

BMJ Open Rotavirus vaccine impact assessment surveillance in India: protocol and methods

Nayana P Nair,¹ Samarasimha Reddy N,² Sidhartha Giri,¹ Venkata Raghava Mohan,² Umesh Parashar,³ Jacqueline Tate,³ Minesh Pradyuman Shah,³ Rashmi Arora,^{4,5} Mohan Gupte,⁴ Sanjay M Mehendale,^{4,6} Investigators of the Rotavirus vaccine Impact Surveillance Network,¹ Gagandeep Kang^{1,5}

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¹Department of IJ Sciences, Christian Medical College, Vellore, India

²Department of Community Health, Christian Medical College, Vellore, India

³Centers for Disease Control and Prevention, Atlanta, Georgia, USA

⁴Indian Council of Medical Research, New Delhi, India

⁵Translational Health Science and Technology Institute, Faridkot, India

⁶National Institute of Epidemiology, Chennai, India

Correspondence to Professor Gagandeep Kang; gkang@imcivellore.ac.in, gkang@thsti.res.in

ABSTRACT

Introduction Rotavirus infection accounts for 39% of under-five diarrhoeal deaths globally and 22% of these deaths occur in India. Introduction of rotavirus vaccine in a national immunisation programme is considered to be the most effective intervention in preventing severe rotavirus disease. In 2016, India introduced an indigenous rotavirus vaccine (Rotavac) into the Universal Immunisation Programme in a phased manner. This paper describes the protocol for surveillance to monitor the performance of rotavirus vaccine following its introduction into the routine childhood immunisation programme.

Methods An active surveillance system was established to identify acute gastroenteritis cases among children less than 5 years of age. For all children enrolled at sentinel sites, case reporting forms are completed and a copy of vaccination record and a stool specimen obtained. The forms and specimens are sent to the referral laboratory for data entry, analysis, testing and storage. Data from sentinel sites in states that have introduced rotavirus vaccine into their routine immunisation schedule will be used to determine rotavirus vaccine impact and effectiveness.

Ethics and dissemination The Institutional Review Board of Christian Medical College, Vellore, and all the site institutional ethics committees approved the project. Results will be disseminated in peer-reviewed journals and with stakeholders of the universal immunisation programme in India.

BACKGROUND

Diarrhoea is the fourth leading cause of global under-five mortality and accounts for 9% of deaths among this age group.¹ Rotavirus infection accounts for 39% of these diarrhoeal deaths, the majority of which occur in low and middle-income countries.² India accounts for 22% of the total global rotavirus mortality.³ As per the Global Burden of Disease Study, 21 357.6 (13 150.8–33 967.0) deaths occur children less than 5 years in India due to rotavirus infection.⁴ Rotavirus is a leading cause of moderate to severe acute

Strengths and limitations of this study

- First project in India to evaluate the impact and effectiveness of a newly introduced vaccine in children.
- Use of test negative control design, a convenient and low-cost technique used in effectiveness studies for several vaccines, including rotavirus vaccines.
- Hospital based surveillance might not be representative of illness or vaccine coverage in the community.

diarrhoea in India; it accounts for 24% of cases of diarrhoea among children less than 23 months of age and 13% of cases of diarrhoea among children aged 24–59 months of age.^{5,6} An estimated 11.4 million episodes of rotaviral gastroenteritis occur among under five children leading to 872 000 hospitalisations annually.⁷ Introduction of rotavirus vaccine in a national immunisation programme is considered to be the most effective intervention in preventing severe rotavirus disease.^{8,9}

The Indian National Rotavirus Surveillance Network, established by the Indian Council of Medical Research (ICMR) in collaboration with US Centers for Disease Control and Prevention (CDC), has played an important role in documenting the disease burden of rotavirus hospitalisations in India. Established in 2005 with seven states conducting rotavirus surveillance, the network expanded over subsequent years.¹⁰ By 2012, 17 states and two union territories in India were conducting rotavirus surveillance using a standardised protocol.¹¹ The surveillance data highlighted the high prevalence (40%) of rotavirus in children hospitalised with diarrhoea, with representation across the country.¹¹ Rotavirus was also found to cause significant disease burden in children <5 years of age treated

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