What’s new in latest transfusion medicine checklist

Valerie Neff Newitt

September 2020—Strong quality management, patient safety, and conformity with regulations are at the heart of the new and revised requirements in the 2020 CAP accreditation program transfusion medicine checklist, released in June.

“Our biggest focus this year was the strengthening of our cellular therapy checklist requirements,” says Yara A. Park, MD, advisor to and former chair of the CAP Transfusion, Apheresis, and Cellular Therapy (TACT) Committee and associate professor of pathology and laboratory medicine, University of North Carolina School of Medicine. “Other important revisions reflect changes in the transfusion medicine industry itself, such as the use of low-titer group O whole blood, pathogen reduction, and *Babesia* testing.”

Dr. Ramsey

Glenn E. Ramsey, MD, TACT Committee chair and professor of pathology at Northwestern Medicine’s Feinberg School of Medicine, says, “Sometimes it was because the standards and the customary procedures have evolved, sometimes it was a new requirement from a regulatory body, and sometimes it was a matter of strengthening and improving what we already had.” The changes followed an extensive review process, he says, “and consultations with our labs, inspectors, and within the committee itself.”

The section of the checklist devoted to hematopoietic progenitor cells contains four new requirements. “We already had checklist requirements related to cellular therapy,” Dr. Park says, “but we wanted to beef it up, strengthen it, so we added four new requirements. Three of them align with the Foundation for the Accreditation of Cellular Therapy [FACT] standards.”

TRM.48060 “Pre-Collection Testing” requires labs to perform a complete blood count, including a platelet count, from each cellular therapy donor no more than 24 hours before collection.

“This one has a focus on donor safety. It makes sure that it is safe for a donor to be put on a machine and have their cells removed by apheresis for this collection,” Dr. Park says. And it does so immediately before the collection instead of days earlier, Dr. Ramsey points out. In prior checklist editions, the CAP did not specify a time frame for this testing.

TRM.48070 “Assessment of Cellular Product” says laboratories must have a process for assessing the quality of each cellular therapy product collected, to confirm its safety, viability, and integrity. A written process for assessing the product and records of cellular product assessment meeting predetermined specifications are the evidence of compliance.

“This is something we hadn’t had before in the cellular product section, although it was in the component preparation, storage, and modification section,” Dr. Ramsey says. “We wanted to make sure that facilities that were not necessarily collecting blood also were aware of this. Now it is required for inspectors to check.” The requirement is generally worded; it’s up to each lab to decide how to do the assessments. “But they must have a written process and maintain records of the assessments,” he says.

TRM.48090 “Donor Eligibility Status—Allogeneic Donors” says the collection facility must provide to the processing

facility records of each allogeneic cellular donor's eligibility, and the record must accompany the product at all times. Evidence of compliance requires a policy for the communication of donor eligibility and records of cellular therapy donor eligibility status. Says Dr. Ramsey: "This requires that whoever collects the product provides records to the processing facility. It is an important distinction because regular blood products usually don't get sent from one lab to another in the same way that cellular products do. This makes sure everybody is aware the donor was eligible."

The requirement ensures the donor is free of risk factors for transfusion-transmitted infections, Dr. Park notes. "And because eligibility records must accompany the product at all times," she says, "the processing facility can correctly label the product before it distributes it to the recipient. The eligibility records will accompany the product through all steps of the product's life."

TRM.60710 "Adequate Space—Cellular Therapy Products" requires that the cellular therapy area have adequate space for collection; storage of equipment, supplies, and reagents; additional emergency personnel when needed; and "minimization of the risk of airborne microbial contamination, mix-ups, and cross-contamination of products."

Dr. Park

That means, Dr. Park says, it must make sure that each donor has his or her own space and processes are in place to prevent mix-ups. "This helps avoid taking a product from one donor and putting it in the transport cooler for another donor."

In the laboratory general checklist are space requirements that apply to all laboratories. "But we realized," Dr. Ramsey says, "there are probably facilities that are only handling cell therapy products, so we made sure they have this space stipulation as well, and that inspectors review the adequacy of space."

It has been a goal of the CAP committee to strengthen the cellular therapy portion of the transfusion medicine checklist, he says. "And I think these are nice yet simple ways to increase the safety for our donors and the quality of our products." The TACT Committee will update this section further for the 2021 edition.

The TRM.40700 "Selection of Blood Components" requirement was revised to say that the selection procedure must be a written one and include, now for the first time, low-titer group O whole blood in addition to ABO group-specific whole blood and components. The requirement says if transfusion of low-titer group O whole blood occurs, the procedure must describe the definition of "low-titer" group O whole blood as mutually agreed upon by the transfusion service and the blood supplier and the indications for the use of these units.

"This was a big one for me," Dr. Park says. "The transfusion community used to use whole blood decades ago, then we moved to component therapy where we'd get a red blood cell or a platelet or plasma. In the past decade we've moved back toward the use of whole blood for massively bleeding patients, the idea being if someone is massively bleeding out whole blood, why give them all these components that have additional preservatives in them, and additive solutions that are just adding volume but not blood? If they're bleeding whole blood, why not give them whole blood? It's a hot topic in transfusion medicine, and people have strong feelings one way or the other." Trauma surgeons, she says, usually favor whole blood. "They don't want the burden of balancing the components."

"This checklist requirement used to say that you had to give ABO group-specific whole blood, or ABO group-specific or compatible red-cell–containing components. That meant if a patient were group A, we would have to get group A whole blood. We always think of O as the universal donor, but group O donors have antibodies to A and B red blood cells in their plasma, so that can be dangerous to non-group O recipients. However, we often do not know trauma

patients' blood types. So there has been a move to use group O whole blood and to require it be low titer, meaning a low level of antibodies to the A and B red blood cells so that it could be a more universal blood product." Now that option has been added, permitting the use of low-titer group O whole blood providing that the transfusion service and the blood center have come to an agreement as to what low titer means.

This is a requirement about selecting which products go to which patients, Dr. Ramsey says. "So for facilities that are using group O whole blood, we are asking them to have criteria on what they mean by low titer and indications for using those units in particular." No uniform titer has been identified, nor has a universally accepted titer cutoff been established. "Whoever is supplying the blood has to define what the titer is, and then the transfusion service has to be in agreement and say, 'Yes, we accept that titer as being a low titer.'"

Similarly, TRM.40720 "Provisions for Special Components" now includes transfusion of low-titer group O whole blood, including the maximum volume/units allowed per event, as one of four listed items for which the laboratory must have written procedures for the provision of appropriate components.

"Some patients have specific antibodies, risk factors, so they need special products. Some places want to limit the numbers of units of low-titer group O whole blood they give per patient because they perceive it as a special product," Dr. Ramsey says. "So it's listed here to be sure a lab has a written procedure for how many units they're giving to a patient."

Other changes to the 2020 checklist are as follows:
• TRM.45270 "Directed Donation Requirements" says laboratories must have a written procedure to ensure that directed donations between blood relatives are irradiated or treated by a method approved by the FDA to prevent transfusion-associated graft-versus-host disease.

"This is important," Dr. Park says, explaining it's not about the directed donation but about using a method to prevent graft-versus-host disease. "In years past the only way to do that was by irradiating the products. But now there is a process called pathogen reduction or pathogen inactivation, which also treats the white cells in a way to prevent transfusion-associated graft-versus-host disease. So if laboratories are using directed donations from a family member, they now have the option to irradiate the product or use pathogen reduction technology for a platelet product. They have a choice. It's a nice addition."

The group took into account that FDA-approved pathogen reduction methods that inactivate viruses and bacteria also inactivate the donor's white cells. "When that is being done," Dr. Ramsey says, "the product does not need to be irradiated. So that may cut out a step."

• TRM.47100 "Infectious Disease Testing" says that for labs subject to U.S. regulations, all FDA-required or -recommended infectious disease tests must be performed on blood samples collected at the time of donation, or at least once in the prior 30 days for a directed donor for a single intended recipient. A note listing the required or recommended tests has been revised to include testing for *Babesia* species in some states.

"With this addition, the CAP is catching up to where the industry is and where the FDA is," Dr. Park says. "The FDA now requires certain states that have *Babesia* to do *Babesia* testing, and those states use nucleic acid testing of donors for *Babesia*. So we changed our requirement to say that nucleic acid testing for *Babesia* species may be required in selected states by the FDA."

Also added is this: "In certain instances, the FDA may approve pathogen reduction methods as an alternative to testing." Says Dr. Ramsey, "In some cases the FDA is now accepting pathogen reduction in lieu of the testing, and it is important to clarify that."

• TRM.50150 "Training and Competency for Critical Tasks" is a new requirement that says transfusion service personnel responsible for performing critical tasks must be trained and then assessed at least annually. A critical task is defined as any non-testing function performed in the transfusion service that can affect patient safety or the quality of the service performed, such as issuing blood components or modifying or manufacturing a blood product.

“This was designed to focus on non-testing issues,” Dr. Ramsey says. “It arose from concern that the laboratory testing requirements might not be covering these areas as well as they should. We have a lot of compliance requirements for testing issues, and we cover those thoroughly. But there are other concerns that are important with regard to patient safety that also need to be addressed. This was created to cover these other areas where it’s not specifically a test but yet it’s important to the patient.”

Laboratories can decide what these non-testing critical tasks are, how competency is assessed, and who will assess that competency, Dr. Park says. “This is recognition of how important it is that we assess competency for the entirety of the transfusion medicine service. Unlike a lot of other laboratories, we in the transfusion medicine service are not only performing testing but also providing a product. When we modify, issue, or label a blood product, we must do it correctly. It is critical.”

• TRM.45254 “Training and Competency for Donor Collection Personnel” has been revised to say that personnel responsible for the donor selection process, pre-donation examination, and phlebotomy must now be assessed for competency at least annually. Previously it required only that they be trained, qualified, and competent.

“For personnel who are not performing a test function per se,” Dr. Ramsey says, “we want to make sure they are properly screening donors and collecting the blood. And we are requiring they be assessed for competency at least once a year.”

• TRM.42750 “Storage Unit Alarms” says all component storage units must be equipped with a monitored alarm system, with alarm checks performed according to the manufacturer’s recommended interval, or at least quarterly if the manufacturer has not specified the intervals. Results must be recorded. The temperature at which the alarm sounds must be compared to the temperature on the recording chart/log. The requirement now lists four examples of recording systems: paper chart records, paper graphs, electronic records, and event logs.

“At one time back in the day,” Dr. Park says, “a lot of places used paper charts and drew on it to record temperature for refrigerators and freezers and such. But now most places have moved to an electronic system. It wasn’t clear in our guidelines and our checklist requirements that it was okay to use an electronic system. So by adding this additional wording to the checklist, we’re saying it is fine to use an electronic recording method as well.”

• TRM.43605 “Component Labeling—Final Inspection” is a new checklist requirement that says the final inspection of the component labeling process must include verification that all information on the label is correct. This verification must be done, it says, by one appropriately trained member of the transfusion service using a validated process, such as an electronic system capable of preventing the release of mislabeled components, or two appropriately trained members of the transfusion service.

“This explains that one person using a validated process, i.e. the computer, can do this validation, or two members of the transfusion service checking each other can do it. It’s giving an option to do it either way,” Dr. Ramsey says. The requirement was added to comply with an FDA requirement.

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