RESTRICTED - MEDICAL

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To: 1 Michael McGimpsey

vCJD PRION PROTEIN FOUND POST MORTEM IN PATIENT WITH HAEMOPHILIA IN ENGLAND

Summary

Issue:	The Department of Health alerted us on 12 February to the first identification of vCJD prion protein in a study of tissue obtained at autopsy of a haemophiliac patient who died from unrelated causes. Haemophilia centres doctors have been informed of this finding and are in the process of informing all their patients.
Timescale	Urgent - press release and notification letters to all UK haemophilia doctors and their patients planned for week commencing Monday 16 February
FOI Status:	
Presentational Issues:	National media interest may be high and there may be local media interest. Some of the local patients with haemophila have spoken to the media on similar issues in the past. Information Office has also had a recent media enquiry from a freelance newspaper journalist on a closely related issue.
Special Adviser's view:	
Recommendations:	That the Minister note the findings and DH handling proposals and suggested lines to take.

Detail

1. Evidence of prion protein associated with exposure to vCJD has been identified in a study of tissue obtained at autopsy of a haemophiliac patient who died from unrelated causes. The patient was 74 years old when he died, and did not shown any symptoms of vCJD or other neurological disease when alive. The transfusion history of the patient is still being

investigated, although it is known that the patient received before 1999 clotting factor from a donor who later developed clinical vCJD.

2. Haemophilia patients, including those living in Northern Ireland, have previously been informed by their clinicians of their possible increased risk of exposure to vCJD via clotting factors. Although it is unlikely that this new finding will change their risk status it is recognised that it will nevertheless be of concern to those who suffer from haemophilia and other bleeding disorders. Therefore the priority is to ensure that patients receive expert advice as soon as possible as to whether there are any implications for each of them. This will be done through their haemophilia centre clinicians.

Background

3. In 2003 the first case of clinical vCJD in a patient who had received whole blood from a donor who later went on to develop vCJD was reported. Since then, a further two cases of vCJD have been identified in patients who received whole blood from two separate donors who also later developed vCJD. A number of actions have been taken in Northern Ireland, as in the rest of the UK, to minimise the risks of transmission of vCJD from whole blood and blood products (see **Annex A**). Patients known to have been exposed to blood or blood products from a donor who themselves later went on to develop vCJD, have where possible been notified of their risk.

4. Although no cases of clinical vCJD have been identified in haemophiliacs, they are recognised to be at potential risk because of their regular and frequent requirements for blood products. The blood product clotting factors used to treat haemophilia patients were sourced from the UK until the introduction of US sourced plasma in 1999. Therefore the CJD Incidents Panel (CJDIP, which advises the UK Health Departments and on CJD risk management) recommended in 2004 that all patients with bleeding disorders who had received UK sourced products between 1980 and 2001 should be notified and managed as a single “umbrella” group potentially at risk of vCJD for public health purposes. This was irrespective of whether they had received clotting factors derived from a donor known to have developed vCJD. The UK Haemophilia Centre Doctors Organisation (UKHCDO) and the Haemophilia Society endorsed this approach.

5. As a follow up to this decision the National CJD Surveillance Unit (NCJDSU) and the UKHCDO are carrying out a study of tissue samples from patients with haemophilia, testing for the abnormal protein associated with vCJD in residual biopsy and autopsy samples.

Implications of this finding for Northern Ireland

6. Whilst this finding is not wholly unexpected and, subject to the investigation of fuller records, has no immediate implications for the management of haemophilia patients it will be of concern to these patients. There is significant public and political interest in blood safety issues, especially in relation to haemophiliacs who have received UK sourced blood products.

7. The Health Protection Agency (HPA) and the UK Haemophilia Centre Doctors Organisation are preparing letters to all Haemophilia Centre Doctors informing them of the case and its implications. The letters will include a core script letter for them to personalise to send to each of the patients "at risk" under their care. The letters to Haemophilia Centre Doctors/haemophilia patients will be sent in the week beginning 16th February 2009 due to increasing concerns around the possibility that the information may make its way into the public domain. This issue of the letters will precede publication of a case report by the NCJDSU.

CJD Incidents Panel and other expert advisory committees

8. Information on the case was presented to the CJDIP on 22 January, though without the further information awaited on other possible routes of exposure. The panel formally approved the precautionary actions proposed by HPA, NHSBT and the UKHCDO. Pending further advice from the CJD Incidents Panel DH has agreed with NHSBT that the National Blood Service (NBS) should continue to accept blood donations from any donors to the haemophilia patient who are still giving blood but not issue them. DH has also asked that steps should also be taken to ensure that all identifiable donors to the haemophilia patient are investigated by the National Blood Service and the NCJDSU, to ensure that none of them has been identified as a vCJD clinical case.

9. Further information about the patient's possible exposure history should be available for the next meeting of the CJD Incidents Panel in May 2009.

10. The Incidents Panel will be asked to consider in the light of this whether:

    - any action is needed regarding identified blood donors to the haemophilia patient;
    - there is any change to the risk status of haemophilia patients who received blood product clotting factors sourced a) from the same

donor as this patient, and b) from other donors who subsequently developed vCJD;

- there is any change to the risk status for haemophilia patients who received UK sourced blood product clotting factors (unlikely since this does not add new information to the risk assessments which took this possibility into account); and
- there is any change in risk status of patients who have received other plasma products such as albumin and immunoglobulin (unlikely since level of risk has not changed).

11. Information on the case will also be presented to the Spongiform Encephalopathy Advisory Committee (SEAC), in confidence, in March and to the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) in April.

DH handling plan

12. The media handling plan is still to be agreed but DH proposes that:
    - a letter and information pack, currently being finalised by the Health Protection Agency (HPA) and the UK Haemophilia Centre Doctors Organisation, will be sent on Tuesday 17 February to all UK Haemophilia Centre Doctors informing them of the finding and its implications; and
    - a press release, announcing this finding, will be issued next week.

Recommendation

13. It is recommended that you note this briefing and the suggested lines to take

Lines to take:

- I am aware of the current situation reported in England. Evidence of prion protein associated with exposure to vCJD has been identified in a study of tissue obtained at autopsy of a haemophiliac patient who died from unrelated causes.
- All UK Haemophilia centres' doctors have been informed of this finding and are in the process of informing all their patients by letter.
- Haemophilia patients have previously been informed by their clinicians of their possible increased risk of exposure to vCJD via clotting factors, and it is unlikely that this new finding will change their risk status. However, I recognise that the new finding will be of concern to those who suffer from haemophilia and other bleeding disorders and their clinicians.

- The priority is to ensure that the patients receive expert advice as soon as possible from their haemophilia centre clinicians
- UK plasma has not been used for manufacture of clotting factors since 1999 and synthetic clotting factors are provided for all patients for whom they are suitable.

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Annex A

Current risk reduction measures in place in the UK to reduce the risk of vCJD transmission via blood/blood products.

Since the theoretical risk of vCJD transmission through blood was first considered, precautionary measures have been introduced to minimise the risk, including:

Applicable to all blood/blood products

- From December 1997, blood components, plasma products or tissues obtained from any individual who later develops vCJD, have been withdrawn/recalled.

  From October 1999, white blood cells (which may carry a significant risk of transmitting vCJD) have been reduced in all blood used for transfusion, a process known as leucodepletion or leucoreduction.

- Following the report of the first possible case of transmission of vCJD by blood transfusion in December 2003, it was 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.

  This exclusion has been extended to include previously transfused platelet donors and donors who are unsure if they have previously had a blood transfusion. This now applies to donors who have been transfused anywhere in the world.

- 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.

- 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.

Platelets

To reduce the need to pool donations in producing platelets collection of platelets by apheresis continues to be extended where possible

Plasma

- In July 1998, it was announced that plasma for the manufacture of blood products, such as clotting factors, would be obtained from non-UK sources.

- In August 2002 it was announced that fresh frozen plasma for treating babies and young children born on or after 1 January 1996 would be obtained from the USA.

  Fresh frozen plasma for treating babies and young children born on or after 1 January 1996 is obtained from the USA, and from July 2005 its use was extended to all children up to the age of 16.

  The NHS has been instructed to purchase imported solvent detergent FFP for adult patients with thrombotic thrombocytopenic purpura (TTP), although there is some doubt about the effectiveness of this measure, and further advice will be sought from SaBTO at its next meeting.

Cryoprecipitate

Cryoprecipitate produced from methylene blue treated-plasma imported from the USA is being implemented for all children up to the age of 16.

Additionally, considerable effort is being extended to promote appropriate use of blood throughout the NHS and the HSC, to target blood use to where it is clinically essential. This work has already achieved notable successes.