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Amend

**NOTES OF THE 21ST MEETING OF THE UKBTS/NIBSC
STANDING ADVISORY COMMITTEE ON THE SELECTION OF DONORS,
MONDAY 13TH JANUARY 1997, AT THE WEST END DONOR CENTRE,
MARGARET STREET, LONDON**

- Present:**
- | | | |
|--------------------|---|----------------------------|
| Dr Virge James | - | Trent (Chair) |
| Dr Pat Hewitt | - | Colindale |
| Dr Chitra Bharucha | - | Belfast |
| Dr George Galea | - | Ninewells Hospital, Dundee |
| Dr Tim Wallington | - | Bristol |
| Mrs Mairi Thornton | - | SNBTS, Edinburgh |
| Dr Frank Boulton | - | Southampton (Secretary) |
| Dr Morag Ferguson | - | NIBSC |
1. **Apologies:** Dr Philip Minor - NIBSC (Represented by Dr Ferguson)

2. **Declaration of Conflict of Interest**

All members present declared no Conflict of Interest due to involvement of outside bodies.

3. **Minutes of the 20th Meeting of the UKBTS/NIBSC SAC on Selection of Donors, 22nd October 1996.**

The following factual corrections were agreed:-

- 3.6 Replace "about associating with other disorders such as Alzheimer's Disease" with "about the statement that they should not donate being made in their self-help booklet. Dr Will is pursuing this matter".

"CMV" to be replaced by "CJD" in the penultimate sentence.

5.1.2 Brian McClelland.

Otherwise the minutes were accepted as a true record.

4. **Matters Arising**

4.1 **Malaria (Item 3.4 of previous meeting)**

Pat Hewitt reported that Peter Chiodini has signed off the second set of results. The system for malarial testing is now suitable and will be referred to the SACTTI for their meeting on 30th January 1997. }

4.2 **Haemophilic Families (3.5)**

Frank Boulton has contacted Brian Colvin who commented that the Haemophilic Directors are unwilling to revise the matter for the time-being but are very willing for this to be discussed before 5 years if thought necessary. There is to be no change to the current MAD Guidelines.

4.3 **CJD (3.6)**

The Ethical Committee of the Lothian Health Board has not yet responded.

4.4 Re-wording of NBTS 110 (3.7)

Revised Progress
Frank Boulton, Virge James and Mary Brennan are due to meet, hopefully in mid-February. This is to ensure uniformity of the entry for PULSE and to ensure that only the points specific to the consenting signature be addressed.

Virge James reported that she has received a copy of an E-mail from Mike Clark to Bridget Jesticoe concerning the "Codes for Medical Information". Mary Brennan has been asked to advise that group (and also Jack Gillon has also received this list on behalf of the Scottish Service).

Action: Frank Boulton to distribute copies of the "Codes for Medical Information" to all members.

Virge James clarified the current position with regard to the Read Codes. Progress has been maintained but is rather slow. There is interaction with the Read Group on Haematology for the coding of clinical data pertaining to blood donors and the CAMS Group (under Paul Amos) is still on course for these discussions. The meeting iterated that the SAC on Donor Selection has a legitimate interest in ensuring uniformity of the final coding systems.

4.5 Post Donation Illness (3.8)

Quint
Tim Wallington reported that he is making progress in developing his proposals.

4.6 Acceptability of Transplant Recipients as Blood Donors (6.0)

Dura Mater
After the last meeting, Virge James has seen a letter from Andre Rejman, indicating that the Department of Health has concerns about rejecting donors who have had implants of *Dura mater*. This is because such implants have had multiple uses and been given to a wide variety of patients for many clinical conditions. The committee is anxious, however, to have the opportunity for understanding the full reasons for such a decision and to enhance the quality of communications between the SAC, the Redbook Liaison Committee and the Department of Health. This is to enable the SAC to have it's own input into such policy matters.

Action: Virge James to write to Bill Wagstaff with copies to Angela Robinson, Morris McClelland, Brian McClelland and Tony Napier.

4.7 British Chiropractic Association (Any Other Business 1.)

Dr Boulton has written to Dr Jay who is satisfied with the progress so far. The British Chiropractic Council is in the process of being formed.

4.8 Preparations affecting platelet function (Any Other Business 3.)

Virge James has issued a letter drawing the notice of donor consultants to this change in the MAD.

5. A-Z MAD 005 Feb 1997

The printed copy of this (Tabled) and the list of minor changes (specified in the advance notice) were noted and approved. The Committee, through Virge James, wishes to express gratitude to Serge Six for his hard work in ensuring the availability of this document in it's current form which will allow further modifications to these Guidelines to be made conveniently.

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6. Update from UKNBTS/NIBSC Executive Meeting of 19th December 1996

Virge James reported that this meeting was well attended by about 20 people. Although it was intended to discuss the relationship of the Executive Committee with competent authorities, the funding of meetings and how to publish guidelines and amendments, most of the meeting was taken up with the legal status and liabilities of the SAC's and the status of the Guidelines. Legal advice from Mr Janisch, Le Brasseur J Tickle, is that the SAC's have "no legal standing". However, the situation is that the employing health authorities in the UK should note that attendees of the meetings represent their employing authorities which therefore carry any liability for them.

There was also some discussion by the Executive of the "face to face" nature of the MAD interviews and the Donor Declaration. Concern had been raised at the SAC on Donor Selection's previous recommendations that these be obligatory. Although the SAC on Donor Selection has been willing to reconsider this to the effect that we strongly recommend that all interviews for first time donors be face to face, it is important to recognise that the committee does not merely "recommend" that this be the normal nature of conducting such interviews, but that every effort should be made to ensure that these interviews are conducted face to face. This advice is in line with opinions about Best Practice from the SAC which comprise the recognised group of experts on this matter.

7. Transplant Recipients

It is agreed that although it is relatively easy to identify people who have been grafted with solid organs - and therefore to exclude them as donors - there are difficulties with some people who have previously received tissue grafts. This is because some tissues - particularly bone chips and tendons - may have been engrafted into many people who are now healthy and otherwise fit to donate. Furthermore, such people do not necessarily know the nature of the surgical treatment that they have received. The recommendations of the paper by Dr Eastlund were discussed.

Action: George Galea to prepare a paper to set out the relevant issues concerning the consideration of donors who have been transplanted with various tissues.

8. Hearsay evidence on the fitness of people to donate

The papers and letters from the Hoxworth Blood Center were previously circulated.

Concern was expressed about the practice of writing to people informing them that their blood could not be used because of "information received". It was agreed that whenever possible, donors should be contacted by the donor consultants and given every opportunity to clarify concerns that may have arisen from hearsay.

Concerning evidence of lifestyle factors affecting suitability to give blood as revealed by virology testing, Pat Hewitt reported that a study had been conducted in North London over the last 5 years which covered 27 reports of hearsay evidence concerning the individual fitness of donors to give blood. Eight of these reports were corroborated from sources felt to be reliable and withdrawn.

Virology testing - particularly anti-hepatitis B core-correlated very poorly.

It was agreed that the principle should be that if the evidence is not given anonymously, it should be acted on. If the information is given anonymously, or is unassessable as from an unreliable source, it should be ignored.

Action: Virge James to invite Dr Chris Moore of North London to talk on this topic at the Donor Consultant's Meeting on 13th February.

The meeting felt that action concerning these issues should not necessarily be in the MAD Guidelines but could be given as guidelines to Donor Care Consultants and that stress should be made on attempts to corroborate the evidence by discussing with the donor before informing the donor that they have been resigned from the Service.

9. Tranexamic Acid

Dr Makar had written to Virge James. The concern is mostly about donors with menorrhagia receiving this medication. The concern was noted and it was decided that no further action need be taken.

10. Basal Cell Carcinoma

The letter from Dr Williams was noted. It was agreed that this was an editorial issue for the next issue of the MAD Guidelines (1998).

11. Body-builders

Pat Hewitt reported that it is thought that there may be up to 3 million people - mostly men - who use steroids by injection in order to increase their muscle bulk.

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Action: Mary Thornton to pursue information from Cardiff.

It will be necessary to review the wording of the general approach concerning all possible exposures to shared needles.

12. Rabies Vaccine

Correspondence from Frank Boulton was noted; the BMJ letter concerning Indian citizens who may have been exposed to rabies vaccine prepared from Scrapie infected sheep brains. There is no indication for further action.

13. Blood Pressure

The letter from Dr Martlew was noted. The Clinical Care Group is led by Pauline Banks. The Committee felt that there is no evidence of any need to measure the blood pressure at sessions except possibly in persons with a history of hypertension.

Action: Virge James to invite Vanessa Martlew to report in detail on the literature concerning this matter and report back to the Committee.

14. Pregnancy

Virge James reported that European Union Guidelines now recommend that donation be deferred from women who have been pregnant according to the length of the pregnancy, the maximum deferral period therefore being 9 months.

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Action: Chitra Bharucha to contact the Royal College of General Practitioners for an opinion.

Virge James to prepare a concessionary letter for Donor Consultants in September 1997.

15. Drug Trials

The correspondence with Professor Curnow was noted. Virge James also reported a later letter enclosing a copy of the Oxford call-up in which Prof. Curnow suggests an additional bullet point indicating that people should not donate if they are on a drug trial. Virge James had telephoned Prof. Curnow indicating that this is not necessarily an appropriate action. The Committee understands that the Ethics Committee in each of the eight English regions can consider such proposals but that local ethical committees can modify them in the light of local circumstances.

It was agreed that the ABPI be written to, stressing the importance of this issue and the need for a code of practice to make it clear to all participants in trials that they should be informed of the possibility that they may be unsuitable as blood donors while on the trial. This clearly depends upon the nature of the trial and the Committee is happy to be consulted on the issue.

Action: Dr Boulton to write to ABPI.

16. AABB

The weekly report issue of November 15th was noted.

17. European Community

No items of interest have been received.

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18. 3rd Donor Consultant Meeting - 13th February 1997

The agenda was discussed. Alistair Sheppard had earlier requested discussion on the following matters:- Donors and the Disability Discrimination Act, payment for GP's, distomia, and donors over the age of 65 (but see item 18.7.)

Frank Boulton also agreed to give an update on the haemoglobin threshold proposals.

19. Outstanding Issues

19.1 Haemoglobin Threshold

Frank Boulton has not yet produced a detailed report. He will be bringing this back to the Committee at a later meeting.

19.2 Post-donation Illness

See item

19.3 Ear-piercing

It was agreed that this should go back on the agenda for future meetings.

19.4 Hepatitis Section

Pat Hewitt will have this rewritten ready for April.

19.5 Sarcoidosis

It was agreed that there need be no change to the current entry into the Guidelines.

19.6 Typhoid/Paratyphoid

Advice has been received from Dr Snow, Infectious Diseases Specialist to the effect that *Salmonella paratyphii* should be regarded as similar to *Salmonella typhi* in that permanent carrier status can be induced. It was agreed therefore that infections that have been established as being caused by *Salmonella paratyphii* should cause donors to be permanently deferred.

Action: Virge James to prepare for this entry for MAD 006, February 1998.

19.7 Donor Age

- 19.7.1** Chitra Bharucha has written to the Chief Medical Officer of Northern Ireland concerning the regular extension of the upper age for donation to the 70th birthday. The Committee agreed that it is now appropriate to remove the special consideration for donors after the 66th birthday and for donations to be allowed to be collected routinely up to the 70th birthday.

19.7.2 Lower Age Limit

Frank Boulton and Tim Wallington reported that the NBA has now received legal

opinion from Mr Janisch of Le Brasseur J Tickle. In summary, this opinion is that although it may not be legal in English Civil Law to lower the age of consent for donation to 17, it is perfectly legal in English Common Law. Indeed it would be legal in English Common Law to lower the age to 16 years.

The Committee therefore agreed to recommend that the National Blood Authority introduce a lower age limit for donation as from the 17th birthday. This would bring it in line with Scotland and Northern Ireland. It should emphasised that the main reason is to extend the right of donation to a responsible group of adults and that it should not be advocated as a solution to blood shortages. There is no need for a letter to the parents or guardian and there is no medical contra-indication to this development.

Action: Virge James to write to Angela Robinson and to prepare an entry hopefully for the English Donor Consultants for September 1997.

20. Any Other Business

20.1 Donors on Prophylactic Penicillin after Splenectomy

George Galea raised this issue on behalf of an enquirer. It was agreed that such people are acceptable as donors.

- 20.2** Pat Hewitt reported that she is now Secretary of SACTTI.

- 20.3** Virge James reported on the following:-

- 20.3.1** The UKTSSA has published information concerning donors of organ transplantation.

- 20.3.2** She has received a letter from a donor who has complained that following a move to another district he is now excluded from donation on the grounds of a brain tumour at the age of seven. It was agreed that although this accords to strict interpretation of the MAD Guidelines, that issues such as these require a pragmatic professional approach and that it is important not to cause offence to such donors. This matter will be emphasised to all Donor Care Consultants.
- 20.3.3** Virge James reported that the Peripheral Blood Stem Cell Working Party Report (of which she is Chairman) met on the 18th December 1996 and produced a document which is in line with the Consensus Conference from Edinburgh on Unrelated Donor BMT. They propose a study of 30 donors being given GCSF with all the relevant investigations. This study is to be regarded as a Phase I trial in 3 or 4 Regional Centres, the donor consultants involved being quite separate from the consultants treating the intended recipients. However, it is necessary for careful protocols to be prepared before being sent to interested parties including Angela Robinson, John Goldman, Brian McClelland, Morris McClelland and Tony Napier.

21. Dates of Next Meetings

Tuesday 11th March 1997

Tuesday 13th May 1997

Monday 23rd June 1997