Current Issues in Patient Safety

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An injury or harm to a patient attributed to the process of care rather than underlying physiological conditions
Hazard

- Anything which has the potential to cause harm

Risk

- The likelihood that somebody or something will be harmed by a hazard, multiplied by the severity of the potential harm
Goals of Patient Safety

- Reduce the risk of healthcare associated (caused by treatment) injury to patients
- Remove or minimize hazards which increase risk of healthcare associated injury to patients
Adjust structure and process to eliminate or minimize risks and hazards of health care associated injuries before they have an adverse impact on the outcomes of care.
Human Behavior
(Active failures)

Process of Care
(Organizational Failures)

Structure
(Technical Failures)

Nested Risks and Hazards
The director of AHRQ shall conduct and support research and build private-public partnerships to:

- *identify* the causes of preventable health care errors and patient injury in health care delivery;
- *develop*, demonstrate, and evaluate strategies for reducing error and improving patient safety; and
- *disseminate* such effective strategies throughout the health care industry.
Congressional Allocations for Patient Safety

- FY 01 $50 Million
- FY 02 $55 Million
- FY 03 $55 Million
- FY 04 $79.5 Million
- FY 05 $84 Million (proposed)
An Epidemic

- Medical Error is an epidemic of worldwide proportion
- We should declare war on medical error
  
  John Eisenberg, MD Director, AHRQ (September 11, 2000)

- This war needs to be fought as coalition warfare with allies from other countries and other disciplines outside of medicine
Epidemic Stage One

- Identification of risks and hazards that patients at risk for harm or injury from the process of care
- Raise awareness that patients are at risk for iatrogenic injury and harm
- Build capacity for research and development
Epidemic Stage Two

- Eliminate hazardous conditions, and practices and policies that lead to iatrogenic injury
- Design, test and implement practices and process that eliminate hazards and reduce the risk of iatrogenic injury
- Develop a positive patient safety culture
Epidemic Stage Three

- Maintain vigilance and a constant state of unease
- Maintain a positive safety culture
Funding Program Areas

- Identifying risk and hazards
  - Reporting System Demonstrations (16 projects)
  - Working Conditions (22 projects)
Funding Program Areas

- Building Capacity
  - Centers of excellence in patient safety research (3 centers)
  - Developing centers of excellence in patient safety research (18 projects)
  - Patient Safety Improvement Corps
Funding Program Areas

- **Raising awareness**
  - Dissemination and education (6 grants)
  - User Liaison Program with states
    - Conferences and workshops
- **Identify proven patient safety practices**
  - System best practices (6 projects)
  - Computer application (11 projects)
  - EPC report on evidence based patient safety practices
The challenge grant program is being undertaken as an activity of the Patient Safety Task Force (PSTF).


The NQF “Safe Practices” report

JCAHO has also issued patient safety priorities for improvement.
1. Assess risks and known hazards to patient in the process of care and devise intervention strategies

2. Implement safe practices that show evidence of eliminating or reducing the known risks and hazards associated with the process of care
US/UK Cooperative Secretary to Secretary Initiative

- Joint participation in research agenda building and review
- Joint projects
- Patient Safety Research Methods
  Workshops Iceland 9/02  2002 Maryland 9/03
- Quality and Safety in Health Care
  - Patient safety methodology published 12/03
  - Organizational learning in press
  - Team training and simulation in press
  - Patient safety by design in press
Identifying Risks and Hazards

- A major focus of stage one has been on reporting and identification systems
- Reporting demonstrations
- Patient Safety Indicators from administrative data (HCUP)
- Integration of existing HHS reporting systems
Identify Risks and Hazards Appropriation Language

- AHRQ to support the development of guidance on the collection of uniform data related to patient safety.
  - How providers are to report.
  - How State may collect data
  - How to analyze and disseminate data
Evidence at Stage One
Identifying Risks and Hazards

- Issue of evidence
  - Incidence
  - Prevalence
  - Rates
  - Rare events
AHRQ to support the development of guidance on the collection of uniform data related to patient safety.
- How providers are to report.
- How State may collect data
- How to analyze and disseminate data
IT Tower of Babel
Avoiding the Electronic Graveyard
Need for Standards in Patient Safety

- Based on the charge of the Congress, AHRQ asked the Institute of Medicine to address this issue
The project is to produce a detailed plan to facilitate the development of set standards applicable to the collection, coding and classification of safety information. The plan will apply to both adverse event data and errors data.
Committee Members

- Paul C. Tang, MD, MS (Chair)
- Molly Joel Coye, MD, MPH (Vice-Chair)
- Suzanne Bakken, RN, DNSc
- E. Andrew Balas, MD, PhD
- David W. Bates, MD, MSc
- John R. Clarke, MD
- David Classen, MD, MS
- Simon P. Cohn, MD, MPH
- Carol Cronin, MSW, MS
- Jonathan Seth Einbinder, MD, MPH
- Larry D. Grandia, ME
- W. Ed Hammond, PhD
- Brent James, MD, MStat
- Kevin Johnson, MD, MS
- Jill Rosenthal, MPH
- Tjerk W. van der Schaaf, PhD
Original IOM Errors report: “An adverse event is defined as an injury caused by medical management [commission] rather than by the underlying disease or condition of the patient.”

Patient Safety definition: “An adverse event results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient.”
Definitions

Near Miss

- Near Miss: “An act of commission or omission that could have harm the patient, but did not cause harm as a result of chance, prevention, or mitigation.”
Recommendation 1

Patient Safety Data Systems

- Improved information systems are needed to support efforts to make patient safety a standard of care, in all settings of care

- All healthcare organizations should implement comprehensive patient safety systems that:
  - Provide immediate access to patient information and decision-support tools
  - Capture patient safety information (adverse events and near misses) as a byproduct of care to design safer care delivery systems
Recommendation 2

**National Health Information Infrastructure**

- NHII – a foundation of systems, technology, applications, standards, and policies – required to make patient safety a standard of care
  - Federal government should fund development and maintenance of patient safety data standards
  - Health care providers should invest in electronic health record (EHR) systems with key capabilities to support safe care
Recommendation 3

Federal Leadership for Data Standards

Congress should direct, authorize and fund HHS to lead and maintain a public-private partnership for the promulgation of data standards for patient safety:

- CHI should work with NCVHS to identify data standards for adoption and gaps needed to be filled
- AHRQ and NLM and others:
  - Provide administrative and technical support to CHI/NCVHS
  - Provide financial support and oversight for standards development activities
  - Ensure development of tools to implement data standards
  - Coordinate activities, maintain clearinghouse
- NLM responsible for mapping and distributing terminologies
Recommendation 4

Work Plan for Standards Development, I

- Accelerate development and adoption of patient safety data standards:
  - Clinical data interchange standards
    - Incorporate CHI standards (HHS, VAH, DoD) into contracts and regulatory requirements
    - AHRQ support accelerated completion of:
      - HL7 version 3 (within 2 years)
      - CDA specifications and implementation guides
      - Analysis to address unique health identifier for individuals
Recommendation 4

Clinical terminologies
- AHRQ should support creation of an integrated, non-redundant core terminology set that includes patient safety requirements
  - Begin with 20 IOM priority areas
- NLM should provide mappings from existing terminologies to core terminology set
- NLM should accelerate completion of RxNorm
Knowledge representation

- NLM should support development of standards for evidence-based knowledge representation
- AHRQ, NIH, FDA, and other agencies should support development of generic guideline representation model to facilitate use by EHR decision support tools
Recommendation 5
Comprehensive Patient Safety Programs

- All health care settings should establish comprehensive patient safety programs operated by trained personnel within a culture of safety that encompass:
  - Case finding
  - Analysis
  - System redesign
- Patients and families should be included
## Reporting vs. Prevention

### Paradigm Shift

<table>
<thead>
<tr>
<th>Patient Safety Reporting</th>
<th>Preventive Safety</th>
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<tbody>
<tr>
<td>● Retrospective</td>
<td>● Culture of safety</td>
</tr>
<tr>
<td>● Acts of commission</td>
<td>● Omission and commission</td>
</tr>
<tr>
<td>● Analysis of errors</td>
<td>● Prevent or ameliorate harm</td>
</tr>
<tr>
<td>● Blame-oriented</td>
<td>● Prospective, hazard analysis</td>
</tr>
<tr>
<td>● Target individuals</td>
<td>● Systems (redesign) approach</td>
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<tr>
<td>● Blue moon reporting</td>
<td></td>
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<tr>
<td>● Harm already occurred</td>
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Recommendation 6

**Applied Research Agenda, I**

- **AHRQ lead research agenda with other federal agencies**
  - Knowledge generation
    - Identify high risk patients
    - Expand scientific basis for near miss analysis (e.g., causal continuum, recovery taxonomy, team-based errors and recoveries)
    - Assess value of integrating retrospective analysis techniques with prospective ones
    - Evaluate cost-effectiveness of patient safety reporting systems
    - Study the role of patients in safety programs
Recommendation 6

**Applied Research Agenda, II**

- **Tool Development**
  - Develop point-of-care decision support tools to prevent errors
  - Develop capabilities for early detection of adverse events
  - Develop data-mining techniques, including natural language processing

- **Dissemination**
  - Deploy knowledge and decision support tools to clinicians and patients
Recommendation 7

Patient Safety Reporting Systems, I

- AHRQ should establish a national patient safety database of de-identified patient information
- AHRQ should develop an event taxonomy and common patient safety report format
  - Event taxonomy includes
    - Adverse events and near misses
    - Errors of commission and omission
    - Multi-factorial causes
    - Incorporated into SNOMED CT
Recommendation 7

Patient Safety Reporting Systems, II

- Standardized report format includes
  - Standardized minimum set of data elements
  - Data required to calculate prospective risk assessment
  - Narrative description of event
  - Data required for Eindhoven Classification Model-Medical Version for root cause analysis, expanded to cover near miss events, corrective actions, patient outcome
  - Narrative description of lessons learned
  - Clinical documentation of patient context
- Used by federal integrated reporting system project (e.g., domain, event type, risk assessment, causal analysis)
Patient safety is the prevention of harm due to acts of commission and omission.

Healthcare organizations should implement EHR systems to deliver safe care and advance patient safety.

Congress should authorize and fund HHS to lead and maintain a public-private partnership for the promulgation of data standards for patient safety.

HHS should accelerate the development of standards regarding clinical data exchange, clinical terminologies, and knowledge representation.
Summary

Achieving the Patient Safety Standard, II

- All health care settings should establish comprehensive patient safety programs that encompass case finding, analysis, and system redesign
- AHRQ should lead an applied research agenda focusing on enhancing knowledge, developing tools, and disseminating results to maximize impact on patient safety
- AHRQ should develop a national patient safety database containing standard data elements from standardized reports
Organizing DHHS Reporting Efforts

Secretary Thompson established the Patient Safety Task Force, charging the body with specific responsibilities, including:

“I am charging the Patient Safety Task Force to work thoroughly and expeditiously to improve our data and reporting systems.”

* HHS press release, April 23, 2001
Current Patient Safety Data Flow

1º Collectors

- 1
- 2
- 3

2º Collectors

- FDA
- CDC
- CMS
- State

3º Collectors

- AHRQ
- Researchers
- Policy Makers
- Accreditors

Users

- Hospitals
- Clinics
- Doctors office’s
- Long term care
- Managed Care Organization
The Patient Safety Task Force

Membership

- AHRQ
- FDA
- CDC
- CMS

- This body coordinates:
  - The integration of data collection on medical errors and adverse events
  - Research and analysis efforts

- The group also promotes collaboration on reducing the occurrence of injuries resulting from medical errors
The National Patient Safety Network’s description

is an IT streamlining effort. The goal is to increase patient safety and reduce the severity of medical errors via improving upon existing reporting systems, enabling the medical community to learn from and reduce adverse medical events and medical errors of all types – latent and active, slips and mistakes, near misses and close calls, and preventable and unpreventable adverse events.

This project is made up of three phases. The first phase is a two year effort, with the following goals:

1. Develop a common user interface for four FDA systems, one CDC system and one joint CDC/FDA system
2. Develop a prototype data warehouse
3. Create a standalone user based software application
4. Analyze and report on vocabulary, coding and classification used by systems
5. Provide training for fifty (50) hospitals
Dissemination of Research Results
Moving from Identifying to Design and implementation

- What are we going to do with the data
- Need to design interventions
- Implement safe practices
FY 04 Priorities

- Disseminate the results of current research
- Continue the development of NPSN
- Continue the Patient Safety Improvement Corps
- Fund patient safety Research through RO1 and R03 grants
- Major Health Information Technology (HIT)
  - Three RFA in Patient Safety HIT for $50
EHR a National Priority

- Stay tuned as EHR has become a national priority
- New IT Coordinator/Leader named to coordinate efforts in DHHS
- Expect more action and support for rapid implementation
Thank You

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