CJDIP 9/03

Draft minutes of Panel meeting 6th February 2003

Key facts

The draft has been circulated to members and amendments included

Questions to the Panel

Members are asked whether any further changes are to be made

Minutes of the 8th Meeting of the CJD Incidents Panel
6th February 2003. Department of Health, Wellington House, G 16/17.

Chairman	
Professor Michael Banner	Ethics
Members	
Professor Don Jeffries (Vice Chair)	Virology
Dr Tim Wyatt	Microbiology
Dr Mike Painter	Public Health
Mr Andrew Tullo	Ophthalmology
Dr Roland Salmon	Epidemiology
Dr Noel Gill	Epidemiology
Professor Dame Lesley Southgate	General Practice
Mrs Gillian Turner	Lay Representative
Professor James Ironside	TSE Infectivity, Neuropathology
Mr John Barker	Sterile Service Management
Professor Mike Bramble	Gastroenterology
Professor John Lumley	General Surgery
Dr Pat Hewitt	Blood Safety
Dr Geoff Ridgway	Microbiology
Professor Ian Cooke	Obstetrics and Gynaecology
Ms Kate Woodhead	Theatre Nursing
Mrs Jean Gaffin	Lay Representative
Dr David Taylor	TSE Infectivity, Decontamination
Expert Adviser	
Dr Peter Simpson	Anaesthesia
Observers	
Dr Liz Mitchell (For Dr Glenda Mock)	Department of Health, Social Services & Public Safety, Northern Ireland
Dr Mike Simmons	National Assembly of Wales
Dr Peter Christie	Scottish Executive Health Department
Ms Helen Janecek	Communicable Disease Surveillance Centre
Mr Stephen Norton	CJD Policy Unit, DH
Dr Pip Edwards	CJD Policy Unit, DH
Dr Rowena Jecock	CJD Policy Unit DH
Secretariat	
Dr Peter Horby	Communicable Disease Surveillance Centre
Dr Nicky Connor	Communicable Disease Surveillance Centre
Ms Katie Oakley	Communicable Disease Surveillance Centre
Ms Duclette St Hill	Communicable Disease Surveillance Centre
Apologies	
Dr Hester Ward	Epidemiology
Dr Geoff Craig	Dental Surgery
Mr Luke Gormally	Ethics
Mrs Diana Kloss	Law
Professor Peter Hutton	Anaesthesia

Ms Susan MacQueen	Infection Control
Ms Carole Fry	Nursing Policy Unit, DH
Mrs Mary Holt	CJD Policy Unit, DH
Dr Mary O'Mahony	Department of Health
Dr Glenda Mock	Department of Health, Social Services & Public Safety, Northern Ireland
Professor Bob Will	Neurology

1. Welcome and apologies (CJDIP 8/01)

The Chair thanked members for attending and announced the apologies above. The Chair welcomed Dr Peter Simpson who is attending today in the capacity of expert adviser on anaesthesia. The Chair welcomed Dr Nicky Connor (Panel Medical Secretariat) back from maternity leave and thanked Dr Peter Horby for his work covering for Dr Connor. The chair welcomed Helen Janecek who takes up the post of Senior Administrator for the Panel Secretariat on 1st April 2003 and is attending this meeting to observe.

2. Changes to Panel Membership (CJDIP 8/02a &b)

The Chair said that Prof Smith has resigned from the Panel as he is retiring from clinical practice. Prof O'Neill has resigned from the Panel for family reasons. In his resignation letter Prof O'Neill raised some concerns about the tone of the Framework Document; this will discussed as part of Agenda item 9c. The Chair thanked both members for all their hard work. Replacement Panel members will be sought. The Chair reminded Members that they are appointed for their expertise, not as representatives of particular groups.

ACTION: Secretariat/Chairman to suggest replacement Panel members to CMO

3. Ratification of the Minutes of the Last Meeting (CJDIP 8/03)

The minutes were agreed.

4. Matters arising

4.i. Counselling Expert (CJDIP 8/04a)

At the last meeting members were asked to suggest names of experts who could provide information on the effects of giving people bad news. The Secretariat reported that no further names had been put forward for consideration.

The Secretariat had met the team looking after recipients of human growth hormone and recommended their counsellor for consideration.

There was discussion as to whether the Panel requires someone with counselling expertise or with expertise in breaking bad news. Members felt that these two areas of expertise were different. Whilst a person with individual experience may bring useful skills, an academic approach might be more helpful in advising the Panel on the best way to manage the breaking of bad news. Content expertise was not needed so much as knowledge of principles and the general approach. Other members suggested approaching bodies such as hospice organisations or the Macmillan Trust.

The Chairman asked Members again to submit names for consideration to the Secretariat and he will agree with the Secretariat a person specification to aid the decision making.

ACTION: Chairman/Secretariat

4.ii. Reuse of brain biopsy instruments (tabled papers: letters from Mr Marsh to Dr Edwards and Mr Marsh to the President of the Society of British Neurosurgeons (SBNS)

Mr Marsh explained that new guidelines are being drafted by SBNS on the reuse of brain biopsy instruments. He will report back to the committee in due course on the new guidelines. The guidelines will recommend that there are some situations in which instruments should not be re-used before a definitive diagnosis has been reached. This will help ensure that brain biopsy instruments are not re-used after use on patients with CJD.

4.iii. Hospital Record Keeping (CJDIP 8/04b &c)

The Secretariat wrote to the CMO who has replied agreeing that retaining hospital records for 8 years is inadequate given the long incubation period of TSEs. The CMO has referred the matter to the departmental records officer. Members were invited to send any further comments, if they wished, directly to the records officer. One member felt that this request to retain records for 20 years could cause considerable logistical difficulties for some NHS Trusts. The general view was that the request was reasonable and important. **ACTION: Members**

4.iv. Haemophilia Directors (CJDIP 8/04d)

The Secretariat presented the letter sent to the Scottish Directorate and noted that haemophiliac patients in Scotland had been informed of potential exposure to contaminated blood products.

It was agreed that there will be difficulties as everyone is working in a vacuum pending the completion of the risk assessments on blood and plasma derivatives.

4.v. Post-mortem strategic brain biopsy (CJDIP 8/04e and tabled letter from Prof Ironside to the Secretariat).

The Secretariat had been asked to discuss with Prof Ironside the possibility of strategic brain biopsy as an alternative when a patient's relatives have refused a full post-mortem. Prof Ironside said that because of problems with sampling, one would need to do a craniotomy and open the skull anyway. He said that another suggestion to biopsy the optic nerve would not help either since this can produce a false negative result. Prof Ironside said that the only way to obtain a definite diagnosis is a full (or limited) post-mortem, and that a strategic biopsy is not reliable.

4.vi. NHS Decontamination (CJDIP 8/11a)

The Secretariat has sent letters following PI 143 and this will be discussed under a later Agenda item.(11i).

The Chairman asked if there were other comments regarding matters arising from the last minutes. The representatives from the devolved administrations said they have not received letters outlining the new arrangements for the Secretariat. DH observers said that a public announcement will need to go out in due course about the new arrangements which Dr Connor said should be in place in March.

ACTION: DH/Secretariat to inform all stakeholders about the new Secretariat arrangements

5. Public Summary (CJDIP 8/05)

The public summary of the October meeting was accepted with a minor correction – that Panel members are appointed by CMOs, not ministers.

ACTION: Secretariat to seek the agreement of the ACDP/SEAC JWG to publish.

6. Annual Report August 2001/02 (CJDIP 8/06)

This has been agreed by Panel Members and accepted by the ACDP/SEAC Joint Working Group and will be published on the DH website. The Secretariat will need to notify a wide range of people that this has happened.

One member asked for information from DH officials on the £200 million quoted in the Annual Report as having been spent on decontamination. DH replied that this applied to England, and that the Panel may find a presentation on the current situation in the 4 countries with regard to progress made on decontamination useful. This will be a future Agenda item.

It was noted, for future reference, that the Panel Terms of Reference no longer reflect the organisational structure of the NHS. It was agreed that the DH would identify generic terms that cover all UK health service arrangements which could be used to update the Terms of Reference.

ACTION: DH/Secretariat

7. Risk Assessments – oral progress reports from the Department of Health

7.i. Blood and plasma derivatives

This has now been considered by expert committees and agreement is near to being reached on the best approach. On plasma derivatives, three possible approaches to calculating the risk were considered. One has been rejected by the scientific committees and the second and third will be presented in the final report.

A sub-group chaired by Prof Dame Lesley Southgate will meet on 10th April 2003 to translate the existing risk assessments, and the uncertainty over which approach is best, into the Panel framework for advice. Invitees will be as follows:

The members of the sub-group:

Profs Banner, Jeffries, Ironside and Will and Drs Salmon, Wyatt, Ward and Hewitt.

The specialist advisers:

Mr David Gorst (MSBT), Mr Peter Foster (SNBTS), Ms Karen Pappenheim (Haemophilia Society), Dr Frank Hill (Haemophilia Centre Doctors Organisation), Ms David Watters (Primary Immunodeficiency Association), Ms Helen Chapel (Primary Immunodeficiency Association), Mr Tim Wallington (NBS).

Observers from the devolved administrations: Drs Mock, Christie and Simmons.

Department of Health Officials: Dr Philippa Edwards, Mr Charles Lister and Mr Andre Hare

Panel Secretariat: Dr Peter Horby. **ACTION : DH**

7.ii. Dental risk assessment

The Panel had a presentation by EOR (Department of Health) in 2002 on an early draft of the risk assessment. The risk assessment looked at two areas:

- contact with lingual tonsil
- root canal work.

The risk assessment will go to SEAC for information in April and be made public soon. A sub group of the Panel will be set up to translate the assessment into the Framework for Panel advice.

ACTION: Secretariat to set up the dentistry sub-group

7.iii. Endoscopy Risk Assessment

Dr Ridgway chairs this sub-group of the JWG. The document produced by the sub-group will go in the ACDP/SEAC JWG revised guidance document as an annex. Responsibility for decontamination procedures guidance rests with the JWG. Previous advice on incidents involving endoscopes will need to be reviewed in the light of the revised guidance. A further report from the DH will be on the Agenda for the next Panel meeting.

ACTION: DH/Secretariat

8. Tissue Banks and Organ Donation Centres (CJDIP 8/08)

A Department of Health Observer confirmed that the Panel is responsible for advice in this area but could not provide advice until a risk assessment was completed on different organs and tissues. Preliminary work on the appropriate membership of a group to carry out the risk assessment had been carried out. The Chairman was advised to write to the CMO requesting this is undertaken as a priority.

The Chairman undertook to reply to the letter from the President of the BATB and also to write to the CMO.

It was agreed that all TSEs are to be considered. A member stated that there are two very different areas involved a) tissue donation and b) organ donation. The view was expressed that the life-saving and often urgent nature of organ donation should be taken into account when developing recommendations in this area. Care should be taken to avoid dissuading people from donating or receiving organs.

It was also requested that the Department of Health should include in these discussions the issue of testing donors of tissues to be stored long-term e.g. lymphoid tissues.

One member said there is a discrepancy at the moment in that tissue banks which are part of the blood service receive information on CJD patients whilst other banks, outside the blood service, do not.

ACTION: Chairman/Secretariat letters & DH to set up group to carry out the risk assessment

9. Framework Document (CJDIP 8/09a, 09b, 09c, 09d)

9i &ii. The Framework document was sent to the UK CMOs with a key issues paper on 4th October 2002. The Chairman is meeting the CMO on 14th February 2003 and hoping for a decision. Members agreed that the Panel is handicapped in its work whilst agreement of the Framework Document remains pending.

9.iii &iv. The Chairman said he regrets Prof O'Neill's resignation and that it was a pity that the points made in his letter were not registered earlier. The Chairman expressed his view that the points made are of emphasis rather than substance. One member pointed out a misunderstanding of the nature of the database on page 2 of Prof O'Neill's letter.

10. Communications toolkit

Prof Dame Lesley Southgate reported on a productive meeting which she had chaired on 14th January 2003 to review the draft communications toolkit prepared by PHLS. The group had defined the purpose, terminology and tone of the documents and agreed there would be three outputs:

- One document for health care workers supporting patients (and anyone else who would like to access technical and detailed information)
- One less technical document for patients
- One document for finding out more about the database

The documents will be looked over by experts in plain English and communicating health information. There are no more sub-group meetings planned. Minutes of the meeting of 14th January 2003 will be circulated with the minutes of this Panel meeting. Further revision of the draft toolkit will be undertaken by email communication followed by presentation of the revised toolkit to the Panel.

The issue of funding was discussed by Panel members since PHLS will need funding to produce the leaflets and develop a web-site presence. It was suggested that the toolkit should carry the CJD Incidents Panel logo since it pertains to implementing Panel policy.

ACTION: Secretariat/DH/subgroup

11. i. PI 143 (CJDIP 8/11a & 2 tabled papers – letter 17/1/03 from Dr Edwards to Dr Lawler and from Dr Campbell to Prof Banner dated 27/1/03)

Panel members will be aware that this incident attracted widespread media coverage and will have caused distress to the patients involved. The case involved the possible exposure of a number of patients to instruments which had been used during a neurosurgical procedure on a patient subsequently diagnosed as having probable sporadic CJD. The Panel has also received a complaint from the Trust indicating that the Panel was unhelpful. The Chief Medical Officer requested Bill Kirkup, the Regional Director of Public Health, to review the procedures followed in this incident and some Panel members have had sight of a draft of the report. Prof Jeffries has had the opportunity to comment on the draft.

Once the report is available, the Panel will be asked to consider whether, as a result of the findings and recommendations in the report, any aspects of the Panel's framework document or the way in which the Panel works could be improved. It was agreed that detailed discussion of the issues raised by this incident should be delayed until the final report is available. The Department of Health agreed to inform Panel Members before the report is made public.

One member, who had seen the draft report, requested that the report come to the Panel as a serious Agenda item as general questions raised about the Panel would profit from discussion.
One member requested that the Panel have input on press releases from DH on Panel matters. The DH official confirmed that this was acceptable.

Consideration of the responses from the four CMOs to the Panel's letter regarding decontamination services will be deferred to the next meeting when there will be a more detailed discussion on progress in decontamination standards.

ACTION:DH/Secretariat

11.ii. PI 163/169/178 (CJDIP 8/11b)

The Secretariat reported that the Panel has been asked about surgery that has been performed on patients considered 'at risk' of CJD where ACDP/SEAC JWG guidance has not been followed. The Framework Document considers previous surgery on CJD patients but does not give advice on 'at risk' patients. This gap in advice will become an increasing problem as the size of the 'at risk' population increases.

Members agreed that the situation will be clearer if the Framework Document and the revised guidelines from the ACDP/SEAC JWG are approved by the CMO.

There will be a need to ensure that there are no gaps in policy therefore the Chairman requested that a sub-group is formed under the Chairmanship of Prof Jeffries to consider advice in relation to 'at risk' patients, and the implications of the JWG guidance on the Framework Document.

ACTION: Secretariat

PI 163:

This case involved internal fixation of a fracture on a patient recipient of injections of human-derived gonadothrophin. One Panel member said he could have helpful information on the subject of human derived gonadatrophin in relation to this case and asked the Secretariat to contact him. Human derived gonadotrophin obtained from urine has not in the past been considered to pose a risk of CJD.

It was noted that the letter for PI 163 states that instruments were removed from quarantine on the advice of one Panel member. The Panel agreed that advice should come from the Panel, not individual members and that whilst the Secretariat could act on behalf of the Panel, this was only possible where there was a clear precedent. It was unwise for individuals to give advice based on their own judgement. This would not however change the advice given in the letter.

ACTION: Secretariat

PI 169:

This case involved subsequent neurosurgery on patients exposed to surgical instruments possibly contaminated with sporadic CJD. The advice given not to withdraw the instruments would not set a precedent and was based on consideration of a number of factors. These factors included the time span after the possible exposure, the fact that only a proportion of the patient in the potentially exposed group will actually have been exposed to the instruments used on PI 143, the numbers of decontamination cycles already carried out on the instruments and the fact that the re-operations carried out did not involve extensive handling or dissection of CNS tissue.

There was some discussion about the acceptability of manual cleaning . Members requested a short paper to be presented by NHS Estates summarising the latest situation on manual cleaning of instruments. This will be an Agenda item for the next meeting.

ACTION: Secretariat

PI 178:

This case involved dental treatment on a patient with a grandparent who had familial CJD.

11.iii. (PI 166/186/190 and a tabled paper from Prof Bramble)

These cases involved giving advice on incidents in which endoscopies had been carried out on patients whose most likely diagnosis is sporadic CJD but vCJD remains a possibility. The Secretariat reported that the advice regarding endoscopes is very clear but that this is not the case for endosope accessories. The Panel members were asked whether they endorsed the advice given regarding the accessories in these incidents and if it could it be used as a precedent in future similar cases. Also whether interchangeable suction valves pose a significant contamination risk.

Prof Bramble explained that there is a risk of inoculation of potentially infectious tissue if an instrument is not properly cleaned following biopsy. The greatest risk is following biopsy of intestinal mucosa (which may contain lymphoid tissue).

Prof Bramble described, with the aid of a diagram, the accessories involved in endoscopy. The air/water channel cannot become contaminated with tissue. The suction channel is the same as the biopsy channel and could become contaminated. Inoculation could occur when another set of biopsy forceps is put down the channel. The suction channel and valve takes matter away from the patient and since the suction valve is above the biopsy port; there is no risk of inoculation of any tissue contaminating the suction valve. Members agreed therefore that, even if cleaning is not perfect the risk of inoculation from suction valves is low. Members agreed that interchangeable suction valves do not pose a significant risk of onward transmission.

A discussion ensued on decontamination procedures and validation procedures and training for endoscopy equipment. It was recognised that MDA guidance was that accessories should remain with their parent endoscopes. Prof Bramble confirmed that the suction and air and water valves, nozzle throat spray and mouth guard are all kept together with their endoscope in his unit and that the rubber biopsy ports (which cost pence) are discarded immediately after use. This is not the case in all units. Prof Bramble also confirmed that obtaining replacement valves when necessary is a straightforward and speedy process.

The Panel agreed that automated endoscope washers do not pose a significant cross-infection risk.

The Panel agreed that when moved to a 'clean' endoscope, contaminated interchangeable accessories are not likely to cross-contaminate the endoscope.

The Panel endorsed the advice given in these incidents. Members agreed that the advice could be used as a precedent in future similar cases.

It was noted that neuro-endoscopy and ENT endoscopy were special cases and the above advice relates only to gastrointestinal endoscopy. **ACTION: Secretariat**

11.iv. PI 172.

This incident involved a patient who had been suspected of having sporadic CJD but was now recovering and back at home. Local clinicians had discussed the case with NCJDSU who think that any form of CJD is very unlikely, although they have not assessed the patient. The Panel agreed that the instruments can be released from quarantine. **ACTION: Secretariat**

12. Endorsement of Advice provided since the last meeting (CJDIP 8/12)

Incidents: PI 162, 164, 176,177,179,181,183,59,117,125.

Members endorsed the advice given in these cases and confirmed that the same advice may be given in future similar incidents.

13. AOB:

Retrospective consideration of CJD cases:

A member asked if all CJD cases are referred to the Panel. The answer was probably not. The issue of actively ascertaining all relevant medical procedures in all CJD cases would need to be considered if the Framework Document is accepted by the CMO. It was noted that the onus of reporting relevant procedures to the Panel was clearly on the local public health professional, not the relatives of patients.

Donation of instruments:

A future agenda item was requested on the issue of instruments being donated to charity and any associated infection control risks. **ACTION: Secretariat**

A query on a paediatric endoscope currently in quarantine.

Prof Ironside asked if a quarantined paediatric endoscope used on a patient with GSS could be reused on the same patient. After some discussion on the distribution of tissue infectivity in GSS, it was agreed that the endoscope could be re-used.

ACTION : DH

14. Date of next meeting

May/June 2003. Date to be confirmed. **ACTION: Secretariat**