FACT SHEET

Monovalent Oral Polio Vaccine Type 1

This sheet is meant to inform health authorities at National and Governorate level. It is not meant for general distribution to all health staff.

The Global Polio Eradication Initiative partners are in the last stretch of the poliomyelitis eradication campaign, launched in 1988. Due to the success of the campaign, by 2004, polioviruses circulated only in limited areas of the world (west and central Africa, South Asia and Egypt). The Global Polio Eradication Initiative is spearheaded by the World Health Organization (WHO), Rotary International, the US Centers for Disease Control and Prevention (CDC) and UNICEF.

Trivalent oral polio vaccine (tOPV)

Three types of wild poliovirus, known as type 1, type 2, and type 3, cause poliomyelitis. The principal weapon used against these viruses in the Global Polio Eradication Initiative is the trivalent oral polio vaccine, (tOPV), which includes three types of polioviruses in a live-attenuated form that gives protection against all types of wild poliovirus.

Monovalent type 1 oral poliovirus vaccine (mOPV1): rationale and benefits

Where more than one type of wild poliovirus is circulating, tOPV is epidemiologically and operationally the best vaccine to use. When this vaccine is used there is actually competition among the three viruses to cause immunity. As a result, protection develops to each of the three types of polio virus, but not with equal efficiency. Protection against type 2 develops most easily, followed by types 3 and 1. As the eradication effort reaches its final stages, only type 1 wild poliovirus continues to circulate in some of the most critical endemic areas.

Wild poliovirus type 2 has not been found circulating anywhere in the world since 1999. In Egypt, no type 3 wild poliovirus has been detected since 2000; in the endemic parts of India, type 1 caused more than 95% of cases.

Despite repeated campaigns with tOPV, type 1 wild poliovirus continued to circulate in these areas, which share many factors favouring wild poliovirus transmission: they have tropical climates with high population density and mobility, very high birth rates, large numbers of people living in poverty and poor sanitation infrastructures.

For the same number of doses, mOPV1 provides an increased immunity to type 1 poliovirus compared to tOPV. With three doses of mOPV1, over 90% of children will develop immunity; the same of tOPV will confer immunity on only 70-75% of children. Monovalent vaccine produces a much stronger response than tOPV in children being immunized for the first time, including very young babies. Since nearly all cases of polio now are children under two years of age, this is a very significant advantage.

With tOPV there is some interference between the three types of poliovirus when they are generating an immune response in the vaccinated child. In monovalent vaccine this does not occur, hence its enhanced ability to confer immunity. Additionally, if children immunized with mOPV1 are subsequently exposed to wild poliovirus type 1, they will excrete less virus and for a shorter period of time, limiting the possibility of further transmission.

Experience with monovalent polio vaccines

Monovalent oral polio vaccines for the three types of polioviruses were used extensively in the early days of polio vaccination in the late 1950s and early 1960s, providing extensive experience of these vaccines. Monovalent vaccine has been generally replaced since 1963 by tOPV for reasons of operational and logistical simplicity. With tOPV, protection against all

three types of wild poliovirus could be given at the same time, a very important consideration when more than one type of wild poliovirus was circulating.

The decision to use mOPV1 in polio eradication

In September of 2004, the Ad Hoc Advisory Committee for Polio Eradication (AACPE) - the independent global technical advisory body for the eradication effort - reviewed various options for enhancing the impact of eradication activities that were taking place, particularly in key endemic countries. Based on strong data showing the potential impact of using mOPV1, the AACPE recommended increasing the numbers of children reached with vaccine and the use of mOPV1 in supplementary immunization campaigns for areas where only wild poliovirus type 1 was circulating. Following their review of the data, the national advisory groups on polio eradication in both Egypt and India recommended accelerated development and use of mOPV1.

Production of mOPV1

After the recommendation of the AACPE, WHO approached all of the suppliers of tOPV to the polio eradication initiative to express an interest in mOPV1 development. The interested manufacturers have undertaken extensive work, in close contact with national regulatory authorities, to determine how mOPV1 can be produced and licensed. The governments of Egypt, India and Yemen have agreed that mOPV1 will be procured through UNICEF, which will ensure that appropriate tenders are formulated.

Use of mOPV1

The governments of India and Egypt, after receiving advice from the national and international oversight bodies of the Global Polio Eradication Initiative, proposed to use mOPV1 as early as possible in national immunization activities in 2005, to enhance the impact of these activities in stopping transmission of wild poliovirus type 1.

Since then many countries have used mOPV1 in outbreak situation, like Yemen, Indonesia, Angola and others.

In all aspects of storage, handling, and use, mOPV1 is exactly the same as tOPV.

Follow-up of mOPV1 use

As mOPV1 vaccine has already proven its efficacy in past decades, no post-licensing clinical trials are required to confirm its immunogenicity. As with any vaccine, post-marketing surveillance will also be carried out to confirm its safety.

Partners

Manufacturing and registration of mOPV1 was made possible through a very close partnership between vaccine manufacturers, WHO and UNICEF, overseen by the French, Egyptian and Indian regulatory agencies (Agence Française pour la Sécurité Sanitaire des Aliments et des Produits de Santé, National Organization for Drug Control and Research of Egypt and Central Drugs Standard Control Organization of India).