Medical Emergency Teams

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Implementation and Outcome Measurement

With a Foreword by Ake Grenvik, M.D., Ph.D.

Springer

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To my wife Sharon, and my children Lizzie, Chris, Tim, and Annie
who are my life
and
to my parents
for challenging me and preparing me to achieve.
MAD

To Sue Williams
a loyal and committed colleague of 20 years.
KH

To Debbie and Hilary
to make your world a bit safer.
RB

I am indebted to my teachers, Dennis Greenbaum, Jim Snyder, Ake Grenvik, and Richard Simmons, who have taught me what critical care excellence is.
MAD

Foreword
Why Critical Care Evolved METs?

In early 2004, when Dr. Michael DeVita informed me that he was considering a textbook on the new concept of Medical Emergency Teams (METs), I was surprised. At Presbyterian-University Hospital in Pittsburgh we introduced this idea some 15 years ago, but did not think it was revolutionary enough to publish. This, even though, our fellows in critical care medicine training were all involved and informed about the importance of "Condition C (Crisis)," as it was called to distinguish it from "Condition A (Arrest)." We thought it absurd to intervene only after cardiac arrest had occurred, because most cases showed prior deterioration and cardiac arrest could be prevented with rapid team work to correct precluding problems.

The above thoughts were logical in Pittsburgh, where the legendary Dr. Peter Safar had been working since the late 1950s on improving current resuscitation techniques, first ventilation victims of apneic from drowning, treatment of smoke inhalation, and so on. This was followed by external cardiac compression upon demonstration of its efficiency in cases of unexpected sudden cardiac arrest. Dr. Safar devoted his entire professional life to improvement of cardiopulmonary resuscitation. He and many others emphasized the importance of getting the CPR team to out-of-hospital victims of cardiac arrest as quickly as possible. Similarly, much attention was given to identify other crisis situations in which trained ambulance personnel and other responders could reach the victims quickly to treat and preferably prevent threatening cardiac arrest by appropriate interventions.

Similar systems would have been logical and easy to arrange within hospitals for admitted patients. But such arrangements would collide with conventional training of physicians. In teaching hospitals, the tradition has been first to engage the intern to recognize all problems and treat the patients accordingly. If not successful, he or she would call on the assigned resident, leaving the attending physician out of the loop, frequently until too late to save a patient in crisis. Only recently has it become obvious that such a system fails. Training must be secondary to optimal and immediate care in evolving crisis.

Because of the above roadblocks, implementation of our Condition C team was not easy. The problem was frequently discussed in our Hospital's ICU Committee but the idea was considered too contrary to traditional clinical education and the concept was not accepted. After two years of ICU Committee debate in the 1980s, seemingly heading nowhere, as Chairman of this Committee, I received an emergency call one day from the chairman of the Surgical Department. He had a patient who was hypotensive and in respiratory distress on the "Gold Coast" ward after drainage of a malignant pleural effusion. We called our first team together, intubated the patient for mechanical ventilation, inserted a chest tube to drain a large hemopneumothorax that was obvious on chest x-ray, infused lactated Ringer's solution intravenously because of hypotension, and admitted her to the ICU. She could be extubated and returned to her ward the following day. This patient never developed cardiac arrest because of rapid resuscitation, work-up, and indicated therapy without delay. It was nothing heroic, but it was such a convincing demonstration of the value of Condition C that the next ICU Committee Meeting unanimously approved the system for immediate implementation.

Using METs should be a mandatory requirement for all hospitals. This system significantly reduces the frequency of cardiac arrest among hospitalized patients. Consequently, many lives are saved. The traditional medical culture must change to earliest possible involvement of a well-trained and experienced team preventing evolving crisis from developing into lethal consequences.

Michael DeVita and his excellent group of editors successfully present the introduction of METs in medicine to prevent unnecessary hospital deaths, first discussing why the current system fails and then describing system-wide approaches, the challenge of implementation, and finally the evaluation of hospital patient safety initiatives. In all, some thirty chapters by carefully selected authors provide a thriller-like and fascinating story of MET development in modern hospital patient management at a time when patient safety and appropriate timely care is recognized to be our most important obligation. Interestingly, the byproduct is improved educational experiences for both physician trainees, nurses, and other health care providers. This is clearly opposite to the anticipated effect of using METs.

In conclusion, this book may very well become a bestseller. Readers are likely to include not only physicians and nurses, but also hospital administrators, insurance agents and government representatives. The message is clear and the editors and authors are to be congratulated to so successfully completing their most important task.

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Preface

As the editors of *Medical Emergency Teams* and as clinicians, we have been working on improving hospital responses to crises for more than ten years. We have learned the hard way how not to build the wrong response, how not to step on toes, how not to intimidate people from calling for help, and how not to lose focus when energizing hospital personnel to prevent deaths by responding early and in a systematic fashion. We have had to convince people to work for and fund the program initially using only enthusiasm and logic. One of us applied for a grant to implement METs only to hear from the agency that not only were such teams impractical, no one would want to do the extra work they required!

We worked in isolation for a period of time, first winning over our own organization, and then, through stronger and stronger evidence of benefit, beginning to convince others of the need for and potential impact of medical emergency teams. Each of us has developed a new culture in our hospital, one that attempts to prevent cardiac arrests rather than responding to them. It a culture that is focused on the patient and on safety. It is a culture that constantly asks what is required for medical crises to be recognized early and reliably, for help to be requested promptly, and for well-designed systematic response to the call for help to arrive quickly and act effectively. Our hospitals had come to learn that mortality can be decreased dramatically, work days become more stable, and job satisfaction improve due to a reduction of perceptions of abandonment and a rise in empowerment. Each on us has begun to try to move this new culture of hospital medicine elsewhere.

The culture that needed to be changed was one that accepted sudden and unexpected death as a status quo event in a hospital. The culture that needed to be created was to one where unexpected death was systematically reduced by the creation of a planned system to respond to crisis: the Medical Emergency Team (MET). The MET goes by many names including a Rapid Response Team (RRT), critical care outreach team, and the Condition C (for Crisis) team. They amount to the same thing: a well-

designed institutional plan for trained health care professionals to come to the aid of patients in distress.

In early 2004, we met and shared our experiences and determined to join forces to create a medical revolution of sorts. There were three things that were needed to change the culture of medicine. First, we need greater recognition that a MET response existed and that METs might be helpful. Until recently, few people had even heard of MET responses. Second, there must be a greater understanding of what METs can do: even if people knew about them, many were skeptical about their merit or outcome benefit. Third, people need a reference manual that includes information (and advice) on how to implement such a team. We have come to learn that even when people are aware and convinced of the benefits of METs, they had no map for implementing a MET response in their hospital.

Therefore, we chose to have a three-fold strategy to change international culture. First: we would hold an international conference to raise awareness. Second, we would bring together the world's experts in MET responses to discuss the quality of the data and determine the best methodology to move the science forward. And third, we would create a manual for those who might want to implement a MET program. This book is that manual.

Chapters 1 to 7 discuss patient safety in hospitals and provides a context for how a MET system fits into the patient safety rubric. Chapters 8 to 19 devoted to the logistics of developing a system. How to create a team, alternatives methodologies for responding to patients in crisis, how to train team members, and how such teams impact important medical and nursing functions like education, staff recruitment and retention, and finally how to identify and overcome political hurdles. Finally, Chapters 20 to 25 describe how to measure the impact of these teams in hospitals: from improved mortality data to reduction in errors and finally to staff satisfaction.

We have assembled the authors who have been most successful in developing a MET (or similar systems) program and who have been prolific in writing about their experiences. We have also attempted to bring authors from a variety of disciplines and geographically far flung areas of the globe in an attempt to create a manual for anyone interested in METs. This book is a "How-To," "Why-Do It," and "Prove-It" manual. We feel it is a tool that can be used by administrators to help convince skeptical staff, for staff to convince unwilling administrators, and for all to use to work through the nuts and bolts of introducing and sustaining a MET response program.

We believe the concept of hospital-wide early recognition of management of seriously ill patients will facilitate a much needed revolution in hospital patient safety by breaking down current professional and geographical barriers and concentrating on systematic patient centered identification and resuscitation of the seriously ill at an early stage in their deterioration. The MET system links real time incident monitoring and response, as well as providing a basis for measuring and comparing hospital quality. While the

glamour of METs is in the rapid response to crisis, perhaps the power is in the way analysis of events preceding them can feed into a process improvement metric.

We recognize that there is some redundancy among chapters. This is to some extent intentional. Our intention is to create a manual wherein each chapter can stand on its own. This design allows the reader to skip between chapters or even read just one or two and still understand the context and importance of the content as it relates to METs. Having said this, we have also tried to create a textbook that the reader can study from beginning to end, with earlier chapters laying the foundation for later ones.

We have truly learned a lot in writing this textbook. We hope the readers will not only likewise become more knowledgeable about METs, but also carry around the manual as they develop their own program and hopefully create a change in culture in their own institution. If clinician investigators from the early 1990s are correct, some 80% of hospital unexpected deaths are preventable. We believe this is unacceptable and have seen the MET system reduce this dramatically first hand. We can yet do better. Patient safety is an agenda with no end. Thus there is much to learn and much more to do. This book we hope is a start.

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1
Measuring and Improving Safety

Peter J. Pronovost, Marlene Miller, Brad Winters, and Elizabeth A. Hunt

Introduction

November 2004 marked the 5-year anniversary of the Institute of Medicine's landmark report *To Err Is Human*, which revealed a significant problem with patient safety in the United States and presented a call to action (1). In response to this report, many health care leaders actively addressed patient safety. Segments of the health care community have educated themselves on methods to improve safety, and some—although not nearly enough—have executed interventions toward this goal (2,3). However, few health care organizations have evaluated the impact of their efforts. Thus, 5 years later, it is difficult to answer the question, "Are patients safer?"

Sorrel King, the mother of Josie King, who died at the age of 18 months from mistakes at the Johns Hopkins Children's Center, asked if Josie would be less likely to die today, 5 years after *To Err Is Human*. She did not want just our perceptions of whether Josie would be less likely to die; rather, she wanted evidence. How do we *know* that our patients are safer and our efforts to improve patient safety are working?

Measuring and improving safety is difficult. Not all safety measures lend themselves to rates. We have come to understand that a critical factor for success in improving patient safety is to actively change the culture of the institution. Considering these challenges, how will we answer the tough question asked by Sorrel King, "How do we know patients are safer?" (2,3)

This chapter provides an overview of the issues in measuring patient safety, and presents a framework for measuring and improving safety. It is important to recognize that safety is a component of the broader concept of "quality," which includes care that is effective, efficient, patient-centered, timely, and equitable (4). The boundaries between these concepts are unclear, and measures can often fall in more than 1 category. For example, is the failure to use an evidence-based therapy a safety measure—a mistake of omission—or an effectiveness measure? Is a complication, such as a catheter-related bloodstream infection that also increases length of stay,

a safety or effectiveness measure? The distinction is less important than having a valid measure. Thus, in this chapter, we will use the term "safety" to refer to both safety and effectiveness.

Approach for the Organizational Evaluation of Patient Safety

Donabedian's approach to measuring quality of care—evaluating how we organize care (the structures), what we do (the processes), and the results we obtain (the outcomes)—also provides a framework for institutions to measure safety (5). Many institutional efforts to improve safety focus on structural measures, such as policies and procedures (6). Institutions may also measure processes and outcomes, although these are generally more difficult to develop and collect than structural measures. For example, organizations may measure how often certain aspects of safe and effective care were performed (a process), or how often certain complications occurred (an outcome) (7,8).

While process and outcome measures are generally preferable to structural measures, they are not sufficient. Generally, process and outcome measures are rates that include a numerator and denominator, but not all measures of safety can, or should, be presented as rates. For example, a single episode of potential harm or actual harm (such as the death of Josie) may be statistically insignificant but sufficient to trigger an organizational change. If organizations do not recognize and learn from such single episodes, they fail to maximize opportunities to improve safety. In addition, measurement of rates is resource-intensive and not feasible for every type of medical error.

Along with the ability to learn, many other aspects of an organization's culture have a significant impact on safety (9,10). In aviation, changes in culture have been responsible for most of the advancements in safety over the last 2 decades (9,11). Within health care, communication failures are a common cause of sentinel events, both at Johns Hopkins and at other institutions across the United States (12) (www.jcaho.org). Indeed, communication patterns within an organization are an important aspect of culture. Thus, the measure of both organizational learning and culture may provide insight into an organization's measure of safety.

W. Edwards Deming once said, "There is no true value of anything that is measured; change the method of measurement and you change the result." The same concept applies to measuring safety. In the absence of standard definitions and methods to measure patient safety, including methods for risk adjustment (e.g. health care–acquired infections) (13), it is unlikely that national measures of patient safety will be achieved.

There are multiple ways to measure each area of patient safety. Consider medication safety: we can have a structural measure, such as the presence

of computerized physician order entry; a process measure, such as prescribing errors; or an outcome measure, such as adverse drug events. Moreover, each category (structure, process, or outcome) can be measured in multiple ways. For example, the methods of surveillance for evaluating adverse drug events—many of which use self-reported events, with the numerator being how the adverse event is defined and the denominator being either patient, number of patient days, or dose—vary widely (Table 1.1)(14–18). Which method provides the "correct" rate of medication safety? They all may. In the absence of standardized definitions, comparisons within and among institutions is problematic (19,20). Even with standard definitions, there is concern that comparing outcomes among hospitals is not scientifically sound, with differences influenced by insufficient risk adjustment and random error rather than variations in patient safety (8, 19–21).

Based on this background, our approach to evaluating patient safety at the organizational level has 4 components and prompts the institution to answer the following 4 questions: (1) how often do we harm patients; (2) how often do patients receive the interventions they should; (3) how often do we learn from our mistakes; and (4) how well have we created a culture of patient safety. This framework is presented in Table 1.2.

Measuring Defects

To measure safety, we often estimate reliability in defects per unit, or Sigma, with 1 Sigma defined as defects per units of 10, 2 Sigma as defects per unit of hundreds, 3 Sigma defects per thousand, 4 Sigma defects per ten thousand, 5 Sigma defects per hundred thousand, and 6 Sigma defects per million. Measuring safety is difficult, and the methods are evolving (8). Often we are not clear regarding the unit of analysis for the denominator—in anesthesia, for example, is the appropriate denominator the minutes of anesthesia, or the number of times we induce anesthesia? The defect rate can be influenced significantly by the chosen denominator.

Moreover, often measures are easy to collect yet lack meaning for the frontline staff expected to use the measure to improve safety. For example, at many health care organizations, the staff is not aware of the quality and safety measures collected by the central administration (often done to satisfy regulatory requirements). System-level measures need to be meaningful to the workers in their local areas.

In our zeal to create measures of safety, we have often compromised validity and viewed the goal as increasing the number of identified defects rather than learning from those defects. Many organizations use rates of self-reported adverse drug events as a measure of safety without recognizing that, as for all outcome measures, variations in the method of data collection/definition/data quality, case-mix, and quality, as well as chance, influence outcomes (19). Moreover, variations in data quality and case-mix

Table 1.1. Sample of methods to measure medication

Study	Number studied	Numerator	Denominator	Assessed by	Rate of events
Leape, et al. NEJM 1991	30195 records	Disabling adverse events	Per record reviewed/ admission	Physician Reviewer	3.7 per 100 admissions
Lesar, Briceland JAMA 1990	289411 medication orders/1 yr.	Prescribing errors	Number of Orders written	Physicians	3.13 errors for each 1000 orders
Lesar, Briceland Stein JAMA 1997	1 year of prescribing errors detected and averted by pharmacist	Prescribing errors	Per medication orders written	Pharmacists, retrospectively evaluated by a physician and 2 pharmacists	3.99 errors per 1000 orders
Cullen, et al. Crit Care Medicine 1997	4031 adult admissions over 6 months.	Adverse drug events	Number of patient days	Self report by nurse and pharmacists, daily review of all charts by nurse investigators.	19 events per 1000 ICU patient days

TABLE 1.2. Framework for an institutional scorecard for patient safety and effectiveness

Domain	Definition	Example from department of anesthesiology
How often do we harm patients?	Measures of health care–acquired infections	Bloodstream infections Surgical site infections
How often do patients receive the interventions they should?	Using either nationally validated process measures, or a validated process to develop a measure, what percentage of patients receive evidence-based interventions	Use of perioperative beta blockers Elevation of head of bed in mechanically ventilated patients Rates of postoperative hypothermia
How often do we learn from our mistakes?	What percentage of months does each area learn from mistakes	Monitor percentage of months in which the department creates a shared story, as in Figure 1.1
How well have we created a culture of patient safety?	Annual assessment of safety culture at the unit level	Percentage change in culture scores for each care area

are likely to be far greater than the variation in safety, which limits our ability to make inferences about quality of care from these measures.

Measures of safety and quality must be important, scientifically sound, feasible, and usable. Important and usable are value judgments that are typically made by the group, institution, or organization that decides to measure a particular area. Scientifically sound refers to validity and reliability. An indicator is deemed valid if the following criteria are met (www.rand.org) (22):

- Adequate scientific evidence or professional consensus exists supporting the indicator.
- There are identifiable health benefits to patients who receive care specified by the indicator.
- Based on experience, health professionals with significantly higher rates of adherence to an indicator would be considered higher-quality providers.
- Most factors that determine adherence to an indicator are under the control of the health professional (or are subject to influence by the health professional, such as smoking cessation).

An indicator is considered to be feasible if (22):

- The information necessary to determine adherence is likely to be found in a typical medical record.

- Estimates of adherence to the indicator based on medical record data are likely to be reliable and unbiased.
- A reliable measure produces similar results when measurement is repeated.

In many efforts to measure quality of care and safety, the measures are collected without the support of additional staff. As such, the feasibility of a measure figures prominently in its success. Finally, a measure must be usable—that is, it must be useful to the people who are expected to improve quality.

To measure quality, we need valid numerators (defects) and denominators (risk pool). To be scientifically sound, both the numerator and denominator must be valid and reliable. Yet there are challenges in measuring both. Most health care areas have not defined what a defect is, limiting the ability to measure a numerator. For example, substantial evidence suggests that controlling blood sugar in patients in an intensive care unit (ICU) reduces mortality, yet we do it infrequently. What might be a defect in glucose control? Is it 1 high blood sugar, 2 high sugars, or the average sugar over some period above a defined threshold?

In addition, it is unclear what the unit of analysis should be for the denominator. The choice of denominator can change performance by several Sigmas. For example, aviation and anesthesia changed its denominators from minutes flown to takeoffs and landings, and anesthesia from minutes of care to a case. Thus, if an average flight was over 100 miles, or an average anesthesia case 100 minutes, the defect rate would change 2 Sigmas without any change in safety. Consider also ways to measure rates of failed extubation: should the denominator be the patient, the ventilator day, or an attempted extubation? There are often tradeoffs between validity and feasibility of data collection.

It is also important to distinguish whether we are measuring the reliability of a process (what we do) or an outcome (the results we get). While commercial aviation is believed to perform at 6 Sigmas for crashes (outcome), it performs at 1 or 2 Sigmas for on-time departures. Intuitively, outcome measures are more appealing than process measures, yet measuring outcomes pose added risk for bias that often leads to little or no useful information (19,23). Reliability of an outcome measure can be influenced by variations in the methods of surveillance, in methods of data collection and definitions, in case-mix, in true variation in safety, and random error (23). Among institutions, variation in quality is often significantly smaller than variation of other variables. In health care, we need to work toward standardized measures of reliability. The gold standard, and perhaps the only valid outcome measure, is the National Nosocomial Infections Surveillance (NNIS) program that provides standardized methods to monitor health care–acquired infections (13).

Evidence-based processes of care (defects of omission) lend themselves to monitoring rates. However, we currently only have a handful of validated process measures, and these are mainly limited to internal medicine. A more diverse group of quality measures is needed. These measures must be appropriately monitored as defect rates.

In addition, health care organizations need to recognize that the value of some defects lies solely in learning from the numerator; the costs of obtaining an appropriate denominator, even if methodologically feasible, would be prohibitive. For example, methods to monitor health care–acquired infections, commonly reported as measures of safety, evolved over 20 years, include rigorous and detailed specifications, and are supported by an entire department devoted to collecting and monitoring the rates of these infections. Even so, data collection is commonly limited to a few areas—will we create departments to monitor medication safety, complications, or other outcomes? Measures of safety need to be valid, yet we can learn from defects that lack denominators.

How might measures be selected? Deming provides some guidance. Measures should be selected to optimize learning: that is, ensure the measure has face validity—does the person expected to use the data to measure specifications believe it measures something important? To develop measures that are clinically meaningful, we need the combined input of front-line staff and researchers with methodological rigor. For example, the exposure risk for a failed extubation is an attempted extubation. Yet rates of failed extubation are often presented using patients or ventilator days as the denominator (24). To estimate feasibility, first test-run the data collection tools. Moreover, the measurement of safety should be approached with the same rigor as that applied in clinical research. Whether we are measuring bloodstream infections as part of a federally funded trial or for hospital safety efforts, we need a valid measure of infections. Much research is needed to advance the science of measuring defects.

Given this, what are some measures of safety for Medical Emergency Teams (METs)? Although ICU admission and number of codes called are common measures, they lack validity. We do not know whether an increase or decrease in the rate of ICU admission is high-quality care. The measure does not differentiate between patients who required ICU care and those who did not, or who may have had a preventable reason for admission. On the other hand, use of chest compressions or intubations may be an appropriate numerator for defects. Deaths may also be an informative numerator.

In addition to the numerator, we need to consider an appropriate denominator or risk group. Although patients are used commonly as the denominator, patient days may be a more valid denominator. A patient's risk for arrest is influenced by, among other things, the length of time they are in the hospital. The longer a patient is in the hospital, the greater the risk.

Hospital mortality and length of stay may be measures of safety for METs but, as with all outcome measures, case-mix will significantly influence these outcomes making comparisons among hospitals difficult to interpret (23). As long as a hospital does not add or drop a product line, case-mix within a hospital is relatively constant, making changes in mortality rate within a hospital potentially important and measurable. Much more effort is needed to produce scientifically sound and feasible measures of safety for METs.

How Might We Improve Safety?

Recently, one of the authors went to the circus with his wife and 2 children. It was both exhilarating and exhausting: 3 rings of nonstop activity, noise, and motion. He noticed how flawless all of the interventions were; the circus functioned without a hazardous event. Trapeze artists flew through the air with perfect timing, and men on motorcycles rode around in a metal globe, perilously missing each other by inches. As he watched the show, he estimated that the number of critical processes was probably equivalent to about a week's worth of activities in 30 operating rooms, yet no defects occurred. He wondered how the circus performed with such high reliability, and noticed that everything was scripted down to the tiniest detail. All the processes were standardized. The cleanup crews in ring 1 did the same things in ring 2. All the events were timed and sequenced by what they were doing and when it was done. One act ended and the next began, flawlessly.

How might this circus performance inform patient safety? It appears that most organizations are aware of the need to improve patient safety, and many have committed to doing so. Yet only a small number have a clear plan of attack to accomplish this goal and even fewer have actually improved safety. This should not be surprising. The drive to improve patient safety is new in health care, and we must view health care delivery as a science as well as an art if we are to improve safety. Here we present an overview of measuring and reducing defects in health care and suggest some potential system-level measures of safety.

A Framework to Improve Reliability

In health care, most of our processes are between 1 and 2 Sigma. For a wide variety of processes, patients can rely on receiving the interventions they should half the time, or 1 Sigma (25). For some outcomes, defects are 2 to 3 Sigmas—for example, catheter-related bloodstream infection rates and rates of ventilator-associated pneumonia are typically between 1 to 20 per 1000 catheter or ventilator days (13,26). Nevertheless, there are some notable exceptions in anesthesia in healthy patients and in blood banking that are estimated to be 4 or 5 Sigma (defects per 10000 or 100000) (27,28).

Caregivers in these areas, and multiple other non-health care organizations, deliver high-reliability care because they are standardized. To improve reliability, we need to create a culture of safety first, where the entire care team makes the patient their "North Star" according to which they create and implement common goals. A culture of safety allows all members of the care team to speak up when they have concerns and listen when others voice concerns. Next comes standardization, specifying what is done and when it should be done (29–31). This contrasts with current practice in which the art of medicine trumps the science—individual caregiver practice is unstructured and at times appears chaotic (i.e., caregivers do what they want, when they want). In the ICU, the therapies that a patient receives depend more on who is making the rounds, rather than what the evidence suggests. Without standardization, reliability will remain at 10^{-1} imparting a significant toll on patients.

An important aspect of standardization is to simplify or reduce complexity. Every step is a process that has an independent probability of failure. As such, processes that have 5 steps are more likely to fail than those that have 4, 3, or 2 steps. An analogy is the telephone game, in which a story is told through a series of people: the risk factors for getting a garbled story (a defect) at the end are defined by how complex the story is and how many people it passes through. If we reduce the number of steps in a process, we have a higher probability of improving reliability. Undoubtedly this is an oversimplification, since there are feedback loops that may catch mistakes. Nevertheless, it is helpful to consider simplification when we examine our work processes.

Let us give you an example of reducing complexity. We had a mistake with transvenous pacing. The physician attempting the procedure had to obtain a sheath (Cordis) and a pacing wire. The wire goes through the sheath, note there are different sizes and types for both sheaths and wires. Unfortunately, the equipment needed for transveous pacing is not packaged together, and physicians need to obtain the equipment through different steps. Predictably, the physician grabbed the wrong combination of pacing wire and sheath, and the patient suffered an air embolism. To reduce complexity and the potential for another mistake, we now have Central Supply package all pieces of equipment for specific procedures together.

Third, we need to identify and learn from defects. This involves creating independent checks to identify defects. A significant challenge we face in health care is a shared definition or concept of a defect. To illustrate, Johns Hopkins developed a glucose protocol in the ICU. Like most protocols, we were only capturing about 80% of patients. To improve reliability, we needed an independent check to identify defects. The problem was that we had not defined a defect. Although we could have defined it in multiple ways, we decided that in the morning during the shift change, the nurses would review a patient's glucose and if 2 blood sugars were out of range, they would talk to the physician and implement the protocol. We defined

the defect first and then created an independent check to identify it. Nurses in the ICU now present a patient's last 3 glucose measures each morning on rounds. If a defect is identified—that is, the sugar levels are out of range—the patient is placed back on another protocol.

To learn from defects, we need to investigate what went wrong and make recommendations for improvement. In the related example, the ICU nurse manager did this beautifully. After implementing the glucose control protocol, she started to hold glucose rounds with the nurses, during which they discussed any patient who was on but then fell off the glucose protocol. These discussions would often surface a variety of system factors that posed barriers to improving glucose care; some were beliefs and attitudes among nurses, some dealt with the availability of supplies to measure glucose hourly, and others involved communication with physicians. We have developed a tool kit to learn from a defect. This tool kit (Table 1.3) helps uncover what happened, why it happened, and what must be done to fix the defect.

These steps—(1) create a culture of safety, (2) standardize what and when actions are done, and (3) identify and learn from defects—provide a framework to improve reliability. Transfusion medicine offers an example of how the application of these principles created a high reliability process: using discharge data, the estimated incidence of a transfusion reaction in health care is 4 per 100 000. How did they achieve such success? They standardized, created independent checks for key processes, and learned from defects (Figure 1.1).

Physicians often resist standardization. I asked several blood bank directors how they achieved their degree of standardization. They uniformly replied that the threat of a Food and Drug Administration sanction created the culture. Several felt they would not have the authority to standardize physician practice without the backing of federal regulation. Although regulations may be an important vehicle for standardization, there are far too many processes for regulators to standardize. Indeed, we need the courage of leaders within our health care systems to support standardization.

Table 1.3. How to investigate a defect

Problem statement: Health care organizations could increase the extent to which they learn from defects.

What is a defect? A defect is any clinical or operational event or situation that you would not want to happen again. These could include incidents that you believe caused a patient harm or put patients at risk for significant harm.

Purpose of tool: The purpose of this tool is to provide a structured approach to help caregivers and administrators identify the types of systems that contributed to the defect and follow up to ensure safety improvements are achieved.

Who should use this tool?

- Clinical departmental designee at morbidity and mortality rounds
- Patient care areas as part of the Comprehensive Unit-based Safety Program (CUSP)

TABLE 1.3. *Continued*

All staff involved in the delivery of care related to this defect ***should be present when this defect is evaluated***. At a minimum, this should include the physician, nurse, and administrator, and others as appropriate (e.g. medication defect includes pharmacy, equipment defect includes clinical engineering).

How to Use This Tool: Complete this tool on ***at least 1 defect per month***. In addition, departments should investigate all of the following defects: liability claims, sentinel events, events for which risk management is notified, case presented to morbidity and mortality rounds and health care–acquired infections.

Investigation Process
I. Provide a clear, thorough, and objective explanation of ***what happened***.
II. Review the list of factors that contributed to the incident and check off those that negatively contributed and positively contributed to the impact of the incident. ***Negative contributing factors*** are those that harmed or increased risk of harm for the patient; ***positive contributing factors*** limited the impact of harm.
III. Describe how you will reduce the likelihood of this defect happening again by completing the table. List ***what*** you will do, ***who*** will lead the intervention, ***when*** you will follow up on the intervention's progress, and ***how*** you will know risk reduction has been achieved.

Investigation process

I. What happened? (Reconstruct the timeline and explain what happened. For this investigation, put yourself in the place of those involved in the event as it was unfolding, to understand what they were thinking and the reasoning behind their actions/decisions when the event occurred.)
An African American male >65 years old was admitted to a cardiac surgical ICU in the early morning hours. The patient was status-post cardiac surgery and on dialysis at the time of the incident. Within 2 hours of admission to the ICU it was clear that the patient needed a transvenous pacing wire. The wire was threaded using an IJ Cordis sheath, which is a stocked item in the ICU and standard for pulmonary artery catheters, but not the right size for a transvenous pacing wire. The sheath that matched the pacing wire was not stocked in this ICU, because transvenous pacing wires are used infrequently. The wire was threaded and placed in the ventricle but staff soon realized that the sheath did not properly seal over the wire, thus introducing risk of an air embolus. Since the wire was pacing the patient at 100%, there was no possibility for removal at that time. To reduce the patient's risk of embolus, the bedside nurse and resident sealed the sheath using gauze and tape.
II. Why did it happen? Below is a framework to help you review and evaluate your case. Please read each contributing factor and evaluate whether it was involved, and if so, whether it contributed negatively (increased harm) or positively (reduced impact of harm) to the incident.

Contributing factors *(example)*	Negatively contributed	Positively contributed
Patient factors		
Patient was acutely ill or agitated *(Elderly patient in renal failure, secondary to congestive heart failure.)*		
There was a language barrier *(Patient did not speak English.)*		
There were personal or social issues *(Patient declined therapy.)*		
Task factors		
Was there a protocol available to guide therapy? *(Protocol for mixing medication concentrations is posted above the medication bin.)*	XX	

Table 1.3. *Continued*

Contributing factors *(example)*	Negatively contributed	Positively contributed
Were test results available to help make care decision? *(Stat blood glucose results were sent in 20 minutes.)*		
Were tests results accurate? *(Four diagnostic tests done; only magnetic resonance imaging [MRI] results needed quickly—results faxed.)*		
Caregiver factors		
Was the caregiver fatigued? *(Tired at the end of a double shift, nurse forgot to take a blood pressure reading.)*		
Did the caregiver's outlook/perception of own professional role impact on this event? *(Doctor followed up to make sure cardiac consultation was done expeditiously.)*		
Was the physical or mental health of the caregiver a factor? *(Caregiver was having personal issues and missed hearing a verbal order.)*		
Team factors		
Was verbal or written communication during handoff clear, accurate, clinically relevant, and goal-directed? *(Oncoming care team was debriefed by outgoing staff regarding patient's condition.)*		
Was verbal or written communication during care clear, accurate, clinically relevant, and goal-directed? *(Staff was comfortable expressing concern regarding high medication dose.)*		
Was verbal or written communication during crisis clear, accurate, clinically relevant and goal-directed? *(Team leader quickly explained and directed the team regarding the plan of action.)*		
Was there a cohesive team structure with an identified and communicative leader? *(Attending physician gave clear instructions to the team.)*		
Training and education factors		
Was the caregiver knowledgeable, skilled, and competent? *(Nurse knew dose ordered was not standard for that medication.)*	XX	
Did the caregiver follow the established protocol? *(Provider pulled protocol to ensure steps were followed.)*		
Did the caregiver seek supervision or help? *(New nurse asked preceptor to help mix medication concentration.)*		
Information technology/computerized physician order entry factors		
Did the computer/software program generate an error? *(Heparin was chosen, but Digoxin printed on the order sheet.)*		
Did the computer/software malfunction? *(Computer shut down in the middle of provider's order entry.)*		
Did the user check what was entered to make sure it was correct? *(Caregiver initially chose .25 mg, but caught error and changed it to .025 mg.)*		

TABLE 1.3. *Continued*

Contributing factors *(example)*	Negatively contributed	Positively contributed
Local environment factors		
Was adequate equipment available and was it working properly? (*There were 2 extra ventilators stocked and recently serviced by clinical engineering.)*	XX	
Was operational (administrative and managerial) support adequate? *(Unit clerk out sick, but extra clerk sent to cover from another unit.)*		
Was the physical environment conducive to enhancing patient care? *(All beds were visible from the nurse's station.)*		
Was enough staff on the unit to care for patient volume? *(Nurse ratio was 1:1.)*		
Was there a good mix of skilled and new staff? *(A nurse orientee was shadowing a senior nurse and an extra nurse was on to cover the senior nurse's responsibilities.)*		
Did workload impact the provision of good care? *(Nurse caring for 3 patients because nurse went home sick.)*		
Institutional environment factors		
Were adequate financial resources available? *(Unit requested experienced patient transport team for critically ill patients, and one was made available the next day.)*		
Were laboratory technicians adequately in-serviced/educated? *(Lab technician was fully aware of complications related to thallium injection.)*		
Was there adequate staffing in the laboratory to run results? *(There were 3 dedicated laboratory technicians to run stat results.)*		
Were pharmacists adequately in-service/educated? *(Pharmacists knew and followed the protocol for stat medication orders.)*		
Did pharmacy have a good infrastructure (policy, procedures)? *(It was standard policy to have a second pharmacist do an independent check before dispensing medications.)*		
Was there adequate pharmacy staffing? *(There was a pharmacist dedicated to the ICU.)*		
Does hospital administration work with the units regarding what and how to support their needs? *(Guidelines established to hold new ICU admissions in the emergency department when beds are not available in the ICU.)*		

III. How will you reduce the likelihood of this defect happening again?

Specific things to be done to reduce the risk of the defect	Who will lead this effort?	Follow-up date	How will you determine the risk is reduced? (action items)
Bedside nurse called Central Supply and requested pacing wires and matching sheaths be packaged together.	Bedside nurse	1 week	Supplies are packaged together

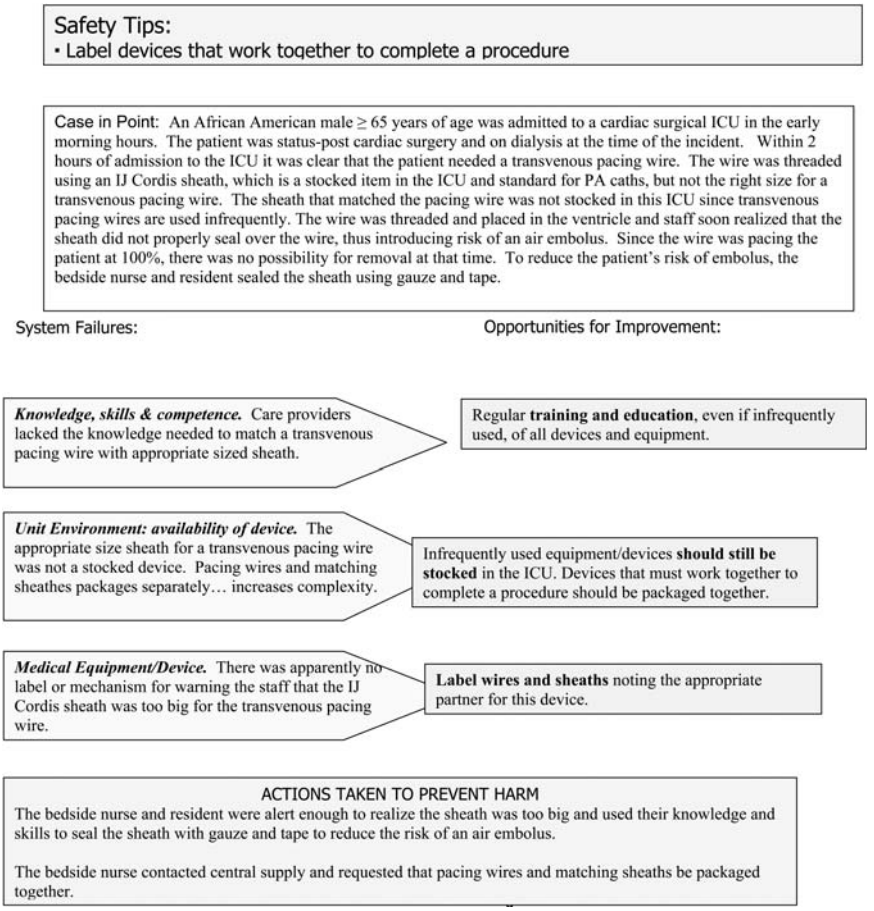

FIGURE 1.1. Case summary.

To date, most efforts to improve reliability of evidence-based therapies in health care have focused on practice guidelines: a series of conditional probability, or "if yes then 'x'" statements (32). The Centers for Disease Control and Prevention's (CDC's) guidelines for preventing catheter-related bloodstream infections, a nearly 100-page document (www.cdc.gov), is one example. It is not surprising that the use of guidelines alone has met with little success (32,33). Under time pressure, it is difficult for caregivers to think in terms of conditional probabilities (34). An additional problem is that most guidelines have been developed for physicians, ignoring other members of the care team who could provide an independent check.

A checklist is one tool to help standardize work processes and increase reliability. Checklists have led to significant improvements in aviation,