10 OCT 1994

Minutes of the ~~10~~ 9th Meeting of the UKBTS/NIBSC Standing Committee on Selection of Donors held at the West End Donor Centre, Margaret St at 11.00 am on Thursday 22nd September 1994.

In Attendance

Dr. Virge James (Chairperson)
Dr. Pat Hewitt
Dr. George Galea
Dr. Peter Flanagan
Dr. Philip Minor
Dr. Tim Wallington
Mrs. Mairi Thornton
Dr. Frank Boulton

1. Apologies: None

2. Minutes of meeting held on Wednesday 15th June 1994 accepted without amendment

3. Matters arising:

3.ii Tamoxifen: PF written to Huw Lloyd, response awaited.

Action: PF to follow up

6. Harold Gunson has agreed to act as editor of A - Z Guidelines

9. VJ raised question of whether all decisions should be incorporated in A - Z guidelines. It was agreed that decisions related to rare conditions need not be included but that a background document should be available to all Donor Consultants outlining positive decisions from the group.

Action: VJ to develop and circulate

4. Report from UKBTS/NIBSC Executive meeting in Birmingham on 5th September 1994.

Main item discussed was the standing of UKBTS/NIBSC guidelines. Approval has been given by NBA, but concerns have been raised by Scotland in relation to lack of managerial involvement in the process. It was decided that the structure should include wide professional representation. The central committee includes National Directors who would naturally consider wider political and financial issues.

Communication was raised covering issues both between committees and to the wider transfusion environment. Chairpersons of individual groups will have a responsibility to update Centre Directors on issues currently being considered by the Group.

5. Revision of AIDS leaflet

see attached paper

6. Acupuncture Update

Meeting planned for 17.10.94.
Details of meeting awaited (subsequently circulated)
GG circulated data on exclusion from Scotland. This relates to 0.24 - 0.58% of all deferral per month. Absolute figure for Sheffield and Colindale are 27 and 20 - 30 per month. Data on exclusions and attendances will be provided.

ACTION: VJ/PH to provide data

7. Chiropody/Electrolysis

See SCD 20/94
Data from Yorkshire indicates 2.8% donors had received chiropody in the previous year, with a figure of approx 2% from Colindale.
There is a need to evaluate data on potential risk arising out of chiropody.
In the light of this there is a need to re-evaluate the policy relating to skin piercing procedures.

ACTION: PF to develop proposal

8. Medication: Diuretics/Hypertension

Papers tabled SCD 21/94.
Further information, including prevalence data required to make definitive decision.

ACTION: VJ to write to Dr. Gabra ✓

9. Prisons

Paper tabled SCD 25/94.
This identifies a high level of injecting drug use within the prison.
It was agreed that the risk is one of IVDU, not simply being in prison. Therefore there is no requirement for a specific exclusion relating to prison.

ACTION: Tim Wallington to review data & report to next meeting

10. Haemachromatosis

Correspondence tabled from Dr. Long SCD 26/94.
Individuals with haemachromatosis are donating for their own benefit and are thus not true volunteers.

DECISION: No change in policy, continue to exclude
ACTION: VJ to write to Dr. Long ✓

11. Bacterial contamination

Correspondence tabled from Dr. Pamphilon 27/94.
The issue of skin cleansing prior to venepuncture is being addressed by the NBA and it is understood that a national policy will be decided.
Further information required to evaluate in the context of current MAD questionnaire.

ACTION: VJ to write to Derwood Pamphilon

12. MALARIA

ACTION: VJ to write to AR regarding acceptance of donors who have visited malarial zones.
PF to bring WHO guidelines to next meeting.

13. POLICY STATEMENT

VJ to circulate

14. ANY OTHER BUSINESS

i. PM raised issue of current recruitment drive for Afrocaribbean donors in S. Thames. He expressed concern over the potential for this drive to increase the level of HTLV infection within the donor pool.

ii. PIZOTIFEN

Letter from Dr. Ala

DECISION: Bring in line with Newcastle Donors on medication. Can accept if no attack in last 24 hrs even if on prophylactic Pizotifen.

ACTION: VJ to update A-Z in next review

15. DATE OF NEXT MEETING

Tuesday 18th October at West End Donor Centre

REVISION OF AIDS LEAFLET

This topic was reviewed during the meeting of the SAC on 22nd September, Dr. Noone attended for this part of the meeting.

The group reviewed the notes of the previous meeting held on 15.6.94. along with correspondence relating to this.

Initial discussion related to the main objectives of the leaflet. These were felt to be:-

1. To reduce the number of potential window period transmissions

2. To reduce the number of anti HIV positive donors entering the donor pool. The screening tests currently available are highly effective in identifying infected individuals. However the recent reports of variant virus strains possibly raise questions of their ability to detect all cases and support the ongoing use of activity based exclusion criteria.

The group then considered the individual risk activities outlined in the paper from 15.6.94 (SCD 15/94). A number of changes were made and these have been incorporated into the second draft (attached).

Summary Recommendations

(A) PERMANENT EXCLUSION

(i) Individuals known to be infected with HIV
(ii) Men who have had sex with other men
(iii) Men or women who have ever injected themselves with drugs
(iv) Men or women who have worked as prostitutes

(B) TEMPORARY EXCLUSION (1 year period recommended in line with international practice)

(i) Individuals who have had sex with a prostitute, either in UK or overseas
(ii) Women who have had sex with bisexual men
(iii) Men or women who have had sex with an individual who has injected drugs
(iv) Men or women who have had sex with individuals believed to be HIV positive
(v) An individual who has had sex with someone of any race who is living in, or who has lived in African countries (other than Morocco, Algeria, Tunisia, Libya or Egypt).
(vi) An individual who has had sex with someone living in Thailand.

(C) CONTENTIOUS AREAS (decisions have been changed during discussions). More information may be needed for definitive decision.

(i) Men or women who have had an episode of gonorrhoea in the last 12 months

(ii) Sexual partners of haemophiliacs (X) OUT.

(iii) Sexual partners of individuals believed to be HIV positive - temporary ~~or permanent~~ exclusion

(D) A trigger clause should be included to identify individuals who believe they have been at risk, or who feel they need an HIV test.

(E) Background information from BTS staff. As well as the leaflet for donors a short background information sheet explaining the logic for the leaflet would be produced. This would enable BTS staff to answer questions and implement the leaflet consistently.

(F) The recent changes in the ways that medical assessment of donors is undertaken may provide a number of ways in which information regarding exclusions is elicited from donors. However it was agreed that a leaflet will be the basic mechanism by which information is made available to donors.

REVISION OF THE AIDS LEAFLET

Proposed exclusion categories, with explanation.

(i) Individuals known to be infected with HIV

This must continue to result in permanent exclusion.

(ii) Men who have ever had sex with other men

This group continue to provide the main reservoir for HIV infection in the UK. It was not considered appropriate to introduce a defined time limit for this risk, and agreed that the reintroduction of a 1977 based exclusion was not desirable.

It was agreed that sex in this context referred to oral and/or anal penetrative sex. This is not a mechanism for acceptance of safer sex and need not be specified in the leaflet. However it was felt that a consistent approach by BTS personnel could only be achieved by the introduction of an agreed definition.

Studies of sexual behaviour had shown a significant level of isolated non penetrative sex between adolescents or young men, often in a boarding school setting. This type of behaviour, so long as isolated, would not result in future exclusion.

(iii) Individuals who have ever injected themselves with drugs

This should continue to result in permanent exclusion. This would also minimize the entry of HCV and HBV into the donor pool.

(iv) Individuals who have undertaken sex for reward (prostitution)

Dr. Johnson indicated that within the UK the prevalence of HIV infection in this group is approximately 1%, and that there is often an association with injecting drug use. This should result in permanent exclusion.

(v) Individuals who believe they have placed themselves at risk, or who think they need an HIV test

Dr. Johnson indicated that a significant proportion of the young sexually active population in inner London will have had an HIV test or consider themselves in need of one.

Unless specific risk activity had been undertaken, as defined in the leaflet, this need not result in

permanent exclusion.
Dr Johnson felt that this type of clause should act as a trigger to make individuals read the leaflet closely rather than represent a specific exclusion. The move towards direct medical assessment should facilitate this approach.

It should however be clearly separated from the section on individuals known to be infected with HIV.

(vi) Individuals who have had multiple heterosexual partners

Prolonged debate took place concerning the desirability of introducing an exclusion in this area. It was agreed that the concept of promiscuity is ill-defined and relative in nature and that it was therefore inappropriate to include a specific exclusion based on number of sexual partners within the leaflet. The feasibility of using a history of sexually transmitted infection as a marker of the high risk lifestyle was discussed. Concern was raised as to the number of donors who may be excluded as a consequence of such an exclusion was raised, as was the efficiency of the exclusion for identifying at-risk individuals.

At the initial meeting Dr. Johnson had suggested that relevant infections might include Gonorrhoea, NSU and Chlamydia. On reconsideration it was felt that any exclusion should be restricted to cases of Gonorrhoea. Further information is needed to make a clear recommendation. Dr. Noone agreed to find data on the number of concurrent episodes of Gonorrhoea with HIV (heterosexually acquired).
It was noted that Gonorrhoea is already included in the MAD guidelines, with a 12 months deferral.

(vii) Heterosexual exposure overseas

(a) AFRICA

Prolonged discussion took place on this subject. It was agreed that the main reservoir of infection related to subsaharan Africa and this should remain a part of the exclusion definition. At the initial meeting Dr. Johnson had indicated that the current exclusion failed to exclude the partners of Africans living within the UK. It was agreed that this should be covered in the next leaflet. The desirability and feasibility of excluding black Africans permanently was discussed, Dr. Johnson having previously had strong feelings on this. It was recognised that the prevalence of HIV in many areas of Africa was not dissimilar to that seen in the UK male homosexual

population. It was however agreed that African individuals do not donate frequently in the UK and that the primary aim of this exclusion was to identify travellers who may have put themselves a risk. It was agreed that any exclusion should be temporary and should include 'any individual who has had sex with someone of any race who is living in, or who has lived in African countries (other than Morocco, Algeria, Tunisia, Libya and Egypt)'.

(b) OTHER COUNTRIES

(i) Sex with prostitute

It was agreed that the exclusion relating to sex with a prostitute should be clarified by inclusion of the term 'in the UK or overseas'. This exclusion would then cover the major overseas risks.

(ii) Thailand

There is increasing concern relating to the level of infection in the general population in Thailand, and a number of cases have now been reported in the UK from this source. The nature of the sex industry in Thailand often disguises the nature of prostitution and it was agreed that sexual contact in Thailand should be specifically included in the leaflet, the exclusion being identical to heterosexual exposure in Africa.

(iii) India, Caribbean, Brazil

The level of risk in these countries was considered. It was however agreed that the exclusion relating to sex with prostitutes and recent STDs would suffice at this stage.

(viii) Females who have had sex with a bisexual male

This category in epidemiological terms is identical to heterosexual sex with an African. This is based on the level of HIV infection in the community at risk. This should continue to result in deferral, but the period of exclusion should be brought in line with geographical heterosexual exposure.

(ix) Sexual partners of injecting drug users

This should continue to result in deferral, however the period should be brought in line with other isolated heterosexual risks. Within the UK the level of HIV infection in the injecting drug user population is lower than that in many African countries.

(x) Sexual partners of haemophiliacs

This exclusion was again discussed in detail. It was noted that heat treated products have only been available for approximately 10 years. Individuals treated prior to the availability of such products may represent a risk of other infections, although it was acknowledged that the number of haemophiliacs in this group is very small.
The majority view of the group was that this exclusion could be removed from the next version of the leaflet.

?HIV+ haemophiliac = X.

(xi) Heterosexual partners of individuals believed to be HIV positive

This item was discussed at length. It was agreed that this risk activity should continue as an exclusion but that this could safely be made a temporary exclusion to bring it in line with other isolated risks.

(xii) Men or women who have had sex with a prostitute

This should continue to result in temporary exclusion. Men who have had contact with a prostitute are also more likely to have had sex with another male. This may therefore be seen as a surrogate for high risk activity. This exclusion will be extended to explicitly state "at home or overseas".

(xiii) Sexual partners of multitransfused individuals

Given the current level of perceived risk from transfusion in the UK it was agreed that these individuals did not require to be excluded.

(xiv) Time period for temporary exclusion

The group unanimously agreed that the 5 year exclusion proposed for temporary exclusion was excessive. It was agreed that the time period for temporary exclusion should be brought into line with international practice, currently believed to be 1 year.
Dr. Galea is currently collating information on international practice and a final decision will be made once available.