

# **Joint Committee on Vaccination and Immunisation**

## **Annual Report 2004**

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# **Joint Committee on Vaccination and Immunisation**

## **Annual Report 2004**

### **Foreword**

The Joint Committee on Vaccination and Immunisation (JCVI) is the prime source of advice on policy over the best means of protecting individual and public health through vaccination and immunisation in England, Wales, Scotland and Northern Ireland. In assessing the undoubted benefits the committee has to take full account of any possible hazards. The obvious success of the current Department of Health programme, notably, but not only, in greatly reducing risk of developing classical childhood infectious diseases has, paradoxically, tended to reduce public perception of the continuing and very real risks of severe illness and of death associated with diseases which inevitably return if immunisation ceases. Careful attention was given by the committee this year, as in all others, to evidence suggesting adverse effects of vaccines, and no reason has been found for believing that current immunisation and vaccination policies are ill-advised on these grounds.

The tasks of the committee are becoming increasingly complex with the expanding numbers of diseases against which vaccination and immunisation are likely to be effective, and in step with this, the enlarging number of potentially useful vaccines becoming available. Particular difficulty arises with the infant immunisation schedule where a large number of vaccines of proven value have to be given over a short period of time so as to provide the best protection early in life. In introducing new vaccines into infant immunisation programmes account has also to be taken of any possible influences of adding one vaccine to another. The recent successful introduction of a five component vaccine immunising against diphtheria, tetanus, whooping cough, poliomyelitis and haemophilus influenza is a case in point. Evidence provided by the Medicines and Health care products Regulatory Agency indicates that combining the vaccines involved has not brought with it particular hazards, whilst it has helped to reduce the number of injections which would otherwise be needed.

Other major issues considered by the committee included protecting against avian influenza. Although immunisation should be a prime method, there are interrelated problems in securing and maintaining that protection. Influenza viruses being inherently unstable, there are consequential uncertainties over the likely nature of any avian influenza virus which might cause pandemic infection in the human population. As a result there are difficulties in ensuring the value of any vaccine and in defining the exact immunising regime needed. The complexities imply a detailed and measured, whilst vigorous approach to overcoming the difficulties.

The duration of immunity from any vaccine cannot be assumed to be life-long, and the committee depends on information provided by the Health Protection Agency in determining whether observed population infection rates are of the level that might be expected if immunisation remains effective, or whether re-immunisation might be necessary.

Securing the outcome of immunisation policy once it is decided depends on a partnership between the Department of Health and those responsible for the delivery in clinical practice. It is much to the credit of those concerned that those outcomes are as clearly beneficial as they are.

Members of the Joint Committee and of its subcommittees and working groups give freely of their time, and we owe a debt of gratitude to those who at all times strive to give advice which is appropriate, clear and unprejudiced.

**Professor Michael J S Langman**

**Chairman**

**Joint Committee on Vaccination and Immunisation**

# **1 Introduction**

The full Committee met three times between February 2004 and October 2004, under the Chairmanship of Professor Langman, with minutes of the meeting placed on the JCVI website: [www.advisorybodies.dh.gov.uk/jcvi/](http://www.advisorybodies.dh.gov.uk/jcvi/). In addition, subgroups and panels of the main Committee were held during this period on a variety of issues such as influenza immunisation, BCG and hepatitis B.

## **1.1 The terms of reference of the Committee**

The terms of reference of the JCVI are:

"To advise the Secretaries of State for Health, Scotland, Wales and Northern Ireland 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, and the responsibilities and obligations, are listed at Annex 2.

### **3 Issues considered by the Committee**

#### **3.1 Pneumococcal vaccine in children**

Data presented in UK clinical trials and US surveillance data suggested likely benefit from a two dose pneumococcal immunisation schedule, with vaccine given at the ages of two and four months. Introduction of the vaccine into current UK childhood schedule posed difficulties. It was unclear how to add in practice to the number of immunisations against individual diseases which were of benefit and which already formed part of the current UK programme. The acceptability of further separate immunisations in the schedule was uncertain, and, though combining vaccines had not proved to be harmful, there remained issues over the potential for multi-component vaccines to interfere with each others beneficial effects.

Two other factors needing more attention were the possibility that protection against serotype varieties in the vaccines available may result in the serotypes not included becoming more common; and the degree to which infant immunisation would confer protection upon adults through reducing the chances of being in contact with a potential source of infection. When further evidence was available on these significant issues the committee would provide definitive advice on an important area in public health protection.

#### **3.2 New Childhood Vaccines**

##### *Poliomyelitis immunisation and the introduction of a new five part vaccine*

The much reduced risk of wild natural poliomyelitis importation with the elimination of the disease from most of the world, apart from some areas of Africa and India, made a switch from the current live oral vaccine to an inactivated injected vaccine appropriate. The oral vaccine, as a live vaccine could, occasionally though rarely, cause paralytic poliomyelitis, whilst the inactivated vaccine did not.

A new five part vaccine (DTaP/IPV/Hib) was therefore introduced into the UK childhood immunisation programme in September 2004. The vaccine has good evidence of efficacy for components protecting against diphtheria, tetanus, pertussis (whooping cough), poliomyelitis, and haemophilus influenzae type b (Hib). A range of information

materials (leaflets, fact sheets, PowerPoint presentations etc) had been produced to support the new programme, and the [www.immunisation.nhs.uk](http://www.immunisation.nhs.uk) website had been redesigned and updated to reflect the changes to the programme. The introduction of the new vaccine had been very successful, and, whilst reducing the number of individual immunisations that might otherwise have been required, had not resulted in any significant change in the risk of adverse effects.

### **3.2a Removal of thiomersal from vaccines**

As part of this programme the committee agreed to the replacement of whole-cell thiomersal-containing pertussis vaccine with non-thiomersal-containing acellular vaccine given that the current acellular vaccine appeared at least as effective in immunisation as the whole cell vaccine. The committee noted that there was no evidence to suggest that thiomersal in UK vaccines caused serious adverse events.

### **3.3 Rabies**

Although a rare disease in the United Kingdom, the first case of rabies in a human for 100 years occurred in Scotland. There are significant issues over post-exposure prophylaxis and the particular need to protect individuals likely to be at-risk, notably bat handlers, given that bats can be carriers of the virus. The committee confirmed that current advice on prophylaxis by deep subcutaneous or intramuscular injection of vaccine remained appropriate, and reiterated the need for bat handlers to receive protection.

### **3.4 Travel vaccines: - Cholera**

The Committee considered a new vaccine against cholera (vaccine brand name: Dukoral™) which was now licensed in the UK. The oral vaccine is well tolerated, with side effects being limited to mild gastrointestinal events. The vaccine has good protective efficacy against *Vibrio cholerae* O1 (in the range 61% to 86%). In children aged 2 to 5 years of age, protection wanes rapidly after 6 months. The Committee agreed that, based on a risk assessment of acquiring cholera:

Vaccination against cholera could particularly be considered for the following categories of travellers:

- Relief or disaster aid workers

- Persons with remote itineraries in areas where cholera epidemics are occurring and there is limited access to medical care.

The appropriateness of cholera vaccination apart from the above is a matter for the individual to discuss with their doctor. Individual risk assessment based on the area of travel and any underlying health conditions is key. The Committee JCVI does not recommend the use of Dukoral™ for protection against travellers' diarrhoea.

### **3.5 Avian Influenza**

The committee gave careful consideration to the possible risks of human influenza pandemic. The H5N1 avian influenza virus currently circulating in SE Asian disease continued to pose a treat. The committee noted the difficulties in predicting the exact nature of any vaccine that would be required in the advance of the clear definition of the immunological and molecular characteristics of a strain responsible for a pandemic. Secondly, once a strain had been clearly identified it would be necessary to have appropriate manufacturing facilities, and to carry out trials to establish the appropriate immunising schedule. Solving these problems requires good surveillance; the ability to take appropriate strains rapidly into vaccine; and being prepared to carry out clinical testing quickly and effectively.

### **3.6 Horizon Scanning**

#### ***HPV vaccines***

The Committee was informed about the progress towards human papilloma virus (HPVs) based vaccines to protect against cervical dysplasia (a precursor to cervical cancer) and genital warts. Phase II vaccine trials were showing promising results, and Phase III studies were well underway. An application for licensing of an HPV vaccine could be possible within the next 2 years.

The cost effectiveness of a HPV vaccine would be challenging to assess. It appeared to give good protection against infection, but producing evidence of value in preventing cancer would be extremely difficult due to the long period over which this disease develops. Assessing value also involved parallel consideration of the potential impact of vaccination in the context of the current UK cervical screening programme.

The Committee noted progress in the development of the vaccine; it asked to be kept informed.

## Rotavirus

As part of the Committee's regular horizon scanning activity, it considered a paper on the epidemiology and burden of disease caused by rotavirus and the availability of a vaccine against the disease.

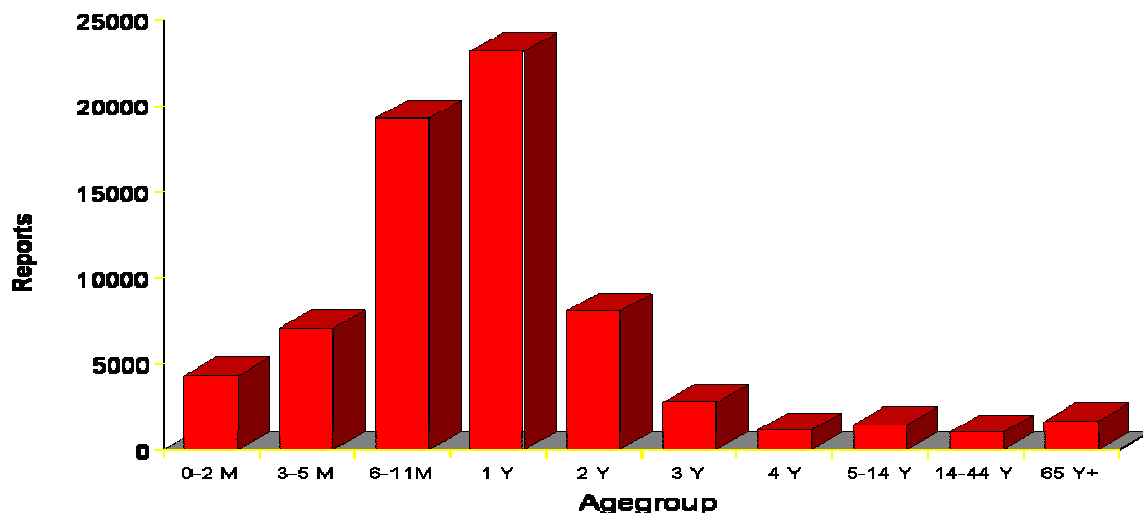
Rotavirus infection is the single most common cause of gastroenteritis in children in the world, and is estimated to be responsible for over 400,000 deaths in children under 5. In the UK, rotavirus infection can occur at any age but is commonly seen in infants between 6 and 12 months. It is not believed to lead to fatalities in the UK, but does to result in a large number of GP consultations and hospitalisations each year.

A rotavirus vaccine may be of benefit to the UK by reducing the incidence of hospitalisations and GP visits in young children. However, work was needed to update the burden of rotavirus disease in the UK and to assess the cost-benefit of introducing a rotavirus vaccine.

The Committee asked for the subject to be kept under review.

Figure 1

### Age distribution of rotavirus infections reported England and Wales 1990-1994 (n=75,059)



Source: Laboratory confirmed reports, HPA

<sup>1</sup> Strains identified from nursery children who had mild asymptomatic rotavirus disease

### 3.7 Long Term effectiveness of Meningitis C and Hib conjugate

The Committee considered the long-term effectiveness of MenC and Hib vaccines. Both vaccines are routinely offered to babies at 2, 3 and 4 months of age. Since the vaccines had been introduced in the UK, the rates of both Hib disease and meningococcal group C infection have plummeted.

The Committee considered a recent paper published by Trotter *et. al* (Trotter *et. al* 2004; Lancet 364; 365 - 366) which suggested that the protection provided by a primary course of MenC in young infants wanes in the second year of life. Similar research has been published on the protection offered by Hib vaccine (Ramsay *et. al.* 2004; Journal of Infectious Disease 188; 481-485).

It was noted that cases of meningitis C in children remained very low in number; and that cases of Hib infection had fallen following the recent Hib booster campaign. Therefore the risk of these infections remains low. It was felt that the issue of waning immunity following a primary course of these conjugate vaccines at 2, 3, and 4 months needed to be examined further. The Committee wanted to consider whether a booster dose of Hib and MenC vaccines was needed to ensure a high level of protection throughout infancy and beyond.

The Committee then agreed to review evidence on how protection against Hib and MenC can be maintained through infancy and beyond.

#### ***ACYW135 polysaccharide meningococcal vaccine in children aged under 5 years***

Current advice for Hajj pilgrims is that children aged 6 months to two years of age should be offered two doses of Meningococcal ACYW135 vaccine, with an interval of three months between each dose. The Committee's attention was drawn to a recent study (unpublished) on the serological response to the meningitis ACYW135 vaccine.

The Committee noted that outbreaks of meningitis, particularly meningitis W135, had previously occurred in association with the Hajj. The Committee also noted that children under 18 months of age in the UK should have already received MenC vaccine during the first year of life, and that other vaccines to protect against A, Y and W135 for this age group were not readily available nor were they likely to provide a better level of protection.

The Committee advised that the recommendation for use in children over six months of age attending the Hajj should remain unchanged. Parents taking children aged 6-18 months of age to the Hajj should be warned that the recommended MenACYW135 vaccine only provides a low level of protection against meningitis Y and W135.

### **3.8 The Meningitis C Vaccine**

The Committee's attention was brought to a change in the licence for Neisvac – one of the MenC vaccines used in the UK routine immunisation programme.

Neisvac, along with the other MenC vaccines used in the routine childhood immunisation programme, was licensed for use in a three dose regime, and had been given at 2, 3 and 4 months of age routinely since introduced. Now one of the MenC vaccines, Neisvac, is licensed for use in a two-dose regime, given 2 months apart from 2 months of age. However the other MenC vaccines remained licensed for a 3-dose schedule.

The Committee considered that using one vaccine in a two-dose programme whilst others were recommended for three doses could cause confusion in the national programme. It might even result in missed necessary doses, so leaving some children poorly protected.

JCVI agreed to continue to recommend a 3-dose schedule for all MenC vaccines used in the routine childhood immunisation programme.

### **3.9 Respiratory Syncytial Virus**

Respiratory Syncytial Virus (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 November 2002, the JCVI recommended that babies under 2 years of age with severe chronic lung disease, who are on home oxygen during the respiratory syncytial virus (RSV) season, should be offered palivizumab to protect them against RSV. It further recommended that treatment should be considered on a case-by case basis for babies with rare conditions such as multiple congenital abnormalities or severe immunodeficiency.

The Committee asked that the JCVI RSV sub-group be contacted to determine whether they were aware of any new relevant information that might influence the recommendation. If needed, the subject would be reviewed.

### **3.10 Vaccination against Q Fever**

The Committee was asked to consider if occupational vaccination against Q fever should be recommended.

The vaccination is currently recommended for occupational use in Australia and has been reported to be 100% effective. However, this report is questionable as other evidence suggests that some immunised individuals acquired the disease. The disease is occupationally acquired but the burden of the disease is difficult to assess. The vaccine contains thiomersal.

There were several unknowns, such as who was at risk of Q fever in the UK, the efficacy of the vaccine; and the data concerning the risk of vaccinating individuals previously exposed to Q fever.

The Committee asked for more information particularly about the burden of disease in the UK before reconsidering the proposal.

### **3.11 StaphVAX for end stage renal disease**

The Committee's view was sought on a NICE briefing paper on the prevention of *Staphylococcus aureus* infections in end stage renal disease. Confirmatory controlled studies remained desirable particularly with regard to the types of *Staphylococcus aureus* the vaccine protects against.

The Committee thought it important that NICE was informed that the Department of Health was funding work through the National Vaccine Evaluation Consortium on the use of this vaccine prior to elective surgery. Reducing the risk of *Staphylococcus aureus* infection in those undergoing surgery would clearly be of great benefit.

### **3.12 Openness**

The Committee reviewed its policy on openness. It was content with the policy to increase the openness of the work of the Committee, and agreed that a greater use of

statements on key policy issues may help explain the position of the Committee to the public.

The Committee reviewed its papers and concluded that the declaration of interests should be explained in plain English.

## **4. Issues brought to JCVI's attention for information and if necessary recommendation.**

### **4.1 Vaccine uptake data**

The Committee reviewed the latest routine childhood immunisation uptake data at each meeting. Quarterly data collected through the COVER programme for England, Wales and Northern Ireland for July 2003 to June 2004 was provided to JCVI for information. In Scotland the equivalent information is collected through SIRS.

At 12 months of age, approximately 90-92% of UK children were fully up-to-date with their routine immunisations. Scotland and Northern Ireland maintained rates of around 95%. The figures for England were lower due to the uptake rate in London being between 80 – 83%.

At 24 months, around 93-94% of UK children were up to date with all routine vaccinations, with the exception of MMR. At 24 months, 80-82% of UK children had had one dose of MMR. By five years of age, 90-91% of children had had one dose of MMR.

Across the board, uptake in Scotland and Northern Ireland are consistently higher than England for all vaccines. Wales reported that they had areas in Wales where uptake was low. Wales also noted that they were considering carrying out a catch up campaign to identify young people under the age of 19 who have not had two doses of MMR because of the risk of mumps in those without adequate protection.

Similar patterns were seen as before, with uptake levels of all vaccines tending to be higher in Scotland, Northern Ireland and Wales than in England. In England, the recorded uptake levels for all vaccines is significantly lower in London than elsewhere in the country.

## *Trends in Vaccine Uptake over the last 10 years*

The Committee considered a paper examining trends in vaccination coverage in the UK over the last 10 years. The paper was based on data collected and published by the HPA and showed a gradual decline in uptake levels of some antigens, even though figures remain higher than 90% for all vaccines apart from MMR. However there has been an upturn in MMR coverage recorded over the last year.

The Committee expressed concern about low vaccination rates in some parts of the country. The following factors may contribute to the lower recorded vaccination coverage in London:

- information data collection methods in some areas are antiquated and may result in poor capture of the information data. Investing resources to ensure information data is recorded more accurately would be expected to increase the recorded vaccine uptake.
  
- the number of staff vacancies, particularly among health visitors in London, and the relatively high turnover of staff in some London boroughs present challenges to implementing effective vaccination programmes.
  
- the relationship between the health professional and parent/patient is considered to be very important in all areas of primary care. Competing priorities within primary care, coupled with the staffing issues above, does put pressure on the quality of service that health professionals made available.

It was pointed out that the priority given at the local level to the various services made available is strongly influenced by whether it is a service for which performance indicators have been set. The priority given to immunisation has gone down in some areas because it is not now an area (with the exception of MMR) where performance indicators are set.

The Committee expressed its concern at the low vaccination rates in some areas, and noted that central performance management may help ensure immunisation receives the priority it merits. The Secretariat was requested to take this recommendation forward with the Department.

The Committee also considered a technical paper on the impact that re-organisation in the NHS may have had on the recording of vaccine uptake figures. This paper showed that recent changes in the NHS have had an impact on the COVER programme. The size of the denominator population measured by the COVER programme tends to be lower than that recorded by ONS. This difference increased significantly in 2002 at the time of major reorganisation of NHS primary care (Shifting the balance of power), suggesting that children were 'lost' to the COVER programme because of the effect of NHS reorganisation both on data flows and on those with responsibilities for ensuring data quality. This effect may result in vaccine coverage being over- rather than underestimated if the "lost" children have lower coverage.

#### **4.2 Hib Immunisation**

Following the recent Hib campaign, the Committee was updated on laboratory confirmed cases of Hib disease for 2003.

For 2003 there were 266 cases compared to 269 in 2002. In the last quarter of 2003 there were 74 cases in total compared to 120 cases in 2002. The rate of disease in the under 4 years (19 cases in 2003 compared to 58 cases in 2002) showed a large reduction in Hib disease suggesting that the Hib campaign had been very effective in those immunised but as yet there was no evidence of a herd immunity effect.

Initial vaccine coverage data from the recent Hib booster campaign was presented. Coverage in the 1-3 year old age group was 64%, and was 72% in the younger (6-12 months) age group. There were concerns that there was a wide range of levels of uptake within a PCT. There was some discussion as to whether any action should be taken in the areas where uptake was low similar to what was done with MMR low uptake areas.

Further work is required to analyse the coverage data with follow-up of the lowest reports to verify the data. Further action will be needed if the coverage was as low as reported from some localities.

It was noted that the UK was not the only country to experience an increase in Hib circulating in the community. It was recognised that the JCVI would need in the future to

review the evidence of whether an additional dose of Hib vaccine should be offered in the routine immunisation schedule and, if so, as what age.

### **4.3 Pneumococcal vaccination for older people**

From April this year, people aged 75 years and over are being offered pneumococcal vaccine. This follows on from the campaign last year to protect those aged 80 and over. No problems with supplies of the adult pneumococcal vaccine are anticipated.

Scotland and Northern Ireland introduced this vaccine to individuals aged 65 years and over in 2003/04. Initial estimates suggests that uptake in Scotland may be 60 - 70%. It was noted that the vaccine uptake data for the campaign for older people in 2003/04 in England would be available in time for the next meeting of JCVI.

The HPA provided an update on their enhanced surveillance of the pneumococcal programme for the elderly. Their report focused on preliminary data from individuals aged 80 years and over who were first vaccinated in England from August 2003.

Significant numbers of older people aged 80 years or over received pneumococcal vaccine prior to the introduction of the universal programme because they fell within one of the at risk groups. The new programme had resulted in a 26% increase in coverage in this age group so that by 31st March 2003, 62% people aged 80 years and over had been immunised.

The initial data suggested that pneumococcal vaccine had not yet resulted in a decrease in invasive pneumococcal disease in this age group. Further analysis of the data were required, and surveillance of disease in these groups will continue. As the programme is rolled out, the surveillance is being extended to cover the new target groups.

The impact of introducing pneumococcal vaccination for all individuals aged over 65 years in Scotland was discussed. Overall uptake was 66%, and preliminary results suggest that there may have been a decrease in invasive disease in the over 65s, in contrast to all other age groups, for which increases were recorded. Surveillance data continue to be analysed and vaccination details for cases of invasive pneumococcal disease have been sought.

#### **4.4 Influenza**

The Committee was updated on the success of the influenza immunisation campaign last winter. The overall vaccine uptake for those aged 65 and over was 71% in England, 1% higher than the 70% target set at the start of the campaign.

The Committee agreed that the 2004/05 programme should focus on the at-risk groups in younger age groups as well as those aged 65 years and over. It was noted that GPs are now required to set up disease based registers which will enable 'at risk' groups to be targeted more effectively. It was noted that the Department could work through the Royal College of General Practitioners and the Royal College of Paediatrics and Child Health to encourage GPs to have accurate 'at risk' registers particularly for vulnerable children. The Committee accepted the recommendation of the Influenza Panel that, at a GPs discretion, main carers of an elderly or disabled person should be recommended influenza vaccine, if maintaining the cared person at home would be jeopardised by the carer catching flu.

The Committee also briefly commented on the risk of influenza to pregnant women and to the developing fetus. The JCVI Flu Panel would consider the available evidence at its next meeting.

The Committee supported the proposal to fund a study by the HPA on the potential benefits of routinely immunising young children. It was agreed that findings should be presented to JCVI in one year.

#### **4.5 Meningococcal immunisation**

The Committee was informed that the CSM had considered the issue of Men C conjugate vaccine and relapses of nephrotic syndrome. CSM, in considering the available evidence noted some uncertainties in the evidence and concluded that a warning of a possible adverse effect rather than a contra-indication in nephrotic patients was appropriate.

#### *Hajj*

The Committee was reminded that in 2000, 45 cases of W135 meningococcal infection were identified in UK residents and eight people died. Some had recently returned from

the Hajj but the infection also spread to people in the community. In 2001, 38 cases and 10 deaths related to the Hajj were reported in the UK.

In 2001, the Department of Health launched an awareness campaign to alert all pilgrims travelling to Saudi Arabia for Hajj and Umrah, about the risk of meningococcal W135 infection and advising vaccination against the disease. Since then, no deaths from W135 infection have been reported in the UK linked to the Hajj. There was however one cluster last year in one family. The Department will continue to run its awareness campaign for those attending the Hajj in 2005, it has also awarded a Section 64 grant to the Association of British Hujjaj, a voluntary organisation working for the welfare of British pilgrims. They will be organising seminars and events around the country regarding health management and prevention of communicable diseases specifically targeted at British Hujjaj (pilgrims) and hard to reach groups. This grant will support efforts to increase awareness of the need for immunisation.

#### **4.6 BCG**

The BCG vaccine formerly supplied by Evans and now by SSI had been associated with an increased reporting rate of suspected adverse reactions, mainly vaccination site reactions including abscesses. There has also been increase in reporting of vasovagal reactions to the injection, including syncope. The overall increase may be due to a combination of the new vaccine being more immunogenic than the previously used vaccine, the need for more precise immunisation technique, and an increased reporter base (nurses were included as reporters to the Yellow Card Scheme at the time when the vaccine was introduced). The Committee on Safety of Medicines had reviewed the evidence and concluded that no new safety signals had been identified. The Department was developing a BCG vaccination training video demonstrating the intradermal vaccination technique, which would be circulated to help staff who administer the vaccine.

#### **4.7 Poliomyelitis**

The Committee was updated on progress to eradicate polio, and was presented with the latest report on the global count of polio cases (see [www.polioeradication.org/casecount.asp](http://www.polioeradication.org/casecount.asp)). Excellent progress was being made in India and Pakistan. However, progress in Nigeria had reversed following a vaccine scare in the north of that country. While the number of cases in Nigeria had increased, the polio

campaign in Nigeria is now back on track with mass vaccination days taking place in the north of Nigeria.

#### **4.8 Pertussis**

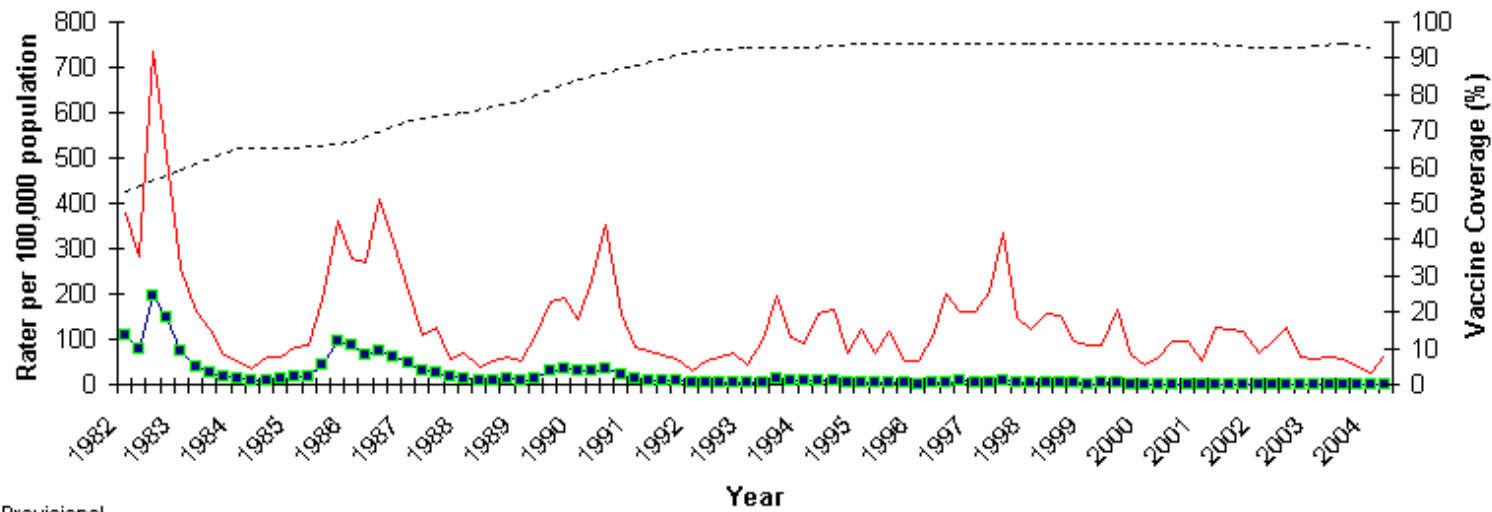
In 2001 a pertussis booster was introduced in to the routine UK schedule. Pertussis is a serious infection that has resulted in 53 deaths in England and Wales over the last 8 years. The UK vaccination programme has been successful in reducing the incidence of pertussis and the death rate (see figure 2). The incidence of disease is now at an all time low, and an epidemic peak that would have been expected in 2000-01 did not occur, which may indicate a lengthening of the inter-epidemic cycle or that transmission has been interrupted. The main burden of morbidity and mortality continues to be in infants under 3 months of age. Although an encouraging reduction in pertussis incidence has been seen in the last two years, it is too soon to evaluate the impact of the booster dose.

The Committee welcomed the review and asked to be kept updated on the issue.



Figure 2

**Pertussis notifications to ONS and vaccine coverage for children by their 2<sup>nd</sup> birthday England and Wales 1982-2004**



\* Provisional

— 0-2 months    —■— all ages    - - - - Vaccine Coverage



## ***Children's Vaccine Tracking Programme***

The Department has started a major new project on vaccine tracking.

The Programme was initiated by recommendations made in the Chief Medical Officers strategy "Getting Ahead of the Curve". The aim is to develop a more fully co-ordinated system within England that will link information about vaccines to individual children's health records.

The general benefits the programme is seeking to deliver are to:

- generally improve the quality of information assessing vaccine value
- enhance electronic links between NHS and DH stakeholders
- strengthen integration and access to relevant information
- develop the accuracy of the information collected
- improve the timing of relevant immunisation information to parents
- reduce wastage and duplication of resources where appropriate

The project is ambitious, complex and will take a number of years to take forward. However it was recognised as key in the future of UK immunisation.

The Committee welcomed this initiative.

### **4.9 National Expert Panel on New and Emerging Infections**

Members were reminded that this Committee was set up in response to the CMO's Infectious Disease Strategy "Getting Ahead of the Curve". Professor Christopher Bartlett chairs the Panel, and Professor Langman attends as Chairman of JCVI.

The Chairs of the various advisory Committees have agreed to propose topics that they believed warrant consideration by the Panel in its first year.

Members were asked to identify any issues which JCVI believe the Panel needs to consider. The Committee accepted that flu and tuberculosis remained critically important.

#### **4.10 Yellow card data**

The Committee was provided with a paper by MHRA outlining the patterns of suspected adverse drug reactions (ADRs) received during 2003 (as compared to 2001 and 2002) in association with DTwP+/-Hib, OPV, MenC, MMR, BCG, DTaP, HepB, HepA and influenza vaccine. With the exception of the DTaP/Hib and reduced efficacy issue and possible nephrotic syndrome relapse associated with MenC (both of which had been presented at previous JCVI meetings) no significant safety issues had been identified.

#### **4.11 Vaccine damage payment**

A summary paper on claims received through the vaccine damage payment scheme (a scheme independent of Department of Health) was provided for information. The only point of note was an increase in the number of claims received which cited DTP and neurological reactions, which was thought to follow recent media articles. It was noted that this information was provided to the department for their information only and that the DH could not influence decisions made on these or any other claims.

## **5. Information Provision**

- How to find JCVI minutes.

Website link to JCVI minutes is as follows;

**<http://www.advisorybodies.doh.gov.uk/jcvi/minutes.htm>**

- Green book chapters.

Website link to Green Book Chapters is as follows;

**<http://www.immunisation.nhs.uk/files/greenbook.pdf>**

- How to find out more about Immunisation.

Website link is as follows:

**<http://www.immunisation.nhs.uk>**

## **6. 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.

## 7. Papers brought to the Committee's attention

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

1. Chickenpox (Varicella) Immunisation and Healthcare workers; CMO letter (PL/CMO/2003/8) and information leaflet introduced in December 2003.  
Website link;  
[http://www.dh.gov.uk/PublicationsAndStatistics/LettersAndCirculars/ProfessionalLetters/ChiefMedicalOfficerLetters/ChiefMedicalOfficerLettersArticle/fs/en?CONTENT\\_ID=4065215&chk=iRTfLc](http://www.dh.gov.uk/PublicationsAndStatistics/LettersAndCirculars/ProfessionalLetters/ChiefMedicalOfficerLetters/ChiefMedicalOfficerLettersArticle/fs/en?CONTENT_ID=4065215&chk=iRTfLc)
2. Lancet 363 March 6, 2004 (commentaries). Expert Rev Vaccines. 2004 Feb; 3: 19-22 DeStefano F, Thompson WW. MMR vaccine and autism: an update of the scientific evidence.
3. DeStefano F, Bhasin TK, Thompson WW, Yeargin-Allsop M, Boyle C. Age at first measles-mumps-rubella vaccination in children with autism and school-matched control subjects: a population-based study in metropolitan Atlanta. Pediatrics.2004;113:259-66.
4. Geier D and Geier M. An assessment of the impact of thiomersal on childhood developmental disorders. Pediatrics Rehabilitation 2003; 6; 97-102.
5. Grier D and Grier M. A comparative evaluation of the effects of MMR immunization and mercury dose from thiomersal-containing childhood vaccines on the population prevalence of autism. Med.Sci. Monit 2004; 10: 133-139.
6. Bradstreet et.al. A case control of mercury burden in children with autistic spectrum disorders. Journal of American Physicians and Surgeons 2003;8: 76-79.
7. Correspondence - Journal of American Physicians and Surgeons 2003; 8 68-70.
8. Clarkson TW, Magos L and Myers GJ. The toxicology of mercury - current exposures and clinical manifestations. NEJM 2003; 349: 1731-7.
9. New England Journal Medical 2004; 350: 945-947.
10. Offit P, Jew RK. Addressing parents concerns: Do vaccines contain harmful preservatives, adjuvants, additives or residuals? Pediatrics 2003; 112; 1394-1401.
11. Clements C J. The evidence for the safety of thiomersal in newborn and infant vaccines. Vaccine.2003.11.017.
12. I Knezevic, E Griffiths, F Regigel. R Dobbelaer. Thiomersal in vaccines: a regulatory perspective WHO Consultation, Vaccine 22 (2004) 1836-1831.
13. The European Agency for the Evaluation of Medicinal Products. Public Statement on Thiomersal in vaccines for human use- recent evidence supports safety of thiomersal-containing vaccines.

14. Hviid A, Stellfeld M, Wohlfahrt J, and Melbye M. Childhood Vaccination and Type 1 Diabetes. *N Engl J Med* 2004;350: 1398-404. Validation of the diagnosis of autism in general practitioner records. Eric Fombonne, Lisa Heavey, Liam Smeeth, Laura C Rodrigues, Claire Cook, Peter G Smith, Linyan Meng and Andrew J Hall. *BMJ Public Health* 2004, 4:5.
15. Muhle R, Trentacoste S V and Rapin I. The Genetics of Autism. *Pediatrics* 113 2004.
16. Hung C-C. *et. al.*(2004). Clinical experience of the 23-valent capsular polysaccharide pneumococcal vaccination of HIV-1-infected patients receiving highly active antiretroviral therapy: a prospective observational study. *Vaccine*, (2004) 22; 2006-12.
17. Chen W. *et. al.* (2004). No evidence for links between autism, MMR and measles virus. *Psychological Medicine*, 34;543-553.
18. Bradstreet J.J *et. al.*(2004). Detection of measles virus genomic RNA in cerebrospinal fluid of children with regressive autism: a report of three cases. *Journal of American Physicians and Surgeons*, 9 (2; 38-45.
19. Jick H & Kaye J.A. (2004). Autism and DPT vaccination in the United Kingdom. *New England Journal of Medicine*, June 24;2722-73.
20. Fombonne E. *et.al.* (2004). Validation of the diagnosis of autism in general practitioner records. *BioMedCentral Public Health* (<http://www.biomedcentral.com/1471-2458/4/5>).
21. Goldman G.S. & Yazbak F.E. (2004). An investigation of the association between MMR vaccination and autism in Denmark. *Journal of American Physicians and Surgeons*, 9; 70-75.
22. Stott C. *et.al.* (2004). MMR and Autism in Perspective: the Denmark Story. *Journal of American Physicians and Surgeons*, 9; 89-91.
23. Heron J. *et. al* (2004). Thimerosal exposure in infants and developmental disorders: A prospective cohort study in the United Kingdom does not support a causal association. *Pediatrics*, 114; 577-583.
24. Andrews N. *et. al.* (2004). Thiomersal exposure in infants and developmental disorders: a retrospective cohort study in the United Kingdom does not support a casual association. *Pediatrics*, 114; 584-591.
25. Parker SK. *et. al.* (2004). Thiomersal-containing vaccines and autistic spectrum disorder: a critical review of published original data. *Pediatrics*, 114; 793-804.
26. Smeeth L. *et. al.* (2004). MMR vaccination and pervasive developmental disorders: a case-control study. *Lancet*, 364; 963-969.

Committee members did not find any evidence, which altered its previous opinions.

## 8. Members of the JCVI Committee

### Chairman:

**Professor Michael Langman BSc, MD, FRCP, FMedSci**

Professor of Medicine Emeritus, University of Birmingham

### Members:

**Professor Keith Cartwright MA, BM, FRCPath**

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

**Professor Jonathan Cohen FRCP, FRCPath, FRCPE, FMedSci**

Infectious Disease Physician; Chairman, Department of Infectious Diseases and Microbiology, Imperial College School of Medicine; Hon. Consultant Physician, Hammersmith Hospitals Trust

**Dr Yvonne Doyle MB FRCPI, FFPHM, FFPHMI, MPH, DCH.**

Director of Public Health & Medical Director, South East London Strategic Health Authority

**Professor Alan Emond MA, MD, FRCP, FRCPHCH.**

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

**Professor David Goldblatt MBChB, MRCP, PhD**

Professor of Vaccinology and Immunology, Institute of Child Health and Great Ormond Street Hospital, London

**Professor Paul Griffiths BSc, MD DSc, FRCPath**

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

**Professor Andrew Hall MB BS, MSc, PhD, FRCP, FFPH.**

London School of Hygiene and Tropical Medicine.

**Professor Simon Kroll MA, FRCP, FRCPCH, FMedSci**

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

**Vivienne Parry BSc (Lay member)**

Writer and Broadcaster.

**Dr Richard Roberts MB BS, BSc, DCH, MPH, FFPH MEPHM.**

Consultant in Communicable Disease Control, Vaccine Preventable Disease Programme, National Public Health Service, Wales.

**Mrs Joan Sawyer RGN (Nursing representative)**

Patient and Public Involvement Manager for the same PCT, Richmond and Twickenham.

**Professor Brent Taylor PhD, MBChB, FRCP, FRACP, FRCPC**

Community Child Health/Community Paediatrician; Professor of Community Child Health, Royal Free and University College Medical School

**Dr Christopher Verity MA, FRCP, FRCPC, DCH, DRCOG**

Consultant Paediatrician and Neurologist, Addenbrook's Hospital Cambridge.

**EX-OFFICIO**

**Dr Claire Cameron BSc (Hons), PHD, MSc.**

Epidemiologist (Immunisation), Scottish Centre for Infection and Environmental Health.

**Professor George Griffin BSc, PHD, MBBS, FRCP(Lon, Edin), FRCPath, F.MedSCI**

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

**Professor David Hill MD, DTMTH**

Director, National Travel Health Network and Centre. Honorary Professor, London School of Hygiene and Tropical Medicine.

**Dr Stephen Inglis, BSc, PhD**

Director National Institute for Biological Standards and Control.

**Professor Angus Nicoll CBE, FRCPH, FFPHM, FRCP.**

Director, Communicable Disease Surveillance Centre (CDSC), Health Protection Agency.

## 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.

**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 .....

## 10. Register of members' declaration of interests

<b>Joint Committee on Vaccination and Immunisation</b>			
<b>Declaration of Members' Interests</b>			
<b>Chairman: Professor Michael Langman</b>			
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	
<b>Professor Keith Cartwright</b>			
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.	
<b>Professor Jonathan Cohen</b>			
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	Cambridge Antibody Technology (and member of the	Zen VC (Scientific Advisory Board, potential share entitlement.

Board)	Scientific Advisory Board)	Company involved in	
<b>NON-PERSONAL INTERESTS:</b>			
<i>Fellowships</i>	<i>Industrial support</i>	<i>Other</i>	
None.	Baxter	None	
<b>Dr Yvonne Doyle</b> PROFESSION/TITLE: Director of Public Health & Medical Director, South East London Strategic Health Authority			
PERSONAL INTERESTS: None			
NON-PERSONAL INTERESTS: None			
<b>Professor Alan Emond</b> PROFESSION/TITLE: Professor of Community Child Health at the 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
<b>NON-PERSONAL INTERESTS:</b>			
<i>Fellowships</i>	<i>Industrial support</i>	<i>Other</i>	
None.	None	None	
<b>Professor David Goldblatt</b> 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 expert panels for Glaxo SmithKline Biologicals, Wyeth Lederle Vaccines and Pasteur Merieux Connaught	Produced a clinical expert report on meningococcal C conjugate vaccine produced by Wyeth Vaccines.  Produced expert reports for GSK on MMR up to March 2003	None	None

NON-PERSONAL INTERESTS:

<i>Fellowships</i>	<i>Industrial support</i>	<i>Other</i>
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None.	Wyeth Lederle Vaccines; Glaxo SmithKline Biologicals, Baxter Aventis-Pasteur	None
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**Professor Paul Griffiths**

PROFESSION/TITLE:  
PROFESSOR OF VIROLOGY, ROYAL FREE AND UNIVERSITY COLLEGE MEDICAL SCHOOLS

PERSONAL INTERESTS:

<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
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Ad hoc consultancies for Pharmacia and Wyeth-Ayerst. Both concern the development of antiviral drugs; neither concerns vaccines	None.	None	None
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NON-PERSONAL INTERESTS:

<i>Fellowships</i>	<i>Industrial support</i>	<i>Other</i>
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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.
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**Professor Andrew Hall**

PROFESSION/TITLE:  
LONDON SCHOOL OF HYGIENE AND TROPICAL MEDICINE

PERSONAL INTERESTS:

<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
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None	None	None	None
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**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>
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None	Participated on vaccine research review panel for Shire.	None	None
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NON-PERSONAL INTERESTS:

<i>Fellowships</i>	<i>Industrial support</i>	<i>Other</i>
None	A current research project in his group is partly supported by Chiron Vaccines. In the past another project has been partly supported by Shire Pharmaceuticals. He has received grants (to cover travel/accommodation/Registration) from Wyeth Vaccines to attend open medical scientific meetings.	He is Vice Chairman of the medical-scientific advisory panel for the Meningitis Trust. He sits on the Wellcome Trust Medical Microbiology Fellowship Committee. Imperial College co-holds with the Centre for Applied Microbiology and Research patent rights in some products of their meningococcal vaccine research, for which they are seeking an industrial partner
<b>Vivienne Parry (Lay Member)</b> 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.		
PERSONAL INTERESTS:		
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i> <i>Other</i>
		None      None
NON-PERSONAL INTERESTS:		
<i>Fellowships</i>	<i>Industrial support</i>	<i>Other</i>
None.	None	None
<b>EX-OFFICIO:</b>		
<b>Dr Claire Cameron</b> 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.	None	
	Support from Wyeth Vaccines to attend the European Society for Paediatric Infectious Diseases Annual Conference (April 2003).		
<b>Professor George Griffin</b>			
PROFESSION/TITLE: PROFESSOR			
PERSONAL INTERESTS:			
<i>Consultancies</i>	<i>Fee-paid work</i>	<i>Shareholdings</i>	<i>Other</i>
Microscience Scientific Advisory Board. Pharmacia Scientific Advisory Board.	None	None	None
NON-PERSONAL INTERESTS:			
<i>Fellowships</i>		<i>Industrial support</i>	<i>Other</i>
Wellcome Trust Research Fellowships		None	None
<b>Professor David Hill</b>			
PROFESSION/TITLE: Director, National Travel Health Network and Centre. Honorary Professor, 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	Acambis	None
NON-PERSONAL INTERESTS:			
<i>Fellowships</i>		<i>Industrial support</i>	<i>Other</i>
None		Glaxo Smith Kline	None
<b>Dr Stephen Inglis</b>			
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:			

NIBSC'S role is to assure the quality of biological medicines. This is achieved through product testing, development of tests and reference materials, and applied research. NIBSC is an Official Medicines Control Laboratory within the EU and in carrying out its role, it interacts with a wide range of product developers and manufacturers. In some instances, NIBSC charges commercial organisation for its products and services, in line with guidance issued from HM Treasury ('Fees & Charges Guide' and 'Selling into Wider Markets'). It conducts official batch release testing (OCABR) on products from a large number of manufacturers. In addition the following specific contract and agreements were in place during 2004:

<i>Fellowships</i>	<i>Industrial support</i>		<i>Other</i>
None	Amgen Aventis Behring GmbH Baxter AG Berna Biotech Bio Products Laboratory Boots/Wellcome BTG Ltd Celsus Labs Inc EBioscience GSK  Hoffmann-La Roche Lipoxen Tech. Ltd Miltenyo Biotec MTL NGI Serono, Italy West Pharma	Product testing Product testing Reference Materials Serology tests Product testing Pyrogen testing Licence agreement Product testing Licence agreement Vaccine testing and research; serology testing Reference Materials Vaccine research Licence agreement Product testing Reference Materials Antibody testing Product formulation	None

**Professor Angus Nicoll**

PROFESSION/TITLE:  
DIRECTOR OF HEALTH PROTECTION AGENCY

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

## **11. 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**

## **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).