Minutes of the Meeting of the CJD Incidents Panel
17th April 2002, 9.00am – 12.15pm, English Room, Central Hall Westminster

Attendees

Chairman

Professor Michael Banner	Ethicist

Members

Professor Don Jeffries	Vice Chair, Virologist
Professor James Ironside	TSE Infectivity Expert, Neuropathologist
Dr David Taylor	TSE Infectivity Expert, Decontamination Expert
Dr Tim Wyatt	Microbiologist
Dr Geoff Ridgway	Microbiologist
Dr Roland Salmon	Epidemiologist
Dr Noel Gill	Epidemiologist
Ms Susan MacQueen	Infection Control
Professor Dame Lesley Southgate	General Practice
Ms Diana Kloss	Law
Ms Jean Gaffin	Lay Representative
Ms Gillian Turner	Lay Representative
Professor Len Doyal	Ethicist
Professor John O'Neill	Ethicist
Mr John Barker	Sterile Service Management
Professor Mike Bramble	Gastroenterologist
Professor John Lumley	General Surgeon
Dr Pat Hewitt	Blood Safety
Dr Geoff Craig	Dental Surgeon

Observers

Dr Glenda Mock	Department of Health, Social Services & Public Safety, Northern Ireland
Dr Mike Simmons	National Assembly of Wales

Secretariat

Dr Pip Edwards	CJD Policy Unit, DH
Miss Claire Mills	CJD Policy Unit, DH
Dr Nicky Connor	Communicable Disease Surveillance Centre

DH Officials

Dr Rowena Jecock	CJD Policy Unit, DH
Ms Mary Holt	CJD Policy Unit, DH

Specialist Advisors

Professor Roger Buckley	Ophthalmic Surgeon
Mr Roger Evans	Chair of Decontamination Steering Group, DH
Dr Peter Bennett	Economics & Operational Research Division, DH
Elizabeth Treasure	Professor of Dental Public Health, Cardiff, DH
Mr Terry Donohoe	Medical Devices Agency

Chairman's Initials GRO-C

Date 12/07/02

Apologies

Mr Luke Gormally	Ethicist
Professor Ian Cooke	Obstetrics and Gynaecology
Professor Peter Hutton	Anaesthetist
Professor Graham Smith	Anaesthetist
Mr Andrew Tullo	Ophthalmologist
Dr Hester Ward	Epidemiologist
Ms Kate Woodhead	Theatre Nurse
Mr Henry Marsh	Neurosurgeon
Dr Mike Painter	Microbiologist
Dr Martin Donaghy	Scottish Executive Health Department
Mr Michael Warren	Shamrock Marketing
Dr Mary O'Mahony	Head of Communicable Disease Unit, DH
Mr Charles Lister	Blood Policy Unit, DH
Ms Carole Fry	Nursing Policy Unit, DH

Welcome, Apologies and Introductions (CJDIP 5/ 01, CJDIP 5/ 02)

1. The Chair thanked the members for attending and announced the apologies as above. Professor Jeffries would chair the first half of the meeting in Professor Banner's absence.

2. It was agreed to change the entries to the membership list of the Panel to reflect members' expertise, rather than affiliations, to make it clear that members are appointed as experts, not stakeholders. Members' affiliations would be recorded in the Declarations of Interest. A revised membership list is attached at Annexe 1. Members are requested to contact the secretariat if they would like any revisions to their entry.

Action: Members to contact the Secretariat regarding the amended membership list

3. Members were reminded that the papers for the meeting should be treated in confidence.

Chairman's Initials GRO-C Date 12/07/02

Ratification of minutes of last meeting (CJDIP 5/ 03)

4. No comments were made and the minutes were agreed.

Matters arising i) Public Summary of October Meeting (CJDIP 5/ 04)

5. The final public summary of the October meeting of the Panel was provided for information.

Matters arising ii) Endoscopes

6. A sub group of the Advisory Committee on Dangerous Pathogens/ Spongiform Encephalopathy Advisory Committee Joint Working Group (ACDP/ SEAC JWG), chaired by Dr Ridgway, had met to discuss the CJD risks associated with endoscopy. The minutes of the meeting were being circulated and would be provided to Panel members once available.

Matters arising iii) Secretariat database of incidents

7. The secretariat database of incidents had been established to allow the tracking of action taken on incidents and to assist in drafting the Panel's Annual Reports. It was stressed that this was a tool for the secretariat, not the proposed database of possibly exposed individuals.

Endorsement of advice provided since October 2001 (CJDIP 5/ 10)

8. Members were content with the advice that had been issued from the Panel since October 2001.

Chairman's Initia GRO-C

Date 12/07/02

9. Members agreed that, in the event that the Panel significantly revises its advice, the secretariat should write and alert previous cases that the advice has been amended.

Management of incidents involving tissue and organ donations

10. The relevant experts to contribute to developing advice regarding organ and tissue donation had been identified, but not yet contacted. This work would be taken forward once the consultation process was completed.

Blood risk assessment (CJDIP 5/ 15, CJDIP 5/ 15a)

11. Det Norske Veritas (DNV) had conducted a blood risk assessment in 1998, but this had required updating and made more relevant to the Panel's work. DNV had also been asked to make their report more transparent. DNV had therefore been approached to revise the document. A first draft had been provided to the Committee on the Microbiological Safety of Blood and Tissue for Transplantation (MSBT) for comment, who provided substantive comments, particularly on the effects of production of plasma derivatives on infectivity. A further revised report had been sent to experts for comment and would then be provided again to MSBT, as well as SEAC and the Medicines Commission. The document would then be put to the Panel.

12. The group turned to discuss recipients of implicated blood products. The Panel had written to Dr Pat Troop expressing concerns that adequate support systems should be in place before informing such individuals. Paper CJDIP 5/ 15a, a reply

Chairman's Initia GRO-C Date 12/07/02

from Dr Troop, had been tabled, agreeing this need and stating that the Department of Health (DH) was actively considering how this could be provided, as well as looking at the scope of hospitals to trace products.

13. The National Blood Service (NBS) had concerns that previous DH advice had been not to inform recipients, whereas Panel advice was that some of these patients would fall into the 'contactable' group. Copies of correspondence between the NBS and the Deputy Chief Medical Officer outlining these concerns was provided for members' information. The NBS needed clarification on what action it should take.

14. It was explained that some haemophilia patients had already been informed that they had received implicated blood products. Within this group the trusting relationship between the patients and their doctors, as well as the availability of support systems, reduces the potential for serious adverse psychological effects on the patients. This example re-inforced the need for adequate, long-term support for all patients, as well as training and support for the clinicians involved in their care. Primary Healthcare Groups across the country should be involved and would each need to identify an individual who would lead in this area.

15. Members suggested that work on the psychological effects of informing patients that they had been placed at a risk of developing CJD be done. It was also suggested that expertise in the consequences of providing worrying information

Chairman's Initials GRO-C Date 12/07/02

should be included in the Panel membership. Also, the National Blood Transfusion Committee, under Professor Gordon Smith, should be contacted for advice.

Action: Secretariat to discuss with the Chair the need for additional expertise on Panel membership.

Secretariat to approach Professor Gordon Smith for advice.

Discussion of incidents i) Dentistry (CJDIP 5/ 09)

16. Dr Peter Bennett of the Economic and Operational Research Unit, DH, provided an update on the progress made with the dental risk assessment. He explained that this was an extension of the previously published surgical instrument risk assessment, stressing that the dental risk assessment was still in progress and subject to approval from an expert group. When drafting the risk assessment, EOR had approached the British Dental Association for advice, as well as other CJD infectivity experts. The assessment concentrated on vCJD, as the sporadic form of the disease would pose a lesser risk than vCJD.

17. The risk assessment examined two main areas: i) that dentistry needed to be covered by generic precautions on decontamination etc, as there were lots of procedures performed and these might encounter infectivity and ii) if any individuals were placed at a significant risk and therefore should be contacted. The risk assessment had produced a number of scenarios based on varying effectiveness of decontamination, focussing on the more negative assumptions.

Chairman's Initials GRO-C Date 12/07/02

18. Present evidence suggested that it looked unlikely that there were significant individual risks involved – that the bulk of dental operations looked likely to fall into the Panel's 'low risk' category of general invasive procedures, rather than the 'medium risk', such as procedures coming into contact with LRS tissue.

19. The assessment had not produced a range of risks from different dental procedures (e.g. root filling risks compared to de-scaling risk), as the expert group's opinion was that the highest risk came from tonsillar abrasion. It was noted that tonsillar abrasion was a rare event and would not normally be recorded in the dental notes

20. Members noted that there was a low level of instrument/ tray tracking for dental procedures and suggested that single-use instruments, in particular reamers, should be considered. It was explained that the BDA jointly with DH were currently revising the guidelines on decontamination of dental instruments and it was hoped that the guidelines would be issued in the autumn. DH had considered the possibility of introducing single-use reamers, but had concluded that the low level of potential infectivity did not warrant this action. It was requested that the revised guidelines should be issued to the Institute of Sterile Service Management and Microbiological Advisory Committee for comment prior to publishing. The Panel indicated that a single patient use of instruments that are difficult to clean should be considered.

Action: DH to forward revised guidelines for comment.

21. The main conclusions of the risk assessment were that infectivity may be present

Chairman's Initials GRO-C Date 12/07/02

in dental tissues but at relatively low levels and that the main risk arose from inadvertant tonsillar abrasion when performing dental procedures. The BDA suggested that tonsillar abrasion would not occur frequently and would not be recorded by dentists. However, the risk assessment demonstrated that, even if this did occur, the risk of infectivity would still be several orders or magnitude lower than procedures involving LRS, such as tonsillectomy.

22. Members were concerned that the conclusions of the expert group were heavily dependent on results obtained from only 2 vCJD patients. It was noted that there was a difficulty in obtaining vCJD dental tissues and that therefore further animal studies were required. It was agreed that DH would explore this possibility. It was also suggested that the Chair of the Panel write formally to the National CJD Surveillance Unit, voicing concerns that further dental tissue samples should be made available. Forensic dentists would be able to assist in providing control tissue samples, but the main difficulty was in obtaining post-mortem samples from vCJD patients.

Action: **DH to consider further animal studies on dental tissue infectivity.**

Chair of the Panel to write to the NCJDSU to emphasise the importance of dental tissues.

23. It was suggested that, although it was available on the DH website and had been made publicly available, the peer reviewed surgical instruments risk assessment should be published in a scientific journal. This would add credence to the document and make it more widely available to the scientific community.

Chairman's Initials GRO-C Date 12/07/02

Action: **Secretariat to pursue with EOR**

24. Members were concerned to learn that The CJD Support Network had been contacted by some family members of vCJD patients, who had been refused dental treatment, due to advice from the BDA and the ACDP/ SEAC JWG that family members should be considered 'at risk' of developing the disease. Members suggested that the refusal of treatment for family members was unacceptable . It was explained that the ACDP/ SEAC JWG advice was being revised. It was requested that a copy of the correspondence be provided to the Chair of SEAC.

Action: Ms Turner to forward correspondence regarding dental treatment to the Chair of SEAC

25. The secretariat queried if the dental history of all index patients should be collated, reminding members that the only method of obtaining this information was to directly approach family members. There was also the concern that, once the dentist has been made aware that the patient suffered from CJD, they may decline to treat the patient's family. The secretariat also drew member's attention to paper CJDIP 5/ 09, which demonstrated that the quality of information regarding dental procedures was often inaccurate and difficult to obtain. Members agreed that, despite these difficulties, the dental history of index patients should be obtained where possible, even though these cohorts would not be in the 'contactable' group. The official responsible for DH dental policy indicated that they may be able to assist in tracking records.

Chairman's Initials ... GRO-C ... Date 12/07/02

26. The secretariat expressed concern that collecting information on index patients without the prospect of recommending action fell outside the remit of the Panel.

Action: Secretariat to investigate the potential for obtaining dental history of index patients.

Discussion of incidents ii) Possible CJD (CJDIP 5/ 09, CJDIP 5/ 09a)

27. Members were asked what action should be taken with incidents where the diagnosis of CJD is uncertain and where further information was not obtainable (e.g. due to no post mortem). Such incidents would normally have been referred to the NCJDSU, but did not match the international criteria for a 'possible/ probable' case. It was explained that, if a case did not match the criteria for CJD, then it should not be classed as a possible CJD case. However, if no post-mortem was performed, it was not possible to formally exclude the possibility of CJD.

28. A previous Panel paper outlining the initial and final diagnoses of patients referred to the NCJDSU was provided for information.

29. Members agreed that decisions on incidents with an uncertain diagnosis of the index patient should be conducted on a case-by-case basis, erring on the side of caution. The algorithm in the draft framework document would require revision to reflect this change.

Publication of Decontamination Review (CJDIP 5/ 05, CJDIP 5/ 06, CJDIP 5/ 07)

30. The Panel was asked whether any information in the reports changed the decisions

Chairman's Initials GRO-C Date 12/07/02

as set out in the draft framework document.

31. The English Decontamination Review had assessed NHS performance with a 'traffic light' system, looking at: i) environment; ii) equipment; iii) training and iv) services. These criteria were based on the Medical Devices Agency (MDA) standards for sterile service departments but included additional criteria. Sites classified as 'red' may have met MDA requirements but failed on the other criteria. The MDA was currently revising its standards to be unified with the new criteria.

32. Members were concerned that some sites appeared to have rapidly changed from a 'red' to 'amber', which suggested that the work was a 'quick fix'. The group was assured that a significant amount of time, manpower and resources had been dedicated to rapidly improving any sites identified to be in urgent need of improvement. This work would be ongoing, and each NHS Trust now had an appointed person responsible for ensuring that standards continue to be met. £200 million had been dedicated to the improvement of decontamination and state-of-the-art Central Sterile Service Departments would be installed over the next three years in each region to maintain standards. £75 million had already been spent. There was also commitment across the NHS to ensure that improvements are made and maintained. It was noted that the decontamination improvement exercise included primary care practitioners and dentists.

33. Members were asked if any revisions were required to the draft proposals

Chairman's Initials GRO-C Date 12/07/02

following the publication of the review. It was agreed that this was not necessary, as the proposals had been based on the Scottish review contained similar results to the English review. Members gave credit to the Chair of the Panel for campaigning to have the document published.

Hospital record keeping (CJDIP 5/ 08)

34. Due to time limitations, this agenda item was not discussed. Members were requested to provide any comments on this issue to the secretariat. The item would be discussed at the next meeting if necessary.

Action: Members to provide comment to the secretariat.

Chairman's Signature ... GRO-C

Date ... 12/07/02

Consultation exercise i) Final report of the consultation process (CJDIP 5/ 11, CJDIP 5/ 11a, CJDIP 5/ 11b, CJDIP 5/ 12, CJDIP 5/ 13, CJDIP 5/ 14, CJDIP 5/ 21)

35. Responses from some key organisations had been accidentally omitted from Annexe 2 of the main report. These responses were provided a tabled paper CJDIP 5/ 11b. Some members had also requested that the analysis of responses provided be broken down by organisation. This work had been done and was provided as tabled Annexe 3 (CJDIP 5/ 11a). Both of these revised papers were also being provided to the delegates attending the open meeting.

Consultation exercise ii) Letters to the BMA, GMC and Information Commissioner (CJDIP 5/ 14d, CJDIP 5/ 14e)

36. Letters from the Panel to the British Medical Association, Information Commissioner and General Medical Council had been issued, and responses from the BMA and GMC were tabled (paper (CJDIP 5/ 14d and CJDIP 5/ 14e). Both groups, particularly the BMA, still had some reservations regarding the Panel's proposals and it was agreed that a meeting should be arranged to discuss the panel's proposals and their concerns.

Action: Secretariat to arrange a meeting with representatives of the Panel and the BMA.

37. The BMA correspondence suggested that the PHLS application to establish the database of possibly exposed cohorts of patients had not been explicit and had

Chairman's Initials GRO-C Date 5.7.02

been 'buried' in a much larger proposal. Prior to receiving the letter, the Secretariat had contacted the Patient Information Advisory Group to determine if any further application explicitly regarding the Panel's proposals was necessary and had been advised that this was not needed. It was also noted that, as the proposals had not been agreed, the PHLS application was only a proposal for work that may need to be done, not a formal request for approval. Members also agreed that the database would need approval from an appropriate ethics committee prior to being established.

38. A response was still awaited from the Information Commissioner and the Panel agreed that this should be chased.

Action: Secretariat to request response from the Information Commissioner.

39. It was queried if any contact had been made with insurers to determine if the placing of a person on the database would affect their ability to obtain life insurance etc. It was explained that representatives from the Association of British Insurers had provided a response and were attending the open meeting. It was agreed that this problem needed further consideration.

Action: Secretariat to contact ABI.

Consultation exercise iii) Amendments required to the framework document

40. There were still legal issues relating to the database that remained uncertain. The Social Care Act contained a clause that may provide a legal basis for implied consent for the database. However, the position regarding the new regulations was

Chairman's Initials GRO-C Date 5.7.02

uncertain. Panel members were of the opinion that the Panel's proposal for a well advertised database of information from which individuals could remove their names or be given the data held was the only morally and ethically acceptable approach. If it was not legally possible to establish the database on this basis then the Panel would need to re-think its overall proposals.

41. Some members were disappointed with the low level of response from the written consultation exercise, but others had been encouraged by the response. It was suggested that the organisations that had provided a detailed response should be carefully considered and any themes that emerged should be addressed.

42. The group agreed that there was a need for a consistent national communications strategy to highlight the existence of the database. It was noted that the establishment of local publicity campaigns received the lowest level of agreement in the written consultation process. This proposal may therefore need further consideration.

43. Several responses showed concern that those in the contactable group were not able to remove their names from the database. Members agreed that the removal of their names would not invalidate the database, particularly as these patients will have been directly contacted to inform them of their risk. It was therefore suggested that this proposal could be removed.

Chairman's Initials GRO-C

Date 5.7.02

Action: Remove proposal that those in the 'contactable' group should not be allowed to remove their name from the database.

44. Further work was required to work out a mechanism for opting out of the database and the basis for the distinction between the database and contactable groups should be clarified. It was also stated that the database would not be used to audit contactable patient compliance with the advice.

45. Members also suggested that the public health basis for the database, i.e. that people could be contacted in the event of a cure/ test being developed, should be made clearer.

46. A draft report of the open meeting, together with a draft submission to Ministers, would be provided for member's comment at the next meeting of the Panel.

Any other business

47. The Panel turned to discuss the open meeting, which was being held in the afternoon of the 17th April. Several questions had been received from delegates attending the meeting, many of which were matters for DH, rather than the Panel. These questions would be forwarded to DH for addressing and the responses would be provided on the DH website.

Date of next meeting

48. The next meeting was due to be held on 20th June.

Chairman's Signature GRO-C Date 5.7.02

Annex 1

Revised CJD Incidents Panel Membership List

Name	Expertise
Chairman	
Professor Michael Banner	Ethicist
Vice Chair	
Professor Don Jeffries	Virologist
Members	
Professor James Ironside	TSE Infectivity Expert, Neuropathologist
Dr David Taylor	TSE Infectivity/ Decontamination Expert
Dr Mike Painter	Microbiologist
Dr Tim Wyatt	Microbiologist
Dr Geoff Ridgway	Microbiologist
Dr Hester Ward	Epidemiologist
Dr Roland Salmon	Epidemiologist
Dr Noel Gill	Epidemiologist
Ms Susan MacQueen	Infection Control
Professor Dame Lesley Southgate	General Practice
Ms Diana Kloss	Law
Ms Jean Gaffin	Lay Representative
Ms Gillian Turner	Lay Representative
Professor Len Doyal	Ethicist
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Miss Claire Mills	CJD/ BSE Policy Unit, DH
DH Officials	
Dr Rowena Jecock	CJD/ BSE Policy Unit, DH
Ms Mary Holt	CJD/ BSE Policy Unit, DH
Ms Carole Fry	Nursing Policy Unit, DH