1. CMO (agreed) — From: Rowena Jecock GHP-HP2

2. PS(PH) — Date: 20 June 2005

3.SofS — Copy: As attached

SECONDARY TRANSMISSION OF VARIANT CJD: RECOMMENDATIONS FOR FURTHER PUBLIC HEALTH PRECAUTIONS

Purpose

1. To alert you to expert recommendations expected shortly to further strengthen measures to reduce the risk of secondary (person-to-person) transmission of variant CJD (vCJD).
2. To update you on the background, key actions taken to date, and the context for the expected new recommendations.
3. To seek your views on our proposed handling strategy, including publication of the risk assessment upon which the recommendations are based.

Issue

4. Two expert committees (the CJD Incidents Panel, CJDIP, and the Committee on Microbiological Safety of Blood, Tissues and Organs, MSBTO) are shortly expected to recommend public health precautions in relation to **donors whose blood has been transfused to a person who subsequently developed vCJD.** We will inform you of the detailed recommendations as soon as we receive them, but in outline, we expect the recommendations to propose that these donors be considered as "at risk of vCJD for public health purposes", and that the donors and their clinicians should be informed of their risk status and asked to implement the public health precautions currently specified by the CJDIP.[1]

5. This differs from past public health precautions, which have focussed on the recipients of blood/blood products from donors who have gone on to develop vCJD, and on donors who themselves have been transfused. Where a transfusion recipient has gone on to develop vCJD, an assessment of risk undertaken by the Department's analysts indicates a significant likelihood of a donor being the source of the transfusion recipient's infection. **Currently, 110 donors have been identified who fall into this category.**

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[1] Individuals are advised not to donate blood, tissues or organs; whenever they are going to have surgery or an invasive medical procedure, to inform doctors/dentists/nurses in charge of their care that they are in an 'at-risk' group for vCJD; to tell their family in case they need emergency surgery. Their GP is asked to ensure that their patient's 'at-risk' status is recorded in their primary care records; that this information is included in referral letters, should their patient require any invasive procedure; and determine whether the patient has given any donations or undergone any surgery since the time of their exposure, and liaise with local Health Protection Team to ascertain whether further action is required.

6. Other recipients of blood from these donors (estimated to be up to 3000 individuals) are excluded from blood donation themselves by the restrictions already in place. However appropriate public health precautions and possible monitoring arrangements for this group will be discussed at the next meeting of the CJDIP (September 2005). NBS has informed us that it is highly unlikely that all recipients in this group could be identified, as old transfusion records may not be retained by hospitals.

Timing

7. Your views on handling would be appreciated as early as possible please. Following interim expert advice in March 2005, the National Blood Service (NBS) is not issuing for clinical use any donations from the 110 individuals identified. However, legal advice to NBS is that this position is not sustainable long-term, and that these donors must be excluded from future donation and told why. Should you agree the recommendations from CJDIP/MSBTO, we advise that these donors be notified of their status as soon as possible, preferably before the start of the main Summer holidays in mid-July, in order to maximise their opportunities for early access to expert advice and support. We are working with NBS and the Health Protection Agency (HPA) to prepare for this now.

Background

8. Expert scientific consensus is that consumption of BSE-infected meat products is the cause of vCJD in humans. It is generally held that the majority of the UK population was therefore exposed to BSE during the 1980s and early 1990s, when the BSE epidemic peaked. To date, the feared vCJD epidemic in the UK population has not materialised. Only a small number of clinical cases have so far occurred (156), but there is now some evidence to support the long-held theory that a proportion of the population may be sub-clinically infected (ie, may never develop symptoms of disease). Such individuals, together with those in the pre-clinical phase, may nevertheless pose a secondary infection risk to others. Such a risk is most likely to arise through exposure to healthcare interventions such as blood transfusion from an apparently healthy, but infected donor.

9. Since 1996, when the first cases of vCJD were identified by the National CJD Surveillance Unit, this Department has continually re-assessed the possible risk of secondary (person-to-person) transmission through various routes (principally blood transfusion, surgery, dentistry, and bone/tissue transplants) as new evidence emerged, and has implemented precautionary policies step-wise to reduce the risk as far as practicable.

10. A number of measures have been implemented to specifically protect the blood supply **(Annex A)**, and these were tightened further following SofS's announcement in December 2003 of the

first case of possible transmission of vCJD between people via blood transfusion. A second case of possible transfusion-associated transmission was identified in 2004.

11. The measures implemented since December 2003 comprise:

- Anyone who has themselves received a blood transfusion since 1980 (considered to be the start of the BSE epidemic) is now excluded from blood donation;
- Identifying certain groups of patients who may be at increased risk of having contracted vCJD via blood or blood products, and informing them and their clinicians of the risk to enable precautions to be taken to reduce the risk of potential onward transmission. These patient groups include recipients of whole blood from donors who subsequently developed vCJD, and those who receive large quantities of certain UK-derived plasma products such as clotting factors. To date, some 4000 patients have been informed of their potentially increased risk, the majority being haemophilia patients.

Context for latest recommendations

12. CMO asked the CJDIP and MSBTO to consider the potential risk posed by donors where a recipient of their blood has developed vCJD. Their forthcoming recommendations are based on an assessment of the likelihood of a donor being the source of infection of the transfusion recipient, and the most stringent public health precautions will apply to donors for whom the risk estimate is assessed to be about 1% or greater.

13. A simple scenario, taken from the DH risk assessment, which shows how the risk estimate is calculated, is appended at **Annex B**

Handling of donor notification

14. The HPA has previously undertaken the notification exercises for at-risk groups identified by the CJDIP. It would be more appropriate for the NBS to undertake some aspects of the communication in this instance, and both organisations are already working closely together.

Proposed Parliamentary and media handling

15. This is a departure from previous notifications, in that those to be told of their possible risk status are healthy donors, rather than patients. It is important that measures to protect the blood supply are implemented and communicated in such a way that they do not deter donors, who are, in the main, highly committed individuals. Some may however be deterred from donation if they feel that they may in future be informed of a potential increased risk to themselves, about which they may prefer not to know, and the possible implications for their insurance status etc.

16. Careful construction of public messages will be necessary to minimise possible adverse impact on the donor base. Both NBS

and the HPA are sensitive to the difficulty associated with conveying a risk message to healthy donors, and we will work with them to ensure the wider public messages are carefully constructed.

17. We will liaise with COMMS to prepare a detailed media-handling plan, but broadly, we propose the following approach:

- We will agree topline messages with NBS and HPA.
- NBS and HPA will jointly prepare information material for the donors concerned and their clinicians, and ensure that support mechanisms are in place for them.
- NBS and HPA will also provide NHS Direct with information to enable them to deal with calls from the general public.
- We suggest a written statement for Parliament, announcing the start of the notification exercise, and will prepare a draft for Ministers to consider.
- As the messages are complex, we suggest a briefing session for journalists might be helpful, together with the chairs of CJDIP and MSBTO, the NBS and the HPA.
- We publish the risk assessment **(Annex C)** on the DH website to coincide with the statement to Parliament. (All empirical data used in the risk assessment are already in the public domain).
- As the majority of affected donors live in the north of England, the local public health and communications experts will need to be closely tied in, to ensure common messages are given.
- Local Trusts will be informed, and asked to direct enquiries to the NBS/HPA/NHS Direct as appropriate.

Summary

18. Are you content that we proceed as outlined in paragraph 17?

Rowena Jecock
Ext GRO-C

Copy:

Frances Smethurst PS/MS(D)	Gerry Robb GHP
Clare Osborne APS/Perm Sec	Peter Bennett SAT
Catherine Pearson APS/CMO	Stephen Dobra SAT
David Harper HPIH&SD	Peter Grove SAT
Gareth Jones HPIH&SD	John Stephenson RDD
Gerard Hetherington HPD	Michael Clarke COMMS
Lindsey Davies RPHG(EM)	Sophie Coppel COMMS
Ailsa Wight GHP	Paul Johnstone RPHG(Y&H)
William Connon GHP	David Walker RPHG(NE)
Eileen Lawrence GHP	John Ashton RPHG(NW)
Carole Fry GHP	Ian Dodge No 10
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Annex A
Precautionary measures implemented since 1997 to protect the blood supply

- Withdrawal and recall of any blood components, plasma derivatives or tissues obtained from any individual who later develops vCJD (December 1997).
- Importation of plasma from the US for fractionation to manufacture plasma derivatives (October 1999).
- Leucodepletion (removal of white cells) of all blood components (Autumn 1999).
- Importation of clinical fresh frozen plasma (FFP) from the U.S. for patients born on or after 1st January 1996 (introduced Spring 2004).
- Promotion of appropriate use of blood and tissues and alternatives throughout the NHS.
- Exclusion of donors who had received a blood transfusion in the UK since 1980 (April 2004).
- Individuals in the following categories are also excluded from being blood donors:
    - individuals with CJD or other prion associated disorder Individuals at familial risk of prion-associated diseases.
    - individuals at familial risk of prion-associated diseases.
    - anyone identified at high risk of developing a prion associated disorder. This includes:
        -recipients of dura mater grafts.
        - recipients of corneal or scleral grafts.
        - recipients of human pituitary derived extracts such as growth hormone or gonadotrophins

Developments expected in the next 6-18months:

- Pall Corporation(USA) have developed a Leukotrap® Affinity Prion Reduction Filter to reduce infectious prions from red cell units prior to transfusion. This filter is estimated to produce a 2.5 log reduction in prions, and at cost of £35-42 per filter would increase the cost to the blood service by £70-80 million/year, should NBS adopt it. NBS is currently undertaking safety testing of these filters.

- A number of companies are developing efficient diagnostic tests for prions that could be used to screen blood donations. It seems possible that tests may start becoming available within the next 18 months or so.

Annex B
Example of estimated risk of a donor being the source of vCJD infection in a transfusion recipient

This example presents a simple scenario, based on the following assumptions:

- an infected blood donation would certainly infect the recipient;
- and there is no way of distinguishing between the contributing donors (and recipient) in terms of risk of primary vCJD infection, eg all were resident in the UK during the height of the BSE epidemic;
- and there is no other significant secondary infection route for the recipient (such as having undergone a surgical procedure considered high risk for vCJD)

Given these assumptions, then a transfusion recipient who developed vCJD stands an equal chance of being infected via the primary route (food) or via any of the donors. If there are 3 donors, there is a 25% chance of the recipient having had a primary infection, and a 75% chance of the infection having been transmitted by any of the 3 donors. The chance of an individual donor being infected is therefore 25%.

The greater the number of donors who have given blood to a single vCJD recipient, the smaller the *individual* risk of one of those donors being infected, although the larger the *combined* risk that a blood transfusion was the source of infection.

For example, using the same set of assumptions, if a transfusion recipient who subsequently develops vCJD has received blood from 99 donors, there is a 1% chance of the recipient having had a primary infection and a 99% chance of the infection having been transmitted by any of the donors. The chance of an individual donor being infected is therefore 1%.