PATIENT SAFETY

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Patient Safety Standards

In July of 2001, the first patient safety standards were introduced into many chapters throughout JCAHO’s Comprehensive Accreditation Manual for Hospitals. Notably missing from the list of included chapters at that time was the Environment of Care®. These standards were developed in response to the widespread concern about medical errors resulting from a number of highly publicized incidents. Key points of a patient safety process expected by Joint Commission include an integrated program throughout the organization, minimization of individual blame as situations occur, and leadership accountability for patient safety.

In the Leadership chapter of the accreditation manual, patient safety standards require that variation in processes be measured. Resources must be assessed in all areas, including those of staffing and information as well as physical and financial resources. Leadership is responsible for an integrated, proactive patient safety program, which receives a high priority within the organization.

Performance improvement standards include those expecting that patient risk be minimized. The organization must determine if a new process really represents an improvement, and not just a change. These standards consider that an individual’s perception of risk is an entity to be managed, whether or not that risk is real. Staff must be encouraged to report errors, and this requires a culture where individuals are not blamed for mistakes.

Under the requirements of the Management of Information chapter, barriers to effective communication among caregivers must be removed, and risks to patients must be lowered.

Patient Rights and Organizational Ethics requires that patients and their families must be informed about procedures and activities that will impact them. The patient (and their family members) must be considered to be part of the team treating the patient, and they are responsible for providing information to and asking questions of the caregivers. The health care organization must present a climate conducive to this communication.

Initial employee orientation must address topics of job-related patient safety, and this must be continued through ongoing inservice and training programs. The approach to this process must be interdisciplinary, breaking down barriers between departments and services.

Six months after the initial introduction of patient safety standards, three new standards were added to the Environment of Care® chapter of the accreditation manual, under standards EC.4.1, EC.4.2, and EC.4.3. All three of these requirements essentially say the same thing, and specify required
communication between the EC safety function and the patient safety function in the organization.

EC safety and patient safety are two distinct functions that have significant overlaps. Medication errors, for example, are unique to patient safety. Occupational illness and injury are clearly in the EC safety arena. In the middle lie such issues as patient falls, medical equipment, fire safety, etc. In fact, these functions are so related that JCAHO suggests that organizations might consider presenting them as a comprehensive program at the time of survey.

There is no prescriptive model under which patient safety must be managed. Most organizations have appointed an individual with a clinical background to be in charge of patient safety. Often, this person comes out of a risk management, performance improvement, or quality background. Some facilities have chosen to have the EC safety officer also responsible for patient safety, and there are certainly other choices. The key point is the communication, and if there is a patient safety committee, the EC safety officer sitting on the patient safety committee and the patient safety point person sitting on the EC safety committee will accomplish that.

National Patient Safety Goals

JCAHO has furthered its approach to patient safety by establishing national patient safety goals. Six goals are established annually in July to be effective during the subsequent year. All recommendations put forth with each goal must be implemented by each health care organization. Any alternative approaches to meeting these goals must be approved in advance by Joint Commission.

For 2003, four of the goals are in the clinical arena:
- Improving the accuracy of patient identification
- Improving communication effectiveness among caregivers
- Improving the safety of high-risk medications
- Eliminate wrong-patient, wrong-site, wrong-procedure surgery

For the most part, these clinical goals are very basic, but we must attempt to solve the basic problems before we go forward.

Two national patient safety goals are in the Environment of Care®. The first is improving the safety of IV infusion pumps, by ensuring that all general use and PCA (patient-controlled analgesia) pumps have free-flow protection. The second EC goal is to improve the effectiveness of clinical alarms. In the broadest sense, many pieces of medical equipment and patient-related utilities equipment have alarms to indicate a potential problem. Each must receive appropriate preventive maintenance and testing, and the alarms must be activated at the appropriate settings. Amid competing alarms in a noisy environment, those that are critical
must be sufficiently audible and receive the appropriate response. It may be prudent to test this with a drill.

At the time of this writing, the 2004 patient safety goals have not yet been released. They will, however, be discussed during the presentation of this program.

**EC-Related Sentinel Events**

Of the 28 *Sentinel Event Alerts* released by JCAHO at the time of this writing, 9 are directly related to the Environment of Care®:

- Inpatient suicide
- Infant abduction
- Fatal falls
- IV infusion pump errors
- Medical gas mix-ups
- Needlestick and sharps injuries
- Ventilator-related deaths and injuries
- Bed rail entrapment deaths
- Infection control related sentinel events

This does not imply that there is no EC role in the other published alerts, only that these primarily deal with an EC-related issue. The two most recent *Sentinel Event Alerts* merit some further discussion.

In 1999, the Food and Drug Administration formed a working group to examine the issue of entrapments and associated deaths in “hospital” bed systems. In this case, the term, “hospital,” applies to all medical beds, including those within long term care organizations. Those most at risk for entrapment incidents include populations significant in the LTC industry, the elderly, frail, and confused. FDA statistics show that 85% of the bed-rail related deaths and injuries occur in the population over 65 years of age. 38% of the incidents occur in acute care hospitals.

On an annual basis, there are 27.4 entrapment incidents, or a rate of 1 entrapment per 3.4 million admissions. These incidents result in 16.9 deaths per year. Concern for patient safety would indicate that no incident of patient entrapment is acceptable, but the current rate already presents performance at a rate of six sigma. No risk can ever be fully eliminated.

Three documents will be forthcoming from the Hospital Bed Safety Workgroup.

The Clinical Guidance document, currently available on the FDA website, addresses issues concerning resident needs and associated risk assessment based on clinical issues. Issues of restraint will be contrasted with those of safety. This document is a publication of the workgroup itself.
Unlike the Clinical Guidance, the Dimensional Guidance will be published by the FDA in the Federal Register in the near future with a 90 day comment period. This will not be enforceable regulation, but rather guidance in the design of new bed systems. It is anticipated that this document will also be used to assess the safety of legacy (existing) bed systems in various health care settings. Two tools have been developed based on anthropomorphic data so that they are sized and weighted to represent appropriate dimensions of a small resident. These tools will be available for purchase by health care organizations. Based on records of incidents, four primary zones of entrapment have been identified, and the tools will be used to measure the spacing and gaps in these zones.

A third document, again a work group publication, will be issued as Corrective Guidance. This document suggests various alternatives for non-compliant bed systems such as manufacturer retrofits (at a charge), lowering or removing bed rails, “stuffers,” mattress replacements, and accessories. It further suggests an ongoing monitoring program.

The JCAHO alert recommends patient assessment as a primary approach to deal with the issue of entrapment in bed systems, followed by a bed assessment if deemed necessary for a particular patient. That approach is echoed by the American Hospital Association.

In January of 2003, Dr. Dennis O’Leary, President of the Joint Commission issued a “dear colleague” letter on the subject of nosocomial infection. Given the high rate of deaths from nosocomial infections, JCAHO has noticed a disproportionately low number of these reported to them as sentinel events. While voluntary, the letter encourages the reporting of any incident of death or permanent patient injury to one or more patient(s) resulting from nosocomial infection.

The letter was followed by the issuance of a Sentinel Event Alert on January 22, 2003. The risk reduction strategies put forth in this publication all relate to clinical aspects of the problem, with strong support expressed for the CDC hand hygiene guidelines. Interestingly, the EC issues relating to nosocomial infection: airborne contaminants, waterborne pathogens, and construction issues are missing from this document.

As part of the CDC guidelines, alcohol-based hand sanitizers are lauded as an effective tool in reducing nosocomial infections. They save time, are less irritating to skin, and can be made easily accessible for use. Therein is the problem. While these sanitizers are valuable assets, they are approximately 60% alcohol by weight, have a 75°F flashpoint, and are class I flammable liquids. Therefore, according to NFPA 101, the Life Safety Code, they are not permissible for installation in the egress corridors.
To try to resolve this situation, ASHE is sponsoring a study by an independent fire protection engineering firm to do computer modeling of the flammability of these products. They will use multiple scenarios to determine the heat and gas generation when they burn. Until those studies are complete, ASHE recommends that these products not be installed in egress corridors. Instead, with the approval of your AHJ, install them just inside the patient rooms. Up to ten gallons may be stored in clean utility rooms, which are one-hour fire resistance rated. More than ten gallons should be stored in flammable cabinets.

JCAHO supports the ASHE recommendations, but adds that these products should not be installed immediately over a source of heat or ignition, an electrical outlet, or a light switch. They will be evaluating the study data when it is complete, and may make adjustments to their recommendations based on the study outcomes.

Meanwhile, if your organization has installed containers of alcohol-based hand sanitizers in the corridors, you may leave them there pending the study outcomes, but do not proceed with new corridor installations.

**Scoring Patient Safety**

JCAHO will be evaluating patient safety based on compliance with all of the recommendations made for each of the six national patient safety goals. Each recommendation will be scored as “in compliance,” “not in compliance,” or “not applicable.” Adverse scoring on these recommendations will result in the organization receiving a “special type 1 recommendation” in the area of patient safety, with a one month written progress report required to be made to JCAHO.

In 2003, aggregate patient safety compliance data will be posted, and 2004 is the earliest date for the disclosure of organization-specific compliance.
PATIENT SAFETY

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PATIENT SAFETY STANDARDS 7/1/01

- Leadership
- Improving Organization Performance
- Management of Information
- Patient Rights & Organization Ethics
- Patient/Family Education
- Continuum of Care
- Human Resources
PATIENT SAFETY STANDARDS

• Medical error reduction
• Integrated program
• Minimization of individual blame
• Leadership accountability
LEADERSHIP STANDARDS

• Variation measurement
• Assessment of resources
  – Staffing, information, physical, financial
• Integrated, proactive patient safety program
• High priority on patient safety
PERFORMANCE IMPROVEMENT STANDARDS

- Minimize patient risk
- Determine if “new” is “improved”
- Perception of risk
- Staff willingness to report errors
MANAGEMENT OF INFORMATION STANDARDS

• Barriers to effective communication among caregivers
• Patient risk reduction
PATIENT RIGHTS & ORGANIZATIONAL ETHICS STANDARDS

• Informed patients & families
• Patient is a member of the team
• Patient responsibilities
  – Providing information
  – Asking questions
MANAGEMENT OF HUMAN RESOURCES STANDARDS

• Job-related patient safety in orientation
• Inservice & training
• Interdisciplinary, collaborative approach
PATIENT SAFETY & EC

• January 1, 2002
• EC.4.1 (The Safety Officer) “directs the integration of environment of care monitoring and response activities into the organization-wide patient safety program.”
PATIENT SAFETY & EC

• EC.4.2  (Safety issues communicated) “(when appropriate) to relevant components of the organization-wide patient safety program.”

• EC.4.3  (Measurement guidelines reported through) “(when appropriate) relevant components of the organization-wide patient safety program.”
PATIENT SAFETY & EC
CLOSED DOCUMENT REVIEW

• Minor revisions 8/12/02
• EC Note:
  – “Take a look at your hospital-wide patient safety program and decide whether it would be useful to consolidate all information into one comprehensive document.”
  – Not required, but “can be helpful”
PATIENT SAFETY MODELS

• Risk Management
• Performance Improvement
• EC Safety
• Reporting to any of the above
• ??????
PATIENT SAFETY GOALS

• Some selected from recommendations in Sentinel Event Alerts
• Replaces surveying all Sentinel Event Alert recommendations
• Goals reevaluated annually
• Announced by July 1 for following year
  – Implement all recommendations or acceptable alternative
2003 PATIENT SAFETY GOALS

• Improve accuracy of patient identification
  – 2 identifiers (not room number)
  – Active communication

• Improve communication effectiveness among caregivers
  – Verbal/phone order verification
  – Standardize abbreviations, acronyms, etc.
2003 PATIENT SAFETY GOALS

• Improve safety of “high-alert” medications
  – Remove from patient care units
  – Standardize & reduce number of concentrations

• Eliminate wrong-patient, wrong-site, wrong-procedure surgery
  – Pre-op checklist
  – Surgical site marking
2003 PATIENT SAFETY GOALS

• Improve safety of using infusion pumps
  – Free-flow protection for all general-use & PCA pumps

• Improve effectiveness of clinical alarms
  – Regular PM and testing
  – Activated with appropriate settings
  – Sufficiently audible
    • Distance
    • Competing noise
2004 PATIENT SAFETY GOALS
2004 PATIENT SAFETY GOALS
2004 PATIENT SAFETY GOALS
EC-RELATED SENTINEL EVENT ALERTS

- Inpatient Suicide
- Infant Abduction
- Fatal Falls
- IV Infusion Pump Errors
- Medical Gas Mix-ups
- Needlestick and Sharps Injuries
- Ventilator-related Deaths and Injuries
- Bed Rail Entrapment Deaths
- Infection Control Related Sentinel Events
BED RAILS

• Hospital Bed Safety Workgroup
  – Convened May, 1999
  – Center for Devices & Radiological Health
  – ASHE & JCAHO participation

• Prevention of entrapments in “hospital” bed systems
FDA STATISTICS

• 1985 – 2001
  – 439 Entrapment Incidents
  – 271 Deaths
  – 98 Non-Fatal Injury
  – 70 No Injury due to Staff Intervention
  – 85% Deaths and Injuries in population over 65
  – 38% Incidents in Acute Care Hospitals

• Statistics not always conclusive on health care setting or entrapment zone
ANNUAL STATISTICS

• 27.4 Entrapment Incidents
  – 1 entrapment per 3.4 million admissions
• 16.9 Deaths
• 62.4 Non-Fatal Injuries

• Already at “six sigma”
PRODUCTS

• Workgroup Publications
  – Clinical Guidance
  – Corrective Action

• FDA Publications – Federal Register
  – Dimensional Guidance
    • For manufacturers
    • De facto standard
DIMENSIONAL GUIDANCE

• Measurement of entrapment zones
  – Patient safety is an issue
  – Labor costs vs. risk assessment

• JCAHO recommendations
  – Patient assessment
  – If necessary, then bed assessment
COMMON SENSE

• “With a multitude of types of beds, and bed/mattress combinations, in each healthcare facility, testing all beds at one time is neither an effective solution nor proper use of resources.”

- AHA
INFECTION CONTROL

• “Dear Colleague” letter – January 03
  – Disproportionately low numbers of nosocomial infection-related sentinel events in database (also LTC and Home Care in general)
  – Importance and high visibility
  – Encourage reporting
    • Death or permanent patient injury in single patient or groups
INFECTION CONTROL

• Sentinel Event Alert 1/22/03
  – High statistics from CDC
  – 10 Sentinel event reports
RISK REDUCTION STRATEGIES

- Orientation and training; competency
- Equipment cleaning
- Handwashing procedures
- Single-use IV flush vials
- Waterless hand cleaners
- Supervisory expectations
- Critical care privileging & ICU admission criteria
- In-service training
- Tracking systems
IC SENTINEL EVENT ALERT

• Emphasis on CDC hand hygiene guidelines
• Manage nosocomial infections with death or loss of function as sentinel events
• Notably missing:
  – Airborne contaminants
  – Waterborne pathogens
  – Construction issues
ALCOHOL-BASED HAND SANITIZERS

• CDC revised “Guideline for Hand Hygiene in Health Care Settings”
  – October 2002

• Effective tool in reducing hospital-acquired infections
  – Accessibility
  – Time
  – Less irritation
CONCERNS

• Approximately 60% alcohol by weight
• 75°F flashpoint
• Class I flammable liquid
COMPLIANCE ISSUES

- JCAHO Sentinel Event Alert recommends compliance
- NFPA 30, *Flammable and Combustible Liquids Code*
ASHE STUDY

• Independent fire protection engineer
• Computer modeling
  – Heat
  – Hot gas generation
• Multiple scenarios
ASHE RECOMMENDATIONS

• Don’t install in egress corridors
• Install inside patient rooms or suites
  – Consult state AHJ
• Store in clean utility rooms
  – 1 hour fire resistance rated
  – Less than 10 gallons
• Bulk storage in flammable cabinets
• Identify procedure for disposal (aerosols)
JCAHO POSITION

• Corridor mounting prohibited by NFPA 101
  – Section 7.3.2: Projections not more than 3.5 inches and not above 38 inches
  – Section 8.4.3.2: No handling of flammable materials where it would jeopardize egress
  – Section 19.7.5.4: No combustible (flammable) decorations (objects) unless flame retardant

• Prohibited by NFPA 30, Chapter 4
JCAHO RECOMMENDATIONS

• Do not make new installations in egress corridors or nursing stations
• Install just inside patient room
• Do not install above
  – Heat or ignition source
  – Electrical outlet
  – Light switch
• NOTE: Existing corridor installations may remain until study is complete
HOWEVER

• Contribution to acceleration of fire “negligible”
• Under review
• Tests pending
SCORING PATIENT SAFETY

• Evolution
  – Safety related standards
  – Sentinel Event Alerts
  – National Patient Safety Goals
SCORING PATIENT SAFETY

• Compliance with patient safety goals
  – 11 specific recommendations
    • In Compliance
    • Not in Compliance
    • Not Applicable

• “Special Type 1 Recommendation”
  – 1 month written progress report
PATIENT SAFETY
DIRECTIONS

• 2003: Applicable in:
  – Long Term Care
  – Behavioral Health

• Critical application of root cause analysis
• Involvement of Facilities Engineering and Safety in process

• 2003: Aggregate compliance data posted
• 2004: Earliest date for disclosure of organization specific compliance