



Questions on Immunization and Vaccination and Short Answers

Bağıışıklama ve Aşı ile İlgili Sorular ve Kısa Cevaplar

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Question 1: Can oral polio vaccine (OPV) be administered to children with immunocompromised individuals in their families?

It has been demonstrated in industrialized and developing countries that the vaccine virus easily spreads from individuals who have received OPV to their contacts after gastrointestinal excretion. The majority of poliovirus shedding occurs in susceptible infants (previously unvaccinated or not having had polio) after receiving OPV (70-90%).

Due to the potential for transmission to contacts, OPV should not be given to individuals living in the same household as immunocompromised individuals.

Furthermore, if there has been a history of immunodeficiency in a family member, OPV should not be administered until it is ensured that the child's immune system is healthy.

In such cases, inactivated polio vaccine (IPV) is recommended for the child and family members. The same precautions apply to the nOPV2 vaccine as there is a potential for transmission through the saliva and feces of vaccinated individuals for up to 42 days. If vaccinated, the individual should not stay in the same household or have contact with an immunodeficient individual for 45 days.

Question 2: What should be done if the child spits out or vomits after receiving OPV?

If the child spits out or vomits within 10 minutes after the administration of OPV, the dose should be repeated immediately.

As a general rule, if vomiting occurs within 30 minutes after OPV administration, a repeat dose is recommended.

Question 3: What should be done if the person has diarrhea and receives OPV?

If the individual has diarrhea and receives OPV, based on clinical studies, especially for types 2 and 3, the seroconversion rates significantly decrease. Therefore, it is preferred to repeat the dose after four weeks. Even if the oral polio vaccine used is a bivalent vaccine containing types 1 and 3, if it was administered in the presence of diarrhea, it is preferred to repeat the dose after four weeks.

After oral polio vaccination, mild diarrhea may occur in approximately 10% of infants and children within 1 to 9 days as an adverse effect related to the vaccine.

Question 4: What is the Novel Type 2 Oral Polio Vaccine (nOPV2)?

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Following the last reported case of wild poliovirus type 2 (WPV2)-associated poliomyelitis in India in 1999, the World Health Organization (WHO) declared in 2015 that type 2 poliovirus had been globally eradicated.

Although rare (approximately one in 2.7 million doses), vaccine-associated paralytic poliomyelitis (VAPP) can occur, often following the administration of the first dose of OPV. Typically, these cases are caused by the type 2 poliovirus contained in the oral live attenuated polio vaccine, which includes poliovirus types 1, 2, and 3.

In areas with low OPV coverage and a high prevalence of susceptible individuals, the prolonged circulation of all three poliovirus serotypes contained in the Sabin oral polio vaccine (OPV) can lead to the emergence of genetically divergent and neurovirulent viruses, known as circulating vaccine-derived polioviruses (cVDPVs), following their excretion from the gastrointestinal system, causing outbreaks.

In 2016, globally, the transition was made from the trivalent oral polio vaccine (tOPV), which contains all three poliovirus serotypes, to a bivalent oral polio vaccine (bOPV) that includes only poliovirus serotypes 1 and 3. This decision was made due to the absence of both wild poliovirus type 2 (WPV2) and vaccine-derived type 2 poliovirus-associated paralytic poliomyelitis (VAPP and cVDPV2) circulation for an extended period.

Following the switch to the bivalent vaccine (bOPA) in 2016, there is no longer the development of antibodies against type 2 poliovirus. This poses a concern, particularly in areas with low pre-existing herd immunity, as the circulating vaccine-derived poliovirus type 2 (cVDPV2) can persist and undergo genetic changes, potentially leading to paralysis. The majority of reported cVDPV cases since 2016 have been associated with type 2 poliovirus.

In response to the cVDPV2 outbreaks that occurred between 2016 and 2020, the World Health Organization (WHO) recommended and utilized a monovalent oral polio vaccine containing only the type 2 Sabin strain (mOPV2).

However, in regions where cVDPV2 cases were detected, the low coverage of mOPV2 due to inadequate outbreak response, delayed immunization campaigns, and suboptimal supplementary vaccination activities resulted in ongoing cVDPV2 outbreaks, importations, and the emergence of new variants.

The novel OPV type 2 (nOPV2) is a genetically enhanced version of mOPA2, which was introduced in 2016 to stop outbreaks due to cVDPV2 variants. The nOPV2 vaccine, which entered the Emergency Use Listing of the World Health

Organization (WHO) on November 13, 2020, has reportedly been administered in supportive vaccination campaigns in 28 countries (as of March 2023), with a total of 600 million doses.

In such a large-scale implementation, monitoring the safety of the vaccine is also crucial. Based on the evaluation of the initial data from the first 370 million doses conducted by the Global Vaccine Safety Advisory Committee, which convenes every six months to review safety data, it has been reported that the rates of adverse events reported for the nOPA2 vaccine are lower than the published rates for other OPV vaccines. Furthermore, comprehensive data from both environmental surveillance based on samples from sewage systems and genetic sequence analysis of clinical surveillance isolates have supported the genetic stability of nOPA2, consistent with the findings observed in preclinical and clinical studies.

However, recently, the reporting of neurovirulent variants, which are considered a public health emergency and deemed to require close monitoring by the WHO due to the low intestinal mucosal immunity against poliovirus, has been observed in areas known as “hotspots” where vaccine coverage has been consistently low. Until May 2023, new variants of the nOPA2 vaccine have been reported in the Democratic Republic of Congo (March 2023), Burundi (March 2023), the Central African Republic (February 2023), and Uganda (February 2022). Among these, one notable finding is the reporting of paralytic cases that have been proven to be associated with the circulating nOPA2 variant of poliovirus in two separate incidents in the Democratic Republic of Congo and its neighboring country, Burundi, possibly due to recombinations with human enterovirus C. The circulation of the new nOPA2 vaccine variants has not yet been confirmed in the Central African Republic (two cases of paralysis) and Uganda (environmental surveillance sample isolate), and investigations are ongoing. The World Health Organization (WHO) and the Global Polio Eradication Initiative (GPEI) have emphasized that, despite encountering only two cases, it is estimated that in a similar-scale implementation of the mOPA2 vaccine, there could be 30-40 public health emergencies of a similar nature.

After the successful completion of Phase III trials, the new vaccine (nOPA2) is anticipated to receive full licensure by the end of 2023.

The Phase I trials of the nOPA vaccines being developed under the leadership of PATH for poliovirus variants of types 1 and 3 have been completed, and Phase II trials are scheduled to commence in 2023. Simultaneously, a preliminary assessment will be conducted regarding the feasibility of developing a multivalent nOPA vaccine. It is anticipated that Phase II trials for these vaccines could be initiated during 2025-2026.