Fundamentals of Patient Safety
1. Creating a Culture of Safety
2. Transparency – The Role of RCA

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Chair, Council for Patient Safety in Women’s Health

Disclosure

- Bayer HealthCare Continuous Quality Improvement Advisory Board, Wayne, NJ
- Consultant, Simulation Center, Baptist Health South Florida, Miami, FL
- Senior Medical Consultant, Stevens & Lee, Lancaster, PA

UM-JMH Center for Patient Safety
“There are some patients we cannot help; there are none we cannot harm.”

Arthur Bloomfield, MD
Learning Objectives
Upon completion of this lecture the participants should be able to:

- Cite the incidence of medical errors
- Define safety culture
- List the most important barriers to creating a culture of safety
- Discuss the most critical strategy to achieve a culture of safety

“Culture Trumps Strategy”

- Concepts of patient safety are simple
- Implementation and sustainability are difficult
- Sustainability requires a receptive culture of patient safety
- A culture of patient safety will not occur without committed and effective leadership at all levels of an organization

P. Gluck
Clinical OB Gyn 2010

“The doctor who doesn’t think that his or her professional identity encompasses a leadership role in patient safety is part of the problem”

Krause and Hidley, 2009
Taking the Lead in Patient Safety
Outline

- Incidence of medical errors
- Principles of Patient Safety
- Safety Culture
- Leadership Tools

IOM – November, 1999

44,000-98,000 (3.7% error rate) deaths annually (more die each year than the entire Vietnam War, or motor vehicle accidents or breast cancer).

Lucian Leape, MD

Leading Cause of Death 1999

1. Heart disease — 725,192
2. Cancer — 549,83
3. Chronic Respiratory Disease - 142,181
4. Medical errors >98,000
5. Injuries — 97,820
6. Diabetes — 68,399
7. Influenza & Pneumonia 63,700
8. Alzheimer's Disease 44,356
9. Nephritis 35,525

Sources: [http://www.ohs.gov/](http://www.ohs.gov/)
Temporal Trends in Rates of Patient Harm Resulting from Medical Care
Landrigan NEJM November 26, 2010

- North Carolina 2002-2007
  - 2341 charts, 10 hospitals, 54 “trigger tools” (ex. stop orders, antidotes, very abn. labs, return to OR, etc)
  - 18% harmed by medical care; 2.4% death
  - 63% preventable
  - Probable under reporting

Adverse Events Medicare Patient
Report of the IG – November 2010

- 780 Medicare Charts – Oct 2008
  - NQF Never Events, CMS Hospital Acquired Events
  - 13.5% adverse events led to patient harm
  - 1.5% contributed to death
  - 44% preventable
  - 200,000 preventable deaths annually
  - $4,400,000,000 additional costs

Global Trigger Tools Show Adverse Events in Hospital 10 Times Greater
Claussen, Resar et al. Health Affairs 4/11

- 3 Hospitals – established patient safety programs
- 795 Charts – Trigger Tools
  - ex. stop orders, antidotes, very abn. labs, return to OR, etc
- 354 adverse events (33.2% of charts)
- Much lower incidence found thru voluntary reporting and AHRQ PSI
Error Rates – Different Methods
PA Gluck, Obstetrics & Gynecology November, 2012

Temporal Trends in Rates of Patient Harm Resulting from Medical Care Landrigan NEJM November 26, 2010

Outline
- Incidence of medical errors
- Principles of Patient Safety
- Safety Culture
- Leadership Tools
DESIGNING SAFE SYSTEMS IN HEALTHCARE

- Principle 1. Provide leadership
- Principle 2. Respect human limits in process design
- Principle 3. Effective team functioning
- Principle 4. Create a learning environment
- Principle 5. Anticipate the unexpected

PRINCIPLE 1. PROVIDE LEADERSHIP

1. Patient safety as a high corporate objective
   Part of “corporate culture”
2. Patient safety is everyone’s responsibility
3. Clear assignment and expectation for safety oversight
4. Human and financial resources for error analysis and system redesign
5. Identify and deal with unsafe practitioners

PRINCIPLE 2. RESPECT HUMAN LIMITS IN PROCESS DESIGN

1. Design jobs for safety
2. Avoid reliance on memory
3. Use constraints and forcing functions
4. Avoid reliance on vigilance—respect stress, workload, fatigue, time pressure
5. Simplify key processes
6. Standardize work process
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Avoid reliance on memory
(Mental and visual prompts)
“Reminders at the Sharp End”

- Patient Specific Information
- Protocols & Guidelines
- Clinical Decision Support
  - On line, pocket guides, PDA
  - CPOE
- Medication Unit Dosing
Constraints and Forcing Functions

- Equipment prompts and interface
  - Infusion pumps
  - Incompatible connections (PISS)
- Processes
  - Remove KCl from floors
  - Allergy history required before meds dispensed

Pin Insertion Safety System

Pin Insertion Safety System
Endometrial Ablation

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Types of Serious Medical Errors

<table>
<thead>
<tr>
<th></th>
<th>Traditional Schedule</th>
<th>Shorter Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td>99.7</td>
<td>82.5</td>
</tr>
<tr>
<td>Procedural</td>
<td>8.5</td>
<td>6.6</td>
</tr>
<tr>
<td>Diagnostic</td>
<td>18.6</td>
<td>3.3</td>
</tr>
<tr>
<td>Other</td>
<td>9.3</td>
<td>7.7</td>
</tr>
</tbody>
</table>
Unintended Consequences

- Every 5th night call and Night Float experienced: (1)
  - More sleep during call, more handoffs
  - Perceived reduced quality of patient care (survey)
  - Reduced availability for teaching conferences
- Reduced duty hours (2011 compliant) (2)
  - Increase in self reported serious errors
  - “Work Compression”


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STANDARDIZATION
Surgical checklist to reduce morbidity and mortality

Haynes AB, et al, NEJM 2009

- >16 years old, non-cardiac surgery
- Before checklist 3733, after checklist 3955
- Developed countries (US, Canada, UK, NZ), developing countries (India, Jordan, Tanzania, Phillipines)
- Complications within 30 days of surgery
Surgical checklist to reduce morbidity and mortality
Haynes AB, et al, NEJM 2009

<table>
<thead>
<tr>
<th></th>
<th>Before Checklist (3733 cases)</th>
<th>After Checklist (3955 cases)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death Rate</td>
<td>1.5%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Inpatient Compl.</td>
<td>11 %</td>
<td>7%</td>
</tr>
</tbody>
</table>

PRINCIPLE 3.
EFFECTIVE TEAM FUNCTIONING

1. Train in teams those expected to work in teams (Multidisciplinary)
2. CRM-support communication against the authority gradient
3. Include patient as resource in safety design and process of care
4. Improve Communication

Outcomes of Team Competencies

- Knowledge
  - Shared Mental Model

- Attitudes
  - Mutual Trust
  - Team Orientation

- Performance
  - Adaptability
  - Accuracy
  - Productivity
  - Efficiency
  - Safety
PRINCIPLE 4.
CREATE A LEARNING ENVIRONMENT

1. Simulations when possible
2. Learning culture with easy flow of communication regardless of hierarchy
3. Encourage and reward reporting of errors and hazardous conditions
4. Nonpunitive reporting – Transparency/Honesty
5. Mechanism for feedback and learning from error
PRINCIPLE 4.
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NASA Aviation Safety Reporting System

35,000 Reports Annually

- Voluntary
- Confidential
- Non-Punitive

Patient Safety and Quality Improvement Act
P.L. 109-41, July 2005

- Confidential, Voluntary reporting system for medical errors and near misses
- Analysis by Patient Safety Organization
- Administration by HHS
A Root Cause Analysis

Environment  Equipment  Leadership

Communication  People  Procedures

PRINCIPLE 5.
ANTICIPATE THE UNEXPECTED

1. Proactive approach (FMEA)
   - examine and redesign processes for latent errors
2. Design for recovery
   - error mitigation
   - redundancy of critical functions
   - Rapid Response Teams
3. Improve access to timely, accurate information (Information Technology)
   Redesign the patient record for standardization, usability & reliability

FAILURE MODE EFFECTS ANALYSIS (FMEA)

- Prospective
- Multidisciplinary
- Process not Outcome
FAILURE MODE EFFECTS ANALYSIS (FMEA)

Environment  Equipment  Leadership

Communication  People  Performance Standards

PROCESS

ANTICIPATE THE UNEXPECTED

1. Proactive approach (FMEA)
   - examine and redesign processes for latent errors
2. Design for recovery
   - error mitigation
   - redundancy of critical functions
   Rapid Response Teams
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Condition O
OB Stat Team
Magee Women’s Hospital
Birch Hospital for Women
Events triggering Code “O”

- Non reassuring FHR 50
- PP Hemorrhage 22
- Shoulder Dystocia 16
- Cord Prolapse 15
- Seizure 15
- Imminent Delivery
  - Preterm 14
  - Term 9
  - Syncope 8
- Imminent Delivery 6
- Malpresentation
- Difficult C/S 4
- Abruptio 4
- Antepartum bleeding 3
- Preterm labor 3
- Placenta previa 2
- Unresponsive patient 2
- Maternal resp distress 1

Outline

- Incidence of medical errors
- Principles of Patient Safety
- Safety Culture
- Leadership Tools

Safe Culture - Definition

ACSN*®, UK 1993

Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures.

*Advisory Committee on the Safety of Nuclear Installations
A Patient Safety Culture is…
- A just culture
- A learning culture
- A collaborative culture

Vision without Execution is Hallucination

Thomas Edison

Domains for Safe Culture Assessment
Colla, Braken, Kinney, et al. Qual Saf Health Care, 2005
- Leaders support individual performance
- Collaboration and Mutual trust
- Job Satisfaction
- Staffing and work load
- Reduce stress and fatigue
- Effective communication
- Transparency and reporting
The evolution of safety cultures

Barriers to Establish Safe Culture

- **LEADERSHIP**
- Resistance to change; physician engagement
- Lack of team work
- Inadequate Resources – staffing & infrastructure
- Culture of individual blame (vs. Just Culture)
- Competing priorities; unclear values
- Inadequate reporting systems and analysis

Outline

- Incidence of medical errors
- Reasons for Medical Errors
- Principles of Patient Safety
- Safety Culture
- Leadership Tools
**Team – Definition**
Eduardo Salas, PhD

Two or more people:
- who interact dynamically, interdependently and adaptively toward a common goal/mission
- each has been assigned specific task(s)
- limited lifespan as a team member

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**KLM Co-Pilot**
“Is he not clear then?”

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The largest loss of life in aviation history

582 Deaths
Tenerife - March 27, 1977
The largest loss of life in aviation history

Hospitals race to learn lessons of Ferrari pit stop

WSJ 11/14/06
TEAM FUNCTION & SAFETY

BEST TEAM
- Least Experience Surgeon
- Cohesive Team
- Simulation
- Pre case planning
- Debriefing
- Results tracked
- Removed hierarchy

WORST TEAM
- Most experienced surgeon
- Team members changed
- No debriefing
- No tracking of results
- No preplanning
- Hierarchical

Outcomes of Team Competencies

- Knowledge
  - Shared Mental Model

- Attitudes
  - Mutual Trust
  - Team Orientation

- Performance
  - Adaptability
  - Accuracy
  - Productivity
  - Efficiency
  - Safety
Leadership vs. Management

- Good leaders relentlessly pursue their vision.
- Leaders have a vision;
  Managers carry out the vision
- Leaders do the right thing;
  Managers do things right

**Medicine is generally over managed and under led**

Leadership & Teamwork:
Lessons from Star trek
Captain James T. Kirk

“One of the advantages of being a Captain is being able to ask for advice without having to take it.”

Paradigm Shift to Team Approach
Captain James T. Kirk vs Jean-Luc Picard

Dual focus (clinical and team skills)
- Team performance
- Informed decision-making
- Clear understanding of teamwork
- Managed workload
- Sharing information
- Mutual support
- Team improvement
- Team efficiency

Single Focus (Clinical Skills)
- Individual performance
- Under-informed decision-making
- Loose concept of teamwork
- Unbalanced workload
- Having information
- Self-advocacy
- Self-improvement
- Individual efficiency

Jean-Luc Picard

“Make it so!”
The Human Factor: the critical importance of teamwork and communication in providing safe care

“Two absolute requirements for successful clinical change are visible support from senior leadership and strong clinical leadership.”

Leonard, Graham, Bonacum

Qual Saf Health Care, 2004

Administrative Leadership
Responsibility of Leaders in support of Patient Safety

- Create and maintain a culture of safety
- Evaluate safety culture with validated tools
- Based on surveys – prioritize and implement safety changes

Responsibilities of Administrative Patient Safety Leaders

- Shape the organization’s value system
- Keep quality and safety central in strategic goals
- Align resources to achieve goals
- Remove obstacles
- Require adherence to proven practices

Clinical Leadership

1. Role
2. Behaviors
3. Skills
Roles of Patient Safety
Clinical Leaders

- Create a compelling safety vision
- Value and empower personnel
- Engage in patient safety efforts
- Lead by example
- Focus on system issues
- Constantly seek improvement

A case for safety leadership team training of hospital managers
Singer, Hayes, Cooper, et al. Health Care Manage Rev, April-June 2011

Leader Behaviors

- Really cares
- Demonstrates non-defensive attitude
- Encourages speaking up
- Seeks input
- Mobilizes team
- Takes action

Clinical Leadership Skills

- Manage Resources
- Ensure Teamwork Behaviors
  - Meetings (Huddles), Briefings, Debriefings
- Facilitate Teamwork Skills
  - Communication
  - Mutual Support
  - Situation Monitoring
- Model teamwork behaviors
- Facilitate conflict resolution - DESC
Huddle Up

Whenever the clinical situation requires a new “play” (CLINICAL MANAGEMENT) or a “substitution” (ADDITIONAL RESOURCES)

Debrief Checklist

- Was communication clear?
- Did individuals understand their roles?
- Was there a shared mental model?
- Was stress or fatigue a factor?
- Were errors made or averted?
- What went well?
- What team function could be improved?

Conflict Resolution – DESC
(20% of leader’s time)

- D – describe the current situation
- E – respectfully express reason for concern
- S – specify how they would alter management
- C – perception of the consequences of the different options
1. Leadership is critical
2. Safety is the first priority
3. Transparency and honesty are core values
4. There must be physician buy in
5. Everyone is accountable
6. Mutual respect and teamwork are prized

Conclusions
- Medical errors remains a significant problem measured by preventable deaths
- Deficient leadership is the most significant barrier in improving medical systems
- Several validated tools will improve both administrative and clinical leadership

Root Cause Analysis:
Essential in Creating a Learning Culture
Learning Objectives
At the conclusion of this presentation the participant should be able to:
- List the 4 basic steps in performing an RCA
- List some typical open ended questions helpful in RCA
- List some common pitfalls of a typical RCA

Root Cause Analysis
- Assemble team
  - Multidisciplinary, junior and senior staff, nurses, doctors, pharmacists, other healthcare professionals
- Investigate the incident
  - Nonjudgmental
  - Accurate event chronology – critical
  - Outside knowledge, human factors
- Recommend system improvement
- Monitor impact of changes

Root Cause Analysis - Questions
- What happened?
- What normally happens?
- How did it happen?
- Why did it happen?
- What should be done to prevent it from happening again?
Look for system issues; not individual blame
A Root Cause Analysis

Environment  Equipment  Leadership

incident

Communication  People  Procedures

Shortcomings of Typical RCA

- Failure to address behavioral issues
- Failure to identify deep-seated latent failures
- Failure to evaluate human factors
- Failure to seek outside knowledge
- Failure to link causes to proposed interventions
- Selecting weak interventions i.e. “staff education” and “downstream double checks”
- Failure to measure results of interventions
- Focus too narrow or too broad
- Unjust punitive actions (Just Culture)

Dig deeper

Ask “why” 5 times!