Department of Biotechnology
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The Need for Rotavirus Vaccines in India: Understanding Efficacy and Impact

Responsible for approximately 453,000 child deaths due to diarrhoea each year,[1] rotavirus is particularly threatening in India, where approximately 100,000 young children die each year from the severe diarrhoea and dehydration caused by rotavirus.[2] This makes the prevention of rotavirus through vaccination an essential element in the fight against deadly diarrhoea.

- *ROTAVAC®* significantly reduced severe rotavirus diarrhoea by more than half—56 percent during the first year of life, with protection continuing into the second year of life. Although data are not fully comparable given variations in study design and populations tested, the efficacy demonstrated by *ROTAVAC®* compares favourably with licensed rotavirus vaccines in clinical studies conducted in low-resource settings. The significant public health impact promised by these new study results means that rotavirus vaccines could save thousands of child lives each year in India and globally.

- Efficacy is only one aspect in understanding the potential impact of a vaccine; the other critical factor is the burden of disease. Where disease burden is highest—such as in India or other countries in Asia and Africa—vaccines will have an even greater impact in reducing severe disease responsible for hospitalization and death.[3]

- Impact in the real world may also be greater than that suggested by clinical studies. Where rotavirus vaccines have already been introduced, rotavirus incidence has also decreased among adults and children too old to be vaccinated,[4] suggesting indirect protection of those not vaccinated.

- Because of the strong public health value, the World Health Organization recommends rotavirus vaccination in all countries and strongly recommends rotavirus vaccination in countries with high diarrhoea-related mortality in children less than age five, including India.[5]

- Lower efficacy of oral vaccines is typical in impoverished, high-mortality settings, as historically seen for orally administered vaccines like those against polio and cholera[6], as well as the currently licensed rotavirus vaccines. In impoverished settings, lower efficacy of oral vaccines has been attributed to other characteristics among the population, such as co-infections in the digestive system and possible interference by maternal antibodies.[7]

- There are currently two licensed rotavirus vaccines that have been introduced in more than 40 countries, but they remain out of reach for many in the developing world. Both vaccines are effective, and there is increasing evidence that they are having a powerful impact on children's health in many parts of the world. Studies are showing major reductions in rotavirus-related hospitalizations and deaths in both the developed and developing countries that have introduced rotavirus vaccines. Some countries have also seen major reductions in diarrhoea deaths due to any cause.

    - In Mexico, diarrhoea-related deaths dropped by approximately 50 percent across three regions of the country among children less than age 5 since the vaccine was introduced. This significant reduction in deaths was seen among children in all socioeconomic regions of Mexico and was sustained for four continuous years.[8]

- In Nicaragua, since the introduction of rotavirus vaccine in 2006, vaccination has reduced severe rotavirus by 70 percent.[9]

- In Brazil, the vaccine led to 30 and 39 percent decreases in diarrhoea-related deaths in 2007 and 2008, respectively, when compared to 2004 to 2005 mortality rates.[10]

- In the United States, vaccination has led to drops in rotavirus-related hospitalizations by as much as 86 percent.[11]

- While rotavirus vaccines have resulted in lowering hospitalizations in developed-world countries and higher-income populations, in the developing world and lower-income populations they have resulted in lowering the number of deaths caused by diarrhoea.

- Research indicates a national rotavirus vaccination program in India would significantly reduce rotavirus-related hospitalizations and deaths and that vaccination would be highly cost-effective at a range of prices. A national rotavirus immunization program in India could prevent approximately one-third of rotavirus deaths and significantly reduce medical treatment-related costs.[12]

- The availability of an affordable and efficacious vaccine in conjunction with the high-quality disease burden generated by the Indian Council of Medical Research creates the foundation for the introduction of rotavirus vaccines into the Universal Immunization Programme of India.

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