

Managing biologics

A unified program to manage biologics

Fifth and final article in a series on managing bone allografts.

A unified program for managing biologics, including tissues and blood, has helped a Massachusetts hospital to meet regulatory requirements, track adverse events, and have a consistent process for bringing new tissues into the organization.

The 2½-year-old Biovigilance Program at Baystate Medical Center in Springfield was created to help meet the expanding requirements of the Joint Commission, the Food and Drug Administration (FDA), and other accrediting and regulatory bodies. Previously, responsibilities for tracking, compliance, and infection control for biologics were split among several departments.

The Biovigilance Program integrates these functions with oversight from the medical directors of transfusion medicine services and of the operating rooms. The program is managed by Theresa Stec, BA, MT (ASCP), who was previously the quality improvement coordinator for transfusion services. She reports clinically to both medical directors and administratively to the director of surgery and anesthesia. Baystate has 18 inpatient ORs, 12 outpatient ORs, and 4 ORs in an off-campus orthopedic facility.

Qualifying tissue suppliers

Baystate's process for acquiring new tissue includes credentialing for suppliers. Tissue suppliers are asked to complete a form. The credentialing information is then entered into the hospital's tissue-tracking software.

"I definitely want to make sure [suppliers] are FDA registered and have a way for tracking tissue," says Stec. Under federal regulations, all establishments that provide human cells, tissue, and cellular- and tissue-based products must register with the FDA. An annual update is required in December.

If the tissue is classified as a medical device, she verifies that it has received FDA 510(k) clearance.

As part of credentialing, the supplier is also asked to provide the package insert and manufacturers' instructions. Stec checks for the supplier's accreditation and for a written quality plan and a recall process. Suppliers are expected to indicate if they have issued customer notifications or recalls. They are asked to supply tissue delivery information, including the shipping method, storage requirements, and standard and emergency delivery times.

Documents are kept in individual supplier files, which also include any supplier issues, complaints, and pricing information.



Value analysis

New biological materials that surgeons want to use, such as a new demineralized bone matrix (DBM), are subject to the hospital's value analysis process. Surgeons who want to use a new material inform the RN service coordinator for their specialty, who submits a request form and related information to the value analysis team (VAT). The request is placed on the VAT's agenda, and the surgeon is asked to attend the meeting and make a presentation.

The VAT then conducts a review, including a cost analysis that considers both direct and indirect costs. For example, a new tissue may cost more than a current material but save OR time because it doesn't have to be mixed. Or the new tissue may be able to be stored at room temperature, while the current one requires refrigeration. A trial of the proposed tissue is then conducted, results are reviewed by the VAT, and the request is granted or denied.

When a request for a new biologic comes in to the purchasing department, the purchasing agent communicates with Stec so the supplier's qualification can be completed before the item is placed on the VAT agenda.

Though some biological materials still find their way into the OR without value analysis, she says the process has helped to better manage the tissue acquisition process.

Tissue tracking

Baystate recently introduced its tissue-tracking software, Tissue TrackCore (TTC) from LPIT Solutions, as part of the Biovigilance Program. Stec has guided the implementation, including training for the clinical staff. Tissue-tracking software is a major boon in meeting FDA and Joint Commission requirements, which stipulate that tissue must be traceable from the donor to the patient and vice versa.

When a new biological material is received, the staff enters prereceiving information, which verifies that the shipping container is intact and conditions were acceptable as well as the date and time of receipt.

When tissues are received in the clinical area, each item in the shipment is inspected for package integrity, expiration date, and temperature range. If these are acceptable, additional tracking information is entered. Each item is assigned a unique identifier in TTC. An item-specific barcode label with that TTC number, item description, and information is printed and applied to each item. Lot numbers aren't sufficient to identify biological materials, Stec notes, because multiple items can have the same lot number and/or serial number.

Which materials are included?

Stec works with the OR staff to determine which materials need to be included in tissue tracking. She interprets the FDA rules as requiring that all tissues need to be tracked, including human tissue as well as tissue from bovine, porcine, or other biologic sources.

"The FDA is concerned about any biological product that goes into a human patient and the ability to trace it in case of an adverse event," Stec says.

The Joint Commission's Transplant Safety chapter covers "human and non-human cellular- and tissue-based transplantable or implantable products," whether classified by the FDA as a tissue or a medical device. The standards

also apply to products classified by the state as a tissue even if that falls outside the scope of the Joint Commission definition. Collagen and tissue products derived from plastics and polymers are not considered cellular-based products and thus are not covered by the standards, the standards state.

“I’ve instructed the nurses that if it’s a synthetic, we don’t need to enter it into Tissue TrackCore. But if it’s a collagen from a bovine source or a matrix, we do include it. We are tracking more than other places are tracking,” she notes.

Scanning tissue in the OR

Barcode scanners are available in the ORs. When tissue is used for a patient, the circulating nurse scans the barcode label to associate the unique TTC ID with the product in the tracking system. The scanners capture the data easily and help avoid data entry errors.

Having a coordinated process has brought the best of both the blood bank and the ORs together for tissue safety.

Stec’s most important advice—“Don’t live in silos. There are other experts in the hospital who can help you with this.” ❖

—Pat Patterson

Registered tissue establishments are posted on the FDA website at www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/TissueEstablishmentRegistration/FindaTissueEstablishment/ucm110270.htm

Reference

Stec T C, Fuller D A, Albert M, et al. Development of a hospital biovigilance program integrating surgical services and transfusion medicine services. Abstract AP167. *Transfusion*. 2009;49 (Suppl):305A.