

# Changing educational paradigms in transfusion medicine and cellular therapies: development of a profession

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The transfusion medicine profession can be easily compared and contrasted with an early 1900 ironclad ship operating in the rough seas of the 21st century. Without modifying the old ship to today's standards, even the captain and crew will begin to expect the ship to meet its demise. The unfortunate passengers, on the other hand, do not expect that they are on an old obsolete ship and, instead, are innocent victims stuck on a doomed course. The old ironclad ship must change into a sleek cruiser and utilize the latest available technology so that its well-educated and competent captain and crew can safely navigate even the most challenging waters.

The transfusion medicine profession must transform itself into a state-of-the-art ship so that it, like the refurbished ironclad ship, can be set on cruise control through the open seas. The question facing our industry is do we have the courage to utilize modern technology and to commit the funds necessary to develop, implement, and maintain our existence?

It is difficult to plot a steady course into the future because of existing challenges that stand ready to sink our profession, including economic wrangling over regulation, technologic changes, generation conflict, and political differences that threaten our excellence. The primary purpose of this article is to focus on the educational needs that affect all personnel involved in transfusion medicine. In addition, this article will address potential adverse outcomes and investigate possible resolutions to avoid the "sinking ship."

Within the next 5 to 7 years, without a corrective course of action, our profession will be at the bottom of the clinical ladder, remembered more for its demise and tragic ending than for its accomplishments. It is hoped, successful implementation of changes in educational paradigms in transfusion medicine may lead to a renaissance within our workforce—generations working together, each sharing and learning from one another.

## STATEMENT OF THE ISSUE

**T**ransfusion medicine is a worthy and honorable profession, associated with transfusing the "gift of life" from one individual to another. We must address the issue of how to sustain a high degree of professionalism and develop a positive image, given that our profession is currently subject to generation differences, nonstandardized training curricula, economic issues, and a shortage of qualified personnel. Respect for the profession must be earned. *Webster's Dictionary* defines the term "profession" as an occupation requiring advanced training and education.<sup>1</sup>

When one chooses transfusion medicine as a profession, one's motivation is likely to include a desire to be challenged and to perform a variety of tasks. Transfusion medicine is composed of many elements that offer opportunities to interact with the public, such as donor recruitment and collection. It offers academic challenges via resolution of patient problems, whether they be based on serologic or product incompatibility. It challenges the legal minds owing to regulatory and accreditation requirements. Transfusion medicine stimulates compassion and emotion when therapeutic measures result in a positive journey for the patient to wellness and recovery.

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**ABBREVIATIONS:** AACCN = American Association of Critical-Care Nurses; ACGME = Accreditation Council for Graduate Medical Education; ASCLS = American Society for Clinical Laboratory Scientists; ASCP = American Society for Clinical Pathology; CAAHEP = Commission on Accreditation of Allied Health Education Programs; IOM = Institute of Medicine; JCAHO = Joint Commission on the Accreditation of Healthcare Organizations; NAACLS = National Accrediting Agency for Clinical Laboratory Science; SBB(s) = specialist(s) in blood banking.

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In the American medical system, the position with the most responsibility is the medical director. This highly compensated individual must be knowledgeable in transfusion medicine, demonstrate positive leadership skills, and offer support in decisions that are best for patients and other professionals. Large medical centers attract the crème de la crème of knowledgeable medical directors. Rural environments and smaller practices often experience difficulty recruiting and compensating this same level of medical director. With only credentialing and continuing medical education requirements, these facilities may not have the knowledgeable leadership to implement the latest standards of practice.<sup>2,3</sup> The future solution to this weakness in our profession may be a requirement to engage a consulting pathologist with *documented expertise* in transfusion medicine.

Nurses and administrative-support personnel (secretaries, clerks, etc.) are valuable assets in fulfilling the mission of transfusion medicine. Nurses are licensed, thus being recognized both legally and formally, to practice in a designated professional niche. They often have either no defined or very minimal required educational training in transfusion medicine, however, to assure their competency in the operation of donor centers, hospital blood banks, or perioperative services. Because the profession fails to address its deficiencies or set high standards for excellence, a potential for minimal performance is created.

There are no known standards for competency assessment or continuing education for administrative support personnel.<sup>4-7</sup> A paradigm change would define minimal educational or competency recommendations for administrative support, for example, required attendance at annual training in good manufacturing practices applicable to job descriptions.

Medical technologists, who are specialists in blood banking, and medical laboratory technicians, who have established standards for education and certification in transfusion medicine, are knowledgeable of this inequity in personnel competency. If a total quality pyramid for education and personnel competency is considered, professional development will evolve, either individually or collectively. The evolution of this profession can only happen if learning is followed by a concern for others beyond oneself and exhibiting pride in one's work.<sup>8</sup>

Transfusion medicine personnel consist of a mixture of generations, each with competencies and knowledge in different areas related to the profession. Generation differences must be acknowledged and dealt with proactively. The workforce encompasses an age time line of approximately 50 years. This is the equivalent of almost two generations trying to work together.<sup>9</sup> The differences in education, experience, and work ethic represent opportunities for significant improvement in our profession.

Each generation has many assets to offer; therefore, we must design working environments that call upon all

these assets. This mixing of generations adds diversity to the workforce, which can reap many rewards of talents, experience, and the latest knowledge. Although job satisfaction for current employees is important, the challenge of recruiting and retaining new employees begins with understanding the sociology of the future workforce.

The workforce, defined as personnel other than physicians, needs education, licensure requirements, and higher salaries to retain personnel. The lack of compensation versus the amount of responsibility results in the submission of resignations and is impossible to overlook. The lack of incentive to pursue learning and seek more training contributes to apathy and departure from the profession.<sup>10</sup>

Education and training curricula need standardization among all groups participating in transfusion medicine. Standard 1.1.1 of the AABB requires medical directors to be qualified through education, training, and/or experience.<sup>11</sup> There is no mention of a competency requirement such as the requirement for laboratory personnel under Standard 2.1.3.<sup>12</sup> The College of American Pathologists has a recommendation that the services of a qualified consulting pathologist be retained when the laboratory director cannot adequately discharge all the responsibilities appropriate for the pathology or medical laboratory service. Typical areas of activity may include tissue review and transfusion review.<sup>13</sup> The Clinical Laboratory Improvement Act of 2003 (CLIA '03) requires an immunohematology medical director to be a licensed MD or DO physician and possess qualifications by education, training, or experience.<sup>14</sup> There are no requirements in CLIA for annual competency. CLIA, however, requires annual competency for testing personnel.<sup>15</sup>

The primary stakeholders in transfusion medicine are the patients, the workforce, and the blood donors. Patient safety needs to be the number one concern. Patient safety is founded in the quality of processes within the American medical system. In the report released by the Institute of Medicine (IOM) in 2000, the US Agency for Healthcare Research and Quality estimates that medical errors are the eighth leading cause of death in the United States.<sup>16</sup> Specimen-management misadventures result in more than 500 serious injuries each year from incorrect blood administration errors.<sup>17</sup>

Experts have estimated that individual errors account for 15 percent of incidents whereas 85 percent are organizational in origin.<sup>18</sup> Therefore, the vast majority of errors are preventable, providing that all processes and systems are designed to enable seamless operation.

Finally, we must accept that cost and politics are hindering the advancement of our profession. We must solicit political action committees to represent us to groups controlling the purse strings and those establishing standards for the practice of transfusion medicine. Political action committees must seek funding, provide representation,

and serve as our advocate to groups mandating requirements upon our profession.<sup>19</sup> Political action committees are experienced in the political arena and can oil the political machine to encourage the various actors to listen to our concerns and address the issues we raise.

## BACKGROUND OF THE ISSUE

The turn of the 20th century witnessed two events of fundamental interest to immunohematology: 1) the rediscovery of Mendel's laws of heredity, and 2) the discovery in 1901, by Dr Karl Landsteiner, of three of the four major blood groups.<sup>20</sup> This opened the door for a new era in the development of transfusion medicine.

As we move into the 21st century, we witnessed two events of notable interest to this current generation of immunohematologists: 1) the use of molecular biology to solve many mysteries of infectious disease transmission and detection, and 2) cellular therapies' advancements for the treatment of degenerative diseases, cancer, autoimmune states, and reproductive medicine.

This past century has presented the world with more medical advances than previously thought possible. The development and utilization of these advances, however, have not solved the problem of human error.

Most errors which have been made can be traced to lack of knowledge and understanding on the part of the investigator, and to the lack of objectivity in making observations due to failure to use the blind technique." (Alexander Weiner, April 4, 1952<sup>21</sup>)

It would be impractical to accept that the reality of error surfaced as a result of Dr Weiner's comments in 1952. Error has been in the medical profession for centuries and will remain in the profession as long as human beings are involved. Present-day accrediting and regulatory agencies require continuous process improvement.<sup>22-25</sup> This requirement may be the impetus for error management and risk analysis in institutions accredited by these organizations. These processes, however, may be failing if one examines the medical error rate in the United States today. Medical errors are estimated to be responsible for 45,000 to 98,000 deaths a year—more than mortalities caused by breast cancer, AIDS, or motor vehicle accidents.<sup>16</sup>

The central theme of this article is that transfusion medicine is in need of an overhaul so that the image of the dedicated individual in transfusion medicine is one of a *complete professional* who serves and contributes as a valued member of the total health-care team. The image today of transfusion medicine personnel suffers for several reasons, with the lack of education and training of medical personnel being a major contributor. These include physicians, nurses, allied health professionals, and administrative support personnel. There were a total of 355 transfusion-associated fatalities reported to the

FDA between 1976 and 1985.<sup>26</sup> All were due to errors, and all were preventable. There were a total of 85 transfusion-associated sentinel events reported to the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) between 1995 and 2004.<sup>27</sup> The largest percentage of errors occurred because of a lack of orientation and training.

Reports from FDA, JCAHO, and IOM raise questions regarding the reasons for these significant number of fatalities.<sup>16,26,27</sup> Assuming that education is critical to assuring good practices and patient safety, the first issue that merits consideration is the quality of education and training being promoted in transfusion medicine within medical schools, residency programs, fellowship programs, medical technology programs, and nursing curricula. The magnitude of the medical error rate should stimulate responsible personnel to scrutinize these variables: the educational programs, the structure of material within those programs, the quality of the instructor, and the validation of the first three variables through the successes of graduates in transfusion medicine. The sustenance of any profession relates directly to the success of graduates in programs related to the profession.

The exodus of qualified personnel from the fields of transfusion medicine and laboratory medicine is an alarming phenomenon. This exodus may also contribute to the medical error rate, as patient care becomes dependent on inexperienced graduates. The US Bureau of Labor Statistics forecasts that by 2010, retirees of the entire health-care workforce will outnumber entrants by 13,800 per day.<sup>10,28</sup> One reason for this exodus may be poor recruitment and retention processes and a poor quality of life for laboratory personnel. The level of compensation versus the amount of responsibility must also be considered. Consideration for the quality of life must be acknowledged for the people who are just entering the medical laboratory profession. Salaries are more lucrative, and work schedules are easier to accept in a biotechnology firm.<sup>29</sup> Within an organization, the less than optimal use of several factors in recruitment and retention processes result in educational deficiencies. These factors include orientation and training or continuing education.

### Orientation

Company orientation programs are prime opportunities to embed a positive image in the minds of new employees. These programs should be an extension of the recruitment process, validating reasons for employment with a firm. They should make employees feel both challenged and excited to be a part of a quality firm. Agendas should be a cumulative summary of what the company offers a new employee and vice versa.<sup>30</sup>

When planning a new employee orientation, generation and cultural differences are a vital part of creating a

compatible workforce. By examining the generation differences, companies can gain a better understanding of what employees expect when they arrive for work, how to create the ideal experience, and how to gain an advantage in recruiting and retaining much needed staff. Members of different cultures can enrich working environments, exposing staff to different methods and thought processes to achieve a common goal.

### Training and continuing education

Training programs typically focus on how processes are completed in a particular organization. With more generations attending training, organizations are struggling to cope with the challenge of creating and maintaining a productive workforce when presented with variations in levels of experience and training needs.<sup>30</sup> Trainers normally focus on the different attitudes and expectations the generations have toward learning. Educators struggle with the challenge of how to keep each generation stimulated after it has achieved competency in current jobs. As the economy changes, programs should incorporate more cross-training to enhance marketability. Surveys of continuing education preferences of employees may make it easier to plan courses and budget for materials. The company's reward for employee-focused training and continuing education may be employee longevity and productivity.

One trend not measured adequately is the hiring of noncertified staff to fill positions that once required certification. Thirty-three percent of laboratories surveyed indicated that applicants did not have the requisite skills or educational credentials.<sup>29</sup> This is a reality facing today's employers as the shortage of qualified personnel worsens. Orientation and training of noncertified staff presents a significant challenge to trainers, specifically with regard to CLIA '03 requirements. There are no requirements for noncertified staff; thus the educational focus must travel a completely different pathway, owing to lack of formal education.<sup>15</sup>

Funding for educational programs remains a major challenge. If the quality of health care is to improve, then avenues to seek funding for educational programs must be explored and utilized. The willingness to address monetary incentives for improvement, invest in information technology, and make changes in the culture of medicine are all parallel needs in improving the medical error rate.

To address the culture of medicine is to begin with a pyramid of personnel structure as well as the generation differences existing among all categories of personnel. As previously noted, the workforce spans approximately 50 years. Automation, computerization, work ethics, quality of education and training, incentives for improvement, and hierarchical recognition contribute to the challenge of two distinct generations trying to work together. Physi-

cians with more experience are generally believed to have accumulated knowledge and skills during years in practice and therefore are able to deliver high-quality care. Evidence suggests that there is an inverse relationship between the number of years that a physician has been in practice and the quality of care delivered.<sup>31</sup> This author suggests that concerns should be raised about the adequacy of physician continuing education in medicine.

The increasing development of nonphysicians in specialty areas in medicine, specifically in transfusion medicine, should preclude the "godlike" syndrome of physicians answering to, and consulting with, only with their peers and not seeking expertise from persons other than their peers. Board certification in transfusion medicine should reflect positively for a medical technologist as it does for physicians, such that this individual will be recognized by non-board-certified physicians as significantly knowledgeable. The creation of a cohesive partnership between specialists in blood banking and medical directors is a paradigm shift encouraged and promoted.

Continuing education should be required of all generations as should training in organizational structure and expectations, work ethics, information technology, and chain of command. Each generation has different standards for quality of life, education and training, and attitude toward the workplace. If these differences become similarities, then the creation of a multitalented, highly educated, and motivated workforce can result. Educational programs are closing because of a lack of funding, a loss of interest in the profession, and a change in attitude toward service versus self-interest.<sup>32</sup> The nation's capacity to train new personnel has been diminished as school closings in the past 5 years have reduced the number of training programs by 30 percent.<sup>33</sup> These closures create personnel shortages in transfusion medicine.

Money and politics play a deciding role in all organizations. For educational paradigm shifts to take place, these issues must be overcome. Senior administrators face a continual budget balancing act: how to address the changes to establish priorities within a certain budget, to meet all critical expenses. A paradigm shift would adequately fund all educational needs that impact on patient care. Nonprofit and for-profit organizations, however, typically fund those cost centers generating the most revenue. Educators and trainers are not able to produce revenue, so rarely are they compensated for such performance compared to their revenue-producing peers.

A primary focus of this article is to encourage change in educational paradigms and establish educational priorities for the development of the profession of transfusion medicine and cellular therapies. A profession adheres to a national set of standards. Selection of, and dedication to, these standards increases credibility and respectability, thus achieving a professional identity. This article evaluates the establishment of priorities in the context of

present educational systems, impact of funding on educational programs, personnel shortages, generation gaps in the workforce, and the medical error rate.

## REVIEW OF THE LITERATURE SURROUNDING THE ISSUE

### Present educational systems

Richard Steinbeck, of the College of Medical Laboratory Technologists of Ontario, defines the characteristics of a "profession" to be concern for others beyond self-interest, pride in one's work beyond compensation, and commitment to lifelong learning.<sup>8</sup> As these professional values develop into a common body of ethics and practice standards, a group achieves a professional identity.<sup>8</sup> This identity is nurtured through formal training programs, professional journals, conferences and conventions, a high participation rate in a voluntary organization that goes beyond self-interest, and ultimately, peer pressure.<sup>8</sup>

The practitioners of transfusion medicine subscribe to a code of ethics and a set of standards of practice. This code consists of integrity, valuing people, striving for excellence, and goal orientation.<sup>34</sup> The standards of practice are the various sets of standards that govern transfusion services, donor centers, etc.<sup>11</sup> The next step in the development of a profession is the willingness of its members to pursue self-regulation, demonstrating their commitment to continuous quality improvement. A critical part of continuous quality improvement is the continuing education of a profession's members.

Present educational systems in transfusion medicine include undergraduate programs for allied health programs with curricula in laboratory science, graduate-level programs such as the specialists in blood banking (SBB), pathology residency programs for MDs, and fellowship programs in transfusion medicine for MDs. These programs are accredited by various organizations that set standards for didactic criteria and practicum requirements.

The Accreditation Council for Graduate Medical Education (ACGME) is the flagship organization for accrediting pathology training programs and subspecialty programs for physicians, such as in transfusion medicine. ACGME makes recommendations about accreditation to the American Board of Pathology. In reviewing training programs, it could not be verified that ACGME has any relationship with the AABB. Board certification is granted to physicians after successful completion of an accredited program and successful passing of specialty or subspecialty boards offered by the American Board of Pathology.<sup>35</sup>

Specialty boards certify physicians as having met certain published standards. Licensure, the legal privilege to practice medicine, is governed by state law and is not designed to recognize the knowledge and skills of a trained specialist. A state board of medical examiners sets

its own procedures to license physicians and sets the general standards for all physicians in that state.<sup>36</sup> Pathology is one of the few American medical specialties that does not require continuing education to maintain certification each year.<sup>37</sup>

Two accrediting organizations exist for allied health professionals. The Commission on Accreditation of Allied Health Education Programs (CAAHEP) is a nationally recognized specialized accreditor of allied health education programs. CAAHEP has a set of standards that it adheres to when considering accreditation of a program. These educational standards are developed with input from communities of interest, public open hearings, and approval by sponsoring organizations.<sup>38</sup>

The second accrediting agency is the National Accrediting Agency for Clinical Laboratory Science (NAACLS), the premier international agency for accreditation and approval of education programs.<sup>39</sup> This agency concentrates on the accreditation and approval of educational programs in the clinical lab sciences and related health-care professions. NAACLS is committed to peer review as the foundation of its accreditation and approval process. There is no mention of a working relationship with AABB in its mission and vision statement. The CAAHEP recognizes NAACLS as a deemed status organization, thus accepting its standards and mission for the education of medical technologists and medical laboratory technicians.

The Committee of Accreditation of Specialist in Blood Bank Training (CoA-SBBT), a committee of the AABB, recommends accreditation of an SBB program to CAAHEP.<sup>40</sup> Graduates from a CAAHEP-approved SBB program are qualified to sit for SBB boards offered by the American Society for Clinical Pathology (ASCP). SBB training is considered a postgraduate-level educational curriculum for non-MDs. Most certified SBBs are medical technologists, having obtained advanced certification in transfusion medicine.

Certification examinations for nonmedically qualified personnel are not recognized in the same light as certification exams offered to physicians by the American Board of Medical Specialties or the American Medical Association. Physicians are granted board certification, which is a stepping stone to qualifying for a license to formally practice medicine.<sup>36</sup> There is no subsequent hurdle for board-certified allied health professionals to surmount. Thus, with no formal license, these professionals are not recognized in the same light as physicians, and they are not recognized as professionals. They do not practice medicine as a legal entity.

The AABB offers numerous continuing education opportunities via teleconferences, publications, a distance learning center, regional workshops, and a national convention. It also offers a consulting service to its membership. Organizations practicing transfusion medicine regard the AABB as the flagship of transfusion medicine.<sup>40</sup>

The ASCP offers numerous opportunities in continuing education for allied health personnel, through many of the same types of venues as the AABB. Its menu is of a broader scope, because it serves all areas of the clinical laboratory.<sup>41</sup>

The American Society for Clinical Laboratory Scientists (ASCLS) includes educational opportunities for its members. It actively supports its members in other arenas such as career development and certification assistance. ASCLS also participates in political issues concerning the medical error rate and equitable enforcement of the Clinical Laboratory Improvement Act of 2003 throughout all laboratories.<sup>42</sup>

The College of American Pathologists educational mission is mainly focused on physician audiences.<sup>43</sup> One focus of this article is to concentrate on those organizations that offer educational programs for both physicians and nonphysicians.

There is a wealth of educational opportunity available to future as well as experienced medical technologists with many tools; readily accessible by Internet links; teleconferences; long-distance learning programs; local, state, and national meetings; and reference materials. The challenge is how to encourage personnel to seek these educational opportunities for self-enrichment and improvement.

### Impact of funding on educational programs

In January 2005, the Allied Health Professions Reinvestment Act, HR 215, was introduced by Representative Cliff Stearns (R-Florida).<sup>45</sup> The purpose of this bill is to increase federal funding for allied health education and training. An annual need of approximately 13,800 laboratory professionals exists; at present, the number of graduates from US schools is approximately 4000.<sup>10,44</sup> HR 215 also addresses personnel shortages through a variety of educational and training programs. It provides federal grants for public service announcements to highlight careers in the allied health profession and creates grant programs for distance learning and fostering new technologies. One of the most important aspects of this Act is a reciprocity clause in a student contract that provides educational funding in return for service. The intent is to assure that graduates commit to a term of service in rural areas presently devoid of the expertise of one or more allied health professionals.<sup>45</sup>

ASCP, ASCLS, and other organizations participating in the Clinical Laboratory Coalition met in January 2005 to set the coalition's legislative and regulatory agendas for 2005.<sup>46</sup> With the current federal budget deficit estimated at approximately \$400 billion, coalition members are focused on the possibility that Congress may seek additional cuts in federal spending on laboratory services. The critical shortage of funding has forced many training programs to close their doors and discontinue operations.<sup>46</sup>

If reimbursements and federal funding are not returned to hospitals or university-based training programs, then institutional budgets must absorb the cost of programs. Over the past 10 years, one-third of clinical laboratory science schools have closed and more may close because of low enrollment.<sup>10</sup> NAACLS will coordinate ways to make additional funding available to prospective students and adults who want to enter the field.

President George W. Bush released his 2006 fiscal year budget on February 7, 2005.<sup>46</sup> The implications for pathology and laboratory medicine are causes for concern. The President's proposals to reduce federal spending on discretionary and mandatory spending programs will exert significant pressure on lawmakers to eliminate or reduce many health-care programs. Deep cuts have been proposed in the Title VII allied health programs, equaling a 96 percent reduction in federal funding. This lack of federal funding directly impacts institutions that sponsor educational programs in laboratory science.

Senator Maria Cantwell (D-Washington) introduced the Allied Health Reinvestment Act (S.473) on February 28, 2005.<sup>45,47</sup> This Act would provide incentives for young people to enter and complete allied health-care training, including recruitment grants; provisions to strengthen recruitment, retention, and practice; and incentives to promote racial and ethnic diversity in allied health professions.

On March 8, 2005, the Medical Laboratory Personnel Shortage Act, HR 1175, was introduced by Representative John Shimkus (R-Illinois).<sup>45,48</sup> The purpose of HR 1175 is to amend the Public Health Service Act with respect to the shortage of laboratory personnel. At the request of Representative John Shimkus, ASCP is contacting organizations that are participants in the Clinical Laboratory Coalition and others to solicit support for this legislation. The AABB is one organization in support of this Act.<sup>49</sup> Schools of allied health and health-care institution-based training programs for medical laboratory personnel are eligible to receive awards under the scholarship and loan repayment program. Under Section 2 of the bill, the Secretary of Health and Human Services is authorized to award grants and contracts to assist institutions with the cost of establishing or expanding programs that increase the number of trained laboratory personnel. Funding for public service announcements is included in this bill.<sup>48</sup> These announcements are very necessary to focus attention on the work of clinical laboratorians.

The Chiron Foundation chose an innovative approach for funding education and training and promoting interest in science and health care.<sup>48</sup> It awarded \$160,000 to five organizations for five projects promoting interest in science and health care through the support of community-based science and math education programs. Chiron hopes to contribute to the education of the next generation of scientists and laboratorians. Endowments, grants,

public and private contributions, and intervention by congressional representatives may be the only pathways to pursue to keep educational programs operational.

### **Educational systems experiencing a shortage of students: outcome is workforce shortage**

The president of the American Society for Clinical Pathology states the following reasons for a shortage of personnel in laboratory medicine:

1. Laboratory professionals are underpaid and under-recognized, even at the institutions where they work. There is lack of compensation for the amount of responsibility inherent to the work.
2. Patients are more isolated from direct contact with laboratory professionals, an unfortunate reality that does nothing to enhance their reputation as professionals.
3. Some health-care administrators do not appreciate the specialized talent required to oversee clinical laboratory operations. They also do not value the special expertise and knowledge required to conduct laboratory testing.
4. Fewer students want a career in laboratory science. They prefer other allied health professions with equally altruistic missions, but with more visibility, higher salaries, and higher recognition factors.

In 1983, there were 638 clinical laboratory scientist programs in the United States. In 2003, the number of programs decreased to 240. Clinical laboratory workers fulfill functions that are crucial in the health-care system, yet their importance is not well understood by the general public. Visibility is limited because clinical laboratory professionals have little to no direct contact with patients. Work processes take place behind the scenes in clinical laboratories. Clinical laboratory professionals are responsible for supplying up to 70 percent of a patient's diagnosis.<sup>10,42</sup>

Low salaries and poor quality of life are two additional factors contributing to the shortage of medical technologists. During 2003, the ASCP Board of Registry conducted a survey to provide the profession with current information about wage scales and vacancies.<sup>29</sup> In summary, the number of respondents provides an overall sampling margin of error  $\pm 2.4$  percent at the 95 percent confidence level for total sample statistics at the national level. Responses were weighted by both laboratory type and region. High salaries for all positions were most likely to be found at high test volume, 300+-bed hospitals that were located in a large city or suburb, in the Far West region of the US. Low-end wages were typical to hospitals with fewer than 100 beds located in rural areas in the South Central Atlantic and West South Central states.

In addition, experienced laboratory personnel see new graduates receiving starting salaries similar to their

salary, despite less experience. This affects morale and commitment to remaining in the field of laboratory medicine. This scenario often occurs in difficult recruitment areas which require pay incentives or sign-on bonuses for contracts that may be limited in duration.

Hourly wages from this survey are as follows:

- Medical technology staff—median average approximately \$20.00.
- Medical technology supervisors—median average approximately \$24.00
- Medical technology managers—median average approximately \$30.00.

This means that a college graduate with a major in mostly biologic sciences and an internship in medical technology makes approximately \$41,600 per year (at 2080 hr worked per year).

Curricula require chemistry, biology, the highest math classes, genetics, immunology, parasitology, and immunohematology. Jean Deitz, coordinator and instructor for the medical laboratory technology program at Southwestern Illinois College, does not see salaries or enrollment improving. In her article, her comments include the difficulty of required subject matter with the resulting salary being less than or equal to other health-care workers whose curricula are more simplistic.<sup>44</sup>

The AABB recently published a survey of salaries collected in the various areas of transfusion medicine.<sup>50</sup> These data are similar to the data from the survey conducted by the ASCP Board of Registry.

Quality of life is an issue to consider when addressing the staffing shortage. The work environment is one of high stress, with demand for short turnaround times for test results. Because many laboratories operate around the clock, holiday and weekend coverage is a necessity. Young graduates are less likely to seek a profession requiring this kind of schedule commitment. Salaries are comparable at biotechnology firms, with a 40-hour, Monday through Friday work week.<sup>29</sup>

### **Generation gaps in the workforce impacting educational priorities**

People are working longer to obtain retirement benefits and to invest in retirement portfolios. The mixing of generations adds diversity to the workforce, but it also lends itself to potential conflict as staff try to work together. The bridging of this generation gap begins with seeking ways to standardize work processes such that all age groups can understand, perform, and support these processes.

Administrators often bridge the generation differences of staff members by encouraging participation in decision making and by creating process improvement activities. Participation is a key element in the development of professionalism in an organization.<sup>51</sup> Mentoring

programs promote participation among different generations through inclusion of different levels of experience in the laboratory environment. Customizing training and education programs often reaches different generations and increases participation. Adults train in different ways and methods vary for different age groups. Incentive systems can assist in bridging the gap. Some generations are motivated by money; others are attracted by flexible work schedules. A successful incentive system will encourage staff to increase their willingness to participate fully in organizations.

Fewer young people are choosing health care as a career; they have more choices available to them today.<sup>29</sup> The image of the health-care profession has changed from an environment of modern technology with job security, to an environment of stress and strict regulation. In addition, the impact of numerous government policies has also contributed to the change in image.

The challenge for today's leaders is to create a viable organizational environment that is conducive to longevity, satisfaction, productivity, and quality patient care. The answer may lie in participation. This is not a new concept or a panacea.

The answer may also lie in continuing education and training.<sup>51</sup> Dr Carol Polifroni<sup>51</sup> writes that, in the current health-care work environment, the patient becomes the entire focus. The organizational challenges to quality of patient care are not the purview of the practicing nurse. This concept is applicable to laboratory personnel as well. A medical technologist who tests and prepares blood products for transfusion rarely sees the end result of his or her efforts. Because of decentralization of phlebotomy, many medical technologists never see patients. This lack of closure, or feedback, leads to confusion about management decisions that impact the patient. Solicitation of process improvement suggestions from employees may offer potential ideas that could ultimately result in improvements in patient care.

The Canadian Health Services Research Foundation recently published an article about the management of the health-care workplace.<sup>52</sup> It concluded that research needs to focus on nurturing the next generation of leaders, as part of a recruitment package. Such items to include would be flex-time work schedules, on-site day care, educational benefits, and compensation equivalent to responsibility.

### **The medical error rate: a dearth of education in quality systems**

The IOM's report *To Err is Human: Building a Safer Health System* was released in November 2000.<sup>16</sup> Most of the evidence published is not new. IOM addressed the issue of responsibility for reducing errors and addressing safety issues. There are four initiatives outlined in this report for

the prevention of errors and improvement of patient safety. Another purpose of this article is to address the possibility of lack of education in quality systems as a root cause for the medical error rate. The outcome of a root cause analysis might be an awareness that medical errors jeopardize patient safety.

According to the IOM report, medical errors manifest themselves in systems that lack critical control points, resulting in mistakes that were easily preventable. Analysts agree that the quality of medicine across the country is uneven, which represents a huge problem. One of the main contributions of the IOM report was to help practitioners understand the principles and practices of quality systems. By lessening variation in behavior, outcomes will improve. In 2001, a second report was released entitled: *Crossing the Quality Chasm: A New Health System for the 21st Century*.<sup>53</sup> This report described specific factors that could be addressed to minimize the risk of errors. These included safety, effectiveness, efficiency, timeliness, patient-centeredness, and equity.

Lingard and coworkers<sup>54</sup> published an article discussing the failure of communication in the operating room in the *Journal of the American Association of Colleges of Osteopathic Medicine*. The authors' findings continue to support the contention that communication failure is the most significant factor leading to medical error. While communication failures account for a large number of medical errors, other authors point to failures in the demonstration of other core competencies and the potential for error. Gaps in the practice of medical knowledge, patient care, systems-based practice, and practice-based learning and improvement competencies have been described by other authors in the Lingard article.

The American Association of Critical-Care Nurses (AACCN) made a commitment in 2001 to promote the creation of a health work environment. This promotion was motivated by the "culture of silence" existing in hospitals.<sup>55</sup> AACCN takes the position that there is mounting evidence that unhealthy work environments affect the medical error rate, effective delivery of care, and conflict and stress among health-care professionals. The phrase, "culture of silence," coined by the AACCN, defines the reluctance of coworkers to report observations of dangerous shortcuts or poor clinical judgment.

In a study sponsored by the AACCN, and conducted by the VitalSmarts group, the concerns were grouped into seven areas: broken rules, mistakes, lack of support, incompetence, poor teamwork, disrespect, and micro-management.<sup>55</sup> Of those persons interviewed in each area, more than 50 percent commented negatively, thus affirming AACCN's position about the impact of a nonsupportive management team on error rates and patient safety. The report concluded that it was critical for hospitals to create cultures of safety, where coworkers can candidly approach each other about their respective concerns,

### Root causes of transfusion events (1995-2004)

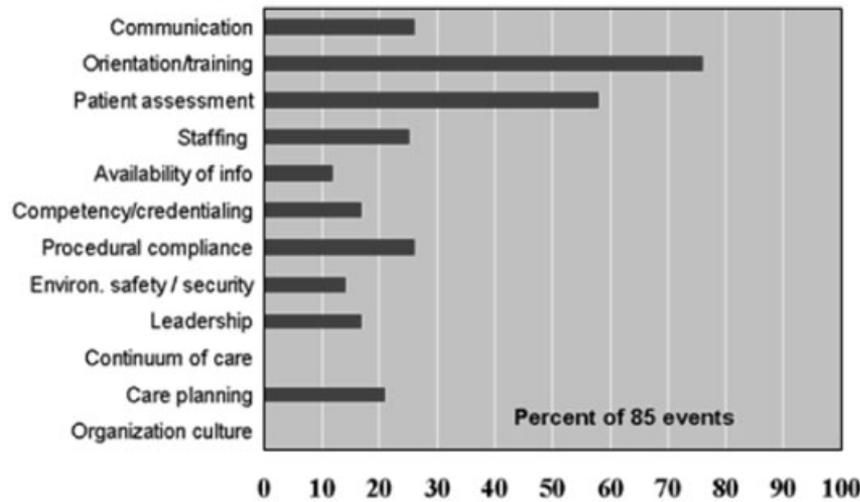


Fig. 1. Sentinel events as reported on the JCAHO Web site (<http://www.jcaho.org/>).

without fear of reprisal or retribution. The added benefits include improvements in productivity, reduction in turnover, and physician cooperation.

To conclude this literature review, Fig. 1 depicts a recent graph from the JCAHO. Though discussed earlier, this graph illustrates the need for improved communication, education, and training in transfusion medicine.

## OPTIONS AVAILABLE TO ADDRESS THE ISSUE

### Option 1: Development of a profession through changes in educational paradigms

The development of a profession begins with the willingness of its members to commit to improving the welfare of others, to lifelong learning, and to pride in their work beyond compensation.<sup>8</sup> As these values develop into a common body of ethics and practice standards, a group achieves a professional identity.

Changes in educational paradigms that would improve process control suggest a positive outcome in patient safety measures. One paradigm shift would be the inclusion of education about risk analysis and risk management for all personnel. For example, a staff member would be taught to think, "Have I done everything possible to make sure my work process is correct?" A second paradigm shift would be educational programs in both risk analysis and risk management for the patient. The patient would be taught to think, "Have I asked every question possible to make sure my outcome will be positive?" The approach to the development of transfusion medicine as a profession must be a global approach. The

final step of patient care through the administration of a blood product begins with input from many sources. Quality of personnel may be the key to a successful outcome in our pursuit of recognition as profession. Successful outcomes from the appropriate use of medical products add credibility to the profession.

Educational paradigm changes include increases in the number of peer groups reviewing educational programs, managing the risks from medical product use, and employer marketing strategies. The development of an international blood bank academy would offer education and standardized training throughout the world. Until lack of training and continued competence are accepted as leading contributors to the medical error rate, we will fail to imple-

ment paradigm changes that will lend credibility and recognition to our profession.

There are several options available to promote paradigm changes:

### Proposal 1: Development of an international blood bank academy

The mission of this academy would be to offer standardized training programs for laboratory personnel, nurses, physicians, donor recruiters and collectors, phlebotomists, and nontechnical support personnel. Its training programs would also include a module for board development and the role of board members in a nonprofit and proprietary organization.

The goal of the academy would be to produce a knowledgeable and competent workforce in transfusion medicine throughout the world. The academy's training programs would be Web-based with modules for each group of personnel. All modules would be self-learning and approved by experts in transfusion medicine. Completion of modules would be required by all accrediting and regulatory bodies, as part of new employee orientation and training. This process would be similar to the OSHA requirement for safety training and education for all employees.<sup>56</sup>

The European School of Transfusion Medicine may be a potential model to utilize when creating an international academy. The European School of Transfusion Medicine created an integrated partnership with the International Society of Blood Transfusion. If this is possible, then the creation of a universal pathway to all countries may offer a means to worldwide standardized education in transfusion medicine.

If political action committees could solicit mandates from the Department of Health and Human Services that participation is mandatory for federal reimbursement, then all institutions would be required to participate. A total quality education pyramid would be the logo of this academy, similar in structure to a quality systems pyramid. It would focus, however, on education from the introduction of the basic principles of transfusion medicine to the top level of quality education management. It would have a zero medical error rate as its overarching goal.

### **Proposal 2: development of more peer review groups whose mission would encompass closer scrutiny of physician training programs in transfusion medicine**

The function of peer review groups would be to solicit the opinions of experts in the profession of transfusion medicine to review proposed educational programs. This would promote standardization of content and increase content quality.

The AABB has its Committee on the Accreditation of Specialists in Blood Bank Training. This committee makes recommendations to the Commission on Accreditation of Allied Health Education Programs for accreditation of SBB schools.

A similar type of committee could be created for review of physician training programs and make recommendations to ACGME and the American Board of Pathology for the acceptability and accreditation of residency and fellowship training programs. There is no comparable committee in existence within the AABB for the review of physician training programs.<sup>40</sup> There is no comparable committee in the College of American Pathologists or the American Medical Association that could be identified.<sup>36</sup>

### **Proposal 3: educational programs in risk management and risk analysis**

Medical products today are developed and used within a complex system involving a number of key participants. Although these products are required to be safe, safety does not necessarily mean zero risk. Programs would be designed to promote a systems framework for risk management and should enable a better integration of the efforts of all parties involved with medical products.

A better understanding of risks and a more integrated risk management system will enable more effective risk analysis and intervention.<sup>57</sup> All participants in medical product development and delivery have a role in maintaining a benefit-to-risk balance by making sure that products are developed, tested, manufactured, labeled, prescribed, dispensed, and used in a way that maximizes benefit and minimizes risk. The ultimate goal

of minimizing risk is to promote patient safety. Increased efforts to promote patient safety adds credibility to our profession.

Programs are needed where staff are trained to rapidly recognize and accurately report adverse events. Clarification and integration of individual roles are goals that must be met in such a training program. Health-care partners and other stakeholders must be trained in risk benefit analysis. Patients, the largest stakeholder group, need to be educated about procedures and benefit versus risk. The process of "informed" consent typically is limited and does not stress the patient's responsibility to seek knowledge and ask, "Have I asked every question possible to assure my own safety?" The process of risk analysis for staff can be summarized in a statement such as, "Have I done everything possible and followed every critical step to ensure that this cross-match is compatible?" The following objectives need to be considered when developing educational programs to manage the risk from medical product use:

1. Ensure and document ongoing professional and core competency training for all participants in patient care.
2. Initiate steps to have each facility establish separate quality assurance or risk management units similar to required safety programs. This means the establishment of a risk analysis program within clinical laboratories.
3. Require mandatory educational programs for health-care professionals and patients about products with special risks.

### **Proposal 4: employers' marketing strategies**

The shortage of the workforce in transfusion medicine and laboratory medicine reflects negatively on the profession. Critical elements in acquiring and maintaining sufficient personnel must be improved to ensure continued existence of the profession and to assure patient safety. These elements include recruitment techniques, retention packages, and career development for laboratory personnel, both in transfusion medicine and in clinical laboratories.

**Recruitment.** Transfusion medicine is not a widely recognized profession. The author defines the term previously in this article; the data to contest this statement were not discovered during the literature review. There has been no statement from the federal government recognizing the profession, and there is no vocational definition of the profession. The concern is about the future and whether our industry is positioned well to have a knowledgeable and competent workforce in the next 5 to 7 years.

Successful recruitment depends on education of a broad base and training of a specific focus. Our curricula must address these issues for recruitment to be successful.

The recruiters' success depends on supply and demand and the quality of the supply. To compete for the most desirable employees, organizations need to understand what appeals to the different generations. They need to create an exciting employee value proposition. A value proposition is a persuasive statement of what is being offered. The statement focuses on a specific on the potential employee and not on the organization. There are two steps to creating a value proposition: 1) knowledge of audience goals and desires, and 2) knowledge of items of importances.<sup>58</sup>

Creative recruitment programs may include collaboration between hospitals and local schools, on-site presentations to future employee bases, Web-based promotional packages, presence at international job fairs, matriculation packages, and retention incentives. In the current competitive job market, it is vital for businesses to recruit and support the best talent. It is mandatory for colleges and universities to provide their students with the best possible competitive edge as they enter the profession. High productivity and quality of work performed, rigorous training, and competency documentation are critical elements to instill in the future workforce.

**Retention.** Retention is a second key to success in a health-care environment burdened with shortages.<sup>59</sup> Increased personnel turnover is paramount for organizations to overcome. The focus must change from being reactive to turnover to proactively developing and retaining the workforce. Empowerment and recognized value of employees leads to increases in quality of work, productivity, and longevity.<sup>60</sup>

Staff must be intrinsically motivated to work well together and provide high-quality care. Extrinsic motivators, such as incentive plans or employee-of-the-month awards have a place in a retention strategy, but attention also must be given to intrinsic motivation. An engaged workforce has a more lasting return on employer investment. Intrinsic motivation increases when people know they are doing meaningful work and they have choices about their work environment.

Retention packages may include educational opportunities, award systems, flex-time work schedules, on-site day-care centers, telecommuting opportunities, and career ladders for professional growth. Employers should also consider packages that contain equitable monetary compensation for the amount of responsibility assumed, respective to each position within the organization.

**Career development progression.** A pathway for career advancement provides a means to reinforce the important role of clinical laboratory professionals and offers them the opportunity to develop professionally and advance within the laboratory.

In the career ladder approach to professional development, each stage of development is clearly defined and can be reached from the prior stage through a series of

articulated steps.<sup>61</sup> A career ladder provides an excellent opportunity for employers to provide a viable mechanism to use for the professional development of their laboratory technical staff.

Sonora Quest Laboratories in Tempe, Arizona, has implemented an entry-level career ladder for line staff of the specimen management department. Since the implementation, employee turnover has been reduced from 39 percent to less than 20 percent. There was a dramatic improvement in productivity and morale (R. See, personal communication, April 2005).

Career ladders provide job enrichment opportunities through company-conducted training and advancement positions. The ladder could contain requirements for productivity, quality of work performed, training accomplishments, and competency documentation. A clearly defined means of advancement and personal satisfaction can be achieved through a career ladder. Employees that climb the ladder develop self-satisfaction from a recognition that they are a valuable member of the health-care team. Employers with a well-defined career advancement opportunity will have a definite advantage in the competitive health-care employee marketplace. A career ladder would address the current shortage of laboratory personnel by increasing public awareness, increasing credibility and respect of laboratory personnel, and increasing the retention of current laboratory employees.

## **Option 2: Development of a profession through a change in dogma**

### **Proposal 1: seek licensure for all laboratory personnel, whether specializing in transfusion medicine or other areas of the clinical laboratory**

One of the milestones of recognition of a profession is the licensure status of its members, as previously defined by the author. Licensure may increase credibility and supply grounds for demanding increases in salaries. The benefits of licensure would be similar to those for physician assistants (D. Killion, written communication, April 2005). Enhanced credibility provides justification for better salaries. Better salaries reduce personnel turnover, which in turn reduces a shortage in the field.

Requirement for continuing education credits increases competency, which in turn decreases errors. Reduction in errors adds reliability and credibility to our profession. Reduction in errors lends itself to increases in revenue. Increases in revenue provide a means for improvement in education and training, one of the first items cut from budgets. Increased reliability and credibility adds many benefits, such as better public perception of the quality of our work as laboratory personnel.

A question posed by both advocates and opponents to licensure is the issue of personal liability of a licensed

professional. Several states include laboratory personnel in their statutes of limitations for personal injury. In summary, the purpose of these statutes is to protect the public health, safety, and welfare of the people of said state from the hazards of improper performance by clinical laboratory personnel. Clinical laboratories provide essential services to practitioners of the healing arts by furnishing vital information that is essential to a determination of the nature, cause, and extent of the condition involved (D. Killion, written communication, April 2005).

The protection of the public requires the licensure of clinical lab personnel who meet minimum requirements for safe practices. It is not known at this time whether all of the states that provide these protections require the protected personnel to be licensed.

Jeff Jacobs, MA, Vice President, Public Policy, American Society for Clinical Pathology, reported that a recent survey of ASCP membership showed the majority of members favoring licensure (D. Killion, written communication, April 2005). Jacobs believes, however, that licensing would not have much effect on pay. It would serve to protect facilities and supervisors from claims of negligence. The fact that a person's livelihood is governed by a state license requirement does not necessarily give rise to greater liability under theories of standard negligence or medical malpractice claims. Typically, a hospital is liable for its employees' negligence under the respondeat superior doctrine (D. Killion, written communication, April 2005).

Although the American Medical Association is arguing against licensure, allied health professional organizations are promoting it. The Alaskan Society of Clinical Laboratory Scientists Board of Directors created a model guide bill for licensure of clinical laboratory science practitioners.<sup>62</sup> It was last updated in July 1997.

Support from state legislatures and funding for a licensure program are two issues that were discussed by peers at a roundtable forum. Notes of the forum were recorded and incorporated into the official record of the Alaska meeting of clinical laboratory scientists in April 2005 (H. Mannion, personal communication, April 21, 2005). First, state legislatures must be educated about the importance and significance of licensure. This educational priority takes precedence in the establishment of a profession. Ironically, the most common defense about licensure presented to state legislatures is the competency of personnel to be preparing and transfusing a blood product. In other words, would they want a nonskilled, nonlicensed individual giving them blood? Notably, the most creditable professional accepted by legislatures is the SBB. They accept this level of education and understand the licensure platform more clearly; the appreciation of the expertise of an SBB seems to lend more credibility to the licensure movement.

Issues to be considered are the funding to maintain a licensure system and the resolution of personnel requirements for licensure. The present workforce in laboratory medicine encompasses levels of education of 2-year associate degrees and 4-year bachelor degrees. Currently the decision rests with individual state requirements. Maintenance of state licensure boards requires funding and personnel. This economic issue would have to be decided by state legislatures. The issue of liability insurance surfaces with professionals. The amount is usually regulated by state law but the payor is typically a contract matter between the two parties involved (D. Killion, written communication, April 2005).

There appears to be little precedent established for licensure. It may be a "mixed bag" from a legal standpoint. The benefits may include certain statutory protections, such as statutes of limitations and claims considered as medical malpractice rather than ordinary negligence claims. There may be burdens, too, such as insurance and continuing education requirements. Several states have licensure requirements; a survey of licensed personnel may tell us if the benefits outweigh the burdens (D. Killion, written communication, April 2005).

### **Proposal 2: move the practice of transfusion medicine from pathology to specialties that deal with clinical practice and patient care**

The study of pathology is the study of the nature, course, and etiology of a disease.<sup>1</sup> A specialty that is so clinically based as transfusion medicine may be better served if moved into a clinical arena.

Changing the directorship of the specialty of transfusion medicine from pathology to a clinical specialty such as hematology and/or oncology would be a paradigm change for most facilities. The Clinical Laboratory Improvement Act of 2003 only requires that the medical director be an MD and be qualified to be the technical supervisor under 42 C.F.R. Subpart M, Section 493.1449(q) or 42 C.F.R. Subpart M, Section 493.1443(b).

Medical directors involved with direct patient care have an appreciation for the patient's condition and the appropriateness of care. The cognizance of risk in the management of medical product use would be better understood by a practicing clinician versus a pathologist, whose diagnostic clinical skills are not used on a daily basis.

This movement away from pathology promotes a model for creating a transfusion team composed of clinicians, SBBs, and other allied health professionals. This team makes recommendations for patient care, thereby improving communication between support services, promoting better utilization of blood products, and drawing on each other's academic knowledge and expertise in transfusion medicine.

### **Proposal 3: solicit support from the federal government to recognize transfusion medicine as a profession**

The goal of this solicitation would be for the federal government to recognize transfusion medicine as a legal entity, with all the benefits and protection afforded a legal profession. Political action committees could be given this charge to lobby on the behalf of the members.

England has made this declaration, with the requirements for continuing education and proven competency. National registration is required for all laboratorians and all must demonstrate competency annually.

### **PROPOSED RESPONSE TO THE ISSUE**

The issue that we must address is sustaining this high degree of professionalism. How do we develop a positive image, given that the profession is currently subject to generational differences, nonstandardized training curricula, economic issues, and a shortage of qualified personnel?

The proposed educational response to this industry concern of transforming transfusion medicine personnel into a transfusion medicine professional is a multifaceted approach. The movement out of pathology and the development of an international blood banking academy are important and necessary processes that should be considered. Along the path to these solutions, the issue of recruitment and retention needs to be understood and incorporated into the solutions.

An international blood bank academy, staffed with licensed blood bank professionals and marketed as the number one accrediting organization for educational programs, would be the ultimate solution to many issues facing our profession. Funding and political arguments must first be overcome, however.

1. Funding can be solicited in several ways for the academy: institute an educational tax on all licensed or registered blood products produced. This tax would be collected to support the academy, similar to the FDA user fee imposed to hire more personnel at the FDA. This increase in personnel was necessary to reduce delays in product approval. The logistics of tax payment and reimbursement go beyond the scope of this article; however, one proposal is to call it a pharmaceutical tax and consider a system similar to a sales tax. The revenue goes to the academy treasury. The tax would only be reimbursable through a deduction on corporate tax returns, similar to a sales tax deduction.
2. A \$1 tax on each unit of blood would generate thousands of dollars for the academy. This tax would be a great public relations tool for blood centers to promote as another way of improving the safety of the

blood supply. Contributing to an academy, with a mission to improve education and knowledge, can only have positive outcome. The American Red Cross and America's Blood Centers would self impose this fee. The fee would be incorporated into annual fee increases for the cost of doing business as safely as possible.

3. A percentage of state licensure fees would go to the academy in return for the academy providing educational programs. Completion of these educational programs would earn credits which are applicable to fulfilling CEU state licensure requirements for individual licenses.
4. Universities, with programs in laboratory science, would pay a user fee to utilize the academy's educational modules as part of their curricula. The most direct route of payment would be a user fee for Web access.

A summary of ideas for an academy should also include the following considerations, similar in meaning, but diverse in thought:

1. Political challenges are numerous, but the threat of universal health-care mandates may resolve most of the arguments against a standardized program such as the academy model being proposed.
2. Organizations that would need to be recruited in support of such an academy include the American Medical Association, American Board of Pathology, AABB, College of American Pathologists, the American Society of Clinical Pathology, the JCAHO, and the Department of Health and Human Series.
3. Major blood organizations such as the American Red Cross and America's Blood Centers play a major role in this support system.
4. If standardization of education in transfusion medicine became a reality, then the potential is there to alleviate many problems within our profession.

The movement of the specialty of transfusion medicine out of the department of pathology is not a new concept. Several independent departments of transfusion medicine exist, mostly in large medical centers with a diverse patient population. Hospitals of smaller size typically locate their transfusion services or blood banks within the department of pathology. Regulatory requirements, under CLIA '03, do not require a pathologist to be the medical director, only a qualified MD, based on education, experience, training, and/or board certification. The AABB and the College of American Pathologists do not require medical directors to be pathologists. Their requirements are identical to CLIA '03.<sup>14</sup> The JCAHO only requires that clinical laboratory services are under the direction of an individual who is qualified by virtue of documented training, expertise, and experience to assume professional

responsibility for the facilities and services rendered and whose qualifications satisfy federal and state law and regulation.<sup>63</sup> In a hospital where the director of clinical laboratory services provides clinical consultation or medical opinion, he or she is a physician and preferably a pathologist.

Discussions to address the difficult questions of legal, financial, and political factors need to be encouraged. As the specialty of transfusion medicine expands, we are challenged to provide our patients with the best possible medical treatment. We need to rethink the roles of our traditional experts and seek avenues to incorporate expertise from clinicians who are actively involved in care plans for our patients. The issue of physician competency surfaces with this proposed paradigm shift. The existing adage of "give the doctor what he wants; he knows his patient better than I do" is a statement repeated many times by medical directors in smaller transfusion services who never see a patient. This statement should be evidence enough of the consideration for change in dogma.

In smaller facilities that cannot support, or do not need, a separate department of transfusion medicine, one suggestion would be to move it to another area such as internal medicine, hematology and/or oncology, anesthesiology, or even pharmacy. Pharmacy handles licensed pharmaceuticals and so should be familiar with managing medical product use. This may mean revisions to CLIA '03 about medical director qualifications.

Blood centers must have an authorizing official in charge of manufacturing. This position is not required to be filled by an MD, only a person knowledgeable in good manufacturing practices.<sup>64</sup> If there is a laboratory on site performing testing on donor specimens, then a CLIA license is required and an MD must be the lab director. This position, however, does not have to be a pathologist.

The credibility of the profession may be enhanced if more clinicians who are MDs serve as medical directors, instead of pathologists. With the expertise provided by SBBs, the concept of a team approach to patient care needs careful consideration.

## IMPLICATIONS FOR THE FUTURE

If no action is taken to address issues identified in this article, then our profession remains status quo. The shortage of personnel will increase. Inequities in compensation will continue. If advocates for licensure are successful, then they need to be prepared for the possibility of increases in liability and subsequent increased costs of insurance. If employers do not address the differences in work ethics and employee incentive packages, the generation gap will lessen and the workforce will be composed of older, antiquated employees. An older workforce means outdated knowledge and imminent retirement, another contributory factor to the workforce shortage.

If action is taken to address and implement changes such as those proposed in this article, then the purpose of this article will have been achieved: to bring to the attention of the readers the present condition of the specialty of transfusion medicine. If members of this profession do not address some of the issues presented, then the potential public outcry will force legislators to take action. This could easily invoke discussion about a nationalized blood service that would enforce quality systems, licensure, and hemovigilance. Public outcry could also lead to the unionization of allied health professionals.

In summary, the key points for consideration are as follows:

1. Addressing the weaknesses of the present educational system in transfusion medicine. We must standardize educational practices, both in content and in the form of education. Development of an international blood bank academy and inclusion of peer review groups in the design of its curriculum would provide a model that can be utilized by many different peer groups.
2. Soliciting the necessary funding from many avenues for support of educational programs. We need to focus on the funding necessary to keep training programs operational. These programs offer solutions to the workforce shortage, possible reduction in the medical error rate, and creation of career ladders. Solicitation of congressional assistance to carry our message to Congress needs to be stressed to all members of this esteemed profession.
3. Developing marketing strategies for recruitment of both students into programs and personnel into the field of transfusion medicine.
4. Design of retention packages by employers to retain current staff and as an incentive to recruit new staff. This would help alleviate the workforce shortage.
5. Solicit government support in defining requirements for quality systems training, which may assist in the reduction of the medical error rate in the American medical system.
6. Licensure lends credibility to a profession. The pros and cons of licensure for laboratorians need to be carefully considered and recommendations made to state legislatures about the benefits of licensure versus incurred liability.
7. A change in venue of transfusion services would represent an extreme change in dogma. The concept of moving this service from a clinical laboratory to a patient care arena has been actively pursued in several large medical centers, but most hospitals still sequester it within the walls of the department of pathology. The consideration of this change of location brings a perspective of actively, rather than passively, participating in patient care. The credibility of

the profession may be enhanced if more clinicians serve as medical directors, with the expertise of SBBs leading to a team approach to patient care.

Paradigm changes must occur if our ironclad ship is to undergo the needed metamorphosis to a sleek cruiser. Economic wrangling and political differences threaten the existence of the profession of transfusion medicine. The profession of transfusion medicine will be transformed into our sleek cruiser with courage, commitment, and conviction.

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