NHS
Dumfries
& Galloway

RESTRICTED

# INCIDENT IN DUMFRIES AND GALLOWAY ARISING IN FEBRUARY 2003 FROM A PATIENT WHO RECEIVED BLOOD FROM A vCJD CASE

## REPORT OF INCIDENT REVIEW

22nd April 2003

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# Executive Summary

On 17th May 2000, a unit of blood donated to the Scottish National Blood Transfusion Service (SNBTS) was issued to Dumfries and Galloway Blood Bank. This unit was transfused to a patient with transfusion-dependant anaemia in the Garrick Hospital, Stranraer. Subsequently the donor developed variant Creutzfeldt Jacob Disease (vCJD). The recipient of the blood was not informed of the circumstances until 21st February 2003.

It transpired that 68 patients had undergone sigmoidoscopy at the Garrick Hospital with the same sigmoidoscope used in the investigation of the recipient of blood from vCJD blood donor.

The possibility of vCJD transmission to these patients was raised and a review of the management of the incident was commissioned by the Chief Executive of NHS Dumfries and Galloway.

***The terms of reference of this review are:***

- To ensure that all measures to protect public health are put in place in this incident;
- To review the procedures adopted in the management of the patient who received blood from the vCJD donor;
- To review the implementation of national and local guidance on decontamination of instruments;
  - contact with patients exposed to sigmoidoscope used in recipient of blood from vCJD donor
  - systems in place to protect the public health for future investigations in the blood recipient from vCJD case;
- To explore arrangements in place at SNBTS for ensuring that the public health is protected as far as possible from CJD patients or blood recipients from CJD patients donating blood.

The chronology of the incident was examined in detail and an assessment of the decontamination procedures in place in D&G Acute and Maternity Hospitals NHS Trust was made. The report then addresses six individual issues (national and local) that are raised by the incident:

- Should the recipient of blood from vCJD donor have been informed earlier?

- Could the D&G Acute and Maternity Services NHS Trust have been more pro-active in protecting the public health?
- Did the D&G Acute and Maternity Services NHS Trust follow available decontamination and instrument tracing guidance properly?
- What arrangements are or should be in place with the Scottish National Blood Transfusion Service (SNBTS) to protect public health and minimise CJD transmission?
- Was the guidance from SEHD and the CJD Incidents Panel adequate and timely?
- Is it correct to prepare a Press Release but not issue it in these incidents, when they are not already in the public domain?

The reasoning supporting informing the patient of potential vCJD exposure from blood arises from the fact that infection control precautions need to be taken at many levels:

- The fundamental right of patients to know if significant risks to their health has been incurred by healthcare or operative procedures, e.g. receiving blood or surgical operations
- Written guidance and education will need to be provided for NHS staff;
- If staff implement this guidance then at some stage prior to surgical procedures an assessment can be made as to the individuals risk status with regard to TSE's. This should occur before all surgery but is most pressing for neurosurgical procedures, ophthalmology, ENT and endoscopies. The best vehicle for such screening questions would be an appropriate questionnaire built into consent documentation;
- Further levels of security should be built in, namely, warnings attached to Hospital and GP records;
- If all else fails an informed patient or relative may alert staff to the patients status;
- Patient notification is essential to the success of this strategy: If the patient is unaware of their status then they cannot correctly answer the formal pre operative assessment;
- If the patient is not notified of their " at risk status" then their Hospital and GP records cannot be marked in such a way as to alert health care staff of their status;
- Finally the patient or relative is deprived of the opportunity to themselves alert staff, if all other precautions appear to have failed.

The report concludes that the decision to inform a patient who receives blood from a CJD case is an important factor in protecting the public health in such an incident. While there is a strong argument that appraising a patient thus exposed can provide an important safeguard, the provision of adequate infection control advice and ensuring that this advice is implemented locally is the key to protecting the public.

***The report highlights a number of areas where systems should be improved and makes a number of recommendations that cover:***

- Development of appropriate protocols and management arrangements for handling CJD or CJD contact incidents;
- Informing the recipient of blood from a CJD donor and providing appropriate counselling;
- Streamlining referral of incidents to the expert CJD Incidents Panel
- Updating the Dumfries and Galloway Area Control of Infection Committee TSE/CJD guidance, clarifying reporting arrangements and provision of practical advice amplified in the light of this incident
- Enhancing advice to NHS Boards and Trusts so that they can address more comprehensively practical matters in CJD incident management.
- Completion of a CJD Panel Framework Document so that patients 'at-risk' of CJD cannot donate blood and so ensure that the public health can be protected as far as possible.

The efforts of staff to address these difficult dilemmas in the light of inadequate evidence is commended.

# 1. Background

1. On 17th May 2000, a unit of blood donated to the Scottish National Blood Transfusion Service (SNBTS) was issued to Dumfries and Galloway Blood Bank. This unit was transfused to a patient in Garrick Hospital, Stranraer. Subsequently the donor developed variant Creutzfeldt Jacob Disease (vCJD). The recipient of the blood was not informed of the circumstances until 21st February 2003.

   It then became apparent that 68 patients had undergone sigmoidoscopy at the Garrick Hospital with the same sigmoidoscope used in the investigation of the recipient of blood from a vCJD donor.

2. Creutzfeldt-Jacob Disease is one of the human transmissible spongiform encephalopathies that can occur in sporadic, familial, and acquired (iatrogenic) forms. A new variant CJD (vCJD) was identified in 1996 as a previously unrecognised form of CJD with a novel pathology and consistent disease pattern, which may be related to bovine spongiform encephalopathy (BSE) in cattle[1].

   All forms of CJD are associated with a conformational change in a protein called a 'prion protein'.

3. Sporadic CJD can be transmitted between patients undergoing certain medical treatments. Transmission has followed neurosurgical procedures, corneal graft operations, and treatment with human pituitary gland hormones.

   One of the reasons that CJD may transmit following such procedures is through contamination of surgical instruments, because prion proteins are resistant to normal methods of decontaminating surgical instruments.

4. Current guidelines state that surgical instruments used to operate on a known CJD patient should be destroyed following the procedure to prevent any risk of transmission of the infection. Surgical instruments used to operate on any patient suspected of having CJD should be set aside, 'quarantined', until the diagnosis is established, and destroyed if CJD is subsequently confirmed.

5. There is no epidemiological evidence that any form of CJD has ever been transmitted as a result of treatment with blood components or plasma derivatives. Studies of recipients of blood donated by people who go on to develop sporadic CJD or studies of sporadic CJD prevalence among haemophiliacs, have not demonstrated an increased risk of developing CJD.

[1] CJD Incidents Panel. Management of possible exposure to CJD through medical procedures – a consultation paper. October 2001.

While there is also no evidence that vCJD can be transmitted by blood components or plasma derivatives, because it is a new disease with a long incubation period, it might be to soon for cases transmitted by this route to be detected.

6. The terms of reference of this review are:

To ensure that all measures to protect public health are put in place in this incident;

To review the procedures adopted in the management of the patient who received blood from the vCJD patient;

To review the implementation of national and local guidance on decontamination of instruments;

- contact with patients exposed to sigmoidoscope used in recipient of blood from vCJD case
- systems in place to protect the public health for future investigations in the blood recipient from vCJD case;

To explore arrangements in place at SNBTS for ensuring that the public health is protected as far as possible from CJD patients or blood recipients from CJD patients donating blood.

7. To carry out this review, I have sought evidence from the 12 individuals most closely involved in this incident both locally and nationally as well as scrutinising available documentation including letters, emails, meeting notes, protocols, and policy documents. I am grateful to all for their time and co-operation. My thanks to Mrs Lisa Ritchie, Community Control of Infection Nurse for assistance and advice.

8. The Review is in a format similar to that of a recent CJD incident in Middlesbrough for the purposes of clarity and comparability [2].

[2] Kirkup B. Incident arising in October 2002 from a patient with Creutzfelt-Jacob disease in Middlesbrough – Report of Incident Review, March 2003 (available at www.doh.gov.uk/CMO/cjdmiddlesbrough) and Mayor S. UK Government advises tighter measures to reduce risk of CJD transmission during neurosurgery. BMJ 2003 ; 326: 517

## 2. Chronology of the Incident

8. On 17th May 2000, a unit of blood donated to the Scottish National Blood Transfusion Service (SNBTS) was issued to Dumfries and Galloway Blood Bank. On 23rd May 2000, this unit was transfused to a patient with refractory anaemia, who was transfusion dependent, in the Garrick Hospital, Stranraer. Subsequently the blood donor developed variant Creutzfeldt Jacob Disease (vCJD).

9. On 16th March 2001 the Director of the SNBTS contacted the Consultant Haematologist with responsibility for Blood Banking at DGRI, informing him that a unit of blood from the donor had been issued to the DGRI Blood Bank by SNBTS, and requesting that the recipient be identified. The fate of the unit of blood was identified and a letter was sent by the Consultant Haematologist to the Director of SNBTS on 22nd March 2001. By coincidence, that unit of blood had been transfused into a patient under the clinical care of the Haematology Department. The Director of SNBTS contacted the Deputy CMO at the Scottish Executive Health Department (SEHD) confirming the fate of the unit of blood on 3rd April 2001.

10. The Consultant Haematologist corresponded with his Consultant Haematologist colleague notifying him of this development on 29th May 2001 and requested his opinion on whether the patient should be informed. He also indicated that he would seek the views of the Medical Protection Society (MPS) on the matter. The Consultant Haematologist, on the same day, revealed his discomfort to the MPS about failing to inform the patient, while recognising that nothing could be offered in the way of therapy. Concern was also expressed that the patient may not be aware of the theoretical risk "which he may represent to relatives and carers". Furthermore the information was conveyed confidentially by SNBTS colleagues and there was a question of whether their trust would be over-ridden.

    The MPS Medical Adviser responded on the 8th June 2001 stating: "I must say (that) I have some difficulty with this confidential transmission of information. If such information has been transmitted within the patient records, there must be an assumption that the patient will have access to these records and therefore will discover this information. If the information has not been transmitted in writing then I would question, why not?" The MPS Medical Adviser advised that the Spongiform Encephalopathy Advisory Committee (SEAC), SNBTS, the Trust, and SEHD be approached for advice in the near future. He concluded: "ultimately if there is bound to be a risk to the patient who has received the transfusion and/or a potential transmissible risk to the relatives and carers, then I believe that the patient has a right to, and indeed, he should be informed".

11. The Consultant Haematologist again wrote to the Director of the SNBTS on the 18th June 2001 expressing his discomfort at not

informing the patient and asking if further clarification on the potential of transfusion-transmitted vCJD had been received.

The SNBTS Director, in his reply of 29th June 2001, expressed his unease about continued delays from the Department of Health in London providing interim or definitive advice. He informed the Consultant Haematologist that the risk to patients who have received blood or blood products from donors subsequently developing vCJD would be considered in a relatively high-risk group when and if definitive advice emerged.

12. The Consultant Haematologist wrote to the Medical Director of the Acute and Maternity Services Trust on 5th July 2001 outlining the events, again expressing his unease at not informing the patient, and attaching correspondence from the MPS and the Director of SNBTS. Both parties met on 13th July 2001 and agreed that the patient would not be informed, at least for a period of 6 months, by which time national guidance was expected. A major factor in this agreement was the assurance from the visiting Consultant Neurologist that the central committee membership debating this subject included ethicists and would soon publish clear guidelines on vCJD and blood transfusion.

13. The Consultant Bacteriologist, whose remit from local Area Control of Infection Committee covered TSEs/CJD commented on 18th July 2001: "While I find myself in agreement with the decision to await central guidance, I do have concerns with regard to the possible wider implications of this course of action. By virtue of his exposure this patient is, within the context of guidance on the prevention and transmission of TSEs, in an 'at-risk category'. While I have been assured that he is unlikely to be accepted as a blood or organ donor, areas of concern remain. As an 'at-risk' individual special precautions would normally be applied were he to undergo, for example, ophthalmic surgery or gastro-intestinal endoscopy. Without disclosure to the patient himself, it may prove difficult to ensure that these precautions are taken. I have requested that guidance be sought centrally with regard to the resolution of this issue".

14. An SEHD letter – 'Transfusion of vCJD contaminated blood to local patient' – from a Senior Medical Officer to the Consultant Haematologist on 25th July 2001 stated that a CJD Incident Panel had been established and "this Panel meets on the 2nd August 2001 to provide draft guidelines on handling incidents"

15. A letter was sent by the Deputy CMO at SEHD to the Medical Director of Dumfries and Galloway Acute and Maternity Services NHS Trust on the 15th August 2001 – 'Transfusion of vCJD contaminated blood to local patient' - to request completion of attached reporting form to formally notify the CJD incidents Panel of the incident and submit it to the Chair of the Panel. The Consultant Haematologist responded to the

Medical Director on 16th and 17th August 2001 providing information for response to CJD Incidents Panel.

16. A letter was received from the Chair of CJD incidents Panel on 25th February 2002 in response to email from Medical Director requesting advice on actions to be taken in relation to the patient who received blood from vCJD case. This stated that "the CJD Incidents Panel is proposing that such recipients should be contacted in order that steps can be taken to protect public health".

17. On the 17th December 2002, the three D&G Consultant Haematologists sent a letter to the Chief Medical Officer at SEHD and received a reply on 19th December 2002. The response stated that "risk assessment in this area is therefore very difficult and it seems unlikely that blanket national guidance will be able to resolve the central ethical dilemma to which you refer and namely whether or not to inform patients that they may, as a result of treatment, now run an unquantifiable risk of a disease, with neither diagnostic test or prospect of therapy. You should be assured however that the CJD Incidents Panel have given this matter the most careful consideration and that officials in the four Health Departments are working with all despatch on a response to the draft guidance".

18. On the 21st February 2003, the Consultant Haematologist informed the vCJD potentially contaminated blood recipient of the incident when the prospect of a further endoscopy was organised by a second Consultant Haematologist to establish the source of continued gastro-intestinal bleeding. The endoscopy was then cancelled, causing considerable anxiety to the patient. This anxiety, in the view of the Consultant Haematologist, made informing the patient of the vCJD incident inevitable and compelling in time. At this interview on 21st February, the patient informed the Haematologist that sigmoidoscopy had been undertaken in November. The Staff Nurse at the Garrick Hospital, who witnessed the conversation between Consultant Haematologist and the patient, informed the Theatre Charge Nurse, who in turn informed the Garrick Nurse Manager and Infection Control Nurse at DGRI, who recommended quarantine of the sigmoidoscope until further notice and begin a retrospective lookback of patients.

On the same day the Consultant Haematologist informed the Infection Control Doctor (ICD)/Consultant Bacteriologist at DGRI of events. The Infection Control Doctor at Dumfries and Galloway Royal Infirmary advised that the incident should be documented, that referral for neurological assessment should be sought. He also recommended that endoscopy should be avoided until advice was available about the risks and whether a rigid metal endoscope was available and was safe to use and decontaminate by recommended methods. The ICD further suggested that any surgery necessary (splenectomy is under consideration) should be deferred until a protocol was agreed for

examining any tissue samples and for proper decontamination and record keeping.

19. The Medical Director requested further advice from CJD Incidents Panel on 26th February 2003 describing in detail the recent developments in the case particularly regarding sigmoidoscopy and upper GI endoscopy.

20. Managerial concerns were raised at a specially convened meeting on 26th March 2003 involving NHS Board Chief Executive, Deputy Chief Executive, Dumfries and Galloway Royal Infirmary (DGRI) Operations Manager, DGRI, Director of Public Health, Medical Director DGRI, Consultant Haematologist, Consultant Bacteriologist and CJD lead, and Consultant in Public Health Medicine (Communicable Disease/Environmental Health). The CPHM was asked to conduct a full review and to ensure that all appropriate public health control measures were in place.

21. The CPHM discussed issues with Director of Scottish Centre of Infection and Environmental Health, recently Senior Medical Officer at SEHD and CJD spokesperson/expert for SEHD and with CPHM at CJD Surveillance Unit. Practical advice was given that CJD Incidents Panel would be very unlikely to recommend contacting 68 patients who had sigmoidoscopy, that sigmoidoscope should continue to be quarantined until official advice is given by the Panel, that SEHD should be kept informed of developments, and that we should not pro-actively go public on the matter but to be ready with a Press Release if the media expressed interest.

22. The CPHM assembled an Incident Management Team on 27th February 2003. An update on advice received from SCIEH and CJD Surveillance Unit was presented while Panel response was awaited.

23. The CPHM corresponded with the CJD Incidents Panel asking specific questions to assist local incident management, following detailed incident description from the Medical Director, DGRI.

24. The CJD Incidents Panel responded to the Medical Director's email and issued the following advice:

- Hold the sigmoidoscope in quarantine until revised ACDP/SEAC TSE Joint Working Group guidance is available;

- Follow the ACDP/SEAC TSE Joint Working Group guidance[3] for the precautions to take for 'at-risk' patients for any future medical procedures carried out on the patient who received a transfusion of blood that may have been contaminated with the agent of vCJD;

[3] ACDP/SEAC Guidance on "Transmissible spongiform encephalopathy agents: Safe working and the prevention of infection". 1988. 1998

- Ensure that the records of the 68 patients on whom the sigmoidoscope has subsequently been used are retained but take no further action. These patients should be treated in the normal way if any subsequent procedures are carried out"

- The CJD Incidents Panel responded to the Consultant in Public Health Medicine's more specific questions on 7th March 2003 (Appendix 1).

## 3. Decontamination Procedures at Dumfries and Galloway Acute and Maternity Services NHS Trust

25. Correct decontamination processes aim to minimise the theoretical risk of iatrogenic transmission of Transmissable Spongiform Encephalopathies (TSEs), especially variant Creutzfeldt Jakob Disease (vCJD)[4,5,3]

26. During March 2001, all Scottish NHS Trusts were asked by the Scottish Centre of Infection and Environmental Health (SCIEH) and the Scottish Executive Health Department (SEHD) to self-assess their decontamination practices and procedures. Representatives from SCIEH and SEHD then undertook an independent, baseline review of all Acute Trusts and Central Sterile Services Departments (CSSDs). The Dumfries and Galloway Royal Infirmary (DGRI) and the CSSD on the Crichton site were inspected during September 2001.

27. A working group was then set-up to comprehensively address the decontamination requirements and meet the Interim Technical Requirements (ITRs) by 30th June 2002.

28. The old Endoscope Washer-Disinfectors (E-WDs) in DGRI Theatres, the Outpatient Department and Day Surgery Unit in DGRI and at the Garrick Theatre, did not comply with Scottish Health Technology Memorandum (SHTM) 2030 requirements, in particular, with respect of rinse water quality and availability of print-outs to demonstrate effectiveness. Three new Labcaire E-WDs were purchased in March 2001 for NHS Dumfries and Galloway. A joint approach ensured that NHS Dumfries and Galloway had a unified purchase policy for both Trusts which ensured value for money and a critical mass of trained "users".

29. At the start of each working day the Labcaire Endoscopy Washer Disinfector machine is set-up to self disinfect. All the scopes are then processed through the machine before they are put into use for that day.

30. Each of the flexible endoscopes are uniquely identified with a scanable tag, as are each of the nurses working in that area. The scopes and the nurses identification are scanned into the machine before a decontamination cycle can begin. The biopsy forceps unique to each scope are sent to CSSD for reprocessing.

31. The cycle print-outs are retained; one is attached to the patients notes and the other is attached to that days clinic sheet. Each of the E-WDs

[3] ACDP/SEAC Guidance on "Transmissible spongiform encephalopathy agents: Safe working and the prevention of infection". 1988.
[4] The Glennie Report, NHS Scotland, Sterile Services Provision Review Group, September 2001
[5] Clinical Standards Board for Scotland, Standards: Healthcare Associated Infection and Infection Control, December 2001

has a smart-card which holds all cycle information and can be downloaded onto a computer.

32. All staff operating the E-WDs have been trained by the manufacturer and can competently discharge their responsibilities (training was completed at the Garrick Theatre on the 2nd and 3rd of April and on the 28th of August 2001. Labcaire have given their commitment to undertake yearly training with all "users". This has been included in next years contract with Lacaire.

33. The engineers from the Estates Department have also received training from Labcaire.

34. Final rinse water testing is now established between each of the designated E-WD "users" and the Bacteriology Laboratory at DGRI, and a process of reporting and trouble-shooting agreed.

35. The only out-standing issue is the scope connectors, which require to be provided by Labcaire.

36. In summary, decontamination procedures, instrument labelling, and patient tracking systems at the Garrick Hospital were fully compliant with the 'Glennie Framework' recommendations and cannot be faulted.

## 3. Issues Raised

### Should the recipient of blood from vCJD patient have been informed earlier?

37. The decision not to inform the recipient of blood from the vCJD patient was understandable in view of the fact that the patient had nothing to gain personally from receiving such information but, on the contrary, such disclosure would inevitably cause considerable anxiety. This anxiety would have to be carefully managed by healthcare staff. The fact that there is no diagnostic test to determine whether patient is at any risk of acquiring vCJD from receipt of potentially contaminated blood and that no treatment is available in the unlikely event that vCJD was transmitted, are further reasons to consider carefully whether disclosure is in the best interests of the patient.

38. In 2001 and 2002, there was considerable debate locally about the matter of disclosure to the patient. National policy was only being formulated at that time and a change in practice leaning towards disclosure and openness throughout the NHS was promoted. The agreement on 13th July 2001 to wait 6 months for further national guidance was taken in good faith and could be defended as being in the best interests of the patient.

39. Advice was sought from the CJD Incidents Panel regarding informing the recipient of potentially vCJD contaminated blood and, on 22nd February 2002, Dr Philippi Edwards of the Panel secretariat replied as follows: *"Thank you for your e-mail following up your request for advice on the actions to take in relation to a patient who received a transfusion of blood from a donor who subsequently developed variant CJD. I can confirm that the CJD Incidents Panel is proposing that such recipients should be contacted in order that steps can be taken to protect public health. The Panel is concerned that such individuals are provided with appropriate information and counselling and has written to the Chief Medical Officers of the UK asking that systems should be established to ensure that this can be provided. The Scottish Executive is considering its response to this request from the Panel. The Panel advises against informing patients until the appropriate support is available.*

*The Panel has set out its proposals in a framework document that has been widely distributed for consultation and the responses to the consultation are currently being considered. If you have not already received a copy of this document, you can find it on the Panel's website at www.doh.gov.uk/cjd/consultation or contact me and I will be happy to send you a hard copy. I apologise for the long delays in reaching a final conclusion but, as I am sure you appreciate, these are difficult*

*decisions and require care in considering all the implications for implementation. I am copying this email to the Scottish Executive so that they are aware of your request."*

40. The reasoning supporting informing the patient of potential vCJD exposure from blood arises from the fact that precautions need to be taken take place at many levels:
    - The fundamental right of patients to know, if significant risks to their health have been incurred by healthcare or operative procedures, e.g. receiving blood or surgical operations;
    - written guidance and education will need to be provided for NHS staff;
    - If staff implement this guidance then at some stage prior to surgical procedures an assessment can be made as to the individuals risk status with regard to TSE's. This should occur before all surgery but is most pressing for neurosurgical procedures, ophthalmology, ENT and endoscopies. The best vehicle for such screening questions would be an appropriate questionnaire built into consent documentation;
    - Further levels of security should be built in, namely, warnings attached to Hospital and GP records;
    - If all else fails, an informed patient or relative may alert staff to the patients status
    - Patient notification is essential to the success of this strategy: If the patient is unaware of their status then they cannot correctly answer the formal pre operative assessment.
    - If the patient is not notified of their "at-risk status" then their Hospital and GP records cannot be marked in such a way as to alert health care staff of their status.
    - Finally the patient or relative is deprived of the opportunity to themselves alert staff, if all other precautions appear to have failed.

41. In the future, the case in favour of patient notification is clearly to provide such information and appropriate follow-up counselling.

## Should the D&G Acute and Maternity Services NHS Trust have been more pro-active in protecting the public health?

42. In accordance with the CJD Incidents Panel Consultation guidance,[1] "Management of possible exposure to CJD through medical procedures", the CPHM (CD/EH), the Scottish equivalent of the Consultant in Communicable Disease Control (CCDC) should have been informed of the incident to ensure that the required procedures to protect public health were put in place.

1. CJD Incidents Panel. Management of possible exposure to CHD through medical procedures – a consultation paper. October 2001.

43. Meanwhile, no systematic plans were made at Trust level (apart from Consultant Haematologist having a discussion with Consultant Ophthalmologist, who was carrying out non-invasive procedures on the patient) to ensure that such procedures would be carried out in accordance with current guidance.

44. In the event, a sigmoidoscopy was performed without the knowledge of the Consultant Haematologist. The Staff Grade Surgeon involved had no knowledge of the circumstances of the patient or of any precautions necessary with decontamination of the sigmoidoscope.

45. A further endoscopy was deferred on 21st February 2003, although clinically this would appear to have been clinically indicated and appropriate. This highlights again the lack of robust protocols for further management of incidents involving this patient.

46. The central theme throughout the management of this incident was the ethical debate about informing the patient, and protecting the public health was mistakenly assumed covered by the routine clinical care of the patient being within the remit of clinical haematology. It is, however, correct to say that the Consultant Haematologists, in their letter to the Chief Medical Officer in December 2002 were concerned about contingency plans should invasive procedures, such as endoscopy or ophthalmologic procedures, be clinically necessary in the patient. The Consultant Bacteriologist also referred to this scenario. All deferred to central advice.

47. The D&G Infection Control Team now need to produce local infection control protocols in the event of further invasive procedures or operations, e.g. splenectomy, in the patient who received blood from the vCJD case. Clinical and Theatre staff need to be appraised of these protocols.

## Did the D&G Acute and Maternity Services NHS Trust follow available decontamination and instrument tracing guidance properly?

48. Following a major SEHD initiative in 2001, decontamination standards at the Garrick Hospital have been extensively reviewed. A new Labcaire Endoscope Washer Disinfector was purchased for the Garrick Hospital in March 2001, which is fully compliant with "Glennie Framework"[4] recommendations. Similar developments were in place in DGRI, where three further Labcaire Endoscope Washer Disinfectors were purchased also in 2001.

49. Staff training in decontamination at the Garrick and in DGRI have been satisfactorily completed also in 2001. Endoscope tracing systems along patient tracking systems following endoscopy are also in place.

50. Furthermore following withdrawal of sigmoidoscope into quarantine a new scope was ordered without delay and a new scope is now in use.

51. In summary, the D&G Acute and Maternity Services NHS Trust were fully compliant with the Scottish medical equipment decontamination standards as set out in the "Glennie Framework[4]"

## What arrangements are or should be in place with the Scottish National Blood Transfusion Service (SNBTS) to protect public health and minimise CJD transmission?

52. The CJD Incidents Panel advised on 7th March 2003 (Appendix 1 Q5) that "no formal arrangements are in place (to ensure that an 'at-risk' patient does not donate blood), pending a completion of the blood risk assessment and agreement in Scotland by CMO Scotland to the general principles set out in the CJD Incidents Panel framework document, submitted to the CMO in October 2002.[1] In the meantime, the Panel is providing advice on individual incidents on a precautionary basis.

53. This statement contradicts the statement in the Panels Annual Report 2001-2 (Appendix 2, p15).

## Was the guidance from SEHD and the CJD Incidents Panel adequate and timely?

54. The SEHD did not offer proactive, practical advice despite being aware of the vCJD –Transfusion incident since 22nd March 2001. Even as late as 19th December 2002, the SEHD might have been more forthcoming in advising on infection control procedures, should invasive investigations be required. SEHD deferred to the CJD Incidents Panel for expert advice.

55. The referral process to the CJD Incident Panel was cumbersome and the Panel reporting form was completed by D&G Acute and Maternity Services NHS Trust on 17th August 2001. The response from the CJD Incidents Panel was slow and no formal advice was received until 25th February 2002. Even then this advice went no further than recommending informing the patient of the circumstances of receiving blood from a vCJD donor.

[4] The Glennie Report, NHS Scotland, Sterile Services Provision Review Group, September 2001
[1] CJD Incidents Panel. Management of possible exposure to CJD through medical procedures – a consultation paper. October 2001.

56. The CJD Incidents Panel Annual report of January 2003 [6] states that incidents of 9 potentially contaminated blood donations with 29 recipients of blood have been reported to them. It also states that "none of these patients have been informed but precautions have been taken to protect the blood supply".

57. However, the CJD Incidents Panel responded authoritatively and comprehensively to the Medical Director's detailed email of 26th February 2003 and CPHM (CD/EH) letter of 3rd March. A detailed Panel response to all the questions was sent on the 7th March 2003 (Appendix 1).

## Is it correct to prepare a Press Release but not issue it in these incidents, when they are not already in the public domain?

58. When the vCJD–Transfusion incident generated serious local professional and managerial concern on 26th February, a Press Statement was prepared by the CPHM (CD/EH) and the NHS Dumfries and Galloway's Head of Communications. There was a contingency plan that the Director of Public Health and the Head of Communications would manage all media queries should the story come to the attention of the media. There are, as yet, no plans to issue a pro-active Press Release regarding the incident.

59. The advice contained in the CJD Incidents Panel Draft Guidance to the Chief Medical Officer states that "the public should be informed of all incidents but that it is necessary to have a communications strategy to ensure that the appropriate messages are given. The Panel considers that local teams will need support from a cadre of experts to carry this out effectively. No formal arrangements for providing such help are in place. You may prefer to wait until agreement to the Panel's proposals have been given by CMO Scotland and the appropriate support has been provided. In the meantime, the Public Health Laboratory Service (PHLS) has been developing some material at the request of the Department of Health and you may wish to contact them for a copy of the draft literature. The Panel is willing to give advice on the accuracy of any material you plan to use locally". This draft guidance has yet to be ratified.

## 5. Conclusions

60. Hindsight bestows a wisdom that is difficult to achieve when taking day-to-day decisions in a hard-pressed service. It is also recognised that:

- issues around CJD incidents are complex;
- scientific evidence on many aspects of CJD transmission is sparse;
- current guidance is largely based on the 'precautionary principle';
- knowledge of CJD is rapidly accumulating;
- advice was changing over the past three or four years, particularly in relation to the rights of the public to information, however unpalatable and the development of a culture of openness in the NHS.

It is in this context that this report draws its conclusions. The efforts of staff to address these difficult dilemmas in the light of inadequate evidence is commended.

61. The report concludes that the decision to inform a patient who receives blood from a CJD case is an important factor in protecting the public health in such an incident. While there is a strong argument that appraising a patient thus exposed provides an important safeguard, the provision of adequate infection control advice and ensuring that this advice is implemented locally is the key to protecting the public.

62. The patient's right to know, where significant risk to their health has occurred through surgical operations or healthcare procedures, including receiving vCJD-potentially contaminated blood, needs to be enshrined as NHS policy unless there are compelling reasons to the detriment of the patient's health for not doing so.

63. Informing the patient would have made it easier to protect the public health by labelling and documenting the incident prominently in the case notes so that other clinicians caring for the patient would be alerted. It would also have provided a fail-safe by advising the patient not to donate blood and to advice his medical practitioner or healthcare worker if invasive procedures were contemplated. Nevertheless, the onus should not be placed on the patient but on the NHS to ensure that the public health was protected.

64. While local CJD guidance had been updated in August 2002, NHS Dumfries & Galloway did not have in place systematic plans for ensuring that any invasive procedures in the patient who received blood from a vCJD donor would be carried out in accordance with current guidance.

65. The understandable but unnecessary protection of confidentiality enabled a situation to develop whereby the appropriate procedures were not in place following the sigmoidoscopy in October 2002.

66. In addition the CPHM (CD/EH) (or in his absence the DPH) should have been informed of this incident at an early stage in accordance with CJD Incidents Panel Consultation Draft Guidance so that they could ensure that the public health was protected and that all appropriate procedures were in place.

67. The referral process to the CJD Incident Panel should be streamlined to enable a quick response (within 7 working days). When specific questions were asked of the Panel, they were in a much better position to respond and did so comprehensively.

68. Decontamination procedures, instrument labelling, and patient tracking systems at the Garrick Hospital were fully compliant with the 'Glennie Framework' recommendations and cannot be faulted.

69. The absence of systematic procedures at the SNBTS to prevent blood donations from recipients of blood from CJD cases is worrying and it is essential that the CJD Incidents Panel Guidance is completed and accepted by the CMOs of the UK at the earliest opportunity.

70. Referral to the 1998 guidance "Transmissible Spongiform Encephalopathy Agents: Safe Working Practices and the Prevention of Infection" [3] for at-risk patients rather than more recent CJD Incidents Panel Guidance of October 2001 is confusing for healthcare professionals. Consultation paper.

# 6. Recommendations

## NHS Dumfries and Galloway

***Recommendation 1***. NHS Dumfries & Galloway should put in place appropriate protocols and management arrangements for handling CJD or CJD contact incidents. This should include implementation of current advice in relation to quarantining instruments and on operative procedures.

***Recommendation 2***. In future, the recipient of blood from a CJD case should be informed and provided with appropriate support and counselling.

***Recommendation 3.*** The CPHM (CD/EH) (or DPH in his absence) should be informed of CJD incidents at the outset to ensure that the public health is protected in accordance with CJD Incident Panel Guidance.

[3] ACDP/SEAC Guidance on "Transmissible spongiform encephalopathy agents: Safe working and the prevention of infection". 1988.

***Recommendation 4***. Referral of incidents to the CJD Incidents Panel should request answers to specific practical questions in relation to CJD incident management.

***Recommendation 5***.The D&G Area Control of Infection Committee TSE/CJD guidance[6] should be updated, to take account of lessons learned from this incident and the Middlesbrough exposure, reporting arrangements clarified and practical advice amplified in the light of this incident.

## SEHD

***Recommendation 6***. The SEHD should consider how best NHS Health Boards and Trusts can be more comprehensively advised about practical matters in CJD clinical management and incident management.

***Recommendation 7***. The SEHD should now assist the CJD Incidents Panel in finalising and endorsing the advice in the CJD Incidents Panel Framework Document so that patients 'at-risk' of CJD cannot donate blood and so ensure that the public health can be protected.

## CJD Incidents Panel

***Recommendation 8***. The CJD Incidents Panel should streamline the procedures for the referral of incidents and endeavour to provide a more proactive response within a reasonable timescale (7 working days).

***Recommendation 9***. The CJD Incidents Panel should amplify previous advice to include practical guidance for 'at-risk' patients who do not have CJD and update in a single document, if possible, all current guidance needed by Health Boards in Scotland and Northern Ireland (and Health Authorities in England and Wales).

# 7. Postscript

***All recommended Infection Control measures are now in place:***

The sigmoidoscope is quarantined until ACDP/SEAC advice is updated and a replacement has been procured;

The recipient of blood from vCJD donor is not eligible to donate blood because of refractory anaemia and has been advised accordingly;

A record of the 68 patients on whom the sigmoidoscope was used following the procedure on the blood recipient from vCJD donor have been documented

[6] NHS Dumfries and Galloway Area Control of Infection Committee. Guidelines on the infection control of Transmissible Spongiform Encephalopathies. August 2002.

and are confidentially held by the Medical Director of the D&G Acute and Maternity Services NHS Trust as recommended by the CJD Incidents Panel.

Protocols are now in process of development by the D&G Infection Control Team, taking into account expertise and systems in place in centres of excellence, to manage future invasive procedures or operative interventions in the potentially contaminated vCJD transfused patients.

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