



Rotavirus vaccine and intussusception

SUMMARY INFORMATION FOR PROVIDERS FEBRUARY 2011

Key Points

1. Inform parents and carers of young infants receiving rotavirus vaccine of the rare risk of intussusception following the vaccine and how to be alert to the signs and symptoms of the condition.
 2. Do not give rotavirus vaccine outside the recommended age limits.
 3. Do not give rotavirus vaccine to a baby with a history of intussusception.
 4. Report any cases of intussusception following rotavirus vaccination through the usual reporting arrangements for adverse events following immunisation in your State and Territory.
- There is new evidence from Australian and overseas studies suggesting a small increased risk of intussusception in infants following rotavirus vaccination.
 - The increased risk appears to occur mainly in the first 1- 7 days following the first dose of rotavirus vaccine.
 - Intussusception is rare, with an annual incidence under 12 months of age in Australia of 80 per 100,000, or about 200 cases per year. The increased risk would result in 2 additional cases of intussusception among every 100,000 infants vaccinated, or 6 additional cases per year in infants in Australia.
 - It is also possible there may be a similar increased risk of intussusception after the second dose of rotavirus vaccine and that a smaller increased risk may continue for up to 21 days after vaccination.
 - Some studies have suggested that there may be a compensatory reduction in intussusception among older infants and children vaccinated against rotavirus as babies.

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continued overleaf

IMMUNISATION

- Studies to further evaluate these uncertainties are continuing and results will be made available as soon as possible.
- There is some indication that giving rotavirus vaccine later than the recommended upper age limits for each dose may increase the risk of intussusception.
- As there may be an increased risk of recurrence, rotavirus vaccine should not be given to a baby who has had intussusception.
- The very low risk of intussusception must be balanced against the benefits of rotavirus vaccination. Prior to the introduction of rotavirus vaccine, there were an estimated 10,000 hospitalisations annually in children under 5 years of age due to rotavirus gastroenteritis in Australia and on average one childhood death from rotavirus each year. Since the introduction of Rotarix® and RotaTeq® to the National Immunisation Program in 2007, this has been reduced by over 70%.
- Both rotavirus vaccines (Rotarix® and RotaTeq®) continue to be registered by the Therapeutic Goods Administration (TGA) for the prevention of rotavirus gastroenteritis.
- Based on the well-established benefits of rotavirus vaccination and the rare occurrence of intussusception, the Australian Technical Advisory Group on Immunisation (ATAGI) recommends the continued use of rotavirus vaccine for infants under the National Immunisation Program.
- Immunisation providers should inform parents and carers of young infants being vaccinated against rotavirus of the rare risk of intussusception and how to be alert for the signs and symptoms of the condition. The risks from rotavirus infection and benefits of vaccination should also be discussed. A Fact Sheet for parents can be downloaded from the Immunise Australia Website www.immunise.health.gov.au
- Health professionals should report any cases of intussusception following rotavirus vaccination through the usual reporting arrangements for adverse events following immunisation in their State or Territory. These reports will then be forwarded to the TGA.
- The TGA has published a report on its investigation of the association between rotavirus vaccine and intussusception on its Website at www.tga.gov.au/safety/alerts-medicine-rotavirus-110225.htm