

32ND MEETING OF THE EUROPEAN REGIONAL COMMISSION FOR CERTIFICATION OF POLIOMYELITIS ERADICATION (RCC)

30-31 May 2018 Copenhagen, Denmark



ABSTRACT

The 32nd Meeting of the European Regional Commission for Certification of Poliomyelitis Eradication (RCC) reviewed annual updates submitted by the Member States of the Region on the status of their national polio eradication programmes. The RCC concluded, based on available evidence, that there was no wild poliovirus transmission in the WHO European Region in 2017 and that WPV importation or circulation of vaccine-derived polio virus, if any, would have been detected promptly by existing health/surveillance systems. Bosnia and Herzegovina, Romania and Ukraine remain at high risk of a sustained polio outbreak following WPV importation or emergence of circulating VDPV due to suboptimal programme performance and low population immunity. The RCC expressed concern at the number of countries, particularly middle-income countries at intermediate risk of polio transmission, where vaccination coverage appears to be in decline and the quality of poliovirus surveillance is suboptimal. The RCC again expressed concern over the number of countries proposing to establish poliovirus essential facilities and urged the countries to carefully consider the stringent requirements for establishing and maintaining PEFs and weigh the costs against any potential benefit to the country.

Keywords

POLIOMYELITIS – prevention and control IMMUNIZATION PROGRAMS EPIDEMIOLOGIC SURVEILLANCE – standards CONTAINMENT OF BIOHAZARDS – standards LABORATORY INFECTION – prevention and control STRATEGIC PLANNING

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Abbreviations

AFP	acute flaccid paralysis
APR	annual progress report
cVDPV	circulating vaccine-derived poliovirus
cVDPV2	circulating vaccine-derived poliovirus type 2
e-APR	electronic annual progress report
EVAP	European Vaccine Action Plan
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
IPV	inactivated polio vaccine
mOPV2	monovalent OPV type 2
MECACAR	Mediterranean, Caucasus and Central Asian republics subregion
NAC	National Authority for Containment
NCC	National Certification Committee
NPCC	National Poliovirus Containment Coordinator
NPEV	non-polio enteroviruses
OPV	oral polio vaccine
POSE	polio outbreak simulation exercise
PV2	poliovirus type 2
PEF	poliovirus-essential facility
RCC	European Regional Certification Commission for Poliomyelitis Eradication
SL2	Sabin-like poliovirus type 2
SOP	standard operating procedure
VDPV	vaccine-derived poliovirus
VPI	Vaccine-preventable Diseases and Immunization Programme of the WHO
	Regional Office for Europe
WPV	wild poliovirus
WPV1	wild poliovirus type 1
WPV2	wild poliovirus type 2

Introduction

The 32nd meeting of the European Regional Commission for Certification of Poliomyelitis Eradication (RCC) was held from 30 to 31 May 2018 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 Chairperson, Professor David Salisbury, who welcomed the Commission members, meeting participants and observer. Rapporteur for the meeting was Dr Ray Sanders. The WHO Regional Office for Europe (Regional Office) serves as Secretariat of the RCC.

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 from all Member States of the WHO European Region (the Region) for 2017;
- to review response and risk mitigation activities in Member States which were defined to be in the high-risk group;
- to review the current status of poliovirus containment in the Region;
- to brief the RCC on progress of IPV introduction and mitigation of risks of delays caused by the global supply constraints;
- to brief the RCC on progress with introduction of electronic annual progress reports (e-APRs);
- to recommend to the Regional Office strategies and/or actions to strengthen efforts to sustain polio-free status of the Region focusing on high-risk countries and territories;
- to review the progress of implementation of the recommendations of the 31st meeting of the RCC;
- to review working procedures of the RCC and to discuss a plan of activities for 2018-2019.

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

Update from WHO headquarters Global Polio Eradication Initiative (GPEI)

In Afghanistan and Pakistan, in addition to detection of WPV type 1 (WPV1)-associated cases in humans, the virus continues to be detected in environmental surveillance samples. Combined surveillance data suggest the existence of three active corridors of WPV1 transmission, one in the area around Karachi in Pakistan, and two that cross the Pakistan-Afghanistan border, one to the north and one to the south. Over the past year there has been a reestablishment of WPV1 transmission in the southern and, possibly, in the eastern regions of Afghanistan. Insecurity and ongoing conflict in some areas in Afghanistan present a significant challenge to the programme with some key areas of virus transmission not under government control. The programme response has been to focus resources on transmission hot spots, identify problems and improve performance, and to provide a rapid investigation and immunization response to any WPV1-positive case or environmental sample.

The last WPV1 case detected in the Nigeria and Lake Chad area was in August 2016, but approximately 104 000 children in Nigeria remain unreached due to security reasons, and the quality of surveillance and population immunity in neighbouring Lake Chad basin countries remains suboptimal. Circulating vaccine-derived poliovirus type 2 (cVDPV2) was detected in Nigeria in January 2018, with the most recent isolations being from environmental samples and one acute flaccid paralysis (AFP) case with onset of paralysis on 15 April. Following notification of the initial cVDPV2 isolates, the programme conducted enhanced vaccination activities using inactivated polio vaccine (IPV) in high-risk wards targeting approximately 55 000 children, and the country has conducted additional AFP surveillance strengthening activities including enhanced active surveillance visits, and community sampling.

A total of 74 cVDPV2-associated cases were confirmed in Syria between March and September 2017, with most cases coming from Deir Ez-Zor governorate. Transmission was limited geographically and appears to have ceased. The Democratic Republic of the Congo has not reported a case of wild poliovirus since 2011, but the country is currently affected by two separate cVDPV2 outbreaks, with cases continuing to be reported into 2018. Children living in the districts affected were vaccinated with monovalent oral polio vaccine type 2 (mOPV2) during December, but continued detection of cases demonstrates the need for further supplementary immunization activities. A highly divergent VDPV2 was isolated from environmental surveillance samples collected from a single site in Mogadishu in October 2017. This was classified as a cVDPV and supplementary immunization and enhanced surveillance were initiated. Two rounds of mOPV2 were delivered in December 2017 and January 2018. Related VDPV2 isolates were detected in environmental surveillance samples from another sampling site in January 2018, and a related isolate was detected in Nairobi, Kenya in March 2018, confirming circulation of the virus. Synchronized supplementary immunization with mOPV2 has been planned for Somalia, Kenya and Ethiopia.

Discussion

While the increasing intensity of polio surveillance in remaining transmission foci is encouraging, the high frequency of detection of WPV1 and cVDPV in environmental samples is of concern. It has been noted, however, that there is limited historical information on the intensive use of environmental surveillance for polio and interpretation of recent results should be approached with caution. Significant periods of silent transmission and the detection of 'orphan' viruses remain a strong indication that immunization services and surveillance programmes need to be strengthened.

Polio programme annual update from the Regional Office

RCC conclusions for 2016

Based on 2016 reporting three Member States, Bosnia and Herzegovina, Romania and Ukraine, were considered to be at high risk of a sustained polio outbreak following importation or emergence of cVDPV, due to suboptimal programme performance, and particularly low population immunity. Twenty-five Member States were considered to be at intermediate risk and 24 at low risk. The risk status of Italy could not be assessed for 2016 due to absence of a national certification committee (NCC) in the country. Application of a more stringent risk assessment approach, including increased scrutiny of the quality of polio surveillance, population immunity and the national plan of action for outbreak response resulted in an increase in the number of countries considered to be at a higher risk.

The European Vaccine Action Plan (EVAP) mid-term report, to be presented to the Regional Committee in September 2018, will include a detailed analysis of progress made in the Region since 2015.

Discussion

While the risk assessment process has become more focussed, the criteria used by the RCC to assess country performance have remained reasonably constant, and it may be time to update some of the assessment criteria. Population immunity, as a factor of greatest concern, should continue to be given the greater weight in the assessment. There have been fluctuations in the quality of polio surveillance in different countries over the years, but there is no conclusive evidence that surveillance quality in general has declined in the Region. Several countries with small populations have for many years struggled to demonstrate adequate polio surveillance quality and it may now be worth considering if the surveillance quality demonstrated by their much larger neighbours can be used as a proxy for the quality of their own surveillance.

Current status of poliovirus containment globally and in the European Region

Implementation of the Global action plan to minimize poliovirus facility-associated risk after typespecific eradication of wild polioviruses and sequential cessation of OPV use (GAPIII) has been a slow process, and while progress is being made, there is an urgent need to accelerate activities. At its 71st meeting in May 2018, the World Health Assembly endorsed a resolution urging all Member States to intensify efforts to accelerate the progress of poliovirus containment certification and to complete inventories for type 2 polioviruses, destroy unneeded type 2 materials and to begin inventories and destruction of unneeded type 1 and 3 materials. Member States wishing to retain poliovirus-infectious materials, including materials for polio vaccine production, are required to establish PEFs that meet highly stringent containment requirements with oversight from the Global Certification Commission (GCC). To date, 30 Member States globally have indicated their intention to establish a total of 99 PEFs.

In the European Region, 13 Member States have indicated the intention to establish at least one PEF. All but two have a nominated national polio containment coordinator, and all but three have certified the destruction of all poliovirus type 2 materials held in facilities other than the nominated PEFs. Four of the countries with intended PEFs do not yet have a formal national authority on containment (NAC), a body essential for the certification of PEFs. Three do not have auditors trained in use of the containment certification scheme (CCS). Member States of concern include France, Italy, Netherlands, Romania, Serbia and Czech Republic. The WHO Secretariat continues to work with Member States to ensure understanding of the exacting requirements for establishing and maintaining PEFs and to potentially reduce the number PEFs in the Region. There are currently 45 potential PEFs in the Region, including several vaccine production facilities and a range of laboratories and research institutions. It is apparent that every facility that handles polio-infectious materials will be required to be certified as a PEF, not simply every organization or institution. If a vaccine producer or scientific institution has several sites handling poliovirus, each needs to be certified as a PEF separately as the risks associated with each site may differ significantly.

The WHO Secretariat, in conjunction with GPEI's Containment Management Group (CMG), have developed a PEF risk-ranking matrix using data on poliovirus material retention based on containment phase I surveys and inventories. The risk-ranking matrix currently takes into account retention of WPV2 and VDPV2, volumes and concentrations of retained materials, retention of other poliovirus types, and access to an improved sanitation infrastructure. Potential PEFs have been ranked into 3 categories, from highest risk (Rank 1), through intermediate (Risk 2) to lower risk (Rank 3). The risk

ranking scheme will be used in the containment phase I validation review, to prioritize countries for technical support, for communications and advocacy and to promote international collaboration on risk management.

Discussion

The WHO Secretariat and CMG were commended for their work in developing the PEF risk-ranking matrix and encouraged to promote its use in other WHO regions. As the risk-ranking scheme continues to be developed, it has not yet been validated and it would now be appropriate to conduct a table-top exercise to review and assess the matrix. While the containment agenda has been promoted and discussed in a number of scientific meetings held in the Region there is now a requirement to engage a broader scientific and medical audience, through meetings and professional associations.

The middle-income country (MIC) challenge

In the European Region there are 13 MICs that are not eligible for financial support from the traditional donors. These countries face similar challenges, including lack of adequate financial commitment to immunization due to competing priorities, difficulties in accessing vaccines at affordable prices, vaccine procurement delays as they rely on domestic financial resources, and difficulty in making evidence-informed decisions on introducing new vaccines and sustaining the performance of the current programmes, anti-vaccine sentiment and vaccine hesitancy affecting uptake. Several of these countries also lie in the migrant corridor from North Africa and Middle East to north-western Europe.

These countries represent 38% of the total population of the Region but have 70% of the undervaccinated children and accounted for 55% of the total measles cases in 2016. Available data do not indicate decline in polio vaccination coverage or polio surveillance, however the evidence exists for declining performance in other programmes, including measles and rubella elimination and hepatitis control.

The WHO Secretariat is in the process of developing a 3- to 5-year roadmap for these countries that will focus on financing sustainability, vaccine equity, support for evidence-based decision making and tools to tackle vaccine hesitancy. The documentation will include costing for the initial years so that potential donors can be sought. A presentation on the roadmap will be made to the WHO Regional Committee in September.

Discussion

While the situation of the MICs is a cause for concern, the evidence is lacking for a decline in polio programme performance and increase in risk in these countries. To determine the level of the threat, data from each country of concern needs to be reviewed and the risks for each country determined. Risk mitigation activities can then be proposed for each country. Grouped data can be disaggregated and provided as a package of country reviews for assessment and determination of overall risk.

Changes to the risk assessment methodology and sub-regional review

A number of changes were introduced to the risk assessment process for the 2017 data. These included a use of the updated 2015 World Bank health services ranking for each country; introduction of an additional binary variable for containment in the list of 'other risk factors'; use of the WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) to standardize assessment of population immunity for previous years; and triangulation of surveillance, population immunity, PV detection and containment data from multiple sources. It was also proposed for the 2019

assessment to consider replacing the variable on the percentage of AFP cases with laboratory results within 28 days with a variable on the percentage of cases with a final classification within 90 days.

The format of the Annual Progress Report (APR) for 2017 was modified to align it with the trialled e-APR, and the NCCs were requested to provide their own assessment of risk status. The section on surveillance was modified to include case investigation reports of any VDPV and type 2 Sabin-like (SL2) poliovirus from AFP and non-AFP sources. The section on containment was revised to include an update of the national inventory and detailed description of the inventory validation procedure, information on poliovirus potentially infectious materials (PIM), information on PEFs in the country, and information on retention of polio types 1 and 3. The section on risk mitigation requested information on risk mitigation activities planned for 2017-2018 and details of the outbreak preparedness plan.

With the APR for 2017, only 32 Member States submitted a plan of action for outbreak response, and of these only 23 were considered to be satisfactory.

Discussion

The changes made to the risk assessment methodology were endorsed, and agreement on changing the variable on AFP cases with laboratory reports to a variable on final classification within 90 days was agreed. RCC requested the Secretariat to actively work with national public health authorities to ensure availability of preparedness plans from all Member States.

e-APR: Status update and further plans

The e-APR is a web application created with the purpose of streamlining submission of annual polio updates by NCCs and their review by the RCC. The current version of the software is already operational in English and Russian and running on the Regional Office's IT infrastructure. In April 2018 the e-APR was tested with selected Member States of the Region, including Azerbaijan, Belarus, Denmark, France, Italy, Kyrgyzstan, Netherlands, and the United Kingdom. Azerbaijan, Denmark, Italy, and Netherlands submitted their 2017 reports in the form of e-APRs. The current e-APR version is to be finalized by the end of 2018 and rolled out to all 53 Member States of the Region by early 2019. The next version of the e-APR will be implemented in 2020 for reporting of 2019 data and will include pre-populated data fields, improvements and fixes.

Discussion

The RCC noted that the four submitted e-APR reports were provided in PDF format that did not permit access to the drop-down boxes or to data that extended beyond the limits of a single box. This occurred because the format was still in development and will be rectified in the final version to be rolled out next year. While the RCC fully endorsed and encouraged e-APR development and rollout, further discussions are required on the format, ability to enter free text and data linkages before the application can be finalized. RCC requested the Secretariat to have demographic data prepopulated in the next version of e-APR for ease of reference and possibility for RCC to comment of reports online.

Plenary session 2: Sustainability of polio-free status in the Region: Review of national updated documents and risk assessment for 2017 by epidemiological zones

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

Southern zone

Based on the information available, the RCC concluded that the probability is high that WPV had not been circulating in the zone in 2017 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 subregion ranges from low to intermediate. The RCC noted the broad improvement in the quality of reports received from Member States in this zone this year. Of concern is the consistently suboptimal quality of AFP surveillance, often in the absence of adequate supplementary surveillance systems. As in previous years, there is a general lack of detailed data provided on the supplementary surveillance systems in use. It is also of concern that two countries (Israel and Malta) have no formal plan of action to respond to WPV/cVDPV detection. Italy has indicated the intention to establish a PEF, and although the country is ranked as presenting lower risk, the absence of an officially designated NAC is of some concern as an NAC is essential for the process of certifying a PEF.

Feedback to the countries

- Andorra is considered to be at low risk, but the RCC is again concerned that the quality of AFP surveillance is suboptimal.
- Croatia is considered to be at intermediate risk on the basis of suboptimal population immunity, particularly with 27% of the population living in districts with <90% coverage with 3 doses of polio vaccine. There is also evidence for a continuing gradual decline in polio vaccination coverage. The Ministry of Health and the NCC should take note that additional efforts are required to improve vaccination coverage or Croatia may be considered to be at high risk next year.
- Cyprus is considered to be at low risk. However, the RCC is concerned that although polio vaccination coverage is believed to be high, once again adequate coverage data has not been provided. Contrary to the terms of reference, members of the NCC are employed in polio eradication activities, presenting potential conflicts of interest. This situation needs to be addressed, with replacement of NCC members with potential conflicts of interest, before the APR for 2018 is prepared and submitted.
- Greece is considered to be at low risk. However, the RCC is concerned that although polio vaccination coverage is believed to be high, once again adequate coverage data has not been provided. The RCC commends the country for responding to the concerns expressed last year and in providing additional data on supplementary immunization of migrant groups. The RCC strongly recommends Greece to nominate a National Poliovirus Containment Coordinator (NPCC) to ensure proper communication on poliovirus containment activities and updates in the country.
- Israel is considered to be at low risk but the RCC is concerned over the lack of a formal
 plan of action to respond to WPV/cVDPV detection, even though Israel has had recent
 experience in responding to a polio outbreak and demonstrated the capacity to control and end
 virus transmission. The RCC would expect the national authorities in Israel to be able to
 develop an appropriate plan of action based on these experiences and forward this to the
 Secretariat for consideration by the Commission.
- Italy is considered to be at intermediate risk based on suboptimal poliovirus surveillance and the decision to establish a PEF in the absence of a designated NAC. The RCC commends Italy on establishing an NCC, developing a preparedness plan and working with the WHO Secretariat in responding appropriately to concerns raised last year.

- Malta is considered to be at low risk but the RCC is concerned over the lack of a formal plan to respond to WPV/cVDPV detection. The RCC expects to see an appropriate preparedness plan submitted to the Secretariat for consideration by the Commission.
- Portugal is considered to be at low risk but the RCC remains concerned over the suboptimal quality of AFP surveillance in the absence of adequate documentation on the quality of supplementary surveillance.
- San Marino is considered to be at intermediate risk on the basis of suboptimal vaccination coverage and the absence of polio surveillance. Contrary to the terms of reference members of the NCC are employed in polio eradication activities, presenting potential conflicts of interest. This situation needs to be addressed, with replacement of NCC members with potential conflicts of interest, before the APR for 2018 is prepared and submitted. The RCC commends San Marino for working with the WHO Secretariat in responding appropriately to concerns raised last year.
- Spain is considered to be at low risk.

Western zone

Based on the information available, the RCC concluded that the probability is high that WPV had not been circulating in the zone in 2017 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 ranges from low to intermediate. AFP surveillance has been all but abandoned in the zone but appears to have been substituted more or less effectively by supplementary surveillance in all countries except Monaco and Switzerland. Polio vaccination coverage is generally high but 8 of the 10 countries in the zone have recognized vulnerable populations, in some cases associated with a recent influx of migrants. It remains of concern that Monaco and France still lack an appropriate plan of action for outbreak response, and that most of the other countries have not yet formally tested their plans. Potential conflicts of interest exist in the composition of the NCCs in Belgium, Germany, Ireland, Luxembourg, Monaco, Netherlands and Switzerland, although for several of these countries the decentralization results in members from one region or authority effectively providing scrutiny over the other regions or authorities.

Feedback to the countries

- Austria is considered to be at intermediate risk due to continued suboptimal polio vaccination coverage and concerns over resultant low population immunity. The RCC would also appreciate receipt of an updated national plan of action for outbreak response in line with the GPEI Standard Operating Procedures. The RCC commends Austria for providing details of supplementary immunization activities conducted among migrant populations.
- Belgium is considered to be at intermediate risk due primarily to the apparent lack of adequate surveillance, either for AFP or for enteroviruses. The RCC recognizes that due to the high quality of clinical detection services provided in the country, any polio cases would likely be detected and investigated. Belgium is, however, proposing to establish a number of PEFs, increasing the risk and increasing the requirement for high-quality poliovirus surveillance and maintenance of high population immunity.
- France is considered to be at low risk but the RCC is concerned over the failure to provide an adequate national plan of action for outbreak response. France is proposing to establish a number of PEFs, increasing the risk and therefore the requirement for high-quality poliovirus surveillance and an appropriate preparedness plan for controlling potential outbreaks. The

RCC expects to see an appropriate plan of action submitted to the Secretariat for consideration by the Commission.

- Germany is considered to be at intermediate risk due to suboptimal poliovirus surveillance consisting solely of enterovirus surveillance at a number of sentinel sites. The RCC commends Germany for providing details of supplementary immunization activities conducted among migrant populations.
- Ireland is considered to be at intermediate risk due to low vaccination coverage, the presence of recognized vulnerable populations and 29% of the population living in districts with <90% coverage with a third dose of polio vaccine. The RCC would also appreciate receipt of a finalized national plan of action for outbreak response.
- Luxembourg is considered to be at intermediate risk due to suboptimal surveillance and the recognition of vulnerable groups in the population.
- Monaco is considered to be at intermediate risk due to the apparent absence of effective surveillance for polio and lack of a national plan of action for polio outbreak response. The NCC is urged to develop an appropriate plan in line with the GPEI SOPs as soon as possible.
- Netherlands is considered to be at intermediate risk due to suboptimal vaccination coverage, recognized vulnerable populations and a reported 2.2% of the population living in districts with coverage with the third dose of polio vaccine <90%. Netherlands has decided to establish a number of PEFs, increasing the risk and hence increasing the requirement for high-quality poliovirus surveillance and a very robust NAC.
- Switzerland is considered to be at low risk despite the suboptimal quality of polio surveillance. The RCC recognizes that due to the high quality of clinical detection services provided in the country, any polio cases would be detected and investigated. The RCC commends Switzerland for working with the WHO Secretariat in responding appropriately to concerns raised last year and developing a quality outbreak preparedness plan.
- United Kingdom is considered to be at low risk. The United Kingdom is, however, proposing to establish a number of PEFs, increasing the risk and increasing the requirement for high-quality poliovirus surveillance and maintenance of high population immunity. The RCC is also concerned that the country's national enterovirus surveillance is predominantly based on the testing of cerebrospinal fluid (CSF) samples instead of stools, which results in lower sensitivity towards poliovirus detection.

Central zone

Based on the information available, the RCC concluded that the probability is high that WPV had not been circulating in the zone in 2017 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 ranges from low to intermediate. Continuing evidence for suboptimal immunization coverage at subnational level in Bulgaria remains of concern with 15.8% of the population living in districts with third dose of polio vaccine coverage <90%. It remains of concern that Bulgaria, Hungary and Poland still lack an appropriate plan of action for outbreak response, and that 4 of the 7 countries in this zone have not yet formally tested their plans. Also of concern is the reported intention of the Czech Republic to convert a vaccine production facility to a PEF, despite a lack of experience in polio facility containment.

Feedback to the countries

• Belarus – is considered to be at low risk. The RCC would appreciate receipt of a finalized national plan of action for outbreak response.

- Bulgaria is considered to be at intermediate risk due to a combination of factors including suboptimal population immunity, particularly among subnational population groups, and suboptimal polio surveillance. The RCC commends the NCC and national authorities for submission of a missing national plan of action for outbreak response by the set deadline.
- Czech Republic is considered to be at low risk. However, the RCC is concerned that the quality of polio surveillance is not high and should be improved. The RCC is also concerned over a recent report that a vaccine producer has proposed converting an IPV production facility into a PEF. Details of this proposal and its current status have not been provided and the RCC looks forward to receiving additional information so that an assessment can be made of the risks posed.
- Hungary is considered to be at intermediate risk due to suboptimal polio surveillance and the absence of a national plan of action for outbreak response. The RCC notes the intention to establish a PEF and again highlights the requirement to maintain both high population immunity and high-quality polio surveillance. The RCC requests Hungary to submit a national plan of action for outbreak response as a matter of urgency.
- Poland is considered to be at intermediate risk due to less than optimal AFP surveillance, absence of a national plan of action for outbreak response and the demonstrated failure to respond adequately to outbreaks of other vaccine-preventable diseases. The RCC urges Poland to improve the quality of polio surveillance and to submit a national plan of action for outbreak response as a matter of urgency.
- Slovakia is considered to be at low risk. The RCC urges that efforts be made to improve AFP surveillance quality but commends Slovakia on the quality of supplementary surveillance conducted.
- Slovenia is considered to be at low risk. However, the RCC is concerned that the quality of polio surveillance is suboptimal and urges that improvements be made.

Nordic-Baltic zone

Based on the information available, the RCC concluded that the probability is high that WPV had not been circulating in the zone in 2017 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 ranges from low to intermediate. It remains of concern that Denmark, Iceland and Latvia still lack an appropriate plan of action for outbreak response, and that most of the other countries have not yet formally tested their plans. The RCC again noted the apparent continuing decline in vaccination coverage in Finland and, while acknowledging some perturbation of estimates associated with introduction of the Finnish Vaccine Registry, is deeply concerned that23% of the population apparently lives in districts with coverage with the third dose of polio vaccine <90%. NCC members for Latvia and Lithuania are employed in national polio eradication activities and, as such, present potential conflicts of interest that need to be addressed.

Feedback to the countries

• Denmark – is considered to be at low risk. However, the RCC notes the absence of a national plan of action for outbreak response and the intention to establish a PEF. The RCC again highlights the requirement to maintain both high population immunity and high-quality polio surveillance in countries hosting PEFs. The RCC requests Denmark to submit a national plan of action for outbreak response as a matter of urgency. The RCC was disappointed that the same request made last year was not met with a positive response.

- Estonia is considered to be at low risk. However, the RCC noted that the outbreak preparedness plan is not in line with the internationally accepted Standard Operating Procedures. The RCC requests that the national authorities redraft the plan in line with the GPEI Standard Operating Procedures and submit it to the WHO Secretariat.
- Finland is considered to be at intermediate risk due to suboptimal reported population immunity well below 95% and a significant proportion of the population living in districts with coverage <90%. The RCC understands that this situation is also of national concern and proposals have been made to review the national coverage data. The RCC would appreciate receiving the details of any such review, together with the findings, conclusions and any national recommendations made to increase polio vaccination coverage.
- Iceland is considered to be at intermediate risk due to suboptimal polio vaccination coverage and lack of a national plan of action for outbreak response. The RCC requests Iceland to submit a national plan of action as soon as possible. The RCC commends Iceland for the efforts made in responding to earlier RCC recommendations.
- Latvia is considered to be at intermediate risk due to suboptimal polio surveillance and lack of a polio-specific national plan of action for outbreak response. The RCC requests Latvia to update and submit its preparedness plan. Three of seven NCC members are employed in polio eradication activities, presenting potential conflicts of interest and this situation needs to be addressed. Action was recommended by the RCC last year and has not been responded to.
- Lithuania is considered to be at low risk. The RCC noted, however, that the quality of polio surveillance could be improved. Six of ten members of the NCC are employed in polio eradication activities, presenting potential conflicts of interest and this situation needs to be addressed. The RCC made the same recommendation last year with no appreciable response.
- Norway is considered to be at low risk.
- Sweden is considered to be at low risk. The RCC noted the intent to establish a PEF, but also noted that polio surveillance consists solely of enterovirus surveillance. The RCC is concerned that enterovirus surveillance alone is not sufficient to establish and maintain a PEF and recommends that additional forms of polio surveillance be investigated and considered for introduction.

Central-eastern zone

Based on the information available, the RCC concluded that the probability is high that WPV had not been circulating in the zone in 2017 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 ranges from low to high. Due to suboptimal immunization services the risk of spread following importation of WPV or cVDPV remains high in Bosnia and Herzegovina, Romania and Ukraine and. Suboptimal and declining immunization coverage in several of the countries in this zone is of major concern. The RCC is also concerned that Romania is considering establishment of a PEF in the absence of adequate population immunity and Serbia is considering establishment of a PEF in the absence of high-quality polio surveillance, a nominated NAC or a national plan of action for outbreak response. Albania and the former Yugoslav Republic of Macedonia have also failed to submit a national plan of action for outbreak response in line with the GPEI Standard Operating Procedures.

Feedback to the countries

• Albania – is considered to be at low risk. The RCC is concerned, however, over the absence of a national plan of action for outbreak response, particularly since Albania has demonstrated a lack of capacity to deal effectively with a measles outbreak in January 2018. The RCC

expects to see an appropriate plan of action submitted to the Secretariat for consideration by the Commission.

- Bosnia and Herzegovina is considered to be at high risk due to suboptimal vaccine coverage, including among vulnerable groups, low-quality AFP surveillance and failure to mount an adequate response to outbreaks of other vaccine-preventable diseases in the previous years. There appears to have been very little tangible progress in the polio situation made since last year. The RCC would appreciate receipt of a detailed updated national plan of action for outbreak response in line with the GPEI Standard Operating Procedures. The RCC requests the country to provide an update on actions taken to improve polio programme by 1 January 2019.
- The former Yugoslav Republic of Macedonia is considered to be at intermediate risk due to suboptimal polio vaccination coverage with more than 40% of the population living in districts with coverage with a third dose of polio vaccine <90%. Lack of a current national plan of action for outbreak response is also of concern and the RCC expects to see an appropriate plan submitted to the Secretariat for consideration by the Commission.
- Republic of Moldova is considered to be at intermediate risk due to suboptimal population immunity with more than 44% of the population living in districts with coverage with a third dose of polio vaccine <90%. The RCC urges that efforts be made to increase vaccine coverage to the levels achieved in past years. The RCC is also concerned that the quality of AFP surveillance appears to be in decline and urges efforts be made to restore quality to the system.
- Montenegro is considered to be at intermediate risk due to suboptimal population immunity with more than 80% of the population living in districts with coverage with a third dose of polio vaccine <90%. The RCC urges that efforts be made to increase polio vaccine coverage to the levels achieved in past years.
- Romania is considered to be at high risk due to suboptimal population immunity and the failure to mount an adequate response to outbreaks of other vaccine-preventable diseases in the past years. The RCC has received no evidence for improvement in vaccination coverage but noted an improvement in the quality of polio surveillance. The RCC is highly concerned that Romania is considering establishing a PEF and reminds the national authorities that any application from a country with inadequate population immunity is likely to be refused. The RCC requests an update on actions taken to improve polio vaccination coverage by 1 January 2019.
- Serbia is considered to be at intermediate risk due to a combination of factors including suboptimal immunity among subnational population groups, and declining quality of polio surveillance. The RCC is highly concerned that Serbia is considering establishing a PEF and reminds the national authorities that any application from a country with inadequate population immunity and suboptimal polio surveillance is likely to be refused. The RCC commends the NCC and national authorities for submission of a missing national plan of action for outbreak response by the set deadline.
- Ukraine is considered to be at high risk due to low reported and uncertain real vaccine coverage and the failure to mount an adequate response to outbreaks of other vaccine-preventable diseases in recent years. The RCC is concerned that there is very little evidence for change in polio activities since last year but recognizes that systemic changes are underway that could result in improvements starting from 2018. The RCC requests Ukraine to provide an update on actions taken to improve polio vaccination coverage by 1 January 2019.

MECACAR zone

Based on the information available, the RCC concluded that the probability is high that WPV had not been circulating in the zone in 2017 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 ranges from low to intermediate. Of primary concern is the apparent declining vaccination coverage in Kyrgyzstan and the reduced capacity of the national programme to improve both polio vaccination coverage and polio surveillance. Armenia and Turkey have not provided a national plan of action for outbreak response, and the draft plan for Kyrgyzstan has not been approved.

Feedback to the countries

- Armenia is considered to be at low risk. The RCC is concerned, however, over the absence of a national plan of action for outbreak response in line with the GPEI Standard Operating Procedures. National authorities and the NCC are urged to provide a national plan of action to the WHO Secretariat as soon as possible for consideration by the RCC.
- Azerbaijan is considered to be at low risk.
- Georgia is considered to be at low risk. The RCC is concerned, however, over evidence for suboptimal vaccination coverage, with more than 15% of the population now living in districts with coverage with a third dose of polio vaccine <90%. The RCC urges further efforts be made to improve routine immunization coverage.
- Kazakhstan is considered to be at low risk. It is noted, however, that the quality of the report received this year was low and the RCC urges the NCC to provide a comprehensive report next year.
- Kyrgyzstan is considered to be at intermediate risk due to suboptimal polio vaccination coverage and apparent declining capacity of the national programme to address major challenges and constraints. The RCC is concerned that the POSE conducted earlier this year did not fully meet its objectives and that the plan of action for outbreak response has not been approved. The RCC urges that the national plan of action be finalized and a copy submitted to the Secretariat for consideration of the RCC. The RCC strongly recommends nominating a NPCC to ensure proper communication on poliovirus containment activities and updates in the country.
- Russian Federation is considered to be at low risk. The RCC has some concerns, however, over the proposal to establish at least 7 PEFs including both vaccine production facilities and research laboratories. Given the rigorous containment requirements placed on PEFs it may be advantageous to reduce the number of planned facilities. The RCC recommended that the national preparedness plan is developed and shared with the WHO Secretariat.
- Tajikistan is considered to be at low risk. The RCC commends the country on efforts made to maintain its immunization coverage and AFP surveillance quality.
- Turkey is considered to be at low risk. The RCC commends Turkey on the efforts made to
 provide immunization services and polio surveillance to the Syrian refugee populations on
 both sides of the border. The RCC is concerned, however, that despite demonstrating the
 capacity to successfully manage outbreaks, Turkey has no national plan of action for outbreak
 response in line with the GPEI Standard Operating Procedures. National authorities and the
 NCC are urged to provide a national plan of action to the WHO Secretariat as soon as
 possible for consideration by the RCC.

- Turkmenistan is considered to be at low risk. The RCC would appreciate receipt of a detailed national plan of action for outbreak response in line with the GPEI Standard Operating Procedures.
- Uzbekistan is considered to be at low risk.

Conclusions and recommendations to Member States and WHO

Conclusions

Based on the evidence provided, the RCC concluded there was no WPV or VDPV transmission in the WHO European Region in 2017. However, Bosnia and Herzegovina, Romania and Ukraine remain at high risk of a polio outbreak following importation or emergence of VDPV, due primarily to low population immunity. These three countries are requested to provide updates on actions taken to improve polio programmes by 1 January 2019, to be reviewed at the RCC extraordinary meeting in January. In addition, Bulgaria and Serbia were provisionally considered to be at high risk, due to the failure to provide an adequate national plan of action for polio outbreak response in conjunction with other risk factors. The ministers of health and NCC chairs of Bulgaria and Serbia were informed of the provisional classification of high risk status and invited to submit appropriate national plans of action before 1 August 2018. As appropriate national plans of action were timely received by the Secretariat, the overall risk status for Bulgaria and Serbia was reduced to intermediate. A total of 21 Member States were considered to be at intermediate risk of polio and 29 considered to be at low risk.

The RCC acknowledged the efforts and professionalism of the WHO Secretariat in working together with the NCCs in the collection, initial review and finalization of the information provided for assessment by the Commission. The RCC also greatly appreciated the high level of sophistication of the polio programme in the Region and congratulated the WHO Secretariat on the continuing development of innovative approaches to communications on immunization, polio outbreak preparedness, polio risk assessment and online reporting of APRs (e-APR). These innovative developments should be of interest to the other WHO regions and to WHO headquarters. Efforts to make these tools and approaches available to other WHO regions for adaptation and adoption are applauded and further efforts to persuade other regions of the value of these approaches are encouraged.

The RCC commended the efforts made by the NCCs, national authorities and the WHO Secretariat to provide APRs from each of the 53 Member States in advance of the start of the meeting. With very few exceptions, the standard of reports provided has again improved over previous years and is now generally regarded to be high. Further development of the e-APR tool has been undertaken by the Secretariat and the limited trial conducted this year was considered to have been a success. It is expected that the e-APR tool will be finalized for use later this year and all NCCs will use this tool to provide their information in 2019.

The RCC acknowledged the progress being made towards global interruption of WPV transmission but remains concerned over the continued detection of WPV from environmental samples collected from many sites in Afghanistan and Pakistan. The ongoing transmission of cVDPV Democratic Republic of Congo, Kenya, Nigeria, and Somalia is also of great concern, particularly where evidence exists for the emergence of circulating type 2 VPDVs following use of mOPV2 in outbreak response activities. The impact that continuing detection and response to VDPV-associated outbreaks may have on the certification process has not yet been fully determined but would clearly provide a further complication.

On the basis of the evidence provided there is no appreciable indication that the quality of polio surveillance in the Region as a whole has declined in recent years, and while not universally accepted, there are indications that it has marginally improved in some key areas. Assessment of surveillance quality remains a key component of the risk analysis process, but of greater concern, and probably of greater importance, is the demonstration of high levels of routine childhood vaccination

coverage and population immunity to polio. There are indications that vaccine coverage is in decline in a small number of countries in the Region, particularly in middle-income countries that are not eligible for external donor support. While there is no evidence of immediate risk to maintaining regional polio-free status at present, declining performance of immunization programmes is of concern.

The RCC urged all Member States to complete the laboratory surveys and inventories of all type 2 poliovirus materials, including potential infectious materials. WHO has recently published guidance for non-poliovirus facilities to minimize risk posed by sample collections potentially infectious for polioviruses¹ and all Member States should be aware of this guidance and use it. Although not strictly required at this time, the RCC advises all Member States to complete the survey and inventory process for type 1 and type 3 polio materials in addition to type 2 polio materials as this will save considerable time and effort in the near future.

The RCC remains concerned over the number of Member States in the Region notifying their intentions to establish PEFs. While most of the proposed PEFs include vaccine production facilities and large research laboratories with ongoing enterovirus research, the expected role of others is not clear at this point. The RCC strongly urges all Member States contemplating the establishment of PEFs to consider whether or not they need a PEF and whether they are likely to meet the stringent requirements for certifying a PEF.

The RCC commended the work of the CMG and the Secretariat in developing a PEF risk ranking scheme. The RCC hopes that based on this scheme, a unified, global system can be adopted by all WHO regions and encourages the Secretariat to take a lead in working with the other WHO regions to make this come about.

Recommendations

NCCs and their reports

• It is essential that all Member States follow the guidelines previously provided on the composition and membership of NCCs. To avoid potential conflict of interest employees of the national immunization programme, ministries of health or public health institutes cannot serve as members of the NCC. Their role is to provide secretariat support to the NCCs. Member States with NCCs that include members with potential conflict of interest are once again strongly recommended to revise the membership of NCC as a matter of urgency.

Preparedness

• All Member States are required to have a current plan of action to respond to detection of WPV/cVDPV that is aligned with the recommended Standard Operating Procedures for a poliovirus event or outbreak in a polio-free country². Failure to provide an adequate

¹ Guidance for non-poliovirus facilities to minimize risk of sample collections potentially infectious for polioviruses – available at http://polioeradication.org/wp-content/uploads/2018/04/polio-containment-guidance-for-non-poliovirus-facilities-20180410-en.pdf

² Global Polio Eradication Initiative. Responding to a poliovirus outbreak Standard Operating Procedures for a new polio outbreak in a polio-free country. World Health Organization, 2015. Available online at:

http://www.polioeradication.org/Portals/0/Document/Resources/PolioEradicators/1a.PolioOutbreakGuideline20150220.p df

national plan of action will be considered to represent a risk and may result in an increased risk status for a Member State.

- Member States are again reminded of the recommendation to test their preparedness through undertaking national polio outbreak simulation exercises (POSEs) as a matter of course and updating the exercise frequently. In conducting a POSE Member States should consider their highest-priority risks, including risk of importation, risk of VDPV circulation and risk of facility containment breach from a PEF.
- The Secretariat is recommended to continue bringing Member States together for regional POSEs, particularly the countries that have not yet developed or tested their national plans. The RCC recommends that the following Member States consider conducting a POSE in the next 12 months: Albania, Cyprus, Greece, the former Yugoslav Republic of Macedonia and Turkey.

Population immunity

• The Commission continues to be concerned over the continuing decline in immunization coverage in some countries. Whilst this decline may be a result of systemic challenges to delivery of immunization services, all Member States are urged to improve vaccination coverage of the population as a whole, and of at-risk groups in particular.

Containment

- All Member States should be aware of the WHO guidelines for the identification of materials potentially infectious for polioviruses (PIM) within laboratories that handle human stool specimens, respiratory samples, or environmental sewage samples. These guidelines should be used to assess the risk of PIMs in their possession and implement the risk reduction actions consistent with GAPIII, as a matter of urgency.
- Member States considering the establishment of PEFs are again urged to make themselves fully aware of the international requirements, including maintenance of an effective national routine childhood polio immunization programme and high national population coverage with polio vaccine for as long as they maintain a PEF. Countries not meeting these requirements are unlikely to have their applications to establish a PEF accepted.

Annex 1. RCC conclusions on risk of sustained transmission in the event of WPV importation or emergence of VDPV, per Member State in the WHO European Region, based on available evidence for 2017

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

Romania	Good	Low	Yes	High
Russia	Good	High	Yes	Low
San Marino	Average	Average	No	Intermediate
Serbia	Average	Average	No	Intermediate*
Slovakia	Good	High	No	Low
Slovenia	Average	High	No	Low
Spain	Good	High	No	Low
Sweden	Good	High	Yes	Low
Switzerland	Average	High	No	Low
Tajikistan	Good	High	No	Low
TFYR Macedonia	Good	Average	Yes	Intermediate
Turkey	Good	High	Yes	Low
Turkmenistan	Good	High	No	Low
Ukraine	Good	Low	Yes	High
United Kingdom	Good	High	No	Low
Uzbekistan	Good	High	No	Low

*Bulgaria and Serbia were provisionally ranked as at high risk because of failure to submit polio preparedness plans. Since they provided the requested plans by 1 August 2018, their risk ranking was downgraded to intermediate.

Annex 2: Programme

Wednesday	30 May 2018
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09:00-09:15	Opening	WHO/Europe, RCC	
07.00 07.13		-	
<u>Plenary session 1</u> :	Update on global polio eradication and sustaining polio free Europe		
09:15-09:45	Update from WHO/HQ/GPEI	Khan, Z. WHO headquarters	
09:45-10:15	Polio programme annual update from the WHO Region Office for Europe	O'Connor, P. WHO/Europe	
10:15-10:30	Discussion		
11:00-11:30	Current status of poliovirus containment globally and in the European Region	Fournier-Caruana, J. WHO headquarters	
		Gavrilin, E. WHO/Europe	
11:30-11:50	Discussion		
11:50-12:00	Changes to the risk assessment methodology and sub-regional review	Huseynov, S. WHO/Europe	
12:00-12:30	Progress on introducing the online annual reporting system on polio eradication activities (e-APR)	Huseynov, S. WHO/Europe	
12:30-13:30	Lunch		
<u>Plenary Session 2</u> :	Sustainability of polio-free Europe: Review of nationa assessment for 2017 by epidemiological zones	al updated documents and risk	
13:30-14:30	Southern Zone	Huseynov, S. WHO/Europe	
14:30-15:30	Western Zone	Bekenova, Z. WHO/Europe	
16:00-17:00	Central Zone	Bekenova, Z. WHO/Europe	
17:00-17:30	Discussion	All	

Thursday, 31 May 2018*

Plenary Session 2:	Continuation	
09:00-10:00	Nordic-Baltic Zone	Bekenova, Z. WHO/Europe
10:00-11:00	Central Eastern Zone	Huseynov, S. WHO/Europe
11:30-12:30	MECACAR Zone	Huseynov, S. WHO/Europe
<u>Plenary Session 3</u> :	Discussion	
13:30-16:30	RCC discussion	
16:30	Closure	

Annex 3. List of participants

RCC members

Professor David M. Salisbury Chairperson United Kingdom of Great Britain and Northern Ireland

Professor Donato Greco Italy

Dr Tapani Hovi Finland

Dr Anton van Loon Netherlands

Dr Ellyn Ogden United States of America

Observer

Dr Rudi Tangermann France

Representatives

European Centre for Disease Prevention and Control Dr Katrin Leitmeyer Sweden

United States Centers for Disease Control and Prevention Dr Mark A Pallansch United States

United Nations Children's Fund (UNICEF) Dr Basil Rodriques Switzerland

Rapporteur

Dr Raymond Sanders United Kingdom of Great Britain and Northern Ireland

World Health Organization

Headquarters Dr Jacqueline Fournier-Caruana A.i. Containment Team Lead (CNT)

Dr Zainul Khan Technical Officer

WHO Regional Office for Europe

Mr Robb Butler Programme Manager, Vaccine-preventable Diseases and Immunization Programme

Dr Patrick O'Connor Technical Officer

Dr Sergei Deshevoi Technical Officer

Dr Eugene Gavrilin Coordinator, European Polio Laboratory Network

Dr Shahin Huseynov Technical Officer

Dr Zhanara Bekenova WHO Consultant Vaccine-preventable Disease and Immunization Programme

Katharina-Sophia Doležal WHO Intern

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.

Member States

Albania Andorra Armenia Austria Azerbaijan Belarus Belgium Bosnia and Herzegovina Bulgaria Croatia Cyprus Czechia Denmark Estonia Finland France Georgia Germany Greece Hungary Iceland Ireland Israel Italy Kazakhstan Kyrgyzstan Latvia Lithuania Luxembourg Malta Monaco Montenegro Netherlands Norway Poland Portugal Republic of Moldova Romania **Russian Federation** San Marino Serbia Slovakia Slovenia Spain Sweden Switzerland Tajikistan The former Yugoslav Republic of Macedonia Turkey Turkmenistan Ukraine United Kingdom Uzbekistan

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