Haut Conseil de la Santé Publique

The High Council for Public Health

Advice

concerning a booster vaccination against poliomyelitis for some travellers in the context of the current public health emergency declared by the WHO

8th July, 2014

On 27th May, 2014, the High Council for Public Health (HCSP) was consulted by the General Health Directorate of France concerning a booster vaccination against poliomyelitis (polio) for some travellers in the context of the current public health emergency declared by the World Health Organisation (WHO) [1].

The HCSP was asked to formulate advices for applying the recommendations from the WHO to France for: 1) travellers coming from countries where poliomyelitis is endemic[1] as well as ii) French residents travelling to those countries, in terms of:

- vaccine type (oral/injection);
- elapsed time between the vaccination and the voyage;
- risks associated with the booster;
- the preferred option in the case of uncertainty surrounding the vaccinations status of the person concerned.

The High Council for Public Health has taken the following into consideration

- **The current context: WHO and ECDC data**

On the 5th May, 2014, the Director General of the WHO, at the request of the Emergency Committee concerning International Health Regulations (IHR), declared that the risk of propagating wild polioviruses from polio-endemic countries constituted a Public Health Emergency of International Concern (PHEIC) [1]. On the 16th May, 2014, the WHO published recommendations temporarily modifying the IHR with a view to limiting this risk by having the recommendations in place before the season of intense poliovirus transmission (May to November/December) [2]. During the period when the poliovirus circulation was reduced, from January to April 2014, transmission of wild polioviruses was observed in Central Asia (from Pakistan to Afghanistan), in the Middle East (from Syria to Iraq) and in Central Africa (from Cameroon to Equatorial Guinea).

Active circulation of wild polioviruses is observed in ten countries, among which three export the virus - Pakistan, Syria and Cameroon. In seven other countries (Afghanistan, Equatorial Guinea, Ethiopia, Iraq, Israel, Nigeria and Somalia), the virus circulates but no exportation to other countries has been documented. In Israel, wild polioviruses have been isolated in environmental sampling, but there have been no reports of any clinical case of poliomyelitis.

The recommendations for temporary modifications to the IHR concern only those countries where there is active circulation of the wild poliovirus.

[1] The countries exporting the wild virus according to the WHO (Pakistan, Syria and Cameroon), plus the polio-endemic countries but where there is no exportation (Nigeria, Afghanistan, Iraq, Ethiopia, Equatorial Guinea, Israel).

WHO recommends for the three poliovirus exporting countries that **the local health authorities ensure** "that residents and those who have spent more than 4 weeks in the country and who plan an international journey are given either an oral polio vaccine or an inactivated polio shot in the period ranging from 4 weeks to 12 months before departure". This period has been chosen to take account of the studies that show that four weeks was the time required for maximum immunity for a newly vaccinated person and that intestinal immunity could have ceased after 12 months. In the case of an urgent departure, the booster dose can be given at the time of leaving. An official vaccination certificate mentioning this booster dose should be given to all vaccinated travellers.

The health authorities in the seven infected but non-exporting countries **have been encouraged to carry out similar vaccination boosters** for their travelling inhabitants.

The aim of this particular vaccination is to strengthen the immunity of the intestinal mucous membranes and avoid travellers from those countries carrying and disseminating the virus.

No specific temporary recommendation has been issued to those countries deemed to be polio-free (other than a strengthening of surveillance and of notifying any case of infection). Nevertheless, certain countries (Saudi Arabia and India) have already demanded evidence of vaccination for entry and others may follow suit. It is important that travellers be made aware of entry requirements for the countries they intend to visit.

In addition, the WHO recommends that people from a polio-free country intending to make a short trip to an infected country check their vaccination status and, before departure, depending on their situation, either take a booster in the form of an oral vaccine or an inactivated shot (those who are up-to-date) or take the full primary polio vaccination programme (those never vaccinated). For long-stay travellers and expatriots, the recommendations for the residents of infected countries apply. They are recommended to take a polio vaccine dose in the home country before leaving in case proof of vaccination is required on their return.

Any vaccine containing the poliovirus 1 valence can be used. Pregnant women can take either live or inactivated polio vaccines. People suffering from immune deficiency must be vaccinated with the inactivated vaccine.

Following the WHO's recommendations, the ECDC (*European Centre for Disease Prevention and Control*) has undertaken an assessment of the risk of re-introducing the wild poliovirus into Europe and published its findings on 28th May, 2014 [3]. The ECDC believes that:

- people vaccinated with the oral polio vaccine have a very low risk of being infected with the poliovirus and of suffering from poliomyelitis;
- people vaccinated only with the inactivated vaccine have a moderate risk of being infected with the virus and a very low risk of suffering from poliomyelitis;
- people not vaccinated have a high risk of being infected with the virus and a moderate risk of suffering from poliomyelitis;

The risk of an epidemic concerns those areas where there is a concentration of people not vaccinated or where people live in unsatisfactory sanitary conditions or where both situations are combined. Both Dutch Orthodox religious communities and Rom communities are specifically cited.

The ECDC recommends member States to modify their vaccination recommendations for travellers to, and ex-patriots living in, the ten countries infected by the poliovirus to avoid such people having to get vaccinated in those countries, and also to plan an additional shot of inactivated polio vaccine within 12 months of returning to their home country.

The ECDC does not recommend member States to check systematically the vaccination status of travellers from infected countries when re-entering their home country. On the other hand, it strongly recommends that member States check the vaccination status of all refugees from infected countries when entering the country. It recommends that people whose polio or other vaccinations are not up-to-date plan an update according to their age and their vaccination

situation (if known) in compliance with the local vaccination calendar. This especially concerns Syrian refugees, 60,000 of whom have requested asylum in Europe since the beginning of the conflict, and some 70% of these have been accommodated by two countries (Germany and Sweden). According to the ECDC, France has accepted 1,975 Syrian refugees.

The ECDC recommendations are summarised in a booklet advising travellers to countries infected by the poliovirus [4]:

- people up-to-date with their polio vaccinations who will travel to these countries are recommended to have an additional dose of the inactivated polio vaccine in the 12 months before their return to the home country;
- all people who live in, or who have spent more than four weeks in, one of these countries and who plan to visit another country must have received an oral dose or an inactivated shot of polio vaccine between 4 weeks and 12 months before leaving the infected country. In the case of an unplanned and urgent departure, this supplementary dose must be given at departure time if the person has not received any polio vaccine in the past 12 months.

Moreover, the ECDC document stipulates that:

- travellers should have in their possession the WHO international vaccination certificate (yellow card) mentioning their polio vaccinations;
- European Union residents whose polio vaccinations are not up-to-date or who do not know their vaccination situation should see a doctor with a view to getting up-to-date, and this irrespective of whether there is any planned voyage or not. These recommendations apply equally to adults and children;
- one can reduce the risk of coming into contact with the virus in infected countries by adopting a strict regime for washing one's hands (washing with soap before preparing meals, before eating and after visiting the toilet) and by washing and peeling fruit and vegetables before eating them.

➢ Epidemiological data

• The French situation/Vaccination coverage in France

The French context

The last case of domestic poliomyelitis in France was in 1969 and the last imported case was in 1995, both involving adults. The last case of wild poliovirus (WPV) in a patient not having recently travelled dates from 1989 [5].

Identifying any possible re-introduction of a WPV in France as early as possible is today facilitated by the enhanced surveillance of enteroviruses in man and in the environment, coupled with the mandatory notification of any case of poliomyelitis (The Action Plan formulated by the National Committee for notification and elimination of poliomyelitis, [6]). Since 2000, clinical surveillance [7, 8] has enabled the identification of 14 vaccine polioviruses (4 of type 1, 5 of type 2 and 5 of type 3) as well as one vaccine-derived poliovirus (VDPV 2) without increased virulence, all imported and without any clinical symptoms. No WPV has been identified. Within the environment, during the past fourteen years, there have been 5 cases of xx type 2 detected (2000, 2003, 2004, 2006 and 2007) and 2 of type 1 (2001 and 2009). The last isolation of a WPV, of serotype 3, was in 1996 [9].

Amongst children, vaccination coverage is very high. At the age of 2 this is around 99% and at age 15 around 90%, figures obtained from the vaccination information respectively from the infant health certificates and surveys in schools [10]. It is less than optimal among adults, with an estimated coverage of around 66% on average. It is only 13% among people over 65, due to the less well-organised follow-up for this age group, which could lead to a greater susceptibility to infection among the elderly. Although antibodies continue to circulate for decades, the titres diminish over time, which may mean that detectable concentration levels may not be found in certain adults. The antibodies directed at type 3 serotypes are, in general, the first to disappear [12]. During a survey in 1998 of seroprevalence in vaccine-preventable diseases as part of the

ESEN, (the European Sero-Epidemiology Network [13]), an analysis was carried out in France concerning the poliomyelitis strain. The analysis of serum from some 3,300 people showed that the immunity coverage for school-age children and young adults to be close to 100%, and that, among elderly people, less than 20% were sero-negative with this being more marked for serotype 3. It also showed a high percentage of sero-negative children aged between 2 and 5, close to 10%, 8% and 5% respectively for serotypes 1, 2 and 3. These results could be explained partially by the rapid decrease in the level of antibodies among children who had received the three doses in the primary vaccination period and were included in the survey before having received the first booster, even though they were already aged 2 or over. The very high level of sero-positive children aged between 6 and 10 - at least 97.5% for the three serotypes - reflects the excellent coverage for the booster at age 6, coupled with the presence of the immune system's memory, even among those children who had only received the three doses during the primary vaccination cycle.

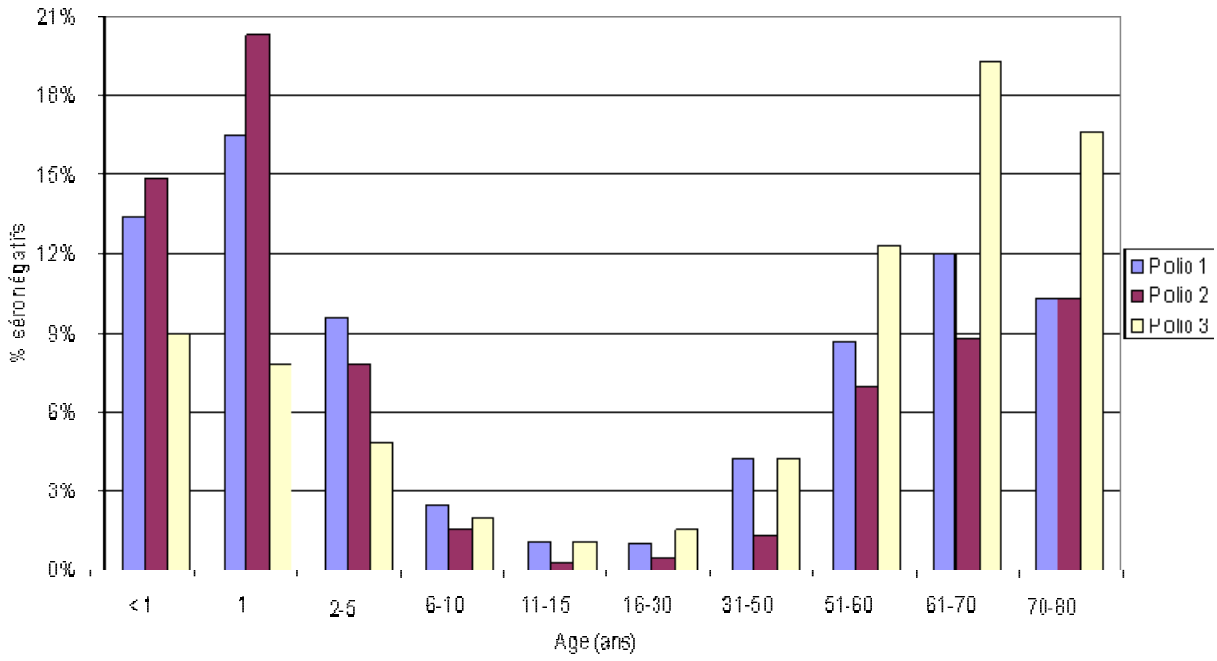

Fig. 1 - Seronegativity vis-à-vis the 3 poliovirus serotypes, as a function of age

ESEN Survey, France, 1998

- **International situation**

At the European level: eradication of poliomyelitis was announced in June 2002. However, following the discovery of a WPV 1 in some sewage water in Israel and then a number of confirmed cases in Syria, the ECDC has carried out an assessment of the risk of poliomyelitis being imported into Europe.

At a global level: twenty-five years after the launch of the Global Initiative for Eradicating Poliomyelitis, the number of polio-endemic countries has dropped from 125 in 1988 to 3 in 2014 (Afghanistan, Nigeria and Pakistan). The deadline given for eradication had nevertheless to be revised as a result of the exporting of cases from polio-endemic countries, followed sometimes by a resurgence in transmission.

Since 1999, no wild poliovirus of type 2 has been isolated, and the last wild poliovirus of type 3 was isolated in 2012. The circulation of WPVs during the first five months of 2014 compared with 2013 is shown in the table below (WHO data as at 10th June 2014, |14]).

Country classification	Total 2013		01 January - 10 June[1]				Date of most recent case
			2013		2014		
	W1	W3	W1	W3	2014	W3	
Endemic							
Pakistan	93		14		75		19-May-14
Nigeria	53		25		3		19-Apr-14
Afghanistan	14		2		4		06-Apr-14
Total	**160**	0	**41**	0	**82**	0	
Outbreak							
Somalia	194		9		1		11-May-14
Iraq					2		07-Apr-14
Equatorial Guinea					4		03-Apr-14
Cameroon	4				3		31-Jan-14
Syria	35				1		21-Jan-14
Ethiopia	9				1		05-Jan-14
Kenya	14		5				14-Jul-13
Total	**256**	0	**14**	0	**12**	0	
Global total	**416**	**0**	**55**	**0**	**94**	**0**	

[1]Data as of 11 Jun 2013 for 2013 data and 10 Jun 2014 for 2014 data.

On the other hand, the appearance of sporadic epidemics due to the circulation of vaccine-derived polioviruses (VDPV), made virulent through genetic mutation, underlines the absolute necessity of remaining extremely vigilant and of applying the same international recommendations to these epidemics as were developed originally for the WPVs.

- **Poliomyelitis: transmission channels, clinical situation** [15,16]

Human beings are the sole carriers and incubators. Transmission is faecal-oral or oral-oral, directly between human beings, or indirectly through contaminated foodstuffs or through the environment, especially water. Contagion is essentially linked to faecal excretion of the poliovirus, whose life expectancy is generally between two and three weeks, but can be much longer with certain patients.

The vast majority of infections are asymptomatic. One case of flaccid paralysis, frequently definitive, occurs for every 100 to 1,000 infections, depending on the serotype. This risk of paralysis increases with age, greater among adolescents and especially among adults than with younger children.

After an incubation period of some 7-14 days, the infection produces pseudo influenza-type symptoms (high temperature, odynophagia, myalgia, frequently severe), digestive troubles (diarrhoea) and meningeal disorders (acute lymphocytic meningitis) often with a favourable outcome.

The neurological forms are usually peripheral flaccid paralyses (affecting the anterior horn of the spinal cord) which appear in an infectious context. These forms of paralysis are characterised by their rapid appearance (in less than 3 days), accompanied by myalgia, and an asymmetric topography, involving the lower regions (legs more commonly than arms) and those parts

thereof closer to the trunk (quadriceps and deltoids). There are generally so sensory problems, either subjective or objective. Osteo-tendon reflexes are reduced or absent in the corresponding areas. Amyotrophy appears rapidly.

These neurological forms can be accompanied by digestive problems, urine retention and respiratory problems or failure due to paralysis of the respiratory muscles (abdominal, inter-costal and diaphragm). The other neurological forms (bulbar, encephalitic) are much rarer.

Progress in unpredictable and recovery is uncertain and incomplete.

➢ Vaccination recommendations in France

Vaccination against poliomyelitis is mandatory in France[2] for children: this obligation concerns the primary vaccinations before the age of 18 months as well as the boosters at age 6 and again at age 11-13.

Since 2013, a new simplified vaccination calendar has been in operation for children. The current calendar [17] requires the primary vaccinations consisting of two doses recommended at the age of 2 months (8 weeks) and at 4 months, with a boost recommended to be given at age 11 months.

Only the inactivated polio vaccine is used in France, in the form of a combined vaccine. The hexavalent vaccine (containing, among others, vaccines against diphtheria, tetanus, whooping cough, *Haemophilus influenzae* (Hib) and hepatitis B) is the favoured choice. Co-administration for primary vaccination and the booster with the pneumococcal conjugate vaccine are recommended.

A tetravalent vaccine booster (DTaP-IPV) is recommended at age 6. Another tetravalent booster is recommended at age 11 using either the Tdap-IPV vaccine (for children who received the DTaP-IPV at age 6), or the DTaP-IPV vaccine for those children who have not been vaccinated with the D and aP strains at age 6. For girls, the booster at age 11-13 can be co-administered with one of the recommended HPV doses.

For adults, since 2013, the vaccination calendar has also been modified, replacing the ten-year boosters with fixed-age boosters given at ages 25, 45, 65 and then at ages 75, 85, 95 etc. These boosters concern vaccination against diphtheria, tetanus and polio (Td/IPV) except for the one at age 25 which includes the vaccine for whooping cough (Tdap-IPV) [17].

Moving from an interval of ten years to one of twenty years for adult boosters was decided based on scientific data showing that the protection time afforded by vaccinating against diphtheria, tetanus and polio was much greater than ten years [18]. Concerning the particular case of polio, it was considered that polio has been eradicated in France thanks to the high level of herd immunity engendered by widespread and regular vaccination using the injectable polio vaccine. This primary vaccination ensures excellent immunity up to adulthood, indeed 100% according to a study by Vidor [19]. Any subsequent shot is a booster that prolongs the immunity for as long again. The wide coverage of infant vaccination is a veritable 'barrier' to any imported strains becoming established.

Several authors even go as far as to say that there is no need to give booster shots to adults [20]. All studies carried out on vaccines combining the three strains of polio show that they achieve the booster effect and a level of antibodies considered as offering protection in 95 to 100% of those vaccinated. Moreover, several countries do not recommend any polio booster for adults.

For people over 65, an interval of ten years has been maintained because of the decreasing immunity with age.

[2] Article L.3111-3 of the public health code.
http://www.legifrance.gouv.fr/affichCodeArticle.do;jsessionid=EE452D49B0698DAC95853AFF4224B160.tpdjo16v_1?idArticle=LEGIARTI000006687783&cidTexte=LEGITEXT000006072665&dateTexte=20140625

➢ Available vaccines

The uncombined polio vaccines that have been authorised for sale in France are listed in the table below. In addition, the hexavalent vaccines DTaP/IPV/Hib-Hepatitis B, the pentavalent vaccines DTaP/IPV/Hib, the quadrivalent vaccines DTaP-IPV and Tdap-IPV all contain inactivated antigens for polioviruses 1, 2 and 3.

In France, as in most of the industrialised world, only inactivated polio vaccines are used. Abandoning the live polio vaccines was a result of the possibility of cases of paralytic vaccinal poliomyelitis occurring, mainly during the primary vaccination of new-born babies and of people with immune deficiency problems. The spread of vaccinal viruses among the immediate entourage of people thus vaccinated may also be at the root of poliomyelitis cases in this same group. In addition, the emergence of strains of vaccine-derived poliovirus circulating within the community with a possible return of neuro-virulence (mainly with poliovirus 2) can also be a cause of paralytic poliomyelitis cases linked to vaccination. Such risks are considered unacceptable in countries where poliomyelitis caused by wild polioviruses has disappeared [21]. Inactivated polio vaccines are well tolerated and highly effective in preventing poliomyelitis, even if their effect on the intestinal mucous immunity (and thus the prevention of carrying and disseminating) is lower than with attenuated live vaccines.

Description	Composition		How to administer	On sale
	What	How much		
Inactivated poliomyelitis vaccine, injectable suspension				
IMOVAXPOLIO Pre-filled syringe	Virus type 1 Mahoney strain Virus type 2 MEF-1 strains Virus type 3 Saukett strains	40 DAgU 8 DAgU 32 DAgU	IM (or SC)	YES
MOVAXPOLIO Multidose	Virus type 1 Mahoney strain Virus type 2 MEF-1 strains Virus type 3 Saukett strains	40 DAgU 8 DAgU 32 DAgU	IM (or SC)	NO
Live poliomyelitis vaccine, oral suspension				
OPVERO	Virus type 1 LS- c2ab strain Virus type 2 P712, Ch, 2ab strains Virus type 3 Léon 12a1b strains	$10^{6.0}$ $DICC_{50}$ $10^{5.0}$ $DICC_{50}$ $10^{5.8}$ $DICC_{50}$	Oral	NO
Oral monovalent poliomyelitis vaccine type 1	Virus type 1 LS- c2ab strain	$10^{6.0}$ $DICC_{50}$	Oral	NO
Oral bivalent poliomyelitis vaccine types 1 and 3	Virus type 1 LS- c2ab strain Virus type 3 Léon 12a1b strains	$10^{6.0}$ $DICC_{50}$ $10^{5.8}$ $DICC_{50}$	Oral	NO

DAgU: D Antigen Unit

$DICC_{50}$: Infecting dose for 50% cellular cultures (viral infection units)

As a consequence of all the above, for the general population, the High Council for Public Health

- **Repeats that the possibility of a re-emergence of infectious diseases exists if there is a lowering or an interruption in the vaccination programmes. It therefore urges:**
  - maintaining the elevated level of vaccination coverage concerning polio for new-born babies and children as a real barrier to the re-establishment of this disease;
  - the updating of the vaccination situation for those adults for whom recourse to boosters has been insufficient.
- **Recommends that:**
  - people aged 25, 45, 65, 75, 85, etc take a booster dose of polio vaccine, in compliance with the current vaccination calendar;
  - adults not covered by the above and not up-to-date with the vaccinations (i.e. having not had a booster in the past twenty years for those aged less than 65 or in the past ten years for those aged 70 or over) take a booster dose of polio vaccine;
  - people unaware or not sure of their vaccination situation consult their family doctor with a view to getting their vaccination situation updated. In any case of doubt, having a polio vaccination shot is recommended. Submitting to serological tests to assess their immunity level is not recommended.

Concerning people intending to travel to polio-infected countries (this list may evolve) for a stay of less than four weeks, the HCSP believes:

- that in terms of personal protection, and if such people are up-to-date with their vaccinations as defined earlier, there is no justification for any further polio vaccination booster since such people are not at risk of contracting poliomyelitis;
- that however, in terms of collective protection, such people may become infected with a poliovirus during their stay and then be the source of dissemination among their entourages, especially if their latest vaccination booster was more than a year earlier.

Therefore, the HCSP recommends that:

- travellers whose last vaccination was more than a year ago receive a polio vaccination booster in the month preceding their departure. The inactivated trivalent non-combined polio vaccine may be used by people who are up-to-date with their diphtheria and tetanus vaccinations (according to the current vaccination calendar);
- people not up-to-date or unaware of their vaccination situation complete their vaccinations before leaving using a combined vaccine containing the polio strain. Submitting to serological tests to assess their immunity level is not recommended.

Concerning people intending to travel to polio-infected countries for a stay of more than four weeks or to live there, the HCSP draws their attention to the fact that polio booster vaccination will probably be demanded by the country visited during their stay or when finally leaving.

Therefore, the HCSP recommends that

- such people receive a booster polio vaccine shot. There are no limitations concerning the timing before leaving France. As far as possible, the date for administering this shot should be planned such that, on return from the polio-infected country, this booster shot is more than four weeks and less than 12 months old. The inactivated trivalent non-combined polio vaccine may be used by people who are up-to-date with their diphtheria and tetanus vaccinations (according to the current vaccination calendar).

WHO has recommended the use of live or inactivated vaccines [2] and ECDC recommends inactivated vaccines [3-4]. It is recalled that inactivated vaccines are effective to prevent

the onset of paralytic poliomyelitis but does not fully preventing the infection and the circulation of the WPV (as set out in Israël). However, it is admitted that polio inactivated vaccine has demonstrated a certain effectiveness on the intestinal immunity while it is not measurable[21].

The HCSP believes that it is not appropriate to reintroduce into France such live-attenuated vaccines and that such vaccination should be effected using the inactivated polio vaccines contained in the various combined vaccines available. The inactivated trivalent non-combined polio vaccine may be used by people who are up-to-date with their diphtheria and tetanus vaccinations (according to the current vaccination calendar).

The HCSP recommends that these polio vaccine boosters be mentioned on the WHO's international vaccination certificate ("yellow card").

It also recommends that these travellers be advised of the best available means of avoiding contamination by the poliovirus during their stay in an infected country.

in accordance with the ECDC recommendations, the HCSP does not recommend checking the vaccination situation of travellers upon entering the country. On the other hand, it recommends that the vaccination status concerning polio of refugees from the three poliovirus-exporting countries (Pakistan, Cameroon and Syria) be checked. Indeed, The environment and the conditions where these people were living , allowed the virus transmission and amongst them, children are shedders of wpv more often. Then, any person not up-to-date in this respect be offered a vaccination booster dose adapted to the person's age and in line with the current vaccination calendar. The theoretical risk of aggravating a poliomyelitic paralysis in incubation by intramuscular injection [21] is not a sufficient reason for refusing the use of inactivated polio vaccines.

Moreover, the HCSP recommends that a test for poliovirus be made on the stools of children who arrive in France with a view to adoption from the countries where the polio virus is circulating These children, as said above, were living in such poor conditions allowing the circulation and transmission of the virus. And probably have not benefited of immunization program. Then they could have a higher risk to shed the virus. In fact, children already benefiting stool investigation for the isolation of parasites and receiving treatment if necessary. So it could be easy to add an adequate investigation on polio virus.

The checking of the immunization status among the close contacts and any person not up-to-date in this respect be offered a vaccination booster dose adapted to the person's age and in line with the current vaccination calendar, and the rigorous of standard measures of protection are necessary for avoiding the WPV dissemination. [5]. This recommendation applies equally to people who have lived clandestinely for a prolonged period in those countries, whenever such cases can be identified.

Advice and recommendations drafted by a group of experts, members of the HCSP and others, together with the Technical Committee for Imported & Travel-related Diseases , the Technical Vaccination Committee and the Expert Committee for Infectious Diseases .

No conflict of interest identified.

Opinion endorsed by the President of the High Council for Public Health

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