YDS

NOT FOR PUBLICATION

WORKING GROUP ON CONTRA-INDICATIONS TO WHOOPING COUGH VACCINATION

Minutes of meeting held on 1 May 1981 in Hannibal House

Present: Dr J Badenoch (Chairman)
Professor J A Dudgeon
Sir David Evans
Dr D Freestone
Dr A H Griffiths
Professor D Hull
Dr C Miller
Professor D L Miller
Dr T M Pollock
Dr E Ross
Dr J W G Smith
Dr P Stone
Sir Charles Stuart-Harris
Dr W O Williams

Miss C Sowerby — Secretary
Dr J Steadman — Medical Secretary

Also present:

Dr T Geffen)
Dr A D Andrews)
Dr J Barnes) DHSS
Mr A W Jones)
Miss E McCarthy)

The Chairman opened the meeting by welcoming Dr Stones from Glaxo Laboratories, and Dr Griffiths and Dr Freestone from the Wellcome Foundation. Members were asked to amend Paper 3, Manufacturers' Data Sheets, to show Trivax triple antigen manufactured by Wellcome.

The Chairman explained that the Group had been set up because the Joint Sub-Committee on Adverse Reactions to Vaccination and Immunization (ARVI), which had been asked by the JCVI to consider contra-indications to whooping cough vaccine, had not been able to reach agreement at its meeting in February. It was extremely important that the present meeting should reach an agreed conclusion because the reports on whooping cough were to be published on the 12 May, and it was desirable for any new contra-indications to be ready as soon as possible after this date. When considering the question of contra-indications, the general principle to be borne in mind was that the right balance had to be struck between the need to keep acceptance rates for vaccination as high as possible, and the need to protect groups of children who had an increased risk of adverse reaction to vaccination.

The Chairman referred to the current contra-indications to whooping cough vaccination as set out in the Appendix to CMO(77)7/CNO(77)2 of 31 March 1977. It was agreed that the meeting should discuss these contra-indications item by item.

The Chairman proposed that the second part of the general contra-indication for whooping cough vaccination referring to a common cold or snuffles should be deleted. He also suggested that the reference to respiratory disease should be deleted in the specific contra-indications to whooping cough vaccination. Members asked whether respiratory symptoms needed to be stressed at all. Sir Charles Stuart-Harris pointed out that the Sudden Infant Death Syndrome (SIDS) occurred at the age when children were being vaccinated against whooping cough. Respiratory illness was often associated with SIDS, and therefore the reference to respiratory disease was a wise precaution to prevent SIDS and whooping cough vaccination being associated. Professor Hull said that there was also a risk when the respiratory symptoms had not developed. It was thought that the reference to respiratory disease was not really a contra-indication; rather it was a move to protect the reputation of whooping cough vaccination by avoiding an association between vaccination and SIDS. It was agreed that in the section on general contra-indications the phrase used in the "Red Book" on Contra-indications to Whooping Cough Vaccination in the United States should be used. This would mean deleting the reference to a common cold or snuffles, and substituting "minor infections without a fever are not regarded as a contra-indication".

With regard to specific contra-indications, members discussed whether a family history of epilepsy should be a contra-indication. There was general agreement that facts were not known with certainty, but there was no good evidence that children with a family history of epilepsy would be more likely to react to vaccination. Professor Miller stressed the need to maintain public confidence in the vaccine and said there was a need to prevent children with epilepsy being vaccinated in order to avoid an apparent association between vaccination and fits. Sir Charles Stuart-Harris suggested adopting the Canadian approach whereby a family history of epilepsy was a relative but not an absolute contra-indication. Dr Griffiths pointed out that the vaccine manufacturers would have to reserve the right to include whatever contra-indications they thought were necessary in their data sheets. This was accepted by the Chairman.

The Chairman referred to the second paragraph in the specific contra-indications that "any severe local or general reaction to a preceding dose" was a contra-indication to vaccination. He supported this contra-indication, but asked members to consider whether it was necessary to specify what constituted a reaction. Dr Griffiths stated that traumatic damage occurred relatively frequently after vaccination, and this might be wrongly interpreted as a local reaction. Dr Pollock stated that local reactions to DTP were often worst at the first injection. These reactions might be due to the diphtheria or tetanus components, and he wanted to exclude local reactions as a contra-indication. Professor Hull quoted from a letter he had received from Professor Illingworth in which he stated that he would not give a second dose of DTP if a delayed local reaction occurred. After some further discussion it was agreed that this contra-indication should stand and that it was not possible or desirable to specify what constituted a reaction.

The Chairman asked members to consider "History of seizures, convulsions, or cerebral irritation in the neonatal period". Professor Hull said that this contra-indication would include children with disguised brain damage; this was good for the reputation of the vaccine in that it prevented an apparent association between vaccination and the discovery of brain damage. However, from the point of view of the individual child, he believed that these children might well be at greater risk if they developed whooping cough and might thus be particularly in need of vaccination.

It was agreed that the risk/benefit balance in this group of children was not known. Dr Griffiths confirmed that there was little evidence on this point, but he referred to a paper from the United States in which children with a history of convulsions were immunized against whooping cough and then followed up. He felt that this data did show a slightly increased risk of convulsions following vaccination in children with a previous history of convulsions. Members asked what exactly was the difference between seizures, convulsions and fits. Dr Ross said that there were problems with children who had suffered twitching due to transient events in the neonatal period, such as immaturity or hypercalcaemia. Sir Charles Stuart-Harris said that this part of the contra-indications should be framed so as to protect the child who has had a difficult neonatal period. Dr Christine Miller pointed out that this part of the contra-indications was ambiguous because it was not clear whether the phrase "neonatal period" referred merely to cerebal irritation or to seizures, convulsions and cerebral irritation. There was general agreement that neonatal period should only refer to cerebral irritation. The Chairman proposed that this sentence should be altered to "history of cerebral irritation in the neonatal period, or who have suffered from convulsions". This was generally agreed.

The Chairman asked the meeting to consider whether the specific contra-indication; "Children with developmental neurological defects" was reasonable, and also to define neurological defect.

It was felt that it was important to avoid vaccinating children with neurological defects; the numbers involved were so small that it would not make much difference to vaccine uptake rates. Professor Hull said that if this was an absolute contra-indication, then all children in this group would be denied the possibility of vaccination. Dr Ross agreed with this and pointed out as an example that this contra-indication might prevent any children with Down's syndrome being vaccinated against whooping cough. The Chairman felt that the approach used in Canada whereby this could become a relative contra-indication to vaccination should be adopted. Dr Smith agreed with this approach, and suggested that the form of words "Caution should be exercised ....." should be used when describing relative contra-indications. There was general agreement that developmental neurological defects should be retained as a contra-indication, but this contra-indication should be relative and not absolute. Professor Hull suggested that the same approach of using a relative contra-indication should be used in other categories of children where the evidence against vaccination was dubious. Dr Williams stressed the need to keep the contra-indications simple and straighforward. He pointed out that if the whooping cough vaccination acceptance rate could be raised to its pre 1974 figure of 80%, then the level of immunity would be such as to reduce the size of whooping cough epidemics and thus indirectly protect children with neurological defects who might not have been vaccinated. Sir Charles Stuart-Harris pointed out that changes in the contra-indications to vaccination, however carefully worded, were unlikely to have any significant effect on the vaccine acceptance rate; this would only rise when general public confidence in the vaccine was restored. It was suggested that the need for referral to a specialist should be specifically mentioned for those children in whom there was a relative contra-indication to vaccination, but Dr Williams advised against this. He felt that many GPs would be unhappy to receive such advice, and that they could be relied upon to refer individual children to specialists if necessary.

Members reconsidered the question of a family history of epilepsy or other diseases of the central nervous system as a contra-indication to whooping cough vaccination. There was general agreement that including other diseases of the central nervous system was unnecessarily restrictive, and that this particular contra-indication should be deleted. The Chairman suggested that a family history of epilepsy should refer only to idiopathic epilepsy, and that epilepsy or a family history of idiopathic epilepsy should only be a relative contra-indication. There was general agreement on this, and also on the Chairman's suggestion that it should be made explicit that family history referred only to first degree relatives.

The Chairman pointed out that the manufacturers' data sheets and the advice of the JCVI differed in respect of the specific contra-indication, that a personal or family history of allergy was no longer a contra-indication; allergy was still mentioned as a contra-indication in the data sheets. Dr Griffiths said there was no good evidence for inclusion of allergy as a contra-indication. Dr Freestone agreed, but said that the manufacturers had been influenced by the reports from ARVI, and also felt that reference to allergy was necessary to protect them from litigation in individual cases. Sir David Evans suggested deleting completely any reference to allergy.

Sir Charles Stuart-Harris pointed out that a history of allergy was a problem which arose very commonly in vaccination clinics and suggested that this problem should be answered by the specific reference to allergy contained in the contra-indication. Dr Smith also felt that a statement about allergy should be retained, and felt that the present statement did not need alteration. It was then generally agreed that the current statement should stand.

The Chairman said that there was now broad agreement by members, with exception of Professor Hull, on the contra-indications to whooping cough vaccination, and thanked the meeting for their co-operation. He stressed again the urgent need to agree a new set of contra-indications, and asked that a draft of the conclusions reached at the meeting be circulated by the Department and agreed as quickly as possible.