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First-ever enterovirus 71 vaccine protects young children

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The first enterovirus 71 (EV71) vaccine candidate to reach phase 3 clinical testing provides young Chinese children with significant protection against disease caused by EV71, a growing public-health threat which has caused over 6 million cases of hand, foot, and mouth disease and 2,000 deaths worldwide over the last decade, according new research published Online First in *The Lancet*.

Since its discovery in 1969, EV71 has caused major outbreaks of HFMD around the world, affecting mostly children. No vaccines currently exist against disease caused by EV71.

The novel inactivated EV71 vaccine was developed for use in the Asia-Pacific region where the greatest number of serious cases, that can cause potentially fatal meningitis and encephalitis, occur.

The randomised trial took place at four sites across China (three in Jiangsu province and one in Beijing), and involved 10245 healthy infants and children aged 6–35 months, who were randomly assigned to receive two doses of placebo (5125) or vaccine (5120) 28 days apart.

The vaccine gave 90% protection against clinical EV71-associated HFMD and 80.4% against EV71-associated disease (including neurological complications) for at least 12 months.

Importantly, the vaccine also demonstrated 100% efficacy against EV71-associated hospitalisation, "suggesting that it could have a

significant impact on public health by preventing severe outcomes of EV71 infection", say the authors.

The vaccine was well tolerated and had a safety profile similar to inactivated poliovirus vaccines. Frequencies of adverse events were similar between the vaccine and placebo groups. No vaccine-related serious adverse events were recorded.

The investigators propose that a titre of 1:32 is the protective antibody level needed to prevent EV71-associated disease.

However, they caution that there was no evidence that the vaccine had cross-protection against coxsackievirus A (CA) 16 that is frequently found to co-circulate with EV71 and cause HFMD.

Moreover, they point out that there are many viruses that can cause HFMD and the vaccine only has an impact on EV71-related disease, "In the 1-year surveillance period, only a small proportion of cases of HFMD were confirmed as associated with EV71…[Therefore] despite its high efficacy for preventing EV71-associated HFMD, the EV71 vaccine might have little part in reducing the overall incidence of HFMD, even by universal mass immunisation of children."

Writing in a linked Comment, Nigel Crawford and Steve Graham from the University of Melbourne and Murdoch Children's Research Institute in Australia say, "The next step is to assess the appropriateness of including an EV71 vaccine in China's national immunisation programme, including a cost-effectiveness analysis…The gains made in Zhu and colleagues' trial need to be shared internationally, including assessment of any potential cross-protection for other EV71 genogroups [prevalent in other epidemic countries or regions eg, Taiwan, Singapore, Malaysia, and Japan]…Monitoring for epidemiological variations in EV71 will also be crucial to determine whether the vaccine has ongoing

efficacy and if any genogroup replacement has occurred."

More information: www.thelancet.com/journals/lan … (13)61049-1/abstract

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