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postnote

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VACCINES & PUBLIC HEALTH

Public anxiety over the MMR vaccine led to decreased MMR uptake and a rise in measles cases. Although latest figures suggest this trend may be changing, public concerns about vaccination could affect the future success of immunisation programmes. This POSTnote summarises trends in outbreaks of disease and vaccine uptake within the UK. Issues addressed include public attitudes, vaccine availability and vaccine safety.

Infectious disease

The emergence of new diseases, the resurgence of known diseases, global travel, and increased numbers of people with weak immune systems (e.g. due to cancer treatment, organ transplants or HIV/AIDS) all provide opportunities for infectious diseases to develop and spread. Although most infections are short-lived and cause no long-term problems, they are a major cause of hospital admissions and can have serious complications. Department of Health (DH) statistics suggest that infectious disease accounted for ~11% of total deaths in the UK in 1998. Vaccines provide an effective way to prevent many infectious diseases and their use has had a major impact on public health (see POST report 66).

Vaccines and their use

Vaccines work by stimulating the immune system to combat infectious agents such as bacteria and viruses. They familiarise the immune system with the infectious agent (or some component of it) without triggering the disease itself. Vaccines may be targeted at selected population groups (anti-flu jabs are given to older people most at risk of influenza) or given universally. Before the age of five children will receive immunisation against polio (polio vaccine); diphtheria, tetanus, pertussis (DTP); some types of meningitis (Hib and Men C); measles, mumps and rubella (MMR) as part of the UK childhood immunisation programme. The aim is to achieve individual and population immunity; this is when the number of people vaccinated is sufficiently high to interrupt the spread of the infection from person to person. This threshold varies from disease to disease. For the more infectious diseases such as measles, an immunity rate of around 95% of children is required.

Benefits of vaccination

As well as providing protection to individuals, immunisation confers wider protection. It can benefit those not able to be immunised (such as those who are too young, or have weak immune systems) by reducing risk of exposure from the rest of the population. Rubella vaccine is given to both boys and girls to reduce the circulation of the virus in children, thus lowering the chance of pregnant women (the group most at risk from the virus) contracting rubella.[1] MMR vaccine has greatly reduced the number of congenital rubella cases. [2]

Safety of vaccination

As with any other medical intervention, vaccination is not entirely free from risk. All vaccines may have some adverse effects. These are usually minor, such as local reactions at the site of the injection or a slight fever, but may very occasionally be severe, such as acute anaphylaxis – an abnormal immune reaction to the vaccine.[3] For instance, anaphylaxis occurs at a rate of about 1 in 100,000 after the first MMR dose. Decisions on whether or not to vaccinate must weigh the risks of the disease against the risks of the vaccine. It is estimated that one in 1,000 people with measles will experience encephalitis (inflammation of the brain), whereas encephalitis occurs in fewer than one in every million doses of the MMR vaccine.[3]

Current regulation/policy

The DH sets policy for the control of infectious diseases through immunisation programmes, procures vaccines and manages vaccine supply. In the UK there is a longstanding policy for vaccinations to be offered on a voluntary basis, with parents required to consent for their child to be immunised. Vaccine programmes are implemented by primary care services in the NHS. The Medicines and Healthcare products Regulatory Agency (MHRA) regulates vaccines, while the Health Protection Agency (HPA) monitors infectious disease and vaccine uptake (see box 1).

Box 1 Regulation of vaccines

Pre-market licensing

Marketing authorisations (licences) for vaccines and medicines are issued by the MHRA. The Committee on the Safety of Medicines (CSM) advises the MHRA on matters relating to the safety, quality and efficacy of vaccines (and medicines). Before a vaccine is licensed for use it must undergo a period of development, research and testing to demonstrate its safety, quality and efficacy.

Immunisation programmes

Decisions on immunisation programmes are taken by ministers on the basis of advice from the Joint Committee on Vaccinations and Immunisations (JCVI). JCVI issues advice on the basis of information received from MHRA and HPA. HPA is responsible for surveillance of infectious disease and monitoring vaccine uptake. It also researches future public health needs, provides the evidence base for policy options and monitors the impact of any changes to immunisation schedules.

The yellow card scheme

Although the pre-market licensing system should show up any obvious safety concerns, less common adverse reactions may only be picked up once a vaccine has been licensed and used more widely. The MHRA is also responsible for the ongoing monitoring of vaccine safety post-licensure. Vaccine safety is continuously monitored through the yellow card scheme through which health professionals can report suspected adverse reactions possibly associated with vaccines (or any prescribed drug) to the MHRA/CSM. As well as the yellow card scheme, other sources of information including the medical literature, post-marketing safety studies, epidemiological databases and other world-wide organisations are used by the MHRA in monitoring and assessing vaccine safety.

Recent trends

Except for MMR, vaccine uptake in the UK is high and relatively stable (see table). Between 1996 and 2003 MMR uptake fell by 10%. There is also considerable regional variation in MMR uptake, ranging from 58% (Kensington and Chelsea) to 92% (West Cumbria).[4] This trend may be reversing; the most recent figures for 2004 show that MMR coverage at age 2 years has increased for the second consecutive quarter, by 1.3% from 79.8% to 81.1%.[5] However the fall in MMR uptake has allowed measles cases to rise (see graph) and increased the likelihood of a measles epidemic. The current rise in measles cases is due to local outbreaks where MMR coverage is low. Cases of mumps have also increased, though mainly amongst a cohort, currently aged 13-22, who did not receive MMR or received only one dose.

Issues

Future success of immunisation programmes depends on a number of factors. They include vaccine uptake - which will be influenced by vaccine safety and public attitudes to safety; attitudes to immunisation; the perceived threat of diseases (which may recede as first hand experience of a disease declines); vaccine availability and supply.

Vaccine safety

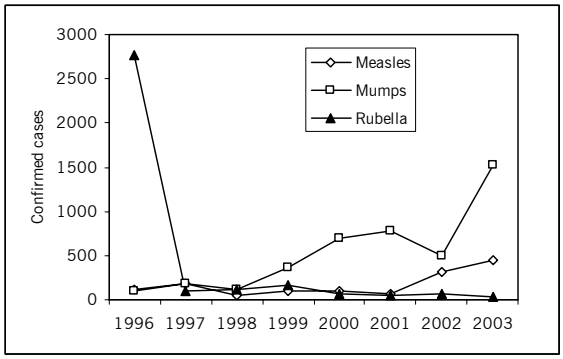
Over the past few years debate has concentrated on the safety of vaccines, in particular the safety of the MMR vaccine (see box 2 and POSTnote 131). Concern has also been expressed about some additives used in vaccines (see box 3). Controversy about vaccines is not new; in the 1970s concerns that pertussis vaccine caused brain damage in some children led to coverage falling below 40%. This was followed by a sharp rise in whooping cough cases amongst children. It took the results of a national study and a high court judgement ruling that there was no link between the vaccine and brain damage in children to restore public confidence.

Childhood vaccination uptake 1995-2003 (at 2yrs of age in England)

Vaccine (% uptake)	Year							
	95/96	96/97	97/98	98/99	99/00	00/01	01/02	02/03
Diptheria	96	96	96	95	95	95	94	94
Polio	96	96	96	95	95	95	94	93
Tetanus	96	96	96	95	95	95	94	94
Pertussis	94	94	94	94	94	94	93	93
MMR	**92**	**92**	**91**	**88**	**88**	**87**	**84**	**82**
Hib	94	95	95	95	94	94	93	93
Meningitis C*							85	92

*First introduced into childhood immunisation programme in 1999. Coverage data not available until 2001. Source: HPA.

Laboratory confirmed cases of measles, mumps and rubella (England & Wales, 1996-2003)



Source: HPA. Note: In 1996, the resurgence in rubella cases was mainly in unvaccinated males aged 17-24.

Monitoring vaccine safety

Potential problems arising from vaccine use are monitored in a number of ways including the yellow card scheme (see box 1). Reporting of suspected adverse drug reactions (ADRs) through this scheme has recently been extended to include nurses and health visitors in addition to doctors, pharmacists, dentists and coroners. JABS (a support group for vaccine-damaged children) has called for this to also include patient reporting. Following an expert review of the yellow card scheme, the Health Minister announced in May 2004 that patients shortly will be able to directly report unexpected effects of vaccines and drugs to the MHRA.

Suspected ADRs are investigated by the MHRA by various means (from ADR database interrogation to epidemiological studies linking data on clinical events to immunisation records). The HPA has developed a system to investigate vaccine safety that links computerised hospital admission records with data on vaccination from computerised child health and GPs' records. This currently covers the South East Thames region and, though not a routinely-funded function of the HPA, has proved a valuable resource in the assessment of vaccine

Box 2 MMR

MMR is a triple vaccine against measles, mumps and rubella. It was introduced into the UK in 1988. Concerns about MMR and its connection to autism were first raised in 1995. But it was the publication of research in the Lancet in 1998[6] that really captured the media's and public's attention. The paper reported a link between inflammable bowel disease (IBD) and autism. It also noted that the parents of 8 out of the 12 children used in the study associated the MMR jab with the onset of brain damage. At the press launch, one of the researchers (Dr Wakefield) recommended that parents should opt for single vaccines rather than MMR.

The paper's publication and the ensuing media coverage were followed by a drop in vaccination rates (see table). Some parents opted to give their children single jabs or to avoid vaccination altogether. In the wake of the publicity triggered by this study, hundreds of parents started litigation proceedings because they believed the MMR vaccine had permanently damaged their children.

Over the past six years various independent expert bodies have reached the conclusion that there is no evidence linking MMR to IBD or autism and there is no need to change the MMR vaccination policy (see POSTnote 131).[3] In October 2003, the Legal Services Commission (LSC) withdrew its funding for the MMR litigation because:

- despite the LSC's significant investment in the case medical research has not proven a conclusive link between MMR and autism;
- no link had been proven by any other medical body;
- there is no acceptance of such a link within the worldwide medical authorities.

In February 2004 the research again received media attention. The Lancet's editor considered that Dr Wakefield had not revealed a potential conflict of interest when the research was first published. Subsequently the editor described the research as *fatally flawed* and formally withdrew the section of the research paper that links MMR to autism. In addition, 10 of the original 12 co-authors published a retraction of their study.

safety concerns.[7] Modernisation of NHS computer systems and introduction of NHS Care Records (see POSTnote 214) should allow national implementation.

Compensation

Since 1979 those who suffer severe disablement following vaccination can apply for a one-off payment through the Vaccine Damage Payment scheme. The criteria for such awards were changed recently:

- the threshold of disability has been lowered;
- the maximum payment has risen (from £40,000 to £100,000);
- the window during which claims can be made has been widened.

Groups such as JABS argue that that these changes are not sufficient. They suggest that the maximum payment is small against the cost of lifelong care of a disabled child and that compensation should be on a sliding scale against disability without a set threshold. Moreover they would like to see more support even when it is not possible to establish a causal link with vaccination.

Box 3 Additives

Chemical additives are often used to preserve, stabilise or boost the activity of vaccines. Concern has been expressed about thiomersal, a preservative containing mercury that is present in some vaccines - DTP, Td (tetanus and diphtheria) and some influenza vaccines in the UK's immunisation programme. The safety of thiomersal-containing vaccines has been extensively studied and the available evidence, including epidemiological studies, reviewed by the CSM. It concluded there is no evidence to support an association between thiomersal exposure through the UK vaccination programme and neurodevelopmental disorders in children. However, US and European regulators, have recommended the phasing out of thiomersal in vaccines as part a wider aim to reduce mercury exposure from all avoidable sources.

Single versus combination vaccines

Part of the childhood immunisation programme is given as combination vaccines (e.g. MMR, DTP). Use of combination vaccines has arisen as an issue in the MMR debate. Based on the suggestion that giving three vaccines at once 'overloads' the child's immune system, it has been said that it might be safer to give vaccination against measles, mumps and rubella as three separate injections at least a year apart. However, DH and the medical profession argue that babies and young children are exposed to a large number of viruses and bacteria each day and their immune systems cope extremely well. DH has rejected calls for single vaccines against MMR to be made available on the NHS on the grounds that:

- While the safety record of the triple MMR vaccine is well studied, the effects of using three single vaccines instead have not been evaluated.
- Giving single vaccines would involve six injections over a longer period of time. Children would be at increased risk of disease between injections.
- Offering single vaccines increases the likelihood that courses of injections will not be completed leading to a fall in coverage and an increased risk of exposure to measles, mumps and rubella.

Although choice is an important part of NHS policy and practice, DH argues it cannot recommend a vaccination programme that allows children and unborn babies to be exposed to the risk of illnesses for longer than necessary. Some medical professionals have suggested it might be better for DH to provide a less effective vaccine which many parents will use than a less well perceived but more effective vaccine that parents may choose not to use. This sentiment is echoed by the public; in a recent opinion poll 64% of parents thought both the triple jab and separate vaccinations should be available.

Public attitudes to vaccination

As vaccination in the UK is voluntary, people's willingness to participate in immunisation programmes is key. One way to encourage them is to provide information about vaccination. Current information published by the DH and used by GPs and Health Visitors concentrates on individual risk and benefit in line with the current healthcare climate where importance is placed on individual choice and responsibility. Some

have questioned why more emphasis is not given to the community benefits of immunisation programmes or even to a public duty to be vaccinated.[8] However, research suggests that parents make decisions on the basis of each individual child, rather than being motivated to immunise their children for other's benefit.[9]

Twice a year DH interviews ~1,000 mothers of children under three about their knowledge of immunisation, where and how they receive information and their concerns.[10] The programme suggests that mothers are more strongly influenced by the perceived risk of a vaccine, rather than balancing the overall risks and benefits. It also shows that fluctuations in spontaneous awareness of immunisations are closely associated with high levels of publicity about vaccines in the media.

Information/education

The House of Lords Science and Technology Committee *Fighting Infection* report[11] recognised the importance of providing clear advice and information to the public. Health professionals (mainly Health Visitors, Practice Nurses and GPs) are the primary source of advice about immunisation for at least two thirds of parents;[13] much of DH's work to restore public confidence in MMR has been aimed at those health professionals.

GPs targets

Concerns were raised during a recent adjournment debate in the House of Commons[12] over the current immunisation target payments system, given a GP's role as a key provider of trusted information to patients. Under the current system, GPs receive payment on achieving 70% and 90% vaccine coverage rates. The public may find it difficult to see GPs as a trusted and impartial source of advice when such an incentive scheme is in place. The British Medical Association (BMA) and the Royal College of GPs support abolishing the target system for immunisation; one suggestion is to add immunisation payment to the core GP contract.

Compulsory vaccination

One way of ensuring high vaccine uptake is to make vaccination compulsory. Some countries, such as USA, Canada and France have some form of compulsory vaccination either in general or for entrance to nursery/school. Neither the DH nor medical profession see compulsory vaccination as an option for the UK .The BMA rejected a call for compulsory childhood immunisation at its 2002 annual conference.

Future research concerns

Researchers have expressed concerns that recent legislation may make it harder to conduct studies into the safety of vaccines. Clinical researchers are concerned that provisions in the Human Tissue Bill may make the collection of routine biological samples (such as blood) for vaccine research purposes difficult. Epidemiological researchers are concerned that recent data protection legislation may prejudice studies into vaccine safety, although they may be helped by the NHS Care Records Service that allows anonymous record linkage.

Vaccine availability

Availability is another factor affecting whether certain vaccines can be included in immunisation programmes. Manufacturers develop their products for a global market and, in the case of MMR, there is little global demand for single vaccine alternatives. Although licensed versions of the single vaccines exist, these are not available in the UK. Instead versions not licensed in the UK have to be imported under an exemption in the Medicines Act, supplied in response to a doctor's prescription to meet the special clinical needs of an individual patient. Only small amounts can be imported by this route.

In its recent report,[13] the House of Commons Public Accounts Committee recognised the need for DH to take steps to protect against vaccine shortages. Also, the House of Lords *Fighting Infection* report[11] highlighted the UK's poor vaccine manufacturing capability and recommended that Government should develop a strategy to ensure secure vaccine access in the face of national disease outbreaks. The Government has said it has taken a number of steps to protect the UK vaccine supply and that it would assess the success of these initiatives, reporting in April 2004.

Overview

- Vaccine uptake in the UK is high, except for MMR where uptake has fallen to less than 80%. However recent figures suggest this trend may be reversing.
- Low MMR uptake has allowed a rise in measles predominantly in areas where coverage is low.
- Health professionals are parents' primary source of immunisation advice; current GP vaccine payments are seen as damaging patients' trust in GPs.
- Advice on vaccination concentrates on benefits and risks to the individual not the wider community.
- In the UK compulsory vaccination is not regarded as an option for achieving high vaccine uptake levels.

Endnotes

1 Before MMR, only pre-pubertal girls and non-immune women of childbearing age were vaccinated against rubella.
2 http://www.hpa.org.uk/infections/topics_az/rubella/gen_info.htm
3 http://www.mmrthefacts.nhs.uk
4 NHS Immunisation statistics. DH SB 2003/16.
5 CDR Weekly,14, no.13, 25 March 2004. Health Protection Agency.
6 Wakefield et al, 1998, The Lancet, 351, 637-41.
7 Taylor et al.,1999, The Lancet,353, 2026-9.
8 Hobson-West, 2003, Health, Risk and Society,5, 273-283.
9 http://www.ids.ac.uk/ids/bookshop/wp/wp224.pdf
10 Yarwood et al., 2004, Cracking mothers' attitudes to childhood immunisation 1991-2001, submitted for publication.
11 HL 138 of Session 2002-03.
12 Hansard Vol 380, column 215 WH.
13 HC 429 of Session 2003-04.

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