MINUTES OF THE UK BTS/NIBSC EXECUTIVE COMMITTEE MTG

Held on 15th June 1998 at the

National Inst. for Biological Standards and Control, Potters Bar, London

		ACTION
	Present Dr T Barrowcliffe Dr M de Silva Dr P Flanagan Prof I Franklin Dr V James Dr E Love Dr M McClelland Dr T Napier Dr P Phillips Dr A Robinson Dr J Saldahna Dr T Snape Dr W Wagstaff (Chair) Dr R Warwick Dr L Williamson	
1.	**Apologies** Dr M de Silva Mr M Kavanagh Dr T Snape Dr Schild welcomed the group to NIBSC.	
2.	**Minutes of the Meeting held on 21.11.97** Corrections have been received from VJ and RW after the last meeting and have been included and circulated. A further correction has been received from the NIBSC. WW to forward to EL. In future it was agreed that the draft minutes would be circulated to all members for comment and any corrections notified within 2 weeks.	WW
3.	**Matters Arising**	

3.1 **NHS Indemnity and Expert Advisory Committees**

WW had confirmed that the NBS would indemnify non NBS members of advisory committees and he had sent a letter to the chairs of advisory committees to this effect.

AR had contacted other National Medical Directors. In principle the SNBTS will indemnify anyone who is a nominee of National Directors. University employees are usually covered under honorary contracts. The NIBSC keeps the matter under control and employees are at present indemnified. The only problem remained of the occasional member who may not be an NHS employee.

Chairs of SAC's were asked to check their membership for anyone who may not be an NHS employee. **Chairs of SAC's**

Once again the importance of the selection of members of SAC's for their expertise was emphasised. **Chairs of SAC's**

4. **Chairmanship of the Executive Committee**

This had not yet been finalised and would be decided by the four National Medical Directors.

IF commented that the incoming Chairman should set down some criteria/terms of reference for chairs of SAC's for the future.

It was proposed that the chair of the Executive Committee should serve a 5 year term with a further 5 year renewable period, if agreed, and that chairs of SAC's should serve for 3 years with a further renewable 3 years in order to preserve continuity. This proposal had been submitted by National Medical Directors. The period of office for SAC members would also need to be reviewed.

The committee agreed that the incoming chairman should formulate a paper for discussion on this subject. **New Chairman**

5. **Blood Pack Group Labelling**
EC1/98

AR said that there had been pressure from hospitals for the NBS to provide written verification to hospital blood banks regarding the assurance of blood group labels, particularly in relation to new donors. A recent incident of transposition of labels at a blood centre had made it necessary to review this subject.

Alan Slopecki had collated data on mislabelled units for an 18 month period and had formed the opinion that there may be one in 3.75 million risk of issue of a mislabelled unit with a 50% chance of this being ABO incompatible.

It was felt that the NBS could not give written verification whilst there was a possibility of error, however remote, in manual steps in the donation process and that it would not be in a position to give information differentiating new and repeat donors.

TN highlighted the problem of pressure and resources at hospitals if asked to repeat the grouping on all units received from the Blood Service and felt that the matter should be referred back to the Transfusion Task Force of the BCSH.

It was agreed that AR would write to the Secretary of the BCSH Transfusion Task Force, enclosing the risk assessment and identifying the residual problem of the risk of switching samples at the donation bedside in new donors. It was hoped that this matter would be raised at the next BSCH Task Force meeting.

In the meantime, AR will take legal advice on the position. **AR**

A copy of Alan Slopecki's paper is enclosed with these minutes(EC29/98)

6. **Handbook of Transfusion Medicine Audit**
EC2/98

The paper had been received from Nicky Anderson and the recommendations were noted.

AR asked what forum could be used to take the recommendations forward.

It was felt that the Handbook of Transfusion Medicine needs to be linked into some formal mechanism for updating/securing its future. The possibilities of the BNF, BCSH, BSH and BBTS were discussed. A professional base would be preferable. Whatever route might be chosen, it was felt that blood services could be involved with distribution.

It was suggested that the incoming chairman should write to Brian McClelland with the suggestion that professional bodies could be approached on this matter. **Incoming Chairman**

7.	**Review of Apheresis Guidelines** **EC3/98**	
7.1	**Medical/Nursing Staff Attendance at Apheresis Donor Sessions (Section 3.6.1)**	
7.2	**Management/Evidence of Citrate Toxicity** AR highlighted concerns about the ambiguity of the wording of this section and proposals from the South West Zone to remove doctors from apheresis sessions. There also needed to be clarification of routine/non-routine procedures with reference to recommended dosage of citrate as some platelet procedures exceed these. It was also noted that there is no section in the Guidelines dealing with the management of citrate toxicity and that practices varied in apheresis centres, with some centres treating the donors with oral calcium containing compounds in order to mitigate the effects of citrate toxicity. This was felt to be bad practice.	
7.3 7.4	**Age Limits (Section 3.2.1)** **Interval between Apheresis Procedures and Whole Blood Donors (Section 3.4.3)** These two sections also need to be reviewed. EL agreed to write to Dr Moji Gesinde copy to Dr James asking her to review these sections and members were asked to send any other comments to Dr Gesindi with a copy to EL.	**EL**
8.	**Clarification of the New Donor Age Limit** AR highlighted a problem with the poster "I am 70, still a lifesaver". Donors are in fact being resigned by their 70th birthday and therefore technically cannot donate at the age of 70. VJ said that the change in age guidelines was intended to allow the donor to donate to their 70th birthday with no extension and the posters appear to have been produced by the Donor Services Dept. without further consultation. There have been complaints from 70 year olds. VJ will take this matter back to the SAC on donor selection for further discussion to ask in principle whether there could be an extension to the 71st birthday although it was agreed to leave the rules as they are. RW asked about the legal situation with regard to blood donors aged 17 who wish to register as bone marrow donors. RW advised that the 18 years lower age limit should be adhered to	**VJ**

as previously and this was agreed in view of the difficulties which had been encountered in reducing the blood donor minimum age.

9. **Council of Europe: Guide to the Preparation, Use and Quality Assurance of Blood Components, R(95) 15, 5th Edition, 1998 version - Consultation period** — COUNCIL

AR has circulated this document with a request for comments by the end of June 1998. Although a May 1998 draft may have superseded the March 1998 draft which had been circulated, it was agreed that comments should be made on the previously circulated draft as there appeared to be few differences. — ALL

NIBSC does not receive a copy of this document and it was agreed to ensure full circulation in the future and that this would be done through the chair of the Executive Committee who would be notified by AR. — AR/CHAIR

10. **European Commission : Recommendation on the Suitability of Blood and Plasma Donors and Screening of Donated Blood in the European Community (adopted 30.4.1998) EC4/98**

VJ pointed out that there are several issues which arise for the SAC on donor selection where practice is different in the United Kingdom. However, any discrepancies would have to be notified to the Department of Health by AR. The SAC on donor selection will work through the document and prepare a paper for AR. — VJ

11. **Standing Advisory Committee on Donor Selection**

11.1 **Minutes of Meeting 12th January 1998. EC5/98**

11.2 **Minutes of Meeting 11th March 1998 EC6/98**

A correction to EC5/98, Section 7.8, EUROCODE was suggested.

VJ summarised the two main subjects which had been the focus of discussions:

- A-Z 1998 had been issued. An electronic version has been produced by Serge Six. Problems of document control of the electronic version have not been fully resolved

- The tick box questionnaire format had been revised, the latest version being 14th May 1998. Chapter 1 of the Red Book will be revised in the near future to reflect the changes.

- VJ also mentioned Dr Andrew Herborn's working party

which is collating issues which arise from the A-Z and require clarification. This has input from nurses, and the UK Blood Services. These comments are fed into the SAC on donor selection.

12. Standing Advisory Committee on Information Technology

12.1 Minutes of Meeting 3rd November 1998 EC7/98

12.2 Minutes of Meeting February 1998 EC8/98

There were no additional comments.

12.3 IT Guidelines

EL mentioned that there are now several documents relating to IT Guidelines (Barcode, Labels and EDI) which currently are produced as stand alone documents. This had been felt by the SACIT to be cumbersome and difficult to administer and a request was made for these guidelines in the future to be incorporated in a 5th Section of the Red Book.

The Barcode Guidelines have been recently revised and published earlier this year. The labels guidelines are due for revision and further EDI guidelines will be written. Therefore it was agreed that the documents could be incorporated for the 1999 edition of the Red Book.

12.4 EDI Guidelines (EC28/98)

EL tabled the first of what is hoped will be a series of standards for EDI which have been produced by a sub-group of the SACIT. Members were asked to approve these and should return comments to EL by mid-July.

ALL

It was agreed that a timetable for future amendments for the Red Book would be drawn up to guide SAC's.

Incoming Chairman

13. Standing Advisory Committee on Transfusion Transmitted Infection

13.1 Minutes of Meeting 21.1.1998 EC9/98

13.2 Minutes of Meeting 12.3.1998 EC10/98

13.3 Minutes of Meeting 19.5.1998 EC11/98

PF summarised the key areas which had been covered in recent activities of the SACTTI. These were:-

- Implementation of NAT testing.
- UK Plasma matters
- Other new variant CJD issues

PF described the three processes which had been taking place in relation to nvCJD. These were the Independent Risk

Assessment commissioned by the DOH, consideration of measures to reduce the risk of CJD transmission and the UK BTS implementation strategy for leucodepletion, if it is decided to take this route.

The UK BTS Services Report had been submitted by the end of February 1998 and the outcome of the risk assessment it still awaited.

The CSM considerations on UK plasma products had been announced at the same time as the CPMP recommendations and these did not significantly differ in key areas. The CSM had completed its review and made its announcement in May 1998 and the first batch of US plasma is imminent at BPL with the last UK plasma delivery being the 1st July 1998.

It was emphasised that the decision on UK plasma should be seen as a temporary measure and that the criteria which would allow the "rehabilitation " of UK plasma were being considered. These would include the availability of a screening test, evidence that the processes involved would destroy the prion agent and / or evidence to refute the risk of transfusion transmission of nvCJD.

nvCJD
One of the main tasks of SACTTI has been to ensure effective mechanisms for communication of the outcomes of all the above deliberations.

NAT Testing
The European target is for 1st July 1998 which states that all products for clinical use should be derived from pools tested for HCV RNA and it had been agreed by the MS BT that the UK should meet this requirement. It had also included a recommendation to develop a mechanism for the introduction of testing for labile components. In the light of the current plasma situation the MSBT had reviewed the situation and considered that the recommendations for labile components should go ahead.

On 8th July a special meeting of the SACTTI will consider the performance of NAT testing systems and hopefully identify some common standards. There are particular concerns regarding process control and monitoring.

Members asked whether methylene blue FFP had been discussed. The risk assessment group has been asked to

consider the relative risks of the various FFP products.

The SNBTS and NIBTS are progressing with the implementation of methylene blue treated FFP, however it is the NBS preferred view that the introduction of methylene blue/leucodepletion should go hand in hand and the SAC on blood components had also been involved in this discussion.

At this point in relation to methylene blue LW asked the position with regard to the validation of medical devices such as methylene blue which had been CE marked.

AR stated that it is the responsibility of the services to evaluate the device to ensure that it fits the circumstances relating to its intended use. The CE mark indicates that it meets the claims of the manufacturer - not that it meets the requirements of a particular user.

Letters EC12/98 and EC13/98 were noted.

14. Standing Advisory Committee on Tissue Banking

14.1 Minutes EC 14/98

14.2 Formation of Haemopoitic Progenitor Cell Working Party EC15/98

14.3 Section 4 Guidelines for Tissue Banking EC16/98.

A limited number of copies of the medical assessment of donors of tissues was tabled at the meeting. RW explained that George Galea represents the donor SAC on the Tissue Group and has responsibility for ensuring consistency with the A-Z for donors. The document has been sent to Serge Six for development of a secure electronic version up to Section 4. The appendices will be circulated as separate documents as for the MAD Guidelines. ie. There will be parallel distribution and consistency where appropriate.

Section 4 of the Red Book will refer to the A-Z for tissue donors and there will be a similar fast-track system for changes, as for the selection of blood donors.

This document is for endoresement by the UKBTS/NIBSC Executive and will therefore be circulated to all members of the group (PF agreed to arrange circulation). For comment by mid-July 1998. **PF/ALL**

15. Standing Advisory Committee on Blood Components

15.1 Generic Protocol for the Evaluation of Novel Blood Components EC17/98

15.2	**Generic Protocol for the Evaluation of Blood Packs EC18/98**	
15.3	**Evaluation of New Red Cell Components for Transfusion EC19/98**	
15.4	**Evaluation of New Platelet Components for Transfusion EC20/98**	
15.5	**Evaluation of New Fresh Frozen Plasma/Cryoprecipitate Components for Transfusion EC21/98** LW guided the Committee through these protocols which had been revised since the last meeting in November 1997 and it was agreed that these could be included as Addendae to the 1998 Red Book.	**LW/Chair**
15.6	**Fresh Frozen Plasma, Methylene Blue Treated, Draft Specification EC22/98** As this component is being produced or will shortly be produced by some UK services it was felt pertinent to consider a separate specification at this stage. It is not intended that the specification should detail specific protocols for the methylene blue FFP process. After some discussion it was agreed that the draft specification should not be included in the next revision of the Red Book but should be reconsidered in 1999.	**LW**
15.7	**Components Suitable for use in Intra-uterine Transfusion, Neonates and Infants under 1 year EC23/98** It was agreed that these should be accepted subject to some suggested amendments for the 1998 revision.	**LW**
	The CMV testing -v- leucodepletion issue was discussed. Unfortunately at this stage the SACTTI is not happy to endorse the equivalence of leucodepletion ($<5x10^6$) and CMV negativity. The SACTTI required more information before making a decision. Therefore, for the time being, the need for CMV testing will remain in the specification.	
16.	**Standing Advisory Committee on Reagents for Immunohaematology**	
16.1	**Minutes of Meeting 31.10.97 EC25/98**	
16.2	**Minutes of Meeting 13.01.1998 EC26/98**	
16.3	**Minutes of Meeting 01.04.98 EC27/98**	
16.4	**EC24/98 Suggested Revisions for Mandatory Testing of Blood Donations (Addendum to Section 1 ,Annexe 3)** Please note on the Agenda this item is wrongly listed under 15.8.	
	PP asked for approval on Section 2.1.6 item 2 and 3.10.4 item 2 and these were ratified for inclusion in the next revision.	**MS/Chair**

17.	**Items Raised by NIBSC** GS mentioned the ongoing work on working standards for HCV/HIV and parvovirus. He also commented that the haematology division had been recently reviewed.	
18.	**Any other business**	
18.1	**Chair of the SACTTI** PF indicated that he would be handing over the chairmanship of the SACTTI to Dr Chitra Bharucha from September 1998.	
18.2	Dr Wagstaff indicated that this would be probably his last meeting.	
19.	**Date of next meeting** To be notified	**Incoming Chairman**

Mislabelling Incidence

A survey of instances has been completed for English Blood Centres, this covers the time period over which PULSE was introduced to the NBS Centres. This has revealed no ABO / Rh group mislabelled packs other than those identified through the National Escalation procedure.

Consequently since Jan 1996 there have been the following ABO / Rh group mislabelling incidents.

- Two packs at Manchester where due to an error in the manufacturer's printing process a roll of rejected donation numbers were supplied for use.
- Two packs at Manchester where due to poor GMP procedures at the session the packs were cross labelled.
- Two packs at Manchester where due to problems in the production process the label sets did not contain identical numbers.
- One pack at Sheffield, where due to problems in the production process the label sets did not contain identical numbers.
- The other affected number set had been used at the manufacturers for Quality Control purposes.

The incidents with the exception of the GMP error at Manchester were detected because the historic group and group this time did not reconcile. The GMP incident concerned two new donors and could not have been identified before cross match (using current best practice).

Therefore in approximately 7.5 million donations there have been 8 potential occasions for units with incorrect groups to be issued, only two were. It can be assumed that this comes close to a reasonable estimate of risk of releasing incorrectly group labelled units.

This is considerably more secure than completely manual systems where my experience tells me that during the 1970s, when the units were manually grouped and manually labelled, 10 incorrectly ABO Rh group labelled packs out of 100,000 issued units would not be unreasonable.

This is an incidence of 1 per 10,000 against the recent survey of 1 per 3.75 million (2 issued units out of 8 potential units in 7.5 million donations).

It is possible that other mislabelling events might happen but if this involved two group identical units it would not be easily detected. There is no evidence to support this having occurred.

The systems endorsed by the NBS are designed to remove the possibility of human error as far as possible but humans are still involved in elements of the process. The incidence of mislabelling currently is much better than has been obtained in the past reducing the risk of issuing an incorrectly group labelled unit significantly. It may be possible to reduce this level of error still further. PULSE is now fully implemented, work is being done to ensure that label suppliers can reach the highest possible standard and the NBS will continue to ensure the importance of meeting GMP is understood by it's workers.

Conclusion

Using manual grouping and labelling systems there has been an incidence of 1 per 10,000 units with incorrect ABO / Rh group labels issued against the recent NBS survey of 1 per 3.75 million (2 issued units out of 8 potential mislabelled units). This represents a significant improvement.

Alan Slopecki
National Quality Manager
30/6/98