WHO/AFRO
REGIONAL IMMUNIZATION
TECHNICAL ADVISORY GROUP MEETING

FINAL REPORT

BRAZZAVILLE, CONGO
05 - 08 JULY 2016
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EXECUTIVE SUMMARY

The newly constituted Regional Immunization Technical Advisory Group (RITAG) met in Brazzaville, from 5th to 8th July 2016. The meeting was officially opened by Dr Joseph Cabore, Director of Programmes and Management (DPM), on behalf of the Regional Director, Dr Matshidiso Moeti. Present during the opening were Cluster Directors and staff of the WHO from the RO, ISTs and HQ.

The primary goals of the meeting were to brief the new RITAG members on the regional priorities for immunization and to seek their advice on current specific challenges. Some of the current priority areas in immunization were discussed in sessions of the meeting after the briefing sessions. In these sessions, the progress made was summarized, challenges highlighted and the RITAG members given the opportunity to discuss and to provide advice. At the end, a number of key recommendations were made.

RITAG Recommendations:

- **Immunization coverage and equity**
  - Countries, especially those reporting high immunization coverage, should triangulate available data (including sub-national surveys, sero-surveys, and surveillance data) to improve the accuracy of population immunity estimates.
  - WHO AFRO to expand research agenda to include the development of new diagnostic tools, mapping, population denominator estimates, and innovative vaccine delivery strategies, and that AFRO move as quickly as possible to implement cost-effective strategies found to strengthen immunization programmes.
  - WHO AFRO to support countries to implement activities to address gaps emanating from the findings of the BMGF and Gavi on vaccine stockpiles as soon as available. AFRO should work with partners to ensure that adequate, sustainable funds are available for sufficient vaccine stockpiles, and that timely and dependable deployment mechanisms are identified and implemented.

- **Polio eradication initiative**
  - In the context of decreased polio funds, a detailed investment case is developed which identifies the resources needed to:
    a. Maintain essential polio programme functions to ensure that the polio-free status remains.
    b. Maintain essential routine (non-polio) immunization programme components (e.g. surveillance [including laboratory networks and information infrastructures], risk mitigation, workforce capacity, safe and effective vaccines, outbreak detection/response).
    c. Introduce and implement activities required to achieve and maintain GVAP and Regional immunization targets
WHO/AFRO to work with partners to mobilize additional resources to fill funding gaps, including the development of detailed advocacy plans to increase country ownership and leadership, and monitoring government commitments (% EPI funded by government) made at the Ministerial Conference on Immunization in Africa, February 2016 to increase EPI funding.

WHO/AFRO to work with countries to intensify surveillance for polioviruses by:
a. Completing implementation of the Brazzaville and Lake Chad Basin Initiatives to strengthen surveillance in localized areas with surveillance gaps; and,
b. Accelerating expansion of environmental surveillance to additional sites in high risk countries.

**Yellow Fever**
- Steps should be taken
  - Reduce response time between identifying cases and implementation of outbreak response interventions.
  - Maintain high immunization coverage in Routine Immunization during outbreaks
  - Revise Laboratory algorithms to include real time PCR.
  - Promote community engagement in vector control activities using lessons from the PAHO region.
  - Review the efficacy and feasibility of the use of fractional doses in situations where stockpiles of vaccine are low.
  - Address cross-border transmission through implementation of IHR 2005.
  - Provide language relevant technical assistance to Angola from PAHO.
  - Appoint two Yellow Fever Focal Points in AFRO to address surveillance and programming.
  - Encourage increased vaccine production capacity and thus improved stockpiling.
  - Offer guidance to develop an integrated package addressing mosquito-borne infections (aedes aegypti): immunization, detection/case management and vector control. Relevant in terms of global health security.
  - Leverage the available in-country PCR equipment for yellow fever diagnosis by providing training and reagents to countries.

**Meningitis**
- Strategies for control of *streptococcus pneumoniae*
  - Noting the changing epidemiology of *S. pneumoniae* meningitis, and the opinion of the expert group, RITAG requests further information on why the expert group believes this was due to biological evolution and not serotype replacement.
  - Noting these outbreaks, the use of PCV in routine immunization should be re-enforced.
  - Re-enforce early diagnosis and improved case management.
• RITAG notes that the pentavalent vaccine (ACWXY) is being developed by Serum Institute of India, and requests that WHO ensures that advanced forecasting is undertaken to address global needs to ensure that Africa has sufficient and affordable supplies to meet requirements.

• Countries planning to introduce MenA into routine immunization need to consider their country specific epidemiology, age-specific attack rates, projected impact, and programmatic experiences.

☐ **Vaccine Regulation**

• Strengthening National Regulatory Agencies (and IRBs) through
  o Joint reviews where multi-country projects are undertaken (e.g. malaria vaccine);
  o Expansion to include all regional bodies such as the East Africa Community, SADC, ECOWAS and OCEAC;
  o Learning from countries in the region with strong NRA capacity; and,
  o Advocacy for adequate funding, communication and support.

• In Implementation Pilots and Phase IV Trials, such as the malaria RTS,S vaccine, document results, develop guidance and share lessons.

• Concerning Emergency Response vaccine trials like for Ebola, monitor the process and share lessons within the region, for use in future outbreaks and emergencies. Document best practices in providing speedy review and approval processes.

• Monitor off-label use of vaccines and provide guidance for appropriate regulatory processes such as fractional doses for yellow fever or changes in target groups.

• Liaise among RITAG and other entities to provide a RITAG perspective as well as foster regional coordination in their activities in strengthening NRAs. These groups include AVAREF, PDVAC, G7 CEPI and disease specific task forces, among others.

• WHO should seek the opinion of RITAG about trials for new vaccines (such as EVD, malaria) and for novel use (YF fractional dose, maternal immunization) that have significance in the African region. Specifically, RITAG requests study plans and regular phase IV reports on RTS,S malaria vaccine, and plans for use of Ebola vaccines in outbreaks.

☐ **Universal Health Coverage**

• RITAG was pleased to receive information on UHC, and will consider this in its future programme of work. In particular the RITAG noted the following:
  o The importance of SGDs and the proposed inclusion of immunization targets
  o The essential interface between health and development
  o Health systems strengthening is a long term developmental issue

Noting the publication experience from Nigeria polio programme and Chad nomadic immunization, RITAG recommends that WHO documents best practices for immunization as a contribution to the attainment of universal coverage.
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<td>AFRO</td>
<td>African Regional Office</td>
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<td>AFP</td>
<td>Acute flaccid paralysis</td>
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<td>ANC</td>
<td>Ante-natal care</td>
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<td>ARCI</td>
<td>African Regional Conference on Immunization</td>
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<td>ARICC</td>
<td>Africa Regional Inter-agency Coordination Committee</td>
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<td>AVAREF</td>
<td>African Vaccine Regulatory Forum</td>
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<td>Bill and Melinda Gates Foundation</td>
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<td>bOPV</td>
<td>Bivalent oral polio vaccine</td>
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<td>CDC</td>
<td>US Centers for Disease Control and Prevention</td>
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<td>cMYP</td>
<td>Comprehensive multiyear plans for immunization</td>
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<td>CRS</td>
<td>Congenital rubella syndrome</td>
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<td>CSF</td>
<td>Cerebrospinal fluid</td>
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<td>CSO</td>
<td>Civil society organisations</td>
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<td>CTC</td>
<td>Controlled Temperature Chain</td>
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<td>cVDPV</td>
<td>Circulating vaccine-derived poliovirus</td>
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<td>DHF</td>
<td>Dengue Hemorrhagic Fevers</td>
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<td>Demographic and Health Surveys</td>
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<td>DOPV</td>
<td>Directly Observed Polio Vaccination</td>
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<td>DQS</td>
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<td>Data Quality Working Group</td>
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<td>EPI</td>
<td>Expanded Programme on Immunization</td>
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<td>Gavi</td>
<td>Global Alliance for Vaccines &amp; Immunization</td>
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<td>Geographic Information systems</td>
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<td>GPEI</td>
<td>Global Polio Eradication Initiative</td>
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<td>GPS</td>
<td>Geospatial positioning system (GPS)</td>
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<td>GVAP</td>
<td>Global Vaccine Action Plan</td>
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<td>HPV</td>
<td>Human Papilloma Virus Vaccine</td>
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<td>HR</td>
<td>High Risk</td>
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<td>HSS</td>
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<td>ICC</td>
<td>Inter-Agency Coordinating Committee</td>
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<td>IDSR</td>
<td>Integrated Disease Surveillance &amp; Response</td>
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<td>IMCI</td>
<td>Integrated Management of Childhood Illness</td>
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<td>JRF</td>
<td>The WHO UNICEF Joint Reporting Form</td>
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<td>LGA</td>
<td>Local Government Area</td>
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<td>LMIC</td>
<td>Low and middle income countries</td>
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<td>LQA</td>
<td>Lot Quality Assurance</td>
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<td>MCIA</td>
<td>Ministerial Conference on Immunization in Africa</td>
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<td>MCH</td>
<td>Maternal and Child Health</td>
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<tr>
<td>MCV</td>
<td>Measles-containing vaccine</td>
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<tr>
<td>MCV1</td>
<td>First dose of MCV</td>
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<td>MCV2</td>
<td>Second dose of MCV</td>
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<td>Ministry of Finance</td>
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<td>MOH</td>
<td>Ministry of Health</td>
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<tr>
<td>mOPV</td>
<td>Monovalent oral polio vaccine</td>
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<td>MNT</td>
<td>Maternal and neonatal tetanus</td>
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<td>MR</td>
<td>Measles-rubella [vaccine]</td>
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<td>Médecins sans Frontiers</td>
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<td>Non-governmental organization</td>
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<td>NIDs</td>
<td>National Immunization Days</td>
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<td>National Immunization Technical Advisory Group</td>
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<td>NNT</td>
<td>Neonatal tetanus</td>
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<td>NRA</td>
<td>National Regulatory Authority</td>
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<td>OPV</td>
<td>Oral polio vaccine</td>
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<td>PAB</td>
<td>Protection at birth</td>
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<td>PAHO</td>
<td>Pan American Health Organisation</td>
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<td>PCR</td>
<td>Polymerase Chain Reaction</td>
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<td>PCV</td>
<td>Pneumococcal conjugate vaccine</td>
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<td>PID</td>
<td>Pneumococcal invasive disease</td>
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<td>Rubella-containing vaccine</td>
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<td>RED</td>
<td>Reaching Every District Approach</td>
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<td>RV</td>
<td>Rotavirus Vaccine</td>
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<td>Supplementary immunization activities</td>
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<td>tOPV</td>
<td>Trivalent oral polio vaccine</td>
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<td>TFI</td>
<td>Task force for Immunization</td>
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<td>TT</td>
<td>Tetanus toxoid</td>
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<td>UNICEF</td>
<td>United Nations Children’s Fund</td>
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<td>VAP</td>
<td>Vaccine associated poliomyelitis</td>
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<td>VCMs</td>
<td>Volunteer community mobilisers</td>
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<td>VHF</td>
<td>Viral Hemorrhagic Fevers</td>
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<td>VPD</td>
<td>Vaccine Preventable Disease</td>
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<td>YF</td>
<td>Yellow Fever</td>
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<td>WHA</td>
<td>World Health Assembly</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>WPV</td>
<td>Wild poliovirus</td>
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1.0 BACKGROUND

This is the first of two regular meetings of the newly reconstituted Regional Immunization Technical Advisory Group (RITAG) of the WHO African Region in 2016. On assumption of office earlier this year, the Regional Director Dr Matshidiso Moeti defined new strategic priorities in engaging the member states, partners, and stakeholders to re-position the organization to address the health priorities of member states. She identified universal health coverage and equity in access as the flagship of the transformation agenda put in place in the Region.

In the light of the above the Regional Director reconstituted and transformed the former Task Force on Immunization (TFI), the principal advisory group to the WHO Regional Office for Africa (WHO/AFRO) for development of policies related to vaccines and immunization, to a RITAG. Additional experts were brought on to work with some of members of the TFI. New terms of references (ToRs) were developed to guide the functioning and role of the new RITAG.

The RITAG is set up to advice the office of the Regional Director on the adequacy of the regional immunization strategic plan and corresponding priority activities to achieve the goals of the Global Vaccine Action Plan (GVAP), taking into consideration the comparative advantages and respective roles of partner organizations. The RITAG is also expected to monitor progress, major risks/challenges and threats, propose recommendations to address these and to achieve GVAP and other global health targets, including the Sustainable Development Goals (SDG) within the WHO African Region.

Noting that 8 out of the 15 RITAG members are newly appointed, and taking into consideration that the mandate of the RITAG now extends to the control of all vaccine preventable diseases, promoting immunization throughout the life course, in the context of health systems strengthening, an in-depth RITAG members’ briefing/meeting was convened at the WHO Regional Office for Africa, Brazzaville, Congo, from 05-08 July 2016. The three-day meeting focused on:

- Briefing RITAG members on the work of WHO in general and its on-going reforms;
- Briefing RITAG member on the transformation agenda of the WHO/AFRO;
- Appraising RITAG members on the WHO’s regional priorities in the area of immunization, and programmatic challenges being faced;
- Agreeing upon the modus operandi for RITAG over the coming 3 year period; and
- Eliciting RITAG recommendations on key immunization related challenges and issues faced by the region, namely yellow fever and meningitis, vaccine regulation, and universal immunization coverage, among others.

This report provides a detailed account of the meeting and its key outcomes.
2.0 INDUCTION BRIEFING

2.1 Opening

The meeting was officially opened on behalf of the Regional Director by Joseph Cabore, Director of Programmes and Management (DPM), on Tuesday 5th July, 2016. He thanked the 15 RITAG members for accepting the invitation to serve on the WHO AFRO RITAG and to offer their skills and experience; 8 for an initial period of 3-years and 7 for continuing to serve for a further 3-year period.

He reminded the members about the Terms of Reference of the RITAG. The DPM also made reference to the first-ever Ministerial Conference on Immunization in Africa (MCIA) that took place in Addis Ababa in February 2016. “We now have the opportunity to build upon this momentum to generate lasting impact by ensuring the signed Ministerial Declaration entitled: Universal Immunization Coverage as a Cornerstone for Health and Development in Africa, is effectively implemented”, he stated.

The two reoccurring themes throughout the MCIA were strong political commitment and the active engagement of communities in demanding vaccines and immunization services, both critical to achieving GVAP goals within the African region. He called upon RITAG Members to advise the WHO Regional Office on actions to take to ensure that the momentum from the Ministerial Conference is built upon – an effort that is particularly timely as the world enters the second half of the Decade of Vaccines.

The RITAG Chair, Professor Helen Rees, welcomed both old members of the TFI, now RITAG and the new members. She underlined the unique role WHO plays in public health as an organization with UN mandate to provide global guidance for health and delivery of health services. She indicated that there is a lot of unfinished work with old diseases like rabies, but also new emerging diseases. The committee will have lots of work to help shape the thinking around how vaccines and immunization can be used to tackle these issues. The RITAG Chair reminded members that in their advisory capacity to WHO, RITAG can make a profound difference to achieving the target of full benefits of immunization to all in the African Region.

Okwo-Belle, Director of Immunization, Vaccines and Biologicals, HQ, noted that RITAG will be expected to advise WHO/AFRO on what should be done to support countries as well as advising countries in what they should be doing to move the immunization agenda forward.

On behalf of Felicitas Zawaira, Director Family and Reproduction Health (FRH), Richard Mihigo, Manager, Immunization and Vaccine Development (IVD) programme, WHO/AFRO presented the programme of work (annex 1) for the meeting. He noted that the organization is keen on hearing RITAG’s advice on yellow fever and meningitis outbreak responses among other issues.
2.2 Overview of WHO/AFRO, SAGE & NITAG

2.2.1 Introduction to WHO/AFRO; its structure, governing bodies; relationship with countries and partners; funding sources

Dr Richard Mihigo, IVD, WHO/AFRO

Richard Mihigo took members through the structure of the organization, highlighting its governing bodies and its relationships with countries and partners as well as its funding sources. In doing this, he illustrated the core values of the organization to include equity, social justice, universality and people centeredness. He noted that the landscape has evolved from 1948, when WHO was the only organization charged with the task of ensuring public health, to-date when multiple players are operating in the health sector.

He also addressed:
1) The WHO Reforms, highlighting the organization’s vision, and its six key programmes of work, the five main areas of WHO managerial reform in pursuit of organizational excellence, as well as the WHO/AFRO’s transformation agenda.
2) Funding and the budget and the top 20 voluntary contributors to the organization.
3) Immunization priorities of the WHO in the African Region.

Comments and Observations
1. WHO AFRO should document the contributions made by member states to immunization both directly to their own programmes and through WHO.
2. The changing landscape with increased involvement of many partners in health should be taken positively. It is the responsibility of RITAG to help WHO strengthen its coherence in a ‘chaotic’ environment, and distinguish itself as leader in the field.
3. In summary, Chair of RITAG noted that the best solutions are win-wins. She stressed the need to think about how with all these partners, the win-win scenario can be achieved. WHO needs to distinguish its leadership role, and exploit its comparative advantage.

2.2.2 SAGE and its link with RITAG

Jean-Marie Okwo-Bele, IVB, WHO Geneva

He presented the mandate of the Strategic Advisory Group of Experts (SAGE) on Immunization, which is the principal advisory group to WHO for vaccines and immunization. SAGE advises on global policies and strategies, ranging from vaccines and technology, research and development, to delivery of immunization and its linkages with other health interventions as well as makes recommendations on use of vaccines, which drive WHO position papers. He discussed the mode of operation of the SAGE as well as the preparations for SAGE meetings and agenda-setting.

He also addressed/noted that:
1) Issues taken into consideration by SAGE include disease epidemiology, clinical characteristics, vaccines and immunization characteristics, and economic considerations. Others include health system opportunities and existence of, and
interaction with other existing interventions and control strategies, as well as social impact/legal considerations/ethical considerations.

2) The pathways for WHO recommendation on vaccine use as well as immunization policy advisory framework, among others.

3) SAGE meetings are often composed of two categories of agenda items, namely the running items and specific topics. Under the running items, the SAGE considers global reports, reports from Gavi and reports from other advisory committee on immunization. The specific topic items are dictated by the current immunization priorities and realities.

Comments and Observations

1. RITAG can request a topic for inclusion on SAGE agenda e.g., vaccine specific to the region or implementation issues related to vaccine delivery. RITAG input would be useful in helping focus the SAGE agenda.

2. RITAG can adopt and adapt SAGE recommendations for the region.

3. It would be helpful to establish a peer review process with a clear window allowing for feedback on publications prior to them being published.

2.2.3 Role of NITAGs in supporting national immunization programme

Blanche Anya, IVD, AFRO

The presence of a functional independent technical advisory group is one of the indicators of this first strategic objective of the GVAP and RSPI. RSPI has a target of 20 countries with functional National Immunization Technical Advisory Group (NITAG) by 2015; 40 countries by 2017; and, all 47 countries by 2020. However, many countries in the Region are yet to establish NITAGs. Additionally, existing NITAGs do not always fulfil all criteria of functionality.

The role of the NITAG is to provide guidance to policy makers and to make evidence based immunization related policy decisions based on local epidemiology and cost effectiveness. NITAG membership consists of 10-15 independent experts with broad range of disciplinary backgrounds. The advantages of having a NITAG include the provision of timely, evidence-based recommendation on vaccine policy in the country as well as placing global and regional recommendations in the context of the country among others.

As of June 30, 2016, only 18 countries indicated having NITAGs in the AFRO region. The main challenges include low appreciation by countries of the role of NITAGs, including difference with inter-agency coordinating committees (ICC) and working groups. Some useful resources that can be accessed from the NITAG Resource Centre through the link http://www.nitag-resource.org

Comments and Observations

1. NITAGs should be locally funded by the government rather than externally if they are going to play a truly independent role in advising the government for services that may be heavily externally funded.

2. Available TORs differentiate NITAGs from ICC; ICCs help countries with implementation, while NITAG provides policy advice.
3. RITAG could propose coordination of meetings so that they can feed into each other from SAGE, RITAG to NITAGs. We should consider rotation of invitations to RITAG for NITAG chairs.

4. Confidentiality clauses should be added to the SOPs of NITAGs, recognizing that meetings of these groups will increasingly become public.

2.3 Briefing on WHO/AFRO Immunization Priority Areas of Work

2.3.1 Regional Strategic Plan for Immunization 2014-2020

Balcha Masresha, WHO/AFRO

He presented the Regional Strategic Plan for Immunization (RSPI) 2014-2020. The development of the RSPI followed a comprehensive consultative process involving countries and partners on the need to develop a regional plan that is aligned to the GVAP, after the 2013 independent evaluation of the Regional Immunization Plan of 2009-2013. The TFI approved the draft RSPI in May 2014, and in November 2014 the Member States of the WHO African Region endorsed the RSPI during the 64th session of the Regional Committee.

The strategy aims to achieve universal immunization coverage within the African Region. The objectives include: to increase vaccination coverage; complete the interruption of poliovirus transmission and ensure virus containment; eliminate measles and advocate for the elimination of rubella and congenital rubella syndrome; as well as attain and maintain elimination/control of other vaccine preventable diseases. The guiding principles include country ownership, partnership and mutual accountability, access to universal health coverage and integration, sustainability, innovation and quality improvements. Clear roles and responsibilities have been defined for all stakeholders including governments, communities, WHO and partners.

2.3.2 RITAG in the Era of Decade of Vaccines

Helen Rees, Chair, RITAG, WHO/AFRO

She recapped the genesis of the decade of vaccines, and noted that all 193 Member States of the World Health Organization approved the need for a global vaccine action plan at the 64th World Health Assembly in May 2011. Our region however still has exceptional unmet needs for vaccines and immunization.

She also noted that:

1) The quality of data currently reported was inadequate to reliably monitor progress and make programmatic decisions.
2) Polio eradication remains a public health priority.
3) We should ensure access to quality vaccines and new technologies to drive progress.

Comments and Observations on Presentations by Dr Masresha and Prof Rees

1. The right to health by all peoples and health as a human right should be referenced.
2. Lessons could be learned from the onchocerciasis programme. Communities should not just be consumers, but be involved in planning and delivering immunization programs.
3. We need to support research and training institutions in the strategic plan. The plan should also address emerging diseases that will need vaccines and immunization.

4. Routine Immunization should continue during emergencies. This should be addressed at the mid-term evaluation next year.

5. The components of the WHO blueprint on R&D should be institutionalized e.g., which pathogens, and design of clinical trials, in advance of epidemics.

6. RITAG can shape the work of GAVI, especially guidance for the region. This has worked well between WHO/SAGE and GAVI.

7. What would be the role of RITAG in terms of advocacy to address financial stability for immunization post-PEI? We should study this strategy, and identify areas where we are lagging behind and discuss at the next meeting.

8. WHO/AFRO will formally notify Polio/Immunization TAG Members and their chairs on the decision made to dissolve these committees.

9. Taking into consideration that a mid-term assessment of the current African Regional Strategic Plan for Immunization in 2017 will be undertaken, RITAG members to take the opportunity to review the current Strategic Plan to determine which areas that need to be strengthened.

10. At the next RITAG Meeting in December 2016, Measles/Rubella elimination goal should be added to the agenda.

2.4 Functioning of RITAG

2.4.1 RITAG Future Working Arrangements & Modalities including RITAG Working Groups

Helen Rees, Chair, RITAG, WHO/AFRO

The key recommendations of the last TFI include: Polio/TAGs remain autonomous from RITAG to be chaired and run by national authorities, while RITAG continues to give advice to WHO Regional Director on overall GPEI progress; nominate an officer to support RITAG, dedicating at least 50% of time to RITAG matters; and, RITAG be more responsive to contingency planning and preparedness to enable WHO to respond well to public health or humanitarian emergencies by proposing to the Regional Director/AFRO recommendations that will enhance contingency planning and preparedness in terms of vaccine development and maintaining immunization services in times of emergencies.

Other recommendations of the last TFI include: the Chair of Regional TAGs (including RITAG) to attend meetings of the WHO/AFRO Independent Advisory Group (IAG) as observers. This would allow Regional TAGs to focus TAG deliberations in line with strategic and policy advice by the IAG; and, update the functions of the RITAG to align with the new strategic directions as outlined in RSPI and GVAP.

She highlighted the mandate of the RITAG. She ended by noting that currently there are four RITAG working groups on country ownership; data quality; demand creation and communications and increasing coverage.
Comments and Observations

1. It was proposed that meetings be fixed for June and December. In addition to this the RITAG have two additional teleconferences between the meetings. The quality of teleconferences should be enhanced.

2. Each time there is an emergency RITAG should meet to define policies for RD.

3. Having meetings in Brazzaville is very important for secretariat support. In the light of this, it was decided that one meeting should be held in Brazzaville.

4. The utility of the four Working Groups will be revisited. TORs and period of performance for the measles TAG will also be considered. If it is measles and rubella and goes into the future, we need to think about how to structure that.
3.0 RITAG MEETING

3.1 Opening

On behalf of Dr Matshidiso Moeti, the Regional Director, Dr Joseph Cabore, the Director of Programmes and Management (DPM), welcomed participants to the meeting. Her absence notwithstanding, she placed high premium on the meeting, and deliver a recorded message.

The RD thanked all Members of the WHO African RITAG for accepting invitation to serve on the RITAG. This is an opportunity to build upon the momentum generated for a lasting impact by ensuring the effective implementation of the signed Addis Ababa Ministerial Declaration. She flagged country ownership, strong political commitment and the active engagement of communities demanding vaccines and immunization services as critical to achieving GVAP goals within the African. She also highlighted integration of activities to support the overall strengthening of the health system.

She also highlighted need to improve data quality, VPD surveillance, surveillance and immunization services in insecure settings. “There is a need to maintain core elements of the polio-funded infrastructure in the post-polio eradication era and I expect to receive constructive advice on the ongoing polio transition planning exercise as well as the feasibility of attaining set goals for special initiatives such as the measles elimination goal set for 2020.”, she added.

She paid a special tribute to Professor Francis Nkrumah, the first-ever Chairperson of the WHO African Task Force on Immunization who, earlier this year, resigned from the African Regional Polio Certification Commission due to personal reasons. In her words, “Professor Nkrumah is a fine scientist of exceptional rigour and self-discipline – virtues which propelled him to the pinnacle of scientific distinction as a professor of paediatrics, and an infectious disease and public health specialist”. She said that it is her honour to recognize Professor Nkrumah in the form of an Award to be presented by the current RITAG Chair – Professor Helen Rees – for his outstanding contribution to immunization within the African Region.

In her remarks, the Chair of RITAG paid glowing tribute to Professor Nkrumah. Two short videos of testimonies of people who have worked with Prof Nkrumah were played. Drs Okwo-Bele and Deo Nshimirimana, who both worked with Prof Nkrumah paid tribute to him. “He is one of those who made the world to believe in Africa”, said Dr Okwo-Bele.

The RD’s award to Prof Nkrumah was handed to the Chair of RITAG by DPM. It will be passed on to Professor Nkrumah.
3.2 Technical Session

Overview

The primary goal for this meeting is to assess the performance of the immunization programme in the African Region in delivering services to protect the African peoples from vaccine preventable diseases; discuss challenges and seek RITAG advice on how to better deliver on the WHO mandate to the people of the region and the world. The focus was on immunization coverage and equity; yellow fever and meningitis as well as vaccine regulation and universal immunization coverage. These were put into a 3-session agenda.

Over 10 presentations were made in plenary, addressing the meeting agenda items. Each presentation comprised the background information, the status of implementation, and the challenges and issues for discussion. The presentations were followed by discussions and actionable recommendations. The presentations, highlights of subsequent discussions and the recommendations are summarized below.

3.2.1 Immunization Overview

Updates on immunization programmes

Updates on immunization coverage and equity in the African Region

Richard Mihigo, IVD, WHO/AFRO

He noted that aim of the 1st ever Ministerial-level conference on immunization in Africa (MCIA) was to secure the commitment of governments and their partners to reach and sustain the required immunization quality and coverage as stipulated in the GAVP and the RSPI. The high point of the conference was the endorsement of the Addis Ababa Declaration on “Universal Access to Immunization as a Cornerstone for Health and Development in Africa”. The presentation also noted that Post-MCIA roadmap is currently being developed.

He also highlighted immunization programme performance across the region for different antigens. Of special note, of the 19 countries that have not eliminated maternal and neonatal tetanus, 11 are from the Region. Six of the 11 made good progress and are ready for validation.

The epidemiology of yellow fever is changing, with central and east Africa as areas with new urban outbreaks, high risk of large deadly outbreaks and high risk of national and international spread. The presentation also addressed the control of MenA outbreaks and re-emergence of non-A outbreaks, and challenges of vaccine availability.

He also highlighted government funding of vaccines and routine immunization (See Fig 1).

Comments and observations

1. The impact of outbreaks is massively disrupting. RITAG members noted the impact of the economy in Angola and devolution in Kenya on resource availability.
2. They also noted: data quality problems affecting countries; the need to explore appropriate technology for maintaining cold chain, and tools for reporting; challenges with manufacturing affecting stock-outs; need to work with MPs to mobilizing funding and hold governments to the MCIA commitments.

Global overview of polio eradication efforts
Michel Zaffran, POL, WHO/HQ
He provided an overview of the global polio situation, with wild poliovirus type 1 (WPV1) being reporting in Afghanistan and Pakistan. Of the 22 circulating vaccine derived poliovirus (cVDPV) cases, 8 were from the African Region. Overall, there has been significantly improved situation with decrease in number of polio cases and environmental samples; and improved access and quality of SIAs. The presentation highlighted four major sources of concern in outbreaks of cVDPV, namely Myanmar, Guinea, Nigeria and DRC.

The presentation addressed the transition planning at country, regional and global levels (See Fig 2).

Comments and observations:
1. The leadership shown by governments and donors should not be allowed to wane; the funding should not be allowed to decline – it should be maintained for routine immunization.
2. The Independent Monitoring Board should continue its work in monitoring progress towards objective 1. The new independent board will focus on objective 4, assessing progress by partners/funders, to ensure enough international attention is put to the transition. Its first meeting will take place in fall 2016.
3. IPV production capacity – we expect to have adequate supply by 2017. Companies are being supported to meet demand. In the future OPV will be replaced with several doses of IPV and this manufacturing capacity will be needed.

4. There are areas in Northern Nigeria that have been inaccessible for several years, and the quality of surveillance is uncertain. The virus could be circulating in this area, and the neighbouring countries (Cameroon, Niger).

5. Other countries should publish their experiences with polio eradication as did Nigeria.

6. There is need to recognize that the polio infrastructure has been the backbone for RI for countries, WHO, UNICEF. We cannot underestimate the likely impact of the transition and there will be consequences for many countries’ and agencies’ ability to conduct surveillance and other key activities.

**Progress and dealing with remaining challenges in the African Region**

**Pascal Mkanda, PEP, WHO/AFRO**

The last case of WPV1 was reported in Nigeria in 2014, and WPV3 was last reported in Nigeria in 2012. cVDPV2 was last reported in Guinea in December 2015, and VDPV2 in DRC in March 2016, while a VDPV2 case was reported in Jigawa State, Nigeria in May 2016.

Environmental surveillance in sewage systems isolated cVDPV2 in Borno, Nigeria in March 2016, and VDPV was isolated in Nairobi, Kenya in December 2015 (see Fig 3).

All 47 member states have effectively switched from tOPV to bOPV, while polio-free country documentation was accepted by African Regional Certification Commission, July 2016 (See Fig 4).

Transition milestones include the finalization of inventory and mapping; finalization of transitional plans and the start of implementation of transitional plans by January 2017.

**Comments and observations**

1. There are 4 countries that share areas where polio surveillance is
weak or not well understood. Immunization activities were integrating surveillance to enhance monitoring of AFP cases in inaccessible areas.

2. We are living through history with the extraordinary achievements. The IPV introduction has been successful, the shortages notwithstanding. The polio strategy has produced best practices we can use for other areas.

3. RITAG needs to look at the country plans for the 16 countries, and advice on funding sources. For polio to be successful, routine immunization must be successful and continue at a very high level. It was also recalled that ministers at the MCIA said they will continue to require donor funding.

3.2.2 Yellow Fever and Meningitis

Yellow Fever in the African Region – an Emerging Public Health Threat

Sergio Yactayo, WHO/HQ

Of the 47 endemic countries, 33 are in Africa and 14 in South America. Approximately 897 million people are at risk and >20% (178 million) are in urban areas. In Africa the burden of yellow fever is 84,000 to 170,000 cases and 29,000 to 60,000 deaths. Before 2006, yellow fever outbreaks were uncommon and occurred mainly in West and East Africa. Increasingly Central Africa has been affected.

The success story of the Gambia was highlighted. Following a national Preventive Mass Vaccination Campaign in 1978/79, followed by introduction in RI 3 months later, to date only two cases have been reported in travellers (see fig 5).

Routine EPI is the second pillar for yellow fever outbreak control. Despite this evidence, 11 out of the 34 countries in the yellow fever belt in Africa are yet to introduce the vaccine in the routine EPI.

![Fig 5: Combined vaccination strategy in the Gambia 1979](image)
Yellow fever surveillance after mass vaccination and vector control
Sergio Yactayo, WHO/HQ
The challenges to yellow fever surveillance include diagnosis that is based on ELISA IgM which persists for 3-5 years; and cross-reactions with other viral infections. Therefore, laboratory confirmation needs to include molecular (< 10 d) and serological methods. Other problems include inability to differentiate IgM from vaccine/wild virus; and the YF case definition that needs to be more specific and include proteinuria. Yellow fever surveillance relied on polio and measles systems. Others strategies include insecticide use (ex. Deltamethrin) could be recommended in some circumstances for urban outbreaks when vaccine is not available or used during a short period of time to decrease vector density.

Comments and Observations
1. The issue of port of entry and transportation of live mosquitoes and larvae through borders was noted. Vectors can be monitored at airports and spraying with pyrethroids is already included in IHR Recommendations). Land borders are very tricky to deal with and require cooperation between countries.
2. YF vector (Aedes aegypti) operates during the day, and likes clean water only – so bednets will not work; nets only used over patients to protect others.
3. Limited access to reference laboratories remains a challenge in diagnosis.
4. The rate limiting factor in the use of fractional dose is the availability of syringes. The polio program has a stock pile of 10m syringes, and there are ongoing discussions to see how to use this stock pile.
5. We need to have communities get involved in planning, and response, otherwise they become suspicious and not cooperate.
6. We need a focal person for the response to handle vaccine issues. The stockpile is 6m is inadequate for global needs. About 18 million vaccine doses have been used already this year. We propose to use fractional dose for Angola, and DRC. Each vial will be used for 4 people for practical purposes (not 5).
7. Normally we do response in 7 days – this was not the case in Angola. The political support was not optimal, and the response was not in emergency mode.

Managing the yellow fever outbreak in Angola
Alda Morais De-Sousa, EPI Manager, MoH/Angola
YF vaccine was integrated into Routine EPI in 1980 with low coverage range of 40-77% from 2008-2015. No previous mass preventive YF vaccination campaigns. There are urban and rural breeding sites for Aedes aegypti mosquitoes. Mining, agriculture and logging present occupation hazards, and there are primate reservoirs. Past outbreaks in 1971 and 1988 were in Luanda province. Fig 6 shows the distribution of yellow fever

The overall management of the outbreak is coordinated by National outbreak Management Committee, chaired by the Minister of Health. The WHO has established an Incident
management system (IMS) to facilitate the MoH coordination of the international partners’ support to the response.

Since the confirmation of the outbreak 13,928,270 doses of YF vaccine was received from ICG. A total of 11,209,178 people were vaccinated in 39 districts in 9 provinces.

Some of the challenges included limited availability of YF vaccines, and language limitation for the provision of technical expertise.

**Comments and Observations**

1. Diagnosis currently uses PCR – capacity has been enhanced in the country. Most of the probable cases had no or inadequate blood samples to conduct the test.
2. We need to re-define the risk and not rely on the IHR assessment done a while back.
3. At the central level in Luanda and in most districts in Angola there is cold chain capacity. Immunization is conducted after local confirmation of outbreak, and takes 2 months; we have enough time to set up the delivery platforms including cold chain, and the teams.
4. DRC developed a response plan once the epidemic started in Angola. The plan addresses all aspects including immunization, case management, and surveillance.
5. Countries should monitor impact of the outbreak on EPI coverage.
6. The Chair of RITAG noted that epidemiology is changing with global warming, and urbanization. She also noted that there is an opportunity with the dry season. She stressed the need to finish the job in Angola, and do for the DRC geographically targeting. Strategy that has been recommended is RI plus mass campaigns, accompanied with vector control, larvicides, community mobilization, surveillance, improved case diagnosis, and how we address the probable cases. Furthermore she noted that we should anticipate that we are going to see more outbreaks with changing climate, urbanization, slums – 6m dose stock pile is not enough.
7. On the use of fractional vaccine dose this should be carefully studied in populations where it is used to establish longevity of immunogenicity. Regulatory requirements when using fractional doses should be met.
8. We need a focal point for the Africa region for YF given who will anticipate in future outbreak responses.
Preparing for the next Meningitis Season and ensuring Long-term control of Epidemics in the Meningitis Belt Countries

Epidemic meningitis in Africa: epidemiology and control strategies

Andre Bita, WHO Intercountry Support Team for West Africa (IST/West)

A review of the epidemiology of meningitis in Africa shows the peak of cases and deaths was in 2009 when 88,199 cases and deaths were recorded. This was the period immediately before the introduction of MenAfriVac. Following its introduction in 2010, cases and deaths due to meningitis in African have dropped significantly to 30,103 and then declined consistently with increase in vaccination, with only 14,338 cases (all sero-groups) reported in 2016. Meningitis outbreaks between 2009 and 2016 affected mostly Niger, Nigeria and Burkina Faso. See Fig 7.

There were also significant decreases of NmA after the introduction of MenAfriVac in 2010. Only 1 case of NmA in BFA in a vaccinated child aged 8 years old over 46 NmA confirmed in 11 countries that conducted MenAfriVac campaigns.

NmA after 2010 was Sp, NmW, NmC (2015, 2016) and NmC likely due to natural evolutionary changes in the bacterial population, probably not a replacement.

Fig 7: Epidemiology of meningitis in Africa

Challenges with introducing MenAfriVac into routine immunization

Carol Tevi-Benissan, WHO/AFRO

The epidemic meningitis control strategy and MenAfriVac introduction were meant to induce herd immunity against MenA, protect new birth cohorts and enhance surveillance and outbreak response capacity.

Mass vaccination with MenA vaccine was conducted 5 - 6 years ago, targeting 1 -29 year olds, brought almost to zero the risk of meningitis A epidemics. There has however been an accumulation of susceptible populations for NmA (from unvaccinated new born cohorts) from 2010 onwards.
Introduction of routine immunization is key to eliminating risk of NmA outbreaks by targeting these susceptible populations. Fig.8 shows the comparison of scenarios for modelling vaccination strategies with MenA.

The presentation also identified opportunities of MenA transition into routine. It noted that there exist high community demand for MenA in all countries; an opportunity to catch up on previously missed vaccinations (MCV1, MCV2, Penta, PCV); future vaccines could take advantage of this contact (malaria vaccine in the second and third years of life) and an opportunity to build a stronger second year of life (2YL) platform (spread out the (crowded) immunization schedule beyond infancy?; other healthy child visits in the 2YL (nutrition, Vitamin A, etc).

The next steps include supporting the remaining countries to conduct mass vaccination campaigns (1-29yrs old); support countries to introduce the MenA vaccine into their routine program; and, ensure that countries conduct a one-time mini catch-up campaign for new birth cohorts not eligible for routine.

**Responding to non-A meningitis outbreaks**

Andre Bita, WHO Intercountry Support Team for West Africa (IST/West)

Non-A epidemics remain a public health problem with an increase in cases of NmC to more than 2,000 in 2015 (See Fig.9).

Since 2010, with the introduction of MenAfriVac, NmA has been drastically reduced. However, NmW and NmC now constitute threats while Streptococcus pneumoniae is priority.

Some of the challenges
facing the control efforts are vaccine availability; epidemiology of non A meningitis such as the emergence of NmC; and unpredictability of serogroup emergence.

The issues raised for consideration by RITAG were:
1. Other types of pathogens emerging, and the development of affordable polyvalent conjugate vaccine. Should we go for CW, CWA or ACWYX?
2. How do we make a longer term vaccine forecast for reactive vaccination?

Comments and observations
1. The RITAG noted that ACW vaccine from GSK was available in the past as polysaccharide, but is not available in sufficient quantity.
2. The programme moved to case-based surveillance during research phase with MenA; do we still need case-based surveillance or simply use the lab to determine the case mix.
3. It is important to communicate to communities that the vaccine is only protective against some forms of meningitis but not all.
4. It would be helpful to know the cost of the different valents to guide decisions. However, given the uncertainty around serotype emergence, we may be safer with a broader rather than a narrow option is there is no big difference in cost.
5. There is need for better clarity on the changing sero-type picture – is this replacement or natural emergence as suggested by the presentation.
6. Funding of surveillance is dependent on donors and donors funding can be tough to mobilize. They also noted that a lot has been said about vaccination hardware, now we need to also focus on the software (institutions, communities).
7. Some countries are reluctant with multiple injections but not all. Sometimes it is more the provider and not the mothers objecting. At the global level there is a reflection on how we can use the 2nd year of life for catch-up for those who have missed vaccination in the 1st year. Using this contact can also help with uptake of all vaccines. The 2nd year of life is a good platform given measles is also being given around this time.
8. The Ghana outbreak was mainly among adults and not vaccine eligible children. The serotypes implicated for outbreak in Ghana were serotype 1 (80%) which is in PCV 13; and the 2nd was 12F, and 4% was 35B. Also in the later 90’s outbreak in Burkina Faso was predominantly serotype 1.
9. In her summary, the Chair noted that there are clear overlaps with YF, and it could be a good idea to reflect on how we integrate surveillance. She also made reference to the ICG study supported by the Gates Foundation and said that it would be very helpful in untangling the issues; If countries are ok with giving MenA in the 1st year, it was not clear why we should do a 2nd year. If the issue is health workers, then we need health worker education. We need to leverage global health security and advocate for support.
3.2.3 Vaccine Regulation and Universal Immunization Coverage

Vaccine regulation: Regulatory pathways for new vaccines in Africa

Overview of vaccine R&D and regulatory challenges in Africa
Dicky Akanmori, WHO/AFRO, IVD, Brazzaville, Congo

There is now a mosaic of regulations to govern product development & oversight. This creates inefficiency, and adds costs to delivery of new vaccines. Greater harmonization could enhance R&D, reduce costs and timelines. Large portion of R&D budgets are spent on differing regulatory requirements across countries for same therapy, for same disease with no obvious added benefits.

He highlighted the pathway for product development, and the role of the WHO in product development i.e. setting norms and standards based on evidence. He discussed the WHO vaccine preparedness blueprint with illustrations using the target product profiles (TPP) for Ebola vaccines and MERS Cov. He also highlighted vaccine clinical trials that have occurred or planned to occur in Africa.

Major challenges to R&D in Africa were discussed to include few developers of de novo products; lack of manufacturing of investigational lots; few sites with capacity for phase 1 trials and large phase 3 trials. He provided updates on the African Vaccine Regulatory Forum (AVAREF) approach to capacity building including: Norms and standards were agreed; Expertise was shared – Ghana hosted review for Sierra Leone; Definition of pathways for approvals of clinical trials; Standard submission; Networking and harmonization; Guidelines and support for review of Clinical Trial Applications and authorization of clinical trials; and, Convenor of joint reviews assisted reviews.

He discussed the vaccine R&D pipeline from the recent PDVAC publications (table 1).

Table 1: New Vaccine Pipeline

<table>
<thead>
<tr>
<th>Pathogen/Dx</th>
<th>Burden</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory Dx Vaccines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RSV</td>
<td>No.1 cause of childhood pneumonia</td>
<td>Novavax’s RSV F-protein based nanoparticle vaccine most advanced - Phase III started at the end of 2015</td>
</tr>
<tr>
<td>GBS</td>
<td>No.1 cause of neonatal sepsis and meningitis</td>
<td>Phase III</td>
</tr>
<tr>
<td>Influenza</td>
<td>20.5M cases; 110k deaths among under-5s Under-5s shed virus longer</td>
<td>2012 WHO recommendation to use existing seasonal influenza vaccines</td>
</tr>
<tr>
<td>Enteric Vaccines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disease</td>
<td>Description</td>
<td>Challenges</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Shigella</td>
<td>40% of moderate-severe diarrhea. Leads to severe stunting in 4.6 million children annually</td>
<td>Several candidates in clinical dev’t challenge - multivalent approach, standardized assays needed</td>
</tr>
<tr>
<td>ETEC</td>
<td>1 candidate in phase 3, others (1&amp;2) Multivalent approach, standardized assays needed</td>
<td>Clinical proof of concept done. Entering Phase IIb</td>
</tr>
<tr>
<td>Norovirus</td>
<td>200,000 deaths annually</td>
<td>ALVAC/protein heterologous prime boost in Phase 2 Readout in 2020</td>
</tr>
<tr>
<td>HIV</td>
<td>2M new cases; 1.3M deaths</td>
<td>6 efficacy trials in 30 years, best efficacy 31% (RV144) Mutability &amp; genetic diversity of HIV a major challenge</td>
</tr>
<tr>
<td>Malaria</td>
<td>198M cases; 0.85M deaths</td>
<td>RTS,S/AS01; positive EMA opinion July’15</td>
</tr>
<tr>
<td>TB</td>
<td>1.3M deaths</td>
<td>Failure of MVA-85A to show efficacy Early stage translational research and exp medicine</td>
</tr>
<tr>
<td>Universal Flu</td>
<td>Hospitalizations in children under 2yr comparable to elderly</td>
<td>PCCs for seasonal influenza vaccines Improved seasonal vaccines in the short term</td>
</tr>
</tbody>
</table>

**Overcoming Regulatory challenges in a emergency situation - Phase III clinical trial of a vaccine against EVD: Guinea Country Experience**

**David Mukanga, WHO AFRO for Binta Bah, DPLM/Guinea**

He discussed experiences from the EVD vaccine trial in Guinea. The challenges included: weak ethics and regulatory capacity (lack of clarity on roles between ethics and regulators, unknown timelines for reviews, and unclear Receipt and Review processes for CTA); inadequate resources including expertise; limited data on product for large trial; first ever vaccine clinical trial in Guinea; unusual accelerate product development pathway; complexity of product, and trial design - replication-competent recombinant Vesicular stomatitis virus based vaccine and Ring immunization adaptive design (not regular RCT) respectively; and, the WHO as sponsor of trial.

Approaches used to overcoming the challenges included: country seeking support from the WHO; availability of data from primate and non-primate studies; data from parallel phase 1 trials in Switzerland, Gabon and Kenya conducted rapidly in 2014; NRA established mechanisms for audit of trial and real time evaluation of safety data.

The lessons learnt from the joint assisted review include: Interpretation of benefit and risk differs. NRA did not have model, and relied on external regulatory assistance. But risk/benefit assessment is specific to population of Guinea where there was ongoing EVD outbreak; NRAs deferred this to their experts, when they should be making this decision; Lack of consistency – No reference to past cases or similar products. No desktop guidelines for conducting assessment; Lack of a model – NRA had no model for assessment. No scoring or weighting
system to arrive at decision; Policies/Legal frameworks incomplete; Separation of administrative and scientific functions; Adoption of model for assessment; and, clear roles, responsibilities and information flow.

Regulatory oversight for the development of the first malaria vaccine in Africa: Country perspectives
Edward Abwao, Head, Clinical Trials Unit, KPPB/Kenya
He provided an overview of the Kenya requirements for oversight of clinical trials including the legal provisions. He noted that the RTS,S/AS01 is a complex pre-erythrocytic stage hybrid recombinant protein vaccine, and this was the first time Kenya was processing an application for a vaccine trial.

Other challenges with application included:
- Using a new adjuvant
- A novel delivery system based on the hepatitis B–malaria antigen fusion protein
- There were no AS01 adjuvanted vaccines licensed yet, although MPL is a component of some licensed vaccines e.g (HPV) vaccine
- A phase 3 trial involving a large number of infants and children with the attendant risks (fig 10)
- There were insufficient safety data from earlier trials

To address the challenges, a joint review process was used through AVAREF and lead by the WHO. WHO PATH/MVI facilitated the pre-submission meeting to discuss the requirements for submission. The advantages of the joint review included: increased pool of knowledge and expertise used to evaluate the application; EMA regulators (country of origin of manufacturer) participating in the joint evaluation; African regulators reviewed the application together and learnt from each other (peer learning); first time the both Kenyan ethics and regulators were reviewing a protocol together; as the applicant was present, they were able to answer some of the concerns raised during the review immediately; after review, applicants responded back to PPB for approval (Independence); Sponsor (GSK) responded to each country individually; After the approval, the sponsor submitted the progress reports of the study each year. Amendments, protocol deviation and violations were submitted to PPB; PPB did not conduct any audit, however GSK set up a portal where all safety reports were uploaded and PPB had access; All amendments were reviewed and approved by PPB and PPB also participated JTEG meetings in Geneva that discussed the accumulating data and asked for clarifications on the ongoing clinical trial; at the JTEG meetings, met with other regulatory authorities from Africa and exchanged information on the ongoing study; and, shortening of protocol review and approval period and that JTEG sessions offered a good opportunity to hear, share and seek clarifications on the progress of the study and issues of concern.
In moving forward we need to consider the issue of joint inspections/audits for the trial sites and develop an information sharing portal for multi-centre studies.

Comments and observations
1. There will be future outbreaks & humanitarian emergencies in the African region and that there will be added value to do joint reviews.
2. A working group should be established in the region for product development that supports R&D in emergencies.
3. Giving the perspective of the WHO/HQ, Dr. Okwo-Bele advised that the role of RITAG should pertain to strengthening regulatory activities in the region. A RITAG member should attend each AVAREF meeting to understand what is being discussed, and provide feedback to all RITAG members.
4. For malaria, it was noted that WHO has recommended a pilot study in 3 to 5 countries. Dr. Okwo-Bele then noted that WHO is ready to proceed with a pilot projects in Kenya, Malawi and Ghana for malaria vaccine based on set criteria. Study will be funded by UNITAD and GAVI. The pilot will start in 2017 and early data released in 2019; could eventually lead to roll out of a malaria vaccine in 2022.
5. In terms of African countries, there are a number of countries that have fairly strong regulatory capacities. The size of a country’s scientific community is a factor - it varies.
6. The next steps for EVD vaccine, regulatory wise, the intention is for the EUAL to be used as a means for using the product in outbreak circumstances.
7. WHO does plays a great role in capacity building, and as a convener. However, the RITAG concern was raised about WHO drifting to serving as a PI was the case in Guinea.
8. It was also argued that WHO is being proactive – not only EVD but also MenA vaccines. For some of these neglected diseases, the normal way of doing business via pharma does not apply. WHO finds ourselves in a situation where someone has to step-in and we find ourselves in a difficult situation to form a partnership and get the work done.
9. In discussing the role of RITAG in setting the agenda for vaccines development, it was advised that RITAG should look at all potential epidemics in Africa and set up a proactive agenda for Africa and puts pressure to fast track the development of vaccines. The WHO should find ways to claim a space on the global platform for an African voice.
10. There will be an Ebola meeting in September 2016 that will look at vaccines and then report back to SAGE. RITAG needs to get involved in this process and give our opinion. Need to make some recommendations to ensure African representation on global decision-making forums.

Attaining universal access to immunization in the context of universal health coverage

Tarcisse Elongo, HSS, WHO/AFRO, Brazzaville, Congo

Immunization is a part of the minimum components of PHC. SDGs (Goal3), target 3.8: Achieve Universal Health Coverage. He illustrated the health system thinking of the immunization system (see Fig.11). He further discussed the problems associated with utilization of services bringing out the equity issues. Some of the challenges to utilization include quality of the services, distances the people have to travel to get services and perennial issues of stock-out of essential supplies due to budget constraints.
As a solution to these challenges, he proposed integration of services, including immunization. He enumerated the attribute of this integration to include robust planning with good alignment, basic package of essential services (sharing human resources, supplies and logistics); own monitoring mechanisms with a system founded information on performance monitoring/management of inputs (quality use).

Examples of integration were mentioned by countries:
1) Ethiopia is integrating polio campaigns with other antigens; other maternal services will also strengthen EPI.
2) In CAR, EPI campaigns involve ITNs, Vit A, and mainstream. In terms of transport – when district head comes for vaccines, they pick other products for different services. Data is jointly collected using the different tools available and the country is thinking of a single budget at district level, that support all services depending on need.

Comments and observations
1. Decentralization provides opportunity for local planning and integration. RITAG stressed that the integration of planning and service at local level described by countries is very impressive.
2. National and regional levels integration should take on prioritization of vaccines, and other priorities, as prices are an issue especially for the GAVI transitioning countries. Integration is not just integration of activities. It starts with planning, identifying commonalities and then executing together. Not everything can be integrated.
3. The RITAG members further stressed that we do not achieve integration by simply piggy backing one service upon another.
4. It was also noted that several governments think immunization is an issue for WHO/UNICEF/GAVI and not them. It was stressed that the health system should start pushing government to recognize that one day there will not be support from external actors, and we need to start taking leadership now.
5. There is also need to address health expenditure in order to address HSS – if the country’s budget is very low, then it becomes difficult. WHO should work with the
World Bank, GAVI to examine public expending, and define a way to improve allocations that allow HSS.

6. Dr Dovlo, the Director of HSS, WHO/AFRO noted that with the Ebola experience, the previous gains varnished; so there is need to build systems that are resilient. There are fundamentals each programme needs to invest in – human resources, core logistics, patient and staff safety, management and accountability specifically at the service delivery level.
WRAP UP AND CLOSURE

In her closing remarks, the Chair thanked everyone present at this meeting for their participation in the very important discussions aimed at advancing the course of immunization programmes in the Region. She expressed her gratitude to RITAG members as well as the WHO Secretariat, and all colleagues in and outside the room who have worked tirelessly to ensure a successful meeting. She also thanked all the colleagues who came from Geneva as well as those from partner organizations for the show of solidarity African member states.

On behalf of the Regional Director, Dr Richard Mihigo, the Manager, Immunization and Vaccine Development (IVD) Programme, thanked the Chair and the RITAG members for finding time to review and guide the Secretariat on its work. He thanked the immunization partners for coming.

He expressed the eagerness of the Region to receive the RITAG recommendations and promised to share them with executive management as well as with EPI managers and other implementation partners.