Challenge and change in blood bank systems marketplace

Access interactive guide

September 2013—From future innovations to tighter regulations, seven users and marketers of blood bank software shared their perspectives on the blood bank systems marketplace with CAP TODAY. Here and on the following pages is what they told us. Beginning on page 20 is the 2013 guide to blood bank information systems.
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In what areas do you think blood bank vendors should be concentrating their efforts, as well as R&D money and resources, in the future?

Meghan Delaney, DO, MPH, assistant medical director, Puget Sound Blood Center; blood bank medical director, Seattle Children's Hospital; and assistant professor, University of Washington: For me, the area would be the transfusion service lab. It's important that vendors focus on being able to handle more complex blood types, including red cell genotyping results, so the record is clear regarding how the results were obtained. We, in the transfusion world, have been undergoing a very slow revolution in typing; we're doing more DNA typing to predict minor blood group types. I don't believe the computer systems are ready to handle this from an operational perspective.

Nicholas Bandarenko III, MD, director of transfusion services and associate professor of pathology, Duke University Medical Center: I think we need to incorporate immunohematology reference testing and molecular red blood cell phenotyping. Right now we have to come up with workarounds or manually enter data, sometimes creatively. I think blood bank vendors should concentrate on products that fit the more complicated academic centers, but from an economic standpoint they'd probably rather have a one-size-fits-all. Also, in the quest for a paperless transfusion service, I would like the vendors to allow documents associated with specific patients to be scanned so they could be attached to patients' computer records as a PDF.

Jerome L. Gottschall, MD, senior medical director, BloodCenter of Wisconsin, and professor of pathology, Medical College of Wisconsin, Milwaukee: It would be valuable if blood bank vendors could continue to improve their integration with the electronic medical record systems in hospitals to be able to capture useful data more effectively and efficiently and in real time—for example, who's getting the product, what were their lab parameters, who's the ordering doctor—and to integrate that data more easily. It would also be helpful if vendors could track inventory so we could improve the ease of movement of products through the supply chain from the blood center to the hospital to the patient and be able to connect all those dots more easily. There's no reason that can't be done.
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What one or two areas of blood banking are of utmost importance to you, as a vendor, for future development?

Scott Dustin, vice president of sales for software business unit, Haemonetics: We have a stake in every step of the blood-management process, and we're putting a tremendous amount of R&D effort into better integration of our devices and software solutions across that continuum. For example, we are working on linking our transfusion software back to our blood establishment computer systems to achieve the following scenario: When a patient is transfused with a blood product, the hospital automatically notifies the blood center that this specific unit of blood was used on a patient today. The community blood center uses that data to identify the donor. It notifies the donor that 'the unit of blood you donated 10 days ago was used today to save a life; and by the way, we have a mobile coming to your area in four weeks, when you'll be able to donate again.' In addition, we're certainly looking at cellular therapy; we have solutions in that space, and there are huge advances being made there.

Brian Keefe, director of laboratory sales, Psyche Systems Corp.: We're serving a niche that comprises the smaller hospital blood banks, many in rural areas, that don't have computerization of any kind. We're focused on giving these hospitals an option so they can be compliant with things like ISBT 128, and then having some of the checks and balances they need to ensure the safety of the blood supply. This includes being able to keep an electronic inventory using bar coding, being able to keep an electronic patient history record, and being able to execute basic checks and balances to look for things like type discrepancies, workup discrepancies, and positive patient ID—just eliminating some of the errors that can happen when you're using a paper-based system.
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What do you think has been the net effect of the FDA implementing tighter regulation of blood bank computer systems two decades ago?

Dr. Delaney (Puget Sound Blood Center and Seattle Children's Hospital): I wasn't practicing two decades ago, but I think there are probably more places doing electronic crossmatch, which allows blood banks to move more towards automation. Patient safety is all about hard stops and not allowing humans to make the kinds of errors that we all make. So I think a measure of safety has been achieved by making the computer responsible for an algorithmic approach to letting blood leave the blood bank in a safe and efficient manner.

Raymond D. Aller, MD, director of informatics and clinical professor in the Department of Pathology, University of Southern California: I think the consensus in the field is that the progress in developing blood bank software has slowed way down relative to other areas of laboratory software over the last 20 years. Whenever changes are made to blood bank software, those have to be reviewed and approved by the FDA, which is a process that's not present for most laboratory software.

Dustin (Haemonetics): It's fair to say that regulation has slowed the development of blood banking software. But what's more important at the end of the day—that you've got the coolest, newest bells and whistles, or that you've got the safest, best product going to the right patient at the right time? We don't have customers clamoring for the next release and the next release, because they have very strict standard operating procedures that have to be modified when they put in a new version of software that's an FDA-cleared product. And they have to validate those procedures, and that all takes time. They want to be sure that it's worth their effort. FDA regulation has absolutely, unequivocally made the industry safer, and anyone who claims that's not true is myopic.

Brian Forbis, director of business and product development, Blood Bank Computer Systems: I believe the net effect is an evolution of the relationship we have with our clients, going from a vendor-client relationship before blood establishment computer software regulation, to more of an integrated partnership, because we're subject to many of the same regulations and have to interact with the same regulatory agency.

Dr. Bandarenko (Duke University Medical Center): On the negative side, vendors may be less willing to develop blood bank software solutions because those products are subject to FDA 510(k) clearance, and this can really slow down how they respond to the needs of the market. That's a problem because it leaves us with fewer choices, making it difficult for laboratories to find the best fit. For example, our new hospital information system has no blood bank package. On the positive side, I think the FDA has created an expectation that, ultimately, patient safety is related to the accuracy of blood establishment computer software, which has increased safety for patients and laboratories

Keefe (Psyche Systems): It's definitely pared down the solutions that are out there, and it's made those few existing solutions very, very solid and safe. There's no question that the cost of developing, maintaining, and supporting blood bank applications has skyrocketed. With other vendors' systems, you're into the $100,000-and-up market. There are a lot of labs out there that could never justify that. But for the labs that do biologics testing, cord blood processing, that warrant systems that are very complex, you need all those bells and whistles. Otherwise those systems would not be as safe.
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Can you cite examples of where FDA regulation has made blood banking software safer or less safe, or both?

Keefe (Psyche Systems): One of the requirements of the FDA relates to how software is developed and how best practices have to be put in place. You end up with software developed in a very controlled environment and that's tested rigorously. So the FDA has made it much safer, because they've eliminated a lot of the things that can fall through the cracks when you're talking about releasing new software, such as bug fixes and beta testing. An example of functionality we had to validate was the ability to compare blood typing results on a specimen versus the blood type the patient has on file historically in the system. Does the ABO type on this current specimen match what the patient had the last time around? Does the system prevent the user from issuing a component on a patient where there's no record of that component ever being worked up on that patient? The FDA doesn't say you must have these features, but if your software does, you have to show that you put that functionality through a risk analysis and that it works in a foolproof manner.

Forbis (Blood Bank Computer Systems): I believe the FDA has had a significant impact on the safety of blood banking software. One good and recent example is the regulation classifying medical device data systems as class I devices, which was issued in February 2011. I think there is still some confusion about how the regulation is being implemented in our industry, but the benefit is that it gives some direction as to how to go about developing these types of systems. Better design controls will help ensure that better and safer systems are created.

Dr. Gottschall (BloodCenter of Wisconsin and Medical College of Wisconsin): Working with a number of organizations in the RFID Consortium, we've had our own experience with the FDA. The agency has been very helpful in the development and approval of a 510(k) clearance for radio-frequency identification technology to track and trace blood products, providing guidance and ensuring that the technology works correctly. That's an example of how the FDA has made blood banking software safer.

Dr. Bandarenko (Duke University Medical Center): I think FDA regulation ensures that the software used by blood establishments meets specific standards and contributes to the safety of blood. As the science and practice of transfusion and blood collection become more complicated, I would urge the FDA and software vendors to become more expedient at incorporating enhancements so we can rely on the use of software rather than manual data entry. If we have to do workarounds while waiting for software enhancements to receive clearance, that's a period of time when there are vulnerabilities.

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Interviews conducted and edited by writer Jan Bowers.