High Integrity Systems in Health Environment

Mark Nicholson
Introduction

National Patient Safety Agency (NPSA - 2003) has described patient safety as a process by which an organisation makes patient care safer involving:

- Identification and assessment of patient safety risk
- Management of patient safety risk
- Reporting and analysis of incidents
- Capacity to learn from and follow up incidents and implement solutions to minimise the risk of them recurring
How Safe is Health Care?


- In the 12 months July '07 to June '08
  - 805,000 patient safety incidents, 73% of which occurred in acute or general hospitals
    - 521,821 - no harm
    - 223,344 – low
    - 49,484 – medium
    - 7,243 - severe
    - 3,375 deaths as a result of incidents
  - cost to the NHS was £2bn as a result of extra bed days (plus litigation costs)
- Clinical errors resulted in 2,400 admissions daily
Or put it Another Way

- **Number of U.S. deaths during:**
  - WW1 116,000
  - WW11 407,000
  - Korean War 54,000
  - Vietnam War 58,000

- **Number of U.S.**
  - Hospital based infections in 2006 2,000,000
  - Deaths from infections in 2006 90,000
  - Additional dollars added to healthcare cost in 2006 5,000,000,000
Risk of Fatality in Different Domains

Source: AHRQ, 2005 / Commission on Systemic Interoperability, 2005
Where May Safety be Compromised?

- Points on Patient pathway where safety may be compromised
Errors

“Errors in health-care are often provoked by weak systems. They are not random, unconnected one-off events. They often have common root causes which can be generalized and corrected. Although each event is unique, there are likely to be similarities and patterns in sources of risk which may otherwise go unnoticed.”

“That is why patient safety, complex and difficult as it is, has become such an important issue for health care organisations. It is a major challenge. The best available evidence-based research suggests that one in 10 patients admitted to hospital may suffer unintended harm.”

Martin Fletcher, Chief Executive, National Patient Safety Agency, as introduction to Patient Safety Congress 2009
Technical Elements

- **Medical Devices**: Pieces of equipment with functionality that allows delivery of care or achievement of a diagnosis
  - e.g. Therac 25 – 6 overdoses & probably deaths
  - ISO 14971 - application of risk management to medical devices
  - ISO 29321 is being developed to extend this principle to manage clinical risk of software in a proactive and systematic fashion

- **Information Systems**:
  - Information - “Knowledge communicated concerning some particular fact, subject, or event; that of which one is apprised or told” [OED]
  - e-health
Electronic Health Services

- EHS include
  - Electronic Health Records (EHR)
  - Hospital Information Systems (HIS)
  - Data feeding, data interpretation, data sharing
  - Evidence Based Medicine (EBM)
  - Intelligent Support Services
  - Medical advise and diagnostics
  - Remote patient monitoring
  - Medical education

- ICT can help
  - prevent medical errors and adverse effects
  - initiate rapid responses to an event
  - provide feedback to learn from
The virtual EHR

- Clinical trials, functional genomics, public health databases
- EHR repositories
- Decision support, knowledge management and analysis components
- Personnel registers, security services
- Mobile devices
- Clinical devices, instruments
- Clinical applications
Archetypes

- NHS England Connecting for Health (CFH) project is using archetypes as ‘an approach for building a detailed national clinical record architecture’.

- An **EHR archetype** is an agreed, formal and interoperable specification of the data and their inter-relationships that must or may be logically persisted within an electronic health record for documenting a particular clinical observation, evaluation, instruction or action.

  - *openEHR / EN 13606* archetype represents this specification as a set of constraints, expressed in a standardised form, for instantiating a particular EHR Reference Model.
Semantic single-source Models
Welcome to HeartBeat, Dr. Dipak Kalra. Your patient is Ahmad Khaliq (29-Jan-1933).

**Allergies**

There are no Allergies records for this patient.

*Create new Allergies record*

**Clinical Conditions**

<table>
<thead>
<tr>
<th>Date committed:</th>
<th>Name:</th>
<th>Current Problem:</th>
<th>Concerns:</th>
</tr>
</thead>
<tbody>
<tr>
<td>09-May-2007</td>
<td>Asthma</td>
<td>true</td>
<td>Acute attacks, esp winter</td>
</tr>
<tr>
<td>08-Jun-2007</td>
<td>Diabetes</td>
<td>true</td>
<td>Fear of needles</td>
</tr>
</tbody>
</table>

*Create new Clinical Conditions record*

**Regular Drugs**

<table>
<thead>
<tr>
<th>Date committed:</th>
<th>Name:</th>
<th>Actual Start Date:</th>
<th>Actual End Date:</th>
<th>Description:</th>
<th>Dosage:</th>
</tr>
</thead>
<tbody>
<tr>
<td>13-Jun-2007</td>
<td>Aspirin</td>
<td>02-Apr-2007</td>
<td></td>
<td></td>
<td>1.0</td>
</tr>
<tr>
<td>13-Jun-2007</td>
<td>Ventolin</td>
<td>07-Jun-2006</td>
<td></td>
<td></td>
<td>1.0</td>
</tr>
</tbody>
</table>

*Create new Regular Drugs record*

**Lifestyle Information**

There are no Lifestyle Information records for this patient.

*Create new Lifestyle Information record*

**Services And Needs**

There are no Services and Needs records for this patient.

*Create new Services and Needs record*
Growing Set of Archetypes
Work with NHS - Richard Paige

- Health informatics as domain in LSCIT Systems
  - Modelling workflows/processes.
  - Take into account organisational processes as well as IT processes
  - Interested in failures (safety) as well as security (e.g., confidentiality and trust)
  - Spaghetti diagrams as well as relevant standards (e.g., BPM).
  - Some of this to be extended to direct collaboration with NHS CfH (discussion on 11 June)

- Collaborations within the CLAHRC on Stroke Care:
  - IT support for gathering data on stroke care (e.g., when was aspirin dispensed, when did full-body scan take place)
  - Supporting evidence-based health care study
  - CS/IT issues related to data collection, UI issues, technical design
People Elements

- Human Factors deals with psychological, social, physical, biological and safety characteristics of user and system user is in
  - NHS has huge army of employees
  - Best way of reducing error rates is to target underlying systems failures, rather than individual members of staff
    - **perfection myth:** if people try hard enough, they will not make any errors
    - **punishment myth:** if we punish people when they make errors, they will make fewer of them

- Technical and People Issues leads to two elements
  - Systematic Risk based approach to developing systems
  - Safety Management Systems
Health Care Specifics

“In healthcare there are few absolute guarantees that the care process will lead to recovery, a longer life, or an increase in the quality of life despite these being the principle objectives” Davis NPSA 2009

So in this case what does harm mean?

What are measures of safety risk that are appropriate?
Severity Example

- United States Veterans Affairs Severity Assessment Code
  - 4 categories

- Catastrophic Event:
  - Patient Outcome:
    - Death or major permanent loss of function (sensory, motor, physiologic, or intellectual) suicide, rape, hemolytic transfusion reaction, surgery / procedure on the wrong body part, infant abduction or infant discharge to the wrong family
  - Visitor Outcome
    - Death; or Hospitalization of 3 or more
  - Staff Outcome
    - Death; or Hospitalization of 3 or more
  - Equipment or facility:
    - Damage more than $100,000

- Minor Event:
  - Patient Outcome:
    - No injury nor increased length of stay nor increased level of care
  - Visitor Outcome:
    - Evaluated and no treatment required or refused treatment
  - Staff Outcome:
    - First aid treatment only, with no lost time or restricted-duty injuries or illnesses
  - Equipment or facility:
    - Damage less than $10,000 or loss of any utility without adverse patient outcome (eg, natural gas, electricity, water, communications, heat/air conditioning)
Risk Measurement: Accident Probability

- United States Veterans Affairs Assessment Code
  - **Frequent**: Likely to occur immediately or within a short period of time (may happen several times in one year)
  - **Occasional**: Probably will occur in time (several times in 1 to 2 years)
  - **Uncommon**: Possible to occur in time (sometime in 2 to 5 years)
  - **Remote**: Unlikely to occur (sometime in 5 to 30 years)
Overall Risk - Examples

United States Veterans Affairs Assessment Code

Connecting For Health Systems applicable where patient safety incidents are already known or can be accurately forecast e.g. prescribing errors

Patient Safety Risk Matrix

<table>
<thead>
<tr>
<th>LIKELIHOOD</th>
<th>PROBABILITY</th>
<th>SEVERITY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequent</td>
<td>Catastrophic</td>
</tr>
<tr>
<td></td>
<td>Occasional</td>
<td>Major</td>
</tr>
<tr>
<td></td>
<td>Uncommon</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Remote</td>
<td>Minor</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
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<th>SEVERITY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&gt;1:10 per patient year</td>
<td>H H H H H H H</td>
</tr>
<tr>
<td></td>
<td>1:10 – 1:100 per patient year</td>
<td>M M H H H H H</td>
</tr>
<tr>
<td></td>
<td>1:100 – 1:1000 per patient year</td>
<td>L M M H H H H</td>
</tr>
<tr>
<td></td>
<td>1:1000 – 1:10,000 per patient year</td>
<td>L L M M H H H</td>
</tr>
<tr>
<td></td>
<td>1:10,000 – 1:100,000 per patient year</td>
<td>L L L M M H M</td>
</tr>
<tr>
<td></td>
<td>1:100,000 – 1:1,000,000 per patient year</td>
<td>L L L L M M M</td>
</tr>
<tr>
<td></td>
<td>&lt; 1:1,000,000 Per patient year</td>
<td>L L L L L M M</td>
</tr>
<tr>
<td></td>
<td>A</td>
<td>Very Low</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>D</td>
<td>Severe</td>
</tr>
<tr>
<td></td>
<td>E</td>
<td>Major/Fatal</td>
</tr>
<tr>
<td></td>
<td>F</td>
<td>Catastrophic</td>
</tr>
</tbody>
</table>
Clinical Risk Process

NHS Connecting for Health is delivering the National Programme for Information Technology.

Scope
- Initial Design
- Detailed Design
- Module Test
- System test
- Integration test
- RFO
- Scalability
- Model Communities test
- Initiation complete
- Go Live

Draft Patient Safety assessment

Patient Safety assessment Version 1

Patient Safety assessment + Relevant measure

Hazard Log (1)

Hazard Log (2)

Hazard Log (9)

ITERATIVE PRODUCT – REVIEWED AT EACH STAGE

RISKS REVIEWED ANY NEW RISKS INTRODUCED

RISKS MITIGATED AT EACH REVIEW

LOG HANDED OVER TO TRUST SAFETY OFFICER TO ADDRESS ANY OUTSTANDING IMPLEMENTATION ISSUES

Safety Case

Safety Closure report

Clinical Authority to release

Clinical Safety Certificate

NHS Connecting for Health is delivering the National Programme for Information Technology.
Link to ICT

- Information is provided to support the hazard log
  - Safety risk increases if this information is not correct
    - information on changes to safety control mechanism
    - information on actual occurrence rates of events
    - identification of hazardous events or causes of hazardous events
  - Developers of ICT make assumptions about the way the system is used
    - if these assumptions are incorrect safety may be compromised

- ICT used as a mechanism to reduce safety risks
  - Data feeding, data interpretation, data sharing
  - Evidence Based Medicine (EBM)
  - Intelligent Support Services
  - Medical advise and diagnostics
  - Medical education
Safety Case

"A Safety Case shall consist of a structured argument, supported by a body of evidence, that provides a compelling, comprehensible and valid case that a system is safe for a given application in a given environment."

ISO/TS 29321:2008(E) Application of clinical risk management to the manufacture of health software

- 8. Clinical safety case report(s)
- 9 Stage reports and pre-release clinical risk management process review

Manufacturers of medical devices and healthcare service providers are required to provide argument and evidence that the devices and services they provide are acceptably safe before they can enter health spine
IT operates safely in Hospital Trust usage
NRLS

- National Reporting and Learning System (NRLS) on patient safety incidents is central to UK clinical SMS strategy.

- Data collected through NRLS helps to:
  - identify trends and patterns of avoidable incidents and underlying causes
  - develop models of good practice and solutions at a national level
  - improve working practices in NHS organisations locally through feedback and training; and to
  - support ongoing education and learning
Patient Safety Systems

Adapted from: Reason J. Human error: models and management. *BMJ* 2000;320;768-770
Seven Steps to Safety Management

**NPSA 2004**

- **Build a safety culture**
  - Create a culture that is open and fair
- **Lead and support your staff**
  - Establish a clear and strong focus on patient safety throughout organisation
- **Integrate your risk management activity**
  - Develop systems and processes to manage your risks and identify and assess things that could go wrong
- **Promote reporting**
  - Ensure your staff can easily report incidents locally and nationally
- **Involve and communicate with patients and the public**
  - Develop ways to communicate openly with and listen to patients
- **Learn and share safety lessons**
  - Encourage staff to use root cause analysis to learn how and why incidents happen
- **Implement solutions to prevent harm**
  - Embed lessons through changes to practice, processes or systems
Summary

- Risk based System Safety Engineering is being introduced for IT and medical devices

- Link between SSE and Patient / clinical safety
  - understanding of the safety status of each piece of the system
  - contribution of each action on safety
  - Contribution of safety management and safety case

- It is clear that this process to achieving high integrity has not yet permeated through the system
  - significant research and implementation issues
  - e.g. A&E nurse in Hexham versus Newcastle