CMO

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Date: 16 April 2008
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Highly Transfused Patients and vCJD

Timing

1. The purpose of this submission is to seek your approval for a letter (draft attached at Annex A) to Mr David Pryer, Chairman, CJD Incidents Panel (CJDIP). It replies to a Report on this topic prepared by a joint subgroup of the Panel and Advisory Committee on Dangerous Pathogens (ACDP) Transmissible Spongiform Encephalopathy (TSE) Working Group.

Timing

2. Routine.

Recommendation (summary)

3. It is recommended that you respond to each of the report's recommendations as suggested in paragraph 7 below, and send a letter thanking Mr Pryer.

Issue

4. Mr Pryer wrote to you on 12 September 2006 recommending that patients in receipt of blood transfusions from 80 donors or more should be considered at risk of vCJD for public health purposes. You requested further work by the Panel and ACDP TSE Working Group on proposals for the identification and management of these patients. The Report now presented by Mr Pryer sets out six recommendations for the identification and handling of highly transfused patients. The Report suggests that there may be around 30,000 patients still living who could fall into this category.

Background

5. There have been four secondary transmissions of vCJD infection via blood. In all cases the recipients received non-leucodepleted blood in or before 1999. There have been no recorded blood associated transmissions of vCJD since the introduction of leucodepletion in 1999. Various other actions to minimise the risk of vCJD infection via blood have been introduced. Twenty three patients who received blood from donors who later developed vCJD

are known and living. The HPA regularly monitors, via general practitioners, the health of these patients.

6. There have been 166 cases of clinical vCJD in the UK (including three of the blood transmission cases; the fourth died of an unrelated disorder and at autopsy protease-resistant prion protein was detected in the spleen but not brain, and so is not counted as a clinical case). There have been no new clinical cases of vCJD in the UK since 2006, and there remain only three living vCJD patients.

Suggested responses

7. The paragraphs below suggest a response to each of the report's recommendations:

Recommendation 1. *Identify and notify highly transfused patients during pre-surgery assessment for surgery in contact with high-risk tissue*

This recommendation is accepted. This recommendation is in accordance with the guidance published in November 2006 by NICE "*Patient safety and reduction of risk of transmission of Creutzfeldt-Jakob disease (CJD) via interventional procedures*". Amendments to the ACDP TSE Working Group infection control guidance on risk groups for whom special measures are required during surgery, have been prepared to take account of this recommendation in readiness for approval by the main ACDP. We agree that assessment before high risk (ie neuro and ophthalmic) surgery should be the primary strategy for identification and notification of highly transfused patients, and is a proportionate public health measure.

Recommendation 2. *Notify those with certain specific diagnoses that are highly associated with 80 or more donor exposures*

The generality of this recommendation to consider the need for further work in specific diagnostic groups is accepted. However, there are difficulties given that in England there is not a database linking diagnostic and transfusion histories. We are hoping that NHSBT will be able to provide data for England on, amongst others, haemoglobinopathy patients, who are high users of blood/blood products and who may be under-represented in the Scottish data. Clinicians are already provided with information for new patients whom they anticipate will need multiple transfusions as part of their treatment but the Blood Service will be considering how this advice could be strengthened.

Recommendation 3. *Identify and notify the very highly transfused (eg. more than 200/400/800 donor exposures)*

This recommendation is accepted in principle. We are in discussion with NHSBT, HPA and others on the practicalities of informing identifiable groups, and if possible would propose to start

notification with the small number who had received over 800 donor exposures. We do not wish to enter into a situation where we notify patients with a lower exposure and later need to denotify them if prevalence estimates change. We therefore suggest starting at a high level and if necessary working down to others with a lower exposure. It is worth noting that the groups themselves were unable to decide where the line should be drawn and left the decision to us whether it should be 200, 400 or 800.

Recommendation 4. *Identification and notification of all highly transfused patients*

It is noted that the Panel does not currently regard it as feasible or proportionate to identify and notify all highly transfused patients.

Recommendation 5. *Establish procedures for standardising and linking blood transfusion databases*

This recommendation is accepted in principle. To include information on the level of donor exposure for each patient on their record, we will work with NHS Connecting for Health and NHSBT to explore the practicalities necessary for implementation.

Recommendation 6. *Communication strategy*

This recommendation is accepted. We are working with the HPA to ensure that suitable materials are available to inform patients identified as at risk of vCJD and their clinicians. In particular, we will ensure that advice in the revised ACDP TSE Working Group infection control guidance is actively drawn to the attention of clinical staff working in neuro and ophthalmic surgery.

8. As this is work in progress, there are no plans to publish the report currently. It will be used as a basis for discussion with stakeholders and other experts, and updated as necessary. Once agreed by the ACDP, the recommendation relating to pre surgical assessment will be issued as revised ACDP TSE Working Group guidance.

9. The CJDIP reports to all four UK CMOs, so the reply to Mr Pryer will be on their behalf. You will wish to note that the situation in Scotland is potentially different from that in England, Wales and Northern Ireland in relation to recommendation 4, as the Scottish Blood National Blood Transfusion Service is able to track patients' transfusion histories. As a result, Scotland may be able to more readily identify all patients (around 3000) who have over 80 donor exposures, though no decision has yet been taken about any notification of such patients. This is not currently feasible in England, Wales and Northern Ireland as no transfusion records are kept centrally.

Conclusion

10. It is recommended that you respond to each of the report's recommendations as suggested above, and send the attached letter responding to Mr Pryer.

Mark Noterman
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Department of Health

Annex A

Our reference:

April 2008

Mr David Pryer
Chairman, CJD Incidents Panel
Health Protection Agency Centre for Infections
61 Colindale Avenue
London
NW9 5EQ

Dear David

Re: Highly transfused patients and secondary transmission of vCJD

Thank you for your letter 17 March 2008, reporting the outcome of the joint group convened by the CJD Incidents Panel and the ACDP TSE Working Group.

I welcome the report and set out below responses to each of your six recommendations.

Recommendation 1. *Identify and notify highly transfused patients during pre-surgery assessment for surgery in contact with high-risk tissue*

This recommendation is accepted. The recommendation accords with the guidance published in November 2006 by NICE "*Patient safety and reduction of risk of transmission of Creutzfeldt-Jakob disease (CJD) via interventional procedures*". I understand that amendments to the ACDP TSE Working Group infection control guidance to implement this recommendation have been prepared in readiness for approval by the Working Group and main ACDP, and I support this action.

Recommendation 2. *Notify those with certain specific diagnoses that are highly associated with 80 or more donor exposures*

The generality of this recommendation is accepted, and I propose to ask that information should be gathered on what further data are available nationally, particularly on haemoglobinopathy and other patients who make large medical use of blood and who may be under-represented in the Scottish data.

Recommendation 3. *Identify and notify the very highly transfused (eg. more than 200/400/800 donor exposures)*

This recommendation is accepted in principle. Discussions will take place with NHSBT, HPA and others on the practicalities of identifying and informing such groups, and if such an exercise is practical will start with those who had received over 800 donor exposures.

Recommendation 4. *Identification and notification of all highly transfused patients*

This recommendation not to undertake wider identification and notification at this time is noted. However, it is important to note that the different information systems in Scotland may make this a feasible option for that country. Colleagues in the Scottish Government Health Directorates are following this up and will liaise with the other administrations and the Incidents Panel in due course.

Recommendation 5. *Establish procedures for standardising and linking blood transfusion databases*

This recommendation is accepted in principle, and we will work with NHS Connecting for Health and NHSBT to explore the practicalities necessary for future implementation.

Recommendation 6. *Communication strategy*

This recommendation is accepted, and I understand that the HPA has already started work to ensure that suitable materials are available to inform both those identified as at risk of vCJD and their clinicians.

I am very grateful to you and your colleagues on the Panel, and to Professor Jeffries and his colleagues on the Working Group, for the thoroughness of your report and hope that you will work with the Department as we take the recommendations forward.

Yours sincerely

Professor Sir Liam Donaldson
Chief Medical Officer

cc. Dr Harry Burns, Dr Tony Jewell, Dr Michael McBride, Dr Peter Christie, Dr Elizabeth Mitchell, Dr Sara Hayes, Professor Don Jeffries, Miss Charlotte Mirrielees.