

5 - 6 Feb | 2014

8th Meeting of the SAGE Polio Working Group

Conclusions and recommendations

Note for the Record



**World Health
Organization**

DRAFT AS OF 3/17/14

Executive Summary

Since the inception of the Global Polio Eradication Initiative (GPEI) in 1988, the number of paralytic cases dropped from an estimated 350,000 in 1988 to 403 reported in 2013, and wild polioviruses currently remain endemic in only three countries (Afghanistan, Nigeria, and Pakistan). However, as long as polioviruses circulate anywhere, they can be exported to polio-free countries. Between 2004 and 2013, for example, exportations caused 179 outbreak events in previously polio-free countries, which resulted in more than 3,500 paralytic cases. The GPEI has expended over \$1.1 Billion in international funds alone, for outbreak response following wild poliovirus importations over the last 10 years (2004-2013). This estimate does not include the indirect costs of diverting public health experts and health workers from other public health work or the opportunity costs associated with using vaccine for outbreak response instead of for intensified eradication activities during times of restricted supplies.

Following the polio outbreaks of 2013 in the Middle East and the Horn of Africa due to international spread of poliovirus, and the threat such events pose to the eradication of poliomyelitis globally, during the World Health Organization (WHO) Executive Board meeting in January 2014, Member States requested that the WHO Director General (DG) convene an Emergency Committee under the International Health Regulations (IHR) to review as a matter of urgency the potential need for additional measures for reducing the risk of international spread of polio within the IHR mechanism for public health emergencies of international concern (i.e. PHEIC). Several WHO Member States (e.g. Saudi Arabia, India, Syria, and Brunei) had already introduced polio vaccination requirements for travellers arriving from polio-infected countries, and some Member States requested additional WHO guidance in this regard.

Given the availability of new information on the impact of polio vaccines on humoral and intestinal immunity, on the role of adults in international spread of the virus, and on the duration of intestinal immunity to poliovirus, the WHO Director-General requested that the Strategic Advisory Group of Experts on immunization (SAGE) review this evidence and, if appropriate, provide advice to WHO for updating its technical recommendations concerning the vaccination of travellers from polio-infected countries.

The SAGE Polio Working Group (WG) convened an extraordinary session on 5 and 6 February 2014 in Geneva, Switzerland to review WHO's technical recommendations on polio vaccination for travellers from polio-infected countries and propose an update for consideration by SAGE at its April 2014 meeting. The WG also discussed potential challenges and practical considerations that might be encountered in implementing such recommendations. Representatives of the governments of Nigeria, Pakistan, Israel, Saudi Arabia, and from the International Civil Aviation Organization (ICAO) and the International Air Transport Association (IATA) were invited to share their perspectives with the WG.

Noting that all polio-free countries remain at risk of importations as long as poliovirus circulation continues anywhere, the WG concluded that vaccination of international travellers from polio-infected countries would help to mitigate the risk of international spread of the virus, especially to polio-free countries with vulnerable populations and at high-risk of importations. The WG also reinforced the importance of all countries ensuring high immunization coverage, especially in high risk and vulnerable populations, and maintaining sensitive surveillance to rapidly detect circulating poliovirus. The WG emphasized that the best way to reduce and eliminate the exportation of wild polioviruses (WPV) and circulating vaccine-derived polioviruses (cVDPVs) was to stop all remaining virus transmission in polio-infected countries. Efforts to reduce spread of polioviruses from infected countries through travellers should complement and not detract from the critical work of terminating transmission in polio infected countries.

RECOMMENDATIONS

The WG reviewed new evidence on the efficacy of polio vaccines and the epidemiology of polio, and recommended that the current advice for international travellers in the WHO document *International Travel and Health (ITH) 2013* should be updated as follows:

Definition of “polio-infected” countries

- The WG reaffirmed the following definitions used by WHO to identify countries with active poliovirus transmission (i.e. ‘polio-infected countries’):
 - **Endemic WPV transmission:** continued transmission of an indigenous WPV which by definition has never been interrupted. Endemic WPV transmission is considered to be interrupted, when all indigenous WPVs have not been detected for > 12 months from any source (e.g. Acute Flaccid paralysis (AFP) cases, their contacts, environmental samples, stool surveys). As of February 2014, three countries were considered endemic (Pakistan, Nigeria, Afghanistan);
 - **Re-established wild poliovirus transmission:** persistence of WPV of non-indigenous origin for > 12 months in a previously polio-free country. Re-established WPV transmission is considered to be interrupted, when the imported strain of WPV has not been detected for > 12 months from any source (e.g. AFP cases, their contacts, environmental samples, stool surveys);
 - **Re-infection with wild poliovirus :** a) at least one AFP case with isolation of WPV in a person who has not travelled outside the country during the two months prior to onset of paralysis or b) detection of 2 or more genetically related WPVs in environmental samples and/or other non-AFP sources (e.g. stool surveys). WPV is considered to be interrupted, when there is no detection of the imported strain of WPV for > 6 months from any source (e.g. AFP cases, their contacts, environmental samples, stool surveys);
 - **Re-infection with a cVDPV:** detection of a genetically related cVDPV in 2 or more AFP cases in a country, or detection of a genetically related cVDPV in 2 or more environmental samples or samples from other sources. Re-infection with cVDPV is considered to be interrupted when there has been no detection of the cVDPV for > 6 months.
- The WG also reaffirmed that an isolated “WPV or cVDPV importation event”, wherein a country detects a WPV or cVDPV in (a) a single AFP case who had proven exposure and/or paralysis onset outside the country, or (b) in a single environmental sample or sample from another source, is not considered evidence of active poliovirus transmission.

Recommended population for vaccination (“Recommended population”)

- Vaccination recommendations for travellers from polio-infected countries should apply to all residents and long-term visitors (i.e. non-residents who spend more than 4 weeks in the country) of all ages;
- Polio vaccination recommendations for travellers from polio-infected countries would not apply to short-term visitors (e.g. those who visit the polio-infected country for periods of ≤ 4 weeks duration) or travellers in transit through an infected country, as they would pose a low risk of poliovirus infection and international spread;

Recommended vaccinations

Travellers from infected countries (those who meet the definition of “recommended population” above)

- All such travellers from polio-infected countries should have received one documented, additional dose of OPV or IPV at least 4 weeks and at most 12 months before departure;
- In addition, all such children travelling from polio-infected countries should have completed their age-appropriate primary series for polio vaccination according to the national immunization schedule (e.g. children too young to have received at least 3 doses of a polio vaccine according to the national schedule should be up-to-date for their age);

- Such travellers from polio-infected countries embarking on last minute/urgent (i.e. less than 2 weeks) travel that cannot be postponed should receive one dose of OPV or IPV before departure if they have not received a documented dose of polio vaccine within 12 months before the date of travel.

Travellers to infected countries

- Per the current WHO *International Travel and Health (ITH) 2013*, travellers to polio-infected countries are advised to have completed the age-appropriate polio vaccine series recommended in their national immunization schedule; adult travellers should have a one-time booster dose of OPV or IPV prior to travel to polio-infected countries

CONSIDERATIONS FOR IMPLEMENTING POLIO VACCINATION RECOMMENDATIONS FOR TRAVELLERS

The WG discussed a number of operational issues related to the implementation of vaccination recommendations and/or requirements for travellers (e.g. for yellow fever, polio) that should be considered in applying such measures.

Documentation of vaccination

- To facilitate international travel, each polio-infected country would need to ensure its travellers have access to a standardized certificate that would be accepted internationally as proof of appropriate polio vaccination;
- The WHO vaccination and prophylaxis 'Yellow Book or Booklet'¹ (preferably), and the 1-page IHR model International Certificate of Vaccination or Prophylaxis in Annex 6 of the IHR (2005) (which is also part of the Yellow Book), are two internationally acceptable documents for proof of vaccination that could be used for this purpose;
- To facilitate international acceptance of any nationally-issued vaccination certificates, authorities should ensure that such documents contain the information included in the above IHR model International Certificate and Annex 6;
- To reinforce the authenticity of the certificates of vaccination, countries should be encouraged to make efforts to ensure the validity, accuracy, and integrity of the certificates they issue (e.g. producing certificates with features that resist falsification). The WG noted that at least 1 country has included a security feature within its vaccine certificate for yellow fever to reduce this problem;

Role of countries of departure (polio-infected countries)

- The WG recognized that exit screening of vaccination certificates is not currently recommended or implemented for any vaccine-preventable disease risk. However, this might be a consideration for polio in some settings given the small number of polio-infected countries;
- At ground-crossing points with a high volume of travellers, and limited capacity for screening (e.g. an uncontrolled land border), implementation of special measures could be considered to boost population immunity in that area (e.g. expanded age group campaigns or vaccination/documentation at the border).

Role of countries of arrival

- Countries receiving travellers within the recommended population for vaccination from polio-infected countries may need to:
 - Validate at border crossings proof of appropriate polio vaccination of such travellers arriving from these countries (including at airport, seaport and ground crossing-points);

¹ The Yellow Book is available as a pdf download on the WHO website. See WHO International Certificate of Vaccination or Prophylaxis: International Health Regulations (2005), at http://www.who.int/ihr/ports_airports/icvp/en/.

- Establish a process for managing such travellers who are not able to produce a valid certificate of vaccination. Options for managing such travellers may include vaccination on arrival, refusal of entry, and/or quarantine, depending on the assessed risk of importation in accordance with any relevant IHR and national and international obligations regarding such measures;
- Establish options for managing such arriving travellers who are not able to produce a valid certification of vaccination and refuse vaccination on arrival;
- Explore the potential value of linking proof of polio vaccination to the issuance of entry visas for such travellers to minimize the number of travellers arriving without proper documentation of polio vaccination.

Acceptable vaccines

- WHO pre-qualified polio vaccines should be considered acceptable for the purposes of vaccinating travellers from polio-infected countries; nationally-licensed polio vaccines, but which have not been submitted for WHO prequalification, may also be considered acceptable for this purpose.

Administrative and financial issues

- Governments of both departure and arrival countries will need to reinforce their capacity to vaccinate, issue certificates, communicate to the public, and, potentially, screen at border points in order to assess the polio vaccination status of travellers within the recommended populations and to manage any health measures applied to them as appropriate;
- The financial and human resources needed to implement polio vaccination recommendations and/or national requirements for travellers, and the potential opportunity costs associated with undertaking these measures, should be assessed for planning purposes so that polio-infected countries can act accordingly;
- To mitigate the financial and administrative impact of any potential polio vaccination requirements for travellers, consideration might be given to a phased introduction, beginning with populations and/or areas at highest risk for transmission of virus to other countries (e.g. guest workers leaving a polio-infected country for another country).

Communication and public education

- Careful planning and communications in polio-infected countries, and also for relevant personnel in countries of arrival, will be important to ensure effectiveness and facilitate implementation of any polio vaccination recommendations or national requirements;
- Although airline companies may play a role in helping to inform passengers about vaccination requirements, such companies should neither be responsible for exit/arrival screening of vaccination certificates nor required to bear expenses related to a failure of passengers to comply with any such requirements, including the transport of Individuals who are not granted entry back to the country of origin

Annex-1: Key WG recommendations and supporting evidence

Current recommendations (ITH 2013)	Proposed Recommendations	Key Evidence
<p>Population recommended for vaccination</p> <ul style="list-style-type: none"> Individuals living in areas where polio cases area still occurring 	<ul style="list-style-type: none"> Population recommended for vaccination should include <u>residents</u> of all ages of polio-infected countries*, as well as <u>long-term visitors</u> (>4 weeks) 	<ul style="list-style-type: none"> Excretion of WPVs has been detected among individuals of all ages, Persons of all ages who excreted WPVs were detected in many areas of active WPV circulation; Some recent outbreaks (4 of 22) showed most paralytic cases occurred among adolescents and adults Several documented cases of international spread of WPVs involved transmission from adults (people > 15 yrs); Short-term travelers likely assume a low risk of community exposure to poliovirus (e.g. staying in hotels), while longer term travellers may assume a much higher risk of household poliovirus exposure (e.g. staying with families).

* “Polio-infected countries include all countries with transmission of indigenous or re-established WPV within the past 12 months and/or transmission of an imported WPV or cVDPV within the past 6 months). The evidence of ongoing poliovirus transmission can come from cases of AFP, environmental samples, and other sources such as stool surveys

Current recommendations (ITH 2013)	Proposed Recommendations	Key Evidence
<p>Vaccination recommendation for travellers <u>from</u> polio infected countries</p> <ul style="list-style-type: none"> • Travellers should have completed a full course of vaccination against polio, preferably with OPV • Travellers from infected areas should receive an additional dose of OPV at least 6 weeks before each international journey 	<ul style="list-style-type: none"> • If the last documented dose of polio vaccine was received <u>more than 12 months</u> before departure, the traveller within the recommended population should receive at least one additional dose of <u>OPV or IPV</u> at least <u>4 weeks</u> before departure • All children (within the recommended population) from polio-infected countries should have completed age-appropriate primary polio vaccination before departure • For last minute and urgent travel that cannot be postponed, the traveller within the recommended population should receive a dose of OPV or IPV, prior to departure. 	<ul style="list-style-type: none"> • Data from polio-infected areas suggest that intestinal immunity wanes within 12 months of the previous vaccination with OPV • More than 90% of those who will seroconvert will have done so by 4 weeks (either by OPV or IPV). • Most poliovirus excretion (wild and vaccine related viruses) is cleared within 4 weeks, especially in OPV-vaccinated populations and areas of endemic transmission • Two randomized controlled trials indicate that IPV can boost intestinal immunity among individuals previously-vaccinated with OPV.
<p>Vaccination recommendation for travellers <u>to</u> polio infected countries</p> <ul style="list-style-type: none"> • These travellers should ensure that they have completed the age-appropriate polio vaccine series as recommended in their national immunization schedule. • Travellers to polio-infected areas who have previously received three or more doses of OPV or IPV should also be given another dose of polio vaccine before departure. 	<ul style="list-style-type: none"> • The WG recommended keeping the current ITH language (2013) that recommends a one-time polio vaccine booster for travellers from polio-free countries who have completed a primary series 	<ul style="list-style-type: none"> • Studies have shown that one dose of IPV or OPV after the primary series is sufficient to boost humoral immunity. In persons previously vaccinated with OPV. Both IPV and OPV also boost intestinal immunity.