

PATIENT SAFETY & QUALITY: An Integrated Approach

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Objectives:

- Early recognition of medical errors.
- Improving patient care quality.
- Patient centered approach.









Patient Safety

- Defined by the **Institute of Medicine (IOM)** as the prevention of harm to patients. Prevention of harm to patients includes a system of care delivery that:
 - ✓ Prevents errors
 - ✓ Learns from the errors that do occur
 - \checkmark Is built on a culture of safety that involves health care professionals, organizations, and patients
- Agency for Healthcare Research and Quality (AHRQ) expands that definition of prevention of harm to "freedom from accidental or preventable injuries produced by medical care."

Adverse Event

- Is used to describe patient harm that arises because of medical care rather than from the underlying disease.
- Subcategories of adverse events include:
 - ✓ Preventable adverse events: those due to error or failure to apply an accepted strategy for prevention.
 - ✓ *Ameliorable adverse events:* events that, while not preventable, could have been less harmful if care had been different.
 - ✓ *Adverse events due to negligence:* those due to care that falls below the standards expected of clinicians in the community.



Near Miss

• An unsafe situation that is indistinguishable from a preventable adverse event except for the outcome. A patient is **exposed to a hazardous situation but does not experience harm** (either through luck or early detection).



Are Hospitals safe for patients?

- A transformative realization on the part of healthcare providers by the 1990s was that despite training of providers, technology and the commitment to healing, hospitals were not safe for patients. In fact, they were <u>inherently dangerous for many patients</u>.
- Numerous studies have found that 10%–12% of hospitalized patients experience adverse events while under the care of healthcare providers and organizations, with approximately half of these events considered preventable.
- Many adverse events and medical errors result in lasting damage requiring extended treatment times or permanent injury, or even unanticipated death.



History of patient safety movement

- The current patient safety movement in the United States emerged in the 1980s and 1990s from a confluence of contemporary factors.
- Modern-day patient safety is product of approaches to quality improvement and industrial engineering that developed following World War II, to which was added statistical evidence of harm caused by medical errors, provided by studies in the 1990s, and pressure from politicians, the public, and the media who reacted with outrage to published research and personal stories about medical harm.



History of patient safety movement

- The concept of keeping patients safe while treating their medical condition is not new to healthcare. Few examples of early recognition that healthcare is inherently risky for patients:
- 1847- Ignaz Semmelweis was able to demonstrate the reduction of puerperal fever using hand hygiene.
- 1850s Florence Nightingale changed nursing practice during the Crimean War by demonstrating a reduced mortality rate for hospitalized soldiers after instituting hand hygiene and environmental cleaning processes.
- Ernest Codman, a surgeon in Boston in the early 1900s developed a systematic method for tracking and studying patient outcomes following procedures, to identify potential harm.

History of patient safety movement

- The 1980s and 1990s saw the development of the Anesthesia Patient Safety Foundation, the Harvard Medical Practice Study, the National Patient Safety Foundation, the Institute for Healthcare Improvement, and the Veteran's Administration (VA) National Center for Patient Safety.
- 1982: Dr. Pierce, a president of ASA, established a new standing committee, the Committee on Patient Safety and Risk Management.
- The Health Care Quality Improvement Act of 1986 (HCQIA)
- 1988: Dr. Berwick, Dr. Bataldin, Mr. Deming ,Gene Nelson Founded Institute for healthcare improvement (IHI).



Anesthesia Patient Safety Foundation (APSF)

- Established in the United States in 1985, APSF was the first organization developed expressly to improve safety for patients.
- APSF has sponsored research, recognized the value of innovative technologies, and codified standards of training and practice to advance the safe practice of anesthesia (Stoelting 2010). In these efforts, the APSF has taken an approach to safety improvement that continues throughout health care today.



Harvard medical Practice study I & II

- 1991, NEJM published the results of two large studies of adverse medical events, which provided a foundation of evidence that significant numbers of patients are harmed by medical treatment and a framework for understanding the types of harm that patients experience.
- Studies, known as the Harvard Medical Practice Study I and II.
- Study I, medical professionals examined more than 30,000 medical records from 1984 in non-psychiatric hospitals in New York State: to develop more current and more reliable estimates of the incidence of **adverse events** and **negligence** in hospitalized patients.



Harvard Medical Practice study I & II

• Studies produced shocking results that are still cited as evidence that many patients are harmed in the course of medical treatment.

• Outcomes:

- adverse events occurred in 3.7% of the hospitalizations;
- 27.6% of the adverse events were due to negligence.
- 70.5% of the adverse events gave rise to disability lasting less than six months.
- 2.6% caused permanently disabling injuries.
- 13.6% led to **death.**
- These results shook many in health care, including the authors, but did not lead to immediate action and change.

Error in Medicine

- In 1994 Dr. Lucian Leape of the Harvard School of Public Health presented statistical evidence of the occurrence of harm caused by medical errors along with lessons from other high-risk industries in an essay titled "Error in Medicine," which appeared in the Journal of the American Medical Association (JAMA) in December 1994.
- He was a researcher and **co-author of the Harvard Medical Practice Study** who quickly became a prominent leader of the patient safety movement.



Error in Medicine

- Summarizing his recommendations, Leape observed,
 - The most fundamental change that will be needed if hospitals are to make meaningful progress in error reduction is a **cultural one.**
 - Physicians and nurses need to <u>accept</u> the notion that error is an inevitable accompaniment of the human condition, even among conscientious professionals with high standards.
 - Errors must be accepted as evidence of system flaws not character flaws. Until and unless that happens, it is unlikely that any substantial progress will be made in reducing medical errors.

TO ERR IS HUMAN: Building a safer health system

- To Err is Human: Building a safer health system, was a landmark report issued in 1999, by IOM, which detailed the scope and breadth of what was previously not known about medical errors that produced a national call for action to focus on the prevention of adverse events/medical errors in healthcare.
- The study found that approximately 44,000 to 98,000 patients each year die because of medical errors, and that many if not most of them preventable.
- Range of 44,000 to 98,000 deaths stated by the IOM in 1999 continues to be a **benchmark and rallying cry for patient safety**.
- IOM estimates <u>268 deaths due to medical errors a day</u> <u>equivalent of a jumbo jet crash every day.</u> (Collin, 2020)
- The authors of To Err Is Human explained that the numbers mean more people die in a given year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516).

To Err is human: summary

- To Err is Human cites the results of the Harvard Medical Practice Studies and a similar study of hospitals in Colorado and Utah (Thomas et al., 2000).
- Two large studies by (IOM, 2000, p.1):
 - one conducted in **Colorado and Utah and the other in New York**, found that adverse events occurred in 2.9 and 3.7 percent of hospitalizations, respectively.
 - In Colorado and Utah hospitals, 6.6 percent of adverse events led to death, as compared with 13.6 percent in New York hospitals.
 - In both of these studies, over half of these adverse events resulted from medical errors and could have been prevented.
- U.S. Congress passed the **Patient Safety and Quality Improvement Act in 2005** in response to a recommendation in To Err Is Human (2000) to report, gather, and analyze data nationally about adverse events and use the knowledge gained to improve patient safety.

IOM REPORT

- The scope of medical errors reported by the Institute of Medicine (IOM) in *To Err is* Human include:
 - \checkmark medication events such as the wrong drug or dose given to a patient,
 - ✓ hospital-acquired infections,
 - ✓incorrect diagnosis,
 - \checkmark or death due to unrecognized underlying medical conditions.



Patient stories that play important role

• Shortly after Leape's essay appeared in JAMA, the story of a patient's death caused by a medication error appeared in the Boston Globe. The story received wide attention from the public and the media and caused some in the medical community to take another look at Leape's "Error in Medicine."



Patient stories that play important role

• In late 1994, **Betsy Lehman was 39 years old**, married to a researcher at Dana-Farber Cancer Institute, mother of two young daughters, the Boston Globe's chief medical columnist, and a breast cancer patient. On Dec. 3, the final day of a hospital stay for intensive chemotherapy treatment, Lehman died unexpectedly, though she had sent a message to a friend that morning expressing distress and awareness that "...something's wrong." (Kenney, 2008). When the **massive overdose of chemotherapy** that lead to her death was discovered in February, many were astonished that such an apparently obvious and egregious error had happened at one of the premier cancer centers in the United States.



Crossing the quality chasm: A New quality healthcare by 21st century

- Crossing the Chasm: A New quality healthcare by 21st century.
- Report published by IOM on March 1st, 2001.
- A follow-up to the frequently cited 1999 IOM patient safety report <u>To Err Is Human: Building a Safer Health System</u>, Crossing the Quality Chasm advocates for a fundamental redesign of the U.S. health care system.
- Mandated the fundamental change in the organization and delivery of health care.
- Provided a roadmap to accomplish those changes.
- Addressed how the health care system can be reinvented to foster innovation and improve the delivery of care.

CROSSING THE QUALITY CHASM

The report focused on six specific aims for improvement. These aims were built around the core need for health care to be:

√Safe

✓ Timely

✓ Effective

✓ Efficient

✓ Equitable

✓ Patient-centered



Patient Centered care

- Patient-centered care is a key component of patient safety.
- Providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions.
- Bringing the patient and family perspectives into the design and delivery of care, with an emphasis on transparency, dignity, mutual respect, meaningful participation and collaboration with the healthcare team/organization.



Patient and Family Considerations in Patient Safety

- **Patient and family engagement (PFE)** is a fundamental aspect of health care quality, safety and reliability.
- Effective patient and family engagement is linked to greater quality and health outcomes, increased patient satisfaction and experience, increased patient buy-in to prescribed treatments, as well as greater satisfaction for healthcare professionals.



Patient and Family Considerations in Patient Safety

Six Attributes of Patient-Centered Care:
Education and shared knowledge
Involvement of family and friends
Collaboration and team management
Sensitivity to nonmedical and spiritual dimensions of care
Respect for patient needs and preferences
Free flow and accessibility of information



Core patient safety principles

- Swiss Cheese Model
- Culture of Patient Safety
- High Reliability Organizations (HRO)
- Human Factors Engineering (HFE)



Swiss Cheese Model: terminology

- Failures at the sharp end are identified as "active failures" direct operational errors with immediate effects, such as giving the wrong dose of a medication to a patient.
- Failures at the blunt end are identified as "latent failures" decisions and actions such as policies, procedures and resource allocation, as well as expectations for performance within the constraints of those policies and resources, that creates an environment with an increased probability of an error to occur.



Swiss Cheese Model





Swiss Cheese Model of Medical Errors

- The basic framework outlined by Reason identifies active and latent failures at both the "sharp end" and "blunt end" of a system.
- The **sharp end** refers to those activities that occur in the care delivery system that are visible, such as administering a medication. Healthcare workers that provide direct patient care are working at the sharp end of the care delivery system.
- The **blunt end** in the care delivery system refers to those actions and decisions that occur behind the scenes, at an organizational management level, setting the culture of the organization and work environment.

Swiss Cheese Model

- In health care, it is common for the sharp and blunt end systems to function as separate entities, resulting in a culture that is **ripe for accidents and errors**.
- Using this framework, the assumption is that medical errors occur because of flaws in the system of defense.
- The systems approach makes the fundamental assumption that medical errors are not caused by incompetent healthcare providers, but that accidents and near misses are the symptoms of a flawed system in need of improvement.



Culture of safety

- "a culture of patient safety" is often used to describe institutions that encourage everyone to speak up when they recognize a hazardous situation or when things go wrong and then follow up with corrective action aimed at improving the system, not aimed at punishing individuals.
- A safety culture, on the other hand, includes the following KEY CHARACTERISTICS:
 - ✓ Openness (Transparency)
 - ✓ Learning, not blaming (though not blame-free)
 - \checkmark Accountability for individuals and their teams
 - \checkmark Accountability for the system, and for the organization and clients
 - \checkmark Outcomes do not determine actions, but guide improvements

Culture of safety: Transparency

- Recognizing that transparency is a key driver for patient safety, the federal government introduced changes to requirements for receiving federal reimbursement to include the reporting of some patient safety information.
- This process has evolved to include different measures, different types of data, and mandatory public reporting of those data.
- The reporting of measures to publicly available repositories is the first step in building a culture of transparency that also includes disclosure and apology after a medical error occurs.
- Transparency is a key component of a culture of safety: the ability to be open and honest, report errors and respond to errors without fear of reprisal.



Culture of safety

- Many organizations are adopting an approach developed by David Marx, called "Just Culture". Marx's view (2007) is that there are **different levels of accountability for different behaviors:**
 - Human error includes inadvertent mistakes, which should be managed by consoling the individual and making changes to processes, procedures, training, and design.
 - At-risk behavior includes choices involving risk that is not recognized or justified. This should be managed by coaching the individual and rewarding healthy behavior, not at risk behavior.
 - **Reckless behavior** includes conscious disregard of unreasonable risk. In this case, remedial and punitive actions are appropriate.



High Reliability Organizations (HRO)

- High reliability organizations (HRO) expect a commitment to safety at all employee levels, from front-line engineers to managers and executives. These organizations establish a culture of safety that encompassed the following key features:
 - ✓ The **acknowledgment** of the high-risk nature of the organization's activities and the **determination** to achieve consistently safe operations.
 - ✓A blame-free environment in which individuals <u>can report</u> errors or near-misses without fear of reprimand or punishment.
 - ✓ The encouragement of collaboration across ranks and disciplines to seek solutions to safety problems.
 - ✓ The organizational commitment of resources to address safety concerns.



Human factors engineering (HFE)

- Human factors engineering is readily illustrated outside of healthcare examples by the automotive industry:
- Audible alert reminds you to buckle up, turn off your lights or remove your keys from the ignition.
- Newer cars will not start unless the car is in park and the brake is engaged.
- These are all systems designed with human factors in mind avoiding a reliance on memory and using forcing functions to ensure safety.



Human factors and the role in medical errors

- Key Concepts:
 - ✓ Human factors engineering is the design of facilities, equipment, and processes to promote safety, while keeping human characteristics, such as fallibility, in mind.
 - ✓ A mechanism for mitigating the temptation to create workarounds is to create systems that prevent them in the first place through the lens of human behavior and human factors engineering.



Key Concepts in System Design that Includes Human Factors:

- Understand human limitations and design processes safety.
- Avoid reliance on memory by providing effective reminders.
- Use constraints, forcing functions, in system designs.
- Simplify and standardize procedures whenever possible.
- Promote effective team functioning.
- Encourage reporting of errors and near-misses and use these reports as opportunities to prevent future errors.
- Include the patient in the design of safe processes.
- Plan for failure, and design for recovery.

Four Federal Laws based on patient safety initiatives:

- The Health Care Quality Improvement Act of 1986 (HCQIA)
- Deficit Reduction Act of 2005
- The Patient Safety and Quality Improvement Act of 2005 (PSQIA)
- The Patient Protection and Affordable Care Act (2010): the <u>Affordable Care Act (ACA)</u>



The Health Care Quality Improvement Act of 1986 (HCQIA)

- generally provides immunity to certain participants in the resolution of the standard of care or other staff-privileging issues for health care professionals.
- passed in 1986 as a means to discourage litigation against medical professionals when they participated in the peer-review process, where certain due process protections are provided to the individual under review.



Deficit Reduction Act (DRA) of 2005

- Grants states flexibility to modify their Medicaid programs.
- DRA provides states with much flexibility which they have been seeking over years to make significant reform to their Medicaid programs.
- States can expand access to affordability mainstream coverage, promote personal responsibility for health and accessing healthcare, and improve quality and coordination of care.
- The DRA provides flexibilities that states can use to pursue innovative ideas in healthcare.

✓ Consumer directed healthcare.

✓ Rebalancing long term care.

The Patient Safety and Quality Improvement Act of 2005 (PSQIA)

- Established to increase reporting of adverse events/medical errors for data analysis and trending via a voluntary reporting system.
- PSQIA also authorizes the Agency for Healthcare Research and Quality (AHRQ) to list patient safety organizations (PSO).
 - Leapfrog: a hospital safety grade.



The Patient Protection and Affordable Care Act (2010): <u>Affordable Care Act</u> (ACA)

• It was enacted to increase the quality and affordability of health insurance, lower the uninsured rate by expanding public and private insurance coverage, and reduce the costs of health care for individuals and the government.



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