Patient Safety: Achieving A New Standard for Care

Institute of Medicine Committee on Data Standards for Patient Safety
November, 2003
Outline

- Committee charge and definitions
- System support of patient safety
- Data standards for patient safety
- Recommendations
- Expanded discussions
  - Creating financing incentives
  - Standards development
  - Patient safety systems and research agenda
Committee Members and Staff

- 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

IOM Staff, Editors
- Philip Aspden
- Janet M. Corrigan
- Julie Wolcott
- Shari M. Erickson
“If we want safer, higher-quality care, we will need to have redesigned systems of care, including the use of information technology to support clinical and administrative processes.”

IOM, Quality Chasm report, 2001
Committee Charge

Patient Safety Data Standards

- Recognizing that patient safety relies on data systems...
- ...and data systems rely on data standards...
  - Produce a detailed plan to facilitate development of data standards applicable to patient safety
  - Identify key standardization issues pertaining to "priority areas" and develop an action plan for addressing them
  - Provide guidance to DHHS on a set of key capabilities for EHR systems
Information Support of Patient Safety

A Brief Re-Examination
Adverse Events in Hospitals
Harvard Medical Practice Study

30,195 randomly selected records from 51 NY hospitals in 1984

Definition of Adverse Events: injuries caused by medical management, and led to prolonged hospitalization or disability at discharge

3.7% of hospitalizations had adverse events

14% fatal

Extrapolation → IOM’s 98,000 annual deaths

58% preventable (=error)

Brennan, NEJM 1991; 324:370
Adverse Events in Hospitals

Harvard Medical Practice Study

- Physician errors
  - Errors of commission (examples)
    - Inappropriate or outmoded therapy
    - Technical surgical error
    - Inappropriate medication
    - Error in dose or use of medications
  - Errors of omission (examples)
    - Failure to take precautions
    - Failure to use indicated tests
    - Avoidable delay in diagnosis
    - Failure to act on results of tests or findings
    - Inadequate follow up of therapy

Leape, NEJM 1991; 324:377
Opportunities to Improve

*Errors of Omissions*

✧ Beta blockers prevent deaths after MI (1981)
  ➢ 34% of Medicare pts received beta blockers (1998)

✧ Hypertension causes strokes, heart failure, deaths (1980s)
  ➢ <25% had BPs < 140/90 (1998)
  ➢ 40% of HTN pts had BPs >160/100 despite >6 visits/yr

✧ 55% overall adherence to recommended care

NEJM 1998; 339: 489-97;1957-63
Definitions

- 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 harmed the patient, but did not cause harm as a result of chance, prevention, or mitigation.”
Current Information Infrastructure

Error-Prone
81% of return visits plagued by missing information

Mean number of DDUs/case = 3.7 (range 1-20)

Coping strategies ineffective

Chart available 95%; finding problem

Computer-Based Clinical Decision Support

_Evidence Shows..._

- 55-83% decrease in hospital nonintercepted serious ADEs using CPOE
- 73% of outpatient drug interaction alerts led to change in prescriptions
- 22-78% increased adherence to preventive health reminders
- EHR users make more appropriate clinical decisions
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.
IOM EHR Project
Add-On Charge

- Provide a common framework for defining, developing, and evaluating an EHR system in four settings of care
  - Inpatient
  - Outpatient
  - Nursing homes
  - Community

- Address care delivery functions, not infrastructure
- 2 month turnaround time
IOM EHR System Letter Report

EHR System Attributes

- Complete patient data
  - Longitudinal collection of electronic health information for and about persons
- Secure, ubiquitous access
  - Immediate electronic access to person and population information by authorized users
- Decision support
  - Access to knowledge and decision-support tools that enhance quality, safety, and efficiency
- Support for efficient processes
Evidence Criteria for Key Capabilities

- Improve **patient safety** (*prevention of harm*)
- Support delivery of **effective patient care**
- Facilitate **management of chronic conditions**
- Improve **efficiency**
- Consider **feasibility** of implementation
  - “Immediate” (2004-5)
  - “Near term” (2006-7)
  - “Longer term” (2008-10)
EHR System
Key Capabilities

- Health information and data
- Results management
- Order entry / order management
- Decision support
- Electronic communication and connectivity
- Patient support
- Reporting and population management
- Administrative processes
Data Standards for Patient Safety

A Systems Approach

✦ Safety should be a system property of patient care information systems

✦ Patient care information systems depend on data standards

✧ Patient safety data standards include:
   ➢ Clinical data standards
   ➢ Patient safety reporting data standards
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

Work Plan for Standards Development, II

- 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
Recommendation 4

Work Plan for Standards Development, III

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

Patient Safety Reporting
- Retrospective
- Acts of commission
- Analysis of errors
- Blame-oriented
- Target individuals
- Blue moon reporting
- Harm already occurred

Preventive Safety
- Culture of safety
- Omission and commission
- Prevent or ameliorate harm
- Prospective, hazard analysis
- Systems (redesign) approach
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)
Summary

Achieving the Patient Safety Standard

- 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
Patient Safety: Achieving a New Standard for Care


- You may read or purchase the report online by following this link: http://www.nap.edu/catalog/10863.html

- For more information on the Data Standards for Patient Safety study, please visit the project’s webpage at http://www.iom.edu/project.asp?id=4629