A surgeon has requested a new tissue graft not in the current inventory. From the company’s literature, it’s not easy to tell whether the tissue is similar to others already in stock.

Decisions like these are challenging because tissue grafts come with a host of safety, clinical, and cost issues.

“We are dealing with donated tissue, the same as a unit of donated blood. This is not just a medical supply,” notes Victoria Steelman, PhD, RN, CNOR, FAAN, of the School of Nursing, University of Iowa Hospitals and Clinics, Iowa City, an expert on tissue management.

A systematic approach can help ensure that surgeons have the materials they need while also making sure newly acquired tissue is safe and avoids unnecessary duplication and cost.

This article, part of a series that began in the October 2010 issue, suggests steps and criteria for selecting bone allografts. Previous articles have covered the donor screening and recovery process, types of bone allografts and their roles in healing, and tissue processing and regulation.

Critical elements in the selection process include:

• a multidisciplinary team
• physician participation
• criteria for selecting tissue suppliers and evaluating tissue.
  (Suggested criteria with questions to ask suppliers are in the sidebar, p 16.)

Know your tissue supplier

The first step is to select suppliers who adhere to strict standards for donor screening, tissue procurement, processing, and distribution.

“You want to make sure you are dealing with a supplier that is highly ethical,” Steelman emphasizes.

The reason became dramatically clear a few years ago when a ring operating in the Northeast procured tissue fraudulently, resulting in 25,000 grafts entering the market without proper donor consent or screening.

A number of patients were harmed, including a Philadelphia woman who developed sepsis after receiving a graft in a hernia repair, a man who tested positive for HIV and hepatitis C after receiving bone implants, and a Colorado woman who needed repeated anterior cruciate ligament repairs after her tendon implant failed, according to Philadelphia magazine.

A few years earlier, a 23-year-old Minnesota man died after receiving a contaminated knee graft. Investigators found 14 patients had received tainted grafts from the same tissue bank, the New England Journal of Medicine reported.
When the tissue was recalled, hospitals and surgery centers had to scramble to identify whether grafts from these donors were in their inventory or had been implanted.

The events led to more stringent requirements from the Food and Drug Administration (FDA) and the Joint Commission.

Check registration, accreditation

To know your supplier, at a minimum, make sure the supplier is registered with the FDA, says Steelman. Registration must be checked annually—“it’s not a one-time check,” she adds. Registered suppliers are posted in the FDA’s online database. (See Resources, p 17.)

Accreditation by the American Association of Tissue Banks (AATB) is also strongly recommended. It’s important to check specifically what the supplier is accredited for; Steelman advises. “Is the tissue bank accredited just for distribution or is it also accredited for processing and procurement?”

Expect the supplier to provide detailed information about its donor selection criteria, tissue testing, and tissue processing as well as evidence that these processes have been validated.

Also find out if the FDA has taken any actions against the tissue supplier. Notices of recalls are posted on the FDA website. The FDA also issues several types of regulatory action letters against tissue banks, available on its website.

Despite today’s stricter standards, one area that still may be difficult to probe is where a supplier obtains its tissue. This information is difficult to get from some suppliers, Steelman notes. If the supplier obtains its tissue from another source, it’s important to ask how the supplier ensures the tissue is safe.

Are tissues delivered appropriately?

One weak point in tissue distribution continues to be hand delivery by vendor representatives.

“The hospital or ambulatory surgery center has no way of knowing how the tissue has been stored and if the requirements for storage have been met,” Steelman points out, adding, “This practice should be prohibited.”

Your facility is accountable for making sure performed strictly aseptically, or are terminal sterilization methods used?

14. If terminal sterilization methods are used, what type is used, and what is the level of irradiation?

15. Please supply a description of your processing protocol.

16. What solutions are used in the processing of soft tissue grafts?

17. Do demineralized bone allografts that you provide possess any osteoinductive potential? Please substantiate such claims.

18. Please provide the percentage bone content and residual calcium levels in your demineralized bone products.

19. Do you have a validation process for package sterility?

• validation tests of the package’s sterility

• use of identifying numbers by which the allograft can be traced to a specific donor as well as the time, place and manner in which the allograft was recovered.

20. Do you have the ability to trace all allograft tissue to the specific donor? Please provide specifics on your tracking methods.

21. What is the shelf life of the package, during which the sterility of its contents is guaranteed?

Source: Musculoskeletal Transplant Foundation.
tissue is transported properly. The Joint Commission tissue management standards require facilities to verify that the package integrity is met and transport temperature is controlled for tissues that require a controlled environment (TS.03.01.01). FDA regulations require tissue suppliers to have conducted validation testing on their packaging methods.

Small distributors of medical devices that provide tissue need to be registered with the FDA, just like any other tissue supplier.

The selection process

In acquiring new graft materials, a well-defined process is the best way to address surgeons’ requests, ensure tissue is acquired from a safe source, and assess whether the tissue is a clinically efficacious and cost-effective addition to the OR inventory, Steelman advises.

This process is most likely to be successful if a strong medical director heads the tissue bank in your facility. The trend, she says, is to centralize tissue management in the blood bank. “There are good reasons for that,” she says. The blood bank is accustomed to the FDA tissue regulations, which were patterned after the regulations for blood.

Process steps

The process for considering new tissue materials might include:

- Criteria for tissue suppliers and tissue selection established in advance by a multidisciplinary team with input from surgeons. (Suggested questions to ask suppliers are in the sidebar.)

- A list, or formulary, of tissue materials that will be stocked in the facility, similar to a formulary for pharmaceuticals.

- A standardized process for considering surgeon requests for tissues not in the formulary. This might include a form for the surgeon to complete justifying the need for the tissue.
A surgeon may have a valid reason for requesting a graft that is not on the facility’s formulary. But having a defined process with a formulary is a good way to manage the inventory and minimize the cost while still providing surgeons with what they need, she says. Then the onus is on the surgeons to support their requests.

**Clinical efficacy**

Determining the efficacy of a tissue material is not always easy. Published evidence from the peer reviewed literature may be sparse or lacking.

In evaluating a new tissue, it helps to know the graft’s intended purpose and how is it classified. Is it osteoconductive, meaning it provides a scaffold for bone formation? Does the graft also need to provide signals to induce bone formation (osteoinductive) or have cells capable of forming bone (osteogenic)? (A chart for classifying grafts was in the November *OR Manager.*)

The American Academy of Orthopaedic Surgeons (AAOS) outlines principles for assessing the clinical burden of proof in its publication, *The Evolving Role of Bone-Graft Substitutes:*

- Consider the healing environment where the graft is needed. Environments have different levels of difficulty for forming new bone. Examples are a metaphyseal defect, a long-bone fracture, or an interbody spinal fusion.
- Seek the highest burden of proof from clinical and preclinical studies to justify the use of an osteoinductive graft material or the choice of one alternative over another.
- Recognize that there is no standardized burden of proof for materials such as demineralized cortical powder or platelet gels with autologous growth factors. These are regulated by the FDA as tissues rather than as medical devices because they involve “minimal manipulation” of tissue.

“As a result,” says AAOS, “there is no standardized level of proof of safety and effectiveness required before these products are marketed and are used in patients.”

There are no easy answers to managing the complex area of tissue grafts. But having a systematic process with strong multidisciplinary involvement and support is a step in the right direction. ✤

—Pat Patterson

This series is a collaboration between *OR Manager* and the Musculoskeletal Transplant Foundation.

**References**
