

### RAPID RISK ASSESSMENT

International spread of wild-type poliovirus in 2014 declared a Public Health Emergency of International Concern under the International Health Regulations (IHR)

### 28 May 2014

#### **Main conclusions**

ECDC acknowledges that the recent spread of wild-type polio virus threatens the eradication of poliomyelitis and welcomes the declaration of a Public Health Emergency of International Concern.

ECDC does not think that previous assessments of the risk of poliovirus importation and re-introduction of polio transmission in the EU following WPV circulation in Israel and Syria need to be changed following the declaration of a Public Health Emergency of International Concern.

On 5 May 2014, the Director-General of the World Health Organization, Dr Margaret Chan, acted on the recommendation of the International Health Regulations Emergency Committee and declared that the spread of wild-type poliovirus in 2014 constitutes a Public Health Emergency of International Concern (PHEIC) in accordance with the International Health Regulations (IHR).

Following the announcement of a PHEIC, WHO issued temporary recommendations for reducing and controlling the spread (i.e. importation) of wild polioviruses from polio-infected countries (10 countries) to a country that has been declared free of polio. This is critical to avoid failing global polio eradication goals and jeopardising efforts made at the international level.

The new WHO recommendations apply to people who visit or live in countries where poliovirus is still circulating and have direct and immediate consequences for EU travellers and EU residents.

At the EU level, the new temporary recommendations by WHO have immediate consequences for i) EU countries which inform the general public and all those involved in the vaccination of travellers, ii) EU countries which issue temporary polio vaccine recommendations in line with WHO requirements, and iii) EU countries which consider systematically issuing vaccination cards to EU travellers.

ECDC agrees that the confirmed circulation of WPV in 10 countries and the documented exportation of WPV to neighbouring countries for three of them, support the fact that there is a potential risk for WPV being reintroduced into the EU/EEA. The highest risk of large outbreaks of poliomyelitis is in areas where unvaccinated populations are geographically clustered or live in poor sanitary conditions, or a combination of both conditions.

It is recommended that EU/EEA Member States should revise their polio vaccination advice to EU travellers
and residents, in particular in the ten countries that reported infections. In order to comply with the WHO
recommendations and avoid having to be vaccinated in a polio-infected country, it is important for
travellers to polio-affected countries to time the administration of the additional IPV dose so that it is given

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within 12 months of the planned departure from the polio-infected country.

- EU/EEA Member States are strongly advised to prioritise the assessment of polio vaccination uptake at the
  national, subnational and local levels, and the identification of vulnerable and undervaccinated populations.
  In areas where polio vaccination coverage is below 90%, efforts should be increased to improve
  vaccination coverage in accordance with national or regional immunisation recommendations.
- Based on a review of available evidence and expert opinion, Member States are strongly advised to assess
  the vaccination status of refugees and migrants from polio-affected countries at the time of entry into the
  EU/EEA; people not vaccinated against polio or other diseases should be offered vaccinations that are
  appropriate for their age and vaccination status (if known); vaccinations should be administered in
  accordance with the host country's vaccination schedule.

The <u>WHO guidance</u> for implementation of the IHR Temporary Recommendations under the IHR (2005) to reduce the international spread of polio (dated 16 May 2014) states that the WHO does

'not recommend that polio-free countries screen arriving passengers for their polio vaccination status. However, some individual polio-free countries will require proof of such vaccination for a visa or for entry. It is important to ensure travellers know the requirements of the country to which they are travelling.'

ECDC continues to support the EU-wide response to the threat of poliovirus spreading across Europe and will, upon request, support individual EU Member States in all areas related to their preparedness, e.g. the detection and control of poliovirus importations.

### Source and date of request

ECDC internal decision, 19 May 2014.

### **Public health issue**

On 5 May 2014, the Director-General of the World Health Organization (WHO), Dr Margaret Chan, acted on the recommendation of the International Health Regulations Emergency Committee and declared that the spread of wild-type poliovirus (WPV) in 2014 constitutes a Public Health Emergency of International Concern (PHEIC) in accordance with the International Health Regulations (IHR) [1]. This is the second time that a PHEIC has been declared under IHR 2005. The first time was for pandemic influenza A(H1N1) in 2009.

In a press conference held by WHO on 5 May 2014, Dr Bruce Aylward, WHO Assistant Director-General responsible for polio eradication, stated that if

'the situation as of today and April 2014 is unchecked, it could result in the failure to eradicate globally one of the world's most serious vaccine-preventable diseases' [2].

As a result of the PHEIC, WHO issued temporary recommendations for controlling the spread of polioviruses.

This Rapid Risk Assessment examines the implications of the temporary recommendations for EU Member States and assesses whether the developments leading to the declaration of a PHEIC represent an increased risk of WPV importation to, and sustained transmission in, Member States of the European Union. It also considers practical suggestions for implementing the WHO recommendations in the EU.

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### **Disease background information**

Poliomyelitis is a severe vaccine-preventable viral disease that is targeted for eradication. For further information on polioviruses, polio vaccines, poliovirus infections, poliomyelitis and disease epidemiology, please consult the WHO position paper on polio vaccines, January 2014 [3].

# **Event background information**

The lowest ever number of new polio cases reported in the world was in 2012, when 293 confirmed cases were reported from nine countries, of which 223 were caused by WPV [4]. In 2013, the number of confirmed polio cases caused by WPV increased to 417, and outbreaks were reported from Somalia and Syria. The circulation of WPV was confirmed in Israel through environmental and human surveillance, but no symptomatic cases were reported. Between 1 January and 31 April 2014, 68 confirmed WPV cases were notified worldwide, 54 of which were reported from Pakistan [4].

The rationale for the WHO declaration of a PHEIC is the observation that

'in 2013 about 60% of polio cases were the result of international spread of wild virus and there was also increasing evidence that adult travellers were contributing to such spread. During the low season in 2014, there were ten countries that are considered to have active transmission of wild poliovirus and in contrast with previous years, there has already been a spread from three of these countries internationally. In Central Asia there has been spread from Pakistan into Afghanistan, in the Middle East from the Syrian Arab Republic into Iraq, and in Central Africa from Cameroon to Equatorial Guinea'.

ECDC responded to the confirmed circulation of wild-type poliovirus (WPV) in Israel and the outbreak of poliomyelitis in Syria in 2013 by, among other activities, conducting several assessments of the risk of importation to, and sustained transmission in, the EU/EEA [5] [6], convening an expert consultation [7], and publishing a technical report on the detection and control of poliovirus transmission [8].

### Public Health Emergency of International Concern

Following the declaration of a PHEIC, WHO has issued temporary recommendations that will be re-assessed in three months [1].

The main purpose of the measures presented in in the temporary recommendations is to reduce the risk of international spread of wild-type poliovirus before the high WPV transmission season in May and June.

The WHO recommendations divide the 10 polio-affected countries into two groups.

- Three 'currently exporting countries' (Pakistan, Cameroon and Syria) from which the virus has been carried to other countries in 2014.
- Seven countries (Afghanistan, Equatorial Guinea, Ethiopia, Iraq, Israel, Somalia and Nigeria) which are affected but are currently not exporting poliovirus.

The control measures reflect this risk stratification:

- The three exporting countries are requested to *ensure* that all residents and long-term visitors (defined as
  those staying in the country for more than four weeks) receive a dose of either OPV or IPV between four weeks
  and 12 months prior to international travel. Countries have to ensure that such travellers are provided with an
  International Certificate of Vaccination or Prophylaxis in the form specified in Annex 6 of the International
  Health Regulations (2005) to record their polio vaccination and serve as proof of vaccination.
- The seven non-exporting countries are requested to *encourage* the same vaccinations and ensure that travellers who receive such vaccination have access to an appropriate document to record their polio vaccination status.

In addition, the 10 countries have to officially declare – if they have not already done so – at the level of head of state or government, that the interruption of poliovirus transmission is a national public health emergency. They have to maintain these measures until the following criteria have been met: (i) at least six months have passed without the detection of wild poliovirus transmission in the country from any source, and (ii) there is documentation of full application of high-quality eradication activities in all infected and high risk areas.

In light of the new WHO temporary recommendations, ECDC published specific polio travel advice on its website on 27 May 2014.

# **ECDC threat assessment for the EU**

### **Risk of importation and sustained transmission following the new WHO temporary recommendations**

ECDC acknowledges that the recent spread of wild-type polio virus threatens the eradication plan for poliomyelitis and welcomes the declaration of a Public Health Emergency of International Concern. It should be noted, however, that 25 years ago the annual number of reported polio cases world-wide was about one hundred times higher than it is now, and although the cases increased last year, we are still at a global record low.

ECDC does not think that previous assessments of the risk of poliovirus importation and re-introduction of polio transmission in the EU following WPV circulation in Israel and Syria need to be changed in light of the declaration of a PHEIC and the WHO temporary recommendations.

The spread of poliovirus in Pakistan and Syria is of particular concern:

- The collapse of the health system and the refugee crisis in Syria have resulted in several birth cohorts having very low vaccination coverage. The armed conflict has restricted access to populations in some parts of the country, which contributed to the outbreak of polio in Syria, with the identification of 17 laboratory-confirmed AFP (acute flaccid paralysis) cases from three different areas, indicating widespread transmission of the virus (as of 4 December 2013) [6,9].
- In Pakistan, targeted killings of vaccinators, anti-vaccination propaganda, and the limited governmental control
  over the north-western parts of the country have led to an increase in cases of poliomyelitis. Environmental
  surveillance has detected wild-type poliovirus in many parts of the country. In the first months of 2014, AFP
  cases increased by a factor of ten compared with 2013 [4].

The outbreak of poliomyelitis in Syria, as well as the situation in Pakistan in addition to established wild poliovirus circulation in eight others countries, shows that there is a continued risk for the disease being imported into the EU/EEA.

In previous assessments, ECDC concluded that in the event of importation of wild-type poliovirus resulting in the re-establishment of virus circulation in the EU, the overall risk to EU residents would be:

- very low in OPV-vaccinated populations for both poliovirus infection and disease;
- moderate in IPV-only cohorts for poliovirus infection and very low for disease; and
- high in low- or unvaccinated groups for poliovirus infection and moderate for disease.

Because of the increasing cross-border movements of people between polio-infected countries and the polio-free EU, it must be assumed that regular importations of WPV to the EU have occurred and continue to occur today. In the absence of a sensitive environmental surveillance system that is also stable over time, it is difficult to accurately estimate the frequency of such WPV importations. There can, however, be no doubts that WPV importations have continued since the latest recorded outbreaks of poliomyelitis in the EU. The fact that these WPV importations have not resulted in outbreaks of poliomyelitis in the EU can only be explained by the high level of immunity in the EU, which has prevented the virus from circulating in the population and reaching unvaccinated individuals.

To limit the risk of reintroduction and sustained transmission of WPV in the EU/EEA, it is crucial to maintain high vaccine coverage in the general population and increase the vaccination uptake in the pockets of underimmunised populations. The highest risk of developing both asymptomatic infections as well as poliomyelitis after exposure to poliovirus is found among unvaccinated people in the EU. Based on historical outbreaks, the groups of highest concern for propagated outbreaks are orthodox Christian groups in the Netherlands and the large Roma populations in the south-eastern parts of the EU. The orthodox Christian groups live under good sanitary conditions but have a low vaccination uptake as a result of religious beliefs. The Roma population is heterogeneous, and the vaccination uptake within this population group varies between countries and sub-national communities. Collectively, however, the Roma remain an undervaccinated group, and a large proportion of Roma are forced to live under sanitary conditions that favour the transmission of poliovirus. Both orthodox Christians and Roma, as well as other smaller population groups with low vaccination uptake, benefit from the herd protection that comes from living within highly vaccinated populations, but otherwise all conditions are met for rapidly evolving outbreaks in the unlikely event of wild-type poliovirus being introduced into either of these two groups.

#### ECDC supports the WHO statement that the

'over-riding priority for all polio-infected States must be to interrupt wild poliovirus transmission within their borders as rapidly as possible through the immediate and full application in all geographic areas of the polio eradication strategies, specifically: supplementary immunization campaigns with oral poliovirus vaccine (OPV), surveillance for poliovirus, and routine immunization'. The overall polio vaccination uptake is high in the EU, and the likelihood of a vaccinated person developing poliomyelitis is very low, regardless of whether the person was vaccinated with OPV or IPV. The likelihood that a person vaccinated with IPV will develop an asymptomatic infection after exposure to an infective dose of poliovirus is higher than for someone vaccinated with OPV. This is likely to be part of the explanation for the circulation of wild-type poliovirus in Israel, despite the high vaccination coverage and the absence of disease there.

### Implications of the new WHO temporary recommendations for EU travellers and visa applicants from infected countries returning from polio-infected areas

ECDC recognises that the declaration of a Public Health Emergency of International Concern may require Member States to revise their advice to travellers to polio-infected countries.

It should be noted that there are no WHO temporary recommendations for polio-free countries, e.g. EU Member States. The temporary recommendations are directed towards polio-infected areas.

While the new WHO recommendations do not necessitate any modifications to previous ECDC assessments on the risk of spread and re-introduction of WPV to EU countries, they clarify the procedures for the vaccination of travellers and residents of infected areas.

To ensure that EU travellers are fully protected and to facilitate their return from polio-infected areas, EU Member States should consider issuing specific advice for polio vaccinations for travellers to the polio-infected countries, in accordance with the WHO temporary recommendations, and alert travellers to the need to carry a valid certificate of polio vaccination.

The <u>WHO guidance</u> for implementation of the IHR Temporary Recommendations under the IHR (2005) to reduce the international spread of polio (dated 16 May 2014) states that the WHO does:

'not recommend that polio-free countries screen arriving passengers for their polio vaccination status. However, some individual polio-free countries will require proof of such vaccination for a visa or for entry. It is important to ensure travellers know the requirements of the country to which they are travelling.' [10]

The WHO guidance also indicates that

'some countries already have polio vaccination requirements for entry (e.g. the Kingdom of Saudi Arabia, India), and others may decide to put additional measures in place to prevent the spread of poliovirus.'

ECDC assessed the potential benefits and the feasibility of systematically screening the vaccination status of people arriving in the EU from polio-infected countries, and whether such a public health measure is likely to further reduce the risk of WPV importation and re-introduction to the EU:

- ECDC assessed the benefit of systematic screening of the vaccination status of travellers from countries
  affected by polio who have remained in those countries for longer than four weeks and visa applicants from
  countries affected by polio.
- ECDC assessed the feasibility of systematically screening the vaccination status of travellers arriving from polioinfected countries in relation to: i) how much it would reduce the risk of WPV importation; ii) the estimated number of passengers arriving from polio-infected countries; and iii) the financial costs and human resources required to conduct systematic screening.

The following sources of evidence were considered:

- A limited, non-systematic (due to lack of time) review of the scientific literature, looking at evidence of the
  effectiveness of systematic vaccination status screening on reducing the risk of importation and re-introduction
  of polio.
- <u>WHO guidance</u> for the implementation of the IHR temporary recommendations under the IHR (2005) to reduce the international spread of polio (16 May 2014) [10].
- The conclusions from an expert meeting on poliomyelitis conducted by ECDC on 5 November 2013 [7].
- A rapid expert consultation with some members of the ECDC Advisory Forum, with responses from France, Finland, Germany, Norway, Spain, Sweden and the United Kingdom. Experts were selected based on their expertise in the subject matter; countries were chosen because they have a high number of travellers to and from polio-infected areas and also host Syrian refugees. The objective of the consultation was to gather expert opinions on options for the planned implementation of the new WHO temporary recommendations and provide evidence which would support these options.

ECDC's limited, non-systematic literature review could not identify direct evidence on the effectiveness of systematically screening the vaccination status of travellers and visa applicants as an intervention to reduce the risk of WPV importation. Indirect evidence exists in the area of other vaccine-preventable diseases, i.e. the systematic screening of the vaccination status for yellow fever and meningococcal disease when entering endemic areas [11,12].

ECDC's rapid expert consultations indicated that screening the vaccination status of travellers was not deemed necessary:

- There is evidence that the high vaccination coverage at the national level has prevented re-introduction of WPV – despite periodic detection in the EU [5].
- Experts agreed that the risk of re-introduction could be considered low.
- Although not officially part of the analysis, several experts pointed out a series of practical issues with
  systematically screening travellers arriving from polio-infected countries, including: technical feasibility, the
  need for trained and dedicated staff, the question of how to manage people who do not have valid polio
  vaccination records, and the high number of travellers.

### **Implications of the new WHO temporary recommendations for refugees**

ECDC considered several options for public health measures that may reduce the risk of WPV importation and reintroduction in the EU through the entry of refugees to the EU. Suggested measures aimed at Syrian refugees were addressed in an ECDC rapid risk assessment dated December 2013 [7]; the risk assessment was released following an expert group meeting held on 5 November 2013. In this document, ECDC strongly advises to use measures similar to those that are applied to refugees from other infected areas.

The focus of the expert consultation was to seek advice from European experts in vaccine-preventable diseases and polio on how ECDC and the EU Member States should respond to the threat of wild-type poliovirus introduction and re-establishment in Europe.

- Refugees arrive in the EU/EEA via different routes: some passed through migrant camps before they entered the EU (where they may have received OPV), other entered the EU directly. Only some carry documentation of previous vaccinations. Because of the conflict in Syria, the vaccination programme has been disrupted since 2011, which puts children under the age of five years (those who have not received any polio vaccination or those who have not received a full course of vaccination) at the highest risk of acquiring or transmitting poliovirus.
- Experts concluded that vaccinating all children from Syria who are under five years of age against polio is a top priority, unless the child already has valid proof of vaccination. Host countries should also ensure that refugees (both children and adults) from all geographical areas have age-appropriate vaccinations, in accordance with the host country's immunisation schedule. All missed vaccinations should be taken into account, not just polio. Serology testing before the vaccination is not recommended.
- Several unresolved questions relate to the use of IPV versus OPV in this population, including ease of
  administration, vaccine supplies, and the risk of intramuscular injections while incubating polio. IPV is currently
  used for routine immunisation in all EU/EEA countries. However, IPV is administered as an intra-muscular
  injection, and there is evidence of an increased risk of paralysis developing in a limb in which an injection has
  been administered [13-15] if the child is incubating poliomyelitis at the time of the injection. An increased risk
  of developing vaccine-associated paralytic polio (VAPP) was observed in Romania following multiple
  intramuscular injections after OPV [16]. However, the same phenomenon was not observed in the US when
  injections were given simultaneously and therefore the authors of a US study concluded that it is safe to
  administer OPV simultaneously with other childhood vaccinations [17].
- Polio circulation/infection in the EU is, of course, not restricted to Syrian refugees but also occurs among
  unvaccinated or underserved EU population groups. Therefore, increasing coverage in the EU population,
  especially in underimmunised population groups is critical and provides the first line of defence against
  poliovirus transmission and disease. All EU/EEA citizens who work directly with high-risk populations (medical
  personnel, social services personnel, host families, etc.) should be fully immunised against polio, as should
  travellers to polio-infected areas and countries.

Member States are strongly advised to assess the vaccination status of refugees and migrants from polio-affected countries at the time of entry into the EU/EEA area by inspecting vaccination records. People belonging to these groups who have not been vaccinated or do not have valid certification of vaccination against polio or other vaccine-preventable diseases, should be offered vaccinations that are appropriate for their age and vaccination status (if known), in accordance with the host country's vaccination schedule [7]. The vaccine provider should record vaccinations given to refugees and migrants in the national records.

# Annex

# Latest estimates: Syrian refugees arriving in the EU – update 27 May 2014

According to data provided by the <u>European Union</u>, almost 60 000 refugees have applied for political asylum in the EU since the start of the current conflict.

In 2011, 8 920 Syrians applied for <u>asylum within EU borders</u>, while in the first three quarters of 2012 applications increased slightly, reaching a total of 11 573. Only 1 490 irregular entries of Syrians were recorded during the last three quarters of 2011, which rose to 2 739 in the first two quarters of 2012. Numbers of Syrians applying for immigration have also remained negligible.

In 2012, Syrians became the single largest group of persons granted protection status in the EU27. <u>Of the 18 700</u> <u>Syrians</u> granted protection status in the EU27, more than 70% were recorded in two Member States: Germany (8 400) and Sweden (5 000). In <u>2013</u>, more than 50 000 asylum applicants were from Syria [4].

#### Three routes to the European Union

1. Land route to Greece or Bulgaria: refugees travel through Turkey – a country Syrians can enter without a visa – and continue on to Greece or Bulgaria. Once in the EU, they are either ordinary travellers or irregular migrants, depending on whether they have a visa or not.

2. Direct flights to any EU Member State: as ordinary travellers originating from a third country, Syrians are registered at the external border; however, no statistics of ordinary travellers by country of origin are routinely produced at the EU level, so the actual number of arriving Syrians remains unknown. Once in the EU, Syrians can either apply for political asylum or remain in an irregular situation, and either stay in the country of arrival or continue on to a third country. Of all refugees arriving in the EU by land, only those applying for asylum and those detected as irregular migrants will be reflected in the statistics.

3. Sea route across the Mediterranean to Greece, Cyprus, Malta or Italy (and possibly France and Spain): only those lacking regular entry documents take this route to Europe. Refugees then enter the EU as irregular migrants before applying for political asylum.

#### **Data source**

Data were obtained through the web asylum map developed by the <u>European Commission</u> [5], which shows the updated number of asylum applications by Syrian refugees by EU country:

- Bulgaria: 3 555
- England: 3 650
- Finland: 455
- France: 1 975
- Germany: 24 940
- Norway: 1 410
- Spain: 895
- Sweden: 23 560

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