

TRIAL AND ERROR

A study tries to prove efficacy of a rotavirus vaccine that might cause more diarrhoea

Researchers conducting the trial have tried to downplay data that suggests the new vaccine causes more diarrhoea by agents other than rotavirus.

by *Jacob Puliyel*

Published 2 hours ago





Health Minister JP Nadda administrating the rotavirus vaccine to a child in Agartala. | IANS

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In March, the *New England Journal of Medicine* published the results of a clinical trial of a rotavirus vaccine developed by the Serum Institute of India. The paper highlighted that the vaccine reduced the incidence of rotavirus gastroenteritis and suggested that this new vaccine would be effective in controlling the disease. What the paper tries to gloss over is data from the trial that shows that the overall incidence of diarrhoea among those who received the vaccine actually increased raising questions about how safe the vaccine really is.

Rotavirus is a virus that causes gastroenteritis and diarrhoea in babies and young children and is the leading cause of childhood diarrhoeal deaths around the world.

The oral bovine rotavirus pentavalent vaccine or BRV-PV developed by the Serum Institute of India was field tested in Niger in West Africa. The authors from France, the United States and Niger **reported** that vaccine efficacy was 66.7% against severe rotavirus diarrhoea. However, while those vaccinated had fewer episodes of rotavirus diarrhoea, diarrhoea caused by other agents increased significantly.

The purpose of the vaccine is to reduce the incidence of diarrhoea. Patients seldom care about what virus or bacteria are causing their diarrhoea. The *New England Journal of Medicine*, which published the study, has this week published a **letter** that I and colleagues have written in response to the original article, which points out that there was a significantly higher rate of gastroenteritis and diarrhoea in the vaccinated group compared to those given the placebo – an inert dummy vaccine. There were 6.59 more cases of diarrhoea among every 100 vaccinated children per year compared to those who did not get the vaccine. This is statistically significant. This data suggests that while the incidence of diarrhoea caused by rotavirus comes down after vaccination, other viruses replace rotavirus as the cause

compared to those who did not get the vaccine. This is statistically significant. This data suggests that while the incidence of diarrhoea caused by rotavirus comes down after vaccination, other viruses replace rotavirus as the cause of diarrhoea and ultimately there is an increase in the incidence of diarrhoea. An anti-diarrhoea vaccine that increases the incidence of diarrhoea is unlikely to find a market.

This highlights how cherry picked data gets published even in the most prestigious medical journals. Fortunately, the *New England Journal of Medicine* has now published a letter pointing out the discrepancy. This could prevent desperately poor countries like Niger from spending billions of dollars on a vaccine that increased diarrhoea instead of controlling it.

This is not the first time that rotavirus vaccine trials have courted controversy. Recently, the internationally licensed rotavirus vaccine Rotarix manufactured by GlaxoSmithKline has also been mired in a similar controversy.

Rotarix in Bangladesh

Rotarix was studied in Bangladesh and the **results** were published in *PLoS Medicine* recently. According to a letter published in *PLoS Comments* there were more cases of children reporting diarrhoea among the vaccinated although the difference was not statistically significant. Jain and Mittal the authors of the comment requested “the authors to publish the data on non-rotavirus diarrhoea in children in the first and in the second year of life, presenting for medical care to the three treatment centers, from the vaccinated cluster and the unvaccinated cluster”. Although *PLoS Medicine* asks its authors to respond promptly to post publication peer review comments, there has been no response from the authors in the two months since the letter was published.

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The efficacy of rotavirus vaccines is much lower in Asia at a mere 50% compared to 90% efficacy in the west. The latest studies quoted above seem to suggest that not only is efficacy against rotavirus infection low, the vaccine may be encouraging shifts in the viral strain and an increase in non-rotavirus diarrhoea.

Adverse effects of Rotavac

The third controversial rotavirus vaccine is Rotavac manufactured by Bharat Biotech in Hyderabad. This vaccine is licensed for use only in India. The vaccine was studied in clinical trials in Vellore, Delhi and Pune. Data on a potentially fatal complication with use of the vaccine – intussusception, where the intestine telescopes into itself and can become gangrenous – has not been published despite repeated requests from various quarters. In response to a public interest litigation filed in the Delhi High Court, lawyers for the government and Christian Medical College in Vellore, which conducted one leg of the study, **argued** that:

“site specific data on safety is inappropriate for release as per protocol and its inappropriate interpretation or publication which would lead to disinformation about the product (that has been) developed by government with great effort and expense, and will give unfair advantage to multinational products which were never tested in India, (and) yet (were) licensed.”

A PIL filed in the Supreme Court by S Srinivasan from LOCOST, a Vadodara-based company that produces low cost medicines for the poor, asked for release of the segregated data from the Rotavac trial. The PIL said:

“concealment of this vital data does severe injustice to the thousands of infants who participated in this study, the researchers who painstakingly conducted the trials, and the medical/scientific community who depend on this data for their work.”

FOR THEIR WORK.”

This case is still pending. Meanwhile, the vaccine continues to be used in a phase IV or post-marketing trial without vaccine recipients being informed of the risks observed in the randomised control trial – a clear violation of basic ethics.

The lack of transparency of data in these three rotavirus vaccine cases boils down to the motives of making profits off the vaccines. Misrepresenting research findings, cherry picking data, and concealing adverse events in clinical trials have become more common and are almost unquestioned practices to this end.

The writer is head of paediatrics at St Stephens Hospital, Delhi and petitioner in the case against Rotavac.

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Rotavirus Gastroenteritis Diarrhea Clinical Trial

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