In the News

CAP TODAY

ARCHIVE: August 1998
Cover Story

Transfusion oversight out of the bag

Anne Paxton

Despite the best precautions, myriad unexpected situations can arise in blood services. A patient's sample might be typed as AB positive and mislabeled as A positive. A unit of red cells might be irradiated but the expiration date not changed. A donor's friend could call and advise the blood bank not to take the donor's blood. A repeat donor might mention that he had taken a cruise down the Amazon River but did not reveal it before because he had stayed on the boat and believes he was not exposed to malaria. An employee could forget to document the temperature of the blood bank refrigerator for three days.

While no one may be injured in such cases, they still qualify as errors or accidents. Do they need to be reported to the U.S. Food and Drug Administration? And more important: What steps can be taken to assure they don't recur?

These questions were the focus of a June conference on error and accident reporting, sponsored by the American Association of Blood Banks. The conference brought together hundreds of blood bank managers and staff to discuss issues and trends in reporting. "It was a most successful conference," said AABB president Ed Snyder, MD, professor of laboratory medicine and director of the blood bank at Yale University and Yale-New Haven Hospital.

The quest to improve the nation's blood supply has been one of the leading public health stories of the decade. Following a crisis of public confidence in the 1980s about the safety of receiving transfusions, blood banking has fought to assure the safety of blood products amid a wide range of threats. But new technologies to detect HIV, hepatitis, and other pathogens have only been part of the solution. As the AABB conference showed, safety lies in the details. The lesser- known story of quality assurance resides in the efforts of thousands of blood banking employees to keep errors and accidents to a minimum.

The role of the FDA continues to be a central one. The scare over HIV

contamination in the 1980s led the agency to launch an extensive investigation of blood banking's quality and safety. In 1991, the FDA's Center for Biologics Evaluation and Research issued a memorandum notifying blood establishments of the increasing number of product recalls due to errors and accidents in manufacturing. Two years later court-enforced consent decrees were imposed on many blood centers, including the American Red Cross.

[Back to top]

Although the regulatory scrutiny resulted in improved transfusion practices, "A majority of blood collection is unfortunately still under a consent decree," Dr. Snyder said, adding that blood banks' responsibility to report to the FDA was broadened by the court mandate, but this did not affect the availability of blood products. The Red Cross, which is a member of the American Association of Blood Banks, just completed a five-year, $287 million overhaul and is looking to have its consent decree lifted.

The pending FDA proposal to expand blood banks' error and accident reporting was the major incentive for the AABB conference. Licensed blood banks-those that are judged to engage in interstate commerce, which is just under half the nation's blood facilities-are already subject to reporting requirements. The FDA rule proposed last September would require unlicensed blood banks and transfusion services to conduct the same kind of reporting.

The FDA once performed inspections of transfusion services, but since 1980 it has adhered to a memorandum of understanding with the Health Care Financing Administration, agreeing to divide responsibility for regulating blood banks.

"By its own choice, the FDA has focused on collection and the components in the bag," said Kathleen Sazama, MD, JD, regional medical coordinator for laboratory medicine at Allegheny University of the Health Sciences, Philadelphia. Dr. Sazama is also a member of the AABB board of directors and the CAPTransfusion Medicine Resource Committee. To use its resources as efficiently as possible, she said, the FDA has left oversight of hospital-based transfusion services to HCFA even though it retains jurisdiction. HCFA is in charge of CLIA regulation of the facilities, but it relies on FDA regulation for reporting of errors and accidents.

The Food and Drug Administration received more than 100 comments from various groups expressing concern about its pending proposal. Agency officials are preparing responses to the issues raised in public comments. The FDA expects to publish the final rule in December and implement it 180 days later.

The AABB was among those submitting detailed objections, although it does not take issue with the basic objective of the proposal. "The association is in no way opposed to the FDA's initiative," Dr. Snyder said. "We are in complete support; what we want is more of a fine-tuning of the process." Heading the AABB's list of desired changes: a shift from what it considers a punitive approach that singles out errant blood banks to an emphasis on improving the quality and safety of the blood supply.

[Back to top]

Specifically, the AABB urged the FDA to require reporting to an independent third party, with trends passed on to the FDA-in part to avoid creating a disincentive for facilities to report out of fear of further regulatory scrutiny and possible enforcement action. The association supports the goal of identifying errors and accidents but wants emphasis on quality systems and prevention through system corrections of underlying causes. The AABB's own quality program stresses quality based on prevention, not detection.

Another key issue to the AABB is the lack of a practical, uniform system for capturing and causally analyzing transfusion events. The association believes the FDA should delay its reporting initiative until tests on various alternative models of error and accident reporting can be completed. How the information collected will be used is an additional concern. The AABB urged the FDA to ensure the reports help identify trends and develop early warning guidance to the field offices and the blood industry.

The AABB wants to ensure that the FDA gets the big picture when errors and accidents are reported, rather than getting bogged down in too much detail, said Dr. Snyder. "The classic example is if a box of plasma breaks and it contains 26 units, would there be 26 errors?" Another problem the AABB sees with the proposed rule: It imposes a substantial paperwork burden on blood facilities in an era of shrinking resources. However, facilities that are AABB accredited are required to follow the association s quality system essentials. "These facilities should be well on their way to being compliant with the rules being proposed," Dr. Snyder added.

Few are predicting the FDA will back off substantially from tighter reporting requirements. Dr. Snyder described the proposed regulations as "part of a continuum" of moving the nation's blood supply to increasing levels of safety and adequacy. FDA officials indicate Congress has maintained pressure on the agency to keep blood banking regulation strong. When they hear adverse information about the blood supply, "Congressional staffers will say 'When did you know, and what did you do about it?'" said Boyd Fogle Jr., director of the FDA's Center for Biologics Evaluation and Research, Division of Inspections and Surveillance.

Only a few days after the AABB conference, the FDA unveiled a Blood Safety Action Plan to respond systematically to oversight reports from congressional committees, the General Accounting Office, and other government bodies. FDA teams will work on plan goals in six areas: updating blood regulations, reinventing blood regulations, emerging infectious diseases, compliance of plasma fractionators, notification and lookback, and emergency response.

The regulatory system has also been working overtime on recalls of blood products. The number of recalls more than doubled between fiscal years 1996 and 1997, according to FDA statistics, which show a rise from 707 to 1,519. Because each recall can involve hundreds of units, Fogle pointed out at the AABB conference, the number of blood components-that is, blood units, vials, diagnostic kits, tubes, and blood bags-that are recalled is considerably higher.

Only 30,225 blood components were recalled in fiscal year 1996, while more than 10 million were recalled last year. More than 9 million of those were Class II recalls, signifying that a health hazard exists that is medically reversible but could be serious. Fully 125,693 were Class I, life-

Blood banking leaders downplay at least part of the increase. There recently have been massive recalls of blood components or plasma derivatives because of fears that donors had Creutzfeldt-Jakob disease, the human version of "mad cow" disease, said Dr. Sazama. She considers these recalls overcautious given the lack of evidence that the agent of CJD is transmissible via transfused blood components. "Although there has been an increased number of withdrawals due to CJD risk factors, these have not been classified by the FDA as recalls." explained FDA safety officer Sharon O'Callaghan. Dr. Sazama noted that this has led to a shortage of vital biological materials, such as albumin and immunoglobulin, forcing clinicians to use second-line alternatives. A second factor triggering the increase has been a redefinition by the FDA of which occurrences would demand a recall, Dr. Sazama said. "Basically, they are finding a broader base of rationales for recalls.

My personal interpretation is that there is not a huge problem being identified, but the FDA is taking a much more conservative approach about the potential for harm." In her view, the recall actions have been more conservative than necessary.

"We're looking at the increase as much as anybody else," said Steve Masiello, acting executive director of CBER's Office of Compliance. He noted that there are many reasons why the recall numbers are going up and cites requirements of the consent decrees as one cause. The Red Cross, for example, is required to initiate a recall when a problem unit is encountered in a retrospective review. "A number of the recalls are from past problems and don't represent current issues," Masiello said. He believes both the FDA and industry are getting better at identifying problems. And "from the error and accident side," he added, "firms are reporting in a more timely manner."

The impact of recalls varies according to the blood product, Dr. Sazama noted. Because platelets are usable only for five days, and red blood cells for 42 days, recalls of these products have no effect on their supply-the basis for the recall often takes longer than that to be discovered. "So when the recall is issued, the red blood cells or platelets have often already been transfused," explained Dr. Sazama. "It's really an information sharing with patients after the fact for transfusion services like ours."

[Back to top]

Plasma, on the other hand, if frozen, is available for transfusion for up to a year. So when a problem is discovered, it is far more likely to be felt in plasma derivatives because they still have the potential of being removed from distribution.

When the proposed rule takes effect, AABB officials said, it will represent a major change for thousands of hospital blood banks and transfusion services. "Licensed facilities, primarily blood centers, have been living with much more intensive FDA regulation and oversight for many years," Dr. Snyder pointed out. Although they have internal reporting systems, hospital blood banks and transfusion services will be facing more stringent requirements, "and they have a way to go." Laura Jean Stanley, MT(ASCP), SBB, is chief technologist at the Stanford Medical School Blood Center, a facility that is registered but not licensed. While her blood center does have a compliance program and documents all errors and

accidents, she believes few transfusion services understand how to set up such a program. "A lot of them are not even aware they will be affected" by the proposed rule, she said.

"You'll see a whole spectrum" of impacts from the FDA's proposed rule, depending on the size and involvement of transfusion services in quality assurance policies and procedures evolving over the last decade, predicted Dr. Sazama. In large transfusion services that employ dedicated transfusion specialists, such as at Allegheny University of the Health Sciences, "I expect it will be just one more step in our activities." In many smaller facilities, though the transfusion director is primarily engaged in other areas. The degree of adjustment "will depend on the level of interest and dedication that person has," said Dr. Sazama.

AABB conference director Jennifer Rhamy, MT(ASCP), SBB, HP, agreed that transfusion services did not receive clear regulatory direction in the past. Rhamy, who is internal product training and communications coordinator for COBEBCT Inc., Lakewood, Colo., hoped the AABBconference could help clarify expectations.

The sentinel event system of the Joint Commission on Accreditation of Healthcare Organizations was included in the conference agenda, said Rhamy, because, "in my mind, it is an excellent example of an existing error and accident system with a long history of studying hospital system incidents. Additionally, our hospital members must maintain compliance with this agency, as well as with the new regulation, so it is essential information. Error management is a system issue impacting multiple regulatory agencies."

JCAHO's sentinel event policy defines an adverse sentinel event as an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. The term "sentinel" is used because the event sends a signal or sounds a warning that requires immediate attention, said Ann McMican, MT(ASCP), associate quality officer at the University of Rochester Medical Center.

A "hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities" is specifically included in the JCAHO sentinel event list. The JCAHO's Accreditation Committee reviewed 200 sentinel events in March and found that eight (four percent) were transfusion-related deaths.

[Back to top]

"Hospital transfusion errors occur at an approximate rate of one in 200,000 components transfused, even with the best practices," McMican said, noting that the vast majority of such errors have not resulted in adverse outcomes. The JCAHO, which accredits all hospitals that treat Medicare patients or train residents, takes these events seriously. "The Joint Commission doesn't think any aspect of the transfusion system is outside the blood bank's control," McMican said.

McMican believes there is value in reporting systems, especially when they can bring together information about rare incidents from separate institutions that would not reveal a pattern when viewed in isolation. For example, in New York State, an air embolism was reported at one institution. But it was discovered through error and accident reporting that four or five such incidents had occurred at other hospitals. "When you get

data from several different facilities, you are able to see where low-level trends might be taking place," she said.

Transfusion medicine services should view all reporting as an opportunity to improve their systems and improve safety, not as a barrier, McMican added. She described an incident in which an outpatient without an armband was addressed by her presumed name and failed to object, possibly due to anxiety, confusion, or hearing problems. The outpatient was not identified correctly, which led to a transfusion error.

[Back to top]

"Investigating that accident helped improve the bedside ID check by including an armband," McMican said.

An integral part of JCAHO's policy is the root cause analysis, "a process for identifying the basic, causal factors that underlie performance variation," explained McMican. Working from the proximate or immediate cause of an incident to the common or systemic cause, root cause analysis is intended to help systems be redesigned to reduce risk.

She described another case in which the root cause turned out to be a flawed equipment backup policy. A young, outwardly healthy person slumped to the floor in the blood center, and staff sent for the code cart to resuscitate the patient. The medical center had a system to share EKG monitors and defibrillators among low-risk areas; the equipment did not have to be on every cart-only the high-risk carts. "When they went to the partner unit to get the equipment, it was not there," McMican said. The code cart had been moved to another floor, and the patient's resuscitation was delayed. Nobody had thought about the possibility of a shared cart being unavailable, McMican said, but the same situation could recur if there were a shared cart and two simultaneous codes. Now all carts have the necessary equipment for full resuscitation.

In the past, the terms "error" and "accident" have often been used interchangeably, but the FDA rule proposes to distinguish between them based on whether the incident was within the blood bank's control. "You can call the event an 'incident' or 'unexpected.' Some words may have less emotional significance than others," said the AABB's Rhamy. An error is defined as an incident that could have been avoided if procedures had been followed appropriately. An accident is defined as an incident outside the control of the blood bank. Rhamy noted that, "Problem resolution tactics may differ based on the root cause of the event."

Howard Taswell, MD, former medical director of the transfusion service of the Mayo Clinic, and the pioneer of process improvement in transfusion medicine, first defined error as "any deviation from standard operating procedures," said Dr. Sazama.

Dr. Sazama situates error and accident reporting within a broader context of process improvement in transfusion medicine. The purpose of the AABB's quality system essential on incidents, errors, and accidents is to define a process for capturing and classifying event information and an approach to problem resolution.

[Back to top]

In her AABB presentation, Dr. Sazama stressed that systems for identifying errors and accidents are necessary to implement process improvement for the benefit of transfused patients. Among the tools and techniques she cited as helpful in quality improvement for nonnumerical data are affinity diagrams, benchmarking, brainstorming, cause-and-effect diagrams, flowcharts, and tree diagrams. For numerical data, tools include control charts, histograms, Pareto diagrams, and scatter diagrams.

Mandatory reporting of errors and accidents to the FDA provides "a high level" of assurance that events are being captured, Dr. Sazama maintained. But the FDA's O'Callaghan noted that some incidents don't affect safety and are not reportable. As she put it: "Not all errors and accidents are created equal."

The most common error/accident, said O'Callaghan, involves donor suitability. (See "Breakdown of reportable errors/accidents in blood establishments.") The blood bank obtains post-donation information that would have deferred the donation had it been known. Since 1991, when the FDA issued a guidance document providing that donors be asked questions orally, "We've started seeing an increase in these [error/accident] reports," O'Callaghan said.

The top four factors in the post-donation category last year were:

- donor received a tattoo, ear or body piercing, needlestick, or transfusion
- donor traveled to a malarial endemic area
- donor became ill with mononucleosis or chicken pox, not hepatitis or AIDS, after donating
- donor had a history of cancer.

In 1998 data, O'Callaghan noted, travel in a malarial endemic area switched with tattooing and body piercing to take the No. 1 spot. Quality assurance programs to prevent these errors/accidents must cover the gamut of issues, O'Callaghan stressed, in part because errors can spring from unexpected sources. For example, a repeat donor described being told by a previous donor screener that it was okay to donate even though she recently had her ears pierced, as long as she removed the earrings.

This lapse in quality assurance pointed to a need to better train screeners to assure they understood how high-risk behavior related to blood purity. The process for evaluating post-donation information reports should include evaluating trends, as well as periodically reviewing donor records, donor history questions, and donor screeners, and interviews with donors *themselves*.

An important key to whether an incident is reportable, O'Callaghan said, is whether the blood product was made available for distribution, as well as where the incident occurred. For example, if an incorrect sample is used for a crossmatch, the event would be reportable only if the unit were made available for a patient. If the blood bank issued a unit intended for the wrong patient, a reportable error or accident has occurred. If the unit is transfused to the wrong patient on the floor, a reportable error or accident has not occurred.

"Just capturing the data is nothing," said Linda Myers MT(ASCP), vice president for technical services at the South Texas Blood and Tissue

Center, San Antonio. "The most important thing is what you do with the data you gather, and how that analysis is funneled into a quality improvement process." Myers, whose blood center was the first to receive ISO 9002 certification, in October 1996, spoke about identifying errors at the AABB conference.

In her facility, error detection stems from several sources: an internal error reporting system, internal quality assurance audit findings, results of external audits, quality control test results, the complaint system, and customer surveys. The internal error reporting system involves systemwide standard operating procedures in which all employees are trained. Myers stressed that in order to work, it must be nonpunitive and focus on process, not people. The facility systematically uses employees to conduct internal quality audits, which help ensure that when external audits occur, they will confirm what blood bank employees already know, Myers said.

Errors and accidents provide valuable information, said Stanley, of the Stanford Medical School Blood Center. "When you discover an error, you should consider it a 'gem,' an opportunity for improvement," she maintained.

[Back to top]

Immediate action is designed to prevent consequences and may include notifying customers, quarantining or destroying the product, recalls, retesting, removing the equipment or supplies, and discontinuing the procedure. But equally important are error investigation and evaluation and corrective action.

Stanley described in her AABB presentation short- and long-term corrective action. Interim measures in response to errors and accidents might include maintaining control until there is a permanent fix, adopting a two-person check, increasing monitoring, slightly modifying standard operating procedures, and retraining. Long-term action could include redesigning processes to correct a system problem, retraining or taking disciplinary action for personnel problems, and revising or creating new standard operating procedures. Also important are follow-up to monitor the effectiveness of corrective action, error prevention to avoid similar problems, and trending. By comparing data to that generated in previous months or quarters, for example, blood facilities can monitor the effectiveness of their corrective actions. An audience member gave an example of how what appears to be a personnel problem may sometimes be a system problem requiring different corrective action. In her facility, employees were required to use 24-hour military time, and many made errors. Efforts to retrain employees did not work, said the blood banker. The solution: installing a digital clock that displayed military time.

Errors and accidents in blood banking need much more attention from researchers, confirmed the AABB's Dr. Snyder. Other industries have already developed far more scientific approaches to error and accident analysis. Dr. Snyder believes blood banking would benefit from sociological as well as marketing research. Dr. Sazama agreed that the research gap is "absolutely huge." Although there have been limited attempts at prospective studies, most of what has been done is anecdotal and observational, she said.

The reporting of errors captures important data about mistakes and is a

necessary first step, but I'm not sure that will address what we need," Dr. Sazama stated. In order to conduct in-depth evaluations and root cause analysis, the focus must be on not only the worst outcomes, but also the close calls-the "near errors," she said.

In other industries where safety is imperative, such as air transportation and the nuclear energy industry, "the really fruitful information comes from the 'oops,' or the near miss," explained Dr. Sazama. "You don't need an actual airplane crash. That's the worst time to figure out what went wrong." When those near-miss data are systematically collected in blood banking, she said, they will help give researchers a truer understanding of the source of, and potentially how to interdict, error.

Editor's note: Boyd Fogle Jr. had left his post at the FDA at CAP TODAY press time.

Anne Paxton is a freelance writer in Rockville, Md.

[Back to top] | [Back to CAP TODAY's Current Issue]
[Back to CAP TODAY Archive]