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GREAT BRITAIN DHSS

THIRD REPORT OF THE
ADVISORY GROUP ON TESTING FOR
THE PRESENCE OF HEPATITIS B SURFACE
ANTIGEN AND ITS ANTIBODY



1981

THE ADVISORY GROUP ON TESTING FOR THE PRESENCE OF HEPATITIS B SURFACE
ANTIGEN AND ITS ANTIBODY: THIRD REPORT

The DHSS Advisory Group has considered whether any alterations in the methods used to test donations of blood for Hepatitis B surface antigen and its antibody are desirable in the light of developments which have taken place in knowledge and technique since the Group's second report was published in 1975. The third report makes a series of recommendations, principal among which is the recommendation that all donations destined to be used for protein fractionation should be tested by techniques with a particular level of sensitivity which, in practice, can be met only by radioimmunoassay (RIA) and enzyme-linked immunoassay (ELISA) techniques.

Copies of the report have been sent to Regional Transfusion Directors, Regional Medical Officers and Scientific Officers, Hepatitis Reference Centres, and other bodies who have an interest. Further copies are available free of charge from Mrs E L Creagh, DHSS Health Services Division 1A, Room 1206 Hannibal House, Elephant and Castle, London SE1 6TE (Telephone: 01 703 6380 Ext: GRO-C).

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The Advisory Group wishes to thank Sir William d'A Maycock and
Dr Elizabeth Boxall for valuable help in preparing this report.

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CHAPTER 1

INTRODUCTION

1. A meeting convened by the Department of Health and Social Security on 20 July 1970 to discuss the problems of what was then known as Australia (hepatitis-associated) antigen in relation to blood transfusion and associated matters recommended that the Department should give any assistance it could "in the institution of testing blood donations for the presence of Australia (hepatitis-associated) antigen and its antibody".

2. In the light of this recommendation, in September 1970 the Advisory Group on Testing for the Presence of Australia (Hepatitis-Associated) Antigen and its Antibody was appointed jointly by the Department of Health and Social Security, the Scottish Home and Health Department and the Welsh Office with the following terms of reference:-

- i. the organisation of and responsibility for testing blood donations and other specimens of blood for Australia (hepatitis-associated) antigen and its antibody in the hospital service;
- ii. the provision of reagents, choice of methods and whether, and if so, what kind of, training facilities are required;
- iii. the scale of accommodation, staffing equipment and other services necessary to implement the group's proposals.

3. The Group's Revised Report (1) published in May 1972, recommended, inter alia, that Regional Transfusion Centres (RTCs) should begin, at the earliest possible date, to test all blood donations for the presence of Australia (hepatitis-associated) antigen and its antibody using, initially, an immunoelectro-osmophoretic method of testing. The Group pointed out, however that knowledge of all aspects of the Australia (hepatitis-associated) antigen was accumulating very rapidly and that its recommendations should therefore be regarded as interim and subject to modification at a later date.

4. The Group, under a slightly amended title, was reconvened on 6 December 1973 and in its Second Report (2) published in September 1975, recommended that reversed passive haemagglutination (RPH) should be adopted by RTCs in place of counterimmuno-electrophoresis (CIE) to screen every blood donation for the presence of Hepatitis B Surface Antigen (HBsAg), formerly referred to as Australia Antigen. It also recommended that the practice of excluding donors with a history of jaundice be discontinued provided that HBsAg was not detected and the donor had not suffered from hepatitis or jaundice during the previous 12 months. Attention was drawn, as had been done in the 1972 Revised Report, to the rapidity with which information on the subject was accumulating and the need not to regard its recommendations as final.

5. In November 1979 the Group was reconstituted and reconvened to consider whether any alterations in the methods used for testing donations were desirable as a consequence of developments in knowledge and technique which had occurred in the intervening 5 years. The Group was asked by the Department of Health and Social Security (DHSS) on this occasion to restrict its recommendations to matters directly connected with testing.

Chapter 2

SCREENING BLOOD DONATIONS FOR HBsAg

6. The general principles of testing were considered in Chapter 2 of the Second report and do not need to be repeated. At that time the Group recommended reverse passive haemagglutination (RPHA) as the method of choice for screening blood donations. Since then more sensitive tests have become widely used and we have considered whether any of these should replace RPHA.

7. As screening tests have become more sensitive progressively fewer additional HBsAg positive donations have been found. The change in the testing method from counterimmunoelectrophoresis to RPHA introduced 5 years ago resulted in a 30% to 40% increase in the number of HBsAg positive donations found, whereas a further change from RPHA to radioimmunoassay (RIA), the most sensitive test currently available, has resulted in only a 5% to 10% increment in the United Kingdom (3).

8. Of the more sensitive screening tests available for the detection of HBsAg we considered the following:-

- Radioimmunoassay (RIA)
- Enzyme-linked immunoabsorbent assay (ELISA)
- Reverse passive haemagglutination (RPHA)

Radioimmunoassay

9. The quality of commercial RIA kits has improved over the past 5 years and more laboratories in the UK are now familiar with this type of test. The delays caused in the past by the use of single-well gamma radiation counters have disappeared with the introduction of 12- and 16- well counters, though the potential hazards involved in handling the radio-isotope I-125 remain. Several commercial RIA kits and also an RIA test developed by Blood Products Laboratory (BPL), Elstree (4) for its own use were compared in the laboratories of members of the Advisory Group. Differences in the detection sensitivity of the various tests were small and likely to be of little practical significance. Factors such as cost, assurance of continuity in supply and ease of use are likely to be of more importance in determining choice between the various RIA tests. It is noted that certain tests employ considerably less radioactivity than others, which is a factor to consider in the interests of safety.

Enzyme-linked Immunoassay

10. Though ELISA tests for HBsAg have so far proved slightly less sensitive than RIA tests they have the advantages that radio-isotopes are not used, the reading of results is more simple, and the reagents have a much longer shelf life (at least 12-18 months).

Reverse Passive Haemagglutination Tests

11. The RPHA test most widely used by Regional Transfusion Centres (RTCs) has been inexpensive, fast and simple to read but it has been less sensitive than some of the other commercially available RPHA tests. Some RTCs have used a modified RPHA which has reduced costs and increased sensitivity (5, 6), but generally RPHA tests have been less sensitive than ELISA tests.

12. At the present time RTCs are finding between 1 in 500 and 1 in 1,000 new donors to be HBsAg positive, but because of previous screening, the overall incidence in blood donors is between 1 in 3,500 and 1 in 5,000. The 5% to 10% increment in the number of HBsAg positive donations found which could be expected to follow a change to RIA screening might mean an additional 1, 2 or 3 HBsAg positive donations found in every 100,000 tested. Fewer than half of any undetected HBsAg positive donations issued are likely to cause icteric post transfusion hepatitis (PTH) (7, 8). The benefits of changing from the present RPH method of screening to a more sensitive method are thus likely to be small in the context of routine hospital blood banking. However, in relation to plasma products they will be greater (see below).

13. The safety of blood products such as Factor VIII made from large pools (3-5,000 donations) of plasma increases as more sensitive HBsAg screening methods are used for testing the individual donations. To minimise the hazard of contamination of the large pools it is necessary to test individual donations by a technique detecting at least 2 British Standard Units/ml. (BSU/ml) of antigen (see Chapter 4). Donor units despatched to NHS Fractionation Centres not tested at this level of sensitivity would have to be retested; this would result in duplication of testing with double standards. For this reason, it is desirable that a suitably sensitive test be carried out at RTCs.

14. We recommend that all donations destined to contribute to protein fractionation at NHS Fractionation Centres be tested by techniques with a sensitivity of at least 2 BSU/ml of HBsAg. With the increasing need for plasma, this would imply all donations collected for transfusion purposes at RTCs.

Sensitivity of Testing Methods

15. It is only possible to lay down approximate guidelines for the sensitivity of testing. RIA or ELISA tests should be able to detect 2 BSU/ml of HBsAg or less. In addition tests must show broad reactivity against a suitable panel of low titre HBsAg positive sera. RPHA tests are likely to be of lower sensitivity, but should detect 100 BSU/ml of HBsAg or less.

CHAPTER 3

OTHER SCREENING TESTS

Tests for Anti-HBs

16. Donations containing high titre anti-HBs are required for the production of hepatitis B immunoglobulin (HBIG). Only one in several thousand donors has suitable levels of this antibody and an anti-HBs screening programme is therefore required to satisfy the demand for HBIG. RTCs using RPHA can employ a simple inhibition test to identify donors with high titre anti-HBs which re-uses the serum dilutions and test cells already used in the screening test for HBsAg (6). A simple blocking test for high titre anti-HBs will be available for RTCs using the RIA test for HBsAg. We recommend that RTCs should screen as many new donors as possible for anti-HBs.

17. Donors identified as possessing high titre anti-HBs are likely to retain a useful level of antibody for many years and therefore panels of suitable donors can be built up.

18. It is desirable that the quality of anti-HBs donations supplied to NHS Fractionation Centres should be controlled by the issue of an appropriate minimum standard anti-HBs serum to RTCs.

Tests for Anti-HBc

19. Blood donations which are negative for HBsAg by RIA and negative for anti-HBs, but positive for core antibody (anti-HBc) may occasionally transmit hepatitis B. Some of these donations are from donors recovering from unrecognised hepatitis B infections who still have minute but undetectable amounts of virus in their blood. At the present time there is no evidence that this type of donation causes more than a few cases of post-transfusion hepatitis (PTH) in the UK.

20. Screening all donations for anti-HBc would be costly and result in discarding many harmless donations from immune donors unless tests for anti-HBs were also carried out.

21. We recommend that there should be no general screening of donations for anti-HBc, but that all donors implicated in cases of PTH should be tested at reference centres for anti-HBc as well as for other hepatitis markers so that more information can be obtained on the dangers of HBsAg negative, anti-HBs negative, anti-HBc positive donors.

Tests for Non-A, Non-B Hepatitis Viruses

22. Non-A, non-B hepatitis viruses are a common cause of PTH in the United States and are thought to have been responsible for cases of PTH in the UK. Hepatitis due to these viruses is common among haemophiliacs and follows the administration of imported, and occasionally of British Factor VIII and Factor IX. There is evidence for the occurrence of sporadic cases of non-A, non-B hepatitis in the general adult population and in association with cryoprecipitate therapy in the UK.

23. There are at the present time no screening tests for detecting non-A, non-B hepatitis viruses in blood donations.

24. We recommend that research is undertaken in the UK to determine the extent and severity of PTH due to non-A, non-B hepatitis viruses. Unless this is done we will not have the knowledge on which to base any possible future recommendations about screening blood donations for these viruses. Regional Transfusion Directors should encourage hospital haematologists to report all cases of post-transfusion jaundice and where these could be due to non-A, non-B hepatitis, the facts should be reported to the appropriate Adviser in Blood Transfusion at the Department of Health and Social Security (DHSS) or Scottish Home and Health Department (SHHD).

Liver Function Tests

25. Several categories of people are found to have raised blood transaminase levels which are not associated with viral hepatitis. Some 3% of new donors may be excluded if the criteria of one raised transaminase level is applied. In addition to the need for confirmatory transaminase testing the worry and inconvenience caused to donors would be unlikely to be compensated for by any clinical benefit. Therefore, we advise against these tests in screening blood donors at the present time but the subject should be kept under review.

26. Sporadic cases of apparent post-transfusion hepatitis due to the hepatitis B virus will continue to occur despite the most rigorous screening of donor blood samples because there are routes of infection other than transfusion; by coincidence, a transfusion may appear to have been responsible. Very few cases of PTH will continue to occur from donations with antigen below the present possible detection level. The donors involved may be in the early stage of incubating Hepatitis B.

CHAPTER 4

A BRITISH STANDARD PREPARATION OF HBsAg

27. For several years there has been a need for an HBsAg standard preparation so that results in one laboratory could be compared with those from another. Any standard preparation of HBsAg has certain obvious disadvantages. For example the surface antigens produced by different strains of hepatitis B virus vary even though all share one common antigen. The relative numbers of the three morphological types of hepatitis B particle in different serum samples is another variable factor. However, we considered that provided its limitations were recognised there were many occasions when reference to a standard would be useful and in co-operation with the National Institute for Biological Standards and Control, we have prepared one.

28. We chose a high titre HBsAg positive donation, sub-type ad, which was positive for anti-HBe. This was diluted 1 in 4 in water and heated at 60°C for 10 hours to reduce infectivity. The preparation was then further diluted, divided into aliquots and freeze-dried.

29. We recommend that the Standard preparation of HBsAg be made available only to laboratories familiar with safety aspects of testing for HBsAg and that these laboratories make their own working standard by comparison with a freshly re-constituted ampoule of the British Standard.

CHAPTER 5

QUALITY CONTROL OF ROUTINE SCREENING TESTS

30. We recommend that the Division for Microbiological Reagents and Quality Control (DMROC), Central Public Health Laboratory, Colindale continues to distribute panels of antigens to RTCs and that these should contain samples of a strength appropriate to the standard of testing. RTCs should make available to the DMROC any low titre HBsAg positive donations which they find and which might be suitable for inclusion in one of these panels.

31. NHS Fractionation Centres receive many fresh frozen plasma donations, as well as 5-litre packs of plasma from time-expired blood donations, for the manufacture of blood products. We recommend that there should be an ongoing quality control assessment of this material at national level.

32. We recommend the establishment of a committee of experts to assess the value of any new tests for hepatitis markers which may be used in testing blood donations and preparations of large pool blood products.

33. The Second Report (2) recommended that HBsAg positive donations found by RTCs should be confirmed as positive by Reference Centres. Because of the growing experience at RTCs we now recommend that they should carry out their own confirmatory tests on all screen test positive donations. However, they should continue to send samples of donations which they confirm as positive to Reference Centres for additional verification. Suitable methods for confirmation testing by RIA have been described (9).

34. Samples of donations which (a) are HBsAg positive, or (b) give equivocal results in confirmation tests, or (c) give repeatable false positive screen tests should be made available for quality assurance programmes.

Training of Staff

35. The full value of screening donations by RIA and other sensitive tests will not be achieved unless staff are properly trained. We recommend that the Blood Transfusion Service has its own training programme.

CHAPTER 6

SUMMARY OF PRINCIPAL RECOMMENDATIONS

- i. All donations destined to contribute to protein fractionation at NHS Fractionation Centres should be tested by techniques with a sensitivity of at least 2 BSU/ml of HBsAg.
- ii. The British Standard of HBsAg should be made available by the National Institute of Biological Standards & Control only to laboratories familiar with safety aspects of testing for HBsAg.
- iii. The Division of Microbiological Reagents and Quality Control of the Central Public Health Laboratory Service, should continue to distribute self-assessment panels of known HBsAg positive samples. Regional Transfusion Centres should make available any low titre HBsAg positive donations for this purpose.
- iv. All Regional Transfusion Centres should screen as many new donors as possible for anti-HBs. Panels of suitable anti-HBs donors should be built up and NHS Fractionation Centres should issue an appropriate minimum standard anti-HBs serum to Regional Transfusion Centres.
- v. Regional Transfusion Centres should now undertake their own confirmation tests as a preliminary to sending confirmed positives to reference centres for more detailed analysis.
- vi. There should be no general screening of donations for anti-HBc. Donors implicated in cases of post transfusion hepatitis should be comprehensively tested at reference centres.
- vii. Liver function tests should not be used for general screening of blood donors.
- viii. Hospitals should be encouraged to report all cases of post-transfusion jaundice and where these could be due to non-A, non-B hepatitis, the facts should be reported to the appropriate Adviser in Blood Transfusion at the DHSS or SHHD.
- ix. Research should be undertaken in the UK to determine the extent and severity of post-transfusion hepatitis due to non-A, non-B hepatitis viruses.
- x. A committee of experts should be established to assess the suitability of any new tests for hepatitis markers.
- xi. The UK Blood Transfusion Services should set up their own training programmes for staff engaged in HBsAg testing.

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APPENDIX

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Mr J H Finnie
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21 July 1981

Dear Mr Finnie

THE ADVISORY GROUP ON TESTING FOR HEPATITIS B SURFACE
ANTIGEN AND ITS ANTIBODY: THIRD REPORT

I am able to send you 50 copies of the report for
distribution. You might like to know that we have sent
copies to Transfusion Directors, Regional Medical and
Scientific Officers (the Scottish Scientific Officer
included because he attends the R Sc O meetings here and
receives papers from the Departmental Secretariat) and
to a number of bodies who have an interest in the report,
eg the Medical Research Council and Health and Safety
Commission. *We have also sent copies to the Hepatitis
Reference Centres.*

You might also like to see a copy of what we propose to
say about the report in our Departmental Quarterly
Bulletin of Publications, which goes out to the NHS.

Yours sincerely

GRO-C

MRS S C YUILLE
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3571

Mr S Peover
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21 July 1981

Dear Mr Peover

THE ADVISORY GROUP ON TESTING FOR HEPATITIS B SURFACE
ANTIGEN AND ITS ANTIBODY: THIRD REPORT

I am able to let you have 40 copies of the Report for
distribution. You might like to know that we have sent
copies to Regional Transfusion Directors, Regional
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Bulletin of Publications which goes out to the NHS.

Yours sincerely

GRO-C

MRS S C YUILLE
Health Services
Division 1.

JS/14

3571

Mr D G Thomas
Welsh Office
Cathays Park
CARDIFF

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2/ July 1981

Dear Mr Thomas

THE ADVISORY GROUP ON TESTING FOR HEPATITIS B SURFACE
ANTIGEN AND ITS ANTIBODY: THIRD REPORT

I enclose 25 copies of the report for distribution.
You might like to know that we have sent copies to
Regional Transfusion Directors (including Dr Napier),
Regional Medical and Scientific Officers (the Welsh
Scientific Officer included because he attends R Sc Os
meetings here and receives papers from the Departmental
Secretariat) and to a number of bodies who have an
interest in the report, eg the Medical Research Council
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Yours sincerely

MRS S C YUILLE
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Division 1

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Copies of the report have been sent to Regional Transfusion Directors, Regional Medical Officers and Scientific Officers, Hepatitis Reference Centres, and other bodies who have an interest. Further copies are available free of charge from Mrs E L Creagh, DHSS Health Services Division 1A, Room 1206 Hannibal House, Elephant and Castle, London SE1 6TE (Telephone: 01 703 6380 Ext: GRO-C).