

## **MINISCULE RISK REDUCTION MAKES \$1 ROTAVIRUS VACCINE (116E) UNECONOMICAL IN INDIA**

The authors must be congratulated for this study and the candid reporting of the absolute risk reduction (ARR) and numbers needed to treat (NNT).

### **LOW DISEASE BURDEN**

Although rotavirus vaccine efficacy is lower in developing countries, it is advocated for poor countries because of the higher disease burden. Severe rotavirus gastroenteritis (SRVGE) was more common in Malawi than South Africa (13.1 vs. 5.4) and even though efficacy was lower in Malawi (49.4% vs. 76.9%) more cases of SRVGE were prevented by vaccination (6.7 vs. 4.2) [Madhi SA, 2010](#). This is often given as the justification for using the vaccine with such low efficacy in poor countries.

The incidence SRVGE was low very low in the unvaccinated in India (3.4%) compared to 13.1 in Malawi and 5.4 in South Africa. This raises questions about the need for the vaccine in India using the 'disease burden' argument.

The absolute risk reduction (ARR) by vaccination was small (1.7). This is much lower than the benefit in Malawi (6.7) and even South Africa (4.2) [Madhi SA, 2010](#).

The NNT was 55. At \$3/child, vaccination will cost \$ 165 per SRVGE avoided. This is four times the societal cost of hospitalized diarrhea in India (\$40.60) [Mendelsohn AS, 2008](#)

### **RISK OF INTUSSUSCEPTIONS**

Intussusceptions are more dangerous in developing countries where facilities for its diagnosis and treatment are not easily available in remote areas. The earlier rotavirus vaccine RotaShield had been approved after clinical trials involving [10,054 children](#). It was then withdrawn from the market for causing intussusceptions (1 in 12,000 children).

After the RotaShield fiasco, FDA approval of RotaTaq based on results of three phase III trials of the drug which treated a combined [72,324 infants in 11 countries](#).

The 116E has been studied in only 4532 with 2187 controls (total 6719). This is grossly inadequate for studying safety of this drug. The authors seem to suggest that this small study is sufficient for licensing the drug and safety can be examined during post marketing surveillance! It will indeed be a very brave licensing authority who, based on this study of 6719 children, will license the drug in countries like India where active post marketing surveillance is non-existent and where there is no proper 'VAERS-like' system available. In this context Paul King has proposed an effective system for [AEFI surveillance](#) with meaningful penalties for any healthcare provider's failure to report any possible AEFI to those maintaining this AEFI database.

Perhaps those keen on the roll out of the vaccine may put such a system in place and some good may come from this vaccine.

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See: [Efficacy of a monovalent human-bovine \(116E\) rotavirus vaccine in Indian children in the second year of life.](#) [Vaccine. 2014.]

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See: [Intussusception risk and disease prevention associated with rotavirus vaccines in Australia's National Immunization Program.](#) [Clin Infect Dis. 2013.]