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UK BTS/NIBSC STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS (SCTTI)

Minutes of the meeting held at Birmingham, on 19th October 1994 at 10.30 am.

Present:

Dr. F. Ala (Chairman) Dr. J. Barbara (Secretary) Dr. E. Follett Dr. R. Mitchell Dr. P. Mortimer Dr. A. Robinson Prof. R. Tedder Dr. L. Williamson

Apologies: Prof. J. Cash Dr. P Flanagan (Dr. P. Minor)

Action

1. The minutes of the previous meeting were approved.

2. Matters arising

2.1. Microbiological assays in Red Cross Centres

Professor Cash presented a table of the range of tests performed by Red Cross Centres in different countries; the data had been collated by Dr. Kothe.

2.2. Anti-HBc screening of donors

Dr. Barbara tabled a draft 'update' for comments by members, prior to resubmission to MSBT, if this is considered appropriate. Blood centre records may require more detailed review, a task that could form part of the job of the person appointed to the joint NBA/CPHL microbiology post.

2.3. HTLV trial at Leeds

- 2.3.1. Dr. Robinson reported that MSBT has reaffirmed that HTLV screening is not warranted in the UK, even if a suitable combined test is available. A combined HIV/HTLV would not therefore be desirable for HIV screening as it would then 'drag in' HTLV screening in the absence of a perceived need to do so. Dr. Ala to inform Launch Diagnostics of this decision. (This was done, subsequent to the meeting).
- 2.3.2. Selective recruitment of ethnic minority donors is necessary in certain areas. Dr. Minor and Professor Tedder have expressed concern at the increased HTLV risk in such donors; an 'anonymous' study of HTLV rates in these donors was therefore recommended.

2.4. Dual ELISAs for anti-HCV & PCR study

It was noted that this study has been somewhat superseded by the donor readmission policy. Dr. Williams will arrange for retesting of fresh samples in those cases where unexpected positive PCR results were obtained.

Dr Williams

2.5. Audit of HCV confirmation practices

Dr. Ala is awaiting a reply from Dr. Galea.

2.6. Microbiology kit approval

The first meeting of the Technical Group for kit approval is on 24th October 1994. As yet Dr. Ala has received no reply from Mr. Garden of the Medical Devices Agency (formerly, the Medical Devices Directorate) asking about increased funding for rapid 'tailor made' kit assessments at CPHL, where appropriate. This remains an urgent requirement. The meeting recommended the formulation of a resourcing structure by the NBA to address this need.

Professor Tedder also expressed an interest in the chance to tender for certain aspects of validation work.

2.7. SCTTI sub-committee

Minutes of the last sub-committee meeting were tabled by Dr. Barbara.

2.8. Evaluation of the testing of 'pools' vs single samples

Dr. Atrah to contact Dr. Kitchen to discuss this.

2.9 Bacterial transmission by blood components

Dr. Ala will circulate to members a proposal for a study of the above; he will incorporate any Dr. Ala comments in his submission to Dr. Robinson.

2.10. HCV 'Look back'

MSBT had several reservations about the SCTTI recommendations which, together with Dr. Gillon's paper, were submitted by Dr. Robinson. MSBT will convene a group (Dr. Robinson, Dr. Gorst and Professor Zuckerman) to examine the implications of look back, with special regard to younger patients. Mr. Kelly, with others, will consider the legal implications of look back in a 'generic' sense.

Considerable discussion followed concerning the actual likely therapeutic benefits for those patients identified as infected and the cost-benefit vs the need for 'openness', the lack of which engendered much criticism with regard to HIV i.e. do the medical authorities have the right to decide whether patients should or should not know they have been infected, regardless of cost-benefit consideration, potential efficacy of therapy or age of recipients? A 'duty of care' was also perceived.

2.11. In-house Reference testing

Dr. Wagstaff has asked SCTTI for clarification on this issue. Several points were raised:

- facilities for a full reference repertoire are increasingly complex (e.g. PCR).
- Reference laboratories see a wider range of 'tricky' samples; therefore their experience is greater; conversely, such samples need to be 'centralised' in Reference laboratories so that the full range of reactivities can be experienced.
- HCV confirmation is relatively simple, but only if a basic 'RIBA-3' protocol is followed.
- can we prohibit 'in house' Reference work in the absence of general quality standards for Reference laboratories?

by erall, it was felt that while 'in house' Reference work was permissible provided that this work was totally 'independent' of the screening functions in terms of documentation and compartmentalisation, the increasing levels of sophistication made external Reference work very desirable. It becomes essential when donor re-admission is involved + PCR

3. Adverse sequelae of transfusion

Dr. Williamson reported on the formation of a UK group to consider all adverse reactions. It will not have a 'policing' function; rather it will audit to assess the frequency of such reactions.

The meeting felt that viral and bacterial reactions warranted specific attention. This requires Dr. Ala protocols for local investigation, and national collation (item to be carried forward).

Dr Mitchell has sent a draft paper on the investigation of bacterial reactions to MSBT.

4. Donors with CJD

Apparently, DoH will not be investigating the 22 blood donors known to have CJD. Dr. Robinson asked if there was any readily available information on the recipients of blood from these donors.

5. HIV-1 subtype O kits

The Technical Group will be considering these kits at their next meeting.

6. Epidemiology of HCV

The question of considering the need for defining and commissioning epidemiological studies, to be carried over. This arises from correspondence to the chairman on:

- sexual partners of 'virology positive' donors (Dr. Shwe, Prof. Tedder). ٠
- sexual transmission of HCV.
- HCV seroconversion in established donors. ٠
- 7. HCV markers in Rh negative women

Dr. Robinson reported that Dr. deSilva is dealing with this topic. Follow-up is continuing at NLBTC; the small number of patients involved at Cambridge were found to be anti-HCV negative. **Dr. Robinson** Dr. Robinson will enquire from Dr. deSilva about progress.

Dr Ala

8. Gambro bags in liquid N₂

Dr. Ala has decanted his liquid N₂ tanks and samples of the sediment have been sent to Professor Tedder for viral PCR studies.

It was stressed that bags should be stored in the vapour phase and not in the liquid N_2 .

9. Correlation of BTS and CDSC records on PTH

Dr. Ala reported that this question appears to be 'equilibrating' between Dr. Heptonstall (to whom he has written) and Dr. Nicholl.

10. Clearance of donors involved in PTH enquiries

Such donors can be reinstated if shown at a Reference Laboratory to be free of markers of infection. These should include genomic analysis, where appropriate, when considering HIV and HCV.

Dr. Ala

Professor Tedder will draft a letter to this effect for Dr. Ala to send to Dr. Gorman. He will also clarify when a donor can resume donation within the false-positive readmission protocol. (A copy of this letter to be sent to committee members).

11. Six month follow-up period for false-positive donor readmission

Dr. Herborn asked if this period could be reduced. It was felt that the 6 month period be retained for safety reasons. Dr. Ala to write to Dr. Herborn. Dr. Ala

12. Leptospirosis

Dr. Barbara's short review on this topic was tabled.

13. Viral inactivation of clinical plasma

Dr. Ala will convene a specific meeting to discuss this topic.

14. Revised AIDS Leaflet

Dr. Hewitt asked Dr. Barbara to canvass members opinions on the revised leaflet, before the next donor selection SAC meeting on 17th January 1995. Dr. Ala will circulate members with a copy of **Dr. Ala** the revised leaflet and will ask for written comments.

15. Member's attendance

It was agreed that committee members finding difficulty in attending would have to be replaced after three successive absences.

16. Date of next meetings

It was agreed that Dr. Ala and Dr. Barbara would organise 2 types of meetings:

- standard SCTTI committee meetings
- meetings to discuss specific topics, to which particular experts could be invited.

Dr. Ala will circulate dates and topics to members.

Dr. Ala

Dr. John Barbara, Secretary, SCTTI

JB/mm/30 Nov 94 micro/meetings/minutes.sctti/19 Oct94

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