Understanding the Foundations of Patient Safety & Applying the Principles of High Reliability to the Healthcare Environment

Laura M. Lee, MS, RN
Director, Office of Patient Safety and Clinical Quality
National Institutes of Health Clinical Center

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Learning Objectives

At the conclusion of this activity, the participant will be able to:

- Describe the magnitude and impact of errors and harm in healthcare; specifically in the medication management domain
- Discuss how the principles of High Reliability Organizations can be applied to the healthcare and pharmacy environments
- Relate how an organization’s culture impacts patient safety and describe strategies to improve an organization’s safety culture

Obtaining CME/CE Credit

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How Safe Is Health Care?

Bungee Jumping – REALLY????
Clinical Research: Heightened Responsibility

Healthcare Complexity

- Diversity of tasks involved in the delivery of patient care;
- Dependency of health-care providers on one another;
- Diversity of patients, clinicians and other staff;
- Relationships between patients, health-care providers, support staff, administrators, family, and community members;
- Vulnerability of patients;
- Impact of technology;
- Clinical research mission

The Language of Harm

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

Sharp end: The “actualizer” of the process—the person actually doing the task (e.g., the nurse administering a medication; the surgeon holding the scalpel)

Latent error: Organizational or design decisions made away from the bedside that impact the care and contribute to the occurrence of errors or allows them to cause harm to patients.

Blunt end: Parts of the process farther away from the action itself; the environment in which we deliver healthcare.

Preventable event: An event that could have been anticipated and prepared for, but that occurs because of an error or other system failure

Reason’s Swiss Cheese Model

Medication Allergy

Levels of defense

Active errors
(Patient safety incident)

Latent conditions
poor design, procedures, management decisions etc.

Factors that Influence Safety

Systems
**Think: Systems!**

**System**
- An interdependent group of items forming a unified whole

**Complex System**
- A system in which there are so many interacting parts that it is difficult, if not impossible, to predict the behavior of the system based on knowledge of its component parts

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**Person vs. System**

**Person Approach**
- Focus on individual
- Errors are a product of carelessness
- Interventions:
  - Naming
  - Blaming
  - Shaming
  - Retraining
- Target is the individual

**System Approach**
- Focus on conditions and environment
- Interventions:
  - Improving the system
  - Targets
  - Patient and provider factors
  - Task Factors
  - Technology and tool factors
  - Team factors
  - Environmental factors
  - Organizational factors

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**Managing Unsafe Events in the Clinical Center: A Strategic Model**

1. Did the employee act intentionally?
2. Did the employee appear habitually or randomly bad at work?
3. Were the consequences as intended?
4. Were the procedures easy to understand and follow?
5. Were there deficiencies in training, experience, and supervision?
6. Was the individual behavior predictable given the individual performance and experience?
7. Was the individual behavior predictable given the individual performance and experience?
8. Was the individual behavior predictable given the individual performance and experience?
9. Was the individual behavior predictable given the individual performance and experience?
10. Was the individual behavior predictable given the individual performance and experience?

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**Human Factors**

Human factors refer to environmental, organizational and job factors, and human and individual characteristics which influence behavior at work in a way which can affect health and safety.
Human Factors & Patient Safety

- The complexity of health care is fraught with human factors issues
- Major contributor to medical error

Human Factors

- Individual Characteristics
  - Knowledge, skill level, experience, intelligence, attitude, fatigue, stress, motivation

- Nature of the Work
  - Design of the work processes, patient loads, presence/absence of teamwork, complexity of treatments, equipment used, interruptions and competing tasks,

- Human-System Interfaces
  - Patient-Device interface, Practitioner-Device interface, Micro-system-Device interface, Socio-technical-Device interface, equipment location, software control, electronic health record (EHR)

Human Factors

- The Physical Environment
  - Architecture, interior design and layout, availability and placement of equipment, work flow in space, lighting, noise, temperature, distractions

- Organizational/Social Environment
  - Authority/power gradients, group norms and culture, communication/coordination, “local” procedures/practice, work life quality, normalization of deviance

- Management
  - Organizational structure, leadership, staffing/patient load, resource availability, culture, accountability of practitioners, employee development

- External Environment
  - Clinical research environment, political pressures, economic pressures, public awareness, new technology, media

Normalization of Deviance

1. Staff believe that rules are not well conceived and inefficient – developed by those who are not in the trenches of care.
2. Staff lack of knowledge – knowledge is imperfect and uneven and some staff may not even know the reasons for the practice and procedure.
3. New technologies – can disrupt ingrained practice patterns, impose new learning demands, or force system operators to devise novel responses or accommodations to new work challenges.
4. Staff belief that it is OK to break a rule for the good of the patient.
5. Staff belief that rules don’t apply to them – they have experience and can be trusted.
6. Staff fear about speaking up when deviant behavior is observed.
7. Leadership awareness of deviant behavior or systems problems but there is a failure to bring it up the chain of command.

Communication
Communication is the “the process by which information is clearly and accurately exchanged between two or more team members in a prescribed manner and with proper terminology and the ability to clarify or acknowledge the receipt of information” (AHRQ, n.d.).

Communication Barriers

**Individual Level Barriers**
- Language
- Lack of trust
- Cultural differences
- Gender difference
- Multiple/split loyalties
- Lack of team experience
- Distractions

**Team or Microsystem Level Barriers**
- Lack of well-articulated goals or purposes
- Role and leadership ambiguity
- Lack of structure or framework for problem-solving
- Workload
- Power and authority
- Traditional hierarchical differentials
- Lack of leadership and vision
- Personal conflicts among team members
- Diffusion of responsibility
- Interprofessional rivalries
- Lack of effective information sharing processes

Authority/Power Gradients

The balance of decision-making power or the steepness of command hierarchy in a given situation.

**Experienced/Leader**

- **Inexperienced/Subordinate**

- **Peer**

- **FLAT**

- **Peer**

- **STEEP**
**Authority/Power Gradients**

It could happen here -

- Pharmacist calling a physician to clarify an incorrect investigational new drug order is met with anger and impatience and this comment: “And when did you get your medical degree??”
- Fellow afraid to question an attending’s anticoagulation order despite her certainty that the order was wrong
- Operating room staff directed by senior surgeon to flash sterilize unconventional item for human use

**Cycle of Assertion**

- Get Person’s Attention
- Express Concern
- Reach Decision
- State Problem
- Proposal Action

**What is your “Safety Language”**

"Stop the line"

**High Reliability Organizations**

- Commercial airlines, aerospace, and nuclear power energy are among the most risky industries but are, in reality, the safest enterprises
- An error or lapse in safety in these industries’ processes can result in tragic outcomes
  - Likewise, a lapse in proper infection control in the care of a patient with Ebola virus infection or an error in the preparation or administration of a high risk medication can be catastrophic from a personal as well as an organizational perspective
- We approach the task of keeping our patients, staff, and organizational mission safe much like managing an airline or a nuclear power plant – we apply the five principles of high reliability

**Preoccupation with Failure**

*Channeling Your Inner Eeyore*

- We all need to be the “Eeyores” of the healthcare
- Always asking about, and looking for, untoward outcomes that could result from our care processes
- We ask “WHY?, WHY?, WHY?, WHY?, WHY?” when things go wrong or nearly wrong (e.g., near miss)
- Tools from high reliability industries help us identify risky processes and behaviors before we have a catastrophic event (e.g. Failure Mode and Effects Analysis)
- Drilling and conducting “Day in the Life” drills/exercises is borne of this Preoccupation with Failure
Deference to Expertise

The C-Suite Plays Second Fiddle

• The old adage “Father knows best” does not rule the day
• Staff involved in the management of high risk procedures and the care of complex high risk patient patients (and all patients, for that matter) are the experts about how the processes we design will perform - or more importantly, won’t perform – and, therefore, play the lead role in designing processes of care
• A challenge is managing the well-intentioned “directives” of staff and leadership who are removed from day to day bench-side or bed-side care but have a vested interest in the care of patients

Built-In Resiliency

I Get Knocked Down and Get Back Up Again

• Every organization must develop strategies to sustain operations and “bounce back” when (not if) an untoward event occurs
• The question “What if?” needs to end every process step designed in the care of high risk patients
  o What if a pharmacist dispenses the wrong drug or if a staff person experiences an occupational exposure?
  o What if the public has a negative reaction to a sentinel event involving a medication or there is a breach in technique?

Sensitivity to Operations

Eyes in the Back of My Head

• Leaders and staff need to be constantly aware of how processes and systems affect the organization
• Each employee pays close attention to operations and maintains awareness as to what is, or isn’t, working
• “Safety huddles” should be used liberally. In safety huddles staff gather briefly (five –ten minutes) to discuss issues/concerns that have developed over the course of their tour of duty
• Leadership huddles are equally important to review what is working or not working each day

Reluctance to Simplify Processes

The Devil is in the Details

• Resist simplifications! Look beyond the obvious!

• May be beneficial to simplify some work processes but avoid failing to dig deeply enough to understand an issue
• The question: “What if?” needs to end every process step designed in the care of high risk processes and patients
• The meticulous attention to detail in the complex operations of a pharmacy and medication management is an example

Patient Safety Culture

An organization’s values and behaviors — modeled by its leaders and internalized by its members — that serve to make patient safety the overriding priority.

Patient Safety Culture

• Acknowledgment of the high-risk nature of our work;
• A dogged determination to achieve safety;
• A blame-free environment where individuals are able to report errors or near misses without fear of reprimand or punishment;
• A commitment to learn from errors;
• Encouragement and expectation of collaboration across departments and disciplines to solve patient safety problems;
• Leadership commitment to, and involvement in, patient safety.
“Error is the starting point; not the conclusion”
Sydney Dekker - "The Field Guide to Understanding Human Error"