

addressing medical injuries comprehensively, including a systematic sequence of methods to identify medical injuries, study their causes, and intervene to reduce their occurrence or severity. A focus on medical injury avoids many of the operational difficulties and institutional and personal barriers to identifying errors. Rather than culpability, it emphasizes preventability, which should be the ultimate goal of patient safety efforts.

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## Patient Safety Efforts Should Focus on Medical Errors

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PHYSICIANS AND OTHER MEMBERS OF THE HEALTH CARE team encounter many problems in trying to make medical care safe. Two reports by the Institute of Medicine (IOM) claim that the medical profession is not organized to deliver high-quality care.<sup>1,2</sup> While we do not dispute the conclusions in these reports, we believe the reports may underestimate the magnitude of the problem as well as the character. Also, if not carefully considered, the report may lead to taking aim at isolated injuries rather than error. In doing this, the perception may be that medical care is being fixed; instead, the stage is being set for worse errors to come.<sup>3</sup> The following case report highlights this issue.

A patient admitted from an emergency department (ED) to an intensive care unit (ICU) died because of, in part, a delay in receiving appropriate treatment. The institution's policy

is that the ICU-admitting teams come to the ED to assess patients prior to transfer. The ICU teams also have a policy that they alone write orders for patients going to the ICU. In this patient's case, the ICU team promptly came to the ED to evaluate the patient, accepted transfer, and returned with the patient to the ICU. The ICU team wrote no orders while the patient was in the ED because computer order entry is not available there and the ED has a separate clinical record system. Therefore, an inpatient chart could not be generated in the ED. The ICU team elected to wait until the patient arrived to the ICU before writing orders to continue treatments given earlier in the ED (respiratory therapy orders, orders for diuresis, and orders to reduce the serum potassium level).

Nearly an hour later, when the patient arrived in the ICU, the ICU team attempted to write orders but could not. While

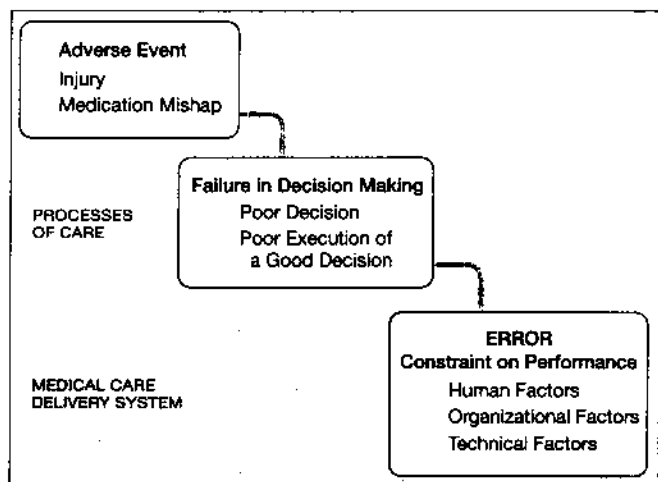
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See also p 1993.

**Figure 1.** Classification Scheme for Medical Error



The sequence of boxes is shown in order of detection, not in order of occurrence.

the ICU does have a computer order entry, the system needs certain information before a patient exists in the computer and the patient must exist in the computer before an order can be processed. For computer order entry to be fully operational, a utilization manager stationed in the ED has to enter financial information, a level of service code, and a bed number. Utilization managers call the patient's insurer to obtain authorization for the code. At the time of the patient's transfer to the ICU, the utilization manager could not be found. He was not available because he had recently been assigned additional duties while in the ED. The ICU team actually wheeled the patient by the utilization manager's desk but no utilization information was entered prior to transfer. Furthermore, when the utilization manager was located, he could not contact the insurance company by telephone.

Because the physician at the patient's bedside in the ICU could not find the patient's record in the computer, she could not write an order. While there is no strict refusal of handwritten orders, incentives are in place to ensure compliance with computer order entry. The physician waited for the entry program to become operational, which was delayed by the absence of the utilization manager. After another hour elapsed, while the physician was busy caring for other patients in the ICU, the patient had a cardiac arrest and resuscitation was unsuccessful. Orders were never written.

As this case illustrates, a method that has been proposed to make patient care safer—computerized order entry—may have contributed to this patient's death. This method missed its mark for this patient because of the failure to understand which system was truly failing within the contextual clinical circumstances that contributed to the unsafe care. However, this assertion may rest on how error is defined and then identified. It is important to realize that the language being used can affect the way mistakes are dealt with in medicine.

**Definition of Error**

The IOM report defines error as "the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim."<sup>1,2</sup> A major practical limitation of this definition is its focus on outcome. Instead, in our view, error is defined as those root or core causes at the system level of medical care.<sup>3,4</sup>

FIGURE 1 shows a proposed scheme for patient safety. Adverse events (including, but not limited to, injury) are random or caused by a failure in decision making (poor decision) or the failure to deliver a good decision. However, some error always causes failure. Therefore, the term error is reserved for those causes that lead to failures that may or may not lead to injuries. For example, the term, *medication error* is never used in this scheme, but is replaced with medication mishap or medication adverse event. The error is the cause of the failure that led to the medication adverse event.

These definitions are at odds with the definitions proposed in the IOM reports. The IOM definitions may not be helpful because failed decisions or processes have deeper-rooted causes.<sup>3,5-8</sup> Focusing on failed decisions or processes and their resulting injuries, such as those discussed in both IOM reports, actually may make it difficult to direct significant change at the system of care. This is because an individual often is prominently displayed at the level of injury, poor decision making, or poor processes. Focusing on individuals and these superficial levels of safety may not help reduce error. By nature, humans are subject to misplaced heuristics, biases, and distractions that make mistakes, slips, and injuries common, especially during complex clinical care situations.<sup>3,6,9</sup> Human judgment always will be precarious and systems must be developed to minimize the effects of human mistakes. Therefore, in our view, a decision failure is too personal to be an error. This focus on persons has serious shortcomings, is ill-suited to the complex medical domain, and may thwart the development of safer health care systems.

Likewise, processes of care are not errors because processes are made up of a complex array of interdependent steps forming a chain of events. The recurrent traps to safe care are hidden in the individual steps in the chain. The performance of the chain is constrained by usually only 1 or 2 weakest steps or links, not every link in the chain.<sup>10,11</sup> FIGURE 2 depicts a hypothetical process that has the output (ie, safe health care) constrained by the weakest link. The maximum output is the output of the weakest link. Fixing a step in the process that is performing better than the step that constrains the output may actually lead to more unsafe care.<sup>11</sup> This may be due to a poorly aimed improvement effort that drains resources from the weakest link.

An important concept of error determination is that the weakest link in the process is the error. The goal of the error-reduction efforts should be to eradicate or minimize error by reconfiguring, bypassing, buffering, or eliminating the weakest links in any process of care that leads to a failure

or an injury.<sup>10</sup> cal in nature, t ter all, the sys that are made.

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or an injury.<sup>10,11</sup> Although these constraints may be physical in nature, they are often policies devised by people.<sup>11</sup> After all, the systems developed are the sum of the policies that are made.

### How to Find Error

Error is likely to be at the policy making, organizational (including educational), and technical design levels of care. Therefore, it is imperative to detect the weakest links in the policy making, organizational, and technical delivery systems of care.

This is not an easy task. One model for finding the cause of injury is epidemiologic in nature.<sup>7</sup> In this model, injuries serve as the target in which failures and potential causes of failures are measured for the purpose of predicting injury. This model may be well received by the public and the academic community because it is an obvious extension of efforts to find the causes of disease and to prevent injury.<sup>12</sup>

However, the epidemiologic approach may not be the best model for identifying error. First, there is no easy data collection method in medical care for measuring injuries, failures, or the potential causes of those failures and, hence, controversy exists about the true error rate.<sup>13-15</sup> There is no standardized test for injuries and errors and, therefore, agreement among physicians about injury and error is poor.<sup>16</sup> Injuries may be easier to measure than failures and errors but even injury measurement is limited by variations in how injuries are uncovered.<sup>17-19</sup> Second, traditional epidemiologic methods are too slow for complex systems like medical care delivery. It takes a great deal of time to build representative data sets that can be examined for cause and effect.

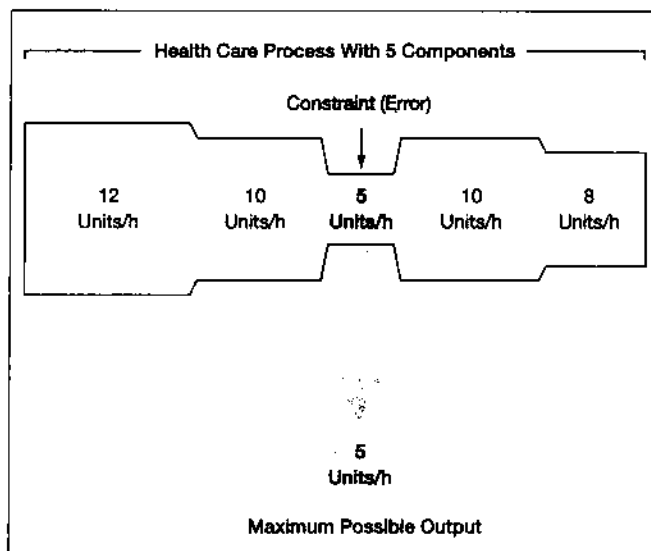
Aside from the measurement issues, there may be a more fundamental issue: finding error in medical care delivery may be more complex than finding the causes of disease and, hence, epidemiology may not be well suited to study such complexity. This is because disease is caused mainly by biological and environmental interactions but medical error is additionally caused by interactions of judgment, power, control, money, organizational policies and planning efforts, and technologic designs. The potential numbers of causes for any injury are staggering and are difficult to measure in any standardized way.<sup>20</sup> The BOX shows a partial list of potential causes for failures and injuries within 3 main domains of cause.

### What Is the Error Among the Potential Candidates?

Efforts to find causes for injuries are not new. Sentinel event committees, quality improvement efforts, and injury prevention models use root-cause analysis.<sup>21,22</sup> Root-cause analysis lists the potential causes of an adverse event. These causes are often categorized within domains such as the design of the system, the procedures used, and environmental, mechanical, and human factors.<sup>3</sup>

Useful, root-cause analysis is not sufficient because it has no formal way to point to those errors that most constrain the delivery of high-quality care. After a root-cause analysis,

Figure 2. Model of Constraint in a Health Care Process



Components within a health care process may occur in an interdependent, non-linear manner. Each component contributes an amount of output toward achieving safe health care, indicated as units per hour. The overall success of the process is limited by the constraint.

there is often a long list of potential causes. For example, for the case involving the patient admitted to the ICU, an analysis team identified 16 potential errors. Some included (1) human factors such as inexperience using computerized order entry and judging severity of illness; (2) organizational factors such as requiring utilization codes before orders can be written, using the utilization manager for jobs other than his/her primary duties, not allowing written orders to encourage the use of order entry, letting only ICU teams write orders for ICU patients, and not letting the utilization team leave the ED to follow patients to the ICU; and (3) technical factors such as not having beepers for utilization managers, flaws in the design of the order-entry program, not having the order-entry program and the same clinical record system that is used for inpatient care available in the ED, and lack of telephone access by insurance companies. Given these diverse potential errors, it is difficult to imagine how epidemiologic methods would assess the contributions of each of these difficult and diverse sets of factors.

Which of the many factors most contributed to this patient's injury? An alternative model for finding the steps that constrain safe care is the theory of constraints (TOC).<sup>10,11</sup> The TOC is a body of knowledge and tools used to improve the performance of any system (eg, manufacturing). Every system is designed to meet a goal and there are conditions necessary to meet this goal. The TOC requires that the goal of the system be known and be measurable. The unit of measure of the goal is called throughput. The main TOC principle is that a system should produce the most throughput while minimizing inventory management and operating expenses. The slowest performing step con-

**Box. Potential Errors for Any Injury by Domain of Cause**

**Human**

- Fatigue
- Lack of training
- Poor communication
- Power/control
- Hubris/hostility
- Distraction/time shortage
- Poor judgment
- Using heuristics
- Logic error

**Organizational**

- Workplace design
- Planning/policies
- Administration/finance
- Incentives/leadership
- Supply management
- Hand-off/transfers
- Supervision/feedback
- Unfamiliarity with tasks
- Mismatch of personnel

**Technical**

- Poor automation
- Poor equipment
- Lack of equipment
- No decision support
- Complexity
- Lack of integration
- No forcing function
- Irreversible error
- Information overload
- No checklist

strains the entire system's throughput (Figure 2). A constraint, then, is anything that limits the performance of the system relative to the goal.

The TOC proceeds via a series of procedures that aim to identify the most likely constraints on performance. First, the undesirable events and potential causes found during root-cause analysis are listed in no particular order. For instance, the injuries, the failed decisions, and the failed processes are, in TOC terms, the undesirable events that show that the system is not working well. Then, these events are linked using principles called sufficiency and necessity logic.<sup>23</sup> By clarifying the how and why questions raised during the linking process, a tree (the current reality tree) is developed that shows the interdependencies of the undesirable events and their potential causes. Some of these undesirable events often have branches that lead back to a single factor. This factor is called a core cause or the constraint. Once found, decisions must be made on how to exploit, bypass, or improve the performance of the constraint. Improv-

ing the constraint involves techniques like simplification, avoiding redundancy, bypassing tightly coupled processes of care, using technology to enforce safe actions, improving communication, and subordinating all other activities in the process to the constraint.<sup>3,10,11,23,24</sup>

One of the main advantages of TOC for error detection is that the data needed to identify constraints are readily available. The data emanate from conversation and debate, not administrative or epidemiologic data sets. The TOC finds that descriptions, stories, and reports are more likely to inform about errors. Logic is used to link cause and effect statements that become parts of the story being told.<sup>10</sup>

**Analysis of the Errors in the Case Example**

The goals of medical care are sound decisions and injury-free delivery of those decisions. For the ICU patient described, the goal was to transfer the patient to the ICU with orders written. Also, the patient should have been transferred to the ICU with a minimum of hand-offs and without having to wait for a utilization manager to make the order entry program become usable. Order entry failed in this instance because of barriers placed by financial and administrative policies and technical shortcomings. The goal was not met.

For this case, the analysis team considered the utilization manager and the policies of utilization management as the constraint to care. The computer order entry program must have some information to create an account. This is not a constraint—it is a necessary condition. The same applies to the need for financial and utilization data. Certainly, the order entry program could be rewritten or individuals other than utilization managers such as physicians could create accounts for their patients. However, the hospital did not have the ability to change the program and physicians are unlikely to understand the financial, utilization, and bed assignment needs for the entire hospital. Therefore, the analysis team considered the computer program outside its sphere of influence and, hence, this potential constraint was not considered amenable to improvement.<sup>10</sup> The team also felt that having distinct clinical record systems for ED and inpatient care contributed to the unsafe care but, again, they could not influence the purchase of clinical information systems.

The potentially amenable bottleneck then falls to the utilization managers and the policy makers who decide how these managers spend their time. The institution had the foresight to have a manager on site in the ED. The managers even had a desk near the hallway leading from the ED to the ICU. So, why did this become a constraint? Because the system of order entry and financial care is tightly coupled, the constraint on orders is the ability to enter necessary information in a timely manner. The utilization manager, however, was gone from his assigned desk during the patient's transfer to the ICU due to another policy—perform more than one job in the ED. This policy, while meant to help the ED staff, led to numerous episodes of patients trans-

ferred to the ICU while bypassing the utilization staff. This is especially dangerous as these patients needed orders written the fastest; however, they are most likely to bypass the very system designed to ensure the orders. The constraint is the policy to have multiple activities for key personnel.

There are several possible solutions to this constraint: (1) bypassing the constraint (letting additional personnel in the ED enter financial information or letting the ICU attending staff enter the utilization data); (2) improving the performance of the constraint (remove the policy for multiple jobs, make the managers available at all times, or let the managers have beepers so that they may be called to the ICU in an urgent situation); and (3) exploiting the constraint (ED physicians should call the utilization managers early in the care of a patient who may need ICU admission). The solutions chosen by the institution included removing the multiple tasks and providing beepers.

This example of the use of principles of TOC may trivialize the effort needed to arrive at these potential common sense solutions. Interviews with many members of the health care team and administrative staff were needed to fully understand all the perspectives and assumptions. Before the formal analysis, most blamed the order-entry program and the ICU physician. After analysis, however, the other constraints became evident. This level of diligence and discovery will be required to truly reduce error.<sup>25</sup> The TOC is also more involved than this simplistic description would suggest.

### Conclusion

In summary, the causes of injury are rooted at the deepest policy and organizational levels of medical care. These policies and organizational interactions are difficult to observe and measure. Errors will not be found without diligent conversations with those who provide care. Error reduction must begin and end with relationships.

Much is already known about how medical care can be safer. These strategies can be implemented now. However, too much effort may be being devoted to measures of injury rather than implementing known methods that reduce injury.

Contemporary efforts to reduce error seem to focus on sub-processes of care such as medication delivery. For example, while computer order entry has helped with some mishaps, order-entry systems may lead to other sorts of injury if the system of care in which order entry resides is not organized to maximize the benefits.<sup>26,27</sup> This is an explicit example of TOC. Having computer order entry does not necessarily remove the constraint to safe care for some situations.

We hope this article raises awareness of the depth to which approaches to reduce error should be directed. Such system science may provide opportunity to reduce injuries by aiming science at the health care delivery system as a whole.

Tools like TOC are helpful to take aim at error by going directly to the core of medical care philosophies and actions. Patient safety efforts should not waste time by aiming at injury. Too much is at stake.

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