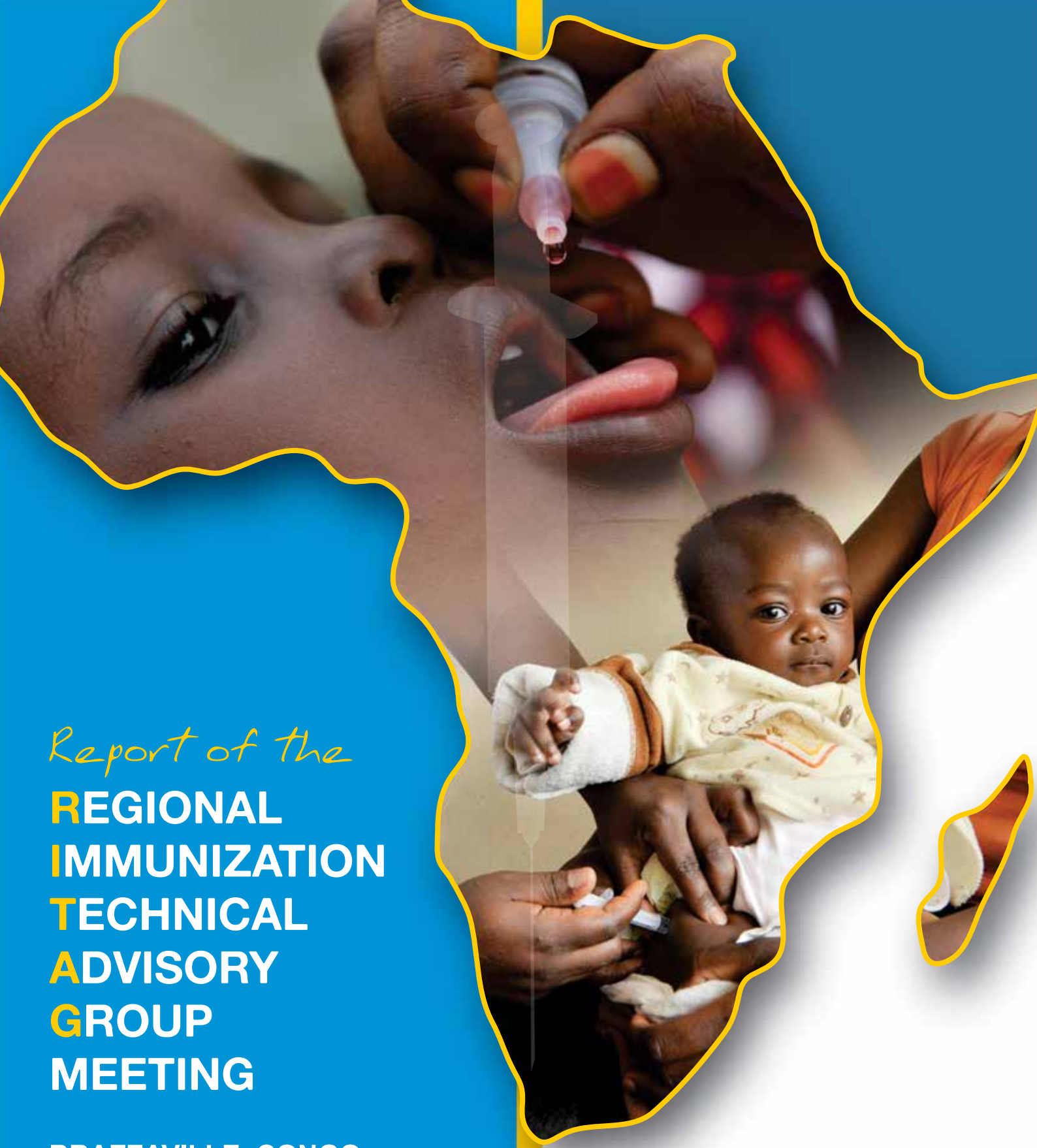

Report of the

REGIONAL IMMUNIZATION TECHNICAL ADVISORY GROUP MEETING

BRAZZAVILLE, CONGO
June 6-7, 2017

World Health Organization
REGIONAL OFFICE FOR Africa

Photo: Bill and Melinda Gates Foundation_Frederic Courbet

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ACRONYMS

ADI	Addis Ababa Declaration on Immunization in Africa
AFRO	African Regional Office
AFP	Acute flaccid paralysis
AGE	Acute Gastroenteritis
ANC	Ante-natal care
AVAREF	African Vaccine Regulatory Forum
BMGF	Bill and Melinda Gates Foundation
bOPV	Bivalent oral polio vaccine
CDC	US Centers for Disease Control and Prevention
cMYP	Comprehensive multiyear plans for immunization
CRS	Congenital Rubella Syndrome
CSF	Cerebrospinal Fluid
CSO	Civil society organizations
CTC	Controlled Temperature Chain
cVDPV	Circulating vaccine-derived poliovirus
DHF	Dengue Hemorrhagic Fevers
DHS	Demographic and Health Surveys
DOPV	Directly Observed Polio Vaccination
DQS	Data quality self-assessment
DQWG	Data Quality Working Group
DTP	Diphtheria-tetanus-pertussis [vaccine]
EPI	Expanded Programme on Immunization
EYE	Elimination of Yellow Fever Epidemics
FRH	Family and Reproductive Health
Gavi	Global Alliance for Vaccines & Immunization
GIS	Geographic Information systems
GPEI	Global Polio Eradication Initiative
GPS	Geospatial positioning system
GVAP	Global Vaccine Action Plan
HPV	Human Papilloma Virus Vaccine
HR	High Risk
HSS	Health systems strengthening
ICC	Inter-Agency Coordinating Committee
IDSR	Integrated Disease Surveillance & Response
IMCI	Integrated Management of Childhood Illness
JRF	The WHO UNICEF Joint Reporting Form
UNICEF	United Nations Children's Fund
LGA	Local Government Area
LMIC	Low and middle income countries
LQA	Lot Quality Assurance
MCIA	Ministerial Conference on Immunization in Africa
MCH	Maternal and Child Health
MCV	Measles-containing vaccine
MCV1	First dose of MCV
MCV2	Second dose of MCV
MNT	maternal and neonatal tetanus
MOF	Ministry of Finance
MOH	Ministry of Health
mOPV	Monovalent oral polio vaccine
MOV	Missed Opportunity for Vaccination
MR	Measles-rubella [vaccine]
MSF	Médecins sans Frontiers
NGO	Non-governmental organization

NIDs	National Immunization Days
NITAG	National Immunization Technical Advisory Group
NNT	Neonatal tetanus
NRA	National Regulatory Authority
OPV	Oral polio vaccine
PAB	Protection at birth
PAHO	Pan American Health Organization
PCR	Polymerase Chain Reaction
PCV	Pneumococcal conjugate vaccine
PID	Pneumococcal invasive disease
RCV	Rubella-containing vaccine
RED	Reaching Every District Approach
RITAG	Regional Immunization Technical Advisory Group
RV	Rotavirus Vaccine
SAGE	Strategic Advisory Group of Experts on immunization
SIAs	Supplementary Immunization Activities
tOPV	Trivalent oral polio vaccine
RITAG	Task force for Immunization
TBA	Traditional Birth Attendants
TT	Tetanus toxoid
VCMs	Volunteer community mobilizers
VHF	Viral Hemorrhagic Fevers
VPD	Vaccine Preventable Disease
YF	Yellow Fever
WHA	World Health Assembly
WHO	World Health Organization
WPV	Wild poliovirus

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EXECUTIVE SUMMARY

The Regional Immunization Technical Advisory Group (RITAG) met in Brazzaville, Congo at the Hotel Ledger from 16th to 17th June 2017 for its first ordinary meeting of the year. Dr Joseph Cabore the Director, Programme Management, WHO AFRO, welcomed the participants on behalf of the Regional Director, Dr Matshidiso Moeti. He also declared the meeting open. Present at the opening and subsequent sessions were immunization partners and donors as well as representatives of civil society organizations, immunization staff from the countries and various levels of WHO (ISTs, Regional Office and Immunization and Polio Directors from HQ).

The primary goals of the meeting were to update the RITAG members on progress made in the programme, current priorities as well as levels of achievement of the recommendations from the previous RITAG meetings and to seek their advice and guidance on current specific challenges and programme plans and activities. Some of the recent priority areas in immunization in the African Region were discussed in sessions of the meeting after the brief presentations made by the secretariat. 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 – JUNE 2017

COVERAGE & EQUITY

1. RITAG recognizes that weak routine immunization programmes and health systems in the region have resulted in slow progress towards meeting the GVAP and Regional Strategic Plan for Immunization (RSPI) targets. The regional DTP3 coverage of 76% falls far below the 90% planned GVAP target. RITAG recognizes also that the RSPI contains strategies aimed at addressing challenges and monitoring progress and that, efforts to achieve set goals and milestones are ongoing. RITAG further recognized that important diagnostic and intervention tools have been introduced in some settings to address low immunization coverage. Specifically, RITAG noted the Missed Opportunity for Vaccination (MOV) tool, the equity assessment tool, and was informed of the ongoing initiative to integrate these and other tools as part of the revised RED approach. To accelerate progress towards the achievement of the RSPI and the GVAP, RITAG recommends that:

   1.1 WHO concludes the analysis of data from the ongoing MOV evaluations in six countries and supports the countries to implement the recommendations. On the basis of the impact of MoV, WHO should identify 10 additional countries which will be best served by this strategy to improve their coverage.

2. In areas of conflict and emergency situations where systems are weak and fragile RITAG commends the strong and systematic integration of immunization services into the emergency responses implemented by WHO's on-ground partners in some of these settings. RITAG also recognizes the ongoing regional initiatives undertaken by WHO to achieve the same objective. However RITAG notes the growing number of countries and affected by emergencies and conflict and requests that:

   2.1 The WHO Secretariat should undertake an inventory of immunization activities in all vulnerable areas/countries and take appropriate steps to strengthen the integration of immunization with the existing emergency response, and report progress to the December 2017 RITAG.

3. Access to immunization varies with different socioeconomic variables. Children born to mothers of low education and economic status are less likely to be fully immunized when compared to their more affluent counterparts. Urban poor face similar barriers to access. With the current rate of urbanization all over the region, it is imperative to develop novel strategies to reach the urban poor, evaluate best practices and develop new strategies on how immunization services can be adapted to reach the urban poor. RITAG recommends:

   3.1 WHO, in partnership with appropriate stakeholders, document best practices in reaching urban poor populations, and develops guidance to countries on how to ensure high immunization coverage among the urban poor with recommendations on established best

practice and new strategies, targeted community mobilization and private sector engagement where appropriate. Progress on this activity should be presented to RITAG in June 2018, with the introduction of new strategies by the end of 2018.

HPV VACCINE

4. The introduction of HPV vaccines into well-resourced countries has resulted in reduction in HPV incidence and HPV related diseases. Many African countries struggle to adequately screen and treat cervical cancer. Current evidence continues to support HPV vaccine introduction for girls as a cost effective strategy to prevent cervical cancer and for wider population protection. While 22 African countries have implemented Gavi supported demonstration programmes with HPV vaccine, only 7 have introduced HPV vaccines into national programmes. To speed up introduction, Gavi recently approved direct nationwide introductions without pilots, and agreed to implement WHO's recommendation of multi-year cohorts (9-14 years) to accelerate impact. Feedback from policymakers suggests that slow introduction is influenced by perceptions of high costs of vaccines and of delivery strategies when introduced through school based programmes. At least one country changed from school based delivery's to a more routine. RITAG was told that some health ministers have recently questioned the evidence demonstrating the impact of HPV vaccines on cancers. RITAG recommends that:

   4.1 Over the next three years all countries, irrespective of their Gavi eligibility status, should prioritize the introduction of HPV vaccines after first undertaking a full evaluation of the costs of the vaccine plus delivery strategies, and use this to mobilize additional resources to ensure sustainable vaccine introduction.

   4.2 Gavi, UNICEF and WHO should work with non Gavi-eligible countries and vaccine manufacturers to access the most competitive available prices for HPV vaccines, including exploring possibilities of pooled procurement which will also guarantee a market for manufacturers.

   4.3 Countries should explore innovative strategies for reaching the target age group using public and private school based programmes and outreach services, and should consider integrating HPV vaccine introduction with existing programmes (e.g. deworming, use of other vaccines - TT or Td, Hepatitis, rubella).

   4.4 Noting the impact of anti-HPV vaccine communications in developed countries, countries in the region should develop advocacy and communication strategies to support HPV vaccine introduction targeting girls, families and communities and key gatekeepers.

5. RITAG recognizes the high rates of HIV infection among young women in the African region, and that HIV infected women are at higher risk of infection with oncogenic HPV types and of developing cervical cancer. RITAG recommends that:

   5.1 The WHO recommendation for three doses of HPV vaccine for HIV infected girls should be implemented.

   5.2 Countries should explore opportunities for integration of HPV vaccine into HIV programmes.

   5.3 Studies determining the impact of new HIV infection on vaccine-induced immunity should be prioritized.

POLIO ERADICATION INITIATIVE

Prevention and response to cVDPV2 outbreaks

6. RITAG was informed that in some countries, after the global "switch" from tOPV to bOPV, vials of unused tOPV were found in health facilities during cVDPV2 outbreak investigations. RITAG was also informed that the Global Polio Eradication Initiative (GPEI) is developing a new guideline for facility sweeps to remove any remaining tOPV stocks from health facilities. RITAG was told that some countries have been reluctant to introduce mOPV2 in response to cVDPV outbreaks, because of concerns that the vaccine will reintroduce attenuated wild type 2 virus into communities.

RITAG recommends:

   6.1 That the new GPEI guidance on undertaking systematic sweeps aimed at identifying and safely disposing of unutilized stocks of tOPV should be rapidly implemented to avoid the

inadvertent use of tOPV in routine immunization or SIAs. Priority should be given to sweeps in areas where there have been reports of tOPV being found.

6.2 That the use of mOPV2 following detection of cVDPV2 or WPV2 described in the GPEI's Standard Operating Procedures (SOP) for responding to a poliovirus event and outbreak and approved by the Polio Committee, should be seriously considered by affected countries, and if used that the removal and disposal of unused mOPV2 after completion of immunisation activities must be enforced.

INTRODUCTION AND USE OF FRACTIONAL DOSES OF IPV

7. RITAG noted with concern the continuous global supply shortage of IPV vaccine and its implication for uninterrupted supply for Tier-3 and 4 countries in the African Region. In December 2016, RITAG was provided that delivery requirements for safe intradermal administration could be met. RITAG recommended that all Polio Tier-2 countries should start using fractional doses of IPV due to the prevailing global supply shortage and evidence supporting the higher protection of two intradermal doses of fractional IPV than the single full dose intramuscular administration originally recommended. Noting the service delivery challenges of changing to fractional dosing, countries considered to be at highest risk of wild poliovirus outbreaks (Polio Tier-1 & 2 countries) have been prioritized by GPEI to continue to receive a single intramuscular dose of vaccine and have been provided with adequate IPV supplies to allow this.

RITAG recommends:

7.1 When IPV is available to Tier-3 & 4 countries, that they should consider using two fractional doses of IPV if immunization services are able to support fractional dosing.

7.2 To assist Tier-3 & 4 countries in their decision-making about whether or not to move to fractional dosing, RITAG requests WHO to further refine their draft algorithm tool designed to assist countries in determining their readiness to introduce fractional dosing. The revised tool, with its methods, should be presented to the EPI managers' meetings in September 2017. This analysis should include consideration of country's current practices and programme capacity, amounts of vaccine available to countries, population size and likely wastage.

Post-certification Strategy

8. RITAG acknowledged the importance of the Post-Certification Strategy being developed by GPEI partners. RITAG requested:

8.1 That before the Post Certification Strategy is presented to Regional and Global Governing bodies, RITAG should contribute to its further refinement, and that the final draft strategy should be presented to RITAG in December 2017 for final input.

VPD SURVEILLANCE

9. RITAG recognizes that in countries receiving support for polio eradication activities, both laboratory and epidemiological surveillance activities are heavily dependent on GPEI funds that are now being reduced. Other disease specific funds, for example measles elimination and rotavirus surveillance, also contribute to country surveillance activities. Countries that are Gavi-eligible can also apply for surveillance funds as part of their HSIS envelope. Some countries use national budgets to support surveillance including laboratory costs and community surveillance costs. Recognizing the critical importance of surveillance data to drive programme strategic decision-making, RITAG recommends:

9.1 In non-Gavi eligible or Gavi transitioning countries, Members States identify sufficient in-country and donor resources for high-quality, laboratory-linked surveillance for priority diseases. WHO/AFRO should help to identify or create effective advocacy materials that demonstrate the ability of surveillance data to identify areas of programme weakness, target supplemental immunization activities, detect and respond earlier to outbreaks, and monitor the impact of vaccines on disease burden.

9.2 In Gavi-eligible countries, Member States should consider applying for Gavi funding for surveillance strengthening during re-negotiation of Gavi country agreements and/or during annual Joint Appraisals.

10. RITAG sees the polio post-certification strategy as an opportunity to reconsider the current and future priorities for polio and VPD surveillance in the African Region. With emerging disease threats, challenges like climate change and conflicts, new vaccine introductions, re-evaluation of country core competencies under IHR, changes from VPD control to elimination targets, and new role players like the Global Health Security Initiative, the establishment of an integrated, innovative surveillance system that has country ownership, financing and accountability should be prioritized. As such RITAG recommends:

    10.1 Before June 2018 that WHO/AFRO convene a consultative platform to discuss future VPD surveillance priorities and funding needs with diverse stakeholders (e.g., government, Africa CDC, US-CDC, USAID, BMGF, Gavi, and NEPAD).

    10.2 WHO/AFRO works with Member States to report back to RITAG at the June 2018 meeting on a regional investment case that details the budget required to support the core laboratory and epidemiology surveillance activities that address new and existing priority VPD threats.

MALARIA VACCINE IMPLEMENTATION PROGRAMME

11. In 2014, a Phase III study of the GSK's RTS,S/AS01 malaria vaccine undertaken in 7 countries in Africa, demonstrated 39% efficacy in protecting children aged 5-17 months against clinical malaria. In July 2015, the vaccine received a positive scientific opinion from the European Medicines Agency through its Article 58 process. Given the possible safety signals and the challenge of administering the first three doses of RTS,S starting as close as possible to 5 months of age and a fourth dose 15-18 months after the primary series, WHO is planning a large-scale pilot implementation in selected areas of Ghana, Kenya and Malawi which had previously participated in the Phase III study. The Malaria Vaccine Implementation Programme (MVIP) consists of three major components: (i) an EPI programme implementation, (ii) rigorous evaluations that aim to assess safety, impact and feasibility and (iii) a Phase 4 Study, sponsored by GSK, which includes active household visits to gain a more in-depth safety perspective on the vaccine as part of a post-approval risk management plan. The pilot will begin in mid-2018 after a joint review by AVAREF and special regulatory approval by the implementing countries. Noting this RITAG recommends:

    11.1 WHO to provide annual updates on MVIP progress to RITAG for RITAG's input.

    11.2 MVIP to introduce the concept of "Standard of Prevention for Malaria" in all study sites which incorporates the best practice for malaria prevention currently available in that participating country, reinforced at each study visit.

    11.3 MVIP to develop an integrated implementation science agenda that can monitor other aspects of study conduct such as maintenance of the cold chain, maintenance of vaccine supplies and vaccine storage issues, attitudes of HCWs, etc.

    11.4 MVIP to consider utilizing the good participatory practice tool (GPP) as used in HIV and Ebola vaccine studies, in all community education, mobilization and engagement activities, paying special attention to community concerns about the introduction of a new, partially protective vaccine and changes in community use of other malaria control interventions.

    11.5 WHO to disseminate a briefing paper or summary of the ongoing GSK component of the programme to RITAG members.

12. RITAG notes that other WHO regions have functional regional Vaccine Safety Committees aligned with the WHO Vaccine Safety Blueprint and commends the Secretariat for its ongoing work to establish an AFRO Vaccine Safety Committee. The RITAG recommends:

    12.1 WHO to consider establishing a Regional Vaccine Safety Committee as a priority action and within one year.

13. RITAG commends WHO for their compilation of progress on previous RITAG recommendations. RITAG requests that:

    13.1 All recommendations from the time of the establishment of RITAG should be compiled and reported on at future RITAG meetings. A separate report should be compiled of those recommendations that are part of the RSPI and these should be reported on at each December RITAG when the RSPI progress is reviewed.

1. BACKGROUND

This is the first of the two scheduled regular meetings of the Regional Technical Advisory Group (RITAG) on immunization in the African Region in 2017. The goal of this meeting was to appraise the performance of the immunization programme since the last meeting in December 2016. Consequently, the implementation of the action points from the last meeting were scheduled to be reviewed along with the review of other programme implementation performances. The level of progress and challenges were also marked for review with suggestions given for remedial actions where necessary.

Specifically, the meeting was called, among others things, to apprise RITAG members on level of successes in implementation of the recommendations from the last meeting. The broad topics discussed include polio eradication and endgame strategy in the African Region as well as the introduction of the Human Papillomavirus Vaccine (HPV) in the WHO African Region. Others are on building resilient vaccine preventable disease surveillance in the African Region and the status of the RTS,S malaria vaccine development. There were also issues presented to the RITAG as information; namely update on status of implementation of RITAG Recommendations, progress report on immunization coverage and equity in the WHO African Region as well as improving immunization coverage through the equity lens and Addis Declaration on Immunization – Roadmap development.

This report presents a detailed account of the meeting and its key achievements.

Photo: Bill and Melinda Gates Foundation_Frederic Courbet

2. OPENING CEREMONY

A video tape of the Regional Director's welcome address was played to all participants at the beginning of the meeting. In it, the Regional Director encouraged participants to have fruitful deliberations that will result in policy recommendations to guide immunization programmes in the Region. The Regional Director reminded the RITAG members that the work is far from done despite the tremendous progress made towards reaching every child in the African Region. She noted the grave concern of the WHO's Strategic Advisory Group of Experts on Immunization (SAGE) with the slow progress towards achieving Global Vaccine Action Plan (GVAP) goal and increasing equitable access to life-saving vaccines. Many countries in Africa still lag behind the rest of the world in achieving immunization targets. She emphasized the need to accelerate the pace to reach the goals committed by Member States. She also reiterated the principles of the Ministerial Conference on Immunization in Africa held in February 2016 in Addis Ababa, Ethiopia, where Ministers of Health and other line ministers launched the Addis Declaration on Immunization (ADI) to spur greater political and financial commitments to immunization in Africa. Having harnessed the political commitment needed to advance our immunization goals, we must act even faster!

Thus she called on RITAG to review the progress made and the challenges faced within the Region, in achieving universal immunization coverage; dialogue on the pace and opportunities for introduction of HPV vaccine and other new vaccines in the Region. Other areas of concern include the RTS,S malaria vaccine pilot implementation commencing in 3 countries within this Region; strategies to build a resilient VPD surveillance network in the African region in the post-polio eradication era; and strategies for moving forward with introduction of new vaccines? She awaits RITAG's advice on these issues as well as on strategic actions to build upon the Heads-of-States' endorsement of the ADI and translate that into increased financing and attention to immunization, especially as the world enters the second half of the Decade of Vaccines. Beyond these issues, she called upon the RITAG to reflect on Yellow Fever, despite its not being included in the agenda. She argued that with a new strategy being developed, it is important for RITAG member to think through how Immunization and Outbreak/ Epidemic preparedness programmes can work better together.

"together, we will ensure that every child in Africa has an equal chance to achieve their full potential"

With confidence that "together, we will ensure that every child in Africa has an equal chance to achieve their full potential", she appreciated the RITAG Members for accepting to serve on this important advisory body. She also thanked EPI managers and partners for investing time to take part in this two day meeting.

Professor Helen Rees, the Chair of the RITAG assured the Regional Director of the resolve of the team to do a good work. On his part, Dr Richard Mihigo, the Immunization & Vaccine Development (IVD) Coordinator took participants through the programme of work for the two days. He then invited Dr Joseph Cabore, DPM/WHO AFRO to declare the meeting open.

3. TECHNICAL SESSIONS

3.1 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 populations of Africa, and indeed the world, against vaccine preventable diseases; discuss challenges and seek expert orientation, from the RITAG members, on how to better deliver on WHO mandate to the people of the region and the world. Of particular interest were broad issues like polio eradication and endgame strategic plan in the African Region as well as building resilient vaccine preventable disease surveillance in the African Region. Others issues focused on realizing the goal of having malaria vaccine as well as issuing about immunization coverage and introduction of the human papillomavirus vaccine (HPV) in the African Region.

A total of 15 technical presentations were made. Three of these were for information while twelve were made for RITAG decision and recommendations. The presentations provided participants with the necessary background information on the status of immunization and key vaccine preventable diseases (VPDs) in the African Region. There were also presentations from colleagues from the WHO/HQ which were on plans to improve on issues concerning VPD, globally, including the African Region. The presentations were followed by discussions leading to actionable recommendations. The presentations, highlights of subsequent discussions and the recommendations are summarized below.

3.2 Issues for Information

UPDATE ON STATUS OF IMPLEMENTATION OF RITAG RECOMMENDATIONS

Dr Masresha Balcha, WHO/AFRO

There were 48 action points in 5 programme areas, discussed during the December 2016 meeting, namely (1) sustainable immunization in the context of polio transition and graduation from Gavi; (2) yellow fever control; (3) polio eradication; (4) maternal neonatal tetanus (MNT) elimination and measles elimination. Of these, seven were fully achieved.

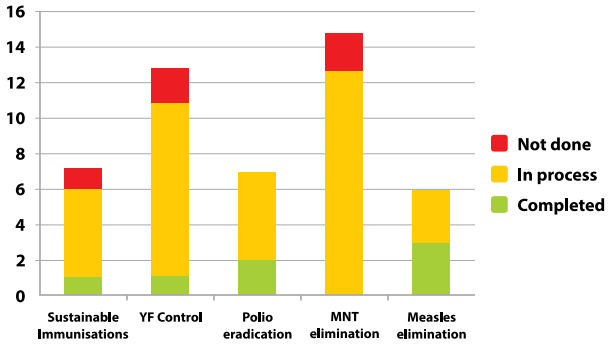


Figure 1: Status of implementation of RITAG recommendations from Dec. 2016.

During a technical session in the RITAG 06-07 June, 2017

Another 5 were not achieved while 36 others were in progress because activities addressing these recommendations are continuous. The presenter then proceeded to give details of actions taken to implement the recommendations in the different programme areas

Comments and observation

RITAG members noted that the steps taken in the implementation of the recommendation were not clear and the term 'in progress' seem too fluid. They requested that the Secretariat ensures that when reports are made on the status of implementation, there should be clear and specific information on status, and not just label them as "in progress". This can mean that some activities could be initiated, while others could be well advanced. It was also suggested that the recommendations should be limited to manageable numbers. Furthermore, the RITAG members advised that future recommendations should be time-bound.

REDUCING MISSED OPPORTUNITIES FOR VACCINATION TO IMPROVE ROUTINE IMMUNIZATION IN THE WHO AFRICAN REGION

Dr Blanche Anya, WHO/AFRO

This presentation provided results of assessment conducted in countries in the AFR Region using WHO strategy to address Missed Opportunities for Vaccination (MOV), as well as interventions being implemented to increase immunization coverage. It showed that there has been a steady increase in the coverage with nearly all antigens between 2000 and 2009, following by stagnation in the past 6 years. The DPT1 and MCV1 coverage improved from 66% and 53% respectively in the year 2000, to 85% and 73% respectively in 2015. At Regional level, there has been a coverage gap of about 9% to 11% between DPT 1 and MCV1 coverage figures throughout the years. The number of countries achieving the GVAP goal of 90% has stagnated at around 15 only. In 2015, 16 countries achieved 90% coverage with 20 countries having at least 80% of districts least 80% coverage of 3rd dose of DTP containing vaccine, With 7 countries having all the districts with at least 80% coverage (Swaziland, Seychelles, Rwanda, Sao Tome, Gambia, Burkina Faso, and Mauritius). The 13 countries that have sustained coverage >90% during the past 3 years are: Rwanda, Tanzania, Gambia (the), Mauritius, Seychelles, Sao Tome and Principe, Algeria, Botswana, Eritrea, Burundi, Lesotho, Cabo Verde and Swaziland.

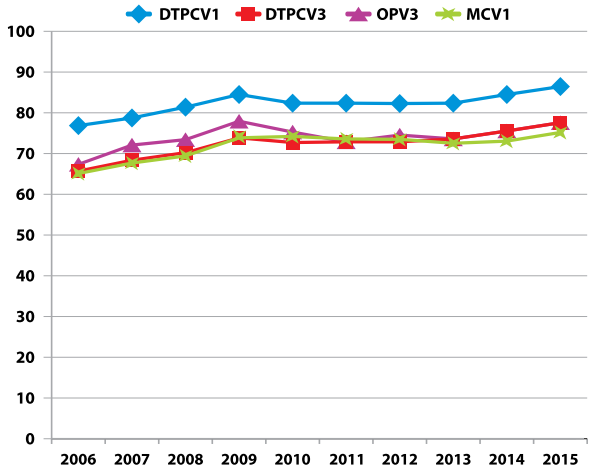


Figure 2: RI coverage of selected vaccines in the African Region, 2006-2015

However, the magnitude of the dropout rate (DOR) is quite high in 15 countries. Most of the worst performing countries are also those with high DOR. The presenter also remarked that there is potential for great improvement of RI coverage by addressing the DOR. One of the interventions with proven results consists of addressing MOV. There is potential for increasing coverage by addressing reasons of high dropout rate. According to her, the field experience in the first 5 countries of implementation in the AFR suggests that small changes can make a big impact. Reducing MOVs will increase immunization coverage simply by making better use of existing vaccination sites (at health centres, hospitals, outreach/mobile services etc.). WHO and partners are promoting a new norm to make every health service contact, (including curative and healthy child visits), an opportunity to vaccinate. This strategy is expected to reduce missed opportunities and improve coverage, timeliness and equity.

EQUITY FOCUSED MICRO PLANNING TO REACH UNDERSERVED/MARGINALIZED COMMUNITIES

Dr Nasir Yusuf – UNICEF/ESARO

According to the presenter, Equity is about ensuring that everyone accesses and utilizes services that meet their specific health needs, regardless of their circumstances. He noted that over the last couple of years, there has been a general recognition by all immunization and public health stakeholders of the need to address the current inequities in service delivery, as the only way to reach the unreached populations. Since most countries launched their EPI programs in the mid -70s, there has been continued

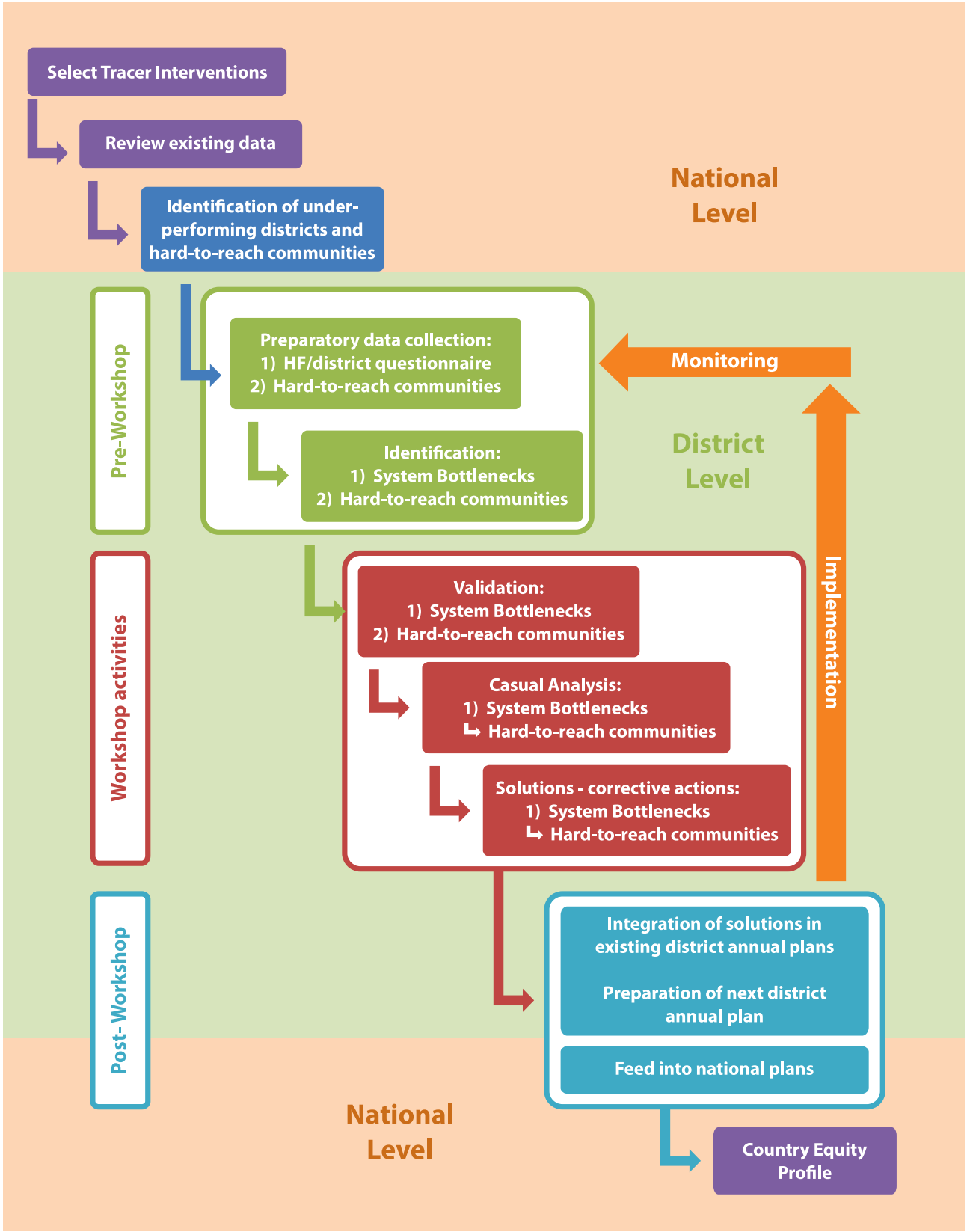


Figure 3: Equity assessment methods and processes

and steady progress in terms of coverage. However, progress has not been uniform across the various regions, with AFRO making the least progress. Within country discrepancies in coverage remains a major challenge. He enumerated steps being taken to address these discrepancies, one of which is micro plans that reduce inequities. The presenter proceeded to discuss the methods and processes of equity assessment.

He noted that this approach to equity assessment is based on bottleneck analysis (Tanahashi model), which pays specific attention to identification of hard-to-reach communities' and causal analysis of

reasons why hard-to-reach communities do not use services, among others.

He finally discussed some of the progress made towards addressing the challenges of inequity in immunization. These include immunization equity assessment in seven countries in the Region between 2013 and 2016; drafting immunization equity profile for 15 countries as well as incorporation of strategies and resources for addressing inequity in Gavi grant proposals among others.

Comments and observations

The RITAG noted that IMCI is a very good strategy to reduce MOV as it is a holistic approach that assessed the child in totality and entails that health workers check immunization status as part of the overall assessment. The RITAG members stressed that training on IMCI recommends daily immunization sessions, but lamented that this is not happening as the HWs are afraid of vaccine wastage. The question was then asked, if there are strategies to make sure this is happening? WHO has just concluded last week a training of 6 countries on the newly developed integrated EPI/IMCI interactive training resource tool, this should be deployed to reduce MOV.

Members also requested that MOV assessment be conducted in other countries in the region and follow up to see if there are improvements over time. In doing that attention should be paid in sensitization of the community and caregivers and more importantly involve the fathers. It was noted that during MOV assessment (interviews and focus group discussions) the need for tailored solutions were proposed per districts. The unavailability of vaccination cards, which is classified under caregiver, is more about health system problem.

On equity, some of the questions include whether there is a standard tool to make sure micro planning takes into account all catchment areas? The experience in using GIS from polio programme came in for mention here. RITAG members noted that there should be direct linkage of outcomes of these meetings with country NITAGs. It was argued that the 5th child we are struggling to reach will be achieved through integration of services and not with immunization alone. The members stressed that it is critical to understand that most bottlenecks to improve coverage are related to health system issues where there is need to ensure better investment. There is also a need to understand challenges in areas affected by conflicts e.g. South Sudan.

3.3 Issues for Discussion and Decision

3.3.1 HPV Introduction in the WHO African Region

INTRODUCTION AND GLOBAL UPDATE ON POLICY RECOMMENDATIONS ON HPV VACCINATION

Dr Tracey Goodman, WHO/HQ

This presentation focused on WHO position, global implementation status, goals and targets as well as early impact of HPV vaccination. It also looked at research developments, global opportunities for HPV introduction and technical supports. The presenter discussed the epidemiology of all types of HPV-related cancer & cervical cancer prevalence in particular. The distribution revealed that the African Region is among the worst hit with HPV-related cancer.

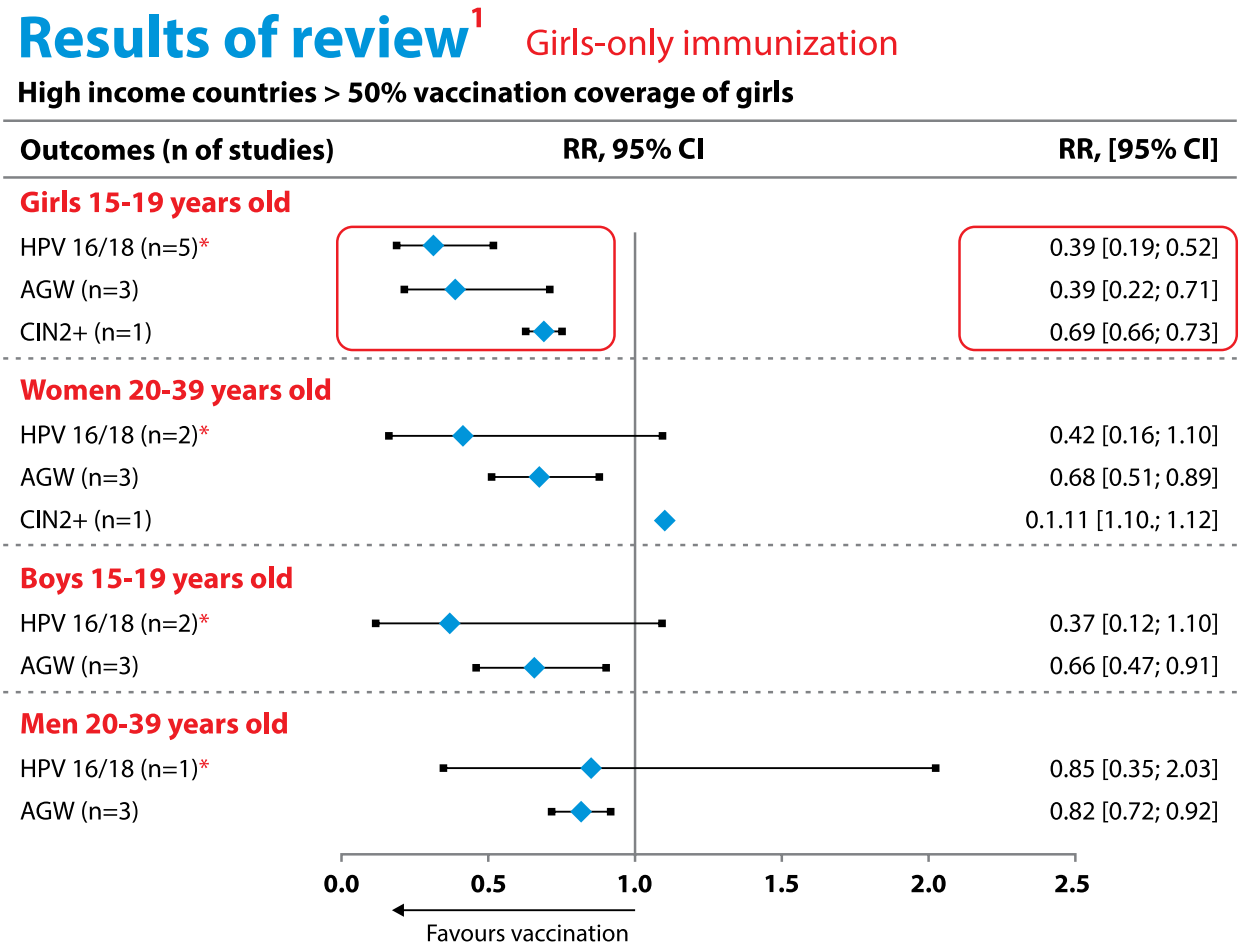


Figure 4: Results of meta-analysis suggesting girls on immunization with HPV

She discussed the effectiveness of HPV vaccine against cervical cancer and illustrated the characteristics of the vaccine as well as the protection offered by HPV vaccines. She noted that HPV types 6 and 11 lead to genital warts and are included in 4 and 9 valent Gardasil. Gardasil has been introduced in many countries around the world but only four from the African Region, namely Botswana (9 valent) , Rwanda, Seychelles Uganda, (4 valent). (South Africa and Mauritius introduced the Bivalent vaccine)

She remarked that at the Oct 2016 Sage meeting, a meta-analysis of available impact studies from countries with high coverage (> 50%) in nine high-income countries showed impact within 5 to ten years after the HPV vaccine introduction (1). The highlighted box in Figure 4 shows that the effects – as expected, are strongest among the 15-19 year olds who had the highest likelihood to be vaccinated (smaller percentage of 20-39 year old women received the vaccine). The prevalence of high risk HPV types 16 and 18 significantly decreased (>60%);

(2) Ano-genital Warts (AGW) decreased considerably (>60%) and (3) High grade cervical lesions (CIN2 and higher) reduced

The Figure 4 further indicates that herd effects are observed even among non-vaccinated boys. Particularly, it was clear that there is a statically significant reduction in ano-genital warts – not only in younger boys – but also in older men. It is on the basis of this evidence of strong herd effects and modelling around impact that SAGE recommended that females should continue to be prioritised for vaccination. The presenter also discussed the results of a modelling of different scenarios around the world, including Uganda in the African Region. They show that reaching 80% coverage among girls will convey a similar level of protection to boys. With respect to safety of the vaccine, she presented statements from WHO Global Advisory Committee on Safety (GACVS)[1] , some of which allude to the fact that there has not been any safety issue to alter the recommendation for the use of the vaccine.

All the same, the elevated price of the HPV vaccine remains a challenge. In addition to vaccine price, costs of vaccine delivery to this non-traditional age group for immunization programmes can be considerable. EPI programmes are hesitant to add expensive new vaccines to their programmes in light of the overall financing challenges. While GAVI eligible countries pay the co-financning on the GAVI price of 4.5 /4.6 US$ per dose,, the cost for UMICs is far higher. In 2014 & 2015 (non-weighted) average price for HPV vaccines paid in AFRICA by UMICs was around $16 dollars/ dose, comparable to the global figure. Following this, she posed some questions for RITAG, which had to do with scaling-up, vaccine confidence and integration.

LESSONS LEARNED ON HPV VACCINE INTRODUCTION IN THE AFRICAN REGION

Dr Mutale Mumba, WHO/Harare

This presentation focused on status of HPV vaccine introduction in the African Region, lessons learned from country introductions and regional opportunities. The presenter started with the status of HPV vaccine introduction and plans for 2017-2018. The presentation revealed that only seven countries have introduced the vaccine to date. Others are either under Gavi demonstration projects or planned to introduce in 2018. Table 1 show that countries that have introduced the vaccine.

He then proceeded to summarize the lessons learnt under timely planning and coordination with the right partners; delivery systems; reaching hard-to-reach girls; and demonstration programmes and phased introduction. Others include communication; integration; and costing, financing and sustainability.

Table 1: Summary of results of national introduction of HPV Vaccine

Country	Strategy	Primary target / catch up	HPV2 Coverage (admin)
Rwanda 2014 (Gavi)	Bi annual School based (campaign -> routine) & HF/outreach	**12 yrs** / initial catch up to 18 years	96% (2015)
Uganda 2015 (Gavi)	Continuous HF & Routine outreach. PIRI coinciding with Child Health days (April/ October)	**11 yrs** No catch up (possibly 2017)	< 23% (2016)
Lesotho 2012	Schools	Status: Interrupted due to **high cost of vaccine**	
Seychelles 2014	Bi annual School based outreach, integrated in school health programme	**Primary 6** / no catch up	76% (2014)
South Africa 2014	Bi annual School based outreach integrated in school health programme	**Grade 4 (9 yrs +)** / no catch up	70% (2015)
Botswana 2015	Bi annual Schools and HF/outreach	**Standard 5-7; 9-13 yrs (OOS)**	97% (2015)
Mauritius 2016	Bi annual, School based, integrated in school health programme	**Grade 5 (9 yrs +)**	

1 *http://apps.who.int/iris/bitstream/10665/255870/1/WER9228.pdf?ua=1*

ADOLESCENT AND SCHOOL HEALTH: OPPORTUNITIES FOR INTEGRATION

Dr Symplice Mbola Mbasi, WHO/AFRO

This presentation focused on integrated approaches and opportunities for linkages for HPV vaccination in the African Region. It explored experiences in HPV programmes, regional opportunities for integration, planning and costing. According to the presenter, WHO defines adolescents as individuals who are going through a very special phase in their lives. This is a phase during which enormous physical and psychological changes occur, as do changes in social perceptions and expectations. It is a phase when an individual is no longer a child, but not yet an adult. Although according to WHO's definition, adolescents are aged between 10-19, WHO is conscious that adolescence is a phase in an individual's life, rather than a fixed time period.

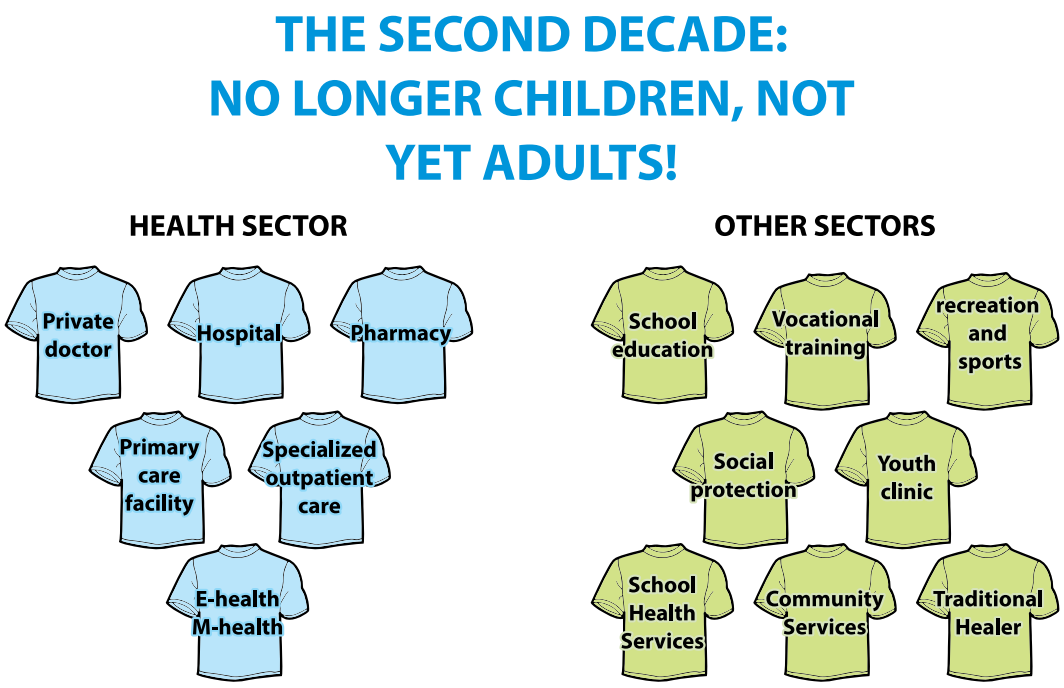


Figure 5: Network of opportunities for adolescent health

He highlighted other sectors beyond the health sector that provide opportunity for reaching the adolescents. He stressed that using routine contact to deliver another health intervention at the same facility, and the same day *(e.g: HPV vaccination, tetanus vaccination, hepatitis vaccination)* could confer immense benefits to the health of the adolescents. He also discussed combined campaigns which entails using time-limited activity *(e.g: HPV vaccination campaign, child health week, African immunization week)* to deliver additional health interventions.

The presenter however, enumerated some challenges to include weak collaboration between RMNCH and EPI programmes; limited domestic resources for integration; leadership conflict between MOH and MOE actors; and poor decentralization of interventions. He also listed some lessons learned from previous efforts at integrated delivery of adolescent health.

Comments and observations

On integration, the RITAG noted that many countries have a school-based deworming programme mainly in primary schools. This is a platform that should be used to target 9 year olds. They stressed the need for effective utilization of the three main delivery strategies – e.g. school-based, health facilities, and community outreach to cost-effectively deliver HPV vaccine. They also flagged the wisdom on the best way to bring together Ministry of Health & Ministry of Education to work together first before embarking on HPV vaccination. On reaching the out of school youth, RITAG stressed the need to devise strategies to reach out-of-school girls and bring on board Parent/Teacher Association to cover as many girls as possible. They also called for deliberate steps to be taken to reduce missed opportunities for girls coming with mothers to health facilities. Also vaccinate mothers against tetanus, etc.

The need to integrate with Ministry of Education, Ministry of Women, Ministry of Finance, etc was clearly highlighted, with coordination at a much higher level (perhaps President's Office). It was also noted that the coordination of programme within the Ministry of Health (e.g. EPI, SRH, NCD, etc.) should be strengthened at the intra-ministerial level and ensure to engage community leaders in the planning process from the onset. The RITAG lamented the very low HPV awareness, compounded by cultural & traditional beliefs. It was thus noted that there is a need to assess what people know and address the gaps; then move to integration.

Addressing equity by vaccinating boys with Td when HPV vaccination is delivered was discussed. Challenges of adding another vaccine to school health was also discussed. The RITAG also discussed the issue of HPV supply situation as Malawi, Ethiopia and Senegal are due to introduce HPV vaccines in 2018. Some of the major barriers that the RITAG confronted include the high cost of the vaccine and fact that impact will show only after (20 to 30 years). They noted the need to advocate with governments, professional associations, etc. Girls who are HIV+ should receive the HPV vaccine with a guarantee that they will be receiving ARVs. Thus HIV programmes should be made to understand that these girls should receive the HPV vaccine - and should always receive an additional (third) dose - and possibly boys too. Identify the key role players for young girls and ensure they are engaged in the strategies as they are being developed. It is important for communities to understand what HPV disease is – thereby strong advocacy and communications plans need to be developed and implemented. Furthermore, strong advocacy and communications plans need to target healthcare workers medical and nursing professional societies, parliamentarians, etc. Note was taken of the important role that NITAGs can play to roll-out the HPV vaccine.

3.3.2 Polio Eradication and Endgame Strategy

GLOBAL POLIO UPDATES

Dr Michel Zaffran, WHO/HQ

The presentation highlighted the progress made in WPV eradication between 1988 and now. Dr Zaffran noted that huge success has been recorded in polio eradication with only 7 WPVs reported globally since February 2017 as against 20 cases in February 2016. The African Region has maintained the no WPV status so far.

Given the significant role of IPV in the next era of polio eradication, he proceeded to discuss the status of IPV globally. He noted that 17 countries, mostly in the African Region are experiencing delayed resupply, while 18 countries have experienced delayed introduction. Under the ongoing IPV shortage, he

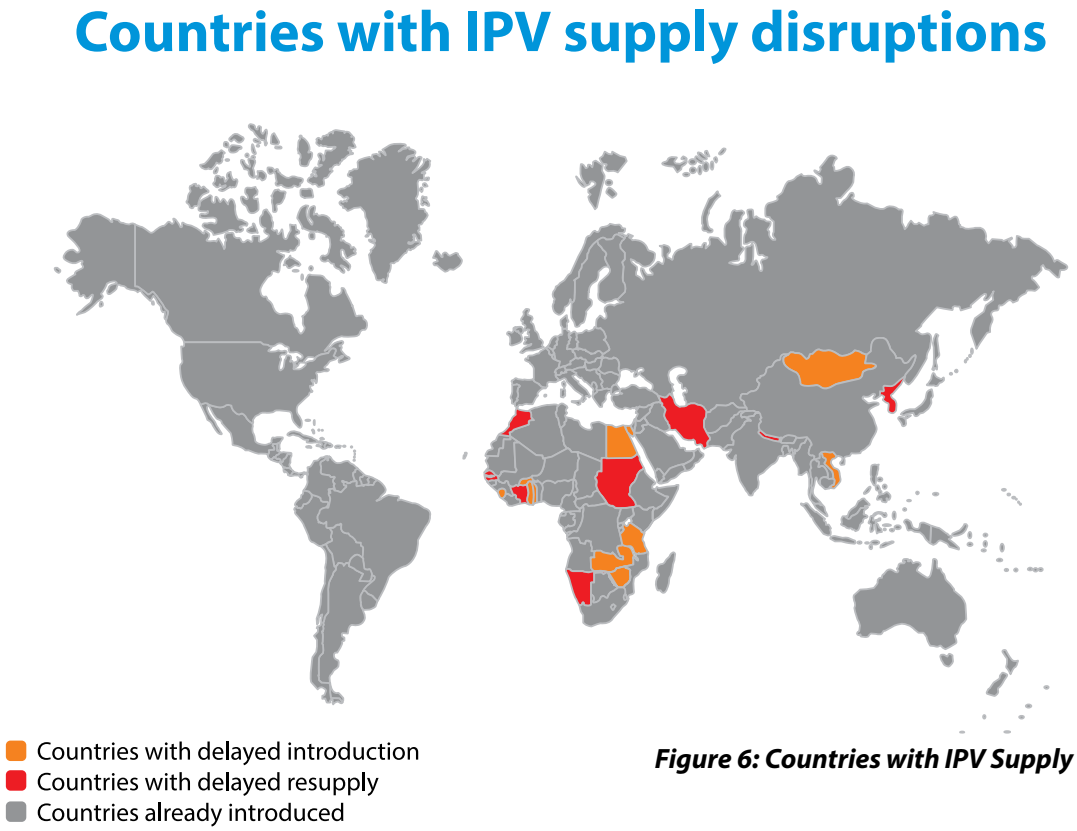


Figure 6: Countries with IPV Supply disruption

noted that SAGE recommended that, in the short-term available IPV supply is prioritized for use in routine immunization in high risk countries. Regional and National immunization TAGs are encouraged to recommend 2 fractional IPV doses in routine immunization schedules, provided there is access to appropriate IPV presentations (e.g. single-dose or 5-dose vials); capacity to administer intradermal injections; and good advocacy and communication plan for parents and health-care providers. It was mentioned that WHO reviews risk classification of countries to take into account of the size of the population with no IPV protection and the recent VDPV2 events.

He also noted that some countries, among which are Cameroon, Chad, Niger and Nigeria, have conducted post switch mOPV2 containing campaign rounds. Furthermore, he discussed the situation of AFP and environmental surveillance. In terms of containment, he noted that 29 countries have designated 78 facilities which plan to retain poliovirus type 2. These countries are distributed across the globe. However, within the African Region there are two countries compared to 31, 20 and 16 in Europe, Americas and Western Pacific.

He also discussed the new developments in oversight. The Global Commission for Certification of Polio Eradication (GCC), Containment Working Group (CWG), Containment Advisory Group (CAG) and Expert Committee on Biological Standardization (ECBS) are fully constituted. Similarly he discussed developments in Global Certification Commission. He noted that a meeting is scheduled for July 2017, where issues of surveillance quality criteria, 3-year-rule, and certification criteria for countries with conflict-affected inaccessible areas, among others, will be discussed.

POLIO ERADICATION UPDATE IN THE AFRICA REGION

Dr Pascal Mkanda, WHO/AFRO

The presentation highlighted the fact that there were four wild poliovirus type 1 (WPV1) cases confirmed in July 2016 from insecure areas of Borno State in Nigeria. In response to this, ministers of Health from Lake Chad Basin countries declared the outbreak a sub-regional public health emergency and five synchronized outbreak response rounds were conducted in in 2016 and 2 rounds in 2017.

He noted that nine months have passed since the last WPV1 case with onset on 21 August 2017, in Borno State, Nigeria. Nine VDPV2 isolated from environment

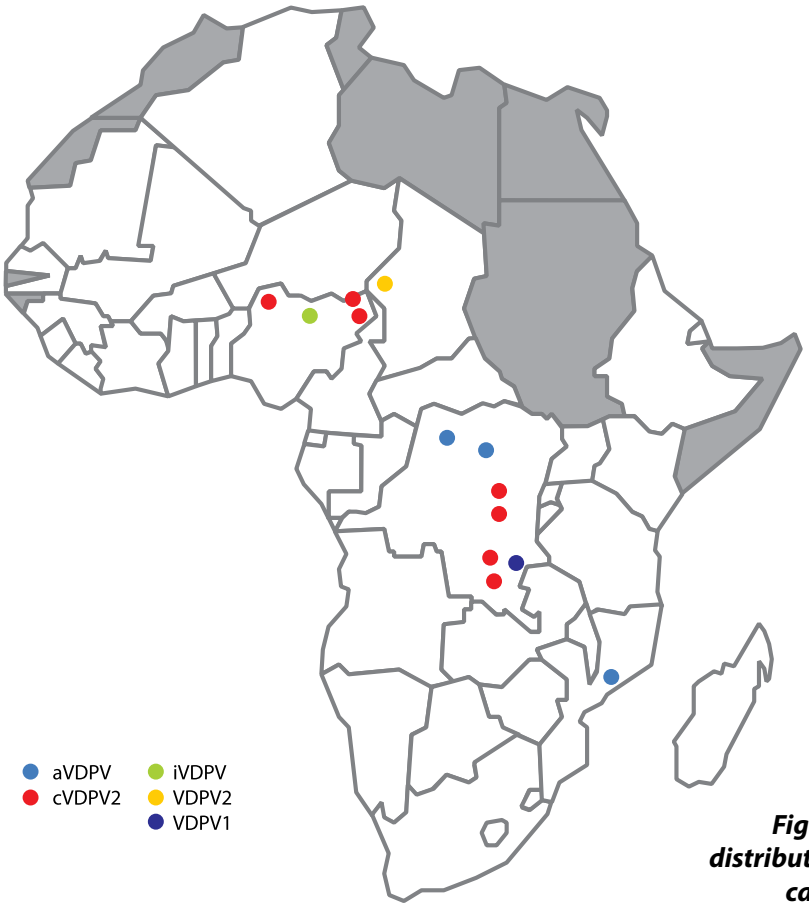


Figure 7: Geographical distribution of VDPV/cVDPV cases, AFR 2016-2017

al surveillance in Sokoto State and 1 VDPV2 case from Katsina States in Nigeria and one VDPV2 isolated from environmental surveillance in Lac Region in Chad. Furthermore, he noted emergence of VDPVs from areas that conducted monovalent type 2 (mOPV2) round with poor quality from Dec 2016 – Jan 2017. Also 4 cVDPV2 cases were confirmed from DRC in Maniema and Haut Lomami Provinces in DRC between February – April 2017 and 1 VDPV type 1 confirmed in Tanganyika province in DRC with onset in April 2017. According to him, the districts where VDPVs are isolated have low population immunity and weak routine immunization systems.

He proceeded to discuss the initiatives to strengthen surveillance in areas with gaps (both inaccessible and accessible). Some of the initiatives include increasing the number of local surveillance informants for community based surveillance; and expanding Geographical Information System (GIS) technologies for tracking and providing "real-time" evidence of conducted passive and active surveillance activities. He also listed the use of other innovations and technologies such as Auto-Visual AFP Detection and Reporting (AVADAR) by communities through use of smartphones, focusing on high risk areas; Electronic surveillance (eSurv) for real time information on field activities; Brazzaville initiative on selected high risk countries. Others include establishing an Accountability Framework for polio-funded personnel to ensure surveillance activities are conducted as planned as well as expanding environmental surveillance to complement acute flaccid paralysis (AFP) surveillance to increase sensitivity of detecting polioviruses

He noted some issues and challenges for polio eradication in the African Region. These include insecurity affecting implementation of planned surveillance and vaccination activities; localized surveillance gaps and data quality issues; and low population immunity due to weak routine immunization systems performance, among others.
Consequently, priorities for 2017 are to accelerate interruption of all types of poliovirus outbreaks in the Region; strengthen AFP and environmental surveillance performance to avoid mission any circulation and in preparation of eradication certification of the Region. Others are to advocate for global prioritization of IPV supply to the high risk low population immunity areas in countries; support countries in completion of phase 1b and capacity building of polio essential facilities and support countries in preparing robust documentation for polio eradication certification of the Region.

MAPPING SUITABILITY OF AFRICAN COUNTRIES TO IMPLEMENT FRACTIONAL DOSE OF IPV

Diana Chang Blanc, WHO/HQ

The presenter started by showing that clinical studies support the use of fractional dose of IPV vaccine. She noted that clinical studies have shown that 2 fractional doses offer better protection than one full dose of IPV. SAGE has strongly encouraged countries to adopt fractional IPV (fIPV). She also noted that currently 22% of the global cohort is receiving fIPV in routine immunization. She made illustrations from other WHO Regions like SEAR and PAHO.

The objectives of the proposed mapping in the African Region are to assess the suitability of the 47 AFR countries to implement fractional dose IPV (fIPV) intradermally in the context of IPV full dose supply shortage and to provide indicative assessment of countries programmatically capable to switch from 1 IPV full dose (given intra-muscularly) to 2 fIPV (given at 6 and 14 weeks intra-dermally). She described the methodology proposed for the mapping which comprises 10 indicators grouped along 2 axes ***(Feasibility of fIPV implementation and Perceived risk of VDPV2)***; and a simple un-weighted scoring system of 0, 1 or 2 points (feasibility highest score is 13 points and risk of VDPV2 highest score is 3 points).

She also gave the criteria for assessing feasibility. This includes annual birth cohort, DTP3 coverage trend for 2013, 2014 and 2015; dropout trend for the same period and percentage of districts below 80%. Others include effective vaccine management (EVM) composite score; procurement mechanism, IPV introduction status and preferred vaccine presentation; IPV tier ranking as well as duration of missed cohort (in months). Each of these criteria had clearly set thresholds.

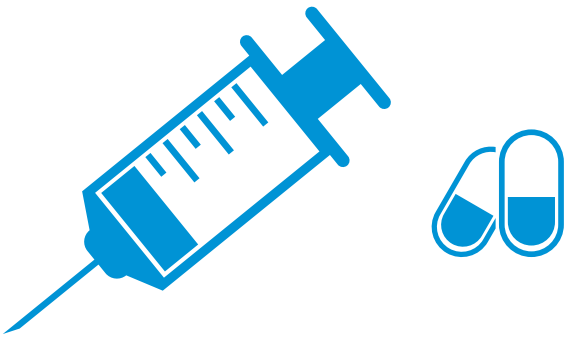


Table 2: Classification of countries for fIPV implementation

Feasibility	Higher risk		Lower risk
High feasibility for fIPV implementation	**QUADRANT I – RECOMMENDED**		**QUADRANT II - FOR CONSIDERATION**
	Burkina Faso*	Madagascar	Algeria
	Burundi	Rwanda*	Mauritius
	Cabo Verde	Uganda	Sao Tome and Principe
	Cote d'Ivoire	Tanzania*	Senegal
	Gambia	Zimbabwe*	Seychelles
	Ghana*		South Africa
Low feasibility for fIPV implementation	**QUADRANT III – NOT RECOMMENDED**		**QUADRANT IV – NOT RECOMMENDED**
	Angola*	Malawi*	Botswana
	Benin	Mali	Namibia
	Cameroon	Mauritania	Swaziland
	CAR	Mozambique	
	Chad	Niger	
	Comoros	Nigeria	
	Congo	Sierra Leone*	
	DRC	South Sudan	
	Eq. Guinea	Togo*	
	Eritrea*	Zambia*	
	Ethiopia	Kenya	
	Gabon	Lesotho	
	Guinea	Liberia*	
	Guinea-Bissau		

With these criteria she presented the emerging quadrants and classification of countries. She however presented the limitations of the method to include dependence on quality of reported data; no scoring possible where there is missing data and the fact that the model gives only an indicative assessment of what is potentially feasible and needs to be reviewed on case by case basis for country issues outside scoring system.

The next steps will include update of data with 2017 JRF data so the time series coverage and dropout changes to 2014, 2015 and 2016; further discussion on applicability/refinement of methodology and thresholds defined. Others include review of IPV supply situation with UNICEF SD and outline pathway to discuss with countries and provide adequate support for fIPV implementation.

GPEI POST CERTIFICATION STRATEGY

Suchita Guntakatta, BMGF

The presenter opened the presentation with a contextual discussion for the basis of putting in place post certification strategies. She explained the risks for the emergence of poliovirus after certification. She enumerated the post-certification strategy goals, which are encapsulated in sustaining a polio free world. She highlighted the opportunities to integrate polio essential functions into other health priorities and shift ownership from partners to national governments as one of the ways of getting this to work post GPEI. Other platforms include the use of existing governance mechanisms as much as possible; and use of learnings from other regions (PAHO, EURO, and WPRO) that have been certified as polio free as well as experience with keeping the world free of smallpox to develop governance, management, research and monitoring frameworks.

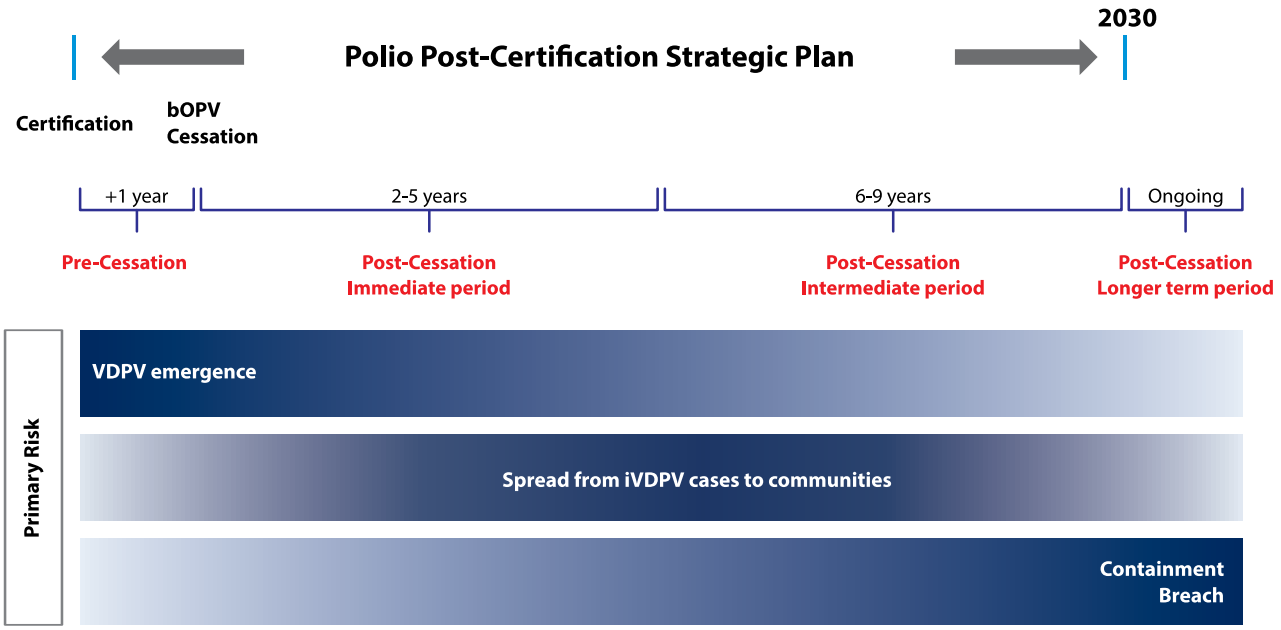


Figure 8: Risk of poliovirus emergence after certification

According to her, the PCS will provide high level policy guidance on the necessary quality of polio essential functions, monitoring framework, etc. that countries will be expected to implement (for example, integrated into core capacities required under the International Health Regulations). Specific approaches and activities will vary based on the country risk profile. However, the PCS will not direct countries on how polio essential functions should be mainstreamed or funded within national health systems at the country level. All countries must ensure that national management of polio essential functions that sit within integrated surveillance and outbreak response systems is strong enough to adopt and implement the high-level guidance provided in the PCS. Country asset mapping should be done in parallel with PCS development.

She demonstrated that in the African Region, to date only South Africa has communicated their intention to have a Polio Essential Facility (PEF). Kenya is still considering having one PEF as well; their official communication is still awaited. PEF and NAC ensure that all safeguard measures are implemented as per GAPIII and PEF has a "certificate of containment". PEF and NAC are to ensure timely renewal of containment certificates and provide updates on samples from facility inventories in annual reports to NCC and oversight body.

She stressed that before cessation regional and national immunization TAGS should recommend 2 fractional IPV doses in national routine immunization schedule, where practical, provided that countries have access to appropriate IPV presentations (e.g. single dose or 5 dose-vials), with capacity to administer intradermal injections. In addition IPV supply should be prioritized for use in routine immunization (especially in Tier 1 and 2 countries) and clear communication to care givers. She noted that SAGE also requested that WHO reviews its tier classification of countries with respect to prioritization of IPV to take into account the size of the population with no IPV protection and the recent type 2 VDPV events.

In April 2017 recommended that after bOPV cessation countries should include at least two doses of IPV in their routine immunization schedule, the first at or after 14 weeks (e.g. with the 2nd or 3rd dose of DTP-containing vaccine) and the second dose ≥4 months after the first dose, administered either as full or fractional doses. Countries without Poliovirus Essential Facilities should maintain IPV in their routine immunization schedule for at least 10 years after global OPV withdrawal, to address: immediate (VDPVs), intermediate (iVDPV) and longer-term (e.g. containment failure) risks. Countries with Poliovirus Essential Facilities should continue to use IPV as long as mandated by the Global Action Plan to minimize poliovirus facility-associated risk (GAP III). At this point, she made a note that countries most likely to experience a Poliovirus re-introduction or re-emergence and also high potential for rapid transmission are considered high risk. Risk will vary by category of virus (WPV, cVDPV, iVDPV) and change over time.

Comments and Observations

The RITAG members found the updates very informative with feelings of optimism. However, the RITAG noted that the dilemma is whether polio certification strategy should be added to the IHR. They wanted to know the possible interface between IHR certification and post certification. The RITAG further asked if the use of fractional dose will be a temporary or permanent recommendation.

On the issue of certification issue, the RITAG stressed that as long as the environmental surveillance picture is unclear, one needs to be cautious. There was also concern about tOPV being found in some health care facilities after the tOPV-bOPV switch. With regards to the post certification strategy, they stressed that one challenge in the Region is PCS which is in the early stage and still unclear how the RITAG can come in to make relevant input.

With regards to the presentation on mapping African countries for feasibility of fIPV and the post certification strategy, the RITAG also queried the criteria and quadrants for the fIPV mapping. It noted that most African countries are in the not recommended area for fIPV use. Nigeria and DRC are in the pink (see Table 2 above). This is an apparent contradiction. RITAG asked the colleagues to take another look at the criteria and allocation of countries. In clarifying this, it was explained that priority for full-dose IPV allocation is given to highest risk countries such as Nigeria and DRC. Being highest risk, they are secured access to IPV. The discussion on fIPV is focused on countries that currently lack access to IPV.

3.3.3 Building Resilient VPD Surveillance in the African Region

VPD SURVEILLANCE IN THE AFRICAN REGION: CURRENT STATUS AND FUTURE PROSPECTS

Dr Balcha Masresha, WHO/AFRO

The presenter noted that surveillance is a tool to sharpen the focus of Epi programmes. However, this might be challenged by a significant disruption of health systems, e.g., EVD outbreak, war/ civil conflict, etc as well as significant loss of funding. He also showed the funding available for surveillance between 2015 and 2016 for polio, measles and new vaccines. In 2015 there was $29.68m for polio, while measles and new vaccines had $3.00m and $2.4m respectively. Similarly, in 2016 Polio had $34.55m while measles and new vaccines had $2.60m and $2.1m respectively. While funding for polio increased, funding for measles and new vaccines declined. He stressed the urgent need to incorporate new elements / target populations in the surveillance system; eg, adding Zika surveillance, mass population movement, etc.

INTEGRATED VPD LABORATORY NETWORKS AND SENTINEL SITE SURVEILLANCE IN THE AFRICA REGION

Dr Jason Mwenda, WHO/AFRO

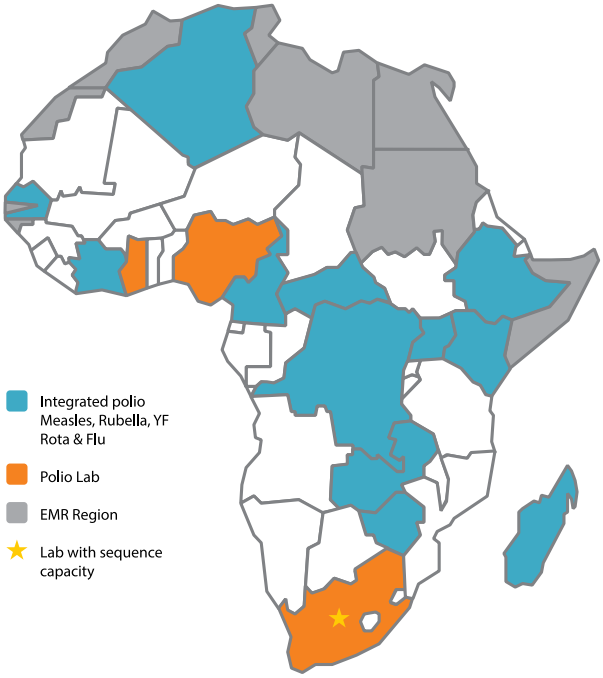


Figure 9: Current status and functions of Regional Polio Lab Network

The presentation covered a review of the status of polio lab network in the Region. According to him, the labs network was established in 1993 to support PEI in African Region. Polio lab network made up of 16 labs in 15 countries. The functions include detection, confirmation and characterization of polio viruses in stool of AFP cases. Each lab supports at least one other country. Twelve AFR polio labs have integrated function(s): Measles, YF, Rotavirus and influenza programs. The presenter further stated that there are 49 labs in 44 countries (one lab per country except Nigeria with 4 and Ethiopia with 3). No labs in Equatorial Guinea, Sao Tome and Principe. There are three Regional Reference Labs with capacity for molecular typing and sequencing. Funding is mainly from the measles rubella initiative with support from WHO & CDC.

Photo: Bill and Melinda Gates Foundation_Frederic Courbet

He went on to discuss the contributions of the VPD surveillance and laboratories to include provision of data to update Regional and country specific VPD disease burden estimates; system for monitoring VPD disease trends over time, vaccine impact and serotype shift and safety following vaccine introduction; and strengthening capacity (lab, surveillance, research, human resources etc) in the region. Others included contribution to response to disease outbreaks (meningitis, diarrhea etc) and raising awareness of the VPD disease burden and advocacy for continued investment

He also presented the challenges to include gaps in country ownership and high level commitment to support laboratory systems (under-funded national Labs and lack of maintenance of Lab equipment). Others included dependency on donor funding and inadequate funding for Lab networks (VPD surveillance/lab networks depend on Polio funding and lack of funding for Yellow Fever control program and labs); among others.

Comments and Observations

The RITAG members commended the two presentations. RITAG should be an advocate to countries and partners for the provision of adequate funds for the Labs and remind Ministers of Health of their commitment. They stressed that frontline surveillance requires national resources.

The RITAG also inquired on the status of the investment case. Members wanted to know if there has been any investment case made for VPD in the Region. Has there been any documentation of the return of the money for the national governments. They stressed that surveillance is not going to be cheap and there are lots of diseases that confront the same systems. It will be necessary to outline the needs not covered and build a case for ownership. Members also emphasized the needs for countries to invest more on surveillance. They called for a simple communication system that will help the government to appreciate the need to invest. The additional dimension, according the RITAG is that the funding of Labs is a BIG mandate and they emphasized the need to differentiate the services of the lab network to the global community and the surveillance need of the countries.

They expressed their worries on whether the expansion of antigens will not compound the funding challenge. It was noted that in the past there has been many disease specific investment case but not on

surveillance and this was linked to the absence of a clear tool. The cost for surveillance changes as the disease goal changes from control to elimination and eradication. The RITAG thus stressed that because of the interest in global health security and IHR, at the country level, the Ministry of Health should be talking to people in charge with emergencies.

The RITAG lamented that this is a massive regional threat. The opined that the exit of polio should serves as a leverage to argue for local funding of the Labs. At the country level, countries may pay for surveillance but at the Regional level, it will be paid for by WHO and polio is pulling out. Donors can be sensitized to see the emerging pathogens. The big case needs to be tied into the post-polio eradication case.

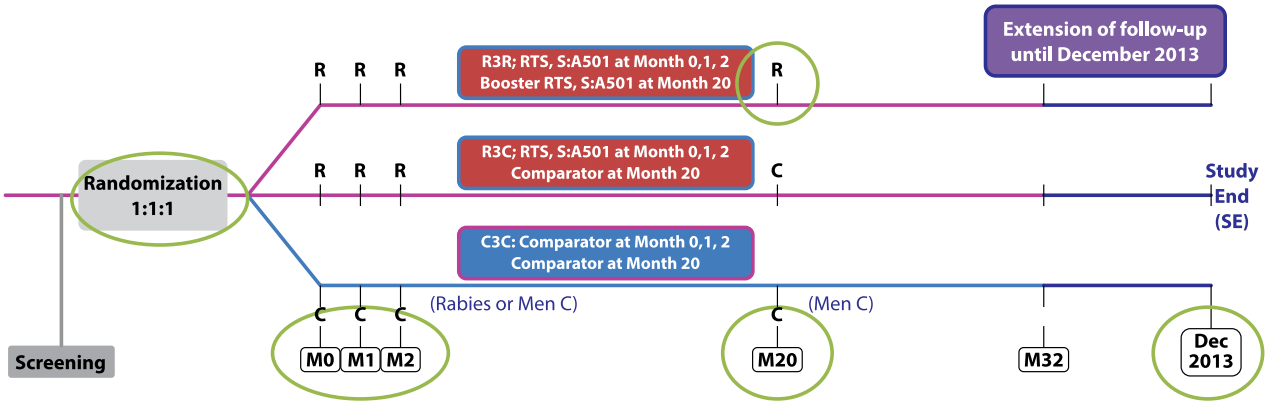
3.3.3 RTS,S Malaria Vaccine

OVERVIEW OF RTS,S MALARIA VACCINE PILOT IMPLEMENTATION IN THE AFRICAN REGION

Dr David Schellenberg, WHO/HQ

The presenter noted that over the years, efforts to control malaria have been built on imperfect application of imperfect tools. Meanwhile malaria remains a ravaging disease that kills millions of people. According to him, malaria remains a major cause of childhood morbidity and mortality, especially in African children leading to 212 million new cases of malaria in 2015 and 429,000 malaria deaths in 2015. He stressed that 10s-100s of infective mosquito bites are experienced every year in areas with poor coverage of protective devices. Six or more P. falciparum malaria episodes are recorded for each child per year. All of this constitutes enormous strain on health system with pp to 30% of pediatric admissions and 60% of outpatient visits. With emerging resistance to drugs & insecticides new interventions are required.

The malaria vaccine (RTS,S/ASO1) targets the circumsporozoite (CS) protein on the P. falciparum sporozoite. It combines CS protein, hepatitis B surface antigen, and AS01 adjuvant to induce a strong immune response and aims to stop infection before parasites are released from the liver (symptoms). In terms of the presentation of the vaccine, two vials are attached together by a "clip" (Antigen RTS,S lyophilized in one vial and Adjuvant AS01 liquid in the other vial). Vaccine Vile Monitor (VVM) is on AS01 vial, but not on antigen vial (i.e. not on the vial used for reconstitution) and is to be used within 6 hours of reconstitution. He gave the packing dimension of inner carton as 100 vials (= 50 pairs, 100 doses) per pack with volume = 9.92 cm^3/dose. In terms of design of the RTS,S/ASO1 Phase III trial, he gave graphic picture for the administration of the vaccine. See Figure 11 below.



Median follow-up to study end:
48 months for 5-17 months age group
38 months for 6-12 weeks age group

Figure 10: Design of RTS,S/ASO1 Phase III trial

He mentioned that the vaccine has 32% efficacy for severe malaria and 39% for clinical malaria. In terms of malaria hospitalization (37%) and all cause hospitalization (15%). For incident severe malaria anaemia it showed 61% efficacy. He stressed that while efficacy is modest, the number of cases of malaria averted in high transmission settings is substantial. He then proceeded to give an overview of the malaria vaccine implementation pilot (MVIP). According to him, the overall design will include (1) Sub-national introduction of the RTS,S malaria vaccine (Vaccine to be authorized for use in the pilots; Introduced and

delivered by EPI using existing mechanisms). In close collaboration with NMCP, ensuring continued use of other malaria prevention and treatment measures. Sub-national introduction enables some areas (clusters) to introduce RTS,S at the beginning of the programme, while other clusters act as comparison areas. Allocation of clusters into implementation or comparison areas will be randomized. Clusters defined (e.g. district, sub-country) based on country context and evaluation requirements. (2) Rigorous Evaluation, supported by research institutions, of Operational feasibility of providing RTS,S at the recommended four-dose schedule when implemented through the routine EPI; impact of the vaccine on all cause child mortality (overall and by gender), malaria-specific mortality and severe malaria; and safety: frequency of adverse events following immunisation (AEFI), with an emphasis on meningitis and cerebral malaria.

He argued that it is essential that standardized monitoring systems are set up in RTS,S and comparison areas to record outcomes of interest. He also presented a timeline showing that the study will span from 2017 to 2022 for phase 1. He also presented the procedure for the selection of countries for the study. This began with a call for expression of interest from African Ministries of health in December 2015. Three out of the ten countries were selected using standardized criteria. These are Kenya, Malawi and Ghana.

ETHIC AND REGULATORY PATHWAY FOR SPECIAL AUTHORIZATION OF RTS,S MALARIA VACCINE

Prof Dicky Akanmori, WHO/AFRO

This presentation demonstrated the regulatory processes leading and WHO support for defining a regulatory pathway for special, non-conventional marketing authorization of the product for use exclusively in the WHO pilot as well ethics review and approval of the phase 4 study.

The presenter illustrated AVAREF practices and commitments which included harmonization of requirements, processes and timelines; optimization of timelines for ethics and regulatory procedures; and implementation of quality management systems. According to him license or approval is as good as the quality of the review. Others include joint reviews for clinical trials, product registration, Good Clinical Practice Inspections and other activities and reliance on work done by Stringent Regulatory Authorities/ Better Resourced Regulatory Authorities, without repeating full reviews and inspections among others. He also traced the consultations that took place between February and June 2017 on the RTS,S vaccine for malaria. The consultations led to agreement by countries for RTS,S to be given a special restricted marketing authorization through an AVAREF joint review to be used in the pilot. He concluded by raising issues for RITAG to discuss and give orientation for the way forward.

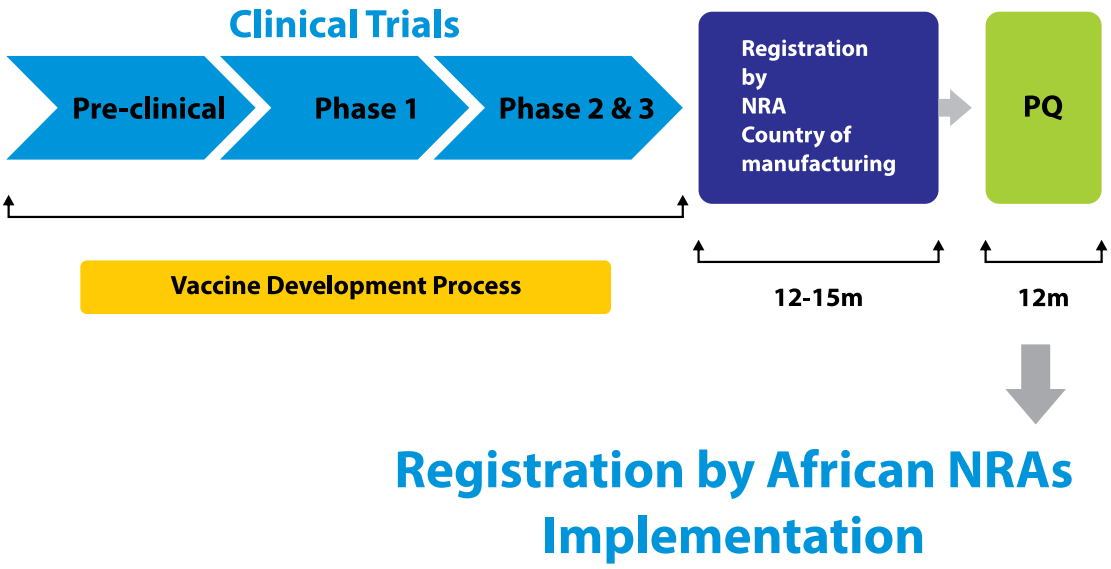


Figure 11: Common pathway for licensure & use of vaccine

INTEGRATING RTS,S MALARIA VACCINE IN IMMUNIZATION PROGRAMMES IN MALAWI: OPPORTUNITIES AND CHALLENGES

Geoffrey Chirwa, MOH/Malawi

This presentation described the EPI programme in Malawi and how RTS,S malaria vaccine introduction can further strengthen the integration of the delivery of vital child interventions. It identified the challenges and opportunities for successful implementation of RTS,S in the pilot.

Comments and observations

The RITAG noted that the vaccine will reduce mortality and morbidity and therefore recommended the implementation of the MVIP. However, they stressed the need for community engagement and strengthening pharmacovigilance. Members noted that RITAG will clearly fit in the advisory role.

Issue of communication also came up very strongly, hence a need to engage journalists/communities and think through what will be communicated about safety. The RITAG stressed that this is an opportunity to strengthen pharmacovigilance and called for regular feedback to the RITAG, as a link to Regional Safety Committee, and not waiting until something is wrong. The RITAG considered the invitation to participate on the MVIP's programme advisory committee and will review the MVIP's Terms of Reference once available, and decide whether it is relevant for RITAG to engage at this level. If yes, RITAG will nominate an appropriate RITAG member to join the committee.

Photo: WHO/S Gborie

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