	The Johns Hopkins Hospital Interdisciplinary Clinical Practice Manual Infection Control	<i>Policy Number</i>	IFC032
		<i>Effective Date</i>	07/01/2011
		<i>Approval Date</i>	06/28/2011
	<i>Subject</i> Precautions for Patients with Known or Suspected Transmissible Spongiform Encephalopathies (TSE) / Prion-Associated Disease (PAD)	<i>Page</i>	1 of 6
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I. OBJECTIVES


- A. To define transmissible spongiform encephalopathies (TSEs), also known as prion associated diseases (PAD).
- B. To outline the necessary steps for notification when a patient with TSE is suspected or known.
- C. To provide guidance on infection control measures for healthcare workers caring for patients with suspected or known TSEs.

II. INDICATIONS FOR USE

- A. This policy shall be implemented to prevent the spread of transmissible spongiform encephalopathies.
- B. This policy shall be used for any patient who is identified with suspected or known transmissible spongiform encephalopathies (TSEs) which include: Creutzfeldt-Jacob Disease (CJD), Variant CJD (vCFD), Gerstmann-Straussler Scheinker Disease (GSS), Kuru, Fatal Familial Insomnia (FFI).

III. DEFINITIONS


- A. Transmissible spongiform encephalopathies (TSEs): A group of rapidly progressive, invariably fatal, neurodegenerative diseases:
 1. Creutzfeldt-Jacob Disease (CJD)
 2. Variant Creutzfeldt-Jacob Disease (vCJD)
 3. Gerstmann-Straussler Scheinker Disease (GSS)
 4. Kuru
 5. Fatal Familial Insomnia (FFI)
- B. Prions: An abnormal, transmissible agent that is able to induce abnormal folding or normal cellular prion proteins in the brain.

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- C. High Risk Patient:
1. Patient with known prion disease (CJD, GSS, FFI)
 2. Rapidly progressive dementia consistent with possible prion disease
 3. Patient undergoing brain biopsy with a specific lesion has not been demonstrated (e.g., abscess, brain tumor)
 4. Familial history of CJD, GSS or FFI
 5. Patient known to carry a mutation in the PrP gene involved in familial transmissible spongiform encephalopathies (TSEs)
 6. Exposure to iatrogenic transmissions (e.g., dura mater graft, human gonadotrophins, corneal transplant)
- D. Prion Precautions: Measures employed to reduce risk of transmission since prions are resistant to a number of standard sterilizations and disinfection procedures. This precautionary category facilitates identifying patients who may undergo a surgical procedure and the need to follow more stringent disinfection, sterilization and labeling protocols.
- E. TSE Advisory Group: An interdisciplinary team including the Hospital Epidemiologist(s), Infection Control Practitioner(s), a neurologist, and neuropsychiatrist who will collaborate and provide guidance when questions arise during care of a patient with known or suspected TSE disease.

IV. RESPONSIBILITY

- A. Admitting Authorized Physician Prescriber shall:
1. Notify the HEIC on call pager (410 283-3855) when a patient with suspected or known TSE is identified and if an invasive procedure is scheduled.
 2. Notify the unit nurse manager/charge RN.
 3. Notify the laboratory when a specimen is sent for identification of 14-3-3.
 4. Notify the Surgical Coordinator or manager of other procedural areas in advance when a patient with suspected or confirmed TSE is scheduled for an invasive procedure in which there may be exposure of surgical instruments.
- B. Supervisor/Managers of All Departments shall:
1. Ensure employee compliance with this policy.
- C. Clinical and Support Personnel shall:
1. Follow the requirements of this policy.
- D. Laboratory shall:
1. Notify HEIC when a specimen is sent for identification of 14-3-3.
 2. Perform necessary testing or send out specimens to referral lab.
- E. Department of Hospital Epidemiology and Infection Control (HEIC) shall:
1. Post prion precautions for patients with suspected or known TSE in Theradoc and send isolation report to the nursing unit of the identified patient.
 2. Provide education and training as needed.
 3. Assist with questions concerning the policy and measures to initiate "Prion Precautions."
 4. Collaborate with treating teams as needed when questions arise regarding infection prevention/control strategies during patient care, practices related to cleaning and disinfection of the environment, and cleaning and disinfection of surgical instruments.
 5. Notify the lab customer service (5-1921) when a suspected or confirmed TSE patient is identified.
- F. The TSE Advisory Group shall:
1. Collaborate with medical teams when questions regarding patient care related to infection prevention in procedural areas arise to assess patient risk level.

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2. Provide guidance related to risk of transmission when non-disposable surgical instruments/medical devices are used including consideration of notification of patients exposed to such devices.
- G. Surgical Coordinator shall:
1. Notify HEIC on call pager at 410-283-3855 when a scheduled or confirmed TSE patient is posted for surgery.
- H. Health, Safety and Environment (HSE) shall:
1. Provide guidance for use of hazardous materials used in disinfection and sterilization of equipment and the environment.


V. PROCEDURE

A. TSE Risk Assessment


1. Evaluating risk of transmission in the healthcare environment:
 - a. Risk of transmission is dependent upon three (3) considerations:
 - i. The probability that an individual has or will develop TSE
 - ii. The level of infectivity in tissues of these individuals (See Appendix A).
 - iii. The route of the exposure to these tissues via procedures and use of medical device
 - b. TSE Infectivity
 - i. Infectivity of tissue must be considered together with the route of exposure when determining risk of transmission of **TSE**.
 - ii. Always use standard precautions when contacting blood, body fluids and tissue.
 - iii. Cutaneous exposure of intact skin or mucous membranes (except those of the eye) poses negligible risk.
 - iv. Transcutaneous exposures, including contact exposures to non-intact skin or mucous membranes, splashes to the eye, and inoculations via needle, scalpel or other surgical instruments, pose a greater potential risk.
 - v. CNS exposures (e.g., inoculation of the eye or CNS) with any infectious material pose a very serious risk. . PrionP

B. Prion Precautions

1. When a suspected or known TSE patient is reported to HEIC, the patient shall be posted/identified as “Prion Precautions” in Theradoc to facilitate identification and communication that the patient is suspected or known as having TSE and will appear on the Theradoc daily isolation report.
2. All healthcare workers shall follow standard precautions at all times: (e.g., when handling feeding utensils, food trays, feeding tubes, laundry, laboratory specimens, or trash during routine patient care). See policy IFC 023 Infection Control and Prevention: Standard and Isolation Precautions.
3. Cleaning and disinfection of contaminated environmental surfaces
 - a. For routine cleaning and disinfection of the environment (including exposures to tissues with no detectable infectivity and tissues with low infectivity) follow standard disinfection procedures. ([Sterilization and High Level Disinfection of Products policy IFC-031](#))
 - b. For cleaning and disinfection of areas with exposure to HIGH RISK tissue (brain, spinal cord, and eye) thoroughly clean the surface and then decontaminate with a 1:5 dilution of bleach and water (see Appendix B for detailed cleaning instructions).
4. Healthcare workers with percutaneous or mucous membrane exposure shall follow guidelines in the Bloodborne Pathogens Exposure Control Plan (HSE;005).
5. Specimen Labeling and Handling
 - a. Label requisitions for laboratory and pathology specimens of high risk tissue (Appendix A) as suspected TSE (e.g. , rule out CJD).

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- b. Hand carry CSF specimens for known or high clinical suspicion cases to Pathology.
 6. Dental Procedures
 - a. The general infection control practices recommended by the National Dental Association are sufficient when treating patients with suspected or known prion disease during procedures not involving neurovascular tissue.
 - b. Additional precautions listed in Appendix D, shall be followed for major dental procedures.
 7. Diagnostic Procedures
 - a. Patients with prion disease who develop intercurrent illnesses may have the need to undergo diagnostic procedures which include ophthalmoscopic examinations, endoscop, vascular catheterization, bone marrow biopsies, and cardiac or pulmonary function tests. In general, these procedures may be conducted without any special precautions, other than standard precautions, as most tissues with which the instruments come in contact contain no detectable infectivity (see Appendix A).
 - b. When there is known exposure to high or low infectivity tissues, the instruments shall be subjected to the decontamination procedure outlined in Appendix B.
 - c. Lumbar puncture and other procedures involving tissues with low infectivity shall use disposable items when possible. If non-disposable instruments are used they must be disinfected in the same manner as items with high infectivity (see Appendix FA).
 8. Surgical procedures
 - a. Communication to the operating room staff regarding a procedure on a patient with suspected or known prion disease shall occur in sufficient time to allow for planning and obtaining suitable instruments (such as single use items).
 - b. Disposable instruments for high risk tissue/patients shall be used (e.g., brain biopsies)
 - c. The case shall be scheduled at the end of the day (last case in the room).
 - d. Staff must adhere to protocols (see Appendix B) during the pre-operative and post-operative management of the patient
 - e. Consult with Hospital Epidemiology and Infection Control if there are any question regarding a patient/ procedure
 9. Surgical Instrument Handling
 1. If non-disposable instruments are used, the Central Sterile Processing supervisor shall be notified of the suspected/known TSE case prior to the beginning of the procedure to ensure that instruments are processed as soon as possible after completion of the surgical procedure.
 2. Non-disposable Instruments shall be kept wet in sterile water until they are decontaminated.
 3. Instruments shall be decontaminated in an automated washer-disinfector as soon as possible after use.
 4. Prion-contaminated medical devices/instruments that are impossible to clean or unable to be fully exposed to steam shall be discarded.
 5. After the instruments are cleaned/disinfected through the automated washer-disinfector the instruments shall be sterilized by:
 1. Autoclave at 134 degrees C for 18 minutes in a prevacuum sterilizer or
 2. Autoclave at 132 degrees C for 1 hour in a gravity displacement sterilizer
 6. Flash sterilization shall NOT be used for reprocessing.
 7. Discard items that permit only low-temperature sterilization (e.g., sterilization with ethylene oxide).
 8. Recall contaminated items that have not been processed according to these recommendations and appropriately reprocess them in the event that they were used on a patient later diagnosed with TSE.

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9. For all other equipment, standard cleaning procedures are sufficient.
10. Organ Donation

1. If a patient expires, notify the autopsy service and funeral home that the patient had suspected or know TSE.
2. Patients with known or suspected TSE shall not serve as donors (e.g., organs, tissues, blood components).

VI. REPORTABLE CONDITIONS

- A. TSE is a reportable disease in the state of Maryland.
- B. For surveillance purposes, consider reporting clinical information to National Prion Disease Pathology Center.

VII. EDUCATION AND COMMUNICATION

This policy will be communication to the appropriate JHH personnel via the following channels:

1. Updates and revisions will be communicated via Medical Staff and Nursing publications.
2. Nurse Managers, Physician Advisors, Residency Coordinators, Department Chiefs and Department Management will be responsible to train new employees regarding the policy as appropriate, and to communicate updates to the protocol.
3. This policy will be placed in the Interdisciplinary Clinical Practice Manual on the JHH Intranet site: <http://www.insidehopkinsmedicine.org/hpo> . Paper distributions will be made to Functional Unit Nursing Offices in the event of web access difficulty.
4. Placement of policy online at www.hopkinsmedicine.org/heic

VIII. SUPPORTIVE INFORMATION

See Also:


Johns Hopkins Health Safety Manual

- Bloodborne Pathogens Exposure Control Plan, HSE501 www.hopkinsmedicine.org/hse/Policies/HSE_Policies/indiv_sections/HSE501.pdf

National Dental Association Infection Control Practices www.cdc.gov/mmwr/preview/mmwrhtml/rr5217a1.htm

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Sponsor:

- Medical Care Evaluation Committee

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- Hospital Epidemiology and Infection Control

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Vice President for Nursing & Patient Services

Vice President for Medical Affairs

Date:

Date: