RISK ASSESSMENT

Wild-type poliovirus 1 transmission in Israel – what is the risk to the EU/EEA?

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Errata: On 26 September 2013, Table 10 was updated to include some missing responses from Member States.

On 8 October 2013, supplementary information in two sentences on p.2. (Event background information) was deleted and added to the footnotes.

The title was also amended from 'Wild-type poliovirus 1 transmission in Israel – what is the risk to Europe' to 'Wild-type poliovirus 1 transmission in Israel – what is the risk to the EU/EEA'. This is to clarify that the risk assessment concerns the EU/EEA Member States within the remit of ECDC.

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Stockholm, September 2013

Contents

Abbreviations

AFP	Acute Flaccid Paralysis
CISID	Centralized Information System for Infectious Diseases (WHO)
cVDPV	circulating vaccine-derived poliovirus
EBM	Evidence-based medicine
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
EEA	European Economic Area
EMA	European Medicines Agency
EPIS	Epidemic Intelligence Information Systems
EVACO	European Vaccination Coverage Collection System
GPEI	Global Polio Eradication Initiative
GPLN	Global Polio Laboratory Network
IPV	Inactivated polio vaccine
OPV	Oral polio vaccine
PCR	Polymerase chain reaction
RCC	European Regional Certification Commission for Poliomyelitis Eradication
SIA	Supplementary immunisation activities
SOP	Standard operating procedures
VAPP	Vaccine-associated paralytic polio
VDPV	Vaccine-derived poliovirus
VENICE	Vaccine European New Integrated Collaboration Effort
VPD	Vaccine-preventable diseases
VRPV	Sabin vaccine-related poliovirus
UNICEF	The United Nations Children's Fund
WHO	World Health Organization
WPV	Wild-type poliovirus

Executive summary

The EU/EEA countries and the rest of the WHO European Region, have been officially polio-free since 2002. Wild-type polio virus 1 (WPV1) has been isolated in sewage and in the faeces of asymptomatic carriers in Israel since February 2013. An assessment has been made of the potential impact of this public health event on the risk of poliovirus importation and re-established circulation in EU/EEA.

Three populations have been evaluated for the risk of infection with WPV (asymptomatic infection and shedding of virus) and the risk of clinical disease (paralytic poliomyelitis) in the EU: cohorts vaccinated with OPV; cohorts vaccinated exclusively with IPV-containing vaccines and population groups with low vaccination coverage, including people for whom the vaccine has failed or who have waning immunity.

Risk assessment

Based on the evidence, there is a risk of importation and re-establishment of WPV into the EU via a recently infected person shedding the virus, if we consider the significant population flow from and to countries where WPV is still circulating, as well as the sub-optimal potential for early detection of the virus in both the environment and the population.

The overall threat posed by poliovirus re-establishment 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 moderate for disease.

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.

Summary of recommendations

Thorough assessment of polio vaccination uptake (in the general population and specific sub-groups), and strengthening of surveillance and laboratory capacity, should be a high priority.

Environmental surveillance, enterovirus surveillance and other types of supplementary surveillance should be strengthened, and EU-level standards and performance indicators should be agreed.

EU/EEA Member States should recommend that all travellers to areas where WPV circulates have an up-to-date polio vaccination status.

Operational and contingency plans are needed in the EU/EEA to mobilise polio vaccine stockpiles in case of evidence of WPV transmission. The availability of poliovirus vaccines for use in the context of an outbreak should be assessed.

Source and date of request

Internal ECDC request – 20 August 2013[1]

Public health issue

Wild-type polio virus 1 (WPV1) has been isolated from sewage water and subsequently in faeces from asymptomatic cases in Israel since February 2013. We need to ascertain the impact of this public health event on:

- the risk of wild-type poliovirus importation into the EU
- the risk of re-establishment of wild-type poliovirus circulation in the EU, and
- the risk of paralytic poliomyelitis in the EU.

In addition, we need to determine the capacity of the polio surveillance systems in the EU/EEA Member States for detecting wild-type poliovirus transmission in a timely manner, and their ability to respond effectively to outbreaks.

[1] The template of the public version of the risk assessment differs from the EWRS version.

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ECDC acknowledges the valuable contributions from the above-mentioned experts and institutions. All external experts have made declarations of interest. It should be noted that while these experts have made comments on the draft text of this document, the final decisions on the content of the risk assessment were made by ECDC's in-house experts. ECDC would also like to acknowledge the valuable contribution of the European Medicines Agency (EMA) , WHO Regional Office for Europe, European Food Safety Authority and the Ministry of Health for Israel.

Event background information

Wild-type poliovirus 1(WPV1) was first isolated from sewage samples collected on 9 April 2013 in Rahat, southern Israel. The isolated strain is related to strains circulating in Pakistan and to the strain detected in sewage in Cairo in December 2012. It is unrelated to the strain currently affecting the Horn of Africa. WPV1 has been detected in a total of 91 sewage samples from 27 sampling sites in southern and central Israel, collected from 3 February to 25 August 2013 [1]. In addition, WPV1 has been isolated in stool samples from 42 people (4.4% of the sampled population) tested in the area [2]. Detailed information about the carriers is missing but all the 42 cases are reported to have been vaccinated with IPV-only schedules, according to Israeli national recommendations (personal communication)[2]. No cases of paralytic poliomyelitis have been reported. This event is significant as it is the first record of widespread wild polio virus circulation with, to date, no identified cases of clinical disease.

Israel implemented a combined IPV + OPV immunisation schedule from 1990 to 2004 and switched to universal IPV-only vaccination in 2005 [3]. The primary series of IPV is given at two, four, six, and 12 months of age and a booster dose is given at seven years. The country has been free of indigenous WPV transmission since 1988 when an outbreak of WPV1 in the Hadera district resulted in 15 cases of paralytic poliomyelitis [4]. Wild-type poliovirus has occasionally been detected in environmental samples collected between 1991 and 2002, without the occurrence of paralytic poliomyelitis cases or evidence of sustained transmission[3].

Supplementary immunisation activities (SIA) with bivalent oral polio vaccine type 1 and 3 started on 5 August in parts of southern Israel and escalated to a nationwide campaign targeting all children below 10 years of age from 18 August 2013 [5]. To date 800,000 of the potential 1.3 million (ages 0-9) are reported to have been vaccinated in the campaign (personal communication). The objective of the OPV SIA is to rapidly boost mucosal immunity in OPV-naïve children vaccinated with IPV in an attempt to interrupt virus circulation.

[2] Three positive samples were collected from the occupied Palestinian territory on 20 August 2013.

[3] Environmental surveillance samples from the occupied Palestinian territory have consistently tested negative for WPV1 from 2002 until the recent isolations.

ECDC threat assessment for the EU

In order to assess the overall threat posed by poliovirus importation and re-establishment in the EU/EEA, the following risks were assessed:

- risk of poliovirus infection and disease according to the immunisation status of the EU/EEA population;
- likelihood of poliovirus importation and re-establishment to the EU/EEA;
- impact on public health in the event of WPV re-establishment in the EU/EEA; and
- availability of operational plans including OPV availability in EU/EEA.

More information on the methods applied and a detailed description of the evidence collected and considered in the risk assessment are available in the annexes and in the 'Supporting evidence' section.

Risk of poliovirus infection and disease according to the immunisation status of the population

Susceptibility of the EU/EEA population to poliovirus

Based on the evidence presented in the *Supporting evidence* section, the following populations have been evaluated for the risk of infection with WPV (carriage and shedding) and clinical disease:

- Populations vaccinated with OPV;
- Cohorts of the EU population only vaccinated with IPV-containing vaccines;
- Low- or unvaccinated population groups in the EU including those for whom vaccine has failed and those with waning immunity.

Given that countries have different vaccination programme histories, the three population groups considered vary in size. To assess the situation at the Member State level, the following parameters need to be taken into account:

- Year of initiation of the polio vaccination programme;
- Historical use of OPV and IPV;
- Historical vaccination coverage by birth cohort;
- Current vaccine coverage at national and sub-national level.

In addition, possible pockets of unvaccinated populations (clustering) should be taken into account.

Box 1. Risk of poliovirus infection and disease according to the immunisation status of the population

As presented in Table 1, the following evaluation assesses the risk of the three populations becoming infected and shedding virus or developing disease, if exposed to the WPV.

- OPV vaccinated are not at risk of getting infected and shedding the virus, or developing the disease.
- Cohorts of the EU population only vaccinated with IPV-containing vaccines are at risk of getting infected and shedding the virus (see *Supporting documentation on population susceptibility and identification of potential risk groups in the EU/EEA*). Moreover, the recent findings in Israel confirm that IPV recipients can carry and sustain the circulation of polio virus in the population. The risk of developing disease is the same as for those vaccinated with OPV.
- Low- or unvaccinated population groups, including those for whom the vaccine has failed and those with waning immunity, may carry and shed the virus and be at increased risk of developing the disease.

The evidence that IPV-vaccinated individuals can become re-infected and shed the virus comes from studies where vaccinated people have been given a challenge dose of OPV vaccine. The main limitation to such OPV challenge studies is that natural exposure to polioviruses may involve different amounts of ingested virus (generally lower) and different media (e.g. contaminated food and water or aerosol droplets). Moreover there is limited knowledge on OPV and IPV vaccines and waning immunity.

Table 1. Probability of infection and/or disease in the three population groups

Population groups at risk by immunisation status	Probability of infection	Probability of disease
OPV vaccinees	Very low	Very low
IPV-only cohorts	Moderate	Very low
Low- or unvaccinated groups	High	Moderate

Likelihood of poliovirus importation and re-establishment into the EU/EEA

Potential routes of importation from countries where WPV is still circulating

Because humans are the only reservoir for polioviruses, travel and migration patterns between the EU/EEA and countries in which WPV circulates will largely determine the risk of the virus being imported into the EU/EEA. Europe has continuously been at risk since it was declared polio-free in 2002.

Countries where WPVs are currently circulating can be grouped into:

- Countries with endemic transmission: Nigeria, Pakistan and Afghanistan
- Countries with recently re-established transmission and paralytic disease: Somalia, Kenya and Ethiopia
- Countries with evidence of transmission but no disease: Israel.

Based on national statistics, 1 778 437 migrants from the six countries with reported polio outbreaks and Israel were living in the EU/EEA in 2010. The countries with the largest expatriate populations were the UK, Germany, Italy, Spain and the Netherlands [6].

Migration for permanent settlement to the UK was at its highest level in 2010, with an estimated 951 191 migrants from the countries in question living in the UK at the time. The largest groups originated from Pakistan (451 712), Kenya (152 999), Nigeria (150 918) and Somalia (110 326).

In Germany, there were 202 638 migrants from polio-affected countries in 2010, the largest groups originating from Afghanistan (79 444), Pakistan (46 253), Nigeria (22 987) and Ethiopia (21 085).

In Italy, the resident population from the countries in question was 148 416 in 2010, the largest groups originating from Pakistan (64 161), Nigeria (52 845), Ethiopia (17 226) and Somalia (8 110).

In 2010, the resident population from the countries in question in Spain was 99 982, the largest groups originating from Pakistan (54 576), Nigeria (38 775) and Israel (2 972).

The resident population from the countries in question in the Netherlands in 2010 was 76 713, the largest groups originating from Afghanistan (30 986), Somalia (13 521), Pakistan (11 113) and Ethiopia (8 144).

Israel is a popular destination for EU travellers and vice versa, and the circulation of WPV1 in Israel is likely to have increased the risk of WPV importation into the EU.

Previous experience and evidence of poliovirus circulation in the EU/EEA

In the recent past, poliovirus, both vaccine-derived (VDPV) and wild (WPV), have been detected in sewage and stool samples in various EU/EEA countries (see *Supporting documentation on the situation in Europe*). The last outbreak in the EU/EEA was in 1992 in the Netherlands, in a religious community opposed to vaccinations. This WPV3 outbreak resulted in two deaths and 71 cases of paralysis. All cases were unvaccinated and there was limited spread of polioviruses outside of the religious community [7].

Another smaller outbreak occurred in Finland 1984 with ten individuals developing clinical disease due to WPV3 and at least 100 000 people estimated to have been poliovirus excretors. The virus was identified in both faecal samples of healthy, fully IPV vaccinated excretors from Finland (adults and children), and in sewage water collected in fourteen cities geographically spread throughout the country [8,9]. However, both the Netherlands and Finland have used inactivated poliovirus vaccine produced by different manufacturers for the elimination of poliomyelitis in their respective countries. The Netherlands used IPV vaccine produced in-country from 1957 and Finland used IPV vaccine manufactured by RIT in Belgium from 1960 to 1985, when they changed to the more potent IPV vaccine produced in the Netherlands.

Based on the latest surveillance data, the European Regional Certification Commission for Poliomyelitis Eradication (RCC) recently concluded that evidence suggests there was no circulation of WPV and VDPV in the European Region in 2012, confirming the polio-free status [10].

Likelihood of detecting circulating poliovirus in the EU/EEA

Poliovirus may be released into the environment through urban sewage (including sewage from healthcare facilities) in areas where poliovirus is shed. Depending on the initial virus concentration and the type of wastewater treatment applied, the probability of finding infectious virus particles in the effluent varies [11-13]. However, once released into the environment, poliovirus is able to survive well in soil or on crops [13-15].

The potential risk of transmission to humans occurs at critical points in the water cycle, depending on the possible usage of treated wastewater. Scenarios for potential transmission across the water cycle are displayed in Table 6. Poliovirus detection in Europe and Israel (2002–2013) [42] (under *Supporting documentation on poliovirus circulation in the environment*). According to EU legislation on water quality, it is not necessary to monitor for poliovirus or Enteroviruses, either in relation to the discharge of wastewater in the environment after treatment, bathing water, or drinking water [16-18]. In areas with potential exposure, such as Israel, environmental surveillance of wild poliovirus can be essential to prevent re-transmission to humans. If such environmental surveillance systems were to be set up in European countries, they would need to target specific populations/areas/practices.

Surveillance programmes for polio in non-endemic or polio-free regions, such as the EU/EEA, are important to detect re-introduction of the virus, prevent further spread of the virus, and prevent new cases of paralytic disease. Regional certification of polio-free status only occurs when all Member States demonstrate the absence of WPV transmission for three consecutive years with agreed performance targets [19]. In 2010–2011, 27 out of 29 EU/EEA countries had compulsory comprehensive reporting for polio cases [20]. However, since Europe has been a polio-free region since 2002, and no cases have been reported in the EU/EEA since 1998, other indicators are used to determine the sensitivity of surveillance for polio. The RCC uses several criteria to assess the performance of polio surveillance [10,21]. These include a health services criterion; the reported rate and completeness of investigation of acute flaccid paralysis cases; timeliness of AFP reporting and the use of supplemental surveillance (enterovirus and/or environmental sampling). The latter three criteria are discussed in *Supporting documentation on surveillance systems for polioviruses in the EU/EEA countries.*

There are many limitations on evaluating the surveillance of polio in the EU/EEA including; the heterogeneity of surveillance systems in terms of sensitivity, timeliness and completeness; the fact that numerous countries do not have a sensitive AFP surveillance system and the lack of supplementary surveillance systems (enterovirus and/or environmental) in some countries. Surveillance for AFP to identify polio cases is currently considered to be the 'gold standard' [22]. A total of 20 out of 30 EU/EEA Member States use AFP surveillance. However, as reported by WHO, only four of 20 EU/EEA Member States had a calculated AFP rate of $\geq$ 1/100 000 persons in 2012 and only three had a calculated surveillance index of >0.8 (Latvia, Lithuania and Cyprus) [23]. In 2012 only seven of the countries reported data in a timely fashion more than 80% of the time [24].

Given the poor quality of AFP surveillance in the EU/EEA, the RCC has encouraged the use of supplementary surveillance [10]. The ten EU/EEA countries electing not to use AFP surveillance use supplementary surveillance for Enteroviruses, environmental samples (primarily sewage), or a combination to detect polio (other AFP surveillance countries may also use some combination of supplementary surveillance). In 2011, WHO European Regional Office determined that Denmark, Finland, France, Iceland, Luxembourg, Netherlands, Sweden, and the UK (all of which did not have AFP surveillance) had 'high quality' supplementary surveillance [24]. There are currently no standards to evaluate the supplemental surveillance used by the other 10 EU/EEA Member States for polio surveillance.

A minority of EU/EEA Member States currently use supplemental surveillance. From varying sources, there are at least six Member States using environmental surveillance and ten using enterovirus surveillance (see Table 8 under *Supporting documentation on surveillance systems for polioviruses in the EU/EEA countries* and personal communication WHO Regional Office for Europe).

Environmental surveillance can be an important tool for shortening the response time between awareness of a PV re-emergence event and response. It plays a critical role during the period between interruption of WPV transmission and certification of polio eradication. Ideally it should also continue to monitor for the emergence of VDPVs, re-emergence of WPVs, or disappearance of all OPV-related strains during the post-eradication and OPV cessation periods [25].

Based on the surveillance data and the reports submitted by Member States, the RCC concluded that the evidence gave no indication of WPV and VDPV circulation in the European Region in 2012 [10]. At the same time, however, RCC expressed increasing concern about the deteriorating quality of AFP surveillance in the European Region and the lack of reports from several Member States [26]. The RCC called upon Member States to improve surveillance for polio. Improving adherence to standard methods of surveillance is critical while developing new, more sensitive methods of surveillance for polio.

In response to the Global Polio Eradication Initiative in 1988, WHO initiated a global laboratory network to support surveillance activities in polio endemic and non-endemic regions. As of 2013, 145 laboratories participate as accredited members of the Global Polio Laboratory Network (GPLN) [27]. The network is coordinated by WHO and through standardised methodology has the primary task of supporting the detection of poliovirus in AFP screening specimens as well as in environmental samples.

Based on the above considerations (potential routes of importation; previous experience and likelihood of detecting circulating poliovirus), there is a likelihood that poliovirus may be imported and re-established in the EU/EEA. Furthermore, based on the limited evidence collected on existing surveillance systems, there is a risk that poliovirus circulation will go undetected if it is imported.

Impact assessment on public health in the event of WPV re-establishment

The following assessment estimates the public health impact in the event that WPV is re-introduced into the EU Member States, depending on the immunity status of the population. The elements considered in the algorithm are: immunisation status of the population (OPV vaccinees, IPV-only cohorts, and low- or unvaccinated groups); vaccination coverage; modes of transmission (oral-oral; faecal-oral); type of immunity induced by OPV vaccines versus IPV vaccines; severity of the disease; ratio of inapparent infection to clinically recognised polio infection and availability of operational plans.

Immunity to polioviruses in EU/EAA populations

Assessing immunity to polioviruses in EU/EEA populations is complex and dependent on a variety of factors such as genetics, previous environmental exposure to one or several wild-type or vaccine-type polioviruses, previous exposure to other Enteroviruses, type/s of vaccine offered throughout life, number of doses and timing of earlier vaccinations and (in infants) presence of maternal antibodies. The current EU/EEA population is a mix of individuals born in an EU/EEA Member State or elsewhere. Wild-type viruses circulated widely in Europe and world-wide until the early 1960s and large populations living in the EU/EEA may therefore have been exposed to wild-type polioviruses (one or several serotypes) in Europe or elsewhere.

Poliovirus shedding in OPV & IPV recipients

Polio virus (PV) is highly contagious: infected individuals shed virus in faeces and from naso-pharyngeal mucosa. The mode of transmission is person-to-person, both via the faecal-oral and the oral-oral routes (the latter being most probable in developed countries with high hygiene standards). Poliovirus excreted through the faecal route may be identified in sewage water. The period of communicability lasts for as long as virus is excreted (also from asymptomatic persons).

Both IPV and OPV induce an immune response that protects individuals from disease, including paralytic poliomyelitis. A significant difference between the two vaccines is that the IPV induces weaker gut mucosal immunity compared to OPV. This means that IPV-vaccinated individuals are at higher risk of asymptomatic intestinal infection and shedding of virus than OPV-vaccinated individuals. IPV-vaccinated individuals are therefore more likely than OPV-vaccinated individuals to contribute to the circulation of poliovirus [28,29]. However, during the outbreak in the Netherlands in 1992 no poliovirus excretors were identified in healthy IPV-vaccinated (produced in the Netherlands) individuals [30]. No evaluation has been conducted comparing mucosal immunity and or excretion following different IPV vaccines. Therefore, although infection in individuals with prior immunity through vaccination does not lead to disease, prior immunisation with IPV may not protect individuals from the infection itself and may potentially play a role in poliovirus transmission *(Supporting documentation on population susceptibility and identification of potential risk groups in the EU/EEA)* [31].

Vaccination coverage in the EU/EEA

Vaccination coverage levels in the EU/EEA can be considered satisfactory as a whole (>90% for three doses of either IPV or OPV) and can largely justify the absence of WPV circulation in the region so far. However, in the EU/EEA there are significantly large pockets of population sub-groups that are under-immunised or not immunised at all. Moreover, a gradual accumulation of unvaccinated children (from 5% up to 20% every year in some EU countries) progressively increases the overall susceptible population. A rough estimate, based on officially reported vaccine coverage data indicates that in the EU/EEA population aged of 0–29 years, up to 12 million people are not vaccinated against polio (see Table 2). These calculations represent a two-year coverage period and may therefore over-estimate the number of people susceptible as they do not take into account late immunisation.

According to historical changes in the polio vaccination programmes, a large proportion of the EU/EEA population can be considered OPV-naïve. In fact, in most of the Nordic countries and the Netherlands, IPV has been used for the universal routine programme since polio vaccination was introduced (and OPV was only used when facing outbreak situations). Several EU countries adopted IPV-only vaccination in the 1990s and as of 2010, all EU/EEA[4] countries had switched to IPV-only schedules for the primary vaccination series. Only one EU/EEA Member State, Poland, uses a mixed schedule and provides OPV as a booster dose. In the age group 0–29 years up to 70 million

[4] Note: Liechtenstein has not been included in this analysis

people have been vaccinated using an IPV-only schedule. This population represents a large potential reservoir for sustaining wild poliovirus circulation in the event of a re-introduction of polio into the environment.

The highest risk of re-introduction and sustained circulation of WPV occurs where susceptible populations are clustered together with a large potential reservoir.

Table 2. Polio immunisation status in the age groups 0–29 years among the EU/EEA population (in millions). Estimate based on WHO/CISID vaccine coverage and Eurostat population data

Age groups	Unvaccinated	IPV-only	OPV
0–9	2.3	43.7	7.1
10–19	2.7	17.7	34.2
20–29	6.5	7.4	51.0
Total 0–29	**11.5**	**68.8**	**92.3**

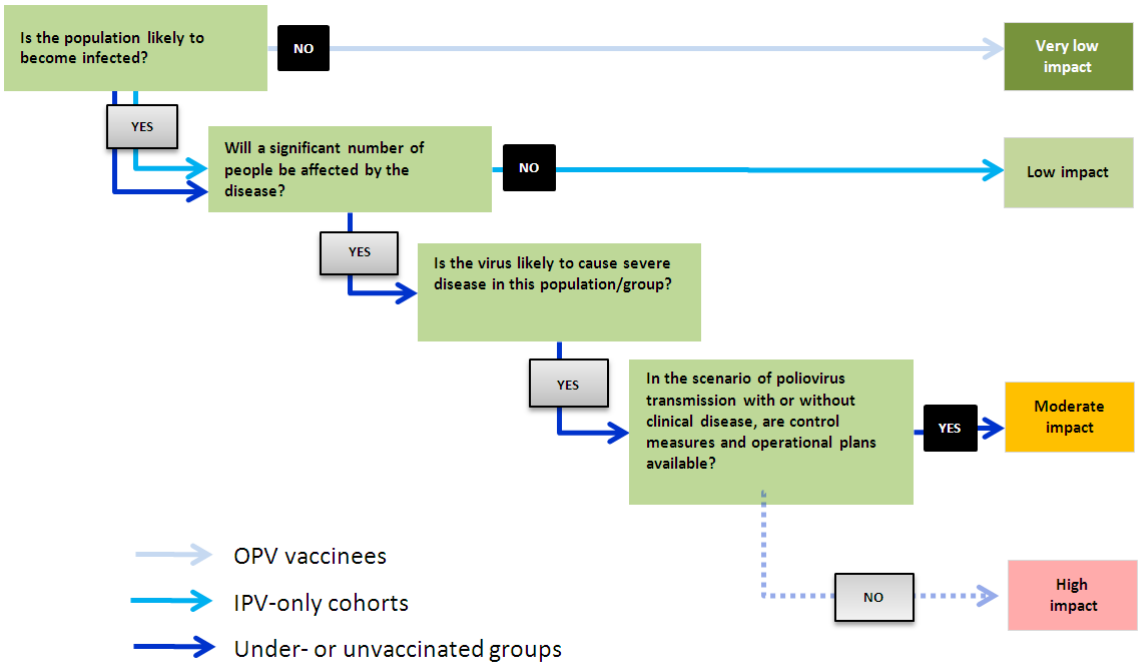
Box 2. Main conclusions from the impact algorithm

In the event of WPV being re-introduced, based on the evidence, the following conclusions can be drawn from the impact algorithm:

- As OPV vaccinees are unlikely to become infected, the impact is considered to be very low;
- Although IPV vaccinees are protected against disease, they are more likely to be susceptible to gut mucosal infection and therefore more likely than OPV vaccinees to contribute to the circulation of virus, even if they are unlikely to develop the disease. For these reasons the impact is considered to be low;
- Unvaccinated individuals are at high risk of becoming infected and at moderate risk of developing the disease. However, the presence of control measures and operational plans in numerous EU/EEA Member States reduces the impact to moderate.

Figure 1 shows the algorithm and the assessed impact for each population at risk.

Figure 1. Public health impact in the event of WPV re-introduction by population at risk



Operational plans including OPV availability in EU

The Global Polio Eradication Initiative Strategic Plan 2013–2018 [32] includes:

- Strategic approaches to end all polio disease (wild and vaccine-related);
- An urgent emphasis on improving immunisation systems in key areas;
- The introduction of new, affordable inactivated polio vaccine;
- Options for managing long-term poliovirus risks and potentially accelerating wild poliovirus eradication, risk mitigation strategies to address new threats, particularly insecurity in some endemic areas;
- Contingency plans, should there be a delay in interrupting transmission in such reservoirs;
- A specific timeline to complete the programmes and a legacy planning process to extrapolate lessons learned from the Global Polio Eradication Initiative and put in place the infrastructure to deliver other critical health and development resources and ultimately, complete the Global Polio Eradication Initiative programme.

The four main objectives of the new plan are:

- Poliovirus detection and interruption (by 2014);
- Strengthening of immunisation systems and the withdrawal of oral poliovirus vaccine (OPV) (by 2016);
- Containment and certification (by 2018);
- Legacy planning.

To map the current availability of IPV stockpiles in the event of an outbreak and the existence of outbreak control plans in EU/EEA Member States, the ECDC carried out a rapid inquiry through the EPIS-VPD platform. Of the fifteen responding Member States, five reported having IPV stockpiles, albeit limited, and 13 reported having an updated outbreak control plan for poliovirus outbreaks (see Table 5 and Table 10 in the section *Supporting documentation on operational plans including OPV availability in the EU*).

In order to assess the availability of and access to OPV outbreak control, EMA (the European Medicines Agency) and ECDC conducted a joint rapid survey through their official contact points in the EU/EEA Member States (see Table 5 and Table 10 under *Supporting documentation for operational plans including OPV availability in the EU*). From the two surveys mentioned we can conclude that IPVs are authorised in all EU/EEA Member States and readily available for use in universal childhood vaccination programmes. Furthermore, trivalent oral polio vaccines (tOPV) are authorised in eight Member States but no country maintains OPV stockpiles for possible outbreak response. Poland uses OPV in its routine immunisation schedule as a booster dose at the age of six years after

primary IPV vaccination during the first year of life and therefore only has limited OPV stocks for supplying the vaccination programme. Italy has authorised trivalent OPV, bivalent OPV (PV1 and 3), monovalent OPV (PV1) and monovalent (PV3) produced by Novartis, a supplier to UNICEF. However, although OPV vaccines have national marketing authorisation in Italy (according to Dir. 2001/838/EC), the products are not available on the market as they are not part of the current national immunisation schedule. All countries that responded to the survey plan to use IPV as their first choice for outbreak control.

In the event of extensive transmission not being controlled by IPV vaccination, the use of monovalent OPV (mOPV) is considered to be the standard response to an outbreak, according to WHO guidance [33]. However, mOPV is currently not available on the EU market, and would therefore have to be used as an unlicensed product or licensed by means of an emergency procedure to rapidly authorise the use of a non-licensed OPV vaccine in response to an outbreak.

The experience from Finland in 1984 and from the current situation in Israel suggest that OPV may be necessary to clear the transmission of polioviruses in the respective populations. In addition, the impact of IPV vaccines in an outbreak setting needs to be further explored since there appear to be countries where no WPV transmission into the vaccinated populations has been observed (e.g. the Netherlands).

Threat posed by poliovirus re-establishment in the EU/EEA

The threat posed by poliovirus importation and re-establishment in the EU/EEA has been assessed combining the probability of infection/disease and the impact on public health (see Figure 1). This was done for the three population groups at risk. In case of uncertainty and identified knowledge gaps, the algorithm adopts a precautionary approach, stepping up the level of risk by one (see *Annex – Methodology*)

Box 3. Assessed threat posed by poliovirus importation and re-establishment into the EU/EEA

Using the algorithm (Figure 3 in the annexes), the overall threat posed by re-establishment of poliovirus into the EU/EEA can be assessed as follows:

- Very low in OPV vaccinees for both poliovirus infection and disease;
- Moderate in IPV-only cohorts for poliovirus infection and low for disease;
- High in low-or unvaccinated groups for poliovirus infection and moderate for disease.

Conclusions

Europe has been polio-free since 2002 and the latest assessment by the RCC concludes that in 2012 there was no evidence of wild-type or vaccine-derived polio viruses circulating in the region.

Detection of WPV in environmental samples is a signal of WPV transmission in the population and consequently a potential risk of paralytic poliomyelitis. A risk of asymptomatic gut mucosal infection and virus shedding remains after both IPV and OPV vaccination, although the risk is higher for those who are IPV-vaccinated. Israel is a popular destination for EU travellers and vice versa, and the circulation of WPV1 in Israel is likely to have increased the risk of WPV importation into the EU.

Given the significant population flow from and to countries where WPV is still circulating, the existence of areas with low vaccine coverage and the sub-optimal potential for early detection of the virus in both the environment and the population there is risk that WPV could be imported and re-established in the EU via a recently infected person shedding the virus.

However, lack of observed WPV circulation in the EU/EEA to date may be due to the limited number of locations in the world where WPV circulates; the fact that infected persons do not shed much virus, or for a very long time, and the high vaccination uptake of visitors to these areas. Moreover, proper sewage treatment in EU countries may contribute to mitigating the risk. In support of this statement, although there are large migrant populations in EU countries that have frequent contact with polio endemic countries (Pakistan, Nigeria) or countries with recent onset of large outbreaks (Somalia), importation of WPV has to date not been documented in such populations.

Consequently, assuming that WPV is imported and re-established in the EU/EEA, the overall threat posed by poliovirus re-establishment can be considered:

- Very low in OPV vaccinees for both poliovirus infection and disease
- Moderate in IPV-only cohorts for poliovirus infection and low for disease
- High in low- or unvaccinated groups for poliovirus infection and moderate for disease.

If WPV is imported into the EU/EEA, the highest risk for establishment of circulation is within unvaccinated groups. The risk is also high in geographically clustered, under-vaccinated groups and in groups that live in poor sanitary conditions. If WPV were to be introduced into an unvaccinated group with close social contact among the members, then it is likely that the virus would spread quickly through a large proportion of the group, and that the circulation would result in paralytic cases.

There are several under-vaccinated groups at particular risk of polio in the EU. Orthodox religious groups, among whom low vaccination coverage is often reported, are likely to be at increased risk of exposure to the WPV1 currently circulating in Israel as a result of frequent direct or indirect contacts with that country.

Other potentially under-vaccinated groups in the EU at increased risk of exposure to poliovirus through contacts with family and friends in polio transmission areas include those linked to countries with sustained poliovirus circulation. In addition, ethnic Roma represent a large, under vaccinated risk group often living under socio-economic conditions that increase the risk of imported poliovirus being transmitted.

Vaccination uptake of IPV, and previously of OPV, is high in the EU and both vaccines effectively prevent disease. The risk of asymptomatic WPV infection is likely to be higher among IPV-vaccinated individuals than among OPV-vaccinated, but both vaccines significantly reduce the risk of infection and the overall quantity of viruses shed in the event of infection. The use of either vaccine has resulted in the elimination of WPV circulation in the EU countries.

Satisfactory levels of vaccination coverage (>90% for three doses of either IPV or OPV) can largely justify the absence of disease in the EU/EEA (see Figure 5 and Table 14 in the annexes). On the other hand, the recent events in Israel raise new questions on the potential for the importation and re-establishment of WPV in the general population or in selected population subgroups, fully immunised with IPV.

Interventions aimed at preventing poliomyelitis cases and the re-establishment of WPV circulation in the EU are likely to reduce the risk of established virus transmission in low or unvaccinated population groups. A reduction in the risk of virus circulation in under-vaccinated groups can, in the short term, be achieved by increasing vaccination uptake in these risk groups and through the early detection of WPV transmission. All EU travellers to areas where WPV is circulating should be up-to-date with their polio vaccination status.

Experiences from the Netherlands show that people who object to vaccination on religious grounds are unlikely to change their opinion and accept vaccination unless an outbreak has been established. However, once the outbreak is a fact, uptake often increases even among vaccine opponents.

AFP surveillance is a blunt instrument for detecting WPV circulation because of the high ratio of asymptomatic-to-symptomatic polio cases and the fact that few EU/EEA countries meet current guidelines for APF surveillance. By the time a case of polio is detected through AFP surveillance, the WPV virus is likely to have spread widely in an unvaccinated population. Environmental surveillance has the advantage of potentially signalling WPV circulation before cases of poliomyelitis have occurred, as exemplified by the developments in Israel. However, although a limited number of EU/EEA Member States (at least five) conduct environmental surveillance, there are no agreed standards for routine environmental surveillance in polio-free areas, and the chance of environmental surveillance identifying just one imported case is considered to be very low [22].

Established outbreak guidelines have the potential to improve the timeliness and effectiveness of outbreak control measures. The number of EU/EEA Member States with outbreak control guidelines is sub-optimal (see *Supporting documentation for operational plans including OPV availability in the EU*).

Therefore, international cooperation can be the key to an effective outbreak response. Prior information on stockpile availability (in Member States and at UNICEF) is needed, as well as the existence of political approval processes for exchanging the existing stockpile between donor and recipient countries (shipment procedures, customs clearance and product liability issues). Outbreak management is the responsibility of the EU/EEA Member State and careful monitoring of the outbreak response is crucial.

Recommendations

- EU/EEA Member States should give high priority to the assessment of polio vaccination uptake at national, sub-national and local level, and to the identification of vulnerable and under-vaccinated populations.
- Countries where the overall national vaccination coverage is below 90% should increase efforts towards improving vaccination coverage under the national schedule.
- The highest level of risk is posed by the proximity of low- or unimmunised population clusters to large populations vaccinated using IPV-only schemes, however suboptimal hygiene and crowded living conditions may also play a role in facilitating the spread of infection. In particular, religious groups having contact with Israel, migrant residents visiting family and friends in countries where WVP is circulating, and vulnerable groups living in poor sanitary conditions are key risk groups. Countries with groups living in such conditions should urgently consider implementing targeted action and improving vaccine coverage in these groups.
- EU/EEA Member States should recommend all travellers to areas where WPV is in circulation to have an up-to-date polio vaccination status.
- Member States not meeting the polio surveillance requirements established by the Regional Certification Commission for Polio Eradication should urgently consider strengthening their surveillance systems, and to at least comply with the minimum AFP surveillance standards if this is the only surveillance system in place.
- Member States with pockets of unvaccinated individuals should consider strengthening or establishing environmental and enterovirus surveillance in these areas, as a complement to AFP surveillance.
- Member States should consider assessing their current laboratory capacity for polio virus detection.
- The role of environmental and enterovirus surveillance should be further discussed at the EU/EEA-level with a view to agreeing on common standards and indicators. ECDC and the Member States, in close collaboration with WHO, should engage in the development of guidance for the establishment of environmental and enterovirus surveillance.
- Member States identifying positive environmental or enterovirus samples should be prepared to use WHO guidelines to assess WPV circulation in the affected areas.
- Member States that have not yet developed national response plans should develop these plans and consider requesting support from ECDC and WHO.
- In the event that positive human samples are detected, Member States should implement their national poliomyelitis response plan. In the unfortunate event that a national plan is not yet available, an emergency plan should be developed on the basis of WHO guidance and recommendations.
- Member States should be undertaking exercises to test their poliomyelitis response plans.
- Operational and contingency plans are needed in the EU/EEA for the possible mobilisation of IPV and OPV stockpiles in case of evidence of WPV transmission.
- The availability of poliovirus vaccines to be used in the context of an outbreak should be assessed.

Supporting evidence

Risk assessment – working table for risk assessment

To assess the risk to the EU/EEA population of being infected and/or affected by the disease; the likelihood of poliovirus being imported and re-established in the EU/EEA; the impact that such an event would have on public health in the EU/EEA and the overall threat posed by poliovirus re-establishment to the EU/EEA a working table was compiled and then used as the basis for this risk assessment (see Table 3).

Table 3. Working table for risk assessment

Question/issue under consideration	Parameters to consider	Summary of evidence	Source of evidence	Quality of evidence	Comments (to address gaps, doubts and uncertainties)
1. Are there specific groups at increased risk of infection? **YES**	• Vaccination coverage to identify countries, regions or specific low-vaccinated population groups. • Switch from OPV to IPV in the majority of EU Member States (description of cohorts fully vaccinated with IPV) • Population protection vs. individual protection provided by vaccination. • Last circulation of VDPV/WPV (last outbreak, last case) in the EU. • Waning immunity following IPV and OPV vaccination. • Vaccine failures. • Persons with impaired B cell immunity.	• OPV vaccinees. • Cohorts of the EU population only vaccinated with IPV-containing vaccines. • Low- or unvaccinated population groups in the EU (including vaccine failure and waning immunity).	• Risk assessment - *Supporting documentation on population susceptibility and identification of potential risk groups in the EU/EEA* • Text books • Peer-reviewed references • ECDC technical documents • Expert opinions	Good	• Limited knowledge of risk of infection and spread of wild virus by cohorts of individuals only vaccinated with IPV.

Question/issue under consideration	Parameters to consider	Summary of evidence	Source of evidence	Quality of evidence	Comments (to address gaps, doubts and uncertainties)
2. Is poliovirus likely to be imported into EU Member States? **YES**	• Humans are the only reservoir for polioviruses. Travel and migration patterns between the EU/EEA and endemic countries will influence the risk of WPV introduction into the EU/EEA. There has been an ongoing risk in Europe since it was declared polio-free in 2002. • Countries where wild poliovirus is currently in circulation can be grouped into the following categories: – endemic countries - Nigeria, Pakistan and Afghanistan – countries with recent transmission: Somalia, Kenya and Ethiopia – countries with evidence of an environmental presence of WPV and human carriage (no polio cases) (Israel). • Risk factors for infection among travellers to and from areas with active transmission of polioviruses include: – vaccination history – age (under six months not fully vaccinated) – destination – hygiene standards (type of accommodation, length of stay).	• Spread to Member States from affected countries. (endemic, recent transmission and isolation). • Probability of virus being introduced varies according to country of importation and nature of contact patterns. • To date, no documented importation of WPV into the EU/EEA from endemic countries. • OPV shedding is occurring in the EU as one country is still using OPV as part of their immunisation schedule. • WPV1 has been detected in 91 sewage samples from 27 sampling sites in southern and central Israel, collected between 3 February and 25 August 2013. • WPV1 has also been isolated in stool samples from 42 people (4.4% of the sampled population) tested in the area.	• Risk assessment - *Supporting documentation on the global polio situation* and *Supporting documentation on the situation in Europe)* • Peer-reviewed references • ECDC technical documents (Annual Epidemiological Reports) • World Bank • ECHA (European Chemicals Agency) • UNOCHA • Bio.Diaspora • ECDC Risk Assessment 2009 (summary table)	Satisfactory (Frequent connection with affected areas in the world but difficult to quantify the risk of importation).	• Re-consider the need for OPV booster doses. • Need to follow national vaccine recommendations for travel to endemic areas.

Question/issue under consideration	Parameters to consider	Summary of evidence	Source of evidence	Quality of evidence	Comments (to address gaps, doubts and uncertainties)
3. Is there potential poliovirus circulation in the environment in the EU? **YES (cVDPV)**	• Environmental surveillance • (Standards for environmental surveillance?) • Infectivity and infectiousness, availability of route for introduction/spread, size of susceptible population and likely number of cases. • Likelihood of WPV and cVDPV circulating in the environment. • Procedures for wastewater sanitation in the EU.	• Annual country report to RCC (performance of surveillance systems and laboratories) • Sporadic detection of vaccine-derived poliovirus in Europe in the recent past (and wild poliovirus detection in Switzerland in 2007-2008) • The release of poliovirus may occur in the environment through urban sewage (including sewage from healthcare facilities) in areas where poliovirus is shed.	• Risk assessment - *Supporting documentation on the situation in Europe* and *Supporting documentation on surveillance systems for polioviruses in the EU/EEA countries*) • 27th RCC report 2013 • Member States' surveillance data • ECDC Rapid risk assessment 2009 • Peer-reviewed references (procedures for wastewater sanitation).	Satisfactory	• How likely is it that a similar scenario to that in Israel could develop in EU Member States (i.e. in a country with high polio vaccination coverage with IPV, environmental and enterovirus surveillance in place)? • No EU-wide environmental surveillance of WPV. The detection of virus in sewage in Israel may indicate the likely presence of the virus in all neighbouring countries. The virus may already be present in sewage from some EU countries. • Monitoring of poliovirus or Enteroviruses is not specifically required under EU legislation on water quality, (including discharge of wastewater into the environment after treatment), bathing water, or drinking water.

Question/issue under consideration	Parameters to consider	Summary of evidence	Source of evidence	Quality of evidence	Comments (to address gaps, doubts and uncertainties)
4. Is there a risk that poliovirus circulation will go undetected in the EU/EEA and thereby delay timely and effective control measures? **YES**	• Regional certification of polio-free status only occurs when all Member States demonstrate the absence of WPV transmission for three consecutive years with surveillance meeting performance targets. • Probability of timely detection of infected people through existing surveillance systems: – Consider the types of surveillance systems in place: AFP, environmental, enterovirus or other – Sensitivity and timeliness of the surveillance system.	• WHO-EURO epidemiological brief (sensitivity of AFP, number of cases) • Heterogeneity of surveillance systems in terms of sensitivity, timeliness and completeness • Majority of countries do not have a sensitive AFP surveillance system (according to WHO threshold of >=1/100 000) • Not all countries have supplementary surveillance systems (enterovirus and/or environmental) • Data available from the existing environmental surveillance systems in Europe are not representative of the EU/EEA overall.	• Risk assessment - *Supporting documentation on surveillance systems for polioviruses in the EU/EEA* and *Supporting documentation on detection and diagnosis (laboratory capacity)* • 27th RCC report 2013 • WHO-EURO/AFP surveillance.	Unsatisfactory	• AFP: Probably not useful for detecting transmission • No agreed threshold at EU level for enterovirus testing • No published guidelines for timing, location, frequency, or population size for environmental samples.

Question/issue under consideration	Parameters to consider	Summary of evidence	Source of evidence	Quality of evidence	Comments (to address gaps, doubts and uncertainties)
5. Is the population likely to become infected? • OPV vaccinees: **NO (apart from a small proportion of individuals with waning immunity)** • Cohorts of the EU population only vaccinated with IPV-containing vaccines: **YES** • Low- or unvaccinated population groups in the EU: **YES**	• Agent • Reproductive rate • Modes of transmission (oral/oral, faecal/oral) • Period of communicability • Vaccination status • Contact patterns • Living conditions	• Wild poliovirus: three serotypes WPV1, WPV2 and WPV3. • Highly contagious: infected individuals shed virus in faeces and from the naso-pharyngeal mucosa. • The mode of transmission is person-to-person, both via the faecal-oral and the oral-oral routes (the latter being the most probable in developed countries with good standards of hygiene). • The period of communicability lasts as long as the virus is excreted (also from asymptomatic persons). • OPV induces mucosal immunity in the gut (being a prerequisite for reducing intestinal reinfection with poliovirus), in subsequent virus shedding, faecal-oral transmission to susceptible contacts and nasopharyngeal immunity • IPV induces a weaker mucosal immunity in the gut than OPV, but induces nasopharyngeal immunity.	• Risk assessment - *Supporting documentation on population susceptibility and identification of potential risk groups in the EU/EEA* • Text books • Peer-reviewed references (OPV challenge studies) • Expert opinions.	Satisfactory	• Poliovirus shedding in IPV recipients: limited knowledge, main findings come from OPV challenge studies. • Limitation to all OPV challenge studies is that natural exposure to polioviruses may involve different amounts of ingested virus (generally lower) and different media (e.g. contaminated food, aerosol droplets). • Limited knowledge on the waning immunity of OPV and IPV vaccines.

Question/issue under consideration	Parameters to consider	Summary of evidence	Source of evidence	Quality of evidence	Comments (to address gaps, doubts and uncertainties)
6. Is the population likely to develop disease? • OPV vaccinees: **NO** • Cohorts of the EU population only vaccinated with IPV containing vaccines: **NO** • Low or unvaccinated population groups in the EU: **YES**	• Vaccination coverage to estimate the size and characteristics of the susceptible population. • Seroprevalence studies. • Asymptomatic infections with laboratory confirmation versus clinical infections. • IPV versus OPV herd immunity.	• Europe has been a polio-free region since 2002. • Vaccination coverage is at sub-optimal level in some areas. • Evidence of short- and long-term carriage in vaccinated population (depending on immunological status of subjects) • Herd immunity can be achieved through OPV-only, combined IPV/OPV and IPV-only schedules. • However, it is important to point out that the evidence for herd immunity with IPV vaccines comes from countries where oral-oral transmission was probably the dominant mode of transmission.	• Risk assessment - *Supporting documentation on population susceptibility and identification of potential risk groups in the EU/EEA*) • WHO-EURO CISID • EVACO (ECDC/VENICE pilot project on vaccine coverage) • Peer-reviewed references • ECDC technical documents • Text books	Satisfactory /unsatisfactory	• Proportion of population needing to be vaccinated to avoid/interrupt transmission not known. • Does carriage exist? How to differentiate from asymptomatic infections? • Limited number of studies on serology (and no standardised threshold for protection correlates).

Question/issue under consideration	Parameters to consider	Summary of evidence	Source of evidence	Quality of evidence	Comments (to address gaps, doubts and uncertainties)
7. Will a significant number of people be affected by the disease? • OPV vaccinees: **NO** • Cohorts of the EU population only vaccinated with IPV containing vaccines: **NO** • Low- or unvaccinated population groups in the EU: **YES**	• Distinction between asymptomatic infections (shedding virus) and clinical cases • Vaccination coverage to estimate the size and characteristics of the susceptible population.	• Both IPV and OPV induce serum antibodies that protect individuals from disease, including paralytic poliomyelitis • Unvaccinated population will be at risk, including: – those who have not been vaccinated (hard to reach, sceptics or just missing vaccinations) – those in whom vaccine has failed (primary or secondary).	• Risk assessment - *Supporting documentation on population susceptibility and identification of potential risk groups in the EU/EEA* • Text books • WHO CISID • EVACO (ECDC/VENICE pilot project on vaccine coverage).	Unsatisfactory	• Carriers vs. asymptomatic infections • Vaccine coverage data missing or non-reliable in some countries, for some regions or sub-groups.

Question/issue under consideration	Parameters to consider	Summary of evidence	Source of evidence	Quality of evidence	Comments (to address gaps, doubts and uncertainties)
8. Is the virus likely to cause severe disease in this population/group? • OPV vaccinees: **NO** • Cohorts of the EU population only vaccinated with IPV containing vaccines: **NO** • Low or unvaccinated population groups in the EU: **YES**	• The majority of infected persons (95%) do not have any clinical symptoms. • Vaccination coverage in the general population and other groups. • Increased severity in immunocompromised groups.	• The ratio of inapparent infection to clinically recognised polio infection ranges from 60:1 to 1000:1, depending on many factors including population's immunisation status. • Minor illness is the most common form of clinical disease (4–8% of infections) and characterised by unspecific symptoms such as fever, headache, nausea, vomiting, abdominal pain, sore throat. • Non-paralytic aseptic meningitis usually begins as minor illness and resolves completely within 10 days. • Flaccid paralysis occurs in <1% of cases.	• Risk assessment - *Supporting documentation for disease background information* • Text books.	Good	

Question/issue under consideration	Parameters to consider	Summary of evidence	Source of evidence	Quality of evidence	Comments (to address gaps, doubts and uncertainties)
9. In the scenario of wild poliovirus transmission, with or without clinical disease, are control measures and operational plans available at EU level? **YES**	• Stockpile of OPV in the EU/EEA • Stockpile of IPV in the EU/EEA • Financial resources for OPV vaccination Availability of preparedness/response plans	• No availability of OPV stockpiles in the EU/EEA • No availability of IPV stockpiles in the EU/EEA • Majority of Member States plan to use IPV in the event of poliomyelitis outbreaks • Less experience with the control of polio in EU/EEA.	• RA - *Supporting documentation for operational plans including OPV availability in the EU* • RCC report • Text books • Vaccine registration • Current OPV Supply & Outlook 2013 report by UNICEF[5] • EMA survey in Member States • ECDC EPIS survey in Member States.	• Unsatisfactory	• Consider logistics and cost of supplementary campaigns in the event of poliomyelitis outbreaks • Choice of vaccine (IPV versus OPV) for first line response to an outbreak. • Monitor the impact of first line response to an outbreak of poliomyelitis. • Indicators for switching from IPV to OPV in outbreak settings. • Benefit-risk assessment studies are needed.
10. Are there contextual factors that may affect the risk assessment? **YES**	• Strong political interest (polio due for elimination) and media attention. • Severe disease • Pressure from anti-vaccination groups • Financial crisis • Global commitment to control and eradication		• Romania/support from UNICEF for 2012 campaign in some regions.	• Good.	

[5] UNICEF Supply & Outlook Report 2013. Available at: http://www.unicef.org/supply/files/Oral_polio_vaccine_update.pdf

Supporting documentation on the global polio situation

So far in 2013, 256 cases of poliomyelitis have been reported worldwide (up to 10 September 2013), compared with 136 for the same period in 2012. Six countries have reported cases in 2013: Afghanistan (4), Pakistan (28), Nigeria (46), Somalia (163), Kenya (14) and Ethiopia (1) [34].

The majority of poliomyelitis cases (178) this year have been reported from Somalia, Kenya and Ethiopia – three previously non-endemic neighbouring countries facing an outbreak of WPV1 that started in May 2013. The ratio of asymptomatic to symptomatic polio infections is usually high. The high number of reported cases from the Horn of Africa suggests that thousands of people have become infected and that the virus is circulating widely in the population.

In Somalia, the outbreak is currently spreading geographically, although there have been fewer new cases in the Banadir region, which was considered to be the starting point of the outbreak. On 31 August, Puntland confirmed its first polio case in Bossaso. The large majority of the poliomyelitis cases are being reported from southern and central Somalia, where more than 600 000 children are at risk of polio. To slow down the spread and boost population immunity, intense vaccination activities have been undertaken across the country. Outbreak response measures across the region continue to be implemented. Six rounds of country-wide vaccination campaigns have been carried-out in Somalia.

The affected area in Kenya is around Dadaab in the North Eastern province, an area with almost half a million Somali refugees and where nearly 50% of the children remain un- or under-immunised (compared to less than 5% in Kenya overall).

The confirmation of a case in Ethiopia underscores the risk that this outbreak continues to pose to countries across the region [1,3,34-36].

Table 4. Distribution of wild polio virus (WPV) cases by endemicity status and year-to-date [34]

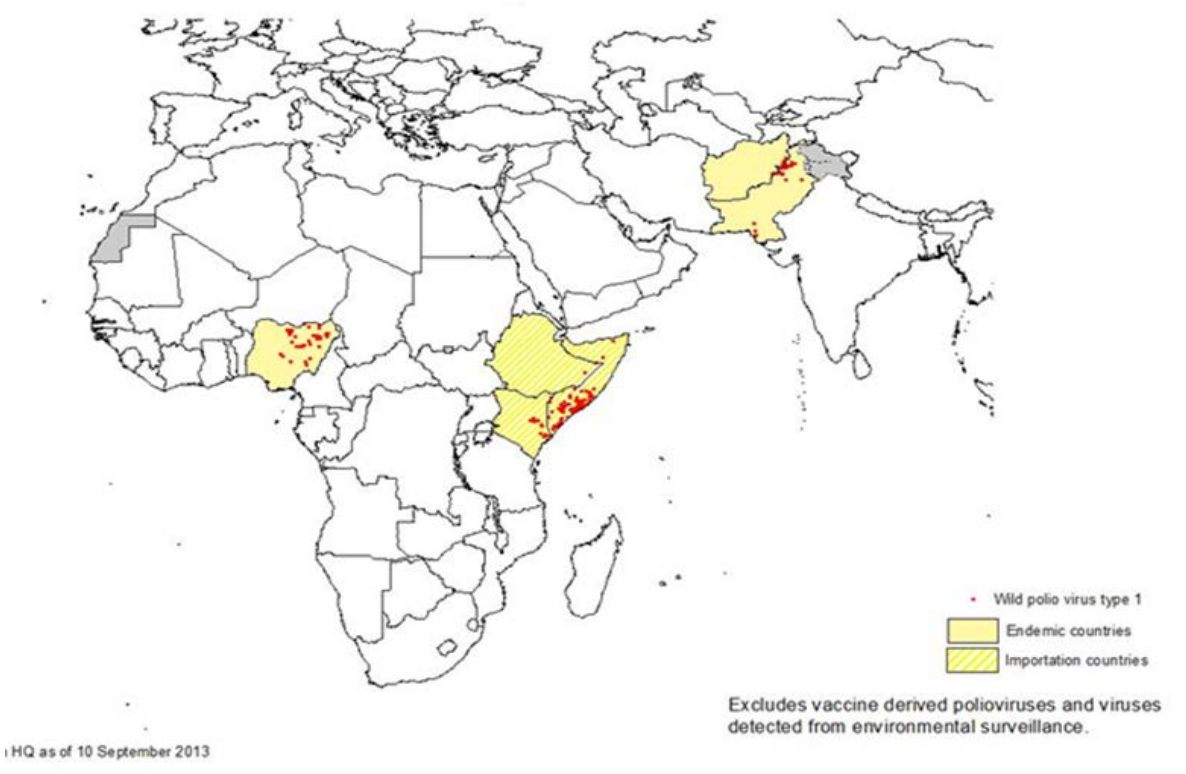
	Year-to-date 2013	Year-to-date 2012	Total in 2012
Globally	256	136	223
In endemic countries	78	131	217
In non-endemic countries	178	5	6

Table 5. Distribution of cases by country and reporting year[(1)] [34]

Country	Year-to-date 2013				Year-to-date 2012				Total in 2012	Date of most recent case
	WPV1	WPV3	W1W3	Total	WPV1	WPV3	W1W3	Total		
Pakistan	28			28	27	2	1	30	58	19 Aug 2013
Afghanistan	4			4	17			17	37	23 Jul 2013
Nigeria	46			46	67	17		84	122	17 Aug 2013
Chad					5			5	5	14 Jun 2012
Ethiopia	1			1					0	10 Jul 2013
Kenya	14			14					0	14 Jul 2013
Somalia	163			163					0	07 Aug 2013
Niger									1	15 Nov 2012
Total	256	0	0	256	116	19	1	136	223	
Total in endemic countries*	78	0	0	78	111	19	1	131	217	
Total outbreak	178	0	0	178	5	0	0	5	6	

(1) Data at WHO as of 11 September 2012 for 2012 data and 10 September 2013 for 2013 data
** Pakistan, Afghanistan and Nigeria are considered to be endemic countries.*

Figure 2. Reported wild-type polioviruses (1 January–10 September 2013)[34]



Supporting documentation on the situation in Europe

The last case of poliomyelitis caused by endemic wild-type poliovirus in the WHO European Region occurred in eastern Turkey in 1998, in a two-year-old unvaccinated boy [37]. The region was officially declared polio-free in 2002. Importation of virus from polio-endemic areas remains a threat to the polio-free status. In 2001, three polio cases were reported among Roma children in Bulgaria [38] and one non-paralytic case was reported in Georgia, all caused by polioviruses originating from the Indian subcontinent. The last outbreak in the EU/EEA was in 1992 in the Netherlands, in a religious community opposed to vaccinations [7]. Another smaller outbreak occurred in Finland in 1984, where ten individuals developed clinical disease due to WPV3 and at least 100 000 people were estimated to have been poliovirus excretors [8,9].

The latest outbreak in the WHO European Region was in 2010, when WPV1 imported from Pakistan caused a large outbreak in Tajikistan that spilled over into neighbouring countries [39]. In total, the outbreak resulted in 479 confirmed cases of poliomyelitis in five countries: Tajikistan (461), Russia (14), Turkmenistan (3), and Kazakhstan (1). Neighbouring Uzbekistan also reported a peak in AFP cases (146) but poliovirus was not confirmed in any of the 15 stool samples that were sent to the WHO Regional Reference Laboratory in Moscow [40]. The outbreak in Tajikistan and surrounding countries, which accounted for more than 70% of all global cases in 2010, was contained within eight months following extensive supplementary immunisation activities [41]. Enhanced AFP surveillance was implemented in the affected and surrounding countries following this outbreak. The outbreak did not result in re-establishment of endemic polio, defined by WHO as 'uninterrupted transmission occurring for more than twelve months'.

Table 6. Poliovirus detection in Europe and Israel (2002–2013) [42]

Country, year of finding	Virus	Source	VP1 similarity	Reference
Romania 2002	VDPV type 1(*)	Faeces samples from one AFP case and eight healthy contacts	VP1 sequence similarity 98.8%	[43]
Estonia 2002	Type 3 VDPV	Sewage water	VP1 sequence similarity 86.7%	[44]
Slovakia 2003–2004	>100 type 2 VDPVs	Sewage water	VP1 sequence similarity 84–87%	[45,46]
Spain 2005	1 type 2 VDPV	One immunodeficient child from Morocco.	?	[47]
France 2006	1 type 2 VDPV	One immunodeficient child from Tunisia.	?	[47,48]
Czech Republic 2006	10 type 1 VDPVs	Sewage water	VP1 sequence similarity 98.6–98.9%	[47,49]
Israel 2006	9 type 1 and 3 type 2 VDPVs	Sewage water	?	[50]
Israel 2007 and 2008	Type 2 VDPV	Sewage water	?	[51,52]
Switzerland, 2007	Wild poliovirus	Sewage water	Closely related genetically to virus in Chad.	[53]
Switzerland 2008	One type 1 in Zurich and one type 2 in Geneva	Sewage water	?	[51]
Estonia 2008–2010	Type 2 VDPV in September, type 3 in December	Sewage water	VP1 sequence similarity a. 85.49% (Type 2) and 84.33% (Type 3)	[52,54] Personal communication
Finland 2008–2013	Several type 1, type 2 and type 3 VDPV	Sewage water	VP1 sequence similarity 86–88%	[55] [52,55] [52] Personal communication
Latvia 2011	TVDPV type 1	Sewage water	Sabin type 1	Personal communication

(*) Vaccine-derived polio virus (VDPV)

Supporting documentation for disease background information

Polioviruses belong to the Enterovirus genus. Poliomyelitis is a highly infectious disease caused by three serotypes of wild polio virus; WPV1, WPV2 and WPV3. Vaccine-derived poliovirus (VDPV) strains can cause disease in susceptible individuals. WPV2 has been eradicated but because attenuated type 2 virus continues to be used in the in the trivalent OPV vaccines, the risk of infection with vaccine-derived polio virus type 2 (VDPV2) remains.

The clinical manifestations of poliovirus infection vary greatly. The majority of infected persons (95%) do not have any clinical symptoms. Minor illness or abortive poliomyelitis is the most common form of clinical disease (4–8% of infections) and characterised by unspecific symptoms such as fever, headache, nausea, vomiting, abdominal pain and/or sore throat. Non-paralytic aseptic meningitis usually begins as minor illness. One to two days later, meningeal signs such as stiffness of the neck and pain in the limbs and back become apparent but these commonly resolve completely within 10 days. The ratio of unapparent infection to clinically recognised polio infection ranges from 60:1 to 1000:1, depending on many factors including the population's immunisation status.

A small proportion of cases develop mild muscle weakness or paralysis. Paralytic illness is rare, affecting less than 1% of infected individuals. The flaccid paralysis is usually asymmetric, with lower limbs and proximal muscles being more frequently affected. Maximum extent of paralysis is usually reached three-to-four days after onset of symptoms. The disease becomes life-threatening if the nerve cells that control respiratory muscles and swallowing (bulbar paralysis) are affected. The case-fatality is 5–10% among those paralysed but much higher with bulbar involvement. Symptoms persisting for more than 60 days tend to become chronic and lead to permanent sequelae.

Post-poliomyelitis syndrome is a condition of muscle weakness, pain, fatigue and atrophy with onset anywhere between 15 to 40 years after the initial disease. It affects up to 20–30% of poliomyelitis patients and may involve previously unaffected limbs. Treatment options are limited [56].

The incubation period of the paralytic forms is nine to 12 days with a range of five to 35 days until onset of prodromal symptoms and 11 to 17 days (range eight to 36 days) until onset of paralysis [56].

Poliovirus is highly contagious and infected individuals shed virus in the faeces and from the naso-pharyngeal mucosa. The mode of transmission is person-to-person, both via the faecal-oral and the oral-oral routes [57]. Poliovirus shed through the faecal route may be retrieved in sewage water. The period of possible transmission lasts for as long as polio viruses are excreted. In symptomatic patients it is highest during the days just before and after onset of symptoms. Asymptomatic infected persons may shed the virus as well.

Humans are the only reservoir of polioviruses and individuals with asymptomatic infections are the main source of transmission. Immunocompromised patients have been shown to excrete VDPV for up to 18 years post vaccination [58-60].

Polioviruses can be isolated from throat secretions in the first week of illness and from faeces for several weeks after onset of symptoms. The virus is rarely isolated from the cerebral-spinal fluid. The diagnosis can also be established serologically by testing paired sera for neutralising antibodies which can distinguish between the different serotypes. It is not always possible to distinguish infections caused by wild-type virus from vaccine-type virus using serological methods (see also *Supporting documentation on detection and diagnosis (laboratory capacity)*).

No specific antiviral treatment exists. Prevention through vaccination is therefore essential.

Poliovirus isolates are divided into three serotypes: type 1, type 2, and type 3. Isolates are divided further into three categories, based on the extent of VP1 nucleotide sequence divergence from the corresponding Sabin OPV strain:

- WPVs (no genetic evidence of derivation from any vaccine strain)
- Sabin vaccine-related poliovirus (VRPV) (≤1% divergent)
- VDPVs (VRPVs that are >1% divergent from the corresponding Sabin strain).

VDPVs can cause paralytic polio in humans and have the potential for sustained circulation. VDPVs resemble WPVs biologically and differ from most VRPV isolates by having genetic properties consistent with prolonged replication or transmission. Since poliovirus genomes evolve at a rate of approximately 1% per year, Sabin VRPV isolates that differ from the corresponding OPV strain by >1% of nucleotide positions (usually determined by sequencing the genomic region encoding the major viral surface protein, VP1) are estimated to have replicated for at least one year in one or more persons after administration of an OPV dose. This is substantially longer than the normal period of vaccine virus replication: four to six weeks in an OPV-recipient.

Supporting documentation on vaccines against polio

Two types of polio vaccines, an oral live attenuated vaccine (OPV) and an inactivated vaccine (IPV) were developed in the 1950s [61,62]. Both vaccines contain the three poliovirus serotypes 1, 2 and 3 in combination, since all are needed to provide protection against the three wild-type polio virus strains.

For the elimination of polio, most EU/EEA Member States have relied upon the use of OPV. However, the risk of vaccine-associated paralytic polio (VAPP) among OPV vaccinees (estimated to one case in 750 000 children receiving their first dose of OPV), and the risk of outbreaks caused by vaccine-derived poliovirus (VDPV) strains have motivated all EU/EEA countries to change their polio vaccination schedules from OPV to either IPV-only schedules, or to combination schedules with IPV in the primary series followed by a booster dose of OPV (see *Supporting documentation on population susceptibility and identification of potential risk groups in the EU/EEA*) [8,63,64]. Only one country in the EU/EEA, Poland, maintains a combined schedule with IPV in the primary series while providing OPV as a booster. The other Member States offer IPV–only schedules for routine immunisation of children. The number of doses in the primary series and when they are recommended, as well as number of booster doses and when they are recommended vary among EU/EEA Member States. Poliovirus vaccines induce good immune responses. However, waning immunity occurs and the number of booster doses to provide life-long protective immunity is currently unknown.

Three EU countries, Finland, the Netherlands and Sweden, have relied exclusively on IPV for polio elimination. In response to outbreaks following importation in Finland in 1984 and in the Netherlands in 1992, OPV was offered as a control measure [8]. In Sweden, a single case of poliomyelitis (WPV2) occurred in 1977 in a two-year-old child. Excretion of polioviruses was documented in 25 unvaccinated close contacts of the child [63]. At this time, Sweden had reached close to 100% IPV vaccination uptake among children and a majority of adults had also been vaccinated. None of the vaccinated pre-school contacts of the two-year-old case was found to excrete virus and OPV vaccination was not deployed in the control of this outbreak. Sweden is one of few countries that has never offered OPV to their population.

Herd immunity can be achieved through OPV-only, combined IPV/OPV or IPV-only schedules. Evidence of herd immunity with IPV was demonstrated in the US when IPV was introduced for routine use in 1955. The reduction in the number of cases observed exceeded expectations based on the number of children vaccinated [61]. Similarly, during the outbreaks in the Netherlands in 1978 and 1992, despite widespread circulation of the virus in communities refusing vaccination throughout the country, there was only one case of polio in other Dutch communities [7,61]. However, it is important to point out that the evidence for herd immunity with IPV vaccines comes from countries where oral-oral transmission was probably the dominant mode. It is less clear if IPV is able to induce herd immunity in countries where the faecal-to-oral route is thought to be the primary means of transmission [61].

Breakthrough infections following OPV vaccination after several doses (five to seven doses) in impoverished populations has mainly been reported from India [19,65]. Waning immunity has been documented in similar settings. Clinical experience with breakthrough infections following IPV-only schedules in European populations that travel extensively shows that the IPV-only schedules provide excellent protective immunity. However, there are no formal studies confirming this clinical observation. Many travel vaccine clinics provide a booster IPV dose for Europeans travelling outside Europe.

Supporting documentation on poliovirus circulation in the environment

Scenarios for potential modes of transmission throughout the water cycle are displayed in Table 7. Potential transmission pathways of poliovirus, if present in sewage. EU legislation on water quality, including that covering the discharge of wastewater in the environment after treatment, bathing water and drinking water, does not specifically require monitoring for poliovirus or Enteroviruses [16-18]. The potential risk of poliovirus transmission as a result of activities using treated wastewater has been assessed using quantitative approaches. Recommendations for the microbiological quality of treated wastewater used in agriculture are provided by the WHO [66,80]. The annual risk of contracting at least one poliovirus infection from exposure to recycled wastewater was evaluated for different exposure scenarios based on a concentration of 111 viral units/100 ml: landscape irrigation for golf courses (10–5), spray irrigation for food crops (10–4 to 10–7), unrestricted recreational impoundments (10–1 to 10–3) and groundwater recharge (10–8 to 10–9) [67,68].

If there is a point source of wild poliovirus, it may be circulating in the environment, but the risk of transmission to humans requires a combination of specific scenarios (lack/absence of wastewater treatment, irrigation of crops with contaminated water, groundwater contamination). The reuse of treated wastewater is common practice in European countries and this is regulated at the national level. Reclaimed wastewater is reused predominantly for agricultural irrigation in the southern Europe, while uses are mainly for urban, environmental or industrial applications in northern Europe [69].

Table 7. Potential transmission pathways of poliovirus, if present in sewage

Step in the water cycle	Critical points/usage	Environmental surveillance/regulation	Possible exposed population	Health risk
Sewage before treatment	Accidental: disruption in the sewage system, cross contamination of sewage with drinking water.	Up to local public health authorities.	Population using tap water in affected area.	++ in affected area, event-related
During wastewater treatment	Depending on the type of treatment, can be more or less effective for poliovirus.	Up to local public health authorities.	Workers in treatment plants (aerosols, oral/faecal route).	+/- (not specific to poliovirus)
Discharge of treated wastewater into the environment	Depends on downstream activities.	EU directive (chemical & biological indicators) Specific national/local public health regulations		+/- (not specific to poliovirus)
Wastewater reuse for irrigation	Aerosols from sprinklers. Soil and crop contamination.	WHO guidelines based on coliforms and nematodes. Does not include enterovirus. National regulations may take into account enterovirus.	Farmers, population living in the irrigated area, crop consumption.	++ in affected area
Recreational water	Drinking water while swimming.	EU directive (coliforms and *E.coli)*, no enterovirus. Possibility of monitoring enterovirus in some countries (e.g. UK).	Swimmers and bathers.	+ in affected area
Risk associated with sludge	Used as a fertiliser			
Acquifer recharge with recycled water	Potential contamination of water resources for drinking water or other usage.	No specific EU legislation apart from the EU directive on drinking water.	Contamination of well or other specific scenario.	+ (event-related)

Supporting documentation on surveillance systems for polioviruses in the EU/EEA countries

The European Regional Certification Commission for Poliomyelitis Eradication (RCC) uses several criteria to assess the performance of polio surveillance. These include a health services criterion; the acute flaccid paralysis index; timeliness of AFP reporting and the use of supplemental surveillance (Enterovirus and/or environmental sampling). The latter three criteria are discussed below in relation to the EU/EEA countries.

All RCC criteria are evaluated together to generate a summary score of the surveillance quality. According to the RCC, in 2012 two of the 30 EU/EEA Member States were assessed as having 'high' quality surveillance; 12 had 'good' surveillance; 15 had 'average' surveillance; and one had 'low' quality surveillance [10]. However, much of the assessment was based on limited information obtained from the Member States and the RCC expressed concern over the sub-optimal state of surveillance in many countries [10].

Surveillance for acute flaccid paralysis

Surveillance for acute flaccid paralysis (AFP) is the most common surveillance method for polio in the EU/EEA (20 of 30 countries in 2012) [10]. However, although paralytic polio presents with AFP, there are several other causes of AFP besides poliovirus (including Guillain–Barré syndrome, tropical spastic paraparesis and others) that occur at predictable rates in a population. Adequate surveillance is therefore based on a system which is sensitive enough to be able to identify AFP cases for all causes, the timely completion of laboratory tests on cases (see *Supporting documentation on detection and diagnosis (laboratory capacity)*) and the timely reporting of results to clinicians and the public health system.

Benchmarks for AFP surveillance have been set by the Global Polio Eradication Initiative (GPEI). Countries in polio-free regions such as the EU/EEA, should be able to identify and report ≥1 case of AFP in 100 000 persons <15 years of age in the population [19]. Of the AFP cases identified, at least 80% should have two stool specimens taken within 14 days of symptom onset and test results should be available on 80% of the specimens within 28 days. In addition, the WHO Regional Office for Europe calculates an AFP index (the AFP rate [up to 1.0] x the percentage of one adequate stool specimen in 14 days) and sets a benchmark of 0.8 for the AFP index [23].

As reported by WHO, only four of 20 EU/EEA Member States had a calculated AFP rate of > 1/100 000 persons in 2012 and only three had a calculated surveillance index of >0.8 (Latvia, Lithuania, and Cyprus)[23]. Only seven of the countries reported data in a timely fashion more than 80% of the time in 2012 [24].

Supplementary surveillance

Environmental surveillance

Infected persons may shed polioviruses in their faeces for many weeks and these can be identified in sewage samples. Since poliovirus can circulate widely without causing symptoms, especially in highly-immunised populations, environmental sampling may identify a circulating virus (wild-type, vaccine strains, or vaccine-derived polio) long before the first case of clinical disease. Environmental surveillance may be quite sensitive and able to identify low levels of viral shedding [25,70].There are comprehensive laboratory guidelines for the detection of polio in sewage samples [22].

However, there are important limitations to environmental surveillance. There are no agreed benchmarks for the timing, frequency, location, or population size required to ensure that environmental surveillance is both representative and sensitive enough to identify individual cases of polio. It also requires significant investment in laboratory resources and personnel. For this reason, WHO states that environmental surveillance should be considered for 'selected populations where deficiencies in AFP surveillance are suspected and where conditions exist that render the population at risk for poliovirus circulation' [22].

Enterovirus surveillance

Enteroviruses cause a wide range of illnesses, including respiratory and gastrointestinal symptoms and aseptic meningitis. Polioviruses are just one of many known Enteroviruses. Many clinical laboratories may only have the ability to identify Enteroviruses as a 'generic' group and lack the ability to differentiate between types of enterovirus (polioviruses, echoviruses, Coxsackie viruses, etc.). The goal of enterovirus surveillance is to determine if any of the circulating Enteroviruses are actually polioviruses.

At the time of writing, there are no published standards listing benchmarks to determine the minimum number of enterovirus samples that should be tested in Member States (depending on population); the representativeness of the samples; the age range for testing/reporting; the specimen type(s), or the clinical syndromes. Such benchmarks would be very useful to guide Member States in the development and evaluation of their enterovirus surveillance systems. New guidelines on enterovirus surveillance are anticipated from WHO later in 2013 and these may help Member States to strengthen their supplemental surveillance.

Comparison of surveillance systems

There are advantages and disadvantages to polio surveillance systems. AFP surveillance has clearly defined standards and does not rely on significant laboratory resources. It has been used successfully in countries around the world. However, it requires sustained cooperation from clinical personnel which is hard to maintain in polio-free regions (as evidenced by the current state of AFP surveillance in the EU/EEA) and it only identifies cases of polio after there may have been sustained community transmission of the virus. As such, AFP surveillance may not provide adequate warning of polio importation and transmission.

Supplemental surveillance systems, such as environmental surveillance and enterovirus surveillance, may provide earlier identification of poliovirus circulation in a community before illness occurs. As such, it would allow public health officials time to intervene before paralytic cases of polio occur. However, such systems would require investment in laboratory personnel and resources and there are no specific standards on the number of samples that should be obtained/population size, timing of the samples, etc. Such standards are urgently needed in order to exploit these sensitive methods in a cost-effective manner. Until such standards are developed and accepted, Member States should meet the minimum criteria for surveillance as outlined by the RCC and WHO.

With the aim of gaining a rapid overview of ongoing surveillance activities and the availability of operational plans in the EU/EEA for polio virus outbreaks, ECDC performed a rapid inquiry through the EPIS-VPD platform. Countries were specifically asked about the availability of routine environmental surveillance for polioviruses; routine surveillance for human Enteroviruses and updated outbreak control plans (contingency plans) for poliovirus outbreaks. Of the fifteen Member States that responded (see Table 3), six reported having routine environmental surveillance for polioviruses and ten had routine surveillance for human Enteroviruses.

Table 8. Environmental and human Enterovirus surveillance in EU/EEA Member States

Country	Is routine environmental surveillance for polioviruses in place? (*)	Is routine surveillance for human Enteroviruses in place? (*)
Austria		
Belgium		
Bulgaria	No	Yes
Croatia	No	Yes
Cyprus		
Czech Republic		
Denmark	No	Yes
Estonia	Yes	n.a.
Finland	Yes	No
France	Yes	Yes
Germany	No	Yes
Greece	Yes	Yes
Hungary		
Iceland	No	n.a.
Ireland	No	Yes
Italy		
Latvia	Yes	Yes
Lithuania		
Luxembourg		
Malta	No	n.a.
Netherlands		
Norway		
Poland		
Portugal	No	Yes
Romania	Yes	No
Slovenia		
Slovakia		
Spain	No	Yes
Sweden		
United Kingdom		

(*) Source: ECDC EPIS-platform urgent inquiry

Supporting documentation on detection and diagnosis (laboratory capacity)

Laboratory systems in general

The Global Polio Laboratory Network (GPLN) consists of a three-tiered structure: (1) national reference laboratories responsible for the isolation and identification of polioviruses from faecal samples, mainly received from national AFP screening, and subsequently the reporting and referral of positive samples, (2) regional reference laboratories in each of the WHO regions responsible for intratypic differentiation of isolates from the region, and (3) global specialised laboratories responsible for performing definite identification and genetic characterisation of polio isolates [71]. All laboratories at the three hierarchical levels of the GPLN are accredited on an annual basis by WHO according to predefined criteria to assess and document the capacity to detect, identify and report cases from clinical or environmental specimens [71]. In addition to ensuring that laboratories in all countries meet specific standards, the accreditation system is also listed as a criterion for a country to be certified as polio-free.

Laboratory methods and testing

Laboratory testing for polio viruses at accredited laboratories requires the use of standardised procedures, methodologies and reagents. Standard operating procedures (SOPs) for these methods, together with details on laboratory quality assurance, specimen handling, isolation, transport and data management are described in detail in the Polio Laboratory Manual [71]. An overview of laboratory methods is also set out in Table 9 below.

Table 9. WHO-endorsed laboratory methods for poliovirus detection and characterisation, listed according to the respective laboratory category

Purpose of laboratory test	Hierarchical level	Description
Isolation	National reference laboratories	Virus culture on L20B and RD cell lines
Exclusion tests for other Enteroviruses	National reference laboratories	Neutralisation assay (RIVM protocol)
Intratypic differentiation	Regional reference laboratories	PCR (CDC protocol)
Definitive identification and characterisation of poliovirus	Global specialised laboratories	All available technologies, including sequencing.

Laboratory situation in the EU/EAA for polio detection and characterisation

The WHO Regional Office for Europe in Copenhagen coordinates the activities of all polio reference laboratories within the Region, including the EU/EEA. After the accreditation process in 2011, all WHO national reference laboratories for poliovirus detection within the WHO European Region were reported to be fully accredited, with the exception of one (Uzbekistan) [27].

During 2011 and 2012, almost 7 600 samples from AFP cases were processed in laboratories accredited by the WHO European Region. Approximately 2% were positive for poliovirus (either Sabin or VDPV) though the VDPV numbers may be an underestimate [10]. Key performance indicators for laboratory services within the WHO-European Region were met during 2012 (non-poliovirus isolation rate, timeliness of reporting, etc.) It should be noted, however, that most of these laboratory tests were performed in countries within the WHO European Region that are not part of the EU/EEA.

Environmental testing

All suspected poliovirus isolates from environmental specimens should be sent for intratypic differentiation to a WHO accredited regional reference laboratory. Results should in principle be reported following the same principles as for clinical surveillance in terms of regularity and timeliness.

Supporting documentation on population susceptibility and identification of potential risk groups in the EU/EEA

Vaccination coverage in the EU/EEA

Vaccination coverage levels in the EU/EEA can be considered satisfactory as a whole (>90% for three doses of either IPV or OPV) and can largely justify the absence of disease in the region (see Figure 5 and Table 14 in the annexes).

It is estimated that in the EU/EEA almost 70 million people in the age group 0–29 years can be considered OPV-naïve (see Table 13 on IPV cohorts and Table 14 on birth cohorts in the annexes). This population represents a potentially large reservoir for the sustainment of wild poliovirus circulation in the event that polio is re-introduced into the environment.

Moreover, in the EU/EEA there are significantly large pockets of population sub-groups that are under-immunised or not immunised at all. Low immunisation levels can be identified in selected population groups (travelling communities, disadvantaged groups, those opposed to vaccine due to religious or philosophical beliefs) but also in the general population in many areas of the EU/EEA. According to a recent survey of the EVACO project[6], low vaccination coverage areas (<90%) can also be detected in countries reporting satisfactory immunisation rates at a national level (personal communication VENICE consortium, unpublished data). Lack of immunity in such population sub-groups represents a potential risk for symptomatic polio cases in the event of widespread circulation of the wild virus in the environment.

Assessing protective immunity

Protective and waning immunity can be assessed either by means of seroepidemiological studies and determination of neutralising polio-type specific antibodies or through human challenge studies using the oral attenuated vaccine strains. The significance of reducing antibody titres over time among vaccinated individuals to the risk of poliovirus transmission remains an open scientific question.

Seroepidemiological studies

Seroepidemiological studies, assessing serotype-specific neutralising antibodies, have been conducted in several EU/EEA Member States [72-74]. A sample of studies are presented here, indicating that the polio vaccines used induce a good immune response but that there are individuals susceptible to the different poliovirus serotypes in all age groups. Comparisons of results are hampered by the use of different vaccines (OPV and/or IPV) and variations in the number of doses recommended.

One longitudinal study following IPV-vaccinated (SBL Vaccine, Sweden) Swedish infants (n=220) for eighteen years indicates a decline in antibody titre to the three poliovirus serotypes over time although all children involved were still seropositive during the study period. Antibody response to poliovirus serotype 3 was lowest in this cohort, suggesting that this was the weakest component in the trivalent combination vaccine used.

Cross-sectional randomised population-based sero-surveys (which aimed to capture fully vaccinated, partially vaccinated and unvaccinated individuals) show varying degrees of susceptible individuals to one, two or even all three poliovirus serotypes in all age groups. One example is a Dutch study conducted on serum samples collected in 1995–96, where sero-positivity in a younger age group 10–14-year-olds was higher (PV1 100%, PV2 99.4%, PV3 98.6%) than in the 30–34 year-old age group (PV1 100%, PV2 95.4% and PV3 87.4%). This study confirmed that the weakest component in the vaccine used in the Netherlands (RIVM, Netherlands) was also serotype 3.

Of concern for the EU/EEA is an assessment of immunity to polioviruses in future healthcare workers, exemplified by a study conducted using serum samples collected in German medical students during 2008–2010. Only 63.9% of the students were protected against all three poliovirus serotypes. This study confirmed the results of the previously-mentioned study in that most of the students were susceptible to serotype 3 (32.1%).

The evidence for herd immunity with IPV vaccines comes from countries where oral-oral transmission has probably been the dominant mode of transmission, given that oropharyngeal immunity is excellent with both IPV and OPV. However, it is less clear whether IPV is able to induce herd immunity in countries where the faecal-oral route is thought to play the primary role in transmission [61,62].

[6] EVACO: European Vaccine Coverage project. ECDC/VENICE

Poliovirus shedding in IPV and OPV vaccinated

Several studies discussed below have shown the effect of IPV-vaccination on poliovirus excretion following OPV-vaccination (OPV challenge studies) or following natural exposure.

A recent review identified and assessed 66 OPV challenge studies, including five on IPV-only vaccinated individuals (≥3 doses) [31]. Overall, the moderate grade evidence, as assessed in the review, suggested that there is no significant effect of IPV on susceptibility to polio infection. Studies included on the duration of faecal excretion showed that the longest excretion time was among fully susceptible individuals, with a similar or slightly shorter excretion time among IPV recipients, and the shortest average duration among OPV vaccinees. The concentration of virus excreted in faeces of IPV-only recipients was lower than in fully susceptible individuals, but higher than in OPV vaccinees. In summary, IPV displayed a limited effect on susceptibility to viral exposure, and a moderate effect on the duration and concentration of excretion. Additionally, the authors reviewed the duration and concentration of oropharyngeal excretion. The weight of evidence was graded as low; however the evidence suggested a very low probability of oropharyngeal excretion for any type of immune individual, regardless of whether they had been vaccinated with IPV or OPV.

Another systematic review from 2012 assessing poliovirus shedding in stools or nasopharyngeal secretions after an OPV challenge [75], showed that, compared with unvaccinated individuals, those who were IPV-vaccinated had no protection from viral shedding, suggesting no significant protection from infection. Furthermore, when IPV was given in addition to OPV and individuals compared to those who were OPV-only vaccinated, the IPV-vaccinated individuals had no protection from viral shedding. Lastly, the authors acknowledged that the impact of IPV vaccination itself on poliovirus transmission is unknown in countries where faecal-oral spread is common but this impact is likely to be limited when compared with OPV.

A limitation on all OPV challenge studies is that natural exposure to polioviruses may involve different amounts of ingested virus (generally lower) and different media (e.g. contaminated water, food, aerosol droplets) which could have an impact on the probability of infection or an effect on the probability, duration and concentration of excretion, as has been indicated in published studies [31]. Another limitation is that a substantial number of the OPV challenge studies were performed using the original IPV vaccines, and results cannot be extrapolated to the new, enhanced IPV vaccines.

Until recently, OPV was the only vaccine used in Mexico. A study in the US, in an area close to the Mexican border [76], assessed the circulation of polio virus in an IPV-vaccinated population constantly challenged with an OPV immunised population. All 664 children and 22 sewage samples were found negative, showing that the risk of circulating vaccine-derived poliovirus (VDPV) is low among fully IPV-immunised populations in countries with similar structures and resources that border OPV-vaccinated populations.

Several VDPV findings have been reported so far from different EU/EEA countries and neighbouring regions [42]. A study in Switzerland revealed continuous introduction of poliovirus into the sewage system [29], however there was little evidence that these viruses had established long-term circulation in the community. High standards of hygiene possibly prevented the more efficient route of faecal-oral transmission, only permitting the less efficient route of oral-oral transmission. The contribution of hygiene towards breaking the chain of poliovirus transmission to family contacts has also been noted elsewhere in published studies [77].

In summary, a switch from OPV to IPV could potentially result in a situation where it might be possible to transmit OPV-derived viruses from chronically-infected persons or imported locations. However, several studies provide evidence to dispel this suspicion [25]. Additionally, many countries that have been using IPV-only for several years have not found any signs of emerging transmission of OPV-related virus in their routine AFP, environmental surveillance or via passive case notification Therefore, all available information supports the idea that it is safe to switch from OPV to IPV in countries with high immunisation coverage [25].

There are still several areas of uncertainty with regard to poliovirus immunity and transmission. As described in a recent review by Duintjer Tebbens RJ et al. [78], key topics requiring further research that would help in the understanding of polio immunity are:

- the ability of IPV-induced immunity to prevent or reduce excretion and affect transmission;
- the impact of waning immunity on the probability and extent of poliovirus excretion;
- the relationship between virus excretion and ability to transmit, and
- the relative role of faecal-oral versus oropharyngeal transmission.

Supporting documentation for operational plans including OPV availability in the EU

According to a report from the 27th meeting of the European Regional Certification Commission for Poliomyelitis Eradication (RCC), many, but not all EU/EEA countries have established national certification committees providing annual reports to the RCC [10]. The RCC requests the development of national preparedness plans and organised exercises to test these plans. According to the report, there are EU/EEA Member States that can improve their activities in this area. The RCC also noted that in some countries the continuity of polio vaccination programmes has been compromised by procurement problems and issues related to national immunisation schedules and has recommended improvement where needed. WHO EURO is aiming to work closely with affected countries in the coming years to improve vaccine availability for routine immunisation programmes.

When deciding on the vaccine to be used in response to an outbreak of wild-type polio virus circulation, there are three options: IPV, monovalent OPV (mOPV) of the outbreak type or bivalent OPV (bOPV). IPV avoids the risk of VAPP or circulation of VDPV associated with oral polio vaccines but there are questions about the effectiveness of IPV in stopping circulation. Finland and the Netherlands, two countries that have always used IPV for routine immunisation, both opted for OPV vaccination campaigns in order to stop poliovirus circulation in their populations.

Current WHO guidance on responding to a polio outbreak states that prudent preparedness to respond to a polio outbreak requires a stockpile of monovalent OPV and that UNICEF would maintain the ownership of the international stockpile, to ensure universal access and rational use [33]. However, maintenance of national vaccine stockpiles may also be considered.

In order to assess the availability of and access to OPV for use in outbreak control measures, EMA (the European Medicines Agency) and ECDC conducted a joint rapid survey through their official contact points in the EU/EEA Member States (see Table 10).

With the aim of gaining a rapid overview of ongoing surveillance activities and the availability of operational plans for polio virus outbreaks in EU/EEA countries, ECDC performed a rapid inquiry through the EPIS-VPD platform, specifically asking about the availability of routine environmental surveillance for polioviruses; routine surveillance for human Enteroviruses, availability of IPV stockpiles and updated outbreak control plans (contingency plans) for poliovirus outbreaks. Of the fifteen Member States that responded (see Table 5), five reported having an updated outbreak control plan for poliovirus outbreaks.

Table 10. Availability of oral and inactivated polio vaccines for use in outbreak control and outbreak control plans among EU/EEA Member States

Country	Valid marketing authorisation for OPV? (*)	Products and manufacturers(*)	Stockpiles of OPV for use in outbreak control? (*)	Stockpiles of IPV for use in outbreak control? (**)	Is there an updated outbreak control plan (contingency plan) for poliovirus outbreaks? (**)
Austria	No	n.a.	No		
Belgium	Yes	n.a.#	No		
Bulgaria	Yes	tOPV (GSK)	No	Yes (limited)	Yes
Croatia	No	n.a.	No	No	Yes
Cyprus	No	n.a.	No		
Czech Rep.	No	n.a.	No		
Denmark	No	n.a.	No	Yes	Yes
Estonia	No	n.a.	No	No	n.a.
Finland	No	n.a.	No	Yes (limited)	Yes
France	Yes	tOPV (Sanofi Pasteur) #	No	No	Yes
Germany	Yes	tOPV (GSK)	No	No	Yes
Greece	Yes	tOPV (Pasteur Merrieux)	No	Yes	Yes
Hungary	No	n.a.	No		
Iceland				n.a.	n.a.
Ireland	No	n.a.	No	Yes (limited)	Yes
Italy	Yes§	tOPV (Novartis) bOPV (Novartis) mOPV1 (Novartis) mOPV3 (Novartis)	No		
Latvia	No	n.a.	No	No	Yes
Lithuania	No	n.a.	No		
Luxembourg					
Malta	No±	n.a.±	No±	No	Yes
Netherlands	No	n.a.	No		
Norway	No	n.a.	No		
Poland	Yes	tOPV (GSK)	No		
Portugal	No	n.a.	No	No	Yes
Romania	No	n.a.	No	No	Yes
Slovenia	No	n.a.	No		
Slovakia	No	n.a.	No		
Spain	Yes	tOPV (GSK)	No	No	Yes
Sweden	No	n.a.	No		
UK	No	n.a.	No		

** Source: ECDC and EMA joint rapid survey of EMA official contact points*
*** Source: ECDC EPIS-platform urgent inquiry*
§ Novartis holds marketing authorisation for four OPV products in Italy but none of the products are marketed in Italy or elsewhere in the EU.
± reply received through the EPIS platform urgent inquiry
n.a. = not applicable, mOPV=monovalent oral polio vaccine, bOPV=bivalent oral polio vaccine (type 1 and 3), tOPV=trivalent oral polio vaccine
 # These countries have production of mOPV and bOPV for global use (personal communication).

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Annexes

Methodology

The methodology for evaluating this risk followed the *Operational guidance on rapid risk assessment methodology* developed by ECDC in August 2011 [79].

This assessment considers characteristics of the virus and the type of vaccines (whether inactivated or live attenuated) that may have been administered to EU populations in the past.

Collecting and appraising the evidence used as the basis for the risk assessment

As described in the operational guidance document, when producing a rapid risk assessment it is acknowledged that time and evidence will be limited. Moreover, the assessment may need to rely on published reviews of evidence and expert knowledge, as was the case with this assessment.

It may be difficult to rapidly assess a potential threat where some of the information necessary to inform the risk process is unknown, and this uncertainty is documented and managed in the algorithms by adopting a precautionary approach and moving through the algorithm to a higher level of risk. For the purpose of this exercise, such uncertainties, where known, were included in the algorithm.

In contrast with evidence-based medicine (EBM) where randomised controlled trials are ranked highest and observational studies ranked lowest, in a rapid risk assessment the evidence may be limited. This may give rise to a need for greater reliance on observational studies, including case reports and specialist expert knowledge. For most infectious disease threats only observational data are available. Following the procedure described in the guidance document, the quality of the evidence collected for the current exercise was graded. For examples of how evidence is graded, see Table 11.

Table 11. Assessing the quality of evidence

Quality of evidence = confidence in information, design, quality and other factors assessed and judged for consistency, relevance and validity. **Grade:** good, satisfactory, unsatisfactory	**Examples or types of information/evidence**
Good Further research unlikely to change confidence in information.	• Peer-reviewed public studies where design and analysis reduce bias (e.g. systematic reviews, randomised control trials, outbreak reports using analytical epidemiology) • Textbooks regarded as definitive sources • Expert group risk assessments, or specialised expert knowledge or consensus opinion of experts.
Satisfactory Further research likely to have an impact on confidence of information and may change assessment.	• Non peer-reviewed published studies/reports • Observational studies/surveillance reports/outbreak reports • Individual (expert) opinion.
Unsatisfactory Further research very likely to have an impact on confidence of information and likely to change assessment.	• Individual case reports • Grey literature • Individual (non-expert) opinion.

Assessing the risk

To estimate the overall threat posed by poliovirus importation and re-establishment into the EU/EEA, a risk matrix was compiled, as described in the ECDC guidance (see Figure 4).

Briefly, the probability of infection in the three listed population groups was assessed along with the public health impact in the event of WPV being re-introduced by the population groups at risk. These two parameters were then assessed in relation to one other to calculate the overall threat (expressed as the product of probability and impact). (See Figure 4 on the risk matrix exercise for a figurative explanation).

Figure 3. Risk matrix template

Probability (part A) x impact (part B) = risk (part C)

Probability / Impact	Very low	Low	Moderate	High
Very low	Very low risk	Low risk	Low risk	Moderate risk
Low	Low risk	Low risk	Moderate risk	Moderate risk
Moderate	Low risk	Moderate risk	Moderate risk	High risk
High	Moderate risk	Moderate risk	High risk	High risk
Very high	Moderate risk	High risk	High risk	Very high risk

Figure 4. Risk matrix exercise assessing the overall threat posed by poliovirus importation and re-establishment into the EU/EEA

Probability of infection/disease / Impact on public health	Very low	Low	Moderate	High
Very low	Very low risk of infection (OPV vaccinees) Very low risk of disease (OPV vaccinees)	Low risk	Low risk	Moderate risk
Low	Low risk of disease (IPV-only cohorts)	Low risk	Moderate risk of infection (IPV-only cohorts)	Moderate risk
Moderate	Low risk	Moderate risk	Moderate risk of disease (under- or unvaccinated groups)	High risk of infection (under- or unvaccinated groups)
High	Moderate risk	Moderate risk	High risk	High risk
Very high	Moderate risk	High risk	High risk	Very high risk

Figure 5. Coverage with three doses of polio vaccine in Europe, 2011. Source CISID/WHO

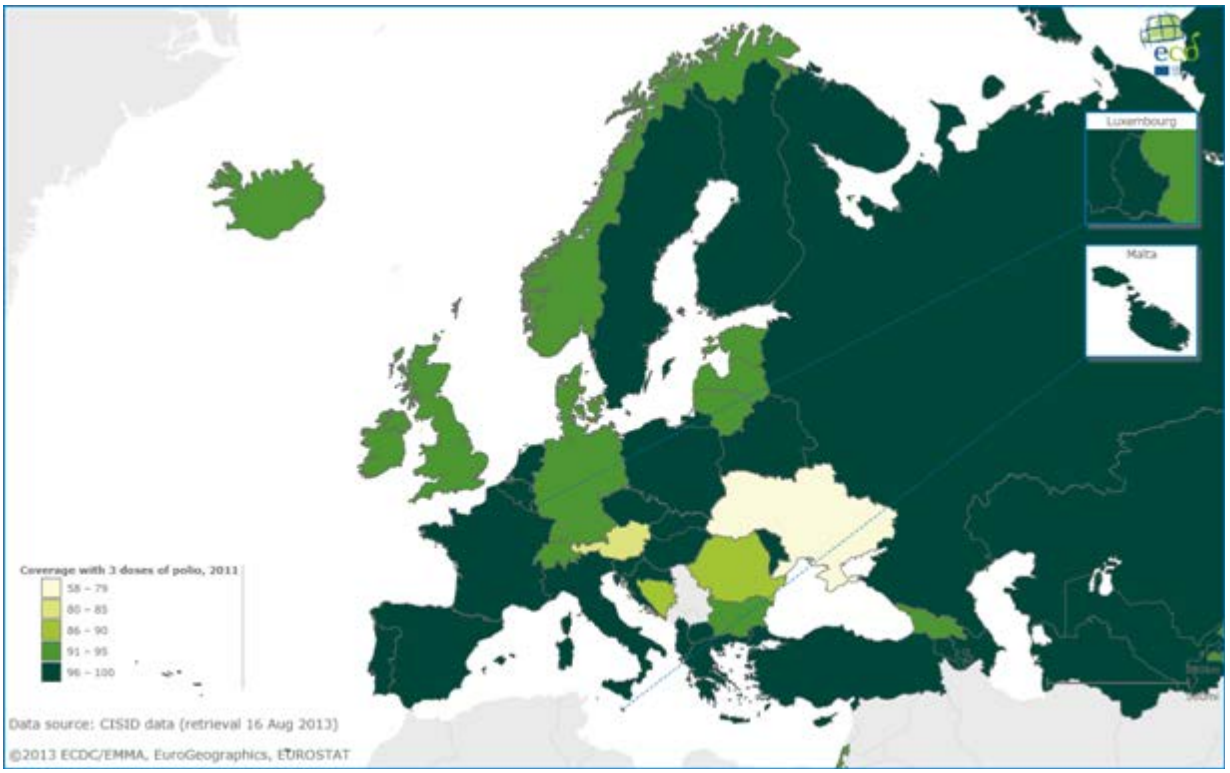
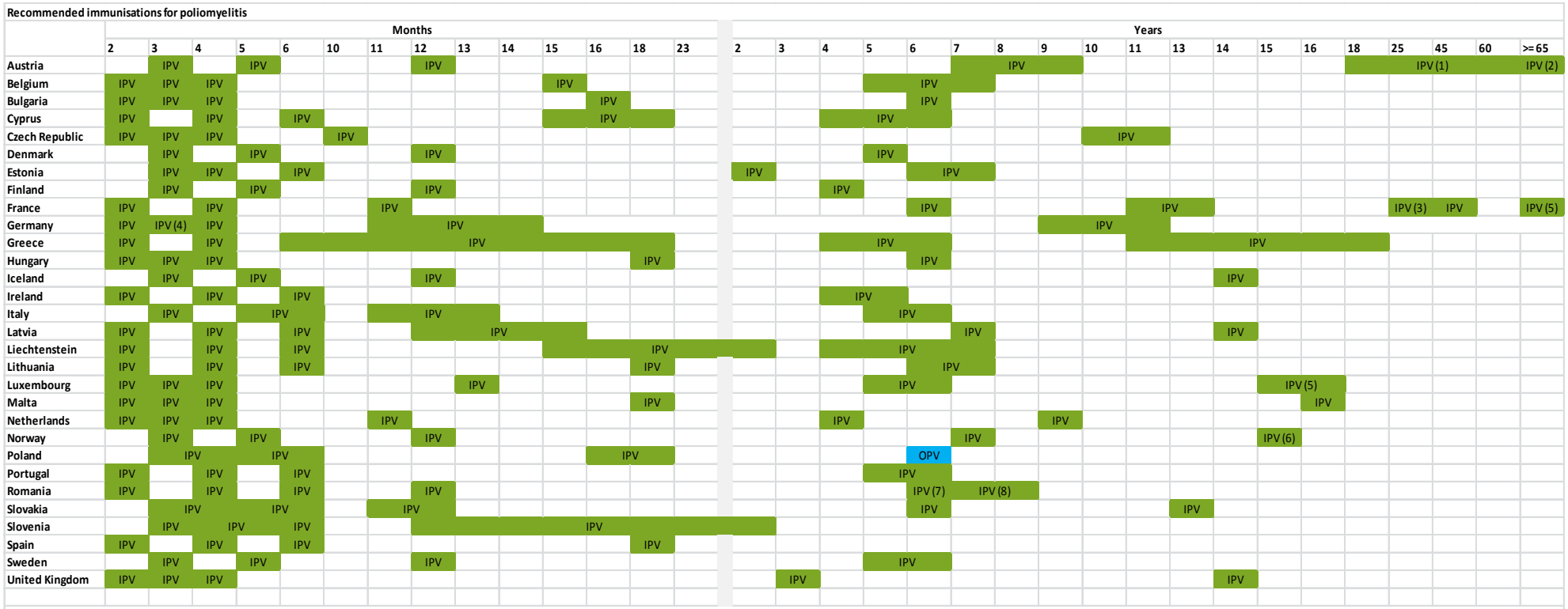


Table 12. Recommended immunisation schedules for polio in EU/EEA Member States



Recommended immunisations for poliomyelitis	Months													Years																		
	2	3	4	5	6	10	11	12	13	14	15	16	18	23	2	3	4	5	6	7	8	9	10	11	13	14	15	16	18	25	45	60	>=65
Austria		IPV		IPV				IPV												IPV									IPV (1)			IPV (2)
Belgium	IPV	IPV	IPV								IPV								IPV													
Bulgaria	IPV	IPV	IPV									IPV							IPV													
Cyprus	IPV		IPV		IPV						IPV						IPV															
Czech Republic	IPV	IPV	IPV			IPV																	IPV									
Denmark		IPV		IPV				IPV										IPV														
Estonia		IPV	IPV		IPV										IPV				IPV													
Finland		IPV		IPV				IPV									IPV															
France	IPV		IPV				IPV												IPV					IPV					IPV (3)	IPV		IPV (5)
Germany	IPV	IPV (4)	IPV					IPV														IPV										
Greece	IPV		IPV					IPV										IPV							IPV							
Hungary	IPV	IPV	IPV										IPV						IPV													
Iceland		IPV		IPV				IPV																		IPV						
Ireland	IPV		IPV		IPV												IPV															
Italy		IPV		IPV				IPV										IPV														
Latvia	IPV		IPV		IPV			IPV												IPV						IPV						
Liechtenstein	IPV		IPV		IPV						IPV						IPV															
Lithuania	IPV		IPV		IPV								IPV						IPV													
Luxembourg	IPV	IPV	IPV						IPV									IPV									IPV (5)					
Malta	IPV	IPV	IPV										IPV															IPV				
Netherlands	IPV	IPV	IPV				IPV										IPV					IPV										
Norway		IPV		IPV				IPV												IPV							IPV (6)					
Poland		IPV		IPV								IPV							OPV													
Portugal	IPV		IPV		IPV													IPV														
Romania	IPV		IPV		IPV			IPV											IPV (7)	IPV (8)												
Slovakia		IPV		IPV			IPV												IPV					IPV								
Slovenia		IPV		IPV	IPV			IPV																								
Spain	IPV		IPV		IPV								IPV																			
Sweden		IPV		IPV				IPV										IPV														
United Kingdom	IPV	IPV	IPV													IPV										IPV						

Footnotes:

1: dTaP-IPV every 10 years between 18 and 60 years of age.

2: dTaP-IPV every 5 years from 65 years of age

3: dTT-IPV every 10 years from 65 years of age

4: optional dosis if monovalent and other combination vaccines are used

5: Subsequent Tdacp-IPV booster every 10 years

6: TdacP-IPV for children born from 1998. Poliomyelitis monovalent for children born up to 1997

7: DTacP-IPV at 6 years to begin in 2015

8: ongoing until 2014, including

Table 13. IPV cohorts in the EU/EEA

Country	Schedule	Birth cohorts full IPV
Austria	Full IPV 1999	1999–2013
Belgium	Full IPV from 2001	2001–2013
Bulgaria	Primary IPV from 2010	2010–2013
Cyprus	Full IPV from 1/8/2002	2002–2013
Czech Republic	Full IPV from 2007	2007–2013
Denmark	Always full IPV	All
Estonia	Full IPV from 2008	2008–2013
Finland	Always full IPV	All
France	95% of vaccinations are IPV since 1990	1990–2013
Germany	Full IPV from 1998	1998–2013
Greece	Full IPV from 2005	2005–2013
Hungary	Full IPV from 2006	2006–2013
Iceland	Always full IPV	All
Ireland	Full IPV from 2001	2001–2013
Italy	Full IPV from 2002	2002–2013
Latvia	Full IPV from 1/1/2010; previously, OPV booster at 18 months	2009–2013
Liechtenstein		
Lithuania	one booster OPV given at least until 2004	2005–2013 ?
Luxembourg	Full IPV at least from 2006	2006–2013 ?
Malta	Full IPV from 1/1/2010;	2010–2013
Netherlands	Always full IPV (OPV used in outbreak situations)	All
Norway	Always full IPV	All
Poland	OPV booster given at 6 years	2008–2013
Portugal	Full IPV from 2006	2006–2013
Romania	Full IPV from 2008	2008-2013
Slovakia	Full IPV from 2005	2005–2013
Slovenia	Full IPV from 2003	2003–2013
Spain	Full IPV at least from 2006	2006–2013 ?
Sweden	Always full IPV	all
United Kingdom	Full IPV from 2004	2004–2013

Table 14. **Birth cohorts vaccinated using IPV-only schedule (indicated in red)**

Table 15. Advantages and disadvantages of the three poliovirus vaccination schedules [61,62]

Attribute	OPV only	IPV only	IPV/OPV sequential
VAPP	2–4 cases per million birth cohort*	None	≥95% reduction from OPV-only schedule
Other serious adverse events	None known	None known	None known
Systemic immunity	High	High	High
Mucosal immunity	High	Lower	High
Secondary transmission of vaccine virus	Yes	No	Some
Emergence of circulating vaccine-derived poliovirus	Yes	No	Probably reduced
Extra injections or visits needed	No	Yes	Yes
Compliance with immunisation schedule	High	Possibly reduced	Possibly reduced
Future combination vaccines	Unlikely	Likely	Likely (IPV)
Current cost	Low	Usually higher	Intermediate

IPV: inactivated poliovirus vaccine, OPV: oral poliovirus vaccine, VAPP: vaccine-associated paralytic poliomyelitis.

Adapted from Centers for Disease Control and Prevention. Poliomyelitis prevention in the United States: introduction of a sequential vaccination schedule of inactivated poliovirus vaccine followed by oral poliovirus vaccine: recommendations of the Advisory Committee on Immunization Practices. MMWR 46(RR-3):1-25, 1997.