Minutes on the 25th Meeting of the UKBTS/NIBSC STANDING ADVISORY COMMITTEE ON THE SELECTION OF DONORS held on Monday, 22nd September, 1997, at the West End Donor Centre, Margaret Street, London

Present:- Dr. V. James - Trent Chair
Dr. P. Hewitt - North London
Dr. C. Bharucha - Belfast
Dr. P. Minor - NIBSC
Dr. G. Galea - Dundee
Dr. F. Boulton - Southampton (Secretary)

In attendance for the first part of the meeting, Kristina Bird, Health Education Authority

1. Apologies received from

Dr. T. Wallington - Bristol.

2. Declaration of Conflict of Interest

All members present declared no conflict of interest due to involvement of outside bodies.

3. Minutes of the Meeting held on 23rd June, 1997

Accepted as factually correct.

4. Matters Arising

4.1 Hydrocephalus (4.6)
Virge James reported that Dr. Bayston wishes to pursue the matter of people with hydrocephalus and an internal shunt. Such people should be able to be provided with a certificate confirming that they have been tested within the past 12 months for bacterial contamination of the shunt. We await further information from Dr. Bayston.

4.2 Acupuncture (4.7)
The letter in the BMJ of 16th August, 1997, was noted, particularly the fact that the author (J Uddin - Chair of the British Acupuncture Council) stated "Indeed, the National Blood Transfusion Service allows patients who have recently had acupuncture treatment by members of the British Acupuncture Council to give blood ....."

4.3 Haemophiliacs (11.1)
The Meeting considered the further correspondence from Dr. Ludlam and notes that he hopes to send further data. It was noted that the case presented in the Journal Hepatology 1985, was not entirely conclusive. Professor Eric Preston is also being approached for his views.

4.4 Sky Diving/Parachuting (11.4)
We recognise that regular "professional" sky divers should be deferred from donation. This SAC proposes that persons who are occasional sky divers may be allowed to donate only by plasmapheresis. As such persons need to give a full blood donation prior to being accepted as plasmapheresis donors, they will need to become accredited blood donors at a time when they were not participating regularly in sky diving or parachuting.

5. **Post Donation Illness**

Tim Wallington had spoken to Frank Boulton to whom he had attempted to send an up-dated E-mail, and attachment. In the event this was not received prior to the Meeting. It was agreed to defer this item to the next meeting. It was noted that it was important to include B.P.L. in some of the notifications.

6. **The Work of the Health Education Authority and Its Relevance to Donor Selection**

Kristina Bird introduced herself to the Meeting.

Currently she manages the National HIV Prevention Information Service which is under the Health Education Authority in England. The work of her section is to support people working in HIV and health promotion, and on the way health with regard to HIV is promoted in the U.K. Her section is now funded directly by the Department of Health.

They also conduct research into sexual behaviour and have insight into drug usage behaviour. Currently they are unable to give so much weight into other STD's but there is some expertise, particularly with regard to Chlamydia. They do use the services of the PHLS, particularly the Hepatitis Laboratories, and receive copies of the CDC Publications on HIV. They are in contact with Kate Soldan and in turn do get asked for advice on diagnostics. They are also in contact with the Centre for Research on Drugs and Behaviour. They are linked in Scotland to the Health Education Board and to Dr. Ahelia Noone. They may be able to assist in tracing the habits of bodybuilders and their perception of any health risk they may have.

Kristina Bird went on to comment on several important facets:

With regard to the changing epidemiology of HIV, she reported that the proportion of new infections being associated with male homosexuality is dropping - it was 58% in 1996. It is mostly being replaced by heterosexual risk, particularly from black Africans from abroad. On the international scene there is great concern for South East Asia, including India, but this is not yet very visible in the immigrant population of the United Kingdom. The anonymised surveys do not break down data on an ethnic basis, but the pregnancy surveys do indicate a preponderance of problems among black Africans. A particular feature of this group is that they often present late in the course of HIV infection with overt illness.

Those people who know that they are HIV infected are mostly homosexual men and they are varying their testing patterns probably in response to new available therapies. There was some interesting discussion about the way homosexual men who have HIV infection may respond psychologically to modern chemotherapy, even regarding themselves as being cured and fit for donation. There is also some information regarding the concept (and sometimes practice) of a "morning after pill" for HIV which might be offered to people after sexual contact. Apparently clinical protocols for this approach are being worked out.

The bottom line is that there is a continuing danger of Transfusion Services being used as a free test.

With regard to wording of literature, the H.E.A. conducts research at the London School of Hygiene concerning people's terminology with regard to sexual health. This can be heavily biased by ethnicity as well. Kristina Bird will search out papers and give information.

7. **Malaria**

Pat Hewitt's letter of the 27th August was noted. There were three separate events.

- Firstly, the transfusion transmitted Falciparum Malaria (although proof is not absolute with regard to tracing the infection in the donor).
- The donor had resided previously in an endemic area, had been resident in the U.K. for 20 years and then visited another malarial area on prophylaxis. The donor did develop a febrile illness.

- The donation was allegedly given 3 years after the return of the latest visit although actually it was 2 years 11 months.

There was some discussion with regard to the general validity of reports of febrile illnesses and indeed what a 'febrile illness' in donors returning from malarial areas might mean. The guidelines are clear what to do if there has not been a febrile episode, but are less clear if there has. In practice, such events should be regarded as a malarial episode and all affected persons should have a malaria antibody test.

There is a difference between "ex-residents" and "visitors". Ex-residents are people who have resided for at least 3 months in the first 5 years of life. "Visitors" are people who were not resident in childhood, but who have visited for short periods in adult life.

This SAC agreed to recommend that all past residents of malarial areas - as defined above - be given a malarial antibody test at their first donation. If cleared past residents re-visit a malarial area, a malarial antibody must be repeated at their next attendance at a donor session. Visitors must wait 12 months after return, or have a negative malarial antibody test at 6 months.

In practice, if in doubt conduct a malarial antibody test.

ACTION : Pat Hewitt to re-write the malarial clause to include these points.

It was noted that it will be necessary to prepare the entry in time for PULSE 4.1 (November).

ACTION : Virge James to liaise with Liz Caffrey and to up-date Consultants at the October 8th Meeting.

8. <u>Dominican Republic</u>

There is conflicting advice in the literature, whether from America or from London. It was agreed to regard ALL the Dominican Republic, as a malarial area, as well as Haiti.

ACTION : Entry in A-Z to make clear (John Witcher)

9. <u>CJD Up-Date</u>

In the past 2 weeks Pat Hewitt has distributed forms to Centres reporting possible cases.

Dr. Mike McGovan (who has replaced Dr. A. Rejman at the Department of Health) and Bob Will are working on nv CJD; apparently 3 cases are now known to have been blood donors. Dr. McGovan and Angela Robinson have asked what Centres are able to do by way of retrieving information.

It is unlikely that the 3 cases of nv CJD are on the donor databases of the National Transfusion Services. There is also a particular problem with regards to plasma collected and sent for fractionation; although it may be possible to trace recipients of coagulation factors, it is not possible to trace recipients of albumin. It was noted that the National CJD Unit is probably in a better position to get data when they scrutinise patients' health records than would be hospital haematologists who would find it much more difficult to trace such records.

ACTION : Virge James to ask Angela Robinson to write to Bob Will.

10. <u>Corneal Grafts</u>

Virge James reported that Angela Robinson has commented that Europeans are of the opinion that donors who receive corneal grafts should not be excluded as blood donors. There is only one indefinite case on record and the UK Transfusion Services may have over-reacted. It was noted that the FDA do not exclude corneal graft recipients.

This SAC's recommendations should be consistent with the Council of Europe who do not exclude such donors. Mary Brennan has drafted a letter to persons who have had corneal grafts who offer to donate blood. Comments have been sent to Dr. Robinson.

ACTION: Dr ~~Gabra~~ Galea to revisit the original advice.

11. **Donor Questionnaire Up-Date**

Virge James presented the latest developments. It was agreed that within England the questions will relate to recipients safety only; the safety of Blood leaflet questions have to be included and it is acceptable to group them with one tick for a group. It is not necessary for the donor to tick the boxes as staff may read the questions to the donors and tick on their behalf; the questionnaire will need piloting when a different system is in use.

Outstanding issues on the donor questionnaire include an assessment of how the tick box system would work. It was noted that since July in Scotland, donors have been ticking the boxes (unless they need help). In Northern Ireland the questionnaire is sent with the call-up and donors bring the form to the session, having completed it within 7 days of giving blood. Other Northern Ireland donors get the questionnaire as they enter the session venue. Donor Attendants examine the questionnaire, spot if there are problems and sign if a change is required. A quick audit by Dr. Bharucha indicated that only two questions out of 190 new donors have needed to be referred to the Session Officer for a change.

With regard to travel questions, these are to remain limited to the geographical descriptions 'W Europe and N America'. John Witcher has been asked to trial whether specific countries with malarial problems should be indicated or not -

ACTION: Dr Boulton to check.

Mary Brennan is helping in the trialing of the questionnaire. The final agreed workable questionnaire will need to be approved at the Red Book Executive on November 21st.

12. **Donor Care Doctor's Meeting**

It was agreed that as not all Doctors attending are Consultants, the title of this group should be broadened.

Virge James reported some difficulty in compiling the Agenda but has confirmed that Bill Wagstaff will be able to speak on the European dimension, Terry Snape on the European Pharmacopoeia, someone from Switzerland will talk about experience with a detailed questionnaire at their session, and that Cees van der Poel from Holland will talk about the ISBT Working Party on Donor Epidemiology. Pat Hewitt
will be able to talk about her Working Party's report on how to interview a viral positive donor. It is also hoped that Dr. McGovan will be able to address the Meeting.

13. **Donation Interval**

The Red Book is quite clear concerning this, although it differs from the European Guidelines. The problem has been how to integrate the Red Book requirements with PULSE.

Frank Boulton had circulated members in advance with the Table on the effect of frequency of donation on subsequent deferral rates for low Hb (which was part of his Review of criteria for selecting donors according to their Hb concentration - this report will be considered by the Red Book Executive Committee in November). The Table clearly shows that increasing frequency of donation among Wessex donors in 1995 was related to increasing deferral rates for low Hb at the first attendance in 1996 in donors of both genders, although there is some evidence of a 'selective' effect, particularly on women who donated three times in 1995.

It was appreciated by this SAC that any change resulting from either the change of required haemoglobin levels proposed in Frank's Review or in the frequency of collections would

eventually produce a new equilibrium of donor attendances/rejects; even if the two changes were introduced simultaneously, a new balance would develop. However, shortening the donation interval would lose donations and donors, often long-term or permanent. Caution should be advocated with regard to calling donors any more frequently than at present.

Hence, although in theory with PULSE donors could be called 4 times a year, this would not be desirable. It may well be advisable to up-grade PULSE in order to accommodate this. In practice, it would be acceptable to allow donations to be collected 12 weeks apart on occasions, but such donors should not donate more than three times a year.

ACTION: Virge James to reply to Dr A Robinson. ✓

14. **Factor V Leiden**

Ferydoun Ala's correspondence was noted. It was agreed that this item is actually of no relevance to transfusion practice: A-Z to state "not relevant"

15. **Babesiosis**

Angela Robinson's letter was noted. However, as we have no experience of this entity in the U.K. it has not been included in previous versions of the A-Z. It was also commented that Malaria, which is the most common parasite transmitted by blood in the U.K, has only been transmitted 10 times in the last fifty years.

ACTION : Frank Boulton to enquire further.

16. **Role of SAC in Promoting Donor Interview**

It was agreed that there is no going back on the philosophy of a properly conducted interview. Hence, staff training for the interview is vital and is to be encouraged in all parts of the U.K.

17. **A-Z Changes for 1998**

It was agreed that the next implementation date should be April, 1998.

18. **Reports from other SAC/Working Parties**

18.1 SACTTI - Pat Hewitt reported that recent discussions have centred on CJD, Malaria and SD FFP. With regard to the latter, there are no guidelines currently available and Eddie Follett has indicated that current analysis has not compared like with like, particularly with regard to the estimation of the risk from currently prepared FFP.

On the re-entry of donors, the Red Book is specific but there is a need for clarification on the nature of "false reactive". This needs work with Reference Laboratories. It was also commented that in time genome testing is likely to be necessary.

18.2 Waste Materials - Virge James reported that there is a need to seek donor approval for the sale of surpluses. Wording to the effect "I entrust my donation to the UK Transfusion Services to be used for the benefit of patients" will need to be considered as part of the donor's signature when donating.

18.3 Donor Services Functional Group - Nothing to report

18.4 ISBT - On evidence based on donor selection this will be presented at Frankfurt and Cess van der Poel will be reporting at our October 8th Meeting.

18.5 SAC on Tissue Banking - Standards have been written and accepted by the Red Book Committee. A-Z for live and non-live donors should be available by April 1998.

19. **Borna Virus**

Literature noted.

20. **European Union**

Nil to report

21. **AABB**

A list of drugs by the American Armed Services has been prepared with regard to donor suitability.

ACTION : Frank Boulton to circulate to members

22. **Any Other Business**

Andrew Herborn has agreed to work on the A-Z presentation and has asked Pauline Banks and John Whitcher to join him.

23. **Date and Time of Next Meeting**

12th January, 1998, 11 am, West End Donor Centre, Margaret Street, London.

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