Patient safety governance for national and cross-border safety initiatives for health IT

Farah Magrabi, Dean Sittig, Maureen Baker, Jan Talmon, Enrico Coiera

The University of New South Wales, Sydney, Australia
University of Texas
Health & Social Care Information Centre, England
Maastricht University, The Netherlands
Panelists

1. Enrico Coiera: Chair

2. Farah Magrabi: Overview + Australia


4. Jan Talmon: European Union

5. Dean F. Sittig: USA & Canada
Alongside benefits IT can pose risks to patient safety

- Health Information Technology is computer hardware and software used by health professionals and consumers to support care.

- Safety problems are a “side effect” or “unintended consequence” of IT.
  

- Risks to patient safety arise from poor design, build, implementation and use.
  
  (US IOM 2011 report, Coiera et al. 2012)

- Evidence about IT-related clinical errors is emerging
  - 42% of 1164 prescribing errors were system-related (78/100 admissions).
  
  (Westbrook et al. 2013)
Evidence about patient harm is mounting

<table>
<thead>
<tr>
<th>Source</th>
<th>Australia</th>
<th>England</th>
<th>Wales</th>
<th>USA</th>
<th>USA</th>
<th>USA</th>
<th>Pennsylvania</th>
</tr>
</thead>
<tbody>
<tr>
<td># of incidents</td>
<td>99</td>
<td>850</td>
<td>149</td>
<td>436</td>
<td>120</td>
<td>171</td>
<td>3,099</td>
</tr>
<tr>
<td>Patient harm incidents</td>
<td>12</td>
<td>22</td>
<td>50</td>
<td>46</td>
<td>n/a</td>
<td>25</td>
<td>16</td>
</tr>
<tr>
<td>Time frame</td>
<td>24 months</td>
<td>6 years</td>
<td>28 months</td>
<td>30 months</td>
<td>18 years</td>
<td>3 months</td>
<td>8 years</td>
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</tbody>
</table>

Magrabi et al. JAMIA 2010; JAMIA 2012; under review
Myers et al. 2011, Edwards et al. ACI 2012;
Penn. Patient safety authority 2012; ECRI 2012
Large-scale effects: IT incidents can affect multiple patients

Multiple records, single site
A patient administration system automatically cancelled pathology orders on patients discharged from the emergency department. In total 36,080 orders that related to 5,100 encounters for over 4,665 patients were cancelled.

Multiple records, data storage
2500 radiology images used for diagnostic and pre-operative purposes could not be accessed due to a database failure.

Many practices, migration of historical records
Patient records were wrongly merged when migrated between practices; 2700 practices required follow up and 27 had 900 transactions that needed manual checking.
Internationally IT safety is being addressed within national programs

- National Health Service (NHS) Connecting for Health (CfH) program in England.

- American Reinvestment and Recovery Act (ARRA) “meaningful use” program for adoption and use of EHRs.

- Australian **personally controlled EHR** launched in July 2012.
Objective

To review current national and cross-border initiatives to address IT safety.

Comparative review
International Journal of Medical Informatics May 2013

Magrabi, Aarts, Nohr, Baker, Harrison, Pelayo, Talmon, Sittig, & Coiera,
Methods

• **Safety initiative:** Publicly promulgated set of advisories, recommendations, guidelines, or standards addressing safe system:
  – design, build, implementation or use.

• Searched websites of agencies
  – England
  – Denmark
  – The Netherlands
  – USA
  – Canada
  – Australia
Results

Types of safety initiatives

1. **Standardisation**
   - Guidance
   - Standard
   - Regulation mandated standard

2. **Oversight**
   - Certification
   - Regulation
   - Incident monitoring
## Results

### 27 initiatives by type

<table>
<thead>
<tr>
<th>Standardisation</th>
<th>Oversight</th>
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</thead>
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<tr>
<td>Guidance</td>
<td>Certification</td>
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<tr>
<td>Standard</td>
<td>Regulation</td>
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<td>Regulation mandated standard</td>
<td>Incident monitoring</td>
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<table>
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<th>Region</th>
<th>Standardisation</th>
<th>Oversight</th>
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<tr>
<td>Canada</td>
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<tr>
<td>Australia</td>
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</table>
Current initiatives address safety of software with limited oversight

- Guidelines
- Standards
- Certification

Diagnosis & treatment software
(are regulated in some nations as medical devices)

IT

Hardware: devices & networks

Software

Medical devices
Main findings

• There are significant gaps in IT safety initiatives.

• **Current measures are largely focused on software.**

• Safety of the most common IT systems is not being explicitly addressed in most nations (such as EHRs and CPOE without decision support).

• Greater standardisation and oversight is required throughout the lifecycle of **all** IT including hardware.
IT Safety Initiatives in Australia
• Standards, specifications: interoperability, security, privacy
• Safety management program
• Compliance & Conformance Authority
IT incident monitoring in general practice (ambulatory care/family physicians)
Welcome to the website for the TechWatch Study

We are tracking computer problems that affect the safety of Australian general practice

The TechWatch Study is the world’s first study of critical incidents specifically involving information technology and patient safety in general practice. Information technology has many benefits for clinical medicine. But problems with computer use can introduce new errors that affect the safety and quality of clinical care and may risk patient harm.

Over 4000 general practitioners from across Australia have been invited to join the TechWatch Study and help identify and track safety and quality issues arising from the use of computers in general practice.

Information collected though the TechWatch Study will be used by researchers to gain a better understanding of how to improve the safety of using computers in clinical practice. Our findings will guide the safe design and use of information technology in general practice.

Join now to report a computer problem or call us on 1800 892 824 (1800 TWATCH)!
Answer six questions to describe an IT incident

1. Describe the incident when you were using your computer and its peripherals (e.g. printer).

2. What was the result? Describe actual & potential consequences.

3. Indicate the nature of actual and potential consequences.

4. What did you do to fix the problem?

5. Why did this incident happen? Describe any contributing factors.

6. How could the incident have been prevented?
Track results

Results

Incidents reported to TechWatch

Consequences of incidents reported to TechWatch

- Harm to a patient
- Near miss
- Incident with noticeable consequence but no harm
- Incident with no noticeable consequence
- Data loss
- Other

Percentage %

2 9 16 23 30
Acknowledgements

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TechWatch research team
Prof. Michael Kidd
Prof. Siaw-Teng Liaw
Prof. Enrico Coiera
Ms. Diana Arachi
EHealth Safety – the NHS approach

MedInfo 2013 – 21st August 2013

Presented by
Dr Maureen Baker CBE DM FRCGP
“Humans are fallible and errors are inevitable”.

“Systems approach takes holistic view of causes of failure”.

“Cannot change the human condition but can change conditions in which people work and minimise opportunities for error”.

Human Error (Reason, 1990)
The NHS in England

• Universal healthcare, free at the point of delivery
• Population of 56 million
• Around 1 million contacts daily (900,000 in primary care, 100,000 in hospitals)
• 1 Billion prescriptions *per annum* from general practice
• 1.35 million NHS staff
NHS IT - What can go wrong?

- **Patient Identification**
  - wrong notes, wrong results, wrong procedures.

- **Data Migration**
  - re-start discontinued drugs, incorrect preservation of meaning.

- **Data Mapping**
  - mapped to non-identical preparation, e.g. long acting or slow release.

- **Data Corruption**
  - over-writing of demographic info on NHS Spine.
Safety Critical Industries with Safety Approach

- Aviation
- Railways
- Oil and Gas
- Construction
- Nuclear
- Military
Safety Standards

• Designed to ensure the safety of products, activities or processes.

• Standards are generally international and have input from suppliers and regulators.

• Standards may be advisory or compulsory (higher safety criticality, more likely to be compulsory).
First NHS Standards for Clinical Risk Management

In 2009, two standards were issued by the NHS Information Standards Board:

• DSCN 14/2009 (Manufacture)*
  o Set clinical risk management requirements for suppliers of health software.
  o Defined a simple framework of documentation (evidence) to be produced by suppliers.

• DSCN 18/2009 (Deployment and Use)**
  o Specified a framework within which patient safety hazards associated with the deployment and implementation of new health software can be managed.
  o Required suppliers to provide suitable information to support Health Organisations analysis.

* now known as Information Standards Board for Health and Social Care ISB 0129
**now known as Information Standards Board for Health and Social Care ISB 0160
Structure of the Standards

- Specification: Slimmer specification stating simple requirements
- Implementation Guidance: Separate implementation guidance but text linked to specific requirements
- Additional guidance and best practice: Additional guidance for specific technologies or products
Key Elements of the Safety Standards

- Hazard identification
- Clinical risk analysis
- Clinical risk evaluation
- Clinical risk control

Risk Management Activities

- Clinical Risk Management Plan
- Hazard Log
- Clinical Safety Case Report
- Safety Incident Management Log

Documentation
NHS IT safety incident management system

- Incidents related to health IT reported and logged
- Assessed and managed by Clinical Safety Group [clinicians and safety engineers]
- Aim to ‘make safe’ [remove potential for harm] within 24 hours
- **1100** incidents reported since 2005
- **97%** made safe within 24 hours
Our Conclusions

- Healthcare is a safety critical industry.
- Health IT Systems don’t deliver care, but are used by clinicians in the delivery of care.
- Good safety practice requires proactive work - systems as safe as design and forethought will allow.
- Standards set an expectation and provide a framework - ultimately provide consistency and benchmark.
- Logging and management of safety incidents supports learning and development
Patient Safety and The EU medical device directive

Jan Talmon

HI-WAY – Health Informatics Advisor
Patient Safety

- In the EU there are no explicit directives that address patient safety in relation to health information technology
- However, the Medical Device Directive considers software a medical device
What is a medical device

- Any instrument, apparatus, appliance, *software*, material or other article, whether used alone or in combination, including software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, **intended by the manufacturer** to be used for human beings for the purpose of
  - Diagnosis, prevention, monitoring, treatment or alleviation of disease
  - Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
  - Investigation, replacement or modification of the anatomy or of a physiological process
Relevant concepts

- Essential requirements (Annex I)
- The classification of devices into several categories. (Annex IX)
- Conformity assessment procedures (several annexes dependent on the classification of the device)
  - Exemption for custom-made devices and those intended for clinical investigations, but ... 
- Clinical evaluation
Essential requirements I

- Devices should **be designed and manufactured** such that they do not compromise the clinical condition or **safety** of patients, **users** or other persons.
  - Risk analysis to demonstrate that risks are outweighed by the benefits
- **Reducing the risk of use error due to ergonomic features**
- **Education and training of intended users**
Essential requirements II

- Devices must be designed according to state of the art safety principles
  - Eliminate or reduce risk as far as possible
  - Take adequate protection measures where risks remains
  - Inform users on the residual risks

- Conformity with the essential requirements must include a clinical evaluation (Annex X)
Essential requirements III

- For devices which incorporate software or which are medical software in themselves, the software must be **validated** according to the state of the art taking into account the **principles of development lifecycle, risk management, validation and verification.**
Clinical evaluation and Clinical Investigation

- Evaluation:
  - Critical evaluation of the scientific literature related to safety, performance, design characteristics and intended purpose of the device or
  - Critical evaluation of all clinical investigations or
  - Critical evaluation of the combined clinical data provided in the two studies mentioned above

- It suffices to demonstrate equivalence with existing devices to fulfill the requirement for clinical evaluation through the scientific literature
Clinical investigations
Annex X part 2

- Objectives
  - To verify the performance of the device is in conformance with what is claimed by the manufacturer
  - To determine any undesirable side-effects

- Ethical considerations
  - Should be carried out in accordance with the Helsinki Declaration
How to decide what is a medical device

- MEDDEV-2.1.6 gives guidance
  - Software that performs storage, archiving, lossless compression, communication or simple search is NOT a Medical Device
  - Software should be directed to the benefit of individual patients
  - Must address the purposes as listed in the definition
### Examples of what is and isn’t a MD

<table>
<thead>
<tr>
<th>Hospital Information System</th>
<th>No</th>
</tr>
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<tbody>
<tr>
<td>Decision Support System</td>
<td>Yes</td>
</tr>
<tr>
<td>Diagnostic Image viewer</td>
<td>Yes</td>
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<tr>
<td>Medication module</td>
<td>Yes</td>
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<tr>
<td>PDMS</td>
<td>No</td>
</tr>
<tr>
<td>Pre hospital ECG</td>
<td>No</td>
</tr>
<tr>
<td>RIS and LIS</td>
<td>No, but</td>
</tr>
<tr>
<td>Telemedicine (alarms)</td>
<td>Yes</td>
</tr>
<tr>
<td>Telesurgery</td>
<td>Yes</td>
</tr>
<tr>
<td>Monitoring medical performance</td>
<td>Yes</td>
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</tbody>
</table>
From a broader perspective

- Not all countries are willing to consider software a medical device.
- The MDD promotes cross-border trade, patient safety is an aspect that products should address to get CE marking.
- Patient safety is not in the interests of the notified bodies.
- Patient safety in relation to HIT is poorly supported by the MDD.
HIT Safety Initiatives in the USA and Canada

Dean F. Sittig, PhD
Federal Food, Drug, and Cosmetic Act (FD&C Act, 1976) – provides it with authority to regulate EHRs...to date they have not exercised this authority.

2011 - Draft Guidance for Industry and FDA Staff - Mobile Medical Applications
• Health care accrediting organizations should adopt criteria relating to EHR safety.
• ONC should work with the private and public sectors to make comparative user experiences across vendors publicly available.
• Secretary of HHS should establish a mechanism for both vendors and users to report health IT–related deaths, serious injuries, or unsafe conditions.
• Congress establish an independent federal entity for investigating patient safety deaths, serious injuries, or potentially unsafe conditions associated with health IT

Secretary of HHS: publish an action and surveillance plan working with the private sector to assess the impact of health IT on patient safety and minimizing the risk of its implementation and use.
3 phase framework for HIT-specific patient safety goals

1. Make health IT safer

2. Make use of health IT safer

3. Use health IT to monitor and improve
MAUDE - Manufacturer and User Facility Device Experience

- MAUDE data contains voluntary reports since June 1993 of adverse events involving medical devices.
- On-line search allows you to search for information on medical devices which may have malfunctioned or caused a death or serious injury.
- MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices.

Final Report
Health IT Hazard Manager Beta-Test

Prepared for:
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850
www.ahrq.gov
Health Information Technology
Patient Safety Action & Surveillance Plan
July 2, 2013

Health IT Patient Safety Strategies and Actions

Improve
Target resources and corrective actions to improve health IT safety and patient safety

Learn
Increase the quantity and quality of data and knowledge about health IT safety
User Centered Design must be applied to each of the 8 EHR certification criteria (e.g., Drug-drug interaction checks, e-prescribing)

- Lab-based summative testing must be performed
- EHR vendors need to review their current software design and development processes and document how they do or do not meet the specified quality management principles and processes
- No EHR patient safety event reporting
Guide to Reducing Unintended Consequences of Electronic Health Records

The Guide to Reducing Unintended Consequences of Electronic Health Records is an online resource designed to help you and your organization anticipate, avoid, and address problems that can occur when implementing and using an electronic health record (EHR). Our purpose in developing the Guide was to provide practical, troubleshooting knowledge and resources.

The Guide was developed with all types of health care organizations in mind — from large hospital systems to solo physician practices. We anticipate that the primary users will be EHR implementers such as Regional Extension Centers, chief information officers, directors of clinical informatics, EHR champions or "super users," administrators, information technology specialists, and clinicians involved in the implementation of an EHR. Frontline EHR users (such as physicians and nurses) may also find the Guide useful.

The Guide is based on the research literature, other practice-oriented guides for EHR implementation and use, research by its authors, and interviews with organizations that have recently implemented EHR. The Guide represents a compilation of the known best practices for anticipating, avoiding, and addressing EHR-related unintended consequences. However, this area of research is still in its infancy. Therefore, the Guide is a work in progress. We invite you to revise its tools and recommendations in keeping with your own experience and in response to emerging research findings.


See suggested citation format »
Technical Evaluation, Testing, and Validation of the Usability of EHRs

• Rationale for EHR Usability Protocol
• Procedures for evaluation and testing of EHRs
  – EHR Application Analysis
  – EHR User Interface Expert Review
  – EHR User Interface Validation Testing

www.nist.gov/healthcare/usability/index.cfm
A Human Factors Guide to Enhance EHR Usability of Critical User Interactions Supporting Pediatric Patient Care

A TURF Model of Critical Risks for Pediatric EHR

Intrinsic Complexity
- Physical characteristics
  - Weight, height, Body Surface Area (BSA), Body Mass Index (BMI)
- Developmental issues
  - Fetal to postnatal to adulthood
  - Gestational age and actual age
- Change of organ systems with age
  - Age, weight, and height dependent disease states, symptoms, exam findings, lab results, and treatments
- Complexity of medications
  - Change of dosage with age, weight, and BSA
  - Many formulations; liquid can be continuous
- Rounding of dosage
- Patient identification issues
  - Date of birth, names, temporary names, pre-admission identification
- Unique information requirements
  - Growth chart
  - Vaccination history
  - Parental and sibling information
  - Information from third person
  - Graph variables over time
  - Genetic information
  - Privacy

Extrinsic Difficulty
- Pediatric Electronic Health Record

Functions
- Dosage support
- Growth chart
- Vaccine schedule
- Medication order
- Alerts for abnormal values
- Privacy
- Other pediatric-specific functions

Users
- Pediatricians
- Nurses
- Patients
- Caregivers

Representations
- Navigational structure
- User interface entities
  - Objects (information items, e.g., MIM, text, graph, etc.)
  - Operations (actionable items, e.g., buttons, checkboxes, etc.)
- Organizational structures
  - Spatial layouts
  - Color, texture, shape, shade, contour

Tasks
- Task goals
- Task sequences
- Individual operations
- Temporal constraints

Function Root Causes
- Data accuracy error
- Data availability error
- Data integrity error

User Root Causes
- Unintentional
  - Slips (attention)
  - Lapse (memory)
  - Mistake (knowledge)
- Intentional

Representation Root Causes
- Patient identification error
- Mode error
- Interpretation error
- Truncation

Task Root Causes
- Recall error
- Feedback error

Adverse Events
- Wrong patient action of commission
- Wrong patient action of omission
- Wrong treatment action of commission
- Wrong treatment action of omission
- Wrong medication
- Delay of treatment
- Unintended or improper treatment

http://dx.doi.org/10.6028/NIST.IR.7865
SAFER: Safety Assurance Factors for EHR Resilience*

To develop resources for proactive assessment of safety in the EHR-based clinical work system

*Funded through ONC Task Order HHSP23337003T, Westat Contract No. HHSP23320095655WC0095655
Health Information Technology
Patient Safety Action & Surveillance Plan
July 2, 2013

Health IT Patient Safety Strategies and Actions

Lead
Promote a culture of safety related to health IT

Improve
Target resources and corrective actions to improve health IT safety and patient safety

Learn
Increase the quantity and quality of data and knowledge about health IT safety
Food and Drug Administration Safety and Innovation Act (FDASIA)

**Charge:** Develop an appropriate risk-based regulatory framework for health IT that promotes innovation, protects patient safety, and avoids regulatory duplication.
Canadian Health Infoway’s certification programme

• Includes: consumer software, shared records, EHRs and core modules including medications, imaging, and registries for patients, providers and immunisations

• Criteria focus on privacy, security, and interoperability

• Also manufacturer practices for managing risk, data, system security, as well as third party solutions and services

• Programme requires manufacturers to report all changes to certified software and report incidents involving the software
Health Canada’s regulation of software

- **Class I device**: software used to store, acquire, transfer, or view clinical data or images
- **Class II device**: manipulates the data and images upon which clinical decisions are based; Consumer HIT incl.

- Software that replaces patients’ paper records is excluded if only intended to store and view patient information (e.g.: age, weight, notes about patients’ appointments, test results, order processing, scheduling, or managing patient movements).
- Software that (i) performs administrative calculations and manipulations (e.g.: appointment and workflow management systems); or (ii) connects two or more HIT applications (i.e.: middleware) so that they can exchange data is also excluded.

Health Canada
www.hc-sc.gc.ca
Thank you!!

Enrico Coiera
e.coiera@unsw.edu.au

Farah Magrabi
f.magrabi@unsw.edu.au

Maureen Baker
maureen.baker@hscic.gov.uk

Jan Talmon
talmon@maastrichtuniversity.nl

@DeanSittig
Dean.F.Sittig@uth.tmc.edu
Discussion

IT safety initiatives at multiple levels:

- International
- National
- Local

Devices

Standardization

Oversight

Certification

Regulation

Hardware

Software