Not for Circulation

30/4/97 V.J

Blood Transfusion Epidemiological Study

Briefing document for Transfusion Centre Coordinators

There has been no proven, or even probable, instance of CJD transmission from human to human by blood transfusion or blood products, but observation must continue (WHO, 1997). To this end, the UK Transfusion Services have agreed to perform a limited study in collaboration with the CJD Surveillance Unit. The study has been submitted to the Lothian Local Ethical Research Committee which has granted ethical approval.

A number of issues arise from the proposed study. As there is no evidence that CJD has been transmitted by blood transfusion, it would be completely unethical to notify, or in any other way provide information to a recipient, who had received donations from an individual who subsequently developed CJD. As an extension of this, any clinician caring for such a patient could be placed in an exceedingly difficult position, if provided with this information. The proposed study is not therefore a look-back study as normally understood. It does not involve notification or counselling of identified recipients, nor notification of their caring clinicians. It cannot involve screening or testing since there is no screening test available to identify individuals at increased risk of developing CJD, there is no diagnostic test available other than brain biopsy, and there is no intervention which can be offered to those who develop the disease. For all these reasons, it is unethical and unacceptable to take any action which would alert a recipient (or

a clinician caring for such a recipient) to linkage with a donor who had subsequently developed the disease.

Because of the sensitivities of the whole area, and the need to avoid any possible misinterpretation of this study, it has been agreed to include both cases and controls. Information on the cases and the controls will be provided to the Transfusion Services in a blinded manner. Whenever an individual on the CJD register is identified with a history of blood donation, details of a control patient (without CJD, but with a history of blood donation) will be provided. It will be impossible to identify which are cases and which are controls. Hospitals will be asked only to provide information about the fate of the donations originating from such donors, but will not notify clinicians who were, or are, caring for the patient concerned. Since neither Transfusion Centre staff nor hospital laboratory staff will know whether the particular donation being pursued is from a case or a control, it would clearly be unethical for any information to be passed beyond the hospital transfusion laboratory.

For the reasons stated above it has been decided to refer to this project as "blood transfusion .epidemiological study". This term will be used in internal communications within the blood transfusion services. Use of this title, and avoidance of "CJD look-back study" should clarify two issues: 1) Remove the impression that notification of recipients would take place, as happens with usual look back studies and 2) Remove the inference that CJD will have been transmitted by the donations under question. The proposed new title of this study

more accurately reflects its purpose; to provide further information and data on the lack of any epidemiological link between receiving a blood transfusion from a donor who has subsequently developed CJD, and development of CJD in the recipient. A reverse study will also operate: investigation of the donations transfused into recipients who are subsequently reported as suffering from CJD. The donations concerned would be traced back to the donors, and a search made for any linkage through the CJD register.

Proposed operation of the study

1. Information from the CJD register is supplied to Dr. Jack Gillon (for Scotland and Northern Ireland) and Dr. Pat Hewitt (for England and Wales).

2. Information will be forwarded to relevant Transfusion Centres from the two primary Centres. A method for recording the fate of the documentation is required.

3. Transfusion Centres will examine their records and identify the fate of donations, as far as possible.

4. Consultant Haematologists in charge of hospital blood transfusion laboratories which have received units under investigation will be contacted personally by the Transfusion Centre Coordinator. An

explanation of the reason for the study, and for carrying it out in the agreed form, will be given. It will not be sufficient to communicate in writing, nor should any correspondence refer to CJD or a look-back study. Until transfusion centre records have been examined, it is difficult to predict how many hospitals will be involved, and how many components for each hospital. Nevertheless, the numbers are likely to be small and it is recommended that every effort should be made to visit hospital haematologists and explain the study in person, in order to clarify any possible concerns and misunderstandings.

5. A simplified, one page, enquiry form will be prepared for each component in question. The forms will be forwarded to the relevant hospital, with a request to identify the fate of the component. The information required would be name, and date of birth (as a minimum). This will provide sufficient information from tracing of a recipient through NHS records.

6. No further action would be required at the hospital. The information would be returned to the Transfusion Centre, for subsequent onward transmission to the central coordinators (Jack Gillon and Pat Hewitt), and ultimately the CJD Register.

Proposed plan

1. System for recording receipt of information from CJD Unit and onward transmission to Transfusion Centres to be designed (Pat Hewitt/Jack Gillon).

2. Transfusion Centre coordinators to define what documentation will be necessary at each Centre and pass this to Pat Hewitt.

3. An example of the proposed documentation to be sent to the hospital will be provided.

Distribution:

Transfusion Centre Coordinators
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} for info

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BLOOD TRANSFUSION EPIDEMIOLOGICAL STUDY

Component Details:

DONATION NUMBER		COMPONENT TYPE	
ISSUED TO		DATE OF ISSUE	
ABO & Rh GROUP			

To be completed from hospital transfusion laboratory records

1. Are records available to identify receipt of component YES/NO

2. Are records available to identify fate of component YES/NO

3. If YES to above questions, please indicate fate (tick one box)

TRANSFUSED TO PATIENT		go to 4
RETURNED TO TRANSFUSION CENTRE		go to 5
DISPOSED OF WITHIN HOSPITAL		go to 5
TRANSFERRED TO OTHER HOSPITAL		go to 5

4. If unit transfused to patient please indicate

PATIENT SURNAME	
PATIENT FORENAME	
DATE OF BIRTH	
HOSPITAL NUMBER	
DATE OF TRANSFUSION	

5. If unit NOT transfused to patient please indicate (tick one box)

DATE UNIT RETURNED TO TRANSFUSION CENTRE	
DATE & DESTINATION IF UNIT TRANSFERRED	
REASON FOR DISPOSAL	

7. Details of individual completing form

NAME		SIGNATURE	
DESIGNATION		DATE	

Please return form to:

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