



TSE guidance review - Part 1 (Introduction), Annex C (Decontamination and waste disposal) and Annex F (Endoscopes)

Background

1. The papers of the TSE guidance review that have yet to be published are attached. They include Part 1 (Introduction), Annex C (Decontamination and Waste Disposal) and new Annex F (Endoscopes) of the Advisory Committee on Dangerous Pathogens (ACDP) and SEAC guidance on: TSEs: Safe working and the prevention of infection (the 'TSE guidance').
2. The revised sections (appended as Annexes 1-3) were produced by the JWG guidance-drafting sub-group and approved by the TSE JWG and the Advisory Committee on Dangerous Pathogens (ACDP) at their meeting on the 16th September 2003.

Remainder of Guidance

3. ACDP and SEAC both approved the first tranche of guidance, which contained Parts 2 & 4 and Annexes A.1, B, E and H. This guidance was published on the DH CJD web site at: <http://www.doh.gov.uk/cjd/tse> guidance.
4. ACDP and SEAC have also approved the second tranche of guidance which comprises Part 3 "Laboratory containment and control measures"; and Annex D "Transport of TSE-infected material". This tranche is pending publication until the section on 'Decontamination and Waste Disposal' (Annex C) is finalised to ensure consistency on the decontamination of low risk clinical waste between these sections.
5. The TSE guidance is provided to Members for information only.

List of Annexes attached:

Annex 1: Part 1- Introduction of the JWG TSE guidance.

Annex 2: TSE guidance (Annex C) on Decontamination and waste disposal.

Annex 3: TSE guidance (Annex F) on Endoscopes.

PART ONE

Background and Introduction

- 1.1. Transmissible spongiform encephalopathies (TSEs), otherwise known as prion diseases, are rare, fatal, degenerative diseases affecting the central nervous system (CNS), that occur in humans and certain other mammals.
- 1.2. There are several recognised TSEs, including Creutzfeldt-Jakob Disease (CJD) in humans, bovine spongiform encephalopathy (BSE) in cattle and scrapie in sheep. These and other TSEs are summarised in Box 1.
- 1.3. TSEs are in many ways unique, and exhibit biological properties that are different from those of other microbiological diseases^{1,2,3}. A useful summary about these diseases has been published previously by the Spongiform Encephalopathy Advisory Committee (SEAC)⁴. Some of the important features relevant to occupational exposure are summarised below:
 - (a) TSEs are caused by unconventional infectious agents currently thought to be infectious proteins (apparently without nucleic acid) known as prions which do not share the normal properties of viruses or bacteria. The CNS contains the highest levels of infectivity which is associated with accumulation of a modified host-encoded protein, prion protein. In TSEs, prion protein undergoes a structural change (involving re-folding) to a conformer with an increased beta – sheet structure. This conformational change renders the abnormal prion protein more resistant to degradation, and is associated with infectivity. The abnormal form of prion protein is only found in TSEs, but the mechanism and site of its conversion are still uncertain.

- (b) A common feature of all TSEs is the appearance of microscopic vacuoles in the grey matter of the CNS, giving a sponge-like appearance, from which the conditions derive their name. This change is accompanied by the accumulation of the abnormal form of the prion protein in the CNS.

- (c) The commonest form of CJD occurs as a sporadic disease, the cause of which is unknown, although genetic factors (particularly the codon 129 polymorphism in the prion protein gene (*PRNP*)) influence disease susceptibility. The familial forms of human TSEs (see Box 1) appear to have a solely genetic origin and are closely associated with mutations or insertions in the *PRNP* gene. Most, but not all, of the familial forms of human TSEs have been transmitted experimentally to animals. There are no known familial or genetic TSEs of animals, although polymorphisms in the *PRNP* gene of some species (sheep for example) may influence the length of the incubation period and occurrence of disease.

- (d) Although TSEs are not contagious, they are experimentally transmissible by inoculation and in some cases by oral challenge. Some animal TSEs, such as scrapie, are naturally transmissible to sheep and goats and chronic wasting disease (CWD) is naturally transmissible to several North American species of deer and elk, but how this is effected is still uncertain. Transmissible mink encephalopathy (TME) and BSE are feed-borne diseases. Transmission of TSEs to humans has occurred from both human and bovine sources, resulting in iatrogenic CJD and variant CJD respectively (see Box 1). Other animal TSEs, including scrapie, do not appear to cause human disease.

- (e) TSE agents are not uniformly distributed in the tissues of affected individuals and infectivity levels vary at different stages of incubation. In general, during the clinical disease, CNS tissues (including the retina) pose the highest risk, lymphoid tissues, cornea and dura mater are lower risk and most body fluids and other tissues negligible risk (for more detail see Tables A1 and A2);
- (f) TSE agents exhibit an unusual resistance to conventional chemical and physical decontamination methods. They are not significantly affected by disinfectants like formalin and ethylene oxide, and infectivity persists after standard autoclaving (e.g. 134°C for 3 minutes). They are also extremely resistant to high doses of ionising and UV irradiation and some residual activity has been shown to survive for long periods in the environment;
- (g) All TSEs are invariably progressive and fatal once clinical signs appear; there is currently no known effective treatment or prophylaxis, although this is an area of active research and clinical trials in humans have been established.
- (h) There have been no confirmed cases of transmission of TSE to humans as a result of occupation. If TSEs could be transmitted in the occupational setting this would be most likely to occur from exposure to infected tissues or materials by direct inoculation (e.g. puncture wounds, 'sharps' injuries or contamination of broken skin), by splashing of the mucous membranes or, exceptionally, by swallowing.

1.3. The unconventional nature of the agent, together with the appearance of BSE in the mid-1980s and variant CJD in the mid-1990s, has led to a considerable amount of scientific research. This in turn means that there is a need for updated guidance on safe work practices in laboratories and small and large laboratory animal accommodation as new information on these

diseases continues to emerge. There is also a need to provide guidance for health practitioners on the risks from humans infected with TSE agents.

Scope of this guidance

- 1.5. Health and safety law sets out a series of general duties on employers, employees and self-employed people. There are specific regulations which cover work with biological agents such as those causing TSEs, notably the Control of Substances Hazardous to Health Regulations 2002 (COSHH)⁵. These require employers to assess the risks in all cases where there may be exposure to biological agents and when appropriate introduce measures to either prevent or adequately control exposure. COSHH applies whether there is a deliberate intention to work with the agent (such as in a research laboratory) or whether exposure is incidental to the work (such as in a hospital ward or operating theatre).
- 1.6. This guidance is therefore divided into three main sections as follows:
 - Hazards and risk associated with workplace exposure to TSE agents (including information on health and safety law);
 - Containment and control measures for laboratory work with TSE agents, materials and infected animals (i.e. where there is deliberate intention to work with the agent or where laboratory workers are handling material that may contain the agent;
 - Infection control of CJD and related disorders in healthcare settings (i.e. where any exposure to the agent is incidental to the work).
- 1.7. The purpose of this document is to provide guidance to employers on the precautions to control the risk of exposure of employees and others to TSE agents from work activities. The guidance applies to many occupations that involve contact with people or animals infected with TSE agents, or potentially contaminated material. It should also be drawn to the attention of those responsible for advising

others who may come into contact with TSE during the course of their work. Included in these groups are:

- laboratory staff (including experimental animal house staff);
- healthcare workers (including infection control staff; medical and nursing staff particularly in neurology, ophthalmology, neuro- or ENT-surgery, oral and maxillofacial surgery; and dentistry; sterile services supply staff and medical engineers);
- staff involved in hospice and community care;
- pathologists (including veterinary pathologists), pathology laboratory staff, post mortem technicians;
- funeral, cemetery and crematorium workers;
- local Consultants in Communicable Disease Control (CsCDC) and Health Protection Teams.

1.8. Additional advice for veterinary surgeons and those involved in the transportation, slaughtering and processing of cattle and cattle products can be found in a separate Advisory Committee on Dangerous Pathogens publication “BSE Background and general occupational guidance”⁶. Guidance on handling meat-and-bone-meal (MBM) material⁷ and an information sheet on common zoonoses in cattle⁸, which will be of interest to farmers and others involved in animal husbandry, have also been published by the Health and Safety Executive. Details of these publications are given in the References.

Box 1 Human and Animal TSEs

The human TSEs occur in 3 groups:

- Idiopathic diseases: Sporadic CJD and sporadic fatal insomnia
- Familial diseases: Familial CJD, Gerstmann-Sträussler-Scheinker disease (GSS) and fatal familial insomnia
- Acquired diseases: Human agents: Kuru and iatrogenic CJD
Bovine agent: Variant CJD

All human TSEs are very rare; the world-wide incidence of CJD is about 1 per million people each year. Sporadic CJD accounts for around 85% of all human TSEs; familial TSEs account for around 10-15% of cases and the remaining smaller numbers include the acquired human TSEs. In sporadic CJD the usual age of onset is late middle age (average age 65 years). Most patients present with rapidly progressive dementia with focal neurological signs including ataxia, myoclonus, visual disturbances and rigidity. Death usually occurs within 4-6 months of clinical onset. The clinical features of familial TSEs are much more variable, even within affected families. Some patients exhibit clinical features which resemble sporadic CJD, while in GSS most patients present with ataxia and other movement disorders before the onset of dementia. In sporadic and fatal familial insomnia, patients usually suffer from prominent sleep disturbances before the onset of other neurological abnormalities.

Kuru occurred as an epidemic in the Fore-speaking people in the Eastern highlands of Papua New Guinea and was first reported in 1957. Its transmission was associated with funeral rites involving ritual contact with, preparation of, and consumption of the entire body (including brains) of relatives who had died of kuru. The similarity, especially of the neuropathology, between kuru and scrapie, a disease of sheep that had been shown to be transmissible some 20 years earlier, led to the subsequent successful experimental transmission of kuru to primates. A link was thus established between human contact with kuru-infected tissues, their consumption and the eventual development of kuru. The incidence of kuru has been markedly reduced following the abolition of cannibalism coupled with health education, although recent cases still arise from historical exposure,

indicating a maximum (to date) incubation period of around 40 years. The shortest incubation period in kuru is reported to be about five years.

The first case of iatrogenic transmission of CJD was identified in 1974 in a corneal graft recipient. Since then several hundreds of cases of iatrogenic CJD have been reported, most of which have occurred in recipients of human-derived pituitary hormones or human-derived dura mater grafts. Other rarer sources of infection include contaminated neurosurgical instruments and intracerebral electrodes. Incubation periods for iatrogenic CJD range from 1-2 years for neurosurgical routes of transmission to over 30 years in some pituitary hormone recipients. World Health Organisation guidelines on TSE's in relation to biological and pharmaceutical products have been published recently⁹.

In 1996, the National CJD Surveillance Unit in the UK^{10,11} identified a new form of CJD, which is now known as variant CJD. Variant CJD generally affects young adults (mean age at onset 28 years) with a clinical illness that lasts on average for 14 months. The initial features include psychiatric abnormalities and sensory abnormalities, which are usually followed by ataxia, myoclonus and other movement disorders and accompanied by dementia. At the time of writing, over 140 cases of variant CJD have been identified, over 90% of which have been in the UK. Considerable uncertainty exists over the likely future numbers of variant CJD cases in the UK; there has been a small but important decline in the incidence of the disease in 2002. There is a substantial body of evidence from multiple transmission studies to indicate that the agent responsible for variant CJD is biologically indistinguishable from the BSE agent, making this the only known human TSE which has arisen from infection from another species.

There have been no confirmed cases of transmission of TSE by virtue of occupation. There have been a small number of reports of sporadic CJD in healthcare workers (including a neurosurgeon, retired laboratory workers and a pathologist) but their link with their occupation is speculative. There is no evidence at present that occupational exposure to BSE is a risk factor for variant CJD.

The animal TSEs are:

- scrapie in sheep, goats and moufflon;
- bovine spongiform encephalopathy (BSE) in cattle;
- transmissible mink encephalopathy (TME) in farmed mink;
- chronic wasting disease (CWD) in deer and elk species;
- feline spongiform encephalopathy (FSE) in domestic cats and captive exotic felines;
- spongiform encephalopathy in captive exotic ungulates.
- Spongiform encephalopathy reported in primates in a French zoological collection.

BSE was first confirmed in the United Kingdom in 1986. Up to December 2002 about 183,000 native-born cattle in the UK are known to have been affected, and a total of over 3,000 native-born cattle in several other countries, including most countries of the EU. Current statistics can be found on the Defra website¹². A few cases have occurred in these and some other countries following export of live cattle from countries with BSE.

Affected animals become unsteady on their feet, lose weight and become nervous, hence the term 'mad cow disease'. The BSE epidemic has been in continuous decline since 1992/3 in the UK as a result of successive bans on feeding ruminant-derived protein and subsequently mammalian-meat-and-bone-meal to ruminants. All animals suspected of having BSE are compulsorily slaughtered and completely destroyed. Ruminant or more extensive feed bans are now applied throughout the EU and in many other countries of the world, even those unaffected by BSE.

Scrapie occurs in sheep, and more rarely in goats and moufflon, and has been recognised for more than 250 years. Affected animals often scrape themselves against objects to alleviate itching, become unsteady on their feet and lose condition. It is endemic in flocks in many countries, but there is no evidence that it can be transmitted to humans.

TME was first recognised in farmed mink in 1947 and has occurred sporadically since then, but there have been no reports since the 1990s. CWD in Rocky Mountain elk, mule deer and some other deer species is also a TSE. Originally seen only in wild-life facilities

in the USA, CWD is now reported in free-ranging and farmed deer and elk in the USA and in Canada. There have been recent reports of CWD in elk exported from Canada to Korea. CWD has not been reported in Europe and TME has not been reported in the UK. TSEs have been recognised in domestic cats and captive, exotic felines and ungulates, most, but not all of which were born in the UK. Strain typing studies have indicated that at least some of these cases and perhaps all are due to exposure to the BSE agent, presumably by the dietary route. These 'mini-epidemics' appear to have subsided to obscurity as a result of the various bans to protect animal species from feed exposure to TSE agents.

Report of a spongiform encephalopathy in primate species in France, and a captive golden cat from Europe that died in Australia, did not involve any residence in the UK.

Reference List:

1. Collinge J (2001) Prion diseases of humans and animals: their causes and molecular basis. *Annu Rev Neurosci.* 2001; **24**: 519-50.
2. Lasmezaz CI (2003) The transmissible spongiform encephalopathies. *Rev Sci Tech* **22** (1): 22-36.
3. DeArmond SJ, Prusiner SB (2003) Perspectives on prion biology, prion disease pathogenesis, and pharmacologic approaches to treatment. *Clin Lab Med* 23 (1): 1 -41
4. Transmissible Spongiform Encephalopathies - a summary of present knowledge and research. Spongiform Encephalopathy Advisory Committee. HMSO 1995. ISBN 0 11 242 9874.
5. Control of Substances Hazardous to Health Regulations (Fourth Edition): The Control of Substances Hazardous to Health Regulations 2002. Approved Code of Practice and Guidance. HSE Books. ISBN 0-7176-2534-6
6. BSE (Bovine Spongiform Encephalopathy): Background and General Occupational Guidance. HSE Books. 1996. ISBN 0-7176-1212-0.
7. Guidance for handling meat and bone meal material. MISC 088 1998, (Free supplement to the occupational BSE guidance available from HSE Books.)
8. HSE Agriculture Information Sheet No. 2 (revised) "Common zoonoses in cattle". <http://www.hse.gsi.gov.uk/pubns/ais2.pdf>.
9. WHO/BCT/QSD/03.01 'WHO Guidelines on Transmissible Spongiform Encephalopathies in relation to Biological and Pharmaceutical Products. World Health Organisation 2003.
10. Will RG *et al.* (1996) A new variant of Creutzfeldt-Jakob disease in the UK. *Lancet* **347** (9006): 921-5.
11. National CJD Surveillance Unit (NCJDU) Home page: <http://www.cjd.ed.ac.uk/>
12. Department for Environment, Food and Rural Affairs. BSE Home Page: <http://www.defra.gov.uk/animalh/bse/>

Formatted: French (France)

Field Code Changed

Formatted: French (France)

Formatted: French (France)

Annex C Decontamination and Waste Disposal

General Introduction

C.1: This Annex provides guidance on how to decontaminate surfaces and equipment, clean up spillages and dispose of clinical waste associated with the causative agents of TSE diseases in:

- hospitals and other health care premises;
- patient's homes; and
- laboratories (diagnostic, research etc).

Table C.1 lists some of the relevant information and guidance available in this area.

TABLE C.1 SELECTED GUIDELINES AND STANDARDS RELATED TO DECONTAMINATION AND WASTE DISPOSAL

| | |
|---|---|
| 93/42/EEC - The Medical Devices Directive | Directive under European Law for medical devices other than active implantable and <i>in vitro</i> diagnostic devices. UK law since 1998. Two essential requirements in the Directive are relevant: "8.4: Devices delivered in a sterile state must have been manufactured and sterilised by an appropriate validated method." "8.5: Devices intended to be sterilised must be manufactured in appropriately controlled (e.g. environmental) conditions." |
| ISO 9001:2000 | 2000: Quality management systems - requirements. Specification for production, installation and servicing |
| HBN ¹ 13 ⁶ | Design of Sterile Service Departments |
| HTM ² 2010 ⁶ | Sterilizers |
| HTM 2030 ⁶ | Washer Disinfectors |
| HTM 2031 ⁶ | Clean Steam for Sterilizers |
| Standards and Practice | 2000: Institute of Sterile Services Management Manual of resource and quality standards |
| 'Glennie' Guidance | NHS Scotland: Sterile Services Provision Review Group: 1 st Report [Scottish Executive 2001] [inc hyperlink to report - http://www.show.scot.nhs.uk/sehd/publicati |

| | |
|---|--|
| | ons/sspr/sspr.pdf |
| MDA ³ DB 2002/05 | 2002: Decontamination of Endoscopes |
| MDA DB 2002/06 | 2002: Benchtop steam sterilizers: guidance on purchase, operation and maintenance |
| MAC ⁴ Manual | 1999, 2000, & 2002: Three part rolling update of guidance on decontamination. ISBN1 518.9 |
| DH/BDA ⁵ Infection control in dentistry | 2003: Contains decontamination guidance for dental practitioners. Also known as "A12 document" |
| NHS Estates: A guide to the decontamination of surgical instruments and equipment. ⁷ | 2003: summary document of essential practices for decontamination of medical devices (In Press) |
| HSE | 1999: Safe disposal of clinical waste. Health Services Advisory Committee |
| Environment Agency | Hazardous waste technical guidance (WM2) [hyperlink to EA site] |

- 1 HBN = NHS Estates Health Building Note
- 2 HTM = NHS Estates Health Technical Memorandum
- 3 MDA = Medical Devices Agency now the Medicines and Healthcare Products Regulatory Agency
- 4 MAC = Microbiological Advisory Committee to Department of Health Medical Devices Agency now the Medicines and Healthcare Products Regulatory Agency
- 5 BDA = British Dental Association
- 6 In Scotland, the relevant documents are SHBN 13, and SHTM 2010/2030/2031: these are similar, but not identical to their NHS Estates counterparts
- 7 Will not automatically be adopted in Scotland, where 'Glennie' guidance also applies

C.2: TSE agents are particularly resistant to standard physical and chemical methods of inactivation and decontamination. **Therefore, effective cleaning is the most efficient method of eliminating these agents.** The standard laboratory autoclave regimen of 121°C for 15 minutes is ineffective, and autoclaving at 134°C to 137°C held for 3 minutes cannot be relied upon to remove the infectious agents. Previous recommendations of 134-137°C for a single cycle of 18 minutes, or 6 successive cycles of 3 minutes each, are also now known not to be reliably effective for removal.

C.3: Gases such as ethylene oxide and formaldehyde are ineffective, as are most chemical disinfectants such as alcohols, formaldehyde and other aldehydes (such as glutaraldehyde), β -propiolactone, hydrogen peroxide, iodophors, peracetic acid and phenolics.

C.4: Sodium hypochlorite has been shown to be effective but only at concentrations (20,000 ppm available chlorine) that pose certain practical constraints. Sodium hydroxide (1M for 1 hour) has a substantial effect, and will reduce infectivity to an acceptable level when used at ambient temperature to disinfect spillages (Table C.2). Ionising or UV irradiation at conventional doses and dry heat are also not effective. The effectiveness of other processes and agents, such as gas plasma, has yet to be fully evaluated. Formic acid (96% for 1 hour) may be used for histological samples that have previously been fixed in formaldehyde. Table C.3 lists those chemicals and processes ineffective against TSE agents

Table C.2 CHEMICALS AND PROCESSES EFFECTIVE
AGAINST TSE AGENTS

| Chemical disinfectants | Gaseous disinfectants | Physical processes |
|--|------------------------------|---------------------------|
| 20,000ppm available chlorine of sodium hypochlorite for 1 hour 1M sodium hydroxide for 1 hour For formalin-fixed histological samples only, 96% formic acid for 1 hour | None | None ¹ |

¹ Note: even use of a porous load steam sterilizer 134-137°C for a single cycle of 18 minutes is ineffective. Six successive cycles of 3 minutes each was previously recommended but is now known not to be completely effective. Strains of TSE agent vary in their sensitivity to heat. However, autoclaving still remains an important method of reducing infectivity.

It should be noted that combinations of some processes could be effective (e.g. chemical/physical), for example, autoclaving with sodium hydroxide.

Important note:

The so-called 'Prion Cycle' found on some bench-top sterilizers is ineffective and should not be used (see MHRA Safety Notice 'SN2002(11) Benchtop vacuum steam-sterilizers - the 'Prion Cycle' [DN: inc hyperlink to site; address is

<http://devices.mhra.gov.uk/mda/mdawebsitev2.nsf/webvwMDASafetyWarnings/8BF37507CCA31E0880256B8F0041F6?OPEN>]

Table C.3 CHEMICALS & PROCESSES INEFFECTIVE AGAINST TSE AGENTS

| Chemical disinfectants | Gaseous disinfectants | Physical processes |
|--|------------------------------|---|
| Alcohols | Ethylene oxide | Dry heat |
| Ammonia | Formaldehyde | Ionising, UV or microwave radiation |
| β-propiolactone | | |
| Chlorine dioxide | | |
| Formalin | | |
| Glutaraldehyde and related compounds ¹ (e.g. orthophthalaldehyde [OPA]) | | Autoclaving at 121°C for 15 minutes and porous load autoclaving for extended cycles and times |
| Hydrochloric acid (Not reliably effective for practicable use) | | 'Prion Cycle' on some bench top analysers |
| Hydrogen peroxide | | |
| Iodophors | | |

| | | |
|--|--|--|
| Peracetic acid | | |
| Phenolics | | |
| Sodium dichloroisocyanurate (e.g. 'Presept') ² | | |
| 10,000ppm sodium hypochlorite (Not reliably effective for practicable use) | | |

1 These agents are strong fixatives, and may decrease the efficiency of the decontamination process.

2 The rate of release of chlorine from this product is insufficient to ensure complete inactivation of the agent.

Decontamination In The Hospital And Other Health Care Premises

Hospitals:

C.5: Where possible all surgical instruments should be re-processed in a Sterile Services Department (SSD) that meets the essential requirements of the Medical Devices Directive 93/42/EEC. Those departments not following the Directive should comply with the standards and guidance defined in the National Decontamination Strategy [inc hyperlink to '<http://www.doh.nhsweb.nhs.uk/health/decontamination-guidance.htm>']. Acceptable standards for decontamination are implemented via the 'Glennie' Technical Group in Scotland.

C.6: Where procedures that could lead to contact with high or medium risk material are performed on definite, probable or high-risk cases, surfaces should be covered with disposable absorbent plastic backed material, which can then be removed and incinerated. Absorbent material should be used to soak up spillages of high or medium

risk material, which can then be contained and incinerated. Contaminated surfaces should be cleaned thoroughly - using only recommended decontamination procedures (paragraph C.14 - C.15). Secure, leak-proof containers, e.g. double bagging, should be used for the safe handling of clinical waste. External contamination of the waste container should be avoided. Appropriate personal protective equipment [PPE] should be worn at all times where contact with infectious material is possible. It is essential that an effective tracking system be in place so that instruments can be related to use on a particular patient.

Other healthcare premises e.g. Primary Care:

C.7: There is a trend in primary care towards central processing of instruments, for example at a SSD (paragraph C.5); this should be encouraged. Where local processing is occurring the same principles apply, including provision of a separate decontamination area and the use of ultrasonic bath, washer/disinfector and autoclave. Effective monitoring, validation and maintenance of this equipment and processes with periodic testing are most important (see NHS Decontamination website at www.decontamination.nhsestates.gov.uk/guidance_information/index.asp - [DN: please include a hyperlink])

C.8: The types of surgical procedures performed in Primary Care are not normally considered to present a risk of transmission of TSE agents. After use, instruments should be processed in the normal way.

Surgical instruments used on High and Medium Risk Tissues in patients who are Definite/Probable/At Risk of CJD:

C.9: Instruments used on definite/probable/at risk patients (Table 4a 'Categorisation of patients at risk') should be single-use as far as possible. Paragraphs 4.37-4.41 of Part 4 and the matrices they contain advise whether instruments that are normally used and reprocessed should be:

- permanently removed from use and destroyed or kept for research purposes;

- quarantined (Part 4, paragraph 4.46); or
- require no special precautions and are processed in the usual way.

Instruments used on all other patients irrespective of whether surgery involves High or Low risk tissues:

C.10: No special precautions are required for these instruments and they can be processed in the usual way.

Endoscopes:

C.11: See Annex F, and MDA DB 2002 (05), July 2002 Decontamination of Endoscopes.

Dental Instruments:

C.12: There appears to be no evidence that human dental tissue including dental pulp contains abnormal prion protein; therefore the likelihood of TSE agent transmission by dental instruments particularly endodontic files and reamers is low. Similarly the likelihood of tonsillar abrasion i.e. contact with a known high-risk tissue during dentistry is normally considered to be remote.

C.13: Dental instruments are frequently difficult to clean effectively and guidance given in A.12 from the British Dental Association should be followed.

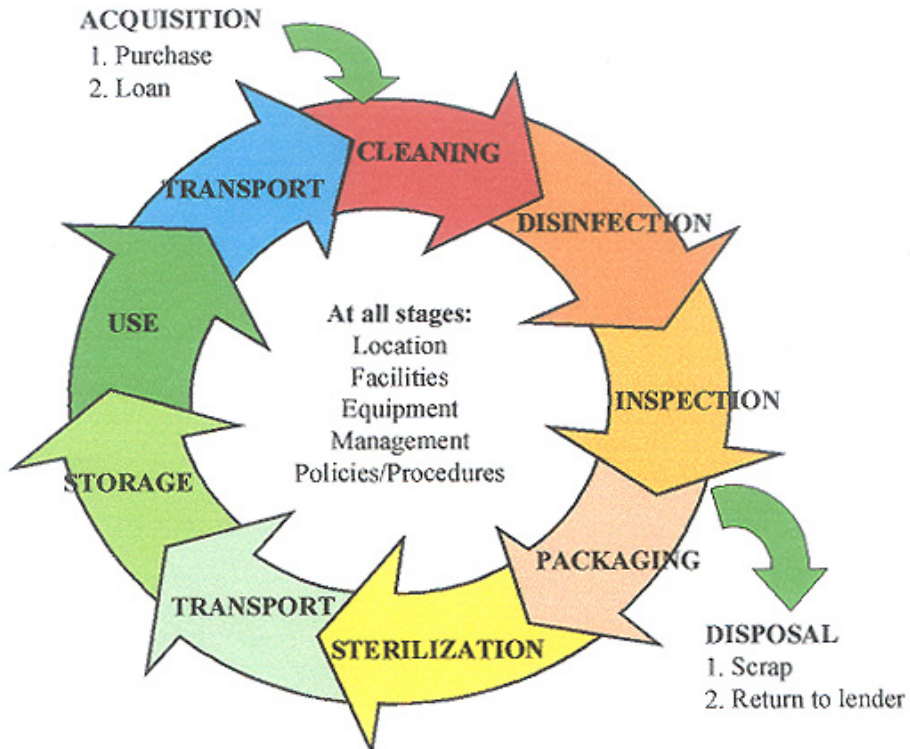
Surface decontamination and the management of spillages:

C.14: Paragraphs 4.26 and 4.27 of Part 4 give some guidance on dealing with spillages in the healthcare setting. Sodium hypochlorite containing 20,000ppm available chlorine or 1M sodium hydroxide should be used for the decontamination of surfaces in contact with high or medium risk material from definite, probable or high-risk cases. Care should be taken when handling these chemicals at these concentrations. Simple precautions such as the use of gloves, eye protection and plastic

aprons should be taken. Needs may differ according to different circumstances but in any event a full risk assessment will be required. Repeated wetting with the disinfectant over the 1-hour treatment period is necessary. As this concentration of hypochlorite can be corrosive for some commonly used surface finishes it should be used with caution. All materials used in the cleaning operation should be disposed of by incineration.

C.15: For minor spillages of low risk materials such as blood and urine [see Annex A.1] from definite, probable or high-risk cases, the surface should be disinfected using standard infection control precautions. For spillages of larger volumes of low risk liquids, absorbent material should be used to take up the spillage. A number of proprietary absorbent granules are available for such use but it should be noted that those containing dichloroisocyanurate would not deactivate TSE agents. After disinfection (see paragraph C.4), all waste should be disposed of as clinical waste. Disposable gloves and an apron should be worn when removing any spillage and these should also be disposed of as clinical waste (see paragraphs C.28 - C.32).

Life-cycle of re-usable surgical instruments



(Reproduced from "A review of the decontamination of surgical instruments in the NHS in England" NHS Estates 2001.)

The Patient's Home

C.16: It is unlikely that procedures will be adopted when managing a patient at home that will lead to surgical instruments coming into contact with high or medium risk material from definite, probable or high risk cases. If surgical instruments are used in the patient's home, then the guidance in paragraph C.9 should be followed for procedures likely to involve contact with high or medium risk material. The procedures in paragraph C.10 should be followed for all other instruments.

C.17: The procedures outlined in paragraphs C.14 and C.15 should be used to clean up spillages that occur in the patient's home. The procedures for dealing with bed linen are outlined in paragraph 4.30 of Part 4.

Laboratory Decontamination

C.18: To limit surface contamination, it is recommended that laboratory work with TSE agents or infective material should, when appropriate, be carried out in stainless steel, heat-stable plastic or disposable trays. Reusable trays should be autoclaved after thorough cleaning. Disposable items should be disposed of as clinical waste.

C.19: Surfaces should be resistant to the chemicals used for disinfection but disposable, absorbent, plastic-backed coverings could be used as an alternative.

C.20: Sodium hypochlorite containing 20,000ppm available chlorine or 1M sodium hydroxide should be used for the decontamination of surfaces that have been in contact with high or medium risk material from definite, probable or high-risk cases. As these concentrations of sodium hypochlorite and sodium hydroxide are caustic and potentially harmful for individuals, and also corrosive for some commonly used surface finishes, they should be used with caution. Appropriate precautions should be used when handling chemicals at high concentrations (e.g. the use of appropriate gloves, eye protection and plastic aprons). Repeated wetting with the disinfectant over the 1-hour treatment period is necessary. All materials used in the cleaning operation should be disposed of as

clinical waste.

C.21: For minor spillages of low risk material, such as blood, CSF and urine [see Annex A.1 and A.2] from definite, probable or high-risk cases, standard laboratory disinfection procedures can be followed. For spillages of larger volumes of low risk liquid, absorbent material should be used to absorb the spillage. A number of proprietary absorbent granules are available for such use but it should be noted that those containing dichloroisocyanurate would not deactivate TSE agents. After disinfection, all waste should be disposed of as clinical waste. Disposable gloves and an apron should be worn when removing any spillage and these should also be disposed of as clinical waste (see paragraphs C.28-C.32).

Inactivation of laboratory samples:

C.22: All tissue blocks for histological examination should be immersed in 96% formic acid for 1 hour after routine fixation. It should be noted that formic acid decontamination is not effective on unfixed tissue. **If tissue samples have been exposed to phenol it is not considered safe to then expose them to formic acid because of the risk of explosion.** Such samples should therefore be handled as un-decontaminated tissue.

C.23 Paraffin sections from blocks of tissue not previously decontaminated should be immersed in 96% formic acid for 5 minutes after de-waxing.

C.24: In your laboratory you may already treat clinical samples prior to disposal, using methods such as autoclaving. Clinical specimens of low risk material (eg urine) could also be autoclaved to reduce infectivity (although this process will not completely remove it - see Table C.3). Samples can then be disposed of as described in paragraph C.32.

Decontamination of safety cabinets:

C.25: Formalin, as gaseous formaldehyde, which is the conventional medium for the fumigation of safety cabinets, is not effective against TSE agents.

Nonetheless, fumigation will be required as a precaution against other infectious agents that may be impacted on the surface of a cabinet's HEPA filter. The unit should be decontaminated according to protocol before changing filters.

C.26: Owing to the difficulties associated with their decontamination, it is recommended that safety cabinets used for work with TSE agents should be of the type with the facility for removing HEPA filter units by bagging. Whether or not bagging of the filter as it is withdrawn is possible, spraying the filter face after fumigation and before removal, with e.g. hair spray lacquer, will help to limit the shedding of particulate matter. Where a Class II cabinet (BS:5762:1992) is to be used, a model that has the main HEPA filter immediately below the work surface is preferred, as this will prevent contamination of the plenum of the cabinet. With the filter in this position, liquid latex can be used to seal the filter surface before removal. Pre-filters (dust filters) are generally easily removed, and after immersion treatment with 1M sodium hydroxide solution [see above] they should be contained securely before incineration. Alternatively, they may be treated with hypochlorite solution containing 20,000ppm available chlorine.

C.27: Working in a shallow tray in the cabinet will limit dispersal onto work surfaces by splashing, but it is essential to ascertain, by testing the cabinet with the tray *in situ*, that containment for operator protection is not affected (see BSEN 12469: 2000 and ACDP guidance - The management, design and operation of microbiological containment laboratories - for details of testing). Another option is to tape disposable plastic-backed absorbent paper to the work surface in order to minimise contamination. The covering must be renewed regularly (preferably after each period of work) and incinerated.

Disposal of clinical waste:

C.28: General guidance on the safe management of clinical waste is given in the Health Services Advisory Committee's guidance *Safe disposal of clinical waste*. According to the above guidance high and medium risk tissues/fluids, from definite/probable/at risk patients,

are defined as Group A waste (or Group C waste if coming from a laboratory setting). Such clinical waste should be disposed of by incineration. This also applies to items that have been contaminated with these materials, e.g. dressings.

C.29: Duty holders who create waste also need to consider the Environment Agency's Hazardous Waste Technical Guidance [*inc hyperlink to EA site*] when considering how to dispose of their clinical waste. Under the Special Waste Regulations 1996 (as amended) only healthcare waste containing Hazard Group 4 organisms (other than sharps or body parts) is classed as special waste. As TSE agents are not Hazard Group 4 agents, there is no need to consider these Regulations when deciding how to dispose of clinical waste from definite/probable/at risk patients. Contact details for the EA for those with further enquiries can be found at the end of this section.

C.30: Appendix C of the Hazardous Waste technical guidance considers the assessment of infectious waste (H9). The guidance states that the underlying principle to consider when assessing H9 is the recognition that many waste streams contain pathogens. However, where there is a low probability that infectious substances are present, where the concentration is at a level naturally encountered, or where the infectious fraction has been removed by specific segregation at source, a waste would not be hazardous by H9. The current scientific evidence suggests that there is a low probability of infectious TSE agents being present in low risk TSE material. This means that waste containing low risk material, such as urine and faeces, and the items contaminated by such waste (e.g. disposable bed pans) are not hazardous waste and therefore do not have to be incinerated. Low risk material can be classed by duty holders as controlled waste and can be disposed of as clinical waste according to local practices.

C.31: The following laboratory waste should be incinerated:

- waste from definite/probable/at risk patients that could contain high or medium risk tissue;

- waste from the post-mortem examination of definite/probable/at risk patients; and
- carcasses and other associated material from all animals experimentally infected with a TSE agent (see paragraph 3.45, Part 3).

C.32: Other human clinical waste from laboratories, which will contain low risk material or items contaminated by such material, can be disposed of by routine methods for disposing of clinical waste. Animal bedding and faecal waste, from animals experimentally infected with a TSE agent (following any initial shedding phase) can be disposed of in the normal way (e.g. by landfill burial or discharge to the sewer system). Note that the disposal of such animal waste is subject to the requirements of DEFRA, the Environment Agency and the Local Authority (see paragraph 3.45, Part 3).

EA contact details for further enquiries relating to the disposal of waste:

General Enquiry Line: 0845 9333111
enquiries@environment-agency.gov.uk

ENDOSCOPES

Decontamination of endoscopes

F.1 The general procedures set out in the MDA Device Bulletin MDA DB2002(05), available at www.medical-devices.gov.uk, should be followed. In order to decrease the risk of transmission of TSEs through endoscopic procedures, additional precautions for the decontamination of flexible endoscopes are recommended in this annex:

(a) Channel cleaning brushes and the valve on the biopsy/instrument channel port used with flexible endoscopes should be disposed as clinical waste after each use. This guidance endorses the advice of the MDA Bulletin that other accessories should be single-use wherever possible, but where this is not possible, they must be kept together with the endoscope, forming a unique set, until the accessories are disposed of. It is essential to have systems in place that enable endoscopes, together with all re-usable accessories, to be traced to the patients on whom they have been used.

(b) Aldehyde disinfectants with fixative qualities (such as glutaraldehyde and OPA) tend to stabilise, rather than inactivate prions. The use of non-fixative disinfectants, if this is in accordance with the manufacturers' instructions, is therefore preferable. Disinfectants with fixative properties should not be used on flexible endoscopes used for any procedure on patients or patients with a diagnosis of definite, probable or possible CJD or where the diagnosis of CJD is unclear (see Annex B, paragraph B12) or the patient is at risk of developing CJD. Contact the endoscope supplier for advice on appropriate alternatives.

Definitions

F2 The definitions of different types of patients are as set out in paragraphs 4.16 – 4.17 in Part 4 and Annex B of this guidance.

F3 PrP^{res} has been detected in the olfactory epithelium, but not the respiratory epithelium, of sporadic CJD patients (see paragraph 4.5 of Part 4 of this guidance). The olfactory epithelium is normally located deep within the nasal turbinates but its distribution varies between individuals. The advice of the consultant carrying out the endoscopic procedure in the nasal cavity should be sought to determine whether a risk of contamination of the endoscope with olfactory epithelium can be excluded with confidence. If such contamination

cannot be excluded, take precautions appropriate for medium infectivity tissues.

Sporadic and other non-variant CJD

This includes sporadic CJD, iatrogenic classical CJD and familial prion diseases.

Symptomatic sCJD patients (definite, probable)

- F.4 Neurological endoscopes would not normally be used on patients whose diagnosis is probable or definite CJD. However, should use be necessary, the endoscope should be single use if possible. If this is not appropriate, the endoscope should be destroyed¹.
- F.5 Endoscopes that come into contact with the nasal cavity may, on occasion, be used in patients with CJD. If there is a risk that the endoscope could become contaminated with olfactory epithelium (see paragraph F3 of this Annex), a single use endoscope should be used if possible. If this is inappropriate, the endoscope should be destroyed¹.
- F.6 For all other types of endoscopy, normal decontamination procedures, as set out in the MDA Device Bulletin MDA DB2002(05) should be followed, with the additional precautions for flexible endoscopes as set out in paragraph F.1 above.

Symptomatic CJD patients (possible and diagnosis unclear²)

- F.7 Neurological endoscopes would not normally be used on patients whose diagnosis is possible CJD or for whom the diagnosis of CJD is unclear. However, should use be necessary, a single use endoscope should be used if possible. If this is not appropriate, the re-usable endoscope should be quarantined pending a more definitive diagnosis. The quarantined endoscope may be re-used exclusively on the same individual patient if required. If further clarification of the diagnosis is not possible, the endoscope should be destroyed¹.
- F.8 Endoscopes that are used in the nasal cavity may, on occasion, be used in patients with CJD. If there is a risk that the endoscope could become contaminated with olfactory epithelium (see paragraph F3 of this Annex), a single use endoscope should be used where possible. If this is not appropriate, the endoscope should be quarantined pending a more definitive diagnosis. The quarantined endoscope may be re-used exclusively on the

¹ Instruments that are destined for disposal by incineration may be collected for use in research. Anyone considering such a course of action should contact the Department of Health (Dr Philippa Edwards on tel. 0207 972 5324, e-mail: philippa.edwards@doh.gsi.gov.uk).

² Patients with neurological disease of unknown aetiology who do not fit the criteria for possible CJD but where a diagnosis of CJD is being actively considered (see also Annex B of this guidance)

same individual patient if required. If further clarification of the diagnosis is not possible, the endoscope should be destroyed¹.

- F.9 For all other types of endoscopy, normal decontamination procedures, as set out in the MDA Device Bulletin MDA DB2002(05) should be followed, with the additional precautions for flexible endoscopes as set out in paragraph F.1 above.

Asymptomatic patients at risk of for CJD

- F.10 No special precautions are required for the use, in at risk patients, of rigid endoscopes without lumens that can be autoclaved. The guidance in Part 4 for all surgical instruments can be followed.
- F.11 For other types of endoscopes that are used for central nervous tissue investigations, single-use instruments should be used if possible. Where this is not possible without compromising clinical standards, the endoscope should be quarantined after use until the absence of CJD can be confirmed by eventual post-mortem. The quarantined endoscope may be re-used exclusively on the same individual patient if required. If confirmation of the absence of CJD is not practicable, the endoscope should be destroyed¹.
- F.12 If there is a risk that an endoscope used in the nasal cavity could become contaminated with olfactory epithelium (see paragraph F3 of this Annex), a single use endoscope should be used where possible. If this is not appropriate, the endoscope should be quarantined pending a more definitive diagnosis. The quarantined endoscope may be re-used exclusively on the same individual patient if required. If further clarification of the diagnosis is not possible, the endoscope should be destroyed¹. For some procedures, the endoscope may be protected from contamination by a disposable sheath, which should then be destroyed by incineration. In practice, however, it may be difficult to ensure effective protection and advice should be sought from the surgical staff carrying out the procedure and the manufacturer of the endoscope to determine practicality of this option.
- F.13 For all other types of endoscopy, normal decontamination procedures, as set out in the MDA Device Bulletin MDA DB2002(05) should be followed, with the additional precautions for flexible endoscopes as set out in paragraph F.1 above.

Variant CJD

Symptomatic vCJD patients (definite, probable)

- F.14 Neurological endoscopes would not normally be used on patients whose diagnosis is probable or definite variant CJD. However, should use be necessary, the endoscope should be single use if possible. If this is not appropriate, the endoscope should be destroyed¹ after use.

F.15 For all other types of endoscopy, a single use endoscope should be used if possible. If this is not appropriate, the endoscope should be reserved for use exclusively on this CJD patient or a dedicated endoscope used³

Symptomatic vCJD (possible or diagnosis unclear²)

F.16 Neurological endoscopes would not normally be used on patients whose diagnosis is possible vCJD or for whom the diagnosis of vCJD is unclear. However, should use be necessary, a single use endoscope should be used if possible or the endoscope should be quarantined pending a more definitive diagnosis. The quarantined endoscope may be re-used exclusively on the same individual patient if required. If further clarification of the diagnosis is not possible, the endoscope should be destroyed¹.

F.17 Endoscopes that are used in the nasal cavity, or the respiratory or gastrointestinal tracts may, on occasion, be used in CJD patients, and there is a risk that the endoscope could be contaminated with infectivity from the olfactory epithelium, or lymphoid tissue in these regions. Single use instruments should be used where possible. If this is not appropriate, the endoscope should be quarantined pending confirmation of the diagnosis. The quarantined endoscope may be re-used exclusively on the same individual patient if required. If further clarification of the diagnosis is not possible, the endoscope should be destroyed¹.

F.18 For all other types of endoscopy, normal decontamination procedures, as set out in the MDA Device Bulletin MDA DB2002(05) should be followed, with the additional precautions for flexible endoscopes as set out in paragraph F.1 above.

Asymptomatic patients at risk of vCJD

F.19 Endoscopes that are used for central nervous tissue investigations may, on occasion, be used on patients at risk of developing vCJD and there is a risk that the endoscope could be contaminated with infectivity from the nerve tissue. Single use instruments should be used if possible. Where this is not possible, the endoscope should be quarantined after use until the absence of CJD can be confirmed by eventual post-mortem. The quarantined endoscope may be re-used exclusively on the same individual patient if required. If confirmation of the absence of CJD is not practicable, the endoscope should be destroyed¹.

F.20 Endoscopes that are used in the nasal cavity (e.g. Hopkin's rod endoscopes), or the respiratory or gastrointestinal tracts may, on occasion, be used on patients at risk of developing vCJD and there is a risk that the endoscope could be contaminated with infectivity from the olfactory epithelium (see paragraph F3 of this Annex), or lymphoid tissue in these regions. Single use instruments should be used if possible. Where this is not possible, the endoscope should be quarantined after use until the absence of CJD can be confirmed by eventual post-mortem. The quarantined endoscope may be re-

³ A small number of endoscopes dedicated for use in the upper intestinal tract and the respiratory tract in patients diagnosed as probable or definite CJD cases are available on loan. Please contact the National CJD Surveillance Unit for details of availability.

used exclusively on the same individual patient if required. If confirmation of the absence of CJD is not practicable, the endoscope should be destroyed¹.

- F.21 For all other types of endoscopy, normal decontamination procedures, as set out in the MDA Device Bulletin MDA DB2002(05) should be followed, with the additional precautions for flexible endoscopes as set out in paragraph F.1 above.

Summary of precautions advised for the use endoscopes

Table F1. CJD other than vCJD

| Tissue Infectivity | Status of patient | | |
|--|---|--|--|
| | Symptomatic | | Asymptomatic |
| | Definite/probable | Possible/diagnosis unclear ¹ | At risk ² iatrogenic/familial |
| High: <ul style="list-style-type: none"> Brain Spinal cord | single use OR destroy ³ after use | single use OR quarantine ⁴ pending diagnosis | single use OR quarantine ⁴ pending exclusion of CJD |
| Medium: <ul style="list-style-type: none"> Olfactory epithelium* | single use OR destroy ³ after use | single use OR quarantine ⁴ pending diagnosis | single use ⁵ OR quarantine ⁴ pending exclusion of CJD |
| Low/none detectable <ul style="list-style-type: none"> All other tissues | no special precautions ⁶ | no special precautions ⁶ | no special precautions ⁶ |

* The advice of the consultant carrying out the endoscopic procedure in the nasal cavity should be sought to determine whether a risk of contamination of the endoscope with olfactory epithelium can be excluded with confidence. If such contamination cannot be excluded, take precautions appropriate for medium infectivity tissues (see paragraph F3 of this Annex).

¹ This includes patients with neurological disease of unknown aetiology who do not fit the criteria for possible CJD but where a diagnosis of CJD is being actively considered (see also Annex B of this guidance).

² This advice refers to the use of flexible endoscopes and endoscopes with lumens in patients at risk of developing CJD. For guidance on the use of rigid endoscopes without lumens that can be autoclaved, refer to the guidance for the use of all surgical instruments in at risk patients in Part 4 of this guidance.

³ Instruments that are destined for disposal by incineration may be collected for use in research. Anyone considering such a course of action should contact the Department of Health (Dr Philippa Edwards on tel. 0207 972 5324, e-mail: philippa.edwards@doh.gsi.gov.uk).

⁴ Quarantined endoscopes may be re-used exclusively on the same individual patient if required.

⁵ For some procedures, the endoscope may be protected from contamination by a disposable sheath, which should then be destroyed by incineration. In practice, however, it may be difficult to ensure effective protection and advice should be sought from the surgical staff carrying out the procedure and the manufacturer of the endoscope to determine practicality.

⁶ The decontamination procedures advised in F1 of this guidance, taken together with the MDA Device Bulletin MDA DB2002(05), should be followed.

Table F2 vCJD

| Tissue Infectivity | Status of patient | | |
|---|--|---|---|
| | Symptomatic | | Asymptomatic |
| | Definite/probable | Possible/diagnosis unclear ¹ | At risk ² iatrogenic |
| High: <ul style="list-style-type: none"> Brain Spinal cord | single use OR destroy ³ after use | single use OR quarantine ⁴ pending diagnosis | single use OR quarantine ⁴ pending exclusion of CJD |
| Medium: <ul style="list-style-type: none"> Olfactory epithelium* Lymphoid tissue** | single use OR use dedicated endoscope ⁷ OR destroy ³ after use | single use OR quarantine ⁴ pending diagnosis no special precautions ⁶ | single use ⁵ OR quarantine ⁴ pending exclusion of CJD no special precautions ⁶ |
| Low/none detectable <ul style="list-style-type: none"> All other tissues | | | |

*The advice of the consultant carrying out the endoscopic procedure in the nasal cavity should be sought to determine whether a risk of contamination of the endoscope with olfactory epithelium can be excluded with confidence. If such contamination cannot be excluded, take precautions appropriate for medium infectivity tissues (see paragraph F3 of this Annex).

**For the purposes of this Annex, lymphoid tissue refers to the spleen, thymus, tonsils and adenoids, lymph nodes, the appendix and other lymphoid tissue associated with the gastro-intestinal tract^{1,2,3,4,5} and ⁶ see footnotes to Table F1 above.

⁷ The NCJSU holds a few flexible endoscopes dedicated for use on probable CJD cases. If these are suitable for the clinical purpose intended, they may be borrowed from the Unit. They should **not** be used on patients with possible CJD, patients for whom the diagnosis of CJD is unclear or patients at risk of CJD.