



Letter to the Editor

116E rotavirus vaccine may have less impact in India than projected

According to an article published in Science, impact evaluation of global health programs is becoming more stringent [1]. The Center for Global Development in Washington is demanding hard evidence in real-life field conditions, whether interventions have directly led to lower numbers of cases or deaths and whether the improvements are sufficient to justify the costs. In this milieu we find some of the projections in this Editorial [2] disconcerting. Empirical data from the multi center trial of the 116E rotavirus vaccine published in the same issue of Vaccine by the corresponding author and her team, presents a different picture [3].

Rotavirus vaccine is being recommended for all countries. While the efficacy of rotavirus vaccine is nearly 90% in Western countries it is barely 50% in the tropics. The new 116E vaccine also has only 50% efficacy but it is being recommended on the grounds that it matches the efficacy of the other licensed vaccines and is much cheaper.

The justification for using the low efficacy vaccine in tropical countries is that here the burden of disease is often higher, so more disease may be avoided. Madhi's work is often quoted in this context [4]. 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 in Malawi (6.7 vs. 4.2).

This need not apply to all tropical countries. The present multi-center study found the incidence SRVGE in the unvaccinated in India was 3.4% compared to 13.1 in Malawi and 5.4 in South Africa. The absolute risk reduction (ARR) by vaccination was tiny in India (1.7), much lower than the benefit in Malawi (6.7) and even South Africa (4.2). The 'disease burden' argument does not hold in India. Blanket recommendation for all countries for the vaccine is not appropriate.

The editorialists suggest that each year in India, there are 11.37 million diarrhea episodes due to rotavirus in children under 5 and 78,500 deaths. The mortality rate for rotavirus diarrhea works out to be 0.7%.

In the 2 year multi-center study (3), 21 infants needed to be vaccinated to prevent one episode of rotavirus diarrhea. 14% of control babies had rotavirus diarrhea. 70% rotavirus diarrheas occur in the first 2 years. Projecting this to under-5 babies, it is evident that 20% develop rotavirus diarrhea. In a birth cohort of 25 million,

over 5 years there will be 5 million episodes of diarrhea (instead of the 11.37 million projected in the editorial) and 34,520 deaths (instead of the 78,500 deaths projected) assuming mortality of 0.7%. The figures projected in the editorial seem to exaggerate the problem 200%. Vaccination of the entire birth cohort in 1 year, with 50% efficacy (making the generous assumption that vaccine efficacy does not wane over the 5 years), will reduce 17,000 deaths over 5 years. The cost of vaccinating the birth cohort at \$3/child will be \$75 million.

Hard evidence from this well performed multi-center community study shows that the benefits from use of rotavirus vaccine are far less than what was projected for the country using modeling techniques, and these models cannot be relied upon. One must be especially careful about making recommendations for developing countries because they have far fewer resources for their numerous health care needs. We wonder if the authors will clarify how they reconcile the data from their study and the projections they make in this editorial.

References

- [1] Cohen J. A hard look at global health measures. *Science* 2014;345(Sep (6202)):1260–5 <http://www.sciencemag.org/content/345/6202/1260.full> (accessed on 23/9/14).
- [2] Tate JE, Arora R, Bhan MK, Yewale V, Parashar UD, Kang G. Rotavirus disease and vaccines in India: a tremendous public health opportunity. *Vaccine* 2014;32(Suppl. 1):viixii.
- [3] Bhandari N, Rongsen-Chandola T, Bavdekar A, John J, Antony K, Taneja S, et al., India Rotavirus Vaccine Group. Efficacy of a monovalent human-bovine (116E) rotavirus vaccine in Indian children in the second year of life. *Vaccine* 2014;32(Suppl. 1):A110–6.
- [4] Madhi SA, Cunliffe NA, Steele D, Witte D, Kirsten M, Louw C, et al. Effect of human rotavirus vaccine on severe diarrhea in African infants. *N Engl J Med* 2010;362:289–98.

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1 October 2014