CMO

From: Mark Noterman
Date: 9 August 2012
Cleared: Ailsa Wight
Copy: see list at end

CMOPO00699418 (PO80/2012) Mr David Pryer, Highly transfused patients and secondary transmission of vCJD

Issue

1. Attached at Annex A is a draft reply to a PO case for your consideration.

Recommendation

2. That you send the attached letter to Mr David Pryer.

Timing

3. Routine, though due to ongoing discussions between officials and the HPA the response has been delayed.

Background

4. There is evidence of person to person transmission of vCJD via blood transfusion. There have been three clinical cases and one case of asymptomatic infection presumed to have been related to transfusions of non-leucodepleted red cells in or before 1999, and one case of asymptomatic infection of a haemophilia patient who had amongst other risk factors received blood products know to have included a donation from a donor who later went on to develop clinical vCJD.

5. Because of the potential for person to person spread it has been thought that those exposed to high levels of donated blood or blood products would be at much greater risk of vCJD than the wider population. A figure of 80 or more donor exposures, based on an increase of 1% over population risk as a basis of "increased risk" designation for public health purposes, has been used as a working guide by the CJD Incidents Panel that an individual is at increased risk over the population risk (most of the UK population were exposed to such risk through meat consumption).

6. Whilst any person transfused is deferred from blood donation, so closing off this potential route of secondary transmission, there remains the potential that the "highly transfused" may be a potential source of surgical transmission of vCJD infection.

7. Recent revision of blood related risk by the Advisory Committee on Dangerous Pathogens has led to a revision donor number related to increased risk from 80 to 300 exposures. Those with more than 80, or now 300, donor exposures are referred to as the "highly transfused".

8. Dealing with the potential vCJD infection from those who have been "highly transfused" via surgery has been an issue that the CJD Incidents Panel and the Advisory Committee on Dangerous Pathogens have grappled with for some years. Various attempts have been made to tackle elements of the issue, including via pre-surgical patient assessments. However, as David Pryer's letter makes clear, this has led to operational difficulties for hospitals.

9. There is no indenfified case of vCJD transmission via surgery, and indeed the known numbers of sporadic CJD transmissions by this route is also very small. Given this lack of cases of scondary transmission, the small numbers of CJD cases (of all types) and the complexity of the guidance that has been previously tried, it has been very difficult to achieve successful implementation of risk management measures.

Proposal

10. The recommendations set out in Mr Pryer's letter are an attempt by the expert scientific opinion of the ACDP and the Panel to achieve an evidence-based, balanced and effective risk management. Briefly, this would mean raising the cut-off of 80 donor exposures to 300. Annex B provides additional information on the four recommendations and the suggested responses to each. We agree that taken together these would overall be practical and proportionate.

11. Colleagues at the HPA have already started to engage with clinicians affected by these issues (including Dr Sara Trompeter at UCL), and will also work with key patient groups (eg. haemophilia, sickle cell and thalassaemia patients) as the work develops.

Conclusion

12. That you send the enclosed letter, and await an update on progress from the HPA requested for December 2012.

Mark Noterman
Infectious Diseases and Blood Policy
Public Health Directorate

cc:

Claire Vittery
Felicity Harvey
Clara Swinson
Peter Bennett
Natalie Reynolds
Andrew Riley – Scotland
Elizabeth Mitchell – Northern Ireland
Tracey Gauci – Wales

Department of Health

Annex A

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

August 2012

Dear Mr Pryer

Highly transfused patients and secondary transmission of vCJD

With apologies for the delay, I write in reply to your letter of 26 April.

I am very grateful for the detailed deliberations of the Panel and the Advisory Committee on Dangerous Pathogens (ACDP) Transmissible Spongiform Encephalopathy Risk Management Sub-Group (the Sub-Group) in reaching the four recommendations set out in your letter. It is reassuring that your recommendations aim to reduce risk whilst at the same time maintaining high quality patient care and not imposing unreasonable burdens on health services.

On your first recommendation, that "pre-surgical assessment of blood transfusion history prior to high risk surgery should be stopped", I agree that in the light of the general difficulties and ineffectiveness in operation that have been identified, and of recent ACDP advice on blood risk scenarios, such pre-surgical assessment should be stopped. I would be grateful if the Sub-Group would work with HPA officials to ensure that the existing guidance is revised and services are notified of this change.

On your second recommendation, for a review of the current Sub-Group advice "on management of endoscopes and other medium risk surgical procedures", I have noted the publication in June 2012 of the Choice Framework for local Policy and Procedures (CFPP) 01-06, the content of which was informed by members of the Sub-Group, of the Panel and

other endoscopy and decontamination experts. I accept your recommendation that current Sub-Group guidance should be revised to ensure that it aligns with the CFPP. This will ensure that health services are not receiving potentially conflicting advice. In this context I would be grateful if HPA officials would revise this specific guidance, publish the revision with ACDP's agreement. Whilst this revision should be undertaken and published as soon as is feasible, it should be part of a wider revision of all Sub-Group and Panel guidance to ensure that it is clear, practicable and meets the requirements of application by local services. Guidance should be provided in a form that gives clarity on actions to be taken and on where responsibilities lie.

On your third recommendation, on the operation of the Sub-Group's operational guidance on pre-surgical assessment, I agree that the first option should be applied and that all patients should continue to be asked if they have been notified of an increased CJD risk.

On your fourth recommendation, I agree with your proposal to apply a donor exposure limit of 300, rather than 80, to categorise an individual as at increased risk of vCJD.

On the management of those patients so categorised, I agree in principle that those affected should be identified and notified where practicable. However, before such a policy is implemented I ask that the HPA secretariats to the Panel and the Sub-Group should consult with haematologists and other specialists caring for those likely to be notified, and appropriate patient representative groups, and prepare a report to me on the potential impact of such an exercise on individuals and services, perhaps focussing initially on those who received non-leucodepleted blood prior to 1999.

Thank you again for all the careful thought you, the Panel and the ACDP have given this issue. I would be grateful if you would report back to me by December 2012 on progress in implementing your recommendations.

Yours sincerely

Professor Dame Sally Davies
Chief Medical Officer

Copies:

Dr Harry Burns – CMO Scotland
Dr Tony Jewell – CMO Wales
Dr Michael McBride – CMO Northern Ireland
Dr Elizabeth Mitchell – Northern Ireland
Mrs Tracey Gauci – Wales
Dr Nicola Steedman - Scotland
Dr Felicity Harper – Director General - Public Health
Duncan Selbie – Chief Executive Designate Public Health England

Annex B

Recommendation 1 - That pre-surgical assessment of blood transfusion history prior to high risk surgery should be stopped

- Suggest - agree. A process for assessing at pre-surgical assessment whether patients were "highly transfused" defined as over 80 donor transfusion exposures was introduced three years ago. The system is acknowledged to have been a failure both in terms of practicality and achievement of results.

Recommendation 2 – that the Advisory Committee on Dangerous Pathogens TSE Risk Management Sub-Group advice on the management of endoscopes be reviewed.

- Suggest – agree. Currently various guidance documents provide confusing, and potentially contradictory, advice on instrument - particularly endoscope - decontamination. It is important that these be reviewed revised and, once agreed by the relevant advisory committee, updated.

Recommendation 3 – that the Advisory Committee on Dangerous Pathogens TSE Risk Management Sub-Group's operational guidance should require all patients should be asked if they have been notified of an increased CJD risk.

- Suggest - agree. This guidance refers to the need to ask about other CJD risk factors such as whether a patient has received cadaveric derived human growth hormone or has a family history of one of the rare familial forms of human prion disease. Such questions should continue as part of remain pre-surgical assessments.

Recommendation 4 – that a donor transfusion exposure limit of 300 be used to categorise an individual as at increased risk of vCJD, and that those affected should be identified and notified where practicable (to replace the measure to stop, as per Recommendation 1).

- Suggest – the first element to be agreed, and the second agreed in principle, subject to additional work by the HPA in consultation with haematologists and patient representative groups. Whilst the change in limit is evidenced by the blood risk assessment revision the impact of a notification exercise is uncharacterised and requires additional work prior to implementation. Given evidence that non-leucodepleted blood, used in and before 1999, presents a higher infection risk than that used since, it is suggested that those who received over 300 donor exposures pre-1999 should be the initial focus of such work.