



Reply to Letter to the Editor

Evaluation of rotavirus disease burden and vaccine effectiveness in India**Keywords:**

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Measurement of the burden of disease for common childhood conditions can be challenging, particularly when most healthcare data capture systems are based in hospitals. There are few ways to estimate the burden of milder disease, which might be managed at home and the most severe disease, which might result in death before a child reaches a healthcare facility. Among study designs, observational cohorts measuring the incidence and the severity of disease could be considered best suited for estimating disease burden but are resource intensive. Within the context of a clinical trial, particularly one that is placebo-controlled, research teams have the responsibility of provision of appropriate care for children, which can alter the natural progression of disease. The design of a clinical trial, the frequency of contact and the resources available and utilized to manage ill children can all affect the severity of disease, as has been highlighted in an important comparison of rotavirus vaccine trials in developing countries [1].

We are fortunate that in India, unlike most other developing country settings, there have been several observational cohorts, as well as hospital based studies, from which burden of disease has been estimated as described in John et al. [2]. It is reassuring to note that despite the differences in study designs and geographic locations of the observational studies the estimates are similar, and in line with that reported from South Africa. It is revealing that the intensity of monitoring and the prompt provision of care within the context of a clinical trial, resulted in a >30% reduction in the incidence of severe rotavirus gastroenteritis, even though the trial was conducted in the same location as the observational studies from which disease burden estimates were derived [3].

It is always challenging to merge data from multiple sources to evaluate burden and to project possible impact. Measurement of impact of rotavirus vaccination has been conducted in several countries around the world, using trend analyses, case-control,

and other approaches. These evaluations have not only unequivocally demonstrated the reduction in severe rotavirus disease in vaccinated children, but have also resulted in the detection of unexpected beneficial effects such as the remarkable reduction in all-cause diarrheal deaths in Mexico and herd immunity in older children and adults in the US [4,5]. In order for India to use and evaluate the public health opportunities offered by introduction of the rotavirus vaccine into the national immunization program, the conduct of such effectiveness studies is essential to measure the real world impact of the vaccines. Such studies are being planned, and their results will serve to confirm or refute the projections on the possible impact expected by the introduction of rotavirus vaccines.

Conflict of interest

None of the authors report a conflict of interest.

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