Hemolysis—can better processes add up to millions?

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February 2013—If anybody is a believer in programs to reduce hemolysis rates in the hospital, it's Dennis Ernst, MT(ASCP), director of the Center for Phlebotomy Education. Ever since he left the bench 15 years ago, Ernst has been traveling the country with a mission: to show clinical laboratories, nursing departments, hospital administrators, and clinicians that the payoff from high-quality phlebotomy is much greater than they might realize. Despite hemolysis being the No. 1 reason the laboratory rejects blood specimens, hemolysis does not strike randomly, and it's not inevitable, Ernst emphasizes. "Typically the causes of hemolysis are all behavioral," he says.

But even Ernst was taken aback at the dazzling results of a Lean process improvement program launched to tackle hemolysis rates about four years ago at Sarasota (Fla.) Memorial Health Care System. As powerful as Lean principles have proved to be, it isn't often that they produce seven-figure savings to an institution's bottom line. "At Sarasota, they decided hemolysis was not only a threat to patient quality of care, but a threat to the facility's well-being. They rolled up their sleeves and said 'we're not going to take it anymore.' And it's incredible what they projected their savings to be when they really got serious," Ernst says.

It all started with the laboratory confronting a stark fact: Blood specimens collected in Sarasota's Emergency Care Center (ECC) and throughout the 806-bed hospital had significantly higher hemolysis rates than those collected by phlebotomy staff. In a 2009 count, "the hemolysis rate facility-wide was about three percent, while the ECC had a rate of about eight percent," says Charlene Harris, FACHE, MT(ASCP), director of laboratory services. When hemolysis was measured by nursing unit, only two of 18 units were meeting the goal of keeping hemolysis at two percent or below.

Dana Rickard (left) and Charlene Harris at Sarasota Memorial, where a phlebotomist was assigned to collect blood in sections of the ECC for a period, and the hemolysis rate dropped. "That's what convinced them that it really made a difference," Harris says. [Photo: Kenneth Gronquist]

With more than 94,000 visitors a year, Sarasota's ECC qualifies as very active,

and the laboratory generally does not perform draws there. In fact, only about a third of blood draws in the hospital are done by phlebotomists. “We had nurses drawing, we had respiratory care and others drawing, so that added a little bit of complexity to the situation,” Harris says. It meant that addressing hemolysis wouldn’t be so much a laboratory issue as an interdepartmental issue.

At Sarasota, the laboratory decided to conduct a positive improvement study, says Dana J. Rickard, MT(ASCP), preanalytical manager. In the summer of 2009, with the help of Charlotte Damato, a Six Sigma/Lean Quality coach and expert in work and role redesign, “we did a value stream analysis of turnaround time in the lab in connection with the ECC.” In addition, Harris says, “we did some Lean studies of physical workflow in the ECC and the lab to see structurally where improvements could be made. So we used Lean and everything that goes along with that methodology.”

Representatives from Becton Dickinson, which provides the hospital’s blood collection supplies, worked with the process improvement team to arrive at a non-confrontational way to observe how blood was being drawn, Rickard says. “The BD consultants didn’t directly watch; they would individually ask the nurses, technologists, and phlebotomists to explain the blood collection supplies they would use and how they would collect the specimen. So it wasn’t as though the laboratory was actually coming to nursing to ask how blood was being drawn. And that helped tremendously.”

BD consultants determined through observation that staff were using several different procedures to collect blood, but most blood specimens were collected using an 18- to 20-gauge IV catheter. To collect the blood from the catheter, most staff attached a multi-sample adapter and Single Use Holder. In some cases, blood was collected off the catheter using a syringe, then transferred into tubes using a straight needle. For repeat tests, sometimes specimens were collected by flushing the catheter and then drawing blood from the catheter.

But an early meeting of BD consultants, catheterization lab staff, and nursing staff showed that the nurses believed that after they drew the blood, the laboratory was doing something that caused the red cells to burst, Rickard says. So the challenge to the laboratory was clear. “We had to figure out a way to get the nursing staff on board with how the specimens should be drawn.”

“Hemolysis is probably one of the greatest preanalytical errors that occurs to specimens that arrive at the laboratory,” says Frederick L. Kiechle, MD, PhD, medical director of clinical pathology at Memorial Healthcare System, Hollywood, Fla., and editor of the CAP’s phlebotomy guide, *So You’re Going To Collect a Blood Specimen*. Among other problems, the concentration of potassium inside red blood cells is much higher than in plasma, and ruptured red cells add potassium to the specimen. It’s important that potassium be normal before surgery, so one danger is that hemolysis may mislead clinicians to rely on falsely high potassium levels in laboratory results.

The earlier trend toward decentralization of phlebotomy in many hospitals—the model employed at Sarasota—has not generally been good for controlling hemolysis, Dr. Kiechle believes. “Phlebotomy is no longer being done by a team that resides under the control of the laboratory. Nurses and sometimes doctors on all the floors have this function, and the level of training varies a lot.”

While some facilities can make decentralized phlebotomy work, Ernst agrees it’s exceedingly difficult. “In larger facilities, you’ll see an attempt to decentralize phlebotomy as a way to make the staff more efficient, when in fact that’s really not what the outcome is. Plenty of studies have shown that in general it’s a failed concept. By and large, most facilities don’t have the time or resources to implement or maintain it successfully.” That’s one reason why, at least for blood cultures, the Centers for Disease Control and Prevention recommends that a dedicated team of phlebotomists be responsible for performing draws.

Theoretically, any sample could have a slight degree of hemolysis. “It has to be pretty severe before you even see the change in the color of the serum, because even unhemolyzed serum can be a shade of yellow that borders on pink, so it’s hard to visually determine,” Ernst says. Many analyzers now chemically determine how much

hemoglobin is in the serum, so if the hemoglobin exceeds a certain threshold, personnel can be notified and make a judgment on whether or not the test result is being influenced. On the other hand, if the sample is tested as whole blood and not centrifuged, “then the hemolysis would not even be detected and the test results could be reported without any knowledge that the sample is hemolyzed.”

Just how easily red blood cells can hemolyze is one of the major teaching points Dr. Kiechle emphasizes when trying to educate people about phlebotomy. “For someone who has perhaps not been doing phlebotomy for a while or has never done it, it’s very important to realize that just having patients clench their fist a number of times, or keeping pressure on the patient’s arm with a tourniquet for too long, can lead to rupture of these red cells.”

If people think of red blood cells as fragile crystal orbs, they might have an appreciation for how delicate phlebotomy needs to be to avoid hemolysis, Ernst says. “Once you respect the fragility of red blood cells, you’re naturally more careful with them. You don’t pull really hard on a plunger syringe, you don’t draw from IV devices if you can help it, and you don’t force blood into a tube when you’re emptying a syringe into it.”

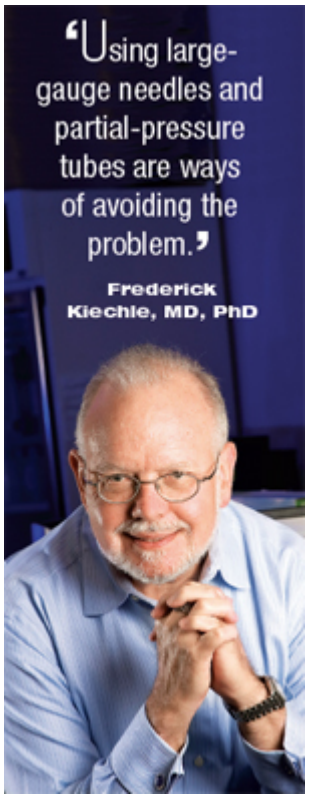
Exposure to alcohol, perhaps still left on the skin before the draw is performed, is one chemical problem that can cause blood specimens to hemolyze. But many cases of hemolysis can be explained in terms of fluid dynamics and the mechanical effects of temperature, shear rate, or pressure. Shear forces, created by any flow of the specimen fluid, generate friction. The more force exerted to move the fluid, the more shear it encounters, and the more likely red blood cells, which are deformable particulates in the fluid, will be ruptured.

Sometimes these forces can hemolyze samples in ways that aren’t all that obvious. For example, in breaking the seal on a syringe, in the manufacturing process the manufacturer has “seated” the plunger, Ernst explains. “So that plunger is kind of stuck on arrival. If you don’t ‘unseat’ the plunger and it’s still somewhat adhering to the barrel of the syringe, and you draw the sample, then the unseating of the plunger causes an instant increase in the force with which the blood is pulled. There is this rapid negative pressure on the first mL of blood in the sample that’s drawn, so the cells rush into the syringe rather than being gently coaxed.”

A sluggish draw, occurring when the needle is not centered in the vein, generally means the bevel opening of the needle is partly in the vein and partly in the vein walls. Or, as also frequently happens, a vein may collapse onto the needle. “Therefore, the narrow opening the red cells have to pass through is partially occluded, and you have the same effect as if you were drawing through a very narrow cannula,” Ernst says. “Whenever the blood just trickles, then you know that something is occluding the needle and probably hemolyzing the sample.”

The addition of air to a sample can also cause hemolysis, Ernst says. “When the device used to draw the blood is not properly fitted—for example, the syringe is not properly fitted to the vascular access device—then air gets into the fitting, it foams up the blood, and instead of having nothing but straight liquid blood in your syringe, you end up with a bubbly mixture.” Hemolysis can occur because this “frothing” introduces more turbulence, or shear, into the sample as it’s withdrawn.

At times, phlebotomists “milk” capillaries without realizing that squeezing the skin, too, can cause hemolysis. “When phlebotomists are performing a capillary puncture or finger stick and didn’t pre-warm the site, they may attempt to excessively squeeze the site or milk blood out of the puncture, and whenever you’re doing that, you’re forcing red cells through the incision. Any kind of force is unfriendly to red cells, and that includes forcefully milking blood out of the site.”



Shaking the tubes after they are filled with specimen is another way to expose them to excessive pressure and cause hemolysis. For related reasons, Ernst has found, sometimes the culprit may be the design of a pneumatic tube system used to transport samples. He was asked to visit a health care facility in the Southwest where the tube manufacturer was being blamed for hemolyzed samples. "We came in and did a thorough audit of what the samples were being subjected to, and we eliminated everything except the pneumatic tube system. We watched the phlebotomists draw blood on morning rounds, and we drew two samples of the same type of tube but walked one sample down and pneumatically transported the other one." That's how they ascertained that the pneumatically transported samples were more susceptible to hemolysis, and they devised a measure to fix the problem. "We found the pneumatic tube system had really dramatic drops and turns, so we recommended they add better padding to the canisters."

Taking a blood draw from an IV start is often thought to be an efficient way to save time and avoid subjecting patients to another venipuncture, but it's the biggest factor contributing to high hemolysis rates in emergency rooms, Dr. Kiechle says. "It's driven by a need to move patients through the process of registration and get them gowned up and ready to go to surgery or early admission or some other process such as chemotherapy. And the phlebotomy activity usually takes place when they put in the catheter and collect blood into a syringe."

The amount of hemolysis will depend on the gauge of the needle, he adds. "If you use a 24-gauge needle you'll get 100 percent hemolysis; if you use a 21-gauge needle you'll get four percent. If you're having problems with hemolysis, you're probably using a needle with too large a gauge or too small a diameter. The manufacturers offer vacuum tubes with full pressure or partial pressure, so the other issue is that if you are using that small diameter needle and forcing the blood into the test tube, you're going to hemolyze many more red blood cells than if you use one with not so much pressure. So using large-gauge needles and partial-pressure tubes are ways of avoiding the problem."

In a recent case at Dr. Kiechle's hospital, the patient's iStat potassium, as tested on a whole blood specimen, was 4.1 mmol/L, which is in the normal range, but when a different serum specimen was tested upstairs in the clinical lab as part of an electrolyte panel, the actual value was 2.5 mmol/L, which is low. "So here we had hemolysis occur when collecting whole blood for the iStat through too small a needle and a full vacuum tube."

Unfortunately, while the nursing staff in a hospital may believe they are saving the patient a second procedure, they could be delaying test results by an hour should those samples be hemolyzed, Ernst says. The CDC says it is a best practice not to draw blood during an IV start, and Ernst believes that, ideally, draws from an existing IV should be avoided as well.

At Sarasota Memorial Hospital, the laboratory found a way to translate these principles of avoiding hemolysis into concrete process improvement steps in the emergency department and throughout the hospital. "With Lean, you look at every possible way to improve," Harris says.

Following the observation phase of its process improvement and based on BD's recommendations, the hospital implemented changes in blood collection policy. Nursing educators and the laboratory developed a standardized protocol including "best practices": ensuring alcohol is dry before inserting the needle, reducing tourniquet time to

less than one minute, following the CLSI order of draw and filling tubes to the correct blood-to-additive ratio, gently inverting tubes to mix the blood with additives, and using a separate blood collection site when doing a re-draw.

A step-by-step “tip sheet” was developed and disseminated throughout the ECC and the nursing units, illustrating the best-practices process steps for blood collection and order of draw. In addition, the laboratory stocked different BD products for more effective draws through an IV catheter and for ensuring that tubes are filled with the correct blood-to-additive ratio.

By having BD come in to explain hemolysis and how to avoid it, and by making it a hospital initiative rather than one run by the laboratory, the process improvement team was able to get better acceptance from the nurses, Rickard says. “We actually had BD do the education, so it wasn’t the laboratory telling the nurses how to do it. It was the facility doing it, and it was based on the manufacturer’s recommendations.”

The hospital saw results immediately. “Just from our first meeting, the catheterization lab went back to their area and implemented the correct order of draw. And their hemolysis rate came down about three percentage points just from that. Then the nurses in other units started telling other staff about the order of draw and how it would lower their hemolysis rates too. So we started to have a nursing staff that felt empowered to get hemolysis under control.” Helped by one-on-one demonstrations of standardized blood collection practices housewide and in the ECC, the nurses became enthusiastic about performing draws correctly. “They had never had a formalized program on how to draw blood specimens and they wanted to do it right,” Rickard says.

But one roadblock remained. “The nursing staff still thought they were saving the patient a stick when they drew a sample from the patient’s IV in the ECC, and they continued to go on and draw the ‘rainbow’ of tubes”—a vial of every color—“at the time they initially started the patient’s IV.”

“A lot of times, the ECC nurses think starting an IV and drawing a rainbow for a possible test order is the best-case scenario for the patient” because it avoids a second venipuncture, Rickard explains. “But we found that the key reason for delay in turnaround time at the ECC was hemolysis from that initial draw. Plus those specimens are delayed while waiting for orders.” The laboratory realized it had to convince nursing to change what had become a standard practice: drawing blood at the IV start.

How did the laboratory manage that? “With data,” Harris says. Taking the value-added and workflow analysis, “we showed if they drew a rainbow before they did the actual lab orders, it increased their turnaround time by 25 minutes. We talked with the medical director of the ECC, because he didn’t understand why drawing ahead of the order would create a delay. But once we showed him the data, he was all on board, and actually spearheaded a project with the ECC to do specimen ID and bedside bar coding when they do the draws. The main goal is to have the orders entered first.”

The ECC in cooperation with the laboratory implemented a pilot project. A phlebotomist was assigned to perform all blood collections in two sections of the ECC for three months. “We had a drastic decrease in hemolysis in specimens coming out of the ECC, and that’s what convinced them that it really made a difference.” The nurses started taking fewer specimens at IV starts, and began using a different cannula that was less subject to hemolysis, Harris says.

As a result of Sarasota’s process improvement program, the ECC hemolysis rate, which was running about eight percent before the program started in June 2009, has averaged 0.88 percent from April 2011 to June 2012, while the hospital-wide rate has dropped from three percent to an average of 0.86 percent. According to Harris, based on a model created by Frost & Sullivan health care economists in conjunction with BD, which calculated the impact in terms of cost, lost time, and patient shortfall, the potential savings for the hospital was $3.7 million in avoided costs through its process improvement program in hemolysis. Conservatively estimated, the model showed, the improvements would save an average of $2 million to $3 million per year.

That was a pleasant surprise even to the process improvement team, Rickard confesses. “We approached this project more from a quality standpoint than from a financial standpoint,” she says. “We were thinking collection supplies, a little bit of nursing time, a little technologist and phlebotomist time” would add up to something modest. “We didn’t take into account how much an ECC bed was costing, how long hemolysis was delaying getting the patient to the floor, what about that person waiting out in the lobby, and the doctors’ time. I was totally blown away by all the information that was rolled into the analysis to show how much we were saving.”

“One of the reasons we started on the conference circuit with this is that, for years and years, laboratory people have expected two things,” Rickard adds. “First, you’re going to have hemolysis when somebody outside the lab draws blood, and second, you’re always going to have that—it’s something you cannot improve. So we wanted other labs to know we’ve broken the feeling that this is impossible. Laboratories *can* significantly improve their hemolysis rates, and they can even get their hemolysis rates down to unheard-of levels.”

Sarasota’s success can be duplicated anywhere, Ernst believes. “They have a method, they have a strategy, and they have a proven success with their strategy.” If every facility worked to educate staff on how hemolysis occurs and the cost to the patient and hospital of doing nothing, “then there would be more cooperation across the spectrum of health care professionals to reduce hemolysis. I think if people know, then they will make the adjustments in their technique.” Proper and comprehensive training is the key, he adds.

But process improvement in blood collection is not something that can be done on a one-time basis, Dr. Kiechle warns. “The minute you stop doing a really good job of training hospital staff in correct blood collection practices, you’re going to find hemolysis increase. Any time you find phlebotomy being done in a really high-pressure area where nurses are extremely busy and they may not have the time to devote to take care to do things correctly, there are going to be problems. And somebody has to raise the red flag.”

“Everybody and anybody with success stories in reducing hemolysis needs to talk about them to get their story heard,” he adds. “Hemolysis is an ongoing problem and it needs continuous vigilance.”

Anne Paxton is a writer in Seattle.