Report of the

REGIONAL IMMUNIZATION TECHNICAL ADVISORY GROUP MEETING

December 2017
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## Introduction

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## RITAG Members
Executive Summary

The second 2017 meeting of the Regional Immunization Technical Advisory Group (RITAG), the principal advisory group to the WHO Regional Office for Africa took place at the Protea Balalaika Hotel Sandton, in Johannesburg, South Africa, on 5–7 December 2017. The meeting focused on progress towards regional immunization goals, maternal & neonatal tetanus elimination, polio eradication & end-game strategy, challenges facing middle-income countries, cholera control and immunization research in the African Region.

The annual progress report on immunization in the African Region highlighted some progress in 2017 but concluded that much remains to be done if regional 2020 immunization targets are to be met. The ten countries that collectively account for 80% of under-immunized children present a particular challenge. Furthermore, national data can mask significant variation in vaccination coverage within countries, highlighting the need to map and respond to variation in service provision at a more granular subnational level.

Despite commitments made in the Addis Declaration on Immunization, and although some countries have invested significantly in new vaccine introductions, the proportion of countries supporting financially their immunization programmes wholly or mostly through domestic resources remains virtually unchanged since the previous year. With external funding declining as the Global Polio Eradication Initiative (GPEI) winds down and countries transition out of Gavi support, it is increasingly important that countries honour their investment commitments, and explore the use of innovative approaches to boost domestic funding.

The mid-term review of the Regional Strategic Plan for Immunization, carried out by an independent expert panel, was presented to the RITAG meeting. The Regional Strategic Plan seeks to energize efforts to bring the benefits of immunization to all target groups of the African region, particularly those in underserved and hard-to-reach populations. The mid-term review highlighted areas of progress but concluded that the region was not on track to achieve most of its 2020 targets. The review was well received by RITAG and, once feedback from RITAG members has been incorporated, it will be adopted by RITAG and its recommendations endorsed.

Middle-income countries (MICs) are home to two-thirds of the world’s poorest people and two-thirds of vaccine-preventable deaths occur in these countries. Gavi-ineligible MICs and Gavi-graduating countries, including those in the African Region, face particular challenges. These were addressed in a Middle-Income Country Strategy developed by WHO and partners which was endorsed by the WHO’s Strategic Advisory Group of Experts on Immunization (SAGE) but has not been adequately funded or implemented.

Pooled procurement mechanisms may be one approach for facilitating vaccine access in such countries. There is also a need to address regulatory issues that may affect timely access to vaccines for routine and emergency use and evaluation in clinical trials.

The implications of Gavi transitions are of concern, including the risk that countries enter transitions ill-prepared to absorb increasing co-financing commitments and eventually to assume full responsibility for immunization systems. This could potentially lead to reversals of new vaccine introductions.

There is real hope that polio can soon be eradicated in the region. No new cases of wild poliovirus have been detected in the African Region since August 2016. RITAG applauds the emergency response launched in Nigeria and the countries surrounding Lake Chad. Technologies and approaches applied here may have application in control of other infectious diseases. Nevertheless, concerns remain about the possible continued transmission of wild polioviruses and the emergence of vaccine-derived polioviruses in areas where insecurity constrains high-quality surveillance and high vaccination coverage.

As GPEI funding declines, it is vital that polio transition plans safeguard essential surveillance functions for polio and other vaccine-preventable diseases and routine immunization activities, to protect national populations and regional health security. Declining levels of human and financial resources for surveillance in the region may potentially compromise the quality and completeness of data and jeopardize the regional certification of polio eradication, as well as complicate efforts to achieve measles and rubella elimination.

Affordable oral cholera vaccines (OCVs) combined with water, sanitation and hygiene (WaSH) and other control strategies represent a valuable new tool for cholera control, and it is essential that they are used effectively in the region. It is important that procedures for accessing the OCV global stockpile facilitate rapid access in emergency situations, and in particular do not impose impractical data collection requirements on countries. Countries also need to ensure that their vaccine regulatory policy frameworks enable the rapid importation of OCV when required, to establish effective surveillance systems to underpin timely disease control, and to collect and analyse the data required to develop evidence-driven policies and programmes, including the use of OCVs, to mitigate the risk of cholera outbreaks.

Great progress has been made towards achieving and maintaining maternal and neonatal tetanus elimination (MNTE). Nevertheless, the region is off-track to reach its elimination target in 2020. The seven countries yet to achieve MNTE face significant challenges, including civil conflicts and infectious disease outbreaks, and require support during a final push towards elimination. Although it has been suggested that MNTE could be accelerated through greater use of compact pre-filled auto-disable devices, which can be used by individuals with minimal training and enhance access to hard-to-reach populations, question marks remain about the true demand and appropriateness of this technology and the likelihood of reliable supply.

A further important theme was research – particularly the need for research driven by local priorities and involving or led by African researchers. These are core principles of the draft Strategic Framework for Research on Immunization in the African Region. Once finalized, the Strategic Framework will provide a key resource to support the generation and use of evidence required to prioritize and support new vaccine development, in order to strengthen national immunization programmes and bring its benefits to larger numbers of people, including those currently being missed.
Recommendations

**Annual Progress**

**1.1 Targeting Priority Countries**
A stronger advocacy strategy, including targeting of senior government officials, should be developed and implemented for the ten priority countries with the greatest numbers of under-immunized children, to ensure that each country implements a remedial plan to ensure that regional targets are met by 2020.

- **Deliverable/Outcome:** Measure and timescale: Draft advocacy strategy to be presented to RITAG in June 2018
- **Main responsibility:** WHO Regional Office; other key stakeholders: countries, partners, RITAG

**1.2 Optimizing use of Subnational Data**
Countries should be supported to use subnational data to identify low-coverage areas and populations (including the urban poor), and to conduct and evaluate the impact of activities targeting such groups.

- **Support plan:** To be presented to RITAG in June 2018
- **Main responsibility:** WHO Regional Office; other key stakeholders: countries

**1.3 Securing Political Commitment**
WHO should engage with the African Union to request regular progress reports from member states on Addis Declaration commitments, including a summary of domestic financial commitments.

- **Progress reports:** To be initiated by Q2 2018
- **Main responsibility:** WHO Regional Office; other key stakeholders: African Union, countries: political leaders, ministers of health, ministers of finance

**1.4 Exploring Innovative Financial Instruments**
A comprehensive review of best practice in innovative domestic financing of immunization and other aspects of healthcare provision should be undertaken and findings shared with countries.

- **Draft review:** To be presented to RITAG in December 2018
- **Main responsibility:** WHO Regional Office; other key stakeholders: partners, health economists

**Mid-term Review of the Regional Strategic Plan for Immunization 2014 - 2020**

**2.1 Mid-term Review**
RITAG should provide comments on and oversee finalization of the mid-term review, and support its dissemination.

- **Finalization of mid-term review:** By end of January 2018
- **Main responsibility:** WHO Regional Office; other key stakeholders: RITAG, mid-term review panel

**Middle-Income Countries and Vaccine Procurement**

**3.1 Middle-Income Country Strategy**
Given the crucial importance of MICs to achieving 2020 goals, the existing Middle-Income Country Strategy should be fully resourced and implemented.

- **Implementation of strategy:** Initiated by end of 2018
- **Main responsibility:** Partners; other key stakeholders: WHO Regional Office, countries

**3.2 Gavi Transitioning**
In countries projected to transition out of Gavi support, advanced planning should be undertaken up to 5 years ahead, to systematically address all relevant issues well in advance of the initial stages of Gavi transitions.

- **Summary of proposed dialogue:** To be presented to RITAG in June 2018; countries to be approached by end of 2018
- **Main responsibility:** WHO Regional Office; other key stakeholders: WHO Regional Office, countries

**3.3 Regional Pooled Procurement**
A consultative study should be undertaken to explore the potential of pooled vaccine procurement, for example at a sub-regional level, and to identify and address potential barriers to the development of such mechanisms and potential solutions.

- **Summary of study:** To be presented to RITAG in December 2018
- **Main responsibility:** WHO Regional Office, UNICEF Supply Division; other key stakeholders: countries, NGOs engaged in pooled pharmaceutical procurement

**3.4 Vaccine Procurement**
To explore the potential for cost savings in vaccine procurement, countries should be offered support to develop an analysis of financial options, including transition to UNICEF reimbursable procurement, and the possibility of creating a revolving fund to enable countries to make advance payments should be investigated.

- **Option analysis:** To be reported to MICs consultation Q1 2018
- **Main responsibility:** WHO Regional Office, UNICEF Supply Division; other key stakeholders: countries
Polio Eradication and Endgame Strategy

4.1 Leveraging Innovative Practices
Innovative practices and technologies deployed in Nigeria and other countries as part of the GPEI should be documented and shared to encourage their adaptation for other vaccine-preventable disease control and elimination activities, including emergency responses, and to raise routine vaccination coverage in hard-to-reach populations.

4.2 Transition Planning
Summaries of polio transition plans for the seven priority countries in the African Region should be reviewed by RITAG, so it can assess their implications for regional health security including surveillance.

4.3 Polio Surveillance
Subnational-level reporting of acute flaccid paralysis cases, as specified in the WHO-recommended surveillance standard of poliomyelitis, should be enforced in all countries, in light of its importance to regional certification of polio eradication.

Cholera Control

5.1 Stockpile Applications
The process for developing the dossier to apply for OCV stock should be simplified to provide speedier response to outbreaks and humanitarian emergencies.

5.2 Regulatory Frameworks
Countries should ensure that their regulatory frameworks facilitate the rapid importation of OCV (and other unregistered vaccines required for emergencies), by encouraging manufacturers to register OCV in advance and adopting mechanisms developed by the African Vaccine Regulatory Forum (AVAREF) for use of unlicensed products.

5.3 Cholera Surveillance
Countries at risk of cholera outbreaks should strengthen their cholera surveillance capacity at the district level, including laboratory capacity, ideally integrating cholera surveillance into routine surveillance activities, to facilitate rapid responses to outbreaks.

5.4 OCV Research Agenda
Countries at risk of cholera outbreaks should identify the evidence required to establish a national strategy for use of OCV and other measures, developing and implementing a cholera control research and evaluation agenda, and ensuring that African institutions and scientists play a lead role in the resulting agenda.

Maternal and Neonatal Tetanus Elimination (MNTE)

6.1 Resourcing for MNTE
WHO should engage with partners to ensure that adequate resources, including human resources, are available to drive forward the final stages of MNTE elimination in the region, including the development of business case to justify funding efforts.

6.2 Progress Reports
In the seven high-priority countries yet to achieve MNTE, RITAG should receive annual progress reviews on maternal and neonatal tetanus elimination, including district-level data on tetanus and diphtheria disease mortality noting the WHO recommended use of Td, incidence and vaccination coverage.

6.3 Compact Pre-filled Auto-disabled Devices
A review should be undertaken to clarify the price, availability and demand for compact pre-filled auto-disable devices in the region and to synthesize the views of manufacturers and other stakeholders, to identify a route out of the current impasse.

Regional Research Agenda

7.1 Strategic Framework for Research
A RITAG working group should be established to revise the draft Strategic Framework for Research on Immunization and oversee its dissemination across and beyond the region with a view of raising interest among research bodies and potential funding sources.
Introduction

The Regional Immunization Technical Advisory Group (RITAG) serves as the principal advisory group to the WHO Regional Office for Africa, providing strategic guidance on regional immunization policies and programmes. It holds two meetings a year, in June and December. The December 2017 RITAG meeting took place at the Protea Balalaika Hotel Sandton, in Johannesburg, South Africa, on 5–7 December 2017.

The meeting was chaired by Professor Helen Rees, RITAG Chair and Founder and Executive Director of the Wits Reproductive Health and HIV Institute at the University of Witwatersrand, Johannesburg, South Africa, with Dr Felicitas Zawaira, Director of Family and Reproductive Health Cluster at the WHO Regional Office for Africa, Dr Richard Mihigo, WHO Programme Coordinator, Immunization and Vaccine Development in attendance throughout the meeting. Dr Zawaira welcomed participants on behalf of the WHO Regional Director Dr Matshidiso Moeti, and an introductory address was delivered by Dr Yogan Pillay, Deputy Director-General of Health in South Africa, whose responsibilities include maternal, child and women’s health, on behalf of the Minister of Health.

The agenda for the meeting included:

- Annual progress towards the goals set out in the Regional Strategic Plan for Immunization 2014–2020, as well as a Mid-term Review of the Regional Strategic Plan.

Other topics discussed were the:

- Challenges facing middle-income countries
- Polio Eradication
- Maternal and Neonatal Tetanus Elimination (MNTE)
- Cholera Control
- and the Regional Immunization Research Agenda.
Annual progress report on implementation of the Regional Strategic Plan for Immunization

Dr. Richard Mihigo, WHO/AFRO

Progress toward the objectives outlined in the Regional Strategic Plan for Immunization 2014–2020 is slow against a challenging backdrop, with much of the continent affected by conflict and insecurity, natural disasters and disease outbreaks. With its relatively young population, Africa will also experience marked demographic changes in coming years, alongside mass migration to urban centres.

Infectious disease continues to pose a major threat – to health, wellbeing and economic development: just four vaccine-preventable diseases (pneumococcal disease, measles, rubella and rotavirus) account for an annual economic burden of US$13 billion. The region also faces the challenge of the ramp down and closure of the GPEI funding by 2020, while some countries will be affected at the same time by transitions out of Gavi support.

Yet there is considerable momentum for change. The Addis Declaration on Immunization, signed by heads of state in January 2017, signaled the highest possible level of political commitment to immunization in Africa. The transformation agenda instigated by WHO Regional Director Dr Matshidiso Moeti is providing new impetus and strategic direction to WHO activities. Moreover, the potential returns on investment in immunization are immense: between 2020 and 2030, control of four key vaccine-preventable diseases could save 1.9 million lives, avert 167 million cases of disease, and deliver US$58 billion in total economic benefits.

While some progress has been made towards regional immunization objectives, much remains to be done. Immunization coverage rates remain below targets.

The figure below shows the location of missed children having missed DPT3 in the African Region in 2016 (WUENIC)

Countries with large populations pose a particular challenge – just 10 countries account for 80% of unvaccinated children. Equity targets have also not been achieved and, while males and females benefit equally from immunization, rural/urban location, education and wealth still have a significant impact on access.

Major progress has been seen in polio eradication, with the last case of wild poliovirus reported in the region in August 2016 (see below). Circulating vaccine-derived poliovirus (cVDPV) outbreaks were reported in one country (Democratic Republic of the Congo) in 2017 and concerns persist about the quality of surveillance in the Lake Chad region and Northern Nigeria. Although coverage with the first dose of measles-containing vaccine (MCV1) has plateaued at around 75%, MCV2 coverage has been on a sharp upwards trajectory (albeit from low levels). New vaccine introductions have been a regional success story – pneumococcal conjugate vaccine has been introduced by 39 countries and rotavirus vaccine by 32 countries.

Studies have generated important data on the impact of new vaccines in Africa – use of rotavirus vaccine, for example, averted an estimated 135,000 hospitalizations and 21,000 deaths in 2016. In addition, use of MenA vaccine has prevented an estimated 300,000 cases of meningitis A and 30,000 deaths.

Some progress has been made on achieving and maintaining MNTE, with 38 countries and one zone in Nigeria validated for MNTE by December 2017 (see below). However, the region remains off-track for elimination by 2020. An updated risk map has been developed for yellow fever, but vaccination coverage remains low in many high-risk countries.

More encouragingly, the numbers of countries with national immunization technical advisory committees (NITAGs) has more than doubled since 2012; 23 NITAGs now exist, including 13 achieving six key process indicators suggesting that they are functioning effectively. Less positively, the proportion of countries funding most or all of their national immunization programmes has scarcely changed over the past five years, with just 11 providing more than 50% financial support in 2016.

**National immunization programmes funding by the Government, 2012 - 2016 (JRF)**

<table>
<thead>
<tr>
<th>Years</th>
<th># supporting 100%</th>
<th># supporting 50%&lt;100%</th>
<th># supporting &lt;50%</th>
<th># missing data</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>4</td>
<td>8</td>
<td>19</td>
<td>16</td>
</tr>
<tr>
<td>2013</td>
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<tr>
<td>2016</td>
<td>3</td>
<td>8</td>
<td>30</td>
<td>6</td>
</tr>
</tbody>
</table>

Looking forward, the new WHO strategy being developed by Director-General Dr Tedros, with its strong focus on universal health coverage, should favour immunization as a global priority. On the ground, a revised Reaching Every District (RED) manual provides updated guidance on enhancing access and closing equity gaps, while addressing missed opportunities for vaccination has the potential to significantly improve routine coverage. A major programme of work with partners is examining data quality and the need for greater use of subnational data where it is generated, while efforts are being made to align and integrate immunization with other global health agendas such as health security, health systems strengthening/universal health coverage and the Sustainable Development Goals.

RITAG members emphasized the importance of addressing coverage in the ten priority countries with the most under-immunized children. Furthermore, while rural populations have typically been underserved relative to urban populations, rapid urbanization is creating marginalized urban populations at risk of exclusion from immunization services. More granular subnational data should be analysed to identify underserved populations, as well as the underlying social and environmental factors affecting access to services. Such data could underpin targeted immunization programmes in order to close gaps in equitable service delivery.

With external funding from, for example, the GPEI projected to decline and stop, the importance of countries honouring their immunization investment commitments was stressed. Opportunities may exist to explore the use of innovative approaches to domestic funding, such as greater involvement of the private sector, health insurance schemes, trust funds and taxation, and to deepen engagement with other potential partners such as the World Bank or the African Development Bank.

RITAG members also focused on the importance of community mobilization and engagement. Civil society can play a key role in stimulating demand for vaccination but also in promoting political accountability. It was also suggested that emphasis may need to shift from individual behaviour change to more societally oriented norm-shifting in order to internalize the value immunization more effectively.

The forerunner of RITAG asked the WHO Regional Office to coordinate a mid-term review to assess progress towards the objectives set out in the Regional Strategic Plan for Immunization 2014–2020. The review was carried out by an independent panel supported by the WHO Regional Office for Africa. The Review confirmed the continuing relevance of the Regional Strategic Plan and its alignment with the Global Vaccine Action Plan, including its monitoring and evaluation framework. However, it identified shortcomings in the achievement of several strategic targets and recommended their revision based on the current state of progress.

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**Summary of Technical Sessions - Regional Technical Advisory Group Meeting**

Vaccine shortages and stockouts have been on the rise, often due to internal factors such as funding delays and forecasting errors.
For the first strategic objective, on immunization coverage, the review panel found that coverage with traditional vaccines had plateaued in recent years. Progress has been achieved towards the second strategic objective, polio eradication. There was great concern that the third strategic objective, measles elimination and rubella control, would not be achieved by 2020. Finally, variable progress has been seen towards the fourth strategic objective, control of other vaccine-preventable diseases. The Regional Strategic Plan also identified six strategic directions, covering national commitments to immunization, community awareness, equitable access, integration with other health services, funding and vaccine supply, and research and development. Mixed progress was seen in these areas, and there may also be a need to develop a more appropriate range of indicators.

The review panel made specific recommendations in six areas: (1) leveraging commitments made in the Addis Declaration; (2) defining community-centered approaches to improve equitable access; (3) fostering a universal health coverage approach with immunization at the core of primary health care; (4) improving the availability and quality of data; (5) involving new players and approaches to enhance human resource capacity; and (6) employing innovative instruments to sustain financing.

The review was warmly welcomed by RITAG. Once feedback from RITAG members has been incorporated, the review will be adopted by RITAG and its recommendations endorsed after a further round of review.

**Middle-income Countries: Improving Access to Affordable Vaccines**

Tania Cernuschi, WHO HQ

The world’s 107 MICs are home to two-thirds of the world’s poorest people and two-thirds of vaccine-preventable deaths occur in these countries. Globally, there are also concerning signs of declining vaccination coverage in Gavi-ineligible MICs. Of the 65 Gavi-ineligible MICs, ten are in the African Region, including three transitioning out of Gavi support. Gavi-ineligible MICs have limited access to other sources of financial support, and may struggle to sustain the delivery of newly introduced vaccines.

In light of the challenges facing these countries, particularly those around vaccine procurement, in 2015 WHO and partners developed a Middle-Income Country Strategy, with the aim of enhancing coverage and enabling the introduction of new vaccines. Although the strategy was endorsed by SAGE in 2015, it has not been adequately funded or implemented.

Vaccines represent the largest single budget item for national immunization programmes. Gavi-eligible countries benefit from Gavi vaccine procurement mechanisms, while the Revolving Fund of the Pan-American Health Organization operates pooled procurement for the Region of the Americas, and countries can also use the UNICEF reimbursable procurement mechanism. Alternatively, many countries self-procure directly from suppliers.

A lack of market information is a major disadvantage for self-procuring countries. To enhance price transparency, WHO has developed the Vaccine Price, Product and Procurement (V3P) database (www.who.int/immunization/programmes_systems/procurement/V3P/platform/en/), which collates information on prices, volumes, procurement methods and other key data. By the end of 2017, some 144 countries were contributing information, including all but one country in the African Region.

Analysis of V3P data has revealed that self-procuring countries pay considerably more for most vaccines. For several vaccines, countries in the African Region are paying higher prices than equivalent countries in other regions.

### Vaccine price change Pool-procurement compared to self-procurement

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Dose</th>
<th>Pool Procurement</th>
<th>Self Procurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>DT 10</td>
<td></td>
<td>$0.45</td>
<td>$0.42</td>
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<tr>
<td></td>
<td></td>
<td>$0.35</td>
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<td></td>
<td></td>
<td>$0.00</td>
<td>$0.00</td>
</tr>
</tbody>
</table>

### Vaccine price change non-Gavi MICs in the Afro region compared to non AFR countries

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Doses</th>
<th>AFR</th>
<th>non-AFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCV</td>
<td>1 800 000</td>
<td>$17.26</td>
<td>$16.67</td>
</tr>
<tr>
<td>Rota</td>
<td>1 400 000</td>
<td>$4.08</td>
<td>$4.27</td>
</tr>
<tr>
<td>Influenza (adult)</td>
<td>1 200 000</td>
<td>$5.17</td>
<td>$5.91</td>
</tr>
<tr>
<td>HepB (adult)</td>
<td>1 000 000</td>
<td>$1.32</td>
<td>$0.89</td>
</tr>
</tbody>
</table>

Source: The Vaccine Price, Product, Procurement Initiative (V3P)
WHO offers a range of mechanisms to support more effective self-procurement. Alternative options include adoption of UNICEF reimbursable procurement or sub-regional pooled procurement agreements, such as the arrangement successfully used by small Baltic States in the European Region to achieve costs savings.

RITAG members focused on the possibility of establishing pooled vaccine procurement for the African Region. An attempt to develop such a mechanism in the Eastern Mediterranean Region has not been successful to date, and a consultation exercise within the African Region in 2008 identified significant barriers to pooled procurement. However, sub-regional collaboration has improved (for example through Regional Economic Communities such as the Economic Community of West African States and the Southern African Development Community), suggesting there may be emerging opportunities for cooperation in procurement.

It was also suggested that countries could be supported to undertake an option analysis as carried out in Swaziland, to explore the possible benefits of UNICEF reimbursable procurement. Innovative funding mechanisms might be required to address one potential obstacle to UNICEF procurement – the need for advance payments. It was also suggested that valuable lessons could be learned from, and collaborative opportunities explored with, NGOs that have experience of procurement of pharmaceutical products.

Discussions also covered the importance of simplicity of national regulatory systems processes to facilitate timely vaccine access, for routine and emergency use and evaluation in clinical trials. During the 2016 Ebola outbreak, it became clear that many national regulatory authorities (NRAs) and ethics committees did not have policies and procedures in place to support rapid clearance for clinical trials. In addition, in some countries, access to cholera vaccines has been hampered by the reluctance of industry to apply for registration. The legal framework governing NRAs in the region together with certain regulatory practices may discourage vaccine manufacturers from applying for licensure of important vaccines (unfavorable ratio of cost and complexity of registration versus the expected financial return). If a limited number of vaccine products are registered in a country, this can lead to a dependence on a small number of suppliers, increasing the risk of vaccine stockouts. Building on WHO's ongoing activities to strengthen NRAs through the AVAREF network, countries need to identify and eliminate unnecessary regulatory obstacles that limit vaccine availability. In addition, the harmonization of regulatory systems between countries could deliver efficiencies and generate more sustainable vaccine marketplaces.

RITAG members also welcomed Gavi’s recent acknowledgement of the challenges that some countries (including those in the Africa region) were experiencing in their transitions out of Gavi support. A range of supportive measures has been announced, including the development of a tailored plan for Nigeria, the possibility of funding for new vaccine introductions and targeted technical support during transitions, and an analysis of the risks to successful transitions in Angola and Republic of Congo.

COUNTRY CASE STUDY

Swaziland: Experiences in Vaccine Procurement

Dr Njabuliso Lukhele, Ministry of Health, Swaziland

Swaziland is classified as a lower middle-income country but is ineligible for Gavi support. The Government fully funds vaccine procurement and 96% of routine immunization costs. Expenditure on immunization has increased significantly since 2010.

As a relatively small country, Swaziland faces several challenges in vaccine procurement. Orders are small and payment sometimes delayed, which deters some suppliers. This can lead to a dependence on a limited number of suppliers and difficulty in negotiating fair prices.

To identify more efficient methods of procurement, in April 2017 the country was visited by representatives from the UNICEF Supply Division. A cross-departmental task team was established, including WHO and external partners, and a forecast of vaccine needs was developed. Following the signing of a memorandum of understanding between the Ministry of Health and UNICEF, this information was used to generate cost estimates for vaccine supply through UNICEF.

Preliminary analysis suggests that UNICEF reimbursable procurement system could deliver annual cost savings of more than US$1 million (almost 25% of the total vaccine budget). Should Swaziland adopt this mechanism, it would need to adapt some of its policies and procedures, as UNICEF requires full payment in advance and waivers would be required to address tendering regulations.
The prospect of certification of polio eradication in the African Region has been raised by the absence of any confirmed cases of wild poliovirus since August 2016. Cases of type 2 circulating vaccine-derived poliovirus (cVDPV2) were however detected in the Lake Chad area in 2016 and in the Democratic Republic of Congo in 2017. Nevertheless, in much of the Africa Region, the impact of ongoing civil conflict, insecurity and population displacements on vaccination coverage and vaccine-preventable disease surveillance poses a significant risk to polio eradication. Furthermore, the substitution of tOPV with bOPV combined with low immunisation coverage has increased the threat of cVDPV as evidenced by the outbreak in the DRC.

There are particular concerns over polio surveillance due to localized performance gaps in detection of AFP cases and stool adequacy, which are mostly attributed to insecurity (inaccessibility) and weak surveillance networks, particularly at sub-national levels.

Several innovations have been introduced to improve surveillance. For example, in areas with weak health systems, the Auto-Visual AFP Detection and Reporting (AVADAR) system enables members of local communities to use mobile phones to report AFP cases for investigation. Approaches based on geographic information system (GIS)-enabled devices, such as eSurv and Integrated Supported Supervision (ISS), have been used to enhance surveillance and to collect data on immunization facilities in more than 20 countries. These tools have made possible the identification of AFP cases not detected through conventional surveillance, and improved reporting from insecure areas and silent districts.

After wild poliovirus was detected in northern Nigeria in August 2016, an emergency response was launched in Nigeria and countries surrounding Lake Chad. An Outbreak Response Assessment (OBRA) was completed in these countries as well as in the Democratic Republic of the Congo and in the Central African Republic in October 2017. In December 2017, the Lake Chad Technical Advisory Group highlighted a continuing risk of transmission, and recommended that control efforts be extended to mid-2018, using a variety of innovative approaches to access hard-to-reach populations in challenging circumstances (see Box).
Inactivated poliovirus vaccine (IPV) has been widely introduced in the African Region, and the remaining 11 countries have made a formal commitment to introduce IPV. Ten countries experienced IPV stockouts in 2017, but global supply of IPV is expected to improve in 2018. IPV shortages led to a recommendation for use of fractional intradermal dosing; with supplies improving, some countries are reverting to administering the full intramuscular dose, although fractional dosing remains an option when suitably trained health workers are available.

Progress has continued on implementation of the Global Action Plan on polio containment (GAP III). Just one country has yet to complete containment phases 1a and 1b. South Africa is the only country in the Region that plans to maintain wild poliovirus samples in secure poliovirus-essential facilities.

In terms of certification of polio-free status, nine countries have yet to present evidence of interruption to the Africa Region Certification Commission (Gabon was certified after the RITAG meeting).

**Polio-free Certification status in the African Region as of December 2017**

- **Accepted (38)**
- **Pending (9)**

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Regional certification could be threatened by the declining quality and completeness of AFP surveillance in several countries, while a continuing risk of wild virus reintroduction has been highlighted in some countries certified as polio-free.

Polio transition planning continues in the seven priority countries hosting the majority of polio infrastructure in the Region, all of which are now developing transition plans (see Box). A reduction in WHO human resources in the region began in 2017.

Future priorities include the continuing efforts to improve surveillance and immunisation coverage around Lake Chad, including increased use of innovative new technologies, sharing of lessons learned from GPEI, and further progress on transition planning.

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**Lake Chad Technical Advisory Group**

Professor Daniel Tarantola, RITAG Member and Chair of Polio, Lake Chad TAG

Following the detection of wild poliovirus in Borno state in Nigeria in August 2016, a Declaration of Emergency was signed by health ministers in five countries in the Lake Chad region (Cameroon, Central African Republic, Chad, Niger and Nigeria). The Lake Chad Coordination was put in place to organize local activities, initially focused on outbreak response supplementary immunization activities (SIAs).

The latest OBRA (outbreak response assessment), carried out in October–November 2017 in the northern Nigerian states of Borno, Sokoto and Ademaya, sought to determine whether transmission had been interrupted. Key criteria include the absence of any confirmed cases of wild poliovirus for six months, the adequacy of surveillance, and plans for targeting high-risk populations.

Although no new wild polio or cVDPV cases have been reported in 2017, population displacements due to civil unrest make it hard to judge the reliability of vaccination coverage figures. Furthermore, the completeness of surveillance is open to question. On the balance of evidence, OBRA could not conclude that transmission had been interrupted and recommended that activities around Lake Chad be extended, intensified and re-assessed in 2019, and that greater attention to the vulnerability of other Nigerian states close to the Lake Chad area and challenged by insecurity (e.g. Yobe State) be included in this re-assessment.

These conclusions were echoed by the Lake Chad Technical Advisory Group (TAG). While applauding the efforts of the Lake Chad Coordination, the TAG identified a range of issues, including the need for more granular analysis of surveillance data, the need to ensure adequate quality of samples sent to laboratories, and the need to remove trivalent oral polio vaccine from some facilities. The TAG also supported targeting of high-risk populations, particularly those living on Lake Chad’s islands and nomadic populations.
**Post-Certification Strategy**

Dr Michel Zaffran, Polio Eradication, WHO HQ

The Polio Post-Certification Strategy has two aims: to define the functions required to maintain a polio-free world and to identify and address potential impacts on other health programmes drawing on GPEI support. The GPEI leads in the former area while countries are expected to take the lead in the latter.

A draft Post-Certification Strategic Plan provides high-level guidance on how a polio-free world can be maintained after eradication. Once endemic transmission has been interrupted globally, a three-year pre-certification period is envisaged, the last year of which will see an overlap between GPEI and post-GPEI programmes; the GPEI will be dissolved at certification.

Key risks after certification will initially be the emergence of cVDPV, until oral vaccine use is discontinued, then the shedding of VDPV from immunocompromised individuals. In the longer term, the major risk is the circulation of virus following a laboratory containment breach.

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**Polio Virus Containment status in the African Region**

*as of December 2017*

- **Submitted**
- **Updating is required**
- **Submitted with issues**
- **Not submitted**
- **Non AFRO countries**

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The goals of the Post-Certification Strategy are to contain wild and live vaccine poliovirus sources; to protect populations by switching from oral vaccine to IPV; and to maintain systems to detect and respond rapidly to any reintroduction. Each goal is supported by specific responsibilities at global, regional and national levels.

The Post-Certification Strategy is due to be reviewed by the SAGE Polio Working Group and SAGE itself, before presentation to the World Health Assembly in May 2018. However, it is intended to be a ‘living document’ updated as circumstances demand prior to certification.

Among the key discussion points on polio eradication was the need to analyse polio surveillance data at a more granular level, to identify gaps in surveillance, and in particular to distinguish between zero-reporting wards (‘silent’ wards) and wards that do not report at all (‘mute’ wards). As emphasized by the Lake Chad Technical Advisory Group, this analysis needs to extend below district level, to ward level or its equivalent.

RITAG applauded the emergency response launched around Lake Chad. The innovative approaches and technologies used were felt to have applicability in other areas of infectious disease control. Lessons might also be learned from Nigeria on the targeting of under-served populations in its emergency plan for routine immunization. The coordinated response also illustrates the importance of cross-border collaboration and of strong political leadership in response to health emergencies—essential in the battle against infectious diseases that are unconstrained by national borders.

A recurring theme in this and other RITAG sessions was the importance of vaccine-preventable disease surveillance. Effective surveillance will be essential for certification of polio eradication, measles and rubella elimination and MNTE, but also for timely use of vaccines to control outbreaks (for example, of cholera and yellow fever), and more generally to inform national immunization activities. Surveillance and immunization are both critical components of national and regional health security, and the IHR Joint External Evaluations that countries are now undertaking provide a measure of countries’ ability to deliver on both these aspects of public health—as well as an opportunity to strengthen systems through the resulting national action plans.
COUNTRY CASE STUDY

Nigeria: Innovations to Reach Children in Accessible Areas
Fiona Braka, WHO/Nigeria

Polio eradication efforts in Nigeria have focused on Borno state, where the last case of wild poliovirus was detected in August 2016. Innovative approaches have been adopted to improve coverage in difficult-to-access populations in areas of high insecurity.

Settlements have been divided into three groups – accessible, partially accessible and inaccessible. Accessible settlements have been reached through house-to-house campaigns, while immunization workers received the protection of civilians with military experience to visit partially accessible settlements. The only feasible strategy in inaccessible areas was for the Nigerian army to conduct immunization exercises, which ensured that nearly 50,000 children were vaccinated in 2,500 inaccessible settlements.

Although these three strategies have improved coverage, many gaps remain. Following advocacy visits to the military commander and the Executive Governor of Borno State, a plan has been agreed to increase the use of military teams to reach additional inaccessible settlements.

Alongside these efforts, other innovative approaches have been adopted. For example, various locations have been targeted to reach migrating children at checkpoints and transit points, leading to the vaccination of nearly 300,000 children since January 2017.

Satellite imaging has also been used to track the persistence, growth or abandonment of settlements, giving a clearer picture of population size and distribution and population movements. GIS-based technologies will be used to support the next wave of activities to reach remaining unvaccinated populations.

The Government of Nigeria has also recognized that gains are not sustainable without a strengthening of routine immunizations systems. A state of public health concern was announced and an emergency plan for routine immunization was introduced in June 2017, focusing on priority states with low coverage.
As envisaged in the Polio Eradication and Endgame Strategic Plan 2013–2018, Ethiopia has been working with WHO to develop a national polio transition plan to manage the withdrawal of GPEI resources.

A multisectoral national Polio Transition Planning Committee has been established, with the representation of external stakeholders. This committee has overseen the development of a range of documents feeding into a draft Polio Transition Plan for Ethiopia (2018–2020). The development of the plan was significantly influenced by a desktop polio transition simulation exercise.

Analyses have included a detailed breakdown of GPEI-funded resources and their contributions to polio and other immunization activities. The annual polio fund amounted to US$39.8 million in 2016, with GPEI donors contributing US$21.7 million; this is projected to be reduced to US$4.6 million in 2018.

Ethiopia has conducted a risk analysis to prioritize future activities to maintain its polio-free status. Of particular concern is the possibility of the introduction of poliovirus from neighboring fragile states such as Somalia, in view of extensive population movements. This risk is compounded by low levels of vaccination coverage and weak surveillance in hard-to-reach and nomadic populations living near Ethiopia’s borders.

The transition plan has been developed to maintain minimal assets until certification is achieved, with responsibilities then transferring to the Ethiopian Government from 2020. Strengthening surveillance and immunization activities in the border regions will be a particular focus. The transition plan includes a detailed budget breakdown, and a significant projected budget gap is being discussed with potential partners.
Cholera in the African Region
Dr Linda Omar, WHO/AFRO

Sub-Saharan Africa experiences a high burden of cholera. By mid-September 2017, more than 139,000 cases and 3,000 deaths had been reported; numbers that likely underestimate the true situation. Multiple factors increase the risk of cholera outbreaks in the region, including conflict and population displacements, lack of access to clean water, poor health infrastructure and climatic factors. Cholera control is further challenged by a lack of political commitment, weaknesses in disease surveillance and laboratory capacity, and limited national water, sanitation and hygiene (WaSH) initiatives.

Affordable oral cholera vaccines (OCVs) represent an emerging tool for effective cholera control. Available vaccines have shown adequate efficacy and safety profiles, although they have drawbacks, including limited protection of young children, a need for two doses and unpleasant taste; improved OCVs are being developed.

OCVs have potential use in both emergency (humanitarian emergencies and cholera outbreaks) and non-emergency (endemic cholera) situations. A global OCV stockpile has been established, with an International Coordinating Group enabling rapid access in emergency situations and the OCV Working Group of the Global Task Force on Cholera Control overseeing access to non-emergency supplies. Since 2013, OCV use has increased rapidly, with humanitarian crises accounting for most use in 2017.

The Global Task Force has developed a plan for eradicating cholera epidemics that occur repeatedly in the same geographic areas by 2030 (Ending Cholera: A Global Roadmap to 2030). This envisages a greater emphasis on long-term WaSH-based prevention and control, with effective case management and OCVs playing a critical role in this transition. A Cholera Implementation Framework has been developed for the Africa Region, based on an integrated multisectoral strategy incorporating intensified surveillance and effective case management alongside OCV use, to underpin national cholera control programmes.

RITAG members stressed the need for the application procedure to the global stockpile to be fit for purpose and not to impose unrealistic data requirements on applicants. The importance of effective cholera surveillance and laboratory capacity was stressed, and concerns were expressed about the impact of the withdrawal of GPEI resources on this surveillance. It was also recognized that NRAs need to ensure that national policy frameworks are compatible with the rapid import of OCV when required; importation can be delayed if OCVs have not been registered in advance or if regulatory requirements are obstacles to the rapid importation of unregistered vaccines in emergency situations.
In 2017, Sierra Leone deployed OCV for the first time to prevent a cholera epidemic in Freetown, following flooding and a landslide that displaced nearly 6,000 people. The country has had a history of outbreaks – the last major one, in 2012, affecting more than 23,000 people.

With partners, the Ministry of Health rapidly developed an emergency response, and within 72 hours secured approval from the International Coordinating Group to access OCV from the global stockpile. Two rounds of vaccination targeted more than 500,000 people at risk, with health workers moving house to house and visiting schools, and operating from fixed health facilities.

Reported vaccination coverage was high (generally above 95%). A follow-up coverage verification survey of nearly 7,000 individuals found slightly lower coverage (around 80%), particularly among adolescents. Of those vaccinated, around 30% received only one dose. Concerns about cholera were by far the most commonly cited reason for presenting for vaccination. Reasons given for non-vaccination were almost all practical; there was little evidence of vaccine hesitancy.

A range of factors were suggested to be important to the success of emergency OCV campaigns. These included central coordination and planning, training of vaccinators, community engagement, detailed implementation plans, and rapid post-campaign monitoring. Despite significant technical difficulties inherent to study design, an attempt is being made to evaluate the impact of the OCV mass campaign on cholera mortality and morbidity in the targeted population.
COUNTRY CASE STUDY

Cholera Control: Lessons Learned from Tanzania
Mr Christopher Kamugisha, WHO Tanzania

An ongoing cholera outbreak in Tanzania began in Dar es Salaam in August 2015 and rapidly spread throughout the country. A Public Health Emergency Operations Centre was established in the Ministry of Health and a national task force meets weekly. Daily surveillance reports provide a snapshot of the epidemic, although periodic nationwide data validation exercises suggest some under-reporting of cases. Control responses have focused on social mobilization and promotion of WaSH practices.

Tanzania used OCV to control a cholera outbreak affecting refugees at Kagunga village in Kigoma District on the shores of Lake Tanganyika in April 2015. UNHCR moved refugees by boat to Kigoma Port then to a refugee camp at Nyarugusu. By September 2015, the camp was home to more than 150,000 people.

In May 2015, a cholera outbreak occurred at Kagunga and the transit camp and spread to the main camp at Nyarugusu. Within days, cholera had also spread to local village communities. The Ministry of Health and WHO jointly developed an application to the global stockpile, with vaccine being delivered within a week. An emergency national inter-agency coordinating committee (ICC) meeting endorsed use of two doses as an emergency response and Tanzania’s NRA fast-tracked registration enabling an import permit to be issued. The ICC also decreed that local communities as well as individuals in camps should be vaccinated. By July, the outbreak had been brought under control in the camps and local communities.

The vaccination exercise was considered to have been successful, largely thanks to effective social mobilization and micro-planning. However, the fact that the vaccine had not been registered prior to the outbreak had delayed implementation. It was also felt that the application process to the global stockpile was challenging, calling for data that were not easily available.
Maternal and Neonatal Tetanus Elimination (MNTE)
Attaining and Maintaining MNTE in the African Region
Dr Balcha Masresha, WHO/AFRO

MNTE is one of the objectives of the Regional Strategic Plan for Immunization. Although more countries have achieved MNTE, the region did not achieve its target of MNTE in 42 countries by 2017 and is off-track to reach its target of all 47 countries by 2020.

The strategy for MNTE is based on tetanus toxoid (TT) vaccination in pregnancy supported by SIAs in high-risk areas (alongside clean delivery practices and surveillance for neonatal tetanus). WHO now recommends a six-dose vaccination strategy (three doses initially and three boosters in childhood and adolescence). WHO also recommends tetanus–diphtheria (Td) for the booster doses, which have been introduced by 18 countries. This is especially relevant as globally there have been several outbreaks of diphtheria particularly in areas of civil conflict including in the African region.

Vaccination coverage at birth has been relatively stable at around 80%. During 2014–17, 13.3 million women of childbearing age received two or more TT doses in SIAs targeting 390 high-risk districts in nine countries. Not all these activities could be completed, due to funding and security issues.

By December 2017, 38 countries and one zone in Nigeria had been validated for MNTE; two (Kenya and Chad) are likely to be validated early in 2018.

A global investment case for MNTE is currently being finalized, targeting 16 countries, including nine in the African Region. This will include consideration of the use of compact auto-disable devices, which can be used by vaccinators with minimal training, facilitating access to hard-to-reach populations.

MNTE was identified as a key issue in equitable access to health services – infection typically affects the most disadvantaged families. As well as the need to drive forward MNTE, it was also emphasized that vaccination coverage must be sustained to prevent disease resurgence – maintaining MNTE must still be a priority in countries validated for MNTE. Elimination strategies must combine safe clean delivery practices with strengthening routine immunization and SIAs in situations where vaccination coverage among pregnant women is inadequate. Implementation of the six-dose strategy, which should reduce the need for SIAs, and the drive towards increased Td use will be challenging.

RITAG members also focused on the potential value of compact pre-filled auto-disable devices. A ‘catch 22’ situation currently exists, with manufacturers reluctant to commit to large-scale production in the absence of clear demand, and programmes unwilling to adopt the technology in the absence of price data. There is an urgent need to assimilate the extensive dialogue that has taken place between manufacturers and other stakeholders to generate clarity on demand, pricing and the likelihood of reliable supply, noting that these devices have also been identified as a potentially important technology for hepatitis B vaccine delivery. RITAG requested clarity on the status on pre-filled auto-disabled devices as they felt that this technology would increase immunisation coverage in hard to reach areas.

A range of activities are being planned in the remaining seven countries, many of which are affected by civil conflict and/or infectious disease outbreaks.
COUNTRY CASE STUDY

Challenges in Achieving MNTE: The South Sudan Experience
Dr Anthony Laku, Ministry of Health, South Sudan

South Sudan has been affected by a protracted civil conflict that has significantly affected healthcare delivery – more than half the country’s population of 12.3 million people do not have access to health facilities. An estimated 7.4 million people have been affected by conflict, with 3.9 million displaced. South Sudan has been affected by multiple disease outbreaks and food insecurity, and the country is experiencing a severe shortage of health workers.

Given these challenges, the country has struggled to achieve its routine immunization and SIA objectives: 61% of counties had less than 80% coverage in a third round of TT SIAs and 27 out of 80 counties were not accessible at all. Similarly, routine vaccination coverage has been in decline, although estimated protection against tetanus at birth was 68% in 2016, a small increase on previous years.

Promoting clean delivery practices has been challenging, with only 13% of mothers having access to skilled delivery services, in part because of a chronic shortage of health workers and attacks on health services. Surveillance is suboptimal, with no case-based surveillance and incomplete reporting from counties.

The country has developed strategies to enhance vaccination coverage, including 'hit and run' approaches for insecure areas and targeted strengthening of routine services in specific geographic areas. A new comprehensive multiyear plan for MNTE has been developed for 2018–2022, spanning SIAs, routine immunization services, a switch from TT to Td, and case-based surveillance. The aim is also to enhance integration with other health services and with an overarching health human resourcing plan.
The R&D Blueprint is being developed by WHO in response to the uncoordinated R&D response to the Ebola epidemic. It is intended to provide a global framework to support more rapid and coordinated R&D responses to emerging infectious disease outbreaks, and more effective and equitable collaboration among partners. Agreement on the terms of the Blueprint in advance would ensure that data of public health value on vaccines and other interventions could be generated more rapidly when outbreaks occur.

The Blueprint will encompass three areas: improving coordination, accelerating R&D, and developing new norms and standards. To facilitate product development, a list of priority pathogens has been established, alongside an R&D roadmap and target product profiles. Discussions are being held on appropriate and standardized clinical trial designs and harmonization of regulatory mechanisms.

Activities are guided by a Scientific Advisory Group, a Global Coordination Mechanism, and Monitoring and Evaluation structures.

The ongoing process includes discussion of the methodological tools used to evaluate vaccines, as well as the current level of preparedness of NRAs. The norms and standards strand is also developing guidance and practical tools to facilitate collaboration and data and sample sharing.

RITAG members emphasized the importance not just of the region being prepared to carry out clinical trials in outbreak situations but also of ensuring that African researchers are at the heart of such research. The Ebola experience also revealed significant issues related to specimen ownership and data sharing that need to be addressed. The important role of AVAREF in developing the capacity of NRAs, promoting consistency in clinical trial evaluation and licensure of vaccines and enhancing regulatory preparedness was also acknowledged.
Strategic Framework for Research on Immunization in the WHO African Region
Dr Joseph Okeibunor, WHO/AFRO

Research is a powerful tool for achieving the objectives of the Regional Strategic Plan for Immunization. Yet research on immunization in the Africa Region does not always reflect regional and national priorities, often being driven by the interests of external sponsors. To address this issue, in 2013 the forerunner of RITAG proposed that a Strategic Framework for Research be developed to set the agenda for immunization research in the region.

Following an extensive consultation, a working group has developed a draft Strategic Framework, designed to enable countries to design and undertake high-quality immunization-related research relevant to their needs and to disseminate evidence to inform policy and practice. Ultimately, this should accelerate the development of vaccines and improve the delivery of immunization services.

The Strategic Framework covers all stages of the research process, including formulation of research questions, design and conduct of research studies, and dissemination of results. It identifies three priority research areas: epidemiology of disease and impact of vaccines; clinical trials; and implementation research and community participation. Once finalized, it will provide essential guidance on the development of needs-led immunization research in the region.

As well as identifying the need for RITAG to provide feedback for the finalization of the Strategic Framework and to advise on its dissemination, discussions also emphasized that African researchers should play a leading role in national programmes of immunization research. It was recognized that this would depend on the long-term development of research capacity in the region, including approaches to attract back and retain African researchers who are working outside the region.

While RITAG commended WHO AFRO for the progress made towards developing a Regional Strategic Framework for Research on Immunization, it’s recommended that further input should be solicited from additional stakeholders to reflect the broad spectrum of research needs in the region.

Conclusion

To conclude the meeting, Professor Rees presented a summary of the draft recommendations and thanked participants for contributing so full to discussions throughout the meeting. Her comments were reinforced by Dr Mihigo, who also identified the important contributions made by representatives of national immunization technical advisory groups. Closing the meeting, Dr Zawaira urged all participants to seize the moment and build on the momentum created by the Addis Declaration and the reinvigoration of the WHO Regional Office to drive forward the immunization agenda in Africa.
## RITAG Members

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