

27th November, 2002

SCOTTISH EXECUTIVE HEALTH DEPARTMENT HAEMOPHILIA CENTRES IN SCOTLAND THE SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE

PRESS BRIEFING

Blood transfusion, Clotting Factor Concentrates and variant Creutzfeld-Jacob Disease (vCJD)

A blood donor in Scotland, who much later developed variant Creutzfeld-Jacob Disease (vCJD), donated twice in the late 1980s. These donations contributed plasma that was used to manufacture Scotlish National Blood Transfusion Service (SNBTS) factor VIII and factor IX concentrates for the treatment of haemophilia in 1987 – 1989. Some other products were made from these batches. All of these products would have been used or expired before the end of September 1990. None was exported outside Scotland and Northern Ireland.

After being informed of this by the CJD Surveillance Unit, SNBTS reported this incident to the Scottish Executive Health Department, the CJD Clinical Incidents Panel (Banner Committee), and Haemophilia Directors in Scotland and Northern Ireland in November 2001. Detailed examination of patients' past records has identified that a number of patients with haemophilia in Scotland treated with SNBTS factor VIII or factor IX received concentrates to which this blood donor contributed. After continued discussions between all these parties, particularly the CJD Clinical Incidents Panel, Haemophilia Directors for Scotland have written to all patients who received any SNBTS factor VIII or IX concentrates during 1987 – 1989, informing them of this event. Counselling has been offered to those patients who wish to have further information, particularly in relation to their own treatment.

Professor Ian Franklin, Medical Director of the Scottish National Blood Transfusion Service, said

"There is still no evidence anywhere in the world that either classic or variant CJD has been transmitted by blood transfusion or use of blood products between humans. Despite this, the UK Blood Services are taking a number of precautionary measures. This includes, importing plasma from the USA and Germany for the past four years as a precaution against vCJD for the manufacture of plasma products such as immunoglobulin, albumin and clotting factors. In addition, haemophilia patients in Scotland now receive recombinant (synthetic) factor VIII and IX concentrates, which are believed to carry a lower risk of transmitting infectious agents than plasma products."

While we acknowledge that informing patients of this incident may cause concerns, SNBTS and the Haemophilia Directors consider that openness in these matters is important in maintaining confidence in blood transfusion. The Haemophilia Society and the United Kingdom Haemophilia Centre Doctors' Organisation have also been informed.

A similar episode arose in England last year with regard to concentrates from a different manufacturer, and patients with haemophilia in the UK were informed of that event by Haemophilia Directors.

All those involved in considering the issues related to the safety of clotting factor concentrates are aware of the sensitivity of the issues raised and wish to ensure that patients are given information and counselling appropriate to their individual situations. NHSScotland is committed to ensuring that all patients with haemophilia receive the highest quality care.

Key Messages

- The tests currently used by SNBTS for virus screening cannot be applied to variant CJD as it is a different type of disease. 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.
- ❖ Blood services look at all possible measures regarding blood safety and balance these against other risks and the risk to supplies. Therefore, having a blood transfusion is safe by most clinical standards, but it can never be zero risk.
- Blood transfusions save tens of thousands of lives in Scotland every year. They also improve patients' quality of life and speed their recovery after various treatments, but blood components, like any other treatment, are not free of risk and the risks of receiving a blood transfusion must be balanced against the risk of not receiving one.
- SNBTS continue to need 1,000 donations every day to meet the needs of Scotland's patients.

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| GRO-C | | | | | | | |

Note to the Editors

The CJD Incidents Panel was established by the Departments of Health, with Professor Michael Banner as Chairman, in order to offer guidance in relation to CJD episodes involving patients. The Panel published its interim advice, for consultation, in November 2001. This advice recommended that certain groups of patients should be told of possible vCJD exposures. Prior to November 2001, the advice had been that patients were not to be informed of possible exposure. The Panel has not yet

published definitive advice on the management of incidents involving clotting factor concentrates, and what patients should be told.