

[Team science and the creation of a novel rotavirus vaccine in India: a new framework for vaccine development.](#)

Bhan MK.Lancet. 2014.

[Jacob Puliyel2014 Aug 15 06:14 a.m.](#)

**Team science must not be allowed to influence objectivity**

**Projections of deaths exaggerated 5 times**

The authors must be congratulated for describing the team effort involved in the development of the new 116E rotavirus vaccine. In this process the Government of India through its funding of the Department of Science and Technology, the Bill and Melinda Gates foundation and PATH; all became partners who had a stake in getting this vaccine licensed and commercialized. Objectivity can become a casualty in the process.

The authors for example argue that the need for this vaccine is evident from the fact that rotavirus causes 75000-122000 deaths each year. The magnitude of the problem is not in disputed but the efficacy of the remedy needs to be evaluated. The vaccine is said to have efficacy of 50%. However it reduces only 10% of the projected mortality.

**Empirical data from the trial with the 116E vaccine however suggests that at best, (assuming 100% coverage with the vaccine,) deaths prevented will only be one tenth of the 100,000 deaths said to be caused by rotavirus.**

Data from the trial of the 116E vaccine showed that during the first two years after vaccination, the number of infants that needed to be immunized to prevent one episode of rotavirus diarrhea of any severity was 21 (NNT = 21) [Bhandari N, 2014](#). Assuming case fatality from rotavirus diarrhea (all cases regardless of severity) is 1% with community management [Lal S, 1994](#) [Kosek M, 2003](#), 2100 babies will have to be vaccinated to prevent one death from diarrhea in the first 2 years of life. If the birth cohort of 25 million are vaccinated only 11,904 lives may be saved. Either the efficacy figures are wrong or we must assume the projections of death from rotavirus infection are exaggerated - multiplied 5 times.

Empirical evidence on intussusception from the same trial, have been described elsewhere in PubMed Commons [http://www.ncbi.nlm.nih.gov/pubmed/25091662#cm25091662\\_5770](http://www.ncbi.nlm.nih.gov/pubmed/25091662#cm25091662_5770).

Thus we salute the effort that went in to make the vaccine, but that enthusiasm must not stand in the way of dispassionate evaluation of risks and benefits of the drug.