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Team science and the creation of a novel rotavirus vaccine in India: a new framework for vaccine development.

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- Jacob Puliyel2014 Aug 23 6:43 p.m.

116E Rotavirus Vaccine Efficacy Against Death is 10% of Projected Figures

A member of the National Technical Advisory Group on Immunization (NTAGI India) responded to my posting and I quote him below.

"With respect to your recent comments on 116 E Rota virus vaccine, inferring that it will save only one fifth of the projected deaths, I think an error has occured in presuming that rotavirus diarrhea of any severity, if managed in the community, shall result in 1% deaths. **The articles cited Lal S, 1994 Kosek M, 2003 for this presumption mention diarrhea cases and deaths and not specifically rotavirus diarrhea deaths.** We all know that case fatality rate due to rotavirus diarrhea is more than all cause diarrhea because of its severity and in most children occurrence of severe vomiting, thus not permitting oral rehydration therapy. I hope, after correcting this error, number of children required to be vaccinated to avert on death due to rotavirus diarrhea will come down and will be in line with the article published on 116 E vaccine."

As this was written in an email to me (and not as a response on PubMed) I will maintain his anonymity. However as it was a response to my PubMed posting I feel the objection and my response to him must be published on the forum. I have redacted his name.

I accept that objection that the mortality (1%) I used for calculations is from figures for diarrhea due to all causes and not specifically for rotavirus diarrhea. I will recalculate with data for rotavirus, specifically.

"Kang in her article Tate JE, 2014 suggests that there are 11.37 million diarrhea episodes due to rotavirus each year, in children under 5 years and there are 78500 deaths. She states that 70 to 89% of hospital admissions (more severe rotavirus infections) occur under 2 years. Professor Bhan writes Bhan MK, 2014 that 70% admissions occur under 1 year. Extrapolating the 70% figure of Dr Bhan, we can calculate that 7.9 million episodes or rotavirus diarrhea occur in the first year.

If 78500 deaths occur in 11.37 million episodes of diarrhea the mortality is 0.69%. The rotavirus deaths prevented by vaccination will be only 8213 rather than 11904, that I had calculated.

If we assume more mortality in infants, that there is zero mortality in the 30% rotavirus infection that occur after age 1 year and all the 78500 deaths occur among the 7.9 million rotavirus diarrhea in the first year (and there are no deaths in the 3.5 million rotavirus diarrhea after 1 years), the mortality rate works out to be 1% which matches the figure I used for my calculations. (It must be noted that I have used the NNT over 2 years not the first year.) If 8000 deaths are prevented (of the projected 78500 deaths said to be caused by rotavirus) efficacy against rotavirus death is a mere 10% not 50%!

If the efficacy against death is 50% and only 8000 deaths are prevented, one must conclude that the total deaths caused by rotavirus are about 16,000 (and the 78500 deaths from rotavirus projected, is an exaggeration – the real figure has been enhanced 500%). The recommendation to use the vaccine was based on projections that are not supported by properly acquired empirical evidence. I hope you agree with these estimates and calculations or else I will be happy to revise my estimates.

The time lines described by Professor Bhan Bhan MK, 2014 suggest that the private manufacturer to set up the plant for manufacture of this vaccine was funded by PATH, B&MG and the Government of India (DBT) in 2000, where as the Phase 3 trial only started in 2008. It is clear that regardless of efficacy in the phase 3 trial (or any objections by NTAGI members,) the vaccine had to be rolled out, if there was to be any returns on the investment.

I am less concerned about this waste of scarce resources. I am more concerned about safety http://www.ncbi.nlm.nih.gov/pubmed/25091662#cm25091662_5770. Dr Bhan has promised complete transparency with the data. I have written to him asking for the safety data in each of the three centers (which has not been published except in an aggregated form). This will help us understand the situation with regard safety issues better. I await his reply which he could share with this group in the interest of transparency."