



# e-Network Forum

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### **Reporting of Critical Values by transfusion service laboratories**

**A colleague in group practice in a multi-hospital network** has a question about how facilities are complying with the following item on the [CAP Checklist](#):

TRM.40220 Phase II: "Are critical values established for certain tests that are important for prompt patient management decisions?"

NOTE: The laboratory must establish critical values for certain tests in immunohematology, in conjunction with the medical staff, to ensure immediate notification of a physician or other clinical personnel responsible for patient care. These critical values may be indicated in the procedure manual and /or in a separate manual or policy. The bench technologists must be familiar with critical values and the related procedures."

She reports that their pathologists and lab managers **do not believe there are critical values in the Transfusion Service (TS)** as there are in other areas of the laboratory with values that can be quantified and ranges set. Since TS does not fit into the usual method of alerting physicians, and documenting the notification, they **question if TS really has critical values**. Some of the locations, in order to meet this requirement, have developed a policy that states that there are no critical values in the TS, but there are critical situations that would require immediate physician notification. Some of these critical situations are any results from a transfusion reaction work up that suggests a hemolytic transfusion reaction, release of a unit on emergency waiver that later proves to be incompatible, etc. And of course some of our facilities feel that this a **policy on this issue is not warranted as the information is clearly covered in our individual procedures**, and that this policy is only prepared to placate the CAP inspector and offers no value to the facility. Her group is wondering how others are complying with this item on the CAP checklist.

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The following responses have been received.

**ADDENDA** Aug. 4, 2005

- 1. Dr. James P. AuBuchon, Chair of the CAP Transfusion Medicine Resource Committee** (attribution used with permission) comments that the intention of the CAP checklist requirement (TRM 40220) is to ensure that information that is critical for the care of a patient be relayed to a responsible provider promptly. Information generated in the laboratory and remaining there is of little value! The requirement for the establishment of "critical values" is most readily evident where quantitative results are generated, but assays yielding qualitative results can also be considered as potentially yielding "critical" results. He adds that "One could peruse the list of assays or procedures performed in a laboratory and ask the simple question: **What outcomes or results might be encountered that should be immediately relayed to the healthcare provider to ensure that the best possible care is provided to the patient?** Just as the finding of malarial parasites on a peripheral blood smear would probably be considered "critical", so too would findings suggestive of acute hemolysis during a transfusion reaction workup. If problems were to arise in the processing of hematopoietic stem cells or the handling of autologous bone in a Transfusion Service Laboratory, these, too, might be considered critical "results" since knowledge of the outcome might prompt the patient's physician to immediately take another course of action. Therefore, **the concept of creating a "criticals list" is applicable in all sections of the laboratory**. A careful review with the medical director of the analyses and procedures performed, and possibly discussions with clinicians about their reaction to certain outcomes, would help establish an appropriate list for the lab. Questions regarding this - or any other - item on the CAP's TRM checklist may be directed to me ([james.p.aubuchon@hitchcock.org](mailto:james.p.aubuchon@hitchcock.org)) or the CAP. The Transfusion Medicine Resource Committee is always anxious to help clarify issues such as this or learn how the checklist can be made a more useful tool for the improvement of the delivery of laboratory medicine services.
- 2. A transfusion medicine physician in Boston** reports that at his hospital they treat the following situations as a 'critical value' and therefore phone the patient care area each time either of the following situations occurs:

1. Transfusion Reaction Investigation Results: the clerical and serologic results (to evaluate for hemolysis) are called back to the floor (nurse or doctor) for all suspected transfusion reactions.
2. Unacceptable samples and miscollected samples (designated as Wrong Blood In Tube "WBIT")\*

A call back is made whenever the laboratory receives either a sample with unacceptable labeling or whenever there is an ABO/Rh result that is unexpectedly discrepant with previous results suggesting that the labeled specimen contains the blood from another patient.

\*References:

- Murphy, MF; Stearn, BE and Dzik, WH. [Current performance of patient sample collection in the UK](#). *Transfus Med*. 2004 Apr;14(2):113-21.
- Dzik, WH. [An international study of the performance of sample collection from patients](#). *Vox Sang*. 2003 Jul;85(1):40-7.

3. **Dr. Steve Apfelroth, a transfusion medicine physician in the Bronx, NY** reports that at his hospital the following "critical values" in their blood bank are phoned to the responsible physician:
  - Positive DAT on cord blood
  - Positive DAT on transfusion reaction workup specimen, or results which support an interpretation of hemolysis or mistransfusion
  - Incompatible crossmatch completed after emergency uncrossmatched issue of red cells.
  - Blood issuing error (wrong patient or unit number)
  - ABO discrepancy of current type and screen specimen with previous record.
  
4. **A transfusion medicine physician in Virginia** reports that the [attached table](#) lists 'critical values' that were used by the transfusion service at his 'old place' in Texas. Some of the categories represent 'situations' while others are specific test results. He comments that he is not sure there can be a clear distinction. He adds "**Thinking about critical values as based only on quantifiable results is a bit narrow - the issue in my mind is that one needs to clearly delineate when rapid communication is needed**, whether based on a test result or on a situation as it were. The comment that situations are covered by information in policies/procedures other than the critical value procedure begs the question in that the CAP checklist question note already states that the list need not be in a separate procedure. Be that as it may, it **can be very useful to have staff think of these results/situations as critical and that notification has to occur, particularly if generalists are covering the blood bank** (2nd/3rd shift) who may be more in tune to a critical value policy related to electrolyte, TDM results, etc., than they may be to a immediate notification section of a Blood Bank procedure."
  
5. **Dr. Ronald E. Domen** (attribution used with permission) reports that at the **Penn State Milton S. Hershey Medical Center** they do not have a separate procedure in the Blood Bank that details "critical values" but each procedure, as appropriate, indicates when a resident or attending physician should be notified. In the transfusion service all transfusion reactions and panel workups are reviewed by their residents and attending physicians and a separate, consultation report is generated that goes to the patient's medical record. They also have a "deviations from standard operating procedure" policy that defines certain clinical situations (e.g., change in blood type of units issued by the blood bank, factor VII administration, continuous platelet infusion, etc.) that is reviewed and documented on a consult form that goes on the patient's medical record. A change in blood type following a bone marrow transplant that necessitates a change in the ABO/Rh type for transfusion also gets reviewed by a physician. Another example is an antibody titer and hemolytic score in a pregnant patient that also generates a consultation report. If necessary, the patient's physician is contacted by telephone, e-mail, or other means. For blood donors, all positive infectious disease tests get reviewed by the medical director. In the Apheresis Service, all moderate to severe patient reactions get reviewed by the medical director. And, so on. It would be virtually impossible to list every possible clinical scenario for the transfusion or donor services. Dr. Domen speculates that perhaps part of the problem with the CAP Checklist question (and its accompanying note) is relating the intention of the requirement and the wording that is used. He says "**The intent, I think, is to notify the appropriate physician(s) about something identified in the laboratory that is potentially harmful to the patient** (i.e., a critical value). What is a critical value? It implies a definable number, as in chemistry, where it might be a potassium of 7.0; or, in microbiology (another gray area) where it might be any positive spinal fluid culture; or, in the transfusion service where it might be a transfusion reaction. But, a transfusion reaction is not a numerical "value," it is a clinical event that has multiple layers of significance. The same is true for a positive antibody identified in an antibody screen. Thus, these events are reviewed by the blood bank physician who makes the appropriate decisions on interpretation, clinical significance, and what further course of action should be taken." **He agrees with the comment above that since appropriate courses of action are defined in individual procedures, the intent of the Checklist question has been met.** He concludes saying that trying to put all critical events/situations that could conceivably occur in the transfusion service into one policy is unnecessary, virtually impossible, and does nothing, that he can see, to improve patient care.

6. **A transfusion medicine physician who practices in Illinois** comments that as reviewed in a **CAP Q-Probe publication** (Howanitz PJ et al, Arch Lab Pathol Med 2002:126:663), the concept of "critical values" traditionally refers to chemistry, hematology, microbiology and drug-level test results which warrant prompt notification of physicians and other caregivers about "a potentially life-threatening situation." The responding physician adds that the word "value" implies quantitation, but microbiology results are not quantitative, so perhaps "**critical results**" would have been a better term. Seen from this perspective, he believes that there are a **small but important set of critical results in the blood bank which fit this definition**. In fact, the inquiring colleague who initiated this discussion mentioned two: a possible hemolytic transfusion reaction, or a retrospectively incompatible emergency transfusion. He adds "We could also include serious recall notices from the blood supplier about blood components which have been recently issued but which might pose an infection risk, such as detection of bacteria in a platelet unit or a co-component, or a blood donor who reveals very recent HIV or hepatitis exposure; in these cases, immediate notification could prevent or interrupt transfusion, or trigger rapid antimicrobial therapy as indicated. As discussed by Howanitz, **some labs have expanded this concept to include non-life-threatening but important results which warrant prompt and confirmed communication to the caregiver**." He reports that his hospital uses the term "alert value" rather than "critical value," and in this context, their transfusion service considers a positive fetomaternal hemorrhage screen as an alert value needing prompt followup (i.e., fetal RBC quantitation within the 72-hr recommendation for giving extra RhIG if needed). He adds "We have also included discovery of delayed hemolytic transfusion reactions and of clinically significant RBC alloantibodies in women during pregnancy, although these are more for confirmation of the physician's awareness than for urgency. If the laboratory covers "critical values" in individual procedures, then a very brief policy which lists and refers to these individual procedures may be helpful for laboratory staff and for internal and external assessments."

**ADDENDA** Aug. 5, 2005

7. **A medical technologist at a hospital in the San Fernando Valley in Southern California** reports that their blood bank critical values list includes positive direct antiglobulin tests (DATs) on newborns and hemolytic transfusion reactions.

Please submit comments to the [e-Network Forum](#).

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**Addenda:** Aug. 4, 5, 6, 8 & 10;  
Sept. 14 & 15, 2005



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### **Reporting of Critical Values by transfusion service laboratories** (Page 2)

8. **A medical technologist in Indianapolis, Indiana** reports that their transfusion service considers evidence of a hemolytic transfusion reaction and any abnormal delay in providing blood for transfusion or surgery as "critical values". They 'respect' the intent of the CAP checklist item in that in their opinion the aforementioned events are important enough to require immediate notification of the attending physician, who may alter the patient's treatment based on the new information. Their SOP requires both the notification of the physician (or primary caregiver for inpatients) and a call to the pathologist.
9. **Dr. Holli M. Mason, Director of Transfusion Medicine and Serology at Harbor UCLA Medical Center in Southern California** (attribution used with permission) thinks that the term 'panic value' is a **little more difficult to define in the blood bank because the blood bank has so few "values"**. She thinks that, though a matter of semantics, the **spirit of the CAP Checklist item is satisfied with a policy on situations requiring immediate physician attention**, and her service has a policy entitled: "Situations in which a physician must be called, AKA "Panic Values" ". Most of these situations require that a pathologist be called (in their case a resident or the transfusion service medical director) but many also require that the primary care physician be notified as well. Strictly speaking, "values" that would initiate physician contact urgently in her practice would be increases in the antibody titer of a pregnant woman, positive direct antiglobulin tests and blood that has been issued uncrossmatched only to be found incompatible upon completing testing. Situations requiring physician notification include: suspected acute or delayed hemolytic reaction, significant delay in providing blood (medical director to be involved if patient's Hgb is below 6), inventory/blood shortages, transfusion requests against established policy, switching Rh negative patients to Rh positive red cells, unable to result Rh of newborn and requests for incompletely tested blood products. Dr. Mason acknowledges that colleagues might wonder why she has specified that she is to be involved in delays in providing blood to patients with a Hgb below 6. As she works at a teaching hospital, she has found that new interns often simply accept the notification that there will be a delay as something they are "stuck with". To ensure good patient care and to make sure to take advantage of a teaching opportunity, she likes to get involved and evaluate patients who may be at serious risk for complications of anemia and educate the interns on the options available to them in such situations.
10. **A medical technologist in Long Beach, California** reports that her facility feels that **transfusion services do have some critical values** and includes these on a list that their Department of Pathology provides to the medical staff:
1. incompatible crossmatch
  2. unexpected results on transfusion reaction workups (ie, unexplained post transfusion hemolysis, positive post transfusion DAT, different ABO type on post transfusion specimen, etc)
- She comments that they do not feel that they are doing the aforementioned "just to meet CAP regs", but to assure their physicians that they will be notified of what the transfusion service considers serious situations relating to blood bank test results.
11. **A transfusion medicine physician in New York agrees with those who state there are no "critical values" in transfusion medicine.** In his view, **a critical value is a laboratory determination whose result is not already obvious from clinical findings.** He states "This must be a result that is of extremely urgent interest to the patient and their care giver. Examples include severe laboratory abnormalities that may indicate impending clinical crisis but that may be partially or totally asymptomatic. Wildly abnormal potassiums and calciums come to mind, as well as PTs and PTTs that are off the wall. But the finding of a new alloantibody, or positive direct antiglobulin test obviously do not qualify. The workup of a hemolytic transfusion reaction is invariably initiated by the clinical staff, so the results hardly constitute a critical value. I think all laboratories should have procedures for how urgently and when and by/to whom clinically important findings are to be communicated, but I think we've taken this critical value thing to the point of a reductio ad absurdum."

12. **A Blood Bank Management Consultant** is of the opinion that having a "critical values" list is quite appropriate in the transfusion service. She recommends to her clients a list such as one attached ([pdf](#)) file which is often termed a "Medical Director Notification Guidelines Policy."
13. **A transfusion medicine physician in Cleveland** argues that **there are situations which qualify as 'critical' and require a transfusion service to urgently notify a patient's physician**. For example, when a patient is in urgent need of blood, but all selected donor units are 'incompatible' due to a strong pan-agglutinin. While the aforementioned situation is NOT a TEST VALUE in the traditional sense, it nonetheless represents a lab result, which in her opinion should trigger immediate notification of the clinical service and the physician responsible for the Transfusion Service. In fact, she believes that anytime there is an actual or anticipated delay in availability of blood there should be a communication with the patient's clinician regarding the urgency of the clinical need. She has personal knowledge that **lack of proper communication between transfusion service and clinician can result in an unnecessary patient death**. Alternatively, there might be a situation in which sufficient blood or components are not available to meet clinical needs due to very low product inventory. In that situation, while there are no lab results to respond to per se, there is certainly a need to notify the appropriate clinical services in a timely manner to help utilize the inventory in a clinically most appropriate manner. She also believes that a blood bank test result suggesting the receipt of a WBIT (wrong blood in tube sample; see [posting #2](#) on prior page) should elicit an immediate notification of the physician responsible for the Transfusion Service. Such notification is vital to prevent a potential mistransfusion by ascertaining whether another patient is also party to a specimen mix-up. She personally feels that cases requiring immediate notification, while possibly "buried" in other policies, need to be culled out into **a separate list and supported by a separate policy thereby establishing the vital importance of communication in such circumstances**. In her facility, they have a form that their Blood Bank lab utilizes to document calls to the physicians covering their Transfusion Service and Donor Room. She reports that she and her staff are in the process of updating this form and developing a corresponding policy.
14. **A technical coordinator at the Chicago hospital** reports that they have a "**Physician Alert Policy**" which defines certain situations that require notification of a physician. They employ an "Alert Value/Situation Log" that blood bank staff must use to document when they notify the Blood Bank Medical Director and/or the patient's physician of an "Alert Value/Situation". Attached is an example of their Log ([MS Word](#)).

Their policy requires notification of the Blood Bank Medical Director OR patient's physician for situations like:

- a. Transfusion error or serious transfusion reaction
- b. Delayed hemolytic transfusion reaction
- c. New hemolytic antibody identified during pregnancy
- d. Excess fetomaternal hemorrhage

Examples of log entries include:

- Positive Fetal Maternal Hemorrhage Screen
- New Anti-Jkb and eluate contains Anti-Jkb on a recently transfused patient
- New anti-K1 on a pregnant woman
- Eluate contains Anti-A – Transfusion Reaction work-up
- Anti-D titer = 32, last month was 8
- Transfusion Reaction required intubation with pulmonary edema possible TRALI
- Newborn. 4+ DAT and eluate contains anti-D

The **Blood Bank Medical Director reviews each Alert Value/Situation entry** in a timely manner to ensure appropriate action has been taken and the appropriate physician has been notified if applicable. The Blood Bank Medical Director documents the review, and any comments as applicable, in the space provided on the Alert Value/Situation Log. Quality Improvement Reports (QIR) related to the Alert value/situation are generated as appropriate.

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### **Reporting of Critical Values by transfusion service laboratories** (Page 3)

**ADDENDA** Aug. 8, 2005

15. **The transfusion service medical director at an urban hospital in Los Angeles** is of the opinion that while some of the critical 'values' used by her transfusion service are not necessarily indicative of life-threatening condition or require immediate action, the laboratory's notification of the patient's physician (as well as the transfusion service director) serves as an **educational exercise, as well as an alert of a potential severe situation**. She reports that their critical value notification policy includes the following:

1. Incompatibility found in blood issued
2. Confirmed hemolytic transfusion reaction or suspected bacterial contamination
3. Transfusion/issue of ABO/Rh discrepant blood
4. Mislabeled sample-wrong patient drawn
5. Any ABO/Rh discrepancy not resolved technically
6. Antibodies known to cause hemolytic disease of the newborn in prenatal patients
7. Positive DAT in recently transfused patient or in neonate
8. Multiple clinically significant antibodies identified in patient's serum (implication being delay in issuing blood for transfusion)
9. No compatible units available for a specific patient
10. Positive fetal cell stain test

**ADDENDA** Aug. 10, 2005

16. **According to Dr. Kathleen Sazama who practices at M.D. Anderson Cancer Center in Houston, Texas** (attribution used with permission), the concept of critical value reporting arose from the practice of ordering 'panels' of tests (rather than medically indicated individual tests), creating the opportunity for an abnormal test result that the laboratory could not determine was related to a patient's medical condition. She points out that the **definition of what is called a 'critical' (older term, 'panic') value is often misunderstood**. In her opinion, one suitable definition is as follows: "A critical value is a clinically unexpected laboratory result that, if not quickly recognized and acted upon, may be life-threatening to the patient." Using this definition and strictly applying the concept of a "laboratory test result" to immunohematology, she argues that it is difficult to accept that anything other than reporting the presence of hemoglobin in plasma and/or urine (usually due to sepsis or a hemolytic transfusion reaction) and/or a new positive DAT because of a hemolytic transfusion reaction (and alerting staff to look at the surrounding events (e.g., sample misidentification, another unit mistransfused to a second patient, etc.)) would be critical values in immunohematology. She continues that "Granted there can be a number of clinically unexpected immunohematology test results -- new appearance of an allo- or autoantibody, incompatibilities at crossmatch, positive DAT on cord blood or positive fetal cell screens -- but either the action is managed entirely within the laboratory so that no 'life-threatening' patient events transpire OR the test was ordered for a specific clinical indication (e.g., fetal cell screening), so it cannot be considered 'clinically unexpected.' Physicians order individual tests because they are looking for abnormalities (or confirming an existing condition), so any single test result that is abnormal, even one that could be life-threatening to the patient, cannot be considered 'clinically unexpected.' When physicians order individual laboratory tests, they (and NOT the laboratory) are responsible for managing those test results, whether or not the result is a critical value." She adds that she is **troubled by the definition's limitation to just laboratory testing**. In the transfusion service, she believes it to be critical if there is an unforeseen delay in providing transfusions or if only incompatible RBC units are available for transfusion. However, definitionally, the test results indicated are probably the only ones that strictly meet the definition of 'critical values.'

**ADDENDA** Sept. 14, 2005

17. **A transfusion medicine physician at a Northern California academic medical center** reports that he and his associates use the following "critical values" for their transfusion service, which provides immediate notification of the following results:

1. a positive transfusion reaction work-up for hemolysis
2. an antibody panel evaluation for a type and cross request, when the work-up is inconclusive and cross match compatible blood is not available.
3. a patient with autoimmune hemolytic anemia, multiple alloantibodies, HTLA antibody, or antibody against a frequent antigen, and cross match compatible blood is not available
4. an ABO grouping result that indicates that a specimen is from the wrong patient

**ADDENDA** Sept. 15, 2005

18. **A Blood Bank/Hematology Coordinator in Bryan, Texas** reports that in reading the above discussion on critical values, she has NOT seen mention of a critical value that is on their local list. They call as critical for a pregnant patient any titer of 16 or above for an antibody known to cause hemolytic disease of the newborn (HDN). She justifies her position quoting the AABB Manual 14th Edition, p. 500-501 "The critical titer for anti-D should be established at each facility and usually is 16 or 32 in the antihuman globulin phase." "The critical titer for anti-K1 may be lower than anti-D, typically a value of 8." She adds that **they also set "Alert Values"** that are important but not life-threatening at the moment, and include in their list of Alert Values a positive antibody screen.

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