

Joint Committee on Vaccination and Immunisation

Annual report 2003

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Joint Committee on Vaccination and Immunisation

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Foreword

The Joint Committee on Vaccination and Immunisation (JCVI) is an independent expert Committee that advises the Secretary of State for Health in England, and the respective health ministers for Scotland, Wales and Northern Ireland on matters relating to communicable diseases, preventable and potentially preventable through immunisation. Vaccination and immunisation have major roles in protecting individual health in childhood and adult life, and their beneficial effects are very obvious in the marked and even dramatic reductions that can be induced in disease occurrence or death rates. The outstanding success of the meningitis C immunisation campaign in 2002 is a recent and notable example. Immunisation policy and practice are always newsworthy. As is often the case, it tends to be the alleged negative features rather than the evident benefits, which are found worthy of press or broadcast comment. Many of these negative comments give uncritical publicity to non-mainstream science despite the existence of a substantial body of scientific evidence that indicates that the news items are unlikely to reflect real problems.

To help redress the balance, the Committee has taken steps to publicise its advice. The first has been the publication of open minutes where, as deliberate policy, as much detail as necessary is given to show the Committee's mode of thinking and its conclusions derived from the relevant evidence. A second has been the start of the production of position papers, which consider the broad basis for immunisation policy and the consequential benefits. A third is the production of this annual report. The fundamental reasons are to make immunisation policy-making more transparent and to demonstrate its underlying logic based on sound scientific evidence.

The quality of the work of the Committee derives from scientific expertise of the members who give their time freely. The secretariat is provided by the Department of Health, and background material, which informs the recommendations of the Committee, comes from a variety of sources including the Medicines and Health care products Regulatory Agency (MHRA) and the Health Protection Agency (HPA). There

is usually a broad degree of common understanding, but the Committee members' decisions are, nevertheless, their own.

Professor Michael J S Langman

Chairman

Joint Committee on Vaccination and Immunisation

1 Introduction

The full Committee met three times between November 2002 and October 2003, under the Chairmanship of Professor Langman, with minutes of the meeting placed on the JCVI website: www.advisorybodies.doh.gov.uk/jcvi/. In addition, sub-groups and panels of the main Committee were held during this period on a variety of issues such as influenza immunisation, BCG, hepatitis B, pneumococcal, and *Haemophilus influenzae* type b (Hib) immunisation.

1.1 The terms of reference of the Committee

The terms of reference of the JCVI are:

‘To advise the Secretary of State for Health, the Scottish Ministers, the Northern Ireland Ministers responsible for health and the National Assembly for Wales on matters relating to communicable diseases, preventable and potentially preventable through immunisation.’

In fulfilling its remit, the Committee has a responsibility to provide high quality and considered advice and recommendations on matters of both a 'routine' nature and also on any specific or special matters that the ministers may from time to time request. In formulating its advice and recommendations, the Committee must take into account the need for and impact of vaccines; the quality of individual vaccines and their safety; and the strategies to ensure that the greatest benefit to individual and the public health can be obtained from the most appropriate use of vaccines.

1.2 The status of the Committee

The Committee is a non-departmental public body (NDPB). It is a statutory expert standing advisory Committee established in England and Wales under the NHS Act 1977 and the NHS (Standing Advisory Committees) Order 1981 as the Standing Advisory Committee on Vaccination and Immunisation. The Committee has no statutory basis in Scotland or Northern Ireland but, nonetheless, fulfils the same role and has the same responsibilities in those countries as in England and Wales.

2 Members of the Committee

Members of the Committee are listed at Annex 2

2.1 Responsibilities and obligations

The chair and members of the Committee play a critical role in ensuring the Committee's continued standing as an internationally recognised leading body in the field of immunisation. Members of JCVI will:

- be committed to the continued development and improvement of this important area of public health;
- bring relevant experience to the Committee;
- contribute to the provision of high quality and considered advice to UK ministers of health;
- be expected to make a full and considered contribution to the work of the Committee and to contribute fully to the debate and to the decision-making processes of the Committee;
- provide expert guidance when an issue that falls within their particular area of expertise is under discussion;
- contribute to the debate in the capacity of a well-informed health professional where the issue does not fall within their expertise;
- take into account the need for and impact of vaccines, the quality of vaccines and their safety and the strategies to ensure that the greatest benefit can be obtained from the most appropriate use of vaccines;
- recommend the best public health advice to ministers;
- be prepared, as requested by the secretariat, to occasionally provide expert advice on relevant issues outside of Committee meetings;
- be prepared, as requested by the secretariat, to attend and contribute to the deliberations of one or more of the panels or sub groups of the JCVI which report to the main Committee.

In exercise of its duties, the Committee and its members, ensure that it continues to observe the highest standards of propriety including impartiality, integrity and objectivity in the execution of its role and responsibilities. Members are required to observe the 'Seven principles of public life' and the Code of practice as promulgated in the advice of the Committee for Public standards, first chaired by Lord Nolan.

In addition, the Committee and its members follow government advice on declarations of interests. Members are requested to declare an interest at meetings where they may have a conflict of interest about an issue being considered.

Members must:

- undertake on appointment to comply at all times with the Committee's Code of practice
- act in good faith and in the best interests of the Committee;
- not use information gained in the course of their public service for personal gain or for political purposes, nor seek to use the opportunity of public service to promote their private interests or those of connected persons, firms, businesses or other organisations;
- ensure that they comply with the Nolan Committee's rules on the acceptance of gifts and hospitality.

2.2 Terms of appointment

Appointments to the Committee are the prerogative of the UK health ministers; they are normally of four years duration. A second term can be served. Appointments may, however, be terminated, without compensation, in the event of unsatisfactory attendance at meetings or conduct that renders the member unfit to remain in office, or at the discretion of the UK health ministers.

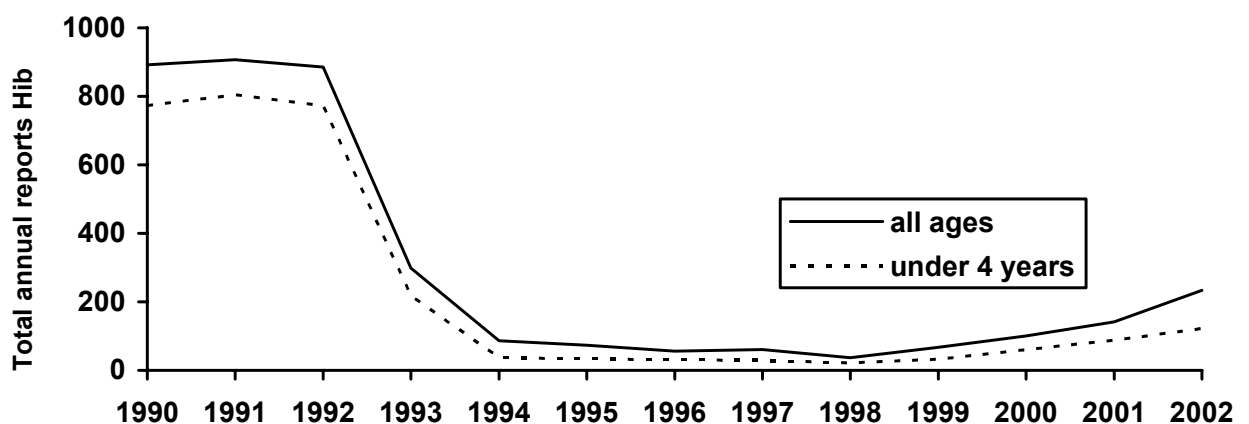
Appointments to the Committee are unsalaried and are not pensionable but members are able to claim reimbursement for travel, subsistence and, if applicable, any childcare costs that they may incur incidentally in carrying out the duties of the post.

3 Issues considered by the Committee

3.1 Hib immunisation

JCVI advice was sought on the small but consistent rise in cases of *Haemophilus influenzae* type b (Hib) infections since 1998 after a six-year sustained and large reduction.

Laboratory reports of Hib disease in England and Wales (1990 –2002).



Source:Health Protection Agency

Background

Hib used to be an important cause of morbidity and mortality, especially in younger children. Hib vaccine was introduced into the UK childhood immunisation programme in 1992, leading to a huge reduction in rates of disease.

The Committee recognised that the introduction of Hib vaccine had been a great success in cutting the rates of disease in children. Rates fell by 98% following the introduction of the Hib vaccine.

The Committee has carefully monitored the rate of Hib disease in the UK in recent years. While the rate of Hib disease was very low from 1994 to 1998 following the introduction of Hib vaccination, there had been a small but sustained increase in the number of cases since 1998. The reason for the increase was unclear but seemed likely

to reflect a complex of factors, including a reduced Hib response in children receiving a particular combination vaccine.

JCVI advice

Having considered all the evidence, the JCVI recommended that all children aged six months to four years inclusive should be offered an additional dose of Hib vaccine. The rationale was that:

- Children under 12 months of age used to be at greatest risk from Hib disease, and cases still occur in this age group. An additional dose of Hib vaccine is expected to boost the antibody levels in these children to ensure adequate protection during this period;
- The Hib immunisation campaign in 1992–3 demonstrated the significant and rapid decline in rates of disease when all children under four were offered Hib vaccine;
- The carriage and therefore transmission of Hib in childhood from and within immunised groups would be expected to fall.

In order to ensure that the rationale for the Committee's advice was clear and widely available, a JCVI statement on Hib was prepared and placed on the JCVI website. A copy is attached in Annex 6

Further action

Following the advice from the Committee, the health departments implemented a campaign to offer all children aged six months to four years an additional dose of Hib vaccine (ref: 2002/CMO letters). The campaign started in May 2003 and ran for four months.

The Committee also discussed the possibility of cases of Hib disease increasing again some time in the future after the impact of the current campaign has passed. It was agreed that they would need to consider whether a fourth dose of Hib vaccine needed to be added to the routine childhood immunisation schedule. This could be done when research on the impact of the current campaign had been collected and analysed.

3.2 Pneumococcal vaccine for older people

The Committee considered the evidence regarding the use of pneumococcal vaccine for older people.

Background

Invasive pneumococcal disease (wild systemic bacteraemia and pneumomonia), is a major cause of morbidity and mortality in the elderly. It is estimated that the disease is responsible for 18,000 hospitalised cases of pneumococcal pneumonia infections and 3400 deaths in the over-65-year-old population every year. The Committee acknowledged that the burden of disease due to pneumococcal infection is high. It also recognised that the current measures of the rate of infection were likely to be underestimates, because many pneumococcal infections are not routinely investigated.

A particular difficulty lies in determining the individual and relative value of vaccines immunising against different numbers of disease serotypes, the likely variation in the duration of protection with plain and conjugated vaccines, and the possibility that the prevention of disease due to some serotypes would promote disease due to others. Furthermore, these problems have to be set against the difficulty in being sure of the actual burden of disease in the community associated with specific serotypes.

A pneumococcal polysaccharide vaccine is available and licensed in the UK for use in adults. It is designed to protect against 23 of the strains of pneumococcal bacteria. It is recommended for individuals in certain high risk groups (ref: CMO letter 2003/6). The Committee reviewed the evidence of effectiveness of the pneumococcal polysaccharide vaccine in the general elderly population. The scientific and medical literature on this topic is varied, and there is considerable uncertainty surrounding estimates of likely vaccine effectiveness in the community. The Committee concluded that the best estimate was that the vaccine was 50-70% effective against bacteraemic disease in the elderly, although there were wide confidence limits.

The duration of protection afforded by the polysaccharide vaccine was not known, and might vary between the different serotypes against which the vaccine protects. There was some evidence that the plain polysaccharide vaccine resulted in lower quality antibodies being produced when compared to alternative conjugate vaccines. However, it was recognised that the conjugate vaccines appeared to protect against pneumococcal strains responsible for only about 50% of infections in the elderly.

JCVI advice

Members of JCVI were aware that the evidence was not as robust as they would have wished. However, given the burden of disease, particularly in the over-65s, and the safety of the vaccine, the Committee agreed by majority that the vaccination programme should be extended to include all those aged 65 and over.

The Committee noted that an appropriate surveillance strategy to measure the impact of a new immunisation programme in the elderly had been developed by the PHLS (now the HPA).

Further action

The duration of protection afforded by the vaccine is not known with confidence, and the Committee considered there was not enough information at present to give a definitive answer regarding the need to give a further vaccination and at what interval. There is some evidence to suggest that response to a second dose is reduced compared with the first. Whether this is significant in terms of protection is not known. The Committee would revisit this issue when further evidence became available.

3.3 Pneumococcal vaccine in children

The Committee also considered the evidence on the benefits of pneumococcal vaccine in young children.

Background

Pneumococcal disease is a significant cause of illness in young children and can lead to death. It can cause pneumonia, bacteraemia and meningitis. A pneumococcal conjugate vaccine for infants is licensed in the UK. It protects against seven strains of pneumococcal bacteria.

The Committee considered the evidence of the possible impact of offering the vaccine to children, but found that the evidence contained significant uncertainties. In particular, it was difficult to measure the burden of pneumococcal disease in young children. It was also difficult to estimate with any degree of confidence how much of the disease caused by pneumococci was preventable using the vaccine.

The lack of certainty in the data meant that the outcome of attempts to measure the benefits of the vaccine, were considerably influenced by the assumptions within the model. The Committee concluded that more detailed evidence was needed to gain a better understanding of the potential impact of offering pneumococcal vaccine to children, although it should continue to be available on the NHS to certain groups of children with particular conditions, e.g. asplenic.

JCVI advice

The Committee concluded that good evidence of benefit in the community from the pneumococcal vaccine conjugate was not yet available. The disease burden was uncertain, the possibility of serotype replacement by non-vaccine strains was unresolved, the need for repeated doses of vaccine disadvantageous and the cost high. However, that conclusion could change if:

- adequate protection could be achieved from fewer doses;
- the burden of disease in the community from which protection could be obtained was shown to be significantly higher than estimated;
- the 'herd immunity' benefit effect, suggested by early data from the US, was confirmed;
- there was a significant protection against antibiotic-resistant strains, as well as reducing antibiotic usage, and
- the price of the vaccine was lower

The Committee also noted that serotype replacement in the community (in which the strains of pneumococci that this vaccine protects against are replaced by other strains which the vaccine does not protect against) would undermine the benefits of this vaccine. If this replacement was shown to occur, then the reduction in the overall burden of pneumococcal disease would not be as great.

Further action

The Committee agreed to keep this subject under close review as new evidence becomes available.

3.4 Licensed single rubella vaccine

The Committee was asked for its advice on protecting women of childbearing age and healthcare workers against rubella in view of the difficulties in sourcing supplies of licensed single rubella vaccine.

Background

Rubella is usually a mild infection. However, it can have a devastating impact on the unborn child if the mother catches the disease during the early part of the pregnancy. Multiple birth defects are common: This is known as Congenital Rubella Syndrome (CRS).

Rubella is controlled in the UK through:

- offering rubella vaccine (in the MMR vaccine) to young children. This reduces the circulation of the disease and reduces the risk of children passing the disease to their mothers and their mother's contacts;
- offering single rubella vaccine to those health care workers who are not already protected against the disease. This reduces the risk of rubella being caught by a healthcare worker and passed on to others; and
- offering single rubella vaccine to unprotected women of childbearing age, in order to protect those at most risk.

However, supplies of licensed single rubella vaccine were becoming difficult to source. In light of this, advice was needed from the Committee on how unprotected women of childbearing age and healthcare workers should be protected against rubella should licensed single rubella vaccine no longer be available.

JCVI advice

The Committee concluded that:

- rubella infection in pregnant women, particularly at the beginning of pregnancy, can have extremely serious consequences on the unborn child;

- the policy of offering MMR vaccine to children, and rubella vaccine to women of childbearing age, has proved very effective in preventing the transmission of rubella and reducing the incidence of CRS in the UK;
- this policy has also reduced the number of terminations of pregnancies associated with rubella infection;
- the policy in the UK is consistent with the World Health Organization (WHO) recommendation for the elimination of rubella and CRS;
- women of childbearing age who are unprotected against rubella continue to need to be offered a rubella-containing vaccine, and
- MMR is an appropriate and safe alternative to single rubella to protect such individuals, which can give additional benefit through simultaneous protection against measles and mumps.

3.5 Meningococcal immunisation for people going abroad

Advice was sought from the Committee on the appropriate travel vaccine to protect against meningococcal infection when abroad.

Background

The largest meningitis epidemics occur across a belt in Africa from Senegal to Ethiopia, and have traditionally been caused by meningococcal A infection. However, accurate determination of the strain of meningitis is challenging in parts of Africa. Currently, the combined meningococcal polysaccharide A and C vaccine is the recommended vaccine for travellers.

Meningitis outbreaks have been clearly documented following the annual pilgrimages to Mecca (the Hajj). After a large outbreak of meningococcal A infection in 1977, Saudi authorities required all pilgrims attending the Hajj to be immunised against at least meningitis A.

An outbreak of meningitis W135 among pilgrims in 2000 resulted in cases in many countries, including 45 cases and eight deaths in the UK. Since then, the Department of

Health recommends, and the Saudi authorities require, that all pilgrims receive the quadravalent meningococcal ACWY vaccine. Outbreaks of W135 infections have been reported in Burkina Faso in 2001 and 2002, and cases of W135 infection have been reported to the WHO from Benin, Ghana, Mali, Niger and Nigeria.

JCVI advice

The Committee considered this evidence and recommended that people in the recognised risk groups intending to visit high risk areas be offered the meningitis ACWY vaccine, which gives protection against meningitis strains A, C, W and Y.

The Committee was also asked to advise on whether meningococcal vaccine should still be recommended to people travelling to Bhutan, Brazil, Mongolia and Nepal.

Background

The risk to travellers (apart from the pilgrimages) was considered very low, except for certain travellers to the African meningitis endemic zones during the dry season (when the risk is greatest), specifically those on longer trips and/or backpacking or working with the local population.

There have been no recent outbreaks or documented cases in travellers to non-African countries. Most European and the American and Canadian authorities have removed all non-African countries from the list of countries where vaccination is recommended for visitors. This change in advice has resulted in no increase in cases among travellers.

JCVI advice

In light of this evidence, the Committee recommended that Bhutan, Brazil, Mongolia and Nepal should be removed from the list of countries for which meningitis vaccine is recommended.

3.6 The use of palivizumab

The National Institute for Clinical Excellence (NICE) requested that JCVI consider use of the monoclonal antibody, palivizumab, in protecting at-risk groups against Respiratory Syncytial Virus (RSV).

Background

RSV is a leading cause of lower respiratory tract infections in infants and young children. Most of these RSV infections cause minor upper respiratory illness. However, in certain high-risk paediatric patients, RSV infection may cause serious lower respiratory tract disease.

In order to make an overall impact on the rates of disease, a vaccine against RSV was required. However, the Committee recognised that there was not one available.

Following advice from an expert consultation, the Committee considered that the at-risk groups were:

Group 1.

Babies under two years of age with severe chronic lung disease, on home oxygen during the RSV season (around 500 babies each year).

Group 2.

Babies under two years with chronic lung disease not on home oxygen (around 1000 babies a year, about a quarter of whom are likely to have been on oxygen in the last 6 months).

Group 3.

Babies with rare conditions such as severe multiple congenital abnormalities or severe immuno-deficiency; this would include severe congenital cardiac disease.

Group 4.

Babies born at less than 32 weeks' gestation.

While these were recognised as the at-risk groups, it was agreed that these groups represented only a small proportion of the burden of RSV illness.

JCVI advice

Until an effective vaccine against RSV becomes available, the Committee recommended that:

- palivizumab should be offered to babies in Group 1. These babies had a two-fold risk of re-admission with RSV. Palivizumab was likely to reduce admissions by about 40%.

- palivizumab was not used for babies in Group 2 because the treatment did not appear to reduce the number of babies requiring ventilation or of deaths. The recommendation was accompanied by recognition of the need for further evidence upon which to reassess this issue. It was recognised that further data may be produced by the five year follow-up study by Greenough following the retrospective study of RSV hospitalisations in infants with chronic lung disease.
- treatment for children in Group 3 with palivizumab should be recommended on a case-by-case basis following advice from a specialist. It was recognised that Group 3 consisted of children with a variety of disorders, often multiple, including severe congenital heart disease and severe immuno-deficiency. The small numbers meant that evidence was unlikely to be obtained to underpin a recommendation. The decision to offer palivizumab may depend on the likelihood of a child being admitted to hospital during the RSV season because this was likely to increase their risk of acquiring infection.
- treating all Group 4 babies could not be recommended at this time, based on the available evidence.

3.7 Core principles

The Committee considered the need to develop 'Core principles' in order to improve the transparency of its decision-making process.

Background

The report by the MMR Expert Group to the Scottish Executive (ref) published in 2001, included among its recommendations the following:

'The Joint Committee on Vaccination and Immunisation should develop and publish core principles for immunisation policy in order to provide all interested parties with a clear framework against which future policy options might be assessed in an open and transparent manner.'

JCVI advice

The Committee agreed that core principles could be a useful aid to transparency regarding its working practices and its independence. Following a detailed discussion, the following core principles for the Committee were agreed:

- the Committee is independent of UK government and the devolved administrations.
- the Committee comprises members whose expertise and experience cover the broad area covered by the terms of reference.
- the Committee aims to provide rigorous, evidence-based advice about matters relating to communicable disease that are preventable or potentially preventable through immunisation.
- the Committee provides, and regularly reviews, advice based on the most up-to-date scientific and medical evidence about:
 - the diseases against which vaccines are targeted;
 - the impact of those diseases in terms of mortality and morbidity for the individual and for the population;
 - the incidence of preventable and potentially preventable disease by immunisation and prediction of future trends;
 - the mode and frequency of carriage of the infection;
 - the safety, quality and efficacy of vaccines, taking particular account of the Committee on Safety of Medicines' responsibilities and advice;
- the impact that the vaccine will have on the individual, and
- the development of new vaccines; and new disease threats.
- the Committee provides advice that reflects current expert opinion.

- the Committee seeks advice and information from appropriate individuals and bodies on issues outside its remit.
- the Committee is committed to the seven 'Nolan' principles of public life.

The Committee aimed to ensure that its information and advice are made public in a clear, understandable manner.

3.8 Working practices

Background

In light of the general thrust towards greater openness and transparency in decision-making and advice provided to government, the Committee reviewed its working practices and procedures. The minutes of meetings are already placed on the JCVI website.

JCVI advice

The Committee confirmed that:

- it needed to maintain its horizon-scanning activities, particularly on new and emerging diseases, including changing epidemiology; new vaccines in development, and new approaches for stimulating immune responses.
- it should review the range of its balance and expertise annually. A template giving the range of expertise currently covered by the Committee should be published on the website.
- it would review its workload annually, and that a forward work plan would be prepared on a regular basis. It was recognised that the reactive nature of much of the Committee's work meant that any forward planning would not necessarily be comprehensive.
- new members of the Committee should meet with the Chair, in addition to the Secretariat, before their first meeting. This would provide opportunity to discuss fully what is expected as members of the Committee, and cover other relevant issues such as the rules about conflicts of interest, advice on media issues, etc.

- the Chair would continue to represent the Committee to the media, although there might be times when the chair called upon individual members to assist with this task.
- members were free to discuss issues with the media on a personal basis.
- minutes would be agreed by correspondence and published on the website within six weeks of the meeting where possible, and notes of JCVI sub-groups and panel meetings should be provided on the website.
- an annual report on its activities would be published.

In addition, the Committee discussed the issue of openness. The Committee recognised and accepted the benefits of openness. There would be great benefit if the Committee could explain clearly for the public the basis of its decisions. However, there was also concern that any moves to greater openness must not adversely affect the quality of the decision-making of the Committee. In addition, it was recognised that much of the information considered by the Committee was confidential.

JCVI advice

The Committee agreed that:

- it was in favour of being open about its work;
- agendas of meetings would be published;
- it would produce expanded minutes, appendices, and statements, where appropriate, to help ensure that the basis of its scientific decision-making was made clear. Much of this work was under way; and
- it would review its procedures regarding openness on an annual basis.

It was agreed that the following information would be maintained as confidential and therefore would not be published:

- information whose disclosure could harm national security or defence;
- information relating to commercial confidences, trade secrets or intellectual property – it is very unlikely that commercially sensitive information would be made available to the Committee if it was going to be made public. However, it is important for the Committee to have the option of seeing such information because it allows the Committee to make decisions on the best evidence that it is available to it.
- information that compromises the privacy of an individual or identifiable group – the Committee recognises that the right to privacy of individuals or groups cannot be compromised in the pursuit of openness;
- information supplied in confidence, and for which no consent for its disclosure has been given. From time to time, the Committees seek advice and opinion from experts not on the Committee. This is an important way in which the Committee ensures that it has access to the most appropriate advice and expertise. If that advice is given on a confidential basis, the Committee will honour that request for confidentiality.
- pre-publication research results – scientific research papers must include original research that has not been published elsewhere. If the Committee were to publish pre-publication research results, the results would no longer be original and hence not appropriate for publication in leading scientific journals. The Committee therefore recognised that it should only use pre-publication research results if they were not disclosed publicly, but recognised that the research would be published at a later date.

The Committee discussed holding its meetings in public. The Committee concluded that routine meetings of JCVI should not be open to the public. The Committee was concerned that this would inhibit detailed and frank discussion and debate, and thereby risk adversely affecting the quality of the advice put forward by the Committee to health

departments. The Committee did note, however, that the annual report could present the opportunity for its work to be presented to the public.

3.9 MMR

JCVI regularly reviewed evidence purporting to link MMR and autism, and other conditions.

The Committee is very aware of the continued high level of media interest in MMR and the alleged link with autism. The Committee reviewed new scientific evidence on MMR as it became available. A list of the papers considered by the Committee is attached in Annex 1.

The Committee was reassured that a large body of high quality published evidence continued to find no link between MMR and autism. The body of work finding no link was substantial, came from many different scientific workers, and employed a variety of robust methods.

3.10 Single vaccines

The Committee was updated on the importation of single mumps vaccine – Pavivac - from the Czech Republic that was claimed to contain the Jeryl Lynn strain being used in private clinics in the UK.

Background

Pavivac was claimed to be based on the Jeryl Lynn strain of mumps virus and was unlicensed in the UK. It was grown in primary dog kidney cells and there appeared to be limited data on safety and efficacy. It was also noted that the vaccine had unusual storage requirements (between -20° and -10° C).

The Committee on Safety of Medicines had reviewed the data and remained concerned about lack of evidence on the safety and efficacy of this vaccine, and it had advised that this vaccine should not be imported into the UK. Similar safety concerns had been expressed over a measles vaccine from the same source, though none of the measles vaccine was thought to have been used in the UK.

JCVI advice

JCVI endorsed the concerns about the safety and efficacy of the vaccines used by these clinics.

The Committee was updated on a recent concern raised by the Director of Public Health for Hertfordshire, where a local private clinic had been providing single measles, mumps and rubella vaccines. There were serious concerns about the procedures used by the clinic for transporting vaccines; reconstituting the vaccine with the correct amount of diluent; using bottles that had been repeatedly sterilised for vaccine storage; and using disinfectant to treat bottle stoppers. These practices might have affected the safety and the efficacy of the vaccines used.

The Committee also noted that the case had been taken to the General Medical Council (GMC)

The Committee recommended that private vaccine clinics should be better controlled in order to ensure the safety of patients, and requested that this recommendation be brought to the attention of the National Care Standards Commission.

3.11 Thiomersal

The Committee was informed that the Committee on Safety of Medicines (CSM) had recently considered further evidence that supports the safety of thiomersal (which contains ethylmercury and not methylmercury) in vaccines. A statement by the CSM had been published and is available at

medicines.mhra.gov.uk/whatsnew/thiomersalstatement_210203.pdf.

There had been two recent independently-conducted UK epidemiological studies that investigated the safety of thiomersal-containing vaccines for infants. These studies showed no evidence of adverse developmental effects from levels of thiomersal at the amounts used in existing UK vaccines, which are, in any case, low. A further study had shown that ethylmercury is rapidly excreted from the body following administration of thiomersal-containing vaccines, and provides good evidence that it does not accumulate in the body.

A paper by Geier and Geier (*Journal of American Physicians Surgeons* (2003) 8:6-11) was considered by the Committee. JCVI commissioned an independent review of this

paper from a group of scientists working in this area and their critique highlighted that it was difficult to work out from the paper its general robustness, and specifically what methods had been employed; what data was used; and what the results really meant. The study relied on analysis of a US system through which parents and healthcare workers can report adverse events, which they believe to be linked to a vaccine. These adverse events were suspected rather than confirmed events. Overall, the paper was considered to be of poor quality.

JCVI advice

JCVI concluded that it agrees with the CSM statement on the issue, which supported unequivocally the safety of current UK vaccines containing mercurial preservatives. On general principle, but not because of demonstrated risk, JCVI also supports the removal of mercurial substances from vaccines when practicable, as a precautionary measure to reduce the level of avoidable exposure of mercury.

3.12 Rabies

The Committee was updated about the first indigenous human case of rabies in the UK for 100 years.

Background

A suspected case of rabies was admitted to Ninewells Hospital, Dundee in November 2002, and the clinical diagnosis was subsequently confirmed. The case occurred in Tayside and unfortunately the patient died.

In the light of this incident, the Committee was asked to consider the advice in the current edition of *Immunisation against infectious disease* 1996 (the 'Green Book') as it applied to immunisation of the healthcare workers caring for the case. In particular, they were asked to advise on the use of the intradermal route for pre- and post-exposure prophylaxis.

The intradermal route in four sites was considered to be effective for routine pre-exposure prophylaxis. Following a detailed discussion, the Committee agreed that the advice for post-exposure treatment (paras 27.4.8 - 27.4.11) was very clear, and did not require modification. Use of the intradermal schedule may result in a speedier response, but there was no evidence of greater efficacy and there must be greater uncertainty over the full dose being administered as the technique is more difficult.

JCVI advice

It was agreed that the wording in the current edition of the Green Book was appropriate (see Chapter 27, paras 27.4.1 to 27.4.19), and needed no amendment. This advice would be kept under review. The Committee recommended that all bat handlers, whether volunteers or employed people received immunisation against rabies.

4. Issues brought to JCVI's attention for information

4.1 Vaccine uptake data

The Committee reviewed the latest childhood vaccine uptake data at each meeting. Quarterly data on uptake collected through the COVER programme for England, Wales and Northern Ireland for April to June 2002 to April to June 2003 were provided to JCVI for information. In Scotland the equivalent information is collected through SIRS.

During the above period, the percentage of infants by 24 months of age completing their primary courses of diphtheria, tetanus, pertussis, meningitis C and polio vaccinations remained stable at around 92-94%.

The Committee noted a decline in MMR uptake at aged two years from 84 to 80% during this period. However, it was encouraging that a figure of about 90% of children aged five years having received at least one dose of MMR had remained stable during this period, suggesting that parents were delaying rather than cancelling immunisation.

It was noted that the immunisation data for MMR at 24 months would have included data collected during July 2001 to January 2002 during which time there had been significant adverse publicity surrounding MMR.

The Committee had been, and remained, concerned at the low uptake of MMR, particularly in London. The Committee continued to support unequivocally the value and safety of MMR.

In general, immunisation rates in Northern Ireland and Scotland were consistently higher than those in England and Wales, particularly for MMR.

It was noted that vaccination uptake rates in London were consistently lower for all vaccines compared to other parts of the UK.

The Committee noted that the reorganisation of primary care services from health authorities to primary care trusts in England was leading to short-term difficulty in collecting reliable vaccination uptake data. PCTs were recognised as having a key role in immunisation, but the Committee was concerned that childhood immunisation was not covered in this year's PCT performance indicators. The Committee considered that this omission was unfortunate as it sent out the wrong message regarding the importance of childhood immunisation.

The Committee agreed that it was important to have clearly defined immunisation targets, and supported strongly the inclusion of childhood immunisation targets in PCT performance indicators.

4.2 Poliomyelitis elimination

The Committee was kept regularly updated on the global strategy to eradicate polio. The European region of the World Health Organization (WHO) was certified polio-free on 21 June 2002.

4.3 EMEA reviews hexavalent vaccines: Hexavac and Infanrix Hexa

The MHRA informed the Committee that the European Agency for the Evaluation of Medicinal Products (EMA) through its scientific Committee (Committee for Proprietary Medicinal Products (CPMP)) had reviewed the safety of two vaccines, Hexavac and Infanrix Hexa. This review followed five reports of unexplained deaths in children in Germany and Austria occurring within 24 hours of receiving these vaccines. Neither of these vaccines is used in the UK immunisation programme.

The overall conclusions were that, apart from the temporal association, there was no evidence to link the vaccines to the events and possible alternative explanations existed. Nonetheless, on the basis of the available evidence, a causal relationship could not be established or excluded. CPMP concluded that there was no change in the benefit/risk profile of these vaccines and did not recommend any change to their use. JCVI endorsed this recommendation.

4.4 Influenza immunisation

The Committee was informed that the target coverage for flu vaccine in those aged 65 years and over had increased from 65 to 70% in the winter of 2002/03. A mean uptake (median 70%) had been achieved, with 241 individual PCTs in England and Wales exceeding the 70% target.

4.5 Mumps outbreak in Sheffield

Between 1 January 2003 and 28 April 2003 there had been 175 suspected and confirmed cases of mumps in Sheffield. Over 100 cases were among students at the University of Sheffield, with some cases also reported at Sheffield Hallam University. The rate of complications and hospitalisation rate was about 10%, with three cases of meningitis, two of pancreatitis, one of oophoritis and pancreatitis, and one of orchitis. In light of the large numbers of cases and the high rate of complications, the Committee was informed that MMR had been offered to students aged 18 to 25 years old, as people born before 1984 would not have been offered MMR previously.

The Committee noted that the 1996 edition of *Immunisation against infectious disease*' (the Green Book) stated that students who have not received MR or MMR vaccine should be offered MMR at or before entry to college or university, and noted that the Department of Health had updated the advice in 2001 when advising immunisation coordinators that students who had either received no or one dose of MMR should be offered another dose of the vaccine. This outbreak of mumps demonstrates the importance of this advice.

5. Declaration of members' interests

Should questions considered by the Committee bear directly on specific products of the pharmaceutical (or other) industry, members are asked to declare any interest they may have in any part of that industry.

The Declaration of Interests' Code of Practice reflects the advice of the Committee for Public standards (originally chaired by Lord Nolan) and includes a pro forma:

Declaration of interests: Code of practice

Introduction

This code of practice guides the Chairman and the members of the Joint Committee on Vaccination and Immunisation (JCVI, the Committee) as to the circumstances in which they should declare an interest in the pharmaceutical products (or other) industries.

In this code, 'industry' means:

- companies, partnerships or individuals who are involved with the manufacture, sale, promotion or supply of medicinal products;
- trade associations representing companies involved with such products;
- companies, partnerships or individuals who are directly concerned with the research, development or marketing of a medicinal product which is being considered by the Committee.

References to 'the industry' include cases involving a single company.

In this code, 'the Department' means the Department of Health, and references to 'member(s)' include the Chairman.

Different types of interest

The following is intended as a guide to the kinds of interests which should be declared.

Where members are uncertain as to whether an interest should be declared, they should seek guidance from the Chairman or the Secretariat or, where it may concern a particular product which is to be considered at a meeting of the Committee, from the Chairman at that meeting. **If members have interests not specified in these notes but which they believe could be regarded as influencing their advice they should declare them.** However, members are not under an obligation to search out links between one company and another, for example where a company with which a

member is connected has an interest in another company of which the member is not aware and could not reasonably be expected to be aware.

Personal interests

A personal interest involves payment to a member personally. The main examples are:

- consultancies - any consultancy, directorship, position in or work for the industry which attracts regular or occasional payments in cash or kind.
- fee-paid work - any work commissioned by the industry for which the member is paid in cash or kind.
- shareholdings - any shareholding in or other beneficial interest in shares of the industry. This does not include shareholdings through unit trusts or similar arrangements where the member has no influence on financial management.

Non-personal interests

A non-personal interest involves payment which benefits a department for which a member is responsible but is not received by the member personally. The main examples are:

- fellowships - the holding of a fellowship endowed by the industry;
- support by the industry - any payment, other support or sponsorship by the industry which does not convey any pecuniary or material benefit to the member personally but which does benefit their position or department; for example:
 - a grant from a company for the running of a unit or department for which the member is responsible;
 - a grant or fellowship or other payment to sponsor a post or a member of staff in the unit for which the member is responsible. This does not include financial assistance for students;
 - the commissioning of research or other work by, or advice from, staff who work in a unit for which the member is responsible.

Members are under no obligation to seek out knowledge of work done for or on behalf of the industry within departments for which they are responsible if they would not normally expect to be informed.

Declaration of interests to the Department

Members of the Committee should inform the Department in writing when they are appointed of their current personal and non-personal interests. Only the name of the

company and the nature of the interest are required; the amount of any salary, fee, shareholding, grant, etc. need not be disclosed to the Department. An interest is current if the member has an on-going financial involvement with the industry, for example if they hold shares in a relevant company, if they have a consultancy contract with the industry, or if they or the department for which they are responsible is in the process of carrying out work for the industry. Members are asked to inform the Department, through the Secretariat, at the time of any change in their personal interests. Changes in non-personal interests can be reported annually. (Non-personal interests involving less than £1000 from a particular company in the previous year need not be declared.)

Declaration of interests at meetings

Members are required to declare relevant interests at Committee meetings, and to state whether they are personal or non-personal interests and whether they are specific or non-specific to the matter or product under consideration.

- A member must declare a personal specific interest if they have at any time worked on the matter or product under consideration and have personally received payment for that work, in any form, from the industry.
- A member must declare a personal non-specific interest if they have a current personal interest in the company concerned which does not relate specifically to the matter or product under discussion.
- A member must declare a non-personal specific interest if they are aware that the department for which they are responsible has at any time worked on the matter or product but the member has not personally received payment in any form from the industry for the work done.
- A member must declare a non-personal non-specific interest if they are aware that the department for which they are responsible is currently receiving payment from the company concerned which does not relate specifically to the matter or product under discussion.

The examples of 'personal', 'non-personal', and 'current' interests given in the previous paragraph should be read in the context of paragraphs 'Declaring interests at meetings' (A-D). A member who is in any doubt as to whether they have an interest that should be declared, or whether they should take part in the proceedings, should ask the chairman for guidance. The secretary of state and/or the Committee has the power to determine whether or not a member with an interest shall take part in the proceedings.

If a member is aware that a product under consideration is or may become a competitor of a product manufactured, sold or supplied by a company in which the member has a *current personal* interest, they should declare their interest in the company marketing the rival product.

Declaring interests at meetings

Members are required to declare possible personal or non-personal interests, which could result in conflicts as agenda items arise. In applying Committee guidance the chairman is advised by the secretariat on proper procedure. The practice of the Committee follows the Code of practice as generally applied.

- A Non-personal interests where there is also no specific interest in the material or product under consideration. Full participation on discussion is allowed.
- B Non-personal interests with a specific interest in the material or products under consideration. Generally members may take part in discussion but would not participate in any decision.
- C Personal interests but without a specific interest in the product or material under consideration. Members may not take part in any discussion and any participation would be limited to specific questions where the rest of the Committee consider this of value.
- D. Personal interest with a specific interest in the product or material under consideration. No participation of any sort allowed save in exceptional circumstances where particular advice was likely to be of benefit to the Committee.

As a non-departmental public body it is particularly important that there can be no real, possible or perceived conflict of interest between members' current responsibilities or previous positions and their responsibilities as members of the JCVI. Members should declare when they or a close family member may have a personal, business, private pecuniary or other interest likely to prejudice the performance of the member's duties or which may conflict with their responsibilities as a member. Such interests should be declared in any particular matter to be considered by the JCVI and the member should refrain from participating in any discussions on that matter, unless the chairman, as

guided by the secretariat, rules the interest does not preclude the member participating. When a member refrains from participation in the consideration of any particular matter, they should normally withdraw from the meeting.

When an interest is not of a direct pecuniary kind, members should consider whether participation in the discussion or determination of a matter would suggest a real danger of bias. This should be interpreted in the sense that a member might unfairly regard with favour or disfavour the case of a party to the matter under consideration. In considering whether a real danger of bias exists in relation to a particular decision, members should assess whether they, a close family member, or a firm, business or other organisation with which the Committee member is connected is likely to be affected more than the generality of those affected by the decision in question.

A register of members' interests is maintained by the secretariat and members are required to provide the information requested in the form at Annex 3 and to ensure that any updated information is passed to the secretariat as appropriate. The final decision on whether any particular interest could be seen as being likely to prejudice the performance of a particular members' duties rests with the chairman as guided by the secretariat.

Members should not accept hospitality or gifts offered in their capacity as a member of the JCVI where this might be construed as being in conflict with the requirements of public service.

As a non-departmental public body, JCVI members are expected to observe certain rules on participation in political activities. Committee members are expected not to occupy paid party political posts or hold particularly sensitive or high-profile unpaid roles in a political party. This restriction does not, however, apply to Committee members who are MPs, local councillors or to Peers in relation to their conduct in the House of Lords. Subject to that, members are free to engage in political activities, provided that they are conscious of their general public responsibilities and exercise a proper discretion, particularly in regard to the work of the Committee. Members are free to maintain associations with trade unions, co-operative societies, trade associations etc. to the extent that such associations do not conflict directly with the interests of the Committee.

If members have any doubt about any of these matters, advice should be sought from the secretariat.

Any legal proceedings initiated by a third party are likely to be brought against the Committee as a whole, although in exceptional cases proceedings (civil or, in certain cases, criminal) may be brought against the chairman or other individual Committee members. The Committee as a whole or individual Committee members who have acted honestly, reasonably, in good faith and without negligence will not have to meet out of their own personal resources any personal civil liability which is incurred in execution or purported execution of their responsibilities as a member of the Committee. Committee members who misuse information gained by virtue of their position may be liable for breach of confidence under common law or may commit a criminal offence under insider dealing legislation.

The JCVI provides advice to the UK health ministers. Any legal challenge to any action taken on the advice or recommendations of the Committee will be the responsibility of the UK health ministers rather than the JCVI.

The membership of the JCVI is in the public domain. Members of JCVI are often approached by members of the media for views, comments and statements on particular matters of public health concern; they are sometimes asked to state the Committee's views or recommendations on particular matters. Members are advised to refer all such enquiries to the secretariat.

6. Papers bought to the Committee's attention

The following papers were brought to the Committee's attention :

1. Neuro-immunopathogenesis in autism. Singh V. *New Foundation of Biology* 2001, 447-58.
2. Banbury Center Cold Spring Harbor Meeting on microbiology, immunology and toxicology of autism and other neurodevelopment disorders; 11-14 February 2001.
3. A population-based study of measles, mumps and rubella vaccination and autism. Madsen K M , Hvid A, Vestergaard M, Schiendel D, Wohlfahrt J, Thorsen P, Olsen J, Melbye M. *New England Journal of Medicine* 2002, **347**:1477-82.
4. Neurological disorders after measles-mumps-rubella vaccination. Makela A, Pekka Nuorti J, Peltola H. *Pediatrics* 2002, **110**:957-63.
5. Effect of Pentavac and measles-mumps-rubella (MMR) vaccination on the intestine. Thjodleifsson B, Davidsdottir K, Agnarsson U, Sigthorsson G, Kjeld M, Bjarnason I. *Gut* 2002, **51**:816-17.
6. Parental confidence in measles, mumps and rubella vaccine: evidence from vaccine coverage and attitudinal surveys. Ramsay M E, Yarwood J, Lewis D, Campbell H, White J M. *British Journal of General Practice* 2002, **52**:912-16.
7. Recall bias, MMR and autism. Andrews N, Miller E, Taylor B, Lingam R, Simmons A, Stowe J, Waight P. *Archives of Diseases in Childhood* 2002, **87**:493-4.
8. Viral studies in the cerebrospinal fluid in subacute sclerosing panencephalitis. Anlar B, Pinar A, Yasar Anlar F, Engin D, Ustacelebi S, Kocagoz T, Us D, Akduman D, Yalaz K. *Journal of Infection* 2002, **44**:176-80.
9. Report to the legislature on the principal findings from the epidemiology of autism in California; A comprehensive pilot study. M.I.N.D Institute, University of California,

Davis. 17 Oct, 2002. Available at
www.mindinstitute.ucdmc.ucdavis.edu/news/report.htm.

10. Abnormal measles-mumps-rubella antibodies and CNS auto-immunity in children with autism. Singh V.K, Sheren, L.X, Newell, E, Nelson,C. *Biomedical Science* 2002, **9**:359-64
11. Small intestinal enteropathy with epithelial IgG and complement deposition in children with regressive autism. Torrente F *et al. Molecular Psychiatry* 2002, **7**(4):375-82
12. Development of an 'allelic discrimination' type assay to differentiate between the strain origins of measles virus detected in intestinal tissue of children with ileocolonic lymphonodular hyperplasia and concomitant development disorder. Sheils O, Smyth P, Martin C, O'Leary J. Abstract presented at the Pathological Society of Great Britain and Ireland in July 2002.
13. Review article: the concept of entero-colonic encephalopathy, autism and opioid receptor ligand. Wakefield A J, Puleston M, Montgomery S, Anthony A, O'Leary J, Murch S. *Alimentary Pharmacology and Therapeutics* 2002, **16**:663-74.
14. Relation of childhood gastrointestinal disorders to autism; nested case-control study using data from the UK General Practice Research Database Black C, Kaye J, Jick H. *British Medical Journal* 21 August 2002, **325**:419-21.
15. Testimony before Congressional Oversight Committee on Autism and Immunization. Arthur Krigsman. House Committee on Government reform; June 2002.
16. Measles. Donald A and Muthu V. *Clinical Evidence* 2002, **7**:331-40.
17. MMR and autistic enterocolitis: consistent epidemiological failure to find an association. Fombonne E, Cook Jr EH. *Molecular Psychiatry* 2003, **8**:133-4.
18. Prevalence of autism in a US metropolitan area. Yeargin-Allsopp M, Rice C, Karapurkar T, Doernberg N, Boyle C, Murphy C. *JAMA* 2003, **289**: 49-55.

19. Autism, vaccine link considered, Benjamin M. Washington politics & policy desk.
20. Bacterial infections, immune overload, and MMR vaccine. Miller E, Andrews N, Waight P, Taylor B. *Archives of Diseases in Childhood* 2003, **88**:222-3.
21. 'MMR vaccine – how effective and how safe?' The independent review from consumers' association. *Drugs and Therapeutics Bulletin* 2003, **41**: 25-29.
22. Pediatric MMR vaccination safety. Geier M R, Geier D A. *International Pediatrics* 2003, **18**:108 -13.
23. Vaccine programmes and policies Jackson . Salisbury D M, Beverley P C L, Miller E. *British Medical Bulletin* 2002, **62**: 201-11.
24. Editorial. On the 2002 Measles vaccination furore in the UK. Spier R E. *Vaccine* 2002, **20**:2845-7.
25. Acquisition of W135 meningococcal carriage in Hajj pilgrims and transmission to household contacts: prospective study. Wilder-Smith A, Barkham T M S, Earnest A, Paton N I. *British Medical Journal* 2002, **325**:365-6.
26. Sustained outbreak of W135 meningococcal disease in East London (correspondence). Klaber R, Booy R, El Bashir H, Mifsud A, Taylor S, Wilder-Smith A, Barkham T M S, Paton N I. *The Lancet* 2002, **360**:644-5.
27. Perspective. Suspicions about the safety of vaccines. Campion E W. *N Eng J Med* 2002, **347**:1474-5.
28. Editorials. The prevalence of autism. Fombonne E. *JAMA* 2003, **289**:87-9.
29. The cause of autism spectrum disorders. Szatmari P. *British Medical Journal* 2003, **326**:173-4.
30. Thimerosal in childhood vaccines, neurodevelopment disorders, and heart disease in the United States. Geier M R, Geier DA. *Journal of American Physicians and Surgeons* 2003, **8**:6-11.

31. MMR vaccine and idiopathic thrombocytopenic purpura. Black C, Kaye J A, Jick H. *British Journal of Clinical Pharmacology* **55**: 107-11.
32. Hospitalisation for RSV infection in ex-preterm infants – implications for use of RSV immune globulin. Thomas M, Beckford-Russell A, Sharland M. *Archives of Diseases in Childhood* 2000, **83**:122-7.
33. Respiratory syncytial virus infection in high risk infants and the potential impact of prophylaxis in a United Kingdom cohort. Clark S J, Beresford M W, Subhedar N V, Shaw N J. *Archives of Diseases in Childhood* 2000, **83**:313-16.
34. Home oxygen status and rehospitalisation and primary care requirements of infants with chronic lung disease. Greenough A, Alexander J, Burgess S, Chetcuti P A J, Cox S, Lenney W, Turnbull F, Shaw N J, Woods A, Boorman J, Coles S, Turner J. *Archives of Diseases in Childhood* 2002, **86**:40-3.
35. Letters to the editor. Palivizumab and RSV prevention. Lenney W. *Archives of Diseases in Childhood* 2000, **83**: 87-92.
36. Letters to the editor. RSV prevention. Deshpande S. *Archives of Diseases in Childhood* 2000, **82**:88-90.
37. Editorials. Preventing respiratory syncytial virus bronchiolitis. Sharland M, Bedford-Russell A. *BMJ* 2001, **322**:62-3.
38. Contribution of RSV to bronchiolitis and pneumonia-associated hospitalizations in English children, April 1995-March 1998. Muller-Peabody B, Edmunds W J, Zambon M C, Gay N J, Crowcroft N S. *Epidmiol.Infect* 2002, **129**:99-106.
39. Thiomersal and the occurrence of autism: Negative ecological evidence from Danish population-based data. Madsen K M, Lauritsen M B, Pedersen C B, Thorsen P, Plesner A, Andersen P H, Mortensen P B. *Pediatrics* 2003, **112**: 604-6.

40. Neurotoxic character of thiomersal and the allometric extrapolation of adult clearance half-time to infants. Magos L. *Journal of applied toxicology* 2003, **23**:263-9.
41. Evidence of brain overgrowth in the first year of life in autism. Courchesne E, Carper R, Akshoomoff N. *JAMA* 2003, **290**:337-44.
42. Autism and thiomersal-containing vaccines: lack of consistent evidence for an association. Stehr-Green P, Tull P, Stellfeld M, Mortenson P, Simpson D. *American Journal of Preventative Medicine* 2003, **25**: 101-6.
43. An epidemiological study on Japanese autism concerning routine childhood immunisation history. Takahashi H, Suzumura S, Shirakizawa F, Wada N, Tanka-Taya K, Arai S, Okabe N, Ichikawa H, Sato T. *Jpn Journal of infectious diseases* 2003, **56**:114-17.
44. Article. Association of autistic spectrum disorder and the measles, mumps, and rubella vaccine. Wilson K, Mills E, Ross C, McGowan J, Jadad A. *Arch Pediatr Adolesc Med.* 2003, **157**:628-34.
45. Prevalence of autism and parentally reported triggers in north east London population. Lingam R, Simmons A, Andrews N, Miller E, Stowe J, Taylor B. *Arch Dis Child* 2003, **88**:666-70.

7. Members of the JCVI Committee

Chairman:

Professor Michael Langman BSc, MD, FRCP, FMedSci

Professor of Medicine, University of Birmingham

Members:

Dr Barbara Bannister MSc, FRCP

Clinical Head of Service, Infection and Immunity, Royal Free Hospital

Professor Keith Cartwright MA, BM, FRCPath

Microbiologist/bacteriologist; Group Director, Public Health Laboratory Service South West

Professor Jonathan Cohen FRCP, FRCPath, FRCPE, FMedSci

Dean, Brighton & Sussex Medical School and Professor of Infectious Diseases.

Professor Alan Emond MA, MD, FRCP, FRCPCH

Professor of Child Health, University of Bristol. Director of the Centre for Child and Adolescent Health, Bristol

Dr David Goldblatt MBChB, MRCP, PhD

Institute of Child Health and Great Ormond Street Hospital, London,
Paediatric Immunologist, Reader/Honorary Consultant

Professor Paul Griffiths BSc, MD, DSc, FRCPath

Virologist; Professor of Virology, Royal Free and University College Medical School

Professor Andrew J Hall MB BS, MSc, PhD, FRCP, FFPH

Professor of Epidemiology, London School of Hygiene and Tropical Medicine

Dr Christopher Harling MA, FFOM, FRCP, FFPHM

Consultant Occupational Physician, Avon Partnership NHS Plus Occupational Health Service, Bristol

Professor Simon Kroll MA, FRCP, FRCPCH, FMedSci

Paediatric Infectious Disease Physician; Professor of Paediatrics and Molecular Infectious Diseases, Imperial College School of Medicine

Mrs Vivienne Parry Bsc (Hons) (Lay member)

Writer and broadcaster

Professor Lewis Ritchie OBE, BSc, MSc, MD, FRCP(Edin), FRCGP, FFPH, FBCS

Principal General Practitioner; Head of Department of General Practice and Primary Care, University of Aberdeen; Mackenzie Professor of General Practice, University of Aberdeen; Honorary Consultant in Public Health Medicine, NHS Grampian

Dr Michael Roworth BSc, MB, ChB, FFARCS, MSc, MFPHM

Consultant in Public Health Medicine (communicable diseases and environmental health) (Scotland representative); Public Health Medicine Service, Tayside Health Board, King's Cross Hospital, Dundee

Mrs Joan Sawyer RGN (Nursing Representative)

Smart care project manager, Richmond & Twickenham PCT

Dr Richard Smithson MB, ChB, MFPM, FFPHM

Consultant in Communicable Disease Control (Northern Ireland representative); CCDC/Immunisation Co-ordinator, Western Health and Social Services Board

Professor Brent Taylor PhD, MB ChB, FRACP, FRCPCH

Consultant Paediatrician, Royal Free and University College Medical School, London

Dr Christopher Verity MA, FRCP, FRCPCH, DCH, DRCOG

Consultant Paediatric Neurologist, Addenbrooke's Hospital Cambridge,
Director of Child Development Centre

Ex-Officio:

Dr Claire Bramley BSc(Hons), PhD, MSc

Epidemiologist (immunisation), Scottish Centre for Infection and Environmental Health

Professor Brian I Duerden BSc, MD, FRCPath

Director of the Public Health Laboratory Service

Professor George Griffin BSc, PhD, MBBS, FRCP(Lon, Edin), FRCPath F.Med Sci

Professor of Infectious Diseases and Medicine, Vice Principal for Research, St Georges Hospital Medical School, University of London

Dr Stephen Inglis BSc, PhD

Director of the National Institute for Biological Standards and Control

Dr Angus Nicoll FRCPH,FFPHM,FRCP

Director of Communicable Disease Surveillance Centre (Colindale)

Advisory Committees

**Declaration of interests in industry
in accordance with the Code of practice**

Personal interests

(For definition see paragraphs 4(a), (b) and (e) of the Code of practice)

- Consultancies, directorships and similar positions held
- Fee-paid work
- Shareholdings
- Other (please specify)

Non-personal interests

(For definition, see paragraphs 5(a) and (b) of the Code of practice)

- Fellowships
- Industrial support
- Other (please specify)

Signature.....

Name.....

Date

9. Register of members' declaration of interests

Chairman: Professor Michael Langman			
PROFESSION/TITLE: PROFESSOR OF MEDICINE, UNIVERSITY OF BIRMINGHAM			
PERSONAL INTERESTS:			
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
None.	None.	None	None
NON-PERSONAL INTERESTS:			
<i>Fellowships</i>	<i>Industrial support</i>	<i>Other</i>	
None.	Astra, Novartis, Merck Sharp & Dohme.	None	

Dr Barbara Bannister			
PROFESSION/TITLE: CLINICAL HEAD OF SERVICE, INFECTION AND IMMUNITY, ROYAL FREE HOSPITAL			
PERSONAL INTERESTS:			
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
Consultant to Centre for Applied Microbiology and Research (paid post)	None.	None	None
NON-PERSONAL INTERESTS:			
<i>Fellowships</i>	<i>Industrial support</i>	<i>Other</i>	
		None	None

Professor Keith Cartwright			
PROFESSION/TITLE: MICROBIOLOGIST/BACTERIOLOGIST GROUP DIRECTOR, PUBLIC HEALTH LABORATORY SERVICE, SOUTH WEST			
PERSONAL INTERESTS:			
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
Consultancy work for Wyeth Lederle	None.	Celltech	None
NON-PERSONAL INTERESTS:			
<i>Fellowships</i>	<i>Industrial support</i>	<i>Other</i>	
None.	Vaccine trials including products of Wyeth Lederle, Chiron, Baxter, RIVM, Aventis Pasteur	Medical Consultancy to New Zealand Department of Health regarding meningitis B vaccine.	

Professor Jonathan Cohen			
PROFESSION/TITLE: DEAN, BRIGHTON & SUSSEX MEDICAL SCHOOL AND PROFESSOR OF INFECTIOUS DISEASES			
PERSONAL INTERESTS:			
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
GlaxoSmithKline; Lilly; Baxter; Pfizer	ICOS (Data Safety Monitoring Board)	Cambridge Antibody Technology (and member of the Scientific Advisory Board)	Zen VC (Scientific Advisory Board, potential share entitlement. Company involved in
NON-PERSONAL INTERESTS:			
<i>Fellowships</i>	<i>Industrial support</i>		<i>Other</i>
None.	Baxter		None

Professor Alan Emond			
PROFESSION/TITLE: PROFESSOR OF CHILD HEALTH, UNIVERSITY OF Bristol. DIRECTOR OF THE CENTRE FOR CHILD AND ADOLESCENT HEALTH, BRISTOL			
PERSONAL INTERESTS:			
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
None	None	None	None
NON-PERSONAL INTERESTS:			
<i>Fellowships</i>	<i>Industrial support</i>		<i>Other</i>
None.	None		None

Professor David Goldblatt			
PROFESSION/TITLE: PROFESSOR OF VACCINOLOGY AND IMMUNOLOGY and DIRECTOR OF CLINICAL RESEARCH AND DEVELOPMENT, INSTITUTE OF CHILD HEALTH and GREAT ORMOND STREET HOSPITAL, LONDON			
PERSONAL INTERESTS:			
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
Occasional member of advisory boards for GlaxoSmithKline and Wyeth Lederle Vaccines	Produced expert report on MMR up to March 2003 Chairman, Aventis Pasteur pneumococcal protein vaccine project DSMB	None	None
NON-PERSONAL INTERESTS:			
<i>Fellowships</i>	<i>Industrial support</i>		<i>Other</i>
None.	Produced expert report on MMR up to March 2003 Chairman, Aventis Pasteur pneumococcal protein vaccine project		None

	DSMB	
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Professor Paul Griffiths			
PROFESSION/TITLE: PROFESSOR OF VIROLOGY, ROYAL FREE AND UNIVERSITY COLLEGE MEDICAL SCHOOL			
PERSONAL INTERESTS:			
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
Ad hoc consultancies for Bayer and Lilly. Both concern the development of antiviral drugs; neither concerns vaccines	None.	None	None
NON-PERSONAL INTERESTS:			
<i>Fellowships</i>	<i>Industrial support</i>	<i>Other</i>	
None.	None	Work in Professor Griffiths' Department has led to the submission of a patent application in the name of the Medical School concerning the possible prevention of cytomegalovirus infection by means of vaccine.	

Professor Andrew Hall			
PROFESSION/TITLE: PROFESSOR OF EPIDEMIOLOGY, LONDON SCHOOL OF HYGIENE AND TROPICAL MEDICINE			
PERSONAL INTERESTS:			
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
None.	None.	None	None
NON-PERSONAL INTERESTS:			
<i>Fellowships</i>	<i>Industrial support</i>		<i>Other</i>
None.	1998 SUPPORT FROM Merck Sharp & Dohme to fund research - follow up vaccines in Keneba & Manduar, The Gambia		None

Dr Christopher Harling			
PROFESSION/TITLE: CONSULTANT OCCUPATIONAL PHYSICIAN, AVON PARTNERSHIP NHS PLUS OCCUPATION HEALTH SERVICE, BRISTOL			
PERSONAL INTERESTS:			
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
None	None	None	None
NON-PERSONAL INTERESTS:			
<i>Fellowships</i>	<i>Industrial support</i>		<i>Other</i>
None	None		None

Professor Simon Kroll			
PROFESSION/TITLE: PROFESSOR OF PAEDIATRICS AND MOLECULAR INFECTIOUS DISEASES, IMPERIAL COLLEGE, LONDON			
PERSONAL INTERESTS:			
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
None.	None.	None	None
NON-PERSONAL INTERESTS:			
<i>Fellowships</i>	<i>Industrial support</i>	<i>Other</i>	
None.	A recent research project was partly supported by Chiron Vaccines. Received grants (to cover travel/accommodation/meeting registration) from Wyeth Vaccines to attend open medical scientific meetings.	Chairman of the medical-scientific advisory panel of the Meningitis Trust. Imperial College co-holds with the HPA (Porton Down) patent rights in some products of their meningococcal vaccine research.	

Vivienne Parry (Lay Member)			
PROFESSION/TITLE: WRITER AND BROADCASTER			
PERSONAL INTERESTS: Baxter Fenwal: Occasional media training sessions outside Britain for the blood products division of the company.			
Wyeth: Speaker for the RCGP leaderships course sponsored by Wyeth. Payment will be from the RCGP.			
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
		Nonee	None
NON-PERSONAL INTERESTS:			
<i>Fellowships</i>	<i>Industrial support</i>	<i>Other</i>	
None.	None	None	

Professor Lewis Ritchie			
PROFESSION/TITLE: GENERAL PRACTITIONER.HEAD OF DEPARTMENT OF GENERAL PRACTICE AND PRIMARY CARE, UNIVERSITY OF ABERDEEN. PROFESSOR OF GENERAL PRACTICE, UNIVERSITY OF ABERDEEN. HONORARY CONSULTANT IN PUBLIC HEALTH MEDICINE, NHS GRAMPAN			
PERSONAL INTERESTS:			
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
None.	Occasional lectures/seminars/discussion groups sponsored by pharmaceutical companies.	None	None
NON-PERSONAL INTERESTS:			
<i>Fellowships</i>	<i>Industrial support</i>		<i>Other</i>
None.	Fees for occasional lectures/seminars at pharmaceutical industry-sponsored meetings. Clinical trial undertaken by his GP practice and his University Department – not in the field of vaccines.		None

Mrs Joan Sawyer			
PROFESSION/TITLE: SMART CARE PROJECT MANAGER			
PERSONAL INTERESTS:			
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
None.	None.	None	None
NON-PERSONAL INTERESTS:			
<i>Fellowships</i>	<i>Industrial support</i>		<i>Other</i>
None.	None		None

Dr Richard Smithson			
PROFESSION/TITLE:			
CONSULTANT IN COMMUNICABLE DISEASE CONTROL (NORTHERN IRELAND REPRESENTATIVE. CCDC/IMMUNISATION COORDINATOR, WESTERN HEALTH AND SOCIAL SERVICES BOARD			
PERSONAL INTERESTS:			
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
None.	None.	None	None
NON-PERSONAL INTERESTS:			
<i>Fellowships</i>	<i>Industrial support</i>	<i>Other</i>	
None.	None	None	

Professor Brent Taylor			
PROFESSION/TITLE:			
CONSULTANT IN COMMUNITY CHILD HEALTH/COMMUNITY PAEDIATRICIAN; PROFESSOR OF COMMUNITY CHILD HEALTH,ROYAL FREE AND UNIVERSITY COLLEGE MEDICAL SCHOOL			
PERSONAL INTERESTS:			
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
None.	None.	None	None
NON-PERSONAL INTERESTS:			
<i>Fellowships</i>	<i>Industrial support</i>	<i>Other</i>	
None.	None	None	

Dr Christopher Verity			
PROFESSION/TITLE:			
CONSULTANT PAEDIATRIC NEUROLOGIST, ADDENBROOK'S HOSPITAL			
PERSONAL INTERESTS:			
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
None.	None.	None	None
NON-PERSONAL INTERESTS:			
<i>Fellowships</i>	<i>Industrial support</i>	<i>Other</i>	
None.	None	Since 1997 – Department of Health grant to fund epidemiological study of children with progressive intellectual and neurological deterioration	

Ex-Officio

Dr Claire Bramley			
PROFESSION/TITLE: EPIDEMIOLOGIST (IMMUNISATION), SCOTTISH CENTRE FOR INFECTION AND ENVIRONMENTAL HEALTH			
PERSONAL INTERESTS:			
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
None	None	None	None
NON-PERSONAL INTERESTS:			
<i>Fellowships</i>	<i>Industrial support</i>	<i>Other</i>	
None	Grant from Wyeth Vaccines to develop mathematical models of pneumococcal infection. Support from Wyeth Vaccines to attend the European Society for Paediatric Infectious Diseases Annual Conference (April 2003).	None	

Chairman: Professor Brian I Duerden			
PROFESSION/TITLE: DIRECTOR OF PUBLIC HEALTH LABORATORY SERVICE			
PERSONAL INTERESTS:			
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
NON-PERSONAL INTERESTS:			
<i>Fellowships</i>	<i>Industrial support</i>	<i>Other</i>	

Professor George Griffin			
PROFESSION/TITLE: PROFESSOR OF INFECTIOUS DISEASES AND MEDICINE, VICE PRINCIPLE FOR RESEARCH ST GEORGES HOSPITAL MEDICAL SCHOOL, UNIVERSITY OF LONDON			
PERSONAL INTERESTS:			
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
Microscience Scientific Advisory Board. Celltech Scientific Advisory Board.	None.	None	None
NON-PERSONAL INTERESTS:			
<i>Fellowships</i>	<i>Industrial support</i>	<i>Other</i>	
	None	None	

Dr Stephen Inglis			
PROFESSION/TITLE:			
DIRECTOR OF THE NATIONAL INSTITUTE FOR BIOLOGICAL STANDARDS AND CONTROL			
PERSONAL INTERESTS:			
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
None.	None.	Xenova	None
NON-PERSONAL INTERESTS:			
<p>NIBSC's role is to assure the quality of biological medicines through a mixture of product testing, development of tests and reference materials, and applied research. In carrying out its role, the Institute interacts with a wide range of product developers and manufacturers. In some instances, NIBSC charges commercial organisations for its products and services, in line with guidance issued from HM Treasury (<i>'Fees & Charges Guide'</i> and <i>'Selling into Wider Markets'</i>).</p>			
<i>Commercial Contracts</i>	<i>Work area</i>		
Amgen	Product testing		
Aventis Behring GmbH	Product testing		
Baxter AG	Coagulation Factor Standards		
Berna Biotech	Mumps serology		
Bio Products	Product testing		
Boots/Wellcome	Pyrogen testing		
BTG Ltd	Interleukin 1 Derived Peptides, Influenza Vaccines		
Celsus Labs Inc	Anticoagulant Activity of Heparins		
EBioscience	Hybridoma licence		
GSK	Modelling of HIV Immunopathogenesis, influenza serology testing, polio testing		
Hoffmann-La Roche	Interferon Standard		
Lipoxen Tech. Ltd	Influenza Vaccines		
Miltenyo Biotec	Hybridoma licence		
MTL	Product testing		
NGI	Multiplex NAT standard		
Serono, Italy	Detection of Interferon Antibodies		
Scottish National Blood Transfusion Service	IVIgG Testing		
UKTSSA	Transplant Laboratory Service, Cell Bank & Serum Bank Agreement		
West Pharma	Product formulation		

Dr Angus Nicoll			
PROFESSION/TITLE: DIRECTOR OF COMMUNICABLE DISEASE SURVEILLANCE CENTRE			
PERSONAL INTERESTS:			
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
None.	None.	None	None
NON-PERSONAL INTERESTS:			
<i>Fellowships</i>	<i>Industrial support</i>		<i>Other</i>
None.	HPA (of which he is Director) receives some funding from non-Government sources.		None

Annex 5

10. The seven principles of public life

Selflessness

Holders of public office should take decisions solely in terms of the public interest. They should not do so in order to gain financial or other material benefits for themselves, their family, or their friends.

Integrity

Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations that might influence them in the performance of their official duties.

Objectivity

In carrying out public business, including making public appointments, awarding contracts, or recommending individuals for rewards and benefits, holders of public office should make choices on merit.

Accountability

Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office.

Openness

Holders of public office should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands.

Honesty

Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interest.

Leadership

Holders of public office should promote and support these principles by leadership and example.

Annex 6

11. Statement from the expert group convened to discuss Hib rates, September 2002

Having reviewed the evidence base on the increase in Hib infections and vaccine failures, the expert group concluded that:

- the UK's three-dose primary course without a booster still provides excellent control of Hib incidence when compared with pre vaccine figures;

- efficacy of routine infant immunisation is less than that observed in the catch-up campaign in older children;
- rates of invasive Hib infections (vaccine failures) have been increasing since 1998, principally in those aged one to four years;
- there had been a further rise in Hib cases in 2001, including young infants. The age at which Hib disease presents after vaccination has fallen progressively and declined markedly in children born during 2000 and 2001;
- other countries do not appear to be affected by this sudden increase in Hib incidence. Social trends such as changes in daycare for young children may play a role in the UK;
- limited studies of carriage provide no evidence of a re-emergence of Hib carriage. However, further studies will be necessary to investigate the source of Hib transmission to children;
- an unpublished study suggests a five-fold increased risk of Hib disease in infants immunised with three doses of one specific DTaP/Hib vaccine compared to those who receive one or more doses of a DTwP/Hib combination;
- published evidence suggests that the Hib antibody is lower in those children receiving the DTaP/Hib vaccine than in those receiving DTP/Hib. This effect is most marked in accelerated schedules and is strongly related to the number of doses received. The biological significance of this observation has not been clear, since despite the lower primary responses, this vaccine has been shown to prime adequately for memory.

The expert group advises JCVI that::

- DTP/Hib should be the recommended vaccine for use in the UK childhood immunisation programme at present and this is the only vaccine being issued;
- any remaining DTaP/Hib should be recalled from GPs; and
- children who have completed their primary immunisations with three doses of Infanrix-Hib at least one month previously should be offered a booster dose of single Hib vaccine as soon as possible. For practical

reasons, any children in the target age range where receipt of at least one dose of DTP/Hib cannot be easily documented should be re-called and offered a Hib booster.

18 October 2002

Annex 7

12. Glossary

Acellular vaccine

Without whole cells. An acellular vaccine contains only parts of cells which can produce immunity in the person receiving the vaccine (see DTaP).

Adverse reaction

The occurrence of an adverse event following exposure to treatment or vaccine. This may be coincidental rather than causal.

Allergic reactions

A specific immunologically-based sensitivity to certain substances that can lead to conditions such as asthma, eczema and hay fever

Anaphylaxis

An immediate and severe allergic reaction.

Antibodies

Proteins produced by the body which neutralise or destroy toxins and disease-carrying organisms.

Antigen

A substance which, under appropriate conditions, triggers an immune response. Vaccines are specially prepared antigens.

Bacteraemia

Where the bacteria have entered the bloodstream.

Bacterium/bacteria

Single cell micro-organisms. There are many different types or strains of bacteria, some of which cause disease. Others are essential for our bodies to work properly.

BCG

Stands for Bacillus Calmette-Guérin after the two scientists who developed the vaccine that protects against TB.

Conjugate vaccine

These vaccines are made with part of the germ which is combined (conjugated) with a protein (such as tetanus or diphtheria) which makes it work better and gives better protection over a long period of time. The conjugate vaccines in the childhood immunisation schedule are Hib and MenC.

Contraindication

A reason why a vaccine or other substance should not be given.

Convulsions

Uncontrolled, irregular movements of the limbs and body caused by rapid contractions and relaxations of the muscles, often accompanied by unconsciousness and caused by abnormal electrical activity in the brain.

Diphtheria

Diphtheria is a disease which usually begins with a sore throat and which can quickly cause problems with breathing. It can damage the heart and nervous system and, in severe cases, it can kill.

DTaP/Hib

Combined vaccine that protects against four different diseases – diphtheria, tetanus, pertussis (or whooping cough) and *Haemophilus influenzae* type b (Hib). Contains acellular pertussis vaccine.

dTaP/IPV and DTaP/IPV

Combined vaccines that protect against diphtheria, tetanus, pertussis (whooping cough) and polio. Diphtheria vaccines are produced in two strengths, abbreviated to 'D' for high strength and 'd' for the low strength.

DTaP/IPV/Hib

Combined vaccine that protects against diphtheria, tetanus, pertussis (whooping cough), polio and *Haemophilus influenzae* type b (Hib) disease.

DTwP-Hib

Combined vaccine that protects against four different diseases – diphtheria, tetanus, pertussis (or whooping cough) and *Haemophilus influenzae* type b (Hib). Contains whole-cell pertussis vaccine.

Efficacy

The measure of a vaccine's effectiveness. It is measured by the proportion of those who are immunised and who don't get a disease when exposed to it, or by the number of antibodies produced by the immune system.

Encephalitis

Inflammation of the brain.

Encephalopathy

Any disease or disorder affecting the brain.

Endemic

A disease occurring in a place, region or population.

Febrile convulsion/seizure

Convulsion brought on by a high temperature or fever.

Genetic

Inherited from a parent.

Haemophilus influenzae

The bacterium that causes Hib disease. It occurs in two forms – those with capsules (encapsulated) and those without (nonencapsulated). Serious disease is usually caused by the encapsulated organisms of which there are six types (a to f). Type b caused the majority of Hib disease before the vaccine was introduced. Nonencapsulated strains are associated mainly with ear and chest infections.

Herd immunity

The protection conferred on individuals who have not been immunised because sufficient numbers of the rest of the population have been immunised.

Hib

Haemophilus influenzae type b – known as Hib - is an infection that can cause a number of major illnesses such as meningitis, blood poisoning and pneumonia. All of these illnesses can kill if they are not treated quickly.

Invasive disease

Serious disease in which the bacteria have spread through the body, because they have entered the bloodstream.

Immune response

The body's response to an immunisation or infection.

Immunisation

The priming of the body's immune system with a vaccine.

Immunodeficient

Lacking in complete immunity.

Immunogenicity

The ability to produce an immune response.

Immunoglobulins

Antibodies.

Immunosuppressive

Something that reduces the body's ability to fight infection by suppressing the immune system.

Measles

A disease typically of childhood caused by a very infectious virus that can lead to chest infections, fits, brain damage and even death as well as skin rash.

MenC

Abbreviation referring to meningococcal C infection.

Meningitis

Meningitis is an inflammation of the lining of the brain. Hib can

be a cause of meningitis and can also cause septicaemia (blood poisoning). Hib septicaemia differs from that caused by meningococcal bacteria in that there is only very rarely an accompanying rash. Babies and children under four years of age are at most risk from Hib meningitis or septicaemia.

Mercury

A heavy fluid metal which, with its salts, has been used in medicine for many years. Thiomersal, which contains ethyl mercury has been used as a preservative in vaccines but is gradually being discontinued even though there has been no evidence of adverse effects from its use.

MMR

The combined vaccine that protects against measles, mumps and rubella.

Morbidity

The state of being diseased. A country's morbidity ratio is the proportion of diseased individuals to healthy ones.

Mortality

The death rate of a population or a group within it. Often expressed as so many deaths per 100,000 of the population.

Mumps

A disease caused by a virus that causes painful, swollen glands in the face, neck and jaw, fever and headache. It can lead to deafness, meningitis and encephalitis.

Neomycin

A preservative used in vaccines to prevent them from being contaminated. It might lead to an allergic reaction in some people who have been vaccinated.

Neurological

Relating to or affecting the nervous system/nerves.

Neurological condition

A disorder of the nervous system.

Pertussis (whooping cough)

Whooping cough is a disease that can cause long bouts of coughing and choking which can make it hard to breathe. It can last for up to ten weeks. It is not usually serious in older children, but it can be very serious in babies under one year of age.

Pneumonia

Inflammation of the lung.

Poliomyelitis/polio

A disease caused by a virus that attacks the nervous system leading to paralysis of the muscles. If it affects the chest muscles it can kill.

Polysaccharide vaccine

Polysaccharide vaccines are manufactured from parts of the sugar (polysaccharide) coat of bacterium, eg. Pneumococcus, Hib and meningococcus

Rubella

A mild disease, also known as German measles, caused by a virus. If caught during pregnancy, it can affect unborn babies leading to blindness and deafness.

Septic

Describing tissue destroyed by disease-causing bacteria or their toxins.

Septicaemia

Septicaemia is a form of blood poisoning, which can be caused by the same germs that cause meningitis. Septicaemia caused by Hib differs from that caused by meningococcal bacteria in that there is only very rarely an accompanying rash.

Strain

Different types of the same bacteria or viruses.

Surveillance

The routine monitoring of disease levels, and also of how many people are being immunised against the disease and of the impact of immunisation programmes.

Td/IPV

Tetanus, low dose diphtheria and inactivated polio vaccine. It is given to young people aged 13 to 18 years to top up their levels of protection against these diseases.

Thiomersal

An ethyl mercury-based preservative used in some vaccines. It is gradually being phased out on the recommendation of several health organisations.

Thrombocytopenia

A reduction in the number of platelets in the blood, tending to lead to internal bleeding.

Toxin

A poison. Some diseases are caused by the toxins produced by bacteria.

Toxoid

An inactivated bacterial toxin that stimulates an immune response when used in a vaccine.

Tuberculosis

A serious disease mainly affecting the lungs which can also affect the glands, brain and bones.

Vaccines

Vaccines are manufactured in different ways using part of the germ or virus which causes the disease. Except very rarely (oral polio vaccine only) they cannot cause the disease for which they give protection.

Vaccine associated poliomyelitis paralysis (VAPP)

Extremely rare condition of paralysis caused by the oral polio vaccine.

Virus

An organism that needs to live inside a cell to grow and reproduce. Viruses cause many types of disease, including the common cold.

Whole-cell vaccine

A vaccine that is manufactured using the killed, whole cell of a bacterium. The pertussis (whooping cough) part of the DTwP vaccine uses killed, whole cells of the pertussis bacterium. It works well for babies but it causes a higher rate of mild reactions in older children (see DTwP).