Introduction to Patient Safety
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CLINICAL VIGNETTE
An outbreak of norovirus has left the nursing staff at the hospital short-handed. Healthy staff members are asked by hospital leadership to cover additional shifts and many shifts are left understaffed. Rob, a new nurse who recently completed his orientation to the unit, feels well and is eager to pitch in and help his colleagues. Rob volunteered to work a double shift even though he was exhausted after coming off of night shift. Joan, a nurse that Rob worked with extensively during his orientation, asked if he could help her out by giving blood pressure medications to her patient, “Jon Smith,” since she was busy with an unstable patient. While Rob was obtaining the medication from the Pyxis machine, he was interrupted by Dr. Jones who had a question about the patient in room 2 and the physical therapist who wanted to know if the patient in room 8 was stable to participate in therapy. After the interruptions, Rob removed the medications for Jon Smith. He was unaware that there were two patients with similar names on the floor; one was Jon Smith, the other John Smythe. He entered room 12 and asked the patient to state his name. The patient responded, “John Smythe.” Rob thought it was a little strange that the patient pronounced his name differently than Joan had called him but thought this must be the right patient. Although he was taught in school the appropriate steps to verify that he was administering medications to the right patient, the nurses who oriented him to the floor had told him that all of those steps were unnecessary and a waste of time. Rob administered the medication to the patient and returned to taking care of his other patients. Approximately 1 hour later, John Smythe had an episode of syncope while getting out of bed. He was found to be hypotensive. After reviewing the events, it is discovered that the medications for meant Jon Smith where given to John Smythe, causing the hypotension.

What factors contributed to this error?
What systems or processes could be put in place to prevent an error like this?

INTRODUCTION
A patient in the hospital should not be harmed due to medical errors while receiving care. However, based upon estimates from the Institute of Medicine report, “To Err is Human,” an estimated 44,000–98,000 people are harmed in the hospital each year. Every person can expect to have at least one misdiagnosis during his or her life. These staggering statistics highlight the need to evaluate and reform how health care
is delivered. The field of patient safety is a “discipline in the healthcare sector that applies safety science methods towards the goal of achieving a trustworthy system of healthcare delivery…it minimizes the incidence and impact of, and maximizes recovery from, adverse events.” Patient safety is a relatively new discipline in health care and focuses on preventing harm to patients. The components of patient safety include a culture of safety to limit blame to individual providers, redesigning systems to create high reliability, promoting transparency and learning from medical errors, and making health care systems accountable to eliminate preventable harm. Approaches to analyzing patient safety include Donabedian “Structure–Process–Outcome” Model, Reason “Swiss Cheese” Model, Rasmussen Model of System’s Migration, and error analysis.

PATIENT SAFETY MODELS

Donabedian Structure–Process–Outcome Model

In 1966, Avedis Donabedian published a seminal paper titled “Evaluating the Quality of Medical Care” in which he outlines a formalized approach to patient safety and quality improvement, now known as the Structure–Process–Outcome Model.  

• Outcomes include all the effects of health care on patients or populations, such as recovery, restoration of function, and survival. Examining outcomes is the most natural and intuitive means of evaluating quality since the goal of “good” health care is a positive outcome. Any outcome is, by definition, linked to a series of actions, which are dependent on the structure where health care is provided and the processes by which health care is delivered.
• Structure comprises the setting in which health care occurs. The structure consists of the physical infrastructure, the staffing, the material and supplies, and all the various support systems involved in providing health care. The quality of care provided inherently depends upon the structure in which it is provided. A flaw in the structure can propagate, resulting in an error and potentially in a bad outcome. In the above clinical scenario, the structure of the medical unit requires the nurse, Joan, to divide her time among too many patients due to understaffing. The structure creates the backbone for the health care process and outcomes.
• Process encompasses all of the actions and interventions undertaken by the health care providers operating within the above-defined structure. Process includes the decisions, operations, orders, and procedures that lead to a given outcome. The process in which health care is delivered is dependent upon the structure of the health care setting but can also be an independent factor in patient outcomes. For example, the process of medication administration is influenced by the structure of the unit but has specific procedures and protocols. In the previous example, the failure by the nurse, Rob, to confirm that the right medication was given to the right patient would be considered a failure of process. At times, processes can help to balance or correct shortcomings in structure. For example, the Pyxis machine is often located in a busy area on a medical unit, causing nurses to be frequently interrupted while obtaining medications. Establishing a “no interruption zone” around the Pyxis machine could have helped prevented this error by not allowing Rob to be interrupted as he obtained the medications.

Swiss Cheese Model

James Reason proposed the Swiss Cheese Model in his 1990 paper “The Contribution of Latent Human Failures to the Breakdown of Complex Systems.” Recent human
history has seen the evolution of multiple very complex, high-risk systems, including aviation, nuclear power, and health care, that have developed multiple safeguards to prevent bad outcomes. Medicine, like many complex high-risk systems, is perpetually devising and revising procedural safeguards to attempt to minimize the potential for harm. Overlapping layers of safeguards often catch an error before harm occurs. In the Swiss Cheese Model, multiple failures in safeguards must happen in order for an error to reach a patient. None of the individual failures is sufficient to cause harm; multiple failures must occur along the system safeguards. The model’s name arises from the analogy that each barrier to a bad outcome is akin to a slice of Swiss cheese, with the holes in the cheese being analogous to potential errors, circumstances, or events that could overcome that particular barrier. If a sufficient number of holes line up in a series of slices of cheese, a bad outcome could occur (Fig. 11-1).

In the opening vignette, multiple safeguards designed to prevent incorrect medication administration had to fail. The multiple holes in the Swiss cheese included having two patients with very similar names, lack of following the policy for medication administration, understaffing of the unit due to a norovirus outbreak, and multiple interruptions while retrieving the medication. A combination of unusual circumstances, deliberate choices, and unintentional errors led to an adverse event. This example demonstrates that despite the engineering of multiple procedural safeguards designed within a system, the correct alignment of system failures can overcome these barriers, potentially leading to patient harm.

The Human Component of Patient Safety
A key component of any model of patient safety must take into account the human component of a system. A series of high-profile accidents, including the Chernobyl reactor meltdown and the Zeebrugge ferry incident, highlighted the human component of safety. In both these examples, humans deliberately drifted away from standard operating procedure. Rasmussen describes the human tendency to drift toward
the minimal acceptable safety margin. Rasmussen states there is “a natural migration of activities toward the boundary of acceptable performance.” Many factors may cause humans to cut procedural corners.

- Pressure exists to increase productivity and decrease cost. Completing the appropriate steps of medication administration takes more time than simply giving the medication. The time spent on medication administration means there is less time for other work to be completed.

- As humans frequently perform routine tasks, habit and memory are often substituted for knowledge-based decision making. As individuals become more comfortable completing a task, they have a decrease in analytic thought and increased laxity in adherence to precise procedure.

- A person who does not follow the policy will usually not see patient harm. Individuals may not be aware of the potential for harm because subsequent safeguards catch any errors before they reach the patient. The fact that harm does not occur each time the individual deviates from standard practice may reinforce the behavior. As multiple individuals within a system or process begin to stray from established practices, the entire system slowly becomes increasingly unsafe until an accident or bad outcome occurs that forces a re-evaluation and realignment of the general safety practices. Amalberti et al. have applied Rasmussen’s ideas to the tendency to drift toward unsafe practices over time in medicine (Fig. 11-2).

- “Legal zone” is where practices begin and all rules are followed.

- “Illegal–normal zone” is where minor variations in safety practices occur, and adaption is not only tolerated but sometimes encouraged depending upon the circumstance. Migration is due to pressure for greater performance (horizontal axis) and personal gain (vertical axis). Borderline tolerated conditions of use (BTCUs) are violations that

**Figure 11-2.** The tendency to drift toward unsafe practices over time in medicine. (From Amalberti R, et al. Violations and migrations in health care: a framework for understanding and management. *Qual Saf Health Care.* 2006;15:i66–71.)
are considered to provide the maximum benefit for the minimum and accepted probability of harm. On the medical unit in the clinical vignette, staff believed that not following the protocol for medication administration was accepted and encouraged to increase productivity and the probability of harm to the patient was low.

- “Illegal–illegal zone” where safety practices become extreme and most practices are considered “forbidden” under essentially all circumstances. The boundary between “illegal–normal” and “illegal–illegal” is where close calls occur. The “illegal–illegal” territory is where the majority of accidents and bad outcomes occur.

- A commonly used analogy is how most individuals follow the speed limit. If the speed limit is 30 miles per hour, few people drive in the legal zone of <30 miles per hour under normal circumstances. Most people drive in the illegal–normal speed of 30–40 miles per hour. People driving above 45 miles per hour are considered in the illegal–illegal category.

In the medical field, long work hours, large patient care burdens, and immense financial pressures provide a perfect mix of conditions to promote migration toward minimal acceptable safety practices. This erosion was examined more closely in the field of anesthesia in a 2010 paper looking at anesthesia practices in the operating room (OR). The authors noted that there are two different types of perceived safety regulations: “need-to-follow” and “nice-to-follow.” They found that failure to observe “nice-to-follow” rules frequently leads to violations of “need-to-follow” rules, endangering patients and leading to further accidents and bad outcomes.

**ERROR DEFINITIONS**

**Types of Errors**

Many different terms are often used to describe a bad outcome. Clarifying these terms is important both to prevent misunderstanding and to facilitate more efficient communication. Using the correct terminology is crucial to communicate the etiology of the error and nature of the outcome. When discussing bad outcomes, one can describe it as an *adverse event*, a *near miss*, or simply as an *error*. These terms are not interchangeable.

- An *adverse event* implies a bad outcome due to medical management that could be, but is not necessarily, the result of a mistake or flaw in the system. If a patient with a known penicillin allergy receives amoxicillin because no one ever asked about her allergies, that would be an adverse event. An adverse event is also if a penicillin-naive patient has an allergic reaction to an amoxicillin; there is no way to foresee and prevent an allergic reaction. The term does not imply causation, merely an undesirable outcome due to interaction with the medical system.

- A *bad outcome* is an undesirable outcome due to a disease process. A patient with septic shock who dies despite receiving appropriate antibiotics and medical therapy had a bad outcome, not an adverse event.

- An *error* means an unintended event or a mistake. An error does not necessarily imply outcome. An error can be caught and corrected before reaching the patient, can reach the patient but not cause harm, or can directly lead to a bad outcome for a patient. Regardless of whether or not the patient with the penicillin allergy actually receives the medication, the act of prescribing a medication to a patient with a known allergy is an error. The prevention of errors is a central focus of the field of patient safety and one of the driving forces behind the evolution of new safeguards and precautions.
A near miss is an error without a subsequent adverse event. If the patient with the penicillin allergy is prescribed amoxicillin, but the nurse notices the error prior to giving the medication and alerts the physician, who cancels the order and prescribes a new medication, that is classified as a near miss. Near misses are difficult to track and address and are some of the most frequent errors. In a complex system with multiple redundant safeguards, much of the design of the system is intended to create near misses in lieu of adverse events. However, by their very nature, they are less noticeable and thus harder to track. In addition, there is an inherent reluctance by health care workers to report the event, due to either embarrassment by the individual who made the error or concern by the individual who caught the near miss that they might get someone else in trouble. A tendency exists to see near misses as “no big deal” since an adverse event actually occurred. As a result, near misses, though a frequent product of a well-designed series of safeguards, are often underreported and obscure.

Classification of Human Behavior
A critical aspect of evaluating an error or adverse event lies in analyzing the intentions underlying the behavior that lead to the error. Though there is increasing emphasis on a Just Culture in medicine, in which individuals are not held solely responsible for errors, individuals are still responsible for their actions. There are three different categories into which individual actions leading to an error can fall: human error, at-risk behavior, and reckless behavior. The crucial difference between each category is the awareness of the individual regarding the risk inherent in their actions and their choices regarding how to proceed. Evaluating the individual’s intentions is a critical step in event analysis to identify system changes to prevent similar errors.

• Reckless behavior, or a deliberate disregard of risk, is the easiest to define and the category most clearly requiring individual consequences. Most commonly, this behavior occurs when someone, despite knowing the risks of their behavior, chooses to ignore safeguards and proceed with their actions, deliberately putting patients and coworkers at risk. This behavior leaves the individual culpable and requires that the individual’s choices and behavior be explicitly addressed in rectifying the situation. Designing safeguards against consciously reckless behavior is very difficult.

• At-risk behavior involves a person putting a patient or coworker at risk through unsafe practices, without necessarily realizing the situation is unsafe. This behavior usually occurs due to an effort to save time or improve efficiency, thereby accidentally leading to an unsafe situation. A nurse drawing blood to match for a transfusion and not immediately labeling the blood per policy is engaging in at-risk behavior. The distinction between reckless behavior and at-risk behavior revolves around that fact that with reckless behavior, the individual deliberately places another at risk through their actions, but in at-risk behavior, unsafe actions are taken without awareness of the risk involved. The individual remains culpable, however, as they are nonetheless engaging in unsafe behavior. Prevention of at-risk behavior frequently involves training in appropriate safety practices and sufficient oversight to ensure practices and policies are followed.

• Simple human error involves an individual taking action they believe to be safe, which nonetheless can result in a bad outcome. Fatigue, miscalculation, and lack of attention often underlie these types of errors. These errors include an accidental
contamination of a sterile field, mislabeling of a specimen, wrong-side surgery, or even just ordering the wrong dose of a medication. Many of the system safeguards and redundancies focus on attempting to prevent or correct human error. Witnessed blood draws, procedural checklists, and surgical site marking are common safety practices intended to prevent human error. Of note, the category of human error does not include mechanical or technical errors. An intra-venous pump breaking, an incorrect lab result, or a computer glitch would not be counted as human errors given that they are not directly due to human actions. A slip of the hand, a mental miscalculation, and a failure of human memory are inherent dangers in any system that involves a human component and the potential for error implicit in the human presence that drives much of the development of the field of patient safety.

Active Failures and Latent Conditions

In his paper proposing the Swiss cheese model, Reason notes that the majority of failures leading to an adverse event are human in nature and are frequently present long before the actual event occurs. He states that prior to an adverse outcome occurring, two different types of errors can occur: active failures and latent conditions. An active failure consists of “those errors and violations having an immediate adverse effect.” Active failures are events that usually occur on the “front line” (in the OR, the patient’s bedside, etc.) that directly lead to adverse events. A latent condition includes “decision or actions, the damaging consequences of which may lie dormant for a long time, only becoming evident when they combine with local triggering factors” to create an adverse event. Latent failures are errors or mistakes that set up conditions for failure.

Most often, an adverse event depends upon both types of events occurring. A surgeon operating on the wrong arm is an active failure. However, this active failure depends upon a latent condition: the hospital not having a policy regarding advance labeling of the appropriate limb. In the majority of highly complex systems with multiple safeguards, the only way the “Swiss Cheese holes” all line up is for a latent condition (or several of them) to prepare a situation that is triggered by an active failure.

CONCLUSION

In the opening vignette, a patient was harmed from a preventable medical error due to receiving the wrong medications. Yet, patients safely receive medications in the hospital every day. So what happened to this particular patient? What can be done about it? Using the ideas and patient safety modeling systems outlined in this chapter, let us look back at the events to decipher what went wrong. The structure of the medical unit and the process of medication administration led to the bad outcome. The policies and procedure were not followed due to the natural tendency to drift toward the minimal safety standards. An active failure by a tired, overworked nurse aligned with the multiple latent conditions allowed the error to reach the patient. The patient safety models presented in this chapter help us analyze and classify this error and begin redesigning systems to eliminate preventable harm to patients.
KEY POINTS

• There are often multiple safeguards in place to prevent errors from reaching patients and causing harm. However, when all the holes in the “Swiss Cheese” align, errors may reach patients.
• Although errors have the potential to cause harm, they are not all due to negligent behavior.
• Both active failures and latent conditions may align to result in patient harm.
• In order to fully understand the factors that contribute to patient harm, one must have a full understanding of human behavior and the systems and processes involved in delivering health care.

ONLINE RESOURCES

1. Institute for Healthcare Improvement: http://www.ihi.org/Topics/PatientSafety/
2. VA National Center for Patient Safety: http://www.patientsafety.va.gov/media/factsheets.asp

REFERENCES