# Transfusion medicine checklist: Record and other requirements updated in new release

## Amy Carpenter Aquino

August 2018—One new requirement and several modified requirements in the CAP transfusion medicine checklist are part of the new edition of CAP accreditation program checklists released this month.

In work led by the CAP Council on Accreditation, the checklists are examined anew and revised yearly, where needed. In transfusion medicine, the changes this year center on computer crossmatches, record retention, forward/reverse typing, and ABO group and Rh(D) type verification.

The 2018 updates address questions that laboratories have had about some requirements since the 2017 transfusion medicine checklist revision, says CAP Checklists Committee member Manish J. Gandhi, MD. "In this version those important items were clarified," says Dr. Gandhi, a consultant in Mayo Clinic's Division of Transfusion Medicine and associate director of the component processing and product testing laboratory and director of the histocompatibility laboratory.

Dr. Gandhi

The recent changes make the transfusion medicine checklist an "even better, stronger list," says Yara Park, MD, chair of the CAP Transfusion Medicine Committee, who with other committee members reviewed every requirement and reference for the 2017 checklist revision. The 2018 changes now provide more detail on some of those revisions and better direction in other areas where there were questions, says Dr. Park, 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.

The new computer crossmatch requirement, TRM.40665, will serve as an introduction to the checklist's computer crossmatch section.

"When we were trying to fix all the things that mention computer crossmatch, we felt like we were missing an overarching checklist [requirement] to say, 'This is what a computer crossmatch is and this is who can have it,'" Dr. Park says.

Dr. Park

The FDA allows computer crossmatches in place of serologic methods, Dr. Gandhi says, "if you have enough checks and balances where the patient sample has been screened for preformed antibodies—not ABO but other antibodies—and it's found

to be negative, and if you're sure about the patient's type."

The new requirement calls for written procedures for computer crossmatch methods based on validated decision rules for verifying donor and recipient compatibility. The requirement says a computer crossmatch may not be used if the patient has a current or past history of clinically significant alloantibodies or if there are unexplained typing discrepancies on the current sample. This clarification of when a computer crossmatch is acceptable "keeps everyone"—CAP members and inspectors—"on the same page," Dr. Gandhi says.

New additions to the record retention requirement, TRM.32250, further align the CAP's requirements for blood banks with those of other accrediting organizations. "Since CAP has deemed status with other regulatory agencies, we needed to make sure our checklist requirements met all the other requirements, at a minimum," Dr. Gandhi says, who notes the updated TRM.32250 requirement is "more inclusive."

Added to the list of donor records that must be retained for 10 years is documentation of the acceptability of returned units into inventory. Under patient records, a new 10-year requirement is documentation of the evaluation of delayed transfusion reactions. New retention requirements also include, among several others, records of the identification of individuals who performed each significant step in collection, processing, compatibility testing, and transportation; container qualification/process validations; the final inspection and verification of blood before issue; and blood supplier agreements.

The change to the historical record requirement, TRM.40300, makes it acceptable for blood banks to use a validated computer system capable of performing historical checks to compare ABO, Rh, and antibody screen test results against results of the same tests recorded previously. The alternative is a manual check performed by qualified personnel.

"Most blood banks now use a pretty sophisticated computer system of some sort that can do that logic and that check for us," Dr. Park says. "We have added it to make it an acceptable practice. It is a nice change for blood banks because it removes a manual step that they had to somehow, somewhere document on paper."

Dr. Park predicts blood banks will welcome this time saver. "Although it looks like a minor change, I think it will be very much appreciated."

Also clarified in the 2018 checklist is that the use of molecular-based screening assays alone for ABO and Rh(D) blood type assignment is unacceptable for transfusion or transplantation. "We still do not know completely everything about ABO and Rh molecular typing," Dr. Gandhi says, which is why TRM.40550, "Forward/Reverse Typing," now says an FDA-cleared or -approved serological method must be used. ABO/Rh typing for transplant or transfusion has to be done "by an FDA-approved method, and right now that's only serology," Dr. Gandhi says.

"We use molecular-based testing for a lot of blood bank phenotyping now," Dr. Park says, "but it is not acceptable and it's just not the right testing and methodology for ABO and Rh." ABO and Rh typing by molecular methods is complicated and not without risk, she says, adding, "Serology is very simple, so go with the simple one that works well."

TRM.40650, "Serologic Crossmatch," has two changes. One is to define neonate as it applies to transfusion. "Neonate in the blood banking world means an infant less than four months, because after four months, infants can start to make their own antibodies, so they need to be treated like anyone else," Dr. Park says. In infants under four months, less can be done. Only one antibody screen is required, for example, on infants from birth to four months.

The second is to clarify that if a specimen is eligible for computer crossmatch, a serologic crossmatch need not be done. "This is just to say we understand that if it's eligible for a computer crossmatch, you can do a computer crossmatch," Dr. Park says.

The addition of the word "unexplained" provides much-needed clarity to TRM.40670, "ABO Group and Rh(D) Type Verification," which addresses the need for serologic crossmatch in the event of ABO typing discrepancies.

For the most part, the causes of ABO typing discrepancies are known. “When a patient gets a bone marrow transplant, their blood type can change. That’s an expected ABO discrepancy,” Dr. Park says. Most blood banks would prefer to rely on a computer crossmatch in those cases, but the previous version of the requirement did not permit them to opt out of the serologic crossmatch in the presence of any discrepancy. “It was making more work for people.”

The requirement now says serologic techniques must be employed “when unexplained ABO typing discrepancies exist on the current sample.” Says Dr. Park, “We allow laboratories to not have to do the serologic crossmatch if they can explain the discrepancy.”

Other changes in this year’s checklist include the following:

- TRM.41025, “Transfusionist Training,” says there must be records of initial training and in-service at least annually for personnel involved in transfusion. Language was also added to clarify that it must be in accordance with federal, state, and local laws and institutional policies and procedures for alignment with the Centers for Medicare and Medicaid Services requirements for nursing services. The elements of what needs to be covered in the annual training are listed.
- TRM.40790, “Fetomaternal Hemorrhage Detection,” requires the use of standardized formulas for translating the milliliters of fetal blood into vials of RhIG for laboratories that provide RhIG dosage recommendations to physicians. “We just want to make sure that if a laboratory is doing it, they’re doing it in a standardized fashion” and can document it, Dr. Park says.
- TRM.40925, “Blood/Component Compatibility Label or Tag” is the former TRM.41350 and lists the minimum elements required on the label or tag: identification of the recipient with two patient identifiers, blood (or component) unit identifier, and interpretation of crossmatch tests, where applicable. Some of the elements previously in this requirement (for example, recipient and donor blood types) are already covered in TRM.40950, “Clerical Identification and Transfusion Records Final Check,” which has also been reformatted to list the elements that need to be verified at time of issue.

These changes clarify which elements need to be checked at the time of issue and which need to be attached to the bags. “There are overlaps,” Dr. Park says, “but they’re also different.”

*Amy Carpenter Aquino is CAP TODAY senior editor.*