Defining, Identifying, and Measuring Error in Emergency Medicine

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Abstract. The findings of a consensus committee created to address the definition, measurement, and identification of error in emergency medicine (EM) are presented. The literature of error measurement in medicine is also reviewed and analyzed. The consensus committee recommended adopting a standard set of terms found in the medical error literature. Issues surrounding error identification are discussed. The pros and cons of mandatory reporting, voluntary

reporting, and surveillance systems are addressed, as is error reporting at the clinician, hospital, and oversight group levels. Committee recommendations are made regarding the initial steps EM should take to address error. The establishment of patient safety boards at each institution is also recommended. **Key words:** error; public health; emergency medicine; safety. ACADEMIC EMERGENCY MEDICINE 2000; 7:1183-1188

DEFINING AND MEASURING ERROR

The term "medical error" has been the focus of much discussion recently, stimulated by the Institute of Medicine (IOM) report "To Err Is Human."¹ The report brought to the attention of the public that adverse events in medicine are common and are one of the leading causes of morbidity and mortality within the United Sates. The report estimates that 44,000–98,000 patients hospitalized in the United States each year die as a result of medical errors, making this one of the leading causes of deaths. Although the methodology of the IOM report has stimulated controversy,^{2,3} a recent report from the United Kingdom's National Health Service confirms the magnitude and global impact of medical errors.⁴

Between 3% and 4% of patients admitted to the hospital have adverse events resulting in injury or disability. About 30% of these adverse events are thought to be preventable and represent suboptimal care. The total national cost for medical errors are estimated to be 37-50 billion, with preventable adverse events accounting for 17-29 billion.¹

Medication errors have been more extensively studied and are estimated to account for about

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7,000 deaths per year.¹ In a meta-analysis of prospective studies of adverse drug reactions in hospitalized patients, it was found that the overall incidence of serious adverse drug events (ADEs) was 6.7% and the incidence of fatal ADEs was 0.32% of hospitalized patients.⁵ Extrapolation of these data led to estimates that in 1994 more than 2.2 million hospitalized patients had serious ADEs and 6.000 had fatal ADEs, making ADEs between the fourth and sixth leading causes of death in the United States.⁵ Serious ADEs were those that necessitated hospitalization, were permanently disabling, or resulted in death. The U.S. Pharmacopeial Convention (USP) has developed a systematic taxonomy of medication errors.⁶ Such standardized definition sets are needed in order to conduct meaningful research and to quantify progress.

It is clear from these data that medical errors are a major cause of morbidity and mortality in the United States. There are few data in the literature about medical errors in emergency medicine (EM). However, studies in the literature imply that EM is a key area for preventable medical errors.⁷

In a recent major study on adverse events in hospitalized patients, researchers selected a sample of hospitals in Utah and Colorado and randomly sampled 15,000 discharges in 1992.^{8,9} Trained nurse reviewers retrospectively reviewed hospital records for any one of 18 indicators of possible adverse events. Criteria included subsequent or previous hospital admission, hospital-incurred trauma, ADEs, transfer to a special care unit or another hospital, return to the operating room, complication, myocardial infarction, stroke, pulmonary embolus, neurologic deficit, fever, cardiac arrest, death, unplanned procedure, and litigation. Charts meeting one or more of these criteria were

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then reviewed by a trained internal medicine or family practice physician who made a decision about whether an adverse event occurred and whether this event was due to negligence. Negligence was defined as medical care that fell below the standard expected of physicians in the community. Judgments about adverse events were made on a six-point confidence scale where 3 represented just under a 50% likelihood of error and 4 represented just over a 50% likelihood of error. Confidence scores of 4 or higher were then collapsed to make a decision about negligence. The authors found that adverse events occurred in 2.9% of hospitalizations. Negligence was the cause of the adverse event in 33% in Utah and 27% in Colorado. Death occurred in 6.6% of patients with adverse events and 8.8% of patients with negligent adverse events. Operative adverse events comprised 45% of all events, with 17% being due to negligence. Adverse drug events comprised 19% of all adverse events, with 35% being due to negligence.^{8,9} Adverse events in the emergency department (ED) were analyzed as a subgroup. The authors note "Although only 1.7% of adverse events were attributed to nursing staff and emergency physicians, a notable 74.2% and 94.8%, respectively, were negligent, mostly caused by failed diagnoses.... Among locations, the emergency department had the highest percentage of negligent adverse events (52.6%), and a remarkable 94.8% of adverse events attributed to emergency physicians were judged negligent."9

The second major study used a similar methodology. The Harvard Medical Practice Study investigated adverse events and negligence in hospitalized patients in New York State. The researchers reviewed more than 30,000 randomly selected records from 51 acute care hospitals.¹⁰⁻¹² Nurse reviewers screened the charts for 18 defined criteria. Charts meeting the criteria were then reviewed by two physician reviewers to determine whether an adverse event occurred and was due to negligence. The researchers found that adverse events occurred in 3.7% of hospitalized patients, with 27.6% due to negligence, and 13.6% of adverse events resulted in death. In this study 48% were associated with surgery and 19% with medications. The ED accounted for only 2.9% of the total adverse events. However, 70.4% of these ED adverse events were judged to be negligent.¹⁰⁻¹²

Both of these studies focused on the issue of malpractice litigation and its relationship to injury caused by negligence. These studies, nevertheless, have become very important in characterizing medical errors and iatrogenic injuries. Although the studies were flawed because emergency physicians were not the peer reviewers in determining the standard of care, the studies raise intriguing questions that cry out for further research of errors in EM.

Emergency medicine should adopt the definitions that are consistent with the Institute of Medicine report, the USP taxonomy, and the major studies in the medical literature. The def*initions are listed in Table 1*. While these terms are useful for categorization, many of the terms are charged with meanings that may interfere with our goal of improving emergency care for patients. The panel proposes that EM focus on preventable adverse events and potential adverse events. A preventable adverse event is when an injury occurs as a result of substandard medical care; the judgment is made that standard care would have reasonably prevented the injury. A potential adverse event involves substandard care that could have resulted in injury. Potential adverse events are "near-misses." By accumulating a database of these near-misses, we can better understand how preventable adverse events occur and build systems to prevent injury.

The identification of potential and preventable adverse events can occur only in an environment in which patient safety is a high organizational priority, individuals are not blamed for mistakes, and there is a nonpunitive system for reporting problems in medical care to peer-review protected committees that are empowered to institute changes in the system.

Emergency medicine should focus on identifying preventable and potential adverse events.

ERROR IDENTIFICATION

Error identification, a well-defined process in many industries,^{13–16} is still in its infancy in EM.¹³ The state of the art in error identification systems is derived from the relatively small body of knowledge in the medical field (especially the advancements made in anesthesiology17), as well as the body of knowledge and experience in systems with effective error identification processes in place (e.g., nuclear reactor systems^{13,15,16}). Without error identification an error may remain occult, so that rescue measures after the occurrence of an error may not be undertaken and corrective system changes for greater patient safety are unlikely. This is especially true in the ED, the location of the highest proportion of negligent adverse events in the hospital. $^{\bar{9}-12}$

Solutions for errors in medicine should focus on changes to the system and processes rather than punitive targeting of individuals. A nonpunitive system for identifying and reporting preventable and potential adverse events in EM *must be encouraged.* The panel is firm in its belief that lasting error reduction will be made through system changes and the processes by which medical decisions and care are made. Errors made by an individual often reflect system-wide problems.^{1,16,18-20} For example, the urine culture result on an ED patient is reported two days after the patient's discharge from the ED. No one informs the patient that she needs antibiotics, and the patient returns a week later with urosepsis. This case would meet the definition of a preventable adverse event as well as medical error. The typical reaction is to blame the physician who ordered the culture for not following up on the results and to educate the physician to be more diligent the next time. This approach is certain to fail and result in similar errors in the future. Individual punitive measures in this case will not solve the system-wide problem of an inadequate followup system for culture results in the ED.

Cognitive errors may contribute to a large proportion of preventable and potential adverse events. It is crucial, however, that these events be recognized. A punitive approach will discourage reporting of potential adverse events. Further, it is well known from other industries that error reduction will not be achieved through punitive measures but rather through changes in the medical system and the medical decision-making process.

The panel recognizes the inherent complexity of systems, and their recommendations should be reevaluated as new information arises. Error identification is not an easy process. If error identification were straightforward, it would not be the subject of major investigation today. The difficulty in error identification stems from the subjective nature of medical care,²¹ combined with the com-plexity of the system.¹⁶ A defining characteristic of a complex system is that change can have unpredictable effects.¹ It is impossible to say with certainty that any action will have a positive impact, a negative impact, or no impact at all on the system. The panel recognizes that EM operates in a complex systems environment, and consensus in this document should be reevaluated as new data arises.

THE "WHO, WHEN, WHERE, AND HOW" OF ERROR IDENTIFICATION

There are generally three methods of error identification: mandatory reporting, voluntary reporting, and active surveillance systems.

In most industries where *mandatory reporting* exists, a regulatory agency or governmental body mandates reporting of errors resulting in signifi-

TABLE 1. Recommended Definitions*

Error—Failure of a planned action to be completed as intended (error of execution) or use of a wrong plan to achieve an aim (error of planning); the accumulation or errors results in accidents.¹

Active error—An error that occurs at the level of the frontline operator and whose effects are felt almost immediately.¹

Latent error—Errors in the design organization, training, or maintenance that lead to operator errors and whose effects typically lie dormant in the system for lengthy periods of time.¹

Slip errors—An error of execution when the action conducted was not what was intended; the wrong action is observable.¹

Lapse errors—An error of execution when the action conducted was not what was intended; the wrong action is not observable.¹

Mistake—An error in which the action proceeds as planned but fails to achieve its intended outcome because the planned action was wrong; error of planning.¹

Accident—An event that involves damage to a defined system that disrupts the ongoing or future output of the system.¹

Patient safety—Freedom from accidental injury; ensuring patient safety involves the establishment of operational systems and processes that minimize the likelihood of errors and maximize the likelihood of intercepting them when they occur.¹

Quality of care—Degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.¹

Adverse event—An injury resulting from a medical intervention.^{1,8-12}

Preventable adverse event—An injury that occurs as a result of medical error; with standard medical care the injury would not have occurred.¹

Potential preventable adverse event ("near-miss")—A medical error that could have resulted in injury.^{1,24}

System—A set of interdependent elements interacting to achieve a common aim.⁴

*For complete citations, see the reference list.

cant injury.^{1,13,18} These errors are discoverable by audit (allowing enforcement), and they are the types of errors for which punitive action can be taken. Typically, there is at most limited confidentiality to the reports, and limited or no immunity from penalty. This type of reporting satisfies the "public's right to know," and it typically identifies a series of many events that coincided to threaten patient safety.¹ The lack of confidentiality often brings attention to the individual rather than to the system deficiencies that led to the errors. The resulting cycle of punishment may fail to root out system-wide problems that cause or contribute to error.^{13,16,18}

Voluntary error reporting systems are usually used to identify "latent" errors (errors in system design that pose a risk to the patient).^{1,18} An example is to name one medication "Norflex" and another "Norflox," which will predictably lead to confusion. Such latent errors are identified either by a near-miss potential adverse event (error not leading to injury) or by recognition of the potential for danger before a mistake has actually occurred. Identifying these errors may allow corrective systems changes before an injury occurs.^{1,18} Hospitals, safety "societies," governmental bodies, and regulatory agencies are all candidates to manage voluntary reporting systems. In most industries these systems are confidential (and sometimes anonymous), and they often confer immunity from penalty.^{1,13,18} Nonpunitive and confidential systems tend to have high compliance rates.^{13,18} The aviation safety reporting system has received and saved more than 500,000 voluntary reports of near-misses.¹³ Without individuals as targets, safety committees focus on systems changes that can prevent future error.

Active surveillance is the identification of error through observation. This can be direct observation while providing care (such as an observer watching clinicians "in action") or through chart review, or observation of error "markers" (e.g., tracking abnormal drug levels as a medication dosing error marker).^{9,11,21-25} Active surveillance may identify error before injury actually occurs (e.g., software that will not allow a drug to be given to a patient who has a known allergy to it). Most active surveillance systems are highly objective, simply flagging all occurrences of an error marker.^{22,24,25}

Error identification by clinicians allows those with the greatest medical and situational knowledge to provide insightful reports. Clinician reporting may be biased by concerns of penalty or embarrassment.^{13,18} Clinicians may not have the system-wide view necessary to recognize dangerous trends among disparate patients. Clinicians are unlikely to be able to implement change without the assistance of a larger institution.¹

Hospitals can identify error through random chart sampling, quality assurance systems, reporting, or active surveillance systems. Hospitals may best be able to implement active surveillance systems. Hospitals may have a broad system view that can identify some errors among disparate patients. A hospital will not have the health care system-wide view of a state or federal regulatory agency, nor the power to implement change outside the institution.¹ Hospitals may be biased in reporting to protect themselves from penalty or negative press.²³

Error identification involving an oversight

group (often a governmental agency) can occur through mandatory or voluntary reporting systems, and active surveillance by audit and direct observation. Oversight groups can best recognize health care system-wide problems, especially among widely disparate patients. They may have the resources and power to implement and enforce change throughout the entire health care system.¹ Error identification by an oversight group is a standard element of high-risk, complex, yet highly safe systems such as airline travel.^{1,13} However, medicine differs in that its errors are smaller-scale (one person injured at a time), yet far more frequent. With the potential for nearly 100,000 investigations per year, it is unclear that an oversight group will be able to handle health care's volume of errors. Confidentiality or anonymity, and immunity from penalty are significant concerns when reporting to a governmental organization. Oversight groups might find it easier to penalize individuals than to enforce corrective system changes. Even the fear of penalty may hinder compliance by hospitals and clinicians.^{13,18} The large bureaucracy of an oversight agency may make error management sluggish.

Human and computerized active surveillance systems hold great promise for error identification. Errors can be flagged using "markers" such as the use of reversal agents (e.g., naloxone) or other therapeutics (e.g., diphenhydramine, epinephrine), abnormal laboratory data (e.g., hypoglycemia), a change in patient location or level of care (e.g., ICU admission), an unplanned emergent procedure, an overlong length of stay for diagnosis, and diagnostic codes (e.g., allergic reaction diagnostic code).^{1,22,25} Making errors more visible when they occur facilitates error identification.¹⁵ An example is the color-coding of ophthalmologic medication caps. Pupillary dilation drops come in red-capped bottles, and pupillary constriction drops come in green-capped bottles. If the pharmacy sends a green-capped bottle when cyclopentolate (a dilator) is ordered, an error has probably occurred.

Rapid error identification facilitates corrective action to prevent or limit injury.¹⁵ Therefore, it is imperative to create a system that can identify error at the earliest possible moment.

In summary, error identification systems solely involving clinicians may be easy to implement, but are unlikely to effect system change without the involvement of the hospital or an oversight group. Adding hospital resources and involvement to the system adds some complexity, but the net effect will likely be positive. Members of the health care system will probably resist the involvement of an oversight agency due to concerns over bureaucratic sluggishness, immunity, and confidentiality. Voluntary reporting systems are typically confidential or anonymous, confer immunity, and do not require compliance audits. They will probably be easier to implement than mandatory systems. Voluntary reporting may identify error-prone systems before injury occurs. Active surveillance systems are likely to be highly effective, but they require significant resources and infrastructure to implement (such as computer hardware and software).

Patient safety must be made a high organizational priority in each hospital. While the exact system for identifying and evaluating medical errors will vary with the needs of the institution, each institution should have an oversight body that is peer-review protected and capable of carrying out the functions of a patient safety **board.** The panel recommends that EDs work within their hospitals to promote the IOM recommendation for the creation of a hospital safety programs with defined executive responsibility.¹ Each hospital should create a committee or collection of committees that can serve as a patient safety board to champion patient safety for all patients. including those in the ED. This board would serve the following roles:

• implement systems to monitor preventable and potential adverse events

• review reports of error in a peer-review-protected fashion

• implement system-wide changes to promote patient safety

The safety committee(s) should serve the role of monitoring the institution for preventable and potential adverse events, reviewing reports of error in a peer-review-protected venue and be empowered to make system-wide improvements to prevent future error. The panel emphasizes that the committee must be empowered to make the necessary system changes. Due to the interdepartmental nature of system-wide problems, it is expected that representatives from multiple departments will serve on the committee(s).

The patient safety board may be wrapped into existing hospital committees and structures. Smaller hospitals might join with larger hospitals to pool resources and perspectives.

Political factors may play a role in the ability of a committee to achieve results. The official recognition of a patient safety director who is responsible to the institution's chief executive officer may facilitate cross-departmental cooperation for error reduction.

The panel encourages blinding reviewers to outcome in error investigations to maintain a focus on system improvement. It is human nature to assign blame when suffering has occurred. Strong anecdotal evidence suggests that review committees are more likely to decide that error has occurred if an outcome was poor than if the same steps were taken but the outcome was unremarkable. The panel encourages objectifying the reviews of cases by initially blinding reviewers to outcome. Blinded to outcome, reviewers may focus on system correction rather than assignment of blame.

Systems to begin to reduce error should be implemented today. Without action and only further study, a year from now, no patient will have benefited from the effort to improve patient safety in EM. The panel recommends that each hospital begin implementing systems to identify and correct error within its ED. Each institution will need to determine its own resources and focus until more is known about the scope of errors in EDs.

Systems should be designed to catch error as early as possible. The modern advance of technology has made real-time data processing possible. Computerized systems for order entry, drug dispensing, and electrocardiogram analysis are all currently available, giving us the potential to recognize and prevent error as it occurs. Early error recognition may allow corrective or rescue steps to be taken before injury occurs.

The identification of potential and preventable adverse events by clinicians and hospitals consisting of active surveillance systems, voluntary, nonpunitive reporting, quality improvement systems, and chart sampling is a reasonable starting point for the institutional patient safety board. Each hospital's patient safety board will be responsible for creating error identification systems. Among many options, these may include a secure internal web page that employees can use to anonymously report errors, an error hotline for patients, a specialty review committee that monthly pulls charts for review, computerized surveillance systems, and the existing quality improvement process. Importantly, a regular system of review is recommended to determine a baseline level of error. Following changes in this baseline can help evaluate error-reducing interventions.

The panel recommends broad measures for error identification, but at this point it does not recommend mandatory reporting systems. The tendency of mandatory reporting to lead to punitive measures, the tendency to lack confidentiality or anonymity, and the need for auditing to ensure compliance make further work necessary before such systems can be recommended. The IOM currently suggests that the Forum for Healthcare Quality Measurement and Reporting manage mandatory reporting efforts.¹ The panel currently defers further recommendations on mandatory reporting until more progress is made in that process. The panel sees benefit in creating a centralized agency for tackling the broader issue of error in EM (e.g., a National Board for Quality Care in Emergency Medicine), but is deferring recommendations until future research and development can guide that discussion.

CONCLUSIONS

To see the future of error reduction in medicine, visit a department store. Salespeople, tags, and signs help you choose the right items. Store design lowers the chances you will head away from something you need. Bar codes ensure rapid and accurate item identification. Laser scanning devices reduce the errors that were common in handentering prices at the counter. Credit card units allow rapid identification of credit limit, preventing you from spending more than allowed by the card. A combination of security cameras, security personnel, and sensors at the door prevent you from "accidentally" walking out of the store without paying for an item. A sign at the exit encouraging submission of comments and suggestions allows management to identify additional problems and errors. The benefits of these systems must more than pay for their costs or they would not be instituted. Customers receive better service and are more satisfied while the companies reap greater profits.

Error identification is possible in medicine as well, in many cases using the same systems and technologies. Identification of systems problems that cause error is the first step in saving the lives of nearly 100,000 people per year. The stakes may be high, but so is the potential payoff. By setting the example in an environment as chaotic, fastpaced, and difficult as the typical ED, EM will set the standard for error identification for the entire medical profession.

References

not exaggerated. JAMA. 2000; 284:95–7.

3. McDonald CJ, Weiner M, Hui SL. Deaths due to medical errors are exaggerated in Institute of Medicine report. JAMA. 2000; 284:93-5.

4. Department of Health. An organisation with a memory. Report of an expert group on learning from adverse events in the NHS, chaired by the Chief Medical Officer. London, United Kingdom: Copyright Unit, Her Majesty's Stationery Office, 2000.

5. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies [see comments]. JAMA. 1998; 279:1200–5.

6. National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). NCC MERP Taxonomy of Medication Errors. Rockville, MD, 1998.

7. Chin MH, Wang LC, Jin L, et al. Appropriateness of medication selection for older persons in an urban academic emergency department. Acad Emerg Med. 1999; 6:1232–42.

8. Studdert DM, Thomas EJ, Burstin HR, Zbar BI, Orav EJ, Brennan TA. Negligent care and malpractice claiming behavior in Utah and Colorado. Med Care. 2000; 38:250–60.

9. Thomas EJ, Studdert DM, Burstin HR, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. Med Care. 2000; 38:261–71.

10. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. N Engl J Med. 1991; 324:370–6.

11. Leape LL, Brennan TA, Laird N, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. N Engl J Med. 1991; 324:377–84.

12. Localio AR, Lawthers AG, Brennan TA, et al. Relation between malpractice claims and adverse events due to negligence. Results of the Harvard Medical Practice Study III [see comments]. N Engl J Med. 1991; 325:245-51.

13. Barach P, Small SD. Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems. BMJ. 2000; 320:759–63.

14. Helmreich RL. On error management: lessons from aviation. BMJ. 2000; 320:781–5.

15. Nolan TW. System changes to improve patient safety. BMJ. 2000; 320:771-3.

16. Reason J. Human error: models and management. BMJ. 2000; 320:768-70.

17. Gaba DM. Anaesthesiology as a model for patient safety in health care. BMJ. 2000; 320:785–8.

18. Cohen MR. Why error reporting systems should be voluntary [editorial]. BMJ. 2000; 320:728–9.

19. Reinertsen JL. Let's talk about error [editorial]. BMJ. 2000; 320:730.

20. Vincent C, Taylor-Adams S, Chapman EJ, et al. How to investigate and analyse clinical incidents: clinical risk unit and association of litigation and risk management protocol. BMJ. 2000; 320:777–81.

21. Thomas EJ, Brennan TA. Incidence and types of preventable adverse events in elderly patients: population based review of medical records. BMJ. 2000; 320:741–4.

22. Nightingale PG, Adu D, Richards NT, Peters M. Implementation of rules based computerised bedside prescribing and administration: intervention study. BMJ. 2000; 320:750–3.

23. Pietro DA, Shyavitz LJ, Smith RA, Auerbach BS. Detecting and reporting medical errors: why the dilemma? BMJ. 2000; 320:794–6.

24. Weingart SN, Wilson RM, Gibberd RW, Harrison B. Epidemiology of medical error. BMJ. 2000; 320:774-7.

25. Bates DW. Using information technology to reduce rates of medication errors in hospitals. BMJ. 2000; 320:788–91.

Kohn LT, Corrigan JM, Donaldson MS (eds). To Err Is Human: Building a Safer Health System. Institute of Medicine Report. Washington, DC: National Academy Press, 1999.
Leape LL. Institute of Medicine medical error figures are