

## **RESTRICTED - MEDICAL**

MS(PH)

From: Ailsa Wight GHP

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Copy: As attached

### **LANCET ARTICLE re. CASE OF VARIANT CJD LINKED TO BLOOD TRANSFUSION FROM AN INFECTED DONOR**

#### **Issue**

The attached article will be published in The Lancet tomorrow Friday 8 December on the third case of vCJD transmission via blood transfusion from an infected donor, originally notified to the Department in January 2006. The Medical Research Council are publishing a press release. This relates to the third case which has previously been announced in an HPA press release earlier this year, Rowena Jecock's submission of 30 January 2006 refers. The transmission of vCJD by blood transfusion is not news but the publication of the article has attracted press attention.

#### **Recommendation**

1. For information only at this stage. Details of this patient's infection were already in the public domain. Further investigations have been conducted both by the clinicians who cared for the patient, and by the National CJD Surveillance Unit (NCJDSU) together with the blood services.
2. There are another 24 patients who received prion infected blood from donors known to have developed vCJD. The HPA ensured in February 2006 that the GP's of these patients are fully informed and briefed.
3. We have already implemented a series of precautionary measures to reduce the risk of vCJD being transmitted through the blood supply (listed at Annex A), all in the public domain.

A fourth case (the patient currently survives) of vCJD transmission by blood transfusion is being investigated, and has now been confirmed by tonsil biopsy, but this information is not in the public domain.

#### **Background**

##### **Implementation of measures to protect the blood supply**

5. To date, there have been 164 cases of probable or definite vCJD in the UK, with six people still alive (1/12/06). The most likely cause is considered to be consumption of beef products from BSE-infected cattle.
6. Shortly after vCJD was first identified in 1996, the possibility of human-to-human transmission through blood was considered, and DH

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implemented precautionary measures to reduce what was, at that time, a theoretical risk.

7. These measures were further tightened as evidence of transmission via blood began to emerge from animal studies, and following the first possible case of transfusion associated transmission in humans. An important additional step, introduced in March 2004, was to exclude from blood donation those people who had themselves received a blood transfusion since January 1980 (the beginning of the BSE epidemic in cattle). A full list of precautionary measures is attached at Annex A.

### Proposed holding lines to take

8. We suggest the following holding lines to be used in the event of media interest:

- We are deeply sorry to hear of the death of the patient referred to in the Lancet article;
- This is not a new announcement but confirms in a scientific journal a case widely reported in early 2006;
- It is widely accepted that a transfusion of blood from a person suffering from vCJD can transmit vCJD, but the probability of this happening is not known.
- We have already implemented a series of precautionary measures to reduce the risk of vCJD being transmitted through the blood supply (listed at Annex A, all in the public domain).
- As part of our approach to risk reduction, people who have themselves received a blood transfusion have been deferred from donating blood since 2004.
- We keep the situation under constant review, and will continue to implement measures to reduce this risk as far as we reasonably can.
- **[Only If pressed :** We were aware that a possible fourth case of vCJD linked to blood transfusion is being investigated.]

### Conclusion

9. The HPA contacted the GPs of all individuals identified as at risk in earlier in the year and asked them to provide update information about their patients. The HPA continues to work with the GPs to ensure feedback on these patients. The response so far has been very good. All the individuals concerns had been notified previously, through their GPs, of their at risk status and have been provided with information and support.

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Dr Ailsa Wight

GHP

**Copy:**

Dani Lee APS (SofS)

Alan Reiss MS/(HS)

Matt Tagney PS/MS(R)

Richard Kelly PS(CMO)

Mike de Silva PS (David Harper)

Greg Hartwell APS/Perm Sec

David Harper HPIH& SD

Gareth Jones HPIH&SD

Liz Woodeson HPD

Ailsa Wight GHP

Mark Noterman HP-GHP8

William Connon HP-GHP5

Geoff Ridgway HP-GHP6

Peter Bennett SAT

Stephen Dobra SAT

John Stephenson RDD

Janet Gibson HP-GHP2

Neil Ebenezer HP-GHP5

Brenda Iron-Roberts COMMS

Katie Robinson COMMS

Liz Kendall Sp Adv

Karen Livingstone Sp Adv

Matthew Swindells Policy Adviser

Paul Corrigan No 10

Kate Richards SEAC secretariat

Peter Christie SEHD

Mike Simmons NAW

Liz Mitchell DHSSPS(NI)

**ANNEX A**

**Measures taken to date to improve the safety of blood in relation to vCJD**

- From December 1997, blood components, plasma products or tissues obtained from any individual who later develops vCJD, have been withdrawn/recalled.
- In July 1998, we announced that plasma for the manufacture of blood products, such as clotting factors, would be obtained from non-UK sources.
- From November 1999, white blood cells (which may carry a significant risk of transmitting vCJD) have been removed from all blood used for transfusion.
- In August 2002 we announced that fresh frozen plasma for treating babies and young children born on or after 1 January 1996 would be obtained from the USA.
- In December 2002, the Department of Health completed its purchase of the largest remaining independent US plasma collector, Life Resources.
- The report of the first possible case of transmission of vCJD by blood transfusion was in December 2003. Following this, we announced in March 2004 that individuals who had themselves received a transfusion of whole blood components since January 1980, would be excluded from donating blood. (In July 2004, the second possible case of transmission of vCJD by blood transfusion was reported.)
- In July 2004, the exclusion criteria for blood donation were extended to include two new groups, who had received transfusions of whole blood components since 1980:
  - Previously transfused platelet donors
  - Donors who were unsure if they had previously had a blood transfusion.
- This means that for blood donation the full exclusion criteria are:
  - Recipients of dura mater grafts.
  - Recipients of corneal or scleral grafts.
  - Recipients of human pituitary derived extracts such as growth hormone or gonadotrophins.
  - Individuals at familial risk of prion-associated diseases. This includes individuals who have had two or more blood relatives develop a prion -associated disease and individuals who have been informed they are at risk following genetic counselling.
  - Individuals who had themselves received a transfusion of whole blood components since January 1980 are excluded from donating blood.
  - Individuals identified as 'at risk' by CJD Incidents Panel.
  - Previously transfused platelet donors.

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- Donors who were unsure if they had previously had a blood transfusion.
- In September 2004, the Department of Health announced further precautionary measures for patients who had received certain batches of plasma products.
- In July 2005, the use of USA sourced fresh frozen plasma (FFP) was extended to all children up to the age of 16.
- In July 2005, the Department of Health announced further precautionary measures for around 100 patients who donated blood to three people who later developed vCJD. (The notified patients have been asked not to donate blood, tissues or organs and to inform health care professionals so extra precautions can be taken when they have surgery or other invasive procedures).
- In November 2005, the Department of Health announced an extension of the notification exercise in July 2005. A further 50 people who had received blood from some of the 100 or so donors notified since July are being traced and notified of their potential exposure to vCJD.