

Global Polio Eradication Initiative

New England Journal of Medicine: first clinical trial of monovalent OPV confirms benefits for newborn children

Synopsis

On 16 October 2008, Egyptian researchers report – in the New England Journal of Medicine (NEJM) – findings¹ demonstrating increased efficacy of monovalent oral polio vaccine type 1 (mOPV1), over the traditionally-used trivalent OPV, in newborn children. The study results provide strong support for the use of mOPV1 to eliminate the last chains of type 1 transmission in the remaining polio-endemic countries.

mOPV1 seroconversion trial

Fast Facts

- ✓ mOPV1 more effective than trivalent OPV
- ✓ mOPV1 effective in infants and very young children, key 'at risk' target population
- ✓ Reduced excretion of vaccine-viruses significant to 'post-eradication' era

Study results

Researchers from the Egyptian Ministry of Health and Population and from three universities (Ain Shams, Alexandria and Cairo) along with other national and international counterparts, evaluated sero-conversion rates to mOPV1 and trivalent OPV among newborn children. In the double-blind randomized trial, subjects received either mOPV1 or trivalent OPV at birth, followed by an additional mOPV1 dose ("challenge" dose) thirty days after birth. Researchers found that sero-conversion rates to type 1 polio in the mOPV1 arm of the study were at 55.4%, compared with 32.1% in the trivalent OPV arm. Additionally, a significantly lower proportion of children in the mOPV1 arm of the study (25.9%) excreted vaccine-virus seven days after the second mOPV dose, compared to children in the trivalent OPV arm (41.5%).

Interpretation and significance

The results of this study demonstrate that mOPV1 is more effective in inducing immunity against type 1 polio than the trivalent vaccine and support its use for eliminating the remaining reservoirs of poliovirus type 1. This is particularly significant because in the remaining endemic areas of the world, primarily infants and very young children continue to be paralysed by polio: they have not yet received sufficient doses of OPV; and traditionally, maternal antibodies (present during the first months of life) have interfered with a birth-dose of OPV, lowering its efficacy. This study shows that the remaining immunity gap can be overcome, even in infants and very young children.

The reduced excretion of vaccine-viruses observed in recipients of the mOPV1 trial arm additionally suggests that this vaccine is more effective than the trivalent vaccine in decreasing the transmission of poliovirus in the community, thus facilitating eradication. With the efficacy of this "sharper tool" affirmed, the key to achieving a polio-free world lies in rapidly overcoming the remaining operational challenges to reaching every child in the remaining endemic and re-infected areas.

¹ Monovalent type 1 oral poliovirus vaccine in newborns. N Engl J Med. 359;16. 16 October 2008.