ADVISORY GROUP ON HEPATITIS

MINUTES OF MEETING HELD ON 27 OCTOBER 1981 IN HANNIBAL HOUSE

Present: Sir Robert Williams (Chairman)
Dr D M S Dane
Dr T H Flewett
Professor A C Kennedy
Dr R Lane
Dr S Polakoff
Dr R S Williams
Professor A J Zuckerman

Also present: Dr Thomas

Dr M Sibellas - Medical Secretary
Mr R T Anderson - Secretary

Dr R Alderslade )
Dr R D Andrews )
Dr B S Ely )
Dr T Geffen )
Mr A W Jones ) DHSS
Dr A M Milne )
Mr M F Rose )
Miss M E Stuart )
Miss B Weller )

Dr W Lovett - Welsh Office
Dr W Prentice - Scottish Home and Health Department

Introduction

The Chairman welcomed Dr Thomas who had come to speak to item 7(ii) in conjunction with Professor Zuckerman.

1. Apologies for Absence

Apologies were received from Dr Bird, Dr Logan and Dr Young.

The Group agreed with the Chairman's suggestion that their best wishes should be conveyed to Dr GRO-A for a speedy recovery from his recent operation.

2. Minutes of last meeting

The minutes were agreed.

3. Matters arising

a. Radioimmunoassay test based on monoclonal antibodies

Dr Dane expressed his concern that the charge should reflect the economic cost and advised the Group that he would be taking up the matter with BPL and the Department.

b. Dr Beale's letter

Dr Beale's letter of 18 August was discussed. Professor Zuckerman stated that he could confirm the evidence heard and that the Purcell vaccine was the less thoroughly tested. The Group agreed that the minutes of the meeting of 11 May 1981 could stand.

4. CMO letter : Hepatitis B and NHS staff (AGH(81)8)

Dr Sibellas reported that the letter had not yet been issued. The Group expressed their deep concern that the issue of the letter was to be further delayed. The Group confirmed that their advice was still the same.

5. HB(s) Ag positive patients (AGH(81)9)
Paper by Dr Prentice

Dr Prentice tabled a paper giving details of the recommendations to be issued by the Greater Glasgow Health Board to Medical, Nursing and other staffs dealing with hepatitis B carriers. He reported that the recommendations had been approved by all interested parties and were of particular interest because they had been approved by local Trade Union Officers.

The Group agreed that it was a useful document. The Chairman invited members to send comments to Dr Sibellas, which would be passed on to SHHD.

6. Hepatitis B Immunoglobulin

i. Discussion on the protocol for the study on the control of hepatitis B in neonates born to HBe antigen positive mothers (AGH(81)10)

Dr Polakoff introduced her draft protocol for the protection of newborn infants at risk of acquiring hepatitis B virus infection.

It has been estimated that approximately 400 infants are infected each year forming a pool of highly infective carriers in the child population in this country. There were problems with the recognition of the children at risk because of the low numbers involved and their highly scattered distribution and the fact that many of the mothers are immigrants with language and social problems.

In discussion it was agreed that screening should be restricted to those of the ethnic groups, defined in the draft protocol. Dr Polakoff advised the Group that details of follow-up treatment for the mother and method of delivery of the baby would be given in an appendix to the draft protocol, which was still being prepared.

The Group commended to the PHLS Epidemiological Research Laboratory (Dr Polakoff) the monitoring of this study. The Chairman stated that he would report on this item to the JCVI at their meeting on 3 November.

Dr Lane informed the Group that 1 ml vials of hepatitis B immunoglobulin (HBIG) were now being manufactured at Elstree. Professor Zuckerman asked that the dose should be expressed in international units on the vial.

ii. (a) MRC report of the Working Party on the clinical use of a specific immunoglobulin in hepatitis B (AGH(81)11a)

The Group expressed their concern at the delay with the report but agreed that the report was still useful and suggested that the MRC should proceed with publication.

ii. (b) Letter from Dr Lane, dated 23 September

The letter described how specific immunoglobulin should be used in hepatitis B prophylaxis and recommended that there should be some form of audit. The Chairman suggested that Dr Lane and Dr Polakoff should discuss the details of an auditing system.

7. Hepatitis B Vaccine

i. General Policy for use in the UK (AGH(81)12)

Dr Sibellas introduced the paper which defined priority groups for the use of hepatitis B vaccine in the health service. Dr Williams suggested that staff in high risk special units, eg liver units, should be added. Dr Lane pointed out that there was one very select group missing and that this was people who handled infected material in the laboratory. Dr Geffen stated that the paper was not intended for publication but that there was a need for a list of priority groups when the vaccine became available in Britain.

The Group were informed that the Merck, Sharp and Dohme vaccine was in the final stages of consideration by the FDA in the United States. Although there was a strong probability of the vaccine being licensed in America the vaccine was not yet licensed in Britain and would probably not be available in Britain for some time. The Group agreed that subject to some amendments of the first paragraph and the use of the correct terminology, the paper could go forward to the JCVI. The Chairman stated that he would be attending the JCVI on 3 November in order to give the preliminary views of the AGH on this matter.

ii. Progress on the development of a British hepatitis B vaccine

Professor Zuckerman introduced this item with a summary of the progress made. The British vaccine is the development of a second generation vaccine based on specific polypeptides incorporated in micelles. Safety tests on the micelle vaccine using susceptible chimpanzees had been completed and an assay of the immunogenic potency (recommended by WHO) indicated that the vaccine was more potent than the Merck vaccine given the limited sample available. An American

test on two chimpanzees supported this finding. The British vaccine tested so far was produced from chimpanzee plasma, but antigen derived from human plasma has now been shown to be suitable for the production of micelles. A pilot scale production line was being set up to encourage interest by potential British manufacturers but the main problem was the supply of human plasma and its storage.

Dr Thomas spoke to his paper, "Purification of HBsAg from human serum by affinity chromatography using RF - HBs - 1 monoclonal antibody" (AGH(81)16)

The Group discussed the practical implications of the manufacture of the vaccine. Dr Dane stated that given sufficient quantities of plasma and specialised equipment including a specialised cell separator costing £16,000 the vaccine could be easily produced. It was stated that the potential commercial production had been discussed with the Wellcome Foundation and Mr Rose advised the Group that Supply Division had formally approached Wellcome and were investigating the availability of the plasma. The greatest problem was the safety testing in chimpanzees which are rare and expensive. The only safety test currently acceptable was using chimpanzees but it was possible that if autoclaving or radiation was used for inactivation, some other test might become acceptable in the future. Professor Zuckerman urged Supply Division to continue their discussions with Wellcome and Dr Geffen stated that the volume of vaccine required and a policy for use would be drawn up to stimulate interest among potential manufacturers.

iii. Offer of vaccine (Merck, Sharp and Dohme) (AGH(81)13)

Dr Sibellas informed the Group that this offer had been withdrawn by the company who had now offered it to the Swiss Health Authorities.

8. PHLS study. Hepatitis B surveillance

Dr Polakoff informed the Group that the PHLS surveillance study designed to identify clusters of cases of hepatitis B that might indicate common-source infection in hospital and dental practice had made good progress, but statistical analysis of the results required grant support. Three clusters, each of two patients had been recognised. Two of the clusters appeared to be related to dentists, but in neither case was the dentist a carrier. The two patients apparently related to one surgical team proved to be infected with different subtypes of HBV.

9. i. "Hepatitis B Immune Globulin (HBIG) efficacy in the interruption of perinatal transmission of Hepatitis B virus carrier state". The Lancet - 22 August 1981. (AGH(81)14a).

ii. "Conflicting Duties to Patients : The case of a sexually active Hepatitis B carrier". A.I.M. - April 1981. AGH(81)14b).

These articles were for information.

10. Any other business

There were no other items of other business raised.

11. Date of next meeting

To be arranged.