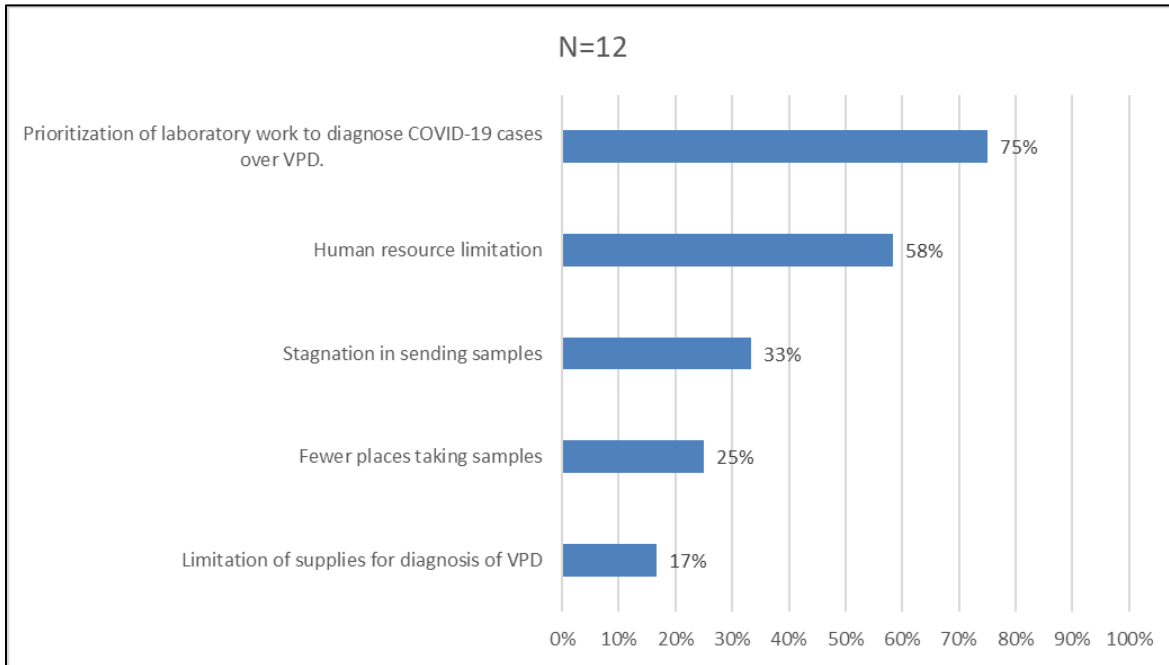
Figure 5. Factors Affecting Epidemiological Surveillance of Vaccine-preventable Diseases, 2020



Source: Poll on national immunization programs in the context of COVID-19 to focal points and country immunization advisors in PAHO country offices.

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Figure 6. Challenges Faced by Laboratory Surveillance of Vaccine-preventable Diseases, 2020



Source: Poll on national immunization programs in the context of COVID-19 to focal points and country immunization advisors in PAHO country offices.

As of the date of the fifth survey, six countries in the Region (Argentina, Brazil, Guatemala, Haiti, Mexico, and Venezuela [Bolivarian Republic of]) reported ongoing outbreaks of VPDs, some with more than one VPD.

In conclusion, as restriction of movement policies have relaxed in the Region, the provision of vaccination services has improved. Unfortunately, there has also been a decline in vaccine demand, with a significant reduction in vaccination coverage and an increase in existing immunity 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 and community engagement. It is crucial to communicate the importance of immunization in keeping people healthy and protected from VPDs to the population.

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Access to COVID-19 Vaccines in Latin America and the Caribbean

While there are currently no licensed vaccines against COVID-19, the world hopes to soon have safe and effective vaccines available to control the pandemic and reduce its health, economic, and social impact. IM and PAHO's Revolving Fund for access to vaccines (RFV) jointly briefed the TAG Members on PAHO's ongoing efforts on facilitating access to SARS-CoV-2 vaccines in Latin American and Caribbean Countries. IM provided an update on the SARS-CoV-2 vaccine development pipeline, the respective technology platforms, and progress to date with regards to clinical trial phases. IM also provided information on the "Access to COVID-19 Tools (ACT) Accelerator" and global partnership and collaboration structures in response to the COVID-19 pandemic.

Various technologies are being used to develop vaccines: nucleic acid (DNA, RNA) vaccines, viral vector vaccines (nonreplicating or replicating vectors), protein-based vaccines, and whole-virus vaccines (attenuated or inactivated). As of 22 September 2020, there are 38 candidate vaccines in clinical evaluation in humans (13 in phase III clinical trials) and 149 candidate vaccines in preclinical evaluation³. Some of the vaccine clinical trials will take place in sites located in Latin America. Several vaccines will be needed to respond to the global demand⁴.

PAHO has been part of the discussions to establish a multilateral collaboration, the "Access to COVID-19 Tools (ACT) Accelerator"⁵, as a global effort to support equitable access to three pillars related to COVID-19: diagnostics, treatments, and vaccines. The vaccine pillar includes three components: development and manufacturing, coordinated by the Coalition for Epidemic Preparedness Innovations (CEPI); policy and allocation, coordinated by WHO; and procurement and delivery at global scale, coordinated by Gavi in close collaboration with participating countries, international partners, and vaccine manufacturers.

There was an explanation on the importance of globally coordinated access mechanisms for increased access possibility and risk pooling in comparison to national and regional group access mechanisms. The COVID-19 Vaccine Global Access (COVAX) Facility falls under the vaccine pillar as a historical global mechanism; the Revolving Fund engaged with the COVAX Facility to provide better access and affordability options to the participating Member States in the Americas.

³ WHO. DRAFT landscape of COVID-19 candidate vaccines. More information is available at: <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>

⁴ More information is available at the Frequently Asked Questions (FAQs) about COVID-19 Candidate Vaccines and Access Mechanisms: <https://www.paho.org/en/documents/frequently-asked-questions-faqs-about-covid-19-candidate-vaccines-and-access-mechanisms>

⁵ The Access to COVID-19 Tools (ACT) Accelerator: <https://www.who.int/initiatives/act-accelerator>

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All countries have been invited to participate in the COVAX Facility, regardless of their income classification. Two categories of countries were defined as part of the COVAX Facility: self-financing countries and those that may receive a subsidy from the COVAX Advanced Market Commitment (AMC) to support the cost of purchasing COVID-19 vaccines.

In a COVAX Facility technical design document from 11 June, the Revolving Fund mechanism is recognized as a unified bloc and viable procurement mechanism, representing 42 participating Member States, 40 of which submitted their interests. Based on this response, PAHO forwarded to Gavi a consolidated Expression of Interest (EOI) as PAHO bloc on 10 July 2020. Even the countries in the Region that have bilateral agreements with suppliers can participate in the Facility.

On 30 July, the Gavi Board approved the Gavi Secretariat as the legal administrator for the COVAX Facility and the Gavi Secretariat's current plan is to engage in direct contracts with Member States. The Gavi Board also approved 92 countries to be within the scope of COVAX AMC support, 10 of which are from the Region of the Americas: Bolivia, Dominica, El Salvador, Grenada, Guyana, Haiti, Honduras, Nicaragua, St. Lucia, and St. Vincent & the Grenadines. The remaining 23 Member States and seven territories are projected as self-financing countries under the COVAX Facility. Regardless of support eligibility or self-financing status, PAHO envisions all participating Member States from the Region as one bloc with solidarity and equity principles.

PAHO has been engaged with ministers of health and immunization managers through informative sessions during the previous weeks (weeks of 13 July and 20 July). PAHO will continue to respond to queries from Member States and continue discussions and negotiations with Gavi, WHO HQ, CEPI, UNICEF, the Inter-American Development Bank (IDB), and other partners to ensure optimal outcomes for Member States. There were four important pending areas of work with the COVAX Facility that were presented to the TAG Members for their information and guidance on:

1. Pricing: As a principle, PAHO encourages Gavi and partners to target a price commitment to close-to-marginal cost pricing as part of the COVAX Facility for all participating countries. COVAX Facility design cluster discussions and the 11 June preliminary technical design document for the COVAX Facility also pointed out the importance of achieving flat (same price for all countries based on marginal costs of production with minimal returns) and most affordable prices possible. Achieving flat pricing will require concerted efforts and strategy leveraging demand volumes, supplier willingness to accede to extraordinary pandemic times. Unless all partners (like Gavi, CEPI, UNICEF, BMGF, World Bank, and WHO HQ) are onboard in this effort and leverage existing systems (such as PAHO RF and UNICEF Supply Division), flat pricing will be a missed opportunity for the global community, COVAX Facility, and countries that are already struggling to confront the pandemic and economic downturn.

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On the other hand, PAHO noted that a 30 July Gavi Board paper analysis was based on a tiered pricing approach (differentiating projected pricing levels for countries based on gross national income [GNI] per capita). PAHO was informed that some suppliers were suggesting a tiered pricing approach to the COVAX Facility.

2. Financing: In principle, PAHO advocates to minimize financial requirements (like down-payment requirements) and risks (like countries cannot come up with financial guarantee letters) that might hinder or delay participation from self-financing Member States. In the coming weeks, it is expected that Gavi will communicate the requirement of down payments to participate in the COVAX Facility for self-financing countries. Self-financing countries will be requested to make a binding financial commitment based on the estimated cost per dose multiplied by a number of doses that the country would like to receive (i.e. 20% of the country's population) during the initial allocation of phase 1, then 15% of the total initial cost estimate projection is planned to be requested by the COVAX Facility as the down payment by 31 August. PAHO is engaged in discussions with Gavi and CEPI to understand the risk involved in using 15% down payment as a speed/risk premium. In Gavi briefings, it is indicated that most down payments are projected to be channeled as manufacturing scaling up at-risk investments for pipeline candidates.

PAHO is also engaged in discussions with the Inter-American Development Bank (IDB) on financing options to help countries participate in the COVAX Facility, i.e. restructuring of existing loans for the down payment and other options. PAHO is also conducting costing analyses on possible innovative financing mechanisms through the Revolving Fund credit line to support small island states and territories in the Caribbean.

3. Governance Issues: PAHO's Revolving Fund is not included in COVAX Facility Governance structures in the 30 July Board Papers except as AMC stakeholders. This was very concerning and PAHO communicated to Gavi Secretariat in July that it wishes to be a part of the:

1. Market sensitive decisions committee (along with UNICEF, WB, Gavi, BMGF)
2. Shareholders council (as bloc representative of PAHO-participating countries)
3. Research & development & manufacturing investment committee (as public health experts/technical programmatic experts).

PAHO will continue to negotiate with the Gavi Secretariat for appropriate representation in the right decision-making bodies of the COVAX Facility.

4. Procurement Issues: PAHO would very much like to initiate an overall updated approach with UNICEF SD to institute a strategic procurement approach including end-to-end process mapping and combining core capacities/skills of partners. Roles of the Revolving Fund and UNICEF Supply Division should not be diminished to transactional issues, i.e. two agencies are only dealing with delivery of vaccines and not being integrated to deal making and market shaping strategies.

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PAHO and UNICEF initiated discussions on developing a roadmap for a procurement strategy and tendering process. There is a need to deploy a total supply chain support package to complement overall programmatic, regulatory, and procurement aspects (i.e. syringes, vials, freight, cold chain, etc.) rather than have fragmented approaches. PAHO has considerable experience and lessons learned from the procurement of vaccines in response to the H1N1 pandemic. The Region had the highest access rate in the world to H1N1 vaccines at that time.

Finally, indicative milestones for the COVAX Facility were shared with TAG Members. As of the week of 3-7 August, Gavi is expected to submit term sheets (outlining participation requirements from the countries) and advance payment requirements for the participation of self-financing Member States to the COVAX Facility. Then countries might be requested to provide official commitments along with down payments to the COVAX Facility before the end of August, according to tentative timelines provided by the Gavi Secretariat.

TAG members pointed out that PAHO should provide an update to the Directing Council on access and affordability issues of potential COVID-19 vaccines, especially on future pricing implications. PAHO should also continue to monitor the progress of potential manufacturers in Latin America, given the implications for vaccine availability in the Region. In the past, other regions have requested help from PAHO to establish affordable vaccine access mechanisms for self-financing countries. PAHO could also support other regions with its expertise during this crisis and further collaboration options could be explored and established. TAG members noted that it may be necessary to mobilize resources and generate concrete vaccine forecasting requirements. Issues around the COVID-19 vaccine development pipeline, COVAX Facility, and access may be complex for Member States, therefore TAG stressed the importance of establishing a clear communication strategy and regular/consistent/coherent outreach to Member States.

When safe and effective COVID-19 vaccines obtain regulatory approval, there will be substantial demand while supply will likely be limited. Global partners are working together to set up the framework and mechanism required to ensure fair allocation through the WHO Fair Allocation Framework. During phase 1, it is expected that vaccines will be delivered to countries, in a manner that is proportional to their populations and in a way that vaccines are initially provided to 3% of the population and later expanding to cover up to 20%. For the first-round, priority groups will likely consist of essential workers (including healthcare workers), adults over the age of 65 years, and other high-risk adults with underlying health conditions. As more vaccine becomes available during phase 2, WHO is considering a weighted allocation model based on risk assessment to cover additional populations. WHO's Strategic Advisory Group of Experts (SAGE) on immunization, PAHO's TAG, and National Immunization Technical Advisory Groups (NITAGs) will play a key role in providing recommendations about immunization policies and priority groups for COVID-19 vaccination.

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TAG highlighted that current allocation thinking is focused on supply constraints; however, in the event of more supply than initially projected, advance thinking elements, such as more extensive priority group ranking and planning, could be integrated in order to support better country decision-making. TAG offered its support to provide more guidance on such issues.

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Regional Guidance for Planning the Introduction of COVID-19 Vaccines

While there are still many unknowns (e.g. vaccine supply availability, country allocation, priority groups for vaccination, vaccine presentation, cold chain requirements, administration route, number of doses required for protection, and co-administration with other vaccines, to name a few), based on the current information available and the assumption that COVID-19 vaccines might be available in the countries of the Region in 2021, it is important to start planning for the introduction of COVID-19 vaccines.

At the regional level, PAHO is currently developing a regional plan that would serve as a roadmap for technical cooperation to Member States for the period 2020-21. It will focus on supporting the introduction of COVID-19 vaccines.

Countries should also advance in planning and preparing the infrastructure to introduce COVID-19 vaccines, prioritizing the components of the NIP for which progress can be made (strengthening the cold chain, information systems, systems to monitoring adverse events following immunization [AEFIs], demand generation activities, among others). PAHO has recently published a guidance document⁶ to guide the development of national COVID-19 vaccination plans. The document describes the main actions to consider for each of the following technical and operational components:

Technical components	Operational components
Definition of COVID-19 vaccination objectives	Organization and coordination
Legal basis	Planning and micro-planning
Technical recommendations	Cold and supply chains
Definition of target groups and goals	Information systems
COVID-19 vaccines	Safe vaccination
National regulatory authorities	Monitoring, supervision, and evaluation
Vaccine access and distribution	Communication, information, and social mobilization
	Human resources and training
	Operational research
	Waste management
	Closure of vaccination campaigns
	Budget and timelines

The document also encourages countries to engage NITAGs in the development of national plans and to leverage the lessons learned and experiences from vaccination during the 2009 H1N1 influenza pandemic, annual vaccination against seasonal influenza, and other vaccination campaigns. Existing pandemic preparedness tools could be also be used⁷.

⁶ PAHO. Guidelines to Plan for COVID-19 Vaccine Introduction. 10 July 2020: <https://www.paho.org/en/documents/guidelines-plan-covid-19-vaccine-introduction-version-1-10-july-2020>

⁷ <https://www.paho.org/en/influenza-vaccine>

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Conclusions and Recommendations

Conclusions

- TAG commends PAHO for its strong support to countries of the Americas to respond effectively to the COVID-19 pandemic. The TAG also recognizes the good work of PAHO in monitoring the impact of COVID-19 on immunization and VPD surveillance in the Americas.
- TAG expresses concern that VPD surveillance and immunization coverage have been adversely affected in most countries due to the COVID-19 pandemic. Additionally, several important immunization campaigns have had to be postponed, such as those against measles and diphtheria. These challenges have arisen in the context of a serious decline in immunization coverage in the Americas over the past decade with DTP3 coverage falling from 94% in 2010 to 84% in 2019.
- TAG endorses the view that countries must re-instate or sustain immunization as an essential health service during the SARS-CoV-2 pandemic; otherwise, countries will face VPD outbreaks in addition to COVID-19 cases.

Recommendations

- TAG urges PAHO to provide guidance to countries on the implementation of immunization catch-up and coverage recovery activities. TAG stresses that PAHO should adopt a more hands-on approach in accompanying these efforts. Strategically placed PAHO international field staff need to be continually supported and offered to countries. More specifically, countries should:
 - Monitor the performance of immunization programs at national and subnational levels (including coverage, vaccine stocks and supplies, epidemiological and laboratory surveillance) and take data-driven actions to correct pitfalls.
 - Prioritize vaccination as an essential health service and implement immunization strategies to reach all target populations, especially the underserved and vulnerable population groups.
 - Take advantage of the universal health coverage approach to strengthen all components of the immunization program during the pandemic (micro-planning, human resources, training, information systems, among others). Countries should also implement integrated primary care strategies such as administration of anti-parasitic treatment or vitamins with vaccines.
 - Sustain investments in epidemiological and laboratory surveillance of VPDs in the context of COVID-19 and leverage resources and systems in place for COVID-19 to strengthen VPD surveillance systems.
 - Develop and implement social communication strategies to encourage the community to safely access vaccination services during the COVID-19 pandemic.
 - Engage local communities in the planning of immunization coverage recovery activities and preparation for the successful implementation of a COVID-19 vaccine when it becomes available.

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- TAG urges PAHO to investigate the reasons for the secular trend in the decline of immunization coverage in the Americas and to share the findings with TAG, with a view on developing a sustainable strategy to strengthen immunization services and improve VPD control, including their continued elimination from the Region.
- With regards to access to SARS-CoV-2 vaccines, TAG encourages PAHO, with support from Member States, to assume a leadership role in the global governance processes related to COVID-19 vaccine procurement, allocation, and delivery.
- TAG recognizes the value of the COVAX Facility and commends countries in the Americas for expressing their interest in being represented as a single bloc by PAHO's Revolving Fund.
- TAG recommends that the PAHO Secretariat provide a briefing to PAHO's Directing Council on COVID vaccine and COVAX Facility development, with a special emphasis on the unresolved pricing and governance issues that threaten the future role of the Revolving Fund.
- TAG urges PAHO to finalize a regional plan for COVID-19 vaccination 2020-21 and set up an internal coordination mechanism (including country representatives, where relevant) to ensure timely and effective technical cooperation to countries for COVID-19 vaccine introduction and implementation.
- TAG urges countries to develop national plans for the introduction of COVID-19 vaccines, engaging NITAGs, as early as possible, in the process.
- Understanding that strong national immunization programs are the foundation for the introduction of COVID-19 vaccines, TAG encourages countries to strengthen their cold chain capacity, information systems, and vaccine safety surveillance, among others. Countries should consider delivering other vaccines concurrently, where and if possible and appropriate, with COVID-19 vaccines (e.g., delivery of influenza and pneumococcal vaccines).
- TAG urges PAHO and countries to lay the groundwork for demand generation for COVID-19 vaccination through community engagement and exploring mapping stakeholders' perceptions around future COVID-19 vaccination. Given the current spread of misinformation, TAG encourages countries to begin planning and budgeting for demand generation activities before COVID-19 vaccines are available for deployment.

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