



Clinical Software Risk Management

A Global Vendor Perspective

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Introduction

Clinical Software Systems and Patient Safety

- Focus on the manufacturers of EHR software and clinical software systems
 - Other areas: medical device manufacturers
 - Other areas: workflow induced errors based processes EHR
 - Office of the National Coordinator for Health IT kicks off an \$80,000 EHR safety initiative to allow clinicians to report safety issues within the EHR workflow

Clinical Software Systems

- Vendor safety initiatives
- Healthcare systems safety initiatives from various countries

Global Perspective: Medical Errors

- In the U.S., medical errors are 3rd leading cause of death¹
- The Veterans Administration has similar or lower statistics²
- Other Countries

Table 2. Medical, medication and laboratory errors in seven countries*

	AUS	CAN	GER	NETH	NZ	UK	USA
Medical, medication errors in past 2 years (percent yes):							
Been given the wrong medication or wrong dose?	8% c	6%	5% g	6%	6%	6%	7%
Had a time when you thought a medical mistake was made in your treatment or care?	11% b,c,d,f	7% d,g	6% g	5% e,f	8% f	5% g	9%
Either medical or medication error	15% b,c,d,f	10% g	9% g	9% g	11%	9% g	13%
Laboratory errors							
Had blood tests, radiographs or other tests in past 2 years (percent yes)	82% b,d,f	79% c,d,f	81% d,f	72% e,f,g	79% f	62% g	79%
Been given incorrect results for diagnostic or laboratory test	5% c,d	4% c,d,f	2% g	2% g	2% g	2% g	5%
Experienced delays in being notified about abnormal results	7% c,g	9% c,e	2% d,e,f,g	7% g	7% g	8%	11%
Either laboratory or diagnostic error	11% c	12% c,d,e	4% d,e,f,g	8% g	9% g	10% g	14%
Combined medical, medication, or laboratory errors							
Any medical, medication or laboratory error (percent yes)	20% c,d,f	17% c,f,g	12% c,g	14% g	16% f,g	13% g	20%
Any error, number of doctors seen in past year							
One	15% h	13% h	7% h	9% h	13% h	9% h	17% h
Three or more	27%	30%	16%	27%	34%	29%	33%
Any error, number of chronic conditions							
One	19% h	17% h	14%	15% h	20%	13% h	21% h
Two or more	26%	28%	16%	25%	22%	24%	32%
Among adults with chronic condition, any error for those with and without a medical home							
Has medical home	18% h	17% h	11% h	17% h	15% h	11% h	21% h
No medical home	30%	29%	19%	22%	30%	26%	34%

AUS = Australia; CAN = Canada; GER = Germany; NETH = The Netherlands; NZ = New Zealand; UK = United Kingdom; USA = United States of America.

* Reading from left to right starting with Australia, the letter indicates significant differences with countries to the right ($p < .05$), as indicated: b = different from Canada; c = different from Germany; d = different from The Netherlands; e = different from New Zealand; f = different from the United Kingdom; g = different from the United States; h = indicates difference within country ($p < .05$).

Source: Commonwealth Fund International Health Policy Survey, 2007. Table and notes reproduced with permission from Schoen et al. (2007).

Digital Health Canada

- Point of departure
- The COACH patient safety team identified several examples of e-Safety issues, such as:
 - Report sent to the wrong physician
 - Missing information
 - Data quality
 - Client and provider identity issues



Medical Errors Related To Clinical Software

- Clinical Software Systems mitigate clinical risk BUT can introduce risk as well
 - For clinical system involvement in medical errors⁴:
 - Computerized Physician Order Entry (CPOE) systems: 25%
 - Clinical Documentation systems: 17%
 - Electronic Medication Administration Records (eMAR): 15%
- Adverse Incidents:
 - Medication Problems: 41%
 - Clinical Process Problems: 33%
 - Exposure to radiation: 15%
 - Surgery problems: 11%

Risk Management

Application of management policies, procedures and practices to the tasks of analyzing, evaluating and controlling risk⁴

- Complex: social, technical, clinical environment
- Ownership: multiple ownership
- Goal: reduce patient harm

Vendor Ownership

- Clinical software risk management

Vendor Example

One Vendor Example

- Reports & Advice reviewed within 24 hours
- Assign Risk Score & Set Policy
 - Risk Matrix: **Risk score = Impact x Likelihood - Mitigation**

This field will be auto-calculated based on the set levels of severity and likelihood.

Likelihood	Frequent L=0	9	10	20	24	25
	Probable L=1	7	13	17	22	23
	Occasional L=2	4	8	14	18	21
	Remote L=3	2	6	11	15	19
	Improbable L=4	1	3	5	12	16
		Negligible S=4	Minor S=3	Serious S=2	Critical S=1	Catastrophic S=0

Severity

Global Perspective

U.S. Risk Management for Vendors vs. National Health Services

- U.S. – some government initiatives & market liability based
 - eClinicalWorks
- UK, NZ, CA – Initiative based

Clinical Safety

- How vendor manages risk when developing applications
- How society mitigates risk

UK Initiative

- The NHS standard is aimed at ensuring the safety of Health IT Systems through the application of clinical risk management.
 - Guidance to Manufacturers of clinical systems
 - Clinical Risk Officer
 - Clinical risk
 - Identify risk...
 - Evaluation of risk
- SCCIO129: Clinical Risk Management: its Application in the Manufacture of health IT Systems
 - Based on Adrian Stavert-Dobson's work
 - Health Information Systems – Managing Clinical Risk

SCCIO129: Process Highlights

(UK Initiative)

- Management
 - Provide Competent Resources
 - Nominate Clinical Safety Officer
 - Regularly Review Process
- Project Documentation
 - Clinical Risk Management File
 - Clinical Risk Management Plan
 - Establish & Maintain a Hazard Log
 - Clinical Safety Case (safe for release)
 - Safety Incident Management Log
- Clinical Risk Analysis
 - Identification of risk to patients
 - Estimation of clinical risks
 - Severity, Likelihood, Total clinical risk
 - Initial Risk
- Clinical risk control option Analysis
 - Controls (mitigations)
 - Clinical Risk benefit analysis
 - ALARP
 - Implementation of controls

SCCIO129: Clinical Risk Management Process (UK Initiative)

- Risk Analysis
 - Scope Definition
 - Clinical Hazard identification
 - Clinical Risk Estimation
- Risk Evaluation
 - Initial Clinical Risk Evaluation
- Risk Control
 - Control Option Analysis
 - Clinical Risk Benefit Analysis
 - Control Measure implementation
 - Completeness Evaluation
- Delivery
- Post-deployment Monitoring
- Modification

Summary

- Increasing patient safety through use of Clinical Software Systems mitigates some existing risk to patients but introduces other risks
- Global healthcare systems trending towards ensuring manufacturers of clinical systems have a robust risk management process

Medicine used to be simple, ineffective, and relatively safe.

Now it is complex, effective, and potentially dangerous

- Sir Cyril Chantler, the Kings Fund

Questions?

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