RESTRICTED - MEDICAL

DRAFT Minute of Meeting of CJD Incidents Panel
Monday 4th June 2001, 10.00am – 6.00pm, Room 136B, Skipton House

Attendees:

Acting Chairman

Professor Don Jeffries	Vice Chairman, Virologist, St Bartholomew's Hospital (JWG)

Members

Professor James Ironside	Neuropathologist, National CJD Surveillance Unit (JWG)
Dr Hester Ward	National CJD Surveillance Unit
Dr Mike Painter	Consultant in Communicable Disease Control, Manchester (JWG)
Dr Tim Wyatt	Consultant Microbiologist, Belfast (JWG)
Dr Geoff Ridgway	Consultant Microbiologist, London (JWG)
Dr Roland Salmon	Public Health Laboratory Service, Wales (JWG)
Dr Noel Gill	Public Health Laboratory Service, London
Ms Susan MacQueen	Chair, Infection Control Nurses Association
Professor Dame Lesley Southgate	Royal College of General Practitioners
Ms Diana Kloss	Law Faculty, University of Manchester
Ms Jean Gaffin	Lay Representative
Professor Len Doyal	Ethicist, Bartholomew's & Royal London School of Medicine & Dentistry
Mr Luke Gormally	Ethicist, Linacre Centre for Healthcare Ethics
Professor John O'Neill	Ethicist, Lancaster University
Professor Mike Bramble	British Society of Gastroenterologists
Professor Graham Smith	Vice-President, Royal College of Anaesthetists
Mr Andrew Tullo	Royal College of Ophthalmologists
Ms Kate Woodhead	Chair, National Association of Theatre Nurses
Professor Ian Cooke	Royal College of Obstetricians and Gynaecologists
Dr Pat Hewitt	National Blood Authority
Mr Henry Marsh	Society of British Neurological Surgeons
Mr John Barker	Institute of Sterile Service Management
Dr Geoffrey Craig	British Dental Association
Dr David Taylor	SEDECON 2000

Secretariat

Dr Pip Edwards	CJD/ BSE Policy Unit, DH
Dr Nicky Connor	CJD/ BSE Policy Unit, DH
Miss Claire Mills	CJD/ BSE Policy Unit, DH

DH Officials

Dr Mary O'Mahony	Communicable Disease Branch, DH
Mr Alan Harvey	CJD/ BSE Policy Unit, DH

Observers

Dr Glenda Mock	Department of Health, Social Services & Public Safety, Northern Ireland
Dr Martin Donaghy	Scottish Executive Health Directorate

Dr Mike Simmons	National Assembly of Wales
Ms Carole Fry	Communicable Diseases Branch, DH
Dr Eqbal Sram	Legal Division, DH

Specialist Advisors

Mr Howard Roberts	Legal Division, DH
Mr Charles Collins	Royal College of Surgeons
Mr Charles Lister	Blood Policy Unit, DH

Apologies

Rev. Professor Michael Banner	**Chair**, Ethicist, Professor of Moral and Social Theology, Kings College, University of London
Professor Peter Hutton	President, Royal College of Anaesthetists
Professor John Lumley	Royal College of Surgeons
Mr Peter Jones	CJD/ BSE Policy Unit, DH
Dr Elaine Gadd	Ethics Division, DH
Dr Steve Deacon	Institute of Occupational Health and Safety
Mr Harry Cayton	Lay Representative, Alzheimer's Society
Mr Phil Walker	Information Policy Unit, DH

Welcome and Introductions

1. The Chair, Professor Banner was unable to attend the meeting. Therefore, Professor Jeffries, the Vice-Chair, chaired the meeting.

2. Professor Jeffries welcomed the members and thanked them for attending and the apologies were announced as above. The new members and observers of the group were introduced. It was stressed that the papers for the meeting should be treated in confidence.

Ratification of minutes of last meeting (CJDIP 3/ 02)

3. The minutes were agreed subject to the following revisions:
   - Minute 55. L.1: 'possible' to be amended to 'acceptable'

Matters arising, not covered on the agenda

4. It was pointed out that tonometry had been associated with sporadic CJD in one study in the scientific literature. However, it was noted that visual problems were a common early sign of sporadic CJD and that the ~~need for~~ cataract surgery and associated tonometry were thus likely to ~~result from sporadic CJD~~. The Panel doubted that, in practice, tonometry presented a risk factor.

5. Panel members were concerned that their request to be provided with a copy of the English Decontamination Review had been refused and requested again that this should be provided to them. It was noted that the Scottish review had been published, and that this had been provided with the papers for the meeting of the Panel in February 2001.

Action: Secretariat

Draft Public Summaries (CJDIP 3/ 03)

6. The Public Summaries were drafted at the request of Panel members, in order to inform the public on the Panel's position and actions and were not intended to provide guidance to professionals.

7. Members requested that the summaries should be more detailed and reflect any contentious issues and ongoing debates within the Panel, as well as encouraging public debate of the issues surrounding CJD incidents.

8. It was suggested that these could be placed on the DH website, following agreement from Panel members and approval from the Spongiform Encephalopathy Advisory Committee and Advisory Committee on Dangerous Pathogens Joint Working Group (SEAC/ ACDP JWG, hereafter referred to as the JWG). The group confirmed that they were content with this procedure. The Secretariat agreed to revise the current drafts and re-circulate to members for comment, prior to putting to the JWG for approval.

Action: Secretariat

Draft Framework Guidance (CJDIP 3/ 04)

9. It was explained that the draft framework guidance had been divided into five sections and a foreword and had been drafted and discussed in Panel sub-groups. The document was intended for use by the Panel in order provide consistent advice and to explain to the profession how the Panel reached decisions. It would be revised in the light of new information.

10. The sections of the document relating to blood and blood products had not been agreed, and would be discussed as a separate agenda item. There had already been considerable discussion of sections 1 and 2 of the guidance. Therefore it was agreed that discussion should start with sections 3, 4 and 5.

Draft Guidance, Section 3: Public Health Investigation

11. Some members expressed concern that the proposed policy of informing those who have a '1 in 100' chance of being exposed to the agent was unsustainable in practice and questioned the basis for this figure. It was explained that this decision was based on a pragmatic cut-off point applied to the modelling graphs (figures 2, 3, 4 and 5). After discussion, it was agreed that the boundary point of 1 in 100 should be retained and an explanation given that the boundary point was derived from models, based on the best information available together with a pragmatic approach, recognising the need to draw a distinction between groups at different levels of risk. However, the decision to include patients in the 'contactable group' would need to be made on a case by case basis, particularly if it was not possible to trace the instruments used on the index patient.

12. The decisions on the level of risk to which patients may have been exposed would need to be based on an evaluation of all the factors surrounding the case, such as the tissues involved, the complexity of the instruments, traceability etc.

13. The group was informed that work on tracking trays of instruments in hospitals had been initiated and systems should be in place by 2002. It was not possible to trace individual instruments, with the exception of endoscopes. The current and

retrospective lack of tray integrity would have a major impact on investigating cases and determining cohorts. Measures to improve tracking of instruments did not apply to primary care. The Panel would need to decide the level of uncertainty caused by the inability to trace instruments that would alter their advice on the destruction of instruments, and the inclusion of possibly exposed patients in the 'contactable' or 'database' risk groups.

Draft Guidance, Section 4: Public Health Management
Patient Management

14. It was suggested that the term 'high risk', used for those patients who should be directly informed as they had a significant risk of being exposed to infectivity, was an emotive term and misleading. It was acknowledged that the level of risk was unknown but that it was possible to estimate the risks to some patients in relation to other patients. The Panel agreed that this phrase should be replaced with 'contactable', which more accurately reflected the group of patients.

15. It was questioned who would be responsible for informing those patients who were identified as 'contactable'. It was agreed that, whilst helplines could be the first point of contact, these would not be able to provide support over long periods of time. It was suggested that the local team investigating the incident should be able to determine who would be the best person to inform a patient, but there was a need for flexibility when making this decision. However, there was a general consensus that the patient's GP should be involved, as he/she would be able to provide long-term care and support. The Panel stressed that resources should be made available to provide training for the clinicians/ GPs responsible for informing and counselling. The Panel sub-group responsible for advising on the incident would be able to provide wording for the informant regarding the level of risk to the patient.

16. Members were content with the conclusions shown in Table 8, but requested that the term 'incubating' needed amending to '1 to 10 years before developing symptoms'.

17. The group was provided with an oral summary of papers CJDIP 3/ 06, CJDIP 3/ 09 and CJDIP 3/ 27, regarding the data protection issues surrounding the compilation of a database of cohorts of patients possibly exposed to infectivity. The Data Protection and Human Rights Acts both allowed for patients' privacy, except where actions needed to be taken for public health reasons, and where implied consent was provided. Implied consent was usually taken to apply to situations relating to the treatment of the individual. A case could also be made that the database would be primarily for research purposes, although this may require that the database be anonymised.

18. The Panel agreed that implied consent was needed, as the database needed to contain patients' names, as this would be necessary in linking any actual cases of CJD to the database. Informed consent was required on ethical grounds, as it was considered wrong to hold information on a database without making the public aware of its existence. A high level of information to the general public would therefore be required. It was also noted that it may be desirable to be able to

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I am not sure what this means in terms of
use lawyer's wording

contact those listed on the database, should a diagnostic test or treatment become available.

Instrument Management

19. The group discussed the decision that an instrument that had undergone10 re-uses since being used on the index patient could be continue to be used. This was a pragmatic decision and would be subject to the Panel's discretion when advising on individual incidents. It was explained that decisions on instrument management should take a range of factors into account, including the number of re-uses undergone, the complexity of the instrument and the type of operation.

20. It was suggested that the first sentence of paragraph 3.27 should be amended to state 'This advice should not be interpreted as *necessarily* meaning that possibly contaminated instruments may be repeatedly decontaminated and then returned to use.'

21. Some members expressed concern that instruments would be destroyed if the Panel believed that they would pose a significant risk of infection, regardless of the cost of the instrument, and with the possibility of compromising patient care due to a lack of equipment available. It was explained that the guidance provided for the option of using implicated quarantined instruments, with the patient's (or proxy) consent, in emergency situations.

express informed

Draft Guidance, Section 5: Public Awareness

22. The Panel agreed the need to be open about how it reached decisions, and the need to place the debate of the issues surrounding CJD incidents in the public domain. It also agreed that the draft document should be put for public and professional consultation prior to adoption.

23. Members suggested that public relations experts should be contacted for advice on this issue and that the NHS National Plan may contain useful information. The Secretariat confirmed that they were in the process of collating information on how the consultation exercise could be performed, and would keep members informed of progress. It was noted that the consultation exercise and public information campaign could be done in tandem, in order to speed the process.

24. It was suggested that a single case may involve multiple procedures, including body piercing, dentistry etc, as well as more invasive procedures and the effort of launching a helpline to advise on all of these procedures may be disproportionate to the risks involved. It was explained that a helpline would only be set up if the Panel decided that the procedure was of a significantly high risk that the public should be made aware/ informed of the incident.

25. The Panel stressed the need to bring the existence of the database of cohort of patients to the public's attention, in order to gain implied consent. The Secretariat agreed to investigate how this could be done.

Action: Secretariat

26. Some members suggested that this section should include the principle 'to let those know who think that they might have been exposed, that there is little or no benefit in them knowing'.

Draft Guidance, Section 1: Introduction

27. Members requested that paragraph 1.5 be amended, to more accurately reflect the guidance provided in the current (1998) version of 'Transmissible Spongiform Encephalopathy Agents: Safe working and the prevention of infection' drawn up by the JWG.

Action: Secretariat

Draft guidance, Section 2: Supporting Evidence

28. It was noted that DH were currently in the process of compiling a risk assessment for CJD and dental procedures. It was agreed that dentistry should be omitted from the document, until DH had finalised the risk assessment. However, the document should state that this is currently under review. Ophthalmic tissue infectivity was also under review, although it was agreed that the text relating to this area should remain in the document, as incidents involving ophthalmic surgery often arose.

29. It was noted that the document did not cover tissue and organ donation. These would be added to the document as soon as possible.

Draft Guidance, Annexes

30. A Glossary had been added to the document (CJDIP 3/ 04a), as requested by Panel members, and the Secretariat requested members to send written comments.

31. Panel members suggested that Annex 3 required some further drafting to provide clearer, more useful information. Members were requested to forward comments on to the secretariat, who would provide an electronic version of the draft framework, annexes and glossary. It was agreed that the re-drafting of this annex should not prevent the document from going to the JWG for endorsement.

Action: Members to provide comments

Blood and blood products (CJDIP 3/ 14, CJDIP 3/ 25)

32. Members had been provided with paper CJDIP 3/ 14, which outlined revisions required in the framework document to include blood components and blood products. The figures contained in this document had been checked by the DH Economics and Operational Research Unit, and were as accurate as possible. However, there were few data currently available on the infectivity levels in blood.

33. The document suggested that pooled plasma products carried a lower order of risk due to the dilution factor, whilst some specific immunoglobulins came from a smaller pool of donations, and therefore were of more risk. Pooled plasma products were not a continuing problem, as since 1998 plasma had been sourced from outside of the UK. However, it was likely that more retrospective cases would emerge.

34. It was questioned if repeated use of a product increased the risk of being exposed to infection, as they may receive several contaminated doses. It was explained that many haemophiliacs have home treatment, and may therefore get several bottles of the same batch. This area was well documented, and the DH Blood Policy Unit agreed to provide information to the Panel.

Action: DH Blood Policy Unit

35. The Panel confirmed that they were content with sections 1 and 2 of the draft document relating to blood and blood products. It was noted that the figure of 450 ID_{50} per unit for whole blood quoted in Table 6 was very high, but this figure reflected the current uncertainty and was a reasonable pessimistic assumption. Therefore, recipients of the blood components and certain derivatives listed in Table 6 would be in the 'contactable' group.

36. It was confirmed that tracing batches despatched from hospitals should be no more difficult than tracing of surgical instruments, although tracing from pharmacies was generally not possible.

37. The Panel agreed that sections 3 and 4 of the draft document should be further discussed at a meeting of a sub-group of the Panel. The meeting should also representatives from the Medicines Control Agency, Committee on the Microbiological Safety of Blood and Tissues (MSBT) and the National CJD Surveillance Unit, which also had some responsibility for advising on blood and blood products. The document should also be issued to bodies such as the MSBT and Haemophilia Association for consultation. Again, this re-drafting should not prevent the document from going to the JWG in July for endorsement.

Action: Secretariat

Discussion of incidents awaiting advice: PI 47 (CJDIP 3/ 15a)

38. This case involved patients who had been potentially exposed to vCJD via contaminated immunoglobulin treatment and who required dental treatment. The Panel agreed that these patients were in the 'contactable' group, as they may have been placed at a significant risk of being exposed to the disease. Therefore, they should be prevented from donating organs and tissues. They would be unable to donate blood, as they were immunodeficient.

39. It was noted that there were few data currently available on the infectivity levels of oral tissues, although a risk assessment of dental surgical instruments was underway. There was some data to suggest that the risk of contracting infection increased if doses were administered within a few days of each other. This model was applicable to this incident, as haemophiliacs received doses approximately four times a week, although it was not known if all of these doses would have been infective. Members requested that the level of contaminated dosage each recipient received should be determined.

40. The Panel agreed that, until a risk assessment on dental procedures had been completed, the patients should be treated as a 'contactable risk' group, and therefore should receive dental treatment in a specialist unit, and the instruments used be destroyed.

41. It was questioned if instruments could be reserved for use on haemophiliacs who had received implicated batches of blood. Members agreed that this should not be done, as it may place some haemophiliacs at risk who had not previously been exposed to risk. It may also stigmatise these patients and compromise their care.

Discussion of incidents awaiting advice: PI 51 (CJDIP 3/ 15b)

42. The index patients were in the same group as those in cases PI 47, having received clotting factors potentially contaminated with CJD and were awaiting knee replacement surgery. The Panel considered that, as this procedure did not involve any high-risk tissues, the instruments used could be reprocessed and put back into circulation.

43. These patients would be in the 'contactable' group, from the assessment of the possible risk of being exposed to infection, and should be prevented from donating blood, tissues and organs. Special precautions should be taken if they needed any procedures on 'high-risk' tissues.

44. As a separate issue it was noted that, to date, no cases of secondary vCJD had been documented.

Discussion of incidents awaiting advice: PI 52 (CJDIP 3/ 15c)

45. This was a general enquiry concerning action that should be taken when adult and paediatric haemophilia patients who had been potentially exposed to vCJD via blood products undergo invasive procedures, particularly endoscopy. It was considered that the patients would probably fall within the 'contactable' group.

46. The Panel was concerned that patients within the 'contactable' group should have adequate treatment. It was noted that studies were available to show that infectivity could be removed from an endoscope, provided that the instrument was thoroughly washed. The Panel therefore agreed that the endoscope used on the such patients could be placed back in circulation, providing it had been properly cleaned. The forceps and valve on the implicated endoscope should be destroyed, as these may have come into contact with some 'medium risk' tissues.

Discussion of incidents awaiting advice: PI 11 (CJDIP 3/ 15d)

47. This incident involved sporadic CJD, gastroscopy with biopsy and cataract removal. The biopsy forceps used had been destroyed, and the cataract surgery did not involve the use of phacoemulsification equipment. A Panel letter advising that the endoscope did not pose a risk and could be returned to use was re-affirmed.

48. The Panel agreed that the equipment used in the cataract surgery could be put back in use, since the instruments had been through more than ten re-uses since the operation on the index patient. However, the quality of the instruments should be checked prior to being placed back in use, as they had been in quarantine for some time.

49. The Panel reserved the right to consider whether the cohort of patients should be included on the database proposed in the draft framework document. Therefore, a publicity campaign may need to be undertaken. The Trust should be advised to retain all relevant records.

Discussion of incidents awaiting advice: PI 13 (CJDIP 3/ 15e)

50. The Secretariat now had detailed information from the team investigating this case. It was agreed that the case would be discussed at a meeting of relevant members of the Panel.

Action: Secretariat

Endorsement of advice provided since 22 February 2001 (CJDIP 3/ 16)

51. The incident concerned a suspect case of CJD who had been placed on three different ventilators. The Secretariat had contacted Professor Jeffries and other relevant Panel members for advice, as there was some concern regarding the risk from the sputum and other fluids from the index patient. The advice given in the Panel letter dated 11 April was endorsed.

52. The JWG were planning to have detailed presentations on ventilators and renal dialysis machines at their next meeting.

53. The Trust had since been in contact to confirm that the patient had not been suffering from CJD. (CJDIP 3/ 16a, tabled)

CJD Incidents Database (CJDIP 3/ 19)

54. It was explained that this database could be used by the Secretariat to keep track of the Panel's work, as well as performing other tasks such as comparing similar incidents etc. It was also hoped that, after precedents had been set, the database would help the Secretariat to provide advice without relying on Panel members' comment, as well as ensuring consistent advice.

55. Members were content with the proposal for the database. The Secretariat would develop the database further to put the information in a more accessible manner.

Action: Secretariat

Relations to other committees (CJDIP 3/20)

56. A meeting was planned for 12 June 2001 with the chairs of the Panel, JWG and SEAC to take stock of how the committees were working together and how working practices could be improved. Members were invited to indicate any points they wished to be raised at the meeting.

57. Members expressed concern that work by the Panel should not be subject to long delays whilst awaiting approval from its two parent committees. The Panel comprised all the expertise necessary to fulfil its remit, and therefore had good grounds for being 'self-standing'. It was also pointed out that SEAC's main task was to provide opinions based solely on scientific evidence, and was not responsible for carrying out practical tasks, unlike the Panel.

Draft report to the JWG (CJDIP 3/ 21)

58. The draft report would be provided to members of the JWG, along with the minutes of all full CJD Incidents Panel meetings, for endorsement. Members were content with the overall structure and content of the draft report. The Secretariat requested that members provide any further comments on the draft in writing as

soon as possible. Members were also reminded to provide a Declaration of Interests form to the secretariat, if they had not already done so.

Action: Panel members

Any other business

59. It was questioned if it was possible to contact SEAC for clarification regarding the advice it had recently provided that it was not possible to rule out the present of infectivity outside the eye and CNS for sporadic CJD.

Date of next meeting

60. The next meeting of the Panel would be held on 18 October 2001. Full details would be provided to members in due course.

Summary of Main Action Points

i. Secretariat to re-draft Public Summaries and put to members for comment;
ii. Members to provide further comments on the draft framework document and annexes by the close of 15 June 2001;
iii. Secretariat to revise draft framework guidance document as requested by members;
iv. Secretariat to investigate methods of conducting a consultation and publicity campaigns;
v. Members to provide any further comments on the Report to the JWG to the Secretariat;
vi. DH Blood Policy Unit to provide information regarding doses of contaminated batches;
vii. Secretariat to arrange meeting to discuss sections 3 and 4 of the guidance, relating to blood and blood products;
viii. Secretariat to revise CJD Incidents Panel Database of cases received;
ix. Secretariat to repeat request for the English Decontamination Review Report