

This Month

■ Patients wearing personal clothing into the OR

Key words: *patient attire, underwear.*

■ Tracking and documenting implants

Key words: *implant, implant documentation, infection prevention.*

■ Returning explants to patients

Key words: *implant, returning explanted devices.*

■ Patients wearing personal clothing into the OR

QUESTION:

The anesthesia personnel and circulating nurses at our facility disagree about patients wearing their own clothing, especially silk or satin underwear, into the OR. Those who are against the patient wearing personal clothing state there is a risk for burns associated with use of an electrical surgical unit. Can patients wear their own clothing into the OR?

ANSWER:

AORN does not have a recommendation regarding whether patients may wear their own clothing into the OR. The health care organization should specify in a policy the amount of personal clothing that the patient may wear into the OR. The reasons for and against patients wearing their own clothing should be considered during creation of

the policy and procedure. The reasons for allowing patients to wear their own clothing include personal dignity,^{1,2} decreased preoperative processing time, and decreased physical discomfort for patients related to removal of their clothing. The reasons against allowing patients to wear their own clothing include concerns of OR personnel related to a patient becoming incontinent, having difficulty accessing the patient (eg, getting to the patient's thigh to apply the electrosurgical grounding pad) when necessary, and increased risk for infection.

Historically, surgical patients were forbidden to wear silk or satin undergarments because of the potential for sparks created from static electricity. These sparks could cause a fire because of flammable anesthetic agents. This prohibition is no

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longer relevant because flammable agents are no longer used; also there are no known associations between electrosurgical unit fires and the type of undergarments worn.

The decision to allow patients to wear personal garments should be determined on an individual patient basis within the constraints of the organizational policy and procedure. A discussion between the care provider and the patient should occur before the decision is made. The discussion should include a presentation of the potential events that may occur related to the pending procedure, such as the inability to gain access to the patient, constriction resulting in alterations in blood pressure, positioning complications,³ potential for electrosurgical burns,⁴ and soiling of the patient's garments.

Examples of required access are application of an electrosurgical unit dispersive electrode or IV access. For these examples, access to the thighs and both arms would be required, respectively, assuming these are the safest or required locations. If the garment is severely restrictive, then the patient may experience hypotension when the garment is released, or the garment may create pressure areas caused by fluctuations in capillary pressure. Positioning complications may be caused by the clothing, creating a pressure area on the underside of the patient because the patient is required to lie in one position for a long period of time. The pressure area may be caused by a wrinkle in the clothing or items in a pocket. An example of this situation is when a person has a wallet in the hip pocket; the pressure would be increased between the wallet and the hip on that side. Another consideration is the potential for

electrosurgical burns if the patient's clothing contains metal and the metal is located between the active and passive electrodes of the electrosurgical unit.⁴ The final consideration is the potential for soiling the patient's garments. The soiling may be caused by skin prep agents, incontinence during the surgical procedure, or blood and other body fluids released during the procedure.

If the organization allows the patient to wear personal clothing, then it should be covered with clean linen as soon as possible before or immediately after the patient enters the OR. If the patient is transported to the OR on a stretcher, then he or she should be covered with clean linen. If the patient ambulates to the OR, then he or she should wear a robe to cover his or her own clothes.⁵ The preoperative nurse should also cover the patient's hair with a bouffant cap before the patient enters the semirestricted area.⁵ **AORN**

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References

1. Topo P, Iltanen-Tähkävuori S. Scripting patienthood with patient clothing. *Soc Sci Med*. 2010;70(11):1682-1689.
2. Edvardsson D. Balancing between being a person and being a patient—a qualitative study of wearing patient clothing. *Int J Nurs Stud*. 2009;46(1):4-11.
3. Recommended practices for positioning the patient in the perioperative practicing setting. In: *Perioperative Standards and Recommended Practices*. Denver, CO: AORN, Inc; 2012:421-444.
4. Recommended practices for electrosurgery. In: *Perioperative Standards and Recommended Practices*. Denver, CO: AORN, Inc; 2012:99-118.
5. Recommended practices for traffic patterns in the perioperative practice setting. In: *Perioperative Standards and Recommended Practices*. Denver, CO: AORN, Inc; 2012:95-98.

■ Tracking and documenting implants

QUESTION:

Our facility infection preventionist instructed perioperative personnel to add internal surgical staples (eg, gastrointestinal staples), wire used for

sternal closure, bioabsorbable dual eyelet suture, adhesion barriers, ureteral stents, breast expanders, and absorbable screws to our list of implants. She stated that this change is related to

new requirements for infection prevention follow-up. This statement leads me to ask the following questions: What is an implant? What are the requirements for tracking? What elements are required for documentation? In what area of the medical record should implants be documented?

ANSWER:

Tracking and documentation requirements are directly linked to the definition of an implant. The definition is determined by the organization that receives the tracking information. In the situation you describe, there are two organizations that receive the tracking information: the US Food and Drug Administration (FDA) and the National Healthcare Safety Network (NHSN). The NHSN is an Internet-based surveillance system managed by the Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention. The system's membership is composed of hospital, ambulatory, and other facilities.¹

The FDA has two definitions of the term *implant*; one overarching and the other specific to tracking. The overarching FDA definition of an implant is

*a device that is placed into a surgically or naturally formed cavity of the human body. A device is regarded as an implant for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner determines otherwise in order to protect human health.*²

This definition is used by the FDA for determining the process a manufacturer must follow when applying for FDA medical device clearance. The tracking-specific definition of an implant is

a device that is intended to be placed into a surgically or naturally formed cavity of the human body for more than one year to continuously assist, restore, or replace the function of an organ system or structure of the human body throughout the useful life of the device. The term does not include any device which is intended and

*used only for temporary purposes or which is intended for explantation in one year or less.*³

The NHSN requires members to track implants from an infection prevention perspective and has created an independent definition. The NHSN defines an implant as

*A nonhuman-derived object, material, or tissue that is permanently placed in a patient during an operative procedure and is not routinely manipulated for diagnostic or therapeutic purposes. Examples include: porcine or synthetic heart valves, mechanical heart, metal rods, mesh, sternal wires, screws, cements, internal staples, hemoclips, and other devices. Non-absorbable sutures are excluded because infection preventionists may not easily identify and/or differentiate the soluble nature of suture material used.*⁴

The FDA requires an implant to be tracked only if the FDA has issued an order to the manufacturer and the device meets one of the following criteria:

- device failure would be reasonably likely to have serious adverse health consequences,
- the device is intended to be implanted in the human body for more than one year, or
- the device is a life-sustaining or life-supporting device used outside a device-user facility.⁵

The FDA can issue an order to the manufacturer to start tracking any device that meets the statutory requirements or to discontinue device tracking. This decision is based on additional guidance factors and relevant information, such as the likelihood of a sudden catastrophic failure that would result in an adverse clinical outcome and therefore require prompt professional intervention. The manufacturer should notify the end-user of any decision by the FDA, because the end-user possesses the information required for tracking.³

The FDA updates the list of items that require tracking intermittently and has removed the following items that previously required tracking:

- annuloplasty rings,

- arterial stents used in coronary or peripheral arteries,
- dura mater,
- electromechanical infusion pumps,
- infusion pumps designated and labeled for use exclusively for fluids with low potential risks (eg, enteral feeding, anti-infectives),
- interarticular disk prostheses (ie, interpositional implants),
- intraocular lenses,
- penile inflatable implants,
- silicone gel-filled testicular prostheses,
- chin prostheses,
- angel chik reflux valves,
- silicone inflatable breast prostheses,
- tracheal prostheses, and
- vascular graft prostheses of any size.³

The appropriate health care organization representative should contact the manufacturer if questions arise regarding the need for an item to be tracked. The perioperative administrator should collaborate with the facility risk manager and a materials management representative to evaluate facility compliance with federal, state, and local requirements regarding implant documentation. The perioperative administrator also should be aware of updates to the FDA document titled “Medical device tracking; guidance for industry and FDA staff.”³

The FDA requirements for tracking refer to the responsibilities of both the manufacturer and the final distributor. The final distributor is the person (eg, physician) or health care organization that owns the device at the time of implantation.² If the health care industry representative delivers implants on a consignment basis, then the health care facility is still considered the final distributor. The FDA requires that the manufacturer be notified when the device was received by the final distributor and from whom the device was received, such as a third-party distributor. Frequently, the industry representative obtains the information from the patient’s medical record and

provides it to the manufacturer for the final distributor. To achieve compliance with this requirement, the final distributor must submit the following information:

- name and address of the final distributor;
- lot, batch, model, or serial number of the device or other identifier necessary to track the device;
- name, address, telephone number, and social security number (if available) of the patient receiving the device, unless the patient refuses to release the information to the manufacturer;
- date when the device was provided to the patient;
- name, mailing address, and telephone number of the prescribing physician; and
- name, mailing address, and telephone number of patient’s primary care physician.

When applicable, the final distributor also must report to the manufacturer the date that the implant was

- explanted and include the name, mailing address, and telephone number of the explanting physician;
- rendered out of use related to patient death;
- returned to the manufacturer; or
- disposed of permanently.⁶

Internal surgical staples (eg, gastrointestinal staples) and wire used for sternal closure are considered implants under the FDA general definition.² These items do not meet the FDA definition for tracking³; however, the NHSN does require tracking.⁴ The NHSN requires participating health care organizations to track patients with implants for a period of one year to determine whether an infection is present. Penrose drains, ureteral stents, urinary catheters, percutaneous endoscopic gastrostomy tubes, nasogastric tubes, and chest tubes are not considered implants by any of the definitions. Many of these devices are not totally contained within the body and most will be removed shortly after insertion. Myringotomy tubes and Kirschner wires would not be included as

implants if the plan is to remove them or, in the case of myringotomy tubes, if they are expected to work their way out of the ear canal as the tympanic membrane heals.

The FDA and the NHSN do not specify how a health care organization must maintain implant documentation. The FDA requires the final distributor to make applicable records available to the manufacturer upon written request from the manufacturer.³ These records are frequently maintained as a logbook, but, if the information is available and retrievable elsewhere, then a logbook is not required. If electronic documentation is used, then software is available to electronically generate a logbook in the form of a report. The report can be a summation of what is documented in the implant section of the surgical record or other areas where the information is documented. If a logbook has not been maintained, then personnel will have to search through every schedule and patient medical record to find the information.

Health care facility administrators should develop and implement a guideline or policy on implant documentation. This document should provide a definition of the information to be entered into each section of the record. If allowed by the policy, an item that does not meet the definition of an implant (eg, central venous catheter, percutaneous endoscopic gastrostomy tube) may be documented in the implant area of the form. The entire patient health care record may be used for obtaining the information needed for compliance with the FDA requirements for reporting information to the manufacturer. Information needed to meet the FDA requirements is frequently documented by the perioperative nurse on the intraoperative record or, if applicable, on a separate form. This information includes

- type and size of implant,
- placement and location of the implant,
- name of the manufacturer or distributor,

- lot and serial numbers, and
- expiration date as appropriate.⁶

This information is frequently unavailable to others; therefore, the perioperative nurse is responsible for documenting it.

The information needed to complete the NHSN tracking includes whatever information is necessary for the facility infection preventionist to be able to track the patient.⁴ Frequently, the information required includes the patient's demographics, a description of the implant, and the anatomical location of the implant. The infection preventionist and the perioperative documentation team should jointly determine where this information should be documented within the health care record; examples include the implant or narrative section of the perioperative nursing record, the physician's postoperative summary, or the implant documentation form. If electronic documentation is used, then this information may be available as a report that combines the necessary data points.

The FDA does not dictate the time frame for implant record retention by the final distributor but does require the manufacturer to retain the records for the useful life of each tracked device. The useful life of a device is the time a device is in use or in distribution for use.⁷ For example, a record may be retired when it becomes known that the device is no longer in use, the device has been explanted or returned to the manufacturer, or the patient has died.⁷ **AORN**

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References

1. National Healthcare Safety Network (NHSN). Centers for Disease Control and Prevention. <http://www.cdc.gov/nhsn>. Accessed October 21, 2011.
2. 21 CFR §821—Medical and device tracking requirements, Subpart A—General provisions, Section 821.3 Definitions. Revised April 1, 2011. US Department of Health and Human Services, Food and Drug Administration. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=821.3>. Accessed October 21, 2011.

3. Medical device tracking; guidance for industry and FDA staff. Issued January 25, 2010. US Department of Health and Human Services, Food and Drug Administration. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071756.htm>. Accessed October 21, 2011.
4. Surgical site infection (SSI) event. In: *NHSN Patient Safety Component Manual*. Atlanta, GA: Centers for Disease Control and Prevention; 2011. <http://www.cdc.gov/nhsn/PDFs/pscManual/9pscSSICurrent.pdf>. Accessed October 21, 2011.
5. 21 CFR §821—Medical and device tracking requirements, Subpart A—General provisions, Section 821.1 Scope. Revised April 1, 2011. US Department of Health and Human Services, Food and Drug Administration. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=821.1>. Accessed October 21, 2011.
6. 21 CFR §821—Medical and device tracking requirements, Subpart C—Additional requirements and responsibilities, Section 821.30—Tracking obligations of persons other than device manufacturers: distributor requirements. Revised April 1, 2011. US Department of Health and Human Services, Food and Drug Administration. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=821.30>. Accessed October 21, 2011.
7. 21 CFR §821—Medical and device tracking requirements, Subpart D—Records and inspections, Section 821.60—Retention of records. Revised April 1, 2011. US Department of Health and Human Services, Food and Drug Administration. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=821.60>. Accessed October 21, 2011.

■ Returning explants to patients

QUESTION:

In the past, we cleaned up explants (eg, plates, screws, joint prostheses) and returned them to the patients if requested. We stopped this process last year after one of our staff members attended a conference at which this practice was discouraged. Now we are being asked by the patients to change our policy again. What should we consider as we evaluate our policy and procedure for handling explants?

ANSWER:

Involved physicians and representatives from the perioperative, pathology, infection prevention, sterile processing, materials management, risk management, and legal departments should work collaboratively to evaluate the facility policy and procedure covering explanted devices.¹ The pathology department representative determines whether an explant is considered a specimen and can clarify the pathology department's involvement in the process for returning the explant to the patient.^{1,2} If the explant is not sent to pathology for examination and disposal or returned to the patient, then perioperative personnel should dispose of it in the regulated medical waste container (eg, red bag).

The infection prevention, perioperative, and sterile processing representatives help determine

the process for cleaning, labeling, and packaging the explant. If the explant is to be returned to the patient, then it should be thoroughly decontaminated before returning. The decontamination process may not remove all of the biohazardous material because of the structure of the implant or the presence of substances, such as bone cement, that cannot be removed by routine decontamination. A biohazardous warning label should be attached to the package before the explant is returned to the patient because of the potential for inadequate decontamination. Using a peel pack to package the item before exposing it to the sterilization process enables the patient to display the item while keeping it in the package, if that is what he or she desires. Administrative personnel should consult appropriate state agencies that regulate biohazardous waste to identify the regulations for proper packaging and handling of the explant.

A materials management representative who has knowledge of implant recalls can assist in determining a process to confirm that the explanted device does not need to be returned to the manufacturer. If the device must be returned to the manufacturer, then the organization is required by the US Food and Drug Administration to comply with this request, and the device cannot be returned to the patient.³

The risk management and legal department representatives can assist in verifying compliance with official guidelines and the necessity for specific documentation to be completed before an item is released. An example of a guideline would be the US Food and Drug Administration guideline that states

final distributors, which include hospitals that implant devices, are responsible for providing information to the manufacturer about explants. Although a hospital that explants a device that did not implant the device has no legal responsibility to inform the manufacturer, the explanting institution should notify the manufacturer identified on the device. If the manufacturer of the explanted device cannot be identified by the device itself, the institution must make a good faith attempt to discover the manufacturer's name and report the device's explantation. If the hospital cannot, then a record of the explantation and attempt to identify the manufacturer should be maintained in the hospital's tracking files.³

The risk management and legal departments also can assist in determining community standards regarding ownership of the explant. In many communities, the explant is considered the property of the patient because he or she purchased it at the time of the surgical procedure. The decision regarding who will return the explant to the patient should be a consensus decision made by the team. Some health care organizations have decided that the intraoperative nurse should return the explants; other organizations require the physician to return the explants. The decision is made based on the knowledge of the person regarding proper cleaning and proper post-discharge handling of the explant and on who has the time and opportunity to complete the task. The explant may be returned while the patient is in the hospital or after discharge.

Team members should consider documentation requirements, including who, what, when, and where. The documentation should be completed

by each person who has a role in the return of the explant. This would include

- the person who receives the request for the return of the explant,
- the preoperative or circulating nurse who confirms the request,
- staff members involved in the decontamination and sterilization process, and
- the person who returns the explant to the patient.

The information should be documented in the appropriate record for the time and place that the actions occur or on an explant form. The explant form may be similar to a chain-of-custody form. For example, the physician receives the request in the office before the surgery, documents the request on the patient's clinical record or on an explant form, and then communicates the information to the perioperative department. The form should contain patient identification, implant identification, identification of the person receiving the explant (eg, the patient or his or her representative), and any chain of custody signatures deemed necessary by the organization. A section may also be included that releases the organization from liability related to an injury that occurs to the patient or others from handling the explant. Documentation also should include the education provided to the patient or his or her representative. The education should include proper handling of the explant, associated risks, and responsibility for proper disposal. The health care organization may or may not accept responsibility for the disposal of the device after the person who receives the explant removes it from the building. **AORN**

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References

1. College of American Pathologists policy on surgical specimens to be submitted to pathology for examination. College of American Pathologists. http://www.pathology.med.umich.edu/intra/Inspection_Resources/General%20Information/

- Surgical%20Specimens%20to%20be%20Submitted%20to%20Pathology.pdf. Accessed October 21, 2011.
2. Recommended practices for the care and handling of specimens in the perioperative environment. In: *Perioperative Standards and Recommended Practices*. Denver, CO: AORN, Inc; 2012:333-340.
 3. Medical device tracking; guidance for industry and FDA staff. Issued January 25, 2010. US Department of Health and Human Services, Food and Drug Administration. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071756.htm>. Accessed October 21, 2011.

The author of this column has no declared affiliation that could be perceived as posing a potential conflict of interest in the publication of this article.

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PURPOSE/GOAL

To educate perioperative nurses about providing safe nursing care throughout the perioperative continuum.

OBJECTIVES

To what extent were the following objectives of this continuing education program achieved?

1. Discuss practices that could jeopardize safety in the perioperative area.
Low 1. 2. 3. 4. 5. High
2. Discuss common areas of concern that relate to perioperative best practices.
Low 1. 2. 3. 4. 5. High
3. Describe implementation of evidence-based practice in relation to perioperative nursing care.
Low 1. 2. 3. 4. 5. High

CONTENT

4. To what extent did this article increase your knowledge of the subject matter?
Low 1. 2. 3. 4. 5. High
5. To what extent were your individual objectives met? *Low 1. 2. 3. 4. 5. High*

6. Will you be able to use the information from this article in your work setting? *1. Yes 2. No*
7. Will you change your practice as a result of reading this article? (If yes, answer question #7A. If no, answer question #7B.)
- 7A. How will you change your practice? (*Select all that apply*)
 1. I will provide education to my team regarding why change is needed.
 2. I will work with management to change/implement a policy and procedure.
 3. I will plan an informational meeting with physicians to seek their input and acceptance of the need for change.
 4. I will implement change and evaluate the effect of the change at regular intervals until the change is incorporated as best practice.
 5. Other: _____
- 7B. If you will not change your practice as a result of reading this article, why? (*Select all that apply*)
 1. The content of the article is not relevant to my practice.
 2. I do not have enough time to teach others about the purpose of the needed change.
 3. I do not have management support to make a change.
 4. Other: _____
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