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

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

Present:	Dr. F. Ala	(Chairman)	Dr. E. Follett
	Dr. J. Barbara	(Secretary)	Dr. R. Mitchell
	Prof. J. Cash		Dr. P. Mortimer
	Dr. H. Gunson		Prof. R. Tedder
	Dr. P. Flanagan		
Apologies:	Dr. A. Robinson		
	Dr. L. Williamson		
	(Dr. P. Minor)		

Action

1. **The minutes of the previous meeting were approved.**

2. **Matters arising: correction:**
   Item 5 of previous minutes; Abbott anti-HCV ELISA-3 is still subject to further investigation before approval.

3. **Matters arising: agenda items**

   3.1. **anti-HBc screening**
   Dr. Barbara was asked to produce an updated position paper on the question of anti-HBc screening. **Dr. Barbara**

   Dr. [redacted] papers on anti-HBc testing of established and new donors (enclosure A) and on a comparison of the ADI and modified corecell tests (enclosure B) were tabled.

   3.2. **Management of anti-HCV positive donors**
   Rather than organising a symposium on this topic, it was recommended that the manner of counselling and referral of anti-HCV positive donors at BTS level should be audited. Similar audits for the other microbiological agents might subsequently be undertaken. (See letter from Professor Cash: enclosure C). Dr. Ala will write to members to ask for suggested questions for auditing current confirmation, counselling and referral practices. **Dr. Ala**

   Professor Tedder will write to Dr. Ala to point out the lack of funding for HCV referrals and clinical care. **Prof. Tedder**

   3.3. **PHL charges for microbiological Reference Testing**
   Dr. [redacted] has written to Dr. Ala to inform him that the PHLS will not charge for HIV and HBV reference work. In contrast, they have not been nationally funded for HCV reference work and will therefore need to charge for this service.

   It was noted, however, that some PHLS laboratories (e.g. Leeds and Birmingham) were charging for HBV confirmation.

   The topic will be taken up at the next SCTTI meeting and a formal announcement of arrangements will then be planned. **Dr. Ala**

   3.4. **Lyme disease**
   'Any questions' article in BMJ tabled (enclosure D).

   3.5. **Dual anti-HCV ELISAs and PCR**
   Deferred to next meeting, for presentation of Dr. Williamson's results. **Dr. Williamson**

Action

3.6. **Abbot anti-HCV ELISA-3**

Newcastle have tested 3000 consecutive donor samples by Abbott anti-HCV ELISA 2 and 3 in parallel, and found a 50% increase in non-specific reactivity with the latter assay. Overall the results were similar to those from Scotland. A draft report is with [redacted]

Scotland has mandated the third generation assay. In England, the second generation assay is to be used until Dr. Mortimer's evaluation is reviewed for confirmation that there has been no decrease in sensitivity overall. Dr. Follett expressed his concern at any delay in introducing the Abbott anti-HCV ELISA-3, and will write to Dr. Ala with examples of samples showing the enhanced sensitivity of the test compared with Abbott anti-HCV ELISA-3 (subsequently received: enclosure E).

A protocol for 'fast-track' evaluation of potentially enhanced assays is under discussion. For any modified assays, this will concentrate on confirming that there is no impairment of sensitivity and detection range. There should be consistency between Scottish and English policies on this matter.

With respect to third generation anti-HCV ELISAs it was noted that the latest version of the Murex anti-HCV ELISA (with an NS5 antigen modification) appears to be showing enhanced specificity in trials at Edinburgh.

3.7. **Syphilis testing**

Referred to the SCTTI sub-committee.

3.8. **Proposed study on testing pools of samples**

The centres at Birmingham, Brentwood and Colindale have jointly purchased BBI seroconversion panels for this study. Dr. Follett reported that only the very weakest reactive samples in seroconversion panels are not detected at a 1 in 5 dilution, similar to the report by Parry et al (enclosure F). Dr. Barbara pointed out that the proposed study will however, include experiments on testing pooled samples (including weakly reactive specimens) where the volume of sample diluent is proportionately reduced to take the pooling dilution into account.

Although a European directive in 1989 specified that *individual* samples be tested, WHO have not ruled out the testing of pools if defined protocols are followed. The committee felt that the proposed study (for which protocols are in preparation) was worthwhile.

3.9. **BacTalert study of bacterial contamination**

Regretfully, this study is now unlikely to proceed due to lack of funding.

In relation to bacterial transmission, it was noted that an unambiguous definition of what should trigger a report from a hospital to its transfusion centre about a suspected post-transfusion bacterial reaction was still not available. This is needed before an effective reporting system can be structured. Dr. Mitchell will contact Dr. Napier (BCSH) to try and reactivate this issue

Dr. Mitchell

3.10. **HCV 'look-back**

Conflicting impressions of the effectiveness of anti-viral treatment for HCV infected patients and the cost-effectiveness of such treatment were discussed. Therefore, the value of 'look-back' to trace previous recipients of donors found to be anti-HCV positive, together with the question of who would be responsible for 'look-back' and subsequent patient management was difficult to assess. However, the issue needs resolution and will be examined in more detail by a group to be convened to consider it further.

Action

In the meantime, Professor Tedder will ask [redacted] to write to Dr. Ala reviewing the data on the effectiveness of anti-viral treatment and Dr. Ala will seek a written response from the experts that he previously canvassed informally. **Prof. Tedder** **Dr. Ala**

3.11. **Combined HTLV/HIV screening trial**
The potential implications of the availability of a satisfactory anti-HTLV/HIV screening assay at a similar price to existing anti-HIV assays were discussed. The meaning of 'satisfactory' in relation to sensitivity and specificity awaits the completion of the Leeds' trial before decisions can be reached. The question of price would include significance of bulk purchase i.e. what constitutes 'bulk' in terms of total number of tests per annum as far as the supplier is concerned, and will the prices match those from multiple marker contracts, suitably discounted (especially when extra confirmatory requirements for HTLV are taken into account).

Launch Diagnostics have been told that a decision awaits the completion and final analysis of the Leeds' trial and consideration by MSBT.

Dr. Flanagan's interim report was submitted (enclosure G). It was noted that the repeatable-reactive rate for the assay appeared to be operator dependent.

Dr. Ala will copy the Red Cross summary of screening tests used in Europe (provided by Professor Cash) to members. **Dr. Ala**

4. **Reference Laboratories**
Professor Tedder has sent Dr. Ala a copy of the anti-HCV confirmatory protocol agreed with the London Transfusion Centres, as an example of a 'defined' procedure for confirmation. Dr. Mortimer felt it was entirely reasonable for the PHL to follow that approach and would endorse it at the PHL Hepatitis and HIV sub-committees. **Dr. Mortimer**

Professor Cash asked if Professor Tedder's document might serve as the basis for an SCTTI recommendation. He also advocated Reference Laboratory (CPA) accreditation.

Dr. Ala will circulate copies of the London confirmatory protocol to committee members. Item 12.4 of the previous minutes (provision of a draft list of requirements for confirmatory testing) to be revived by Dr. Mortimer. **Dr. Ala** **Dr. Mortimer**

5. **Trial of SD treated FFP**
The MCA has granted a CTX for this trial.

6. **CJD and donor selection**
Dr. Flanagan has talked to Dr. James who is seeking further information.

7. **SCTTI and Tissue Banks**
Dr. Ala will consult Dr. Wagstaff about the setting up of a 'Red Book' Committee relating to Tissue Banks. MSBT are also gathering information with a view to producing guidelines or recommendations. **Dr. Ala**

8. **HIV-1, subtype O**
WHO consider that the risk from subtype O in most countries is so low that manufacturers should not precipitately provide modified assay which might jeopardise overall anti-HIV kit performance (e.g. specificity).

Dr. Ala to write to [redacted] about the need to provide a suitable panel for modified kit assessment; also to Abbott and Murex, to inform them that any modified kits will require approval. **Dr. Ala**

Action

9. **Eligibility of sexual partners of anti-HCV positive donors**
   Dr. Ala will carry this question forward to the next agenda, following letters from several consultants asking for confirmation of policy. Policy in relation to all viruses for which we screen should be consistent with recommendations from the committee for selection of donors. **Dr. Ala**

10. **Irish iv RhD IgG**
    Dr. James is collating information on this topic: Dr. Ala will copy her letter to members. **Dr. Ala**

11. **HBV contamination in liquid nitrogen**
    Professor Tedder's report was tabled (enclosure H).

12. **PTH-B cases reported to CDSC**
    Dr. Ala to write to Dr. Heptonstall to ask about the extent and accuracy of reporting of PTH-B from hospitals. **Dr. Ala**

13. **Post-transfusion infection enquiries**
    Letter from [redacted] tabled (enclosure I); Dr. Ala to carry this item forward to the next agenda. **Dr. Ala**

14. **HCV seroconversion in blood donors**
    Dr. Barbara will canvass transfusion centres to obtain data on this subject. **Dr. Barbara**

15. **Date of next meeting**
    As the meeting on 14th July 1994 has been cancelled, the next meeting will be at WMBTC, Birmingham, on 19th October 1994.

Dr. John Barbara,
Secretary, SCTTI

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