Transfusion, Vol. 41, No. 7, 964-967, July 2001

COMMENTARY

Is it time for blood banking to take off?

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ABBREVIATIONS: ACBSA = Advisory Committee on Blood Safety; ASAP = Aviation Safety Action Partnership; FAA = Federal Aviation Administration; GAIN = Global Aviation Information Network; GMPs = good manufacturing practices; MERS-TM = Medical Event Reporting System for Transfusion Medicine; QA = quality assurance

Those of us in the field of blood banking and trans- fusion medicine have spent much time and effort and much of our resources over the last several years responding to and, in large measure, incorporating the concepts of quality assurance (QA), total quality management, and good manufacturing practices (GMPs). Acceptance of these concepts has now become more rapid and pervasive, and we have come to acknowledge them as the way that we conduct our operations. The 20th edition of the AABB's *Standards for Blood Banks and Transfusion Services*[1] embodies the "quality system essentials" for our field, which incorporate internationally recognized quality standards that have assisted many organizations in finding ways to continually improve. While further efforts to inculcate these principles of quality management lie ahead of us, more than one blood banker undoubtedly smiled in recognition that many of the concepts suggested by the Institute of Medicine to reduce health care errors in this country[2] closely paralleled steps we have already taken in recognition that our processes need to be error-proof.

The concepts we have been working toward to help ensure that our output meets our customers' requirements were not invented by us. We have learned much from the seminal work of Deming and his disciples about how to structure systems that can deliver what is required with the level of certainty expected by our patients, our regulators, and our profession. We believe it is time to borrow again from others who are equally committed to safety and who have learned how to manage systems in a regulated environment, to ensure that the systems of scrutiny embodied in the blood banking system work

cohesively and constructively toward that end.

Many gurus of QA have stressed the importance of making compliance (or "quality") everyone's job. Everyone involved must be enlisted in active participation to find better ways of doing a task or to be on the lookout for situations of "noncompliance." When areas of potential trouble or improvement are encountered, these must be reported so that they can be investigated and, if necessary, acted upon. In the reporting of deviations, many behavioral and quality systems experts strongly counsel that punitive actions against the reporter are counterproductive, as they deprive the system of the information needed to solve problems.[3-6] These problems almost always have their roots in the system, and a systems approach is needed to ensure their eradication.[7,8] Whether this involves improving training or revamping the process so that inevitable human error does not lead inevitably to a human catastrophe, sharing the information with others in the field helps to ensure that identical problems are found before they lead to preventable error.

As members of the Advisory Committee on Blood Safety and Availability (ACBSA) of the Department of Health and Human Services, we have been privileged over several recent meetings to hear excellent presentations on how safety is managed in other complicated endeavors. Not only is error-and-accident prevention the subject of much fruitful academic investigation; logical theories have also been placed into practice to simplify and solidify preventive efforts to ensure safety. These applications in the airline industry are particularly enlightening, and we would do well to adopt them in our field.

A forceful example was presented at the April 2000 meeting of ACBSA by the chief pilot of American Airlines. He described a system that closely paralleled one that Kaplan[9] and Battles[10] and their colleagues have been refining for transfusion medicine for several years. The American Airlines self-reporting system, Aviation Safety Action Partnership (ASAP), is based on gathering reports of errors or unexpected trouble (deviations) encountered by the airline's employees. The airline evaluates the problem and decides upon the most appropriate corrective action. An important part of the system comes from the special relationship the airline has with its regulator, the Federal Aviation Administration (FAA). Provided that deviations and corrective action captured in the system are reported to the FAA and deemed acceptable, and that any violations are not deliberate or criminal, the FAA has agreed to take no punitive action on the basis of information contained in the report.[11] In addition, specific details of the event (other than the corrective action) are expunged from records once the FAA has acknowledged the adequacy of the corrective action. As a result of the FAA Reauthorization Act of 2000, the FAA recently issued a proposed notice of rulemaking that would protect airlines and their employees from enforcement action for voluntarily reported information.[12]

The success of this effort in improving safety is remarkable. It was reported that less than 0.5 percent of the incidents uncovered through this system would otherwise have been known to the FAA. The encouragement given to the staff to report deviations, the lack of reprisal against persons uncovering and reporting their own mishaps and near misses, and the freedom from punitive action taken by the government have combined to uncover a wealth of opportunities for American Airlines to make flying safer. Others have benefited, also, as data generated by all airlines about safety problems are collated by

the National Aeronautics and Space Administration on a voluntary, nonattributed basis and then periodically analyzed for trends.

This same approach has now been adopted worldwide through the Global Aviation Information Network (GAIN). This is a private, global, industry initiative provided with technical support by the FAA. Its purpose is to improve aviation safety by "promoting and facilitating the voluntary collection and sharing of safety information by and among users in the international aviation community."[13(p 1)] To date, GAIN has successfully developed a number of products and tools that facilitate standardized data reporting and analysis, and it has achieved some success in removing legal impediments worldwide to voluntary, nonpunitive error reporting.

Not all believe that voluntary, confidential, nonpun-itive reporting is the best approach to improving safety. Tort lawyers, steeped in a successful tradition of instigating change through litigation, argue that legal protections against disclosure are detrimental to public safety. Clearly, a measure of trust on the part of the public, and of the regulatory body that represents it, is necessary for the functioning of a confidential reporting system intended to detect systems problems. With the aim of "draining the swamp rather than swatting mosquitoes," the system is geared toward continually searching for opportunities to improve.

The FAA has adopted this approach while under many of the same pressures as the FDA and experiencing a similar degree of public scrutiny. Although the FAA is charged with responsibilities in addition to safety (such as maintaining a complete and continuous system of continuous air transportation for small communities; preventing unfair, deceptive, predatory, or anticompetitive practices; and avoiding unreasonable industry concentration), air safety is its highest priority. The FAA is the watchdog of the industry, without whose clout as a regulatory body the public would have significantly less trust in air travel. When unfortunate events, accidents, or obvious errors occur, these regulators are often called upon to explain what more they might have done to prevent the deviation. Presentations from airline personnel at the ACBSA meeting made it clear that they regard the FAA in the same manner that we approach the FDA, acknowledging its ultimate authority and hoping that the agency will see the world from their perspective. The fact that the FAA has been able to work through the potential problems of congressional overseers second-guessing their efforts and their own understandable reluctance to loosen some features of the control system to make the reporting and correction system viable is a credit to their understanding of the importance of error prevention and their dedication to root-cause analysis.[14]

Can this system work to improve transfusion safety? Today, in blood banking, the FDA imposes the most punitive actions (fines, license revocations, or indictments) only for the most egregious regulatory violations. Furthermore, many blood bankers already have in place systems to identify and correct problems. However, the frequency of significant issues cited on FDA inspection, the continuing situation that over half of the blood collections in this country occur under a consent decree because of past difficulties in maintaining regulatory compliance, and the acknowledgment of the incredibly large number of significant errors throughout the medical system[15] indicate that an alternative system for

dealing with error in our field must be implemented.

Our error-management systems have not been optimized. How many of us have implemented systems that actively seek out problems and reward, rather than pillory, those involved in their discovery? Once uncovered, do our analyses truly root out the underlying system problem, and do we revise our processes to prevent a recurrence, or do we often point a finger at the involved staff and engage in the "blame and train" exercise? Licensed blood establishments are required to report certain occurrences to the FDA; registered and unregistered facilities will soon be required to do the same. The agency reviews these reports for completeness and attempts to distill aggregate information that would be of help to others in preventing similar problems, but to date the volume of reports has been daunting and the utility of information released to the blood community is little. While the publication of recalls and withdrawals may still be necessary, there may be a better way to obtain useful information from FDA-reportable and non- reportable events. Can we take the opportunity to develop an integrated system that would allow all of us, on a timely basis, to learn from the problems encountered by others?

Anticipating that reporting alone will address underlying problems is, of course, foolhardy. However, sharing experiences so that we can all learn from each other and track how we are doing makes sense. Therefore, we would suggest that a new approach to managing error in blood banking and transfusion medicine is needed (Fig. 1).

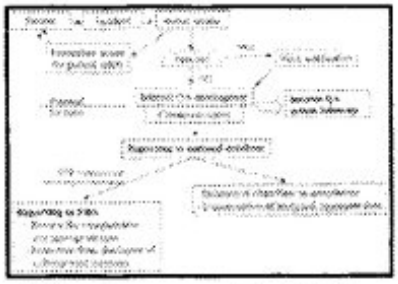

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Fig. 1. Proposed incident-response system. Any deviation from normal or expected procedures or outcomes discovered by a facility would generate an initial, internal review. The facility would investigate all incidents and institute appropriate remedial or corrective action. All incidents and the results of the investigations into them and their remediation would be reported to a national data center in a confidential manner to allow for analysis, tabulation, and dissemination. The FDA would continue to receive reports of incidents it deemed appropriate, but these reports would pass through the national data center. Reports to the regulatory body based on self-discovered incidents would not lead to punitive action and would be maintained with confidentiality. Patients would be advised if the incident had placed them at potential risk.

The Medical Event Reporting System for Transfusion Medicine (MERS-TM),[9,10] now being piloted in several locations, has shown the benefits of nonpunitive, confidential reporting of deviations. This approach should extend from the level of the involved staff up to the regulatory bodies that ensure the safe outcome of our efforts. We propose building on our existing successes and implementing a standardized reporting system based on the MERS-TM model. We propose that Congress fund a national database, preferably through a nongovernmental entity, to accept these reports and analyze creatively and publish regularly the problems encountered in our field. (If we truly are making close to 100,000 reportable errors annually, either we are not learning from our mistakes or we are reporting

mistakes that are not worth correcting.) These reports would be collected in such a manner that identifiers were removed once the veracity of the information was confirmed in a manner similar to the National Aeronautics and Space Administration data collection system.

Uniform criteria could be developed in partnership with the FDA to determine whether a particular incident reported to the database was reportable to the agency. Deviation reports that must be widely disseminated to prevent immediate harm to other patients obviously need to be released by the FDA. The FDA would also continue to ensure that violations of the Code of Federal Regulations are met with an appropriate response. Once the event has been adjudged, redacting from the files the names of the parties and institutions involved would provide assurance of confidentiality and freedom from exposure that was unlikely to yield greater safety. The proposed system would then mirror what has been successfully evaluated in the aviation industry. The regulatory body would receive the information necessary to continue to discharge its important oversight duty. Confidentiality safeguards would undoubtedly increase the number of reported incidents. The FDA, however, would no longer need to serve as the "data warehouse" and "error prevention center" of the industry. Those jobs would fall to the private sector, where they rightfully reside. A body of experts, such as the staff and consultants in the National Blood Data Resource Center, could provide meaningful insight into the problems we encounter.[6] These reporting and analysis systems would mesh nicely with the MERS-TM system at the operational end, where the reports are generated and the solutions put into play. A real regulatory–private partnership in this area, such as exists in the airline industry, could truly improve transfusion safety.

A system such as described here would undoubtedly increase the number of incidents reported, but this can only be good news for a profession dedicated to the safety of transfusion. We know we are not perfect, but, to improve our aim, we need to determine how and why we sometimes miss the mark. Simply noting errors and reporting them will not improve our operations. We will need to utilize our quality management systems to improve our processes and then share these experiences nationally through a system that can fruitfully and confidentially examine and tally them. Hopefully, our implementation of quality management systems will have engendered sufficient trust on the part of the public we serve to allow us to deal with this opportunity creatively, as has been accomplished in the airline industry.

FOOTNOTES

The opinions expressed herein are solely those of the authors and do not reflect the official policy of the AABB or of any institution with which either of the authors is affiliated.

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Received for publication October 27, 2000; revision received January 26, 2001, and accepted February 5, 2001.