CJD INCIDENTS PANEL

Twelfth Annual Report
1st January 2012 to 31st March 2013
to Advisory Committee on Dangerous Pathogens
Transmissible Spongiform Encephalopathies
Risk Management Sub Group

Foreword

I am pleased to introduce the 12th and final annual report of the CJD Incidents Panel. The Panel was set up in 2000 by the Chief Medical Officer to advise hospitals, trusts and public health teams across the UK about the management of incidents involving all forms of CJD, in order to reduce the risk of secondary transmissions given the potential of a self-sustaining epidemic of variant CJD. The Panel has been a unique entity with only one similar body based in Australia, and therefore notwithstanding a UK responsibility, a world class resource. This is the last report as the Panel was dissolved on 31st March 2013. The reasons for this are linked to economic constraints, and the fact there is no evidence of a self-sustaining epidemic becoming established. A large number of people remain considered as at increased risk of CJD through their possible exposure. The Panel leaves a strong legacy based on decision precedents and framework advice, documentation of which remains available through the National Archives. They have also been incorporated into a new guidance document, approved by the Panel and available on the Public Health England website. The management of incidents of healthcare exposure to CJD is now devolved to hospitals, trusts and public health teams who are able to readily access the wealth of information and advice left from the Panel's considerations.

As has been the case in previous years, the work covered during 2012 demonstrates considerable focus on those who may have been exposed to CJD through exposure to high numbers of blood transfusions, and treatment with blood products. This work has been highly challenging, not least because of what is still unknown. Modelling exercises using results of prevalence studies of abnormal prion protein in lymphoid tissue suggest that there may well have been further blood-borne transmissions of variant CJD, which we have not seen as clinical cases so far. In addition, advice has been provided for notification processes for those possibly exposed through subsequent use of surgical instruments after use on a patient later diagnosed with CJD. The Panel has remained an outstanding forum for discussion and debate on new evidence relating to all forms of CJD taking into consideration new data on prevalence and infectivity of tissues and organs.

During the period covered by this report, much of the Panel's focus, other than providing guidance to specific incidents, has revolved around developing further the options for how to manage those who have been highly transfused. Panel representations have also contributed to discussions of preparing national guidance for those who may have to implement a 'notifications process' not just for CJD incidents, but including a wider range of healthcare issues ranging from systems failure in screening process to potential infections which may have been transmitted through healthcare workers. Most important, since notice of the end date for the Panel, has been preparation of published CJD specific guidance, for investigation and management of surgical incidents, in a format compatible with devolving this critical work to trusts and other bodies.

Until 31st March the CJD Incidents Panel worked very closely with the Advisory Committee on Dangerous Pathogens TSE Working Group, now known as the ACDP TSE risk management sub group. This group will be the likely forum for issues which cannot be resolved by trusts alone as it retains a cohort of members who have a broad base of experience working in this field.

In acknowledging the high commitment of Panel members, not just in the period 2012 to 31st March 2013, but throughout its duration, considerable thanks also goes to the Panel Secretariat, which was provided by the CJD Section of the Health Protection Agency, who worked tirelessly to ensure that advice is communicated effectively to those working in the field and dealing with any subsequent question or issue arising. Ensuring Panel members are kept fully up to date on developments in the understanding of Prion Disease is invaluable in an area where science and medicine still has much to learn.

As lay and independent Chairman between 2005 and 2013, I take this opportunity to thank all those involved; it has been my privilege to work with esteemed colleagues considering this most complex of issues. On this basis I commend this report to you as a fair and accurate account of the work achieved during this final period.

David Pryer

Chairman.

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Following the dissolution of the CJD Incidents Panel, on the 31st of March 2013, the following arrangements apply:

- Responsibility for investigating, assessing and managing CJD incidents (and where appropriate notifying patients) rests with local trusts, health boards and health protection teams in the same way as most other incidents that place patients at infection risk. National guidance on CJD incident management is available to support this[1].
- Long term public health surveillance of CJD exposures will continue and trusts, health boards and health protection teams are asked to continue reporting the occurrence of incidents to the CJD Section of Public Health England, in particular if they involve a patient notification exercise.
- Novel issues that arise with respect to CJD risk management and infection control, or difficulties with interpretation of current guidance, can be referred to the CJD Section at Public Health England. If necessary advice may be sought from the ACDP TSE Risk Management Subgroup.

[1] CJD Guidance and Advice CJD website, Public Health England (2013)

1 Introduction

This is the twelfth and final annual report of the Creutzfeldt - Jakob disease (CJD) Incidents Panel (the Panel). This report summarises the activities of the Panel (and related events) during the period 1st January 2012 to 31st March 2013 and presents data on annual trends. Previous Panel reports are available from the CJD Incidents Panel website[i].

1.1 Background

The Panel was an independent expert advisory committee established in 2000 on behalf of the UK Chief Medical Officers (CMOs). It advised all those bodies responsible for the provision and delivery of healthcare on how to manage incidents involving the potential transmission of CJD between patients. The CJD Section of Public Health England (formerly the Health Protection Agency (HPA)) provided the Secretariat for the Panel. The Secretariat transferred from the Department of Health in 2003.

1.2 Role

The Panel advised organisations which provide and deliver healthcare, on the management of CJD incidents. CJD incidents (incidents) arise when there is potential transmission of any form of CJD between patients through clinical interventions, including via surgical instruments, tissues, organs and blood (see section 2.1 for definitions of incidents). The Panel gave advice on a case by case basis. By 2010/2013 a significant amount of this advice was based on precedent and did not require specific discussion by the Panel. The principles underlying the advice are set out in the 'CJD Incidents Panel Management of possible exposure to CJD through medical procedures: Framework Document'.

1.3 Accountability and membership

The Panel also advised healthcare teams on the need to follow up patients potentially exposed to CJD, how to conduct patient tracing and notification exercises, and how to deal with equipment that may have become contaminated with abnormal prion protein. The Panel advised, rather than instructed. However, if Panel advice was not being taken in a particular situation, the Panel would advise that good reasons for this should be available, and might need to be given to the Strategic Health Authority or the Care Quality Commission.

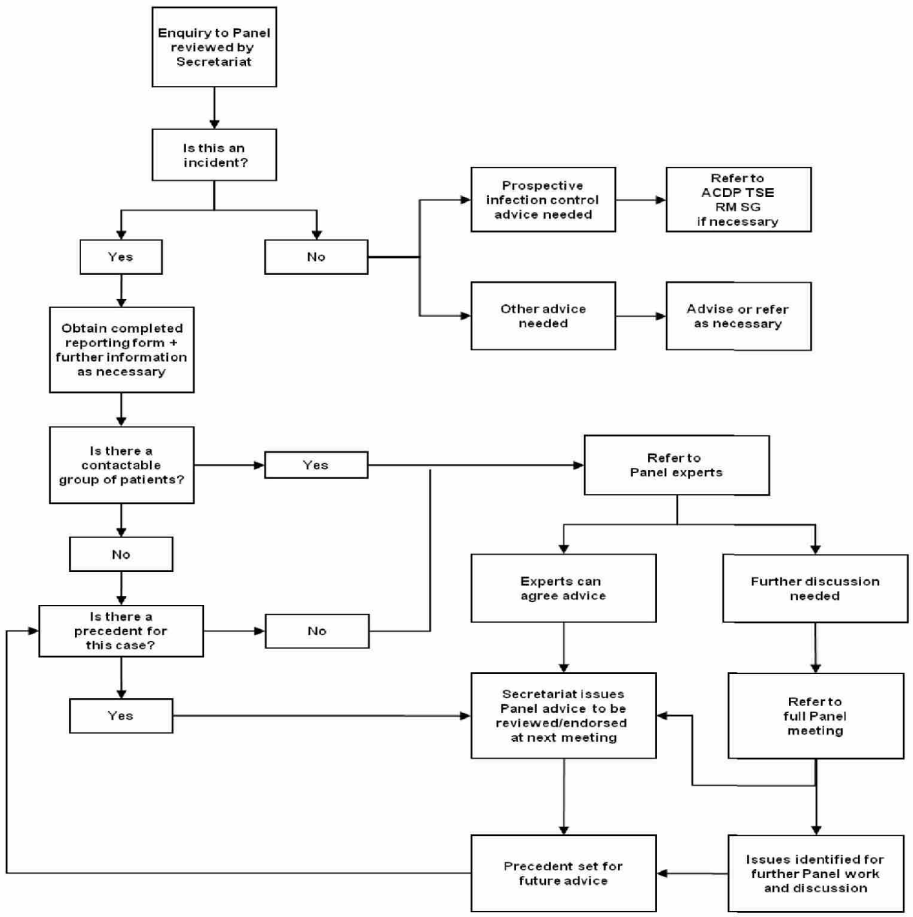
1.4 Panel meetings and advice for incidents

The full Panel met four times in this reporting period. The minutes of full Panel meetings are provided, in confidence, to the ACDP TSE RM SG[a]. Summaries of full Panel meetings are published on the Panel website[i].

In addition to the full Panel meetings, subgroups of the Panel considered details of specific issues. Between meetings, individual Panel members (and other experts if required) provided the Secretariat with advice by telephone and correspondence as necessary.

Figure 1 shows an overview of how enquiries to the CJD Incidents Panel were managed, and how Panel advice was prepared.

Figure 1: Overview of management of enquiries to the CJD Incidents Panel



[a] ACDP TSE RM SG – Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy Risk Management Subgroup

2 Incidents and reports notified to the Panel to 31st March 2013

2.1 Definitions and procedures

An incident arises when a patient who is diagnosed or suspected of having CJD, or who is identified as at risk' of CJD, has undergone a medical procedure which could put other patients at risk of CJD through contaminated instruments and/or devices, blood or other tissues or organs. Healthcare professionals have been asked to report these incidents to the Panel.

When a patient who is diagnosed or suspected of having CJD, or who is identified as 'at risk' of CJD, has undergone a medical procedure but it is assessed that others have not been exposed, this is termed a "CJD report" rather than an incident. Both incidents and reports are monitored. CJD reports do not involve the tracing and notification of exposed patients.

This extended annual report covers incidents and reports notified to the Panel, via the Secretariat to 31st March 2013 and is based on the information to 5th April 2013. Box 1 categorises the different types of incidents by the status of the index patient and the types of medical procedures involved.

Box 1: Incident types reported to the CJD Incidents Panel

Reason for incident	Index patient	
	Symptomatic CJD or vCJD or suspected CJD/vCJD	**Asymptomatic** 'at risk' of CJD/vCJD
Surgery Subsequent use and exposure to instruments after high/medium risk surgery within the relevant infectivity period, usually before the index patient was diagnosed.	Surgical incident	'At risk' surgical incident[a]
Blood Allogenic blood donation collected during (presumed) incubation of disease, and transfused to an identified patient[b]	Blood incident	'At risk' blood incident[a]
Plasma products Plasma donation collected during (presumed) incubation of disease and used to manufacture plasma products[b]	Plasma product incident	'At risk' plasma incident[a]
Organ/tissue donation or receipt Donation of any tissue during (presumed) incubation of disease or receipt of any tissue from a case during (presumed) incubation of disease	Organ/tissue incident	'At risk' organ/tissue incident[a]
Other Any other incident the Panel considers appropriate for review and advice	Other incident	Other 'at risk' incident[a]

[a]The 'at risk' prefix used here to describe the criteria for an incident is not used through the text to this report, i.e. 'surgical incidents' in the body text of this report include those where the index patient was diagnosed with CJD and those who are 'at risk'.
[b]Reporting of blood donations (including plasma donations) from diagnosed cases is initially done via the National CJD Research & Surveillance Unit (NCJDRSU) and UK blood services (under the Transfusion Medicine Epidemiology Review (TMER) 2 protocol) and only reported as an 'incident' to the CJDIP if the implicated components are known to have been transfused to an identifiable recipient, or if the plasma is known to have been used in the manufacture of products for the treatment of humans.
vCJD: variant CJD

Other enquiries made to the CJDIP are termed "non-incidents". The Panel Secretariat gave advice on a range of these during the reporting period. These included consultation about non-UK incidents, infection control, and clarification of 'at risk' status. These other enquiries are discussed in section 3.

Some of the incidents reported to the Panel concerned patients who subsequently received an alternative diagnosis. They continue to be counted as incidents as they represent Panel workload and give an indication of the difficulties of diagnosis.

2.2 Changes in Panel data collection

In June 2010 an algorithm for reporting surgical incidents was posted on the HPA (now PHE) website. This stated that only surgical procedures which required further investigation or action (i.e. procedures involving high or medium infectivity tissues during the period of tissue infectivity for different CJD types) should be reported to the CJD Incidents Panel. In November 2010 the algorithm was modified to request that all procedures be reported, but those which did not require further investigation or action would be categorised as 'CJD reports'. The data collected on CJD reports collect limited information on the index patient, the procedures identified, speciality and the country of the report. Therefore the summary data on reports are limited to these details.

2.3 Overview of surgical incidents and reports

Between 1st Jan 2012 and 31st March 2013, 8 surgical incidents and 27 surgical reports were notified to the Panel Table 1 shows the breakdown of these by the categories outlined in Box 1.

Table 1: Requests for Panel advice on CJD incidents and reports by incident type and index patient status, 1st January 2012 to 31st March 2013

Incident/report type	CJD Incidents		CJD Reports	
	Symptomatic	'At risk'	Symptomatic	'At risk'
Surgical	2	6	22	5
Blood	-	-	-	-
Plasma	-	-	-	-
Organ/tissue	-	-	-	-
Other	-	-	-	-

2.3.1 Country

Between 1st January 2000 and 31st March 2013, 457 surgical incidents and 71 reports were notified to the Panel, 528 notifications in total. Of these, 443 (84%) were from England, 44 (8%) from Scotland; 25 (5%) from Wales and 14 (3%) from Northern Ireland (Table 2).

Table 2: Surgical incidents and reports by country, 2000-2013

Country	Year incident/report notified to Panel														Total	
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013[b]	N	%
England	14	30	45	47	40	50	53	25	31	21	24	37	25	1	**443**	**84**
Scotland	-	7	4	2	5	4	7	1	2	3	2	4	3	-	**44**	**8**
Wales	2	-	5	1	-	1	1	-	-	4	1	9	1	-	**25**	**5**
Northern Ireland	-	1	1	-	-	1	2	1	-	1	-	2	5	-	**14**	**3**
Unknown	-	-	1	-	-	-	-	-	-	-	-	1	-	-	**2**	**0**
Total incidents	**16**	**38**	**56**	**50**	**45**	**56**	**63**	**27**	**33**	**29**	**23**	**13**	**8**	**-**	**457**	
Total reports[a]	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**4**	**40**	**26**	**1**	**71**	
TOTAL	**16**	**38**	**56**	**50**	**45**	**56**	**63**	**27**	**33**	**29**	**27**	**53**	**34**	**1**	**528**	

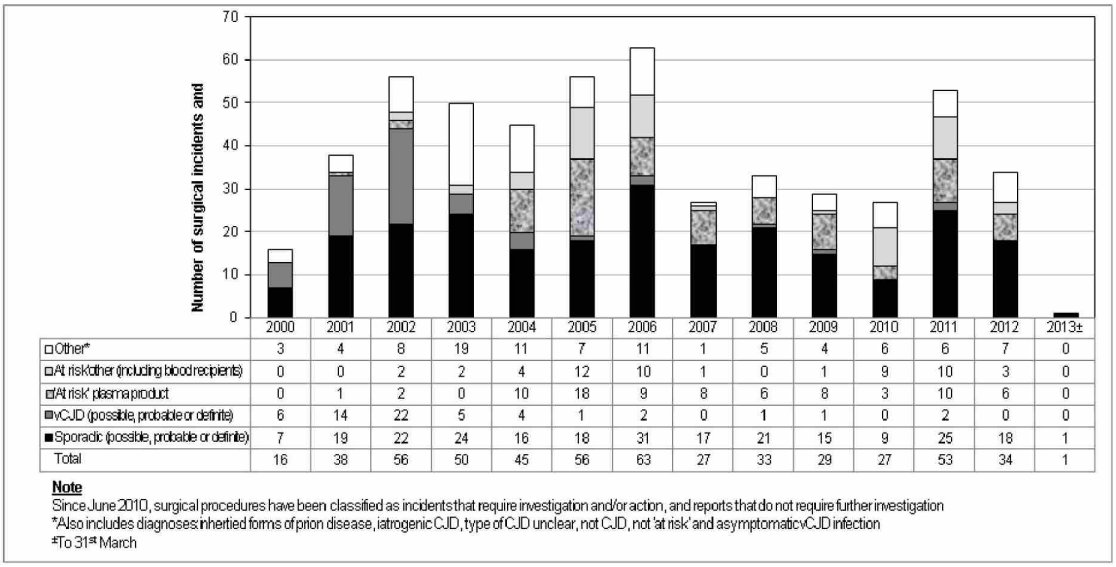
[a]Data for surgical reports were collected from November 2010
[b]To 31st March

2.3.2 CJD status of index patient

Panel advice regarding incidents and reports is based on standard international CJD classifications. For symptomatic cases, local incident teams are requested to provide the Panel with the National CJD Research and Surveillance Unit (NCJDRSU) or National Prion Clinic (NPC) diagnosis.

Figure 2 below shows the number of CJD surgical incidents and reports by diagnosis of index patient and year of reporting.

Figure 2: Surgical incidents and reports by diagnosis of index patient, 2000 – 2013



	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013±
Other*	3	4	8	19	11	7	11	1	5	4	6	6	7	0
At risk'other (including blood recipients)	0	0	2	2	4	12	10	1	0	1	9	10	3	0
'At risk' plasma product	0	1	2	0	10	18	9	8	6	8	3	10	6	0
vCJD (possible, probable or definite)	6	14	22	5	4	1	2	0	1	1	0	2	0	0
Sporadic (possible, probable or definite)	7	19	22	24	16	18	31	17	21	15	9	25	18	1
Total	16	38	56	50	45	56	63	27	33	29	27	53	34	1

Note
Since June 2010, surgical procedures have been classified as incidents that require investigation and/or action, and reports that do not require further investigation
*Also includes diagnoses: inherited forms of prion disease, iatrogenic CJD, type of CJD unclear, not CJD, not 'at risk' and asymptomatic vCJD infection
±To 31st March

Of the 457 surgical incidents reported between 1st January 2000 and 31st March 2013 (Table 3), there were 197 (43%) in which the index patient had sporadic CJD; 57 (13%) in which the index case had variant CJD (vCJD); and 101 (22%) in which the index patients were 'at risk' of vCJD either because they were blood component recipients (22 cases), or because they were plasma product recipients (79 cases). In 30 (7%) incidents the index case either had, or was 'at risk' of, inherited prion disease; and in 10 (2%) incidents the diagnosis of CJD was unlikely, or the type of CJD was unclear.

The majority (6 of the 8) of surgical incidents reported in 2012 involved index patients who were 'at risk' of vCJD because they were recipients of UK sourced plasma products. One involved an index case with an inherited form of prion disease and one involved an index case who was subsequently classified as not having CJD and given an alternative diagnosis. For the first year since the formation of the Panel, no incidents involved index patients with sporadic CJD.

Of the 27 reports received in 2012/2013 the majority (N=19, 70%) involved index patients with sporadic CJD. Three (11%) involved index cases who were 'at risk' due to exposure through previous surgery. One involved an index case with a diagnosis of iatrogenic CJD. Two involved an index case where the patient was subsequently found not to be at increased risk of CJD and two where the diagnosis has been proven to not be CJD.

Table 3: Surgical incidents by CJD status of index patient, 2000-2013

CJD status of index patient	Year incident notified to Panel														Total	
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013[b]	N	%
Sporadic (possible, probable or definite)	7	19	22	24	16	18	31	17	21	15	5	2	-	-	**197**	**43**
vCJD (possible, probable or definite)	6	14	22	5	4	1	2	-	1	1	-	1	-	-	**57**	**13**
Familial & 'at risk' familial	-	2	2	7	1	3	7	-	2	3	2	-	1	-	**30**	**7**
'At risk' vCJD blood component recipient	-	-	-	-	3	10	5	1	-	-	2	1	-	-	**22**	**5**
'At risk' vCJD plasma product recipient	-	1	2	-	10	18	9	8	6	8	3	8	6	-	**79**	**17**
'At risk' other[a]	-	-	2	2	1	2	5	-	-	1	7	-	-	-	**20**	**4**
CJD type unclear/ CJD unlikely	1	1	-	4	1	1	2	-	-	-	-	-	-	-	**10**	**2**
Not CJD/other CJD/no longer considered 'at risk'	2	1	6	8	8	3	2	1	3	-	4	1	1	-	**40**	**9**
Asymptomatic vCJD infection	-	-	-	-	1	-	-	-	-	1	-	-	-	-	**2**	**0**
Total	**16**	**38**	**56**	**50**	**45**	**56**	**63**	**27**	**33**	**29**	**23**	**13**	**8**	**-**	**457**	

[a]Includes 'at risk': surgically exposed, highly transfused, other blood recipients, blood donors, past recipients of human growth hormone, dura mater grafts or gonadrotropin.
[b]To 31st March

2.3.3 Clinical specialties

The 457 surgical incidents reported to the Panel between 1st January 2000 and 31st March 2013 involved 1174 procedures (Table 4). The number of procedures reported per surgical incident varied from one to 17 with a median of two.

Procedures reported involved contact with a range of tissues of differing levels of potential CJD infectivity and a variety of medical specialties. The four most common types of procedures involving tissues with high- or medium-infectivity levels were gastroenterology (240), ophthalmology (116), orthopaedics (107), and neurology/neurosurgery (73).

The 71 surgical reports reported to the Panel between November 2010 and 31st March 2013 involved 245 procedures. The number of procedures reported per surgical report varied from one to 12 with a median of two.

The four most common types of procedures reported for surgical reports were gastroenterology (34), orthopaedics (17), urology/renal (15), cardiology & cardiothoracic procedures (15).

Table 4: Clinical specialties involved in incidents by number of procedures and year incident notified to Panel, 2000-2013

Specialty	Year incident notified to Panel														Total	
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013[b]	N	%
Gastroenterology	4	10	32	9	25	25	25	35	12	15	21	18	9	-	**240**	**20**
General surgery	5	8	8	16	28	25	26	11	10	1	5	4	8	-	**155**	**13**
Ophthalmology	2	7	6	7	12	16	14	17	15	8	7	4	1	-	**116**	**10**
Orthopaedics	2	10	16	23	8	15	10	6	3	8	3	2	1	-	**107**	**9**
Neurology/Neurosurgery	2	8	11	10	4	9	15	4	2	1	5	-	2	-	**73**	**6**
Ear, nose and throat	3	7	13	9	5	6	9	2	6	5	6	-	1	-	**72**	**6**
Obstetrics & Gynaecology	2	7	9	12	5	3	12	3	9	3	1	1	1	-	**68**	**6**
Urology/Renal	1	5	4	6	20	8	4	2	1	1	1	1	-	-	**54**	**5**
Dentistry	-	5	10	8	5	5	3	-	5	-	1	3	2	-	**47**	**4**
Cardiology & Cardiothoracic	4	3	9	5	4	4	2	2	1	4	-	2	-	-	**40**	**3**
Other[a]	2	5	11	23	10	12	22	11	51	37	8	10	-	-	**202**	**17**
Total	**27**	**75**	**129**	**128**	**126**	**128**	**142**	**93**	**115**	**83**	**58**	**45**	**25**	**-**	**1174**	

[a]Includes a range of specialties e.g. accident and emergency, anaesthesia, dermatology, general practice, radiology and pain clinic
[b]To 31st March

2.3.4 Initial Panel advice on surgical instruments

The Panel have assessed the risk that instruments used in surgical incidents could transmit CJD infection. As a result advice is sometimes given to:

- quarantine identified instruments, to protect other patients.
- remove or quarantine several instruments If hospitals cannot identify which instruments were used on the index patient

As further information about an incident becomes available the advice may change and certain instruments may be released from quarantine and returned to use or advised to be destroyed or kept for exclusive use on the index patient.

Initial advice to quarantine was given in 160 (35%) of the 457 surgical incidents reported to the Panel 2000 to 31st March 2013 (Table 5). A Trust may also independently quarantine instruments before reporting an incident; whilst awaiting advice from the Panel, so it is likely that the overall number of instruments removed from use will be higher.

Table 5: Proportion of incidents where the Panel has advised initial quarantine of surgical instruments, 2000-2013

	Year incident notified to Panel														Total
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013[a]	
Surgical incidents where initial advice to quarantine was given	13	22	28	15	18	14	19	9	5	4	5	8	-	-	160
Total surgical incidents	16	38	56	50	45	56	63	27	33	29	23	13	8	-	457
% of surgical incidents where initial to quarantine was given	**81**	**58**	**50**	**30**	**40**	**25**	**30**	**33**	**15**	**14**	**22**	**62**	**0**	**-**	**35**

[a]To 31st March

2.3.5 Final instrument advice

Where several instruments are identified during investigation of a single incident, the final advice for each depends on the tissues involved and the type of procedure. This means that within a single incident there may be different advice for different instruments involved. Advice is reviewed as new information on CJD diagnoses becomes available.

Table 6 shows the different types of advice given more than one action advised during an incident, means the total actions advised (N = 489) exceed the total number of incidents (N = 457). In 77% of incidents, the Panel either advised that quarantined instruments could be returned to use or to take no action if the instruments remained in use. These figures do not include instruments that were quarantined or destroyed according to recommended infection control procedures, which did not therefore lead to a CJD incident.

Table 6: Final Panel advice for instruments, 2000-2013

Final advice for some/all instruments	Year incident notified to Panel														Total	
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013[b]	N	% of incidents
Return to use or no action	8	25	27	46	37	42	53	20	28	28	19	10	7	-	**350**	**77**
Destroy	4	8	6	3	4	12	4	3	2	-	-	-	1	-	**47**	**10**
Quarantine	3	6	13	2	2	1	2	4	2	-	-	1	1	-	**37**	**8**
Missing information	2	3	12	1	-	1	1	-	-	-	-	-	-	-	**20**	**4**
No advice given	-	-	-	1	3	3	5	2	4	-	-	-	-	-	**18**	**4**
Remove from general use[a]	-	-	-	-	-	-	-	1	-	4	6	4	2	-	**17**	**4**
Total	**17**	**42**	**58**	**53**	**46**	**59**	**65**	**30**	**36**	**32**	**25**	**15**	**11**	-	**489**	
Total incidents	**16**	**38**	**56**	**50**	**45**	**56**	**63**	**27**	**33**	**29**	**23**	**13**	**8**	**0**	**457**	

[a]In 2009 the Panel started advising Trusts that they could choose between destroying instruments, reserving them for exclusive use on the index patient, sending them to Porton Down instrument store for research purposes, or in the case of endoscopes, refurbishing them.
[b]To 31st March

2.3.6 Instrument traceability

If an index patient has had an operation or endoscopy which could have involved contact with medium- or high-infectivity tissues then local healthcare teams should identify the instruments involved. If this can be done, the local teams will then identify the patients who were subsequently exposed to these instruments (referred to as surgical contacts of the index case) and notify them that they are at an increased risk of CJD for public health purposes where appropriate.

If the local team is unable to identify the instruments or instrument trays used on the index patient, or to identify the subsequent patients on whom these instruments were used with certainty, then in general no individuals are notified that they are 'at risk'. In these circumstances patients are considered to be at uncertain risk since their exposure to potentially contaminated instruments cannot be confirmed.

In 2000, a Health Service Circular[ii] advised NHS Trusts to have 'taken steps towards having systems in place to enable the tracing of surgical instrument sets to patients on whom they have been used' by 31st March 2002. Incidents can involve operations carried out before that date and difficulties in tracing instruments may not reflect

current hospital practice. Table 7 shows that overall, in 54% of incidents, some or all instruments were reported to be traceable.

Table 7: Traceability of surgical instruments from incidents, 2000-2013

	Instrument traceability reported	Year incident notified to the Panel														Total
		2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013[b]	
Number of incidents	Some or all instruments traced	9	17	27	19	30	28	31	19	18	16	14	12	7	-	**247**
	No instruments traced	6	7	12	19	5	14	7	5	13	5	2	-	-	-	**95**
	Information not provided	-	12	16	12	9	12	22	2	2	8	7	-	-	-	**102**
	Not applicable[a]	1	2	1	-	1	2	3	1	-	-	-	1	1	-	**13**
	Total	**16**	**38**	**56**	**50**	**45**	**56**	**63**	**27**	**33**	**29**	**23**	**13**	**8**	-	**457**
% of incidents	Some or all instruments traced	56	45	48	38	67	50	49	70	55	55	61	92	88	-	**54**
	No instruments traced	38	18	21	38	11	25	11	19	39	17	9	-	-	-	**21**
	Information not provided	-	32	29	24	20	21	35	7	6	28	30	-	-	-	**22**
	Not applicable[a]	6	5	2	-	2	4	5	4	-	-	-	8	12	-	**3**

[a]For example, if the instruments used were disposable.
[b]To 31st March

2.4 Other incidents and reports

No incidents concerning potential transmission of CJD though organs and tissues, blood or plasma were reported to the Panel in 2012/13.

3 Identification and Notification of patients at increased risk of CJD

3.1 Patients informed that they are 'at risk' of CJD for public health purposes

The Panel has usually advised that patients should only be informed that they are 'at risk' of CJD if they have been identified with certainty as having been exposed to CJD as a result of their healthcare. People who are 'at risk' of CJD should follow public health precautions to reduce the risk of transmitting CJD to other patients.

'At risk' patients are first identified through one of the following routes:

- Incident management (recipients, donors, other recipients, plasma and surgical 'at risk'),
- Pre-surgical assessment (highly transfused, see section 3.1.2)

The Panel has advised that all living 'at risk' patients should be notified. In a small number of cases, local teams have decided that the potential psychological harm to the patient caused by the notification would have adverse consequences and they have decided not to notify the patient. In some cases, local teams may be unable to locate a patient or their GP and therefore are unable to confirm that the patient has been notified. Therefore, a small number of 'at risk' patients will be recorded as 'alive but not notified'.

In some circumstances, patients may be 'notified by proxy', whereby relatives/carers are informed instead of the patient because the patient is thought unable to understand the information; for example, children and patients with dementia.

'At risk' patients may have died before they were identified as being at increased risk of CJD. In this case they will be recorded as having 'died before notification'.

3.1.1 Surgical 'at risk' patients

Between 1st January 2000 and 31st March 2013 the CJD Incidents Panel had identified 210 individuals from 29 surgical incidents as being surgical contacts of an index case and at increased risk of developing CJD. Local decisions were taken not to notify six individuals, 29 died before being notified and 12 patients are pending notification leaving a total of 163 surgical 'at risk' patients who have ever been notified, six of whom were notified by proxy. Figure 3 shows the notification history for these 210 surgical 'at risk' patients ever identified following invasive procedures. Following re-assessments of tissue infectivity in 2005, 2006 and 2009 the Panel advised that 38 patients/proxies should be denotified, and informed that they were no longer considered to have an increased CJD risk. An audit of the denotification process in 2011 found that four patients were never notified, 26 denotifications were confirmed, and eight had died before denotification.

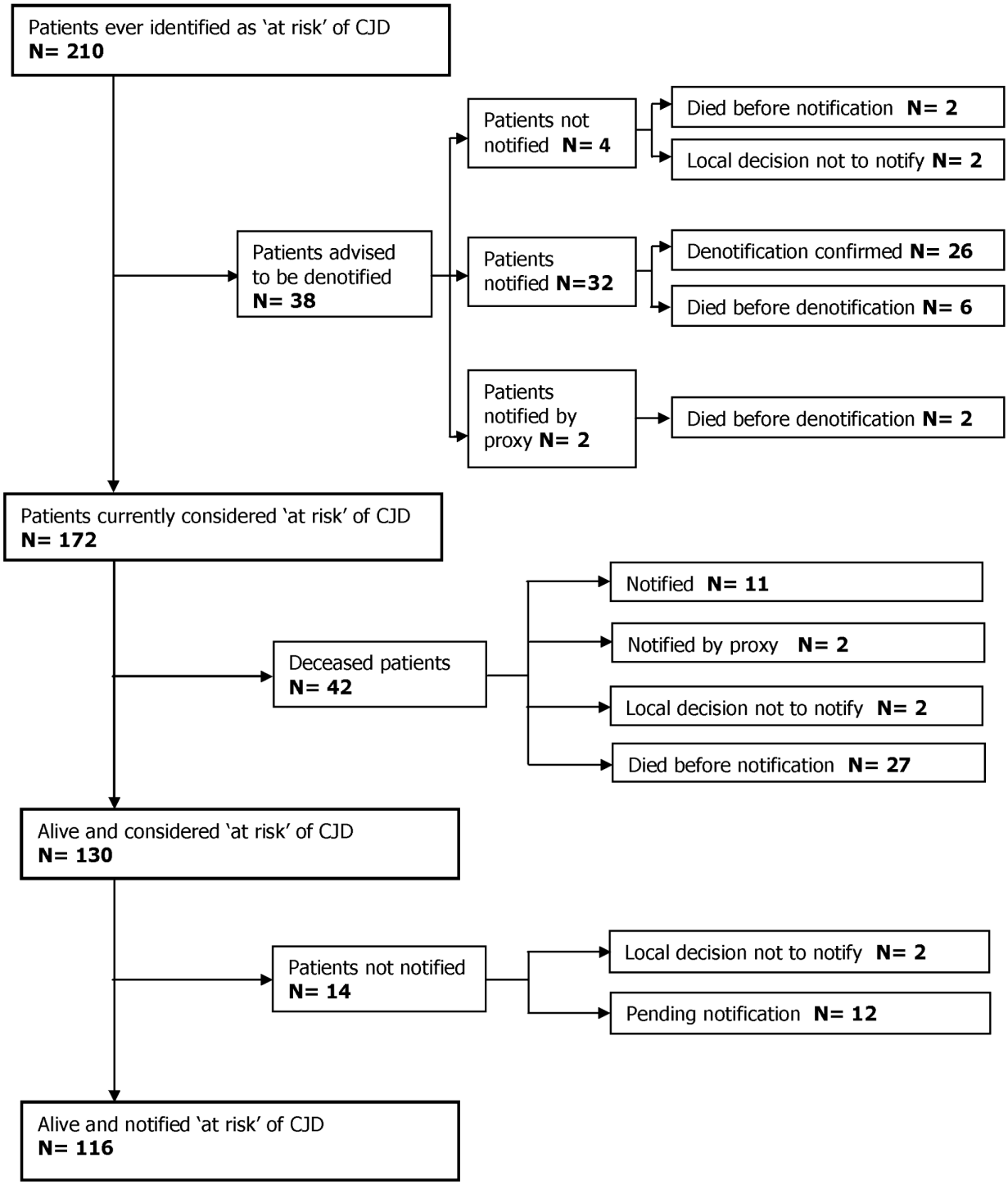
As at 31st March 2013, 172 patients were considered to have an increased risk of CJD following a surgical incident. Of these, 130 were alive and 116 alive and notified (including two patients notified by proxy).

In 2012/13:

- 18 patients were identified as 'at risk' as a result of an incident involving intradural neurosurgery on an index patient with inherited prion disease. At the time of reporting, 6 of these patients were reported to have died since the exposure and the remaining 12 are pending notification.

- One patient was identified as 'at risk' due to surgery with instruments previously used on a patient who was subsequently found to have received blood components from a vCJD case. The patient died before notification.
- One patient was notified as 'at risk' of CJD due to surgery with instruments previously used on a patient who was subsequently diagnosed with sporadic CJD.

Figure 3: Breakdown of patients ever identified as 'at risk' of CJD following an invasive surgical procedure by notification status as at 31/03/2013



3.1.2 Highly transfused patients

In 2009 the guidance for pre-surgical CJD assessment was revised to identify and notify highly transfused patients with ≥80 donor exposures if they present for high risk surgery.

Between July 2009 and the end of 2012, eleven highly transfused patients had been identified in this way. Of these only four had been correctly identified prior to high risk surgery, others were identified preceding medium risk procedures. The total number identified falls short of the estimated numbers expected (50-60 per year in England). A review of the pre-surgical assessment approach to identifying and managing surgical risks for CJD in these individuals has since been conducted and an alternative approach to surgical risk management for highly transfused patients is under consideration in 2013. This alternative is yet to be formally defined and is subject to further discussion and consultation with stakeholders.

4 Other enquiries to the Panel in 2012/13

In 2012/13, 77 other enquiries were received by the Panel Secretariat. The majority of these enquires (55) related to infection control advice; three involved CJD cases with no surgical history, two involved non-UK incidents and the remaining 17 enquiries included queries about a patient's CJD risk status, the CJD risks associated with medical products, interpretation of the incident management and highly transfused guidance and advice on occupational health issues.

5 Precedents, guidance and publications

5.1 Procedure risk clarifications

The following risks were clarified through Panel discussions in 2012/13:

- Craniotomy for acute on subdural haematoma – discussions by the Panel, including expert neurosurgery input, concluded that this procedure involved formally opening the dura surrounding the brain in a patient with symptomatic inherited prion disease and therefore should be regarded as involving high risk tissue
- Laparotomy and small bowel resections and laparotomy and formation of bowel stoma and lavage – both procedures were discussed by the panel who concluded both involve tissue of medium infectivity for patients with vCJD or at risk of vCJD.

5.2 Revision of Annex F of the ACDP TSE RM SG guidance

Annex F provides infection control guidance on the use of flexible endoscopes on patients with or at an increased risk of CJD/vCJD. In 2012 it was agreed that flexible endoscopes used for most individuals at increased risk of vCJD, could be returned to use following a single cycle of decontamination to an approved standard. This was based on a report to the Department of Health prepared by the Advisory Committee on Decontamination Science and Technology taking account of the considered view of a group of protein chemists, TSE researchers and decontamination experts, which was subsequently translated into the guidance document CFPP 01-06. Annex F was revised to align with the advice in CFPP 01-06 which allowed for endoscopes that have been used on most patients at increased risk of vCJD to be returned to general use providing they have been decontaminated according to the national standards, with a few additional precautions, now set out in both documents. The revisions to Annex F mainly concern gastrointestinal endoscopy. These changes will significantly reduce the number of endoscopes that have to be removed from general use and will likely also reduce the number of CJD surgical incidents.

5.3 Guidance to identify and manage CJD surgical incidents

As a result of the dissolution of the CJD incidents Panel a guidance document has been produced[b]. The document is intended for use by trusts, hospitals, local health protection teams and health boards. It provides advice and information for the public health follow up required following a report of:

- a newly diagnosed or suspected case of CJD
- a person at increased risk of CJD
- a surgical procedure carried out on a patient with CJD or at increased risk of CJD where TSE infection control guidelines were not followed.

5.4 Organ and tissue position statement revision

The organ and tissue position statement, which describes the risk assessment and public health action for donors and recipients of organs and tissues to/from individuals diagnosed with CJD, was revised in 2012 to state that:

[b] CJD Guidance and Advice CJD website, Public Health England (2013)

- No actions are required for donors of low infectivity organs/tissues to recipients who later develop sporadic CJD
- No actions are required for the other recipients of low infectivity organs from these donors
- No actions are required for recipients of low infectivity organs and tissues (including anterior eye) from donors who later develop sporadic CJD (and other non variant types of CJD)

6 People exposed to CJD risks

6.1 Occupational exposure to TSEs

A joint project between the NCJDRSU and HPA was initiated in 2010 to set up a registry to standardise reporting, establish a central database, and monitor the risk of CJD in healthcare and laboratory workers. The registry has two components:

6.1.1 Review of possible occupational exposures of reported CJD cases who were Healthcare or Laboratory Workers:

In order to investigate the possibility of transmission of TSEs from CJD patients to healthcare workers and from TSE infected tissues or animals in laboratories to laboratory workers. The NCJDRSU identified all individuals diagnosed with sporadic or variant CJD who had a history of working in a laboratory or in healthcare. Two vCJD and two sCJD cases who were previously laboratory workers were identified and their history of possible occupational exposure was followed up. No potential exposures were identified. A similar exercise to retrospectively review potential exposure to/from healthcare workers through contact with patients is ongoing.

6.1.2 Registry of occupational exposures to CJD and other TSEs that have been reported to occupational health departments or to PHE (and previously the Health Protection Agency (HPA)):

A register was set up in 2010 to allow the prospective long term follow up of any possible occupational exposures to CJD. In 2010 and 2011 two laboratory workers were enrolled into the registry.

6.2 Public Health Monitoring of people at increased risk of CJD

Individuals at increased risk of CJD as a consequence of their medical care are informed of their risk and asked to follow public health precautions to avoid transmitting the infection to others. They are also followed-up to help determine the risks of CJD spreading to patients through different routes and to ascertain whether any people who may have been exposed to increased CJD risks go on to develop CJD.

Follow-up activities include clinical monitoring, GP updates, genotyping individuals, collecting blood or tissue specimens and carrying out post mortem investigations to determine whether asymptomatic individuals in these groups have been infected with the CJD agent. These activities are performed by a number of different organisations: Public Health England (and previously the Health Protection Agency (HPA)), Health Protection Scotland (HPS), UCL Institute of Child Health/Great Ormond Street Hospital (ICH), NHS Blood and Transplant (NHSBT), National CJD Research and Surveillance Unit (NCJDRSU), National Prion Clinic (NPC), and UK Haemophilia Centre Doctors' Organisation (UKHCDO).

Data are collected from these different organisations every six months. Here, we present data correct as at 31st December 2012.

Table 8: Summary of all 'at risk' groups (Data correct as at 31st December 2012*)

'At risk' group	Identified as 'at risk'	Notified as 'at risk'		Cases	Asymptomatic infections[b]
		All	Alive		
Recipients of blood from vCJD cases	67	27	17	3	1
Blood donors to vCJD cases	112	107	104	0	0
Other recipients of blood donors to vCJD cases	34	32[c]	22[c]	0	0
Plasma product recipients(all except one are non-bleeding disorders)	11	10	4	0	0
Surgical contacts of all CJD cases	154	129[d]	119[e]	0	0
Highly transfused patients (recipients of blood from over 80 donors identified at pre-surgical assessment)	11	10	9	0	0
Total for 'at risk' groups where PHE holds data	**389**	**315[f]**	**275[f]**	**3**	**1**
Patients with bleeding disorders who received UK sourced plasma products[a]	3,871	National information is incomplete	National information is incomplete	0	1
Recipients of human derived growth hormone[a]	1,883	1,883	1,513	71	0
Total for all 'at risk' groups[a]	**6,143**	**>2,198[f]**	**>1,788[f]**	**74**	**2**

*Data for recipients of human derived growth hormone as at 30/06/2012

[a] These are minimum figures. Central reporting for bleeding disorder patients is incomplete, and seven patients have opted out of the central UKHCDO database. A small number of 'at risk' growth hormone recipients are not included in the Institute of Child Health study. Not all of 'at risk' growth hormone recipients have been notified. There is no central record of who has been informed.

[b] An asymptomatic infection is when an individual does not exhibit any of the signs and symptoms of CJD in life but abnormal prion protein indicative of CJD infection has been found in tissue obtained from them. In these cases the abnormal prion protein was identified during post mortem after the individuals had died of other causes.

[c] One patient was notified by proxy.

[d] Four of these were notified by proxy.

[e] Two of these were notified by proxy.

[f] Includes patients who were notified by proxy.

6.3 Research involving people at increased risk of CJD

PHE coordinates an Enhanced Surveillance study, the aim of which is to undertake long term monitoring of individuals who have been identified as at increased risk of CJD because of their healthcare. This study began in 2008. The NPC has approached certain 'at risk' patients via their GPs for enrolment in the National Prion Monitoring Cohort (NPMC) following a Panel sub-group meeting in 2010 where it was actioned that they should do so. The NPC recruited some additional patients onto the NPMC that had previously not been recruited onto the Enhanced Surveillance study. However, there are still a relatively limited number of individuals enrolled as research participants. Public health monitoring of patients enrolled on the enhanced surveillance study and NPMC will continue.

Appendix 1: CJD Incidents Panel membership for the period 1st January 2012 to 31st March 2013*

Chairman	**Expertise**
Mr David Pryer	Lay Chairman
Deputy Chairman	
Dr Roland Salmon	Epidemiology
Panel members	
Dr Miles Allison	Gastroenterology
Dr Oliver Blatchford	Health Protection Scotland CJD lead
Dr Gerry Bryant	General Practice and Public Health Medicine
Dr Adam Fraise	Microbiology
Dr Martin Fulford	Dentistry
Dr Patricia Hewitt	Blood safety
Mrs Joanna Hoskins	Lay member
Prof James Ironside	TSE infectivity, neuropathology
Dr Michael Kelsey	Microbiology
Prof Diana Kloss	Law
Professor John Lumley	General Surgery
Professor Theresa Marteau	Health Psychology
Dr Simon Mead	Neurology
Dr Anna Molesworth	Epidemiology
Dr Bernadette Nazareth	Consultant in communicable disease control
Dr Derek Norfolk	Haematology
Dr Mike Painter	Public Health Medicine
Mr Ian Pearce	Ophthalmology
Mrs Janice Price	Infection Control Nursing
Dr Geoffrey Ridgway	Microbiology
Prof John Saunders	Medical Ethics
Mr Alun Tomkinson	Ear nose and throat surgery
Mrs Gillian Turner	Patient support
Mrs Jan Waters	Sterile Services Management
Mr Barrie White	Neurosurgery
Prof Bob Will	Neurology
Mr Terence Wiseman	Ethics
Ms Kate Woodhead	Theatre nursing
Dr Tim Wyatt	Microbiology

*Note, the list above comprises those who have been Panel members for all or part of the reporting period.

Appendix 2: CJD Incidents Panel membership from establishment to dissolution

Chairmen	**Expertise**
Mr David Pryer	Lay Chairman
Professor Michael Banner	Ethics
Deputy Chairmen	
Dr Roland Salmon	Epidemiology
Professor Don Jeffries	Virology
Panel members	
Dr Miles Allison	Gastroenterology
My Adam Balen	Obstetrics and Gynaecology
Mr John Barker	Sterile Service Management
Dr Oliver Blatchford	Health Protection Scotland CJD lead
Professor Mike Bramble	Gastroenterology
Dr Gerry Bryant	General Practice and Public Health Medicine
Ms Patricia Cattini	Infection control nursing
Mr Harry Cayton	Lay Representative, CJD Support Network
Professor John Collinge	Director, MRC Prion Unit
Dr Geoff Craig	Dental Surgery
Professor Ian Cooke	Obstetrics and Gynaecology
Dr Steve Deacon	Institute of Occupational Health and Safety
Professor Len Doyal	Ethics
Professor Lesley Fallowfield	Communication with patients
Dr Calliope Farsides	Ethics
Dr Adam Fraise	Microbiology
Dr Martin Fulford	Dentistry
Ms Jean Gaffin	Lay Representative
Dr Noel Gill	Epidemiology
Mr Luke Gormally	Ethics
Dr Patricia Hewitt	Blood safety
Mrs Joanna Hoskins	Lay member
Professor Peter Hutton	Anaesthesia
Prof James Ironside	TSE infectivity, neuropathology
Dr Michael Kelsey	Microbiology
Prof Diana Kloss	Law
Professor John Lumley	General Surgery
Ms Susan MacQueen	Infection Control

Professor David Mant	General Medical Practice
Mr Henry Marsh	Neurosurgery
Professor Theresa Marteau	Health Psychology
Dr Simon Mead	Neurology
Dr Anna Molesworth	Epidemiology
Dr Bernadette Nazareth	Consultant in communicable disease control
Mrs Caroline Ness	Lay Member
Dr Derek Norfolk	Haematology
Professor John O'Neill	Ethics
Dr Mike Painter	Public Health Medicine
Mr Ian Pearce	Ophthalmology
Mrs Janice Price	Infection Control Nursing
Dr Patrick Radford	Anaesthesiology
Dr Geoffrey Ridgway	Microbiology
Dr Douglas Russell	General Practice
Prof John Saunders	Medical Ethics
Dr Peter Simpson	Anaesthesia
Professor Graham Smith	Anaesthesia
Professor Dame Lesley Southgate	General Practice
Dr David Taylor	TSE and Decontamination
Mr Alun Tomkinson	Ear nose and throat surgery
Mr Andrew Tullo	Ophthalmology
Mrs Gillian Turner	Patient support
Dr Hester Ward	Epidemiology
Mrs Jan Waters	Sterile Services Management
Mr Barrie White	Neurosurgery
Prof Bob Will	Neurology
Mr Terence Wiseman	Ethics
Ms Kate Woodhead	Theatre nursing
Dr Tim Wyatt	Microbiology

[i] www.hpa.org.uk/CJDIncidentsPanel
[ii] Health Service Circular. HSC 2000/032. 18th October 2000. Decontamination of medical devices.