Introduction of immunisation against rotavirus in the UK

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Rotavirus is the infectious agent responsible for over half of all cases of childhood diarrhoea and vomiting. By the age of five all children will have had at least once episode of gastroenteritis caused by rotavirus. In November 2012 the Department of Health announced that after a successful tendering process GlaxoSmithKline’s Rotarix vaccine would be introduced to the UK’s childhood immunisation schedule in September 2013.1

In the UK, childhood diarrhoea and vomiting remains a significant public health problem. Due to our high standards of food hygiene and good sanitation bacterial causes are now relatively uncommon but the viral causes (such as rotavirus) are too infectious to be controlled by these methods alone.

Many vaccine-preventable diseases are rare but lead to high morbidity/mortality. Rotavirus vaccination in the UK requires a different paradigm. Deaths are rare and most children have a minor self-limiting illness managed at home without requiring medical treatment. Some children are more seriously affected, with an estimated 45 hospitalisations, 98 emergency department attendances and 250–440 GP attendances per 10 000 children under five per year, equating to an annual cost for the NHS of £14.2 million.2

But perhaps the most significant cost is the almost universal secondarily lost income and productivity for the parents and carers taking time to look after a child with what is a preventable illness.

Available vaccines
Two rotavirus vaccines are currently licensed in Europe. GlaxoSmithKline’s Rotarix is a live attenuated human strain of rotavirus given orally at two and three months of age. Sanofi Pasteur MSD’s RotaTeq is also an oral live vaccine but derived from bovine rotavirus modified to also contain components of five common human rotavirus strains. It is given in three doses.

In high-income countries both vaccines have repeatedly been shown to be very effective. Case control studies in the USA,2 Australia1 and Belgium3 (the first country in the EU to introduce rotavirus vaccine) have all shown ≥90 per cent efficacy at preventing hospital admission due to rotavirus gastroenteritis.

For reasons that are still poorly understood, vaccine efficacy is significantly lower (50–60 per cent) in less industrialised countries, but due to a higher burden of disease in these environments the net potential health benefits are paradoxically often much greater. The introduction of rotavirus vaccination in Mexico resulted in a halving of childhood mortality due to gastroenteritis.6

Safety
Both vaccines had massive prelicensure studies because the first marketed rotavirus vaccine (RotaShield) was quickly withdrawn from use after it appeared to be associated with an increased risk of intussusception.

Although no link was detected for the two current vaccines prior to being licensed, careful monitoring of their routine use in the USA,7 Australia,8 Mexico9 and Brazil10 has suggested that there may still be a weak temporal association. However, with this risk estimated to be in the region of one additional intussusception event per 50–100 000 vaccinations, it is now considered firmly outweighed by the benefits of vaccination.11

The WHO Strategic Advisory Group of Experts (SAGE) has recommended12 that rotavirus vaccine be included in all national vaccination programmes, and in October 2011 55 countries/regions had already introduced it or planned to within the next two years.

Cost
The independent body that advises the Department of Health on vaccination, the Joint Committee for Vaccines and Immunisation (JCVI), reviewed the evidence for rotavirus vaccination in 200913 and 201114 and concluded that: ‘Rotavirus vaccines would reduce the incidence of gastroenteritis in the population. However, at the vaccine prices considered (£35 per dose for Rotarix and £25 per dose for RotaTeq) they do not meet the current economic criteria for the introduction of a new vaccine. Introduction of
rotavirus vaccines would only become cost-effective if the vaccine prices are much less than those at which they are currently being offered.’

In April 2012 the Department of Health put out a tender for vaccine, which led to Rotarix being chosen to be used in the UK for the next three to four years.

Conclusion
As a result of our national procurement system and firm bargaining position, over the coming years we will see a near elimination of both gastroenteritis and the misery caused to families caused by rotavirus for a mutually acceptable price.

References

Declaration of interests
Adam Finn undertakes consultancy and clinical research for all the main vaccine companies, the fees payable to the University of Bristol and University Hospitals Bristol NHS Foundation Trust. Robin Marlow has received two travel bursaries from GSK to attend educational meetings.

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