Patient Safety: Requirements, Experiences and Information Needs

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Course Objectives

• To reinforce why Patient Safety is an important focus in today’s environment
• To benefit from a case study
• To understand key accreditation and regulatory issues
• To understand the importance of data and information to Patient Safety issues and see examples of data collection tools
Why is the focus on Patient Safety increasing in the U.S.?
Focus on Patient Safety

• 98,000 deaths each year in U.S. due to preventable errors, based on 14 categories of patient-safety incidents (*To Err Is Human*, Institute of Medicine, 1999)

• If add categories “failure to diagnose and treat a serious medical problem in time” and “unexpected death in a low-risk hospitalization”, project 195,000 deaths each year due to preventable errors (*Modern Healthcare Daily Dose*, July 27, 2004 and *HealthGrades Quality Study – Patient Safety in American Hospitals*, July 2004)
• 54.9% of study participants received the recommended care
• Essentially same result whether preventive care, acute care or chronic type of care

Public Awareness

• Recent reports and news in the media lead the public to become more aware of issues
  – Maryland General Hospital impact on lab accreditation/regulation in the future?

• Public demands data and improvements and gets the ear of Congress

• Senate unanimously passed a bill (House did in March 2003) that would set up a confidential, voluntary system of reporting medical errors …. intent is to allow providers to report without fear of being sued (Modern Healthcare’s Daily Dose, July 23, 2004)
• JCAHO
  – Reducing medical errors and improving patient safety become a focus
  – New standards go into effect on July 1, 2002 requiring emphasis on patient safety

• Medicare Quality Assurance and Performance Improvement Program
  – Requires hospitals to develop and maintain a quality assessment and performance improvement program
  – Effective as Condition of Participation on March 25, 2003
Lessons from the Duke Experience
“Quality is very much affected by complexity, which increases with the size of the organization, the number of people involved in a process, the number of steps in the process, even the distance traversed by the process. With a bigger organization and more people involved in the treatment of a single patient, there are more chances for miscommunication, etc – many more ways for dropping the ball”

James O. Westgard, PhD, FACB, “2004 JCAHO Patient Safety Goals: What our goals say about where we are now”, www.westgard.com/essay53.htm
• Teaching Hospitals and larger hospitals (>200 beds) had slightly higher patient safety incident rates… as compared to non-teaching hospitals (HealthGrades Quality Study)

• Duke University Hospital experience demonstrates that errors can occur even in the finest of clinical centers
Errors Occur at Multiple Levels

“Patient Safety Hits the Laboratory Industry: Early Findings from the CDC”, Stankovic, War College 03

“BLUNT END”
Macroclimate

Institutional Support Systems

Equipment and Tools

Clinicians and Patients

“SHARP END”

Adverse event

James Reason, 1998 Ashgate

SAFER • HEALTHIER • PEOPLE™
Experience at Duke Hospital: The Transplant Case
Timeline of Events

Feb 7 – Transplant of incompatible organs
Feb 13 – First meeting of RCA (Root Cause Analysis) Task Force
Feb 17 – Voluntary report to JCAHO & DFS
Feb 20 – Second transplant
Feb 20-24 – DFS Complaint Investigation (numerous condition level deficiencies)
Feb 22 – Patient pronounced brain dead
Role of DFS (State of NC)

DFS = Dept of Facility Services (NC)

Designated investigator for CMS (Centers for Medicare & Medicaid Services)

-- Conditions of Participation (CoP)
-- EMTALA (Emergency Medical Treatment and Active Labor Act)
-- Beneficiary concerns

Enforcer of NC Licensure Laws/Regulations
Patient Advocate
Timeline of Events

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(numerous condition level deficiencies)
Feb 22 – Patient pronounced brain dead
March 4 – Notified of JCAHO’s intent to visit
March 6 – JCAHO Focused Survey
   (numerous Type 1 recommendations)
March 24-31 – CMS Full Validation Survey
   (numerous condition, standard and element level deficiencies)
April 14-17 – Dialysis/Kidney Transplant CMS Survey (immediate jeopardy, numerous Condition & standard level deficiencies)
Timeline of Events

May 6 – Presentation of RCA and Recommended process improvements to JCAHO
June 2 – PICU (Peds ICU) Fire
June 4 – Voluntarily report to DFS & JCAHO; first meeting of RCA Task Force; DFS investigation commences
June 6 – DFS revisits
Timeline of Events

June 11 – DFS revisits (no deficiencies Identified)
June 20 – JCAHO Focused Survey (f/u to March)
July 8-10 – CMS re-survey (f/u to Feb, March and April visits; found to be back in compliance with conditions of participation)
Timeline of Events

August 31 – Thermal injury to neonate
Sept 4 – Self-reported to DFS
Sept 5 – DFS arrives to investigate
Sept 8 – DFS investigation concludes
(potentially condition level)
Sept 12 – Receive notice of immediate jeopardy status
Sept 19 – Receive deficiency report & notice of intent to notify public of termination on September 24

Sept 22 – Present corrective action plan in Atlanta (accepted)

Oct 1 – Notified by JCAHO of acceptance of PICU fire RCA as thorough & credible

Oct 9 – CMS re-survey; found to be back in compliance with conditions of participation
Rapid process improvement can be achieved in a large complex organization with a history of resistance to change!

- Immediately revised protocol for acceptance of donor organs – inclusive of external agency duties
- Immediately amended duties of procuring surgeon to include ABO compatibility verification
- Immediately changed oversight structure for pediatric thoracic transplants
Focusing performance improvement efforts on high volume, high risk processes is not sufficient.

- Quality control is essential
- Low volume, high risk processes require attention outside of those immediately involved
Lesson #3

Assumptions are dangerous

• Absence of an attention grabbing issue does not equate to quality
• Presence of a policy does not assure uniform compliance
• Quality oversight of services provided by an external organization by the recipient of the services is not sufficient
Lesson #4

Good can come from a crisis

• DUH learned how strong it is
• Board of Directors established Patient Safety and Quality Assurance Committee and Patient Safety Action Task Force
• JCAHO learned that low volume, high risk processes need attention
Good can come from a crisis (cont’)

- UNOS is allowing direct access to donor information by recipient hospitals
- DUH/S established process for responding to a crisis
- Rapid change in culture was achieved and is being sustained
Using performance improvement techniques to achieve compliance with regulations works:

- Define the problem (regulation + barriers)
- Analyze the data (audits, prevalence studies, observations)
- Intervene (education, measure again & again, continuous data feed to end user)
- Evaluate (measure again & again, re-survey)
Lesson #6

Transparency works

- Accurate information is vital to the organization & its people
- Honest self-examination requires it
- Assists with recovery from grief process
The “Stockdale Paradox” is true

Admiral Jim Stockdale, highest ranking officer in the Hanoi Hilton

“Retain faith that you will prevail in the end, regardless of the difficulties AND, at the same time confront the most brutal of facts about your current reality, whatever they may be.”

*Jim Collins & Jim Stockdale*
Lesson #8

Let Your Mission Guide You

• **Decisions driven by:**
  -- What is best for our patients?
  -- What is best for our staff?
  -- What would we do under ‘normal’ circumstances?
  -- What message will we send?
Lesson #9

Take Care of Your Own

- Information Flow
  -- Local and hospital-wide
  -- Staff should be the first to hear new information
  -- Stop the rumor mill with accurate information
- Employee assistance service/critical incident response team
- Visible support from hospital leadership
Take Care of Your Patients

- Present in hospital & past/future patients
- Respond to questions
- Communicate accurate information
- Consider targeted communications with patient populations closest to the issue
Lesson #11

Manage the Facility Issues

- **Access**
  - Hospital-wide
  - Local unit
- **Adhere to policies**
  - Photographing of patients/staff
  - Visitation
  - Brain death declaration
DUH Chief Operating Officer assigned to review all aspects of Nursing Services, Clinical Engineering and other operations that have been identified in recent incidents.

“He will be free – indeed is being encouraged – to investigate any area(s) that he believes might pose a safety problem and implement necessary changes in these operations.”
The Pediatric Safety Center is established to carry out a comprehensive review of all Pediatric Care Services. The Physician Director has full authority to take any steps deemed necessary to protect the safety of Pediatric Patients. Marlene Miller, M.D. who has earned a national reputation in the field of Quality and Safety Initiatives at the Johns Hopkins Children’s Center is serving as a Consultant.
Currently recruiting a Physician Patient Safety Officer to oversee care across the entire Duke University Health System.

This new position reports directly to the Patient Safety and Quality Assurance Committee of the DUHS Board of Directors and the President and CEO of the Health System.
Outside Expertise

- DUHS Board of Directors will invite outside experts to serve on the DUHS Board Patient Safety and Quality Assurance Committee
- Joe and Terry Graedon, the Syndicated Columnists who host “The People’s Pharmacy” on NPR and are well known for their advocacy of Patient Safety have already agreed to serve on this committee
Partnership with Medical review of North Carolina

- DUH/DUHS and MRNC will collaborate on a continual monitoring program to assist DUH/DUHS in reviewing, assessing and developing a comprehensive plan for Patient Safety across the Pediatric Services of the Institution.

- While initial collaboration is with the new Pediatric safety program, it is anticipated that DUH will expand this partnership to other Clinical Services.

- Duke and MRNC will regularly inform and seek advice from CMS on the programs and initiatives being undertaken to ensure the public of the Quality of Care and commitment to Patient Safety of our Health Care Delivery System.
Accreditation Response To Patient Safety
• Elements of IOM Recommendations:
  – Provide immediate access to decision support alerts and reminders
    • JCAHO Patients Safety Goals 2005 focus on Alert Value notification monitoring and improvement
  – Capture information on patient safety as a by-product of care
    • Example of reporting system from Duke University Health System shared later in this presentation
JCAHO Hospital National Patient Safety Goals 2005

- Improve accuracy of patient identification
- Improve effectiveness of communication among caregivers
  - V/O or critical results “read-back” requirement
  - Standardize abbreviations, acronyms & symbols
  - Monitor reporting & timeliness of report/receipt of critical results to licensed caregivers
- Improve the safety of using medications
- Improve the safety of using infusion pumps

www.jcaho.org/
JCAHO Hospital National Patient Safety Goals 2005

- Reduce the risk of health care-associated infections
- Accurately and completely reconcile medications across the continuum of care
- Reduce the risk of patient harm resulting from falls
• Improve the accuracy of patient identification
  – Use at least two patient identifiers (neither to be the patient’s location) whenever collecting laboratory samples or administering medications or blood products, and use two identifiers to label sample collection containers in the presence of the patient.
  – Processes are established to maintain samples’ identity throughout the pre-analytic, analytical and post-analytic processes
• Improve the accuracy of patient identification (continued)
  – Immediately prior to the start of any invasive procedure (bone marrow collection or FNA), conduct a final verification process to confirm the correct patient, procedure, site and availability of appropriate documents.
  – This process to use active, not passive, communication techniques.
• Improve the accuracy of patient identification (continued)
  – The patient’s identity is re-established if the practitioner leaves the patient’s location prior to initiating the procedure.
  – Marking the site is required unless the practitioner is in continuous attendance from the time of the decision to do the procedure and patient consent to the initiation of the procedure.
• Improve the effectiveness of communication among caregivers
  – For verbal or telephone orders or for telephonic reporting of critical test results, verify the complete order or test result by having the person receiving the order or test result “read-back” the complete order or test result
  – Standardize abbreviations, acronyms and symbols……..
• Improve the effectiveness of communication among caregivers (continued)
  – Measure, assess and, if appropriate, take action to improve the timeliness of reporting, and the timeliness of receipt by the responsible licensed caregiver, of critical test results and values
  – All values defined as critical by the laboratory are reported directly to a responsible licensed caregiver within time frames established by the laboratory (defined in cooperation with nursing and medical staff).
• Improve the effectiveness of communication among caregivers (continued)
  – When the patient’s responsible licensed caregiver is not available within the time frames, there is a mechanism to report the critical information to an alternative response caregiver.

• Reduce the risk of health care-associated infections