NOT FOR PUBLICATION

JCVI(00)1

JOINT COMMITTEE ON VACCINATION AND IMMUNISATION

MINUTES OF THE MEETING HELD ON FRIDAY 7 MAY 1999

Agenda Item Number 2.

JOINT COMMITTEE ON VACCINATION AND IMMUNISATION

Minutes of the meeting held on Friday 7 May 1999
10.30 Room 102A/124A, Skipton House

ATTENDING

Members:
Professor Sir David Hull (Chairman)
Dr Robert Aston
Dr Barbara Bannister
Professor Keith Cartwright
Dr Stephen Conway
Miss Gillian Creighton
Dr David Goldblatt
Dr David Joynson
Dr Marie Ogilvie
Professor Lewis Ritchie
Dr Richard Smithson

Ex-Officio:

Dr Ian Jones	-	SCIEH
Dr Geoffrey Schild	-	NIBSC

Observers

Ms Jo Yarwood	-	HEA
Mr Zoltan Bozoky	-	HEA
Dr Barbara Davis	-	SODoH
Dr Bill Smith	-	Welsh Office
Mr Mike Burns	-	Welsh Office
Dr Elizabeth Mitchell	-	DHSS, NI
Wg CDR Andy Green	-	MOD
Dr A Croft	-	MOD
Dr Norman Begg	-	PHLS
Dr Elizabeth Miller	-	PHLS/CDSC
Dr Mary Ramsay	-	PHLS/CDSC
Dr Barbara MacFarlane	-	MRC
Dr van Wijngaarden	-	Ministry of Health, The Netherlands

Department of Health:

Dr David Salisbury	-	Medical Secretary to JCVI
Mr Nick Adkin	-	Administrative Secretary to JCVI
Dr Jane Leese		
Dr Hugh Nicholas		
Mr Robert Freeman		
Dr Tsintis	-	MCA
Dr Rogers	-	MCA
Ms Carole Fry		
Dr Arlene Cook		
Mrs Debby Webb		
Miss Josie St Juste		
Mrs Loraine Gershon		
Miss Emma Wilbraham		
Mrs Monica Francis		

1. ANNOUNCEMENTS AND WELCOME

The Chairman welcomed the following observers to their first meeting of the Committee: Dr MacFarlane (Medical Research Council); Dr Tsintis (Medicines Control Agency); Dr Croft (Ministry of Defence, replacing Lt. Col. St. John Miller); Mr Burns (Welsh Office); and, Dr Cook (replacing Ms Campbell who was on maternity leave) and Mrs Francis from the Department of Health.

Apologies were received from Professors Anderson, Hall and Langman and Drs Kennedy, Nicholson, Walford and Bartlett from the Committee; Dr Devlin (Republic of Ireland), Mrs Godfrey (DHSS, Northern Ireland), Miss Mithani from the Department of Health and Dr Lee from the Medicines Control Agency.

The Chairman announced that Dr John Lunn had resigned from the Committee.

Dr Salisbury informed the Committee that Professor Hull was attending his final Committee meeting as Chairman; Dr Salisbury thanked Professor Hull on behalf of the Secretary of State for his input and leadership.

The Chairman reminded members that the minutes and proceedings of the JCVI were confidential. Politically and clinically sensitive material was dealt with by the Committee and this should be borne in mind, especially when dealing with the media. Members were at liberty to express personal views when speaking to the media, but should not speak on behalf of the Committee. Any enquiries should be redirected to the secretariat at the Department of Health. If there were any conflicts of interest over any items on meeting agendas these should be declared and members would be asked not to participate in discussions on those points.

2. MINUTES OF THE MEETING HELD ON FRIDAY 30 OCTOBER 1998 JCVI(99)1

These were accepted as a true record with the following amendments to paragraph 2.1 on ITP. Dr Miller commented that the statement that MMR may only precipitate ITP not cause it as there was no evidence of an overall increased risk with respect to the background was not correct. The paper presented had indeed shown an increased risk within 6 weeks of vaccination relative to the background rate in children of this age, which is evidence of a causal association. (See also 6.8 below).

3. JCVI MEMBERSHIP

Members were reminded that the terms of appointment of several members ended this May. The Secretariat was in the process of looking into new appointments and re-appointments; this would be done in accordance with guidance from the Commissioner for Public Appointments. The Secretariat would be writing to those members affected shortly and it would be appreciated if they could give thought as to whether or not they would be prepared to be considered for reappointment.

Members were reminded that some updated Declaration of Interests forms were still outstanding. Papers before the Committee (the 'Sunday Times' article and Ann Winterton's PQ) showed the current level of public and media interest in the private and professional interests of members' of advisory and other statutory bodies. The information members provided was in the public domain and members should keep the Secretariat informed of any changes.

A revised Code of Practice for members was being prepared. It would take into account the fact that members' Declaration of Interests is now in the public domain and also some clarification of detail eg. political role, liability which had been suggested by Cabinet Office. It was confirmed that only members needed to sign the Code of Practice; observers were covered by their terms of employment.

The Secretariat was to prepare an Annual Report for the Committee to be placed in the Library of Parliament. It would be a very modest document which would list the Committee's membership, terms of reference, a brief note on the topics discussed by the Committee (but not the outcome of the discussions which is confidential advice to Ministers and appeared in due course in HSCs/CMO letters and, ultimately, 'Immunisation against Infectious Disease') and Declaration of Interests.

4. COVERAGE AND OTHER REPORTS

4.1 COVER Report and Immunisation Statistics JCVI(99)4

Report by Dr Mary Ramsay and Joanne White

Little new information had been received since the last meeting of the Committee. MMR uptake had fallen by 0.1% suggesting that public concerns about the vaccine had

been arrested. Data on MMR uptake at five years of age was now being regularly received and some catch-up had been seen by the time of the pre-school boosters, although uptake of MMR at pre-school age remained disappointing. The quality of the five-year data was not as good as the 24-month data.

4.2 Immunisation Coverage – Northern Ireland **JCVI(99)5**
Report by Dr E Mitchell

MMR uptake had stabilised.

4.3 Immunisation Coverage – Wales **JCVI(99)6**
Report by Dr B Smith

There were still some local pockets of opposition to MMR. An exercise had been conducted comparing media interest with outcome. Where local papers were against the vaccine there had been a drop in uptake. Parents did not now question the alleged side effects of the vaccine so much as the availability of single doses. There had been particular difficulties in Swansea where there was both a firm of solicitors specialising in suing doctors and a Health Authority Chairman who had said that single doses should be made available. Wales's efforts at increasing MMR uptake were commended.

4.4 Immunisation Coverage – Scotland **JCVI(99)7**
Report by Dr Barbara Davis

There had been a slight increase in MMR uptake. Uptake was lowest in rural health boards but poor reporting may have made the figures appear worse. Scottish data on uptake of the pre-school boosters was tabled. There was some suggestion that MMR uptake was under-reported in some areas. It was noted that, if coverage by age 5 had gone up, then coverage with the second dose had also gone up. Increase in uptake of the first dose was encouragingly 10% higher than for the second dose.

The committee discussed the issue of incentives for GPs to encourage MMR2 uptake. GPs were presently paid an Item of Service fee for MMR2 but this would become part of the pre-school booster target payment in due course. The move to include MMR2 in the target payments programme had been postponed from January 1999 because of the difficulties concerning MMR. There was, in practice, no net difference between an Item of Service fee and a target payment. The Department's approach to this issue was agreed, but the Committee asked that financing of the second dose be re-visited.

4.5 BCG Questionnaires - Data Summaries **JCVI(99)8**
Report by Dr Mary Ramsay

The results of this survey reinforced concerns about the implementation of the selective BCG immunisation policy with huge diversity being seen on when BCG was given, by whom and how it was monitored. The survey results suggested that advice on such as which group should be targeted and how to deliver the vaccine was needed in order to improve uptake. The implementation of recommendations

arising from this exercise depended on local circumstances. Dr Aston had conducted an audit of BCG immunisation in his authority that had shown that only 7% of risk groups received antenatal BCG. It was felt that policy was unclear, that there was no protocol and that the success of any programme locally depended on individual clinicians. In Dr Aston's authority, cases had been followed through and, with the Immunisation Co-ordinator (with whom the responsibility rested) working with the chest physician, big improvements in uptake had been seen. A creative approach, making full use of training opportunities, was essential. 'Immunisation against infectious disease' was not clear on selective BCG vaccination policy and there was variation of practice across the country.

The Department was to convene a group to review the results of the latest PHLS survey of notifications of TB in England and Wales that would consider BCG immunisation policy. It was agreed that the Committee should revisit this issue at a later date once this further information became available.

4.6 (i) (a) Surveillance of Congenital Rubella in Great Britain 1971 to 1996 **JCVI(99)9 & 10**

Report by Dr Pat Tookey and Professor Catherine Peckham

This was presented for information. There had been no cases of CRS in 1997 and probably none in 1998. The 1996 increase may therefore, have been a one-year 'blip' reflecting the increase in rubella in 1994/95. There continued to be some cases of rubella in universities, mainly in overseas students.

4.7 Vaccine associated Adverse Reactions

(i) (a) Vaccine Associated Adverse Reactions **JCVI(99)11**

Report by Dr Arlene Cook

This was a summary of data provided by the MCA relating to suspected adverse reactions and vaccines. On the whole, the same types of reaction were reported to previous years. The main differences were described in the paper.

a) MMR - There was substantially less reports in total (serious and non-serious) for MMR in 1998 in comparison to 1997, but similar to 1996. The numbers of serious reports were also less than in 1997. The majority of reactions were neurological. The total number of reports of autism and related disorders in 1998 were similar to the previous year.

b) Combined DTP-Hib – There was a slight increase in the number of reactions reported in 1998 in comparison to 1997, with the total number of serious reactions remaining the same. There were a slightly greater number of reports of hypotonic and febrile convulsions but overall the total number of neurological reactions was similar to the previous year.

c) Polio – A substantially greater number of reports were received in 1998 in comparison to 1997. This was due to an increase in the number of non-serious

reactions, particularly general disorders. However, there was an increase in the number of cardiovascular, neurological and respiratory reactions but to a lesser extent. There was no overall change in the total number of serious reactions.

d) Hep A – There were substantially less hepatitis A reports in 1998 but the types of reactions and number of serious reactions were similar.

e) Hep B – There was a slight decrease in the total number of serious reports in 1998 compared to 1997. There were proportionately less neurological reactions. Although the number of reports was small, there was a slight increase in the number of eye disorders in comparison to 1997.

(i) (b) Vaccine Damage Payment Scheme **JCVI(99)12**
Report by Dr Arlene Cook

There had been 265 claims for damage allegedly associated with vaccines since April 1996. 63% of these were for MMR, 14% for OPV and 16% for DTP. The predominance of neurological reactions was noted as was the one death from anaemia. The Committee expressed particular concerns about the claims against OPV.

4.7 (ii) (a) Long Term Studies of Adverse Reactions
Oral Report by Dr David Salisbury

Officials had considered how well placed the Department was to respond to claims regarding vaccines and possible long-term ADRs, however valid. It was often very difficult to identify what claims might arise in the future. In order to take this forward, the views of Ministers had been sought and it had been agreed to convene a meeting of, at least, the Chairman of relevant Committees, such as JCVI and CSM, to see how best to bring together all the relevant data and resources when claims of a long-term ADR arose. The group would look at what data we have now, decide what was needed to be done next, consider the mechanisms necessary and work out a strategy of how to react to suggested ADRs. It was recognised that studying the vaccines held in long-term repository such as at NIBSC (the cost of maintaining which was under-estimated) would prove valuable. The Committee felt that this was a difficult but an important task. It was requested that the Surgeon General be involved in this process.

4.7 (ii) (b) Task Force on Safer Childhood Vaccines **JCVI(99)13**
Report by the National Institutes of Health

The future of vaccines depended on public confidence in their safety as much as on good science and this report was recognised as a very useful document. In particular, the safety statement on page 2 was considered to be a useful definition. The paper was available on the Internet (at the NIAID site) together with the Jordan Report. It was noted that the paper recognised (at pages 23 and 24) that conducting large-scale studies to look for rare events was extremely difficult.

5. HEALTH EDUCATION AUTHORITY

Report by Jo Yarwood

JCVI(99)14

A preliminary paper reporting on Wave 16 of the Tracking Survey was tabled; it had not been fully analysed yet. A more complete summary would be provided.

6. MMR

6.1 Report from MCA on Progress on Autism Cases

Oral Report by the MCA

This was a progress report. After intense representation from a firm of solicitors, the CSM had agreed to review the cases of children received by the solicitors whom it was claimed had been damaged by MMR. An independent working group had been established to do this. 200 case reports had been received by the MCA and the working group had looked at 110 of these; after this number the working group had concluded that reviewing more cases would not change the balance of their views. A report was to be presented to CSM and this would be discussed at their meeting in May. Views on how best to present the conclusions of the working group and how to disseminate them were sought. The Committee asked to see a copy of the report as soon as it was available.

6.2 to 6.7 For Information

JCVI(99)15 to JCVI(99)20

It was noted that the annotations on page 6 of Dr Wakefield's paper on gastro-enteritis had been done before the paper had been received by the Department.

6.8 ITP

Oral Report by Dr David Salisbury

(Item 8.12(a) of the minutes of 30 October 1998 refers).

Common ground between the views of CSM and JCVI on this issue had been sought and the MCA and the Department had agreed the JCVI recommendation on this. It had also been agreed that the MCA would meet with Professor Hull and Dr Salisbury to discuss this further. The amended minutes to the CSM would then be discussed.

Following on from the request for information made at the last meeting (item 8.12(a)), it was reported that there was not any relevant data available at present from Finland. The Gillberg paper (JCVI(99)15) was considered very helpful and easily understood; the second opinion was very reasonable.

7. COMMUNICABLE DISEASE STRATEGY

Report by Dr Jane Leese

JCVI(99)21

This item was discussed after item 9.

8. MENINGOCOCCAL MENINGITIS

Use of new conjugate Group C meningococcal vaccines

i. This was the main agenda item for the meeting. Much information had been made available and important decisions were required of the Committee, particularly about the introduction of meningococcal Group C conjugate vaccine, of which three brands would soon become available. Any decisions would be dependent on the granting of product licences and the wording of those licences and, during the discussion, the Committee had to act on the assumption that licenses would be granted. The MCA was responsible for the safety, efficacy and quality of vaccines. The question for consideration by the Committee was how it would recommend that the vaccine should be introduced.

ii. Committee members were reminded that this issue, and the papers presented, was extremely sensitive, commercially and politically. It was requested that confidentiality be maintained. The Chairman asked for any declarations of interest. Professor Cartwright was involved in manufacturers' studies on the vaccines, including health trials. Dr Goldblatt was involved in one company-sponsored study and had provided a clinical expert report to the MCA for one manufacturer. Dr Jones was involved in trials for two of the companies involved. Dr Schild said that NIBSC was evaluating the vaccines. There were no objections to these members continuing to take part in the meeting and it was agreed that they would be able to provide a valuable input to the discussion in common interest.

8.1 Cases and deaths from Group C Meningococcal Disease 1997-99 — JCVI(99)22

Introduction by Dr David Salisbury

This data - which covered England and Wales - was an update on that presented at the last meeting of the Committee. The epidemiology continued to change and there was a continuing shift to more Group C disease with more cases and deaths in older people, especially in the 15 to 19 age group (Table 1). The deaths' data was probably better ascertained in older children than in younger ones. It was noted by the Chairman that the histograms for incidence were a little misleading since the numbers of children in the age bands were not equal.

8.2 Policy for Meningococcal C vaccine — JCVI(99)23

Report of meeting held on Friday 9 April by Dr Arlene Cook

8.3 Estimating the burden of Serogroup C meningococcal Disease — JCVI(99)24

Report by Dr Norman Begg

i. It was recognised that the incidence of disease was getting worse and that the pace of the research into new vaccines and the manufacturers work had increased. This had resulted in the necessity of bringing the issue to JCVI for advice sooner than originally anticipated.

ii. There was much data available. There were subtle differences in the incidence of mortality between the age bands. PCR testing had been introduced which had increased the discrepancies between laboratory and clinical reports. Some cases were not fully investigated and only the clinical diagnoses were available. Five epidemiological years (1993 to 1998) had been looked at to get the best estimates of meningococcal Group C disease incidence and mortality for England and Wales. The baseline was laboratory-confirmed cases from the Manchester Meningitis Reference Laboratory which had been extrapolated to cover the years before the introduction of PCR and adjusted for under reporting. Hospital episode statistics had been reviewed separately.

iii. Highlights in the data included: Table 2 (the unadjusted laboratory data). Table 4 (the rate per 100,000 population after all adjustments for PCR, under reporting etc) the final column of which showed clearly that the highest rates were in the under 1s, the second highest rates were in the under 5s and then the 14-19 year olds (16–17 year olds especially). Table 6 gave the unadjusted deaths data (the actual deaths through ONS) and showed that the age groups with the highest incidence had the highest mortality; the under 4s and the 15-19 year olds had similar figures. Table 7 had been scaled up for deaths in laboratory confirmed and clinically diagnosed cases: it showed fatality and ITU numbers. The conclusions from all this data were that the greatest burden was in the 0-4 and 15-19 year age groups, with case fatality rates being higher in teenagers than in the under 4s.

iv. A review of the literature on sequelae over a 30 year period had provided little good age specific data. The Canadian study, where 400 surviving cases had been looked at, was the best available. This had concluded that 15% of patients who had had meningococcal Group C disease had suffered sequelae. Of these, 5% were amputations, 12% were scarring, 2% were hearing loss and 1% were renal failure.

v. The Committee concluded that routine reporting underestimated the burden of disease, perhaps by as much as 1,000 cases over 5 years. Enhancing the surveillance of meningococcal disease would, therefore, be helpful. It was estimated that the burden of the disease was 5,000+ cases over a 5 years period. There was a significant burden of disease in adults with 25.4% of cases being in people over the age of 20 years. It was felt that the numbers were too small to show if age affected the rate of sequelae although other complications increased with age which suggested that this might be an underestimate. The National Meningitis Trust had been asked if they had any data as had Dr Kroll at St Mary's Hospital. The list of sequelae from the Trust was gruesome although the rate was very difficult to assess; much depended on clinical practice and the Trust's cases were probably the worst. There were also confounding factors such as the rate of disease and age. Whether the immunisation programme should focus on those with the highest rates or those with the most deaths depended on what the aim of policy was to be. It could be possible to find another 15% of cases not covered by the ONS data.

vi. It was agreed that it was important to think about the groups with the highest disease and equally the highest death rate. It was felt that the public image was of adolescents dying. Certainly, case fatality was highest in adolescents.

8.3 (a) Current epidemiology of meningococcal disease in Scotland and scope for prevention of group C disease by vaccination **JCVI(99)24a**

Report by Dr Peter Christie and Mr John Mooney

i. The data for Scotland mirrored England and Wales except for late 1997 when Group C disease started to overtake Group B. Figure 2 showed the changing epidemiology in Scotland. The deaths data at Figure 5 was not robust. More deaths occurred in the 15-19 year age group; it was not known why there were more deaths in this group in Scotland.

ii. The Committee was told that The Netherlands saw predominantly Group B cases (85%). Other European countries had more Group C disease than Group B. Spain had had a sudden increase in Group C cases 3 years ago, caused by a new strain, and had conducted local immunisation campaigns. It was not possible to explain why neighbouring countries had different rates of disease.

8.4.1 Meningococcal C Conjugate (MCC) Vaccine Evaluation Programme **JCVI(99)25**

Report by Dr Elizabeth Miller

i. Papers providing data on the new vaccines' safety and efficacy and data from the Department of Health funded studies were looked at; no other country had conducted similar studies. The Medicines Control Agency had also gathered lots of information and NIBSC was evaluating the vaccines. The data provided to the Committee related to the Wyeth product, which would be the first to become available. All available ADR data was included; the follow-up of ADRs had been up to the end of 4 to 6 weeks.

ii. It was an important feature of the infant studies (at 2, 3 and 4 months) that the vaccine had been shown to be highly immunogenic. The NAVA vaccine appeared to be immunogenic after only one dose whilst the other brands needed at least two doses. All the children in the study had had three doses and had been tested for immunogenicity after one dose. There was evidence for long-term induction of immune memory. A substantial body of data on the vaccine's immunogenicity in infants had been gathered and the new conjugate vaccine had been shown to provide apparently longer lasting protection than the polysaccharide vaccine used in adolescents. As with Hib vaccine, although some children had had undetectable levels of antibodies after one year, the vaccine had been shown to have induced an immune memory. There was no good evidence for the efficacy of the meningococcal Group C conjugate vaccine, only the surrogate of antibodies compared with those known to be protective against invasive disease. To actually test the efficacy of the conjugate vaccine it would be necessary to introduce the vaccine and then conduct a Phase III or Phase IV study to test efficacy; this would be very difficult to do and would delay introduction by 3 – 5 years.

iii. The Department of Health funded vaccine studies and other studies had looked at up to 3,000 children. Estimates of protection had been based on SBA

titres, where a SBA count greater than 32 indicated protection. The Chiron vaccine protected against Group C infection only (Group A had been taken out) and had been studied in Manchester. The highest immune response had been seen after one dose. There were no real differences in immunity levels after the second or third doses: it was neither better nor worse, only earlier. The immune protection following the NAVA meningococcal C conjugate/tetanus toxoid vaccine was better than that produced by the Wyeth vaccine. Protection came earlier through the NAVA vaccine and one dose may suffice. However, the NAVA vaccine was less developed than the others and the vaccine license would eventually be for a 2, 3 and 4 dose programme and there was no data for anything other than 3 doses until additional studies on 1 dose were completed. It was felt that it was important to plan the programme now and confirmation that the vaccines were equally effective could follow.

iv. The number of doses necessary to protect older children was considered as was the response to the later use of the polysaccharide vaccine. The response to the conjugate vaccine in older children was extremely good; only one had failed to achieve a SBA of more than 32. The polysaccharide response had been reduced. It was agreed that there was good evidence that one dose of the conjugate vaccine provided good protection in children greater than 1 year old.

v. Figure 1 showed the older age group; studies in this group were less complete, especially in respect of large safety studies in primary and secondary schools. The first study was not due till October 1999, but the Liverpool study had already started. The vaccine is similar to the diphtheria vaccine so it might be expected that some interference with response to other vaccines would be seen and, with the polysaccharide linked to the same proteins, it might be a concern regarding reduced immunogenicity when it was administered with other DT vaccines. This matter had been looked at (tables 8 to 10) and no safety concerns had arisen. However, these studies were incomplete and were insufficient to pick up small difficulties.

vi. The ELISA data showed no evidence of interference in immunogenicity arising from the new vaccine through prior immunisation with DT vaccine. Table D (for the school leavers) showed that the levels of antibodies pre-vaccine were as would be expected. No significant interference with the efficacy of other vaccines had been seen and giving other vaccines before or after giving the new conjugate vaccine did not inhibit the response to those other vaccines. The carbohydrates in the new conjugate vaccine may be significant for its efficacy and the levels of protection it gave and tests of the vaccines had shown them to be of very good quality. NIBSC quality assurance tests had been worked up and were ready to implement before the immunisation programme might start.

vii. In summary, the studies had shown that the meningococcal Group C conjugate vaccine was well tolerated in children at 2, 3 and 4 months as well as in toddlers, pre-school children and adolescents. Surrogate makers had shown that it is likely to produce good levels of protection. The question for the Committee was: should the vaccines be licensed and available in good quantities, how should they be

introduced into the national immunisation programme? Options had been listed by age groups. The Committee would have to decide what, if the vaccine was available only in limited amounts, the priorities should be and how it would be fitted into outbreak use.

viii. The Committee agreed that, if the vaccine was licensed and in ample supply and if safety and efficacy were proven – and the rider was that the Committee felt it was not well informed regarding the protection the vaccine offered – then there was a place in the routine programme for the vaccine. The Committee expressed caution in a number of areas which it felt needed to be measured very carefully.

ix. Members were asked how the vaccine should be introduced. **Dr Bannister** said that the high priority groups should be young children as the polysaccharide vaccine could be used in older groups, had no disadvantages and had some advantages. **Dr Conway** said that we needed to immunise both age groups but that he favoured vaccinating the adolescents first. **Professor Cartwright** said that the arguments for whether the 0–4 or the 15-19 year olds should be immunised first were very finely balanced. Immunising 15-19 year olds would be better because they would develop herd immunity which might benefit infants as most infants got infection from their older siblings. Of paramount importance was the need to cover both age groups as soon as possible and it was vital presentationally that the programme moves smoothly. The catch up programme was needed for other adolescents and then infants and then the rest. **Ms Creighton** agreed with Professor Cartwright. **Dr Smithson** said that there was very little to chose between the priority age groups but suggested that infants were easier to target. **Professor Goldblatt** said that, from the PR point of view, we should go for older children. **Professor Ritchie** said that the public would all want the vaccine but agreed with Professor Cartwright on presentation and logistics. **Dr Joynson** spoke of parental pressure; parents would feel that they had invested more in adolescent children and therefore adolescents should be targeted first. There should, however, be an absolute commitment to immunising everyone. **Dr Aston** said that mothers identified meningococcal C as primarily a childhood disease; a systematic approach and programme were required. **Dr Ogilvie** said that doing the teenagers brought protection to the home although delivery to 14 to 15 year olds would be difficult. Dr Rogers (MCA) pointed out that the vaccine would go further with the adolescents because one dose only would be required.

x. **In conclusion**, the Committee felt that, if sufficient vaccine was available, all children should have it: all those of school age (one dose) plus 2, 3 and 4 month olds (three doses). Targeting young people at university was more challenging, although the Committee felt that all up to 18 years old should get the vaccine. A strategy was needed, starting with the oldest and going down. Those between 4 months and 1 year would get two doses, 1 year on would get one dose. The Hib catch-up exercise provided a useful template. The Committee still needed reassurances on the safety and efficacy and cost benefits of the vaccine.

8.4.1 Availability of Meningitis C Conjugate Vaccines
Oral Report by Dr David Salisbury

i. It was thought that supplies from all 3 manufacturers would be available by the third quarter of 2000. This had been discussed with the manufacturers who had been asked if they could make it available in 1999. One manufacturer had already submitted a licence application, an action that they had made publicly known. This company could, subject to a product licence, sell the UK Government 3 million doses between October and December 1999; continuing availability of vaccine from this manufacturer after Christmas was unsure. Another manufacturer was able to make 1¼ million doses available from January 2000. The NAVA product was not due till mid 2000.

ii. It would be impossible to, at once, get 15 million doses to immunise all 0-20 year olds in the UK. To immunise in schools would mean immunising thousands of children per day. Immunising through GPs would be very different. 2, 3 and 4 month old children were already coming to GPs for vaccines and would, therefore, be reached easily. It was felt that it might be possible to deal with both ends of the target group simultaneously. The programme would be organised by monthly cohorts. 2, 3 and 4 month olds meant 300,000 doses would be used over 3 months; the rest of the vaccine would be for 16-17 year olds. It would only be possible to vaccinate as fast as the manufacturers could make the vaccine. Availability of the vaccine should be strictly controlled; it would not be possible to just flood the market and allow a 'free for all'. Resource provision was not yet resolved. Using this programme would ensure the higher risk groups were immunised first; the license did not control who was able to receive the vaccine.

iii. It was agreed that the vaccine should be given to 2, 3 and 4 months old children and 15-17 year olds and that other groups should be added as vaccine became available. It was noted that, during the Measles/Rubella immunisation campaign, 8 million school children had been immunised in one month. Whilst the seasonal peak of the disease was at the end of the year, the seasonality in teenagers was different. The new vaccine would not be ready for the next group of university entrants. The Committee said it was desirable to have two suppliers (although this was not the Committee's responsibility) as there was always a slight risk when only one supplier was available. It was recognised that problems could arise, such as parents of 15 month old children turning up for MMR and then asking for the new meningococcal vaccine and any local case of meningitis causing a scare and a rush for vaccine. It was felt that using the polysaccharide vaccine in older children would be unacceptable to parents who would view it as a second class vaccine. The HEA noted that 94% of parents of children under 2 said that meningitis was their main worry.

iv. Practicalities in deciding whom to immunise had to be taken into account. Most of the available vaccine would go to 15-17 year olds; trying to give it to under 4s would leave a lot of unimmunised children. Priorities should be the 2, 3 and 4 month olds and upward. Immunising all the under 5s would require 2.4 million doses and would mean that nobody over 5 could have the vaccine. All the parents

would turn up meaning vaccine supplies would not be available; a free-for-all would be a disaster. It was agreed that it was best to issue the vaccine in a regimented way at 2, 3 and 4 months and for 15-17 year olds, filling in the gaps as supplies became available.

v. The Secretariat advised the Committee that it was not possible to resolve these issues at the meeting until more was known about supplies but the Committee's views would be taken into account in arrangements with the manufacturers. Dr Smithson said that, in order to control demand, GPs would need a firm ruling to say "No" to requests out of schedule. However, it was noted that, with Hib vaccine, despite having the situation explained, there had still been a shortage of vaccine because people turned up demanding it; it was felt that this would happen whatever the arrangements. Dr Aston said that the health departments should be transparent in saying that supplies were limited. Dr Jones suggested that the polysaccharide vaccine could be used for older children as a short term measure. Dr Joynson felt that maximum benefit from the vaccine would be achieved if it was given to the 14, 15 and 16 year old age group. Professor Ritchie said that adverts for parents should clearly set out the logistics and the schedule so that they did not rush. Professor Cartwright said that we needed to make a firm recommendation; it was a finely balanced decision, but schools would clamour for the vaccine.

vi. The Committee agreed that all children would benefit from the vaccine but that the 2, 3 and 4 month programme, then going upwards, should apply if there was a limitless supply. If supply was limited then 2, 3 and 4 month olds should get the vaccine first; adolescent age groups should get the rest. GPs should not freely get vaccine; more should be supplied when it became available. Adding it for those coming for MMR should be the next step. An accelerated call-back programme should be used so that children could be picked up when the supplies for January 2000 onwards was known. **It was agreed** to immunise first the 2, 3 and 4 month olds, the 6-11 month olds and 15 - 17 year olds. Different groups would require different programmes. **The caveats which the Committee laid** were that we should have a regular supply of vaccine, very careful monitoring and surveillance to see the real efficacy of the vaccine. Enhanced surveillance should do this but this would need stepping up to check the vaccine failures.

vii. There was some concern that the Committee had discounted the views of its CCDC members. The Chair agreed that we should protect the vulnerable young and that the school service would be able to target more children more easily than GPs could. Managing public expectations was the most important aspect of this programme; getting the correct message across was a serious challenge and central to the behaviour of the public. It was queried whether the schools' services were capable of delivering the programme. The Committee agreed these recommendations but felt that some decisions had to be taken without some facts being available to them, especially on supply and strategy.

Use of current available Group C Meningococcal Vaccine

8.6 PHLS Meningococcus Forum
Minutes of meeting held on Friday 5 March **JCVI(99)26**
Report by Dr Norman Begg

The views of the Committee were sought on whether the polysaccharide vaccine should be used only in outbreak control and family protection or on a wider basis. Should the conjugate vaccine be used for infants and the polysaccharide vaccine for others? There would be a large cost implication if the polysaccharide was used and then followed up with the conjugate; would having the polysaccharide now affect use of the conjugate later? The polysaccharide had not been used because of its limited duration of protection and because subsequent doses may be less effective, factors which did not apply to the conjugate vaccine. Giving conjugate vaccine to sixth formers might leave freshmen at risk. Immunising with the polysaccharide vaccine would be very expensive and people would query why policy had changed. It was agreed to revisit the use of the polysaccharide vaccine once the conjugate vaccine became available. It was agreed that it was necessary to explain to the public the concerns about the polysaccharide vaccine and also to give the professions full information. The prime reasons for not using the polysaccharide vaccine should be set out as its short duration and its ineffectiveness in children; its refractory nature should not be highlighted as the meaning of these observations were not clear still. This advice should be included in 'Immunisation against Infectious Disease'.

9. PERTUSSIS

9.1 Pertussis is increasing in unimmunised infants: is a change of policy needed? (Archives of Disease in Childhood) **JCVI(99)31**
Paper by Dr Robert Booy et al

9.2 Pertussis vaccination and wheezing illnesses in young children: a prospective epidemiological study **JCVI(99)32**
Paper by Dr John Henderson et al

These papers were noted.

7. COMMUNICABLE DISEASE STRATEGY **JCVI(99)21**
Report by Dr Jane Leese

This paper was presented for information. The CMO was leading the development of the CDS for England. There was no time scale for this work which was still at the information gathering stage. A wider group of people had been identified for consultation and Dr Elizabeth Miller was preparing a report. Any major points regarding vaccines which Committee members might wish to make should be made known to Dr Leese. Professor Hull was to attend the meeting and a draft document

would be prepared by the autumn. The Committee was advised that the CDS was much better worked out than the strategies for other areas.

10. IMMUNISATION OF HEALTH CARE WORKERS JCVI(99)33

Report by Dr Jane Leese

This was provided for information; comments should be passed to Dr Leese. The timetable for this work had fallen behind. The Advisory Group on Hepatitis would be considering matters concerning a new policy for hepatitis B, which may delay matters further. Policy on the use of varicella vaccine was also to be considered.

11. INFLUENZA

11.1 Influenza Update

Oral Report by Dr Jane Leese

The Respiratory Panel had undertaken much work on influenza immunisation policy and full papers were available if required. The introduction of immunisation for all those aged over 75 years had been implemented from the 1998/99 season. The cost benefit of extending the programme to 65 to 70 and 70 to 74 year olds was being looked at by a working group set up by the Panel; the Netherlands had available a good cost benefit analysis on the 65-74 and 75 year olds onwards age groups.

It was accepted that there was an additional risk of GBS of one case per million people immunised with influenza vaccine.

On the neuraminidase inhibitors, Zanamivir was now available for treating influenza. It gave a reduction of 1½ to 2 days of illness if given in the first 36 hours after symptoms arose. There were concerns that the neuraminidase inhibitors would become like Viagra and have an expensive effect on the management of influenza. Its wide use would encourage resistance. Vaccine remained a cheaper and more effective option.

A paper on the immunisation of health care workers was tabled. In order to try and avoid a repeat of some of the difficulties the NHS had experienced during the winter of 1998/99 and also to deal with millennium holiday planning, NHS Trusts were to consider immunising their staff against influenza as a contingency for 1999/2000 only. Whilst it was acknowledged that this strategy was clearly not a policy recommended by JCVI, the Committee recognised the NHS's problems and, as long as it did not affect routine influenza immunisation policy, the Committee would not object to the strategy. The rationale for the strategy was to make it easier for the Trusts; there was no evidence that health care workers had a greater or lesser risk of catching or passing on influenza and the strategy did not appear to be directly in the interests of health care workers. The strategy was a management issue. It was agreed that data collection on the effect of implementing this strategy would be helpful. Opportunities should also be created to remind people to continue to target vaccine at the risk groups,

11.2 Minutes of the Respiratory Panel Meeting – Influenza **JCVI(99)34**
Report by Mr Robert Freeman

These were noted.

12. PNEUMOCOCCAL
Minutes of the Respiratory Panel meeting - Pneumococcal **JCVI(99)34**
Report by Mr Robert Freeman

These were noted. It was acknowledged that, given the vaccine currently available, this was the best policy possible at present.

13. CURRENT PROBLEMS WITH POOR AVAILABILITY OF CHILDHOOD VACCINES

Report by Mrs Debby Webb **JCVI(99)35**

This paper set out the current problems regarding vaccine supply. The Committee noted that vaccines available elsewhere in Europe only had country-based licenses meaning that they could be used in the UK only on a 'named patient' basis. DTP/Hib vaccine was not used in children over one year old as the rate of adverse reactions in children over one were higher than in those under one. The Department of Health had asked for the license for DTP/Hib to be amended.

14. HEPATITIS B
Progress Report by Dr Hugh Nicholas **JCVI(99)36**

Funding had been obtained to provide more vaccine to immunise high risk groups.

15. POLIO VIRUS CONTAINMENT

15.1 Oral Report by Dr David Salisbury

15.2 Proposed Global Action Plan and Timetable for Safe Handling and Maximum Laboratory Containment of Wild Polioviruses and Potential Infectious Materials **JCVI(99)37**
Report from World Health Organisation

15.3 Comments on WHO Plan **JCVI(99)38**

15.4 Department of Health meeting on WHO Plan **JCVI(99)39**
Minutes of Meeting

15.5 Guidelines for Implementing Phase I of the Global Action Plan for Laboratory Containment of Wild Polioviruses

JCVI(99)40

Once poliomyelitis had been eradicated, immunisation would end and samples of the wild virus would need safer, higher containment, probably at Category 3 or 4 level. Eventually, the vaccine virus would need similar containment was well. This issue required serious consideration. The UK had had the world's last cases of smallpox occurring in Birmingham; this had been caused because of a breakdown in containment facilities in a laboratory. NIBSC anticipated that it would need to work with both the wild and the vaccine virus over the next 30 years and would need to use Category 4 containment. NIBSC was discussing this issue with the Department of Health. People with suppressed immunity around the world would continue to excrete the virus for many years.

16. ARTICLES FOR INFORMATION

JCVI(99)41

T G Kimman et al: 'Ending polio immunisation: when and how are we sure that the needle is out of the haystack?'. Vaccine 17 (1999), 624-627.

'Prolonged poliovirus excretion in an immunodeficient person with vaccine-associated paralytic poliomyelitis'. MMWR, Vol.46/28, 641-643.

I Chitsike, R van Furth: 'Paralytic poliomyelitis associated with live oral poliomyelitis vaccine in child with HIV infection in Zimbabwe: case report'. BMJ 318, 27 March 1999, 841-843.

National Vaccine Information Centre announces: advocacy groups call for research to investigate link between autism increase and vaccination.

J-A Leask, S Chapman: ''An attempt to swindle nature': press anti-immunisation reportage 1993-1997'. Australia and NZ Journal of Public Health, 1998. Vol.22, No.1 (17-26).

M A Kane: 'Commentary: public perception and the safety of immunization'. Vaccine 16 (1998), S73-S75.

D S Diekema, E K Marcuse: 'Ethical issues in the vaccination of children'. 1998 Elsevier Science BV, 37-47.

D M Salisbury, S Dittmann: 'Immunization in Europe'. Vaccine (Third Edition), Chapter 43, 1033-1046.

17. ANY OTHER BUSINESS

Influenza: H9N2 influenza had been isolated in Hong Kong. The virus had been transmitted from poultry to two children. The virus had been isolated and was being used for vaccine development; it grew well. Small amounts of vaccine against the H5N2 virus were also now available. H9 was not as virulent as H5.

18. DATES OF FUTURE JVCI MEETINGS

Future meetings were confirmed for Fridays 5 November 1999, 5 May 2000 and 3 November 2000.