



WHO/CDS/CSR/APH/2000.3

**WHO Infection Control Guidelines for Transmissible
Spongiform Encephalopathies**

**Report of a WHO Consultation
Geneva, Switzerland, 23-26 March 1999**

World Health Organization

**Department of Communicable Disease Surveillance and
Response**

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Section 1. INTRODUCTION

Transmissible spongiform encephalopathies (TSEs), also known as prion diseases, are fatal degenerative brain diseases that occur in humans and certain animal species. They are characterized by microscopic vacuoles and the deposition of amyloid (prion) protein in the grey matter of the brain. All forms of TSE are experimentally transmissible.

The following guideline on the prevention of iatrogenic and nosocomial exposure to TSE agents was prepared following the WHO Consultation on Caring for Patients and Hospital Infection Control in Relation to Human Transmissible Spongiform Encephalopathies, held in Geneva from 24 to 26 March 1999. The meeting was chaired by Dr Paul Brown. Dr Martin Zeidler and Dr Maurizio Pocchiari kindly agreed to be Rapporteurs. The full list of participants is given in Annex I. Presentations made at the Consultation are listed in Annex II.

This document provides guidance upon which infection control practitioners, healthcare practitioners, medical officers of health, and those involved in the care of persons suffering from TSE can base their care and infection control practices, to prevent events which are either extremely rare (e.g. transmission of TSE through a surgical procedure) or hypothetical (e.g. transmission of TSE to a healthcare worker or family member). Throughout the document there is specific and assumed reference to country or region-specific guidelines for matters which lie within the legal jurisdiction of that country or region, i.e. International Air Transport Association (IATA) regulations for transportation of hazardous goods, or bio-safety containment levels for laboratories. Readers should be familiar with such requirements for their own country or region.

Issues on which the consultants could not agree, or where the consultants did not feel there was sufficient expertise to render an opinion, have been noted. The consultation recognized that its recommendations to ensure maximum safety to caretakers and the environment may under some circumstances be regarded as impractical. However, they urged personnel involved with TSE patients or tissues to endeavour to comply as far as possible. There is no reason for a patient with a TSE to be denied any procedure, as any associated risks should be reduced to negligible levels by following the recommendations in this document.

Section 2. GENERAL CONSIDERATIONS

2.1 Transmissible Spongiform Encephalopathies in humans and in animals

Human TSEs occur in sporadic, familial, and acquired forms. The most common form, sporadic Creutzfeldt-Jakob disease (CJD), has a worldwide death rate of about 1 case per million people each year, and typically affects people between 55 and 75 years of age. The disease usually begins with a progressive mental deterioration that soon becomes associated with progressive unsteadiness and clumsiness, visual deterioration, muscle twitching (myoclonus), a variety of other neurological symptoms and signs, and is often associated with a characteristic periodic electroencephalogram. The patient is usually mute and immobile in the terminal stages and in most cases, death occurs within a few months of onset of symptoms. TSEs are invariably fatal and there is no proven treatment or prophylaxis.

Table 1 Human TSEs

Human TSE	First Reported
Creutzfeldt-Jakob Disease (CJD): ¹	
Sporadic (85-90%)	1921
Familial (5-10%)	1924
Iatrogenic (<5%)	1974
Variant (vCJD)	1996
Gerstmann-Sträussler-Scheinker Syndrome (GSS)	1936
Kuru	1957
Fatal Insomnia	
Familial	1986
Sporadic	1999

Similar neurodegenerative diseases also occur naturally in some animal species (scrapie in sheep and goats, chronic wasting disease in deer and elk), or as a result of exposure of susceptible species to infected animal tissues (transmissible mink encephalopathy, bovine spongiform encephalopathy, and spongiform encephalopathy in domestic cats and a variety of captive zoo animals).

TSE agents exhibit an unusual resistance to conventional chemical and physical decontamination methods. They are not adequately inactivated by most common disinfectants, or by most tissue fixatives, and some infectivity may persist under standard hospital or healthcare facility autoclaving conditions (e.g. 121°C for 15 minutes). They are also extremely resistant to high doses of ionizing and ultra-violet irradiation and some residual activity has been shown to survive for long periods in the environment. The unconventional nature of these agents, together with the appearance in the United Kingdom, Republic of Ireland and France of a new variant of CJD (vCJD) since the mid-1990s, has stimulated interest in an updated guidance on safe practices for patient care and infection control.

2.2 Diagnosis of Human Transmissible Spongiform Encephalopathies

The February 1998 Report of a WHO Consultation the Global Surveillance, Diagnosis and Therapy of Human Transmissible Spongiform Encephalopathies^{2,3} provides a guideline for diagnostic criteria of human TSEs. Readers should be aware of efforts to revise diagnostic criteria for CJD and vCJD due to the introduction of new diagnostic tests and intense surveillance efforts. Surveillance case definitions (which may not be the same as diagnostic criteria) for both forms of the disease may also be subject to change.

2.3 Iatrogenic transmission

TSEs are not known to spread by contact from person to person, but transmission can occur during invasive medical interventions. Exposure to infectious material through the use of human cadaveric-derived pituitary hormones, dural and cornea homografts, and contaminated neurosurgical instruments have caused human TSEs. The Report of a

¹ Percentages vary somewhat from country to country.

² All cited WHO reports and consultations are available at the WHO Web site <http://www.who.int/emc/diseases/bse/>.

³ WHO Consultation on Global Surveillance, Diagnosis and Therapy of Human Transmissible Spongiform Encephalopathies. WHO/EMC/ZDI/98.9 Geneva, 9-11 February 1998.

WHO Consultation on Medicinal and other Products in Relation to Human and Animal Transmissible Spongiform Encephalopathies⁴ can be consulted for more information and guidance on these issues.

2.4 Evaluating risk in healthcare environments

When considering measures to prevent the transmission of TSE from patients to other individuals (patients, healthcare workers, or other care providers), it is important to understand the basis for stipulating different categories of risk. Risk is dependent upon three considerations:

- the probability that an individual has or will develop TSE (see Section 2.4.1);
- the level of infectivity in tissues or fluids of these individuals (Section 2.4.2);
- the nature or route of the exposure to these tissues (Section 2.4.3).

From these considerations it is possible to make decisions about whether any special precautions are needed. Specific TSE decontamination procedures are described in Section 6. If TSE decontamination is required, the question remains as to how stringent it should be. The specific recommendations are described in sections devoted to Patient Care (Section 3), Occupational Injury (Section 4), Laboratory Investigations (Section 5) and Management After Death (Section 8).

2.4.1 Identification of persons for whom special precautions apply

Persons with confirmed or suspected TSEs are the highest risk patients. They must be managed using specific precautions which will be described in this and subsequent sections. All precautions recommended in the body of this document apply to the care of confirmed or suspect cases of TSE, or the handling of tissues from such patients, and unless otherwise noted, no distinction will be made between confirmed and suspect cases.

However, the concept of 'persons at risk for TSE' is useful in infection control, as it allows for the development of intermediate precautionary measures. The following persons have been regarded as 'at risk' for developing TSEs. The bracketed numbers are the number of reported occurrences of CJD transmitted through that route:

- recipients of dura mater (110 cases);
- recipients of human cadaver derived pituitary hormones, especially human cadaver derived growth hormone (130 cases);
- recipients of cornea transplants (3 cases - 1 definite, 1 probable, 1 possible);
- persons who have undergone neurosurgery (6);
- members of families with heritable TSE (5-10% of all cases of TSE are heritable, but the number of families varies widely from country to country).

The discussion and recommendations for healthy asymptomatic individuals considered to be at risk for TSE are described in Annex IV and referred to in Table 9.

The consultants did not extensively discuss the management of persons who have confirmed or suspected vCJD, due to the absence of specific data for review and the

⁴ Report of a WHO Consultation on Medicinal and other Products in Relation to Human and Animal Transmissible Spongiform Encephalopathies. Geneva, World Health Organization, 1997. WHO/EMC/ZOO/97.3 or WHO/BLG/97.2.

geographical isolation of the current cases. The discussion and their recommendations are described in Annex V and Table 9.

2.4.2 Tissue infectivity

From published and unpublished information, infectivity is found most often and in highest concentration in the central nervous system (CNS), specifically the brain, spinal cord and eye. This document will refer to these tissues as ‘high infectivity tissues’.

Infectivity is found less often in the cerebrospinal fluid (CSF) and several organs outside the CNS (lung, liver, kidney, spleen/lymph nodes, and placenta). This document will refer to these tissues as ‘low infectivity tissues’.

No infectivity has been detected in a wide variety of other tested tissues (heart, skeletal muscle, peripheral nerve, adipose tissue, gingival tissue, intestine, adrenal gland, thyroid, prostate, testis) or in bodily secretions or excretions (urine, faeces, saliva, mucous, semen, milk, tears, sweat, serous exudate). Experimental results investigating the infectivity of blood have been conflicting, however even when infectivity has been detectable, it is present in very low amounts and there are no known transfusion transmissions of CJD. This document will classify these tissues as having no detectable infectivity (‘no detectable infectivity tissues’) and, for the purposes of infection control, they will be regarded as non-infectious.

Table 2 Distribution of infectivity in the human body⁵

Infectivity Category	Tissues, Secretions, and Excretions
High Infectivity	Brain Spinal cord Eye
Low Infectivity	CSF Kidney Liver Lung Lymph nodes/spleen Placenta
No Detectable Infectivity	Adipose tissue Adrenal gland Gingival tissue Heart muscle Intestine Peripheral nerve Prostate Skeletal muscle Testis Thyroid gland Blood ⁶
	Faeces Milk Nasal mucous Saliva Semen Serous exudate Sweat Tears Urine

⁵ Assignment of different organs and tissues to categories of *high* and *low infectivity* is chiefly based upon the frequency with which infectivity has been detectable, rather than upon quantitative assays of the level of infectivity, for which data are incomplete. Experimental data include primates inoculated with tissues from human cases of CJD, but have been supplemented in some categories by data obtained from naturally occurring animal TSEs. Actual infectivity titres in the various human tissues other than the brain are extremely limited, but data from experimentally-infected animals generally corroborate the grouping shown in the table.

⁶ See discussion this Section and Section 5.2.

The consultants agreed that an international effort to identify stored tissues from persons who later developed CJD or that were collected during the investigation for CJD (sporadic, iatrogenic or familial) should be initiated. These specimens should be tested in order to clarify the extent and level of infectivity during the pre-clinical phase of disease. Collections of these tissues, which are potentially infective, should be properly labelled as to their source and potential infectivity and appropriately stored to avoid cross contamination.

2.4.3 Route of exposure

When determining risk, infectivity of a tissue must be considered together with the route of exposure. Cutaneous exposure of intact skin or mucous membranes (except those of the eye) poses negligible risk; however, it is prudent and highly recommended to avoid such exposure when working with any high infectivity tissue. Transcutaneous exposures, including contact exposures to non-intact skin or mucous membranes,⁷ splashes to the eye,⁸ and inoculations via needle^{9,10} or scalpel and other surgical instruments¹¹ pose a greater potential risk. Thus, it is prudent to avoid these types of exposures when working with either low infectivity or high infectivity tissues. CNS exposures (i.e. inoculation of the eye or CNS) with any infectious material poses a very serious risk, and appropriate precautions must always be taken to avoid these kinds of exposures.

Section 3. PATIENT CARE

3.1 Care of patients in the home and healthcare settings

3.1.1 Patient care

Normal social and clinical contact, and non-invasive clinical investigations (e.g. x-ray imaging procedures) with TSE patients do not present a risk to healthcare workers, relatives, or the community. There is no reason to defer, deny, or in any way discourage the admission of a person with a TSE into any healthcare setting. Based on current knowledge, isolation of patients is not necessary; they can be nursed in the open ward using Standard Precautions.

As the disease is usually rapidly progressive, the patient will develop high dependency needs and require ongoing assessment. It is essential to address the emotional, physical, nutritional, psychological, educational, and social needs of the patient and the associated needs of his or her family. Coordinated planning is vital in transferring care from one environment to another.

Private room nursing care is not required for infection control, but may be appropriate for compassionate reasons. Patient waste should be handled according to country, regional or federal regulations. Contamination by body fluids (categorized as no detectable infectivity tissues) poses no greater hazard than for any other patient. No special precautions are required for feeding utensils, feeding tubes, suction tubes, bed

⁷ TSE can be experimentally transmitted to healthy animals by exposing abraded gingival tissue to infected brain homogenate.

⁸ By analogy with cornea transplants.

⁹ A documented route of transmission in humans, from contaminated human cadaver extracted pituitary hormones (hGH and gonadotropin).

¹⁰ Intraperitoneal, intramuscular and intravenous administration of *low infectivity tissue* extracts can cause transmission of TSE in experimental animals.

¹¹ By analogy with transmissions following neurosurgical procedures.

linens, or items used in skin or bed sore care in the home environment. Section 7 provides detailed information on disposal of medical waste.

3.1.2 Psychiatric manifestations

Caregivers both in the home and healthcare setting should be made aware and anticipate the possibility of labile psychiatric symptoms e.g. mood swings, hallucinations, or aggressive behavior. For this reason, training and counselling of professional and non-professional caregivers is recommended.

3.1.3 Confidentiality

Current heightened awareness requires special sensitivity to confidentiality of written and verbal communications. Special measures to safeguard the privacy of the patient and family are essential.

3.2 Dental procedures

Although epidemiological investigation has not revealed any evidence that dental procedures lead to increased risk of iatrogenic transmission of TSEs among humans, experimental studies have demonstrated that animals infected by intraperitoneal inoculation develop a significant level of infectivity in gingival and dental pulp tissues, and that TSEs can be transmitted to healthy animals by exposing root canals and gingival abrasions to infectious brain homogenate. The consultants agreed that the general infection control practices recommended by national dental associations are sufficient when treating TSE patients during procedures not involving neurovascular tissue. The committee was unable to come to a consensus on the risk of transmission of TSEs through major dental procedures; therefore, extra precautions such as those listed in Table 3 have been provided for consideration without recommendation.

Table 3 Optional precautions for major dental work

1.	Use single-use items and equipment e.g. needles and anaesthetic cartridges.
2.	Re-usable dental broaches and burrs that may have become contaminated with neurovascular tissue should either be destroyed after use (by incineration) or alternatively decontaminated by a method listed in Section 6 (Annex and III).
3.	Schedule procedures involving neurovascular tissue at end of day to permit more extensive cleaning and decontamination.

3.3 Diagnostic procedures

During the earlier stages of disease, patients with TSE who develop intercurrent illnesses may need to undergo the same kinds of diagnostic procedures as any other hospitalized patient. These could include ophthalmoscopic examinations, various types of endoscopy, vascular or urinary catheterization, and cardiac or pulmonary function tests. In general, these procedures may be conducted without any special precautions, as most tissues with which the instruments come in contact contain no detectable infectivity (see sub-Section 2.4.2). A conservative approach would nevertheless try to schedule such patients at the end of the day to allow more strict environmental decontamination (see Section 6.3) and instrument cleaning (see Section 6.2). When there is known exposure to high or low infectivity tissues, the instruments should be subjected to the strictest form of decontamination procedure which can be tolerated by the instrument. Instrument decontamination is discussed in more detail in Section 6.2 and decontamination methods are specifically described in Annex III.

3.4 Surgical procedures

Before admission to a hospital or healthcare facility, the infection control team should be informed of the intention to perform a surgical procedure on any person with confirmed or suspected TSE. Every effort should be made to plan carefully not only the procedure, but also the practicalities surrounding the procedure, e.g. instrument handling, storage, cleaning and decontamination or disposal. Written protocols are essential. All staff directly involved in these procedures or in the subsequent re-processing or disposal of potentially contaminated items, should be aware of the recommended precautions, and be adequately trained. The staff should be made aware of any such procedures in sufficient time to allow them to plan and to obtain suitable instruments and equipment (such as single use items), and it may be useful to schedule the patient at the end of the day's operating list. Staff must adhere to protocols that identify specifics regarding pre-operative, peri-operative and post-operative management of the patient, disposable materials, including bandages and sponges, and re-usable materials. Ancillary staff, such as laboratory and central instrument cleaning personnel, must be informed and appropriate training provided.

Basic protective measures are described in Table 4. Recommendations listed in Section 6 and Annex III for decontamination of equipment and environment, and in Section 7 for disposal of infectious waste should be followed. Supervisors should be responsible for ensuring that the appropriate procedures are followed and that effective management systems are in place.

Table 4 Precautions for surgical procedures

<p>Wherever appropriate and possible, the intervention should:</p> <ol style="list-style-type: none"> 1. be performed in an operating theatre; 2. involve the minimum required number of healthcare personnel; 3. use single-use equipment as follows: <ol style="list-style-type: none"> i) liquid repellent operating theatre gown, over a plastic apron ii) gloves iii) mask iv) visor or goggles v) linens and covers; 4. mask all non-disposable equipment; 5. maintain one-way flow of instruments; 6. treat all protective clothing, covers, liquid and solid waste by a method listed in Section 6; and Annex III; incineration is preferred 7. mark samples with a "Biohazard" label; 8. clean all surfaces according to recommendations specified in Section 6 and Annex III.

Procedures which are normally carried out at the bedside (e.g. lumbar puncture, bone marrow biopsy) may be performed at the bedside, but care should be taken to ensure ease of environmental decontamination should a spillage occur.

3.5 Handling of surgical instruments

3.5.1 General measures

Methods for instrument decontamination are fully discussed in Section 6. Determination of which method to use is based upon the infectivity level of the tissue and the way in which instruments will subsequently be re-used. For example, where surgical instruments contact high infectivity tissues, single-use surgical instruments are strongly recommended. If single-use instruments are not available, maximum safety is attained by destruction of re-usable instruments. Where destruction is not practical, re-usable instruments must be handled as per Table 5 and must be decontaminated as per Section 6 and Annex III.

Although CSF is classified as a low infectivity tissue and is less infectious than high infectivity tissues it was felt that instruments contaminated by CSF should be handled in the same manner as those contacting high infectivity tissues. This exception reflects the higher risk of transmission to any person on whom the instruments would be re-used for the procedure of lumbar puncture.

Table 5 General measures for cleaning instruments and environment

1.	Instruments should be kept moist until cleaned and decontaminated.
2.	Instruments should be cleaned as soon as possible after use to minimize drying of tissues, blood and body fluids onto the item.
3.	Avoid mixing instruments used on no detectable infectivity tissues with those used on high and low infectivity tissues.
4.	Recycle durable items for re-use only after TSE decontamination by methods found in Section 6 and Annex III.
5.	Instruments to be cleaned in automated mechanical processors must be decontaminated by methods described in Section 6 and Annex III before processing through these machines, and the washers (or other equipment) should be run through an empty cycle before any further routine use.
6.	Cover work surfaces with disposable material, which can then be removed and incinerated; otherwise clean and decontaminate underlying surfaces thoroughly using recommended decontamination procedures in Section 6 and Annex III.
7.	Be familiar with and observe safety guidelines when working with hazardous chemicals such as NaOH and bleach.
8.	Observe manufacturers' recommendations regarding care and maintenance of equipment.

Those instruments used for invasive procedures on TSE patients (i.e. used on high or low infectivity tissues) should be securely contained in a robust, leak-proof container labelled "Biohazard". They should be transferred to the sterilization department as soon as possible after use, and treated by a method listed in Annex III, or transferred to the incinerator as per Section 3.5.2. A designated person who is familiar with this guideline should be responsible for the transfer and subsequent management.

The consultation did not address the issue of post-exposure notification in the event that an instrument used on a high-risk tissue and/or high-risk patient was subsequently re-used without adequate decontamination.

3.5.2 Destruction of surgical instruments

Items for disposal by incineration should be isolated in a rigid clinical waste container, labelled 'Hazardous' and transported to the incinerator as soon as practicable, in line with the current disposal of clinical waste guidance described in the Teacher's Guide: Management of Wastes from Health-care Facilities¹² published by WHO. To avoid unnecessary destruction of instruments, quarantine of instruments while determining the final diagnosis of persons suspected of TSEs may be used.

3.5.3 Quarantine

If a facility can safely quarantine instruments until a diagnosis is confirmed, quarantine can be used to avoid needless destruction of instruments when suspect cases are later found not to have a TSE. Items for quarantine should be cleaned by the best non-destructive method as per Section 6 and Annex III, sterilized, packed, date and 'Hazard' labelled, and stored in specially marked rigid sealed containers.¹³ Monitoring and ensuring maintenance of quarantine is essential to avoid accidental re-introduction of these instruments into the circulating instrument pool. If TSE is excluded as a diagnosis, the instruments may be returned to circulation after appropriate sterilization.

3.6 Anaesthesia

3.6.1 General anaesthesia

TSEs are not transmissible by the respiratory route; however, it is prudent to treat any instruments in direct contact with mouth, pharynx, tonsils and respiratory tract by a method described in Annex III. Destruction by incineration of non re-usable equipment is recommended.

3.6.2 Local anaesthesia

Needles should not be re-used, and in particular, needles contacting the CSF (e.g. for saddle blocks and other segmental anaesthetic procedures) must be discarded and destroyed.

3.7 Pregnancy and childbirth

TSE is not known to be transmitted from mother to child during pregnancy or childbirth; familial disease is inherited as a result of genetic mutations. In the event that a person with TSE becomes pregnant, no particular precautions need to be taken during the pregnancy, except during invasive procedures as per Section 3.4. Childbirth should be managed using standard infection control procedures, except that precautions should be taken to reduce the risk of exposure to placenta and any associated material and fluids. These should be disposed of by incineration. Instruments should be handled as for any other clinical procedure (Table 5). In home deliveries, the midwife (or any other persons in charge of delivery) should ensure that any contaminated material is removed and disposed of in accordance with correct procedures for infected clinical waste.

¹² Pruess A, Townend WK. Teacher's Guide: Management of Wastes from Health-care Activities. Geneva, World Health Organization, 1998. WHO/EOS/98.6.

¹³ Although the intention of quarantine is to avoid destruction of instruments and will permit the re-introduction of instruments only if TSEs are not diagnosed, the use of a decontamination method for TSEs will confer additional safety should an instrument unintentionally come in contact with staff or patients.

Section 4. OCCUPATIONAL INJURY

4.1 Occupational exposure

Although there have been no confirmed cases of occupational transmission of TSE to humans, cases of CJD in healthcare workers have been reported in which a link to occupational exposure is suggested. Therefore, it is prudent to take a precautionary approach. In the context of occupational exposure, the highest potential risk is from exposure to high infectivity tissues through needle-stick injuries with inoculation; however exposure to either high or low infectivity tissues through direct inoculation (e.g. needle-sticks, puncture wounds, ‘sharps’ injuries, or contamination of broken skin) must be avoided. Exposure by splashing of the mucous membranes (notably the conjunctiva) or unintentional ingestion may be considered a hypothetical risk and must also be avoided. Healthcare personnel who work with patients with confirmed or suspected TSEs, or with their high or low infectivity tissues, should be appropriately informed about the nature of the hazard, relevant safety procedures, and the high level of safety which will be provided by the proposed procedures described throughout this document.

4.2 Post-exposure management

Appropriate counselling should include the fact that no case of human TSE is known to have occurred through occupational accident or injury. A number of strategies to minimize the theoretical risk of infection following accidents have been proposed, but their usefulness is untested and unknown. For the present the following common-sense actions are recommended:

- Contamination of unbroken skin with internal body fluids or tissues: wash with detergent and abundant quantities of warm water (avoid scrubbing), rinse, and dry. Brief exposure (1 minute, to 0.1N NaOH or a 1: 10 dilution of bleach) can be considered for maximum safety.
- Needle sticks or lacerations: gently encourage bleeding; wash (avoid scrubbing) with warm soapy water, rinse, dry and cover with a waterproof dressing. Further treatment (e.g., sutures) should be appropriate to the type of injury. Report the injury according to normal procedures for your hospital or healthcare facility/laboratory.
- Splashes into the eye or mouth: irrigate with either saline (eye) or tap water (mouth); report according to normal procedures for your hospital or healthcare facility/laboratory.
- Health and safety guidelines mandate reporting of injuries, and records should be kept for no less than 20 years.

Section 5. LABORATORY INVESTIGATIONS

5.1 Safety in the healthcare laboratory

Adherence to the following routine precautions during any diagnostic procedure or laboratory work will reduce the risk of infection. General protective measures and basic precautions as outlined in Table 6 are recommended for hospital-based diagnostic laboratories as well as during decontamination procedures in those laboratories. Detailed descriptions of these general protective measures can be found in the WHO document:

Safety in Health-care Laboratories¹⁴ from which Table 6 is adapted. Where local or national regulations and guidelines exist, these should also be consulted. Only persons who have been advised of the potential hazards and who meet specific entry requirements (i.e. training) should be allowed to enter the laboratory working areas, or to participate in the collection of high infectivity tissues from patients with confirmed or suspected TSEs.

Table 6 General protective measures

1.	Eating, drinking, smoking, storing food and applying cosmetics must not be permitted in the laboratory work areas.
2.	Laboratory coveralls, gowns or uniforms must be worn for work and removed before entering non-laboratory areas; consider the use of disposable gowns; non-disposable gowns must be decontaminated by appropriate methods (see Section 7 Waste Disposal and Annex III).
3.	Safety glasses, face shields (visors) or other protective devices must be worn when it is necessary to protect the eyes and face from splashes and particles.
4.	Gloves appropriate for the work must be worn for all procedures that may involve unintentional direct contact with infectious materials. Armoured gloves should be considered in post mortem examinations or in the collection of high infectivity tissues.
5.	All gowns, gloves, face-shields and similar re-usable or non re-usable items must be either cleaned using methods set out in Annex III, or destroyed as per Section 7.
6.	Wherever possible, avoid or minimize the use of sharps (needles, knives, scissors and laboratory glassware), and use single-use disposable items.
7.	All technical procedures should be performed in a way that minimizes the formation of aerosols and droplets.
8.	Work surfaces must be decontaminated after any spill of potentially dangerous material and at the end of the working day, using methods described in Section 6 and Annex III.
9.	All contaminated materials, specimens and cultures must be either incinerated, or decontaminated using methods described in Section 6 and Annex III and Section 7 before disposal.
10.	All spills or accidents that are overt or potential exposures to infectious materials must be reported immediately to the laboratory supervisor, and a written record retained.
11.	The laboratory supervisor should ensure that adequate training in laboratory safety is provided and that practices and procedures are understood and followed.

5.2 Clinical diagnostic laboratories

The vast majority of diagnostic examinations in clinical laboratories are performed on blood (e.g. complete blood counts) and serum (e.g. chemistries), usually with automated analyzing equipment. As discussed in Section 2.4.2, blood and its components, although found to contain very low levels of infectivity in experimental models of TSE, have never been identified to be responsible for any case of CJD in humans, despite numerous exhaustive searches. The consultation felt that this epidemiological evidence was more relevant and more persuasive than the experimental evidence, and strongly recommended that blood specimens from patients with CJD not be considered to be infectious, and that no special precautions were needed for its handling in clinical laboratories. Similarly, except for CSF, other body fluids, secretions and excretions contain no infectivity, and need no special handling (Section 2.4.2, Table 2).

¹⁴ Safety in Health-care Laboratories. Second Edition. Geneva, World Health Organization, 1992. ISBN 92 4 154450 3. This edition is under revision.

CSF may be infectious and must be handled with care. It is recommended that analysis not be performed in automated equipment, and any materials coming in contact with the CSF must either be incinerated or decontaminated according to one of the methods listed in Section 6 and Annex III. There is no reason for a diagnostic test to be denied if these measures are observed.

5.3 Surgical pathology

Although brain biopsy tissue is (at least historically) the most likely tissue from a patient with a TSE to be examined in the surgical pathology laboratory, it may also occur that other tissues are sent to the laboratory for examination, when patients with TSE undergo surgical procedures of one sort or another for intercurrent problems during the course of their neurological illness. The tissue categories of high infectivity, low infectivity, and no detectable infectivity are listed and discussed in Section 2.4.2 and Table 2. Precautions to be taken when handling different tissue specimens are presented in Table 7. Since histopathological processing of brain tissue is most often conducted upon autopsy (WHO does not recommend brain biopsy for the diagnosis of CJD), detailed instructions for histopathological processing are described in Section 8.2 (Post Mortem Examination, sub-Section 8.2.2, Histopathological Examination).

Table 7 Precautions for working with high and low infectivity tissues from patients with known or suspected TSEs

1. Whenever possible and where available, specimens should be examined in a laboratory or centre accustomed to handling high and low infectivity tissues; in particular, high infectivity tissue specimens should be examined by experienced personnel in a TSE laboratory.
2. Samples should be labelled 'Biohazard'.
3. Single-use protective clothing is preferred as follows:
 - liquid repellent gowns over plastic apron;
 - gloves (cut-resistant gloves are preferred for brain cutting);
 - mask;
 - visor or goggles.
4. Use disposable equipment wherever possible.
5. All disposable instruments that have been in contact with high infectivity tissues should be clearly identified and disposed of by incineration.
6. Use disposable non-permeable material to prevent contamination of the work surface. This covering and all washings, waste material and protective clothing should be destroyed and disposed of by incineration.
7. Fixatives and waste fluids must be decontaminated by a decontamination method described in Section 6 and Annex III or adsorbed onto materials such as sawdust and disposed of by incineration as a hazardous material.
8. Laboratories handling large numbers of samples are advised to adopt more stringent measures because of the possibility of increased residual contamination, e.g. restricted access laboratory facilities, the use of 'dedicated' microtomes and processing labware, decontamination of all wastes before transport out of the facility for incineration.

Note: This document contains recommendations designed for healthcare laboratories and is not intended as a guideline for scientific research laboratories. WHO has identified a number of reference laboratories¹⁵ which may be contacted for advice on safety protocols for investigational laboratory environments.

¹⁵ Global Surveillance, Diagnosis and Therapy of Human Transmissible Spongiform Encephalopathies: Report of a WHO Consultation. Geneva, World Health Organization, 1998. WHO/EMC/ZDI/98.9.

5.4 Transport of specimens by air

The transportation of pathology samples by air must comply with the International Air Transport Association (IATA) Restricted Articles Regulations and any additional requirements of the individual carriers. Documentation required by the IATA includes Shipper's Certificate for Restricted Articles, which requires that the content, nature and quantity of infectious material to be disclosed. The WHO Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens¹⁶ provides more information on the safe transport of material. Where properly packaged according to these guidelines, there is no danger to the carriers.

Section 6. DECONTAMINATION PROCEDURES

6.1 General considerations

TSE agents are unusually resistant to disinfection and sterilization by most of the physical and chemical methods in common use for decontamination of infectious pathogens. Table 8 lists a number of commonly used chemicals and processes that cannot be depended upon for decontamination, as they have been shown to be either ineffective or only partially effective in destroying TSE infectivity. Variability in the effectiveness appears to be highly influenced by the nature and physical state of the infected tissues. For example, infectivity is strongly stabilized by drying or fixation with alcohol, formalin or glutaraldehyde. As a consequence, contaminated materials should not be exposed to fixation reagents, and should be kept wet between the time of use and disinfection by immersion in chemical disinfectants.

Table 8 Ineffective or sub-optimal disinfectants

Chemical disinfectants	Gaseous disinfectants	Physical processes
<u>Ineffective</u> ¹⁷ alcohol ammonia β-propiolactone formalin hydrochloric acid hydrogen peroxide peracetic acid phenolics sodium dodecyl sulfate (SDS) (5%)	<u>Ineffective</u> ethylene oxide formaldehyde	<u>Ineffective</u> boiling dry heat (<300°C) ionising, UV or microwave radiation
<u>Variably or partially effective</u> chlorine dioxide glutaraldehyde guanidinium thiocyanate (4 M) iodophores sodium dichloro-isocyanurate sodium metaperiodate urea (6 M)		<u>Variably or partially effective</u> autoclaving at 121°C for 15 minutes boiling in 3% sodium dodecyl sulfate (SDS)

¹⁶ Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens. Geneva, World Health Organization, 1997. WHO/EMC/97.3.

¹⁷ Some of these chemicals may have very small effects on TSE infectivity and are not adequate for disinfection.

6.2 Decontamination of instruments

Policy makers should be guided by the infectivity level of the tissue contaminating the instrument and by the expectations of how the instrument will be re-used, as per Section 2.4. In this way, the most stringent recommendations are applied to instruments contacting high infectivity tissues of a person with a known TSE, which will also subsequently be re-used in the CNS or spinal column. Policy makers are encouraged to adopt the highest decontamination methods feasible until studies are published which clarify the risk of re-using decontaminated instruments.

Annex III lists the decontamination methods recommended by the consultation in order of decreasing effectiveness. It was emphasized that the safest and most unambiguous method for ensuring that there is no risk of residual infectivity on surgical instruments is to discard and destroy them by incineration. While this strategy should be universally applied to those devices and materials that are designed to be disposable, it was also recognized that this may not be feasible for many devices and materials that were not designed for single use. For these situations, the methods recommended in Annex III appear to remove most and possibly all infectivity under the widest range of conditions.

Those surgical instruments that are going to be re-used may be mechanically cleaned in advance of subjecting them to decontamination. Mechanical cleaning will reduce the bio-load and protect the instrument from damage caused by adherent tissues. If instruments are cleaned before decontamination, the cleaning materials must be treated as infectious waste, and the cleaning station must be decontaminated by one of the methods listed in Annex III. The instruments are then treated by one of the decontamination methods recommended in Annex III before reintroduction into the general instrument sterilization processes. A minority opinion held that instruments should be decontaminated before mechanical cleaning, and then handled as per general instrument sterilization processes.

Annex III recommends that, where possible, two or more different methods of inactivation be combined in any sterilization procedure for these agents. Procedures that employ heat and NaOH (either consecutively or simultaneously) appear to be sterilizing under worst-case conditions (e.g., infected brain tissue partly dried on to surfaces). Moreover, hot alkaline hydrolysis reduces biological macromolecules to their constituent sub-units, thereby cleaning as well as inactivating.

The consultation recognized that complex and expensive instruments such as intracardiac monitoring devices, fiberoptic endoscopes, and microscopes cannot be decontaminated by the harsh procedures specified in Annex III. Instead, to the extent possible, such instruments should be protected from surface contamination by wrapping or bagging with disposable materials. Those parts of the device that come into contact with internal tissues of patients should be subjected to the most effective decontaminating procedure that can be tolerated by the instrument. All adherent material must be removed and, if at all possible, the exposed surfaces cleaned using a decontamination method recommended in Annex III. Some instruments can be partly disassembled (e.g. drills and drill bits). Removable parts that would not be damaged by autoclaving, NaOH, or bleach should be dismantled and treated with these agents. In all instances where unfamiliar decontamination methods are attempted, the manufacturer should be consulted. These cleaning procedures should be applied even if the instrument has been re-used before discovery of its potential contamination.

Contaminated instruments or other contaminated materials should not be cleaned in automated washers without first having been decontaminated using a method recommended in Annex III.

6.3 Decontamination of work surfaces

Because TSE infectivity persists for long periods on work surfaces, it is important to use disposable cover sheets whenever possible to avoid environmental contamination, even though transmission to humans has never been recognized to have occurred from environmental exposure. It is also important to mechanically clean and disinfect equipment and surfaces that are subject to potential contamination, to prevent environmental build-ups. Surfaces contaminated by TSE agents can be disinfected by flooding, for one hour, with NaOH or sodium hypochlorite, followed by water rinses (see Annex III for detailed instructions). Surfaces that cannot be treated in this manner should be thoroughly cleaned; consider use of a partially effective method as listed in Table 8. Cleaning materials treated as potentially contaminated (see Section 6.4).

6.4 Decontamination of wastes and waste-contaminated materials

Decontamination of waste liquid and solid residues should be conducted with the same care and precautions recommended for any other exposure to TSE agents. The work area should be selected for easy containment of contamination and for subsequent disinfection of exposed surfaces. All waste liquids and solids must be captured and treated as infectious waste.

Liquids used for cleaning should be decontaminated in situ by addition of NaOH or hypochlorite or any of the procedures listed in Annex III, and may then be disposed of as routine hospital waste. Absorbents, such as sawdust, may be used to stabilize liquids that will be transported to an incinerator; however, this should be added after decontamination.

Cleaning tools and methods should be selected to minimize dispersal of the contamination by splashing, splatters and aerosols. Great care is required in the use of brushes and scouring tools. Where possible, cleaning tools such as brushes, towelling and scouring pads, as well as tools used for disassembling contaminated apparatus, should either be disposable or selected for their ability to withstand the disinfection procedures listed in Annex III.

Upon completion of the cleaning procedure, all solid wastes including disposable cleaning materials should be collected and decontaminated. Incineration is highly recommended. The cleaning station should then itself be decontaminated using one of the methods in Annex III.

Automated cleaning equipment must not be used for any instrument or material that has not previously been thoroughly decontaminated following the recommendations in Section 6.2 and Annex III.

6.5 Personal protection during decontamination procedures

Persons involved in the disinfection and decontamination of instruments or surfaces exposed to the tissues of persons with TSE should wear single-use protective clothing, gloves, mask and visor or goggles, as noted in Section 5.1, Table 6. The recommendations found in Table 6 can be adapted to different situations. All individuals involved with disinfection and decontamination procedures should be familiar with these basic protective measures and precautions. Handling of contaminated instruments during transfers and cleaning should be kept to a minimum.

6.6 Decontamination risk categories

The recommended levels of decontamination are shown in Table 9 for different patient and tissue risk categories (including patients at risk of TSE, and patients with vCJD). The table reflects the consensus of the consultation, and should be used in conjunction with Section 2.4.2 (Table 2) which lists specific high and low infectivity tissues, and Annex III, which describes specific decontamination options.

Table 9 Decontamination levels for different risk categories

Patient category	Tissue category	Decontamination options
Confirmed or suspect cases of TSE	High infectivity	Annex III
	Low infectivity	Annex III (but note that CSF, and peripheral organs and tissues are regarded as less infectious than the CNS)
Persons with known prior exposure to human pituitary derived hormones, cornea or dura mater grafts	High infectivity	Annex III
	Low Infectivity	Routine cleaning and disinfection procedures
Members of families with heritable forms of TSE	High Infectivity	No consensus was reached. The majority felt that TSE decontamination method should be used, but a minority felt this was unwarranted.
	Low Infectivity	Routine cleaning and disinfection procedures
All of the above categories	No detectable Infectivity	Routine cleaning and disinfection procedures
Confirmed or suspect cases of vCJD	All tissue categories	Annex III

Section 7. WASTE DISPOSAL

Infectious healthcare waste is defined as the discarded materials that have been in contact with blood and its derivatives, or wastes from infection isolation wards. These include but are not limited to cultures, tissues, dressings, swabs or other items soaked with blood, syringe needles, scalpels, diapers, and blood bags. The term ‘TSE infectious healthcare waste’ applies to high and low infectivity tissues from persons with confirmed or suspected TSEs, or high infectivity tissue from persons with known prior exposure to cornea, dura matter or human growth hormone, and any disposable items that have come in contact with these tissues.

In the absence of a national standard, disposal of biological waste contaminated by a TSE is to be performed in accordance with the best practice that is most consistent with this document or equivalent standards. Practitioners should review guidelines prescribed under the laws, procedures, codes of practice or other regulatory provisions in force in the relevant state or territory. All material classified as clinical waste should be placed in secure leak-proof containers and disposed of by incineration at an authorized incineration site. Avoid external contamination of the container to ensure safe handling of clinical

waste. The WHO guide, *Safe Management of Wastes from Health Care Activities*,¹⁸ provides recommendations on medical and laboratory waste disposal.

TSE infectious waste should be incinerated or treated by a method that is effective for the inactivation of TSE agents (see Annex III). In regions where no incineration facilities are available, it is recommended that these wastes be chemically disinfected and then burnt in pits dedicated to final disposal. Residues should be checked for total combustion. Authorities should ensure that waste is adequately managed, as in certain big cities of the developing world it has been estimated that as much as one half of infectious waste is cleaned, re-packaged and sold in the marketplace.

In hospital or healthcare facility environments, drainage equipment, linens or swabs contaminated by high infectivity tissues or CSF should be collected into tough plastic bags or containers labelled 'Biohazard' and incinerated. Low infectivity tissues and drainage from low infectivity tissues¹⁹ should be handled cautiously.

For tissues, secretions, or excretions with no detectable infectivity, no special requirements beyond Standard Precautions are required for the handling of body fluids or body-fluid contaminated linen, equipment or environments. Other infectious wastes from home care require no special precautions beyond those taken for any other disease. Sharp waste items (i.e. syringe needles) used during home care of TSE patients should be collected in impermeable containers and returned to the treating physician or healthcare establishment for disposal.

The use of enamel, heat-stable plastic or disposable trays when working with infectious specimens will help to confine contamination. If re-usable, they should be treated by a method listed in Annex III. Disposable items should be incinerated after use, although methods listed in Annex III may be used before disposal. Use absorbent material to soak up spills, which can then be contained and incinerated or treated by a method described in Annex III. Spills of potentially TSE infectious materials in the ward should be removed using absorbent material and the surface disinfected according to Annex III.

Use secure leak-proof containers, e.g. double bagging, for the safe handling of clinical waste. Avoid external contamination of the waste container. Disposable gloves and an apron should be worn when removing such spills and should subsequently be disposed of by incineration, together with the recovered waste and cleaning materials, although a method described in Annex III may be used.

Section 8. AFTER DEATH

8.1 Precautions for handling of the deceased patient

On the death of a patient with confirmed or suspected TSE, the removal of the body from the ward, community setting, or hospice, should be carried out using normal infection control measures. It is recommended that the deceased patient be placed in a sealed body bag prior to moving, in line with normal procedures for bodies where there is a known infection risk. Where the skull is open or there is CSF leakage, and where sutures do not completely control this leaking, the bag should be lined with materials to absorb any fluid, and the body should be moved in a sealed body bag. Refer to

¹⁸ A. Prüss, E. Girault, P. Rushbrook, eds. *Safe Management of Wastes from Health Care Activities*. Geneva, World Health Organization, 1999.

¹⁹ Drainage from *low infectivity tissue* that has not been specifically tested for infectivity, however, may retain infectivity.

country-based guidelines and regulations for more information on care and handling of a deceased and infected patient.

8.2 Post mortem examination

Post mortem examinations remain an essential element in confirming the clinical diagnosis and the cause of death as TSE. Ideally, three people should be present during the examination: the pathologist assisted by one technician, and one further person to handle and label specimen containers. Except for training purposes, observers should be prohibited or kept to a minimum. All personnel should be made aware of the relevant history of the patient and fully informed of procedures for such post mortem examinations.

8.2.1 Conducting the autopsy

To the extent possible, disposable protective clothing should be worn including surgical cap and gown, apron, double gloves, and a face visor which completely encloses the operator's head to protect the eyes, nose and mouth. Consideration should be given to the use of hand protection, such as armoured or cut-resistant gloves.

Disposable or dedicated reusable instruments are recommended in order to minimize the risk of environmental contamination. Manual saws are recommended in order to avoid the creation of tissue particulates and aerosols and for ease of decontamination after use. Electric saws, if used, should be operated inside an aerosol-containing bag unless ventilated helmets with an appropriate filter are worn. Instruments and mortuary working surfaces should be decontaminated following the guidance in Section 6 and Annex III.

Restricted post mortem examinations on TSE cases can be undertaken in any mortuary. If examination is limited to the brain, a plastic sheet with absorbent wadding and raised edges is first placed underneath the head to ensure containment of tissue debris and body fluids (e.g., CSF). The scalp is reflected in the normal way and the cranium is opened. After removal of the brain, replacement of the skullcap and suturing of the skin, the plastic sheet containing all tissue debris and drainage is bagged and sealed and sent for incineration. A full post mortem examination is discouraged except in dedicated facilities, unless special circumstances warrant the added difficulty of infectivity containment.

8.2.2 Histopathological examination

Only persons who have been advised of the potential hazards and trained in the specific methods used for TSE infectious tissues should be permitted to work in laboratories where high infectivity tissues are being processed. Facilities conducting a large number of histological examinations on high infectivity tissues should dedicate laboratory space, processors, instruments, glassware and reagents for this purpose. Guidelines in some countries and regions require Bio-Safety Containment Level 3 for handling these tissues.

It is important to note that formalin and glutaraldehyde-fixed TSE tissue retains infectivity for long periods, if not indefinitely. As a result, they should be handled with the same precautions as fresh material and be considered infectious throughout the entire procedure of fixation, embedding, sectioning, staining, and mounting on slides, until or unless treated with formic acid. Treatment with formic acid reduces infectivity to negligible levels. Although exact procedures may vary, formic acid treatment consists of

placing small pieces of fixed tissue, no more than 4 to 5 mm thick, in 50 to 100 ml of 95% formic acid for an hour, and then transferring them to fresh formalin for another two days before further processing. The entire procedure is conducted using continuous, gentle agitation.

All of the serial steps involved in bringing the blocks from formalin into paraffin and, after sectioning, bringing the mounted paraffin sections back into aqueous staining solutions, can be carried out manually, or in an automatic processor dedicated to TSE tissues. Similarly, it would be advisable to dedicate a microtome for sectioning non-formic acid treated tissue blocks, as there is no practical way to disinfect the instrument. Formic acid treated sections can be cut on a standard microtome (if possible, using a disposable knife or dedicated blade) and processed as usual. Processing fluid should be decontaminated and debris (such as wax shavings) from section cutting should be contained and disposed of by incineration (see Annex III for decontamination methods). Formic acid treated sections tend to be brittle, but show good preservation of histologic morphology.

Slides made from sections which have been treated with formic acid can be considered non-infectious. Slides made from sections that have not been treated with formic acid may also be handled without specific precautions, once the cover slip is sealed to the slide and chemically disinfected to ensure external sterility, but should be labelled as a hazardous material. These slides, if damaged, should be treated using a method described in Annex III, and destroyed.

Containers used for the storage of formalin-fixed tissues should, after secure closing, be cleaned using a method in Annex III, marked "Hazardous", and stored separately (e.g., in sealed plastic bags). When tissue is needed, the container can be removed from the bag, set upon a water-resistant disposable mat, and manipulation of the tissue confined to the mat. After the tissue is replaced, the area and container are cleaned according to methods described in Annex III, and the container put into a new plastic bag for further storage.

8.2.3 Electron microscopy

Electron microscopic examination of tissue sections is not indicated for diagnostic purposes, and is not recommended except as an investigational research tool. Preparation of specimens for electron microscopy should be performed with the same precautions as for histopathology. Electron microscopy of tissue sections poses negligible risk both to the microscope and the operator due to the very small amount of tissue deposited on a grid. An electron microscope section 0.01 micron thick x 0.1 mm x 0.05 mm contains approximately 50 pg of tissue. Even the most infectious models of the disease producing 10^{10} ID₅₀/g of brain would result in less than 0.5 ID₅₀ immobilized on the grid. Handling requires no special precautions except for disposal of such grids as infectious waste through incineration.

8.3 National and international transport of bodies

If there is a need to transport the deceased patient nationally or internationally, it will be necessary to comply with the International Civil Aviation Organization (ICAO), International Air Transport Association (IATA) Restricted Articles Regulations, and any additional requirements of the individual carriers. It should be noted that the IATA Regulations require the embalming of the body.

8.4 Undertakers and embalmers

8.4.1 General measures

Mortuary procedures may be performed on the bodies of patients who have died from CJD with a minimum of inconvenience to ensure the safety of personnel and avoid contamination of the workplace. Transportation of the unembalmed body to the mortuary should be in an sealable, impermeable plastic pouch. Ordinary contact or handling of an intact, unautopsied body does not pose a risk, and cosmetic work may be undertaken without any special precautions. If the body has undergone autopsy, care should be taken to limit contamination of the workplace by any leaking bodily fluids (especially from the cranium) when transferring the body from its transport bag to the mortuary table that has been covered with an impermeable sheet. No other precautions are required, except for embalming (see Section 8.4.2).

8.4.2 Embalming

An intact (unautopsied) body can be safely managed with only minor adjustments to the usual procedures. The body should be placed on an impermeable sheet or body pouch to avoid surface contamination from perfusion drain sites, and all drainage fluids should be collected into a stainless steel container. Perfusion sites should be closed with cyanoacrylates (super glue) and then wiped with bleach.

Embalming an autopsied or traumatized body is not encouraged, but may be safely performed when the following precautions are observed. Disposable masks, gowns, and gloves should be worn, just as is done by pathologists performing an autopsy. The body should be placed on an impermeable sheet or body pouch so that suture site leakage can be contained, and perfusion drain sites should be similarly arranged to avoid surface contamination. All drainage fluids should be collected into a stainless steel container. Perfusion and autopsy incision sites should be closed with cyanoacrylates (super glue). The entire body should be wiped down with bleach, and special care taken to ensure contact of bleach with perfusion sites and closed autopsy incisions.

At the conclusion of the perfusion procedure, the container of drainage fluids should be decontaminated by adding sodium hydroxide pellets at the rate of 40g per litre of fluid. The mixture should be stirred after a few minutes and care should be taken to avoid spillage, as the fluid will be hot. It should then be left undisturbed for at least one hour, after which it can be disposed of as for any other mortuary waste. Plastic sheets and other disposable items that have come into contact with bodily fluids should be incinerated. Mortuary working surfaces that have accidentally become contaminated should be flooded with sodium hydroxide or bleach, left undisturbed for at least one hour, then (using gloves) mopped up with absorbent disposable rags, and the surface swabbed with water sufficient to remove any residual disinfectant solution.

Non-disposable instruments and tools should be decontaminated using one of the methods recommended in Annex III. At the conclusion of the decontamination procedure, the instruments are washed with water to remove residual disinfectant fluid before drying and re-use. Sodium hydroxide or bleach can be disposed of as uninfecious (but corrosive) waste fluid.

8.5 Funerals and cremations

Relatives of the deceased may wish to view or have some final contact with the body. Superficial contact, such as touching or kissing the face, need not be discouraged,

even if an autopsy has been conducted. Interment in closed coffins does not present any significant risk of environmental contamination, and cremated remains can be considered to be sterile, as the infectious agents do not survive incineration-range temperatures (1000°C). Transport and interment are subject to local and national guidelines, and transport overseas is governed by international regulations.

8.6 Exhumations

Standard procedures are conducted according to local and national guidelines. The body should be considered as having the same infectivity as at the time of burial and the precautions used for an autopsy should be followed.

8.7 Body donation for teaching purposes

Anatomy departments should not accept, for teaching or research purposes, any body or organs from persons confirmed, suspected, or at risk for TSE, unless they have specific training or research programs for TSEs, including access to specialized equipment, procedures, appropriate containment facilities and training for managing TSE contaminated tissues. Departments should make inquiries of those responsible for donating the body, and of the medical staff involved in the care of the donor, to insure the rigorous adherence to this recommendation.

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Annex II List of Presentations**Wednesday, 24 March 1999**

09.00-09.10	Welcome and introduction to the meeting	Dr Lindsay J Martinez
09.10-09.20	Selection of Chair	
09.20-09.30	Goal of meeting and opening remarks from Secretary to the meeting	
09.30-09.45	Results of the Consultation on Reagents Meeting	Chair of Reagents Meeting
09.45-10.00	Questions	ALL

Epidemiology and projections

10.00-10.30	Extent of BSE exposure worldwide	Dr Raymond Bradley
10.30-11.00	Coffee break	
11.00-11.15	vCJD epidemiology	Dr Robert Will
11.15-11.30	Predictions of the epidemic of vCJD	Dr Peter Smith
11.30-12.00	Questions on BSE, vCJD, CJD epidemiology	ALL
12.00-13.00	Lunch break	

Identification of risk

13.00-13.15	Diagnosis of CJD (iatrogenic, familial, sporadic and vCJD)	Dr Martin Zeidler
13.15-13.30	Risk assessment and ethical issues	Dr Burleigh Trevor-Deutsch
13.30-13.45	Questions	ALL
13.45-14.15	Distribution of infectivity in CJD (iatrogenic, familial, sporadic)	Dr Paul Brown
14.15-14.30	Distribution of infectivity in vCJD	Dr James Ironside
14.30-14.45	Questions on tissue, blood and organ infectivity	ALL

Decontamination procedures

14.45-15.00	Decontamination procedures	Dr David Taylor
15.00-15.25	Instruments and environment; waste disposal	Dr R. Rohwer Ms Annette Pruess
15.25-15.45	Questions on decontamination	ALL
15.45-16.15	Coffee break	
16.15-17.00	Review of day's issues and conclusions	Chair, Working Group
17.30-19.30	Cocktail party	All

Thursday, 25 March 1999***Providing care to the ill***

09.00-09.30	Care givers issues	CJD Support Network, CJD Voice, Human BSE Foundation
09.30-09.45	Nursing care in the home and hospital	Ms Blair Smith-Bathgate
09.45-10.00	Questions on provision of care	ALL

Protecting healthcare and allied workers: preventing iatrogenic transmission

10.00-10.15	Nursing practice in the hospital, long term care facility and nursing home	Miss Shirley Patton
10.15-10.30	Operating theatre	Dr Martinez-Lage
10.30-11.00	Coffee break	
11.00-11.15	New results from the Australian Case-Control Study	Dr Colin Masters
11.15-11.30	Post-exposure prophylaxis for prion diseases	Dr. Sebastian Brandner
11.30-12.00	Questions on protection of HCW and patients	ALL
12.00-13.00	Lunch break	
13.00-13.30	Clinical laboratory, pathology, and autopsy procedures	Dr Herbert Budka
	Questions and comments	
13.30-14.00	Dentistry	Dr J. Cleveland
	Questions and comments	
14.00-14.30	Mortuary	Mr George Lamb
	Questions and comments	
14.30-14.45	Remarks of Chairs, table draft	Chair(s), Secretariat
14.45-15.30	Group discussion	All
15.30-16.00	Coffee	
16.00-17.00	Revisions of draft document	Chair(s), Secretariat, Rapporteur(s)

Friday, 26 March 1999

09.30-10.30	Summary of previous day and revisions	
10.30-11.00	Coffee break	
11.00-12.00	Revision of draft document	
12.00-13.00	Lunch break	
13.00-14.30	Final discussions	
14.30-15.00	Final recommendations to secretariat	
15.00-15.30	Coffee break	
15.30-16.00	Meeting of Chairs, secretariat, speakers regarding revision of document	
16.00	Close	

Annex III Decontamination methods for Transmissible Spongiform Encephalopathies

The safest and most unambiguous method for ensuring that there is no risk of residual infectivity on contaminated instruments and other materials is to discard and destroy them by incineration. In some healthcare situations, as described in the guidance, one of the following less effective methods may be preferred. Wherever possible, instruments and other materials subject to re-use should be kept moist between the time of exposure to infectious materials and subsequent decontamination and cleaning. If it can be done safely, removal of adherent particles through mechanical cleaning will enhance the decontamination process.

The following recommendations are based on the best available evidence at this time and are listed in order of more to less severe treatments. These recommendations may require revision if new data become available.

1. Incineration

1. Use for all disposable instruments, materials, and wastes.
2. Preferred method for all instruments exposed to high infectivity tissues.

2. Autoclave/chemical methods for heat-resistant instruments

1. Immerse in sodium hydroxide (NaOH)²⁰ and heat in a gravity displacement autoclave at 121°C for 30 min; clean; rinse in water and subject to routine sterilization.
2. Immerse in NaOH or sodium hypochlorite²¹ for 1 hr; transfer instruments to water; heat in a gravity displacement autoclave at 121°C for 1 hr; clean and subject to routine sterilization.
3. Immerse in NaOH or sodium hypochlorite for 1 hr.; remove and rinse in water, then transfer to open pan and heat in a gravity displacement (121°C) or porous load (134°C) autoclave for 1 hr.; clean and subject to routine sterilization.
4. Immerse in NaOH and boil for 10 min at atmospheric pressure; clean, rinse in water and subject to routine sterilization.
5. Immerse in sodium hypochlorite (preferred) or NaOH (alternative) at ambient temperature for 1 hr; clean; rinse in water and subject to routine sterilization. Autoclave at 134°C for 18 minutes.
6. Autoclave at 134°C for 18 minutes.²²

²⁰ Unless otherwise noted, the recommended concentration is 1N NaOH.

²¹ Unless otherwise noted, the recommended concentration is 20 000 ppm available chlorine.

²² In worse-case scenarios (brain tissue bake-dried on to surfaces) infectivity will be largely but not completely removed.

3. Chemical methods for surfaces and heat sensitive instruments

1. Flood with 2N NaOH or undiluted sodium hypochlorite; let stand for 1 hr.; mop up and rinse with water.
2. Where surfaces cannot tolerate NaOH or hypochlorite, thorough cleaning will remove most infectivity by dilution and some additional benefit may be derived from the use of one or another of the partially effective methods listed in Section 5.1 (Table 8).

4. Autoclave/chemical methods for dry goods

1. Small dry goods that can withstand either NaOH or sodium hypochlorite should first be immersed in one or the other solution (as described above) and then heated in a porous load autoclave at $\geq 121^{\circ}\text{C}$ for 1 hr.
2. Bulky dry goods or dry goods of any size that cannot withstand exposure to NaOH or sodium hypochlorite should be heated in a porous load autoclave at 134°C for 1 hr.

5. Notes about autoclaving and chemicals

Gravity displacement autoclaves: Air is displaced by steam through a port in the bottom of the chamber. Gravity displacement autoclaves are designed for general decontamination and sterilization of solutions and instruments.

Porous load autoclaves: Air is exhausted by vacuum and replaced by steam.

Porous load autoclaves are optimized for sterilization of clean instruments, gowns, drapes, towelling, and other dry materials required for surgery. They are not suitable for liquid sterilization.

Sodium Hydroxide (NaOH, or soda lye): Be familiar with and observe safety guidelines for working with NaOH. 1N NaOH is a solution of 40 g NaOH in 1 litre of water. 1 N NaOH readily reacts with CO_2 in air to form carbonates that neutralize NaOH and diminish its disinfective properties. 10 N NaOH solutions do not absorb CO_2 , therefore, 1N NaOH working solutions should be prepared fresh for each use either from solid NaOH pellets, or by dilution of 10 N NaOH stock solutions.

Sodium hypochlorite (NaOCl solution, or bleach): Be familiar with and observe safety guidelines for working with sodium hypochlorite. Household or industrial strength bleach is sold at different concentrations in different countries, so that a standard dilution cannot be specified. Efficacy depends upon the concentration of available chlorine and should be 20 000 ppm available chlorine. One common commercial formulation is 5.25% bleach, for which a 1:2.5 dilution (1 part bleach plus 1.5 parts water) yields the desired working solution. Working solutions should be prepared fresh for each use.

6. Cautions regarding hazardous materials

In all cases, hazardous materials guidelines must be consulted.

1. Personnel

NaOH is caustic but relatively slow acting at room temperature, and can be removed from skin or clothing by thorough rinsing with water. Hot NaOH is aggressively caustic, and should not be handled until cool. The hazard posed by hot NaOH explains the need to limit boiling to 10 minutes, the shortest time known to be effective.

Hypochlorite solutions continuously evolve chlorine and so must be kept tightly sealed and away from light. The amount of chlorine released during inactivation may be sufficient to create a potential respiratory hazard unless the process is carried out in a well-ventilated or isolated location.

2. Material

In principle, NaOH does not corrode stainless steel, but in practice some formulations of stainless steel can be damaged (including some used for surgical instruments). It is advisable to test a sample or consult with the manufacturer before dedicating a large number of instruments to decontamination procedures. NaOH is known to be corrosive to glass and aluminum. Hypochlorite does not corrode glass or aluminum and has also been shown to be an effective sterilizing agent; it is, however, corrosive both to stainless steel and to autoclaves and (unlike NaOH) cannot be used as an instrument bath in the autoclave. If hypochlorite is used to clean or soak an instrument, it must be completely rinsed from the surfaces before autoclaving. Other decontamination methods may need testing, or consultation with the manufacturer to verify their effect on the instrument.

Annex IV Management of healthy ‘at risk’ individuals

Tissue recipients

The consultation felt that the risk from *recipients of dura mater, cornea transplants and human pituitary hormones, and from persons who have undergone neurosurgical procedures*, is no longer sufficient to warrant classifying this population as a risk for transmitting TSEs, except under conditions where there could be exposure to their high infectivity tissues (see Section 2.4.2). The consultants considered that appropriate control measures have immensely reduced or eliminated exposure to contaminated dura mater and pituitary hormones, and noted that there are only three reports of TSE transmission through cornea transplantation, and six reports (all before 1980) of transmission via neurosurgical instruments. In addition, it was recognized that recipients of dura mater are largely unaware of the fact, making identification of many of the dura mater recipients unlikely.

Countries not applying appropriate control measures cannot assume similarly low levels of current risk among tissue recipients.

Familial Transmissible Spongiform Encephalopathies

Consensus was not reached as to whether asymptomatic persons at risk for *familial TSE* should be classified as ‘at risk’ when determining appropriate infection control levels. It was argued that the identification of familial risk among asymptomatic people would confer a lifetime requirement for high-level infection control for a transmission risk that remains only hypothetical. Discrimination against such persons and legal implications regarding their access to insurance, employment and healthcare was described by several participants in the consultation, and it was proposed that such discrimination would inevitably lead to a harm which exceeded any evidence of risk posed by them to others.

Others argued that if a familial risk were identified, then more stringent levels of infection control could be adopted even in the absence of firm evidence of risk, particularly during procedures involving *high infectivity tissues*. All consultants agreed that persons ‘at risk’ for familial TSE should not be denied access to treatment or surgical procedures, particularly given the range of decontamination options available. Scientific resolution of these issues was impossible due to a lack of precise information about tissue infectivity during the pre-clinical phase of human disease, and the consultants emphasized the need to study any available tissues (including blood) from mutation-positive, but still asymptomatic, members of TSE families.

Annex V Management of individuals with confirmed or suspected variant Creutzfeldt-Jakob Disease

The TSE agent causing vCJD has shown certain differences from that of sporadic CJD, including the detection of prion protein (PrP) in a range of lymphoreticular tissues. Patients with vCJD might therefore pose a greater risk of transmitting iatrogenic infections than sporadic CJD. However, this hypothetical risk has to be balanced against the real danger of stigmatizing patients and causing distress and anxiety to the patient's relatives by the introduction of rigorous and possibly unnecessary infection control procedures in general patient care.

On current evidence, the infection control procedures in nursing care settings for sporadic CJD may be applied to cases of vCJD without the need for additional precautions, although a more conservative approach may be taken for interventions involving surgical procedures, or when handling tissues and body fluids in the laboratory. See Section 6.6 (Table 9) for measures that have been recommended for high infectivity tissues in patients with other forms of TSE, that could be applied to all tissues of persons with vCJD. It is noted that considerable safety is afforded through the measures described in Section 6 and Annex III, and that no person should be denied a diagnostic test given the efficacy of the recommended measures. Comparative tissue risks for vCJD and a case definition of possible vCJD cases will need to be redefined as further research findings emerge. If vCJD is suspected, consultation with persons expert in this disease, such as The Edinburgh CJD Surveillance Unit, Western General Hospital, United Kingdom, is recommended.