EC 11/96

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

Minutes of the meeting held at NLBTC, Colindale, on 18th October 1995 at 11.00 am.

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

1. Ms Soldan — Action

Three items were tabled (reports appended)

1.1. TTI surveillance.

1.2. HCV seroconversions.

1.3. Anti-HBc and residual PTH-B.

Points arising:

1.4. The HCV seroconversion rate of 1 in 400,000 *donations* ideally requires conversion into the rate in *donors*, although derivation of a denominator will be more difficult. — Dr Barbara/ Ms Soldan

1.5. Professor Tedder's suggestion of a case-control study for HCV seroconversion risk to be looked into. — Dr Barbara/ Ms Soldan

1.6. Seronegative (while infectious) risk estimates for HCV and HBV should be attempted from the data on seroconversion for these viruses. — Dr Barbara/ Ms Soldan

1.7. Anti-HBc: Cambridge study.
Dr. Williamson to update the committee on this study at the next meeting. — Dr Williamson

1.8. Anti-HBc: proposal for MSBT.

This topic will remain under review. SACTTI will reassess the available evidence in Autumn 1996, with a view to forwarding a submission to MSBT if this is felt to be appropriate. This review will include the following:

- National PTH-B collation.
- Outcome of Cambridge anti-HBc study.
- Results of enhanced-security PCR on 'anti-HBc-only' donors.
- Outcome of Professor Tedder's combined anti-HBc/anti-HBs assay evaluations.
- Information arising out of HCV look-back programme (anti-HBc only donors).

2. Dr. Chiodini: Malaria assay

An early draft of the manuscript of a paper describing the evaluation of an anti-malaria ELISA had been previously circulated. Dr. Chiodini spoke to this draft with the aid of some background slides. He will send copies of the text of these slides to Dr. Ala for circulation to members. — Dr Ala

The proposition is that there will be a 'TA exclusion' of 6 months coupled with an anti-malaria test for anyone with a suggestion of TA-risk. If the proposal is endorsed, the test's negative result in such cases will enable release of blood and components. As emphasised by Professor Cash, the purpose of this is to minimise wastage, and not to enhance malarial safety of transfusion. Dr. Flanagan pointed out that the 'Red Book Guidelines' already allow an option for release of 'TA-risk' components if the exposure was more than 6 months prior to donation, and the donation is anti-malaria negative by a validated assay.

With Dr. Chiodini's endorsement, the committee gave its approval for the strategy as outlined, to decrease wastage and to improve operational simplicity and integrity.

There remained one proviso. Dr. Chiodini reported that the latest batch of kits exhibited technical problems relating to specificity. He has already shown in his laboratory that these problems can be readily corrected, and the manufacturers have undertaken to resolve this issue, prior to a transfer of the technology to the Australian company Cell Labs, who have taken over production from Dr. Voller.

Once Dr. Chiodini is satisfied that the manufacturers have resolved the problem, the Chairman will make a recommendation to UK National Medical Directors that the strategy outlined above is suitable for adoption by those laboratories wishing to do so. **Dr Flanagan**

At this point, having thanked our guests, the Chairman returned to the original agenda order.

3. <u>SACTTI Chair</u>

Dr. Ala announced that as he is retiring next year, the Chairmanship of the SACTTI would now be taken up by Dr. Flanagan. The committee unanimously expressed their personal and collective thanks for all his hard work.
At the same time Dr. Barbara will hand over secretarial duties to Dr. Williamson.
Dr. Flanagan will inform members of the dates and venues of meetings for 1996.

[At this point Professor Tedder left for a prior engagement]

4. <u>Relationship of SACTTI to MSBT</u>

Dr. Ala had previously circulated relevant correspondence.

This issue has been clarified in recent correspondence from Dr. Metters, Chairman of MSBT.

"SACTTI is part of the 'Red Book' structure and formally reports to the UKBTS/NIBSC executive committee. SACTTI is responsible for providing professional advice to the UKBTS/NIBSC Committee and to National Transfusion organisations on all matters concerned with the possible transmission of infection by the transfusion of blood, its components and via donor plasma, fractionated plasma products. This advice should also cover the possible transmission of infection by other banked tissues processed by and held at Transfusion Centres".

The professional advisory role of SACTTI contrasts with that of MSBT which is to advise ministers on policy. It is considered that formal links between the committees would compromise the respective remits of the two groups.

5. <u>Audit of donor counselling procedures</u>

The committee discussed the previously circulated documents, suggesting audit of how counselling is performed, and the outcome of such counselling. SACTTI might consider whether the circulated documents are adequate, the role of SACTTI in audit and how to set about such audit.

Action

Dr. Flanagan reported Dr. Robinson's view that there was a clear need to define best clinical practice and she is satisfied with the forms circulated.

Dr. Hewitt reported that the SE designate zone had made an analysis and were adopting common practice, but would be willing to participate in a national initiative as well.

Professor Cash has not yet discussed the matter with Dr. Galea, but was satisfied with the forms. He wondered whether any investigation should be part of a medical audit programme, where the SAC on care and selection of donors would be more appropriate than SACTTI.

Dr. Flanagan will write to the UK national Medical Directors to say that SACTTI recommend that they consider implementation of a counselling audit programme with UK collation. The letter will be copied to Dr. James' SAC on care and selection of donors. **Dr Flanagan**

6. **Funding of NBA Microbiology test kit evaluations**

Dr. Flanagan noted the previously circulated letter informing Dr. Barbara that the current situation for MDA funded assessments by CPHL will pertain for the time being, but any rapid assessments will require funding by the companies concerned. It was noted that in Scotland, companies are charged for assessments.

For NBA kit assessments, in accordance with the advice of the MDA, a 'certification' of suitability will be replaced by a 'letter of notification of suitability' which is being drafted at the NBA.

Dr. Follett will send Dr. Barbara a copy of the Scottish letter of notification, for comparison. **Dr Follett**

7. **Bacterial contamination of blood**

Dr. Ala still awaits word from Dr. Snape about possible BPL involvement in a study. **Dr Snape**

8. **National HCV look-back**

Dr. Flanagan summarised a briefing from Dr. Robinson. Professor Tedder's letter to Dr. Robinson concerning inclusion of certain anti-HCV RIBA-3 indeterminate donors in look-back has been previously circulated. Confirmatory algorithms vary in English Reference Laboratories; furthermore, some Centres have already included some indeterminate donors in look-back, who are outside the original MSBT definitions. It is therefore timely to clearly define which indeterminates should be included (paper circulated at meeting enclosed).

MSBT have endorsed the proposal, but require further information on the projected impact (i.e. the extra number of donations involved). Professor Tedder reported that the increase is approximately 10% of donors in the SE designate zone. Recognising the increased workload, MSBTS have agreed in principle that this extension to look-back will be introduced by April 1996. **Dr Flanagan**

Dr. Follett reported that between October 1992 and September 1994, 945 HCV indeterminates were PCR tested in Scotland and 5 (0.5%) were positive (1, c100 4+; 1, c33 2+; 3, c22 4+). Between September 1994 and September 1995, one further 'indeterminate (c33 3+) was found PCR positive.

It would be very informative to know how many of the Scottish indeterminates were positive on at least 2 'independent' ELISAs, especially those that were PCR positive. Dr. Follett will analyse this, for circulation to the committee **Dr Follett**

Action

9. CJD and proposal for discrete look-back

Mr. Metters has responded to Dr. Ala's letter regarding this (correspondence enclosed). Because there is no evidence of CJD transmission by transfusion, there was no evidence for a need for look-back. (Some committee member felt this was a rather circular argument). Furthermore, the number of cases of CJD where the patient has a previous history of donation or transfusion are too small to be amenable to statistically significant analysis. Nevertheless, the situation will remain under review.

Dr. Ala had previously circulated a letter from Dr. Boulton concerning CJD in relation to donor selection. The extent to which one probes for relevant CJD factors during donor selection requires clarification. Professor Cash felt that European consideration of recommendations on CJD should be channelled to national Medical Directors via the Department of Health as quickly as possible.

Dr Flanagan outlined his current understanding of the UK position on CJD and transfusion. Transfusion Services will be required to continue to exclude donors who have received pituitary derived gonadotrophin and growth hormone, and also to exclude immediate family members of individuals diagnosed with CJD. At this stage it is not considered necessary to extend the exclusion to include recipients of dura mater and corneal transplants. There is no epidemiological evidence to suggest that CJD can be transmitted by blood or its products. The above position is believed to be consistent with European requirements for plasma fractionation.

[At this point Professor Cash left for a prior engagement].

10. Minutes of HCV Epidemiology Special Meeting - (previously circulated)

One correction was noted i.e. p3: Dr. McMenamin is from Ruchill (Glasgow), not Birmingham.
It was noted that practically all the recommendations in the minutes have been, or are being, addressed.

11. SHOT project

On behalf of Dr. Williamson, Dr. Barbara summarised the main points of her previously circulated report. [Subsequently, Dr. Barbara informed Dr. Williamson of two corrections; NBA does not cover Wales; and Medical Directors for Wales and Northern Ireland need to be included].

[At this point Dr. Mortimer left for a prior engagement].

12. Dr. Snapes's reply to Dr. Barbara re review of viral infectivity in donors whose plasma has been sent to BPL. Previously circulated.

13. Any other business

13.1. HIV 1, subtype O

Dr. Robinson had briefed Dr. Flanagan: since some cases of infection with this virus had been identified in Nigeria (in addition to those in Cameroon) the agent was considered to have a potential (though still small) chance of appearing in UK blood donors. The Council of Europe European Pharmacopoeia Committee Group of Experts no. 6B (human blood and blood products) propose that plasma for fractionation is screened by anti-HIV assays that can detect HIV 1 subtype O. This document has recently been circulated to National Authorities for comment. Currently, UK 'approval' for kits enhanced for HIV 1 subtype O detection were based on whether they retained adequacy for detecting anti-HIV 1 and 2, because of the lack of subtype O samples against which to evaluate kits.

Action

[Subsequent to the meeting, Dr. Flanagan informed Dr. Barbara that subtype O samples should now be more readily available and that evaluations including subtype O sensitivity should now go ahead. Dr. Flanagan will provide formal notification of subtype O assessment requirements so that a uniform policy with regard to screening kits can be maintained]. **Dr Flanagan**

13.2. Dr. Barbara's response to Mr. Rogan's letter concerning details of reinstatement of donors reacting falsely-positive, via alternative assays. Correspondence previously circulated.

13.3. Microbiological aspects of cord blood programmes

Since such programmes are only at the pilot stage, proposed protocols and further data are needed before SACTTI is asked to review policy decisions.

13.4. Declarations of Interest

Dr. Flanagan reported that the 'Red Book' steering committee has recommended that all 'Red Book' committees should log declarations of interest (personal and professional) in a manner similar to those of NIBSC and the Committee of Safety of Medicines and these should be updated annually. Committee members should state whether any agenda items might involve a potential conflict of interest. Detailed proposals will be circulated for discussion at the next meeting. **Dr Flanagan**

14. Date and venue of next meeting

To be announced by Dr. Flanagan. **Dr Flanagan**

Dr. John Barbara.

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