eSafety – Guidelines Out, Adoption In Progress

HIC 2014
Melbourne

Don Newsham,
Chief Executive Officer
COACH: Canada’s Health Informatics Association
Drivers and foundations for eSafety

- **Early Leader** - NHS England’s Clinical IT Safety

- **Institute of Medicine (IOM)** – Health IT and Patient Safety

- **Research**
  - *JAMIA May 2013* The safety of electronic prescribing: manifestations, mechanisms, and rates of system-related errors associated with two commercial systems in hospitals (Westbrook J, et al.)
  - *ECRI Institute February 2013* PSO Deep Dive™ analysis on HIT-related safety events
    ECRI Guidance Article, adapted from Vol.42, No.11, November 2013 Top Ten Health Technology Hazards for 2014
Drivers and foundations for eSafety

• Standards
  ISO/TR 17791 December 2013 Health informatics — Guidance on standards for enabling safety in health software

• Regulators (FDA) and National Agencies
  FDA, FCC, ONC April 2014 FDASIA health IT report

  International Medical Device Regulators Forum (IMDRF) SaMD Definitions December 2013 and SaMD Possible Framework for Risk Categorization and Corresponding Controls (under development)

  ONC July 2013 Patient safety action and surveillance plan (with previous reports and drafts available from ONC)
<table>
<thead>
<tr>
<th>eSafety: Adverse Events - Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>System fails to produce appropriate alert for patient</td>
</tr>
<tr>
<td>Patient mis-identification</td>
</tr>
<tr>
<td>Software maintenance update not fully tested and causing patient lab results going to wrong physician</td>
</tr>
<tr>
<td>Drug mapping errors or errors in displaying data in the correct context</td>
</tr>
<tr>
<td>Incorrectly computed ages for pre-natal screening</td>
</tr>
<tr>
<td>Data migration errors in converting data from one system to another</td>
</tr>
<tr>
<td>RX system-to-EMR interfaces misfire</td>
</tr>
<tr>
<td>Pathology results dropping from EMR results review or original results not being replaced by secondary reviews</td>
</tr>
<tr>
<td>Stat results not being picked up by physicians because their MD inbox function only displays them passively (rather than via an alert)</td>
</tr>
</tbody>
</table>
eSafety: Adverse Events – Example Categories

- Unmet display needs
- Software modifications
- System-system interface
- Hidden dependencies in distributed system
Canada’s eSafety Program & Guidelines

- Based on Program Plan and Advisory Input
- Developed with the help of a national team of health informatics professionals and clinicians
- Trialed with 8 volunteer organizations on current eHealth projects
The Premise of eSafety

Why COACH Guidelines & Professional Practices?

Protect patients against risk / harm due to unintended safety risks introduced through the development, implementation and use of ‘e’ systems

Action required, (see previous drivers list) to ensure ‘e’ systems are well-designed, well-implemented and safe.

Being proactive / building trust with all stakeholders
Reinforces priority of qualified / involved HI Professionals
Canadian eSafety Program - Goals

Protect patients against harm throughout development, implementation and use of ehealth solutions and health software.

Provide Awareness and Education

Use Guidelines and Standards

Implement, Monitor and Report eHealth Safety

© COACH: Canada’s Health Informatics Association 2014
Canadian eSafety Program - Stakeholders

Health Organization Champions

COACH

Governments (Provincial and Federal)

CMA

CNIA

CPA

ITAC

CPSI

Canada Health Infoway

CIHI

Accreditation Canada

Physicians

Nurses

Allied Health Providers

Academics & Researchers

Vendors & Consultants

Healthcare Delivery Organizations

Patients

Taking Health Informatics Mainstream

© COACH: Canada’s Health Informatics Association 2014
eSafety: All of us Working Together

• Ecosystem-based

• Lifecycle approach

• Disciplinary expertise in integrated collaboration

• Roles & Responsibilities for ongoing accountability
Trial Participants & Early Adoption

Project: Centricity Perinatal Information System

Project: Clinical Data Integrity (DIS)

Project: ACD Bariatric Interdisciplinary Assessment Notes

Project: Hospital Report Manager Solution

Project: Personal Computer Video

Project: NWT Xero Viewer
## Real Life eSafety Examples

<table>
<thead>
<tr>
<th>Ontario</th>
<th>Manitoba</th>
<th>Saskatchewan</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Report sent to wrong physician</td>
<td>• Missing information</td>
<td>• Client and provider identity issues</td>
</tr>
<tr>
<td>• Missing hospital name</td>
<td>• Data Quality</td>
<td></td>
</tr>
<tr>
<td>• Reports delayed</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Getting the team ready for eSafety

Starting to Build an eSafety Culture

Characteristics Include:

• Senior leadership support
• A learning organization participating in education opportunities
• Strong staff morale
• Adequate resources
• Appropriate autonomy and discretion for individuals
• Commitment to processes and work flow
• Adoption and uptake of guidelines and leading practices
Starting to Build an eSafety Culture

• Start pragmatically
• Reinforce behaviours through formal and informal means
• Seek out role models for the new behaviour
• Enlist your current cultural carriers (the lynchpins to spread adoption)
• Use the culture that already exists before you change (vision)
• Visible and consistent role modelingrs need to walk the talk
• Clarify the implications of this new behaviour
Learning and using esafety methodology

Consult & Communicate
Assemble documentation & recruit safety case team.

Establish the Context
Set risk tolerance threshold, describe the system or program & determine internal and external factors.

Risk Assessment
Define scope, document process and data flows, identify potential safety failures & conduct risk analysis.

Risk Treatment
Complete Risk Register and safety assessment summary report.

Monitor & Review
Integrate with enterprise management.
Focusing on the eSafety Case

Ask Yourself: What Could Possibly Go Wrong?

• Set a risk tolerance
• Identify the risks
• Determine scope of eSafety Case
• Follow the method / action the results
OMD’s HRM eSafety Case

From OMD Vice President, COACH Board Member and eSafety Council Chair – ELIZABETH KELLER

The OntarioMD Hospital Report Manager (HRM) eSafety trial focused on applying the COACH eSafety Guidelines to both the Product Enhancements/Upgrades and the Project (deployment/roll-out) to include eSafety considerations and additional risk mitigation prior to go-live.

Benefits of eSafety Trial for HMR

• Increased risk mitigation to manage and minimize any potential patient safety risks associated with HRM
• Increased stakeholder confidence in HRM and its ability to improve the continuity of patient care using national leading practice/guidelines in eSafety
• As HRM directly deals with patient records by supplying hospital reports associated to a patient, a risk tolerance level of low was deemed acceptable and approved
HRM eSafety Case

Approach

• “What can possibly go wrong?” Workshop
• Walkthrough of the information flow
• Review of the Privacy Impact Assessment (PIA)
• Included many different stakeholders, including product, project, operations, change management, physicians and physician office managers
Findings

- The safety culture was already well established in the organization.
- Many existing process and tools were already in place to ensure HRM had minimal risk, including but not limited to:
  - Standardized specifications
  - Legal agreements
  - Checks and balances within the product
  - PIA
  - Stringent operational processes
  - Extensive testing and validation with vendors, data senders and receivers
“The eSafety Guidelines help prevent adverse events as new e-health information systems are introduced. Our product (HRM) enables the secure transmission of hospital reports directly into my EMR; and applying the COACH eSafety Guidelines helped increase confidence in the product and the ongoing processes like eSafety to support it.”

Dr. Darren Larsen
HRM Physician Champion
Ontario Medical Association
Next Steps for eSafety in Canada

• Continue to provide **education** and **awareness** on how to successfully apply the eSafety Guidelines

• Building **adoption, promotion** and **deployment strategies** with key advisors from health ministries, national organizations, clinical professions and key health agency levels through COACH eSafety Council and other forums
Next Steps for eSafety in Canada

The eSafety Guidelines are now available for purchase or license. For more information, please visit www.coachorg.com or email COACH at info@coachorg.com
<table>
<thead>
<tr>
<th>Level</th>
<th>Maturity Characteristic or Trail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 0</td>
<td>• Little to no recognition of the need for addressing safety with respect to eHealth systems.</td>
</tr>
<tr>
<td>Level 1</td>
<td>• Early recognition of the importance of eSafety, but no formal eSafety management program (eSMP), policy, processes or practices are in place to address eSafety.</td>
</tr>
<tr>
<td>Level 2</td>
<td>• High-level eSafety framework is in place, but lacks management support and resources to enforce/enable optimal adoption within the organization.</td>
</tr>
<tr>
<td>Level 3</td>
<td>• A formal eSMP is in place and documented.</td>
</tr>
<tr>
<td>Level 4</td>
<td>• A formal eSMP, policy and supporting processes are in place and documented. The eSMP, its policy and processes may be integrated into the organization's enterprise risk management and patient safety policies.</td>
</tr>
<tr>
<td>Level 5</td>
<td>• A formal eSMP, policy and supporting processes are in place, documented and well integrated into the organization's enterprise risk management and patient safety policies.</td>
</tr>
</tbody>
</table>
eSafety – Guidelines Out, Adoption In Progress

Thank You!

HIC 2014
Melbourne

Don Newsham,
Chief Executive Officer
COACH: Canada’s Health Informatics Association