The Attributes of Medical Event–Reporting Systems

Experience With a Prototype Medical Event–Reporting System for Transfusion Medicine

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• ***Objective.***— **To design, develop, and implement a prototype medical event–reporting system for use in transfusion medicine to improve transfusion safety by studying incidents and errors.**

Methods.—**The IDEALS concept of design was used to identify specifications for the event-reporting system, and a Delphi and subsequent nominal group technique meetings were used to reach consensus on the development of the system. An interdisciplinary panel of experts from aviation safety, nuclear power, cognitive psychology, artificial intelligence, and education and representatives of major transfusion medicine organizations participated in the development process.**

Setting.— **Three blood centers and three hospital transfusion services implemented the reporting system.**

Results.—**A working prototype event-reporting system was recommended and implemented. The system has seven components: detection, selection, description, classification, computation, interpretation, and local evaluation. Its unique features include no-fault reporting initiated by the individual discovering the event, who submits a report that is investigated by local quality assurance personnel and forwarded to a nonregulatory central system for computation and interpretation.**

Conclusions.—**An event-reporting system incorporated into present quality assurance and risk management efforts can help organizations address system structural and procedural weakness where the potential for errors can adversely affect health care outcomes. Input from the end users of the system as well as from external experts should enable this reporting system to serve as a useful model for others who may develop event-reporting systems in other medical domains.**

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Several sentinel events (eg, the death of Betsy Lehaman from an overdose of cancer chemotherapy) have increased discussion of ways to deal with errors in medicine.[1] Leape[2] has emphasized the seriousness of the problem and has stressed that the rate of error in medicine is unacceptably high compared to rates in other industries or services. Two recent books have addressed the subject of medical error: *Medical Accidents*[3] presents a British perspective, while *Human Error in Medicine*[4] presents a comprehensive examination of the issue. The recent multidisciplinary leadership conference on Examining Errors in Health: Developing a Prevention, Education, and Research Agenda[5] (October 1996) allowed experts in medical error to explore possible mechanisms to reduce the incidence of error in health care.

Errors in medicine are not unique,[6–12] sharing important common causal factors with errors in other industries in which they are critical (eg, aviation, railroads, automobiles, nuclear power). Rasmussen's[13,14] taxonomy for identifying types of human behavior explains the sources of many human errors. Skill-based behavior refers to routine tasks requiring little or no conscious attention during execution. Rule-based behavior refers to familiar procedures applied to frequent decision-making situations. Knowledge-based behavior refers to problem-solving activities, such as when one is confronted with new situations for which no readily available standard solution exists. Reason[9,15] has two different ways of looking at error. First, human or active errors are committed when individuals commit either a slip or a mistake. A slip is a skill-based error, including omission (knowing what to do but doing nothing) and commission (inadvertently doing the wrong thing). A mistake includes both knowledge-based errors, made in a novel situation where there is no established protocol, and rule-based errors, such as selecting the wrong rule to solve a problem or choosing the right rule but executing it incorrectly. Second, Reason states that incidents occur because of system or latent errors, which are the delayed consequences of technical design or organizational issues and decisions. Accidents and adverse

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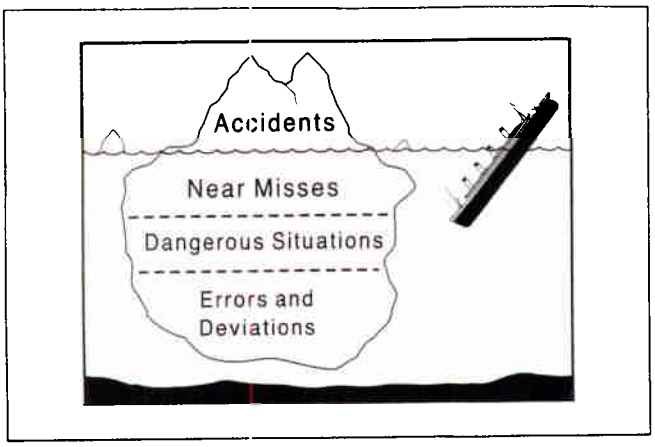

Fig 1.—*An iceberg concept of errors and accidents.*

events happen when latent or system errors combine with active human error. Thus, error researchers stress the importance of examining both human or active errors and underlying system problems that can contribute to error. Reason has referred to these latent or system errors as organizational pathogens that wait for the right opportunity to become active. These pathogens are very real in medicine, as Haley et al[16] found in their study of infections acquired by patients during hospital stays.

The ability of the system to degrade softly and/or the health professional to identify and recover from these combinations of active and latent conditions is what prevents an event from becoming one with adverse consequences.[17] Major accidents or sentinel events, however, grab the headlines and cause a great deal of concern. Fortunately, these events rarely occur. "Benign errors," which cause no harm or lack an adverse outcome, occur more often. Such events are referred to as "precursor events" or "near misses." Studies of commercial aviation have shown safety incidents associated with "benign" precursor events to be very similar to those associated with full-blown disasters.[18] The relationship between the accident and near misses has been compared to an iceberg or a pyramid, representing a continuum from the rare visible accident to the much more frequent near misses.[19] This concept is illustrated in Fig 1, with the sinking of the *Titanic* as an example of a sentinel event. Van der Schaaf[20,21] has described the rationale for precursor event–reporting systems.

> Accidents are very rare relative to the number of near accidents and human errors. Fortunate as it may seem, this poses a real problem for complex systems with a high "catastrophe potential" (nuclear power plants, chemical plants, commercial aviation): few accidents means few cases to analyze and hardly any feedback to learn from. This leads to the undesirable situation of ad-hoc corrective measures after each single accident, because the database is far too small to generate statistically sensible preventive measures.
>
> Hence, it is necessary to collect "near miss" data as well as accident data. The much more numerous unsafe situations (both chronic and sudden) and even more abundant human errors not resulting in serious consequences are assumed to have the same root causes as the tiny subset that actually develops into an accident. The same database size may thus be reached much sooner, or a certain observation period may yield a much more reliable insight into the causes of (near) accidents. Also the effects of implemented preventive measures may be monitored and evaluated much sooner and more reliably in this way.[21(p20)]

A near miss or precursor event–reporting system has existed in aviation for over 25 years,[22] and growing numbers of systems are emerging in other industries.[20] However, the use of near miss event–reporting systems in medicine has been limited. Runciman and colleagues[23] have reported on the development of a system in Australia to report errors, incidents, and accidents in anesthetic practice. The value of such a near miss management system in other industries suggests that the development of event-reporting systems in medicine would be a practical step in the process of dealing with errors.

Issues of Error in Transfusion Medicine

Transmission of the acquired immunodeficiency syndrome via blood transfusion has been what one could call a sentinel event that has increased the public's perception of the risk of infection and intensified concerns about the safety of the blood supply.[24–28] While all elements within transfusion medicine are required by regulation and accreditation policy to have an incident-reporting system, there has been no systematic collection and analysis of data among organizations. Further, most current reporting efforts describe only what occurred, with limited attention to what actually caused the event. This lack of a standard and comprehensive event-reporting system severely hampers the ability to study and understand error and thereby to enhance transfusion safety.

The University of Texas Southwestern Medical Center at Dallas received a National Heart, Lung, and Blood Institute grant to design, develop, and implement an event-reporting system in transfusion medicine. We designed a prototype medical event–reporting system for transfusion medicine (MERS-TM) that is being implemented in three blood centers (New York Blood Center, New York, NY; Oklahoma Blood Institute, Oklahoma City, Okla; and Blood Care, Dallas, Tex) and in three hospital transfusion services (New York University Medical Center, New York, NY; Parkland Memorial Hospital, Dallas, Tex; and Baylor University Medical Center, Dallas, Tex).

METHODS

We determined that an interdisciplinary consensus development approach was needed to design and implement the prototype system. A project steering committee was created with representatives of stakeholder agencies and organizations, including the US Food and Drug Administration (FDA); the American Association of Blood Banks; the American Red Cross; Blood Systems, Inc; and America's Blood Centers, to oversee the design and operation of the prototype system. Representation from these stakeholder organizations was considered critical if the resulting system were to be adopted in transfusion medicine. Participating in the design of the prototype system would give the eventual users a sense of ownership and, we hoped, limit resistance to its adoption. People tend to use that which they have helped to develop. We also sought participants from outside transfusion medicine, since most of the work in the area of human error exploration and safety improvement comes from multiple disciplines. Our challenge, then, was to select a method that would guide us through the design process and effectively bring these interdisciplinary experts together to assist with the design.

The IDEALS Concept of System Design

We selected Nadler's IDEALS concept of design[29] as a conceptual framework for our design process because of our prior success with this approach.[30,31] Nadler indicates that it is much easier

Table 1.—The Results of a Three-Round Delphi to Identify the IDEAL Parameters of a Medical Event–Reporting System for Transfusion Medicine

System Characteristics
Overall
Collect and analyze reports of errors and interpret results
Nonreprisal system; no adverse consequences are attributed to the reporter
Report all errors, including no-harm or near miss events
Solicit input from anyone with firsthand information about an error or event
Solicit input from all those involved in the error or event
System input
Have the ability to track back from the reported error to the root cause
Identify the specific procedures involved
Indicate whether there was misidentification of blood sample, patient, or product
Indicate the location of error in the transfusion process
Identify any equipment malfunctions involved in the event or error
Data collection
Allow further contact with reporters for data clarification, while maintaining anonymity
Make blank report forms available to all who might wish to report errors or events
Emphasize narrative descriptions of events (usefulness of reports resides in the narrative)
Use adaptable on-line, interactive computer system for easy reporting
Have a trained system operator with knowledge of domain to receive reports
Analytical process
Look beyond a single error to the entire blood system
Categorize errors as to where they occurred in the process
Identify links between active human errors and latent system failures
Categorize errors as slips, mistakes, or system design errors
Identify common problem areas across institutions
Intervention
Find underlying system failures by analysis of all errors
Make recommendations based upon error analysis to apropriate levels of decision makers
Target problem areas prone to error for additonal study
Track implemented corrective actions to determine their effectiveness
Develop intervention strategies by multidisciplinary groups

and more efficient to conceive of an ideal system and work backward, introducing increasing levels of reality to develop a system that can be recommended for use.

Specifying the IDEAL System Parameters

We chose the Delphi method[32,33] as means to establish the ideal design parameters and functions for the prototype system. Twenty-three experts in aviation safety, nuclear power, cognitive psychology, industrial engineering, artificial intelligence, education and training, and transfusion medicine from the United States, Great Britain, and Australia participated in the Delphi. The Delphi resulted in a set of ideal design parameters, listed in Table 1. The steering committee then converted the theoretical specifications of the Delphi into a more realistic target plan, using the nominal group technique described by Delbecq et al,[34] during a series of three consensus development meetings. They reviewed the results of the Delphi to refine the specifications toward implementing a functioning system within 18 months, and they set important requirements for the proposed reporting system: (1) integration with quality assurance (QA), (2) capability to deal with a high volume of reports, (3) inclusion of a selection or screening process to sort reports as routine events or new or unique incidents, and (4) ability to provide a consistent method of classification that could be used by existing QA personnel without extensive training.

The steering committee considered it essential that MERS-TM be part of existing QA programs at the participating blood centers and hospital transfusion services, since QA is an organizational requirement consistent with current good manufacturing practices and required by the FDA. To do otherwise, the steering committee believed, would be burdensome and impractical. As part of the QA activity, existing guidelines for quality control (ie, those published by the America Association of Blood Banks), served as a reporting framework. Confidentiality and no-fault reporting were considered essential. Completely anonymous reporting is not a workable solution for an operational MERS-TM; it was considered essential that QA personnel contact reporters to investigate events fully. Confidential reporting implies that confidentiality will be maintained in a no-fault context to protect the reporter from any adverse consequences of reporting an incident or an event. Without such protection, few errors would be reported. Since the emphasis was on the study of multiple events rather than single incidents, anonymity could be created by not identifying individuals in a database once the investigation was completed.

Event-reporting programs such as those in place at the American Red Cross and other transfusion medicine organizations are designed to capture thousands of precursor events each month. Such a large volume of reports can easily overwhelm the input process. To maximize the learning effect, a selection procedure is necessary to separate the interesting reports that will be analyzed further from known problems or events with little impact on the transfusion process. The relative speed with which information can be entered into appropriate databases for analysis is also affected by a high volume of event reports. A technologically workable solution to deal with high volume and its impact on data entry is to make the paper forms serve as computer input devices. Off-the-shelf technologies that are currently available for direct computer input of paper forms use a combination of optical mark recognition and optical character recognition. Designing forms that combine fixed fields for optical mark recognition and structured text boxes for optical character recognition minimize the dependence on free text and facilitate rapid and accurate data entry. The structured text blocks allow reporters to use their own words, while placing some limitations on the narrative input. All of the event reports for MERS-TM use this combination of optical mark and character recognition technology (ie, "smart paper") that can be scanned into the computer or faxed to a central location. The person initially completing any form literally does the data entry. Both the coding and the structured narrative can be placed in the database for analysis. Coding and structured text blocks allow one to process and analyze more events than would otherwise be possible with conventional unstructured narrative–based reporting formats.

RESULTS

The MERS-TM System

An operational prototype for MERS-TM was developed (see Fig 2) once the design elements of a technologically workable prototype system were determined. The system has seven major functional components: detection, selection, description, classification, computation, interpretation, and local evaluation. This follows closely the framework of the near miss management system developed by Van der Schaaf.[20,21]

Detection

Because MERS-TM works within the QA structures already in place in participating organizations, the reporting process begins at the blood center or transfusion service.

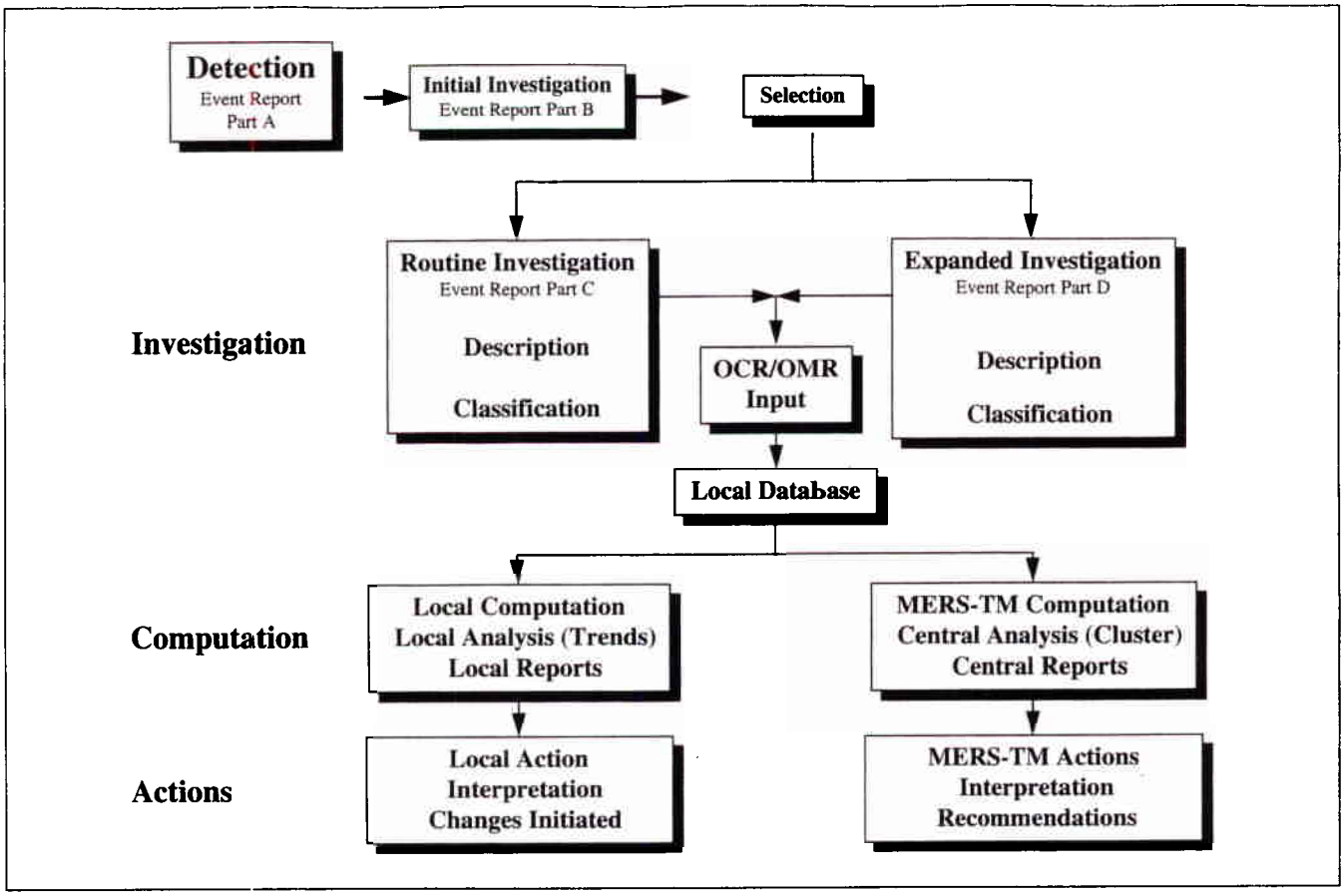

Fig 2.—*Medical event–reporting system for transfusion medicine (MERS-TM) process flow. OCR indicates optical character recognition; OMR, optical mark recognition.*

The individual who discovers an event completes a discovery form, which triggers actions at the local level. The individual completing the discovery form need not have been involved in the event. The discovery form serves several vital functions: (1) it states where and when an event was discovered, (2) it determines the number of barriers or critical control points that were breached before the event was discovered, (3) it specifies the event's consequences (if known), (4) it identifies individuals who might have been involved in the event, and (5) it documents actions taken to minimize the adverse consequences of the event as well as recovery actions taken by individuals after the event's discovery.

Once a discovery report has been submitted, it becomes the responsibility of the QA component of the participating organization to review and screen all discovery reports. We adopted the term *systems operator* (Sys Op), as used in the field of aviation in the Aviation Safety Reporting System, to designate the QA individual who reviews and investigates the reported events.

Selection

After reviewing the report, the QA Sys Op determines whether an event was new or in some way unique, in which case it requires an expanded investigation. Events that are considered to be new or unique or that meet the predetermined screen receive an expanded investigation involving complete description and classification of all root causes. For routine events, the QA Sys Op codes the event as to type and assigns causal codes. The report forms are then scanned directly into the computer and the data transferred to the MERS-TM central computer for multi-institutional analysis.

Description and Classification

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. Therefore, an important part of MERS-TM is a common classification scheme that reports and classifies an event in this way. We needed a means to classify the type of event that could be applied consistently across the field of transfusion medicine to reduce the dependence upon unstructured narrative. The FDA had developed a classification scheme for recording the types of errors reported over the past years.[35] The scheme's reliance on unstructured text is limited and consistency in reporting is good, so we used the FDA classification scheme with a subset added for hospital transfusion services.

Most existing QA incident-reporting systems only describe what happened and pay little attention to why the event occurred. When root cause analysis is performed, it is often cursory and incomplete and may lead to inappro-

Table 2.—Eindhoven Classification Model for Medical Domain

Category	Description	Code
Latent errors	Errors that result from underlying system failures	
Technical	Refers to physical items, such as equipment, physical installations, software, materials, labels, and forms	
External	Technical failures beyond the control and responsibility of the investigating organization	TEX
Design	Failures due to poor design of equipment, software, labels, or forms	TD
Construction	Correct design was not followed accurately during construction	TC
Materials	Material defects not classified under TD or TC	TM
Organizational		
External	Failures at an organizational level beyond the control and responsibility of the investigating organization	OEX
Transfer of knowledge	Failures resulting from inadequate measures taken to ensure that situational or domain-specific knowledge or information is transferred to all new or inexperienced staff	OK
Protocols/procedures	Failures related to the quality and availability of the protocols within the department (too complicated, inaccurate, unrealistic, absent, or poorly presented)	OP
Management priorities	Internal management decisions in which safety is relegated to an inferior position in the face of conflicting demands or objectives. This is a conflict between production needs and safety (eg, decisions about staffing levels)	OM
Culture	Failures resulting from collective approach to risk and attendant modes of behavior in the investigating organization	OC
Active errors (human)	Errors or failures resulting from human behavior	
External	Human failures originating beyond the control and responsibility of the investigating organization	HEX
Knowledge-based behaviors		
Knowledge-based errors	The inability of an individual to apply existing knowledge to a novel situation	HKK
Rule-based behaviors		
Qualifications	Incorrect fit between an individual's qualifications, training, or education and a particular task	HRQ
Coordination	Lack of task coordination within a health care team in an organization	HRC
Verification	Failures in the correct and complete assessment of a situation, including relevant conditions of the patient and materials to be used, before starting the intervention	HRV
Intervention	Failures that result from faulty task planning (selecting the wrong protocol) and/or execution (selecting the right protocol but carrying it out incorrectly)	HRI
Monitoring	Failures during monitoring of process or patient status during or after intervention	HRM
Skill-based behaviors		
Slips	Failures in performance of fine motor skills	HSS
Tripping	Failures in whole-body movements	HST
Other		
Patient-related factor	Failures related to patient characteristics or conditions that influence treatment and are beyond the control of staff	PRF
Unclassifiable	Failures that cannot be classified in any other category	X

priate corrective action. After reviewing several existing error classification schemes and rejecting the possibility of developing a completely new approach, we selected an existing classification system, the Eindhoven Classification Model developed by Van der Schaaf.[21] This model had been tested in various industries, including hospitals, which provide a medical domain–specific reporting framework.[36,37] We felt that this operational classification scheme was a technologically workable solution consistent with the IDEAL design parameters that had been specified by the MERS-TM steering committee. In a cooperative effort, the authors from Eindhoven University of Technology and the University of Texas Southwestern Medical Center at Dallas incorporated this classification model into the overall MERS-TM framework. Three major categories of causes are grouped in the model: technical (equipment, software, and forms), organizational (policies, procedures, and protocols), and human causes (knowledge-based, ruled-based, and skill-based). The classification of human failures is consistent with the theoretical frameworks of Reason[9,15] and Rasmussen.[13,14] Table 2 outlines the Eindhoven Classification Model, Medical Version,[38] for transfusion medicine.

Once the event has been described, the QA Sys Op draws a diagram to represent the incident using a causal tree. Causal trees are very useful for displaying critical activities and decisions in both logical and chronological order. The event is diagrammed with all possible causes

Table 3.—Event–Grouping Analysis Grid		
	Clustering by Condition	
Clustering at Site	Yes	No
Yes	Site- and condition-specific	Site-specific
No	Condition-specific	Nonspecific

and recoveries gathered during the investigation.[39] The causal tree shows the variety of underlying or root causes of an event. Each root cause is assigned a causal code using the Eindhoven Classification Model. On the investigation report form, a narrative description of a few terms further defines each code used. Once the investigation report form is completed and scanned into the local computer system, it is transferred to the central MERS-TM system for computation and interpretation.

Computation

A major consideration in developing the computation component was the fact that all events, incidents, errors, and accidents are multifactorial and that the underlying causes and contributing factors are nested within the event itself. This limits the amount of meaningful data that can be obtained from simple trending of events. The problem of nesting or system interrelationships is compounded because we are looking across multiple institutions and systems. We accommodated systems within systems as part of the framework of transfusion medicine on a national basis. Therefore, we looked for an analytic approach that could accommodate this nesting phenomenon. the nested nature of medical problems and cases has been noted in other work in medical education by Battles.[40]

Root cause analysis[41] was considered the most appropriate way to link the causal event clustering with the domain-specific identification of incident location codes in the stages of the transfusion process. At the central system level, we determined whether any specific event was limited to one blood collection or transfusion center or whether similar events were being reported from multiple centers. This led us to divide event groupings into four broad categories. (1) Nonspecific events are distributed randomly or evenly across both the transfusion process and geographic locations. At first, all events or errors may be perceived as unique or nonspecific events because of their situational context. (2) However, as more events are reported, other patterns may appear (eg, when a tight grouping of events occurs in a specific part of the transfusion process, such as donor history). These types of error patterns are referred to as condition-specific events. (3) A large group of single event types at a specific blood or transfusion center suggests a site-specific event. (4) A large number of single event types, tightly grouped at a particular site and at a specific point in the process, represents a site- and condition-specific event (see Table 3).

Interpretation

The real value of MERS-TM is its ability to interpret data that have been generated and analyzed from multiple institutions. This broader information resource includes all reports—those undergoing routine investigation and those for which a causal tree was generated—and generates specific recommendations toward eliminating or preventing identified errors or potential errors within the field of transfusion medicine as a whole. Individuals at specific sites may analyze and interpret their local databases. A classification/action matrix[21] is used to develop effective preventive and corrective actions at the local level. For most categories in the final matrix, a recommended action has been identified (Table 4).

The rows in the classification/action matrix represent the different categories from the classification model, while the columns define the optimum type of action or solution for each category. The recommended action is represented with an X in the matrix. Particularly ineffective management responses are marked NO. These are the "blaming and training" methods still used frequently as error management techniques in much of industry and medicine today, with little long-term success.

The goals for collecting and interpreting the data generated by MERS-TM at the central level are modeling, monitoring, and increasing alertness.[20] Modeling the types of events and recovery steps that occur in the transfusion process allows us to identify factors or system elements that have the potential to cause future errors, providing greater insight into incident evaluation and prevention. Monitoring existing areas of concern to determine whether the incidence of near misses and accidents is changing also helps in evaluating the impact of corrective actions. Finally, an effective risk management system that includes dissemination of information about potential risks and error-producing precursors heightens a state of alertness, which makes the field more proactive in its daily operation.

Evaluation

The evaluation of the system occurs at two levels. At the local level, the database is evaluated regularly to assess the effectiveness of the system and the impact of corrective actions. After evaluation, regular feedback about the system to all staff, and immediate feedback to individuals reporting incidents, is required. This feedback helps maintain staff interest and motivation to continue to provide input. All personnel must be included, emphasizing the positive influence of their input on the safety of the system.

At the central level, analysis reports are produced at varying intervals, and the results are sent to all participating sites and to the major organizational stakeholders. Comparative data are provided to all participants so that they may examine their local data in relation to data contained in the central system. Reports on significant trends or identified problem areas that are common across participating institutions are provided through publications and alerts. Information on successful corrective actions that have been implemented by participants or provided by the central system is also included.

Implementation Results

A telephone survey of QA Sys Ops was conducted as part of a formative evaluation of implementation in the participating blood centers and transfusion services. The QA Sys Ops reported that the coding and classification system was easy to use and provided a new way of looking at errors and their causes. They also reported that the MERS-TM process helped them to identify multiple causes instead of recording only a single cause, as they had done in the past. With the adoption of no-fault confidential reporting, the number of reported events has increased, with one institution reporting a 10-fold increase in the

Table 4.—Preliminary Classification/Action Matrix*

Code	Equipment	Procedures	Information and Communication	Training	Motivation
T-EX†					
TD	X				
TC	X				
TM‡					
O-EX†					
OP		X			
OK			X		
OM§			X		
OC		X			
H-EX†					
HKK			X		NO
HRQ				X	
HRC				X	
HRV				X	
HRI				X	
HRM				X	
HSS	X				NO
HST	X				NO
PRF‖					
X					

* Eindhoven classification model codes are defined in Table 2. X indicates a recommended area of action; NO, an area in which management action will be particularly ineffective.

† Further investigation by external organization.

‡ Immediate action should be considered, if not already taken.

§ Refer to higher management level, above the levels implicated by OM position.

‖ Emphasis on possible trends.

number of reports received each month. An overall increase in the number of events reported is considered a significant sign of success of a near miss reporting system[21] and is consistent with what others have found when no-fault reporting was initiated.[42]

The reaction of management personnel within participating organizations has been extremely positive, proving MERS-TM to be a valuable tool in monitoring system operations. On the basis of the success of MERS-TM to date, transfusion medicine organizations and providers have recommended to the FDA and the National Heart, Lung, and Blood Institute that the MERS-TM system be further evaluated as a national standard for reporting events in transfusion medicine. Expansion of MERS-TM beyond the initial six participating institutions is planned for 1998. This expansion will include all major blood provider organizations and a sample of 20 hospital-based transfusion services.

COMMENT

The need to consistently record and analyze data from incident reports motivated the development of an event-reporting system for transfusion medicine. Active involvement of all of the major stakeholders in transfusion medicine created a sense of ownership in the completed prototype system and enhanced the high level of acceptance of the system. Use of the IDEALS concept of design in combination with the Delphi and nominal group processes helped structure multidisciplinary input, resulting in a final system that was much more complete than would otherwise have been possible. Combining existing QA efforts into a prototype incident-reporting system allows information sharing without duplicating efforts at the local institutions. The use of an existing and tested causal classification system, the Eindhoven Classification Model, helped make MERS-TM consistent with event-reporting systems in other industries.

A basic structure for event-reporting systems now exists and can benefit others who wish to implement such a system as a means of managing error and dynamically analyzing their systems for potential error vulnerability. Adoption of systems like MERS-TM throughout medicine can provide a proactive method of dealing with elements within the structure and process of medical care that have the potential for adverse effects on the outcome of care. Such dynamic reporting systems can improve the quality of care before adverse outcomes occur.

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