

Joint Commission

Tissue-tracking requirements: Putting all the pieces together

If you receive a recall letter from a tissue supplier, how quickly could you identify which patients received that tissue? If one of your surgeons reports an infection in a patient who received a tissue graft, how will you follow up?

Tracking of tissue is a patient safety issue—consider the well-publicized scandals and recalls of the past year or two. It's also a requirement of the Joint Commission. The standard is intricate, with many pieces to address.

OR Manager interviewed 5 managers about their tracking systems. One described a patient tracer on tissue tracking that occurred during a recent Joint Commission survey (sidebar, p 17).

The biggest challenges, say managers:

- complying with the requirement to verify that the tissue temperature is controlled en route from the supplier
- making sure all tissue is included in the tracking process—a large OR can have 100 different tissue products
- managing the many pieces of information so they are retrievable from either end of the process—condition of tissue on arrival, storage temperature, alarms, patient documentation, and monitoring for adverse events
- educating the staff and monitoring compliance with the requirements.

Verifying tissue condition

For tissue received, the Joint Commission requires hospitals to verify package integrity is met and the temperature range during transport was controlled and acceptable (PC.17.10 EP 10). Managers say this is unrealistic.

To attempt to meet the requirement, they request a letter from tissue suppliers stating that their products are always shipped so the temperature is maintained within the recommended range.

"Most of our tissue comes from the same vendor. The vendor supplied us with a letter stating that their containers had been verified to keep the tissue at a certain temperature," says Linda Rains, CST, who guided development of the tracking system at Tuomey Healthcare System, Sumter, SC. Frozen tissue is packed in dry ice. "As long as the packaging and dry ice are intact, and the package arrives overnight, we consider the package to have kept its integrity."

Temperature monitoring

Temperatures must be monitored and recorded for areas where tissue is stored, including refrigerators and freezers, with alarms to warn if temperatures are out of range. Must the temperature also be monitored in areas where tissue is stored at room temperature?

Megan Sawchuk, MT(ASCP), associate director of the Joint Commission's Standards Interpretations Group, told *OR Manager*: "For room temperature tissue storage, we require the temperature to be documented at least once a day, and there is no requirement for continuous monitoring or alarms."

The storage area temperature is checked once a day and logged at Charleston Area Medical Center (CAMC) General Hospital in Charleston, W Va.

During a Joint Commission survey in August 2006, the surveyor "didn't really

comment on the ambient air log. But she impressed on us the importance of maintaining the continuous tracking of temperature for the refrigerated and frozen products," says Cathy Dorsey, RN, BSN, CPAN, clinical management coordinator for surgical services. The surveyor also wanted to know how CAMC was meeting the standards, including the backup plan for maintaining the temperature 24 hours a day 7 days a week.

CAMC's refrigerators and freezers have continuous temperature monitoring with a visual check once a day. Temperature logs are sent to the lab administrator, who is the hospital's tissue coordinator, for review.

At Holland Hospital in Holland, Mich, the room-temperature storage area has a digital thermometer that records the current temperature as well as minimum and maximum temperatures for a 24-hour period. Each morning, the staff records the current temperature and pushes the button to record the minimum and maximum.

The director of surgical services, Kathy Shaneberger, RN, MSN, CNOR, created a spreadsheet to log tissue and record temperatures, with a tab for each element, including instructions. Tabs include:

- refrigerator temperature
- room temperature
- freezer temperature
- refrigerator and freeze-dried tissue log
- frozen tissue log.

Managers said their refrigerators and freezers have alarms wired to the plant operations department or hospital switchboard where they are monitored 24 hours a day. Their tissue policies outline action to take if an alarm goes off.

Tissue documentation

Tissue tracking is primarily a paper process for the managers we spoke with. Some have automated intraoperative documentation and can capture information on implanted tissue as part of the patient record. But they use manual logs for tissue tracking and monitoring temperatures.

Tissue-tracking software is on the market, which some are adopting (sidebar, p 17).

Tuomey uses a 3-column paper tissue-tracking form that covers the preoperative, intraoperative, and postoperative phases of care.

"We think it's important to have a system that's simple and doesn't add to OR nurses' burden," says Rains.

Jefferson Regional Medical Center in Pittsburgh, which performs 12,000 cases a year, uses a paper tracking form maintained by an OR team leader.

When a patient receives tissue, that fact is documented in the automated intraoperative record, notes Cynthia Ragan, RN, BSN, MBA, director of surgical services. All tissue is verified with the physician by the RN in the OR before being implanted. In case of a recall, the OR can run a report on all patients who received grafts of that type. Temperature logs are kept in another notebook.

Ragan cautions managers to be sure they have defined what products are covered by the standard and to be sure that all units using tissue, such as wound care, are aware of the tracking requirements. She suggests reviewing the Joint Commission's list of 72 examples in the 2007 Hospital Accreditation Standards.

"There are items like bone putty that the staff doesn't immediately think of as tissue," she comments.

Adverse event reporting

How do organizations interpret the Joint Commission's requirement to have a process for investigating adverse events related to tissue or donor infections?

Holland Hospital sent a letter to all surgeons who have implanted tissue asking them to inform the hospital if they have had an event or do in the future. Shaneberger created a form to document the response and to follow up.

Surgeons at Jefferson Regional Medical Center inform the hospital if there are adverse events, which would be referred to the risk manager. If a patient returns to the

OR with a tissue-related complication, that is documented and reported to the performance improvement department. Surgical infections are monitored by an infection control professional for both outpatient and inpatient surgery.

Staff education

Getting 100% compliance from the staff is perhaps the most challenging aspect of meeting the tissue standard, managers say.

Dorsey says education and teamwork with the central service staff are the keys to being successful. Tissue tracking is part of the staff's annual competency training at CAMC. Over the past 3 years, CAMC has developed a standardized documentation system, education, and competency validation for its 3 hospitals.

"We require all staff members who have a part in this process to take a written test that is adapted from year to year to address areas we have identified as possible problem areas as well as to demonstrate correct documentation of the tracking process," she says.

"We have had to shift the staff's thinking to document tissue the same way they would a blood product in the patient record," she says. Documentation takes close attention because tissue labels are not consistent. Some have complete information, but others do not. For the first year, tissue documentation sheets were reviewed daily.

"Now we're doing random reviews and maintaining 100% compliance," Dorsey says.

All tissue at CAMC comes through the CS department. Like the nursing staff, the CS staff must pass an annual competency to demonstrate they are assessing tissue condition on arrival, logging it, and signing it out properly. ❖

A Q&A with the Joint Commission on its tissue standard was in the June 2005 OR Manager, p 19, 20.

Joint Commission tissue standard

These are the tissue-tracking standards for hospitals. (This does not include the specific requirements under each standard.)

Standard PC.17.10

The hospital uses standardized procedures to acquire, receive, store, and issue tissues.

Standard PC.17.20

The hospital's record keeping permits bidirectional traceability of all tissues.

Standard PC.17.30

The hospital has a defined process to investigate adverse events [due] to tissue or donor infections.

A tracer on tissue

During a Joint Commission survey in August 2006 at Charleston Area Medical Center (CAMC) in Charleston, W Va, the surveyor reviewed tissue tracking as part of a patient tracer.

The surveyor "was very thorough. She wanted to know exactly how we tracked tissue from arrival to the time of implantation," says Cathy Dorsey, RN, BSN, CPAN, clinical management coordinator for surgical services at CAMC's General Hospital.

For the tracer, the surveyor requested a patient chart. When she noted the patient had received a tissue graft, she asked to review the tissue log kept in the Central Service (CS) Department.

How tissue is tracked

CAMC uses a 4-part tracking form, which is initiated by CS staff as tissue products are received. A copy is kept in CS with the tissue log. When tissue is needed for a patient, the form is attached to the tissue product, and an OR nurse verifies that the information on the form matches the product. When the tissue is implanted, the nurse attaches the patient's identification label to the remaining 3 copies of the form. One copy is returned to CS to complete the tissue log, 1 copy is used for QI, and the remaining copy is used for billing.

During the tracer, the staff showed the surveyor the log and identified the tissue used for that patient. They then showed her the tracking form.

"The surveyor was able to look at the form to see that the product was received in good condition and that the tissue's expiration date, lot number, manufacturer's name, and so forth matched the tissue log entry," Dorsey says.

In the patient record, the surveyor reviewed the implant documentation completed by the OR nurse. She verified that the OR nurse's copy of the tracking form had been completed and sent back to CS and that the patient's identification and entries in the tissue log were complete.

The surveyor also checked the temperature logs and asked what training had been provided for the CS staff who receive and log tissue.

Tissue-tracking software

ReadyTracker-Tissue

IMS (Integrated Medical Systems International)
Birmingham, Ala
Contact Whitney Ligon
whitneyligon@imsred.com
800/783-9251
www.imsred.com

ReadyTracker-Tissue (formerly ImplantMotion) is a web-based solution that helps facilities quickly comply with Joint Commission standards. It manages and tracks tissue inventory from receipt to final disposition, maintaining a history of events related to implants, patient recipients, and physicians. ReadyTracker-Tissue strengthens accountability for patient safety, alerts of inventory nearing expiration, provides pre-configured reports, and enables quick response to tissue recall.

SafeNET

Rosebud Solutions
Ann Arbor, Mich
888/980-8255
www.rosebudsolutions.com

SafeNet is a software tool for proactively managing tissue and device implants, providing:

- simplified, accurate record keeping
- improved inventory management
- Joint Commission and FDA compliance.

SafeNET manages implants through the entire process, from receipt to patient implant and disposal.

OR Manager attempted to identify the companies that offer tissue-tracking software. If any companies were not included, we apologize.
