

[Jacob Puliye](#) 2014 Apr 18 06:03 a.m.

The authors have not responded to my invitation to participate in this discussion on the PubMed Commons as yet.

One of the authors Professor Gagandeep Kang has however sent a response to another discussion group discussing the comment. I will quote her concluding statement below.

*“While I agree with Dr. Puliye that AEFI surveillance is essential (and more critically, providing increased access to care in any medical emergency), I would question the ethics of waiting for a rate of a rare event before licensing a vaccine, that while imperfectly effective at 56% efficacy, clearly did not produce intussusception in 4500 immunised children. Based on available evidence, I do not think that this live oral vaccine is perfectly safe and I anticipate that in post-marketing surveillance we will find that there is a risk of intussusception, but I do believe that all testing so far has shown that the vaccine has the potential to prevent more morbidity and mortality in India than it could possibly cause, particularly among those most vulnerable.”*

I will respond to that on this forum, as I feel it is more appropriate.

1) In the study there were 50% more intussusceptions among the vaccinated. There seems to be 1 excess case of intussusceptions (?vaccine induced intussusception) for every 2000 babies vaccinated. Obviously the sample size was not adequate to look for statistical significance. For the present we have to assume that this difference will hold when the sample size is enlarged.

This is 6 times worse than Rotashield which was withdrawn for causing 1 case of intussusceptions for every 12,000 vaccinated.

2) NNT for preventing 1 case of diarrhea (SRVGE) was 55. When 2000 children are vaccinated 36 cases of diarrhea would be avoided and 1 child may develop intussusception.

Intussusceptions are difficult to diagnose and treat in rural India where the vaccine will be used. Meier and colleagues suggest that children with intussusceptions treated at a hospital in a developing country have a significantly longer duration of symptoms, an increased incidence of nonviable bowel, and a mortality of 18% < PMID: 8798362 > Many in India will not even reach a surgical center before they die.

I submit that it will be dangerous to launch this vaccine without further proof that it is safe.