The Professional, Ethical and Legal Aspects of Patient Safety

Janet Nally Barnes, JD, RN

Center for American Nurses

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Today’s Objectives

- Review Recent developments in the patient safety movement
  - Institute of Medicine Reports
  - Patient Safety and Quality Improvement Act of 2005
- Examine systems approach to error and factors contributing to unsafe practice
- Discuss ethical imperative for disclosure of adverse events
- Examine the concept of “safe harbor” reporting
Institute of Medicine’s To Err is Human report concluded that a sizable number of Americans are harmed as a result of medical errors

- Two studies\(^1\,^2\) found that 2.9 - 3.7 percent of hospital admissions experienced an adverse event, defined as injuries caused by medical management
- The proportion of adverse events attributable to errors (i.e., preventable adverse events) was 58 percent in New York, and 53 percent in Colorado and Utah

\(^1\text{Brennan et al. NEJM, 1991.} \quad ^2\text{Thomas et al. Inquiry 1991}\)
When extrapolated to the over 33.6 million admissions to U.S. hospitals in 1997, the results of these two studies imply that between 44,000 to 98,000 Americans die in hospitals each year as a result of medical errors.

Deaths due to preventable adverse events exceed the deaths attributable to motor vehicle accidents (43,458), breast cancer (42,297) or AIDS (16,516).

Institute Of Medicine, Errors in Health Care, 2000
IOM Follow Up Reports

- 2001 – Crossing the Quality Chasm: A New Healthcare System for the 21st Century
- 2003 – Keeping Patients Safe: Transforming the Work Environment of Nurses
Patient Safety and Quality Improvement Act of 2005

- Act establishes a confidential reporting structure under which health care providers and professionals may voluntarily report information on medical errors to a Patient Safety Organization (PSO)
- PSOs will analyze reported data to develop patient safety improvements
Good News

- Act emanated from 1999 Institute of Medicine Report, To Err is Human
- Health care providers can report and share quality data among participants in a PSO so that errors can be discussed openly within the PSO and health care providers can learn from errors
- Shared data can be federally protected from disclosure
Bad News

- Act is not yet funded
- PSO federal certification process is not yet in place at HHS
- No regulations for PSOs yet at HHS
- Some commentators have said law will have limited utility in fostering open and unfettered system of error reporting
Act is Well Received

- President Bush- “A critical step toward our goal of ensuring top quality patient driven health care for all Americans.”
- AHA- “ A major step toward improving the safety and quality of the care Americans receive.”
- JCAHO- “A breakthrough in the blame and punishment culture that has literally held a death grip on health care.”
Act “will promote cultures of safety across health care settings by establishing federal protections that encourage thorough, candid examination of the causes of health care errors and the development of effective solutions to prevent their recurrence.”

Act will avoid “driving errors underground and slowing progress in improving patient safety.”
Patient Safety and Quality Improvement Act of 2005

Patient Safety Activities

- Efforts to improve patient safety and quality of health care delivery;
- Collection and analysis of patient safety work product;
- Development and dissemination of information to improve patient safety (protocols, best practices);
- Utilization of information to encourage culture of safety and provide feedback to minimize patient risk;
Patient Safety and Quality Improvement Act of 2005

Patient Safety Activities

- Procedures to preserve confidentiality of information (segregation from non-PSO activities);
- Security measures (not yet defined);
- Utilization of qualified staff;
- Activities related to operation of patient safety evaluation system and to provide feedback to participants in patient safety evaluation system.
Who are PSOs Likely to Be?

- Separate legal entities created by large providers.
- Trade associations of smaller providers.
- A component provider-sponsored PSO within a captive insurance program serving multiple providers.
- Unaffiliated or affiliated providers can develop a PSO.
Opportunities for PSOs

- Sharing of quality of care information in large health systems.
- Establishing centralized data bases for trending and analysis purposes so providers can compare themselves with each other.
- Developing uniform protocols and best practices.
Benefits of Participating in a PSO

“Patient Safety Work product” reported to PSO is:

- Not subject to civil, criminal or administrative subpoena or to discovery in any civil, criminal or administrative proceedings with exceptions.
- Protected from Freedom of Information Act requests.
- Cannot be introduced as evidence in any civil, criminal or administrative proceeding or in any professional disciplinary action with exceptions.
Prohibition Against Retaliation

- Act protects individuals who make good faith report to a provider with the intention of having the information reported to a PSO as well as those who make a good faith report directly to a PSO.
- Act provides protection from adverse employment actions against whistleblower.
PSO Law and Accrediting Bodies

- Accrediting body cannot take an accreditation action against a provider based on good faith participation in PSO.
- Accrediting body may not require provider to reveal its communication with a PSO.
Recommended Actions for Providers

- Consider restructuring current peer review and corrective action processes, root cause analyses and state mandated incident/event reporting to utilize the new Act.
- Consider the operational impact of navigating those processes through a PSO evaluation system.
Systems Approach to Error

- Realize that the most important cause of error is faulty systems or design
- Assume that individuals are doing their best
- Analyze the system for defects that allow errors to occur
- Based on human factor principles
  - Many taken from the aviation industry, where risk of fatal crash is 1 in 2 million
Medical Error and Adverse Events

- High error rates occur in highly technical surgical specialties
- In hospitals, errors with serious consequences are most likely in the Intensive Care Unit, Operating Room, and Emergency Room
Medical Error and Adverse Events

– Diagnostic
  » Delay in diagnosis
  » Inappropriate use of tests
  » Failure to act on results of test

– Therapeutic
  » Error in treatment (e.g. operation, drug, etc.)
  » Avoidable delay in treatment

– Preventive
  » Failure to provide prophylactic treatment
  » Inadequate follow-up

– Other
  » Failure of communication
  » System failure

Faulty System Design in Health Care

- Interruptions
- Use of multiple infusion pumps
- Poor work schedules
- Work overload
- “Look-alike” packaging
- “Sound-alike” names
How an accident trajectory forms from a combination of latent and active failures

James Reason’s Swiss cheese model is reprinted with permission from the BMJ Publishing Group. Reason J. Human error: models and management. BMJ. 2000;320:768-70.
If 99% Is Good Enough..

- The IRS would lose over 2 million documents this year
- There would be a major plane crash every 3 days
- There would be 37,000 ATM errors every hour
- 12 babies would be given to the wrong patients each day
- 291 pacemakers would be incorrectly installed this year
Systems Analysis Strategy

- Need top management support
  - Create culture change
  - Resources to identify and make changes

- Multi-disciplinary team with key leader
  - Physicians, pharmacists, and nurses
  - Track events
  - Classify events (severity, preventability) in order to prioritize
  - Analyze events
Process Changes

- Process changes to reduce error
  - Decrease reliance on vigilance and memory
    - Computer order entry
    - Use automatic drug-dose and drug interaction checking
    - Limit shift hours
    - Use checklists
Physician Order Entry

- Decreased the rate of serious medication errors by 55% *(Bates et al. JAMA 1998)*
- Decreased the rate of all medication errors by 81% *(Bates et al. JAMIA 1999)*
- Requires initial investment, but results in quantum improvements in reducing medication errors
- Ultimately improves safety and saves money
“Something Bad Happens”

- Unfortunate Medical Outcome
- Serious Medical Error
- Known Risk or Complication Occurs
- Unknown Risk or Complication Occurs
- “Difficult Patient”
- Negligent Care - who’s liable?
Focus on systems-oriented approaches to reform health care at odds with medical malpractice system

- Medical Malpractice = punitive, individual blame
- Mandatory Error Reporting: Increase in Medical Malpractice litigation?
- Need to reform the legal system?
Driving Forces Behind Lawsuits

- Communication
  - Informed Consent
  - Lack of timely communication of findings
  - Hand-offs (ACGME work hour guidelines)
  - Who is responsible for evolving issues
  - Among team members and attending
  - Inadequate communication with patient esp. after bad outcome
Driving Forces Behind Lawsuits

- Patient Perception/Lack of Caring
  - Minor complications
- Delayed Treatment
  - Anticipation, communication, teamwork
- Intra-professional conflict
- Supervision of resident staff
  - Attending involvement
JCAHO Patient Safety Goals

- Improve the accuracy of patient identification – 2 patient identifiers
- Improve the effectiveness of communication among healthcare workers
- Improve the safety of using medications
- Reduce the risk of healthcare-associated infections
JCAHO Patient Safety Goals

- Eliminate wrong site, wrong patient and wrong procedure events
- Reconcile medications across the continuum of care
- Reduce risk of patient harm from falls
Provider-patient communication key to preventing malpractice suits
  - Most grievances against physicians relate to poor communication or alleged delay in diagnosis

The likelihood of a malpractice suit increases when an adverse event is exacerbated by a poor provider-patient relationship
  - A doctor’s communication skills influence whether he or she will be sued
JCAHO Patient Safety Standards

- Effective 7/1/01
- Disclosure of unanticipated outcomes
- Responsible licensed independent practitioner or designee
- Institutional policy
JCAHO Patient Safety Standards

- Does not require:
  - Disclosing “near misses”
  - An admission of “error”
  - An admission of fault
  - Specific documentation about the disclosure discussion
Ethical Considerations

- **Professional Codes**
  - AMA: “mutually respectful alliance”; “honest in all professional interactions”
  - ANA: “promotes, advocates for and strives to protect the health, safety and rights of the patient”

- **Institutional Values**
  - patient-centered services; providing the highest quality healthcare

- **Reinforcement of Trust**
Barriers to Disclosure and Open Communication

- Psychological
  - Fear of retribution
  - Fear of response
  - Disclosure is unnecessary
  - Outcome not related to the action of disclosure
  - Outcome might have occurred anyway
Barriers to Disclosure and Open Communication

- **Legal**
  - No legal protection for information that is disclosed
  - No legal protection for information in the medical record
  - No clear line for when disclosure is necessary
  - No clear “benefit” to disclose
How Should Disclosure Be Handled?

- In general, obligation to disclose clear mistake that causes significant harm
- Controversial cases:
  - Decision to disclose should not be left to the individual’s judgment
  - Second opinion
  - Involve the institution rather than an informal consultation
How Should Disclosure Be Handled?

- **Timing** - as soon as possible after the event occurs
  - When the patient is physically and emotionally stable

- **Who discloses?**
  - Attending physician
  - Nurse manager
  - Team approach - resident, hospital rep
How Should Disclosure Be Handled?

- What to say?
  - Regret to say that a mistake has been made
  - Describe the decisions made
  - Describe the course of events, using non-technical language
  - Express personal regret and apologize
6 Step Process for Disclosure

- Set the stage
- Determine the extent of the patient’s knowledge
- Finding out how much the patient wants to know
- Share the information
- Respond to the patient’s feelings and reactions
- Plan and follow through
What Matters Most to Patients and Families

- Seeking prompt help
- Just being there – do not abandon the patient
- Explaining what happened in an objective and narrative way
- “I’m sorry that things did not go as well as we had hoped” (as an expression of empathy)
What Matters Most to Patients and Families

- Showing comforting support
- Suggesting a second opinion, if appropriate
- Because of the event, medical care will be improved in the future
Poor Detection of Adverse Events

- Most hospitals depend upon spontaneous reporting
- Spontaneous reporting reveals very few events
  - Key reason why hospitals underestimate the issue
- Outpatient setting usually without any formal reporting systems
Why Is There Under-Reporting?

- **Tedious to report**
  - Providers are busy
  - Not a priority

- **Culture of blame**
  - Medicine and society have tended to fault the person, not the system
  - Health care providers have concern for personal consequences
“The biggest challenge is to get people in hospitals- physicians, pharmacists, nurses, and administrators- to recognize that errors are systems problems and not people problems.”

Lucian Leape, MD
Professor, Harvard School of Public Health
Ways To Improve Reporting

- An unreported error cannot be investigated
- Create a culture of safety, similar to the aviation industry
  - Even highly trained people make mistakes
  - Move beyond blaming and punishing and towards improving the system
- Ethical imperative for Just Culture
  - James Reason’s Unsafe Practices algorithm
Safe Harbor Reporting

Safe Harbor: a provision of a statute or regulation that reduces or eliminates a party’s liability under the law, on the condition that the party performed its actions in good faith. Legislators include safe-harbor provisions to protect legitimate or excusable violations.
Safe Harbor Reporting

Texas Administrative Code Rule §217.20

- Safe Harbor Peer Review for Nurses
  - Allows RN to request peer review if in good faith, the nurse believes that she has been requested to engage in conduct that violates her duty to a patient.
To Summarize . . .

- A culture of patient safety permeates the entire organization
  - Embraced from the top down
  - Senior leadership lead by example
  - Focus is on systems approach to error with redesign of provisions of care to support the care provider
To Summarize . . .

- Identification of errors and unsafe practices is encouraged and rewarded
- Team approach to patient care, breakdown of hierarchy
- Organization embraces transparency, including open and honest discussion of adverse outcomes
- “Blame game” is not tolerated - Just Culture is priority
Contact Hours

- The American Nurses Association is providing the nursing education contact hours for this audio conference seminar series. This program has been approved for 1.2 contact hours. Please visit our web site to complete an evaluation and receive credits.

  http://www.centerforamericannurses.org/ce/