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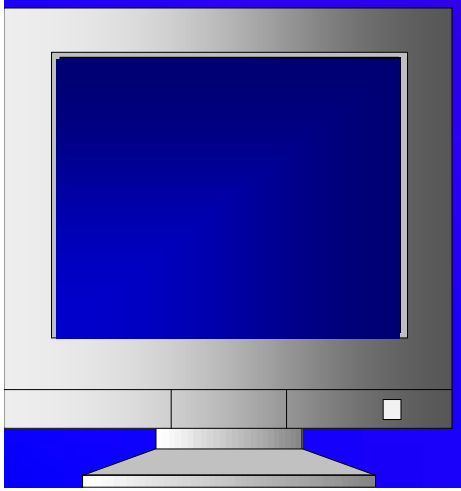
INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

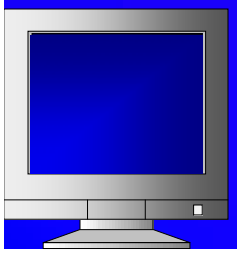
Patient Safety: Achieving A New Standard for Care

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



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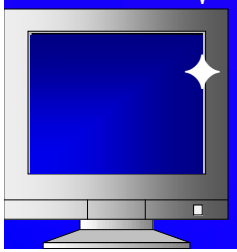
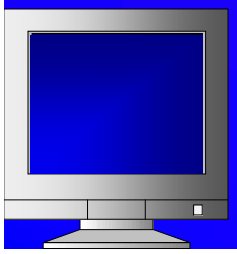


IOM
Quality Chasm Report

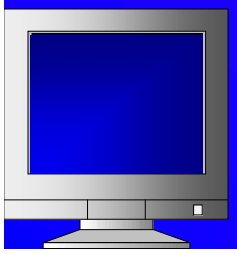
"If we want safer, higher-quality care, we will need to have redesigned systems of care, including the use of information technology to support clinical and administrative processes."

IOM, Quality Chasm report, 2001



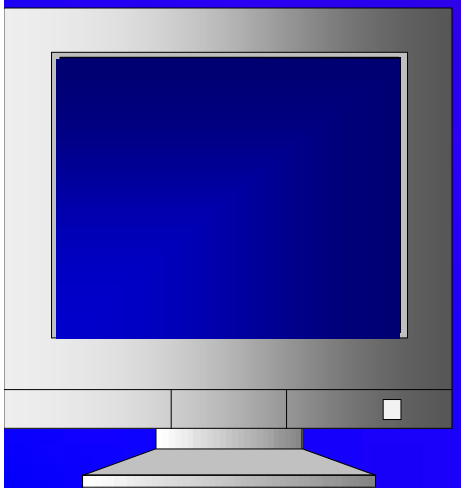
Committee Charge
Patient Safety Data Standards

- 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



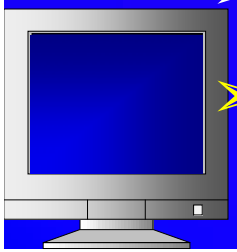
Information Support of Patient Safety

A Brief Re-Examination



Adverse Events in Hospitals
Harvard Medical Practice Study

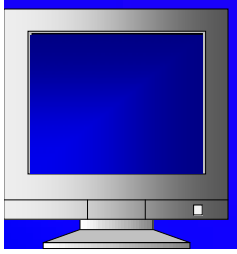
- 30,195 randomly selected records from 51 NY hospitals in 1984
  - Definition of Adverse Events: injuries caused by medical management, and led to prolonged hospitalization or disability at discharge
  - 3.7% of hospitalizations had adverse events
  - 14% fatal
  - Extrapolation → IOM's 98,000 annual deaths
  - 58% preventable (=error)



Brennan,NEJM 1991; 324:370

Adverse Events in Hospitals
Harvard Medical Practice Study

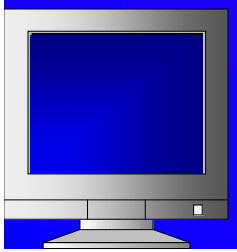
- Physician errors
  - Errors of commission (examples)
    - Inappropriate or outmoded therapy
    - Technical surgical error
    - Inappropriate medication
    - Error in dose or use of medications
  - Errors of omission (examples)
    - Failure to take precautions
    - Failure to use indicated tests
    - 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

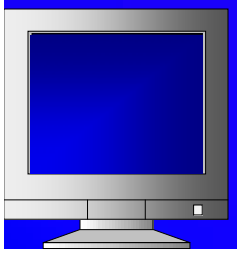
- Beta blockers prevent deaths after MI (1981)
  - 34% of Medicare pts received beta blockers (1998)
- Hypertension causes strokes, heart failure, deaths (1980s)
  - <25% had BPs < 140/90 (1998)
  - 40% of HTN pts had BPs >160/100 despite >6 visits/yr
- 55% overall adherence to recommended care



NEJM 1998; 339: 489-97;1957-63
McGlynn EA, NEJM 2003; 348:2635.

Definitions

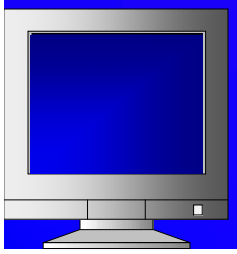
- Original IOM Errors report: “An adverse event is defined as an injury caused by medical management [*commission*] rather than by the underlying disease or condition of the patient.”
- Patient Safety definition: “An adverse event results in unintended harm to the patient by an act of *commission or 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 harm the patient, but did not cause harm as a result of chance, prevention, or mitigation.”



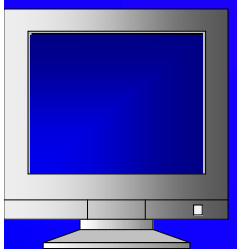
Current Information Infrastructure

Error-Prone

Physicians' Information Needs Study

Problem of Missing Patient Information

- 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

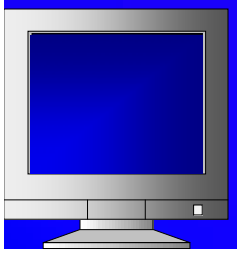


Tang, et al. AMIA, 1994: 575-579

Computer-Based Clinical Decision Support

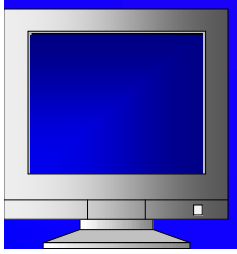
Evidence Shows…

- 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



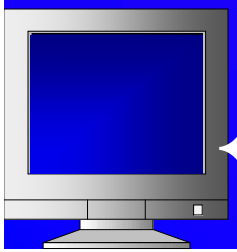
Recommendation 1
Patient Safety Data Systems

- 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

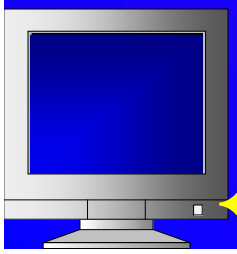
- Provide a common framework for defining, developing, and evaluating an EHR system in four settings of care
  - Inpatient
  - Outpatient
  - Nursing homes
  - Community
- Address care delivery functions, not infrastructure
- 2 month turnaround time



IOM EHR System Letter Report

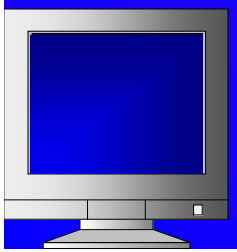
EHR System Attributes

- 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



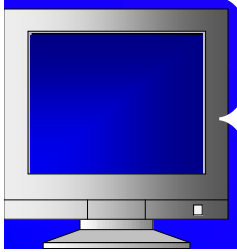
IOM EHR System Letter Report
Evidence Criteria for Key Capabilities

- 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

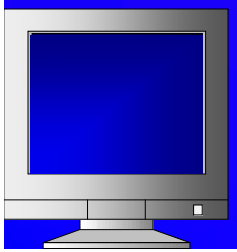
- Health information and data
- Results management
- Order entry / order management
- Decision support
- Electronic communication and connectivity
- Patient support
- Reporting and population management
- Administrative processes



Data Standards for Patient Safety

A Systems Approach

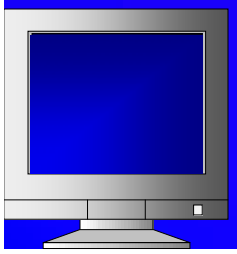
- Safety should be a system property of patient care *information systems*
- Patient care information systems depend on *data standards*
- Patient safety data standards include:
  - Clinical data standards
  - Patient safety reporting data standards



Recommendation 2

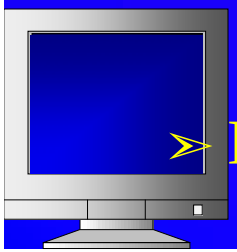
National Health Information Infrastructure

- 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

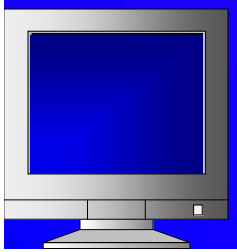
- Congress should direct, authorize and fund HHS to lead and maintain a public-private partnership for the promulgation of data standards for patient safety:
  - CHI should work with NCVHS to identify data standards for adoption and gaps needed to be filled
  - AHRQ and NLM and others:
    - Provide 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

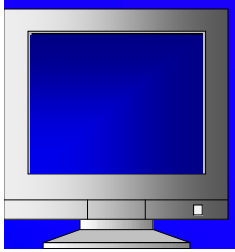
- Accelerate development and adoption of patient safety data standards:
  - Clinical data interchange standards
    - Incorporate CHI standards (HHS, VAH, DoD) into contracts and regulatory requirements
    - AHRQ support accelerated completion of:
      - HL7 version 3 (within 2 years)
      - CDA specifications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



Recommendation 4

Work Plan for Standards Development, II

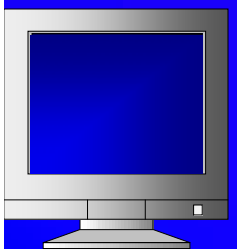
- Clinical terminologies
  - AHRQ should support creation of an integrated, non-redundant core terminology set that includes patient safety requirements
    - Begin with 20 IOM priority areas
  - NLM should provide mappings from existing terminologies to core terminology set
  - NLM should accelerate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



Recommendation 4

Work Plan for Standards Development, III

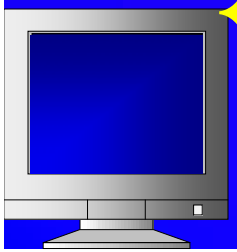
- Knowledge representation
  - NLM should support development of standards for evidence-based knowledge representation
  - AHRQ, NIH, FDA, and other agencies should support development of generic guideline representation model to facilitate use by EHR decision support tools



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



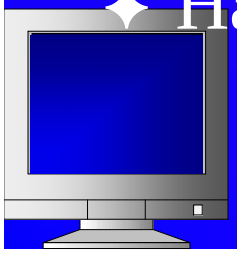
Reporting vs. Prevention
Paradigm Shift

Patient Safety Reporting

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

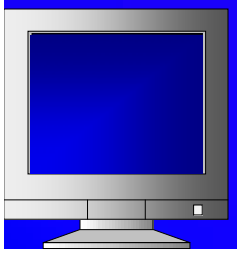
Preventive Safety

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



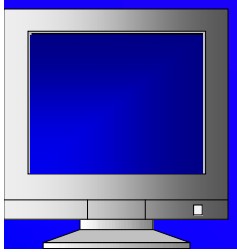
Recommendation 6
Applied Research Agenda, I

- 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

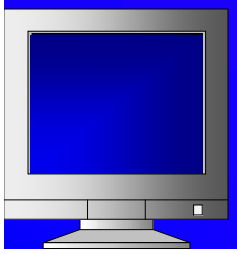
- Tool Development
  - Develop point-of-care decision support tools to prevent errors
  - Develop capabilities for early detection of adverse events
  - Develop data-mining techniques, including natural language processing
- Dissemination
  - Deploy knowledge and decision support tools to clinicians and patients



Recommendation 7

Patient Safety Reporting Systems, I

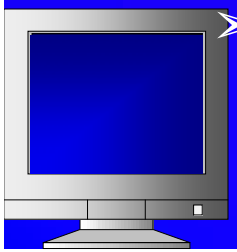
- AHRQ should establish a national patient safety database of de-identified patient information
- AHRQ should develop an event taxonomy and common patient safety report format
  - Event taxonomy includes
    - Adverse events and near misses
    - Errors of commission and omission
    - Multi-factorial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



Recommendation 7

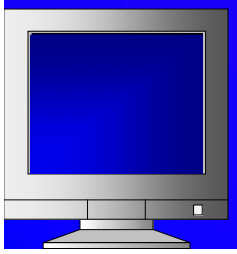
Patient Safety Reporting Systems, II

- 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

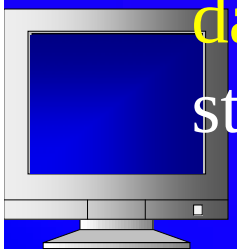
- Patient safety is the prevention of harm due to acts of commission and omission
- Healthcare organizations should implement EHR systems to deliver safe care and advance patient safety
- Congress should authorize and fund HHS to lead and maintain a public-private partnership for the promulgation of 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

- The IOM released the report, *Patient Safety: Achieving a New Standard for Care* on Thursday, November 20, 2003.
- To view the Press Release, go to: http://www4.nationalacademies.org/news.nsf/isbn/0309090776?OpenDocument
- 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