Technology-Induced Errors: A U.S. Perspective

David W. Bates, MD, MSc
Backdrop

– Literature suggests that HIT clearly appears to improve safety overall
  • Many studies which strongly support the benefits
  • However, literature also provides multiple anecdotes that health IT creates new safety risks
– Magnitude of harm and impact of health IT on patient safety is uncertain:
  • Heterogeneous nature of health IT
  • Diverse clinical environments, workflow
  • Limited evidence in the literature
– FDA has authority to regulate HIT in U.S. but has not done so except in limited ways
Examples of Problems Associated with HIT

• Mortality rate increased from 2.8% to 6.3% (OR=3.3) in children transferred in for special care after introduction of a commercial CPOE application ¹

• “Flight simulator” of CPOE across 63 hospital EHRs detected only 53% of medication orders which would have been fatal ²

• Clear problem of providers writing electronic orders on the wrong patient because they don’t realize what record they are in ³

• When even serious safety-related issues with software occur, no central place to report them to, and they do not generally get aggregated at a national level ⁴
Safety Results of CPOE Decision Support Among Hospitals

• 62 hospitals voluntarily participated
• Simulation detection only 53% of orders which would have been fatal
• Detected only 10-82% of orders which would have caused serious ADEs
• Almost no relationship with vendor

Metzger et al, Health Affairs 2010
Mixed Results In The Safety Performance Of Computerized Physician Order Entry, Health Affairs, Vol 29, Issue 4, 655-663
Example of Adverse Effect of Regulation

In closed loop systems, one application may drive another process, for example oxygen monitoring might tell an intravenous device to stop delivering narcotics if hypoxemia is detected. Traditionally there has been a very high regulatory bar for any closed loop approaches at the FDA, which may be preventing some beneficial closed loop approaches from being implemented.

Reference: Standard ASTM F2761-09, Annex B example B2.1

References a death related to this intravenous narcotic use case, and a potentially safer system as described above that could be enabled by integrating sensors (e.g. pulse oximetry, respiratory CO2 monitoring) and infusion technology with decision support to close the loop. The limitations of the current state and potential safety benefits of the proposed state are represented in animations at this site: http://www.mdpnp.org/MD_PnP_Program___Clinical_S.html
FDASIA Charge

The Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 calls for the HHS Secretary to “post a report—within 18 months (or by January 2014) —that contains a proposed strategy and recommendations on a risk-based regulatory framework pertaining to health IT, including mobile applications, that promotes innovation, protects patient safety, and avoids regulatory duplication”.

FDASIA Committee did not have to develop the framework itself—that will be done by FDA, ONC, and FCC—but has been asked to make recommendations which will guide the development of the framework
Overall FDASIA Recommendations (I)

• Definition of what is included in HIT should be broad but have also described exclusions

• Patient-safety risk framework and examples should be used as building blocks to develop a more robust and transparent framework

• The agencies should address the deficiencies, ambiguities and duplication the FDASIA group has identified

• New frameworks with some of the characteristics aimed at stimulating innovation may be helpful
Overall FDASIA Recommendations (II)

• Substantial additional regulation of HIT beyond what is currently in place is not needed and would not be helpful (should be Class 0), except for:
  ✓ Medical device data systems (MDDS)
  ✓ Medical device accessories
  ✓ Certain forms of high risk clinical decision support
  ✓ Higher risk software use cases
    • For the regulated software, it will be important for the FDA to improve the regulatory system
Overall Recommendations (III)

• In addition, we believe that as recommended by the IOM Committee:
  – Vendors should be required to list products which are considered to represent at least some risk and a non-burdensome approach should be developed for this
  – Better post-market surveillance of HIT is needed
    • Standard formatting of involved reports
    • Also post-implementation testing
    • Approaches to allow aggregation of safety issues at the national level, including federal support to enable this
  – FDA and other agencies need to take steps to strongly discourage vendors from engaging in practices that discourage or limit the free flow of safety-related information
Conclusions (I)

• Overall, clear that HIT can introduce new problems, though overall net appears beneficial
  – Critical to track new problems, eliminate them
  – Many organizations don’t adequately do on own
  – Best practices available to do this
  – Post-implementation testing useful

• Need national policies to enable detection and elimination of such problems
  – FDASIA approach represents one potential model
Conclusions (II): Recommendations for the International Community

• Much of HIT now being used across borders
• Will be extremely helpful to begin to aggregate data
  – Should help inform prevention efforts
• Support for this e.g. in EU should be a priority
• While many similarities, HIT-related errors are different than those related to devices, pharmaceuticals
  – Will require new regulatory approaches
Finnish Perspectives: From Technology-induced Errors to Health Information Technology Safety

Kaija Saranto, Professor, PhD, RN
Department of Health and Social Management
Content

• National reporting systems for adverse events in Finland
• Challenges in reporting AEs
• Supporting initiatives for patient research in Finland
Some of the main patient safety actors in Finland
(Modified from: Doupi 2009 National Reporting Systems for Patient Safety Incidents A review of the situation in Europe)
Examples of data sources used for patient safety research

Research data from previous studies
- Primary literature
- Secondary literature

Routine surveillance data
- Vital statistics
- Reporting systems
- Administrative data
- Registries

Quality assurance and risk management data
- Audit
- Investigations and reports when things go wrong
- Credentialing and accreditation activities
- Risk registers

HaiPro - incident reporting system

- Used in Finland since 2007
- The electronic system is used all over in Finland first in hospital settings now also in primary care
- The HaiPro system enables anonymity, confidentiality and freedom from sanctions
- The report is mostly structured, narrative text is used when describing the contributing factors
- The present system is only for professionals' use
- Patients are using web-based platforms and document AEs with narrative text
The content of the incident report

• Background information:
  – WHO: Profession of the reporter,
  – WHEN: Time and place of occurrence
  – WHAT: Incident type

• Specific incident descriptions:
  – Information of the incident,
  – Consequences for the patient and organization, and
  – Reviewer’s comprehension how this kind of incident could be prevented
Incident type

- Not known
- Medication or iv related
- Information management
- Diagnoses related
- Surgical procedures related
- Invasive procedures related
- Caring related
- Laboratory, imaging related
- Devices related
- Aseptics / hygiene
- Injury
- Violence
- Oncology
- other
Communication and information management

![Bar Chart]

- Not known
- Diagnostic procedure
- Providing care
- Documentation
- Verbal communication
- Not selected

UNIVERSITY OF EASTERN FINLAND
Technology-induced adverse events – hard to prove?

- Prevalence hard to tell due to unstable reporting systems at hospitals
- Reports of problems concerning version changes of information systems, system usage interruptions, and prolonged response time were included in the category of communication and information management
- Based on preliminary studies it seems that technology-induced AEs are connected to knowledge and skills how to use information systems, interoperability and usability questions eg. work and information processes are not linked together (data lost, not found)
- Privacy concerns and data protection failures found out in the analysis of events
Examples of patient privacy concerns

<table>
<thead>
<tr>
<th>Item</th>
<th>n=53</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient information is delivered from organization to external persons</td>
<td>24</td>
<td>46</td>
</tr>
<tr>
<td>Patient data is transferred to wrong unit inside hospital</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>Patient data is accessible to personal not responsible for care</td>
<td>12</td>
<td>23</td>
</tr>
<tr>
<td>Documents missing</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>Patient data is documented in irrelevant situations</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Other</td>
<td>6</td>
<td>11</td>
</tr>
</tbody>
</table>
Examples of data protection failures

<table>
<thead>
<tr>
<th>Item</th>
<th>n=94</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong patient</td>
<td>49</td>
<td>52</td>
</tr>
<tr>
<td>Data is lost</td>
<td>41</td>
<td>44</td>
</tr>
<tr>
<td>User id &amp; password problems</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Wrong procedure</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>
Future plans: From studies to large scale research

National Institute of Health and Welfare in Finland has established a multidisciplinary group
- to form an overall picture about the state of art of patient safety research in Finland
- to compose recommendations about research priorities
- to survey resources for funding research
- to propose possibilities for support and service for young researchers
- to share information about patient safety research and
- to find out methods how to access the national AE data repository.

Center for Care Efficiency and Patient Safety at the University of Eastern Finland.
Patient safety research as a sub-discipline of quality research

References


• WHO 2012. [http.www.who.org](http://www.who.org)
Thank you!

kaija.saranto@uef.fi
Japanese Perspectives: From Technology-induced Errors to Health Information Technology Safety

Hiroshi Takeda, MD, PhD
Dean & Professor
Graduate School of Healthcare Sciences
Master Course for Healthcare Safety Management
A Wake-up Call for Patient Safety in Japan

- January 11, 1999
- Wrong patients resulted in wrong surgeries
  - Lung surgery ⇔ Cardiac surgery
- Criminal convictions for nurses, surgeons and an anesthesiologist

2013/8/21

H. TAKEDA
Patient Safety Management Framework in Japan

- **Regulations**
  - E.g., Policies and laws

- **External evaluations**
  - E.g., Accreditation
  - Peer review

- **Industrial patient safety initiatives**

- **Hospital patient safety initiatives**

2013/8/21
H. TAKEDA
Approach for Patient Safety in Japan

- Safety Culture
- Human Factors
- Non-technical Skill
- Technical Skill

1999 → Today

1st Graduate School for Patient Safety

Intra-institutional ⇒ Transitional
in the Year 2025: Eight Perspectives.

② design of the physical environment
③ health information technology
④ patient-centeredness
⑤ device safety
⑥ simulation
⑦ transition of care
⑧ complex system

Agency for Healthcare Research and Quality; 2008 Aug.
http://www.ncbi.nlm.nih.gov/books/NBK43618/
thinking to designing and implementing evidence-based changes that are specifically targeted toward reducing unintended harm in health care.
Safety-I and Safety-II: A new perspective on patient safety

Why only look at what goes wrong?

Safety = Reduced number of adverse events. *Safety-I*

Focus is on what goes wrong. Look for the underlying failures and malfunctions. Try to eliminate causes and improve barriers.

Safety and core business compete for resources. Learning only uses a fraction of the data available.

Safety = Ability to succeed under varying conditions. *Safety-II*

Focus is on what goes right. Understand why normal performance succeed. Use that to perform better and safer.

Safety and core business help each other. Learning uses most of the data available.

10^{-4} = 1 failure in 10,000 events

1 - 10^{-4} = 9,999 non-failures in 10,000 events
Designing for resilience

Responding: Knowing what to do, being capable of doing it.

Anticipating: Finding out and knowing what to expect

Learning: Knowing what has happened

Monitoring: Knowing what to look for

An increased availability and reliability of functioning on all levels will both improve safety and enhance control, hence the ability to predict, plan, and produce.
Relationship between Safety-I and Safety-II

Safety-II Target

Safety-I Target

AE

SAE

Hiroshi Takeda, 2013
Hospital Information System & Trouble Reporting System in Japan

1. system design
2. Inter-operability
3. Renewal
4. Master file
5. System down
6. Data acquisition
7. Assignment
8. Output/display
9. Operation
10. Double registration (patient)
11. Others
System trouble reports (2007)

![Bar chart showing system trouble reports by category and type (hospital, vendor) for the year 2007.](chart.png)

2013/8/21 H. TAKEDA
Ian D Coombes, Danielle A Stowasser, Judith A Coombes and Charles Mitchell
Adapted from Reason’s model of accident causation
System-oriented Quality Management with ICT

Current Healthcare

High quality

① Measure what we can
② Decrease variance
③ Shift the mean we can

High quality

Low quality

EBM
DPC/DRG
Clinical Path
EPR/EHR
Dataware House
Data Mining

AE

2013/8/21
H. TAKEDA
Registration Date after discharge (Semi logarithm)

Survey period: 2010.11 to 12
Discharge patient number: 2536

100% within 2 weeks!
Distribution of registration date for operation-related documents (detailed)

Survey period: Nov. to Dec., 2010
Samples collected: 1305

- Anesthetic Record
- Operation Check-list
- Nursing Record
- Operation Site Confirmation

Distribu+on of registra+on date for opera+on-related documents (detailed)
Department-specific distribution of registration date for clinical records of surgical operations

Survey period: Nov. to Dec., 2010
Samples collected: 1305

Department A

Department B

Medical

Accident
Working Hypothesis II: Optimal Control Model for Patient Safety

Multiple Inter-Professional Work Model

SR; sensor, AN; Afferent network, CNS; Central Nervous System, EN; Efferent Network, EF; Effecter
System: “A collection of elements interacting to achieve a common aim.”

Is it a real resilient function?

Coordination and Integration
Thank you for your attention!

Contact; hirotakeda@aol.com

2013/8/21
H. TAKEDA
Transitions of Care
Robert Wears

• standardized templates, written turnover documents, and fads like SBAR [Situation-Background-Assessment-Recommendation]) fortunately died.

• To develop those new ways of thinking and better understanding, three fundamental changes must occur: demedicalization, increased understanding of technical work, and changed views of transitions.
Complex Systems
Paul Schyve

• These same characteristics can also increase the risk of harm in health care. First, the adaptive nature of complex systems can lead to undesirable changes; self-adjustments are not necessarily guided by participants’ values and priorities. Second, the disconnect between the magnitudes of a cause and its effect can result in a minor “tweak” in one part of a system and lead to a catastrophe elsewhere. Third, failure to appreciate the complexity, contingency, and uncertainty in complex systems can lead to ineffective redesigns with unintended consequences.

• Clinicians and administrators must apply systems thinking to designing and implementing evidence-based changes that are specifically targeted toward reducing unintended harm in health care.
医療安全概念の変遷

医療リスクマネージメント

医療セーフティマネージメント

医療安全文化

テクニカルスキル

ノンテクニカルスキル

生活者・患者参加

2013/8/21
武田 裕
TAKEDA
ヘルスケア・デリバリシステムの概念
患者安全に対する新たな視点

エリック・ホルナゲル（2011）

• Safety-1:
  - これまでは「失敗に学ぶ」→事故予防

• Safety-2:
  - 日常活動を望ましい結果に到達させる
  - レジリエンス（困難な状況にもかかわらず、しなやかに適応して生き延びる力、強靭力）工学
安全のためのシステム設計
（HSE evolution）

1. Fragmented
（個別の活動、バラバラで統制がとれていない）

2. Systematic
（統合されている、標準化された手順、マニュアル）

3. Behaviourinal
（習慣づけられている）
ヘルスケアのプロセス

患者さん中心の制御プロセス

インシデント・アクシデントは複合要因

患者 → 情報収集 → 統合・意志決定 → 記録 → 行為 → 患者
患者安全に対する新たな視点

エリック・ホルナゲル（2011）

• Safety-1：
  － これまでは「失敗に学ぶ」→事故予防

• Safety-2：
  － 日常活動を望ましい結果に到達させる
  － レジリエンス（困難な状況にもかかわらず、しなやかに適応して生き延びる力、強靭力）工学
  － 先行的アプローチ
Safety-IとSafety-IIの関係

Erik Hollnagel, 2013
武田 改変

Safety-IIの対象

Safety-Iの対象

AE SAE