APPENDIX C

ACDP/SEAC/WG/TSE/M16

ADVISORY COMMITTEE ON DANGEROUS PATHOGENS/ SPONGIFORM ENCEPHALOPATHY ADVISORY COMMITTEE

TSE JOINT WORKING GROUP

Minutes of the 16th meeting held on Tuesday 10 July 2001 at the Health and Safety Executive, The Globe Room, Rose Court, 2 Southwark Bridge, London SE1 9HS

PRESENT

Chairman:	PROF D J JEFFRIES	
Members:	MR R BRADLEY	
	MR A CLARE	
	PROF J IRONSIDE	
	DR P JONES	
	DR D MATTHEWS	
	MS D MAY	
	DR M PAINTER	
	DR G RIDGWAY	
	PROF P SMITH	
	Dr D TAYLOR	
	DR T WYATT	
Observers/Others:		
	PROF R BUCKLEY	MOORFIELDS EYE HOSPITAL
	MS K DARWIN	DH
	DR P EDWARDS	CJD INCIDENTS PANEL
	MR P HUNTER	ROYAL COLLEGE OF OPHTHALMOLOGISTS
	MR D KERR	NHS EXECUTIVE
	MISS L MAGUIRE	DEFRA (SEAC)
	MR D McIVOR	DH, MDA
	MR N MOORE	DH, MDA
	DR J STEPHENSON	DH
	MR A TULLO	MANCHESTER ROYAL EYE HOSPITAL
	DR A WIGHT	DH
Secretariat:	MR G CLEMENTS	DH
	MR P JONES	DH
	DR J NEILSON	HSE
	MISS K NORMAN	DH
	MRS L SHEPHERD	HSE

AGENDA ITEM 1 – Chairman's opening remarks and apologies

1.1 The Chairman welcomed members and observers to the 16th meeting of the Joint Working Group (JWG). He introduced Dr Philippa Edwards (CJD Incidents Panel) who was attending her first meeting of the Group to introduce and answer questions on paper ACDP/SEAC/WG/TSE/P68 on the CJD Incidents Panel, and to present papers ACDP/SEAC/WG/TSE/P70 on Ventilators and ACDP/SEAC/WG/TSE/P71on Dialysis Machines. He also introduced Miss Lisa McGuire (DEFRA – SEAC) who was attending in place of Mr Samuel Donkor (DEFRA).

1.2 The Chairman welcomed Mr Andrew Tullo (Manchester Royal Eye Hospital), Mr Paul Hunter (President, Royal College of Ophthalmologists) and Professor Roger Buckley (Consultant at Moorfields Eye Hospital) (afternoon only). They were attending the meeting to give a presentation about the concerns of the Royal College of Ophthalmologists with regard to the JWG's previous advice about adding recipients of ocular grafts to the list of "at risk" patients in the ACDP's TSE Guidance. Ms Kate Darwin (DH) was also attending this meeting (afternoon only) specifically for discussions on this item.

1.3 Mr Doug McIvor (DH, Medical Devices Agency) was attending the meeting (afternoon only) to deal with issues relating to paper ACDP/SEAC/WG/TSE/P70 on Ventilators, and would also field questions on paper ACDP/SEAC/WG/TSE/P71 on Dialysis Machines, in the absence of Ms Tham and Mr Beagle.

1.4 Apologies had been received from Mr Ken Ashley (HSE), Mr Simon Beagle (Charing Cross Hospital), Mr Samuel Donkor (DEFRA –SEAC) (Miss Lisa Maguire was attending in his place), Mr Mike Greaves (MHS), Mr Alan Harvey (DH), Dr Jim Hope, Dr Roland Salmon, Mr Peter Soul (DEFRA) and Ms Samantha Tham (DH, MDA).

AGENDA ITEM 2 - Minutes of the meeting held on 23 February 2000

ACDP/SEAC/WG/TSE/M14

2. Members had been given an earlier opportunity to comment on the minutes. They had the following additional comments/amendments:

- Paragraph 3.1.2 – amend first word of penultimate line to read "genetic sub-groups", and not "generic sub-groups".
- Paragraph 3.1.2 – amend spelling of first word in last line to read "heterozygotes".
- Paragraph 3.4.2 – amend "appendectomies" in the last sentence to read "appendicectomies".

- Paragraph 3.5.1 – add heading "Abattoir practices" to this section/paragraph under Matters Arising.
- Paragraph 6.3 – last sentence to read "... concerns **about risks to individuals through infection from** cuts and abrasions.
- Paragraph 6.4 – amend the third sentence to read" A particular risk to workers was considered to be from head removal".

AGENDA ITEM 3 - Matters arising

Update on number of CJD cases
The Chairman reminded members of the need for strict confidentiality with regard to unpublished data.

3.1.1 102 cases of definite and probable vCJD had been reported in the UK to date, 6 of whom were still alive. 3 cases had been reported in France, and 1 in Eire. A vCJD patient who was still alive and living in Hong Kong had also been identified. The patient, who was of Chinese origin, had lived in the UK in the 1980s and 90s, and then returned to Hong Kong. The Hong Kong authorities were regarding this as an imported case. The recognition of this case had been welcomed by the WHO as an indication that good surveillance procedures were in place.

3.1.2. A vCJD patient, who had died recently, had become ill during pregnancy and undergone a caesarean section. There were now a total of three babies born to vCJD mothers; one had shown early neurological abnormalities, although they did not appear to be progressive; the other two remained well.

3.1.3 There had been a cluster of cases in Leicestershire, which had been investigated by Leicestershire Health Authority. The report into this cluster of cases was now available via the HA Website (www.leics-ha.org.uk). They considered that the most likely explanation was a link with contaminated meat products. There was still no evidence at present of CJD due to occupational exposure. There had been an increase in reports of sporadic (sp) CJD in agricultural workers, but this had also been seen in other countries and was not thought to be significant. The CJD Surveillance Unit's Annual Report contained a breakdown of the statistics for both vCJD and spCJD.

3.1.4 Previous analysis of the statistics had indicated that there had been a significant increase in vCJD cases reported during the last three-quarters of 2000. This increase has been sustained for 2001 to date. The mean age at onset of disease and at death was 27 and 30 respectively, and the average duration of illness was 30 months. There had been an increased number of instances in the younger age groups. A case of vCJD had been identified at autopsy in a 74-year-old man – the oldest so far seen. The genetic background remained unchanged –

of those who had been genotyped (around 90%) all were MM homozygous at codon 129.

Risks in abattoirs from exposure to TSE agents **ACDP/SEAC/WG/TSE/P64**

3.2.1 This paper was mainly for members' information and to update members on actions taken subsequent to the ACDP/SEAC JWG TSE meeting on 25 January 2001. At the meeting on 25 January, members had asked that their concerns on worker safety in OTMS abattoirs be highlighted to ACDP. ACDP discussed the issues at their meeting on 14 March 2001, and agreed with the JWG concerns, and these were brought to the attention of MAFF (now DEFRA) and DH Ministers and the Health and Safety Commission. Copies of recent correspondence on this issue were included with paper ACDP/SEAC/WG/TSE/P64. The main concerns of ACDP and the JWG were: -

- poor compliance with ACDP guidance (particularly the lack of use of PPE);
- risks from pithing;
- insufficient routine supervision to ensure proper safety procedures were in operation;
- unsafe carcase dressing and inspection practices, carried out solely for compensation purposes.

3.2.2 The ACDP Secretariat had also written to the head of the HSE Food and Entertainment Sector to raise the committee's concerns about compliance with ACDP guidance. Their response acknowledged that the guidance was not being universally applied, but the issues were being addressed by HSE inspectors where necessary. There were about 5 OTMS abattoirs which were still failing to meet the required standards, and HSE inspectors were paying particular attention to these.

3.2.3 ACDP were particularly unhappy with the reply from MAFF as they felt that the questions they had raised had not been properly addressed, and there appeared to be less concern about worker health and safety issues than those to do with animal welfare, public health and compensation. The ACDP Chairman has again written to DEFRA (12 June 2001) and a reply was awaited. Members were supportive of the actions already taken and agreed that the further action was warranted because of the inadequacy of the MAFF response. They were also concerned about the possibility of outbreaks occurring outside the UK, where other countries would be looking at the lessons learned by the UK, and the possibility of having to deal with BSE in the UK sheep population – the position on which was, as yet, uncertain.

3.2.4 It was stated that only 0.45% of animals aged five years or over, in the OTMS overall had been found to be infected, and 1.3% of OTM fallen stock. However, a survey of fallen animals carried out in Northern Ireland had shown that around 2% of animals sampled were infected. It was felt this clearly indicated that there was no room for complacency about potential risks to worker health and safety.

3.2.5 The CBI had also been informed about ACDP's concerns, and were in discussions with the industry and trade associations.

3.2.6 The Food Standards Agency (FSA) had acknowledged the ACDP's concerns, but said they had no responsibility for culled cattle as they do not enter the human food chain. At this point, members' attention was drawn to the report from the Royal Society on TSE's, included with the papers for information, which raised concerns about cross-contamination of animals entering the food chain from cull animals being processed in the same abattoir.

3.2.7 Concerns had been raised about abattoir practices in mainland Europe, where OTMS cattle that had been tested after slaughter and found to be BSE-positive, had been processed on the same line as non-BSE infected cattle destined for the food chain. Although the infected animal, plus the one before and two after in the line were removed, there were still questions about the use of the gun used on the BSE animal being used on subsequent animals. It was reported that the decision to remove only a few animals from the line had been a pragmatic one, to avoid having to dispose of a whole day's through-put. SEAC had been informed.

3.2.8 A further issue was the culling by slaughtermen of Foot and Mouth Disease (FMD) animals. Most of these animals were killed using a captive bolt which, it was suggested, could put workers (including vets) at risk from TSE's. It was confirmed that there was no specific guidance to cover risks from TSE's during culling because of FMD, but advice regarding prevention of infection from FMD had been developed which had drawn upon the generic BSE occupational guidance, specifically relating to Personal Protective Equipment (PPE). Copies had been circulated to all contractors, and were available from DEFRA.

3.2.9 It was mentioned that, since the FMD outbreak, there had been no processing of OTMS cattle. Also, the FSA hoped to be able to move to OTMS-dedicated abattoirs in the future, although this situation was thought to be some way off at present. The HSE food sector was aware of current proposals, and were in discussion with plants tendering for the work to ensure the incorporation of safe systems of working. Relevant training and a training video would be available for successful contractors.

AGENDA ITEM 4 - Feedback from related meetings

- **SEAC meetings - 28 February 2001 and 25 April 2001**
- **SEAC Foot & Mouth Disease Working Group meetings – 30 March 2001 and 24 May 2001. ACDP/SEAC/WG/TSE/P65**

4.1.1 The Public Summaries of SEAC meetings held since the last JWG meeting were included with the meeting papers for members' information. The issues raised by the JWG to do with handling of surgical instruments used on non-vCJD patients and "at risk" patients in non-CNS and eye procedures, and the categorisation of "at risk" patients had been discussed at the SEAC meeting on 25 April. These were dealt with under the next Agenda Item.

4.1.2 SEAC had also been updated on the current situation regarding abattoir practices at their meeting on the 25 April 2001. They were advised that ACDP were now taking matters forward, and expressed their support of the course of action the ACDP had taken.

- **TSE Guidance review drafting group**

(i) **Report back from 1st meeting ACDP/SEAC/WG/TSE/P66**

4.2.1 The drafting group set up to review this guidance met for the first time on 23 April 2001. The note of the meeting was included with the papers for this meeting for members' information. This was subject to some minor amendment. The review group anticipated that the revised guidance would be published in a ring-bound format so that any future amendments or additions could be easily incorporated. The next meeting of the review group was on 13 July 2001, and a copy of the note of that meeting would be included with the papers for the next JWG meeting in October.

4.2.2 Revision of the TSE guidance (and development of the CJD Incidents Panel Framework Document) depended upon resolution of some key issues, on which SEAC agreement had been sought. It was noted that opinions of SEAC members had varied quite widely, and it was felt that there had been insufficient debate on the issues put to them at their meeting on 25 April – see paragraph 4.1.1 above, and the JWG expressed serious disappointment at the outcome of the SEAC meeting. Members were particularly concerned about SEAC overturning decisions agreed by the JWG.

4.2.3 SEAC had advised that, because little was known about spCJD in tissues outside the brain, spinal cord and eye, a precautionary approach should be taken

and current recommendations for the use of the more stringent decontamination procedures should not be relaxed. They felt the same about the processing of instruments used on "at risk" patients, even though there was evidence to show that prolonged autoclaving did not improve decontamination. It was, however, stated at today's meeting, that the more pragmatic, rather than ultra-precautionary approach, may be the better way forward. It was suggested that a brief review of decontamination procedures would be helpful.

4.2.4 SEAC also expressed concern about changing the definition of the "at risk" category for familial CJD, despite the fact that it was clear that family members with non-inheritable forms of CJD were being unnecessarily refused health and dental care. There were concerns that those patients at risk from genetic disease should be properly identified.

4.2.5 It was agreed that the TSE guidance review group should continue their work on revising the guidance on the basis of the decisions made by the JWG. The revised draft guidance would be presented, in its entirety to SEAC, at which point it was hoped that a sensible compromise could be reached.

(ii) Containment Level (CL) for automated diagnostic analysis of samples known or suspected of containing a Hazard Group (HG)3 TSE agent ACDP/SEAC/WG/TSE/P67

4.3.1 The appropriate CL for the diagnostic analysis of cerebrospinal fluid (CSF) was discussed at the JWG meeting in January. It was agreed that, for some work with CJD, derogation from full CL3 might be allowed, depending on the nature of the work and the outcome of a local risk assessment. Such derogations needed to be agreed by the ACDP, and were presented to them as Annex 1 of paper P67. The paper asked the Committee to consider all of the automated diagnostic tests currently undertaken on HG3 samples, and the automated analysis of research samples.

4.3.2 ACDP agreed that there was a case for reconsidering the CL to allow such samples to be processed at CL2, although they felt that diagnostic and research samples should be considered separately. They confirmed the necessity of conducting a local risk assessment, and that the required steps had been properly identified in the flow-chart attached to Annex 1 of the ACDP paper.

4.3.3 The Secretariat of the TSE guidance review group had subsequently drafted new guidance for diagnostic laboratories for inclusion in Part 4 of the revised TSE guidance, which was presented as Annex 2 of paper P67. It was acknowledged that what constituted an "at risk" or "high risk" sample should to be made clearer, as did the fact that there was no scope for derogation from

CL3 when handling samples known to contain a HG3 organism, or for non-automated procedures.

4.3.4 Views were sought on what histological procedures local diagnostic laboratories could carry out, and what controls would be required, so that examples could be included in the section on Neuropathology Specimens.

4.3.5 It was mentioned that there would need to be similar considerations for the handling of BSE-infected materials. Much of the testing of these materials was undertaken by private laboratories, most of whom did not possess CL3 facilities. It was acknowledged that the subject of research samples would need to be discussed at some point in the future but, for now, ACDP preferred to restrict their discussions to healthcare matters.

4.3.6 It was noted that implementation of the new COSHH Regulations (likely in 2002) would phase out the use of the current exemption certificates, which would mean that, if there was no derogation already in existence, there would be a need to discuss issues with the HSE before undertaking work at a CL other than CL3. The new draft would be considered further in the light of today's discussions, at the meeting of the Guidance review group on 13 July.

- **CJD Incidents Panel** **ACDP/SEAC/WG/TSE/P68**

(i). Public Summaries

4.4.1 The CJD Incidents Panel proposed that summaries of each meeting, preceded by standard introductory text should be published to ensure as much openness and transparency as possible. Whilst it was agreed that some deliberations would need to respect patient confidentiality, the general advice needed to be placed in the public domain. It was also important that any areas where there was a lack of knowledge or disagreement in advice were acknowledged. The JWG agreed that the CJD Incidents Panel should now publish the public summaries of their first two meetings. Subsequent summaries of meetings would be cleared with the JWG Chairman, on behalf of the JWG, prior to publication.

4.4.2 It was anticipated that the first annual report of CJD the Incidents Panel would be available for the next JWG meeting.

(ii) Framework Document

4.5.1 To guide the CJD Incidents Panel in its task of providing advice on the management of incidents, the draft framework document setting out underlining principles – notably on risk assessment and ethics - had been produced, and was presented as paper 2 attached to the meeting paper P68. The JWG were invited to agree that the document could now be issued for wider public consultation. Members were informed that the document was still a working draft, and amendments could be made at any time prior to or during consultation. A final version of the document, which would be regularly updated as necessary, in the light of emerging information and experience, would be posted on the Internet. It would be made available to all those responsible for making decisions on dealing with CJD incidents.

4.5.2 The document, which was intended to be evidence-based, covered a number of areas of scientific uncertainty and questions of judgement and acceptance of levels of risk. It is intended eventually to cover issues surrounding blood, tissue and organ donation as well as surgical procedures. Blood and plasma had been included in the risk assessment, although further considerations would be necessary here. Work on tissue and organ donations was just beginning.

4.5.3 New information, for example on diagnostics, would be included in the framework document, as it became available. It was reported that research was currently underway on blood and urine tests for abnormal prions, but it was thought unlikely that a validated routine method would be available in the near future. No actual testing had yet been trialled on animals or humans. In all, over 30 research projects into diagnostics were going forward, but any useable preliminary diagnostic tests were thought to be at least 2-3 years away. The Department of Health agreed to provide a report on research into diagnostic testing for the next JWG meeting.

4.5.4 Members' views were sought on the assessment of relative infectivity in different parts of the eye (Table 2 on page 12 of the framework document referred). This suggested that infectivity in parts of the eye other than retina and optic nerve were equivalent to infectivity in the lymphoreticular system (LRS). SEAC had considered this – confidential research had found abnormal PrP in only one component of an eye from a vCJD patient, and none in an eye from a spCJD case. Other research had found abnormal PrP in the retina of a spCJD patient. They had concluded that the level of infectivity in the front of the eye was less than 1/400th of that in brain tissue. It was, however, stressed that the presence of abnormal PrP did not necessarily indicate presence of infectivity, and that there may be infectivity in the absence of detectable PrP.

4.5.5 The JWG agreed that the figures for CNS, retina and optic nerve in Table 2 were reasonable. It was noted that "other eye tissues" were classified as being of "medium" infectivity for both sp and vCJD in Table 4 on page 14, although appendix, tonsil, spleen and other LRS were classified as "low" for spCJD. It was agreed that further consideration of tissues surrounding the eye might be required, although it was stated that levels of infectivity of 1/400th of that in brain would still place "other eye tissues" in the medium risk group. The tables may need adjustment, once more infectivity studies had been done.

- **Meeting of Chairmen of SEAC, TSE JWG and CJD Incidents Panel, with Deputy Chief Medical Officer (DCMO)**

4.6.1 The Chairman and the Chairs of SEAC and the CJD Incidents Panel had met with the DCMO and other senior DH officials on 12 June to discuss issues of co-ordination and interaction between the various BSE and CJD advisory committees and working groups. The Chairman reported that the meeting had been very helpful in highlighting areas of concern about relationships between the various groups and fragmentation of debate. It was important to clarify the roles of the groups, and distinguish between the scientific/risk assessment role of SEAC and the roles of the JWG and the CJD Incidents Panel in advising on policy implementation/risk management. It was agreed that there would be a need to review the Terms of Reference of the respective groups once some of these matters had been clarified.

4.6.2 It was noted that roles had evolved and changed significantly in recent years. SEAC had to become very much more advisory with regard to the science, rather than a policy making body, and the JWG which was originally set up to deal with occupational health risks, particularly for laboratory workers and those handling potentially infected animals, had increasingly been asked to pick-up healthcare/health service issues. This would be reflected in any revised Terms of Reference.

4.6.3 It was suggested that the main committees might not necessarily be best placed to deal with specific areas in detail, and the current use of *ad hoc* Working Groups would, in many instances, be a more appropriate way of taking certain items forward. Nevertheless, the need for good communications, and the retention of collective expertise on the main committees, as well as the good practice of co-opting other relevant expertise when necessary, was emphasised. Whilst there had been some lack of communication between the various committees previously, it was felt that this situation had improved over recent months.

- **Progress on research on the decontamination of surgical instruments, including a report from the research steering group meeting**

ACDP/SEAC/WG/TSE/P69

4.7.1 A copy of the note of the meeting of the Working Group on research into the decontamination of surgical instruments held on 18 January 2001 was included with paper P69. Members were given a brief oral summary of discussions at the most recent WG meeting, which took place on 4 July 2001. The written note of that meeting would be included with papers for the next JWG meeting in October.

4.7.2 It was reported that current research projects were progressing well, although it was difficult to go into too much detail at this stage because of the confidential nature of the work. It was, however, becoming apparent that fears about damage to surgical instruments from hot alkali treatment may be largely unfounded: Only one type of cheaper stainless steel had been badly damaged. The Medical Devices Agency had been asked to undertake an audit of the different types of stainless steel used in the NHS. An UK laboratory has ordered an American machine for processing surgical instruments in hot alkali, and has requested funds from DH to evaluate its use.

4.7.3 It was thought encouraging that research was showing that the assumptions included in the risk assessment models on levels of contamination of surgical instruments appeared to be fairly accurate.

4.7.4 Results from the research being undertaken on the contact theory of disease transmission by implanting stainless steel wires into mice to establish what contact was necessary to transmit disease, were expected within the next 12 months.

4.7.5 Once results from a number of the projects were available, it had been suggested that a technical group would be set up to assess and validate novel procedures to be used in hospital SSDs.

AGENDA ITEM 5 – Advice on special equipment

- **(i) <u>Ventilators</u>** **ACDP/SEAC/WG/TSE/P70**

5.1.1 The CJD Incidents Panel had requested that the JWG consider the potential risk of transmission of CJD/vCJD from one patient to another *via* ventilator equipment. The Chairman thanked Mr McIvor (MDA) for providing the background paper for this agenda item, and for attending to answer technical questions.

5.1.2 A brief description of the main types of ventilators currently being used – intensive care, anaesthesia, transport/ emergency and domicilliary – and how they worked was provided. It was explained that some types of ventilator used components that could be cleaned and autoclaved, while others had components that were impossible to disinfect. Most ventilators used single-use disposable tubing.

5.1.3 Members asked how positive pressure was created. They were advised that several methods were possible, such as putting an endotracheal tube down the throat or using a mask sealed to the face. Putting a tube down the throat could lead to scarifying of the tonsils and blood leakage. Any infectivity present might then contaminate the tubing. There was also often blood on face masks. The MDA advised that endotracheal tubes were generally designated as for single-use only by their manufacturers, and the JWG emphasised the necessity of ensuring that they were not re-used. The MDA had also stressed the need for cleaning circuits between uses. Laryngeal Mask Airways (LMAs) could be used up to 40 times before being disposed of.

5.1.4 Although a precautionary approach was to be advocated, it was felt that the risks were more perceived than real, particularly as it was thought that there was little risk of transmission of vCJD by the respiratory route or from sputum. The use of disposable tubing was essential and disposable filters would further reduce any risks.

- **(ii) Risks of transmission of CJD/vCJD from dialysis machines**

ACDP/SEAC/WG/TSE/P71

5.2.1 The CJD Incidents Panel had also requested that the JWG consider the potential risk of transmission of CJD/vCJD from one patient to another *via* kidney dialysis machines. Ms Samantha Tham (MDA) was thanked, *in absentia*, for providing the background information paper.

5.2.2 The JWG were asked if, under specific circumstances, a patient undergoing haemodialysis on a machine that had been used with a patient incubating CJD/vCJD was at significantly greater risk of transmission of CJD/vCJD than the general UK population. Given that most equipment was monitored for leakages, the JWG were asked to consider whether there were concerns about transmission to subsequent patients of disease from blood, especially in the light of the possibility of presence of low levels of vCJD infectivity in blood.

5.2.3 The JWG agreed that, provided there were no failures in the system, and as most systems comprised single-use components (for example, the valved saline reservoir) there was little risk of CJD/vCJD transmission when using these

machines. They were assured that, as well as being single-use disposable systems, there were also filters between the machine itself and the blood, so the machine did not come into direct contact with blood or other body fluids. Pressure gauges contained filters or were protected by some other sort of barrier. There was also a single-pathway system to dispose of waste fluid.

5.2.4 The JWG went on to advise that re-use of parts of dialysers that were re-used for the same patient did not introduce a risk of transmission.

5.2.5 The JWG's advice applied similarly to haemofilters and diafilters.

AGENDA ITEM 6 – Ocular graft recipients **ACDP/SEAC/WG/TSE/P72**

6.1 The Chairman welcomed Mr Andrew Tullo, Mr Paul Hunter and Professor Roger Buckley, (see paragraph 1.2 above) who were attending the meeting to give a presentation as part of this agenda item. The JWG had previously advised that it would be logical to add recipients of corneal grafts to the "at risk" patients set out in the ACDP's TSE guidance. This advice, which had been endorsed by the ACDP and SEAC, led to an exchange of correspondence between the Department of Health (DH) and the profession via the Royal College of Ophthalmologists, and subsequently a meeting between the College and the DCMO and DH officials, at which the College explained their concerns. As a result, the profession were invited to present their views to the JWG.

6.2 Firstly, an outline of the procedures involved in corneal transplantation was provided. The centre two thirds of the cornea, about an 8mm thickness is transplanted, using small incisions to remove tissue and insert new lenses. There are three main types of transplant: Penetrating keratoplasty, lamellar keratoplasty and epikeratoplasty. Limbal stem cells and sclera may also be transplanted. All of these procedures involve contact with the front of the eye. Retina may also be transplanted, which is part of the back of the eye.

6.3 There are currently 7 eyebanks in the UK. 4 undertake organ culture to facilitate longer storage times, and the other 3 only store tissues for up to 10 days. 90% of the corneas used for transplant in the UK come from 2 of the eyebanks that culture organs. Around 6000 whole eyes come into the system each year, which allows for around 3000 corneal graft operations. The whole eye is removed and stored, as this is the best way of protecting the cornea, and also provides sclera. This entails potential contamination from the tissues at the back of the eye (e.g. retina and optic nerve). The sclera shell is used for ocular plastic surgery.

6.4 The profession is now moving towards the use of single-use disposable instruments for removing tissues and performing grafts. Even though these instruments were not always designed to be single-use, the JWG were assured that the profession was keen to take this route, and that the instruments should be disposed of after use. However, the eye surgeons had particular concerns about the need to dispose of instruments used on patients who had had an ocular graft, which, if the JWG recommendation were implemented, would put them in the "at risk" category when they needed subsequent surgical intervention. They explained that all patients who had received transplanted corneas would need some follow-up surgical procedure(s), such as suture removal, and some may need several subsequent surgical interventions, for example, another transplant. Many of the instruments used in some of those procedures were very expensive, and the profession was concerned that, if they had to dispose of all the instruments, it would seriously prejudice surgical outcomes.

6.5 The number of recorded cases of transmission of CJD *via* human growth hormone (around 100 deaths) and *dura mater* (around 70 deaths), were compared to those from corneal transplant. The literature, to date, had recorded only 3 possible or probable cases of CJD transmission resulting from possibly infected cornea: one had been in Germany in 1965, another in the USA in 1974 and a third case in Japan in 1987. Since the index case, over 600,000 corneal graft operations had been performed in the USA with no further recorded cases of transmission of disease.

6.6 There had been an incident in the UK in 1997 whereby three transplant recipients had received ocular grafts from a patient who had exhibited some neurological symptoms prior to death. The brain had been sent to the CJD Surveillance Unit (CJDSU) who diagnosed sporadic CJD, and the eyebank that had processed the eyes were informed. The case was referred to SEAC who advised removal of the grafts. The transplant recipients were traced and told of the possible risks. In two cases the recipients had agreed to the grafts being explanted, while the third patient declined the offer of tissue removal. The tissues that had been removed were sent to the CJDSU for examination, and no abnormal PrP had been detected. Four years on, none of the three patients had showed any symptoms of CJD.

6.7 It was explained that since the 1997 incident, there had been a number of changes in donor selection and management and surgical practices, and handling of surgical instruments. The information required of donors had been made more stringent. A detailed medical and social history is taken and *post mortem* results are examined. It was suggested that "recent psychiatric illness" could be added to the list of donor contra-indications. Donor serum is obtained which, if necessary, could be stored indefinitely for future examination. Sclera is removed

for named patients only, and only one donor is used when two sclera are required. Eyebank instruments are now generally single-use disposable, and identification of media batch, instrument tray and personnel now takes place. In surgery, disposable trephines and disposable blocks are now used.

6.8 Other initiatives have included improved training for medical and paramedic staff and better information provided for donor families and recipients. A dedicated consent form could be introduced. The completion rate for transplant records was good and continually improving – it was suggested that this could be made mandatory. Follow-up of recipients was also acknowledged as important – it was currently recommended at 1, 2 and 5 years, although it could be done annually for 5 years, and Trusts could keep records of both donors and recipients for a stipulated number of years after the required follow-up period had been completed. A national database had also been set up.

6.9 The profession felt that the recommendation to add corneal graft recipients to the "at risk" category ignored improvements in standards in the last few years. During the presentation they had suggested a number of areas where standards could be improved further (detailed in the preceding paragraphs). In addition, they supported the profession's Code of Practice requirement that eye banks should have a more formal agreement with retrievers. It was also stated that a recipient was, in any case, at no greater risk than the donor. They also felt that implementing the JWG recommendations might lead to public confusion about the risks, adversely affecting donor supply, and have a knock-on effect for the donation of other organs and tissues.

6.10 It was stated that the points made in the presentation represented the views of the profession as a whole.

6.11 In commenting on the presentation, the JWG made a number of points. Firstly, the difference between risks from implanting tissue (primary transmission) and the risks from surgical instruments used on a corneal graft recipient then being used on subsequent patients (secondary transmission) were highlighted. It was the latter which had led to the JWG's original recommendation.

6.12 It was noted that under the policies currently in place for selecting donors, it was unlikely that 2 out of the 3 donors involved in the reported cases of CJD transmission associated with a corneal transplant would have been allowed to donate tissue in any case. Also, the three cases of possible or probable primary CJD transmission had not led to any known secondary transmission. Whilst it was acknowledged that the risks of secondary transmission were very small, it was considered that they could not however be ruled out completely. It was also mentioned that the risks from instruments used in neurological procedures on "at

risk patients" were relatively small, but the advice to dispose of these was widely accepted.

6.13 It was suggested that it might be preferable to store buffy coat from donors rather than serum, and that optic nerve could be stored for future testing. Whilst it was agreed that this was theoretically possible, it was stated that, in the first instance, as there may be a need to store these samples for some years, storage space (which was at a premium) would be a stumbling block and, in the second instance, there was not, at present, sufficient expertise within the profession to undertake such testing.

6.14 The ease of cleaning instruments and their replacement costs were other issues that needed to be taken into consideration in reaching a decision on what advice should be recommended here. Although there was movement towards the use of disposable trephines, the profession thought it unlikely that it would be feasible to develop a full set of disposable instruments, particularly on grounds of cost.

6.15 It was thought that it might be helpful to compare the risks presented by undertaking surgical procedures on corneal graft recipients with those presented by other "at risk" groups, e.g. those at risk from familial forms of CJD. It was questioned why a transplanted cornea from an apparently healthy donor should then mean that the recipient was in a high risk group; this was felt to be very different from including HgH recipients in the "at risk" category, where it was known that infected material had been used in the past.

6.16 It was agreed that, although further delay in reaching a decision on this issue was not ideal, there was a clear case for further consideration in the light of concerns about general patient care and cost benefits, and the feasibility and advantages of putting in place the further improvements to procedures etc proposed during the presentation. It was felt that the steps taken to improve standards so far, particularly on donor exclusion, provided a degree of re-assurance.

6.17 It was suggested that DH's EOR Division should be asked to undertake an assessment of risks of transmission of CJD *via* surgical instruments used in procedures involving the brain, spinal cord or eye of a corneal graft recipient, particularly in the light of the improvement in standards and procedures detailed in the presentation from the eye surgeons, and set out in the paragraphs above. EOR would also be asked to consider the relative risks posed by different types of "at risk" patients, e.g. those at risk from familial forms of CJD versus corneal graft recipients or corneal graft recipients, versus *dura mater* recipients.

6.18 It was agreed that the issues would be discussed further at the next JWG meeting in October, taking into account the risk assessment to be requested from EOR. The aim would be to reach a final recommendation at that meeting, ultimately for ACDP and SEAC agreement.

AGENDA ITEM 7 – Any other business

7. There were no additional items raised.

AGENDA ITEM 8 - Papers for information

8. A number of papers for information were included with the meeting papers, and extra papers for information were tabled at the meeting.

AGENDA ITEM 9 – Date(s) of next meeting (s)

9. The next two meetings had been arranged for Wednesday 17th October 2001 and Wednesday 13th February 2002. Both meetings would be held at the Department of Health, Skipton House, Room 102/124A and would commence at 11am.

Secretariat **September 2001**