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Should India launch a national immunisation programme against rotavirus? Yes

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The World Health Organization recommends inclusion of rotavirus vaccination of infants into all national immunisation programmes, with a strong recommendation for introduction of vaccine in countries like India where diarrhoeal deaths account for ≥10% of child mortality.[1] The health burden of rotavirus in India is well established. WHO estimated that 98 621 Indian children died from rotavirus gastroenteritis in 2008, representing about one third of deaths from diarrhoeal disease and 4% of all child deaths in India.[2] More recent data from the Million Death Study, a nationally representative survey of 1.1 million Indian households, estimated that the virus causes 113 000 deaths a year.[3] Both of these figures are conservative compared with an estimate of 147 000 annual rotavirus deaths obtained by directly extrapolating rates of laboratory confirmed rotavirus mortality from a contemporary community based birth cohort study in India.[4]

Non-fatal rotavirus gastroenteritis results in around 880 000 hospital admissions and 1.26 million clinic visits annually in Indian children, costing $65m (358 crore; £41m; €51m).[5] Because rotavirus affects essentially all children in both developing and industrialised countries by the age of 5 years, interventions to improve hygiene and provide clean water alone are considered inadequate to prevent transmission. In addition, although severe and fatal outcomes of rotavirus diarrhoea can be reduced by timely access to medical treatment, a national survey in 2005–6 found that a quarter of Indian children under 5 years with diarrhoea received no treatment and only 39% received oral rehydration therapy.[6] Vaccination is therefore the best method to prevent deaths and morbidity.

Efficacious vaccines with favourable benefit:risk ratio

Two internationally licensed rotavirus vaccines have shown 85%–98% efficacy against severe rotavirus disease in large clinical trials in middle and high income countries [7,8] and their routine use has led to notable reductions in severe morbidity and mortality from

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childhood diarrhoea.[910] Neither vaccine has been tested for efficacy in India. Concerns about local efficacy have been raised, especially given the large diversity of rotavirus strains prevalent in India. However, pre-licensing and post-licensing data from diverse settings indicate that both vaccines provide good protection against a range of strains (including vaccine mismatch strains).[911] The efficacy of the vaccines in India is likely to be similar to that in low income countries in Africa and Asia (40%–60%, including 42.7% in Bangladesh).[12] Although this efficacy may seem low, the absolute public health benefits of vaccination are likely to be substantial because of the large health burden of rotavirus disease. With coverage similar to the first two doses of diphtheria-tetanus-pertussis (DTP) vaccine (73% and 63%, respectively), a 50% efficacious rotavirus vaccine would prevent around 44 000 deaths and 290 000 hospital admissions in Indian children each year.[5]

The benefits of rotavirus vaccination have to be weighed against possible risks. An earlier rotavirus vaccine was withdrawn in the United States in 1999 after it was linked to an increased risk of intussusception (about one case per 10 000 vaccinated infants).[13] However, risk of intussusception was not increased in pivotal trials of both currently licensed rotavirus vaccines conducted in over 60 000 infants each.[78] Post-licensing data have shown a small risk of intussusception, mainly in the first week after the first vaccine dose, in some high and middle countries but not in others.[14] Data on intussusception risk from India or from other low income settings are lacking. Even if we assumed that the intussusception risk seen in some international settings (1–2 cases per 100 000 vaccinated infants) were to exist in India, the benefits of vaccination (around 44 000 rotavirus deaths prevented) would far exceed this risk. Similar benefit-risk considerations in other settings have led WHO and other policy bodies to continue support for use of rotavirus vaccines globally.[14]

Vaccines are cost effective and being locally developed

In a country where health spending is $54 per capita, cost effectiveness and affordability of vaccination are important considerations. Two separate analyses evaluated cost effectiveness of vaccination at prices ranging up to $7 per dose for a two dose schedule and showed that rotavirus vaccines could be considered very cost effective based on international standards, although substantial resources would be required to provide vaccine at the higher end of the price range.[515] Currently, India has the opportunity to apply for financial support from the GAVI Alliance for procurement of rotavirus vaccines with a cofinancing requirement of $0.20 a dose.

Meanwhile, several Indian companies are manufacturing rotavirus vaccines, including an Indian neonatal rotavirus strain vaccine set to finish phase III testing in 2013.[61314] If trial results are favourable, this vaccine could be licensed in India within two years. The manufacturer has pledged to provide vaccine at $1 per dose,[16] which would make a vaccination programme highly cost effective. Furthermore, the potential availability of low cost, indigenously manufactured vaccines would allay concerns about long term sustainability of financial support from donors and would assure adequate vaccine supply.

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