CJD Incidents Panel and ACDP TSE Working Group
Highly Transfused Implementation Subgroup Meeting
5th February 2009, Royal College of Anaesthetists, London

Minutes

Present

CJD Incidents Panel members
Mr David Pryer (Chairman)
Dr Gerry Bryant
Dr Pat Hewitt (afternoon)
Prof Don Jeffries
Mr Ian Pearce (morning)
Dr Hester Ward
Ms Kate Woodhead
Outside experts
Dr James Nash
Dr Peter Wilson
Department of Health
Mr Stephen Dobra
Mr Mark Noterman
HPA
Ms Dominique Brookes
Dr Nicky Connor
Ms Helen Janecek
Mr Patrick Kirwan
Ms Charlie Mirrielees
Dr Akram Zaman

Apologies

Ms Tracy Coates
Dr Adrian Copplestone
Dr Phil Darbyshire
Dr Adam Fraise
Dr Charles Hay
Prof Frank Hill
Mr Alistair Jenkins
Prof Theresa Marteau
Prof Mike Murphy
Dr Bernadette Nazareth
Dr Derek Norfolk
Dr Roland Salmon
NB Papers considered by the meeting are listed in the Annex.

1. Introduction

The aims of the meeting were to discuss the detailed process of identifying and notifying highly transfused patients at increased risk of vCJD and to consider the draft documentation prepared by the HPA. Participants were thanked for coming on a day of very heavy snow and disrupted travel arrangements.

2. Update

2.1 Participants noted correspondence between the Panel Chairman and the Chief Medical Officer where CMO accepted the Panel's recommendation for a two-pronged strategy:

- Identifying highly transfused patients with ≥80 donor exposures through pre-assessment for surgery and neuro-endoscopy on high risk tissues ie. central nervous system and posterior eye, to start in April 2009.
- Prospective notification of very highly transfused patients with ≥800 donor exposures in July 2009.

2.2 The rationale behind the phased strategy was to focus efforts at the point where highly transfused patients pose the highest risk of potential transmission, in line with the NICE guidance[ref], and to minimise the impact on the health service of removing surgical and endoscopic instruments from use. It was estimated that in the region of 50 highly transfused patients would require high risk surgery in any given year, out of an estimated cohort of around 30,000 with ≥80 donor exposures. The two-pronged approach would also enable evaluation of the first part of the patient notification exercise to inform the second part.

2.3 It was confirmed that the 4th November 2009 letter from the CMO for England accepting the Panel's recommendations had been approved by the CMOs for the other three countries in the UK.

2.4 Annex J of the ACDP TSE Working Group guidance would be revised to support the identification and management of highly transfused patients through pre-surgery screening. An additional Question 4 would be added to Table J1.

3. Communicating the Panel's recommendations

3.1 Potential obstacles to implementing the Panel's recommendations included local variations in trust structures and the dissemination of forms and information within and between hospitals. It would be necessary to impress on trusts that the patient notification exercise was not optional. It was therefore agreed that the initial communication to trusts would be in two parts:

a. It was **agreed** that the Department of Health would initiate the exercise by sending a letter to trust chief executives, summarising the advice and rationale for the patient notification exercise, copied to the Panel, the ACDP TSE Working Group and the HPA to indicate the provenance of the advice and state that detailed instructions and supporting documentation would be available from the HPA. The letter would also need to emphasise the importance of inter-trust cooperation in relation to requests for help in the completion of blood transfusion histories.

b. The HPA would, in parallel, send a complementary second letter to trust chief executives copied to directors of infection prevention and control

(DIPC) and medical directors; with another letter going to local health protection units. These letters would refer to the DH letter and give a brief description of the actions required on the lines of paper 4.

3.2 It was confirmed that the phrase 'at increased risk of vCJD' had replaced the phrase 'at increased risk of vCJD for public health purposes' in the HPA patient literature and **agreed** that the new phrase should also be used in documents for healthcare professionals for consistency.

3.3 The HPA would work with the appropriate patient organisations to obtain their input into the identification and notification process and communications strategy.

4. Roles and responsibilities

4.1 It was recognized that the person who would be responsible for deciding whether individual patients should be classified as 'highly transfused' and whether surgical instruments should be removed from use would vary between trusts.

4.2 On receipt of the highly transfused documentation from the DH and the HPA, it would be expected that senior staff from infection control, blood transfusion laboratories, surgery and theatre departments would develop joint local protocols and procedures to implement the recommendations. The risk assessments required to manage patients with uncertain donor exposures (papers 5 and 8) will be carried out within trusts and will result in joint decisions by haematologists, DIPCs and surgeons. It might be helpful to suggest that each trust choose one lead person e.g. a 'risk assessor', to take overall responsibility on behalf of the trust for the local risk assessments and, if appropriate, the resulting public health actions. The lead haematologist, or other consultant clinician, however, would be responsible for calculating donor exposures. The HPA secretariats to the ACDP TSE Working Group and the Panel would not have the capacity to provide advice about large numbers of local risk assessments.

5. Conducting the pre-assessment screening and local risk assessment

5.1 It is likely that patients being pre-assessed will have better recall of the number of transfusion episodes than the number of units of blood components or plasma products received. This is problematic because the number of donor exposures resulting from one episode of plasma exchange may be very high.

5.2 Although papers 5 and 8 recommend quarantining instruments until the status of a patient whose donor exposure is uncertain has been established, this should be a rare event, since pre-surgery assessment typically takes place c. 10 days before the procedure. This should be emphasised in paper 5. However, it was important that requests for information from other hospitals should be dealt with in a timely manner. Adding the date of an elective procedure to paper 6 might assist in this respect.

5.3 Paper 6 should be re-named 'highly transfused risk assessment form' and used to assemble all the information required to complete the local risk assessment. Whether it should be processed in electronic (ideal) or paper format should be a matter for local decision. Section A therefore needed to be expanded to include all relevant details e.g. date and title of procedure, and all relevant information gleaned from the patient concerning their transfusion history, particularly if they received treatment in more than one hospital. Although GPs would have a role in assisting with the assembly of the full transfusion history, it was reported that pre-surgery assessment staff would be unlikely to contact a patient's GP for information.

5.4 Paper 5, paragraph 7 required clarification. It might be helpful to give an example of a case of uncertainty where the haematologist could make a reasoned judgement concerning the likely number of donor exposures. For example, if a patient started leukaemia treatment in 1983, but local electronic records began only in 1985, a haematologist might be able to make a close estimate of the number of donor exposures before 1985 based on their knowledge of the condition and the likely treatment current at that time.

5.5 It was **agreed** that periods of treatment overseas should be recorded on the risk assessment form but these should not be used to contribute to the overall calculation of donor exposures.

5.6 It was only in very recent years [DN: will ask haematologists for details] that the UK Blood Services had standardised the number of pooled donations for batches of plasma product to five donors. Therefore local haematologists should be asked (papers 5 and 6) to use their knowledge of the number of donations used in plasma products produced locally in their calculations. Failing this, they should use a 'rule of thumb' to be agreed by the implementation subgroup in consultation with the blood services.

5.7 In the case of fresh frozen plasma, paper 6 needed to include three different dates when UK-sourced FFP ceased to be used for different age groups of patients. The dates suggested for the donor exposure calculations also needed to be adjusted to take account of the gradual implementation of the policy changes at local level.

5.8 Papers 5 and 6 should both state that patients' entire transfusion histories should be recorded i.e. doctors should not stop when it was evident that the threshold of 80 donor exposures had been reached.

5.9 Although trusts were being discouraged from identifying highly transfused patients with ≥80 donor exposures independently of high risk surgery, it was possible that patients would self-identify or be assessed as highly transfused in other circumstances. It was **agreed** that the documentation should contain explicit instructions for these situations, including the collection of data and notification process.

<u>Risk assessment matrix</u> (paper 5, page 4)

5.10 The HPA had developed a draft risk assessment matrix to assist the DIPC with the local risk assessment where the blood transfusion history is

uncertain. The matrix was an attempt to give a scientific framework for the decision-making process. There was extensive discussion concerning whether or not the risk assessment should remain and, if it did, whether or not it should include the 'uncertain history' middle row and column. The majority of transfusion recipients would typically have had up to three or four transfusion episodes and therefore would not cross the highly transfused threshold. It is impossible to give a guide to the likely number of transfusion episodes people with different haematological conditions are likely to have had and therefore how likely each group would be to have received ≥80 donor exposures.

5.11 When a patient has a condition which could result in exposure to ≥80 donors, but the transfusion history is incomplete, the final decision as to whether or not they should be managed as at increased risk of vCJD rests with the haematologist, the infection control doctor or the two jointly. Provided the reasons for the decision were recorded, the trust should not be vulnerable from a clinical governance point of view.

5.12 This aspect of dealing with uncertainty in the local risk assessment could be included in the letter to chief executives from either the DH or the HPA. It was also suggested that a group of senior haematologists might be identified to provide support and consistency for local colleagues as they acquired experience in assessing uncertain blood transfusion histories.

6. Actions following the risk assessment (paper 5)

6.1 If the local risk assessment concludes that the patient had <80 donor exposures, the pre-surgical screening staff and the DIPC should be informed. Paper 5 needed to be amended accordingly.

6.2 The GP should be asked explicitly (paper 9) to check the primary care records and to work with the local health protection unit in assembling a highly transfused patient's past surgical history.

7. Further information for clinicians (paper 7)

7.1 This information document complemented paper 5 which had been kept as a brief summary of essential actions to be taken and participants were asked whether the two documents should be amalgamated or remain separate. As both were essential reading, it was **agreed** that papers 5 and 7 should be amalgamated.

7.2 The simple explanation of the rationale for the patient notification exercise on page 2 of paper 7 was felt to be helpful, subject to suggested amendments. The DH planned to publish the documents concerning the calculation of risk in relation to the highly transfused on its website, once it had been agreed with NHSBT whether or not some figures needed to be removed.

8. Letter to GPs (paper 9) and GP report form (tabled)

It was pointed out that it would be possible for a patient assessed as highly transfused to have donated blood before 2004, the date when all blood transfusion recipients were deferred from donating blood.

9. Evaluation of pre-surgical assessment (papers 10 to 12)

9.1 The HPA had prepared a proposal for integrated, real-time evaluation of two aspects of the identification and notification of highly transfused patients through pre-surgical assessment:

- The impact on trusts.
- The impact on patients as perceived by their GPs.

9.2 The proposed evaluation of the impact on trusts within the risk assessment process would add to the complexity of the process, but would provide valuable feedback which could be used to refine and inform both stages of the two-pronged strategy. It was **agreed** that the evaluation should be further developed on the lines of the HPA proposal and it was suggested that GPs should received a follow-up telephone call to increase the return rate of their questionnaire. One important finding from the recent qualitative research into the impact of notification on surgical contacts and donors to vCJD cases was that pre-existing psychological morbidity predisposed 'at risk' patients to a negative reaction (in common with other similar studies). It was therefore **agreed** that the GP questionnaire would include a question about their patient's psychological status.

9.3 A suggestion was made that there might be a retrospective audit concerning the number of instruments quarantined and/or destroyed as a result of the highly transfused patient notification exercise.

10. Patient information documents (papers 13 and 14 and tabled paper)

10.1 There were circumstances where it might be necessary or preferable for hospital personnel rather than the GP to notify a highly transfused patient of their status. It was also possible that patients might require information about the reasons for the vCJD questions during the pre-surgical screening process. It was therefore **agreed** that:

- The documentation should be amended to support patient notification by hospital personnel.
- A brief form of words for pre-surgery assessment nurses and a patient leaflet should be prepared in the event of patients requesting information about the reasons for the Annex J questions concerning vCJD/CJD risk.

10.2 It was suggested that there should be an increased emphasis on the uncertainty of the basis for patients' 'at risk' status. As regards the wording concerning the highly transfused, it was important to state where appropriate that patients with ≥80 donor exposures had been identified as a result of presenting for high risk surgery.

11. Health information card for patients at increased risk of vCJD/CJD (tabled paper)

The function of the proposed card was to help patients alert healthcare professionals to their 'at risk' status. The issue remained unresolved as to whether there should be one card for all 'at risk' patients or different cards for

those at increased risk of variant and sporadic CJD respectively. It was suggested that text should be added to the card itself reminding hospital staff that the patient's 'at risk' status should not result in delay to treatments or investigations.

12. Prospective identification and notification of very highly transfused patients

12.1 CMO had requested that the prospective identification of patients with ≥800 donor exposures should be implemented by the end of July 2009. It was estimated that there were up to 100 patients in this cohort. It was considered likely that haematologists would know which of their patients fell into this category and it was therefore suggested that they choose their own methodology for identifying them. The relevant documentation developed for the identification and notification of patients with ≥80 donor exposures could be adapted to support the process for those with ≥800 donor exposures.

12.2 Should the communications concerning the identification and notification of patients with ≥80 donor exposures include information about the forthcoming notification of patients with ≥800 donor exposures? Would this be confusing? It was **agreed** that information about the second stage of the highly transfused patient notification exercise should be included in the first stage. However, care needed to be taken in the wording in order to prevent confusion, particularly as 80 is a multiple of 800. An alternative suggestion was to include instructions for both stages of the patient notification exercise in the communications to be issued in April.

13. Detailed comments on draft documents

Paper 4

- Actions: Include integrated evaluation of the impact on patients.
- Action 3: Add words 'of these' before 'patients'.
- Provide estimates of the number of patients likely to be affected nationally to allow trusts to assess the possible impact on their service.

Paper 5

- Add introduction saying that:
  - the document sets out how to implement the revised Annex J
  - the process adopted at local level will need to take into account local roles and responsibilities.
- Reverse the pre-surgical screening questions in Box 1, so that it begins with a question such as, 'Are you under the care of a haematologist, or have you been in the past?'
- Emphasise that a risk assessment form should be completed if either the patient has one of the three conditions or has/may have had more than 12 blood transfusions.
- Use a consistent list of haematological conditions throughout paper 5, including the addition of sickle cell disease.
- Substitute 'have you had blood transfusions?' for 'being transfused'.
- Substitute a patient-friendly term such as 'plasma exchange' where appropriate.
- Add excluded plasma products for clarity.

- Clarify paragraph 7. In some instances, a patient's risk status will be clear either at the outset. Gaps matter only if it is not.
- Add 'the appropriate senior surgeon' and 'infection control nurses' to paragraph 13.
- Paragraph 21: change 'help to manage any reported incidents' to 'issue Panel advice on past surgical procedures'.
- remove diagram/risk assessment matrix.

Paper 6

- The paper version of the form should have an additional sheet at the back for the recording of multiple transfusion episodes where needed.
- Ensure section A has sufficient boxes to capture all the information obtained from the pre-surgery assessment.
- Add date and name of procedure.
- Add box for date when patient crossed threshold of ≥80 donor exposures.

Paper 7

- Page 2: change 'have a 1% chance of being infected with vCJD' to 'have an increased risk of vCJD greater than 1%'.
- Page 3, box 1: format.
- Page 4, box 2: amend title to 'high risk surgical procedures on the posterior eye'.
- Page 6, third question: clarify the reply.
- Page 7, second question: add 'current' before 'estimates'; omit 'among blood donors'.

Paper 8

Substitute 'fewer' for 'less' in 'less than 80'.

Paper 9

- Standardise terminology to 'vCJD'.
- Add message, 'even if your patient is infected their risk of developing the disease is uncertain'.
- Clarify that the patient was identified when they presented for high risk surgery.
- Substitute 'assessed' for 'screened'.
- Add 'neuro-endoscopy' to 'surgery' where appropriate cf. Annex J.

GP report form (tabled)

- Omit information re. quarantine of instruments.

Paper 13

- Page 3: add 'endoscopy' to box.