ITEM 4.1.2
0122

1. Purpose of Register

1.1 Primary
To prevent transfusion of blood or blood products from people in the following categories:

1.1.1 Those donors who have themselves declared they are in the high risk (HIV) categories (whether or not the blood has been tested).

1.1.2 Those donors who have been confirmed positive for syphilis, HBsAg, HIV and HCV.

1.1.3 Those donors with a proven history of cancer.

1.2 Secondary

1.2.1 To prevent such persons from donating

1.2.2 To prevent donors who may place themselves at risk by donating, to donate.

It is acknowledged that 1.2.1 should not be pursued until such time as microcomputers are in use at all sessions throughout the SNBTS and 1.1 above is known to be working effectively.

2. Data Protection
The data is already registered to comply with the Data Protection Act and the named officer responsible is the National Medical and Scientific Director.

3. Detailed Proposals

3.1 There should be one person in charge of the register in each region, preferably the Director or Donor Consultant. Only these named individuals should have access to the register for the purposes of inputting/amending/searching data.

3.2 There will be a computer record indicator for NMR donors so that DOBBIN can distinguish them on the database.

3.3 This named person to be responsible for inter-regional consultation and other follow-up, including support documentation, should someone on the register re-attend (be identified).

3.4 Since there are five independent regional databases within the SNBTS, care must be taken to ensure that when a donor is being placed on the National Register any previous records held in another SNBTS Centre and of which we are aware, are updated. This will necessitate regular exchange of data between named officers in charge of the register.

3.5 Regions to develop detailed SOPs for above to suit local situation but these must be consistent with agreed policy. Once a discussion has been taken to place a donor on the Register the automatic data transfer must take place without delay.

3.6 It is mandatory that there is written evidence to support placing someone on the National Medical Register. In the case of hearsay evidence it is incumbent on the named officer in charge to pursue evidence from the donor concerned before placing the him/her on the register. If all reasonable attempts fail, then the donor's name should be put on the Register.

3.7 It is recommended that an appropriate comment is put on the donor record which will alert the session staff should the donor attempt to give blood again, but will maintain confidentiality eg "Donor is Permanently Off Service and has been advised not to donate".

3.8 It is recommended that donors already known to the RTC and who fall into the primary categories above should be placed on the Register.

3.9 The Central Legal Office has advised that it is not necessary to seek the donor's authority to place his or her name on the register. An individuals right of access to the data within the register is covered by the Data Protection Act and Access to Medical Records Act.

3.10 New volunteers who have provided personal details and who are subsequently found to be in one of the risk categories as described above must be added to the register.

3.11 All donors placed on the register must be given a simple and brief letter explaining why they, and if applicable their partners, must not donate again.

4. <u>The Way Forward</u>

4.1 As this is an immensely complex operational challenge full validated implementation will take some time and MSC and SNBTS Board approval is sought on points of principle in this document before we embark on detailed specifications.

4.2 Mike Moores, Glen Howe and John Francis will produce a full system specification (including data flow and hardware requirements) ready for design, coding and testing (including field testing). Full documentation is also essential.

4.3 Once the specification is complete, Regions will require approximately 4-6 weeks for writing SOPs, for staff familiarisation and for clearing the backlog of donors to be placed on the register etc.

4.4 A status report from the implementation team, named above will be available at the end of March and a progress report to the May MSC. It is expected that we should go 'live' in late August.

4.5 Future IT developments (eg one national database) should allow simpler operations of this complex register.

G Galea
M Thornton
17 February 1992