ADVISORY GROUP ON HEPATITIS

Minutes of meeting held on 1 May 1984 in Room 119 Hannibal House

Present:

Sir Robert Williams (Chairman)
Dr M Contreras
Dr J Craske
Dr D M S Dane
Dr T H Flewett
Dr R Lane
Dr S Polakoff
Dr R S Williams
Dr S E J Young
Professor A J Zuckerman

Dr M Sibellas - Medical Secretary
Mrs R C Gorvin - Administrative Secretary

Dr J Barnes
Dr M Duncan
Mr C Howard
Dr R M Oliver
Dr A Smithies
Miss B F Weller
- DHSS

Dr D Gambier - Welsh Office
Dr W Prentice - Scottish Home and Health Department

INTRODUCTION

The Chairman welcomed Dr Contreras to the group. He also introduced Mrs Gorvin as the new Administrative Secretary.

1. APOLOGIES FOR ABSENCE

Apologies were received from Professor Kennedy, Dr Donaldson and Dr Graveney.

2. MINUTES OF THE LAST MEETING

The following amendments were agreed:

Item 7, paragraph 2 - in third line insert after but "if a plasma-derived vaccine was to be produced this should be done" (..... using the most up-to-date technology available).

Item 8, paragraph 1 - in fifth line insert "carrier" before the word "dentists".

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3. MATTERS ARISING

Professor Zuckerman reported that plasma-derived micelle products were now being prepared in the USA and had been given to young adults. No side effects had been reported. The micelle technique had been applied successfully to antigen expressed in yeast and had proved immunogenic. Further development work was continuing at the London School of Hygiene and Tropical Medicine.

4. a. GUIDANCE FOR HEALTH CARE PERSONNEL DEALING WITH PATIENTS INFECTED WITH HEPATITIS B VIRUS (Draft 6) - AGH(84)1

b. DR DANE'S COMMENTS ON DRAFT 6 - AGH(84)1a

There was a detailed discussion on the Department's draft guidance and Dr Dane's comments. It was agreed that the draft should be revised in the light of members' comments. This is attached as an annex to these minutes.

5. OPTIONS IN BRITAIN FOR FUTURE PROTECTION OF NEWBORN OF HBsAg MOTHERS - AGH(84)2

Dr Polakoff presented her paper which set out different options together with estimates of annual costs, excluding central distribution and monitoring. Over 90 per cent efficacy had been shown where immunoglobulin had been given within 48 hours of birth followed by vaccination. Vaccination of all babies would incur considerable expense. Supplies of the vaccine were still limited and the cost remained high. Costs would be reduced if a paediatric form of the vaccine became available. There could be supply problems if the use of immunoglobulin was extended. Usage had already increased from 1200g in 1980 to 1800g in 1982 possibly due to a more liberal interpretation of the criteria rather than on the basis of need.

The problems associated with the supply of immunoglobulin were discussed. Dr Lane said that plasma had been in short supply and in order to achieve production based on projections of demand, the voluntary donors had been boosted with Merck, Sharp and Dohme (MSD) vaccine. The endorsement of the expert committee was sought on this issue so that the voluntary donors could be reassured that the risks involved were no more than those likely to be encountered with an inactivated vaccine and that there was no risk of AIDS. The agreed view of the Committee was that the MSD vaccine, as licensed in this country, was safe, and that there was no evidence to suggest that AIDS was associated with the use of the vaccine. If necessary the Chairman of the Blood Transfusion Authority could seek the advice of the Department regarding the legal aspects relating to the voluntary donors; the Authority carried its own liability and the question of underwriting by the Department should not arise.

The options set out in Dr Polakoff's paper were discussed. Dr Lane indicated that immunoglobulin was not an expensive product to make and therefore there was no financial inhibition to adopting any of the options, provided the supply of sufficiently high titre could be assured. Dr Williams said that too many doses of immunoglobulin were already being used; only one dose should be required, followed by vaccination. Professor Zuckerman pointed out that recently

published studies /Wong et al 'Prevention of the HBsAg carrier state in newborn infants of mothers who are chronic carriers of HBsAg and HBeAg by administration of hepatitis B vaccine and hepatitis B immunoglobulin' Lancet 28 April 1984; 'Prevention of perinatally transmitted hepatitis B infection' Leading Article. Lancet 28 April 1984 / showed that the vaccine alone or immunoglobulin alone was not as effective as administration of combined immunoglobulin and vaccine.

Dr Duncan said that now that there was more information on the use of the vaccine in neonates, there might be sufficient justification to seek a variation of the product licence in order that the vaccine be approved for use in newly born children, in smaller doses. Dr Polakoff suggested that the DHSS should provide hepatitis B vaccine centrally so that there would be no financial constraintson its availability. Dr Barnes agreed to take this up with Supply Division although he thought that Central Supply was unlikely.

After discussion it was agreed that the most practical option was an initial dose of immunoglobulin at birth followed by three doses of vaccine (Option A of AGH(84)2). The aim should be to try to achieve greater coverage of the high risk groups as a first step towards extending screening. The Chairman said that in view of the assurance about supplies of immunoglobulin and the possibilit of extending the licence to provide smaller paediatric doses, the question of vaccination for children born to e antigen positive mothers should be put before the Joint Committee on Vaccination and Immunisation. Consideration would need to be given to ways of issuing any recommendations, possibly by means of a Chief Medical Officer letter. Dr Polakoff said that more time and numbers were needed before her study would be ready for publication but she would consider producing an interim report which might be published as a letter to the editor of a leading medical journal.

Dr Polakoff was thanked for her valuable paper.

6. a. GREATER GLASGOW HEALTH BOARD STANDARD PROCEDURE FOR PERSONS ACCIDENTALLY EXPOSED TO HEPATITIS B - AGH(84)3

   b. "THE HEPATITIS CARRIER" - EXTRACT FROM THE LANCET 11 FEBRUARY 1984, PAGE 332 - AGH(84)4

These papers were for information.

7. ANY OTHER BUSINESS

7.1 Professor Banatvala's letter of 26 April about distribution of hepatitis B immunoglobulin was discussed. The Committee felt that, because of the current shortage of supplies there was no alternative to the present arrangements by which most of the material is distributed through the PHLS. However, sympathy was expressed with the difficulties being experienced by clinical virologists and it was agreed that the representatives of the Blood Products Laboratory and of the Blood Transfusion Service should consider the supply problems and report to the next meeting with options for discussion. The Chairman would write to Professor Banatvala.

7.2 Dr Polakoff reported that another small cluster of hepatitis B cases had been identified, resulting from a surgeon who had been found to be an incubating case. Five patients were being traced but there was no long term risk as the surgeon had not developed persistent hepatitis B antigenaemia.

8. The next meeting would be held on 9 October 1984.