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Dear Mr Hooper

Thank you for your letter of 26 September to Patricia Hewitt detailing your inquest into the death of **GRO-A**

I am deeply sorry for the tragic loss to Mr **GRO-A**'s family and the difficulties they have endured during and after his illness. I am very grateful for the thorough and professional manner in which you conducted the enquiry and for informing me of your deliberations. Your letter highlighted concerns that Mr **GRO-A** had not been told of the risks he faced at the earliest possible stage.

The Department of Health took the decision not to inform potentially exposed transfusion recipients about the possible risk of exposure to the agent of variant Creutzfeldt-Jacob Disease (vCJD) in 1998, following advice from experts in ethics. The level of risk of transmission through blood transfusion was uncertain and the Department commissioned Det Norske Veritas (DNV) to undertake a risk assessment to evaluate the overall risk to patient groups, which was published in 1999 (revised in 2003). The decision was particularly difficult as certain experts thought transmission via blood was unlikely, no test or treatment was available and the incubation period was unknown, but could be decades long. To date, there is still no test or treatment and the incubation period is still unknown. In addition, the early symptoms of disease are the same as for many common and treatable illnesses. Thus, telling people of a potential exposure may result in a lifelong worry that every minor depression or episode of clumsiness is the first sign of impending vCJD. As a result, telling healthy transfusion recipients that they may have been exposed to vCJD agent as a result of their treatment could also undoubtedly do harm.

The situation is now different. The results of experiments in animals have indicated that transmission by transfusion can occur. Furthermore, there has been a general shift in attitudes towards patients' rights to information. In the summer of 2000, the Department of Health established the CJD Incidents Panel. The Panel was asked to advise healthcare professionals on the management of incidents involving potential transmission through medical interventions. The Panel was aware of the difficult decisions involved in relation to the harm caused to individuals by informing them of a potential risk of unknown significance, as balanced against the rights of these individuals to knowledge about themselves and the need to protect public health. The Panel made its proposals available through a consultation process, which included a public meeting held in April 2002. There was a wide range of views expressed.

The Panel revised its proposals in the light of the consultation responses, recommending that patients considered 'at risk' should be notified and that necessary support mechanisms should be in place. The four Chief Medical Officers for England and the Devolved Administrations accepted this proposal in June 2003. At this time, there were still no known cases of vCJD transmission via blood transfusion. However, while the necessary support mechanisms were being put in place, the first case of vCJD transmission via blood transfusion was confirmed in December 2003. The Department acted as quickly as possible to ensure that all similar recipients were contacted and given the information and support needed.

In future, all such patients will be contacted as soon as they have been traced. In addition, the Department has put in place a number of measures, updated as new evidence emerges, to ensure that secondary routes of vCJD transmission through blood and surgery are minimised. This includes sourcing plasma from outside the UK, leucodepleting blood, improving decontamination techniques and developing specific public health precautions in those who may be at greater risk of developing vCJD.

Your letter also refers to the difficulty in diagnosing CJD in the early stages of the disease and you suggested prior knowledge of a particular risk could have helped Mr

GRO-A

With most vCJD cases, it is difficult to establish an early diagnosis and this problem is one that the Department is concerned to tackle. The Department has invested £7.5million in a variety of novel approaches towards developing diagnostic tests for human health.

You also noted that patients should have the opportunity of receiving appropriate assessments, if they wish, and be reliably informed to prepare them for future events. You suggested that advice is given to the individuals and their GPs about appropriate steps to take, including referral for expert assessment. All recipients of blood from vCJD cases have been given (at the time of informing them of their risk) information from the Health Protection Agency about how to access specialist care.

The GPs of these individuals have also been provided with contact details for the National Prion Clinic (NPC) and the National CJD Surveillance Unit, and have been encouraged to consider referral of their patient for assessment. If the individuals prefer to be cared for locally, the Health Protection Agency arranges for referral to a local neurologist, and for the briefing of that neurologist. Dr Wroe is aware that patients such as Mr. **GRO-A** are now offered expert assessment in this way, and is assisting the Health Protection Agency in facilitating this.

We have set up an expert group, under the chairmanship of Sir William Stewart, to re-evaluate and make recommendations for the way individuals who are identified 'at risk' are best cared for, which goes beyond simply reviewing the way we warn individuals they are at risk. As you have rightly pointed out, it is important that the patient be given choice so they can make that decision. To do this, it is imperative that they have access to effective and objective information, and also that support at the local level, for example GP, local neurologists and local psychiatrists is robust. Sir William's Group is examining this and will be making its recommendations later this year. The NPC together with other expert centres, for example the National CJD Surveillance Unit in Edinburgh, and support groups are vital to the patient-care process. However, the emphasis must be on the patient or individual, who has been informed they are at risk. They must be allowed to make an informed choice.

I hope I have addressed your concerns in this letter.

Yours sincerely

GRO-C

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