

Report from the Nineteenth Meeting

Global Commission for the Certification of Poliomyelitis Eradication

Geneva, Switzerland, 26 - 27 February 2019

Abbreviations

Containment:

CAG	Containment Advisory Group
CMG	Containment management group
CC	Certificate of Containment
ICC	Interim Certificate of Containment
CCS	Containment Certification Scheme to support GAPIII
CP	Certificate of Participation
CWG	Containment Working Group
GAPIII	Global Action Plan for Poliovirus Containment
NAC	National Authority for Containment
PEF	Poliovirus-Essential Facility
PIM	Potentially infectious material to poliovirus

Certification

GCC	Global Commission for the Certification of the Eradication of Poliomyelitis
NCC	National Certification Committee
RCC	Regional Commission for the Certification of the Eradication of Poliomyelitis

Viruses and vaccines

IPV	Inactivated poliomyelitis vaccine
OPV	Oral poliomyelitis vaccine (bOPV - bivalent oral poliomyelitis vaccine containing Sabin type 1 and type 3, mOPV2 - Monovalent oral poliomyelitis vaccine Sabin type 2)
PV	Poliovirus (PV1 – Poliovirus type 1, PV2 - Poliovirus type 2, PV3- Poliovirus type 3)
VDPV	Vaccine-derived poliovirus aVDPV Ambiguous vaccine-derived poliovirus cVDPV Circulating vaccine-derived poliovirus iVDPV Immunodeficiency-associated vaccine-derived poliovirus
WPV	Wild poliovirus (WPV1 - Wild PV1, WPV2- Wild PV2, WPV3 - Wild PV3)

Others

AFP	Acute Flaccid Paralysis
CDC	Centers for Disease Control and Prevention (United States of America)
GPEI	Global Polio Eradication Initiative
IDP	Internally Displaced Persons
IHR EC	International Health Regulation Emergency Committee
IMB	Independent Monitoring Board
PEESP	Polio Eradication and Endgame Strategic Plan 2013-2018
SAGE	Strategic Advisory Group of Experts on immunization
TAG	Technical Advisory Group
WHA	World Health Assembly
WHO	World Health Organization AFR – African Region AMR – Region of the Americas / PAHO EMR – Eastern Mediterranean Region EUR – European Region SEAR – South East Asian Region WPR – Western Pacific Region

Foreword:

Abstract from the remarks of the WHO Director General Dr Tedros Ghebreyesus to the Nineteenth GCC meeting.

I am very pleased to attend this important meeting, and I know one of the key topics to discuss includes certification of WPV3 eradication, a virus that has not been detected for over six years. It will be only the third time in history that a human pathogen has been eradicated (the others being smallpox and WPV2). Recently I was in Afghanistan and Pakistan, where a 'final push' is needed to stop transmission of the remaining WPV, type 1. The effort can be likened to running a marathon, and people are feeling tired. However, as in a marathon, at some point fatigue gives way to a new energy, an energy that you do not know from where it comes, as long as motivation is present. Certification of WPV3 eradication could be such a motivator. It will give the polio workers in the field, and everyone involved in this great effort, much encouragement and a cause for celebration. However, this celebration must be done in such a way that it motivates countries to try a little bit harder, gives them a little bit more energy and enthusiasm, and without leading to complacency. The story of WPV3 eradication may therefore bring some good news, to balance the frustration about slow progress in halting WPV1 transmission. We must all give our best on this last mile to eradicate polio once and for all. While one more battle may be over, the war on polio is not finished yet.



Introduction and background

The 19th meeting of the Global Commission for the Certification of Poliomyelitis Eradication (GCC) took place in Geneva, Switzerland, on 26 – 27 February 2019, chaired by Professor David Salisbury.

Commission Members:

Professor David Salisbury, Chair European RCC,

Professor Yagoub Al-Mazrou, Chair Eastern Mediterranean RCC,

Dr Arlene King, Chair American RCC, and Chair, GCC Containment Working Group

Professor Rose Leke, Chair African RCC, and

Dr Nobuhiko Okabe, Chair Western Pacific RCC,

Prof Mahumudur Rahman, Chair South-East Asian RCC.

The agenda and list of participants are included in appendix 1 and 2 respectively.

Aims and objectives

The aim of the meeting was to ensure global certification of poliovirus eradication takes place in a timely manner with credible and transparent processes. Specific objectives were:

- Decide on the timeline and processes to be followed to certify the eradication of WPV3, and review implications of WPV3 certification on poliovirus containment.
- Review the current epidemiology of WPV1 and the progress and barriers toward its eradication.
- Review global polio surveillance, with a focus on conflict affected and inaccessible areas.
- Approve a finalized harmonized global risk assessment tool that can be used to promote a risk based approach to global certification.
- Review progress on completion of GAPIII phase 1 and implementation of PIM guidance for non-Polio facilities;
- Review progress in accelerating and implementation of the Containment Certification Scheme (CCS).

Session 1 Review of Global Progress and Surveillance

Global update

WPV epidemiology: There were 33 cases of WPV1 in only two countries (i.e. Pakistan and Afghanistan) in 2018, and six in 2019 as at 19 February. There has been increased widespread detection of WPV1 in environmental specimens across both countries, but particularly in Pakistan.

Afghanistan

There is ongoing transmission in the Southern and Eastern regions partly related to access and security challenges, bans on house to house campaigns by anti-government elements in the Southern region and increasing inaccessibility in the Eastern region. There are challenges in accessing all children in highly mobile populations.

Pakistan

Transmission continues to persist across the three core reservoirs. The top priority is to focus on reaching persistently missed children in core reservoir areas through continued improvement of operations.

Nigeria

The key risk remains the inaccessible areas around the Lake Chad. Approximately 70,000 children remain unreached in Borno state, a number which has been reduced from 600,000 in 2016.

cVDPV

There are 11 outbreaks currently affecting seven countries:

Type 1: Papua New Guinea and Indonesia

Type 2: Nigeria (two different cVDPV viruses), Democratic Republic of Congo (four cVDPV viruses), Horn of Africa (Somalia and Kenya) and Mozambique

Type 3: Somalia

IPV supply

Supply has improved so that all countries have had access to IPV since mid-2018, and the global demand (for one dose in 87 countries) is being met for the first time since OPV2 withdrawal in 2016. However, there is now a large cohort of missed children, approximately 43 million globally.

Containment

There has been a further small decrease in the number of proposed poliovirus essential facilities (PEF); there are now 26 countries which plan to retain poliovirus type 2 materials in 78 facilities.

Conclusion

WPV1 transmission has still not been interrupted and the number and duration of some cVDPV outbreaks is concerning. However it is likely that Nigeria and Africa are WPV free, and WPV3 is eradicated globally. cVDPV2 outbreaks can be interrupted with good quality mOPV2 SIAs, including in challenging areas as highlighted by the outbreak response in Syria.

Surveillance quality in Afghanistan and Pakistan

An analysis of surveillance quality in Pakistan and Afghanistan shows that ES has increased in scope and distribution of sites, but gaps do still remain. An ES sensitivity assessment based on detection of Sabin viruses suggests that WPV1 is probably detected in most of the locations that have circulation.

Of the 79 ES sites in Pakistan, 27 had no WPV1 detections in 2018, and of these six occurred in districts where other ES sites had detections and another six sites likely have relatively lower sensitivity (based on new sites with low Sabin detection rates). The analysis supports earlier data that ES is more sensitive than AFP surveillance, and thus ES can increase confidence in elimination. However, the detection in 2017 of orphan viruses after substantial gaps in time suggests that silent circulation was still occurring, although no orphans occurred in AFP cases in 2018. This silent circulation may be associated with either low intensity transmission with no or few paralytic cases in an area where ES coverage is not established or due to sub-optimal AFP surveillance quality in parts of the country especially in areas with relatively high immunity or sparse population.

The analysis suggests that WPV1 is still widely distributed across the two endemic countries and that detection is occurring in most of the ES sites where it would be expected. Deployment of ES increases confidence in local elimination which has implications for all of AFG/PAK .

Surveillance quality in the Lake Chad basin

The African Region has made progress towards certification of polio eradication, and it is two and a half years since the latest WPV1 case (August 2016) and confirmed WPV1 positive contact (September 2016) were detected in Borno, Nigeria. The Nigeria polio program continues to strive to reach every last child in the country, including Borno:

- In accessible settlements, seven house to house campaigns were conducted during 2018.
- In partially accessible settlements, the 'Reach Every Settlement (RES)' initiative is employed using civilian teams who are accompanied by armed security to targeted settlements on a monthly basis. 99.6% of all target settlements have been reached at least once.
- In inaccessible settlements, military personnel either vaccinate inhabitants or evacuate residents in the 'Reaching Inaccessible Children (RIC)' initiative. 57% of target settlements have been reached at least once, and 46% of these settlements that are inhabited have been reached at least five times.

Based on a variety of tools including satellite imagery and field work, the current estimate is that approximately 70,000 children under five years old remain inaccessible to any vaccination by the polio program.

Strategies to enhance polio surveillance include:

1. AFP surveillance strengthening
 - Engaging community informants from inaccessible settlements
 - AFP surveillance as part of RES/RIC
 - AFP Surveillance in IDP Camps
 - AFP Surveillance included in special interventions targeting under-served populations throughout Borno
 - AFP Surveillance by Hard to Reach Mobile Teams
 - Intensified community surveillance through expanded implementation of AVADAR (Auto-Visual AFP Detection and Reporting)

- Enhanced active surveillance through expanded use of eSurveillance and Integrated Supportive Supervision tools
 - Active house-to-house case search during campaigns
 - Tracking of community informants zero reports
2. Supplementary Surveillance:
- Healthy children sampling targeting new arrival IDPs, nomadic children, and in newly accessed communities as part of RES/RIC
 - Intensified environmental surveillance including expanded established network, implementing ad hoc ES surveillance in relatively secure LGAs and opportunistic ES sweeps in security-compromised LGAs
 - Systematic contact sampling of all AFP Cases reported

The community informant strategy has been particularly successful in improving AFP surveillance in Borno, where now 88% of AFP reports originate from this source. Informants from inaccessible areas are any persons residing in inaccessible settlements with regular contact (weekly, fortnightly or monthly contacts) with secure areas. The community informants include hunters, drivers, fishermen, and informal health care providers, who are permitted to make contact in secure accessible areas to utilize basic services like health care, visit markets or relatives and others.

In Niger, all 249 Island settlements were assessed for inhabitancy in 2018. 52/249 (21%) of the Niger Islands appear to be inhabited, and these are all inaccessible (due to the government ban). In Chad, there are some areas in the Lake Chad islands that are accessible with security support and two that are fully Inaccessible. In Cameroon, all islands are accessible with security support. In CAR, surveillance continues to deteriorate.

Conclusions and Recommendations: epidemiology and surveillance

GCC concluded that the deeper analysis of WPV1 epidemiology sent prior to the meeting was helpful and should be continued and requested that similar analyses be provided prior to each GCC meeting. GCC similarly found that the work presented on the quality of ES and AFP in Pakistan and Afghanistan and analysis of orphan viruses was very informative, and suggested that the secretariat ensures the country polio teams are aware of the analysis so that any adjustments that are needed to surveillance in the endemic countries could be made.

GCC was concerned by modelling that suggests that the current trends in WPV1 epidemiology indicate that eradication is not on-track. However, the modelling presented increased optimism that WPV1 transmission has ceased in the African Region but noted that this depended on further analysis of the size of the population of under-immunized children, surveillance quality and the degree of isolation of such populations.

GCC concluded that surveillance coverage in key areas such as north-east Nigeria was much improved since the last WPV1 were reported in 2016, and that the technical innovations introduced by AFRO increased confidence that the absence of detection of WPV reflected the absence of transmission. GCC noted that the period of improvement is relatively recent and also that surveillance quality and coverage in other key areas such as CAR had not been similarly assessed.

GCC expressed concern at the number and duration of cVDPV outbreaks, and the barriers to controlling them, in the context of a growing population of children with no intestinal mucosal immunity to PV2. GCC noted that there were currently discussions around the consequences of potential failure to control these outbreaks.

GCC noted the progress in the development of global environmental surveillance for polioviruses, but needs more information on the scope and quality of ES, particularly in endemic countries and high risk countries. This understanding will be very important for the GCC to interpret the absence of WPV for three years prior to global certification of eradication (the negative predictive value).

Recommendation 1.1

GCC recommended that the in-depth analysis of WPV1 epidemiology and surveillance in endemic countries be regularly provided to the GCC ahead of each meeting; in addition, data on the quality of surveillance in key non-endemic conflict-affected and inaccessible areas should be provided.

Recommendation 1.2

GCC requested that an analysis of the coverage and utility of ES be presented at the next GCC meeting, including summary information on location of ES sites, frequency of specimen collection, and the quality of specimens, to enable the GCC to better understand and interpret the absence of WPV detection from ES at the time of global certification.

Recommendation 1.3

GCC recommended that these analyses presented to the GCC should be made available to the EMRCC and AFRCC.

Recommendation 1.4

The GCC recommended that specific modelling should be undertaken using the data from NE Nigeria and the Lake Chad Basin countries to assess confidence that transmission there has ceased. Any future follow-up work on relevant modelling should be also made available to GCC in the pre-read for the next meeting.

Recommendation 1.5

The GCC requested that the AFRCC and secretariat keep the GCC updated on deliberations regarding these high risk areas around Nigeria and Lake Chad, and that the global and regional certification and surveillance teams work together on ensuring high quality assessment of the surveillance risks in the lead up to African certification.

Recommendation 1.6

The GCC and RCCs must be kept informed of discussions regarding cVDPV2 outbreaks and need to consider the polio-free status of regions in which there is persistent cVDPV transmission [defined as more than 12 months of transmission].

Session2: Global WPV3 Certification

At its previous meeting in October 2018, the GCC recommended that a sequential approach to global certification be adopted, with WPV3 certification taking place as soon as appropriate, and independently of WPV1 certification. At this meeting, the GCC reviewed updated data from all six regions, disease modelling, and other aspects such as communication issues.

Global overview of WPV3

No WPV3 cases have been detected since November 2012, when the last WPV3 case in the world was detected from an infant aged 11 months in Yobe, Nigeria with onset of paralysis on 10 November 2012. Since then, data obtained from each WHO region indicates over one million tests have been performed on AFP and environmental specimens, with no WPV3 detected, but WPV1 detected in three regions, and cVDPV detected in all six regions. This absence of WPV3 viruses in a system capable to detect other polioviruses is strongly supportive that WPV3 has in fact been eradicated.

Insights from modelling

It is now more than 6 years of no detected WPV3, and modelling suggests well over 95% confidence of no undetected circulation. Longer delays in WPV3 certification will not significantly increase this confidence, and thus modelling supports the decision to certify WPV3 eradication soon.

Program considerations

The GCC noted the discussion at the recent meeting of the SAGE Polio Working Group when the 'pros and cons' of Sabin type 3 vaccine withdrawal following the certification of WPV3 eradication were discussed; the WG did not recommend Sabin type 3 vaccine withdrawal. However, the working group will revisit this issue, along with further evaluation of the readiness criteria required to withdraw oral polio vaccines.

From a communication perspective, WPV3 certification provides a valuable opportunity to communicate the progress in polio eradication, but the timing of an announcement will be critical to ensure maximum participation of all stakeholders. Messages will need to indicate clearly that WPV1 transmission has not been interrupted yet. Potential activities include:

- A celebratory event;
- Development of core materials (key messages, Q&As, fact sheets) ;
- Media briefing (and pre-briefings building up to event);
- Placement of key messages in existing GPEI communication channels;
- Selected articles in key scientific media.

Target audiences include:

- Immunization policy groups and technical advisory bodies, such as SAGE, TAGs, IMB, etc;
- WHO Member States including members of Regional Committees, the Executive Board, and the WHA;
- Non-technical internal and external stakeholders: core partners, donors, media, influencers.

Concerns were expressed by the African Region about the timing of certification of WPV3 eradication with respect to Regional certification of three years without detection of wild polioviruses as it may pose programmatic and communication challenges.

Conclusions and Recommendations concerning certification options

Noting that new modelling work and updated regional and laboratory data reinforced the previous GCC conclusion that WPV3 has been eradicated, GCC reaffirmed its decision to undertake certification of WPV3 in order to once again demonstrate that eradication of all polioviruses is achievable as a motivator to program staff, volunteers, donors and stakeholders.

GCC discussed the various options for the timeline and process of WPV3 certification, noting both the challenges and advantages of various options, and concluded that the reasons, challenges and benefits of the sequential certification needed to be communicated clearly.

GCC noted that certification of WPV3 could impact the process of containment of polioviruses, but these impacts must be addressed regardless of the timing of the certification of WPV3.

Recommendation 2.1

GCC agreed that the RDs of AFR and EMR be asked to submit requests to their respective RCCs to confirm from their member states that the last WPV3 in each country had been reported more than six years ago. GCC will review these data along with the regional certification reports of the other four certified regions before concluding that WPV3 had been eradicated.

Recommendation 2.2

The GCC recommended that the GPEI communication teams be closely involved in the process of the sequential certification of WPV.

Session 3: Global Risk Assessment

In July 2017, the GCC recommended that a global risk assessment be developed to assess the risks to global certification. Consequently, the Inter-Regional Risk Assessment Working Group (IRRAWG), a semi-formal working group consisting of regional polio focal points, and facilitated by CDC on behalf of the GPEI, developed a draft GCC-specific risk assessment using a single set of globally defined indicators. This allows assessment of certification risks using existing data sources; there would be no additional data required from regions or countries. The tool is to be used by the GCC as a standardized high-level approach for assessing risks for all countries, both those in regions already certified free of indigenous wild poliovirus as well as those in regions not yet certified.

In October 2018, the GCC recommended that a paper on the implementation of the proposed certification RA tool explaining rationale, methods development, use and rollout of GCC Certification Risk Assessment be developed by the IRRAWG in its next meeting, and be presented to the GCC. The IRRAWG met by teleconference, and subsequently in Portugal 31 January – 1 February 2019. The resulting 'White Paper' is in annex 2.

This paper was prepared to more clearly explain the purposes of the GCC RA Tool/Dashboard and its use by the GCC for situational awareness, and its potential use by RCCs in comparison with current regional and country risk assessments. This tool is not intended for use by countries/National Certification Committees, nor to set programmatic priorities or suggest mitigations. Regional and country risk assessments with subnational granularity will continue to guide programmatic priorities for mitigating activities.

Although there remained questions about the weighting of components of the overall score from this Tool, the emphasis will be on the "four-square" Dashboard for individually assessing Population Immunity, Surveillance, Outbreak Preparedness and Containment. For full standardization, the Outbreak Preparedness assessment and the Containment progress assessment will henceforth always be based on meeting quality standards of the WHO regional office. The number of type 2 poliovirus-essential facilities will continue to decrease and this will be reflected in future updated assessments.

A comparison of annual reporting to RCCs indicates that while reporting formats and questions vary, the essential data collected across the regions were for the most part the same. Moves toward electronic submission of final reports being piloted in the European Region could be used to further facilitate consistency.

Conclusions and Recommendations concerning risk assessment

GCC reaffirmed that the Risk Assessment Tool/Dashboard was a useful mechanism to inform future discussions on risks to global certification.

Recommendation 3.0

A revision of the risk assessment should be made when new global immunization data are available mid-year, and the output provided to the GCC before its next meeting. The GCC will review the dashboard for one region to assure the tool/dashboard's utility for the GCC.

Session 4: Progress on poliovirus containment

Reduction in the number of PEFs

A total of 26 countries across all six WHO Regions plan to retain poliovirus type 2 materials in 78 designated PEFs; 24 countries have appointed NACs. Two countries are pending, Serbia and Romania, both in the European Region. Of the 78 PEFs, 45 will retain both WPV2/VDPV2 and Sabin 2 viruses, the remaining 33 will hold Sabin 2 only. Laboratories constitute 56 of the 78 PEFs, the remainder are Salk IPV producers (6) and Sabin IPV producers (16). The population in the 26 countries hosting PEFs constitute 52% of the global birth cohort.

Acceleration of the implementation of the CCS process

This is supported by WHA Resolution 71.16. Of the 26 countries above, only four have commenced implementation of the CCS - South Africa, Indonesia, Sweden and the USA. The USA has submitted CP applications for 7 out of 12 designated PV2 PEFs.

Containment Priorities include the following:

- Negotiate use/availability of S19 and other safe strains for use outside containment
- Update inventories of poliovirus materials with data quality verification
- Implementation of GAPIII-Containment Certification Scheme
- Implementation of the GAPIII auditor training program for national authorities
- Holding to WHA71.16 deadlines and continuing advocacy to reduce the number of PEFs

Containment Working Group priorities are:

- reviewing process for review of CP applications,
- reviewing application form for ICC/CC applications, and
- considering its role with respect to communication/advocacy on behalf of GCC.

Consideration is needed to ensure geographical diversity in the membership of the CWG, as it may be preferable that reviewers of applications are not from the applying country.

Conclusions and Recommendations concerning PV Containment

GCC noted that certification of WPV3 eradication may impact on the containment of polioviruses - the scale of the impact will be dependent on the number of facilities that retain PV3.

GCC noted the challenges inherent in the implementation of the Containment Certification Scheme. Only 10/78 PEF applications have been received, at the time of the GCC meeting, due in part to the desire to maximize the duration of the CP (the rolling deadlines for the next phase of certification are based on the date that the Certificate of Participation is issued). The deadline for applications to be submitted to the NAC is 31 December 2019.

GCC noted with concern that the workload involved in implementing the CCS exceeds existing resources.

The GCC concluded that WHA Resolution 71.16 could be better used as an advocacy tool to reduce the number of PEFs. This is a serious, resource intensive commitment which poses another global biosecurity risk. In addition to the DG and RDs working with country counterparts to ensure they fully understand and acknowledge the risks of hosting PEFs, the CWG could assume a greater role in communication and advocacy.

The GCC concluded that substantial progress on Phase I had been reported by the Regions and HQ in implementing previous GCC recommendations. However, GCC noted some pending issues that should be addressed in a reasonable timeframe.

Recommendation 4.1

The potential impact of WPV3 certification on containment requires review as there could be significant resource impacts. The Secretariat, in conjunction with the CWG, should consider these impacts and make recommendations to the GCC on the timelines for WPV3 containment.

Recommendation 4.2

Development of a guide on the completion of the Certification of Participation (CP) application should be shared to facilitate common understanding of requirements by all regions and countries.

Recommendation 4.3

The GCC approves the proposal to restrict the application submission timeframes and review periods to improve the management of the CP approval-granting process, noting that this is a deviation from the CCS. Furthermore, the GCC recommends that all approved CPs for PEFs that will retain PV2 and that are proceeding to obtain an ICC and/or CC be in effect until the same end date.

Recommendation 4.4

The GCC recommends that the GPEI increase resources (staffing, funding, advocacy, and communication) in order to meet the containment deadlines as per the WHA resolution. Furthermore the CWG, on behalf of the GCC, should assume a greater role in communication and advocacy to reduce the number of PEFs.

Appendix 1: Meeting Agenda

Tuesday, 26th February		
09.00	Welcome remarks	M. Zaffran
09.15	Objectives of the meeting	D. Salisbury
Session 1 Review of Global Progress and Surveillance		
09.30	Global update	M. Zaffran
10.15	Surveillance quality in Pakistan and Afghanistan	S. Kroiss
10.45	<i>Coffee break</i>	
11.15	Surveillance quality Lake Chad countries, especially in conflict and inaccessible areas	J. Ahmed
12.00	Discussion	All
12.30	<i>Lunch</i>	
Session 2 WPV3 Certification		
13.30	WPV1 and WPV3 certification - insights from modelling	K. Thompson
14.00	CRTT and SAGE WG Feb meeting outcomes, and implications for vaccine policy	R. Sutter
14.30	Review of WPV3 country data (annex 2 of PIM guidance)	A. Llewellyn
15.00	Recap of WPV3 data and WPV2 certification	G. Tallis
15.30	<i>Coffee break</i>	
16.00	Communicating WPV3 certification	O. Rosenbauer
16.15	Potential impacts on containment	D. Moffett
16.45	Discussion, including possible recommendations from day 1	all
17.30	Finish	
Wednesday, 27th February		
09.00	Review draft recommendations	all
Session 3 Risk assessment		
09.30	Standardizing annual reporting	A. King
09.45	Electronic annual reporting	P. O'Connor
10.00	Global Certification Risk Assessment - IRRAWG update	S. Wassilak
10.30	Discussion	all
Session 4 Containment		
11.00	<i>Coffee break</i>	
11.00	Regional containment updates since the last meeting (10 minutes each)	Regions
12.00	Dr Tedros Address to the GCC meeting	Dr Tedros
12.15	<i>Lunch</i>	
13.15	Containment Working Group update on certification of PEFs	A. King
13.45	Verification of data inventory and implementation of PIM guidance	D. Moffett
14.15	Discussion	all
14.45	<i>Coffee break</i>	
Session 5 Conclusions and Recommendations		
15.15	Finalization of Recommendations	all
16.45	Wrap-up and next meeting	D. Salisbury
17.00	Finish	M. Zaffran

Appendix 2: List of Participants

GCC MEMBERS

- 1 Professor David SALISBURY
- 2 Professor Mahmudur RAHMAN
- 3 Dr Arlene KING
- 4 Dr Rose LEKE
- 5 Dr Yagob AL-MAZROU
- 6 Dr Nobuhiko OKABE

TECHNICAL ADVISERS AND OBSERVERS

- 7 Dr Kamel Senouci, BMGF
- 8 Dr John VERTEFEUILLE, US CDC
- 9 Dr Steve WASSILAK, US CDC
- 10 Dr Anna LLEWELLYN, US CDC
- 11 Dr Kimberly THOMPSON, Kid Risk
- 12 Steve KROISS, IDM

WHO Regions/Countries/Regional Offices

- 13 Dr Pascal MKANDA, AFRO
- 14 Dr Koffi Isidore KOUADIO, AFRO
- 15 Dr Hieronyma GUMEDE MOELETSI, AFRO
- 16 Dr Humayun ASGHAR, EMRO
- 17 Dr Muhammad Obaid-UI Islam BUTT, EMRO
- 18 Dr Patrick O'CONNOR, EURO
- 19 Dr Shahin HUSEYNOV, EURO
- 20 Dr Sigrun ROESEL, SEARO
- 21 Dr Gloria REY-BENITO, AMRO
- 22 Dr Ana CHEVEZ, AMRO
- 23 Dr Tigran AVAGYAN, WPRO

WHO SECRETARIAT / HQ

- 24 Mr Michel ZAFFRAN
- 25 Dr Roland SUTTER
- 26 Dr Graham TALLIS
- 27 Dr Jamal AHMED
- 28 Dr Zainul KHAN
- 29 Dr Daphne MOFFETT
- 30 Dr Liliane BOUALAM
- 31 Dr Harpal SINGH
- 32 Mr Oliver ROSENBAUER
- 33 Mrs Achouak MAJDOUL

Appendix 3: 'White Paper'

The Risk Assessment Tool for the Global Commission for the Certification of the Eradication of Poliomyelitis

Summary

The objective of this standardized Tool is to enable the Global Certification Commission (GCC) to make assessments of risks across the world approaching (and after) certification of the interruption of indigenous wild poliovirus (WPV) transmission. To permit a comprehensive examination of risks over time to aid GCC discussions, the tool is divided into four categories: Population Immunity, Surveillance, Outbreak Preparedness and Containment. The Tool will help guide discussions within the GCC about each Regional Certification Commission's (RCCs) predominant concerns that are/will be discussed in more detail in RCC meetings. This tool does not set mitigation priorities or criteria for global certification nor imply that all countries be categorized as "low risk" for certification to occur.

Background

WHO regions began assessment of the risk of substantial WPV transmission following importation in the early 2000s in order to prioritize mitigating activities and seek funding to conduct those activities. Nearly all countries that have had WPV or circulating vaccine-derived poliovirus (cVDPV) outbreaks were identified as "high risk" in regional risk assessments (RAs).

Currently, the six WHO regions conduct similar but non-standardized RAs to guide programmatic work and mitigation activities. These RAs allow comparison of risks across countries within regions but because of methodologic differences, not across countries throughout the world. With this in mind, the Chair of the GCC requested that the inter-regional risk assessment working group (IRRAWG) develop a standardized tool that aids the GCC in equitably assessing risks of poliovirus transmission, delayed detection and lack of preparedness across all countries. The GCC RA does not replace regional or national RAs and should not guide programmatic work. Rather, it provides snapshots in time of risk, which aids GCC discussions leading up to and at the time of global certification of WPV eradication.

At the time of eradication, all countries are not expected to have overall risk scores or scores within each category that are "low risk" and indeed there will likely be some countries classified as "high risk." This does not preclude certification, but rather informs the GCC of risks at the time it declares the world polio-free, analogous to regional RAs and the regional certification process.

To generate the overall risk score, the GCC RA Tool utilizes the same groupings of factors as regional RAs. Population Immunity is included as a key component regarding the risk of poliovirus circulation from emergence or introduction of cVDPV, or release of poliovirus from facilities, including undeclared poliovirus potentially infectious materials. Surveillance is an important component regarding timely detection of circulation. Along with some factors such as sanitation and hygiene, Outbreak Preparedness and Containment are included in the Tool's overall risk score to incorporate risks that are becoming increasingly important leading up to and after certification.

The output of the GCC RA Tool should generate conversations within RCCs and regions about the comparisons of the four categories in the Tool with the RAs made by the regions in order to evaluate

the mitigation activities currently addressing risk. **Appendix A** provides more information about the envisioned role of the GCC RA at different levels of the certification process.

Purpose

- The Tool enables the GCC to assess risks across the world approaching (and after) certification of interruption of indigenous WPV transmission.
- The GCC Tool's four categories of risk for each country — Population Immunity, Surveillance, Outbreak Preparedness, and Containment — enable a more targeted discussion within RCCs and with WHO regional staff of mitigation activities currently proposed or underway.
- The four-squares (comprised of a table showing the risk in each of the four categories) in the GCC RA Tool should inform the GCC about progress in all categories.
- In particular, the GCC will assess progress towards meeting GPEI milestones in Outbreak Preparedness and Containment for all countries, especially for those with poliovirus essential facilities (PEFs) to enable global polio-free certification, in alignment with GAPIII guidelines.
- The tool also allows the GCC to look at risk categories, particularly Population Immunity and Surveillance for contiguous countries that are in different WHO regions.

Limitations

- The GCC RA Tool should not replace other RA tools. Unlike assessments made by regional offices and countries, subnational risks are not included in this Tool. For large countries, the Tool's national RAs may mask very low Population Immunization and/or Surveillance performance in smaller geographies as examined in regional/national RAs.
Each WHO Regional Office should continue to assess risks of each component based on current regional and country-level RAs. RCCs may want to examine more carefully those countries for which there are discrepancies in comparisons of RAs by regional offices and the GCC tool.
- The overall risk score is heavily influenced by Population Immunity, which is important to accurately assess risk of poliovirus transmission. Given that Population Immunity may or may not change substantially over time in many countries, these overall risk scores should be interpreted with caution, with more emphasis placed on the four-square analyses to understand the various types of risk (see **Appendix B** for more detail).
- The surveillance subcategory score is largely based on indicators of AFP surveillance quality, which limits its capacity to detect WPV or cVDPV transmission when performance indicators are high despite inadequacy of surveillance infrastructure (not representative of all populations and/or areas), poor active case surveillance and/or weak supervision of fieldwork.
- Containment currently only applies to poliovirus type 2 materials and would need to be modified as sequential certification occurs.
- Data for indicators are of variable quality and therefore can affect the assessed risk.

Appendix A: Role of GCC RA at each level of certification hierarchy

Group	Role of GCC RA
GCC	<ul style="list-style-type: none"> • Utilize four-squares to analyze risks of poliovirus transmission • Utilize GCC RA to track progress toward improving Outbreak Preparedness and Containment
RCC	<ul style="list-style-type: none"> • Discuss mitigation activities occurring in priority countries identified through comparisons of GCC RA with Regional RAs
Regional Offices (RO)	<ul style="list-style-type: none"> • Examine discrepancies between assessments of risk in GCC RA, regional RAs and subnational RA reported by the NCC and/or COs; and conduct in-depth data analysis and/or field assessment as appropriate. • Track mitigations already underway or to be conducted to lower risks in priority countries • Utilize GCC RA to track progress toward improving Outbreak Preparedness and Containment
<i>National Certification Commission (NCC)*</i>	<ul style="list-style-type: none"> • <i>Review subnational risk analyses completed by country offices</i> • <i>Track mitigation activities to filter up to ROs</i> • <i>Respond to regional office concerns about specific risks identified in RAs</i>

**GCC RA is not used at this level for these analyses. Rather, it informs questions at higher levels that will filter down to NCCs.*

Appendix B: Weighting of Population Immunity and Surveillance in the Overall Risk Score

- Like all the current regional RAs, the GCC RA tool **overall risk score** is highly weighted to reflect Population Immunity, with vulnerability being the basis of poliovirus transmission. Again, this weighting does not indicate that persistently low population immunity estimates threaten certification of global wild poliovirus-free status.
- Population immunity indicators, primarily WUENIC Pol3 estimates and non-polio acute flaccid paralysis (AFP) dose histories, even with caveats, are the most robust indicators available.
- WUENIC Pol3 estimates for the past 5 years are used for this risk assessment, with the lowest estimate over that time assigning risk. Given that this uses a 5-year timeframe, it is difficult for risk to substantially decrease in the short-term, even if estimates are revised.
- Even though mitigation activities are already conducted in high and medium-high risk counties, both WUENIC Pol3 estimates and non-polio AFP dose histories have changed little within a few years despite these mitigations.
- Surveillance quality and the extent of programmatic reach in inaccessible regions will be the major consideration for RCCs to certify regional interruption of indigenous WPV transmission, and therefore GCC certification of WPV eradication. There are limits to interpreting surveillance performance indicators as markers of actual performance, even in subnational geographic areas (under the purview of regional RAs); high indicators even sub-nationally have masked substantial weaknesses in case detection.
- Sensitivity testing was conducted on the category weights in the GCC RA tool. When weighing the Surveillance category highest in the overall risk score, the resulting output did not accurately place currently endemic countries and those with WPV and cVPDV outbreaks in the past 10 years into higher risk categories. The alternate weights also placed many countries in certified regions at high or medium-high risk.