Witness Name: David Tonkin

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INFECTED BLOOD INQUIRY

EXHIBIT WITN1567014

NATIONAL DIRECTORATE OF THE NBTS

National Management Committee

Minutes of the thirteenth meeting of the National Management Committee held on Friday 1st February 1991.

Present: Dr. H.H. Gunson (In The Chair)
Dr. F.A. Ala
Dr. J.F. Harrison
Dr. R.J. Moore
Dr. A.E. Robinson
Dr. W. Wagstaff

1. Apologies for absence

Apologies were received from Dr. I.D. Fraser and Dr. S.M. McDougall.

2. Minutes of the twelfth meeting

The minutes of the twelfth meeting held on Thursday 25th October 1990 were approved as a correct record.

3. Matters arising

3.1 Medical Audit : Regional Transfusion Committees

The Committee discussed the findings of Dr. Gunson's survey of Regional Transfusion Committees and the need to make progress in the introduction of medical audit in the NBTS.

At present eight Regions do not have a Regional Transfusion Committee.

However, in discussion it was recognised that the foundations for medical audit in the NBTS are Hospital Transfusion Committees and it is essential that they should be in place and working as soon as possible.

Dr. Gunson agreed to write to Regional Medical Officers advising them of the plans for medical audit within the NBTS and where appropriate requesting their assistance in forming Hospital Transfusion Committees as a first step.

It was noted that the Minister of Health had announced that a further £47M had been allocated for the introduction of medical audit and RTDs could bid to their RHAs for some of these funds.

Action - Dr. Gunson

3.2 National Association of Blood Donors (NABD) : meeting with the National Directorate - 30th November 1990

Dr. Gunson reported that a useful meeting had been held. The NABD saw their role as one of partnership with BTS but also acting as a consultative body for matters affecting donors. In particular they asked that the possibility of allowing them to distribute their literature at NBTS sessions be considered.

Whilst welcoming this exchange of views the Committee felt that such a step would be premature at present.

Dr. Gunson advised the Committee that a further meeting with the NABD will be arranged.

Action - Dr. Gunson

3.3 Organisation and management of NBTS

The DH has not yet produced any proposals for the future or remit of the National Directorate once budget devolution is in place.

In order to stimulate discussion, a shortened version of the Directorate's proposals on the organisation and management of the NBTS has been sent to Catherine Hawkins, Regional General Manager, South Western R.H.A., leading RGM of the Regional General Managers Committee and member of the NBTS Co-ordinating Committee. Her response is awaited.

3.4 Budget devolution

Members reported that with local variations, budget devolution was taking place in all regions with RTCs pursuing Service Agreements with their hospitals. Finalisation of agreements awaits the calculation of product prices.

Members were disappointed to learn that DH would not provide additional funds for anti-HCV testing. DH has recognised that the devolved budgets as presently allocated will not cover increased costs and intends to write an Executive Letter pointing out to General Managers that budgets should not be ring fenced i.e., if blood is needed the money must be found from within other budgets by prioritisation. The Committee was concerned at this approach.

3.5 Policy on donors between 65 and 70 years

It was agreed that henceforward the policy on active donors over 65 will be as set out in NMC 4/91.

The upper age limit for donors will become the seventieth birthday provided the donor remains in good

4.2 **Handling of donations and donors found ELISA anti-HCV positive**

With respect to this topic and confirmatory testing (4.3) there was concern by some members of the Committee that because of financial constraints the ideal policies may not be feasible.

It was not possible to obtain a consensus but it was agreed that there was a preferred policy and this was:

4.2.1 A donation found repeatably ELISA anti-HCV positive would be subjected to confirmatory testing (see section 4.3).

(i) If the confirmatory tests were negative the donor's records should be flagged and the donor allowed to donate on at least one further occasion before the donor was withdrawn.

Cellular components from the index donation should not be used but the plasma could be used for fractionation (see section 4.5) and if subsequent donations continued to be ELISA screen positive but not confirmed the donor could be used for plasma donations.

(ii) If the confirmatory tests were positive/indeterminate the donor should be withdrawn from the panel, ideally should be counselled initially at the RTC and referred to an appropriate consultant physician.

No constituents of the donation should be used. (Please refer to section 4.3.5).

4.2.2

(i) It was pointed out that for economic and logistical reasons annotating donor records at the rate of 1 in 200 repeatable positives and continuing to bleed donors for the purpose of collecting plasma only could not be undertaken at some RTCs in England and Wales.

(ii) Moreover, finance would not be available at some RTCs to carry out the counselling of the donors by RTC staff. The implications for this omission would be that this workload would be transferred to the hospital service or general practitioners.

(iii) The financial implications to implement the proposals outlined in paragraph 4.2.1 would be to significantly raise the costs of both

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cellular components and plasma to the hospitals unless the RHA had allocated separate funding for anti-HCV testing.

4.2.3 The situation in Scotland is different from that in England and Wales and it was considered that SNBTS could implement the proposals in 4.2.1 above.

4.3 **Confirmatory testing**

Once again there was a difference of opinion in the Committee on the two items discussed under this item. A preferred policy was agreed as follows:

4.3.1 Samples of serum from a repeatably positive ELISA screening test should be sent to a reference laboratory and appropriate confirmatory tests should be carried out. In support of this, as against confirmatory testing at RTCs, Dr. Mortimer pointed out that although the 4-Band RIBA-2 test appeared to be the most appropriate at the present time this may be replaced in the future by improved tests and part of the work of reference laboratories is to evaluate novel tests and apply them to the samples from the screening test positives referred from RTCs. Currently not enough is known about these tests and it is important that data are generated and collated. Professor Cash agreed with these conclusions.

4.3.2

(i) The use of a PCR as a confirmatory test was debated at length. It was recognised that, particularly, those samples which gave indeterminate results with RIBA would benefit from having a PCR performed. Also, Professor Tedder reported that he had found three examples, in patients, of RIBA negative, PCR positive patterns of reactivity. This may not be unexpected in patients who are in an early stage of infection and have not produced antibody, although no one was aware of such a pattern of results in a donor.

(ii) It was recognised that knowledge of the presence of viral RNA would be valuable when counselling donors.

(iii) As with other confirmatory tests more information is needed on PCR testing. There was a possibility that this could be achieved, at least in part, from the work being carried out on the two anti-HCV trials in progress at the present time.

4.3.3

(i) It was pointed out by Dr. Barbara and Dr. Mitchell that RIBA-2 was not a difficult test to perform and could be incorporated into the work of the RTC. Dr. Mitchell considered that this would not only reduce the workload of the reference laboratory, but the results of the test would be available more quickly at the RTC.

(ii) Dr. Barbara agreed with these conclusions, but also considered that by performing the test at the RTC it would cost less than having it performed at a reference laboratory.

(iii) It was pointed out that in some RTCs the expertise for performing RIBA-2 may not be available and that the general principle which had been observed in the BTS for many years to have independent confirmatory testing by expert laboratories could be eroded. This would be detrimental to the Service.

4.3.4 The cost of performing PCR tests was the principal deterrent to their use in England and Wales. This, together with the fact that a donor who was confirmed seropositive but PCR negative would have to be referred for further clinical investigation in any case was considered by some members of the Committee to be sufficient reason for not using this test routinely.

4.3.5

(i) It was concluded that it was possible to operate a confirmatory system without including the PCR test, although this may mean that this test would have to be performed, in all likelihood, by the service performing the clinical follow-up of the donor.

(ii) All donors where a RIBA positive was found would have to be regarded as infectious and referred for consultation.

(iii) Those donors where the RIBA result was indeterminate may, with benefit, be retested following a subsequent donation. They would be referred for consultation if the PCR test was positive.

(iv) The major difficulty would arise with screen ELISA positive, RIBA negative donors if they were not retained as plasma donors. This group will comprise the majority of repeatably positives. If they are withdrawn from the panel it will be difficult to reassure them, with 100% certainty, that their health is normal.

4.4 **Counselling**

4.4.1 The appropriate sections of Dr. Gillon's paper on counselling were agreed with amendments. (Appendix III).

(i) The donor should be informed in the standard letter that the test which was positive was one for hepatitis and specifically hepatitis C. This was to reassure the donor that HIV infection was not involved.

(ii) The references to donors informing dentists and the Occupational Health Service (for health care workers) that they were carriers of hepatitis C were deleted. It was agreed that the donor's general practitioner should be informed and every effort should be made to ensure that this was done and a record made accordingly.

4.4.2 It was agreed that the amended paper should be issued to RTCs to be used as guidance for the preparation of their local SOPs.

4.5 **Plasma for fractionation**

4.5.1 It was agreed that plasma sent for fractionation would be anti-HCV negative.

4.5.2 The definition of anti-HCV negative would, at the present time, be non-reactivity according to the manufacturer's instructions using the RIBA-2 test.

4.5.3 It was stressed to the reference laboratories that a clear report of "anti-HCV not detected by RIBA-2" was essential.

4.5.4 The plasma from any donation where a positive or indeterminate reaction was found by RIBA-2 would NOT be used for fractionation.

5. **YERSINIA ENTEROCOLITICA TRANSMITTED BY BLOOD TRANSFUSION**

5.1 The action taken by the FDA was noted. It was reported by the Chairman that this included the close observation of patients receiving cellular components of blood during the first 15 minutes of the transfusion and stopping the transfusion at any sign of a febrile