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CONFIDENTIAL TO COMMITTEE MEMBERS MSBT 15/

ADVISORY COMMITTEE ON THE MICROBIOLOGIAL SAFETY OF BLOOD AND TISSUES FOR TRANSPLANTATION (MSBT)

MINUTES OF THE MEETING HELD ON THURSDAY 4 JUNE 1998

Chairman:
Dr J S Metters

Members present:
Dr A J Cant
Dr D W Gorst
Dr D B L McClelland
Dr P Mortimer
Dr A Robinson
Dr T J Snape
Dr T Wyatt
Dr R E Warren
Dr A Zuckerman

Observers:
Dr A Keel (SO)
Ms J Dhell (DH)
Dr P Doyle (DH)
Dr H Nicholas (DH)
Dr L Tsang (MCA)
Dr N Beckay

Secetariat:
Dr M McGovern
Ms G Skinner
Mr T McHugh

APOLOGIES FOR ABSENCE

Apologies had been received from Dr Perry, Mr Forsyth, Dr Smith and Dr Mairs.

MINUTES OF THE FOURTEENTH MEETING HELD ON 26 FEBRUARY 1998

2. The minutes were agreed.

MATTERS ARISING

Hepatitis C Lookback Study

3. Dr Keel raised the question of continuing activity on this study indicating that Scottish Natational Blood Transfusion Service had reached a stage where further progress on untraced patients would be very time consuming. In a number of cases there were no

further avenues to explore, and it was probable that Scotland had done as much as it was possible to do. However, a decision that no further progress could be made was a sensitive one, and any move in that direction would require transparency, so that it was clear to all that every effort had been made to trace patients.

4. A chart showing the current status of the Lookback Study was tabled. Members agreed that it was necessary to ensure that the figures on the chart were compatible, and that each case where tracing had not been possible should be accounted for, making clear where and why each trail ended. This would take resources and the data on those identified needed to go into the registry, to give more information on the natural history of the disease.

5. While it was open to Scotland to approach their Minister about further work, and for the Minister to then consult his counterparts it would be reasonable not to take that action until the whole picture of those untraced had been assembled.

Virus inactivated plasma

6. Dr Robinson reported that the Octapharma fresh frozen plasma product was now available as a licensed product. Octaplas was pooled from about 5000 donors, solvent detergent treated (virally inactivated), and produced from non-UK plasma whereas FFP from the NBS was unlicensed, derived from a single donor, not virally inactivated, and UK sourced. In addition NBA were developing the methylene blue UV light virally inactivated single unit FFP, again using UK sourced plasma, thus giving clinicians a choice.

7. There were now alternatives to FFP and blood products from non UK plasma will become available by the end of the year. While the risk of infection from single donor unit FFP was small and that from vCJD theoretical from UK plasma, physicians were likely to adopt the broad "better safe than sorry" approach. However as there were no alternatives to UK sourced blood or labile blood components and indeed certain blood products these would continue to be used. It was agreed that advice on the clinical use of FFP should come from the profession

8. Members agreed that the NBA should focus their efforts on leucodepletion which was almost certain to be recommended by SEAC rather that developing MB FFP.

Introduction of NAT Testing

9. Dr Robinson reported that since the announcement of the decision to important plasma because of the risk of vCJD some hospitals were resisting the inclusion of NAT testing costs in the handling charge for blood components. The point was that the technology which the NBA was introducing which allowed minipools NAT testing could be exploited to test labile components also. This could be achieved very quickly and would further improve safety of blood components. Germany was ready to release NAT tested red cells and platelets by April 1999. She requested MSBT's advice and support for the NBA programme.

10. Dr Snape said that at a meeting in Amsterdam the previous day about NAT testing

fractionated products and cellular components the German position was clearly well advanced. Other member states - the Netherlands, Belgium and France - were also starting to follow suit on single component NAT testing and release.

11. Members agreed that it was strategically important to continue to invest in NAT testing, and be seen to invest in the safety of the blood supply. This was especially relevant as Ministers had made clear that the importation of plasma was a temporary measure which would come to an end with the development of nvCJD testing and a better understanding of the TSEs. To stop now would result in future disadvantage.

12. Dr Metters therefore proposed, and members agreed, that to assist the NBA the Committee should formally record its support for NAT testing:

"The unanimous view of the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation was that the position with regard to NAT testing should remain unchanged."

The question of whether NAT testing should be introduced simultaneously at all centres, or phased in, would be on the agenda for the next meeting.

HTLV1

12. Dr McGovern advised that Ministers have again looked at the issues and Baroness Jay and the Secretary of State would be discussing it further with officials. The outcome would soon be known.

PROGRESS REPORT ON nvCJD

Risk Assessment (MSBT 15/1)

13. Dr McGovern outlined the present position. The risk assessment report was ready from Det Norske Veritas and focused on blood components, blood products, and donations from those who had received blood transfusion in the past. It suggested that infectivity was likely to be associated with whole blood and labile products more that fractionated blood products. It also suggested that donors who were past recipients of blood brought a higher risk of perpetuating any possible epidemic. Members raised concerns about this emerging conclusion and maintaining the blood supply. SEAC would meet on 15 June to consider the report and provide advice to Ministers.

Leucodepletion Strategy (MSBT 15/2)

14. Dr Robinson reported that the strategy for the implementation of leucodepletion (if advised by SEAC and accepted by Ministers) was progressing well. The timing of introduction would vary according to zone and locality, but overall implementation within a specified timetable, 15 Months following direction from Secretary of State, would be necessary.

15. With regard to phasing in, when testing for hepatitis C was introduced all centres were asked to start on the same day. In practice some centres were testing beforehand,

but presentationally there was a single start date. For leucodepletion however, filters would be installed progressively, with all installations completed by a certain date. The current Transfusion Task Force Guidelines of the British Committee for Standards in Haematology recommended which patients should receive leucodepleted blood components.

16. Members agreed that the most reasonable advice to Ministers would be

that blood centres would introduce leucodepletion as soon as practicible within a given time frame according to each centre's capability

that by a specified date however all would provide, and hospitals could expect from that date, to receive only leucodepleted blood components and

that in the meantime, leucodepleted blood and blood components would only be specifically given to those listed in the BCSH guidelines.

Blood products - oral update

17. Dr Metters reviewed recent events -the announcement that CSM would be reviewing individual products -that BPL had been given permission to import plasma from outside the UK had been made immediately following the February MSBT meeting -the announcement on 13 May that blood products should not be sourced from UK plasma for until there was clearer knowledge of the TSEs and testing for vCJD became available..

18. Dr Snape outlined the practical arrangements. BPL fractionated the last batch of UK plasma on 29 May. Two US plasma sources of paid donor plasma had been identified and 300-350 tonnes per annum would be imported. This would fully meet the needs of patients in England and Wales. The NBA had audited the plasma sources, and MCA audits would begin in the following week. The BPL plant was currently shut down for full decontamination which would take 4 weeks. The protein removal was being carefully measured, and components were being replaced costing a little over half a million pounds. BPL would be able to demonstrate as fully as possible that they had put clear blue water between UK and non-UK plasma, to satisfy MCA requirements.

19. Fractionation would begin early in July and it was expected that BPL would have all licensable product lines from non-UK plasma from 1 October. The exception was the provision of hyperimmune immunoglobulin which would become available three months later.There would be no shortfall of products in the interim, providing that purchasing continued at anticipated rates.

20. 500 tonnes of plasma would be destroyed by incineration. It might be possible to preserve 2 months supply for the longer term, although there would be a cost because special bags would be needed. BPL had taken on board very seriously its role in rehabilitating UK plasma, and it would explore all options for reintroducing its use as soon as conditions permitted. With regard to hyperimmune products, where alternative sources were less accessible, the CSM had said that there could be stockpiling until the alternatives became available. Dr Metters commended BPL on progress with the enormous task they were addressing.

Update on study of CJD surveillance and blood services - lookback study (MSBT 15/4)

21. Paper MSBT 15/4 gave a brief update. Members who had attended the meeting in Edinburgh on 5 May agreed that it was not clear how far this lookback study had progressed, which patients had been followed up and what further work might be done. In addition there appeared to be a lack of clarity about the protocol and funding. Members agreed the Committee needed better clearer information about the scope, progress, future and funding of the study.

Record keeping for patients who receive blood or blood products (MSBT 15/5)

22. Paper MSBT 15/5 set out the NBA's position on record keeping when blood components and products were used to treat patients - requiring a permanent record in the patient's notes of the component or product, the date given and the unit or batch number. However, patients' records often did not reveal what the patient had received, and it seemed clear that good practice guidelines were needed. Dr Gorst observed that a good laboratory recorded conscientiously, but that the 'chaos' of the ward made it more difficult to be methodical in that setting.

23. Dr Cant commented that as different components were infused into a seriously ill patient, any recording action had to be immediate and carried out by the person setting up the infusion. This could easily be a trained nurse rather than a junior doctor. Nonetheless Chief Executives needed to be reminded that a secure method of recording this information was needed. Members suggested that this be picked up as part of CMO's initiative on the appropriate usage of blood, and that guidance be disseminated widely in the NHS to clinicians and Chief Executives in line with clinical governance and total quality improvement.

MSBT guidance

Implications in the light of the Sir William Stuart enquiry
Implications of PCR testing of bone banked material (MSBT 15/7)

24. The enquiry by Sir William Stuart had been set up by Scottish Ministers after the donation of a cornea by a patient who was later diagnosed as having classic CJD. There had been a communication failure between the hospice, those involved in the post mortem within the trust, and others in the trust. One of the recommendations in the report was that the UK health departments should update their guidance on the microbiological safety of human tissues and organs used in transplantation. This MSBT guidance was now three years old and volunteers for the updating were sought.

25. Dr Warren advised that the Association of Medical Microbiologists had reconvened its panel on tissue transplantation and that he would be happy to be involved in the revision of the MSBT guidance. Dr Mortimer also agreed to be involved. Ruth Warwick was suggested as a transfusion expert, and John Forsyth to represent Scotland, if they were willing.

26. The secretariat would arrange this review of the guidance later in the year.

SHOT report and Bacterial Contamination of Blood Components (MSBT 15/8)

27. SHOT had originated from discussions within MSBT. The 1998 report was its first, and it contained a number of useful recommendations. Members supported the work enthusiastically. The NBA had developed a national policy document providing a national protocol for investigation of suspected contamination of blood components. The PHLS had been developing a 'sister' document to provide a national policy for bacterial investigation of all blood transfusion incidents. Dr Warren would consult rapidly within the PHLS. Most hospitals now had a transfusion committee and when the documents were in their final form the DH could commend them. Comments on the NBA document should go direct to Dr Robinson.

The CMOs' initiative on the Better Use of Blood in the NHS (MSBT 15/9)

28. The seminar on 6 July would be opened by Baroness Jay and chaired by Sir Miles Irving. The medical Royal Colleges, representative bodies and individual experts and users of blood from around the UK had been invited. The venue was St Thomas's and about 70 to 75 delegates were expected to attend. In the morning various aspects of blood transfusion and supply would be discussed, in the afternoon 5 groups would look at specific areas of transfusion practice. The aim was to engage the profession in the issue, not instruct them. The focus would be on, blood safety, translating current guidelines into practice, support for hospital blood transfusion committees and getting the proper management of the blood supply and transfusion practice taken seriously within the NHS. While a prime aim would be to reduce the demand for blood the main aim was to encourage better patient care and use of NHS resources. The seminar would result in a Health Services Circular and signal be the beginning of a series of events over the next two years aimed at improving the use of blood components within the NHS.

EUROPEAN MATTERS

Tissue Banking

29. Dr Doyle reported that the Council of Europe draft outline document on the safety and quality assurance of organs and tissues should be issued shortly. Names of appropriate and interested experts should be forwarded to Dr Doyle, who would arrange distribution for comment.

30. On the question of UKTSSA, the proposal now was for a much more wide ranging review than had been originally anticipated and the whole question of what to do about tissue banking could be subsumed in that review, including regulation. It was possible that there would be an EU Directive in a couple of years. MSBT had in the past advised the Department that tissue banking should be regulated, and Ministers could be reminded that its views had not changed. Every effort would be made to get the EC Directive right.

Recommendations (inc donor selection)of the Council of the EU(MSBT 15/11)

31. The recommendation before the committee,on the suitability of blood and plasma donors and the screening of donated blood in the EC was not legally binding. However, although compliance was not a formal requirement, non-compliance could be used by

those who were critics. Dr Robinson commended the Council of Europe guidance produced by an expert committee chaired by Dr Wagstaff, in preference to the style of the Commission's document. It was noted that the Commission were not inclined to accept and were determined to develop their own.

Impact of donor deferral for past history of blood transfusion on the UK blood supply

32. Paper MSBT 15/12 was tabled. It set out the potential impact of removing blood recipients from the donor pool to reduce the theoretical risk of nvCJD infection. 5% to 10% of donors had previously had a transfusion, and the number of donors would thus be significantly reduced. SEAC would want MSBT's advice. Members were not in favour of permanent deferral, but acknowledged that there was no sound information on the length of time necessary. Professor Zuckerman observed that it was necessary to balance the immediate medical need of the patient against a theoretical risk. There was an increasing need for blood each year, and the extra surgery carried out under the Waiting List Initiative would add significantly to demand. There was a danger of overstepping the mark on safety measures, to the detriment of donor numbers and an adequate blood supply. The known risk had to be balanced against the hypothetical, and there was no alternative to blood for transfusion in the vast majority of cases. The Committee agreed that there would inevitably be theoretical risks and that these would have to be tolerated to ensure an adequate supply. Dr Metters agreed to put this view clearly to SEAC.

AOB

33. Professor Zuckerman referred to a recently discovered virus in Japan, a parvovirus-like agent. It was transfusion transmitted virus (TTV), and needed to be kept under review. It was agreed that this would be put on the agenda for the next meeting and that Professor Zuckerman would send papers to Dr McGovern.

Dates of future meetings

34. Future MSBT meetings would take place on 29 October, 25 February (need to change), 3 June and 28 October.

14 October 1998