SCOTTISH PARLIAMENT

ORAL ANSWER

5 December 2002

Health Department:

Dorothy-Grace Elder (Glasgow) (Ind): To ask the First Minister whether the Scottish Executive has any plans to review the methods of alerting any patients that may have been at risk of exposure to variant Creutzfeldt-Jakob disease.

(S1F-02332)

Mr Jack McConnell:

NHSScotland is advised on these matters by the UK CJD Incidents Panel, which is the expert committee set up to give advice on the management of incidents where one or more patients have possibly been exposed to the CJD or vCJD agent in healthcare settings. The Panel has recently presented proposals for the management of such patients to the CMO for Scotland for consideration. The decision on what to tell a patient ultimately rests with the clinician in charge of their care and will also take account of the risk involved and the patient's underlying medical condition.

SCOTTISH EXECUTIVE

BACKGROUND NOTE FOR PQ S1F-02332

Context

1. This question from Dorothy-Grace Elder MSP follows the decision taken last week by Scottish Haemophilia Directors to advise haemophilia patients of an incident involving a Scottish blood donor, whose donation had been used in the production of clotting factor concentrates, and who subsequently developed vCJD.

2. The media coverage, which followed the issue of the letters, accused the Government of a cover-up in that the SE had known of the incident for two years but did not tell recipients of the affected products.

Issues Specific to This Case

3. SEHD submitted details of the incident to the CJD Incidents Panel in March 2001, and received a request for further information from the CJD Incidents Panel following a second letter in August 2001.

4. In the ~~recent~~ reported. case, Scottish Haemophilia Directors felt that patients should be informed and counselled appropriate to their individual situation. They wrote on 26 November to all haemophilia patients who received any Scottish National Blood Transfusion Service (SNBTS) Factor VIII or IX concentrates during 1987 – 1989 informing them of this event.

5. The donations in this incident were also used in the manufacture of other products (albumin and immunoglobulin) which SNBTS estimate may have been used to treat up to 2,000 patients. Letters have not been issued to these patients because of the perceived low risk and also the difficulty in tracing patients after fourteen years.

One Other Case

6. SNBTS has been informed of one other Scottish donor who subsequently developed vCJD. This donor gave 2 donations, which were used to make red cell concentrates subsequently used to treat two patients. The clinicians involved in the patients care have been awaiting further advice from the CJD Incidents Panel regarding the level of risk involved and how the patients would be best managed regarding information, counselling and support. The Incidents Panel has not yet finalised its view on the risks of red cell concentrates in relation to

transmission of CJD. As at 29 November 2002, neither patient had been formally informed about the incident.

Current Procedures

7. The Incidents Panel is chaired by an eminent ethicist, the Reverend Professor Michael Banner and gives advice to clinicians and the NHS throughout the UK on follow up action, where an individual who develops CJD or vCJD is found to have undergone an invasive medical procedure or to have donated blood or tissues or organs. The recommended management of the situation is governed by the estimation of the risks involved and by the ethical issues appropriate to the individual incident.

8. The Incidents Panel issued for comment to patient and professional groups in ~~November~~ October 2001, draft "framework" guidance for the management of incidents involving blood products and surgical instruments, which would guide its future advice on individual incidents. This recommended that certain groups of patients should be told of possible vCJD exposures. Hitherto DH advice had been that patients (who receive blood from someone who subsequently developed vCJD) should not be told.

General Background Information

9. There is still no evidence anywhere in the world that either classic or variant CJD has been transmitted between humans by blood transfusion or use of blood products.

10. For the past four years UK blood services have been taking precautionary measures against vCJD including importing plasma from USA and Germany for the manufacture of plasma products.

11. Haemophilia patients in Scotland now receive recombinant (synthetic) factor VIII and IX concentrates that do not involve donated human blood. The costs around £17.3m per year.

12. The tests currently used by the SNBTS for virus screening cannot be applied to variant CJD as it is not a virus and current tests for CJD Agent are not sufficiently sensitive to detect levels which might be of concern. SNBTS is working with colleagues to try to develop blood tests, but it is currently unclear whether this will be possible and what the time frame is likely to be.

13. Latest research has shown that BSE can be transmitted experimentally in blood between sheep.

Contact Name: Dr Peter Christie
Department: SEHD
Ext: GRO-C
December 2002

Supplementaries

When was the SE informed of this incident?

SE was informed in March 2001 by SNBTS, and SE immediately informed the CJD Incidents Panel. The Panel was contacted again in August 2001 by SEHD, requesting urgent action on provision of management advice.

Why were patients not informed sooner?

The Incidents Panel was set up to provide advice on how incidents should be handled. Definitive advice on the management of incidents involving clotting factor concentrates has not yet been provided.

There is no blood screening test to detect vCJD and the risk in transmission between humans through blood remains theoretical. There is therefore a need to balance the risk and the unnecessary concern this may cause to people who have received blood and blood products.

Why tell them now?

The Scottish Haemophilia Directors felt that patients should be informed and counselled appropriate to their individual situation.

When will the Incidents Panel report?

The Incidents Panel is awaiting final scientific advice on estimates of risk from blood and blood products. A draft framework for management of patients who may have been exposed to risk was submitted to the 4 UK CMOs on 4 October. There is no formal deadline for this work, but it will be completed as soon as possible.

How many patients received implicated batches of clotting Factor concentrates?

This is a matter involving patient confidentiality. The letters issued leave it open to the patient to decide whether they wish to be informed if they received a product from the implicated batches.

Are there any other reported incidents involving blood or blood products?

SNBTS has been informed of one other Scottish donor who subsequently developed vCJD. This donor gave 2 donations, which were used to make red cell concentrates, and were used to treat patients. The clinicians involved in the patients care have been informed that they should decide whether or not to inform the patients of this taking

into account their underlying illness.

Surgical Instruments?

In Scotland, single-use instruments are to be employed wherever possible. Surgeons are, however, allowed to use reusables on known or suspected vCJD cases providing that the instruments are new and are discarded or quarantined at the end of the procedure. A major programme to evaluate and upgrade standards for routine surgical instrument decontamination is in progress, including central funding for new washer/disinfector plant and monitoring by SCIEH of implementation of new stringent standards with fixed deadlines.