



## RAPID RISK ASSESSMENT

# Outbreak of circulating vaccine-derived poliovirus type 1 (cVDPV1) in Ukraine

2 September 2015

### Public health event

Two cases of paralytic poliomyelitis caused by circulating vaccine-derived poliovirus type 1 (cVDPV1) were confirmed in Ukraine on 28 August 2015. The cases, a 4-year-old child and a 10-month-old infant, had onset of paralysis on 30 June and 7 July respectively and the positive stool samples were collected from 5–10 July 2015. The genetic similarity between the isolates indicates active transmission of cVDPV1. Both children are from the Zakarpatskaya oblast [region], in south-western Ukraine, bordering Romania, Hungary, Slovakia and Poland. Ukraine has been at high risk of vaccine-preventable diseases outbreaks for several years due to persistent low routine vaccination coverage.

### Main conclusions

Global efforts to immunise children with the oral polio vaccine (OPV) have reduced wild poliovirus cases by 99.9% since 1988. OPV is a very safe vaccine but, because it contains live weakened viruses, it can on rare occasions mutate into circulating vaccine-derived poliovirus (cVDPV). The risk of cVDPV strains emerging from OPV is higher when polio vaccination coverage is low, as has been the case in Ukraine for several years.

The outbreak of poliomyelitis in Ukraine is not unexpected, given the low polio vaccination uptake. In fact, the overall low vaccination coverage in the country means that Ukraine is at increased risk of outbreaks of other vaccine-preventable diseases, including measles and diphtheria.

An outbreak of cVDPV in a poorly-vaccinated population is a serious public health event on a par with an outbreak of wild polio virus. The eventual size of a cVDPV outbreak depends on a number of factors, including the size and density of the susceptible population; the duration of virus circulation before the outbreak is detected; the time taken from detection to response vaccination and the potential for the virus to be transported to susceptible communities elsewhere.

It is likely that the cVDPV1 strain has been circulating for many months in Ukraine and that the virus could be found in other parts of the country. Based on experiences from other similar events in the past, we can assume that the risk of more children presenting with paralytic poliomyelitis in Ukraine is high and that it will remain high until large-scale supplementary immunisations have been implemented, in accordance with WHO recommendations for the control of polio outbreaks.

There is a risk that cVDPV will be imported and transmitted in the EU via a recently infected person shedding the virus, particularly if that person enters an area of the EU with low vaccination coverage. Sub-optimal surveillance practices increase the risk of delayed detection of the virus in both the environment and the population.

The highest risk of importation and onward transmission of cVDPV1 is likely to exist in the border areas with Ukraine, particularly in areas where under-vaccinated populations are concentrated on both sides of the border and where there is a high volume of border crossings in both directions.

However, the risk that importation of cVDPV from Ukraine to the EU/EEA would result in a case of paralytic poliomyelitis is low, given the high polio vaccination uptake in EU/EEA Member States.

## Options for response

Member States are encouraged to review the options proposed by ECDC in the 2013 rapid risk assessment 'Wild polio virus 1 transmission in Israel – what is the risk to the EU/EEA?' [1], and to consider the following options with reference to the outbreak in Ukraine:

- Conduct a rapid review of national polio outbreak response plans, particularly with regard to the availability of vaccine for immediate response in case of a confirmed case of polio within their borders. The Regional Polio Eradication Certification Commission for Europe (RCC) regularly assesses the quality of national polio surveillance based on country reports, and the RCC's findings and recommendations should form the basis for action.
- EU/EEA Member States who conduct environmental surveillance for polioviruses, in particular the countries bordering Ukraine, should consider increasing the sampling frequency and geographical area under surveillance until the outbreak has been brought under control.
- Clinicians, in particular paediatricians, should be alerted to the polio outbreak, the low coverage of routine childhood vaccinations in Ukraine, and the possibility that children arriving from Ukraine may be infected with cVDPV. They should also be reminded that acute flaccid paralysis (AFP) surveillance is based on polio virus identification in faecal samples and that negative test results of samples from other bodily substances do not exclude polio virus infection.
- EU/EEA Member States should give high priority to the assessment of polio vaccination uptake at sub-national and local levels, and make efforts to close immunity gaps in geographic areas and population groups with inadequate vaccination uptake.
- Member States should ensure they have an established mechanism to procure vaccine for supplementary immunisation activities should this be required in response to an outbreak. ECDC encourages Member States to liaise with WHO for vaccine procurement if extra doses are required.
- Public health authorities, travel medicine clinics and other healthcare providers should advise EU residents who plan to visit Ukraine of the need to be up-to-date with their polio vaccinations.

## Source and date of request

This rapid risk assessment was requested by DG SANTE, European Commission on 31 August 2015 following unofficial, but later formally verified reports of two cases of acute flaccid paralysis in Ukraine. The cases, diagnosed on 28 August 2015, were caused by circulating vaccine-derived poliovirus type 1 (cVDPV1).

## Public health issue

The outbreak of cVDPV1 in Ukraine represents a threat to public health in Ukraine and in the EU/EEA Member States. There is an urgent need to assess the risks associated with the event, in particular the risk of further spread within Ukraine, international spread from Ukraine and the risk of importation to and transmission in the EU/EEA.

## Consulted experts

ECDC experts in alphabetical order: Niklas Danielsson, Tarik Derrough, Romit Jain, Josep Jansa, Piotr Kramarz, Lucia Pastore-Celentano, Edit Szegedi.

External expert reviewers: World Health Organization Regional Office for Europe, World Health Organization headquarters in Geneva.

Although experts from the World Health Organization (WHO) reviewed the risk assessment, the views expressed in this document do not necessarily represent the views of the WHO.

All experts have submitted declarations of interest and a review of these declarations did not reveal any conflicts of interest.

## Disease background information

Poliomyelitis (polio) is a highly infectious disease caused by polioviruses. Humans are the only reservoir of the infection and poliovirus is targeted for eradication. The virus is transmitted directly from person-to-person through the faecal-oral and oral-oral routes, and via faecal contamination of water or foods. The virus multiplies in the intestine and infected people excrete large quantities of the virus in their faeces. The majority of infected persons (95%) do not develop symptoms but if the virus invades the nervous system it can cause paralysis within a matter of hours [2]. No specific therapy is available against the virus. Polio mainly affects children under five years of age. One in 200 infections leads to irreversible paralysis. Among those paralysed, 5–10% die when their breathing muscles become immobilised.

Wild polioviruses are classified into types 1, 2 and 3 and there is limited cross-immunity between the types. Effective control and eradication of polio is based on achieving universally high vaccine induced immunity. There are two types of polio vaccines: an oral live attenuated (weakened) vaccine (oral polio vaccine; OPV) and an inactivated (killed) vaccine (inactivated polio vaccine; IPV). IPV contains all three virus types while OPV vaccines are produced in different combinations; trivalent OPV (tOPV), bivalent OPV (bOPV) containing types 1 and 3, and monovalent OPV (mOPV) containing weakened strains of type 1, 2 or 3, respectively. Trivalent OPV continues to be the most commonly used polio vaccine in the world.

Most EU/EEA Member States started their polio vaccination with OPV but today all countries use IPV for the primary and booster vaccination schedule. One country in the EU, Poland, has a combined schedule with IPV in the primary series together with an OPV booster dose. Primary vaccination is given early in life and is typically completed before six months of age. The number and timing of the doses in the primary series differs among EU/EEA Member States and the recommendations for individual countries can be reviewed in the ECDC Vaccine Scheduler [3]. IPV has the advantage of having no risk of causing vaccine acquired paralytic poliomyelitis (VAPP) or the development of virulent vaccine-derived polio viruses (VDPV). OPV is more effective in inducing intestinal antibody production and hence more effective in interrupting virus transmission. The cost of OPV is very low and the oral administration facilitates rapid mass vaccination.

## Polio eradication

In 1988, the forty-first World Health Assembly adopted a resolution for the worldwide eradication of polio, the Global Polio Eradication Initiative (GPEI). Since then, the number of cases has fallen by over 99% from an estimated 350 000 to 416 reported cases in 2013. In 2014, only three countries in the world remained polio-endemic: Nigeria, Pakistan and Afghanistan. In 2015 to date, two countries have together reported 37 cases: Pakistan (29 cases) and Afghanistan (eight cases), all due to wild poliovirus type 1.

The last natural circulation of WPV2 was in India in 1999 and the last WPV3 case was detected in Nigeria in November 2012. Since then, WPV1 has been the only circulating wild type virus.

The last case of endemic paralytic polio in the WHO European Region (i.e. with the source of the infection originating in the Region) was reported in Turkey in November 1998, and the Region was declared polio-free in June 2002. The most recent outbreaks linked to importations into the WHO European Region occurred in 2010 in Tajikistan [4] and in 2013–2014 in Israel where WPV1 was circulating in the environment without causing clinical cases [1,5].

The most recent polio outbreaks in what today constitutes EU/EEA were in the Netherlands in 1992, in a religious community opposed to vaccination, and in 2001, when three polio cases were reported among Roma children in Bulgaria [6,7].

On 5 May 2014, WHO declared the international spread of wild poliovirus in 2014 a Public Health Emergency of International Concern (PHEIC) [8] following the confirmed circulation of wild poliovirus in several countries and the documented exportation of wild poliovirus to other countries. On 17 August 2015, WHO announced that the international spread of polio remains a PHEIC and the Temporary Recommendations (as revised) were extended for three more months [9].

The Polio Eradication and Endgame Strategic Plan 2013–2018 [10] sets out the actions required for a polio-free world by 2018 and beyond.

## Vaccine-associated paralytic polio (VAPP)

The use OPV is estimated to cause one case of vaccine-associated paralytic polio (VAPP) per 2.7 million doses of OPV administered, or 4.7 cases per million births in OPV-using countries [11]. This adverse event from vaccination is caused by the spontaneous reversion to neurovirulence of one of the attenuated viruses in OPV. The genetic diversion from the parental OPV strain is very limited and cases of VAPP occur among vaccine recipients and close contacts. There is no sustained community transmission of VAPP and hence no associated outbreaks.

## Vaccine-derived polioviruses (VDPV)

Vaccine-derived polio viruses are genetically mutated OPV strains that have lost key attenuating mutations and resemble WPVs biologically. The live attenuated oral polio vaccine virus replicates in the intestine after vaccination and the vaccine-virus is usually excreted in the faeces for six to eight weeks. VDPV develop through a series of mutations and acquisition of genetic materials from other enteroviruses, a process that is estimated to take on average at least one year [12]. The critical risk factor for VDPV development is the duration for which the vaccine virus circulates in a population. Average circulation time for OPV virus increases with lower vaccination coverage in the population, hence increasing the risk that VDPV strains will emerge.

Circulating VDPV (cVDPV) are strains that have taken on the neurovirulence and transmissibility of WPV. A cVDPV is associated with person-to-person transmission. An outbreak of cVDPV is defined by the appearance of a single or multiple cases of poliomyelitis due to cVDPV [13] in line with the new classification of vaccine-derived polioviruses [14]. The term 'persistent cVDPVs' refers to cVDPV strains that continue to circulate for more than six months after the first detection.

The first documented cVDPV outbreaks were in Hispaniola in 2000 and in the Philippines in 2001. Evidence of previous circulation of VDPVs have been found in Egypt (1983–93, type 2 vaccine strain), Poland (1968, type 3 vaccine strain) and Belarus (1965, type 2 vaccine strain). During the last ten years, 24 cVDPV outbreaks have occurred in 21 countries, resulting in more than 750 cases of paralytic polio [15]. Not counting the current cases in Ukraine, 10 cases of cVDPV have been reported to WHO to date in 2015, nine in Madagascar and one in Nigeria. The cVDPV lineage isolated from the cases in Madagascar in 2015 is genetically linked to a case reported in September 2014, indicating prolonged and widespread circulation of the virus.

**Table 1 Circulating vaccine-derived poliovirus cases, 2000-2015**

| Country             | cVDPV type 1 <sup>2</sup> |           |          |          |          |           |           |           |           |            |           |           |           |           |           | Onset of most recent case |           |
|---------------------|---------------------------|-----------|----------|----------|----------|-----------|-----------|-----------|-----------|------------|-----------|-----------|-----------|-----------|-----------|---------------------------|-----------|
|                     | 2000                      | 2001      | 2002     | 2003     | 2004     | 2005      | 2006      | 2007      | 2008      | 2009       | 2010      | 2011      | 2012      | 2013      | 2014      |                           | 2015      |
| Madagascar          |                           |           |          |          |          |           |           |           |           |            |           |           |           |           | 1         | 9                         | 07-Jul-15 |
| Mozambique          |                           |           |          |          |          |           |           |           |           |            |           | 2         |           |           |           |                           | 02-Jun-11 |
| Myanmar             |                           |           |          |          |          |           | 1         | 4         |           |            |           |           |           |           |           |                           | 06-Dec-07 |
| Indonesia           |                           |           |          |          |          | 46        |           |           |           |            |           |           |           |           |           |                           | 26-Oct-05 |
| China               |                           |           |          |          | 2        |           |           |           |           |            |           |           |           |           |           |                           | 11-Nov-04 |
| Philippines         |                           | 3         |          |          |          |           |           |           |           |            |           |           |           |           |           |                           | 26-Jul-01 |
| DOR/Haiti           | 12                        | 9         |          |          |          |           |           |           |           |            |           |           |           |           |           |                           | 12-Jul-01 |
| <b>Total type 1</b> | <b>12</b>                 | <b>12</b> | <b>0</b> | <b>0</b> | <b>2</b> | <b>46</b> | <b>1</b>  | <b>4</b>  | <b>0</b>  | <b>0</b>   | <b>0</b>  | <b>2</b>  | <b>0</b>  | <b>0</b>  | <b>1</b>  | <b>9</b>                  |           |
| Country             | cVDPV type 2 <sup>2</sup> |           |          |          |          |           |           |           |           |            |           |           |           |           |           | Onset of most recent case |           |
|                     | 2000                      | 2001      | 2002     | 2003     | 2004     | 2005      | 2006      | 2007      | 2008      | 2009       | 2010      | 2011      | 2012      | 2013      | 2014      |                           | 2015      |
| Nigeria             |                           |           |          |          |          | 3         | 22        | 71        | 68        | 155        | 27        | 34        | 8         | 4         | 30        | 1                         | 16-May-15 |
| Pakistan            |                           |           |          |          |          |           |           |           |           |            |           |           | 16        | 48        | 22        | 0                         | 13-Dec-14 |
| South Sudan         |                           |           |          |          |          |           |           |           |           |            |           |           |           |           | 2         | 0                         | 12-Sep-14 |
| Cameroon            |                           |           |          |          |          |           |           |           |           |            |           |           |           | 4         |           |                           | 12-Aug-13 |
| Niger               |                           |           |          |          |          |           | 2         |           |           | 2          | 1         | 1         |           |           |           |                           | 11-Jul-13 |
| Chad                |                           |           |          |          |          |           |           |           |           |            | 1         |           | 12        | 4         |           |                           | 12-May-13 |
| Afghanistan         |                           |           |          |          |          |           |           |           |           |            | 5         | 1         | 9         | 3         |           |                           | 13-Mar-13 |
| Somalia             |                           |           |          |          |          |           |           |           | 1         | 6          | 1         | 9         | 1         | 1         |           |                           | 09-Jan-13 |
| Kenya               |                           |           |          |          |          |           |           |           |           |            |           |           | 3         |           |           |                           | 29-Aug-12 |
| DR Congo            |                           |           |          |          |          |           |           |           |           | 13         | 5         | 18        | 11        | 17        |           |                           | 04-Apr-12 |
| China               |                           |           |          |          |          |           |           |           |           |            |           |           | 2         |           |           |                           | 06-Feb-12 |
| Yemen               |                           |           |          |          |          |           |           |           |           |            |           | 9         |           |           |           |                           | 05-Oct-11 |
| India               |                           |           |          |          |          |           |           |           |           |            | 15        | 2         |           |           |           |                           | 18-Jan-10 |
| Ethiopia            |                           |           |          |          |          |           |           | 3         | 1         |            |           |           |           |           |           |                           | 16-Feb-09 |
| Madagascar          |                           | 1         | 4        |          |          | 3         |           |           |           |            |           |           |           |           |           |                           | 13-Jul-05 |
| <b>Total type 2</b> | <b>0</b>                  | <b>1</b>  | <b>4</b> | <b>0</b> | <b>0</b> | <b>6</b>  | <b>24</b> | <b>71</b> | <b>85</b> | <b>184</b> | <b>55</b> | <b>65</b> | <b>68</b> | <b>65</b> | <b>54</b> | <b>1</b>                  |           |
| Country             | cVDPV type 3 <sup>2</sup> |           |          |          |          |           |           |           |           |            |           |           |           |           |           | Onset of most recent case |           |
|                     | 2000                      | 2001      | 2002     | 2003     | 2004     | 2005      | 2006      | 2007      | 2008      | 2009       | 2010      | 2011      | 2012      | 2013      | 2014      |                           | 2015      |
| Yemen               |                           |           |          |          |          |           |           |           |           |            |           |           | 3         | 1         |           |                           | 12-Jul-13 |
| Ethiopia            |                           |           |          |          |          |           |           |           |           | 1          | 5         |           |           |           |           |                           | 17-May-10 |
| Cambodia            |                           |           |          |          |          | 1         | 1         |           |           |            |           |           |           |           |           |                           | 15-Jan-06 |
| <b>Total type 3</b> | <b>0</b>                  | <b>0</b>  | <b>0</b> | <b>0</b> | <b>0</b> | <b>1</b>  | <b>1</b>  | <b>0</b>  | <b>0</b>  | <b>1</b>   | <b>5</b>  | <b>0</b>  | <b>3</b>  | <b>1</b>  | <b>0</b>  | <b>0</b>                  |           |

Data in WHO HQ as of 25 August 2015

<sup>1</sup>For cVDPV definition see [http://www.polioeradication.org/Portals/0/Document/Resources/VDPV\\_ReportingClassification.pdf](http://www.polioeradication.org/Portals/0/Document/Resources/VDPV_ReportingClassification.pdf). Niger 2006, 2009 & 2010 and Chad 2010 cVDPVs are linked to the Nigeria outbreak. Kenya 2012 cVDPVs are linked to the Somalia outbreak. Nigeria figures include the following cases with WPV1/cVDPV2 mixture: 2005 - 2, 2006 - 1, 2007 - 1, 2008 - 3, 2009 - 1, 2011 - 1; WPV3/cVDPV2 mixture 2007 - 2. <sup>2</sup>Figures include multiple emergences and transmission chains.

Source: *Global Polio Eradication Initiative*

As of early 2015, 19 countries in the WHO European Region use OPV in their routine immunisation schedules, in some cases already in combination with IPV. With support from WHO and partners, planning is underway for withdrawal of the type 2 component of OPV in all affected WHO countries [16].

Once naturally circulating WPV has been eradicated, cVDPV and accidental release of WPV or cVDPV from laboratories and vaccine production plants will be the only remaining sources of poliomyelitis.

## Risk factors for cVDPV emergence

A fully immunised population is protected against both vaccine-derived and wild polioviruses. It takes many months for a cVDPV to emerge. cVDPV outbreaks have the ability to become endemic, can be spread in any under-vaccinated community, and can be imported to other countries. The key factors favouring cVDPV emergence and spread are the same as for WPV circulation: low polio vaccine coverage rates or poorly conducted supplementary immunisation activities in areas where OPV use continues [17]. The duration and extent of spread are dependent on the magnitude of the immunity gap and the intensity of other risk factors favouring poliovirus circulation (poor sanitation, high population density and tropical conditions). The previous elimination of indigenous wild poliovirus circulation increases the risk because the number of susceptible individuals will increase rapidly in the absence of high rates of polio vaccine coverage and naturally acquired immunity. Outbreaks occur when the density of non-immune persons rises to the point where the chains of cVDPV transmission can propagate. The size of a cVDPV outbreak is a function of the size of the non-immune population and the potential for the outbreak virus to transport to susceptible communities elsewhere. Countries that were (or are) major reservoirs for wild poliovirus circulation, and where the potential for person-to-person poliovirus transmission is greatest, are at particularly high risk of cVDPV emergence, and maintenance of high rates of polio vaccine coverage in these settings is essential. Insensitive surveillance is a risk factor for undetected spread of cVDPV. Apart from the outbreaks in the Philippines (2001) and Poland (1968), VDPV circulation has occurred in areas with very low rates of acute flaccid paralysis (AFP) case reporting [11].

## Response strategies to cVDPVs

Vaccine-derived polioviruses appear to be less transmissible than wild poliovirus. However, outbreak response strategies are the same for cVDPVs and wild polioviruses: to immunise every child under the age of five years several times with OPV to stop transmission. Experience shows that cVDPV outbreaks can be stopped with at least three rounds of high-quality, large-scale supplementary immunisation activities [19]. The speed with which the first-response mass vaccination is implemented is a key determinant of the duration of the outbreak.

## Testing for vaccine-derived polioviruses

All cases of AFP among children under fifteen years of age should be reported and tested for wild poliovirus and vaccine-derived polioviruses within seven days following the receipt of samples by a WHO-accredited laboratory. In 2009, the Global Polio Laboratory Network started using a new method for detecting vaccine-derived polioviruses based on real-time reverse transcription-polymerase chain reaction (rRT-PCR), which targets nucleotide substitutions that occur early in the emergence of a VDPV [18].

## Event background information

On 28 August 2015, two cases of cVDPV1 were confirmed in Ukraine. The cases, a 4-year-old child and a 10-month-old infant, had onset of paralysis on 30 June and 7 July respectively, and the positive stool samples were collected from 5–10 July 2015. The genetic similarity between the isolates indicates active transmission of cVDPV1. Both are from the Zakarpatskaya oblast [region], in south-western Ukraine, bordering Romania, Hungary, Slovakia and Poland [19].

## Polio vaccination situation in Ukraine

Ukraine has been of particular concern due to the overall deterioration of the situation in the country and a low vaccine coverage for the past five years [20]. In recent years a sizeable population susceptible to polio has been accumulating due to under-vaccination. It is estimated there are between 1.5 and 1.8 million polio-susceptible children. In 2013, 19 out of 27 districts reported coverage with three doses of polio vaccine to be <90%. There is a lack of vaccines for routine immunisation services. A review of the AFP surveillance system concluded that the system is functional and sensitive. There are, however, concerns over the sensitivity of the environmental surveillance system. Serological surveys have been conducted but are of questionable value.

Routine immunisation services are reported to be dysfunctional [20] and there is concern that unless there is full national commitment and support, the outbreak response activities will not be implemented effectively. The situation has been further worsened in 2015 by the ongoing political changes and social disruption. The risk of polio virus being transmitted within Ukraine is still considered to be high. In 2014, only 50% of children were fully immunised against polio and other vaccine-preventable diseases. The officially reported vaccination coverage is alarmingly low and currently reported estimates paint an even more serious picture. WHO Regional Office for Europe reports that currently just 14% of infants under one year in Ukraine have received the three requested doses of polio vaccine because of a shortage of the vaccine [19].

The WHO Regional Office for Europe, with the full support of its country office and the Global Polio Eradication Initiative (GPEI) partners, deployed an outbreak response manager to Ukraine on 30 August 2015, along with an epidemiologist and surveillance advisor to accompany the Ministry of Health (MoH) in their case investigation in Zakarpatskaya oblast. By 6 September 2015, the rapid response team will be joined by a laboratory/surveillance officer and a communications advisor. In partnership with UNICEF, WHO has advised MoH on standard operating procedures for mounting a robust outbreak response.

An outbreak response of an internationally-agreed standard, as adopted by the World Health Assembly in May 2015, requires a minimum of three large-scale supplementary immunisation activities with an appropriate oral polio vaccine, to begin within two weeks of confirmation of the outbreak and covering a target population of at least two million children aged under five years, and the public declaration of the outbreak as a national public health emergency.

## ECDC threat assessment for the EU

### Risk of further spread of cVDPV1 in Ukraine

The risk of a polio outbreak, as well as the risk of outbreaks of other vaccine-preventable diseases, have been very high in Ukraine for several years as routine vaccination coverage has continued to fall short of targets and the susceptible population has continued to grow. The current outbreak of cVDPV1 is therefore not unexpected and is a serious public health event that can be considered of the same severity as an outbreak of wild polio virus.

Several factors contribute to the dramatically low vaccination rates in Ukraine, many of them chronic in character: financial constraints for public services, recurrent shortages of vaccines, growing vaccination scepticism, and vocal anti-vaccination lobbyists. This situation has been exacerbated further since the beginning of 2014 by the ongoing armed conflict in the country.

The European Regional Certification Commission (RCC) for Poliomyelitis Eradication reaffirmed the European Region's polio-free status at its 29th meeting in Sarajevo, Bosnia and Herzegovina on 9–10 June 2015. The RCC expressed grave concerns that the past three years of low coverage with polio vaccination in Ukraine, along with the current crisis in the country, pose a serious threat of polio that must be addressed urgently by all stakeholders.

### Risk of importation into and transmission within the EU/EEA

According to the latest estimates from 2013, polio vaccination uptake in the EU/EEA is satisfactory at national levels (>90% for three doses of either IPV or OPV) with the exception of Romania (see Table 2). However, there are pockets of under-immunised or unimmunised people in all EU/EEA countries. Low immunisation levels are found in certain population groups: Roma, travelling communities, disadvantaged groups, and those opposed to vaccination due to religious or philosophical beliefs. Such population sub-groups represent potential risks for localised outbreaks of paralytic poliomyelitis in the event of virus importation into these communities or widespread 'silent' circulation in the general population [21].

It should be noted that many countries estimate coverage for childhood vaccination based on the official catchment population and the number of administered doses or even the number of doses delivered to a health area. Children who are not registered with local health services or lack birth certificates or other documentation may be excluded from the denominator. If they miss out on vaccinations, this will not be reflected in the coverage estimates. An additional risk factor related to under-vaccination of socio-economically disadvantaged groups, such as the Roma, is the geographical clustering of such groups. This can result in a situation where vaccination coverage is considerably below the national average in a smaller geographical area of a country.

The countries considered to be at high risk of polio transmission in 2015 are Bosnia and Herzegovina, Romania and Ukraine. The RCC urges these countries to take immediate steps to improve immunisation programme performance and the quality of polio surveillance.

**Table 2. Vaccination coverage (%) of polio 3 in the four EU Member States bordering Ukraine, 2004–2013**

| Year     | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 |
|----------|------|------|------|------|------|------|------|------|------|------|
| Hungary  | 99.8 | 99.0 | 99.0 | 99.9 | 99.9 | 99.8 | 99.9 | 99.0 | 99.0 | 99.0 |
| Poland   | 98.5 | 98.8 | 99.0 | 98.9 | 98.0 | 95.6 | 95.6 | 96.0 | 95.3 | 95.0 |
| Romania  | 97.2 | 96.9 | 97.0 | 96.0 | 95.0 | 95.0 | 94.0 | 89.0 | 92.0 | 88.0 |
| Slovakia | 99.0 | 99.0 | 99.0 | 99.3 | 99.0 | 99.0 | 99.1 | 99.0 | 98.7 | 98.0 |

Source: CISID (Centralized Information System for Infectious Diseases) [23]

ECDC concurs with WHO's assessment that the risk of international spread from Ukraine is currently low. However, when estimating the risk of spread of the outbreak outside of Ukraine several factors need to be taken into consideration: the population flow through the border areas including migrants; the presence of under-vaccinated and highly mobile groups, such as the Roma, and the local polio vaccination coverage in the bordering districts.

As stated in a previous RRA, the overall threat posed by poliovirus can be considered to be very low in OPV vaccinees for both poliovirus infection and disease; moderate in IPV-only cohorts for poliovirus infection and low for disease; and high in low or unvaccinated groups for poliovirus infection and for disease [1]. The highest level of risk is posed by the proximity of clustered un- or under-immunised population groups to large populations vaccinated using IPV-only schemes. Sub-optimal hygiene and crowded living conditions may also play a role in facilitating the spread of infection.

## Conclusions

Global efforts to immunise children with the oral polio vaccine (OPV) have reduced wild poliovirus cases by 99.9% since 1988. OPV is a very safe vaccine but because it contains live weakened viruses it can on rare occasions mutate into circulating vaccine-derived poliovirus (cVDPV). The risk of cVDPV strains emerging from OPV is higher when polio vaccination coverage is low, as has been the case in Ukraine for several years.

The outbreak of poliomyelitis in Ukraine is not unexpected, given the low polio vaccination uptake. In fact, the overall low vaccination coverage in the country, means that Ukraine is at increased risk of outbreaks of other vaccine-preventable diseases, including measles and diphtheria.

An outbreak of cVDPV in a poorly-vaccinated population is a serious public health event on a par with an outbreak of wild poliovirus. The eventual size of a cVDPV outbreak depends on a number of factors, including the size and density of the susceptible population; the duration of virus circulation before the outbreak is detected; the time taken from detection to response vaccination and the potential for the virus to be transported to susceptible communities elsewhere.

It is likely that the cVDPV1 strain has been circulating for many months in Ukraine and that the virus could be found in other parts of the country. Based on experiences from other similar events in the past, we can assume that the risk that more children will present with paralytic poliomyelitis in Ukraine is high and will remain high until large-scale supplementary immunisations have been implemented, in accordance with WHO recommendations for the control of polio outbreaks.

There is a risk of importation and transmission of cVDPV in the EU via a recently infected person shedding the virus, particularly if that person enters an area of the EU with low vaccination coverage. Sub-optimal surveillance practices increase the risk of delayed detection of the virus in both the environment and the population.

The highest risk of importation and onward transmission of cVDPV1 is likely to exist in the border areas with Ukraine, particularly where under-vaccinated populations are concentrated on both sides of the border and where there is a high volume of border crossings in both directions.

However, the risk that importation of cVDPV from Ukraine to the EU/EEA would result in a case of paralytic poliomyelitis is low given the high polio vaccination uptake.

## Options for response

Member States are encouraged to review the options proposed by ECDC in the 2013 rapid risk assessment 'Wild polio virus 1 transmission in Israel – what is the risk to the EU/EEA?' [1] and to consider the following options with reference to the outbreak in Ukraine:

- Conduct a rapid review of the national polio outbreak response plans, particularly with a view to the availability of vaccine for immediate response in case of a confirmed case of polio within their borders. The Regional Polio Eradication Certification Commission for Europe (RCC) regularly assesses the quality of national polio surveillance based on country reports, and the RCC's findings and recommendations should form the basis for action.
- EU/EEA Member States who conduct environmental surveillance for polioviruses, in particular the countries bordering Ukraine, should consider increasing the sampling frequency and geographical area under surveillance until the outbreak has been brought under control.
- Clinicians, in particular paediatricians, should be alerted to the polio outbreak, the low coverage of routine childhood vaccinations in Ukraine, and the possibility that children arriving from Ukraine may be infected with cVDPV. They should also be reminded that AFP surveillance is based on polio virus identification in faecal samples and that negative test results of samples from other bodily substances do not exclude polio virus infection.
- EU/EEA Member States should give high priority to the assessment of polio vaccination uptake at sub-national and local levels, and make efforts to close immunity gaps in geographic areas and population groups with inadequate vaccination uptake.
- Member States should ensure they have an established mechanism to procure vaccine for supplementary immunisation activities should this be required in response to an outbreak. ECDC encourages Member States to liaise with UNICEF for vaccine procurement if extra doses are required.
- Public health authorities, travel medicine clinics and other healthcare providers should advise EU residents who plan to visit Ukraine about the need to be up-to-date with their polio vaccinations.



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