Introducing the rotavirus vaccine in the UK

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- Contraindications of the vaccine

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Vaccination against rotavirus, which causes significant morbidity in preschool children, is due to become part of the childhood immunisation schedule next week.

Rotavirus has been recognised as a human pathogen since the 1970s and accounts for more than 1.3 million deaths per year around the world, with the highest levels of mortality in countries with limited resources (Marlow and Finn, 2012).

In developed nations, death from rotavirus gastroenteritis is extremely rare. However, it causes significant morbidity, an increased burden on healthcare (peaking in the winter season) and associated costs, for example time off work for parents (Marlow and Finn, 2012; Paul et al, 2012). Severe rotavirus gastroenteritis can cause substantial fluid and electrolyte loss, leading to hospitalisation and serious morbidity (Paul et al, 2012).

The only workable strategy against such a wide-scale public health problem is an effective vaccine. In 2009, the WHO Strategic Advisory Group of Experts recommended that rotavirus vaccine be introduced into all national immunisation programmes, with a strong emphasis on its introduction in countries where more than 10% of child mortality is due to diarrhoeal diseases (Marlow and Finn, 2012; Soares-Weiser et al, 2012).

**Rotavirus vaccine worldwide**

The successful introduction of oral rotavirus vaccines in the US and European nations has significantly reduced gastrointestinal and extra-intestinal manifestations of rotavirus illness in young children (Marlow and Finn, 2012; Glass et al, 2011). It is welcome news that the DH plans to introduce oral rotavirus vaccination for children aged under four months. It is expected that the vaccine will halve the incidence of gastroenteritis and reduce the need for hospitalisation by 70% (DH, 2012).

**Rotavirus vaccine in the UK**

The new vaccine is expected to protect against the most common strains of rotavirus and is being introduced into the childhood immunisation schedule in the UK from 1 July 2013 (DH and Public Health England, 2013).
Rotavirus vaccines have achieved 85-100% protection against severe disease in high and middle income countries. Two doses of oral pentavalent rotavirus vaccine (Rotarix) will be administered to infants at two and three months of age in the UK at the same time as other routine childhood immunisations (PHE, 2013). Health professionals should encourage parents to ensure the two doses of Rotarix vaccine are given before the infant reaches 16 weeks of age (PHE, 2013).

The background risk of intestinal intussusception among infants in the UK increases to peak at around five months of age. Completing the two doses of rotavirus vaccine by 16 weeks will avoid any temporal association between rotavirus vaccination and intussusceptions (PHE, 2013).

The expected challenge
The biggest question that health professionals will face concerns the safety of the vaccine. This uncertainty was evident among health professionals in the US when the new oral rotavirus vaccine was introduced in 2006; this was made worse by the abrupt withdrawal of the Rotashield vaccine in 1999 due to its association with intestinal intussusception in infants (Glass et al, 2011).

Reports from the US and elsewhere, however, have established the efficacy and safety of the new rotavirus vaccines. Health professionals will be able to tell parents about the safety data available from around the world for more than seven years. It is hoped that this evidence will contribute to an increased uptake of the new vaccine.

A recent Cochrane review did not find any increased risk of serious adverse events (including intestinal intussusception), but the authors suggested post-introduction surveillance studies were needed to identify rare events associated with vaccination (Soares-Weiser et al, 2012).

Contraindications
Health professionals should remain aware of the groups of children in which Rotarix vaccine is contraindicated, including infants with a confirmed anaphylactic reaction to a previous dose of rotavirus vaccine or any of its components (PHE, 2013).

The vaccine should not be given to infants with a history of intussusception or who were born with a gastrointestinal tract malformation that can predispose them to intussusceptions. It should not be administered to those aged over 24 weeks.

As it is a live attenuated vaccine, its use in severe combined immune-deficiency (SCID) is contraindicated. However, it may be possible to administer it to children with other immune disorders; this should be discussed with experts on a case-by-case basis. Health professionals should enquire about rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency, as rotavirus vaccine should not be administered to affected children (PHE, 2013).

Herd immunity
It is expected that, if the uptake of the rotavirus vaccine among the target group is high, there will be a herd immunity effect that will protect unvaccinated older children and those who cannot have the vaccine (Marlow and Finn, 2012; PHE, 2013).

This is particularly relevant for the immune-suppressed children who cannot be vaccinated (PHE, 2013). There is a need for larger studies to prove this effect; however, smaller cohorts and early observations in countries where rotavirus vaccine has been introduced suggests that there may be indirect protection for unvaccinated individuals (Marlow and Finn, 2012; Pitzer et al, 2012).

Cost effectiveness
In the current economic climate, cost-effectiveness is key to any intervention. The vaccine’s overall cost effectiveness, including societal costs, such as loss of income due to time taken off work, has been proved in countries where that vaccine is administered routinely to children (Atkins, 2012; Marlow and Finn, 2012). A budget impact analysis for England and Wales demonstrated that 58-96% of the cost outlay for vaccination will be recouped within the first four years of the vaccination programme and it is predicted to be not only cost-effective but also cost-saving (Atkins et al, 2012).

Benefits beyond the gut
Extra-intestinal rotavirus illness have been increasingly recognised in the past decade (Paul and Candy, 2012). Rotavirus particles have been found in the blood and cerebrospinal fluid of patients with systemic rotavirus illness. Manifestations of rotavirus illness include:
- Encephalopathic state;
- Vasculitis;
- Acute infantile haemorrhagic oedema;
- Hepatitis;
- Haemophagocytic lymphohistiocytosis.

These can at times cause diagnostic problems, as was highlighted in a recent case series where encephalopathic state with vasculitis in systemic rotavirus illness initially appeared to be meningococcal sepsis and was managed as such (Paul and Candy, 2012). A similar problem was noted in a case of transient acute flaccid paralysis and generalised tonic-clonic seizures associated with rotavirus gastroenteritis in a child (Özalp et al, 2012).

It is hoped that, in addition to reducing the incidence of gastroenteritis, the rotavirus vaccine will also help to reduce these extra-intestinal manifestations some of which are associated with significant morbidity (Paul et al, 2012).

Conclusion
The success of the rotavirus vaccination programme in the UK depends on the cooperation of medical, nursing and allied health professionals. There is a need to highlight the introduction of the new vaccine (provide leaflets, give information verbally), counsel parents about the herd benefits and its safety profile, remove myths and make sure it reaches children in areas where uptake is likely to be low due to a variety of reasons.

Rotavirus vaccination will reduce gastroenteritis. It also has wider implications in preventing extra-intestinal manifestations, reducing need for hospital admission, minimising loss of work for carers and developing herd immunity in the community.

References