COVERING RESTRICTED – MEDICAL

Mr Gregor Lindsay

Copy to Dr A Fraser
Mr J T Brown
Mr N Lindsay
Dr A Keel
Ms S Falconer
Mr S Lindsay, Solicitors

Pip

This was in my 'on return' & I'm not clear about the route through which it arrived. But you will be interested to see the 'tartan' approach to all this. (maybe you've seen via a separate copy?)

GRO-C

20/8

MANAGEMENT OF INCIDENTS INVOLVING POSSIBLE EXPOSURE TO CJD (INCLUDING vCJD) IN HEALTHCARE SETTINGS – INFORMING THOSE WHO MAY HAVE BEEN EXPOSED TO THE INFECTIVE AGENT

In the last 18 months there have been over 50 incidents in the UK involving a possible exposure of a patient or group of patients to the vCJD/CJD agent in healthcare settings. These broadly fall into 2 categories. The first is where a surgical procedure has been carried out on a known or suspected case of CJD/vCJD and the instruments have been reused on a cohort of patients. The the second is where a case of vCJD (not CJD) has donated blood and either blood components or plasma products have been used on one or more patients.

2. In response to these incidents the Department of Health (England), liaising with other UK Health Departments, has established a CJD Incidents Panel to advise Health Boards, Trusts and other healthcare providers on the management of such incidents. Guidance on the need to investigate a medical history of patients with CJD/vCJD has also been issued to Health Boards. The accompanying draft Guidance has been prepared by the Incidents Panel for issue to a range of organisations in the coming months. It is at a relatively late stage of drafting. Pages 33 -36 detail the public health investigation and management of incidents.

3. Patients with a possible risk of acquiring CJD/vCJD are categorised as belonging to two groups:

- *A "contactable" group* who should be informed of the potential risk and would be told that they should not donate blood, other tissues or organs and that they should alert their carers if they were to undergo surgical procedures. This group would be asssessed as being those most likely to have been infected and thus capaable of transmitting the agent to others. Their details would automatically be recorded preferrably with their consent. Although the position is not completely formalised, it is likely that their details would be kept even if an individual in the group witheld consent or requested that his/her details should be removed from any register.

- *A "database" group* whose details would be entered onto a database to enable the real risk to be more accurately assessed in the future. This group would be asssessed as being less likely to have been infected than the "contactable" group and less capaable of transmitting the agent to others. However the risk of infection and secondary transmisson although very low, could not be excluded and there is a need therefore to establish the scale of this risk to inform future action. These people would not be actively contacted but would have the option to find out if they were at risk and would be able to request removal of their names from the database.

The entry of these details onto the database would be supported by a national publicity campaign to inform the public about CJD/vCJD, the risks from medical procedures and the existence of the database. Widespread local publicity for each individual incident should occur. Details of the public awareness aspects are provided in pages 37-38 of the draft guidance.

The database would be held by the Communicable Disease Surveillance Centre of the Public Health Laboratory Service, an English Agency which in this instance would be operating on a UK-wide basis. The purpose of the database would be to hold a register of an individual's demographic and medical details and subsequently data gathered from a follow-up of the development of key health events particularly whether the individual concerned develops vCJD.

5. This proposed method of operating will be the subject of consultation when the draft guidance is issued later this year.

6. In developing the guidance, there has been wide-ranging input from ethicists. Indeed the Incidents Panel is headed by Professor Michael Banner, a noted ethicist himself. The proposals for public awareness have been reached through arriving at a compromise between the individual's right tokeno and his/her right not to know about a potential risk to their health which is unquantifiable and which currently nothing can be done to reduce.

7. DH (England) have also involved legal opinion. We have replicated this and advice from Steve Lindsay was that the DH legal opinion should apply to Scotland. However in Scotland many of the issues of patient confidentiality and sharing information are not being dealt with through statutory means (as in England) but through the proposed guidelines on protecting patient confidentiality formulated by the Confidentiality and Security Advisory Group for Scotland. As such I was requested to send further details of this guidance to you as the lead officer for CSAG, to request your opinion on their application in Scotland.

8 Among the main questions are:

- whether the proposed guidance on the management of CJD/vCJD incidents involving healthcare contravene the principles outlined in the CSAG proposals;

- if so, can the proposed way ahead be amended to concord with CSAG without undermining the key principles detailed in the Guidance document;

- if SEHD were to introduce legislation on this subject, would it embrace the issues raised in the Guidance document.

7. I look forward to your reply and would be happy to meet with you to discuss these issues further. The Incident Pannel's Draft guidelines will be the subject of consultation at a UK-wide level over the coming months and it would be useful to have this issue resolved prior to the draft being published.

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