Identification and classification of the causes of events in transfusion medicine

H.S. Kaplan, J.B. Battles, T.W. Van der Schaaf, C.E. Shea, and S.Q. Mercer

BACKGROUND: Transfusion medicine lacks a standard method for the systematic collection and analysis of event reports. Review of event reports from the Food and Drug Administration (FDA) showed a relative paucity of information on event causation. Thus, a causal analysis method was developed as part of a prototype Medical Event Reporting System for Transfusion Medicine (MERS-TM).

STUDY DESIGN AND METHODS: MERS-TM functions within existing quality assurance systems and utilizes descriptive coding and causal classification schemes. The descriptive classification system, based upon current FDA coding, was modified to meet participant needs. The Eindhoven Classification Model (Medical Version) was adopted for causal classification and analysis. Inter-rater reliability for the MERS-TM and among participating organizations was performed with the development group in the United States and with a safety science research group in the Netherlands. The MERS-TM was then tested with events reported by participants.

RESULTS: Data from 503 event reports from two blood centers and two transfusion services are discussed. The data showed multiple causes for events and more latent causes than previously recognized. The distribution of causes was remarkably similar to that in an industrial setting outside of medicine that uses the same classification approach. There was a high degree of inter-rater reliability when the same events were analyzed by quality assurance personnel in different participating organizations. These personnel found the method practical and useful for providing new insights into conditions producing undesired events.

CONCLUSION: A generally applicable and reliable method for identifying and quantifying problems that exist throughout transfusion medicine will be a valuable addition to event reporting activity. By using a common taxonomy, participants can compare their experience with that of others. If proven as readily implementable and useful as shown in initial studies, MERS-TM is a potential standard for transfusion medicine.

Transfusion medicine lacks a standard method for the systematic collection and analysis of event reports, although many locally developed systems have been put in place to comply with regulatory reporting requirements of the Food and Drug Administration (FDA) and accreditation requirements of the American Association of Blood Banks (AABB). On September 23, 1997, the FDA proposed that mandatory reporting requirements for errors and accidents that currently apply to licensed blood establishments be extended to all blood establishments, including hospital-based transfusion services.[1] It is very probable that the new regulation will take effect sometime in 1999. In part, these proposed regulations are in response to public and governmental concern for transfusion safety.[2-4] A recent Office of the Inspector General report[5] noted that the error rate in transfusion is significant and may be underreported, especially by hospital-based transfusion services. Another Office of the Inspector General report[6] addressed the FDA's responsibilities in monitoring blood safety and stated that the processes for tracking the blood safety incident reports could be more effective. FDA event reporting was the subject of several congressional

ABBREVIATIONS: AABB = American Association of Blood Banks; DSL = detection sensitivity level; ECM = Eindhoven Classification Model; FDA = Food and Drug Administration; MERS-TM = Medical Event Reporting System for Transfusion Medicine; QA = quality assurance; SysOp(s) = system operator(s).

From the Department of Pathology, The University of Texas Southwestern Medical Center at Dallas; and the Office of Medical Education, The University of Texas Southwestern Medical Center at Dallas, Dallas; and the Faculty of Technology Management, Safety Management Group, Eindhoven University of Technology, Eindhoven, the Netherlands.

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hearings.[7] It is expected that there will be a significant increase in the volume of reports received at the FDA when these new regulations take effect. This increase will create the need for improved methods of detecting, reporting, and analyzing events.

Even though incident reports may provide a rich database for improving systems, there has not been a standard means for the systematic collection and analysis of error data, and the comparison of data among transfusion medicine organizations. Current reporting efforts concentrate on describing what occurred, with only limited attention, if any, to the reasons for an event. Most human error events have their origins in more than one condition with multiple root causes. Thus, the lack of a standard and comprehensive event investigation and reporting method severely hampers the ability to study and understand error and thus to enhance transfusion safety. Regardless of the method that one chooses to identify errors, there is a need to classify them once they are discovered.

We reviewed 200 cases obtained (through the Freedom of Information Act) from reports submitted to the FDA and found a relative lack of information about the root causes of the events. Almost one-half of the event records indicated that the corrective action was that the employee was counseled and the procedures were modified.

Gambino stated, "[T]he identification of root causes, and the elimination of root causes, is the way to permanently improve performance."[8(p429)] The lack of in-depth investigation of the root causes of transfusion events could indicate that corrective actions that are taken may be inappropriate or unrelated to the actual cause of the event. Gambino also pointed out, "[An] untapped source of valuable data, however, is the near miss. The near miss is an error that almost happened but was prevented. The near miss has two advantages over an actual error that affects a customer. First, there are far more near misses than actual errors. Second, near misses are a richer source of data because they are likely to reveal a greater variety of problems with your processes."[8(p42-43)] Safety studies of incidents in commercial aviation have shown near-miss events to be very similar to those associated with full-blown disasters.[9] Formal reporting systems have been established in the error-critical fields of aviation,[10] nuclear power,[11] and the petrochemical industry.[12] These systems capture incidents and provide a resource for their study, in the attempt to prevent error or, at a minimum, to better manage error when it occurs.

The relationship between accidents or misadventures and near misses has been depicted as an iceberg, representing a continuum of events from visible, fatal accidents that are few in number to a large number of near misses.[13] Linden et al.[14] calculated the rate of deaths from hemolytic reactions due to ABO-incompatible blood transfusions, the number of adverse reactions, and the number of incorrect units transfused by nurses, as reported to the New York State Department of Health. If we take data from the report of Linden et al. and place them in an iceberg model, as illustrated in Fig. 1, we can begin to see how transfusion incidents relate to the concept of a near-miss reporting system. The number of deaths, which are few in number, becomes the tip of the iceberg. However, the numbers of both adverse reactions and of incorrect units readied for transfusion become large, and the numbers of near-miss events are unknown.

To meet the need for a near-miss reporting system in the field of transfusion medicine, the Medical Event Reporting System for Transfusion Medicine (MERS-TM) was created through a grant from the National Heart, Lung, and Blood Institute. It is being implemented in three blood centers (New York Blood Center, New York, NY; Oklahoma Blood Institute, Oklahoma City, OK; and Carter BloodCare, Dallas, TX) and three hospital transfusion services (New York University Medical Center, New York, NY; Parkland Health and Hospital System, Dallas, TX; and Baylor University Medical Center, Dallas, TX). Organizations represented in the development process have included the American Red Cross, Blood Systems, Inc., America's Blood Centers, the AABB, and the FDA. A major component of MERS-TM was the creation of a standard and uniform method of classifying root causes of reported events. The design and development of MERS-TM have been described by Battles et al.[15]

MATERIALS AND METHODS

In the design and implementation of MERS-TM, a concerted effort was made to take lessons learned about near-

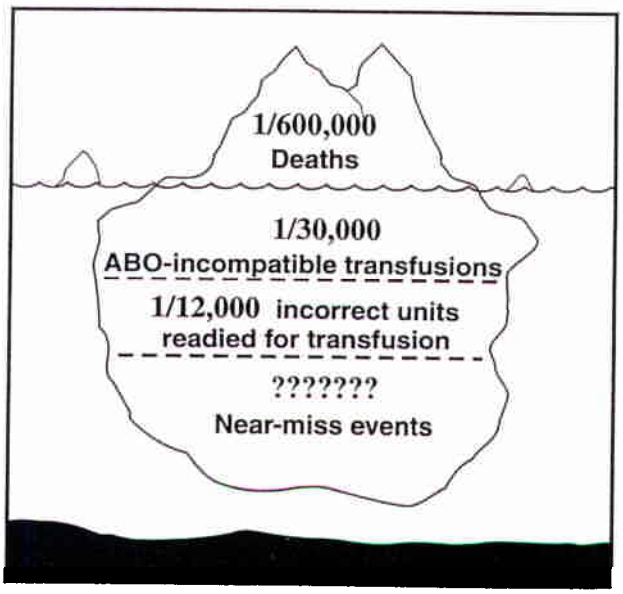

Fig. 1 Iceberg model showing transfusion error rates extrapolated from New York State Department of Health data.

miss reporting systems from industries such as aviation, nuclear power, and petrochemicals and apply them to the medical domain. The major components of the MERS-TM are detection, selection and investigation, description, classification, computation and interpretation, and training.

Detection

Zapt and Reason[16] indicated that error detection is the first step in error management. If an error is not detected, it cannot be managed. They go on to point out, "[F]rom an organizational point of view, it is very important that the error detection rate is high; errors that are not detected for a long time could have disastrous consequences."[16(p429)] Thus, the goal of error management should be to increase error detection and the reporting rate.

The number of events reported is an indicator of an organization's detection sensitivity level (DSL). High reporting rates indicate a high DSL, and a small number of reported events indicate a low DSL. A low DSL might be considered an indicator of an inadequate error-detection and -reporting approach. While the DSL may remain relatively high, the event severity level of the incidents detected should decrease over time as corrective actions are implemented.

To achieve a high DSL, an organization must remove impediments to the reporting of an event. Confidential no-fault reporting is one of the best ways to encourage event reporting. Because the purpose of the event-reporting system is to learn how systems are operating, there must be separation between event reporting and employee performance assessment. Research literature indicates that organizational encouragement such as confidential no-fault reporting significantly increases error detection and reporting. O'Neil et al.[17] found that physician confidential reporting was as effective in identifying adverse medical events as medical chart audit in a no-fault/no-fear environment. Shea,[18] in studies of error in emergency departments in the United Kingdom, reported that physicians and other health professionals are more than willing to report near-miss incidents in such a no-fault environment. Leape et al.[19] reported that, when given the opportunity for no-fault confidential reporting, both physicians and nurses are very willing to report adverse medical events. In organizations where no-fault confidential reporting has been introduced, there is often a dramatic rise in the number of events reported, sometimes as much as a 10-fold increase.

Everyone in the organization should be encouraged to report any and all events that have the potential for having an adverse effect on component production or patient or donor safety. Therefore, with the MERS-TM, the reporting process begins at the blood center or transfusion service with the individual who discovers an event. This individual completes Section A of the Discovery Report that triggers actions at the local level. An example of the form is provided in Fig. 2A. The person completing Section A may or may not have been involved in the event. The detection process makes use of a variety of methods that are already standard in transfusion medicine, including quality assurance (QA) record review, chart audit, supervisory reports, and self-reporting by individuals within the organization. External reports such as customer information and feedback from external agencies or departments are also part of the discovery process. We believe that sole reliance on self-reporting would not be likely to provide an adequate DSL. Section A of the Discovery Report records by whom and where in the transfusion process the event was discovered. Thus, it is possible to track the source of discovery.

Selection and Investigation

MERS-TM has been designed to be compatible with QA guidelines of blood bank organizations, such as the AABB, and the major regulatory agency, the FDA. At each of the participating blood centers or transfusion services, one or more personnel from the QA group serves as an operator of the MERS-TM. We have designated these individuals as QA system operators (SysOps). QA SysOps are the individuals who collect the data from the Discovery Reports and then perform the investigation, root cause analysis, and classification. The QA SysOp investigates all events at some level of detail and completes Section B of the Discovery Report for every event reported. The QA SysOp must ask the question, Have we seen this type of event before? To answer this question, a query is made of the local database.

Section C of the Discovery Report is completed if the QA SysOp finds matching cases in the database. The QA SysOp codes the event type and assigns probable causal codes. The new event is linked to the prior event that has already been fully investigated. At this stage, Sections A, B, and C are scanned directly into the computer for local analysis and transferred to the MERS-TM central database for multi-institutional analysis. If, on the other hand, the event is new or unique, it receives an expanded investigation. The QA SysOp uses causal trees to further characterize the more unusual events. The causal trees are used to draw, chronologically, the critical antecedent activities and decisions that led to the event and the recovery, if any. Although there may appear to be one "primary root cause," it is the combination of causes that is the richest source of information. Casual tree construction is stopped when all known antecedents and their causes have been included and the investigator reaches a point beyond which investigation is not practical (outside the boundary of the investigating organization or ability to make changes). The root causes, which are found at the bottom of the causal tree, are the main product of the first phase and constitute the inputs to the second phase: classification of the root causes of failure. After the event has been completely investigated and a causal tree has been developed, the QA SysOp completes

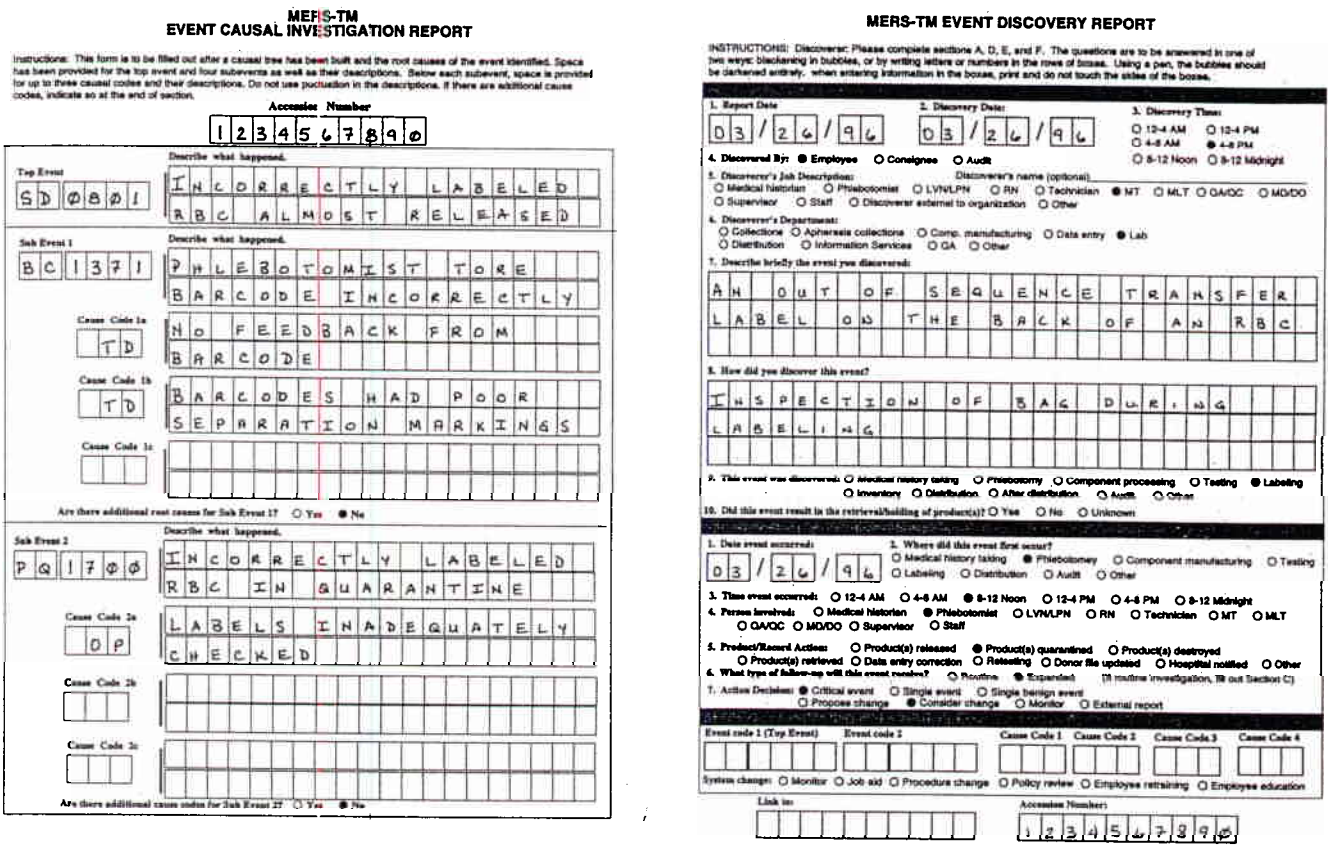

Fig. 2. MERS-TM "Smart Paper" Discovery (A) and Causal Investigation (B) Report forms.

the Causal Investigation Report (Fig. 2B). The Causal Investigation is designed to capture the essence of the completed causal tree within the database. The completed forms can be scanned into the computer or faxed from a remote location. We have developed a computer program that allows the reconstruction of the causal tree directly from the database itself.

Description

In essence, all events are nested within the context of what happened, where in the process it occurred, when it happened, and who was involved in the event. An important part of MERS-TM is a common description and classification scheme for the reporting of both the "what" and the "why" of the event. As the overall transfusion process is relatively universal, from donor blood collection to transfusion to a patient, a uniform terminology was established to identify precisely where in the process the event occurred. The use of event-description coding minimizes the need for lengthy narrative. The innovative work of Taswell et al.[20] in transfusion error includes a method for the classification of errors in transfusion practice. Although of proven utility in his institution, this primarily functional classification scheme has not received wide acceptance. Organizations such as the American Red Cross have developed their own classification systems. We chose an event-descriptive method originally developed by the FDA[21] as the basis of the coding scheme and then modified it to fit the needs of MERS-TM users. The FDA codes are the backbone of the classification of the "what" and the "where". The FDA method has the dual advantage of broad familiarity within the field and congruence with the AABB's systems approach to quality. Table 1

TABLE 1. Descriptive code categories of the MERS-TM

Blood center	Transfusion service
IS, Computer	IS, Computer
CS, Customer service	MS, Miscellaneous
MS, Miscellaneous	PR, Patient request
DS, Donor suitability	OE, Order entry
DD, Donor deferral/reentry/postdonation	SC, Sample collection
BC, Blood collection	SH, Sample handling
CP, Component processing	ST, Sample testing
GT, General testing	US, Unit storage
VT, Viral testing	UM, Unit manipulation
LA, Labeling	SE, Unit selection
PQ, Product quarantine	UI, Unit issue
SD, Storage and distribution	UT, Unit transfusion
PD, Product disposition	

provides a listing of the major code categories of the MERS-TM description.

Classification

The body of literature dealing with human error served as a useful starting place for identifying and classifying the causes of error. There are two main classifications of error—active and latent. Rasmussen[22,23] provided a useful human behavioral taxonomy for the active errors. Reason[24,25] defined latent or system errors as the delayed consequences of technical design or organizational issues and decisions. Accidents (as defined in the human-error literature) and adverse events happen when latent conditions or system issues combine with an active human error. Thus, error researchers stress the importance of examining active human errors while also looking at underlying system issues that can contribute to error. Reason has referred to these latent or system errors as organizational pathogens that lie in wait for the right opportunity to become active. As Leape[26] pointed out, we must look at each step in the process, how errors are caused, and what entities or steps prevent us from discovering the errors before they cause injury. We must ask: What are the latent conditions that may well set the human up for failure? It is also important that we document how health professionals identify errors and recover from combinations of active errors and latent conditions, thus preventing events from having adverse consequences.

Theoretical classification schemes and MERS-TM development

A number of other theoretical models exist that take into account the complexity of human–system interactions. While these theoretical classification schemes provide a useful framework, they are not in an operational format that could provide a practically workable solution for MERS-TM.

One notable exception to this limitation of theoretical schema is the Near Miss Management System developed by Van der Schaaf and colleagues[12] and by Van der Schaaf.[27] Whereas the original version of the Eindhoven Classification Model (ECM) was developed to classify root causes identified in the causal trees of safety-related incidents in the chemical processing industry, it has been successfully tested in other industrial settings and in the medical setting.[18,28,29] After consultation between the authors from University of Texas Southwestern and the Eindhoven University of Technology, the ECM was slightly modified and adopted for the MERS-TM. The new medical version of the ECM is shown in Table 2. The ECM focuses on three main types of causes separately and in a predefined order: technical, organizational, and human. Technical problems are considered first, with assessment of the design of equipment, software, labels, and forms; the possibility of construction problems such as those in the setting up of a mobile blood drive; or unexplainable material defects. The second consideration of root causes focus on the organizational level, examining standard operating procedures, organizational decisions and priorities, and culture and orientation of employees. Only after these evaluations are the human factors considered. This order is chosen to counteract the sometimes strong bias within organizations for starting and stopping analysis at the level of the employee as the end-user, and for leaving unquestioned the technical and organizational (latent or system) context of any mishap.

The human factor classification begins with knowledge-based behaviors at the top of its hierarchy. This method involves the conscious application of existing knowledge to the management of novel situations, whereas rule-based behaviors involve the application of existing rules or schemes to the management of familiar situations. Prolonged, active processing is not required—simply the selection and application of the appropriate rule. Skill-based behavior refers to "automatic" tasks requiring little or no conscious attention during execution.

Examples use of the MERS-TM. To illustrate how MERS-TM operates, we have selected a transfusion event that was reported via our forms and investigated by the use of the causal tree, and for which the causal classification codes were applied. Figure 2 is the completed Discovery Report and investigation form. Figure 3 shows the causal tree and the causal codes assigned as a result of the investigation. Figure 4 is a sample of the printout from the database of the reported event. A medical technologist on the second shift in a blood bank was releasing units from quarantine to inventory when she noticed an out-of-sequence number on the back of a unit of red cells. She immediately notified the supervisor, and the unit was isolated until the labels were corrected. It was determined that no labels had been used in either component testing or in component production, and therefore no harm was done. Clearly this event was a near miss.

The first question to ask in classifying this event would be: Were there any technical failures? The separation markings on the number sequence labels were not prominent, which provided unclear guidance on where to tear the label to separate adjacent numbers. In addition, the markings provide little feedback when the tear has been done incorrectly (which allows little chance of recovery from the error). Clearly, there is a design failure in the label itself (Classification *TD*, Table 2). Next, we would look for any organizational failures. There may have been a failure in the procedure for the checking the accuracy of the label before the unit's placement into quarantine. These procedures should be reviewed. If the procedure is not clearly written, another contributing root cause would be protocols and/or procedures (Classification OP, Table 2). However, even a very clear and explicit procedure might not be effective if the detectability of error (feedback) is poor. The phleboto-

TABLE 2. ECM adopted for MERS-TM

Code	Category	Definition
Latent errors		Errors that result from underlying system failures.
Technical		Refers to physical items such as equipment, physical installations, software, materials, labels, and forms.
TEX	External	Technical failures beyond the control and responsibility of the investigating organization.
TD	Design	Inadequate design of equipment, software, or materials. Can apply to the design of workspace, software packages, blood drive set-up, forms, and labels.
TC	Construction	Correct designs that were not constructed properly. Examples include incorrect set-up of blood drives and installation of equipment in an inaccessible area.
TM	Materials	Material defects found. Examples could be the weld seams on blood bags, defects in label adhesive, or ink smears on previously printed labels or forms.
Organizational		
OEX	External	Organizational failures beyond the control and responsibility of the investigating organization. For blood centers, this could apply to the hospital. For transfusion services, this could apply to blood centers or other departments within the hospital.
OP	Protocols/procedures	The quality and availability of the protocols from the blood center or transfusion service are too complicated, inaccurate, unrealistic, absent, or poorly presented.
OK	Transfer of knowledge	Failures resulting from inadequate measures taken to ensure that situational or site-specific knowledge or information is transferred to all new or inexperienced staff.
OM	Management priorities	Internal management decisions in which safety is relegated to an inferior position when there are conflicting demands or objectives. This is a conflict between production needs and safety. An example of this is decisions made about staffing levels.
OC	Culture	A collective approach (and the approach's attendant modes) to safety and risk rather than the behavior of just one individual. Groups might establish their own modes of function as opposed to following prescribed methods. An example of this is not paging a manager on the weekend because that is not how the department operates; "It's just not done."
Active errors		Errors or failures that result from human behavior
Human		
HEX	External	Human failures originating beyond the control and responsibility of the investigating organization. For a blood center, this could apply to actions by individuals in hospitals. For a transfusion service, this could apply to failures by individuals from another department, such as the emergency room.
Knowledge-based behaviors		
HKK	Knowledge-based errors	The inability of an individual to apply their existing knowledge to a novel situation. An example is a trained technologist who is unable to solve a very complex antibody-identification problem.
Rule-based behaviors		
HRQ	Qualifications	The incorrect fit between an individual's qualification, training or education, and a particular task. An example would be expecting a technician to solve the same type of difficult problems as a technologist.
HRC	Coordination	A lack of task coordination within a health care team in an organization. An example would be an essential task not being performed because everyone thought that someone else had completed the task.
HRV	Verification	The correct and complete assessment of a situation, including related conditions of the patient/donor and materials to be used before beginning the task. An example would be failure to correctly identify a patient by checking the wristband.
HRI	Intervention	Failures that result from faulty task planning and execution. An example would be selecting the wrong rule or protocol (planning) or executing the protocol incorrectly (execution). An example would be washing red cells by the same protocol as platelets.
HRM	Monitoring	Monitoring of process or patient status. An example could be a trained technologist operating an automated instrument and not realizing that a pipette that dispenses reagents is clogged.
Skill-based behaviors		
HSS	Slip	Failures in the performance of highly developed skills. An example could be a technologist adding drops of reagent to a row of test tubes and then missing the tube, or a computer entry error.
HST	Tripping	Failures in whole body movement. These errors are often referred to as "slipping, tripping, or falling." Examples would be a blood bag slipping out of one's hands and breaking or tripping over a loose tile on the floor.
Other factors		
PRF	Patient-related factors	Failures related to patient/donor characteristics or actions, which are beyond the control of the health professional team and influence treatment. An example would be a patient who deliberately uses another patient's identity card in seeking treatment.
X	Unclassifiable	Failures that cannot be classified in any of the current categories.

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mist errored by tearing the label in the wrong place. This action is a skill-based behavioral error (Classification HSS, Table 2). However, without a redesign of the label, this event would likely recur.

Computation and Interpretation

Once the events have been entered into a database, they can be analyzed at both the local institutional level and the central MERS-TM level. One of the primary means of analy-

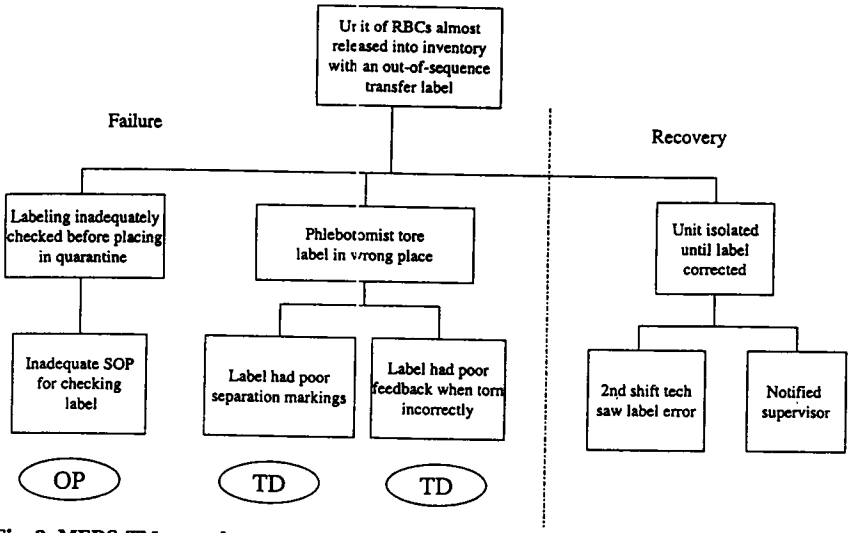

Fig. 3. MERS-TM causal tree: transfusion labeling event. RBC = red cells; SOP = standard operating procedure; OP = organizational protocols/procedures; TD = technical design.

sis is an examination of trends in both the types of events and their causes. The event coding allows one to examine peaks—or, as some say "black spots"—where the most frequent events are occurring. It is then possible to look at individual peak areas and to examine the causes of the events in each area. In addition to examining the peaks, it is essential to monitor changes in the patterns of the types and causes of events reported, so as to determine the effectiveness of corrective actions taken in response to the detected errors. It is necessary, therefore, that the methods used to discover or detect an event be sufficiently sensitive to determine occurrence rates as well any changes in rates secondary to improvements made in the system. Information about changes in the type and nature of events being detected is important in error management. If the same types of events continue to be detected, then the corrective actions implemented may have been ineffective. It is also essential that (at least quarterly) the staff of the local organization receive periodic reports as to the results of event investigations and any system changes made to correct the problems that are identified. At the central MERS-TM level, the major focus of analysis is the comparison of data from one institution to another.

Training

To ensure reliability and consistency in the causal classification of events, a 3-hour workshop was developed to introduce the MERS-TM to personnel of participating organizations. During this workshop, staff members were introduced to the methods of classification and had the opportunity to practice classifying a standard set of cases as well as cases from institutional files. To date, a total of over 1100 individuals have attended our orientation workshops, including two presentations at the annual meeting of the AABB in 1997. Follow-up conference calls and on-site visits by project staff helped to assist the QA SysOps in gaining experience with the MERS-TM.

RESULTS

A number of different methods were used to determine if our near-miss reporting system could be considered successful.

Reliability assessment

To test the reliability of the causal classification process, a comparison study was carried out by the authors. Twenty-five cases derived from the domains of emergency medicine and intensive care were put into causal tree form but not classified as to cause. MERS-TM project staff and the QA SysOps from Carter BloodCare and The Parkland Hospital transfusion service independently clas-

Accession Number 12234567890

What happened?	Out of sequence transfer label of an RBC bag
How was this event discovered	Bag inspection while labeling
Discovery date	03/26/96
Occurrence date	03/26/96
When event was discovered	During labeling
When event first occurred	During phlebotomy
Person involved	Phlebotomist
Investigation type	Expanded
Action/decision	Critical event/consider change

Investigation

Top event:	
Storage and distribution 0801	Incorrectly labeled RBC unit almost released from quarantine
Subevent 1 and cause codes:	
Blood collection 1371	Phlebotomist tore barcode label incorrectly
Technical design	Error was not evident on the barcode
Technical design	Barcodes had poor separation markings
Subevent 2 and cause codes:	
Product quarantine 1700	Incorrectly labeled RBC unit in quarantine
Organizational protocols and/or procedures	Labels inadequately checked

Fig. 4. Example of event description contained in the MER-TM database. RBC = red cell.

sified these cases. When the results were compared for correlation and associations using Yule's Q, a correlation of 0.86 was achieved. This consistency of the application of the classification system, both within the domain of transfusion and across other medical domains, would indicate that the causal classification is reliable within the participating institutions.

Comparison of data structures

The final MERS-TM data structure and that of the FDA were compared (by a graduate student in linguistics from the University of Utrecht, Utrecht, the Netherlands). The two systems deal with their data in different ways. The FDA has more narrative than codes, while MERS-TM focuses on codes for narrative amplification. The layout and content of the forms, the data format (narrative, codes), and the method of entering data in the database were studied. The efficiency of the systems was determined by comparing the data collected to the data entered into the database, the format the data is collected in to the format used for the database, and the effort required to report data to that required to enter data. The results of the study showed that 8 of the 11 items for the FDA system are reported in unstructured narrative and that, for MERS-TM, this number zero. All 11 of the MERS-TM items are reported in codes, or both codes and structured narrative.

Data submitted to the FDA must be entered into the database manually (12 items), while MERS-TM does this automatically (11 items) with scannable forms and software (Teleform, Cardiff Software, San Marcos, CA). The FDA has three items more than MERS-TM that might be reported, but this is highly dependent on what the reporter includes in the narrative description. Because of this uncertainty, those items cannot be readily included in a data analysis.

By comparison with the FDA event-reporting system, MERS-TM successfully limits the narrative by both using codes and structured narrative in the reports. Data entry and analysis are simplified, and the time it takes to complete reports is decreased. In general, computerized data are more readily accessible and analyzable. The FDA system and MERS-TM do not differ in regard to the information that is reported, which is remarkable, considering the significant difference in the number of pieces of paper that are used for the reporting.

Increased reporting

The single greatest indication of the acceptance of the no-fault/no-fear form of reporting by employees of an organization is an increase in the number of incidents that are reported as a measure of the DSL. Figure 5 is a graph showing the increase in reports at the transfusion service of Parkland Health and Hospital System. Before the introduction of MERS-TM in November 1996, an average of three event reports per month were received by the QA Department. Immediately after an orientation to the new no-fault/no-fear reporting system, the number of reports increased to approximately 30 per month, and it has stayed at that level. This 10-fold increase is similar to what others found when a no-fault/no-fear, near-miss event-reporting system was introduced. It is important to note that this increase does not indicate an increased error rate, but rather is a better

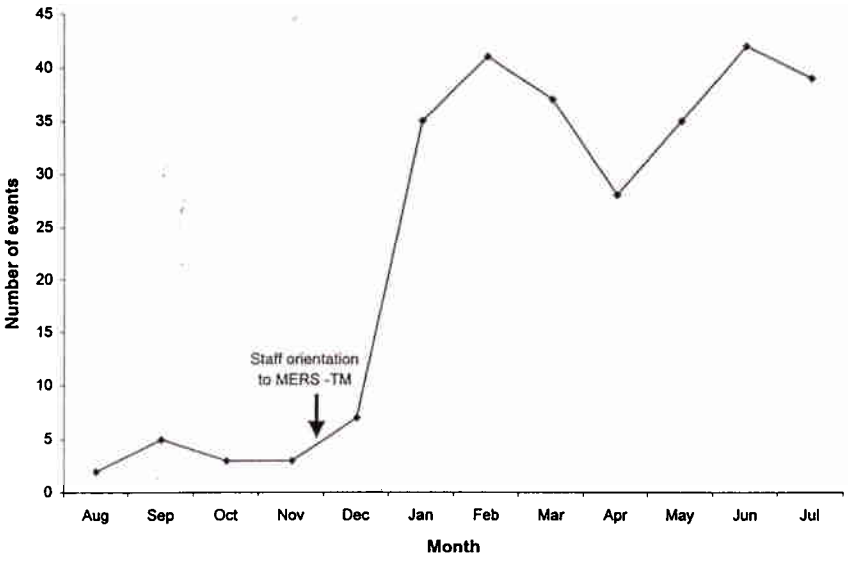

Fig. 5. Number of events reported in 1 year at Parkland Health and Hospital System.

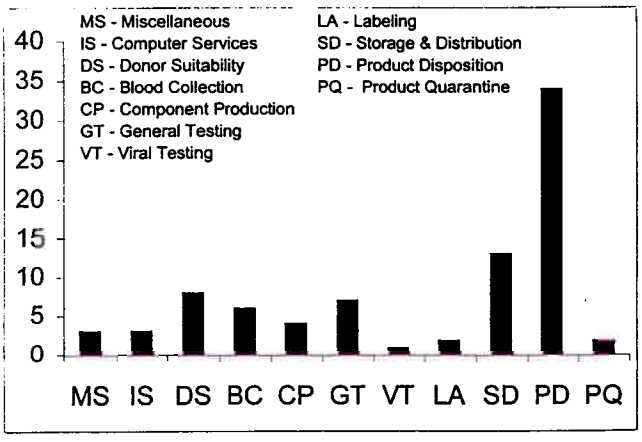

Fig. 6. Distribution of event categories from two blood centers.

reflection of an increased DSL. The increased numbers of event reports are new information previously unknown to the QA SysOp and management.

Utility as a management tool

Because of the structure of the Discovery and Causal Investigation Report forms, it is possible to examine the data in a number of productive ways. The most obvious way is to look at trends in the way events occur within the linear process of transfusion and to look for peaks. Figure 6 is a histogram showing events within the blood collection process as reported by participating blood centers (number of events = 83), while Fig. 7 shows the events from two transfusion services (number of events = 423). It is interesting to note that the peaks in both the blood centers and transfusion services come near the end of the linear process. This indicates that a significant number of events were not discovered or identified until late in the process, even though an event may have begun in an earlier stage. It is also possible to evaluate events as to their causes. The peaks of event occurrence in the blood centers (product disposition) and in the transfusion services (unit issue) can be examined as to their causes. Figure 8 displays the causes by peak areas in blood centers, while Fig. 9 shows the causes by peak area in transfusion services.

Another way to look at the data is to examine the overall causes of transfusion error relative to the three major categories of failures: human, organizational, and technical. Two pie charts compare our causal data from all transfusion events (number of causes = 1238) (Fig. 10A) with those from a petrochemical company in the Netherlands (number of causes = 563) (Fig. 10B) by using the same causal classification method. As can be seen, the distribution and causes of events are very similar in these two error-critical fields. This matching of causal distributions between medicine and industry would seem to indicate that error and its causes follow similar patterns independent of the domain. Despite the limited time that MERS-TM has been in operation, the participating sites have already begun to derive effective interventions

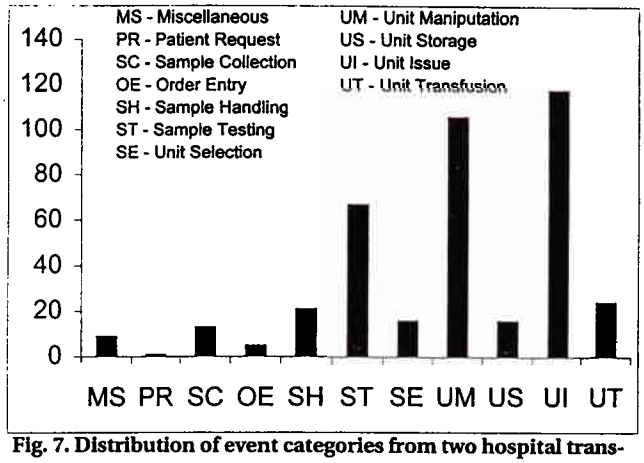

Fig. 7. Distribution of event categories from two hospital transfusion services.

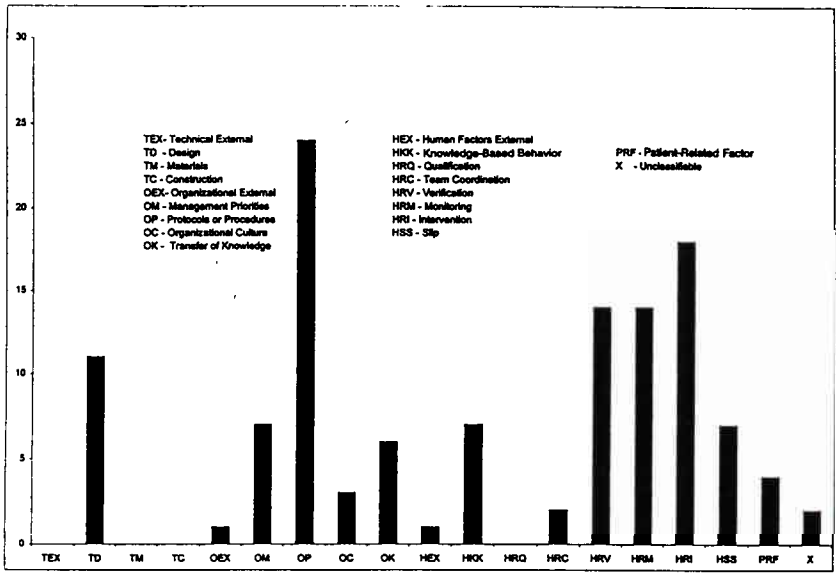

Fig. 8. Distribution of causes for event category Product distribution.

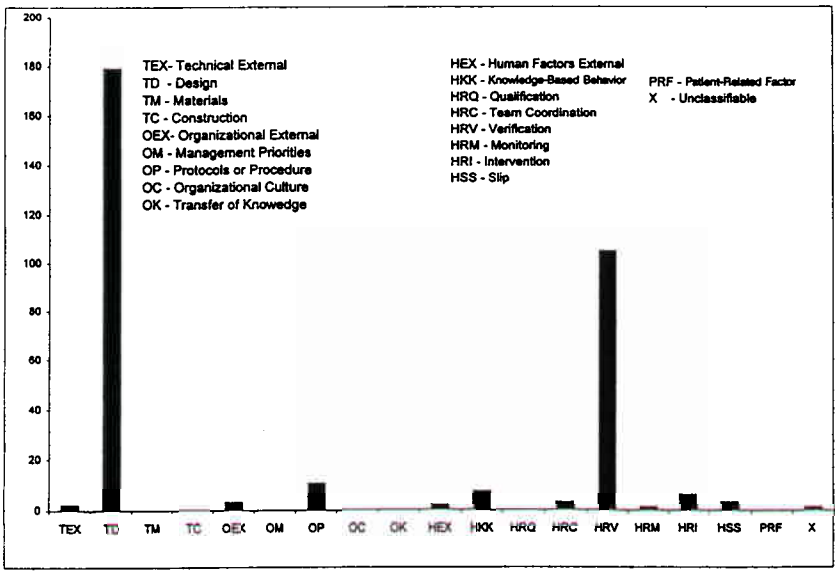

Fig. 9. Distribution of causes for event category Unit issue.

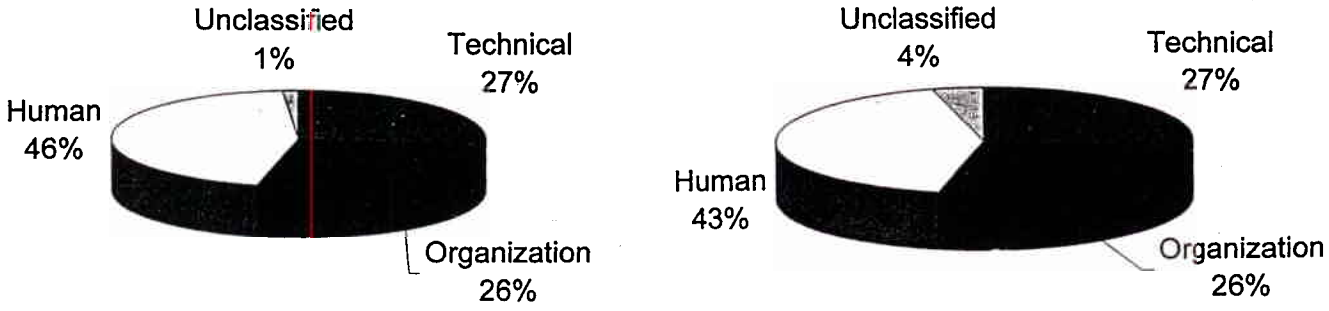

Fig. 10. Comparison of distribution of causes in transfusion medicine (A) and the petrochemical industry (B).

resulting from the data analysis. Examples include: more effective use of the computer in unit selection, more effective documentation of blood irradiation, improved reliability of instrument calibration, and better interdepartmental input on computer system changes. The effectiveness of these interventions reflects the knowledge gained through improved investigation processes introduced by the MERS-TM.

Acceptance

An indication of acceptance of the system is the fact that all three hospitals participating in the project are considering adopting the MERS-TM for a hospitalwide event-reporting system. No system can be of value unless the organization and the personnel responsible for its operation use it; in the case of MERS-TM, these personnel are the SysOps. A telephone survey of QA SysOps indicated that they were comfortable using the system and that the training that they had been provided was adequate for them to use the system effectively.

DISCUSSION

A near-miss reporting system that identifies and classifies the causes of events can be a powerful management tool in increasing our understanding of how transfusion medicine operations are actually functioning. Capturing precursor or near-miss information can facilitate the correction of problems before they turn into major adverse incidents. One should anticipate a significant increase in the number of events reported when true no-fault/no-fear reporting is put into place and staff members are encouraged to report events. Such increases in reports should be welcomed as a measure of the success of the reporting system. It is possible for a near-miss system to function effectively within an existing QA program, thereby increasing that program's scope but not creating an undue burden of implementation.

Having a theoretically sound method of causal analysis as part of an event-reporting system has added value to a required QA activity. The use of a common taxonomy for classifying the causes of events will assist in the comparison of data from one institution to another as well as in the identification of common problems and concerns that exist throughout the field of transfusion medicine. The use of this common taxonomy of error causation also allows the comparison of patterns of error in medicine to those in settings outside the medical domain. This gives some validity to the statement that causes of error in medicine have many commonalties with those in other error-critical settings, such as industry. Indeed, medicine has much to learn from industry, with the method used in MERS-TM being a case in point. The causal classification system included in MERS-TM represents a potential standard for the field of transfusion medicine.

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AUTHORS

Harold S. Kaplan, MD, Professor and Director, Clinical Pathology and Transfusion Medicine, Department of Pathology, University of Texas Southwestern Medical Center, 5323 Harry Hines Blvd., CS3.114, Dallas, TX 75235-9072. [Reprint requests]

James B. Battles, PhD, Professor, Office of Medical Education, University of Texas Southwestern Medical Center.

Tjerk W. Van der Schaaf, PhD, Associate Professor, Faculty of Technology Management, Safety Management Group, Eindhoven University of Technology, Eindhoven, The Netherlands.

Christine E. Shea, PhD, Postdoctoral Fellow, Faculty of Technology Management, Safety Management Group, Eindhoven University of Technology.

S. Quay Mercer, BS, MT(ASCP), Research Project Coordinator, Department of Pathology, University of Texas Southwestern Medical Center.