

## GUEST EDITORIAL

## ROTAVIRUS DIARRHOEA - CURRENT SCENARIO AND PREVENTIVE STRATEGIES

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According to Global Burden of Disease Study 2010, Diarrhoea stands on fourth place in terms of maximum Disability Adjusted Life Years (DALY) lost. Globally, rotavirus is the most common cause of severe gastroenteritis in early childhood. Almost all children have been infected by the time they reach five years of age. In developing countries rotavirus is responsible for approximately half a million deaths per year.

In India, approximately 30% of hospitalised diarrhoea cases are caused by rotaviruses. Of India's more than 2.3 million annual deaths among children, about 334 000 are attributable to diarrhoeal diseases. Rotavirus is the leading cause of severe diarrhoea in children in developed and developing countries.<sup>1,2,3</sup>

Treatment of acute rotavirus infection is nonspecific and involves management of symptoms and, most importantly, maintenance of hydration. In 2004, the WHO and UNICEF recommended the use of low-osmolarity oral rehydration solution and zinc supplementation as a two-pronged treatment of acute diarrhoea.

In 1998, a rotavirus vaccine was licensed for use in the United States. Clinical trials in the United States, Finland, and Venezuela had found it to be 80 to 100% effective at preventing severe diarrhoea caused by rotavirus A, and researchers had detected no statistically significant serious adverse effects.<sup>4,5</sup> The manufacturer, however, withdrew it from the market in 1999, after it was discovered that the vaccine may have contributed to an increased risk for intussusception, a type of bowel obstruction, in one of every 12,000 vaccinated infants.<sup>6</sup> The experience provoked intense debate about the relative risks and benefits of a rotavirus vaccine.<sup>7</sup> In 2006, two new vaccines against rotavirus A infection were shown to be safe and effective in children<sup>8</sup> and in June 2009 the World Health Organization recommended that rotavirus vaccination be included in all national immunisation programmes to provide protection against this virus.

In 2009, the World Health Organization (WHO) recommended that rotavirus vaccine be included in all national immunisation programmes.<sup>9</sup> Two rotavirus vaccines have been shown to be effective against rotavirus and have been licensed in more than 100 countries, including India. The incidence and severity of rotavirus infections has declined significantly in countries that have acted on this recommendation. In Mexico, which in 2006 was among the first countries in the world to introduce rotavirus vaccine, diarrhoeal disease death rates dropped during the 2009 rotavirus

season by more than 65 percent among children age two and under. A 2012 Cochrane review of 41 clinical trials that included 186,263 participants concluded Rotarix and RotaTeq are effective vaccines.<sup>10</sup> Additional rotavirus vaccines are under development. Because improved sanitation does not decrease the prevalence of rotaviral disease, and the rate of hospitalizations remains high despite the use of oral rehydrating medicines, the primary public health intervention is vaccination.

There is considerable controversy in India regarding the introduction of rotavirus vaccines, especially because of uncertainty surrounding the estimates of deaths and hospitalizations caused by rotavirus and because of the current cost of the vaccines. Studies estimate that 90 000–153 000 children die from rotavirus infection in India each year but these numbers are not based on nationally representative samples. Rotavirus was estimated to cause approximately 34% (113 000; 99% confidence interval, CI: 86 000–155 000) of all diarrhoeal deaths in this age group. Shaun K Morris et al. showed that if rotavirus vaccine were delivered as part of a national programme, about 4% of all deaths among Indian children younger than five years could be prevented.<sup>11</sup>

Recently, India has developed new vaccine against diarrhoea in May, 2013. The Phase-III clinical trial of low cost Indian-made rotavirus vaccine Rotavac has demonstrated strong efficacy and excellent safety profile and if approved by the Drugs Controller General of India, it would be available at Rs. 54 per dose.<sup>12</sup> The vaccine reduced severe Rota virus diarrhoea by more than 56 per cent during first year of life, with protection continuing into the second year of life. Moreover, the vaccine also showed impact against severe diarrhoea of any cause.

International non-governmental organization PATH, the WHO, the U.S. Centers for Disease Control and Prevention, and the GAVI Alliance are working to bring rotavirus vaccines to developing countries, where children face the greatest burden.

Aiming to understand the potential health benefits of rotavirus vaccination and also to develop a national representative data on rotavirus burden and strains in India, Indian Council of Medical Research (ICMR) is planning to launch project entitled 'National Hospital based Rotavirus Surveillance Network'. Under this project, ICMR is planning to establish different surveillance unit in tertiary care hospitals in different part of India. The task force projects will focus on: studies to assess the proportion of diarrhoea

cases/deaths attributable to rotavirus among children below 5 years of age in associated hospitals and community sites; studies on determination of the age and seasonal distribution of rotavirus-associated diarrhoea including monitoring of trends; studies on characterization of (G serotyping and P genotyping) strains of rotavirus currently circulating in different geographical areas and strain diversity and trend including the strains newly emerged or unusual strains specially attributed to Zoonotic infections/not identified/typed by standard techniques; and studies on proportion of age dependent children admitted to hospital due to intussusceptions. The projects will also focus on field efficacy studies to assess the expected impact of existing rotavirus vaccine on disease and to estimate the cost-effectiveness of a rotavirus vaccine. Results of this project will guide the Government of India to plan further strategy to combat with rotavirus diarrhoea.<sup>13</sup>

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