CONTROL AND PREVENTION OF CJD AND OTHER TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES (TSES) IN IRISH HEALTHCARE SETTINGS

DRAFT FOR CONSULTATION, JUNE 2011

SUMMARY OF RECOMMENDATIONS

- Irish healthcares settings should apply the current guidance from the UK Advisory Committee on Dangerous Pathogens (ACDP) on transmissible spongiform encephalopathy (TSE) agents: safe working and prevention of infection (available from http://www.dh.gov.uk/ab/ACDP/TSEguidance/index.htm).
- Where aspects of the UK TSE guidance are not applicable to Irish healthcare settings, due to differences in legislative requirements, health structures or differences in population risk of developing a TSE, reference should be made to the list of exceptions, and resulting guidance for Ireland, detailed in Appendix A of this document.
- All patients about to undergo any surgery or endoscopy should be asked if they have ever been informed that they are at increased risk of developing CJD or vCJD, as part of the routine pre-operative assessment process.
- All patients about to undergo neurosurgery, spinal surgery, posterior eye surgery, neuro-endoscopy, or other procedure likely to involve contact with tissues associated with high levels of TSE infectivity, should have their CJD/vCJD risk assessed and documented as part of the routine pre-operative assessment process.
- The Health Services Executive (HSE) CJD Incidents Panel should monitor changes to the UK TSE guidance and, where critical changes occur, alert Irish healthcare settings to relevant changes and, if necessary, update the list of exceptions and resulting guidance for Ireland.

INTRODUCTION

In 2004 the Department of Health and Children (DoHC) published guidelines for prevention and control of Creutzfeldt-Jakob Disease (CJD) and other transmissible spongiform encephalopathies (TSEs) the Irish healthcare settings. The 2004 guidelines were produced at the request of the DoHC National CJD Advisory Committee by a subcommittee of the Scientific Advisory Committee of the National Disease Surveillance Centre (NDSC, now known as the HSE Health Protection Surveillance Centre (HPSC)). In the time since the 2004 guidelines were published, there have been considerable advances in the understanding of the pathogenesis and epidemiology of TSEs, particularly variant CJD (vCJD), and some of the

interventions recommended in the 2004 guidelines are no longer applicable. Thus the Scientific Advisory Committee of HPSC was asked by DoHC and the Quality and Clinical Care Directorate of the Health Services Executive to convene a working group to update the 2004 guidelines.

The terms of reference of the working group were:

"To update the Irish guidelines (2004) on infection control of CJD and other transmissible spongiform encephalopathies in the healthcare setting, in line with best available evidence and international best practice guidelines"

A number of areas relating to the control and prevention of TSE fell outside the remit of the working group, such as issues relating to blood donation and transfusion, handling of laboratory animals, and infection prevention and control in food production and veterinary settings.

The working group agreed to recommend adopting the current UK guidelines, but with some exceptions to reflect differences in vCJD epidemiology, population risk, legislation, standards and health structures between the UK and Ireland. The rationale for recommending adoption of the current UK guidelines includes:

- The UK is closest to Ireland, in terms of vCJD epidemiology
- A large proportion of the potential exposure of people in Ireland to vCJD relates to residence in the UK, or receipt of UK-sourced blood products
- The UK has the most extensive experience with vCJD and have a large body of expertise
- Unlike the UK, Ireland does not have a large number of TSE experts with the dedicated time required to develop and maintain national guidelines
- International guidelines, other than those of the UK, are relatively out of date, and may not be applicable to vCJD epidemiology in Ireland.

Note: Aspects of the UK TSE guidance relating to veterinary and animal laboratory practice are outside of the scope of the TSE Infection Control Working Group.

EPIDEMIOLOGY OF TSES

Transmissible spongiform encephalopathies (TSEs) are fatal degenerative brain diseases that occur in humans and some animal species. The causative agent is a protease-resistant protein, which is an altered form of naturally occurring prion protein (PrP). PrP is normally

present in human and animal brain tissue. In TSEs an altered form (also known as the scrapie agent or PrP^{Sc}) accumulates in the brain to produce the characteristic features of TSEs. These altered prion proteins are remarkably resistant to inactivation by standard chemical, thermal and other means of inactivating microorganisms.

The most common human TSE is Creutzfelt-Jakob disease (CJD). The disease has a worldwide distribution and incidence of 0.5 to 1.0 cases per million population per year. Most cases of CJD are sporadic and the incidence is thought to reflect the rate of spontaneous mutation of naturally occurring prion protein to the altered form [1,2].

Person to person transmission of TSEs through direct contact does not occur. Iatrogenic transmission is rare and has only occurred through contaminated tissue grafts, use of human pituitary-derived hormones and, in a handful of cases, through contaminated medical devices. Despite the rarity of iatrogenic transmission, the fact that prion proteins are resistant to inactivation and that TSEs are invariably fatal has prompted stringent precautions to be routinely taken to prevent iatrogenic transmission. It is perhaps as a result of the introduction of such precautions that no transmission of a TSE via contaminated medical devices has been documented since 1976.

In 1995 a new form of TSE was described in the UK and was labelled variant CJD (vCJD). Patients with vCJD tend to be younger than those with sporadic CJD and have a longer duration of illness, frequently associated with sensory disturbances and psychiatric manifestations. The emergence of vCJD has been linked to bovine spongiform encephalopathy (BSE) in cattle, and vCJD appears to have arisen through the consumption of BSE-infected animal products. The altered prion protein in vCJD is more widely distributed in the body, compared to sporadic CJD, particularly in the lymphoreticular system. A summary of the difference in clinical and pathological findings in vCJD versus sporadic CJD is given in Table 1.

TABLE 1: COMPARISON OF CLINICAL AND PATHOLOGICAL FEATURES OF VCJD VERSUS SPORADIC CJD

Clinical/Pathological Feature	vCJD	Sporadic CJD
Mean age of onset	29 years	60 years
Length of survival	14 months	4 months
Early psychiatric symptoms	Common	Rare
Later cerebellar ataxia	All	Many
Dementia	Commonly delayed	Typically early
Electroencephalogram	Non-specific slowing	Biphasic and triphasic periodic complexes
MRI findings	Signal in pulvinar region of thalamus	Signal in basal ganglion and putamen
Cerebrospinal Fluid	14-3-3 concentration high in 50% of patients	14-3-3 concentration high in most patients
Histopathology of brain	Many florid plaques	No amyloid plaques
Immunostaining of tonsils	Positive	Negative
Polymorphism at codon 129	All homozygous (MM)	Homozygosity and heterozygosity

The role of the human prion protein gene (designated PrNP), which is responsible for the coding of the prion protein, is an important consideration for vCJD. Mutations of the human prion protein gene (PrNP) have not been identified in vCJD, but all confirmed cases of the disease have shown methionine homozygosity (MM) at the polymorphic codon 129, despite the fact that only approximately 40% of the general population are of this genotype. This may indicate a genetic risk factor for vCJD.(4) Whether human infection may yet occur, perhaps with longer incubation periods, in the other codon 129 genotypes (MV or VV) is uncertain.(5) Other TSEs have shown longer incubation times in subjects who have been heterozygous (MV) or valine homozygous (VV).(4) It is not yet known if cases of vCJD from the remaining 60% of the population who show these genetic subtypes could emerge in the future.

As of November 2010, four cases of vCJD have been notified to the Health Protection Surveillance Centre in Ireland. Of these, two are thought to have originated in the UK (11). Ireland has the second highest incidence of vCJD in the world, after the UK.(15) The per-capita incidence of the disease in Ireland is estimated at 1:1,000,000.(16) This is second to the UK, where with 170 cases identified and an estimated population of 58.5 million, the equivalent figure is 1:350,000. In France with 25 cases and an estimated population of 60 million, the incidence is 1:2,400,000.

An overview of the human forms of TSE is given in Table 2.

TABLE 2: OVERVIEW OF THE HUMAN TSES

Disease	Route of acquisition	Incidence/distribution	Comments
Kuru	Oral, via ritual cannibalism	Only seen in highlands of Papua New Guinea: >2,500 cases reported since 1957	Ritual cannibalism stopped in 1958
Sporadic Creutzfelt-Jakob disease (CJD)	Most likely due to spontaneous mutation of prion protein	0.5-1 per million population worldwide	Commonest human TSE

Familial CJD	Inheritance of mutation in gene encoding prion protein (PrP)	10-15% of CJD cases	Autosomal dominant inheritance. ~100 families identified worldwide.
Iatrogenic CJD	Transmission of altered prion protein via a medical procedure	Rare. Most cases related to dura mater grafts or human pituitary-derived hormone use. Only 7 cases (2 definite) associated with contaminated medical equipment.	All of the cases associated with contaminated medical equipment occurred prior to 1980.
Gerstmann-Straussler-Scheinker syndrome (GSS)	Inheritance of mutation in PrP gene	About 50 families identified worldwide	Autosomal dominant inheritance.
Fatal familial insomnia (FFI)	Inheritance of mutation in PrP gene	Very rare. Nine families identified worldwide	Autosomal dominant inheritance.
Variant CJD (vCJD)	Ingestion of BSE-contaminated animal products and, potentially, receipt of contaminated blood products	170 cases reported in UK to date (June 2010). New UK cases peaked in 2000. Four cases reported in Ireland to date.	Wider distribution of altered PrP in human tissues compared to CJD

POPULATION RISK OF VCJD IN IRELAND

The risk of past exposure to BSE-infected meat products in Ireland is lower than that in the UK. Based on surveillance data for cattle older than two years the annual incidence of BSE in Irish cattle was 0.1% to 1.1% that of cattle in the UK up to 1996 (data courtesy of Department of Agriculture, Food and Rural Development (DAFRD)). There are a number of stringent controls in place to ensure that BSE-infected animal products cannot enter the food chain in Ireland. Since 1990 any clinical case of BSE is removed from the food chain with compulsory notification. Mechanically recovered meat was banned in Ireland in 1996. All specified risk material is removed in abattoirs, stained and kept separated from other animal products to ensure that it does not enter the human or animal food chains. Meat and bone meal is excluded from the animal food chain. All cattle are examined prior to slaughter and any clinically suspect cases are removed from the food and feed chain. All cattle aged over 30 months are screened for BSE using an approved test.

An assessment of the total number of future clinical cases of vCJD that might occur in Ireland was published in 2003.(17) This used an established mathematical model based on infectivity of bovine tissue (calculated from UK data) and the relative exposure to BSE-contaminated meat The authors estimated one future occurrence of clinical disease in the Republic of Ireland (95%CI: 0-15) where exposure could be from BSE-infected indigenous beef products or imported UK beef products and taking into account the proportion of the Irish population who resided in the UK during the “at risk” period.

Estimates of the number of future cases of vCJD in Ireland are subject to a number of limitations:

All clinical cases of vCJD to date have been homozygous for methionine (MM) on codon 129 of the PRNP gene,(17) and the population risk estimate assumes that the remaining 60% of the population are not susceptible. However, cases of Kuru, the human TSE that most closely resembles vCJD, can occur in individuals who are methionine heterozygous, following a prolonged incubation period.(19) In addition a methionine heterozygous recipient of vCJD-implicated blood products, who died of unrelated causes, was found to have evidence of accumulation of abnormal prion protein in lymphreticular tissue at autopsy. Thus methionine heterozygous individuals may still be susceptible to vCJD, but with a longer incubation period compared to methionine homozygous individuals.

The future case estimate for Ireland assumed that the vCJD cases in the UK to date were infected as a result of consumption of UK BSE-infected beef.(17) In Ireland, meat and bone meal were banned from the diet of ruminants in 1990, but were not banned from the diet of other animals until 2001.(17) This could, theoretically, increase the number of future cases.

Modelling studies do not estimate the number of people who may be sub-clinical carriers of the disease. While patients with sub-clinical infection may never suffer adverse effects themselves, they retain the possibility of transmitting the disease to others, as a result of

iatrogenic transmission via surgical procedures, such as tonsillectomy or appendicectomy, or as a result of blood transfusion.(17)

INFECTIVITY OF TISSUES WITH TSES

See Annex A1 of UK guidelines

PERSONS AT INCREASED RISK OF DEVELOPING TSE

IATROGENIC TRANSMISSION OF CJD

Iatrogenic transmission of CJD has been associated with:

- Dura mater grafts (~110 cases worldwide)
- Human cadaver pituitary-derived hormone (~130 cases worldwide)
- Contaminated medical equipment (~7 cases worldwide)

One iatrogenic case of CJD was reported in Ireland in 2001, which was linked to prior human pituitary-derived growth hormone use.

There has only been one definite case of iatrogenic transmission of CJD via a corneal graft. This occurred in 1974, and it is possible that the corneal tissue was contaminated by posterior eye segment tissue during processing. Abnormal prion protein has not been detected in anterior eye segment tissue. Thus, corneal transplantation is no longer considered a risk factor for iatrogenic CJD.

Of the 16 countries that have documented dura mater-associated cases, 67 occurred in Japan with a median of 2 (range 1-8) cases in each of the remaining 15 countries [20]. In addition the vast majority of implicated grafts have been the product of a single commercial producer, where decontamination of the grafts with NaOH during commercial preparation was not carried out [19,20]. The implicated commercial product ("Lyodura", manufactured by B Braun Melsungen AG) was one of a number of products licensed for use in Ireland. It was officially withdrawn from the Irish market in 1987 (Irish Medicines Board, personal communication). It is possible that stored Lyodura may have been used in a small number of

neurosurgical procedures in Ireland up to 1993. Dura grafts are no longer used in Ireland and no licensed products are available.

More than half of all human pituitary-derived growth hormone-related CJD cases occurred in France, with smaller numbers of cases in the United Kingdom, United States and New Zealand. All of the cases reported to date appear to be related to growth hormone therapy prior to 1985. Likewise the risk of CJD transmission appears to have been lowest with commercially prepared hormone [20]. Human pituitary-derived growth hormone was used in Ireland up to 1985, when it was discontinued. All of the product used in Ireland was imported and was produced by commercial companies (Irish Medicines Board, personal communication).

There have only been two confirmed cases of transmission of CJD via contaminated medical equipment. These were both related to the use of stereotactic electrodes that were implanted in a patient with known CJD. The electrodes were cleaned with benzene, followed by 70% alcohol and formaldehyde vapour prior to being reused on other patients, a procedure now known to be inadequate for inactivating prion protein [21]. Retrospective studies suggest that five other cases of CJD may have been associated with reuse of contaminated neurosurgical instruments [20]. No CJD cases associated with contaminated medical equipment have been reported since 1976.

FAMILIAL TSES

Approximately 5-10% of TSEs are hereditary. These hereditary forms include familial CJD (about 100 extended families identified worldwide), fatal familial insomnia (nine families) and Gerstmann-Straussler-Scheinker syndrome (about 50 families identified). All demonstrate autosomal-dominant transmission. There is no evidence of genetic or vertical transmission of vCJD. A familial TSE has been described in two generations of one family of Irish decent [22]. A single case of fatal familial insomnia was reported in Ireland in 1997, though no other cases have been identified in the same family to date (Irish National CJD Surveillance Unit, personal communication).

It seems prudent to consider persons who have a documented family history of a familial TSE as being at higher risk of developing a TSE, compared to the general population, as detailed in table 2.3.

PATIENT RISK GROUPS

When considering measures to prevent transmission to patients or staff in the healthcare setting, it is useful to make a distinction between *symptomatic* patients, *i.e.* those who fulfil the diagnostic criteria for definite, probable or possible CJD or vCJD, and *asymptomatic* patients *i.e*. those with no clinical symptoms, but who are potentially *at risk* of developing one of these diseases, *i.e*. having a medical or family history which places them in one of the risk groups – see Appendix A for diagnostic criteria. Table 2.3 below details the classification of the risk status of symptomatic and asymptomatic patients.

TABLE2.3: CATEGORISATION OF PATIENTS BY DESCENDING ORDER OF RISK

1: Symptomatic patients	**1.1:** Patients who fulfil the diagnostic criteria for definite, probable or possible CJD or vCJD (see Annex B of UK guidelines for diagnostic criteria) **1.2:** Patients with neurological disease of unknown aetiology who do not fit the criteria for possible CJD or vCJD, but where the diagnosis of CJD is being actively considered
2: Asymptomatic patients at risk from familial forms of CJD linked to genetic mutations	**2.1:** Individuals who have been shown by specific genetic testing to be at significant risk of developing CJD or other prion disease **2.2:** Individuals who have a blood relative known to have a genetic mutation indicative of familial CJD **2.3:** Individuals who have or have had two or more blood relatives affected by CJD or other prion disease
3: Asymptomatic patients potentially at risk from iatrogenic exposure	**3.1:** Recipients of hormone derived from human pituitary glands, *e.g*. growth hormone, gonadotrophin **3.2:** Individuals who have received a graft of *dura mater.* (People who underwent neurosurgical procedures or operations for a tumour or cyst of the spine prior to 1994 may have received a graft of *dura mater*, and should be treated as *at risk*, unless evidence can be provided that *dura mater* was not used) **3.3:** Patients who have been contacted as potentially *at risk*, including individuals considered to be*: a) at risk of CJD/vCJD due to exposure to certain instruments used on a patient who went on to develop CJD/vCJD, or was at risk of vCJD;

b) at risk of vCJD due to receipt of blood components or plasma derivatives;

c) at risk of CJD/vCJD due to receipt of tissues/organs;

d) at risk of vCJD due to the probability they could have been the source of infection for a patient transfused with their blood who was later found to have vCJD.

*The Irish CJD Incidents Panel, based at the Health Services Executive, will identify contacts of CJD/vCJD incidents who should be considered *at risk* for public health purposes.

NOTE ON LAYOUT OF UK TSE GUIDELINES

The UK guidelines, produced by the ACDP TSE Working Group, are divided into a number of parts and annexes. Some sections in the UK guidelines relate to veterinary and laboratory research settings, and are thus not applicable to the general human healthcare setting. The parts/annexes of the current UK guidelines are outlined below, with the sections most relevant to the Irish healthcare setting highlighted:

Part 1: Background and Introduction

General overview of TSEs, including epidemiology and transmission. Some sections relate only to veterinary issues.

Part 2: Health and Safety Management of TSEs

Overview of health and safety requirements for employers, including details of relevant UK legislation. Irish legislation relating to TSEs is detailed in Appendix X.

Part 3: Laboratory Containment and Control Measures

This section mostly relates to veterinary, research and specialised diagnostic laboratories working with tissues known to contain TSE agents.

Part 4: infection control of CJD and related disorders in the healthcare setting

This section is the most relevant to Irish healthcare settings, and covers all of the major requirements for prevention of transmission of TSEs in healthcare settings.

Annex A1: Distribution of TSE infectivity in human tissues and body fluids

This section has been extensively revised in recent years, and is regularly updated as new evidence is produced. Guidance on precautions to be taken for different types of invasive procedures is based on the details in this section.

Annex A2: Distribution of infectivity in animal tissue and body fluids

Not relevant to the human healthcare setting.

Annex B: Diagnostic criteria

Diagnostic criteria for TSEs have been revised in recent years, with the advent of laboratory testing for TSE-related biomarkers.

Annex C: General principles of decontamination and waste disposal

General principles are in line with recommended procedures in Irish healthcare settings, but should be read in conjunction with HSE Code of Practice for decontamination and DoHC recommendations on management of healthcare waste.

Annex D: Transport of TSE infected material

International transport regulations, detailed in this section, also apply to Ireland. UK transport regulations are similar to those in Ireland, but reference should be made to [?IRISH TRANSPORT REGULATIONS]. Some parts of this annex relate to transport of animals and animal products, so are not relevant to the human healthcare setting.

Annex E: Quarantining of surgical instruments

Guidance on when and how surgical instruments should be quarantined.

Annex F: Endoscopy

Provides detailed guidance on risk assessment of endoscopic procedures and requirements for decontamination and quarantine.

"Endoscopy and individuals at risk of vCJD for public health purposes" (BSG consensus statement)

Consensus statement discusses the risk of vCJD transmission via contaminated endoscopes, and classification of invasive and non-invasive endoscopic procedures

Annex H: After death

Provides advice for undertakers, pathologist and others involved in post-mortem examinations and funeral arrangements. Needs to be read in conjunction with MoDI report and SOP for Public Health Management of TSEs in Ireland.

Funeral arrangements after a CJD death

Frequently asked questions regarding funeral arrangements for individuals who have died with CJD or other TSE.

Annex I: Brain biopsy procedures

Protocol for management of brain biopsies: practical arrangements refer to UK structures. See SOP for Public Health Management of TSEs in Ireland.

Annex J: Pre-surgery/endoscopy risk assessment

Detailed approach to assessment of patients prior to invasive procedures. Blood transfusion exposure assessment does not apply to Ireland (unless patient has received multiple transfusions in the UK). See guidance document on assessment of CJD risk prior to invasive procedures in Ireland.

Annex K: Guidelines for pathology laboratories

Should be read in conjunction with SOP for Public Health Management of TSEs in Ireland.

Annex L: Managing CJD/vCJD Risk in Ophthalmology

Provides details of risk assessment prior to ophthalmology procedures, best practice for minimising the risk of transmission in ophthalmology practice, and detailed classification of low risk and high risk ophthalmology procedures.

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APPENDIX A: EXCEPTIONS TO CURRENT UK GUIDELINES, AS THEY APPLY TO IRISH HEALTHCARE SETTINGS

UK Guideline Section	Section number	UK recommendation	Recommendation, guideline or statutory requirement for Ireland
Part 1: Background and Introduction	1.4	Reference to small and large laboratory animal accommodation	Issues relating to veterinary/animal practice are outside scope of guidance for Irish healthcare setting
	1.8	Reference to UK guidance for veterinary surgeons	Issues relating to veterinary/animal practice are outside scope of guidance for Irish healthcare setting
Part 2: Health and Safety Management of TSEs	Table 2a	UK health and safety legislation	Similar requirements exist under Irish legislation: Health, Safety and Welfare at Work Act 2005
	2.2	Employer responsibilities under health and safety legislation	Similar requirements exist under Irish legislation: Health, Safety and Welfare at Work Act 2005
	2.20	Maintaining a list of exposed employees	Employers are required to maintain a list of employees exposed to microorganisms belonging to hazard groups 3 and 4
	2.23	Maintaining a list of exposed employees	Irish legislation requires a list be maintained for at least 10 years, but not exceeding 40 years
	2.24/Infobox 2	Data protection	Similar requirements are included in Irish data protection legislation

Part 3: Laboratory Containment and Control Measures	3.2	Genetically modified organisms	Equivalent Irish legislative requirements are included in Food Safety Authority/Environmental Protection Agency SI no. 73 of 2001
	3.5/Table 3a	Animal containment levels	Issues relating to veterinary/animal practice are outside scope of guidance for Irish healthcare setting
	3.25	Specialist neuropathology laboratory	Brain or neural tissue specimens from known, suspected and at risk patients should be referred to the Neuropathology Laboratory at Beaumont Hospital, Dublin.
	3.27	Low risk specimens	The recommendations on handling of low risk specimens apply to handling of such specimens from patients with known or suspected TSE, and not to all laboratory specimens.
	3.30 -3.48	Research work with infected animals	Issues relating to veterinary/animal practice are outside scope of guidance for Irish healthcare setting
Part 4: infection control of CJD and related disorders in the healthcare setting	4.4	Caring for patients with, or at increase risk of, CJD/vCJD	See “CJD and other transmissible spongiform encephalopathies: information for healthcare workers” at www.hpsc.ie
	4.4	Appointment of a "key worker" to coordinate hospital/community care for TSE cases	The CJD Infection Control Working Group recommends that all TSE cases should have a designated social worker to coordinate aspects of hospital and community care. The primary responsibility for informing a patient of being at increased risk of a TSE rests with the clinician responsible for the patient’s care (as specified in the National Standards for Prevention of Healthcare Associated Infection, produced by the Health Information and Quality Authority (HIQA)

	4.6-4.9	Compliance with UK health care act requirements	Irish healthcare institutions are required to comply with national standards for prevention of healthcare associated infection, as set down by the Health Information and Quality Authority (HIQA)
	4.10	Health and safety guidance for managers	Guidance for employers and managers may be obtained from the Health and Safety Authority (www.hsa.ie)
	4.15	Precautionary measures for blood transfusion	Details of precautions put in place to safeguard the supply of blood and blood products for transfusion in Ireland can be found at the Irish Blood Transfusion Service (IBTS) website (www.giveblood.ie)
	Table 4a	Patient risk categories	Implicated dura mater graft product was withdrawn from the Irish market in 1987, but stored product could potentially have been used up to 1993. The use of human-derived growth hormone was discontinued in Ireland in 1985.
	4.35	Guidance on safe management of clinical waste	Irish healthcare institutions should follow "Segregation Packaging and Storage Guidelines for Healthcare Risk Waste" (Department of Health and Children, 2004) (www.dohc.ie)
	4.44	Minimising occupational exposure to blood	Irish healthcare institutions should follow "The Prevention of Transmission of Blood-Borne Diseases in the Healthcare Setting" (Department of Health and Children, 2005) (www.dohc.ie)
	4.51	Medical device decontamination guidelines	Healthcare institutions should comply with the HSE Code of Practice for Decontamination of Reusable Medical Devices and decontamination standards (set out in the HIQA Prevention and Control of Healthcare Associated Infection standards)

	4.55	Infection control in dentistry	Dental practices in Ireland should comply with the Irish Dental Council's Code of Practice Relating to Infection Control in Dentistry (available from www.dentalcouncil.ie)
Annex A2: Distribution of infectivity in animal tissue and body fluids	Issues relating to veterinary/animal practice are outside scope of guidance for Irish healthcare setting		
Annex C: General principles of decontamination and waste disposal	C 13	MHRA Safety Notice	Healthcare institutions in Ireland should follow the Health Services Executive Code of Practice for Decontamination of Reusable Invasive Medical Devices (HSE 2007)
	Table C4	Guidelines and standards	Equivalent Irish guidelines and standards include: - Health Information and Quality Authority. National Hygiene Services Quality Review 2008: Standards and Criteria. Ireland: Health Information and Quality Authority; 2008 - Department of Health and Children. Infectious Diseases Regulations 1981, SI No 390 of 1981. The Stationery Office, Dublin - Department of Health and Children. Segregation Packaging and Storage Guidelines for Healthcare Risk Waste. Ireland: Department of Health and Children; 2004
Annex D: Transport of TSE infected material	D1-D27	Legislative background and application	Details of relevant legislation and guidance for transportation of infection risk material can be found in "Healthcare Risk Waste Management: Segregation, Packaging and Storage Guidelines for Healthcare Risk Waste" (DoHC November 2010, available from www.dohc.ie)
	Appendix 1	List of regulations, legislation and guidance	Relevant national legislation for Ireland is "Dangerous substances (conveyance of scheduled substances by road) trade or business regulations" (SI 389 of 1996)

	Appendix 2	Contact details	Advice on transport of dangerous goods can be obtained from: The Health and Safety Authority (HSA) The Metropolitan Building James Joyce Street Dublin 1 Tel: 1890 289 389 Email: wcu@hsa.ie
Annex F: Endoscopy	F1	MDA device bulletin	Equivalent Irish guidelines for decontamination of endoscopes can be found in Part 4 of the HSE Code of Practice for Decontamination of Reusable Medical Devices (available from http://www.hse.ie/eng/services/Publications/services/Hospitals/Code_of_Practice_for_Decontamination_of_Reusable_Invasive_Medical_Devices_.html)
	F1	BSG guidelines	British Society of Gastroenterology (BSG) guidelines are considered to be best practice by the Irish Society of Gastroenterology (ISGE)
	Table F2a (footnote 4)	Refurbishment of scopes used on patients at risk of vCJD	No formal arrangement exists in Ireland for refurbishment of endoscopes used on patients at risk of vCJD
Annex H: After death	H2	HSAC mortuary guidelines	National guidelines on management of infectious risks in deceased individuals will shortly be available (www.hpsc.ie)

	H5	Refunding of removal costs for CJD autopsies	Removal costs can be reclaimed from HSE
Funeral arrangements after a CJD death	National guidelines on management of infectious risks in deceased individuals will shortly be available (www.hpsc.ie)		
Annex I: Brain biopsy procedures	If brain biopsy is being considered, please contact a Neuropathologist at the Irish CJD Surveillance Unit, Beaumont Hospital, Dublin		
Annex J: Pre-surgery/endoscopy risk assessment	Table J1, Q 3a	Neurosurgical procedure before August 1992	For neurosurgical procedures in Ireland, consider at risk if prior to 1994 (Implicated dura mater graft product was withdrawn from the Irish market in 1987, but stored product could potentially have been used up to 1993)
	Table J1, Q 3b	NICE guidance on separate set of instruments for high risk procedures for children born after 1/1/1997	The Working Group do not recommend maintaining a separate set of instruments for high risk procedures on children born after a given date, due to the lower population risk of vCJD in Ireland.

	Table J1, Q 4	Risk relating to blood transfusion/blood products	Patients should only be considered at increased risk of transfusion- derived vCJD if they received UK-derived blood or blood components (more than 50 units, or on more than 20 occasions)
	J6	Actions in response to risk questions	If a patient is found to be at increased risk of CJD or vCJD, the Irish CJD Incident Panel should be informed
	Appendix B	Responsibility if patient doesn't have a GP	If the patient does not have a GP, responsibility for informing the patient of their CJD or vCJD risk falls to the local Department of Public Health
	Appendix D	Highly transfused vCJD risk assessment form	A detailed assessment of a patient's transfusion history is only required if a significant exposure to UK-derived blood products is documented, and should only be carried out following discussion with the Irish CJD Incidents Panel
Annex K: Guidelines for pathology laboratories	K27, K28	Referral of tissue to NCJDSU	Advice on referral of tissue can be obtained from the Irish CJD Surveillance Unit by contacting the consultant neuropathologists at Beaumont Hospital, Dublin (Professor M Farrell or Dr F Brett)
Annex L: Manageing CJD/vCJD Risk in Ophthalmology	L20	Pre-op CJD risk assessment	Please refer to High Risk Pre-Operative CJD Questionnaire for Ireland (available from www.hpsc.ie)
	L22	NICE guidance on separate set of instruments for high	The Working Group do not recommend maintaining a separate set of instruments for high risk procedures on children born after a given date, due to the lower population risk of vCJD in Ireland.

		risk procedures for children born after 1/1/1997	
	L51-L52	National Transplant Database	A national transplant database does not currently exist in Ireland
	L53	UK Human Tissue Regulations: need to maintain records for a minimum of 30 years	No requirement under current Irish legislation
	L54	UK Human Tissue Regulations: statuatory reporting for serious adverse events	No requirement under current Irish legislation
	L55	UK HTM series on decontamination of medical devices	Healthcare institutions should comply with the HSE Code of Practice for Decontamination of Reusable Medical Devices
	L58-L60	CJD Incidents Panel	The Irish CJD Incidents Panel is based at the HSE Quality and Clinical Care Directorate (Chair: Dr Kevin Kelleher)

Reference List

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