Description

Describes the recommendations to prevent the transmission of Sporadic Creutzfeldt-Jakob Disease (CJD) within the healthcare setting.

Rationale

CJD is transmitted by a proteinaceous infectious agent or prion. The CJD prion is hardy and resistant to heat, formaldehyde, glutaraldehyde, ionizing radiation, freezing, drying, and organic detergents. Because it resists routine cleaning, disinfection, and sterilization procedures used in hospitals, diligent adherence to the following recommended practices, specifically for surgical instrument handling is essential. CJD has been shown to be transmitted between humans by only certain tissues that include infected brain, ocular tissue, and pituitary tissue/hormones. "For a surgical instrument to act as a vehicle of prion transmission, it must come into contact with infective tissue (e.g., brain) during surgery of the infected patient, it must retain the infectivity of an adhered matter after being decontaminated and sterilized, and it must have contact with the receptive tissue in the recipient."\(^3\)

Policy

Definitions for High-Risk CJD Patients

1. Patients with known or suspected prion diseases (e.g., CJD, Gertsmann-Straussler Sheinker [GSS] disease, fatal familial insomnia [FFI syndrome]).
2. Rapidly progressive dementia consistent with possible prion diseases.
3. Patient is undergoing brain biopsy when a specific lesion has not been demonstrated (e.g., via MRI, CT).
4. Familial history of CJD, GSS, or FFI.
5. Patients known to carry a mutation in the PrP gene involved in familial Transmissible Spongiform Encephalopathies (TSEs).

Infection Control Measures

These should be based upon epidemiological evidence linking specific body tissues or fluids to transmission of CJD. (See Appendix 1 for a table summarizing the comparative frequency of infectivity in organs/tissue/body fluids of humans with CJD and other TSE.)
1. General Precautions for Patients with Known or Suspected CJD
   a. Patients with known or suspected CJD will have a flag placed in their Infection Status in Epic. This flag may be removed if CJD is ruled out.
   b. Standard Precautions should be followed utilizing appropriate personal protective equipment.
   c. A private room for the patient is not necessary for infection control purposes.
   d. No special precautions are required for handling laundry, food trays or utensils.
   e. Disposable instruments should be discarded in the appropriate receptacle.
   f. Since standard decontamination of tissue samples (e.g., formalin) may not inactivate CJD, all tissue samples should be handled using Standard Precautions (i.e., gloves). High-risk tissues (brain, spinal cord, posterior eyes, pituitary tissue) should be labeled "BIOHAZARD" and "suspected CJD" prior to being sent to the laboratory.
   g. No special precautions are required for disposal of body fluids. Such fluids may be disposed of via a sanitary sewer in accordance with applicable regulations.
   h. Regulated medical waste (i.e., bulk blood, pathological materials, biologic materials, and sharps) should be managed according to the Infection Control Policy: Guidelines for Disposal of Regulated Medical Waste.
   i. When a patient dies, the physician will ensure that the morgue and funeral home are notified that the patient has known or suspected CJD. The UNC Hospitals’ morgue should follow standard precautions.
   j. Patients with known or suspected prion disease should not serve as donors for organs, tissues, blood components, or biologic products (e.g., interferon). Recipients of pituitary hormones or dura mater transplants should not be donors. Transfusion/Transplant services should include this factor in pre-donation surveys.

2. Cleaning and Disinfection of Contaminated Environmental Surfaces
   a. High Risk Tissue (brain, spinal cord, posterior eyes, pituitary tissue) Contamination
      i. Since CJD infectivity persists for long periods on work surfaces, it is important to use disposable cover sheets whenever possible to avoid environmental contamination. Mechanically clean and disinfect equipment and surfaces that are subject to potential contamination, to prevent environmental build-ups. Surfaces contaminated by CJD can be disinfected by flooding, for one hour, undiluted sodium hypochlorite (bleach), followed by rinsing with water.
   b. Low Risk or No Risk Tissue or Fluid Contamination (refer to the attachment Appendix 1)
      i. Use standard disinfection procedures (i.e., any EPA-registered disinfectant/detergent or a bleach wipe).

3. Decontamination of CJD Contaminated Medical/Surgical Devices: Decontamination methods are based upon the type of contamination (i.e., high risk tissues, low risk tissues/fluids, no risk tissues/fluids), and the potential risk of infection involved in the use of the items.
   a. Definitions Categories of Risk of Patient-Care Items
      i. Critical Items: Items that enter sterile tissue or contact the vascular system. High risk of infection if contaminated.
      ii. Semicritical Items: Items that come into contact with mucous membranes or skin that is not
intact. Examples: most endoscopes, respiratory therapy equipment.

iii. Noncritical Items: Items that touch only intact skin. (i.e. blood pressure cuffs).

b. Decontamination Procedures for Surgical Instruments

i. High Risk Tissue (brain, spinal cord, posterior eyes, pituitary tissue) and Critical items from high-risk patients:

- Discard devices that are difficult to clean
- Contact should be made with Central Processing Department (CPD) prior to sending instruments in this category for cleaning and disinfection, to inform them they will be receiving instruments that are from a patient known or suspected to have CJD.
- The items should be labeled "CJD" so the CPD employee receiving them will know they are the ones that will require special processing.
- Keep instruments moist (either wet by use of a transport gel/foam, immersion in water, by use of a wet cloth draped over the instruments after use and during storage/transport prior to decontamination in Central Processing. This will retard adherence of material to the medical device.
- The CJD instruments should be decontaminated and reprocessed as soon as possible using the following 3 steps:
  1. Wearing gown, gloves, face shield, mask, bouffant cover and shoe covers, place instruments in an autoclave at at 134°C for greater than or equal to 18 minutes in a prevacuum sterilizer.
  2. After autoclaving, place the CJD instruments only in the decontamination washer/disinfector. Note that this washer/disinfector uses fresh water for all cycles therefore at completion it is ready for use with other instruments.
  3. After removal from washer/disinfector, assemble/package instruments and autoclave at 134°C for 18 minutes in a prevacuum sterilizer.

  Note: No other instruments/devices may be in the washer basket or sterilizer with CJD exposed instruments.

- Immediate-use steam sterilization should not be used for reprocessing.
- Items requiring low temperature sterilization (e.g., ethylene oxide, hydrogen peroxide gas plasma) should be discarded.
- Items contaminated with high risk tissues not processed according to these recommendations should be recalled and appropriately reprocessed (e.g., medical devices used for brain biopsy prior to diagnosis).

ii. Low/No Risk Tissue (refer to the attachment Appendix 1) and Critical/Semicritical Medical Device: These devices can be cleaned and disinfected or sterilized using conventional protocols or heat or chemical sterilization, or high-level disinfection as appropriate.

4. Percutaneous Intact Skin, Percutaneous or Mucus Membrane Exposure to High Risk Tissues (Brain, Spinal Cord, Eyes)

   a. Intact skin: 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 (one minute, 1:10 dilution of bleach).
b. Percutaneous: Needle sticks or laceration: gently encouraging bleeding; wash (avoid scrubbing) with warm soapy water, rinse, dry and cover with a waterproof dressing.

c. Mucus Membranes: Splashes into the eye or mouth: irrigate with either saline (eye) or tap water (mouth).

d. After cleansing of the wound, the injured health care personnel (HCP) should contact the appropriate occupational health service (Hospital Employees-Occupational Health Service at 984-974-4489 or Needlestick Hotline at 984-974-4480 after hours; University Employees contact University OHS at 984-974-9119 or Healthlink at 984-974-6302 after hours). For large wounds or deep laceration after hours, HCP should be seen in the ED as soon as possible.

5. For further information, contact Hospital Epidemiology at 984-974-7500 for any questions or problems that may arise while caring for a patient with suspected or known CJD. The Infection Preventionist on call 24/7 may be contacted on pager 919-216-2935.

6. Communication

a. Hospital Epidemiology, Central Processing Department, Pathology, Microbiology, and Perioperative Services should be notified prior to any neurosurgical procedure on a patient with known or suspected prion disease or a High Risk CJD patient (section IIIA). The attending physician is responsible for communicating with Hospital Epidemiology and other involved departments (e.g., Perioperative Services, Neurophysiology, Pathology) when a patient with known or suspected CJD is scheduled for any invasive procedure in which there may be exposure of instruments to high risk tissues.

b. Prion sterilization procedures will be used on all contaminated neurosurgical instruments from patients undergoing a brain biopsy when a specific lesion has not been demonstrated (e.g., via MRI, CT). This is to minimize the possibility of use of potentially contaminated neurosurgical instruments from patients later diagnosed with CJD. Since only the neurosurgical attending would be aware of patients meeting this criterion, Hospital Epidemiology, Central Processing and Perioperative Services must be notified when suspected cases are scheduled for the operating room.

c. Follow-Up by Hospital Epidemiology: Upon notification that a patient with known or suspected CJD has been, Hospital Epidemiology personnel will do the following:

i. Investigate if the patient has had or is scheduled to have a brain biopsy or other surgical procedure that may involve contact with high risk infectious tissues. If surgery is scheduled and may involve contact with high risk tissues (i.e., brain biopsy), notify OR personnel and Central Processing Manager to ensure that all reusable instruments are appropriately resterilized. Instruments should be placed in a puncture proof, leak proof container for transport to CPD. The container should be labeled to indicate potential CJD. If a brain biopsy or other procedure involving high risk tissues has been done prior to diagnosis, CPD will be instructed to track all instruments for recall.

ii. Advise OR personnel preparing specimens for transport to Anatomic Pathology that all specimen containers must be properly labeled and tightly closed. Special procedures for fixing tissues possibly infectious with CJD are required.

iii. Hospital Epidemiology will ensure that the following departments have been notified:

- Anatomic Pathology: Notify the Histology Supervisor at 843-1082 of a specimen coming to the lab including the patient's name and differential diagnosis. A formalin-formic acid procedure is required for inactivating virus infectivity in tissue samples from patients with
CJD. For further lab guidelines, refer to Appendix 2 of this policy.

- Neurophysiology: EEG leads contaminated with high risk tissues must be sent to Central Processing Department and are to be sterilized as described above (IIB3bi). Alternatively, they may be discarded in a needle disposal container. EEG leads that have had only skin contact may be reprocessed in the conventional manner.

- Central Processing Department: Provide advice regarding safe transport and proper sterilization techniques for reusable critical and semicritical items by CPD staff.

iv. In the event of patient death, the physician will ensure that the morgue and funeral home are notified that the patient has CJD.

v. Autopsies should not be performed on patients with known CJD.

References


Attachments:

01: Comparative Frequency of Infectivity in Organs/Tissue/Body Fluids of Humans with CJD and other TSE

Approval Signatures

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Applicability

UNC Medical Center