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SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE - GENERAL ISSUES MEETING
14 OCTOBER 1994 - CONFERENCE ROOM E ST. ANDREW'S HOUSE.

In attendance:

Mr. J.T. Donald, GM, CSA	}	
Mr. D. McIntosh, GM, SNBTS	}	Common Services Agency
Dr. R. J. Perry, Director, PFC	}	
Mr. G.W. Tucker, ME-PSDD	}	
Mr. R. Panton, ME-PSDD 2	}	Scottish Office Home
Mr. G. Wildridge, ME-PSDD 2	}	and Health Department
Dr. A. Keel, SMO, MED	}	

Clinical Trials

1. Mr. Tucker explained that there appeared to be an increase in the number of clinical trials being conducted and the ME wished to ensure that the Secretary of State, by indemnifying trials, was not exposed to an excessive liability. He considered that the Department should tighten its controls over clinical trials and maintain a formal register. Dr. Keel was concerned at the trials of some products in unusual indications and was doubtful of the ultimate value of a trial of IVIgG in the treatment of a rare condition such as CIDP.

2. Mr. McIntosh welcomed the proposal of a register. He advised that Dr. Pelly, the new head of the Product Services Department at SNBTS had recently produced an update on all clinical trials currently under way and he circulated copies. He asked if the Department would consider any changes needed in the format so that a formal register could be prepared.

3. Dr. Perry advised that the rise in trials might be more apparent than real. Overall the trend was for a smaller number of trials but for an increasing number of patients. A licence application for the new Factor VIII was being prepared and these trials would be at an end as soon as the MCA granted the licence. Additionally, the MCA had decided that there would be no need in future to obtain an exemption certificate for existing products already licensed for another condition provided the method of administration was the same. This should also help reduce numbers, particularly in IVIgG trials. On the question of CIDP, the quantities of IVIgG used were significant even if the patient numbers were low and in Canada CIDP was now a proven indication for treatment with IVIgG. It was sometimes unavoidable that patients elsewhere in the U.K. would be involved in trials where it had not been possible to secure sufficient patient numbers in Scotland. These would be kept to a minimum and patients outwith the U.K. would not be involved.

4. It was agreed that SNBTS would produce more detailed proposals on its clinical trial programme, including projected recruitment numbers and timeframe. The Department would liaise with SNBTS to establish a tighter system of control.

Supply of Blood Products to Eire.

5. Mr. McIntosh updated the meeting on the continuing interest from Eire to have plasma from Eire fractionated at PFC under contract. Mr. Tucker had reservations about the liability to which the Secretary of State might be exposed outwith the U.K. and the use of NHS facilities even at marginal cost.

6. Mr. McIntosh confirmed that the legal position was that product liability attaches to the manufacturer and that as such SNBTS (and therefore the Secretary of State) would bear this liability. However contract fractionation was common practice in Europe and the potential risk of cross contamination was very small as the plasma would be processed separately and strict arrangements would be in place for testing etc. The MCA would also be responsible for inspecting the systems to ensure that appropriate safety measures were in place. Mr. McIntosh was also confident that SNBTS could increase throughput and operate even more efficiently without increasing fixed costs and that this would result in a saving to the British taxpayer.

7. Mr. Tucker had a concern that the venture would in future require sums of public money to fund non-NHS business. It might be claimed that PFC has too much capacity - the proposed changes in how BPL operates might also cause criticism that SNBTS was poaching business. Mr. McIntosh pointed out that BPL had visited Eire but the Irish do not seem interested in dealing with BPL because of its more limited product range. If the contract for fractionation did not come to Scotland, it would be likely to go elsewhere, outwith the U.K. It was agreed that SNBTS would prepare a detailed business case. The Department would then seek the views of Ministers.

ALT Testing.

8. Mr. Tucker advised that he had attended the recent meeting of the MSBT and had shared the view with many other attendees that since ALT testing made no contribution to blood safety, its introduction should not proceed. However there should be a uniform approach from all Health Departments in the U.K. The MSBT will consider the matter again in the future. Dr. Perry was concerned that if ALT testing were introduced as proposed by NBA, then it would make the U.K. the only country in W. Europe to have higher standards for fractionates than for red cell concentrates. He also questioned the wisdom of introducing the test to develop export markets such as Germany which in the longer term would become self-sufficient. It was more logical for European countries to stop ALT testing than for the UK to begin. The MSBT decision was awaited.

Co-operation with NBA/BPL.

9. SNBTS had sent 750 units to England during the recent shortage and would probably send more in December. England had passed the crisis point but stocks were still below the minimum target.

10. The NBA had produced a public consultation document on the proposed closure of some centres and SNBTS would send the Department a copy. The adverse publicity on the closures was also affecting SNBTS who had needed to remind NBA again that Scotland has its own Service and does not need advertisements used in England to be displayed in Scotland. Dr. Perry was continuing to maintain a constructive dialogue with BPL whilst ensuring that SNBTS interests were protected.

Hepatitis 'C' - Look-back

11. Mr. Tucker advised that the MSBT was examining proposals for a look-back and was returning to the subject in December. The effectiveness of (Interferon) therapy for HCV infection had been questioned at the meeting. Dr. Keel and Dr. Perry awaited the decision but pointed out that MSBT had no real locus in this since it was not a matter of blood safety.

12. Mr. Tucker reported that Mr. Dempsey, who had raised the matter of HCV in the media as well as with the Minister and SNBTS, had written to the Department again. The media is always interested in such stories and this was another potential problem. Mr. Mc Intosh confirmed that if it were decided on a U.K. basis that a lookback were practical, useful and/or legally necessary, SNBTS is prepared to respond quickly. Dr. Perry mentioned that lookback exercises were increasingly important in Europe and that 'quarantine' of plasma for fractionation had even been suggested. The outcome of the MSBT decision is awaited. In the meantime SNBTS will continue to prepare the ground via pilot studies and data analysis.

Informed Consent.

13. This was not felt to be a matter for SNBTS to become involved in. A letter from the Central Legal Office was circulated. It gave the view that informed consent was not necessary for blood transfusion and this was accepted. It was however felt to be important that patients in general are made aware of any significant risks to their safety.

Health Care International.

14. There were reports that HCI was in financial difficulties and the low patient numbers seemed to bear this out. Mr. Mc Intosh circulated a list of products supplied and this confirmed the small quantities involved. HCI had generated a lot of adverse publicity for SNBTS and from their viewpoint it would be preferable if more of the patients treated at HCI were from the NHS.

SNBTS Strategy.

15. Mr. McIntosh circulated an outline paper on the ongoing triennial review of SNBTS strategy. The triennial review was due in 1995 and a number of working parties, mostly headed by doctors had now been established to identify requirements and produce proposals on how to achieve these including, as appropriate, measures to ease the burden on the public purse. Mr. Tucker hoped the strategy would aim to meet clinical demand and, by increasing efficiency, respond to increasing demand without extra cost. Mr. Tucker explained that the revised strategy would need to be with the Department by June 1995 so that the need for any extra resources could be considered during the PES process. It was also important for SNBTS to define its core business and to clarify whether its strategy was based on a response to actual need, rather than demand.

16. Dr. Keel advised that there was a need for clinical audit to have a look at outcomes and relate them to useage. This was particularly the case with Factor VIII which accounts for a majority of SNBTS resources. Dr. Lowe and Dr. Ludlam had applied to CRAG to fund research into audit of FVIII useage but had been turned down. They were now applying to CSO. The cost of the research was understood to be c. £100,000 over 3 years. Mr. McIntosh considered this research as potentially very useful and stated that SNBTS would try to fund this if it were turned down by CSO. To do this, he might try to use some of the income generated from England and defer the purchase of plasma usually made with these funds. The decision of CSO was awaited.

UKBTS/NIBSC Guidelines.

17. Mr. McIntosh sought to clarify the status of the 'Red Book' He considered that a properly controlled statutory body was necessary to establish the authority of the guidelines and was concerned that the book was produced by a self-appointed committee with no legal input and no clear line of accountability. He was concerned at the possible resource implication of future editions of the guidelines and did not wish to sign a 'blank cheque' by adopting the guidelines permanently. Instead he proposed to consider each set of guidelines individually when produced and to decide if they were acceptable.

18. Directors of Transfusion Centres in England appear to have welcomed the guidelines and have recommended to the Board of the NBA that they be adopted. SOHHD does not issue or endorse these guidelines and was supportive of the position that SNBTS reserve the right to endorse only one edition at a time with referral to the CSA Board if necessary. Mr. Panton would attempt to clarify the position with the Department of Health.

Future of SNBTS / CSA.

19. Mr. Peterken's paper on the future of SNBTS (and SAPU) had been circulated in the Department and had generally attracted negative comments. The paper would be considered by the CSA Board. Mr. McIntosh did not see value in spending money setting SNBTS up as a special HB when the statutory provision for it and CSA was already clear. SNBTS was happy to remain a part of CSA provided that central CSA costs were kept to a minimum, that GM, CSA continued to delegate operational responsibility to the GM, SNBTS and that the CSA approach was compatible with the ethos of voluntary blood donation i.e. that sale of blood did not arise.

20. Mr. Tucker noted this view but warned that SNBTS, like any other part of the NHS must be scrutinised to establish its efficiency. Eventually SNBTS should be able to show how much expenditure or effort goes into any particular Trust. Mr. McIntosh stated that costed SLAs were beginning to identify this level of detail and that the costing system being established was already proving very helpful. Fully costed SLAs would be prepared in due course. He welcomed questions from the Department on this subject.

Any Other Business.

Dura Mater.

21. The MSBT had concluded that it would not be appropriate to exclude recipients of Dura Mater from donating blood in view of the extremely low potential risks. SOHHD and SNBTS endorsed this view. It was emphasised that the decision as to whether to accept blood from an individual lay ultimately with the consultant in charge. Even where clear exclusion criteria had not been laid down, it was always possible for the consultant to use his discretion and exclude a potential donor if there was suspicion that the donor had undergone surgery using a dura matter graft.

Tissue Banking

22. Dr. Keel advised that the Department of Health review of tissue banking had praised the arrangements at RTCs in Scotland. Some form of model licensing agreement (probably not MCA controlled) would almost certainly be recommended for these services.

Further meetings.

23. It was agreed that the meeting had been useful and that another should be held in the spring, probably in March.