

PEH/mm/Kennedy

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Professor Ian Kennedy
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Dear Professor Kennedy

New variant CJD and blood transfusion recipients

You may recall a conversation we had some 3 years ago (May 1996) in relation to a proposed lookback for CJD.

The proposal was in relation to joint work carried out by the UK Blood Transfusion Services and the CJD Surveillance Unit. In an effort to establish whether there is any association between CJD and blood transfusion, we proposed that a limited lookback study would be performed. I consulted you prior to submitting a proposal to the Lothian Local Ethical Research Committee. The advice I sought from you was in relation to notification of recipients, who had received blood originating from a donor who later developed CJD. Your advice at the time was that no notification of recipients should take place, in view of:

- the lack of scientific evidence that CJD is transmitted by blood transfusion.
- the lack of a screening or diagnostic test to diagnose infection with CJD.
- the lack of any effective intervention which could be offered to those who are infected.

You raised two important caveats at the time. Firstly, if there was any change in the capacity to diagnose the disease and secondly, if any intervention became available, then the means to contact identified recipients must be in place. You made the point that the information we were seeking to obtain is important for public health purposes in terms of planning the extent of resources needed for possible future cases. Having considered all these factors, you concluded that the balance lay in favour of not notifying identified recipients.

The proposal which was submitted to the Lothian Local Ethics Research Committee followed the advice that you gave. Ethical approval was obtained. I have been asked to write to you again, to ask whether you consider that the ethical advice now needs reviewing. Two factors are relevant. Firstly, a test which might have application as a diagnostic test in the future has been developed by Professor Collinge at Imperial College School of Medicine. This

test is still considered a research procedure and is not included in the criteria for diagnosis of nvCJD at the CJD Surveillance Unit. Secondly, the test is based on a tonsillar biopsy, which is in itself an invasive procedure.

The second factor is more complex. Given the concerns over the lack of scientific evidence which would allow a definitive statement that nvCJD is not transmitted by blood transfusion, the UK Blood Transfusion Services have been asked to take measures to ensure that individuals who have been recipients of donations originating from individuals who themselves later developed nvCJD should not themselves become blood donors. The only practical way of implementing this instruction is for the UK Blood Transfusion Services to enter the names of these recipients onto their records database and ensure that, should such an individual present as a blood donor, no blood donations would be used. It also appears clear that, once such an individual has presented as a blood donor, the Blood Services should take efforts to notify that individual of his/her ineligibility to give blood. This would, of course, result in informing the individual that a previous blood transfusion included blood originating from an individual later identified as suffering from nvCJD. Thus, it is conceivable that in the future a small specified group of these recipients will be notified although the majority will not. The majority of transfusion recipients are elderly, or suffering from underlying medical conditions which would disqualify them as blood donors. Thus, the vast majority would never present as blood donors and would not, in the current climate, be informed had they had received blood from a case of nvCJD.

In the light of these developments, I have been asked to write to you and ask whether you could review the situation and the advice you have given in the past, in the light of new developments. I understand that you are occupied on a major commitment at present. If you are unable to provide advice for the UK Blood Services, I would be very grateful if you could please suggest the name of another expert I could approach.

With very many thanks and kind regards.

Yours sincerely

Dr P E Hewitt
Lead Consultant in Transfusion Microbiology

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