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KEY WORDS: prions, prion disease, CJD, Mad Cow Disease

RESPONSIBILITIES

- | | |
|---|---|
| JHH/JHU/JHMI Staff | <ul style="list-style-type: none"> ▪ To maintain compliance with this policy. |
| Supervisor/Managers of all Departments | <ul style="list-style-type: none"> ▪ Ensure employee compliance with this policy. |
| Department of Hospital Epidemiology & Infection Control | <ul style="list-style-type: none"> ▪ Will bring these policies to the Hospital Epidemiology and Infection Control Committee (HEIC) for review and approval. |
| Admitting physician of patient with known or suspected prion-associated disease (PAD) | <ul style="list-style-type: none"> ▪ Notify HEIC on call beeper and nurse manager of the nursing unit when patient when known or suspected <u>PAD</u> patient is admitted. |
| Hospital Epidemiology and Infection Control (HEIC) | <ul style="list-style-type: none"> ▪ Notify the Customer Service Department of the Central Pathology Laboratory. |
| Health, Safety and Environment (HSE) | <ul style="list-style-type: none"> ▪ Consult about using hazardous materials that will be used in disinfection and sterilization. |

PATIENT CARE OBJECTIVES

Creutzfeldt-Jacob Disease (CJD), variant CJD (vCJD), Gerstmann-Straussler Scheinker Disease (GSS), kuru, and other diseases caused by prions (small, proteinaceous infectious agents) are fatal illnesses characterized by a rapidly progressive dementia, myoclonus, psychiatric changes, often typical EEG changes, and spongiform neuropathologic changes. Prions are resistant to a number of standard sterilization and disinfection procedures.


Most cases are sporadic (about 90%), and most of the rest are inherited. However, in a small number of cases, iatrogenic transmission of CJD has been associated with percutaneous exposure to medical instruments contaminated with prion/CNS (central nervous system) tissue residues. Possible iatrogenic transmission has also been associated with transplantation of CNS and corneal tissues and recipients of human growth hormone and gonadotropin. Recently a case of vCJD has been associated with a blood transfusion. Transmission of CJD has not been associated with environmental contamination or person-to-person skin contact. Although isolated episodes of CJD have occurred in healthcare workers, the incidence of CJD in this group does not exceed what would be expected by chance alone.

This document provides guidance upon which infection control practitioners, healthcare workers, physicians, and those involved in the care of persons suffering from prion disease can base their care and infection control practices. The goal is to prevent transmission of prion disease to another patient, a healthcare worker or a family member.

I. EVALUATING RISK IN HEALTHCARE ENVIRONMENTS

When considering measures to prevent the transmission of PAD 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 PAD,
- The level of infectivity in tissues of these individuals,

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- The nature or route of the exposure to these tissues.


From these considerations it is possible to make decisions about whether any special precautions are needed.

Table 1: Estimation of PAD infectivity of human tissues

Infectivity Category	Tissues, Secretions and Excretions	
High Infectivity	Brain Spinal cord Eye CSF (cerebrospinal fluid) for high-clinical-suspicion cases	
Low Infectivity	CSF (cerebrospinal fluid) for low-clinical-suspicion cases Kidney Liver Lung Lymph nodes/spleen Placenta Olfactory epithelium Tonsillar tissue	
No Detectable Infectivity	Adipose tissue Adrenal gland Gingival tissue Heart muscle Intestine Peripheral nerve Prostate Skeletal muscle Testis Thyroid gland Blood Sputum	Tears Nasal mucous Saliva Sweat Serous exudate Milk Semen Urine Feces Bone marrow Vaginal secretions


A. 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) pose 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, splashes to the eye, and inoculations via needle or scalpel and other surgical instruments, 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 pose a very serious risk, and appropriate precautions must always be taken to avoid these kinds of exposures.

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II. PRECAUTIONS

- A. On admission of known or suspected patients with prion disease to this facility, the admitting physician (or his/her designee) will communicate to the nurse manager of the floor and the Hospital Epidemiology & Infection Control on-call person (beeper 410-283-3855) that such a patient is being admitted. Infection Control will be responsible for calling the Customer Service Department of the laboratory regarding the patient and that area will notify all other JHH laboratories. If any surgery is to be performed, both the nurse manager and admitting physician are responsible for notifying surgical personnel PRIOR to the procedure. Subsequent calls will be made as shown in Appendix A (insert link) of this policy.
- B. All healthcare workers will observe the following precautions when caring for patients with known PAD or vPAD, GSS, or fatal familial insomnia (FFI) and when caring for those at high risk of development of prion disease. Individuals with high risk of PAD may include patients with unexplained, rapidly progressive dementias, patients who received dura mater transplants in the 1980's, and recipients of cadaveric human growth hormone injections.
 1. Follow Standard Precautions for the care of all patients, including those with known or suspected PAD or other prion diseases. Contaminated body fluids/wastes, especially those categorized as NO detectable infectivity tissues (see Table #1), pose no greater hazard than from any other patient or the healthcare worker. No special precautions are required for feeding utensils, feeding tubes, suction tubes, or bed linens. All these items go in the biohazardous trash or are washed as with any other patient.
 2. Double glove when handling low or high infectivity tissues such as CNS tissues, including brain, spinal cord, optic tissues, and cerebrospinal fluid (see Table #1). Avoid accidental parenteral inoculation and follow special procedures for decontaminating equipment in contact with CNS tissues or CSF. Disposable equipment should be used whenever possible.
 3. Healthcare workers with percutaneous or mucous membrane exposure to CNS tissues will be managed as described in the procedure for "Exposure to Bloodborne Pathogens" (HSE501, http://www.hopkinsmedicine.org/hse/manuals/safety_manual/indiv_sections/HSE501.pdf).
 4. No blood or organ may be donated from persons with prion disease or similar unexplained dementias. Furthermore, their tissues must not be used to prepare biological products to be used in humans.
 5. Label the requisitions for laboratory and pathology specimens of CNS tissues and CSF as coming from a patient with definite or suspected PAD or other prion diseases, especially because formalin fixation does NOT inactivate the causative agent. Hand-carry CSF specimens for known or high-clinical-suspicion cases to Pathology.
 6. When a patient expires with known PAD, Gerstmann-Straussler Disease, kuru, or any other disease caused by prions, HEIC personnel should notify the funeral home of the diagnosis.
 7. The nurse manager will notify the circulation nurse and scrub team when a patient with known or suspected prion disease is scheduled to undergo any invasive procedure in which there may be exposure of personnel or instruments that contain potentially infectious tissues.

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C. Dental Procedures

Although epidemiological investigation has not revealed any evidence that dental procedures lead to increased risk of iatrogenic transmission of prions 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 prions can be transmitted to healthy animals by exposing root canals and gingival abrasions to infectious brain homogenate. The general infection control practices recommended by the National Dental Association (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5217a1.htm>) are sufficient when treating prion patients during procedures not involving neurovascular tissue. Extra precautions such as those listed below should be followed for major dental procedures (see Table #2).

Table #2: Precautions for Major Dental Work

<ol style="list-style-type: none"> 1. Schedule procedures involving neurovascular tissue at end of day to permit more extensive cleaning and decontamination. 2. Consider items difficult to clean (e.g., endodontic files, broaches, and carbide and diamond burrs) as single-use disposables and discard after one use. 3. To minimize drying of tissues and body fluids on a device, keep the instrument moist until cleaned and decontaminated. . 4. Do not use flash sterilization for processing instruments or devices.
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D. Diagnostic procedures

During the earlier stages of disease, patients with prion disease 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 Table #1). A conservative approach will be taken and patients will be scheduled at the end of the day to allow more strict environmental decontamination and instrument cleaning. 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 (see Table #4 and Section III).

Bone marrow biopsies and other procedures involving tissues with no detectable infectivity (Table #1) can be carried out using Standard Precautions. Lumbar puncture and other procedures involving tissues with low infectivity should use disposable items and if non-disposable items are used they must be disinfected in the same manner as items with high infectivity (see Table #4).

E. Surgical procedures

Plan carefully not only the procedure, but also the practicalities surrounding the procedure, e.g., instrument handling, storage, cleaning, and decontamination or disposal. 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. The staff must be made aware of any such

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procedures in sufficient time to allow them to plan and to obtain suitable instruments and equipment (such as single use items), and when possible, to schedule the patient at the end of the day's operating list. Staff must adhere to protocols that identify specifics regarding pre-operative and post-operative management of the patient disposable materials, including bandages and sponges.

Basic protective measures are described in Table #3. Recommendations for decontamination of equipment and environment and for disposal of infectious waste will be followed, see Table #4. Supervisors are responsible for ensuring that the appropriate procedures are followed and that effective management systems are in place.

Table # 3: Precautions for Surgical Procedures

<p>The procedure should:</p> <ol style="list-style-type: none"> 1. Be performed in an operating room. 2. Involve the minimum required number of healthcare personnel. 3. Use SINGLE-USE personal protection equipment as follows: <ul style="list-style-type: none"> ▪ Fluid resistant operating gown, over a plastic apron ▪ Gloves ▪ Mask ▪ Visor or goggles ▪ Linens and covers. 4. Cover all non-disposable equipment. 5. Maintain one-way flow of instruments. 6. Incinerate all disposable items. 7. Mark requisition for samples with "Prion Precautions." 8. Clean all surfaces according to recommendations specified in "Decontamination Methods," Section III.

1. Handling of surgical instruments

a. General measures

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 #4, and must be decontaminated.

Instruments contaminated by CSF should be handled in the same manner as those contacting high infectivity tissues. Lumbar punctures should be performed with disposable equipment that is discarded after the procedure is completed.


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Table # 4: General Measures for Cleaning Instruments and Environment

<ol style="list-style-type: none"> 1. Instruments MUST be kept moist until cleaned and decontaminated. 2. Instruments MUST be cleaned as soon as possible after use to minimize drying of tissues, blood and /or body fluids inside the item. 3. Avoid mixing instruments used on NO detectable infectivity tissues with those used on HIGH and/or LOW infectivity tissues. 4. Recycle durable items for re-use only after prion decontamination. 5. Instruments to be cleaned in automated mechanical processors must be decontaminated by methods described below 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 waterproof material, which will then be removed and incinerated; otherwise clean and decontaminate underlying surfaces using undiluted bleach as described below. 7. Know and observe safety guidelines when working with hazardous chemicals such as sodium hypochlorite (household bleach). 8. Consult manufacturers' recommendations regarding care and maintenance of equipment. Infection Control should be consulted if there are questions.
--


Those instruments used for invasive procedures on prion patients (e.g., used on high or low infectivity tissues) should be securely contained in a robust, leak-proof container labeled "Prion Precautions." They should be transferred to the sterilization department as soon as possible after use, and treated by a method listed below, or transferred to the incinerator. A designated person who is familiar with this guideline should be responsible for the transfer and subsequent management of these materials.

2. Decontamination of Equipment and Materials

Historically, nosocomial transmission of the PAD agent or other prion-related diseases is related to contaminated tissues that are transplanted into another individual's neural system. Transmission of PAD to a noninfected person has also occurred when contaminated depth electrodes were implanted into the brain. Because the electrodes were difficult to clean, tissue became entrapped in these devices.

III. DECONTAMINATION METHODS

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, one of the following less effective methods may be preferred. Wherever possible, instruments and other materials subject to re-use should be kept moist after the times of exposure to decontamination. IF IT CAN BE DONE SAFELY, removal of adherent particles through mechanical cleaning will enhance the decontamination process.

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The following recommendations are based on the best available evidence at this time. These recommendations may require revision if new data become available.

A. Incineration

1. Destruction of surgical instruments

Items for disposal by incineration should be located in a rigid clinical waste container, labeled "Prion Precautions" and transported to the incinerator as soon as possible.

2. Anesthesia

- a. General Anesthesia

Prion diseases are not known to be transmissible by the respiratory route; however, it is prudent to treat any instruments in direct contact with mouth, pharynx, tonsils and respiratory tract by these standard methods. **DESTRUCTION BY INCINERATION OF NON RE-USABLE EQUIPMENT IS RECOMMENDED. USE DISPOSABLE LARYNGOSCOPE IF AT ALL POSSIBLE.**

- b. Local Anesthesia


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

B. Autoclave/Chemical methods for heat-resistant instruments

1. Immerse in sodium hydroxide (1N NaOH). Heat in a gravity displacement autoclave at 121°C for 30 minutes; clean; rinse in water, and subject to routine sterilization.
2. Immerse in NaOH or sodium hypochlorite (bleach) for 1 hour; transfer instruments to water; heat in a gravity displacement autoclave at 121°C for 1 hour; clean and subject to routine sterilization.
3. Immerse in NaOH or sodium hypochlorite for 1 hour; remove and rinse in water, then transfer to open pan and heat in a gravity displacement autoclave (121°C) or porous load (134°C) autoclave for 1 hour; clean and subject to routine sterilization.
4. Immerse in NaOH and boil for 10 minutes 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 hour; clean, rinse in water and subject to routine sterilization.
6. Autoclave at 134°C for 18 minutes.

C. Chemical methods for surfaces and heat sensitive instruments

1. Flood with 2N NaOH or undiluted sodium hypochlorite, let stand for 1 hour; mop up and rinse with water.

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- Where surfaces cannot tolerate NaOH or hypochlorite, thorough cleaning will remove most infectivity by dilution and some additional benefits may be derived from the use of one or another of the partially effective methods.

Complex and expensive instruments, such as intracardiac monitoring devices, fiberoptic endoscopes, and microscopes cannot be decontaminated by these harsh procedures. 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. 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.

Prion 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 #5 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 prion infectivity. Variability in 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 # 5: Ineffective or Sub-optimal Disinfectants

Chemical Disinfectants	Gaseous Disinfectants	Physical processes
<u>Ineffective</u> 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 ⁰ C) Ionizing, UV or microwave radiation
<u>Variable or partially effective</u> Chlorine dioxide Glutaraldehyde Guanidinium thiocyanate (4 M) Iodophores Sodium dichloro-isocyanurate Sodium metaperiodate Urea (6M)		<u>Variably or partially effective</u> Autoclaving at 121 ⁰ C for 15 minutes. Boiling in 3% sodium dodecyl sulfate (SDS)

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D. Notes about autoclaving chemicals

1. 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.

2. Porous load autoclaves

Air is exhausted by vacuum and replaced by steam. Porous load autoclaves are optimized for sterilization of clean instruments, gowns, drapes, toweling and other dry materials required by surgery. They are not suitable for liquid sterilization.

3. Sodium Hydroxide (NaOH)

Be familiar with and observe safety guidelines for working with NaOH. 1N NaOH is a solution of 40 g NaOH in 1 liter of water. 1N NaOH readily reacts with CO₂ in the air to form carbonates that neutralize NaOH and diminish its disinfective properties. 1N NaOH solutions do not absorb CO₂, therefore, 1N NaOH working solutions should be prepared fresh for each use, either from solid NaOH pellets, or by dilution of more concentrated NaOH stock solutions.

4. 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 is generally sold in grocery stores as a 5.25% solution of Sodium hypochlorite in the United States. Efficacy depends upon the concentration of available chlorine and should be 20,000 ppm available chlorine. One common commercial formulation is 5.25% bleach, which contains 25,000 ppm chlorine. Therefore, undiluted commercial bleach can be safely used. If solid precursors of hypochloric acid are available, then stock solution and working solutions can be prepared fresh for each use.

E. Cautions regarding hazardous materials

In all cases, hazardous materials guidelines must be consulted. Consult Health, Safety, and the Environment at 410-955-5918 for guidance before proceeding.

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.

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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 sodium 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.

SEE ALSO

Appendix A – PAD Suspected Patient Communication Tree (insert link)

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SPONSOR

- Medical Care Evaluation Committee

DEVELOPERS

- Hospital Epidemiology and Infection Control
- Department of Surgical Nursing

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COMMUNICATION & EDUCATION

This policy will be communicated 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/icpm>. Paper distributions will be made to the Functional Unit Nursing offices in the event of web access difficulty.
4. Placement of policy online at www.hopkins-HEIC.org.

REVIEW CYCLE	▪ Three (3) years	MEDICAL BOARD	Approval Date: 9/28/04 Effective Date: 11/30/04
VICE PRESIDENT FOR MEDICAL AFFAIRS			

Date:			

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Suspected/Confirmed PAD Patient is Admitted to The Johns Hopkins Hospital

The **Admitting Physician** (or his/her designee), at the point of admission of the patient **shall call**:

- ❖ **The Hospital Epidemiology and Infection Control on-call beeper (#3-3855)** to inform them that a suspected or confirmed patient has just been admitted and provide necessary information (Patient name, History #, what area the patient is being admitted to, if any surgical or invasive procedure is planned during the next 24 hours, and the physician and beeper to contact for further information about this specific patient).
- ❖ **Nurse Manager/Charge Nurse** on the floor where the patient is assigned with the same information described above.

NURSE MANAGER/CHARGE NURSE ON THE FLOOR THE PATIENT IS GOING:

- ❖ Notifies Environmental Services regarding proper disposal of hazardous waste
- ❖ Ensures that laboratory specimens are handled properly
- ❖ Notifies surgical charge personnel if invasive surgical procedure is to be done on this patient
- ❖ Investigates the procedures(s) to be done on the patient and notifies floor/surgical nursing personnel if procedures will be done involving any CNS material

OR Nurse Manager/Designee:

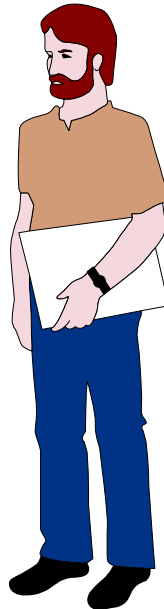
- ❖ Notifies all personnel (surgeons, anesthesiologists, nurses, pathologists and central sterilization) of appropriate regarding disinfection practices required
- ❖ Assures disposable equipment is available and used as needed

INFECTION CONTROL PERSON ON-CALL:

- ❖ Notifies the Customer Service Department of the clinical laboratory (5-2648) to activate PAD Precautions

Customer Service Representative - Clinical Laboratory

- ❖ Notifies all departments of the clinical laboratory



TO FIND THE POLICY CONTAINING ALL TECHNICAL INFORMATION REGARDING THE HANDLING OF PADs:
<http://www.hopkins-heic.org>