

Joint Commission

Meeting JCAHO's new tissue standards

Last year, for the first time, rabies was diagnosed in 4 organ transplant recipients who died. The infection was traced to the donor, an Arkansas man. But there was a delay while officials tracked down who received the diseased tissue and who else might have been exposed.

In 2001, a 23-year-old Minnesota man died after receiving a knee allograft contaminated with *Clostridium sordellii*. There was a nationwide scramble as officials tried to find out who else might have received grafts from the same donor.

New tissue handling standards from the Joint Commission on Accreditation of Healthcare Organizations, effective July 1, are intended to help ensure that organizations have a well-coordinated system for managing tissues they implant. The standards cover 3 major areas:

- standardized processes for tissue handling (PC.17.10)
- traceability of tissue from source to recipients (PC.17.20)
- investigation of adverse events (PC.17.30).

The standards are new for hospitals, critical access hospitals, ambulatory care organizations, and office-based surgery and have been updated for laboratories.

Megan Sawchuk, MT(ASCP), associate director of JCAHO's Standards Interpretation Group, responded to questions about the new standards.

Q What types of tissue do these new standards cover?

Sawchuk: The standards apply to any cellular-based elements, including synthetics. Examples are bone, corneas, skin, heart valves and conduits, tendons, fascia, dura, bone marrow, veins, arteries, cartilage, sperm embryos, eggs, stem cells, cord blood, and synthetics. Regarding synthetics, the standards apply to artificially prepared nonhuman products made from coral but do not apply to synthetic tissue products derived from plastic.

Q How have these standards changed from previous versions?

Sawchuk: The standards are much more specific than in the past. Also, the new standards have been moved from the laboratory manual to the manuals for hospitals and other facilities.

Q What do the standards say about selecting a tissue supplier? Are there requirements on what to look for?

Sawchuk: Under PC.17.10, EP 2 says you must validate that tissue suppliers are registered with the US Food and Drug Administration (FDA) and licensed by state agencies, if that is required in your state. Tissue suppliers must comply with 3 FDA standards:

- "Good Tissue Practices" final in November 2004
- registration of tissue establishments
- donor screening (www.fda.gov/cber/tiss.htm).

Q What type of process do we need for tissue handling?

Sawchuk: This is covered under PC.17.10, which has 10 EPs. Essentially, there needs to be a coordinated process for ordering, receiving, storing, and issuing tissue throughout the organization. This includes verifying packaging integrity, logging the tissue in, handling it according to written directions, monitoring and

recording storage temperatures, providing for alarms and emergency backup, and complying with state and federal regulations.

Q Does JCAHO say who should oversee tissue handling?

Sawchuk: That is up to each organization to determine. You may have physicians in different specialties and locations who implant tissue. We want to see organizations develop a unified, coordinated effort that addresses the needs of these. Typically, we see someone like the OR manager having a level of responsibility, with a physician having the ultimate oversight, but that arrangement isn't specifically required.

Q What do we need to do about how tissue is transported to our facility by the vendor? Do the standards address this?

Sawchuk: Under PC.17.10, EP 10 requires verifying the package integrity and checking that temperatures during transport were controlled and acceptable. If the package comes through the normal shipping process, you can check the packaging, open the box, take the temperature, and check any indicator that may be included. If tissue is kept in the trunk of a vendor's car, that would be more dubious.

When selecting a tissue provider, one criterion should be that the tissue will be transported and delivered in an acceptable condition.

Q What kind of recordkeeping do we need for storage temperatures?

Sawchuk: Standard PC.17.10 has 3 EPs related to this:

- Maintain continuous temperature monitoring for storage refrigerators and freezers.
- Maintain daily records to show that tissues were stored at the required temperatures.
- Storage equipment has functional alarms and emergency backup.

There has been a lot of confusion about how we are going to look at temperature. If tissue is stored at room temperature, such as freeze-dried bone, you would need to record the room temperature once a day. There is no requirement for continuous monitoring or alarms for room-temperature monitoring.

If you are storing tissue in refrigerators and freezers, the temperature has to be monitored continuously but only has to be recorded once a day. Also, the continuous monitor must be linked to an alarm.

Q Please explain what is expected for alarms and emergency backups.

Sawchuk: The alarm needs to be monitored 24/7, including weekends, with a backup plan in case the power fails or the temperature is not maintained. If your organization needs help implementing this, I suggest talking to the blood bank because they have similar requirements. Often, the alarm can be set up to be monitored somewhere else in the organization if no one will be in your unit to hear it.

Q What do we need to do for tissue tracking?

Sawchuk: Essentially, under PC.17.20, you need to be able to track tissue from the moment it enters your organization until it is implanted or disposed of. You need to map out each step in the process. This includes documenting the storage and lot number of any products used to reconstitute or process tissue. Organizations must also send the tissue usage information cards back to the source facility. Important to note, records must be kept for 10 years rather than the current 5 years.

This is an exercise you can do to see if your process is adequate: Take a medical record for a patient who has had a tissue implant. See if you can trace back through your system everything that happened to that tissue, back to the donor facility. Also see if you can track the tissue in the other direction: If the donor facility notifies you of a recall, will you be able to figure out who received the tissue? This is key. In the rabies case last year, there were some traceability issues that delayed determining

who had received the tissue.

When selecting a vendor, ask what kind of tracking tools the vendor provides. The FDA's Good Tissue Practices require tissue manufacturers to have a labeling method that facilitates effective tracking. Some vendors are better than others at providing tracking and reporting systems. Seek out those who will make compliance easier.

Q How will surveyors look at tissue handling? Is this likely to come up during the tracer process?

Sawchuk: Everyone should expect surveyors to pick patients who have had tissue implanted for tracers. They will take a medical record and talk to the staff who cared for the patient, starting with admission. Eventually, they will end up in the OR, where the staff will walk them through the process. They might ask the staff, for example, "What did you do with the tissue when it arrived in your organization?" The staff member would pull out the log and say, "The tissue for this patient arrived on Jan 3. It was logged in by Margaret Jones. It was kept frozen. We record that temperature daily."

Q The third standard deals with investigation of adverse events. Is this new?

Sawchuk: This is not new. But it has been one of the most frequently cited standards in the lab manual. We are working on FAQs [frequently asked questions] to post on our web site about this. This standard is in concert with the FDA's Good Tissue Practices, which require tissue providers to report adverse events.

This needs to be a bidirectional process—that is what many organizations miss. First, you need a policy to investigate suspected problems with tissue reported to you by the donor facility, the so-called "look-back" or recall process. This includes not only hepatitis and HIV but also other infectious agents.

The other piece, which is often missing, is to have a mechanism for physicians to report back to your facility if a patient develops an infection after the surgery or has another complication related to the tissue. Your organization also needs a process to investigate this and report back to the donor facility.

There are a variety of methods to accomplish this. We don't define the mechanism, but we do want a comprehensive process in both directions. For example, some organizations send a letter to their physicians each month asking them to report any tissue complications. This information might be forwarded to the appropriate person, such as the quality assurance coordinator or infection control professional, for investigation, action, and reporting to the donor facility. There are a variety of methods to accomplish this. We don't define that. But we do want a comprehensive process in both directions. ❖

The new tissue standards were published in the February Joint Commission Perspectives. For questions, contact JCAHO's Standards Interpretations Group at 630/792-5900, option 6.

New tissue standards

These are JCAHO's 3 new tissue standards. Each has elements of performance (not included here).

Standard PC.17.10

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

Standard PC.17.20

The organization's recordkeeping permits the traceability of all tissues from the donor or source facility to all recipients or other final disposition.

Standard PC.17.30

The organization has a defined process to investigate adverse events to tissue or donor infections.