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2/270/1

6 December 2004

Faxed & DESPATCHED 7/12/04
NB - enclosure despatched to Professor Sally Davies only
* Also despatched to Lester Firkins 8/12/04 Mike Rawlins

Professor Sally Davies
Director of Research & Development
Department of Health
Richmond House
79 Whitehall
London SW1A 2NL
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Dear Sally

Re: Clinical management, care and therapeutic trial for recipients of blood transfusion from vCJD prion infected donors

Thank you for your letter of 23 November in response to my e-mail to Sir Liam Donaldson, David Harper and Pat Troop of 20 September 2004.

My coleagues and I are grateful for your support with respect to my suggestion that these individuals should be offered access to specialist diagnostic investigation and where appropriate, to the MRC PRION-1 clinical trial protocol - and for your recognition of the potential importance of this group for diagnostics and pathogenesis research. With respect to PRION-1 trial entry, you suggested I raise this at the next Trial Steering Committee meeting. I will certainly do so. However, you may not have seen my e-mail to David Harper of 29 September, in which I expanded on the research issues raised in my earlier e-mail and explained that I had now discussed this issue at the Trial Management Group and it was agreed that entry of such individuals was appropriate and in fact did not require protocol amendment. I enclose this for ease of reference.

Although there are major research opportunities here of crucial importance to public health risk assessment and risk management that I considered to be my duty to bring to the attention of the Department, my principal concern was, and remains, ensuring that the small cohort of known recipients of blood from infected donors is properly counseled and offered access to the specialist clinical services of the National Prion Clinic at the National Hospital for Neurology and Neurosurgery. I am concerned that these people may have been counseled, as were recipients of potentially contaminated plasma products, that their risk is very low, when this does not appear to me to be the case and both diagnostic investigations and access to a therapeutic trial are immediately available.

You indicate that the NBS and NCJDSU are involved and are considering further monitoring activities. Such surveillance activities are certainly appropriate, but I am unclear who is actually talking *clinical responsibility* for the management of their potential iatrogenic prion infection?

My colleagues and I have no means of identifying such individuals or a remit to do so and we have not as yet received any such referrals.

vCJD is a man-made and invariably lethal neurodegenerative condition. Its secondary transmission by iatrogenic routes is tragic. It is however, like all prion diseases, associated with a prolonged clinically silent incubation period when therapeutic intervention prior to neuroinvasion may have the best chance of success. I see this as an urgent clinical matter. More than two months have elapsed since my urgent e-mail to CMO. We must do better than this for this group of individuals, potentially infected albeit accidentally by the NHS in the course of other medical treatment. The NHS has specialist clinical services to manage such patients and my colleagues and I must express our deep concerns that we are not able to do so.

I would be most grateful if you could inform us who is taking clinical responsibility for this matter and confirm what arrangements have been made to ensure specialist clinical management is made available to these individuals?

With best wishes

Yours sincerely

GRO-C

John Collinge CBE MD FRCP FRCPath FMedSci
Professor of Neurology

GRO-C

Dafydd Thomas MA MD FRCP
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Cc Sir Liam Donaldson, CMO
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Enclosure: