National Creutzfeldt-Jakob Disease Surveillance Unit

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23rd May 2000

Dr Ian R Starkey
Chairman, Lothian Medicine/Clinical Oncology
Research Ethics Sub Committee
Department of Cardiology
Western General Hospital
Edinburgh

Dear Ian

Re: Lookback Study in Creutzfeldt-Jakob Disease
Ethical Approval 1702/96/4/169

Thank you for discussing this study with me at such short notice last Friday. I am now writing to ask that the ethical status of this study is reconsidered following recent developments which I discuss below.

The context of this letter is that I received a letter granting ethical approval for this study on 6.1.1997 (appended) and a letter confirming approval of modification to this study to include recipients of blood products as well as labile blood components on 16.10.1997 (appended).

The original application indicated that individuals who were identified as recipients of blood (or blood products) derived from individuals who subsequently developed CJD or variant CJD would not be notified. The reasons for this were:

1. There is no screening test available with can detect the possibility of an individual being susceptible to development of CJD in the future.

2. There is no diagnostic test available to detect whether an individual has been infected with the agent which causes CJD.

3. The diagnosis of CJD can only be made with certainty by examination of pathology specimens post mortem.

4. There is no intervention which can be offered to individuals detected to be at risk of developing disease, or to those who have already developed symptomatic disease.

It is of note that there is no evidence that CJD has been transmitted through blood or blood products and the risk remains theoretical. I enclose a letter dated 6.2.1998 from Dr G Winyard, Director of Health Services for the NHS Executive which reached a similar ethical view and which stated. "In these circumstances the general view is that patients will not benefit from this knowledge, and that

uncertainty created by informing patients could have the contrary effect causing unjustified worry and creating a permanent blight on their lives in relation, for example, to obtaining life or health care insurance". I also enclose a copy of an independent review body report on a lookback study in the USA which reached similar conclusions.

It is of note that this report and our original ethical application indicated that any change in the capacity to diagnose the disease in the incubation period or if any intervention became available the ethical position regarding notification of recipients would be immediately reconsidered. No such test or intervention is as yet, available.

On 22.11.1999 I wrote to Dr Palmer regarding this study and you kindly discussed the ethical issues with me and wrote a letter on 30.1.2000 withdrawing ethical approval for the study. The reason for this was that the National Blood Authority, in line with a directive from the European Union, changed their policy and decided that recipients of blood from patients who later developed variant CJD should themselves be deferred as blood donors and that these individuals might be informed of the reasons for their deferral as blood donors.

I have now discussed the issue of the ethics of the lookback study in CJD with representatives of the Department of Health and the National Blood Authority. There is a view, with which I agree, that it is unethical not to do this study as this may be the only mechanism by which transmission of variant CJD through blood or blood products can be identified. This issue is a matter of great importance to public health and public health policy.

The situation has changed since I wrote to you last November. On 7.12.1999 I received a letter from Dr Ailsa Wight indicating that the issue of recipients of blood donations from patients who later developed variant CJD and individuals who were identified as being operated on using surgical instruments previously used on variant CJD patients was to be considered by a special working group. This group has now met on three occasions and the Department of Health propose setting up "An Expert Group on the Management of CJD Incidents". This is referred to in the enclosed letter from Dr Mike McGovern, dated 12.1.2000 which indicates that this group will consider incidents, including vCJD blood recipients, who act as blood donors, on a case by case basis. In effect a mechanism is to be set up which will deal with each incident as it occurs and my view is that these policy decisions are quite separate from the ethical issues relating to the look back study itself.

My colleagues and I feel that the ethical issues in the original study, which was approved, remain unchanged. It is important to stress that should a diagnostic test for those incubating disease or a treatment be developed this would be immediately reviewed. The policy decisions regarding individual incidents, including recipients who themselves act as blood donors, are to be considered by a separate Department of Health Expert Group on a case by case basis.

In view of these changes I would be grateful if you would reconsider the ethical status of the lookback study and our request that ethical approval for the study be reinstated.

Thank you for your help.

With kind regards

Yours sincerely

GRO-C

R G Will
Professor of Clinical Neurology