

31 May to 2 June 2016 // Copenhagen, Denmark

30th Meeting of the European Regional Certification Commission for Poliomyelitis Eradication



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Meeting report
30th Meeting of the European Regional Certification
Commission for Poliomyelitis Eradication

31 May to 2 June 2016

Abstract

The 30th Meeting of the European Regional Certification Commission for Poliomyelitis Eradication (RCC) reviewed annual updates submitted by the Member States of the Region on the status of the national polio eradication programme. The RCC concluded, based on available evidence, that there was no wild poliovirus (WPV) transmission in the WHO European Region in 2015, but that vaccine-derived poliovirus (VDPV) type 1 was in circulation in Ukraine. While all countries remain at risk of importation, Bosnia and Herzegovina, Romania and Ukraine remain at high risk of a sustained polio outbreak following importation due to low population immunity. The RCC expressed concern at the number of countries, particularly those in the Balkans, where vaccine coverage is in decline, and the quality of poliovirus surveillance has reduced. The Commission was encouraged that the planned switch to bivalent oral polio vaccine (bOPV) throughout the Region in April 2016 was completed successfully, but concerns exist that this Region has been adversely affected by delays in global availability of inactivated polio vaccine (IPV). Affected countries in the Region included those remaining at risk of importation due to their close proximity to the last two endemic countries in the world. The RCC commended the extent and quality of work conducted in meeting the requirements for laboratory containment of poliovirus and noted that the Region is in advance of other WHO regions in implementing the Global action plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of OPV use (GAPIII). Because of the number of global-level polio and enterovirus laboratories and Europe-based polio vaccine manufacturers likely to require polio essential facility (PEF) status, the Region will face a considerable workload in fully implementing all polio containment requirements.

Keywords

POLIOMYELITIS – prevention and control

IMMUNIZATION PROGRAMS

EPIDEMIOLOGIC SURVEILLANCE – standards

CONTAINMENT OF BIOHAZARDS – standards

LABORATORY INFECTION – prevention and control

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Abbreviations

AFP	acute flaccid paralysis
bOPV	bivalent OPV
CSF	cerebrospinal fluid
cVDPV	circulating vaccine-derived poliovirus
cVDPV1	circulating vaccine-derived poliovirus type 1
cVDPV2	circulating vaccine-derived poliovirus type 2
EC	Emergency Committee
EVS	enterovirus surveillance
ENVS	environmental surveillance
GAPIII	Global action plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of OPV use
GCC	Global Certification Commission
GPEI	Global Polio Eradication Initiative
GPLN	Global Polio Laboratory Network
IPV	inactivated polio vaccine
ITD	intratypic differentiation (of poliovirus isolates)
LDMS	Laboratory Data Management System
mOPV	monovalent OPV
mOPV2	monovalent OPV type 2
MECACAR	Mediterranean, Caucasus and Central Asian republics subregion
NCC	National Certification Committee
NPEV	non-polio enteroviruses
OPV	oral poliovirus vaccine
POSE	Polio Outbreak Simulation Exercise
PEF	polio essential facility
RCC	European Regional Certification Commission for Poliomyelitis Eradication
SIA	supplementary immunization activities
tOPV	trivalent OPV
SOP	standard operating procedure
VDPV	vaccine-derived poliovirus
VPI	Vaccine-preventable Diseases and Immunization Programme of WHO/Europe
WPV	wild-type poliovirus
WPV1	wild-type poliovirus serotype 1
WPV2	wild-type poliovirus serotype 2
WPV3	wild-type poliovirus serotype 3

Introduction

The 30th Meeting of the European Regional Certification Commission (RCC) for Poliomyelitis Eradication was held from 31 May to 2 June 2016 in Copenhagen, Denmark. Participants were welcomed on behalf of the WHO Regional Director by Mr Robb Butler, Programme Manager, Vaccine-preventable Diseases and Immunization Programme (VPI).

The meeting was opened by RCC Chairman, Professor David Salisbury. Rapporteur for the meeting was Dr Ray Sanders. The meeting programme is provided as Annex 2 and the list of participants as Annex 3.

Scope and purpose of the Meeting

The scope and purpose of the Meeting were:

- to brief the RCC on the current global and regional status of polio eradication;
- to review annual updated certification documentation on poliomyelitis in all Member States of the WHO European Region for 2015;
- to review Ukraine circulating vaccine-derived poliovirus type 1 (cVDPV1) outbreak response activities, risks and mitigation activities;
- to review response and risk mitigation activities in Member States defined to be in the high-risk group;
- to review the current status of regional laboratory containment in view of the cessation of use of oral poliovirus vaccine (OPV) in routine immunization programmes and global switch to bivalent OPV (bOPV);
- to brief the RCC on the introduction of inactivated polio vaccine (IPV), results of the switch to bOPV in 2016, and mitigation of risks caused by global IPV supply constraints;
- to brief the RCC on post-switch polio outbreak response standard operating procedures (SOPs) from the Global Polio Eradication Initiative (GPEI);
- to recommend the Regional Office strategies and/or actions to strengthen efforts to sustain polio-free status of the Region focusing on high-risk countries; and
- to review working procedures of the RCC and to discuss a plan of activities for 2016-2017.

Update on global polio eradication and sustaining polio-free Europe

Overview of progress on the Polio Eradication and Endgame Strategic Plan 2013-2018

The last detected wild poliovirus type 2 (WPV2) case was reported in 1999, and global eradication of WPV2 was certified by the Global Certification Commission (GCC) in 2015. The last detected cases of polio associated with wild poliovirus type (WPV3) were reported in November 2012. The most recent case associated with wild poliovirus type 1 (WPV1) in Africa was reported in August 2014 and Nigeria has now been removed from the list of endemic countries. As of May 2016, all reported outbreaks of wild poliovirus (WPV)

resulting from importation into non-endemic countries have been interrupted and there is no detected WPV transmission outside of Afghanistan and Pakistan. Circulating vaccine derived polioviruses (cVDPV) continue to present a challenge, with 2 cVDPV type 2 cases detected in Guinea in December 2015 and 4 cVDPV cases detected in Lao People's Democratic Republic in January 2016.

There has been a steady decline since 2014 in the number of reported cases from both Afghanistan and Pakistan. This decline has occurred in the face of intensified surveillance, including environmental surveillance. There are now three main reservoirs of transmission; cross-border areas around Peshawar and Quetta and the Pakistani city of Karachi. Corridors of active transmission link reservoirs on both sides of the international border, and the high level of positive environmental samples in both countries suggest that transmission is ongoing in areas away from the recognised foci.

Implementation of a continuous community protected vaccination (CCPV) policy in Pakistan, deploying nearly 8000 female community volunteers, has resulted in a reduction of approximately 2 million in the reservoir of inaccessible children. Establishment of health camps has permitted immunization services to reach >235 000 recipients, with approximately 130 000 <5 years of age, including 4000 zero-dose children.

Access remains a major challenge in Afghanistan, with an estimated 90 000 children reported as inaccessible in low-performing districts. The deteriorating security situation in the east, northeast and south increases the level of challenge. Many of these areas contain children who have been persistently missed by supplementary immunization activities (SIA). Attempting to meet these challenges, the programme has sought to maintain an openly neutral stance, establishing National Emergency Operations Centres (EOC) for polio eradication in key areas, to focus implementation of the updated National Polio Eradication Emergency Action Plan (NEAP).

A polio Public Health Emergency of International Concern (PHEIC) was declared by the IHR Emergency Committee (EC) in May 2014 and it has been reviewed at 3-monthly intervals since. Ukraine was added to the list of States infected with wild poliovirus or cVDPV but not currently exporting in November 2015 due to the detection of cVDPV1. Under the criteria set by the Emergency Committee, Ukraine will be considered no longer infected by August 2016 if no further cases are detected, and will move to the *vulnerable* category.¹

With the successful global switch from trivalent oral polio vaccine (tOPV) to bOPV, the global stockpile of monovalent OPV against type 2 poliovirus (mOPV2) has become available to respond to outbreaks associated with WPV2 or cVDPV2. The global stockpile is available to all Member States on the basis of need, and consists of 50 million doses in finished

¹ Editorial note: Ukraine no longer infected by cVDPV, but remains vulnerable to international spread as per 22 August 2016 statement on the 10th IHR Emergency Committee regarding the international spread of poliovirus: <http://www.who.int/mediacentre/news/statements/2016/10th-ih-er-emergency/en/>

product, together with another 50 million doses in semi-finished product. A further 419 million doses are held as bulk. The stockpile is located at, and managed by, the vaccine manufacturers on behalf of the GPEI. The stockpile is maintained under the containment conditions required by the WHO Global action plan to minimize poliovirus facility-associated risk (GAPIII). Member States intending to establish a national stockpile must also comply with the requirements of GAPIII. In 2015 the World Health Assembly (WHA) urged all Member States to establish procedures to authorize the importing and use of mOPV2 in the event of a type 2 outbreak. The mOPV2 in the stockpile is WHO prequalified and licensed in the country of origin, and recipient countries may pre-emptively authorize use of mOPV2 based on licensure issued by the stringent national regulatory authority (NRA) process in the producing country and the knowledge that the vaccine is prequalified by WHO.

Discussion

Whilst acknowledging the advances made in implementing the GPEI End Game Strategy, the RCC is concerned over the considerable emphasis placed on achieving global eradication during 2016. There is a strong likelihood that this will not be achieved, and the credibility of the GPEI and, consequently, the task of persuading authorities in polio-free countries to continue to spend resources on maintaining vaccination and surveillance activities will probably become even more challenging.

The RCC also expressed concerns over the criteria used by the Outbreak Response Assessment Team (OBRA) to conclude that Ukraine should no longer be considered infected with cVDPV1: the approach taken to assess the status of virus transmission in Ukraine appeared to lack technical vigour or depth of investigation. The RCC is not convinced that all sufficient evidence has been made available to conclude that transmission of cVDPV1 has ceased in Ukraine.

From available information, there is no indication that IPV-using countries in the Region plan to use mOPV2 in response to a possible type 2 outbreak. Few have established a licence for mOPV2 use and all others would need to rely on emergency legislation to licence the vaccine for use. Many of the national outbreak response plans are superficial and lacking in detail regarding procurement and use of vaccines. This is an area requiring urgent attention by many countries in the Region.

Polio programme annual update from the WHO Regional Office for Europe

There has been a good level of progress in implementing the European Vaccine Action Plan (EVAP) since 2014, with a range of activities successfully completed, including national risk assessments, outbreak preparedness training and the strengthening of National Immunization Technical Advisory Groups (NITAGs). Vaccine supply issues have been exposed in some countries, particularly some of the GAVI-graduated countries, and the influx of refugees and migrants into the Region has presented a challenge to immunization services in several countries. The anti-vaccination lobby has strengthened in some areas,

contributing to a lack of confidence in immunization services and decline in vaccine coverage levels in some countries.

The countries of western Europe now use IPV, usually within a combination vaccine, while the countries of Eastern Europe predominantly use a mixed IPV plus OPV schedule. Central Asian countries predominantly continue to use OPV alone. Although methods of estimating routine vaccination coverage continue to differ between countries, coverage with three doses of polio vaccine appears to be generally high, with most countries reporting $\geq 95\%$. Notable exceptions are Bosnia and Herzegovina, Romania and Ukraine, with low coverage. Current coverage data are not available for some key western European countries, including France and Italy.

Seven Member States conducted supplementary immunization activities (SIA) in 2015: national or sub-national immunization days in Russian Federation, Tajikistan and Ukraine; mop-up campaigns in Azerbaijan, Georgia and the Russian Federation; a catch-up campaign in Montenegro; and targeted vaccination activities for refugees and migrants in Germany.

For polio surveillance, 9 Member States continue to use acute flaccid paralysis (AFP) surveillance alone, 34 employ AFP and supplementary surveillance, and 9 use supplementary surveillance alone. The countries in the eastern half of the Region have generally maintained a high level of AFP surveillance performance, while those in the centre and west of the Region generally have low-quality AFP surveillance where it is employed. The only AFP surveillance review conducted in 2015 was in Ukraine. Supplementary surveillance usually includes enterovirus and/or environmental surveillance, the quality and range of which varies considerably between countries.

Current status of the regional Polio Laboratory Network and laboratory containment in view of the global switch to bOPV

Polio laboratory data for analysis now come from three primary sources; the annual polio update reports from Member States; the annual reports from the Global Polio Laboratory Management System (GPLNMS); and data logs from the WHO/Europe Polio Laboratory Data Management System (LDMS). Compilation of data from these sources shows that the Regional Laboratory Network continues to test approximately 110 000 samples per year, and that these samples originate from AFP cases and their contacts, enterovirus surveillance systems and environmental surveillance. There was an increase in the use of environmental surveillance in 2015, resulting in a higher proportion of poliovirus positive samples, probably reflecting continued use of OPV in several countries. A challenge facing the Network in 2016 is the continued absence of an agreed procedure to link data from enterovirus and environmental surveillance systems with laboratory data. No WPV were detected in the Region in 2015, but 12 VDPVs were reported from 5 Member States. The only cVDPV was reported from Ukraine, the other VDPVs being single isolations of unknown origin or isolates from immunodeficient individuals.

The annual proficiency testing and accreditation of network laboratories has been completed and all 48 laboratories are accredited. The Network has successfully adopted the new algorithm for detection and typing of polioviruses, and there are plans to increase the number of laboratories capable of conducting intratypic differentiation (ITD).

Currently available information suggests there are 18 countries in the Region with facilities holding WPV, of which 14 are specifically holding WPV type 2. There are 50 individual sites in the Region with WPV stocks, and 35 with WPV type 2. To date 14 countries have expressed an interest in establishing a total of 22 potential Poliovirus Essential Facilities (PEFs), several of these hosting major vaccine manufacturing facilities. A working collaboration on poliovirus containment has now been initiated between WHO, the European Commission and the European Centres for Disease Control (ECDC), and collaboration with American and European biosafety associations is in process. The Region is progressing well with meeting the requirements of Phase I of GAPIII, with all countries updating their national inventories of WPV materials.

Discussion

The RCC acknowledges the high quality and level of sophistication of the work conducted by the Regional Laboratory Network that is in advance of the work carried out in other Regions. The good response from Member States in meeting the Phase I requirements of GAPIII is noted and appreciated. The RCC is heartened to be informed of the collaborative association with the EC and ECDC on containment, which will support the process of developing a European legislative basis for poliovirus containment, and commends the Regional Office for taking this step.

Introduction of IPV, results of switch to bOPV in 2016, and mitigation of risks caused by global IPV supply constraints

By the end of April 2016, all Member States in the Region continuing to use OPV (20) had successfully switched from tOPV to bOPV, and National Validation Reports have been received from all of them. Eight countries are procuring bOPV through UNICEF tenders (Albania, Azerbaijan, Georgia, Kyrgyzstan, Tajikistan, Turkmenistan and Uzbekistan), 11 are self-procuring (Belarus, Bosnia and Herzegovina, Israel, Kazakhstan, Montenegro, Republic of Moldova, Poland, the former Yugoslav Republic of Macedonia, Serbia, Turkey and Ukraine), and one is self-producing (Russian Federation).

Six Member States successfully introduced IPV into their routine schedules: Albania and Azerbaijan introduced standalone IPV, Georgia, Kazakhstan, Serbia and the former Yugoslav Republic of Macedonia introduced IPV-containing combination vaccines. While introduction of standalone IPV is planned for Armenia in July 2016, introduction into another 5 countries (Kyrgyzstan, Republic of Moldova, Tajikistan, Turkmenistan and Uzbekistan) has been delayed until at least the fourth quarter of 2017 due to the global shortage of IPV. In March 2014, UNICEF issued awards to two manufacturers for the supply of IPV and long-term supply agreements were established through to 2018, but due to technical challenges in

scaling up IPV bulk production and the associated quality control testing and releases, there is now reduced availability from both manufacturers for all presentations. There has been an approximately 40% reduction in the volume of IPV available for use in 2016.

The IPV supply constraints are expected to remain uncertain until 2018 and a global risk management strategy has been put in place using four criteria to determine the classification of each country, and therefore its prioritization for the allocation of IPV. Countries are considered to be in a higher risk tier if transmission of WPV has not yet been interrupted; the country has a history of cVDPV outbreaks; there are consistently low levels of routine immunization coverage; or the country shares borders with higher-risk countries. As an alternative to the intramuscular injection of a full IPV dose, countries have been recommended to consider the implementation of a two-dose fractional dose schedule (using 1/5 of a full dose), via the intradermal route. There are, however, a number of technical, logistic and legislative challenges over the adoption of this approach in those countries most at need of IPV introduction. The introduction of bOPV in the absence of available IPV will leave a sizable cohort of children in at least five countries in the Region without vaccination against polio type 2.

Discussion

The RCC was encouraged to be informed that the planned switch to bOPV throughout the Region was completed successfully. Grave concerns exist, however, that this Region has been disproportionately adversely affected by delays in global availability of IPV. Affected countries in the Region include those remaining at risk of importation due to their close proximity to Afghanistan and Pakistan. Having these countries delay introduction of IPV until at least the fourth quarter of 2017 places the Region at high risk of cVDPV transmission due to an immunity gap of polio type 2 susceptibles. The RCC urges that as IPV becomes available through 2016 and 2017, countries in the Region that require IPV are prioritized for vaccine allocation. Member States and international partners are advised that when IPV does become available, provision will need to be made for catch-up campaigns to fill the immunity gaps created.

Sustainability of polio-free Europe: Review of national updated documents and risk assessment for 2015 by epidemiological zones

Modifications to the Annual Progress Report and receipt of reports

On the recommendations of the RCC, the format of the Annual Progress Report for 2015 was modified to include new sections, undated sections and new requests for information. Requests for population data and historical poliovirus isolation data were added. Additional information on supplementary surveillance, particularly enterovirus and environmental surveillance data, were added, and updated information on laboratory containment was requested. All Member States were requested to re-submit their national action plans for outbreak response in light of the new GPEI SOPs.

In all, 46 of 53 reports were received in time for review in advance of the meeting. Of these, only 33 were received before the agreed deadline for submission of 15 May 2016. A further 4 were received either immediately before or during the meeting and were therefore not available for review by the RCC. Of the 46 reports reviewed, 2 were missing the required statement from the NCC; 26 were lacking the requested information on supplementary surveillance systems, and 26 failed to include the requested National Plan of Action for outbreak response. Three countries did not submit the Annual Progress Report for 2015: Poland, San Marino and the former Yugoslav Republic of Macedonia.

The results of the risk factor analysis for countries of the Region are shown in Annex 1.

Nordic/Baltic subregion

Based on the information provided, the RCC concluded that the probability was high that WPV had not been circulating in the subregion in 2015 and that WPV importation or circulation of VDPV, if any, would have been detected promptly by existing health/surveillance systems. The risk of transmission following importation of WPV or circulation of VDPV in countries of this zone was considered to be low to intermediate. It is an issue of concern that the majority of countries have inadequate action plans for outbreak response. All Member States are urged to update their national plans of action for polio outbreak response in line with the GPEI SOPs.

Feedback to the countries:

- Denmark – is considered to be at intermediate risk for transmission due to suboptimal reported population immunity. The RCC recognizes that the apparent low level of population immunity in 2015 may be a consequence of changes in the data collection system. The RCC recommends that either the level of vaccination coverage be raised, or if the true rate is high, additional information demonstrating the actual vaccination coverage level be submitted.
- Estonia – is considered to be at low risk with no problems recognized.
- Finland – is considered to be at low risk with no problems recognized.
- Iceland – is considered to be at intermediate risk of poliovirus transmission because of the lack of a national plan of action for outbreak response. The quality of polio surveillance appears to be barely adequate given the absence of AFP surveillance and the small number of specimens tested for enterovirus: there is room for considerable improvement in the quality of surveillance. Iceland is strongly recommended to establish a national plan of action in line with the GPEI SOPs and submit this to the WHO Secretariat for the RCC to review and assess.
- Latvia – is considered to be at low risk. The RCC recognizes the improvement achieved in the level of national vaccination coverage; it trusts the improvement will be sustained, that coverage will be increased in the remaining sub-national districts with suboptimal vaccination coverage, and the national action plan will be updated.

- Lithuania – is considered to be at low risk with no problems recognized. However, the national action plan needs to be updated.
- Norway – the risk of poliovirus transmission has been assessed as intermediate. The RCC is concerned that the quality of the report provided is poor, lacking information and essential detail. The RCC recommends that the NCC ensures the annual report for 2016 accurately documents the quality and extent of poliovirus surveillance and population immunity in the format requested.
- Sweden – is considered to be at low risk with no problems recognized.

Western subregion

Based on available information, the RCC concluded that the probability was high that WPV had not been circulating in this epidemiological zone in 2015, and that any suspected cases of poliomyelitis would have been detected by existing health services. AFP surveillance has been practically abandoned in the subregion but does not appear to have been substituted by systematic and effective supplementary surveillance in some countries, particularly Belgium and Switzerland. The commission notes the lack of global guidance on alternative surveillance methodologies which are increasingly becoming the norm, particularly for countries in this subregion. Guidance on acceptable surveillance indicators is urgently needed for countries that are using virus-based surveillance techniques. Several countries in the subregion are known to have sizable vulnerable populations, in some cases associated with a recent influx of migrants, but the annual reports fail to document these vulnerable populations or the activities undertaken to provide appropriate vaccination cover. Luxemburg, Monaco and Switzerland lack an appropriate action plan for outbreak response. The risk of transmission following importation of WPV in countries of this zone is low to intermediate.

Feedback to the countries:

- Austria – is considered to be at low risk but the RCC would be grateful for more information on how immunization coverage is measured. Furthermore, the RCC recommends that, subject to processes that would create an appropriate response following the detection of a poliovirus, consideration be given to whether continuing to operate an inadequate AFP surveillance system is resource-efficient. Given the circumstances, evidence from an effective laboratory-based enterovirus surveillance system would be more convincing of the ability to detect poliovirus from any source.
- Belgium – is considered to be at intermediate risk because of the apparent lack of adequate surveillance, either for AFP or for enteroviruses. The NCC is urged to provide data demonstrating that effective surveillance is being conducted.
- France – is considered to be at low risk, but the RCC would appreciate receiving current data on vaccination coverage rather than data that is one year in arrears. The RCC noted that the report fails to include information on vaccination coverage of

vulnerable groups, including migrants, and would appreciate receiving this information in future reports.

- Germany- is considered to be at low risk and the RCC commends Germany on the continuing actions taken to address issues with vulnerable and high-risk population groups in the country, including the migrant/refugee populations. The RCC would appreciate more detailed information on the actions taken and vaccine coverage achieved in these groups.
- Ireland – is considered to be at low risk with no problems recognized.
- Luxembourg – is considered to be at intermediate risk due to low reported vaccine coverage and low-quality surveillance. Furthermore, the country has no action plan for polio outbreak response and is urged to establish a plan in line with the GPEI SOPs as soon as possible. The general quality of the annual report provided is not high, and the RCC urges that a better quality report be provided next year. The RCC notes the lack of a statement from the NCC.
- Monaco – is considered to be at intermediate risk. Furthermore, the country has no action plan for polio outbreak response and is urged to establish a plan in line with the GPEI SOPs as soon as possible.
- Netherlands – is considered to be at low risk and the RCC commends the NCC on the high quality of the report provided.
- Switzerland – is considered to be at intermediate risk due to ongoing poor quality surveillance and lack of a polio outbreak response plan. The RCC recommends that the country establish a plan in line with the GPEI SOPs as soon as possible and submit this to the WHO Secretariat for the RCC to review and assess.
- United Kingdom – is considered to be at low risk. The RCC urges that the number of faecal samples tested through the enterovirus surveillance system be increased, and looks forward to receiving data on implementation of the environmental surveillance system.

Central subregion

Based on information available, the RCC concludes that the probability is high that WPV had not been circulating in the subregion in 2015 and that WPV importation or circulation of VDPV, if any, would have been detected promptly by existing health/surveillance systems. The risk of transmission following importation of WPV or circulation of VDPV in countries of this zone is low to intermediate, due to generally good immunization systems, including for high-risk groups, in the presence of average- to good-quality surveillance. Of some concern are Hungary, Poland, Slovakia and Slovenia with suboptimal quality of AFP surveillance. Evidence for declining immunization coverage in Bulgaria, probably associated with vaccine supply issues, is also of concern. Bulgaria and Poland provided either a draft annual report or no report in time for the meeting, and neither has provided a polio outbreak response plan.

Feedback to the countries:

- Belarus – is considered to be at low risk with no problems recognized. The RCC commends the NCC on the excellent quality of the report provided.
- Bulgaria – is regarded as being at intermediate risk due to suboptimal population immunity, particularly among vulnerable population groups. The RCC would appreciate receiving additional information on how the immunization requirements of vulnerable groups are being addressed. No information on the action plan for polio outbreak response has been provided. Bulgaria is encouraged to provide information on the vaccination coverage of vulnerable groups, together with an approved action plan for polio outbreak response to the WHO Secretariat for the RCC to review and assess.
- Czech Republic – is considered to be at low risk with no problems recognized.
- Hungary – is considered to be at low risk, but the RCC commented on the less than optimal AFP surveillance, and given the location within Europe, urges Hungary to make every effort to improve the quality of surveillance. Furthermore, the RCC draws to the attention of the national health authorities that a prerequisite for establishing a polio essential facility (PEF) is the existence of high population immunity and high-quality polio surveillance.
- Poland – is considered to be at intermediate risk due to less than optimal AFP surveillance and the failure to provide an annual report. The RCC urges Poland to submit the report to the WHO Secretariat for review and assessment by the RCC.
- Slovakia – is considered to be at low risk, but the RCC noted that the AFP surveillance quality needs to be improved.
- Slovenia – is considered to be at low risk but the RCC is concerned that a number of indicators are in decline, including vaccination coverage and polio surveillance.

Southern subregion

Based on the information available, the RCC concludes that the probability is high that WPV had not been circulating in the subregion in 2015 and that WPV importation or circulation of VDPV, if any, would have been detected promptly by existing health/surveillance systems. The risk of transmission following importation of WPV or circulation of VDPV in countries of this zone is low to intermediate, due to generally good immunization systems, including for high-risk groups in the presence of average- to good-quality surveillance. The primary issue of concern is the general suboptimal quality of AFP surveillance. Italy is of concern because of the absence of data provided and the indications of decreasing immunization coverage. Concerns have also been expressed over the reliability of the immunization coverage estimates provided by Cyprus and Greece.

Feedback to the countries:

- Andorra – is considered to be at low risk, but the RCC is concerned that more effort is required to confirm the lack of AFP cases and improve polio surveillance.

- Croatia – is considered to be at low risk but polio surveillance fails to meet the required standard and efforts are needed to either improve AFP surveillance or to establish effective, high-quality supplementary surveillance.
- Cyprus – is considered to be at low risk but the RCC has concerns over the reliability of the polio vaccination coverage estimates provided.
- Greece – is provisionally considered at high risk due to the failure to provide meaningful data on population immunity for the past three years coupled with the absence of information on immunization service activities and achievements in response to the large influx of refugees and migrants entering Greece over the past two years. Greece is encouraged to provide information on current vaccination coverage and immunization service achievements in meeting migrant population needs to the WHO Secretariat for the RCC to review and assess.
- Israel – is considered to be at low risk with no problems recognized.
- Italy – has been provisionally assessed as at high risk based on the failure to provide vaccination coverage information for 2015 coupled with the lack of information on immunization service activities and achievements in response to the large influx of refugees and migrants entering Italy over the past two years. Italy is encouraged to provide information on current vaccination coverage and immunization service achievements in meeting migrant population needs to the WHO Secretariat for the RCC to review and assess.
- Malta – is considered to be at low risk with no problems recognized.
- Portugal – has been assessed as at low risk but still needs to improve the quality of polio surveillance.
- San Marino – is considered to be at intermediate risk on the basis of continued lack of information and the failure to provide an annual report. The RCC recognizes that San Marino has a small population, but has expressed its disappointment at the continuing lack of response to requests for information on the national polio programme. San Marino is urged to provide the annual report with information on current vaccination coverage and status of polio surveillance to the WHO Secretariat for the RCC to review and assess.
- Spain – has been assessed as at low risk but the RCC is concerned over the poor-quality polio surveillance conducted. Although AFP, enterovirus and environmental surveillance systems are in place, none are of sufficient quality to instil confidence that they would detect circulating poliovirus rapidly, and greater efforts are required to improve at least one of the existing systems.

Central-eastern subregion

Based on available evidence the RCC concludes that VDPV has been circulating in the subregion in 2015, but it is unlikely that WPV was in circulation. The RCC is not confident that existing health/surveillance systems would be capable of the timely detection of imported WPV or VDPV circulation. Because of a general decline in the level of vaccination

coverage, the risk of transmission following importation of WPV or circulation of VDPV in countries of this zone is intermediate to high. The risk of spread following importation of WPV or cVDPV in Bosnia and Herzegovina, Romania and Ukraine is considered to be high. Issues of particular concern include the apparent declining population immunity in all countries, a suboptimal response to the cVDPV outbreak in Ukraine, and a failure on the part of Albania, Bosnia and Herzegovina and Serbia to provide reports and plans in time for review before the meeting.

Feedback to the countries:

- Albania – is considered to be at low risk but the RCC requests that the national preparedness plan of action be updated and sent to the WHO Secretariat for review and that the report for next year is provided well in advance of the meeting.
- Bosnia and Herzegovina – is considered to be at high risk due to suboptimal vaccine coverage, including among vulnerable groups, and low-quality AFP surveillance. The RCC accepts that there has been a temporary interruption in vaccine supply, but notes that conditions have not materially changed since last year. The RCC is encouraged to learn of the recent signing of the cooperation pact between the country's entities and looks forward to receiving a report next year describing improvements in performance.
- The former Yugoslav Republic of Macedonia – is considered to be at intermediate risk due to declining surveillance performance and the failure to provide an annual report for the meeting.
- Republic of Moldova – is considered to be at intermediate risk due to declining population immunity. The RCC urges that efforts be made to increase vaccine coverage to the levels achieved in past years.
- Montenegro – is considered to be at intermediate risk due to sub-optimal population immunity that appears to be declining further. The RCC urges that every effort be made to increase the level of vaccine coverage in all groups and sub-national areas.
- Romania – is considered to be at high risk due to sub-optimal population immunity and poor quality of surveillance. Given the location within Europe, the RCC urges Romania to make every effort to increase the level of population immunity and improve the quality of surveillance. Furthermore, the RCC draws to the attention of the national health authorities that a prerequisite for establishing a polio essential facility (PEF) is the maintenance of high population immunity and high quality polio surveillance.
- Serbia – is considered to be at intermediate risk due to less than adequate vaccine coverage, which appears to be declining, less than adequate surveillance, and the failure to provide an annual report in time for the meeting. A report was received by the WHO Secretariat after the start of the meeting and will be reviewed and assessed by the RCC.

- Ukraine – is considered to be at high risk due to low vaccine coverage and the suboptimal response to the cVDPV outbreak resulting in prolonged transmission. The RCC recognizes that some positive actions have been undertaken to improve vaccine coverage and looks forward to receiving the 2016 report describing those improvements.

MECACAR subregion

Based on available information, the RCC concludes that the probability is high that WPV had not been circulating in the subregion in 2015 and that WPV importation or circulation of VDPV, if any, would have been detected promptly by existing health/surveillance systems. The risk of transmission following importation of WPV or circulation of VDPV in countries of this zone is low to intermediate. Primary areas of concern include the urgent need to review and update the action plan for outbreak response in several of the countries, evidence for declining immunization coverage in Georgia and the potential accumulation of age cohorts susceptible to poliovirus type 2 in Kyrgyzstan, Tajikistan, Turkmenistan and Uzbekistan due to delays in IPV introduction until the fourth quarter of 2017.

Feedback to the countries:

- Armenia – is considered to be at low risk with no problems recognized.
- Azerbaijan – is considered to be at low risk with no problems recognized.
- Georgia – is considered to be at intermediate risk. The RCC notes the evidence of declining vaccination coverage and urges that efforts be made to improve routine immunization coverage.
- Kazakhstan – is considered to be at low risk with no problems recognized.
- Kyrgyzstan – is considered to be at low risk with no problems recognized.
- Russian Federation – is considered to be at low risk with no problems recognized.
- Tajikistan – is considered to be at low risk with no problems recognized.
- Turkey – is considered to be at low risk and the RCC commends the efforts made to meet the immunization challenges posed by hosting the large numbers of refugees from Syria.
- Turkmenistan – is considered to be at low risk with no problems recognized and the RCC commends Turkmenistan for improvements made in surveillance.
- Uzbekistan – is considered to be at low risk with no problems recognized.

Regional outbreak response and risk mitigation activities

Review of the annual progress reports and national polio outbreak preparedness plans

All Member States were requested to submit an updated National Polio Outbreak Preparedness Plan together with their Annual Progress Report. Only 22 of 53 countries provided Plans in time for analysis before the meeting, and of these only 20 had been updated as of 2015. Only 46 Member States provided annual progress reports in advance of the meeting, and, of these, 24 stated that their outbreak preparedness plan was part of the

national plan to sustain their polio-free status. Ten countries stated that the outbreak preparedness plan was a stand-alone document, and 12 failed to provide a response on their plans.

Only five Member States indicated they had formally tested their outbreak preparedness plans, and one additional country stated the intention to test the plan later in 2016. Most countries stated they had not tested their plans, despite several having tested them during simulation exercises conducted over the past two years. Sixteen of 46 Member States indicated they would use IPV as vaccine of first choice in responding to a polio outbreak; 14 indicated they would use OPV as vaccine of first choice. Four countries indicated that the choice of vaccine was dependent on the nature of the outbreak or polio event. Despite the fact that tOPV is no longer available, 15 Member States indicated that it remains licenced for use in their country. For countries in which OPV is not licenced, 17 stated that emergency provisions were in place for its use in an outbreak situation. Twenty-four countries indicated that reserve funds are available for outbreak vaccines or that a vaccine stockpile has been created for outbreak response.

Discussion

The new outbreak response SOPs have changed the requirements for national outbreak response plans, with Member States no longer required to stockpile OPV, as they are all eligible for supply from the global stockpile. There is a need for additional IPV for use during mop-up activities around outbreaks and polio events, but the current lack of global supply of IPV is a challenge. Many Member States in the Region are using IPV as a combination vaccine, and most have strategic reserves of these vaccines that could be used in first response activities. The current recommendation is that mOPV should be used to contain an outbreak, and all Member States should be aware of this. In light of the new recommendations all Member States are required to update their outbreak preparedness plans as soon as possible.

Experience gained from polio outbreak simulation exercises (POSEs) has shown that funding is a major issue for mounting an outbreak response, with outbreak activities grossly underfunded. Procurement of vaccine is a significant issue for many countries, the assumption being that vaccines for outbreak response will be provided by WHO/UNICEF. The general assumption has been that the GPEI will cover all costs for outbreak response, a situation that may not hold in future.

Response and risk mitigation activities in Member States defined to be in the high-risk group

Romania

At its 29th meeting the RCC concluded that Romania was at high risk for poliovirus transmission due to sub-optimal population immunity and surveillance quality. The national programme was urged to improve vaccine coverage, particularly in those districts with

coverage <90%, and to improve the quality of AFP surveillance, especially the virus isolation rate. It was also recommended to extend the environmental surveillance to include a greater proportion of the total population. Review of the situation in 2016 revealed that although activities had been undertaken, no material improvement in the risk status could be determined.

To improve population immunity, catch-up campaigns have been conducted in the north of the country, but very low coverage appears to have been achieved. AFP supervisory visits have been conducted in some districts and two additional AFP cases were discovered, but reporting was delayed and virus isolation rates from samples collected remain low. Some training of clinicians in AFP surveillance has been provided, and more is planned for 2016. The number of environmental surveillance sites has been increased, but coverage remains below 15% of the total population. A National Plan of Action for outbreak preparedness has been provided, but given the challenges observed, there is concern over whether capacity exists in the country to implement the Plan. It is also of concern that Romania has indicated the desire to establish a Polio Essential Facility (PEF) without being fully aware of the containment requirements for these facilities.

Romania has acknowledged the challenges it faces, attempted to address these challenges and implement recommendations made by the RCC, but has made little material progress towards reducing the risk for transmission of poliovirus. The RCC appreciates the continuing efforts made to implement its recommendations, but is concerned that the situation has not improved and that some elements of the polio programme appear to have deteriorated further. The RCC is interested in meeting with health authorities and service providers in Romania to discuss potential activities that can be undertaken to improve population immunity and surveillance quality, and requests the WHO Secretariat to begin the process of arranging such a meeting.

Bosnia and Herzegovina

The draft report from Bosnia and Herzegovina was received only at the start of the meeting and not in time for a thorough review. It is encouraging that a cooperation pact on vaccines has now been approved by the different entities and that a budget line has been established for vaccines, which should result in an improvement in the vaccine procurement mechanism. It is noted, however, that due to the global shortage, attempts to procure IPV-containing pentavalent vaccine have resulted in delays in delivery. Furthermore, routine vaccine coverage appears to have further declined, to below 75%, and campaigns targeting specific Roma communities achieved only very low coverage. AFP surveillance quality remains low and does not cover the entire country, leaving significant silent areas. The RCC recognizes the attempts made to improve both coverage and surveillance, but considers there has been no material improvement over 2014 and the country remains at high risk for polio transmission.

Current practices in implementing supplementary surveillance for polioviruses in countries of the WHO European Region

A study was undertaken to provide a basis for risk assessment on the sufficiency of current surveillance methods to detect any chain of poliovirus transmission and to confirm the polio-free status of the WHO European Region. While AFP surveillance remains the gold standard system, enterovirus (EVS) and environmental surveillance (ENVS) are widely used within the Region, either in support of AFP surveillance or as alternatives to it. Sources of data used for the study included the annual update reports for 2013, 2014 and some for 2015, together with information provided through the WHO European Regional Polio Laboratory Network Online Laboratory Data Management System (LDMS). Member States were assigned into two groups that were analysed separately; the group of 20 countries using OPV or OPV plus IPV in their immunizations programmes, and the group of 33 countries that did not use OPV.

Almost all countries (50 of 53) employed one or more type of poliovirus surveillance in 2014 and in general, surveillance programmes were directed towards populations more likely to be infected by polioviruses imported from external reservoirs or emerging from vaccination. Thirty-four countries carried out EVS, but no agreed definition of what constituted EVS could be determined from the available data. Information on the number and ages of individuals monitored, presenting symptoms monitored, diagnostic procedures used, types of clinical samples investigated or diagnostic results for all individuals tested was often lacking. It was also apparent that laboratories other than WHO-certified GPLN laboratories were used to perform the initial screening. There was significant variation in the submission rates from these non-GPLN labs, and often only positive samples were forwarded to GPLN laboratories for further investigation. Generally the non-GPLN laboratories do not have direct access to WHO-certified reagents, diagnostic kits, certified cell lines and proficiency tests.

Twenty-one Member States conducted some form of ENVS in 2014 and provided information on the number of polioviruses and non-polio enteroviruses detected. With few exceptions, data were not provided on the numbers of individuals sampled within the catchment areas, on the methodologies used for collecting, preparing or testing samples, or on the number of enterovirus- and poliovirus-positive samples. There are now three recommended methods for collecting samples for ENVS: trap sampling; grab sampling; and composite 24-hour sampling. Each has a different potential for producing semi-quantitative information that may provide an indication of the number of virus excretors in the catchment area.

The study concluded that while the supplementary surveillance being used in the Region appears to have a high probability of detecting polioviruses in a targeted population, they have a lower probability of identifying an index case or initial excretor. Additional technical input is required to enhance surveillance capabilities, decrease the time taken to identify detected poliovirus infections and improve the chance of detecting single excretors. Many

of the national plans of action for outbreak preparedness describe actions to be undertaken following detection of a poliomyelitis case, but few describe actions to be taken after detection of a positive environmental surveillance sample. This needs to be addressed, particularly in those countries relying on ENVS as their main surveillance methodology.

Discussion

The RCC acknowledged the work being conducted in the Region to systematize and standardize supplementary surveillance and noted that this Region is well in advance of other WHO regions in this regard. The annual update reports for 2015 were revised specifically to collect more information on the supplementary surveillance methods being used, and data provided in the latest reports should be included in the analysis. EVS data are most relevant to poliovirus surveillance if results on faecal samples, rather than cerebrospinal fluid (CSF) samples, are provided, and all analysis of EVS surveillance sensitivity should be based only on the results from faecal samples tested.

Event and outbreak response post-switch – standard operating procedures

SOPs have been developed for responding to a polio outbreak during the first year after tOPV withdrawal, the period from 1 May 2016 to 30 April 2017. Revised SOPs will be developed for use after May 2017. The six key functions of the GPEI partners in a polio outbreak (response and assessment; coordination and advocacy; technical and human resources; information management; communication, social mobilization and behaviour change; finance and logistics) have been retained. The concept of grading of the response required has been retained, but revised to include a risk assessment of the outbreak presenting an international threat using a risk matrix.

Included in the new SOPs are recommendations on the choice of vaccines for SIAs responding to a particular event. Response to a WPV, cVDPV1 or cVDPV3 outbreak or event should include use of bOPV plus IPV; response to a VDPV2 or cVDPV2 event should include use of mOPV2 plus IPV. All Sabin type 2 related events are now IHR (2005) notifiable, even though the relative risk for type 2 occurrence during the first year after tOPV withdrawal is high. The principles of the new type 2 event and outbreak response strategy include prompt detection and notification of all type 2 poliovirus events, prompt response to prevent virus circulation, targeted use of mOPV2 from the global stockpile (limiting mOPV2 exposure), and validating the absence of type 2 polioviruses in the population and environment following the response.

Discussion

The new SOP clearly places responsibility on the national authorities to report type 2 events and outbreaks and provide clear guidance on the vaccine response required, but there continues to be some confusion over the difference between an event and an outbreak. The SOP also fails to take into account the current global shortage of IPV, so any response may be restricted by the availability of suitable vaccines.

Procedures for declaring the end of an outbreak before the switch to bOPV included a clear role for the RCC. The new SOP includes no procedural role for the RCC in outbreak closure. This may simply have been due to an oversight, but any role for the RCC in the closure procedure in the post-switch period needs to be clearly defined as a matter of urgency.

Polio outbreak simulation exercises (POSEs): lessons learnt in 2015 and plans for 2016-2017

There are now three presentations of POSE: the original regional inter-country workshop (POSE III); an inter-regional workshop; and new national package for self-delivery. A POSE III inter-country workshop was conducted in Bucharest, Romania in October 2015 for representatives from the Czech Republic, Hungary, Republic of Moldova, Romania and Slovakia. The aims of this workshop were to revise the national plan of action to streamline it with the current GPEI SOPs; develop national risk communication plans for the management of polio outbreaks; identify strategies to reach high-risk/marginalized population groups; advance collaboration for better information sharing; and explore OPV procurement and licensing mechanisms before an outbreak occurs. An inter-regional workshop was held in Almaty, Kazakhstan in November 2015 for representatives from Kazakhstan, Kyrgyzstan, the Russian Federation, China and Mongolia. This workshop opened the door for inter-regional exchange of information and generated ideas on how best to implement outbreak response activities.

Feedback from POSE workshop participants and facilitators has been positive and the exercises were considered worthwhile, having achieved their aims and addressed the objectives. An additional POSE workshop is planned to be held in Almaty, Kazakhstan in August 2016 to include representatives from Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan and Uzbekistan. The exercise will focus on increasing the level of preparedness for a possible event of importation of WPV or emergence of cVDPV; improving understanding of the critical actions needed in responding to a new polio outbreak in line with revised SOPs; and developing/updating a national action plan in response to detection of WPV or detection of cVDPV. On the last day of the workshop participants will have the opportunity to review and discuss their national action plans.

Discussion

The RCC commends the Region on the activities undertaken to develop and distribute POSE and is perplexed at the apparent lack of interest in the POSE model that has been shown by WHO headquarters. POSE is eminently exportable, and packages are available for immediate use in other WHO regions; other WHO regions should be making use of the materials developed and the lessons learnt during the development of POSE. Possibilities for global promotion of the POSE approach should be considered by WHO and the issue be pursued through the various polio management bodies and meetings.

Face-to-face meeting with representatives from Ukraine to review cVDPV type 1 outbreak response activities, risks and mitigation activities

A six-month outbreak response assessment has been carried out to determine if poliovirus transmission has been stopped following the cVDPV outbreak; to determine the level of support required to achieve or maintain surveillance sensitivity and population immunity sufficient to be polio-free; and to provide recommendations to ensure that a comprehensive and adequate outbreak preparedness plan is in place. To make the assessment, the investigating teams posed the following questions:

- Has the Ministry of Health with supporting partners followed World Health Assembly (WHA) guidance for effective polio outbreak control?
- Were recommendations from previous technical support missions fully implemented?
- How likely is it that the country has stopped polio transmission based on SIA, surveillance, and other programme data?
- Is AFP surveillance sensitivity currently adequate to detect all transmission?
- Have caregivers been sensitized and mobilized to positively respond to vaccination campaigns?

During the three-month assessment, the team reviewed the speed of the immediate outbreak response activities, including vaccination coverage achieved, and noted that the WHA standards with regard to achieving at least 95% immunization coverage were not achieved. The team also concluded that recommendations from previous technical support missions were only partially implemented.

The national non-polio AFP rate was 2.2 in 2015 and the annualized rate for 2016 is currently 0.99, but there continue to be subnational territories with rates significantly below 1. The team concluded that Ukraine remains at high risk for the emergence of a new VDPV, particularly for type 2 poliovirus after the bOPV switch, due to the rapid accumulation of children susceptible to type 2. IPV does not induce mucosal immunity and therefore does not reduce transmission, so effective environmental surveillance is the method of choice for rapid detection of circulating virus.

Community demand for and confidence and trust in polio vaccination services and the immunization system has increased during the outbreak response, and there is evidence that special efforts to reach high-risk populations have resulted in increased coverage. However, confidence is fragile and work is needed to further sensitize and mobilize caregivers to accept vaccination.

In conclusion, the assessment team considers that the transmission of cVDPV1 in Ukraine has likely stopped. However, significant concerns remain that large programmatic gaps in immunization and surveillance put Ukraine at high-risk for the possible emergence and circulation of another VDPV. The team made recommendations to improve population

immunity, polio surveillance, vaccination communications, and high-level political commitment. They also recommended a review of progress in implementing recommendations and providing support for development of the International Health Regulation Emergency Committee progress report required by 31 July 2016.

Based on an analysis of all AFP/polio and enterovirus surveillance, the Ukraine NCC has concluded that implementation of supplementary immunization (two rounds in 2015 and one round in 2016) has successfully stopped cVDPV1 circulation. National vaccine coverage achieved through routine IPV immunization and one dose of tOPV in SIAs conducted from October 2015 to February 2016, is at 90%, although at least 10 subnational territories have less than 90% coverage and no information is available from parts of the Donetsk and Lugansk regions. The target group for SIAs conducted in 2015 was children 2 months to 6 years of age, and the age cut-off was raised to 10 years for SIAs conducted in 2016. Overall, 95.4% of children from 2 months to 6 years received at least 1 dose of polio vaccine during the SIA period, and 92% of children aged 6 to 10 years received at least 1 dose.

154 AFP cases were reported in 2015, giving a non-polio AFP rate of 2.54, and 82 cases have been reported as of 16 May 2016. Seventy-two percent of AFP cases in 2015 had received at least three doses of vaccine, but 17% were reported as zero dose. More than 7000 samples were tested from the enterovirus surveillance system in 2015, but the virus isolation rate was generally low. Of the 3777 environmental surveillance samples tested in 2015 <2% were positive for polioviruses and <3% were positive for non-polio enteroviruses (NPEVs).

The Ukraine Ministry of Health developed an action plan for transition to bOPV and two bOPV vaccines are now licenced for use in the country. A total of 2 755 000 doses of bOPV are scheduled to be delivered to the country by 10 June 2016, and 416 500 doses of IPV combined penta-vaccine and will also be delivered in June. There are more than 400 000 doses of standalone IPV already held in the country.

Discussion

There can be no doubt that cVDPV1 was in circulation in the country before the first case was detected as the two detected cases were not geographically or epidemiologically linked. AFP surveillance sensitivity had been in decline before identification of the first case, but was increased rapidly following that discovery. It is possible that cVDPV1 continued to circulate after detection of the first case and before the first SIA was mounted. It would be helpful to see a weekly plot of the environmental surveillance results going back to the time of first isolation of cVDPV1 showing the geographical distribution of sampling sites. This would provide some degree of confidence that the level of sampling was high enough and that potential virus isolates were not being missed.

The RCC appreciated the efforts of the team from Ukraine to present the situation to the meeting and thanked them for their patience in answering the questions raised. The Commission will require a 12-month status update, which hopefully will provide additional

strong evidence that the VDPV circulation has been halted and that polio surveillance and vaccination coverage have been returned to recommended levels.

Conclusions of the RCC and recommendations to Member States and WHO

Conclusions

The Regional Certification Commission (RCC) notes with cautious optimism that the world is closer than ever to interrupting polio transmission in the last two remaining endemic countries. With only 16 wild poliovirus cases in the world as of June 2016, limited to Afghanistan and Pakistan, a successful global switch from tOPV to bOPV, and a global shortfall of IPV, the RCC appreciates the need to rapidly identify vulnerabilities in the Region and risks to global eradication. Looking ahead, the RCC encourages countries to reduce remaining immunity gaps in underserved populations, be vigilant for silent virus transmission of vaccine-derived and wild virus, and reduce the risk of accidental reintroduction of virus through rigorous attention to containment. The RCC is aware that it will soon be called on to verify the evidence needed for global certification and appreciates the cooperation of countries to intensify their search for possible virus circulation.

The RCC greatly appreciates the opportunity provided by the WHO Regional Office for Europe to conduct a face-to-face meeting with representatives from Ukraine to review the cVDPV type 1 outbreak response activities and risk mitigation activities, and receive a status update from the NCC. While accepting that the external outbreak response assessment team concluded that cVDPV type 1 transmission in Ukraine has likely stopped, the Commission is concerned that, at a technical level, the questions posed during the review process do not provide responses capable of generating full confidence that the Region is free of poliovirus transmission. The RCC looks forward to receiving a 12-month report on the outbreak, activities undertaken and status of the immunization programme in Ukraine, as required by the emergency committee of the IHR in August 2016, and hopes that this report will provide the assurances required. It will be particularly important to demonstrate that the recent immunization activities have closed all susceptibility gaps across multiple age groups.

Based on the evidence provided, the RCC concluded there was no wild poliovirus (WPV) transmission in the WHO European Region in 2015, but that cVDPV type 1 had circulated in Ukraine. While all countries remain at risk of importation, Bosnia and Herzegovina, Romania and Ukraine remain at high risk of a sustained polio outbreak following importation: this would be due to low population immunity. Greece and Italy were provisionally considered to be at high risk for virus transmission based on the information provided in their annual status reports. The Secretariat will be writing promptly to the NCC chairs informing them of the specific country-by-country conclusions, and where there are provisional classifications of risk status, the NCCs will be invited to submit additional evidence within eight weeks. This

will provide those countries with an opportunity to be reassigned to a lower risk category, should the provided evidence be convincing.

The Commission expressed concern that considerable emphasis has been placed by the GPEI partnership on achieving the target of global polio eradication in 2016. Although significant progress towards this goal has been made in Pakistan especially, it now appears less than certain that the target will be met. If global interruption of transmission is not achieved in 2016, the RCC is concerned that the credibility of the GPEI will be brought into question, and that Member States' support in maintaining the polio-free status of the Region will be eroded.

The RCC appreciates the measures taken by several countries in the Region to address the immunization needs associated with the recent massive influx of refugees and migrants primarily from Iraq, north Africa and Syria, but would like to receive more detail on the immunization activities taking place. The RCC encourages the NCCs of the affected countries to provide more details on the activities that were undertaken and outcomes that were achieved in providing immunization services appropriate to the needs of these migrant populations.

The RCC noted that although the general standard of reports received from the NCCs has improved, and that most countries are using the report format provided, the number of NCCs submitting reports on time has declined, with only 46 of 53 reports received in time for the meeting, and a further 4 being received during the course of the meeting. As of 2 June 2016 reports had not been received from Poland, San Marino and the former Yugoslav Republic of Macedonia. Of the 46 reports received in time to be formally reviewed, only 33 arrived at the WHO Regional Office before the agreed deadline.

The Commission commended the continuing high standard and sophistication of work being conducted by the Regional Polio Laboratory Network. The RCC noted the extent and quality of work conducted in meeting the requirements for laboratory containment of poliovirus described in GAPIII and is heartened to be informed of the collaborative association established with the European Commission (EC) and the European Centre for Disease Prevention and Control (ECDC). This Region is in advance of other WHO regions in implementing GAPIII, and, because of the number of global-level polio and enterovirus laboratories and Europe-based polio vaccine manufacturers likely to require PEF status, will face a considerable workload in fully implementing all polio containment requirements. Member States considering establishing PEFs should be fully aware of all of the requirements of GAPIII, including the requirement for an effective national routine childhood polio immunization programme and the achievement and maintenance of high national population coverage with polio vaccine.

The RCC noted that requests for information on the quality of supplementary surveillance for polioviruses is now included in national update reports, but that the extent and quality

of information provided in 2016 requires considerable improvement before comparisons can be made of the quality of supplementary surveillance in different Member States.

The Commission was encouraged to be informed that the planned switch to bOPV throughout the Region in April 2016 was completed successfully. Concerns exist, however, that this Region has been disproportionately adversely affected by delays in global availability of IPV. Affected countries in the WHO European Region included those remaining at risk of importation due to their close proximity to the last two endemic countries in the world. The RCC urges that as IPV becomes available through 2016 and 2017, countries in the Region that require IPV are prioritized for vaccine allocation.

The RCC expressed concern at the number of countries, particularly those in the Balkans, where vaccine coverage is in decline, and the quality of poliovirus surveillance has fallen. Urgent measures are needed to reverse these declines as all countries remain at risk of importation of poliovirus, and those with suboptimal vaccination coverage and low-quality surveillance are at greatest risk of re-establishing transmission of imported virus or CVDPVs.

A number of countries have never been able to reach the recommended AFP surveillance indicators. They should consider carefully whether other virus-transmission-targeted surveillance methodologies would be more useful. The RCC noted that apart from the risk of missing potential paralytic polio cases due to suboptimal AFP surveillance, in the absence of environmental or enterovirus surveillance, there is also a risk of missing polio-related events that do not present as AFP.

The RCC is greatly encouraged by the success with which the POSE package and experience has been further developed and deployed. There exists, however, a level of perplexity as to why the POSE approach has not been adopted and promoted by WHO at a global level. POSE is highly relevant to all WHO regions, and it appears improvident not to make best use of the materials developed and the experience gained in the European Region.

Recommendations to Member States and WHO

NCCs and their reports

It is of great concern to the RCC that some countries failed to submit an annual report in time for it to be formally reviewed before the meeting. All Member States should make every effort to prepare their annual reports in the format provided and to ensure they arrive at the WHO Regional Office in advance of the deadline, so that their reports can be given the full attention of the WHO Secretariat and RCC.

Two of the reports received did not include the required NCC statement on their assessment of the national polio status. All NCCs should ensure that annual reports include the NCC statement.

National Plan of Action

All Member States are required to have a current plan of action to respond to detection of WPV/cVDPV, and this plan should be aligned with the SOPs for a new polio outbreak in a polio-free country. Member States are urged to ensure that their national plans of action are both current and aligned with the GPEI SOPs. The RCC would like to see in each national action plan how the country anticipates detecting a polio event.

Vaccines

The RCC urges the WHO Regional Office to continue to press the GPEI to prioritize the provision of IPV for countries in the Region as global supplies of vaccine come on stream through 2016 and 2017.

Immunization

In their annual reports for 2016, Member States affected by the recent influx of refugees and migrants should provide more details on the activities undertaken and outcomes achieved in providing immunization services appropriate to the needs of these migrant populations.

Surveillance

Member States should provide the requested information and results of their enterovirus and environmental surveillance systems, in the revised format of the Annual Update Report, to provide a more comprehensive assessment of national surveillance capabilities and effectiveness.

Member States, that have tried but failed to establish and maintain a fully functional, high-quality AFP surveillance system, should consider very carefully if better, more useful information could be obtained from other surveillance methodologies, such as enterovirus and/or environmental surveillance.

The RCC noted that there were considerable differences between rates by country of faecal specimens that were tested for enterovirus surveillance. Cerebrospinal fluid (CSF) samples are much less valuable than faecal specimens for detection of polioviruses and are not a replacement for the latter. Countries are urged to increase the numbers of faecal specimens and provide their demographic representativeness.

Laboratories and containment

Member States considering establishing PEFs should be fully aware of all of the requirements of GAPIII, including the requirement for an effective national routine childhood polio immunization programme and the achievement and maintenance of high national population coverage with polio vaccine.

POSE

All Member States should undertake POSE as a matter of course. Intercountry and inter-regional exercises have great value and all Member States are urged to make best use of any opportunities to participate.

WHO should take every opportunity to promote POSE and disseminate widely the lessons learnt and experiences gained in the Region.

cVDPV outbreak response in Ukraine

The GPEI outbreak response assessment (OBRA) team should revise the Terms of Reference for outbreak assessments to include the level of supplemental data requested by the RCC for purposes of assuring regional certification. The RCC also notes that several assessment questions have binary answers, such as whether a country met the minimum standards for outbreak response or not. In the 12-month report, partial progress should be noted for context and to highlight areas that need to be addressed.

Annex 1. Risk of wild poliovirus transmission, WHO European Region, 2016

Country	Surveillance quality	Population immunity	Other factors	Composite risk score
Albania	Good	High	No	Low
Andorra	Good	High	No	Low
Armenia	Good	High	No	Low
Austria	Good	High	No	Low
Azerbaijan	Good	High	No	Low
Belarus	Good	High	No	Low
Belgium	Low	High	No	Intermediate
Bosnia and Herzegovina	Average	Low	Yes	High
Bulgaria	Good	Average	Yes	Intermediate*
Croatia	Average	High	No	Low
Cyprus	Good	High	No	Low
Czech Rep.	Good	High	No	Low
Denmark	Good	Average	No	Intermediate
Estonia	Good	High	No	Low
Finland	Good	High	No	Low
France	Good	High	No	Low
Georgia	Good	Average	No	Intermediate
Germany	Good	High	No	Low
Greece	Good	No data	Yes	High*
Hungary	Average	High	No	Low
Iceland	Average	High	Yes	Intermediate*
Ireland	Good	High	No	Low
Israel	Good	High	No	Low
Italy	Good	Average	Yes	High*
Kazakhstan	Good	High	No	Low
Kyrgyzstan	Good	High	No	Low
Latvia	Average	High	No	Low
Lithuania	Good	High	No	Low
Luxembourg	Average	Average	Yes	Intermediate
Malta	Average	High	No	Low
Monaco	Good	High	Yes	Intermediate
Montenegro	Good	Average	No	Intermediate
Netherlands	Good	High	No	Low
Norway	Good	High	Yes	Intermediate
Poland	Average	High	Yes	Intermediate*
Portugal	Average	High	No	Low
R. Moldova	Good	Average	No	Intermediate
Romania	Average	Low	Yes	High
the Russian Federation	Good	High	No	Low

San Marino	Average	Average	No	Intermediate*
Serbia	Average	Average	No	Intermediate
Slovakia	Average	High	No	Low
Slovenia	Average	High	No	Low
Spain	Average	High	No	Low
Sweden	Good	High	No	Low
Switzerland	Low	High	Yes	Intermediate*
Tajikistan	Good	High	No	Low
The former Yugoslav Republic of Macedonia	Average	High	Yes	Intermediate*
Turkey	Good	High	No	Low
Turkmenistan	Good	High	No	Low
Ukraine	Good	Low	Yes	High
United Kingdom	Good	High	No	Low
Uzbekistan	Good	High	No	Low

*Provisional based on receipt of further information

Annex 2: Programme

Tuesday, 31 May 2016

Plenary session 1: Update on global polio eradication and sustaining polio free Europe

09:15-09:45	Update from WHO/HQ/GPEI	Tallis, Graham WHO/HQ
09:45-10:15	Polio programme annual update from the WHO Region Office for Europe	Butler, Robb Deshevoi, Sergei WHO/Europe

Plenary Session 2: Sustainability of polio-free Europe: Review of national updated documents and risk assessment for 2014 by epidemiological zones

13:00-13:10	Introduction to sub-regional review and risk assessment	Deshevoi, Sergei WHO/Europe
13:10-14:40	<ul style="list-style-type: none"> • Baltic/Nordic Zone • Western Zone 	Deshevoi, Sergei WHO/Europe
15:00-16:30	<ul style="list-style-type: none"> • Central Zone • Southern Zone 	Jankovic, Dragan WHO/Europe
16:30-17:00	<ul style="list-style-type: none"> • Central Eastern Zone • MECACAR Zone 	Huseynov, Shahin WHO/Europe

Wednesday, 1 June 2016

Plenary Session 3: Regional risk mitigation activities

09:30-10:00	<p>Response and risk mitigation activities in Member States, which are defined to be in the high risk group (presentations by RCC members 15 minutes; discussion 15 minutes)</p> <ul style="list-style-type: none"> • Romania 	<p>Tapani Hovi, RCC</p> <p>Jankovic, Dragan WHO/Europe</p>
10:00-10:30	<ul style="list-style-type: none"> • Bosnia and Herzegovina 	<p>Donato Greco, RCC</p> <p>Deshevoi, Sergei WHO/Europe</p>
11:45-12:00	Post-switch polio outbreak response SOPs from the GPEI	Huseynov, Shahin WHO/Europe
13:00-13:15	Polio Outbreak Simulation Exercises: lessons learnt from 2015 and plans for 2016-17	Deshevoi, Sergei WHO/Europe

13:15-15:00	<i>RCC discussion on conclusions and recommendations to Member States and WHO</i>	<i>RCC, WHO/Europe</i>
15:20-16:30	<i>Review working procedures of the RCC</i>	<i>RCC, WHO/Europe</i>

Thursday, 2 June 2016

Plenary Session 4: *Ukraine cVDPV outbreak response*

09:00 – 12:00	<i>Face-to-face meeting with representatives from Ukraine to review cVDPV type 1 outbreak response activities, risks and mitigation activities</i>	
	<ul style="list-style-type: none"> • <i>6 months assessment results</i> 	<i>Huseynov, Shahin WHO/Europe</i>
	<ul style="list-style-type: none"> • <i>Status update from the National Certification Committee</i> 	<i>Zadorozhnaya, Viktoria, NCC Chair Ukraine</i>
	<ul style="list-style-type: none"> • <i>Discussion, conclusions and recommendations</i> 	<i>RCC members</i>
12:00-12:30	<ul style="list-style-type: none"> • <i>Closure</i> 	

Annex 3: List of participants

European Regional Certification Commission (RCC) Members

Prof David M. Salisbury, Chair

Prof Donato Greco

Prof Tapani Hovi

Dr Ellyn Ogden

European Centre for Disease Prevention and Control (ECDC)

Dr Sabrina Bacci

United Nations Children's Fund (UNICEF)

Dr Oya Zeren Afsar

Representatives of Ukraine

Prof V.Zadorozhna

Dr Sergii Platov

Rapporteur

Dr Raymond Sanders

Temporary Advisors

Prof Lester Shulman

Mr Jascha Wiehn

WHO headquarters

Dr Graham Tallis

WHO Regional Office for Europe

Mr Robb Butler, Programme Manager

Ms Malika Abdusalyamova

Dr Vusala Allahverdiyeva, WHO Country Office in Ukraine

Dr Sergei Deshevoi

Dr Eugene Gavrilin

Dr Shahin Huseynov

Dr Dragan Jankovic

Ms Maria Edith Nielsen

Mr Simarjit Singh



The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

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Azerbaijan	Finland	Kyrgyzstan	Republic of Moldova	The former Yugoslav
Belarus	France	Latvia	Romania	Republic of Macedonia
Belgium	Georgia	Lithuania	Russian Federation	Turkey
Bosnia and Herzegovina	Germany	Luxembourg	San Marino	Turkmenistan
Bulgaria	Greece	Malta	Serbia	Ukraine
Croatia	Hungary	Monaco	Slovakia	United Kingdom
	Iceland	Montenegro	Slovenia	Uzbekistan

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