Third Meeting of Chairpersons of WHO Regional Commissions for the Certification of Poliomyelitis Eradication (the 'core Global Certification Commission')

(12th meeting of the Global Certification Commission)

New Delhi, India, 29 August 2012

Summary of findings, decisions and recommendations

The third meeting of Chairpersons of WHO Regional Commissions for the Certification of Poliomyelitis Eradication (RCCs) was conducted on 29 August, 2012, following the third meeting of the SEAR RCC. Four RCC chairs (EMR, EUR, WPR and SEAR) are members of the SEAR RCC, and all RCC chairpersons are members of the Global Certification Commission (GCC). While the full GCC has not been convened for several years, the RCC chairpersons, as the 'core GCC', have had two previous meetings, and the opportunity of the SEAR RCC meeting was used for a third meeting of the 'core GCC'.

The meeting was attended by Dr Anthony Adams, Chair, Global Certification Commission (GCC) and also Chair, RCC/WPR, Dr Rose Leke, Chair, RCC/AFR, Dr Ali Jafaar, Chair, RCC/EMR, Dr David Salisbury, Chair, RCC/EUR, and Dr Nazrul Islam, Chair, RCC/SEAR. Dr Carlyle de Macedo, the Chairperson of the Regional Commission for Laboratory Containment and verification of polio-free status in the Americas, was unable to attend.

Participants from WHO were Dr Bruce Aylward, ADG, and Dr Rudi Tangermann, POL, from WHO HQ, Dr Sigrun Roesel, WHO/WPRO, and Dr Patrick O'Connor, WHO/SEAR.

The RCC chairs had already been briefed on the overall status of polio eradication during the SEAR RCC meeting. The 'core GCC' meeting was used (see agenda in ANNEX I) to brief the GCC on the implications of the new 'polio endgame' for regional and global certification activities, to review reports on certification activities in the Regions, and to discuss options to 'revive' the GCC, including to appoint 3 new members, to discuss frequency of meetings and the relationship between the RCCs and the GCC.

1 Main findings, decisions and recommendations

a) Global Certification Commission (GCC) membership

- The current vacancies in the GCC provide an opportunity to reconstitute the GCC and in doing so optimize its membership to meet the evolving demands and timelines of the new 'polio endgame'.
- The GCC suggests that the optimum balance of representation and expertise on the GCC could most efficiently be achieved with a complement of nine members, comprising the six RCC chairs and an additional three members who may be unaffiliated with a specific RCC but bring additional expertise to the deliberations of the GCC in such areas as biosafety / bio-containment, and virology.
- Given the acceleration of the polio endgame and the interface between the endgame and certification processes, the GCC suggests that the full Commission should be appointed by mid-2013. The secretariat should be in a position to support at least annual meetings (and potentially more frequent meetings) during the 2014 to 2018 period.

b) Confirmation of type 2 WPV eradication

- Prior to a tOPV-bOPV switch, there should be a formal conclusion by the GCC that WPV2 transmission has been interrupted globally.
- Given that circulation of WPV type 2 has not been detected globally for > 10 years, despite consistently improving surveillance sensitivity in the remaining endemic Regions, the GCC would consider makingsuch a decision based on a formal statement from:
  - each of the RCCs of the 3 uncertified Regions concluding that WPV2 transmission had been interrupted for > 10 years in each Region's member states and that surveillance was sufficiently sensitive to detect such transmission had WPV2 been present and,
  - each of the RCCs of the 3 certified Regions confirming that WPV2 had not been re-introduced to their Region since regional certification of eradication of all WPV transmission and that surveillance sensitivity had been maintained at a sufficiently high level such that an importation would have been detected.
- The GCC would be willing to consider such a conclusion at its next meeting, as early as mid-2013, if 1) a full complement of GCC members has been established, and 2) all 6 Regions have submitted the necessary documentation at least one month in advance.
- The GCC highlights that its capacity to consider a conclusion regarding the interruption of wild poliovirus type 2 globally would depend on there being a fully functional Regional Certification Commission (RCC) in each of the 6 WHO Regions. Given the need for each RCC to have sufficient time to consider the necessary evidence on type 2 interruption before submission to the GCC, all of the RCCs would need to be functioning at least 6-9 months in advance. In this regard, the GCC notes that the Americas Region no longer has an RCCand that in the Africa Region the RCC has not been convened for over 2 years due to the intense eradication effort ongoing in that Region.

c) Containment of wild poliovirus type 2 prior to a tOPV-bOPV switch

- Prior to a tOPV-bOPV switch, the GCC would consider issuing a conclusion as to whether WPV2 had been eradicated globally, but not yet formally certifying such an achievement. Consequently, the GCC would not be requiring documentation that specific bio-containment landmarks have been achieved.
- However, the GCC would strongly recommend that phase 1 containment activities had been completed globally, for at least wild poliovirus type 2, prior to a tOPV-bOPV switch and that specific measures had been put in place to minimize the residual risks associated with WPV2.

d) Elimination of circulating vaccine-derived polioviruses (cVDPVs)

- The GCC recognizes the need for a process and criteria for concluding if and when cVDPVs have been eliminated globally.
- The GCC recognizes that information on the frequency and potential persistence of type 2 VDPVs following a tOPV-bOPV switch would be quite helpful in informing decisions as to the eventual process and criteria required to conclude whether all cVDPVs have been eliminated.
- Consequently, the GCC recommends that decisions on whether a formal verification or certification process will be required for cVDPVs be deferred until a minimum of 12

months after the tOPV-bOPV switch to allow such decisions to be fully informed by the experience gained with the planned elimination of cVDPV2.

- The GCC recognizes that the mechanism and criteria used to reach conclusions on the elimination of cVDPVs may differ by serotype.

e) Relationship with the IMB

- The GCC recognizes that, unlike the GCC, the IMB is intimately involved in the process of WPV eradication itself. However, the GCC believes that it may be beneficial to be briefed by the IMB Chairman on the work, findings and recommendations of the IMB through cross-participation as observers, when appropriate, in the meetings of the GCC and the IMB.

f) Secretariat support to the GCC & RCCs

- Recognizing the increasing work of the RCCs and the GCC inherent in the new polio endgame,planned tOPV-bOPV switch, and eventual global wild poliovirus certification and containment, the GCC recommends that all WHO RegionalOffices and HQ formally establish by end-2012 a certification focal point to serve as Secretariat to the respective Commission. These focal points should be able to devote at least 50-75% of their time, depending on the Region, to supporting the work of their Commission in 2013-15 and up to 100% of their time in 2017-18.

2 Reports from Regional Commissions

a) African Region

The RCC AFR was established in 1998. Currently, there are 9 active members (of 12 initial members). There is cross-membership between the EMR and AFR RCCs, with a full member from each Commission assigned to the other Commission.

The RCC AFR normally meets once a year; however, due to intense eradication activities and further acceleration following the declaration of PE as a global public public health emergency, the RCC has not met for about 2 years.

A total of 29 (of 46) AFR member states have submitted their complete national documentation on polio-free status, of which 25 have been 'accepted' by the RCC. Acceptance of four country reports was deferred due to declining AFP surveillance performance (Tanzania, Madagascar) and because of WPV importations (B. Faso, Cameroon).

Work to achieve Phase 1 of laboratory containment in AFR has started several years ago. Fourty-two member states have established a 'national task force' for lab containment. Twelve of these 42 countries have completed both the lab survey and inventory.

A brief update on the polio situation in the Region was given, which highlighted the continued risk of WPV re-importations into polio-free countries and areas. Most at risk are polio-free countries in West and Central Africa and in the Horn of Africa, often with low-performing routine immunization systems.

Of relevance in the context of certification, the AFRO team has also begun to use regular quarterly assessments of risk (of WPV importation and spread), conducted at national and district level, using a methodology and set of variables which were standardized between WHO Regions. Identification of areas at highest risk is followed by plans for risk mitigation -

largely to prioritize non-infected areas in the Horn of Africa and West Africa for 'preventive SIAs'.

Next steps and plans for certification activities in AFR include to strengthen the RCCs membership, conduct 2 annual meetings per year from 2013 onwards to continue revieweing national documentation and annual updates, accelerate efforts to finalize Phase 1 lab containment in the Region, and support risk assessments and mitigation activities.

b) American Region

The Region of the Americas (PAHO) had dissolved National Certification Committees (NCCs) and the Regional Certification Commission shortly after regional certification in 1990. A Regional Commission for 'Laboratory Containment and Verification of Polio-Free Status' was re-established in 2004 to independently document that the Phase I requirements for wild poliovirus laboratory containment had been fulfilled and to verify that the polio-free status of the Region remained unchanged.

The new Commissions had it's fifth meeting in Buenos Aires, Argentina, in March 2010, and determined that all AMR member states had achieved Phase 1 of laboratory containment. The RCC also reaffirmed its terms of reference “to evaluate annual PAHO and requested NCC reports on polio immunization, surveillance, and laboratory performance in accord with GCC criteria”.

However, the AMR Commission has not met again since 2010 and had, apart from brief reviews of the status of AFP surveillance in countries of the Region, focused its work from 2004 to 2010 almost entirely on achieving Phase 1 laboratory containment. Unlike the RCCs in EUR and WPR, and in the absence of NCCs, the AMR Commission had also not started to work with member states to request update reports on maintenance of polio-free status (quality of surveillance and immunization activities).

The chairperson of the Commission and the AMRO immunization team were invited to the 3rd meeting of RCC chairpersons, but unfortunately were unable to attend.

c) Eastern Mediterranean Region

The Region has been able to maintain 21 of 23 member states polio-free (all countries except AFG and PAK).

Established in 1995, the EMR RCC, with full members assigned from 3 neighboring Regions (EUR, AFR, SEAR) met initiall once a year, but has met twice a year for several years now. EMR member states submit to the RCC preliminary and final national documentation on polio-free status (in standard format), as well as annual update reports from countries from which the RCC has already accepted national documentation.

NCCs in EMR member states remain active and are invited to present to the RCC, as needed.

The RCC has accepted *basic national documentation* from 20 member states; *final national documentation* has been accepted from 17 countries which have been polio-free for 5 years or more and have completed Phase 1 of laboratory containment (all countries except PAK, AFG, SOM, YEM, SUD, S Sudan). Afghanistan and Pakistan have submitted provisional reports to the RCC, which the RCC deemed to be of sufficient quality.

The EMR RCC requests and receives regular annual update reports from all countries who submitted the basic national documentation; shorter 'abridged' annual updates are submitted by countries which have submitted 'final national documentation' (see above).

Nineteen EMR member states have completed Phase 1 of lab containment (all except AFG, PAK, SOM, S Sudan), and special documentation on the quality of Phase 1 containment activities has been received for all countries except Lebanon and Palestine. Phase 1 activities have *not started* in PAK, AFG and Somalia.

Similar to AFR, the EMR polio team have also started regular risk assessments to identify polio-free areas at highest risk of importation and subsequent spread. As of August 2012, the countries with the relatively highest risk score are Yeman, Somalia, North and South Sudan, as well as Syria and Iraq.

d) European Region

The RCC EUR was established in 1996 and applies the guiding principles recommended at the 1st meeting of the GCC in 1995. With 8 members (including the Chair), the RCC has had 26 meetings since it was established.

Phase 1 of laboratory containment was completed in the Region; the RCC notes that further guidance is need from the GPEI related to continued further containment activities in Regions such as EUR where Phase 1 activities have been completed.

For several years, the RCC has reviewed and assessed risk in the Region using the surveillance performance and immunization levels in 7 sub-regional zones.

A large polio outbreak occurred in 2010 in Tajikistan, a country which had repeatedly been identified previously as being at highest risk for spread of a possible WPV importation. The outbreak spread to 3 other central Asian countries, but was controlled, with the last outbreak-related case reported from the Russian Federation with onset of paralysis on 25 sEptember 2010.

Following the central Asia outbreak, the RCC has placed increasing emphasis on assuring that, in addition to maintaining high quality surveillance and immunization activities, all members states prepare and test national preparedness plans for importation; 44 of 53 EUR member states have such preparedness action plans.

As of August 2012, the following EUR member states are considered at high risk of transmission following importation: Bosnia-Herzegovina, Greece, Romania, South-East Turkey, Georgia, Ukraine, North Caucasus (Russian Federation), and Uzbekistan.

e) South-East Asian Region

India was removed from the list of polio-endemic countries on 25 February, 2012, one year after the last case was detected in West Bengal state. Both India and Nepal have not reported wild poliovirus for more then 12 months, and the remaining 9 countries in the Region have been polio-free for more than 5 years.

All SEAR member states, except India and Timor Leste, had had their full documentation accepted by the RCC. Nine of 11 countries have submitted phase 1 containment documentations; of these, four countries need to resbumit containment documentations.

The National Certification Committee in India, supported by the NPSP, submitted an initial detailed report and plan to eventually finalize and submit full national polio-free documentation to the RCC. India will also accelerate activities towards achieving Phase 1 of laboratory containment.

f) Western Pacific Region

The RCC WPR continues to meet annually and requests written annual reports on the maintenance of polio-free status from NCCs of each WPR member state (including a sub-regional certification committee for pacific island countries). Following the RCC meeting, the RCC chair sends individual letters to NCCs on country-specific conclusions and recommendations. For the last four years, RCC meetings were held in in countries where the RCC presence was used as a strong advocacy tool towards improving the maintenance of polio-free status.

The RCC continues to request that NCCs, assisted by national MOH/WHO secretariats, conduct sub-national assessments of risk (of importation and subsequent spread), and include a description of risk mitigation activities in their report. These risk assessments have become a key finding on which the RCC bases its assessment of the quality of polio activities in a country.

An attempt is made in the WPR to maintain close working relationships between the EPI regional technical advisory group and the RCC, through having the respective committee chairpersons attend each others committee meetings.

Following the polio-free certification of the Region in 2010, it took eight more years until Phase 1 of laboratory containment was finally completed in 2008. The first importation-related outbreak since certification in 2011 in western China has been rapidly brought under control. cVDPV outbreaks in the Philippines (2001) and in China (2004) were also quickly controlled.

The WPR (China) has borders with two of the three remaining polio-endemic countries, Afghanistan and Pakistan; Pakistan was the origin of the virus causing the outbreak in 2011. Six weeks before the outbreak was detected, and following a recommendation from the RCC, China had hosted, in Urumqi, Xinjiang, a workshop on international coordination of readiness for polio importation. Twelve countries from four WHO Regions, as well as several polio partner agencies, participated in the workshop.

3 The new Polio Endgame - Implications for the Global Certification Commission

B. Aylward, WHO, briefed the GCC about core elements of the new 'polio endgame', including the plan for the cessation of OPV2 use, i.e. the replacement of trivalent OPV with bivalent OPV for routine immunization. The GCC was asked to consider the following developments:

(a) following improved and more sensitive surveillance for polioviruses, it is clear now that type 2 cVDPVs continue to be pre-dominant (10 of 11 cVDPV outbreaks over the last three years were cVDPV2); in the absence of wild PV2, reality is that cVDPV2 has been and continues to be a major cause of paralysis in children, with case numbers similar to the number of wild PV3 cases;

(b) cVDPV emergences have caused prolonged outbreaks; for example, while many separate cVDPV2 emergences occurred in Nigeria, one of the emerged cVDPV2 strains has persisted for 5 years, paralyzing more than 500 children, with attack rates similar to wild poliovirus;

(c) until recently, the discussion on 'dropping' OPV2, i.e. on the tOPV/bOPV switch, would have been theoretical since not enough bOPV was available; however, bOPV IS now available in large quantities, and there will soon be up to 8 manufacturers producing this vaccine;

(d) also – countries that may want to use IPV to accompany a tOPV/bOPV switch will soon have affordable IPV options, with a price per dose of around 60 cents likely to become reality soon.

Subsequent to a detailed report from the SAGE Polio Working Group on the plan for OPV2 cessation, SAGE, in November 2011, had stated that phased rather than simultaneous removal of SABIN serotypes is desirable and agreed that a pre-eradication switch from tOPV to bOPV for routine immunization was advantageous. In April 2012, SAGE had re-affirmed the need for OPV2 cessation, and, to mitigate possible associated risks, had recommended for countries to consider to introduce 1 dose of IPV into their routine immunization schedules prior to OPV2 cessation.

While promoting the concept of introducing a universal 1-dose IPV policy in the context of OPV2 cessation, SAGE recognized and accepted that it was highly probable that IPV uptake would be low in low-coverage countries. SAGE requested that WHO and the GPEI continued to work towards making low-cost options for IM and IM IPV available within 1 year, and decided that, while OPV2 cessation was urgent, 2014 was too early as target date for switching from tOPV to bOPV.

In a resolution on PE, the WHA, in May 2012, did endorse the concept of OPV2 cessation, but expressed alarm over current IPV prices, limited IPV supply options, and lack of clear cost-benefit assessments. The WHA requested WHO to work with partners and manufacturers to enhance IPV affordability and availability.

AGENDA

Wednesday, 29 August 2012

8:30 - 8:45	Welcome and introduction *GCC chair*	
8:45 - 9:30	The New Polio Endgame: potential implications for the Global Certification Commission	*B. Aylward*
9:30 – 10:30	GCC discussion and possible decisions on 4 main issues:	

1) *What level of additional evidence, if any, should the GCC require to confirm/verify or validate that type 2 wild poliovirus has been interrupted globally prior to the cessation of OPV2 (i.e., a 'tOPV-bOPV' switch)?*
2) *What role, if any, should the GCC play in verifying the elimination of all Sabin type 2 virus and cVDPV2s following a tOPV-bOPV switch?*
3) *Can validation of WPV2 interruption and, eventually, verification of Sabin type 2 elimination be done by a 'core GCC' (i.e., 6 RCC Chairs) or should it require reconstitution of a full GCC?*
4) *What level of containment should the GCC require for type 2 viruses prior to and following OPV2 cessation and what are the implications for the new polio endgame?*

10:30 - 11:00	**COFFEE BREAK**	
11:00 - 12:00	Further discussion of above points plus discussion on cVDPV certification, frequency of GCC meetings, membership, relationship to IMB.	
12:00 - 13:00	**LUNCH**	
13:00 - 15:00	Presentations from RCC chairs (10-15 minutes each plus 5 for discussion). AFR/EMR/SEAR/EUR/WPR/AMR	
15:00 - 15:30	**COFFEE BREAK**	
15:30 - 16:00	Role of RCCs in polio-free regions	*WHO-HQ/WPR/EUR*
16:00 - 16:30	Annual Summary Reports from RCCs and final documentation required from RCCs to GCC for global certification.	
16:30 - 17:30	Main Core GCC Decisions, Next Meeting Dates, Closing	*GCC Chair*