This policy has been adopted by UNC Medical Center for its use in infection control. It is provided to you as information only.

Status Active PolicyStat ID 9090718

IC MEDICAL

Origination 02/2004

Last 01/2021

Approved

Effective 01/2021

Last Revised 01/2021

Next Review 01/2024

Owner Sherie Goldbach

Policy Area Infection

Prevention

Applicability UNC Medical

Center

Electrophysiology Lab

I. Description

Describes the infection prevention guidelines followed in the Electrophysiology Lab.

II. Rationale

The Electrophysiology (EP) Lab provides invasive procedures such as radiofrequency ablation, pacemaker implantation, and electrophysiology studies. Invasive procedures are associated with a risk of infection. Strict adherence to these guidelines can reduce the risk of infection.

III. Policy

A. Environment

- Ventilation: 15 or greater air changes/hour will be maintained and recirculated through HEPA filters. Three air changes/hour of outside air are provided. The air pressure differential is positive between the operative suite and adjacent hallway. Doors to the EP Lab are to remain closed.
- 2. **Temperature/Humidity**: From an infection control perspective, air changes and pressure differentials need a monitoring frequency but temperature and relative humidity monitoring is not necessary so long as temperature and relative humidity are not excessive (temperature >90°F, relative humidity >80%) for longer than 48 hours.
- 3. **Vents:** Output and intake vent grills are to be inspected regularly and kept free of dust by Environmental Services and Plant Engineering. Routine change of filters is performed by Plant Engineering. Condition of filters is monitored by Plant Engineering.
- 4. **Traffic Pattern**: The EP Lab is divided into 3 zones to orient Health Care Personnel (HCP) to aseptic protocols. Refer to the Infection Prevention policy: Infection

Prevention Guidelines for the Perioperative Services; Attachment 1: Infection Control Attire in Restricted Zones.

- a. Unrestricted Zone: Defined as holding areas, the control room, and corridors outside the EP Lab. Street clothes are permitted.
- b. Restricted Zone: Defined as the Electrophysiology Lab, where surgery and electrophysiology procedures are performed. In addition to O.R. attire, a mask that fully covers the mouth and nose will be applied if a procedure is about to begin or is underway, or if sterile instruments are exposed. (Refer to the Infection Prevention policy: Infection Prevention Guidelines for the Perioperative Services, Attachment 2: Surgical Services/Operating Room -Surgical Mask Protocol. If a member of the surgical team, eye protection must be worn. Shoe covers should be worn as personal protective equipment if there is a reasonable likelihood of exposure to blood/body fluids. Hair on head and face must be fully covered to prevent shedding of hair and squamous cells. Large sideburns and ponytails must be covered or contained. Disposable bouffant and hood style covers will be provided. Bald and shaved heads must be covered to prevent shedding of squamous cells. Personally-owned cloth caps are permitted. Personal head coverings must not be worn for more than one day without laundering. Personal head coverings soiled with blood or OPIM must be discarded and must not be taken home for laundering.
- c. Exiting: When leaving the EP Lab for public areas, HCP will change scrubs if soiled. Mask, disposable bouffant cap, and shoe covers will be removed before leaving the department.

5. **Equipment**

- a. Reuse of Single Use Catheters/Equipment in EP procedures
 - i. Catheters are reprocessed in accordance with the Infection Prevention policy: Reuse of Single Use Devices (SUDs).
 - ii. Background: Diagnostic and therapeutic (radiofrequency catheter ablation) Electrophysiology Studies (EP) require the placement of multiple intracardiac catheters. These catheters have several electrodes positioned at their distal tip (see description below) which are employed in mapping of arrhythmias.
 - These intracardiac catheters are sent to a third party reprocessor. They are not reused more than 5 times. The third party reprocessor will evaluate the catheters for use and will discard if not deemed appropriate for use before the 5 uses.
 - iii. Equipment which has been used and is going to be sent for reprocessing must be marked as used and stored in a manner which will prevent the accidental reuse prior to reprocessing. The EP lab should place these items in the appropriate Biohazard closet.

- b. Equipment brought into the EP Lab for patient care from other areas of the hospital must be maintained by the appropriate department and have a current medical engineering inspection label (e.g., warming unit, anesthesia equipment). Inspection, cleaning/decontamination by the operator are required before entering and upon exiting a procedure room and after patient care. Lab equipment that cannot be sterilized must be kept visibly clean and decontaminated after use.
- c. Decontaminating Beds: If the patient is transported by surgical stretcher, linens are changed and mattress wiped with an EPA-registered disinfectant, (e.g., MetriGuard or Sani-Cloth) between patients.

6. Environmental Cleaning and Disinfection

An aseptic environment will be maintained by daily, intraoperative, interim, and terminal cleaning routines to prevent the spread of patient contamination. (Refer to the Infection Prevention policy: Infection Prevention Guidelines for Perioperative Services, Attachment 3: Environmental Cleaning and Disinfection in the Operating Room. Between cases cleaning and terminal cleaning for the EP Lab is performed by Environmental Services. The procedure table is thoroughly cleaned including mattress, pedestal, above and below arm boards, etc. The bed does not dismantle for cleaning.

- 7. **Waste Disposal** (EP Lab personnel will comply with the Infection Prevention policy: Guidelines for Disposal of Regulated Medical Waste.
 - Saline and water used in the procedure for irrigating and cleaning of instruments must be emptied into a clinical sink or hopper. PPE must be worn.
 - b. Surgical needles and small sharps are collected in needle counter containers. The needle counter container is then placed into a sharps disposal container. Surgical sharps that are too large for the needle counter container should be placed directly into the sharps disposal container.
 - c. Non-surgical needles and syringes with needles attached are disposed of in the sharps.

B. Personnel

- 1. General Information
 - EP Laboratory Services personnel include: nurses, technicians, medical care providers, and administrative staff. The surgical team is identified as the group directly responsible for delivering patient care during a surgical procedure and includes: the surgeon and assistants; the circulator (RN); the scrub nurse or tech; and the anesthesiologist/anesthesia resident or nurse anesthetist.
- 2. HCP should adhere to all personnel guidelines in the following policies:
 - a. Infection Prevention policy: <u>Infection Prevention Guidelines for Perioperative</u>
 Services:
 - i. Attachment 2 Surgical Services Operating Room Surgical Masking Protocol

- ii. Attachment 6 Guidelines for Monitoring of Sterile Items in Storage and Prior to Use
- iii. Attachment 7 UNC Health Care System Procedure Manual Selection of Draping and Gowning Material
- b. Infection Prevention policy: <u>Infection Prevention Guidelines for Adult and Pediatric Inpatient Care</u>
- c. Infection Prevention policy: Exposure Control Plan for Bloodborne Pathogens
- d. Infection Prevention policy: <u>Hand Hygiene and Use of Antiseptics for Skin Preparation</u>
- e. Infection Prevention policy: <u>Infection Control and Screening Program Occupational Health Service</u>
- f. Infection Prevention policy: <u>Tuberculosis Control Plan</u>
- g. Infection Prevention policy: Isolation Precautions
- 3. Surgical Aseptic Practices: HCP will adhere to the following policies regarding appropriate dress and standard aseptic principles and practices as described in Infection Prevention policy: Infection Prevention Guidelines for Perioperative Services, Attachment 1 Infection Control Attire in Restricted Zones and Attachment 5 Surgical Services/Operating Room Surgical Hand Antisepsis.

4. Support Personnel:

- a. Radiologist, Medical Illustrationist, Pathologist, Plant Engineers, etc., whose service is requested by the EP Lab personnel, will adhere to this policy and the Infection Prevention policy: <u>Infection Prevention Guidelines for</u> <u>Perioperative Services</u>.
- b. Anesthesia personnel will also adhere to the Infection Prevention policy: Anesthesiology.
- c. Observers: Observers, including product consultants, professors, unit nurses, student nurses, and allied health students will be permitted to visit the Electrophysiology Lab on an individual basis for a limited time. Observers will be authorized by the attending physician. Observers will comply with this Infection Prevention policy while in the EP Lab. Observers will receive an orientation to pertinent protocols, if necessary. Observers who are not UNC HCP will follow the Administrative policy: Shadow Students or Visitors. Vendors will follow the guidelines set forth in the Infection Prevention policy: Infection Control and Screening Program: Occupational Health Service.
- 5. Family members and clergy will be allowed to visit a patient pre-operatively while in the Holding Room.

C. Patient

1. **Preoperative Prep Protocol**: Post procedure device-related infections can occur due to contamination during the surgical procedure (e.g., *S. aureus*, coagulase negative

Staphylococcus). This risk may be decreased by the patient performing an antimicrobial (CHG) bath or shower the night before and/or morning of the procedure. American Heart Association guidelines include a single dose of pre-op antibiotics prior to EP lab procedures. If hair removal is necessary, the hair should be removed using clippers. Hair removal should take place in the patient's room or in the EP Lab holding room.

- 2. An OR disposable cap will be applied to contain the patient's hair and to prevent temperature loss while in surgery.
- 3. Intra-procedure: Patient care within the restricted zone will be performed by strict surgical aseptic practices and confines patient contamination to the center of the Lab where procedures are performed. Extreme care will be taken to prevent spread of patient contamination to the periphery and outside of the room. Refer to Infection Prevention policy: Anesthesiology for preoperative antibiotic administration guidelines.
 - a. A surgical skin prep of the procedure site will be performed in the assigned procedure room before the procedure, using standard aseptic technique and antiseptics. Chlorhexidine gluconate (CHG) with alcohol is the preferred agent, tincture of iodine 1% - 2%, iodophors or 70% alcohol may be used when CHG is contraindicated or if there is an allergy.
 - b. Draping of the operative site with sterile, disposable, non-woven drapes will be performed using standard *sterile* aseptic technique.
 - c. Specimens must be transported to the laboratory in a leak-proof container with a BIOHAZARD label.
 - d. Areas contaminated with blood or other potentially infectious materials(OPIM) will be cleaned immediately. Gloves should be worn; paper/ cloth towels should be used to wipe up spills. Spills of body fluids will be flooded with a 1:10 dilution of sodium hypochlorite solution or an EPAregistered disinfectant and then cleaned up.
 - e. Circulators are to wear gloves when touching contaminated items. Gloves are to be removed after use and hand hygiene performed.
 - f. At the conclusion of the procedure, the sterile team will remove gowns and gloves, deposit them in the appropriate receptacle inside the room and perform hand hygiene.

D. Surgical Instruments/Supplies

All surgical instruments and supplies used for surgery must be sterile. Refer to the Infection Prevention policy: <u>Sterilization of Reusable Patient-Care Items</u>.

1. Pre-sterilized Manufacturer Products:

Products pre-sterilized by the manufacturer before shipment should be removed from shipping cartons before being brought into the restricted zone. Supplies will be routinely rotated and restocked. Before opening a product, the package should be inspected for sterile integrity.

2. Surgical Implantable Devices:

All implantable devices will be sterile prior to insertion and are received pre-sterilized from the manufacturer. Manufacturers' recommendations should be followed for use of these devices.

3. Reusable Items:

Refer to the Infection Prevention policies: <u>Sterilization of Reusable Patient-Care Items</u> and Infection <u>Prevention Guidelines for the Perioperative Services</u> for additional details.

- a. All items sterilized in the Central Processing Department have an indefinite shelf life and can be used if the integrity of the package is not compromised, punctured, opened or have an unsealed or broken seal/lock.
- b. All items will be inspected before use.
- c. Packages with medications or materials must not be past their expiration date.

4. Sterile Field Preparation:

All surgical procedure setups will be prepared by HCP trained in aseptic principles and techniques. All sterile packages will be assessed for sterility before they are opened and dispensed to the sterile field. Sterile fields should be prepared as close as possible to the time of use. The potential for contamination increases with time because dust and other particles present in the ambient environment settle on horizontal surfaces over time. Once a sterile field is prepared, it cannot be left unattended or moved from one room to another. When there is an unanticipated delay, or during periods of increased activity, a sterile field that has been prepared and will not immediately be used may be covered with a sterile drape. The cover should be placed in a manner that allows the cover to be removed without bringing the part of the cover that falls below the sterile field above the sterile field. Once the patient enters the room, the sterile field cannot be used for another patient if the first patient's surgery is canceled.

E. Implementation

It is the responsibility of the medical director supervisor, attending electrophysiologists, and the nursing staff of the Electrophysiology Lab to implement this policy.

IV. Reference

AORN Recommended Practices for Prevention of Transmissible Infections in the Perioperative Nursing 2016.

APIC Text of Infection Control and Epidemiology. 4th Edition. Chapter 50: Cardiac Catheterization and Eletrophysiology.

Tessarolo F, Caola I, Caciagli P, Guarrera, G, Nollo G. Sterility and Microbiological Assessment of Reused Single-Use Cardiac Electrophysiology Catheters. Infect Control Hosp Epidemiol. 2006;27:1385-1392.

Avitall B, Khan M, Krum D, Jazayeri M. Repeated Use of Ablation Catheters: A Prospective Study. J Am Coll Cardiol. 1993;22:1367.

Levine GN, Bates ER, Blankenship JC, Baily SR, Bittl JA, Cercek B, Chambers CE, Ellis SG, Guyton RA, Hollenberg SM, Khot UN, Lange RA, Mauri L, Mehran R, Moussa ID, Mukherjee D, Nallamothu BK, Ting HH. 2011 ACCF/AHA/SCAI guideline for percutaneous coronary intervention: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Intervention. J AM Coll Cardiol 2011;58.

Chambers CE, Eisenhauer MD, McNicol LB, Block PC, Phillips WJ, Dehmer GJ, Heupler FA, Blankenship JC. Infection control guidelines for the cardiac catheterization laboratory. Catheter Cardiovasc Interv 2005.

Baddour LM, Epstein AE, Erickson CC, et al. Update on cardiovascular implantable electronic device infections and their management: A scientific statement from the American Heart Association. Circulation 2010: 121: 458-477

V. Related Policies

Administrative Policy: Shadow Students or Visitors

Infection Prevention Policy: Anesthesiology

Infection Prevention Policy: Exposure Control Plan for Bloodborne Pathogens

Infection Prevention Policy: Guidelines for Disposal of Regulated Medical Waste

Infection Prevention Policy: Hand Hygiene and Use of Antiseptics for Skin Preparation

Infection Prevention Policy: Infection Control and Screening Program: Occupational Health Service

Infection Prevention Policy: Infection Prevention Guidelines for Adult and Pediatric Inpatient Care

Infection Prevention Policy: Infection Prevention Guidelines for Perioperative Services

Infection Prevention Policy: Isolation Precautions

Infection Prevention Policy: Reuse of Single Use Devices (SUDs)

Infection Prevention Policy: Sterilization of Reusable Patient-Care Items

Infection Prevention Policy: Tuberculosis Control Plan

Attachments

Periop Svcs - Attmt 1 - Infection Control Attire in Restricted Zones.doc

Periop Svcs - Attmt 2 - Surgical ServicesOperating Room - Surgical Masking Protocol .doc

Periop Svcs - Attmt 3 - Environmental Cleaning and Disinfection in the Operating Room .doc

Periop Svcs - Attmt 5 - Surgical Services_Operating Room - Surgical Hand Antisepsis .doc

Periop Svcs - Attmt 6 - Guidelines for Monitoring of Sterile Items in Storage and Prior to Use .doc

<u>Periop Svcs - Attmt 7 - UNC Health Care System Procedure Manual - Selection of Draping and Gowning Material .doc</u>

Approval Signatures

Step Description	Approver	Date
Policy Stat Administrator	Kimberly Novak-Jones: Nurse Educator	01/2021
	Thomas Ivester: CMO/VP Medical Affairs	01/2021
	Emily Vavalle: Dir Epidemiology	01/2021
	Sherie Goldbach: Project Coordinator	01/2021

