Quality and safety

Learn what leading the way to zero means for laboratories
Can you imagine a health care industry with zero complications of care, zero lost revenue and zero harm events of any kind? The Joint Commission envisions a future of zero harm and is committed to helping make it a reality.

In its work leading the way to zero™, The Joint Commission provides tools and resources to help organizations transform the way they work to prevent harm. For laboratories, zero harm means:

- Zero patient harm based on lab testing
- Zero misdiagnoses

These are just some of the examples of how The Joint Commission helps laboratories on the journey to zero harm.

Things laboratories can implement to improve the care they provide as they work toward zero harm are:

- Improving internal self-audits, evaluation and follow-up for complaints and accidents.
- Creating an environment in which employees are comfortable reporting all safety infractions.
- Monitoring improvement initiatives and reviewing processes throughout the organization to identify high-risk procedures.
- Evaluating processes for addressing near misses.
- Ensuring everyone is focused on patient safety.

Learn more about what zero harm looks like in laboratories by watching the “Zero Harm IS Achievable” video or visit The Joint Commission’s Leading the Way to Zero™ webpage.

Focusing in with Barbara Schwarzer: The culture of safety and zero harm
Barbara Schwarzer, MHA, MSOL, CPHQ, MT(ASCP), has nearly 50 years of laboratory experience in hospitals — ranging from the university setting to critical access and multi-site venues. She has served as a generalist, working her way up to hold positions as a laboratory director, laboratory quality director of a multi-site organization, and a director of hospital and infection control. She has been with The Joint Commission for five years as a Laboratory surveyor.

One of the most frequent questions she is asked relates to safety culture — “What are the new standards for the Laboratory program?” Lab Focus recently sat down with Schwarzer to ask her about safety culture and the journey toward zero harm.

Lab Focus: How do you respond to that common question about if there are new standards related to safety culture?

In this issue:

- Learn what leading the way to zero means for laboratories
- Focusing in with Barbara Schwarzer: The culture of safety and zero harm
- Joint Commission lab surveyor: Why massive transfusion protocols are so important
- Reminder: Laboratory Accreditation resurvey window now 3 months
Barbara Schwarzer: The answer is that there are no new standards. Nor are there changes to the Laboratory survey process. What is changing is that there is an enhanced focus on the existing leadership standards to incorporate a culture of safety, a just culture and a learning culture embedded in the journey to reach zero harm.

The specific Leadership (LD) standards that apply are the following:

- LD.03.01.01, element of performance (EP)1, 2, 4 and 5
- LD.03.09.01, EP3
- LD.03.02.01
- PI.01.01 EP 1,2,6 and 7

Leaders play a key role in building an organization’s culture. This culture results from those activities that are performed on a consistent, daily basis. The culture of safety is evident in how leaders and staff communicate with respect, how quickly unsafe conditions are identified, how trust is developed, how comfortable staff are in reporting errors, and how staff are held accountable for following safe practices. All these components contribute to a culture of transparency and learning so that errors will be reduced and harm eliminated. Leadership engagement in all these areas is crucial to reaching zero harm.

LF: How will safety culture be assessed during a Laboratory survey?

Schwarzer: Here are some sample questions that may be asked during the survey or during a specific tracer activity.

For leadership:

- How do you assess the culture of safety in your laboratory? What tool(s) are you using? How often do you repeat this survey? Can you show me an example?
- Do you include safety culture improvement goals in performance expectations of laboratory leadership and middle management?
- What quality improvement projects have you conducted to improve your scores on safety culture?
- Do you have benchmarks to measure your progress in developing a culture of safety? Can you show me an example?
- Do leaders prioritize and implement changes identified by a culture of safety evaluation? How does this work in the laboratory? Can you provide an example?
- How do laboratory leaders support and facilitate application of a transparent, non-punitive approach to reporting and learning from adverse events, close calls, and unsafe conditions?
- Have you adopted specific codes of behavior for physicians and staff? Are they the same for everyone? Can you show me a policy or an example?
- What process do you have in place for reporting a “close call” or an error that occurred but did not reach the patient?
- In the event an error occurs, and a patient is harmed, how do you determine whether it is a blameless error (for learning) or a blameworthy error (for discipline)?
- What do you do to recognize staff who have suggestions for safety improvement?

For staff:

- Have you ever completed a safety culture survey? Have you seen the results of a safety culture survey? Does your supervisor discuss the results?
- Is there a formal process for reporting intimidating behavior? Would you feel comfortable reporting intimidating behavior?
- When an error occurs, do you have the confidence that your leadership will take an appropriate look at how the system or process is accountable versus an individual?
- What process do you have in place for reporting “close calls/near misses” or an error that occurred but did not reach the patient?
- Does leadership conduct root cause analyses of “close calls/near misses” that are reported? Are the results shared with you?
Lab Focus
Issue 2 — 2019
Page 3

**LF:** Why are these changes enhancing the focus of the LD standards to include a safety culture being made?

**Schwarzer:** A culture of safety paves the way to zero harm. When staff trust that they can report errors without fear of punitive treatment, both proactive and reactive risk reductions can occur. A culture of safety also includes a just culture where staff are held accountable for their responsibilities and where reckless actions or failure to follow policies and procedures are not tolerated. It is up to an organization’s leadership to establish the balance between the two.

Surveyors will be looking for engaged laboratory leadership and their participation in developing and sustaining a culture of safety in the laboratory. The above questions, in addition to the Patient Safety Systems (PS) chapter in the *Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing, Sentinel Event Alert 57*, and The Joint Commission *Perspectives* from June 2018 should provide guidance and direction for laboratory leadership in developing a culture of safety that paves the way to zero harm.

**Joint Commission lab surveyor:** Why massive transfusion protocols are so important

Hospitals of all sizes need to be prepared for massive transfusions — also simply referred to as “massive” — and massive transfusion protocols (MTPs) can help staff be better prepared to help patients in need of these life-saving blood transfusions. Diane Avenoso, MPH, MT(ASCP)SBB, CQA(ASQ), Laboratory Accreditation field staff, The Joint Commission, provides insight into MTPs and how to prepare your laboratory staff for them.

Avenoso has specialist certification in blood banking from the American Society for Clinical Pathology. She has worked as a transfusion service manager and technical specialist in two different Level 1 trauma centers, and also helped develop massive transfusion protocols with multidisciplinary teams, coached staff on emergent blood issues, and conducted root cause analysis and deviation reporting. She also has assessed for AABB, inspected for the College of American Pathologists (CAP) and worked as a Clinical Laboratory Improvement Amendments (CLIA) and Centers for Medicare & Medicaid Services (CMS) inspector.

“Massive transfusion is a phenomenon that can scare and immobilize even the most experienced staff,” Avenoso said. “If at a hospital of a certain size (>200 beds), it is likely you’ll encounter a massive. But the situations are never exactly the same. Even smaller hospitals that don’t see trauma need to be prepared for hemorrhagic emergencies in obstetric and aortic aneurism patients.”

Massive is loosely defined as the rapid administration of total blood volume (10-20 red cell units for adults) within 24 hours, or replacing >50% of blood volume within 3 hours. In practice, massive bleed patients can use 20-40 red cell units in an hour or two.

Complications with massive, beyond the initial cause of the hemorrhage, are many. This includes:
- Hypothermia
- Dilutional coagulopathies
- Problems secondary to resuscitation
- Electrolytes (lytes) imbalances that need to be diagnosed and addressed along with blood replenishment

The Joint Commission has standards related to emergency blood product issues — such as Quality System Assessment for Nonwaived Testing (QSA) standard QSA.05.11.01 — that require policies and procedures, justification for releasing blood before pretransfusion testing is complete, and completion of testing as soon as possible. The emergency issue policies are a logical place to address massive.

“MTPs have come a long way in the last 50 years,” Avenoso said. “An MTP streamlines and facilitates this communication, so each team is able to focus without needless interruptions. Inter-laboratory communication between the blood bank, hematology, coagulation and chemistry is critical. When massive situations occur on swing or night shifts with reduced staff, additional challenges arise that may require
extra support, on-call staff, couriers, and hospital runners who are able to anticipate and support critical functions across the entire hospital team.

“One annoyance from transfusion service during massive involves extra phone calls from the care team. This not only steals precious time from preparing the very products urgently needed, but it stresses staff who need time and space to focus on completing the extensive documentation/verification required for issuing blood products.”

Other factors that arise are requests for blood bankers to deliver products to the trauma area or emergency department. Pneumatic tubes may be validated or ancillary staff familiar with the hospital layout may be trained to safely deliver blood products. Please allow blood bankers to focus on appropriate product selection.

Problems also arise when lab results are delayed or not timed with blood product administration, and the patient care team is operating using outdated lab data. MTPs use lab values to guide product selection and timing. Some trauma centers use a comprehensive approach to hemodynamics by incorporating lab data into worksheets (electronic or paper) that also track the type and amount of blood products administered.

The blood product ratios of these MTPs approximate 1:1:1 or 1:1:2 of plasma (FFP) to platelet pheresis (PPH) to red blood cells (RBC).

But MTPs are not standardized, and fixed ratio resuscitation has become more popular recently, which often starts with six RBC, six FFP, and one PPH (6:6:1). In truly massive blood loss situations, lab values may be delayed and empirical replacement of coagulation factors trumps lab values.

Challenges for medium-sized hospitals include not having enough PPH on hand and difficulty thawing enough FFP fast enough. Inability to keep a proper blood product balance can lead to fatal coagulopathies. Some blood centers are actually offering whole blood from one donor, which is essentially 1:1:1. Whole blood offers simultaneous treatment for oxygen debt and coagulopathy of trauma.

In smaller facilities without MTP, a variety of challenges may occur with uncontrolled bleeds. Laboratorians, especially inexperienced staff, sometimes shy away from issuing blood in life-threatening situations, because they are not able to find perfectly compatible or matched products. The immune system does not have time to mount a response in an open circuit, so staff need to be educated, trained and have drills to prepare for emergent situations.

“Someone wise once said, ‘Compatible blood for a corpse is not a triumph,’” Avenoso said. “Doctors should be educated on this, too: Do not give male traumas those precious O negative red cells. Another trend is to give group A FFP rather than AB to conserve the universal stuff for those who only may receive AB. Advocacy and communication by the laboratory medical director with surgery and the emergency department are essential to help critical situations go more smoothly.”

Meanwhile, how many small hospitals have nurseries? Withholding blood from a critical neonate who is being transported to a trauma center is risky/litigious, and staff should consider sending their freshest O negative (non-irradiated) RBC with the care team if approved. Of course, training and drills are paramount to prepare for these situations. The Joint Commission also requires distinct policies for neonatal transfusion-related activities — such as QSA.05.17.01, element of performance (EP) 3.

Customizing MTP to each facility will help make the process go more smoothly and prevent product wastage. MTPs are ideally created using a multidisciplinary team including surgery, transfusion safety officer, anesthesiology, pathology, blood bank and nursing. A transfusion committee, if there is one, is a good place to start.

Massive truly brings several disciplines together in a short and intense manner to save a life. A well-written MTP can make this process more predictable and manageable – excellent communication and preparation make this ordeal less overwhelming and can even help departments understand and appreciate each other better. Debriefings are important to evaluate and improve the process.
“Lab is sometimes an invisible entity in hospitals,” Avenoso said. “But MTP elevates the blood geeks into superheroes who deliver the very products needed by our most critical patients.”

**ACCREDITATION**

**Reminder: Laboratory Accreditation resurvey window now 3 months**

As a reminder, effective Jan. 2, The Joint Commission reduced the resurvey window for its Laboratory Accreditation program from six months to three months for unannounced surveys. This change was made to accommodate the staffing and planning needs of organizations with Joint Commission-accredited laboratories.

Organizations are still be able to select 10 “avoid dates” within the survey eligibility window. Out-of-cycle survey events will not be affected by this change, including:

- For-cause surveys
- Retrospective cytology surveys
- Proficiency testing monitoring surveys
- Accreditation with follow-up survey

Organizations are able to choose their avoid dates on the “Tab 6 - Survey Details - Avoid Dates” page on their Joint Commission Connect® website.

The Joint Commission continues to make every effort to reasonably accommodate an organization’s avoid dates. However, The Joint Commission reserves the right to conduct a survey during an “avoid period” if the reason given to avoid a survey at that time is such that a survey can be reasonably accomplished. Also, The Joint Commission may not honor single avoid dates clustered near the end of the accreditation cycle or other attempts to choose dates that unreasonably narrow the period of time in which schedulers can efficiently accommodate the unannounced survey process.

For more information about this change or if you have questions, contact Heather Hurley, executive director, Laboratory Accreditation, at hhurley@jointcommission.org.