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Welcoming rotavirus vaccine to the UK immunisation schedule

Change in policy promises substantial benefits

SPL

Miren Iturriza-Gómara Wellcome Trust tenure track fellow, Institute of Infection and Global Health, University of Liverpool, Liverpool L69 7BE, UK
Nigel Cunliffe professor of medical microbiology, Institute of Infection and Global Health, University of Liverpool, Liverpool L69 7BE, UK n.a.cunliffe@liv.ac.uk

In November 2012, the Department of Health announced that rotavirus vaccine will be introduced into the United Kingdom's childhood immunisation programme (www.dh.gov.uk/health/2012/11/rotavirus). The live, attenuated, two dose, oral monovalent vaccine (Rotarix, GlaxoSmithKline Biologicals) will be given with other routine vaccines to children by the age of 4 months. Clinical trials in Europe and the Americas with both currently licensed rotavirus vaccines (Rotarix and a pentavalent vaccine Rotateq developed by Merck) led to a recommendation by the World Health Organization in 2006 to vaccinate children in these regions. Subsequent trials in Africa and Asia led to an extension of the recommendation to include all children worldwide.[1] The Department of Health's joint committee on vaccination and immunisation recognised as early as 2008 that rotavirus vaccination would reduce the burden of rotavirus disease in the UK population. However, at that time, the cost effectiveness analysis indicated that at market prices universal vaccination of UK infants significantly exceeded the accepted threshold for intervention,[2] and that universal rotavirus vaccination would become cost effective only if vaccine prices were reduced. Economic aspects remain a barrier to vaccine introduction in western Europe, with only Austria, Belgium, Finland, and Luxemburg having rolled out universal programmes. Currently, more than 40 countries include a rotavirus vaccine in routine childhood immunisation programmes. On the basis of their experience, what can the UK expect?

Rotavirus, the most common cause of severe gastroenteritis in infants and young children, causes an estimated 453 000 deaths each year in children under 5 years, with more than 90% of deaths occurring in developing countries.[1] In industrialised countries, rotavirus is the main pathogen responsible for hospital admissions for diarrhoea. In the UK, rotavirus is estimated to result in 750 000 episodes of diarrhoea and 80 000 general practice consultations each year,[3] together with 45% and 20% of hospital admissions and emergency department attendances for gastroenteritis, respectively, in children under 5 years.[4]

Clinical trials in middle and high income countries showed high (>85%) vaccine efficacy against severe rotavirus gastroenteritis, with much lower efficacy reported from some low income countries.[5] The direct benefits of introducing rotavirus vaccination in high and middle income countries have been similar to those seen in clinical trials, with significant reductions in hospital admissions for diarrhoea caused by rotavirus infection.[6] In the United States, where routine rotavirus vaccination was introduced in 2006, norovirus has replaced rotavirus as the leading cause of hospital admissions and emergency department visits for gastroenteritis in young children.[7] Importantly, post-introduction surveillance has shown reductions in mortality in middle income countries in Latin America. Such reductions could not be detected in clinical trials because of insufficient sample sizes.[8]

Routine rotavirus vaccination has altered the epidemiology of rotavirus infection in some settings. In countries with strong rotavirus seasonality, vaccination has led to a delay in peak activity.[9] Mathematical models, which are supported by observational data,[9 10] predict that in some settings biennial rather than annual epidemics may occur after introduction of the vaccine. It is still unclear whether rotavirus vaccination drives the emergence of vaccine escape strains. The emergence of G2P[4] strains in Brazil, Belgium, and some territories in Australia, and of G9P[4] strains in Mexico after introduction of the G1P[8] Rotarix vaccine, led to concerns over the ability of this vaccine to protect against fully heterotypic strains.[6] However, case-control studies conducted after introduction of the vaccine have reported comparable vaccine effectiveness in relation to hospital admission for diarrhoea caused by such strains.[11] Post-vaccination strain changes may therefore represent natural fluctuation of circulating rotavirus genotypes, as supported by the observation of similar strain distributions in countries in the same region with and without rotavirus vaccination programmes.[6] However, mathematical models predict that subtle differences in vaccine effectiveness against particular rotavirus strains may lead to strain selection that could take years to become apparent.[12]

An unanticipated but beneficial consequence of rotavirus vaccination is the reduction of rotavirus disease in unvaccinated people (herd protection), probably because of reduced virus transmission. Such indirect benefits include reduced disease in non-vaccinated older children and adults in whom the burden of rotavirus disease may have been under-recognised.[13] Decreased immune boosting owing to reduced virus transmission may shift the burden of rotavirus disease into older age groups, although there are no published data to support this.

In relation to vaccine safety, large pre-licensure studies showed no association with intussusception for either of the rotavirus vaccines, at least at the risk level found in the US with RotaShield.[5] However, a low rate of intussusception was recently reported after routine use of Rotarix in Mexico and Rotarix and Rotateq in Australia.[1 6] An increased risk of intussusception has not been detected so far in the US, where data suggest that the benefit from the reduced number of cases of rotavirus gastroenteritis would far outweigh an increased risk of intussusception at the level seen in Mexico or Australia.[14] Nevertheless, these findings underscore the importance of continued safety monitoring by countries introducing a rotavirus vaccine.

The introduction of rotavirus vaccination in the UK is expected to result in substantial health benefits to vaccinated children and to the wider population. There is also expected to be a reduction in the burden of nosocomial rotavirus infection.[15] The impact will be most pronounced in the winter months, when many seasonal infections are at their peak and pressures on the NHS are greatest. Finally, the UK will be able to assess the direct and indirect cost benefits associated with the introduction of universal rotavirus vaccination because of its system of publicly financed healthcare. Such an assessment will provide the largest dataset in western Europe and is likely to inform decision making in other European countries.

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When health professionals promote the desirability of prolonged nocturnal infant sleep they are undermining optimum feeding of newborns and creating false parental expectations

Supporting parents who are worried about their newborn's sleep

Clinicians can help to reframe expectations and support parents to develop coping strategies

Helen L Ball professor of anthropology, Parent-Infant Sleep Laboratory, Department of Anthropology, Durham University, Durham DH1 3LE, UK H.L.Ball@dur.ac.uk

Parents of new babies often struggle with the problems of interrupted sleep, particularly when contemporary lifestyles, parental sleep needs, and infant biology conflict.[1] Recent trends in Western infant care have led to misperceptions of normal infant sleep development. When we ask whether a young baby "sleeps through the night" this reinforces the idea that prolonged infant sleep is important and should be achieved early. It also does not recognise the role of night feeding in successful breast feeding because breastfed babies wake more often during the night than those who are not breast fed.[2] Consequently, what we tell parents about normal infant sleep, and how we provide support, requires reframing.

In a linked paper,[3] Stremler and colleagues highlight that parental sleep disturbance can be profound in the early months of infant life and the associated prolonged lack of sleep may have negative consequences for parental health and wellbeing. This can be exacerbated if, in the transition to parenthood, expectations fail to match reality. When this occurs, new parents may doubt their own competence as care givers or may question whether their infant's night waking is normal. Some may seek medical help for their infant's "sleep problems."[4] Responses to infant night waking have been found to be strongly influenced by cultural attitudes and beliefs, with parents in some societies perceiving this behaviour as normal and unproblematic.[5] This indicates that providing parents with more realistic information on what is normal infant sleep behaviour would probably help them better accept and manage infant night waking.

What parents need to know is that sleep is a developmental process that is biologically driven to mature during the first years of life, and that sleep behaviour and development vary greatly between individuals.[6] Infants are not born with functional circadian rhythms. Their sleep patterns begin to consolidate into a diurnal pattern only from around 3 months of age, with the body clock maturing between 6 and 12 months.[1 7] Night waking is a characteristic of infant sleep that comes and goes during the first year, irrespective of previous consolidation, and with no clearly consistent pattern.[6 8] Therefore, instead of approaching infant night waking as a pathological problem that requires treatment, clinical effort could be more effectively directed at helping parents to anticipate and cope with this normal aspect of infant sleep behaviour.

ANNIE ENGEL/SPL

Night waking is normal in the first year

Interventions that involve both education and support offer the promise of realigning parental expectations with the realities of infant sleep and providing parents with the opportunity to consider strategies for anticipating, coping with, and managing the consequences of sleep loss. Stremler and colleagues randomised primiparous women to usual care or to a novel intervention that involved providing information about normal infant sleep, educating mothers on how to satisfy their own sleep needs, and teaching helpful behaviours.[3] The primary outcome was duration of maternal sleep between 9 pm and 9 am, and a secondary outcome was the longest stretch of infant nocturnal sleep measured by actigraphy at six and 12 weeks postpartum. There was no difference between intervention and control groups in duration of maternal sleep or the longest infant sleep bout, which is not surprising given the young age of the infants and the high proportion of exclusive breast feeding in the sample. The authors acknowledge several other factors that may also have influenced the negative findings. An outcome that was not measured in the current study, but may be worthy of further study, is maternal resilience to sleep fragmentation—for example, through using coping strategies such as daytime napping, sharing night-time care with a partner, or prioritising sleep over other activities.

Programmes designed to manipulate infant sleep patterns or to "train" infants to self soothe have been extensively reviewed and may have a role in late infancy and early childhood,[1 9] although their effects are contested,[10] and altered sleep outcomes seem to be short lived.[11] Sleep training programmes are not recommended, however, for young infants and few have been tested outside clinical settings. Clinicians can best support parents who are considering such interventions by helping them to evaluate their reasons for considering sleep training and educating them about appropriate alternative approaches.

Finally, it is important that new parents are made aware of the lack of evidence that changing the mode of feeding increases the sleep duration of mothers or babies. A common parental response to infant night waking is to give supplemental food or stop breast feeding.[12] Although it is normal for breastfed infants to wake regularly to feed in the night, and for their mothers be woken more often than those of formula fed babies, periods of wakefulness are longer in formula fed babies and the net outcome in terms of sleep duration is the same.[1] When health professionals promote the desirability of prolonged nocturnal infant sleep they are undermining optimum feeding of newborns through breast feeding and creating false parental expectations for infant sleep.

Any interventions that are offered to or discussed with parents of newborns should be culturally appropriate and evidence based, should have been tested in the settings in which they are being applied, and should guide parents towards realistic expectations for normal (particularly breastfed) infant sleep.

Competing interests: I have read and understood the BMJ Group policy on declaration of interests and declare the following interests: I direct the Infant Sleep Information Source (www.ISISonline.org.uk), which provides research information on infant sleep for parents and health professionals. This is a public service organisation providing information for free. It is funded by the Economic and Social Research Council and Durham University.

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Mid Staffordshire should lead to a serious rethink of government policy

The QIPP initiative threatens safe levels of staffing

Allyson M Pollock professor
a.pollock@qmul.ac.uk
David Price senior research fellow, Centre for Primary Care and Public Health, Queen Mary, University of London, London E1 2AB, UK

NHS staffing levels emerged as a key concern of the Francis inquiry into substandard care at Mid Staffordshire NHS Foundation Trust. Inappropriate and low levels of staffing have previously come to light in the corporate nursing home and residential care sector through scandals such as the one at Winterbourne View. Francis notes that as part of the trust's financial recovery plan, "Savings in staff costs were being made in an organisation which was already identified as having serious problems in delivering a service of adequate quality, and complying with minimum standards. Yet no thought seems to have been given in any part of the system aware of the proposals to the potential impact on patient safety and quality."[1]

According to Francis, the solution is training and regulation of staffing levels, including "evidence based tools for establishing the staffing needs of each service," proper risk assessment "when changes to the numbers or skills of staff are under consideration," and advice during commissioning when major changes to staffing or facilities are proposed.[1]

The Department of Health in its initial response published last month focuses on inspection and training and says that although it will work with other agencies "on tools to inform [staffing] decisions," such decisions are a local responsibility.[2] Concerns that inquiry findings might be "diametrically opposed to the direction of travel set out by the government" were last year attributed to David Nicholson, then NHS chief executive.[3] Evidence suggests that the government cannot square the inquiry's findings with the Health and Social Care Act and its productivity targets.

The market brought in by the Health and Social Care Act 2012 abolishes the secretary of state's control over health services. At the same time, the controversial "hands off" duty that requires the minister to promote autonomy of service providers underpins the principle that care providers should be free to determine staffing levels, terms, and conditions.[4] Staffing norms (as opposed to minimum standards) are difficult to reconcile with a market model in which providers are free to manage financial risk by controlling workforce costs.

Last year, the NHS Confederation told the health select committee that defined staffing numbers or ratios for key hospital services could be an effective way of ensuring quality and safety are maintained but could also significantly increase costs.[5] However, staffing norms run counter to the £20bn (€23.6bn; $30.5bn) savings that the NHS is expected to make by 2015 under the Quality, Innovation, Productivity, and Prevention Programme (QIPP), first set out in the NHS Annual Report 2008-09.[6] QIPP is driving controversial service reconfigurations, including the closure of accident and emergency services and hospitals throughout England.

NHS trusts have already prioritised short term QIPP savings to meet financial targets, according to the House of Commons Health Committee,[7] but the targets are not evidence based. Claims by the Department of Health that productivity gains will not be detrimental to patient care rest largely on a set of 120 PowerPoint slides prepared by McKinsey and Company.[8] The company's assertions that, for example, community services can be delivered by "11-15% less staff" or that savings of £0.8-1.6bn in unscheduled care costs can be achieved by reducing variations in emergency admission rates are not grounded in research.


Francis: Staffing levels matter

The House of Commons Public Accounts Committee has highlighted government's failure to spell out how savings are to be made, and its members have questioned whether the Department of Health can reliably differentiate between a productivity gain and a service cut.[9 10] Francis is clear about the impact of financial targets and foundation trust status: "The result was both to deprive the hospital of a proper level of nursing staff and provide a healthier picture of the situation of the financial health of the trust than the reality, healthy finances being material in the achievement of foundation trust status. Although the system as a whole seemed to pay lip service to the need not to compromise services and their quality, it is remarkable how little attention was paid to the potential impact of proposed savings on quality and safety."[1]

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Research shows that staffing norms do matter. Evidence from North America shows that in the mainly for-profit sector, low staffing levels are associated with increased mortality and hospital infection rates, inappropriate prescribing, and other outcomes.[11] California established minimum staffing standards for hospitals in 2004 that improved hospital staffing levels, a policy that healthcare corporations have resisted in other states on grounds of cost.[12] In a study of patient safety, satisfaction, and quality of hospital care in the United States and in 12 countries in Europe, improved work environments and reduced ratios of patients to nurses were associated with increased care quality and patient satisfaction.[13] In European and US hospitals, after adjusting for hospital and nurse characteristics, nurses with better work environments were half as likely to report poor or fair care quality and give their hospitals poor or failing grades on patient safety.

The Francis inquiry shows that staffing levels and norms do matter. A major review of staffing is long overdue across the NHS. Deregulation and privatisation of staff and services is not in keeping with the spirit of the Francis report or his recommendations. A responsible government would suspend the QIPP initiative, restore staffing and needs based planning norms, and reinstate the secretary of state's control and power of direction over health services.

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