Vancouver Coastal Health

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INFECTION CONTROL GUIDELINES FOR THE MANAGEMENT OF CLASSIC CREUTZFELDT-JAKOB DISEASE AND OTHER PRION DISEASES

Revised March 12, 2009

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1. INTRODUCTION

This document is a revision of the September 2004 Vancouver Coastal Health "Infection Control Guidelines for the Management of Classic Creutzfeldt-Jakob Disease" It represents the joint efforts of many disciplines across Vancouver Coastal and provides current knowledge and procedures for this disease. Committee members represent Neurosurgery, Neuropathology, Sterile Supply Division, Regional Environmental Protection, Operating Rooms, Anatomical Pathology, Clinical Laboratories, Autopsy suites, and Infection Control.

2. BACKGROUND

Creutzfeldt-Jakob disease (CJD) is one of a group of rare central nervous disorders called transmissible spongiform encephalopathies (TSE). The transmissible spongiform encephalopathies are caused by infectious agents called transmissible spongiform encephalopathy agents (TSEs) or prions. (Other human TSEs include Gerstmann-Straussler-Scheinker disease and fatal familial insomnia but will not be discussed in this document).

CJD is associated with the accumulation of an abnormally folded CNS protein called *prion protein* (PrP)[3,4,5]. This modified PrP is resistant to the proteases that normally break down protein products and it therefore accumulates in nervous tissue. Over a long period of time, this leads to histologic and clinical changes. Histologically, CJD is characterized by microscopic vacuoles in the brain, astrocytosis, amyloid plaque formation and neuronal loss. Clinically, the disease presents with progressive general cognitive impairment (dementia), myoclonus (muscle jerks) and cerebellar ataxia (imbalance)[1,2].

Approximately 15 percent of cases are familial in origin with a demonstrated pathogenic mutation of the PrP gene. *Classic CJD* also occurs spontaneously at a rate of one case per million people. These affected individuals are usually homozygous at codon 129 of the PrP gene (presumably conferring susceptibility to transmission)[2,5] There have been isolated cases associated with iatrogenic (hospital-associated) contamination from sources such as dura mater grafts however, it must be emphasized that nearly all the contaminated material in these cases were produced before 1987 by a single manufacturer whose processes have since been corrected. (HC reference). Finally there have been reports of acquisition of CJD associated with neurosurgical procedures through inadequate decontamination of surgical instruments. None of these cases were reported in Canada and the rate of transmission from a single contaminated instrument is unknown. Given the few cases of transmission occurring during neurosurgical procedures, it is likely that the current risk of CJD transmission via neurosurgical instruments is very low. The incidence of CJD in Canada does not justify the universal use of anything other than routine sterilization procedures for neurosurgical patients and CJD precautions should only be initiated in the presence of a patient and /or a tissue risk for CJD. It is this scenario that these guidelines address.

One other note: a clinico-pathological phenotype of CJD, called *variant CJD*, first documented in the United Kingdom and causally linked to cattle has been the subject of much discussion. Variant CJD differs in several ways from "classic" CJD. Affected individuals are usually younger, the clinical presentation is more of a psychiatric presentation with sensory symptoms and the EEG pattern and histology differs from classic CJD. This agent is transmitted via contaminated meat products and generally has not been linked to nosocomial transmission. There have been no cases of variant CJD in humans arising from exposure to Canadian meat products to date.

3 RISK ASSESSMENT

CJD is a transmissible but not a contagious disease. Daily patient care is not a risk factor for health care workers except during exposure to central nervous tissue or fluids during neurosurgical procedures, and autopsies. The risk of acquiring CJD depends on the type of patient and the type of procedure (i.e. type of tissue exposure). [see Tables 1 and 2 below] Patients with diagnosed or suspected CJD pose the highest risk for transmission of disease during certain types of invasive procedures. It should be emphasized that there have been no reports of transmission of classic CJD via blood products and all attempts to transmit infection via blood transfusion in animals have failed.

Table 1 Patient Risk for CJD (Health Canada)

High Risk Patient	At Risk Patient
• Diagnosed CJD • Suspected CJD: undiagnosed, rapidly progressive dementia and CJD not ruled out • Asymptomatic genetic TSE – asymptomatic member of a family with a familial form of CJD as determined by genetic testing	• Recipients of human dura mater grafts (until 1992 for Lyodura grafts, until 1997 for tutoplast grafts) • Recipients of human pituitary hormone treatment (either growth or gonadotrophin) • Recipients of a corneal graft originating in a jurisdiction that does not require screening of donors for neurological disease • Patients who have been exposed, via contact with instruments, to high-risk tissue in a confirmed CJD patient

Table 2 Tissue Risk for CJD (Health Canada)

Level of infectivity	Tissues, secretions and excretions
High infectivity	Brain, spinal cord, cranial and spinal cord ganglia; CSF* dura mater, pituitary gland, posterior eye (including optic nerve and retina). Tonsil (New Variant CJD)
Low infectivity	Kidney, liver, lung, lymph nodes, spleen, placenta; dental neurovascular tissue/dental pulp; anterior eye (includes cornea)
No detected infectivity	Adipose tissue, skin, adrenal gland, heart muscle, intestine, peripheral nerve, prostate, skeletal muscle, testis, thyroid gland, feces, milk, nasal mucus, saliva, serous exudate, sweat, tears, urine, blood, bone marrow, semen

CSF has been changed to high-risk tissue as it implies contact with dura mater, a high-infectivity tissue and should be so managed

Procedures considered to be *at risk* for CJD therefore involve *patients with diagnosed or suspected CJD* undergoing neurosurgical procedures, CSF examination or autopsies involving access to high infectivity tissue.

For example, the following are considered **high-risk patients** when **performing neurosurgical procedures, CSF examination or autopsies**.

- patients with known or suspected CJD
- patients with a familial history of CJD
- patients with a history of cadaveric pituitary growth hormone therapy
- patients with a history of human dural engraftment.
- patients with rapidly progressive dementia

Brain biopsies are considered a high-risk procedure when performed on:

- patients with rapidly progressive dementia not yet diagnosed and CJD not ruled out (and no single discrete lesion present on CT scan or MRI)

Biopsy cases for dementia will be reviewed by the neurosurgeons prior to booking. Neurosurgeons are committed to *not* perform biopsies on patients with known or probable CJD. The CJD protocol for brain biopsy will be used in patients who are image negative (i.e. no abnormality on CT, MR or angiogram or other evidence to suggest another diagnosis).

- It is the responsibility of the attending surgeon to identify these higher risk cases to the Neurosurgical Charge Nurse and Booking/Slating prior to surgery and of the attending surgeon to notify the neuropathologist or pathologist on call prior to surgery. There shall be no deviation from the protocol if the above risk factors/conditions are present.
- It is the responsibility of the Neuropathologist or Pathologist to notify the surgeon and the Medical Microbiologist/Pathologist-on-call of the pathology results
- It is the responsibility of the Medical Microbiologist/Pathologist-on-call to notify SPD Management of the Pathology results to ensure that the instruments have been handled appropriately.

4. Decontamination procedures

INTRODUCTION

Few chemical or physical processes can inactivate prions. Experimental work in the 1980's formed the basis for the UK Department of Health recommendations that a porous load cycle of 134-138^{0}C for 18 minutes was sufficient to inactivate CJD. Recent studies demonstrating survival of prions in brain macerate sample of infected rodents after autoclaving under the above conditions have cast doubt on the UK recommendations[1,2,4,6]. Others have questioned whether the use of large concentrations of prions in these study samples were an excessive challenge. In the absence of any additional data, the current recommendation by the Advisory Committee on Dangerous Pathogens in the UK and the Public Health Agency of Canada is to continue to use the 18 minute cycle while recognizing that it may not always be effective[6]. Australia recommends incineration of all contaminated instruments, while New Zealand and some European guidelines recommend the use of two sequential decontamination methods wherever possible. **Canadian guidelines recommend incineration of all potentially contaminated instruments as the preferred method of handling**.

The policy in this region is to:

- use disposable instruments in high risk cases for both surgical procedures and CSF collection and incinerate these items after use [See Waste Management section]
- limit the amount of equipment exposed to neural tissue in surgical cases (e.g. by using the disposable CJD precautions set) [see OR policy]
- have surgical procedure slated in a separate OR or as the last case of the day
- quarantine and incinerate all other non-disposable contaminated surgical instruments after confirmation of CJD by Anatomic Pathology
- Neuropathologist/Pathologist will issue form SDD 8-2000, "Release of Quarantined Instruments".
- decontaminate autopsy instruments and other equipment and surfaces as per decontamination protocols outlined below

By identifying high risk patients in high risk procedures, limiting the number of instruments used in a high risk case (e.g. CJD precautions set for brain biopsies), substituting disposable equipment wherever possible, and incinerating contaminated instruments in histologically confirmed cases, the risk of transmissibility is drastically reduced.

DECONTAMINATION OF HARD SURFACES

The following steps must be adhered to when decontaminating hard surfaces such as tabletops or OR tables:

1. Remove visible soil with a neutral detergent
2. Wet with bleach 2.5% (25,000 ppm) and let stand for one hour
3. Wipe up remaining bleach and rinse with water
4. If surfaces cannot tolerate bleach, thorough cleaning with a neutral cleaner followed by an approved disinfectant for routine cleaning will remove most infectivity by dilution.
5. Surfaces and instruments in the morgue that cannot tolerate bleach can be decontaminated with 2M Sodium Hydroxide

DECONTAMINATION OF INSTRUMENTS

Surgical instruments used in high-risk cases that transgress dura are considered contaminated and a special disposable CJD brain biopsy kit is available for these procedures. (see OR protocol) In the uncommon event that an instrument *not* in the kit becomes contaminated, then that item must be packaged separately by OR staff, **labelled CJD precautions** and sent to SSD for quarantine pending the results of histologic examination of the tissue. If examination rules out the possibility of CJD, the item will then be signed off by the Medical Microbiologist/Pathologist, decontaminated by SSD and put back into circulation. If CJD is confirmed or pathology is suspicious, then the item will be incinerated. It cannot be emphasized strongly enough that disposable instruments are used for high-risk cases and that additional non-disposable instruments are used only if absolutely necessary.

Instruments in the autopsy suite may be decontaminated by wiping clean, soaking in bleach for one hour, and then disinfecting as per routine protocol. Instruments in Medical Microbiology and in Anatomic Pathology may be disposed of. Other laboratory instruments will likely be unaffected. A disposable hemocytometer (cell count chamber) will be used for CSF examination in known or suspected CJD cases. Autoanalysers require no special cleaning.

5. BRAIN BIOPSIES FOR DEMENTIA NOT YET DIAGNOSED (CJD PRECAUTIONS

CJD precautions will be MANDATORY for ALL BRAIN BIOPSIES FOR THE FOLLOWING DIAGNOSES:

a) Dementia not yet diagnosed or no discrete mass lesion and no diagnosis

Day prior to surgery:

The **Surgeon** will notify the Neuropathologist/Pathologist and the slating secretary of the diagnosis. The Neuro PSC or designate will be notified via the Slate in advance of the procedure. The SPD co-ordinator or designate will be notified by the **Neuro PSC or designate** as soon as possible. *Any patient with the above diagnosis will be treated as per the protocol.*

Day of surgery:

At Lions Gate Hospital there is a dedicated circulating nurse outside the OR room. Floor and table surfaces are covered with plastic drapes.

OR room should have minimal supplies and equipment in the room.

No linen shall be used, the OR table shall be draped will a disposable medium sheet impervious side down.

1) The following items will be available on a CJD Procedure cart in the OR.
- signage stating **CJD precautions**
- specific CJD disposable instrument set and other disposables (e.g. basins) as required
- Pathological waste disposal boxes and biohazard bags

2) Equipment prior to procedure:

OR staff assembles:

a) equipment for disposal
- RED garbage bags and pathological waste box (in case cart holding area) (only if material is solid waste, other wise liquid waste should be placed into a red anatomical 5 gallon pail with gasket lid.)
- disposable masks with visor
- disposable sterile gowns #19000 (at VA: from area supply page 87-03334; at LGH, purchase directly as needed)
- disposable boot covers
- disposable suction tips
- disposable regular cauteries (not Malis cautery)
- double gloves

b) OR instrumentation
- Disposable CJD Precautions Set
- use other disposable equipment as needed (e.g. Frazier disposable suctions)
- DO NOT use power tools (no MIDAS REX): gigli saw may be used instead
- **all tissue, instruments and equipment that comes in direct contact with brain, nerve tissue or CSF is considered potentially "contaminated" with CJD (i.e. any instrument that transgresses the dura in a case of dementia NYD)**

- 3) Set up the pathological waste cardboard box and line box with TWO red garbage bags

4) Inform Housekeeping Supervisor of case to ensure that cleaning is done correctly and safely. Only have yellow garbage bags and ONE sharps container in the room.

During the procedure

1. Ensure that instrument tray/container is removed and placed on the clean case cart prior to initiation of surgery.

2. All specimens must be fixed in formalin. The specimen should be placed in a suitable leak proof container to allow for its coverage with ten times its volume of formalin and then placed in a plastic bag. The Pathology Department will then use formic acid to deactivate the prions.

End of case:

1. "Clean" instruments from the gown table are processed as usual – placed in a basin for routine cleaning. It should be noted that in most cases, all instruments will be disposable. The exception may be the "tunneler" used for placement of a VP shunt – this may be sent to SPD provided it did not transgress dura.

2. All instruments from the disposable CJD precautions set and all the disposable bowls and basins from the case will be placed in the pathological waste cardboard box lined with two red garbage bags. This includes disposable CJD Precautions instruments, drapes, cautery pencils, Malis cord, gloves, gowns, masks and sharps container.

3. The scrub nurse will suction up all fluids into the suction liner. The suction liner is placed directly into the red 5 gallon pail with gasket lid in an upright position.

4. At the end of the case, tie each bag securely and fold the lid down or seal gasket lid on the red anatomical pail. Label the box "CJD precautions." The OR is to notify Distribution of material being sent ahead of time. At VGH, place the sealed box in the yellow biohazard cart and call Distribution to move the "CJD Precautions" container(s) to chemical shed #1. At LGH, the OR is to notify the Housekeeping supervisor.

5. At Vancouver Acute, brain tissue specimens shall be treated as "RUSH for Permanent" specimens for Pathology and identified with the "Creutzfeldt-Jakob Disease" label. The nurse delivering the specimen to the front desk will notify the lab by the Tridex system. Call Messenger service to pick up the specimen and HAND DELIVER it to the lab. DO NOT use the pneumatic tube. At Lions Gate Hospital, the OR will phone the lab, prior to the start of surgery to notify them of a pending CJD case. The OR will deliver the specimen to the lab with the appropriate notification of a possible CJD specimen. The lab will handle and distribute.

6. The laboratory will NOT perform frozen sections or touch/squash preparations on tissue suspected of CJD

6. STERILE PROCESSING DIVISION

All CJD instruments should be disposable and should not be sent to SPD. The only exception to this would be the "tunneler" used for exterior placement of a VP shunt – this may be cleaned as usual. If CJD Precautions instruments inadvertently arrive in SPD (identified by the CJD label on them) or disposable basins or bowls are sent to the department, place in a biohazard bag and notify the co-ordinator or designate.

7. LABORATORY INFECTION CONTROL PRECAUTIONS

SPECIMEN COLLECTION AND HANDLING

CJD precautions are warranted when collecting and handling high or low infectivity tissues from a high risk patients or high infectivity tissues and CSF from an at-risk patient (see Table 1 and 2). **CJD precautions are not necessary for collecting, handling, and processing blood, urine and faecal specimens**

- HCWs should wear appropriate personal protective equipment as fits the activity. Protective eye wear must be worn when splashing is anticipated
- Specimens should be sent in a sealed, leak proof, puncture-resistant container inside a plastic bag that is clearly labelled as "CJD Precautions"
- Single use instruments should be used when performing lumbar punctures on high risk or at risk patients
- Sealed containers and closed centrifuge buckets must be used when spinning down CSF from high risk or at risk patients
- All single-use laboratory instruments or equipment should be disposable wherever possible. Non-disposable items can be decontaminated as outlined in the Decontamination section of this document. Disposable hemocytometers and cytospin containers will be used in the Regional Laboratories.
- Work surfaces can be decontaminated with 2.5% bleach (25,000 ppm) as per the Decontamination protocol in this document
- Pathology and Autopsy Services have separate protocols for handling at-risk specimens and patients. (Please see Appendix 1)

SPECIMEN DISPOSITION

CSF specimens:

14-3-3 protein testing – to Laboratory Accession at VGH or LGH
Microbiology – to VGH Medical Microbiology Laboratory
Virology – to BCCDC Virology Laboratory
Hematology – To VGH or LGH Laboratory
Biochemistry – to VGH or LGH Laboratory
Cytology – initial morphology to be performed by Hematology and sent to Pathology as appropriate

Brain biopsies and high risk tissues:
Pathology – to VGH or LGH Pathology Department

Please ensure that all specimens are labelled "CJD Precautions". Pathology specimens should have prior notification by the OR as to the potential for CJD to prevent frozen tissue examination from being performed.

8. DISPOSAL OF WASTE FROM DEMENTIA NOT YET DIAGNOSED CASES AND KNOWN CJD CASES (OPERATING ROOM, PATHOLOGY AREA, CLINICAL AREAS)

Solid Waste

1. OR, Pathology or ward staff to inform housekeeping supervisor (or OR lead) of the situation.
2. OR staff to leave sharps containers and black bags in room.
3. In addition, an "anatomical waste" cardboard box with a red liner will be provided with the case cart from SPD. (This should be ordered through Distribution at VGH (604 686 0002). If there is any issue, page the coordinator (604 709 5091). At LGH call the Aramark call centre 604 694 6300.

All solid biomedical waste (including the sharps container) should be placed in this. At the end of the case, the bag should be tied securely and the lid box folded down. The box should be labelled "CJD Precautions" and then transferred at VGH by Distribution, and at LGH by Housekeeping. Once properly taped and labelled "CJD Precautions", Distribution (at VGH) or Housekeeping (at LGH) will relocate the box to the appropriate storage area for that facility prior to transport and incineration.

Solid Waste – CSF on wards

1. Ward staff to inform housekeeping supervisor of the situation
2. An "anatomical waste" cardboard box with a red liner is needed. This should be ordered through Distribution at VGH (604 686 0002). If there is any issue, page the coordinator (604 709 5091). At LGH call the Aramark call centre 604 694 6300.
3. Lumbar puncture equipment and all items used in the procedure are to be placed in a biohazard bag and tied. At the end of the procedure, the bag should be tied securely and the lid box folded down. The box should be labelled "CJD Precautions" and then transferred at VGH by Distribution and at LGH by Housekeeping. Once properly taped and labelled "CJD Precautions": Distribution (at VGH) or Housekeeping (LGH) will relocate the box to the appropriate storage area for that facility prior to transport and incineration
4. Housekeeping (LGH) or Distribution (VGH) will contact the biomedical waste disposal company to arrange for transport to biomedical waste incinerator.

Liquid and/or flammable waste

1. Place red anatomical pail in a flammable storage container and label with the chemical name and "CJD Precautions"
2. Arrange with the Regional Director, Environmental Management at 604.875.4111, ext.67499, or pager 604 205 0608 to have the material moved to the appropriate storage area to be removed for incineration.
4. If the Regional Director, Environmental Management is not available, arrange with Distribution at 604-686-0002 to transport the containers to Distribution and to inform the Regional Director, Environmental Management of the date, volume and type of material. If there is any issue, page the coordinator (604 709 5091).
4. Arrangements for containers to be shipped to Alberta for incineration will be made by the Regional Director, Environmental Management.

9. RETROSPECTIVE MANAGEMENT OF HIGH-RISK CJD PATIENTS

Mitigation against retrospective management of instruments that contact high-risk tissue from a high- or at-risk CJD patient has been addressed through the use of disposable instrument sets for neurosurgical procedures and lumbar punctures, appropriate triage and screening by the Neurosurgery and Neurology teams, and protocols for management of waste. In the event, however, that there was inadvertent exposure of patients to contaminated equipment, the decision algorithm developed by the Public Health Agency of Canada will be used.

10 POST-EXPOSURE PROPHYLAXIS

It should be noted that occupational exposure to CJD has been reported very rarely. The post-exposure prophylaxis outlined below is theoretical and based on limiting the replication of the prion while allowing for clearance to occur thus blocking initiation of prion disease. In the case of contamination of *intact* skin, the area should be washed with detergent and copious quantities of warm water (avoid scrubbing). Brief exposure to a 1:10 solution of bleach can be considered for maximum safety. Report the injury to Occupational Health. Accidents involving penetrating wounds and/or contamination of damaged skin should be immediately washed with copious warm soapy water (avoid scrubbing) and covered with a waterproof dressing. The Public Health Agency of Canada also recommends that the individual should gently encourage bleeding at the site if possible. Further treatment (e.g. sutures) should be appropriate to the type of injury and should also be reported to Occupational Health. Splashing of mucous membranes should be rinsed with saline (eye) or tap water (mouth) and reported as well.

11. CANADIAN CJD SURVEILLANCE SYSTEM

A surveillance system for CJD in Canada has been established by The Public Health Agency of Canada who request voluntary notification of any CJD suspect cases. Their toll free number is **1-888-489-2999**. The team members can assist with any CJD related issues including diagnosis and containment of the agent, information for relatives of affected patients and genetic testing and counselling. It can also provide CJD CSF testing, neuropathological examination, PrP immunohistochemistry and brain tissue transport at no cost.

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VANCOUVER HOSPITAL AND HEALTH SCIENCES CENTRE
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE

STANDARD OPERATING PROCEDURE

BRAIN CUTTING OF KNOWN AND SUSPECTED PRION DISEASE

AUTOPSY CASES

(Including Creutzfeld-Jakob disease (CJD), Gertmann-Straussler Syndrome, Kuru, Fatal familial insomnia and new variant CJD)

SOP# 14010 AMO

Authorized by: Dr. R. Coupland Regional Medical Director Dr. K. Zis Division Head, Neuropathology Dr. R. Wolber Regional Medical Lead, Anatomic Pathology Technical Specialist, Anatomic Pathology.: John Garratt Date Effective:	Manual: MORGUE

PURPOSE:
To establish a safe procedure for brain cutting of autopsy brains of known and suspected Prion disease patients.

PROCEDURE:

1. The Pathology attendant will assist the neuropathologist in sectioning the brain in half at time of brain only autopsy. Formalin fixation of half brain should be for a minimum of 10 days.

2. The Pathology attendant will set up counter space at sink in isolation room (use 15 mil polyethene sheet).

3. Stainless counter surface will be covered with plastic.

4. Cutting tray for brain dissection will be covered with plastic and tin foil.

5. Instruments required: forceps, scalpel blade and handle, and large dissection knife.

6. Cassettes with plastic lids will be labelled with case number and letter designation.

7. The cassettes should be laid out on a second tray with plastic cover for neuropathologist to place sections.

8. Cassettes containing specimens are to be closed and placed in labelled container with formalin.

9. Remainder of fixed brain tissue will be replaced in original formalin container.

10. Containers of cassettes and brain half are to be placed in fume hood.

11. After five days of fixation cassettes can be treated with 95-100% formic acid **for 1 hour. Thickness of the tissue placed in the cassettes must not exceed 4 mm.**

12. Formic acid is removed and collected.

13. Cassettes are rinsed five to ten times with formaldehyde, collecting the waste for disposal.

14. Prior to forwarding the cassettes to the neuropathology section of the Histology Laboratory, cassettes are to be fixed again in formalin for two days.

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Related Documents:

- Procedure for removal of brain in suspected Prion disease - SOP# 14011 Amo

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VANCOUVER HOSPITAL AND HEALTH SCIENCES CENTRE
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE

STANDARD OPERATING PROCEDURE

REMOVAL OF BRAIN IN KNOWN OR SUSPECTED PRION DISEASE

(Including Creutzfeld-Jakob Disease (CJD), Gertmann-Straussler Syndrome, Kuru, Fatal familial insomnia and new variant CJD)

SOP# 14011 AMO

Authorized by: Dr. R. Coupland Regional Medical Director Dr. R. Wolber Regional Medical Lead, Anatomic Pathology Dr. K. Zis Division Head, Neuropathology Technical Specialist, Anatomic Pathology: John Garratt Date Effective:	Manual: MORGUE

PURPOSE:
To establish the procedure for removal of the brain in known and suspected Prion disease autopsies.

PROCEDURE:

Attendance at autopsy is limited to the neuropathology and two autopsy staff

1. The chart will be carefully reviewed by the neuropathologist/pathologist. If no neuropathologist is available, the attending neurologist should be contacted to discuss the case with the pathologist.

2. If there is suspicion of prion disease, the autopsy should be limited to the brain only.

3. The autopsy is performed in the isolation room in the morgue, one pathologist and one morgue attendant who will handle the removal of the brain and clean-up, and one morgue attendant to assist, as clean person, with the removal and packing of brain

4. All staff involved in the brain removal must be dressed in a scrub suit, barrier impervious apron, gown, double gloves and cut resistant gloves, head covering, surgical mask and eye protection.

5. The dedicated kit of instruments consists of a head rest, clear plastic drapes, large black garbage bags, scalpel blades, scalpel handle, scissors, needle and string, head clamp,hand saw with blade, styker saw, forceps, ruler, head chisel, gauze, and biohazard labels. All these items are contained in a large plastic tray.

6. A 6 L pail will be used to immerse half of the brain in formalin; a second 4 L pail will be used to hold the plastic wrapped brain (in double bag) for freezing. Another 4 L pail will be used for all contaminated liquids. This pail will be disposed of in the 5 gallon red pail. A Biohazard (red) 5 gallon container will be used for all waste collected. When full, the container will be labelled, sealed and placed inside the morgue fume hood.

7. The body is placed in the isolation room and is visually examined by the neuropathologist/pathologist and identified as said person for autopsy. The neuropathologist/pathologist will normally leave the room temporarily.

8. The body remains inside the body bag for the brain removal..

9. The shroud sheet is placed under the head and shoulders of the body.

10. The headrest is placed under the head and rags are placed around head rest and shoulder area. Additional rags should be available for the attendant removing the brain. The head will be set up with plastic barrier tent if using Stryker saw.

11. The calvarium is opened with a dedicated saw. If using an electric saw it should be operated inside an aerosol-containing bag. Extra blades should be available.

12. The brain is removed in the normal way.

13. The clean person will have the counter in the isolation room prepared by draping the counter with a 5 ml polythene sheet.

14. The cutting tray is draped with plastic backed absorbent material for receipt of the brain, once it is removed.

15. The neuropathologist will return and bisect the brain on the cutting tray. One part will be fixed, and the other part frozen.

16. The clean person will direct the neuropathologist/pathologist to place half of the brain into the container filled with formalin. The other half is placed on an open plastic bag.

17. Neuropathologist/pathologist will then remove garments and leave isolation room.

18. The “dirty person” will sew up the scalp, clean the head and remove all dirty rags and bags. These will be placed into a red pail.

19. Dirty instruments will be placed directly in bleach 2.5% (25,000 parts per million) concentration. For example, if using 5% bleach, dilute 1:1 prior to application; 12% bleach is to be diluted 1:5. Treat with bleach for one hour

20. The “dirty person” will:
    (a) remove all drapes and place them in the biohazard pail
    (b) remove all pieces of the protective attire (head cover, protective eyewear, mask, gloves, gown) and place them in the biohazard pail
    (c) clean hands
    (d) The same person (now “clean”) will continue cleaning the room and instruments, wearing

new double gloves, gown, mask, head protection and face shield.

(e) When the instruments have been removed from the disinfecting solution, the solution is collected in the 4 L pail and the pail is closed and placed in the red 5 gallon pail. Outer gloves are removed and disposed of in the red pail and the pail is sealed.

(f) The instruments and trays are then washed, dried and repacked in the dedicated CJD kits.

(g) The protective attire is disposed of following Routine Practices protocol.

21. The body is wrapped up by closing the body bag. The body is then transferred to a second body bag and is moved from the isolation room on a different stretcher.

22. The clean person wraps the brain for freezing. It is then placed in two other plastic bags, labelled and placed in a dedicated –70C° freezer.

23. The "dirty person" will proceed with cleaning of the instruments and room.

24. All specimens are stored by clean person

25. Equipment, instruments are soaked in 2.5% bleach for one hour, washed, rinsed and dried and replaced in kit. Wash and rinse fluids will be disposed of in the biohazard pail.

26. All primary liquid waste is collected for disposal in red pails.

27. All wet biohazard garbage is collected in red pails and sent out for incineration. All dry garbage is collected in biohazard box and sent for incineration.
For garbage pick up, contact the Regional Director, , Environmental Management at local 67499 or pager 709-5493; or Distribution services at local 62729.

28. The funeral home is made aware of infectious nature of case by biohazard labels and other written information on body bag.

Original Prepared By:

Kamil Josifek
Sieghard Brueckner

Related Documents:

- Procedure for brain cutting for suspected Prion Disease cases - SOP# 14010 Amo

References:

3. Neurology 40, June 1990 pages 887-890 (Brown, MD, Wolf, DVM and Gadjusek , MD)

Internet:

- CAP reprint: Creutzfeld-Jakob Disease Safety tips for Anatomic studies of possible CJD, Barbara J. Crain, MD, PhD
- URL-http://www.cap.org/html/publications/cjd.htm#decontissue
- URL-http://www.hc-sc.gc.ca/pphb-dgspsp/predecontamination process

3. Health Canada Infection Control Guidelines Classic Creutzfeldt-Jakob Disease in Canada Canada Communicable Disease Report
ISSN 1188-4169 Nov 2002 vol: 28S5

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VANCOUVER HOSPITAL AND HEALTH SCIENCES CENTRE
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE

STANDARD OPERATING PROCEDURE

PROCESSING SURGICAL AND AUTOPSY TISSUE FROM SUSPECTED PRION DISEASES (Including Creutzfeldt-Jacob Disease, Gertmann-Straussler Syndrome, KURU, fatal familial insomnia and new variant CJD))

SOP# 14013 AMO

Authorized by: Dr. R. Coupland Medical Director Dr R Wolber Regional Disipline Lead, Anatomic Pathology Dr. K. Zis Division Head, Neuropatholoy John Garratt Technical Specialist, Anatomic Pathology : Date Effective:	Manual: MORGUE

SURGICAL TISSUE

Formalin does not destroy the infectious agent. Tissue is to be initially fixed in formalin for a minimum of 48 hours, then treated with concentrated (*greater than 96%*) formic acid for 1 hour and then transferred to fresh formalin for 24 hours. This protocol is effective for tissue blocks up to 4 mm thick.

SURGICAL TISSUES WILL BE CASSETTED AND FORMIC ACID TREATED IN HISTOLOGY

i) Specimens thicker than 4 mm

Specimens must be adequately fixed in formalin first, for 48 to 72 hours

1. Get all instruments, containers, and solutions ready before starting.
2. Wear disposable gown, safety glasses, mask and double-glove.
3. Blocking should be done with minimal handling in as small a space as possible
4. Cover cutting board with disposable incontinent pad
5. Block tissue into sections thinner than 4 mm
6. Place tissue cassettes into concentrated formic acid (*greater than 96%*) for one hour with occasional agitation.

7. Place the container (sealed) with the primary fixative in it in red container for incineration.
8. After blocking, soak instruments and cutting board in bleach for 1 hour (2.5% bleach = 25,000 ppm). Washings can be disposed of in sink

9. Sterilize the outside of containers with bleach, label with biohazard stickers and place in plastic bag.
10. Place all disposables (gowns, masks, gloves, pads, paper towels, etc) in red container for incineration, and seal the container.
11. After the cassetted tissue has been treated for one hour in formic acid transfer to a fresh plastic container of 10% formalin, double bag the container, leave for an additional 48 hrs., and then it is ready to process.

Processing:

1. **Tissue must not be processed until treated as above**. Process treated blocks on the usual Neuro block processing schedule. During the processing (and later cutting) use Routine Precautions and always wear gloves.
2. Because materials are rendered safe, no further special precautions are required and tissues can be processed, cut, stained and filed in the usual manner. Paraffin blocks and slides will be filed in a designated area separate from routine neuropathology cases in the NP filing area.

Disposal: Contact the Diener to complete the process. (remove the red container)

ii) Tissue (biopsy) is less than 4 mm thick

In these circumstances, the procedure can be simplified as follows:

Procedure:

Initial fixation in 10% formalin for minimum of 48 hours.
1. Under full protection, transfer tissue to another container and treat with formic acid for 1 hr
2. After 1 hr formic acid treatment, the tissue can be cassetted and handled as any other non-infectious tissue.
3. Minimum of additional 24 hr fixation in formalin is required prior to VIP processing (48 hrs is recommended, if possible).

Decontamination and Disposal:

1. Only primary fixative (formalin) is to be collected for disposal. Formic acid and secondary formalin fixative can be disposed of in the sink.
2. Any other decontamination (if applicable) and disposal is handled in the same manner as in the previous protocol.
3. Decontaminate water bath with 50% bleach and wipe cutting area with same..

B. AUTOPSY TISSUE:

Autopsy tissues will be cassetted and formic acid treated in Morgue, as per Morgue SOP #14010 (Amo).

Prior to forwarding the cassettes to Neuropathology section of the laboratory, cassettes are fixed again in formalin for 48 hours. They can then be processed as per the usual Neuropathology specimen protocol. No extra precautions are required.

References:

1. Neurology 40, June 1990 pages 887-890 (Brown, MD, Wolff, DVM and Gadjusek, MD)
2. Internet: CAP reprint: Creutzfeldt-Jakob Disease Safety tips for anatomic studies of possible CJD, Barbara J. Crain, MD, PhD
   URL- http://www.cap.org/html/publications/cjd.html#decontissue

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