New requirement, updates in transfusion checklist

Anne Ford

September 2017—Like an old friend with a new facelift, or a high-mileage car with a thorough tune-up, the 2017 edition of the CAP transfusion medicine checklist has undergone a significant number of small changes—none of which is startling in itself, but all of which combine to produce a fresh and streamlined effect. More than 90 of the checklist's requirements have been revised, many in the name of alignment with FDA requirements.

"A lot of this work consisted of reorganizing, clarifying, tightening, editing," says Checklists Committee member Katharine Appleton Downes, MD, who is director of coagulation laboratories and medical director of transfusion medicine/blood bank, University Hospitals Cleveland Medical Center, and associate professor of pathology, Case Western Reserve University School of Medicine.

That's because, says Yara Park, MD, "we had not done a thorough review of the checklist in over five years. This year we took on reviewing the entirety of the list. There are so many changes this year, not because of any big change in the world, but because we felt like we needed to do a very thorough investigation and look at every single checklist item." Dr. Park, chair of the CAP Transfusion Medicine Resource Committee, is associate professor in the Department of Pathology and Laboratory Medicine and director of transfusion medicine services and hematopoietic progenitor stem cell laboratories, University of North Carolina School of Medicine.

Dr. Park

That said, there is at least one new requirement, TRM.42060, which compels transfusion services to track the incidence of transfusion reactions and monitor the rate of transfusion reactions by each diagnostic reaction—febrile, hemolytic, TRALI, and so forth. Drs. Park and Downes perceive the potential effect of this new requirement slightly differently.

"Most laboratories have been doing this and reporting it to their institutional transfusion committees, but it wasn't in the checklist that you had to record it this way," Dr. Park says. "So we decided to add what people are actually doing, and to make the checklist compliant with the FDA."

Dr. Downes suspects it may be a new practice for some laboratories. "I think places may have monitored their transfusion reactions, but perhaps not in a way that included the incidence of the reactions, as well as really looking at the diagnostic reaction type. I think it may be a change for some laboratories to start thinking about transfusion reactions in this manner."

As for the existing TRM.32250 requirement for record retention, "There is a change, but it isn't very sexy," Dr. Park says. "But it's probably good for laboratories." She's referring to the added requirement that competency records be kept for five years and that temperature monitoring graphs and logs of all refrigerated equipment and platelet incubators be kept for 10 years. The change, she says, was made to align the CAP's requirements with those of the American Association of Blood Banks. "Sometimes we don't always match up, and we want to make it easier on checklist users. It's nice when you don't have to try to figure out which entity you're going to try to keep up with," Dr. Park says.

A change to TRM.42285, which is now titled "Therapeutic Phlebotomy Units for Transfusion," relieves laboratories

of the need to obtain a variance from the FDA in order to use blood collected from therapeutic phlebotomies for transfusion.

“As of May 22, 2015, the final rule from the FDA eliminated this requirement. So we’ve deleted it too,” Dr. Park explains. “I feel okay with it because [for laboratories] to use that blood, they [donors] still have to meet all of the qualifications for being an allogeneic blood donor. Patients who have to have phlebotomies for a therapeutic reason, usually hereditary hemochromatosis, are often upset when we throw their blood away, and we did have to throw their blood away, if you didn’t have this variance. Patients know there’s a big need for blood out there, and they want to help. Doing this allows their blood to be used because there’s nothing unsafe about it.” Some patients who have therapeutic phlebotomies wouldn’t meet the criteria for allogeneic donations, she adds, and those patients’ units would still be discarded.

Previously titled simply “Expiration Dates,” TRM.42480 now bears the more exacting name “Blood Components Storage Requirements and Expiration Dates.” But that’s not this checklist requirement’s biggest change. Whereas the previous version of it specified exactly how blood products were to be stored, the current version now states only: “The expiration dates and storage requirements of all blood components comply with the most recent edition of the Circular of Information and the manufacturer’s recommendations. For laboratories not subject to US regulations, expiration dates conform to national and local laws and regulations for all approved component storage systems in use.”

“This was done to streamline the checklist,” Dr. Downes explains. “Laboratories are referred to the Circular of Information, which will have the most up-to-date and the most comprehensive information.” The change will require laboratories to have the most recent copy of the circular on hand—a useful thing during inspections, should the inspector start asking questions such as, “How are you storing your products? What is this based on? Oh, on the circular? Well, where is the circular?”

Skin preparation for blood donors is the subject of the slightly revised TRM.45267. “We added that they have to use an FDA-approved method for skin disinfection prior to phlebotomy,” Dr. Park says. “Before it said, ‘A written procedure requiring the use of sterile prepackaged material is followed,’ but we’ve now made the point that it should be FDA approved. Although there’s lots of ways of doing it, because we’re manufacturing a product from this we should be following the FDA guidelines on what is approved for skin disinfection prior to a phlebotomy for blood donation, because if the skin is not completely cleaned you increase the risk for bacterial contamination of that product.”

More specifics have been added to TRM.41300, the name of which has been changed from “Bedside Identification” to “Donor and Recipient Information Verification.”

“Previously, it was more limited in terms of what was included,” Dr. Downes says. Rather than stating, as it did before, “The recipient is always identified conclusively with two patient identifiers by either two persons (e.g. by checking the wristband for name and hospital number), or using bedside patient identification technology,” the requirement now says donor and recipient information is verified immediately before transfusion in the presence of the recipient and includes several identifiers, such as intended recipient’s blood type, donor unit identification number and donor blood type, and others.

Along similar lines, TRM.41350, “Compatibility Label/Tag,” now stipulates that before issuance, a label or tag including the following information is securely attached to each blood or component unit and remains attached until the transfusion is complete: identification of the recipient with two patient identifiers, a blood or blood component unit identifier, recipient and donor blood types, interpretation of crossmatch tests (where applicable), donor unit expiration date and time (as applicable), and special transfusion requirements (if warranted).

TRM.40670, now titled “ABO Group and Rh(D) Type Verification,” has also been clarified. Not only has “Group and Rh(D) Type” been added to the name, but the requirement’s note now says that for laboratories that employ computer crossmatching, serologic crossmatch techniques must be used when ABO typing discrepancies are present (such as mixed field reactivity, missing serum reactivity, or apparent change in blood type post-

hematopoietic stem cell transplant). “This was added for patient safety,” Dr. Downes says.

For allogeneic blood donations, TRM.45256 now contains an updated minimum age requirement, one that now aligns with FDA guidelines, which stipulate that in the United States, these donors must be at least 16 years old or of an age that conforms to applicable state laws. “It’s nice that we can do this, because most 16-year-olds are adult size and can safely donate as long as they meet all the requirements,” says Dr. Park. “By using younger donors, it opens up the donor pool, obviously, and we try to get donors in the habit of donating younger, so we can make more lifelong donors.”

Dr. Downes

Informed consent for donation is the subject of TRM.45263, which now contains a bulleted list of exactly what is expected, per FDA guidelines. Namely, the donor must: review the required educational material about relevant transfusion-transmitted diseases; agree not to donate if the donation could result in a potential risk to recipients as defined in the educational material; be informed that a sample of their blood will be tested for relevant transfusion-transmitted diseases; be informed that if the donation is determined to be unsuitable or if the donor is deferred, the record will identify the donor as ineligible and the donor will be notified of the basis for and period of deferral; be provided with information about the risks and hazards of the specific donation procedure; and be given the opportunity to ask questions and withdraw from the donation procedure. Nothing too surprising, but, says Dr. Downes, “This is a concise summary for laboratories, and it’s useful to put it in here as part of the checklist.”

Regarding directed donors, the checklist has become more specific about how often units must be collected from them. This pertains to TRM.47100, “Infectious Disease Testing,” which now says: “For laboratories subject to U.S. regulations, all FDA-required or recommended infectious disease tests are performed on blood samples collected at the time of donation, or collected at least once in the prior 30 days for a directed donor for a single intended recipient. Reagents used are licensed or registered by the FDA and procedures are approved by the FDA.”

The checklist item also now spells out the tests currently required by the FDA, such as for HIV-1, HCV, and the West Nile and Zika viruses. It also now contains an additional note stipulating that autologous donations for the patient-donor’s own use are not required to be tested for infectious disease markers unless the units could be used for allogeneic transfusion or will be transferred to another establishment.

Checklist requirement TRM.42460, “Blood and Blood Component Shipping,” now includes a note to reiterate what was added in 2016: Laboratories must validate containers—portable coolers, for example—to ensure they maintain the appropriate shipping temperature. “Some labs may not have thought of portable coolers as needing to be validated,” Dr. Downes says, “and we want to make sure they understand the importance of validating such items.”

Laboratories that use microwave ovens to quickly thaw plasma or cryoprecipitate are likely to be relieved by a change to TRM.44450, “Plasma and Cryoprecipitate Thawing.” The requirement no longer contains the directive that such ovens be FDA cleared/approved as class III medical devices. That’s because the FDA never provided an effective date for that requirement. The microwave ovens these laboratories use are generally class II devices, and class III microwaves seem to be difficult to locate. The checklist requirement now contains a note saying that if a microwave oven is used, any manufacturer’s claim that the temperature of the contents does not exceed 37°C must be verified by the laboratory. In the absence of such claim, the laboratory must validate the device’s preservation of labile coagulation factors.

Finally, non-U.S. laboratories may be interested in a new clarification that appears in TRM.43950, which pertains to red blood cell freezing method. “There’s been a clarifier placed there for labs outside the United States, letting them know to refer to the applicable accreditation requirements or national or local laws and regulations,” says Dr. Downes. The same stipulation has been added to TRM.45251, which addresses the subject of regulatory documents.
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