World Health Organization
REGIONAL OFFICE FOR Africa

Report of the Regional Immunization Technical Advisory Group

Virtual Meeting, 02-03 July 2020

Executive Summary

The Regional Immunization Technical Advisory Group (RITAG) for the WHO African Region, convened its semi-annual meeting on July 2-3, 2020, through a virtual zoom call. Overall more than 220 persons participated in the 2 days meeting. The meeting's main theme was around the pandemic of the Coronavirus disease 2019 (COVID-19) and its impact on immunization services. It also addressed the issue of the COVID-19 vaccine development and access for the region. As wild poliovirus eradication certification is achieved in the region, while there is a recrudescence of circulating vaccine-derived poliovirus (cVDPV) outbreaks, response to the outbreak's situation with the introduction of a novel oral polio vaccine was also discussed.

Updates on immunization in the context of COVID-19 in the region specifically focused on the impact of COVID-19 on routine immunization (RI), the guidance developed and implemented for immunization in the context of the pandemic, and the needs for sustaining communication and demand for immunization. Burkina Faso and Ghana provided firsthand experience with immunization in the context of the pandemic. A review of the COVID-19 vaccine development, licensing & regulation guidelines including the development of the vaccine pipeline was also provided, as well as an update on the COVID-19 advance market commitment and COVAX facility. The discussion concluded with the emergency use listing and regulatory approval pathway for the introduction of the novel oral polio vaccine 2 (nOPV2) in response to the increased occurrence of cVDPV2 outbreaks.

Following the discussions, RITAG members made opinions and key recommendations to address the issues noted.

For immunization in the context of COVID-19

RITAG members noted:

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a rapidly emerging and highly infectious virus that has spread throughout the world, including the WHO African Region. While the extent of damage caused by this coronavirus has not reached levels seen in other continents, the number of cases and deaths continue to rise, and there are challenges with weak health and surveillance systems and testing capabilities to document the true extent of infections in Africa. In addition, because many African countries are taking precautions that involve shutting down economic activities and public services, the collateral impact of the pandemic is extensive. In particular, such precautionary measures have affected essential services, including the availability of and access to RI services and supplementary immunization activities (SIAs). There are concerns, therefore, that while children who become infected with SARS-CoV-2 are generally less vulnerable to severe forms of COVID-19 disease, they may face life-threatening hunger, neglect, illness and death from non-COVID disease such as vaccine-preventable diseases (VPDs).

Consequently, national governments are struggling to coordinate COVID-19 response actions to contain the pandemic, reduce morbidity and mortality, and protect essential health services including immunization. Currently the tools to limit the spread of SARS-CoV-2 are limited to non-pharmaceutical interventions as we await the development of an effective vaccine against COVID-19. Countries are balancing the introduction of lockdown measures with the need to protect the national economy, employment, the social safety net, food supplies and other essential services.

The COVID-19 pandemic has also exacerbated long standing deficiencies in immunization service delivery. The national responses also reflect the differing rates of COVID-19 transmission, background health conditions, the availability and use of non-pharmaceutical interventions, and public health experience gained in earlier disease outbreaks. Given the probability that the pandemic will continue to generate significant COVID-19 morbidity and mortality in the WHO African Region well into 2021, plans for service resumption must focus on increasing resilience, adaptation, and the rapid sharing and promotion of best practices.

The COVID-19 pandemic has highlighted weaknesses in health systems in the WHO African Region and elsewhere including infrastructure such as water and sanitation facilities, adequate staffing levels and access to PPE. Against this backdrop, attention needs to be paid to health care workers' (HCW) increased vulnerability to acquiring COVID-19 and to burn out. Surveys have shown that inadequate infection control measures in health services including poor social distancing, inadequate screening of patients, and lack of adequate personal protective equipment (PPE) for HCWs, is creating fear among the public and making people reluctant to access health services including immunization.

For COVID-19 vaccine pipeline, update on COVID-19 advance market commitment and COVAX facility

RITAG welcomed the global rapid and dynamic approach to COVID-19 vaccine development suggesting that a safe and effective vaccine(s) could be available for introduction in 12-18 months instead of the traditional 5 to 10 years development process.

Global health organizations including WHO, Africa CDC, Gavi, CEPI and other stakeholders are developing strategies and partnerships to ensure global access and equitable distribution of vaccines assuming that they become available.

RITAG also welcomed the COVID-19 Advance Market Commitment and the newly established COVAX Facility aimed at ensuring equitable global access to a COVID-19 vaccine when one becomes available.

RITAG recommended that African research organizations, CSOs and participating communities should be more strongly engaged in the vaccine development process.

RITAG welcomed the announcement of two countries from East and Southern Africa (Kenya and South Africa) participating in COVID-19 vaccine clinical trials.

RITAG noted that despite concerted efforts by countries, with support of the Africa CDC, the African Academy of Science, WHO, National Public Health Institutions (NPHIs) and other country-level stakeholders, testing for SARS-CoV-2 has been limited because of the global shortage of testing kits, related laboratory consumables, and in-country expertise and infrastructure.

For polio eradication in the African Region, Emergency Use Listing and regulatory approval pathway for the introduction of nOPV2

RITAG congratulates the region on pending certification of eradication of all three types of wild polioviruses (August 2020).

RITAG is concerned by the growing numbers of cVDPV2 outbreaks in the region, increased since the switch to bOPV (initiated in 2016) due to: 1) low routine immunization coverage for type 2 containing vaccine, 2) declining mucosal P2 immunity due to switch to bOPV, 3) regional migration patterns, 4) low quality outbreak response, and 5) seeding due to mOPV2 use in outbreak response.

Recommendations

RITAG made the following recommendations.

Immunization in the context of COVID-19

1 National governments, with coordinated support from WHO, partner agencies and Civil Society Organizations (CSO), should urgently develop and implement tailored strategies and activities designed to resolve country-specific obstacles to the provision of Routine Immunization (RI) services, including remedial action to address pre-existing resource deficiencies in services, such as staff shortages, inadequate personal protective equipment (PPE) and infection control.

2 WHO should collect and share field experience on best practices in the implementation of tailored strategies for immunization service delivery in the context of COVID-19 as per the relevant WHO guidance, and identify practices which have not proven effective. WHO and partner agencies should support countries in organizing webinars, developing job aids and use other relevant platforms to ensure that all countries have access to this information.

3 WHO/AFRO should update guidance on integrated service delivery and, in coordination with partner agencies, support countries in resource mobilization efforts to allow integrated primary health care services including RI, SIAs and new vaccine introduction to be urgently re-established.

4 As a matter of priority, national governments, with coordinated support from partner agencies and CSOs, should urgently ensure the provision and maintenance of basic hygiene, infection control and safety measures and sufficient appropriate PPE for all HCWs and care-givers at fixed, outreach, mobile and SIA sites to reduce the risk of exposure and to help convince the public that health facilities are safe. PPE should also be made available for community mobilizers, grave diggers, and community health workers (CHWs) who assist with contact tracing, monitor self-isolation, and who identify individuals for catch-up of RI and SIA rounds.

5 National governments, with coordinated support from WHO, partner agencies and CSOs, should sustain regular reporting, monitoring and analysis of WHO-recommended VPD surveillance, coverage data and process indicators at national and sub-national levels to identify communities and regions where the supply of, and demand for, health services have been disrupted and risk of disease outbreaks exist.

6 Countries should identify innovative ways to implement micro-planning exercises employing the Reaching Every District/Child approach to expand population access and increase vaccination coverage through innovations such as the provision of additional immunization services 5 or 6 days per week, extended clinic opening hours and/or the scheduling of additional outreach services, including mobile services. These services should be tailored in urban and large volume centers. These services must be planned, communicated and organized with effective community participation so that every opportunity for integrated, convenient and reliable service delivery can be explored.

7 National governments should implement guidance to ensure uninterrupted supplies of vaccines and injection equipment at the peripheral level, with the support by WHO/AFRO and partner agencies. This should also address air-freight and local transport disruption, vaccine and injection equipment stock-outs and, where necessary, measures to increase vaccine storage capacity, as part of resiliency planning.

8 WHO/AFRO and UNICEF, with support from Gavi Alliance and other partner agencies, should provide timely technical orientation and advocate with Ministries of Health and NITAGs to incorporate the use of vials of multi-dose vaccines with fewer doses, specifically the use of 5-dose M/MR/MMR vials rather than 10-dose vials, as part of a broad recovery strategy to raise coverage, reduce wastage and avoid HCW reluctance to open a 10-dose vial, especially where session sizes are small.

9 National governments, with coordinated support from partner agencies and CSOs, should capitalize and leverage the technical capacity and available resources of the Global Polio Eradication Initiative (GPEI) and the Measles & Rubella Initiative (MRI) to strengthen VPD surveillance, upgrade logistics and supply efficiency, expand and maintain the cold chain, and share expertise and equipment to resolve disruption in immunization service delivery.

10 National governments, with coordinated support from partner agencies and CSOs, should train and equip HCWs, community health workers (CHWs) and community mobilizers to undertake interactive community consultations to listen to community concerns and to develop people-centered strategies to rebuild public trust in health services, especially immunization. Trusted local voices and communication channels should be engaged in this effort.

11 National governments should be supported by WHO, partner agencies, and CSOs to proactively monitor social and other media to learn what rumors and misinformation the public is hearing about COVID-19 and vaccines and how they respond to those messages, to develop and deliver effective communication and advocacy messaging.

COVID-19 vaccine pipeline, update on COVID-19 advance market commitment and COVAX facility

1. More research should be conducted through synergistic efforts of all relevant parties (WHO/AFRO, Africa CDC, AAS, NPHIs, national and other research institutes, academia, etc.) to obtain better epidemiological and immunological data through scaled up diagnostic testing and seroprevalence studies, aid the identification of all at-risk groups, determine the full extent of population morbidity and mortality that may inform prioritization for future vaccine use, and improve understanding of transmission patterns which are required to inform non-pharmacological interventions in the community.

2. Building on the success of timely regulatory and ethics approvals and oversight for clinical trials of Ebola vaccines, African Vaccines Regulatory Forum (AVAREF) should be prepared to offer rapid clinical trial review supported by rapid in-country review by relevant regulatory authorities.

3. WHO and partners should promote close collaboration between AVAREF, WHO/AFRO, Africa CDC, African Academy of Sciences and other relevant stakeholders to strengthen country-level capacity for review of COVID-19 vaccine clinical trials, vaccine licensure and subsequent vaccine introduction.

4. Vaccine manufacturers, sponsors and trial investigators should actively engage with country research institutions and policymakers to advocate for more vaccine trials to be undertaken in the region. This will produce clinical data in African populations, will allow communities and individuals to contribute to the global scientific effort and will support vaccine acceptance and demand.

5. Countries with support from WHO, UNICEF, partners and CSOs should ensure that advocacy, communication and planning for COVID-19 vaccines and immunization starts immediately at all levels to promote confidence in vaccine development, create vaccine demand, and lobby for equitable vaccine distribution to all suitable populations when it becomes available.

6. Countries must establish a COVID-19 vaccine working group or task force made up of all relevant stakeholders to identify and resolve all issues which can potentially affect availability and access including finance and delivery challenges when a COVID-19 vaccine becomes available.

7. Noting the speed with which vaccines are being developed, countries with technical assistance from WHO, partners and regulatory stakeholders should develop strategies for early monitoring and mitigation plans for potential COVID-19 vaccine adverse events that includes strengthening of pharmacovigilance in countries. This is essential because new COVID-19 vaccines will be given to hundreds of millions of recipients including older populations once a safe and effective vaccine becomes available.

Polio eradication in the African Region, Emergency Use Listing and regulatory approval pathway for the introduction of nOPV2

RITAG recommends the following:

1. Countries should continue to monitor how they can improve the quality of polio outbreak response in the evolving COVID-19 situation.

2. Countries, in consultation with partners, should consider integrated SIAs/outbreak responses whenever possible. WHO should review and update guidelines on integrated SIAs.

3. Countries should strengthen routine immunization with IPV to improve P2 immunity by introducing a second dose of IPV as recommended by SAGE.

4. Using the experience of AVAREF in facilitating approvals of vaccines, NRAs should be fully engaged in the EUL process and country approval pathway for nOPV2 to ensure timely implementation.

5. WHO should inform NITAGs and NRAs about nOPV2, the EUL process and implementation plans to facilitate regulatory decision-making and the programmatic advice required for the introduction of nOPV2.

6. Partners and countries should develop, fund, and implement communication plans to ensure acceptance of, and demand for, nOPV2 and other polio vaccines by communities.

7. Partners should ensure contingency plans are put in place and funded to deal with cVDPV2 outbreaks in the event of an nOPV2 failure.

8. Partners should provide strong support to countries to ensure adequate IPV stockpiles are in place to support the use of IPV in routine immunization services thus increasing population immunity against cVDPV.

9. Countries should continue to use existing polio programme platforms to support country response to COVID-19.

I. Opening Session

Opening remarks

The Regional Immunization Technical Advisory Group (RITAG) for the WHO African Region, convened its semi-annual meeting on July 2-3, 2020, through a virtual zoom call for half a day each day. More than 220 persons participated in the meeting on the first day and over 200 participated on the second day.

Professor Helen Rees, RITAG chair opened the meeting on July 2nd 14:00 Brazzaville time. She acknowledged the participation of Dr Matshidiso Moeti, Regional Director for the WHO African Region, and invited Helena O'Malley host of the meeting to make a roll call of the RITAG members who briefly introduced themselves. RITAG members in attendance were: William Brieger, Ekoe Tetanye Ekoe, Rose Kambarami, Haroon Saloojee, Folake Olayinka, Ifedayo Adetifa, Robert Linkins, Ijeaoma Edoka, Richard Adegbola, Robin Biellik. Following the introduction of the RITAG members, Professor Rees welcomed the audience and presented the three priorities of the agenda. The first priority is the impact of the Coronavirus disease 2019 (COVID-19) on routine immunization (RI) as modeling shows that stopping RI will increase morbidity and mortality of vaccine preventable disease beyond COVID-19; the second priority is the impact COVID-19 on polio which is equally concerning as polio is still an emergency public health issue in the region; the third priority is about the development of COVID-19 vaccine(s) and raising the issue of access for the African Region. She then proceeded to invite Dr Moeti to make her remarks.

Dr Moeti highlighted the focus of the meeting which is immunization in the context of COVID-19 and the vaccines development licensing for COVID-19 as well as concern for polio. She pointed to the unravelling of many essential health services during the pandemic that is threatening the gains made in routine immunization in the region over the past years. Millions of children will be missing doses of vaccinations including measles, meningitis, cholera, polio, and HPV because of the disruption of immunization service due to COVID-19. However, she said, in the region a group has started working on sustaining essential health services and needs ideas on how to resume catch up and routine immunization for children as well as other essential health services without exacerbating the spread of COVID-19. She congratulated South Africa for launching the development of a COVID-19 vaccine and stated her hope that other countries will follow suit. She continued by pointing the need to ensure that COVID-19 vaccines as well as other lifesaving vaccines reach Africa and that no one is left behind.

Despite the current challenges, there is progress and signs of hope in the region. Dr Moeti highlighted the end of the almost-two-year Ebola outbreak in the Democratic Republic of the Congo and the polio free documentation of the last four countries in the region paving the way for regional certification of wild poliovirus. She pointed out that through the polio programme, a capable workforce was built and implemented best practices and innovation that can be maximized to benefit other health priorities. However, she acknowledged the increasing occurrence of cVDPV-2 outbreaks in the region and the need to maintain strong surveillance, improve immunization coverage, introduce nOPV2 and implement effective emergency response.

Dr Moeti requested RITAG's advice on:

- Creative ways to rapidly interrupt cVDPV-2 outbreaks in the region.
- How to ensure that gains made from the polio programme are maximized (capable workforce, best practices and innovations) to benefit other public health priorities.
- How to protect populations from vaccine-preventable diseases, including sustaining the momentum of the 2017 Addis Ababa Declaration on Immunization even in the context of the COVID-19 pandemic.
- Guidance to enhance integration and cross-cutting approaches to strengthen health systems, which, in the long-run, is key to sustaining regional immunization targets and enabling better health and well-being.
- How to raise the voice for equity to access for COVID-19 vaccine(s) and therapeutics for Africa as they become available.

She concluded by reiterating the importance of equity to access for vaccines and therapeutics in the region as well as protecting populations from VPDs in the context of COVID-19.

Professor Rees thanked Dr Moeti for her important remarks and welcomed NITAG chairs in the region who joined the call. She then invited Dr Joachim Hombach who reported on the conclusions and recommendations on the SAGE meeting held virtually March 31-April 1st.

Highlights from March 2020 SAGE meeting

Dr Hombach focused his presentation on the reports from the Director of Immunization, Vaccines and Biologicals (IVB) at WHO, and items discussed during the SAGE meeting. Items on the SAGE agenda included the modelling of COVID-19 epidemiology and status of COVID-19 vaccine development; measles outbreak epidemiology and WHO coordination; poliovirus; Ebola virus vaccines; Immunization Agenda 2030 – monitoring, evaluation and action framework; and the Global Vaccine Safety Blueprint 2.0. In their conclusions, SAGE members stressed the critical need to safeguard immunization services during the pandemic, and plan for catch-up immunization activities; the vital need to protect health workers; the importance for vaccine evaluation to address the needs of low- and middle-income countries, looking at specific concerns and requirements in high risk populations (HIV, Tuberculosis, malnutrition); and called for setting up a SAGE Working Group on COVID-19 vaccination. They recognized that measles is central to IA2030 and will come up for discussion at the next SAGE meeting. They also recommended a comprehensive review of the recent experience of Ebola virus vaccine implementation and policy development during an outbreak response in order to inform future processes for the development of recommendations, the use, and the monitoring of un-licensed vaccines in emergency and outbreak response situations.

Of the items discussed, the members made recommendations for the following items:

Poliovirus

- SAGE endorsed in principle the framework for initial-use criteria under Emergency Use Listing (EUL) of nOPV2 as presented and recommended by the SAGE Polio Working Group.
- SAGE agreed to maintain the existing SAGE recommendations for prioritization of the available IPV supply for 2020: (1) Introduction of one dose into routine immunization, (2) Catch-up of missed children due to delayed introduction, (3) Supplemental Immunization Activities for endemic countries and high-risk areas, based on risk assessments, and (4) Introduction of a second dose of IPV into routine immunization. In 2021, the introduction of a second dose of IPV into routine immunization will become the 3rd priority before SIAs in endemic countries.
- SAGE recommended that tOPV be made available to countries for cVDPV2 outbreak response in subnational areas where there is co-circulation or high risk of co-circulation of cVDPV2 with cVDPV1, cVDPV3 or WPV1 in order to avoid the need to conduct dual mOPV2 and bOPV campaigns.
- SAGE expressed the need for regions or countries to be cautious about moving from a bOPV + IPV schedule to an IPV-only schedule in their routine immunization programmes and recommended that instead they take a gradual approach, by first introducing a second dose of IPV into their routine immunization schedules.

Global Vaccine Safety Blueprint 2.0

- SAGE acknowledged the significant progress made since 2012 in strengthening the capacity of all countries through implementation of the Global Vaccine Safety Blueprint 1.0 and for which the Global Vaccine Safety Initiative (GVSI) was critical.
- SAGE expressed appreciation for the work on the Global Vaccine Safety Blueprint 2.0, proposed additional areas for inclusion and strengthening and then endorsed the document.

II. Immunization in the Context of Covid-19

COVID-19 impact on immunization and surveillance in the African Region

Dr Richard Mihigo, Vaccine Preventable Disease (VPD) coordinator at WHO/AFRO set the stage with a presentation on COVID-19 impact on immunization and surveillance in the African Region. He noted that several personnel were repurposed for the response to COVID-19 including himself. He continued by giving a picture of the COVID-19 situation in the African region, described the impact of the pandemic on immunization services and vaccine preventable disease surveillance in the region and ended with the prospects moving forward.

As of July 1st, there were more than 400,000 cases of COVID-19 and 10,000 deaths in region representing a case fatality rate of 2.5%. However, the cases are unequally distributed across the region with the southern part having the highest burden and the country of South Africa reporting close to 45% of all cases. The second highest burden in the region is seen in West Africa with Nigeria, Ghana, Senegal and Cote d'Ivoire reporting most of the cases. Also, of note, almost 60% of COVID-19 cases are below 45 years of age while 55% of deaths are 61 years of age and above.

The concern of the fast increase of cases in the region was raised. The region is reporting a daily growth of about 6% and doubling time of 12 days and most countries in the region (30/47) have now established sustained community transmission (*Figure 1*).

WHO, UNICEF, Gavi, in collaboration with CDC, the Boost Initiative at the Sabin Vaccine Institute and the International Vaccine Access Center at John Hopkins led an Immunization Pulse poll conducted in May 2020 which included 281 respondents from 82 countries/territories. The results of the survey showed that routine immunization services (outreach 72%, facility based 62%) were among the top essential health services partially or completed disrupted due to COVID-19.

FIGURE 1: ***COVID-19 cases, projections and transmission patterns in the African Region***

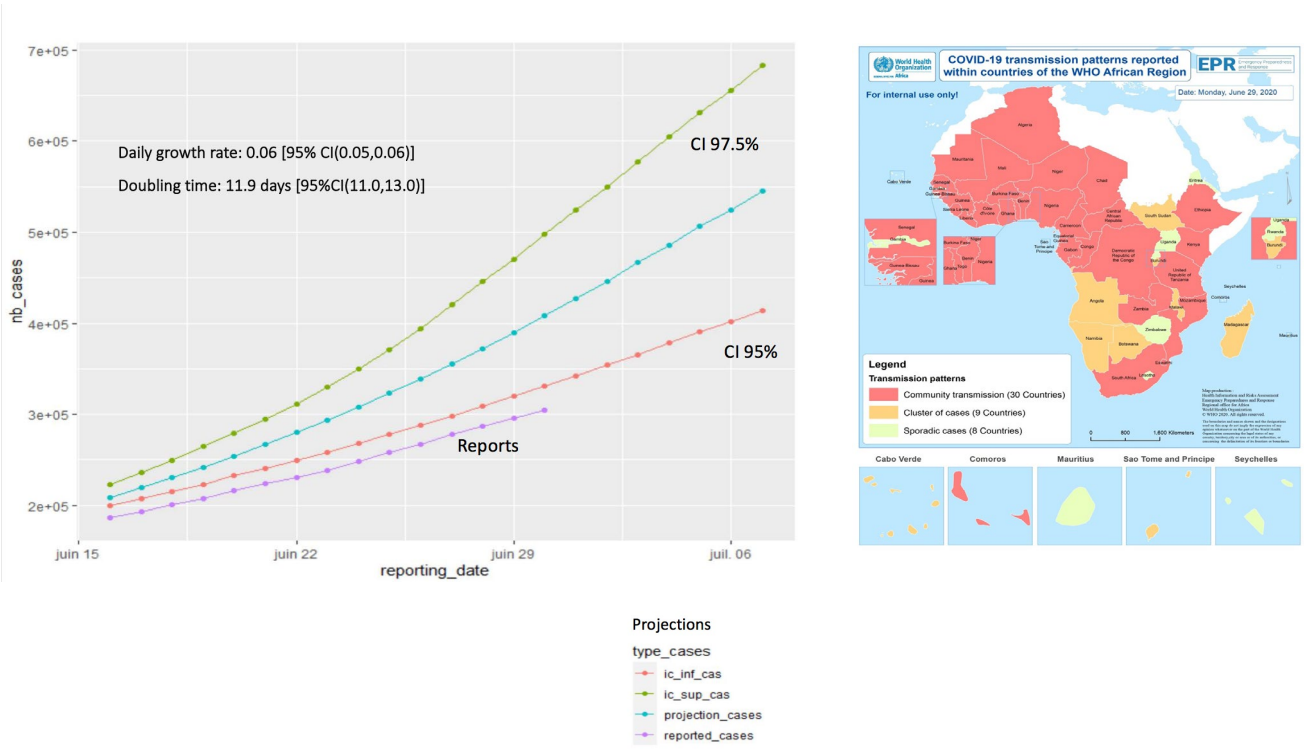
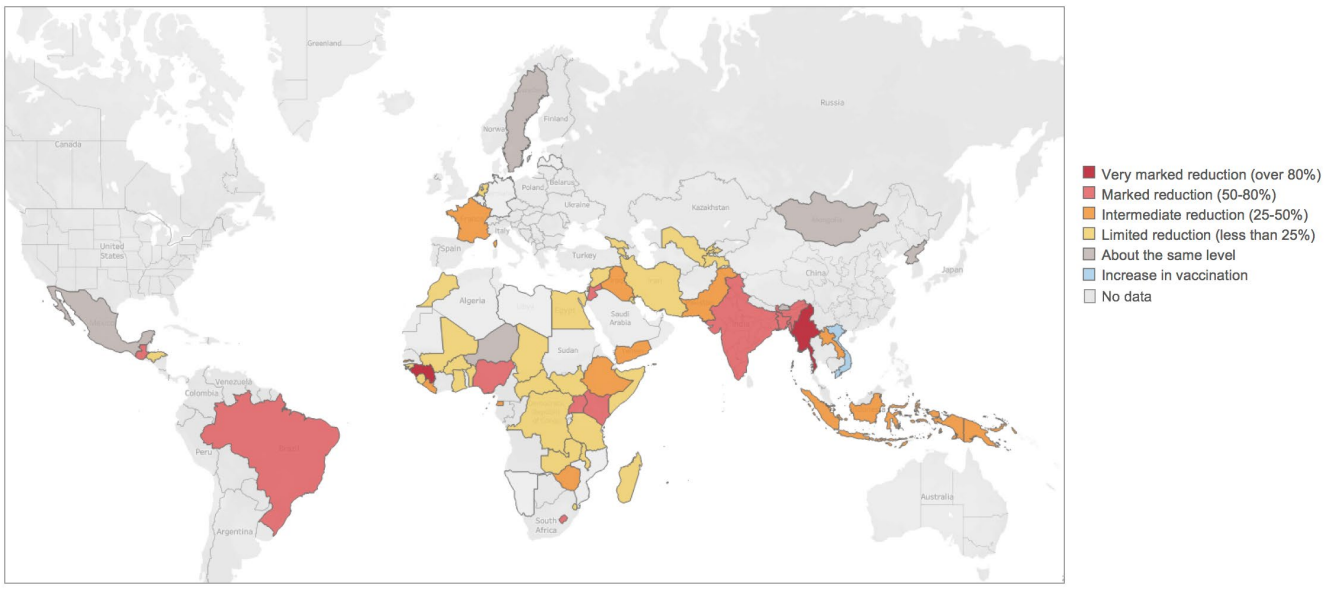


FIGURE 2: ***Reported changes to the current level of vaccination services in May 2020 since January-February 2020***



Source: Immunization Pulse Poll 2. Question 16, National respondents only. Analysis shows average response of all national level respondents within a particular country. The data collected are subject to limitations inherent to voluntary self-reporting, self-selection bias, not all countries responded, countries with only one response vis-à-vis countries with many, possibility of fraudulent responses and not having a sampling frame to make inferences. Furthermore, the information about each country does not represent official reporting from Member States to WHO or UNICEF. Thus, the results presented here need to be interpreted with caution and do not represent in any way a WHO or UNICEF position regarding any country or territory for which one or more replies were received.

In addition to service disruption, demand for service was also disrupted (82%) mainly due to false rumors about the COVID-19 vaccine. More than 50 campaigns, sixty percent of which were polio campaigns, were fully or partially postponed in the region.

Among the most urgent information needs and challenges in the context of the pandemic, countries expressed infection prevention and control (62%), how to continue /resume routine immunization activities (59%) and vaccine demand/ hesitancy (41%) as their top three needs or challenges. In terms of support countries would like to receive to address these needs and challenges, webinars (69%) platform was the top need followed by technical support for production of job aids (67%) and case studies to share lessons learned (46%).

Regarding vaccine preventable disease case-based surveillance, the region has seen a dramatic drop in cases and specimen collection for measles and acute flaccid paralysis (AFP) as well as a decrease in rotavirus and paediatric bacterial meningitis cases in sentinel sites. There was 20% decrease in the proportion of districts reporting suspected measles cases compared to the same time period in 2010, while specimen collection decreased by 27% *(Table 1*).

As for the way forward, the region will continue to track the impact of COVID-19 on immunization programmes. This will include support to countries in implementing guidance and guiding case by case adjustments when needed; identifying good (and bad) practices from the field; supporting planning, supply availability and resource mobilization for resumption of services and catch up activities; and discussing 're-engineering' of immunization in the post COVID-19 period.

TABLE 1: ***COVID-19 impact on measles case reports and specimen collection in the African Region***

Year (epidemiological weeks 1-23)	Suspected measles cases	Specimens collected for serological testing	% districts reporting suspected cases (epi weeks 1-23)
2018	47,895	40,744	86%
2019	126,291	28,443	71%
2020	41,435	20,773	57%

WHO guidance for immunization in the context of COVID-19

Dr Balcha Masresha (WHO/AFRO), started his presentation by recognizing the essential role of immunization as the region is already grappling with the risk of outbreaks of VPDs in many countries and the fragility of the gains made to date. For example, there was an increase in the number of susceptible children that lingered for up to 3-4 years due to disruption of services during the West African Ebola outbreak. It's anticipated that COVID-19 pandemic will have a negative impact on the immunization coverage in the region as there is already data showing declines in the number of children vaccinated. Around 1.5 million children have missed their first dose of measles vaccine in the first quarter of the year as compared to the same period last year.

Since the beginning of the outbreak, WHO has developed guidelines at the global level and regional level (*Figure 3*). The focus of these guideline is to ensure that countries prioritize essential services based on their own contexts, optimize service delivery platforms and health worker capacity, and ensure the establishment of the safe flow of clients assuring the availability of supplies. There is a need to identify those essential services and those essential supplies to sustain the services and make sure that they are made available through the supply chain until the peripheral level, monitoring how much services have been affected and finally providing the right information to communities.

These global guidance documents were developed at different times and adapted at the regional level based on specific operational components, and subsequently adapted to the local context at the country level. Those guidelines also ensure that beyond the continuity of routine services countries put together recovery plans to catch up on missed doses as soon as possible. Currently, there are global guidelines under development to address screening of vaccine recipients and companions and standards for PPE use.

Another part of the global and regional guidance addresses conducting outbreak and preventive vaccination campaigns and activities based on a risk benefit analysis. This analysis takes into consideration the impact of mass vaccination on the VPD burden, the public health impact of not conducting a mass vaccination campaign, the country capacity to implement a high-quality SIA, the strength of community engagement and the potential risk of increased COVID-19 transmission associated with the mass vaccination campaign.

Of note, the Africa Regional Office is documenting the implementation of some of these guidelines and best practices. This documentation will be shared with countries and partners when finalized.

FIGURE 3: ***WHO guidelines on essential services, including immunization, in the context of COVID-19 (March-June 2020)***

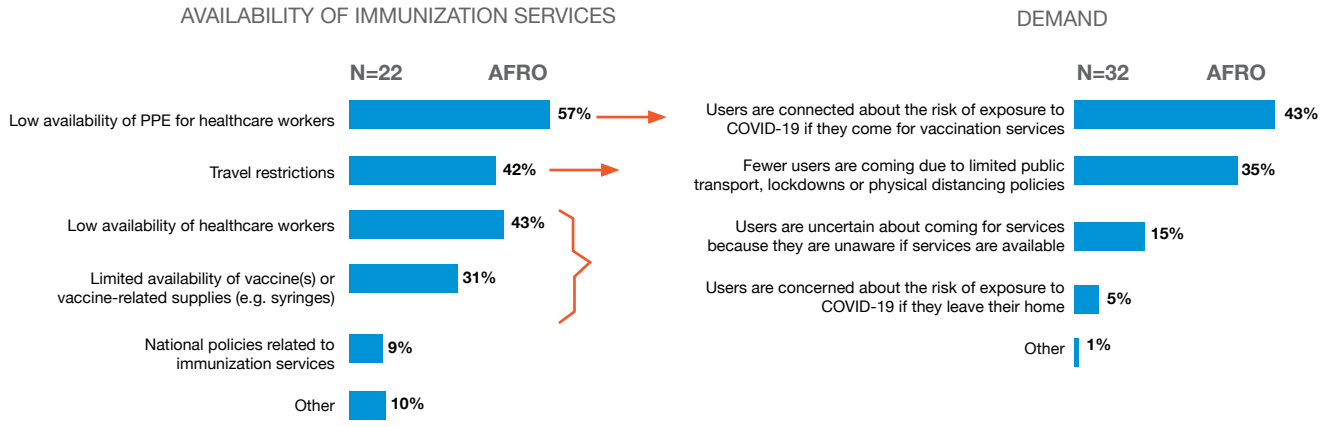
Sustaining communications & demand for immunization during COVID-19

Ms. Helena Ballester (UNICEF) followed up with Dr Mihigo's mention of demand disruption of both fixed and outreach vaccination activities from the Immunization Pulse poll of May 2020 and reiterated the importance of sustaining demand during the pandemic. She pointed out that of the 34 countries in the African Region which responded to the survey, all reported disruptions in services in fixed post, outreach or both vaccination services while 29 reported disruptions in demand. She highlighted that Malawi, Mauritius, Niger, South Sudan and Zambia did not report disruptions in demand for vaccination services and that in Malawi and Niger both fixed post and outreach vaccination services remained also at a relatively high level (75% in both fixed and outreach for Malawi and 100% in fixed and 80% in outreach for Niger). However, for South Sudan and Zambia there is a need to look more in depth as disruptions in outreach services are significant in both countries.

Since the beginning of the pandemic several assessments, polls, key informal interviews, focus group discussions and other anectodical evidence are helping to better understand the reasons behind the current drop of immunization. Some of the COVID response measures may ignite feelings of mistrust and stigmatization that need to be understood and considered when planning interventions.

The Immunization Pulse Poll shows a parallelism between the reasons for reported disruptions in availability of immunization services and those reported in disruptions on demand. For example, where there is low availability of PPE for health care workers, users are concerned about the risk of exposure to COVID-19 if they come for vaccination services (*Figure 4*).

FIGURE 4: ***Reasons for reported disruptions in immunization services***



Pulse poll, May 2020: Respondents from 82 countries/territories. MoH, WHO, UNICEF, Gavi, HF, NGOs/faith-based organizations, NITAGs.

Assessment and polls or other data collection on factors that are enabling or hindering health services uptake in several countries have shown similarities. For example, in Zimbabwe the four top reasons for not seeking treatment for non COVID-19 related health services were 1) fear of contracting COVID-19; 2) lack of money or financial resources (lack of income generation due to closure); 3) no availability of transport (restriction of movement); 4) lack of PPE. While in Uganda, the first reason for not accessing immunization services is lack of transport followed by the lack of immunization services in the community, fear, closure of health facilities and lack of health care workers. In Nairobi, Kenya, reasons for forgoing health services in informal settlements included cost of services, fear of getting infected with COVID-19, closures of clinics and stigmatization (e.g. people will think I have COVID-19 if I attend). In Kinshasa, DRC, a similar assessment found that lack of finances was the top reason for not utilizing health services, followed by limited access to transportation and people will think I have COVID-19.

Common factors that impact the demand for immunization are related to 1) the side effects of preventive measures including the non-availability of transport, curfews, lockdowns and lack of financial means 2) the disruption of service delivery including lack of personal protective equipment and 3) social and behavioral science communication including fear of infection, fear of being arrested, stigma of being seen as a COVID-19 patient, misinformation and disinformation.

It is noted that enforcement of COVID-19 control measures may result in mistrust of authorities with possible longer-term impacts on trust in the benefits of vaccination.

Reinforcing or re-establishing public trust in vaccination and other health related services is essential and to do so there is a need to 1) invest in collecting data through routine systems as well as social listening online and offline in order to understand how caregivers and frontline workers feel and think in order to overcome assumptions 2) reinforce community engagement and feedback mechanisms to codevelop tailored interventions and 3) equip and support service providers and social mobilizers to deliver people-centered and quality services.

Routine immunization services during COVID-19: country experiences

Burkina Faso and Ghana were invited to share their experiences with immunization services during COVID-19.

BURKINA FASO:

Dr Issa Ouédraogo, EPI manager, reported that vaccination services were not significantly interrupted in health centers despite the context of COVID-19, though existing underlying challenges affecting the EPI program such as insecurity and insufficient operational vehicles for transport persisted. Some key activities such polio campaigns and support supervisions were postponed. Vaccine supply was delayed due to closure of borders and staff were quickly reoriented to COVID-19 response. He mentioned that negative rumors about COVID-19 vaccine(s) being tested in Africa generated some mistrust about vaccination. There was a slight drop in vaccine coverage of all antigens, particularly in March, but because of the resilience measures that the country has taken and the relaxing of restrictions measures, the coverage is increasing. Several pockets of measles outbreaks occurred since the beginning of the year and were controlled by immediate reactive campaigns conducted using appropriate PPE and infection control measures.

Some of the measures the country has taken to limit the spread of COVID-19 during immunization include the wide dissemination of the guidelines for vaccination in the context of COVID-19 to health officers at all levels of the sanitary system. Measures also included the development of a vaccination resilience plan in the context of COVID, the installation of handwashing devices near vaccination sites in large centers; the establishment of a weekly vaccination data collection in major vaccination sites (more than 50 children usually vaccinated per session), especially in urban areas; and organizing mothers in small groups for vaccination sessions while respecting social distancing measures. Other measures included immunization upon arrival and individual counseling of mothers, increase of the number of sessions per week in large centers, education and sensitization of mothers to complete vaccination safely through the wearing of masks and systematic hand washing at the entrance to the vaccination site.

GHANA

Dr Kwame Amponsa-Achiano, EPI Manager reported that the pandemic has disrupted immunization service delivery and overstretched the health system in Ghana. Service delivery was initially impacted by lockdown in major cities and restricted movement in all other parts of the country as well as decrease of public transport and re-assignment of staff to COVID response. Vaccination sessions dropped for both fixed and outreach, and reactive and preventive vaccination campaigns were suspended. Vaccine stocks are depleted and need to be replenished for most antigens by the third quarter. A decrease on the demand for services was also noted due to fear among caregivers and restriction in movement. He noted that there is strong leadership in the response to COVID-19 with the President coordinating all strategic decisions and actions related to limiting the spread of COVID and regularly addressing the country.

Efforts to sustain essential health services during COVID-19 include sustained coordination mechanisms by MOH/GHS, WHO and UNICEF; movement authorization to essential staff including EPI, MOH and Partners; virtual meetings with key staff at the periphery to understand challenges faced and better plan for them; supply of PPEs and hand sanitizer for routine/essential health services; development and dissemination of guidelines for continuity of child health services (Figure 6) and use of medical drones to supply vaccines in situations where means of transport was not readily available.

As the COVID situation improves, there are plans for intensifying service delivery including conducting social mobilization and demand generation activities nationwide; performing a desk review to identify most affected regions and districts and provide targeted support; conducting nationwide mop-up to 'catch-up' on all children who were missed using the WHO Catch-Up Policy as a guide; re-activating all outreach sessions and opening up additional outreach points; and actively involving community leaders in the planning, implementation and evaluation of post-COVID mop-up activities.

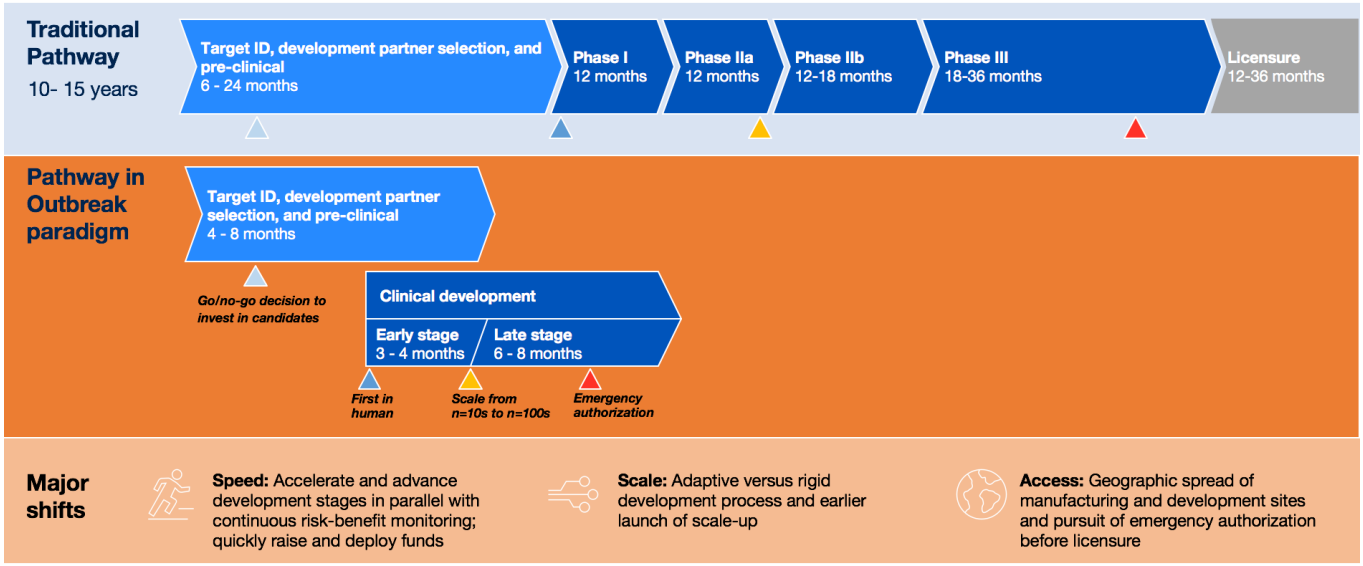
III. Vaccine Development, Licensing & Regulation

Vaccine pipeline for COVID-19

Prof Dicky Akanmori (WHO/AFRO) presented three themes: the vaccines pipeline, the accessibility to vaccines and vaccine implementation. He explained the pipeline of COVID-19 vaccine candidates and access issues noting the normal research and development process of novel vaccines and the current expedited speed and process under pandemic situation (*Figure 5*). He mentioned that 18 vaccine candidates are under clinical evaluation. Two of the vaccine trials are planned to be conducted in Kenya and South Africa which have strong and good regulatory and ethical review systems and oversights on clinical trials.

He highlighted how African Vaccines Regulatory Forum (AVAREF) is operating to expedite the review process of clinical trial applications. Then, he presented issues on access to COVID-19 tools as well as vaccines. He presented the Access to COVID-19 Tools (ACT) Accelerator to improve the access and the "global allocation framework" to expedite the control of COVID-19 products. He argued that prioritization of initial product allocation should be made for threat level and vulnerability.

FIGURE 5: ***Traditional and outbreak pathways for vaccine development***



Learning from the lessons of the Ebola outbreak in West Africa when a vaccine was only made available towards the tail end of the epidemic, efforts are being made to ensure that the development of the COVID-19 vaccine continues at an unprecedented pace. Quick decisions, overlapping trial stages are shortening times in development, without compromising safety and efficacy assessments.

Developers have put mechanisms in place to scale-up production as soon as a vaccine is proven effective. Also, there is close collaboration of manufacturers, organizations, institutions and governments to work for COVID-19 vaccine clinical development. The COVID-19 Vaccine Global Access (COVAX) Facility enables global collaboration and equitable access to vaccines. The objectives of the COVAX Facility are to secure supply rapidly through resilient scale-up of manufacturing and reduce uncertainty and lack of predictability of demand and financing as a barrier to manufacturing expansion.

Development of different vaccine platforms developing vaccines are in progress. The nearly 200 candidate vaccines in development include vector, inactivated, live attenuated, protein sub-units, and nucleic acid. In Africa, the first African COVID-19 vaccine study has started in South Africa and is a Phase 2 study of 2000 participants evaluating the CHADOx1 nCOV2 developed by University of Oxford/AstraZeneca.

AVAREF, representing all Ethics and Regulatory Committees, harmonizes their processes to facilitate clinical trials in Africa. AVAREF utilizes a Joint Review model with the regulatory authorities of countries in which clinical trials are proposed. AVAREF has also developed an action plan to address COVID-19 that includes endorsement for guidelines for clinical trial review that sets a timeline for 15 days for a novel COVID-19 vaccine.

The Access to COVID-19 Tools (ACT) Accelerator is a global collaboration to accelerate the development, production and equitable access to new COVID-19 diagnostics, therapeutics and vaccines. There are three pillars addressing each of these technologies with the vaccine pillar being coordinated by Gavi, CEPI and WHO.

A component of the vaccine pillar is the Global Allocation Framework which aims to ensure equitable and sequential allocation to all countries increasing with time and managing constraints and uncertainties. The framework includes goals, priorities and timings that will ensure all countries receive initial allocation of COVID-19 products and those most at risk are prioritized.

On vaccine implementation, lessons learnt from other epidemics will help for better implementation. The ACT Accelerator together with SAGE have established mechanisms to prioritize vaccine use, to equitably divide vaccines between countries, and to give guidance to countries about vaccine introduction. The guidance being developed covers vaccine shipments, surveillance data collection and use, and strengthening regional coordination and guidance advice from RITAGs and NITAGs.

As all the candidate vaccines are being developed at speed, there is less time to follow up study participants for safety concerns. For this reason, vaccine safety monitoring by strengthened pharmacovigilance systems and in some cases with formal Phase 4 protocols, will be very critical. Also key is identifying gaps, building capacity, ensuring collaboration, engaging national AEFI committees and ensuring mechanisms for active AESI surveillance.

Update on COVID-19 advance market commitment and COVAX facility

Dr Santiago Conrnejo explained the recent development of the COVID-19 Vaccine Global Access (COVAX) Facility Global Coordination Mechanism and future plans to accelerate the access to vaccines based on WHO allocation guidelines.

The ACT Accelerator provides cross cutting pillars (therapeutics, diagnostics, vaccines), while the COVAX pillar has three pillars: 'Development and Manufacturing' which is led by CEPI, 'Procurement and Delivery' led by GAVI, and 'Policy and Allocation' led by WHO *(Figure 6)*.

The national and regional priorities would create competition and uncertainty leading to inequitable access to selected successful candidates. Countries without resources would be left beheld also including middle income countries. This can also lead to inappropriate allocation of resources.

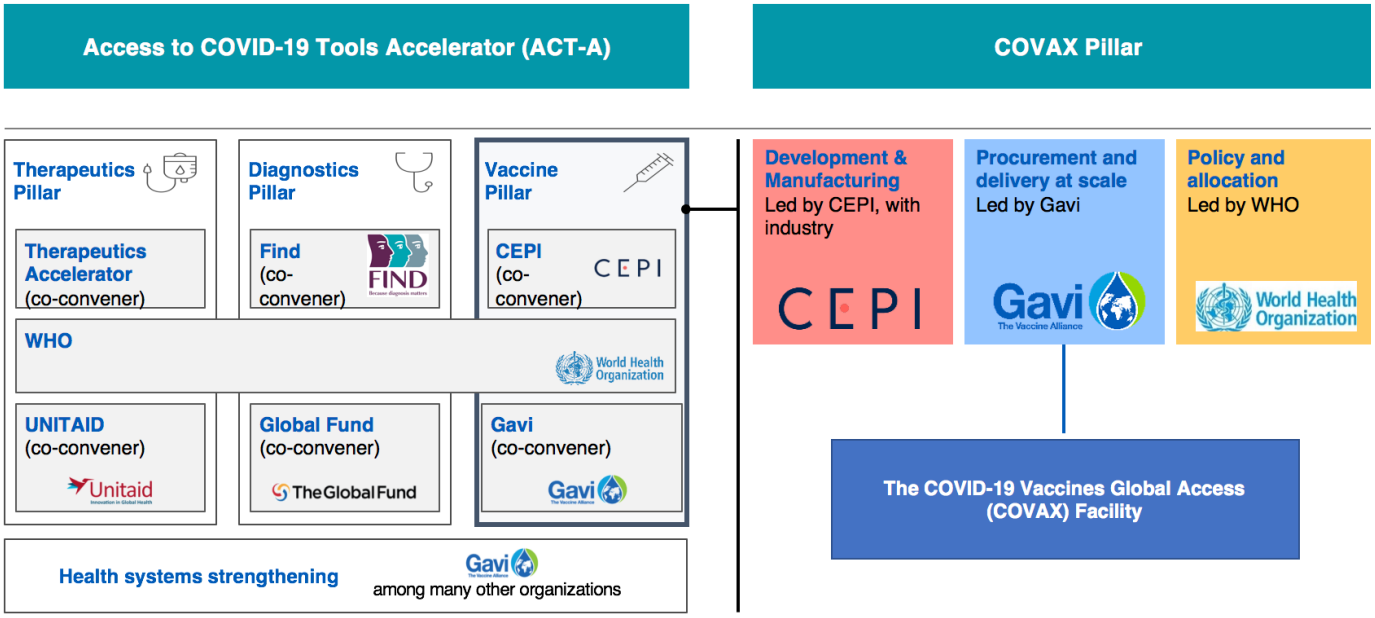
The COVAX Facility would ensure global coordination mechanisms for financing and procurement, securing supply, scale-up of manufacturing and reducing uncertainties. It is a risk-reducing mechanisms for countries and manufacturers. All countries are invited to participate and will receive access to the vaccines based on WHO allocation guidelines.

The Gavi COVAX AMC is an innovative finance instrument within the COVAX Facility to secure access to vaccines specifically for low income, lower middle income (LMIC), and International Development Association (IDA)-eligible economies. The eligibility criteria are yet to be defined.

Donors will contribute on behalf of countries eligible for AMCs and for those not eligible they will make contributions by self-financing. The COVAX Facility would pool commitments from countries that would be leveraged to make supply arrangements. Once a vaccine is proven successful and approved, doses will be available for AMC and self-financing countries through the established supply mechanism. AMC has already raised 500 million USD and aims to raise 2 billion USD to finance LMIC.

Working with all stakeholders, letters were sent to all self-financing and donor funded countries. Non-binding expression of interest by countries is required. AMC eligibility would be decided by the GAVI board by 31st July. The AMC countries would also be provided additional support beyond the vaccine support for which countries can apply through the GAVI processes.

FIGURE 6: ***The COVAX pillar: Accelerating fair and equitable access to vaccines at scale***



Polio eradication in the African Region: WPV & VDPV update

Dr Pascal Mkanda (WHO/AFRO) highlighted the progress, remaining challenges, and potential role of a new vaccine, nOPV2 to contain the outbreaks of cVDPV. He explained the past efforts to eradicate the poliovirus and the strategies for the introduction of the new oral polio vaccine.

The last case of wild poliovirus type 2 was found in 1999 and the global certification of the eradication of polio type 2 was in 2015. The last wild poliovirus type 3 case was found in 2012 and the global certification of eradication of polio type 3 was in 2019. The last wild poliovirus type 1 case was found in 2016 and the wild poliovirus free status of all 47 countries in the African Region was declared in June 2020. The African Region will be certified for eradication of all three types of wild polioviruses in August 2020.

Outbreaks of cVDPV2 continue to occur in the African Region. These are resulting from the withdrawal of tOPV in 2016 resulting in declining mucosal immunity levels to the type 2 virus. The number of countries with cVDPV outbreaks increased from 4 in 2018 to 14 countries in 2020. The main reasons of increasing occurrence of cVDPV2 outbreaks are insufficient routine immunization coverage in some areas, regional population migration patterns, low-quality outbreak response campaigns, and use of monovalent OPV type 2 (mOPV2) in outbreak responses.

Estimates indicate a 75% reduction in the incidence of cVDPV2 following two SIAs for mOPV2 (95% CI 66%- 81%). Five countries (Burkina Faso, Cameroon, Chad, Côte d'Ivoire and Ethiopia) are at a highest risk for cVDPV2 outbreaks, followed by other countries at risk including Algeria, Angola, Benin, Botswana, Burundi, CAR, Congo, DRC, Equatorial Guinea, Eritrea, Gabon, Ghana, Kenya, Liberia, Malawi, Mali, Mozambique, Namibia, Niger, Nigeria, Rwanda, South Sudan, Tanzania, Togo, Uganda, Zambia and, Zimbabwe.

Regarding the introduction of nOPV2, a qualitative assessment of frontline workers, caregivers, and influencers was conducted in Nigeria, the Democratic Republic of Congo, and Kenya in early 2020. Findings from the assessments are used to streamline the nOPV2 introduction.

The use of nOPV2 in three countries in Africa will be implemented by September 2020 following Emergency Use Listing (EUL) by July 2020. The final EUL will be done in December 2020.

Emergency Use Listing and regulatory approval pathway for the introduction of nOPV2

Dr Diadie Maiga (WHO/AFRO) presented the importance of strengthening regulatory systems of countries to ensure the quality and safety of health products. He highlighted the WHO Prequalification concept and then explained how Emergency Use Listing (EUL) was developed to expedite the regulatory approval process in the context of public health emergencies such as Ebola outbreaks. He highlighted the EUL procedure and timeline for the nOPV2 vaccine (Table 2) explaining that the use of nOPV2 in 3 countries in Africa will be implemented by September 2020 following EUL by July 2020. The final EUL will be done in December 2020.

TABLE 2: ***EUL procedure for nOPV 2 vaccines***

ACTIVITIES	STATUS
1. Discussion on quality, safety and efficacy with manufacturers and developers	November 2018, May 2019
2. Roadmap: Visit the WHO website for more	January 2020
3. Establishment of assessment platform	
3.1 Roster of experts	✓
3.2 Consensus on requirements and essential data requirements	✓
4. Preparations for the assessment	
4.1 Receipt of first package of information	28 February 2020
4.2 Joint inspection	February 2020
4.3 Meeting of the evaluation and advisory committee: NRA of impacted countries	9 -13 March 2020
4.4 Testing	Q2/Q3 discussion NRA
5. Assessment of preliminary data and interim recommendation	Q2-Q3/2020
6. Assessment of complete data and final decision	Q3-Q4/2020

The full prequalification assessment process includes three key components. These components are: 1) the review of production process and quality control procedures; 2) laboratory testing and 3) WHO site audit of manufacturing facilities with the responsible National Regulatory Authority.

The EUL procedure was developed following the 2014 West African Ebola outbreak, to expedite availability of medical products needed in public health emergencies. The EUL is not a prequalification, it is a time-limited procedure based on eligibility criteria, a set of quality, safety, and efficacy data, and benefit-risk assessment. Inclusion in the EUL should not compromise the clinical development of the product.

WHO will support the National Regulatory Authorities (NRAs) of high priority impacted countries to review and to approve nOPV2 for use. WHO/AVAREF will support the countries to meet emergency timelines for regulatory review and approval of nOPV2.

World Health Organization

REGIONAL OFFICE FOR Africa