University of Victoria | Engineering

Certification of Health IT Software

Jens H. Weber, PhD, PEng
Software Engineering Director
Associate Professor
Simbioses Research Group
Department of Computer Science
School of Health Information Science

HIT Software: Benefits and Risks

EMR, EHR, PHR, CPOE, PACS, CDSS

- ✓ Research
- ✓ Access
- ✓ Communication
- ✓ Lower cost
- ✓ Surveillance
- ✓ Planning

- ? Safety
- ? Reliability
- ? Security/Privacy
- ? Effectiveness

Huffington Post investigative fund:
237 reports on safety incidents related to
HIT software in FDA Manufacturer and User Facility Device Experience (MAUDE) database between 1/08 and 2/10.

Example MAUDE Report #1

A cpoe device was deployed at **** hospital in 2008. This patient underwent an appendectomy two days later. The patient's care was governed by a cpoe device manufactured by ***.

In the care of this patient after his operation, there were 25 incidents that occurred involving flaws and defects in the device, interface defects, device user bewilderment, device caused hospital wide chaos, and device caused hospital wide near-meltdown and care disruption that resulted in neglect of this patient and his death.

What are the most frequent root causes for HIT failure?

Qualitative analysis of FDA reports (Grounded Theory)

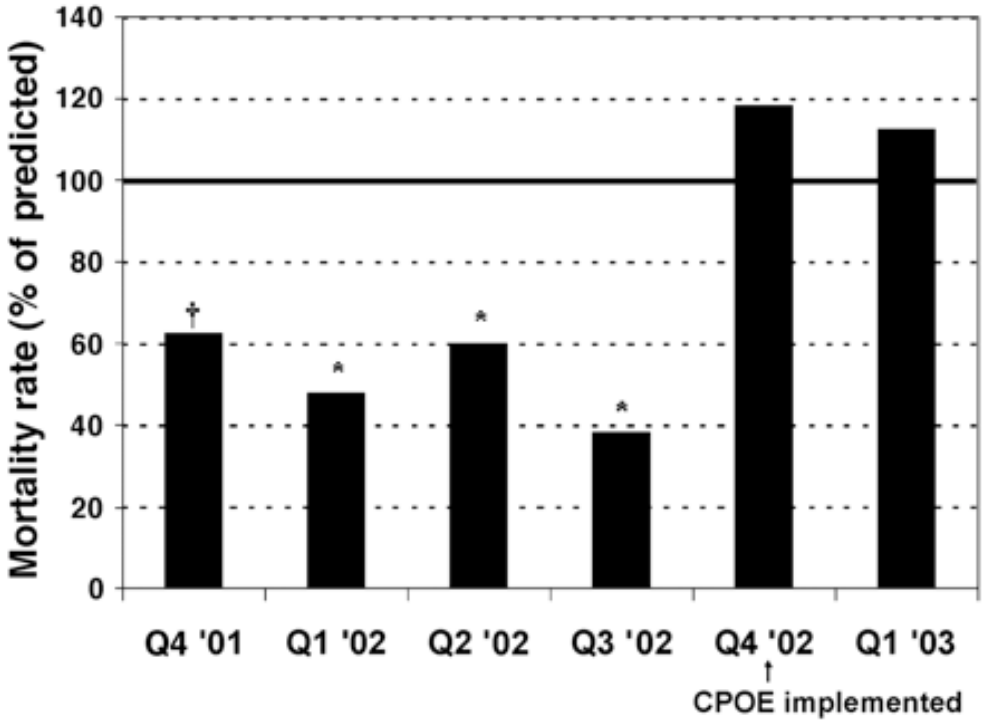
preliminary results based on 55 reports

Code	Total	Min	Max	Mean	Std Dev	Bar Graph
cause _ communication error	2	0	0	0	-	
cause _ data-conversion error	2	0	0	0	-	
cause _ deployment	1	0	0	0	-	
cause _ end-user customization	14	0	0	0	-	
cause _ environment	1	0	0	0	-	
cause _ export data missing info	1	0	0	0	-	
cause _ HCI problem	4	0	0	0	-	
cause _ incomplete report	1	0	0	0	-	
cause _ incomplete update after data changed	1	0	0	0	-	
cause _ inconsistency between multiple reports	3	0	0	0	-	
cause _ incorrect measurement	1	0	0	0	-	
cause _ incorrect report	3	0	0	0	-	
cause _ knowledge-data migration	1	0	0	0	-	
cause _ misidenitication due to opening partially wr	4	0	0	0	-	
cause _ misidentification due to missing labels	1	0	0	0	-	
cause _ misidentification due to multiple identities	1	0	0	0	-	
cause _ misidentification due to partial interface up	3	0	0	0	-	
cause _ misidentification due to switched of info	1	0	0	0	-	
cause _ misread	1	0	0	0	-	
cause _ missing ack of warning	2	0	0	0	-	
cause _ missing data validation	2	0	0	0	-	

kind _ Central Monitoring System CMS	1	0	0	0	-	
kind _ Compounder	1	0	0	0	-	
kind _ CPOE	14	0	0	0	-	
kind _ Data Management System	6	0	0	0	-	
kind _ drug dispensing software	5	0	0	0	-	
kind _ LIS	1	0	0	0	-	
kind _ order entry	3	0	0	0	-	
kind _ PACS	6	0	0	0	-	
kind _ PMS	14	0	0	0	-	
kind _ Software-Bloodbank	1	0	0	0	-	

Commercial CPOE Surprises

Han YY, Carcillo JA, Venkataraman ST, et al. **Unexpected increased mortality after implementation of a commercially sold CPOE system**. Pediatrics 2005;116:1506–12

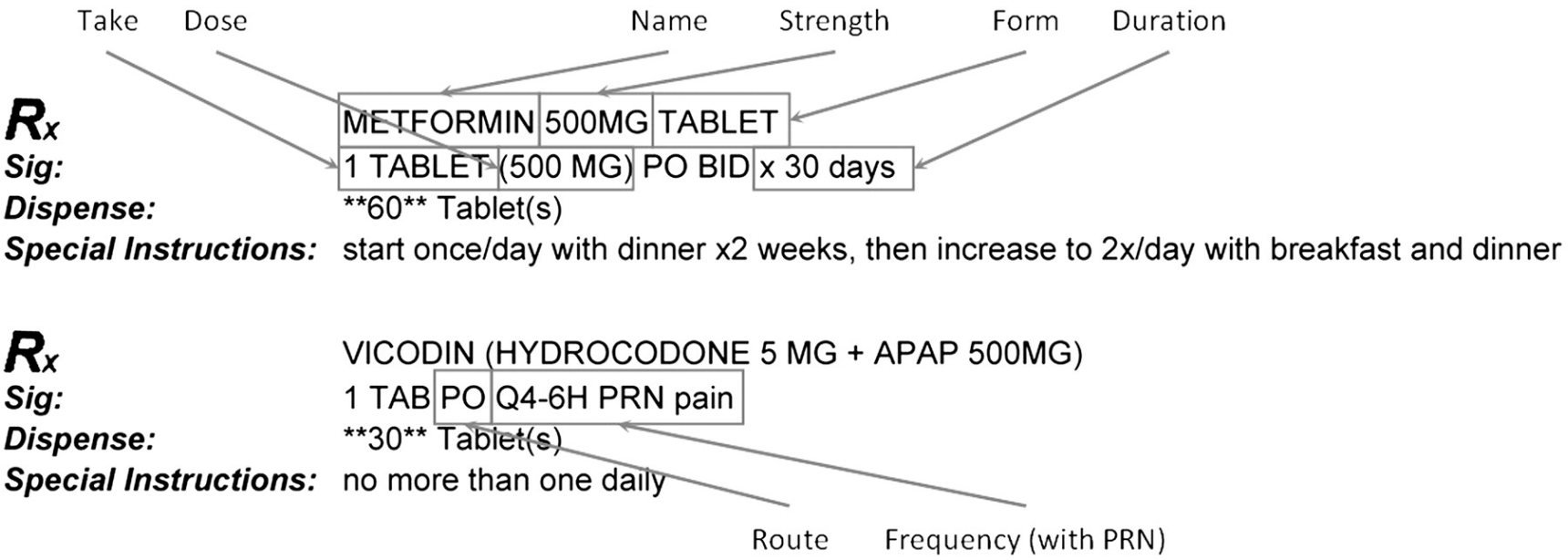


Koppel R, Metlay JP, Cohen A, *et al*. Role of computerized physician order entry systems in facilitating medication errors. *JAMA* 2005;**293**:1197–203

- Medication Discontinuation Failures
- Discontinuation failures
- Procedure-Linked Medication Discontinuation Faults
- Immediate Orders and Give-as-Needed Medication Discontinuation Faults
- Antibiotic Renewal Failure, Diluent Options and Errors
- Allergy Information Delay
- Conflicting or Duplicative Medications
- Human-Machine Interface Flaws: Machine Rules That Do Not Correspond to Work Organization or Usual Behaviors
- Patient Selection
- Wrong Medication Selection
- Unclear Log On/Log Off.
- Failure to Provide Medications After Surgery
- Postsurgery "Suspended" Medications
- Loss of Data, Time, and Focus When CPOE Is Nonfunctional
- Sending Medications to Wrong Rooms When the Computer System Has Shut Down
- Late-in-Day Orders Lost for 24 Hours
- Role of Charting Difficulties in Inaccurate and Delayed Medication Administration
- Inflexible Ordering Screens, Incorrect Medications.

Inflexible Order Screens

- 16.1% of prescriptions are internally inconsistent. (83.8% could lead to ADE and 16.8% to severe ADE, involving a hospital admission or death.)



Palchuck et al. **An unintended consequence of electronic prescriptions: prevalence and impact of internal discrepancies**. JAMIA 2010;17:472-476

Resistance Mounting

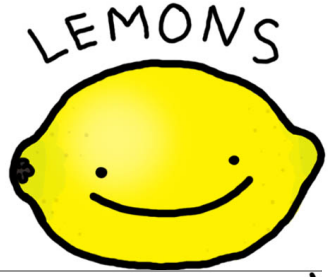
Healthcare information technology (HIT) vendors enjoy a contractual and legal structure that **renders them virtually liability-free**—"held harmless" is the term-of-art—even when their proprietary products may be implicated in adverse events involving patients. This contractual and legal device **shifts liability and remedial burdens to physicians, nurses, hospitals, and clinics**, even when these HIT users are strictly following vendor instructions...HIT vendors are not responsible for errors their systems introduce in patient treatment because physicians, nurses, pharmacists, and healthcare technicians should be able to identify—and correct—any errors generated by software faults.

[Yes - we're all knowing magicians with the power to read minds, infer incorrect lab values via therapeutic touch, and possess encyclopedic knowledge in our heads at all times. This raises the question: if we are that omniscient to be able to identify and correct software faults with 100 percent accuracy to avoid patient harm, then why do we need electronic medical records at all? - ed.]

Health Care Renewal Blog

Health Care Information Technology Vendors' "Hold Harmless" Clause - Implications for Patients and Clinicians, Ross Koppel and David Kreda, Journal of the American Medical Association, 2009;301(12):1276-1278

The Market for Lemons and Asymmetric Information



100 used cars for sale in a town:

50 well maintained, worth $2,000

50 ‘lemons’, worth $1,000

What is the market price for a used car?

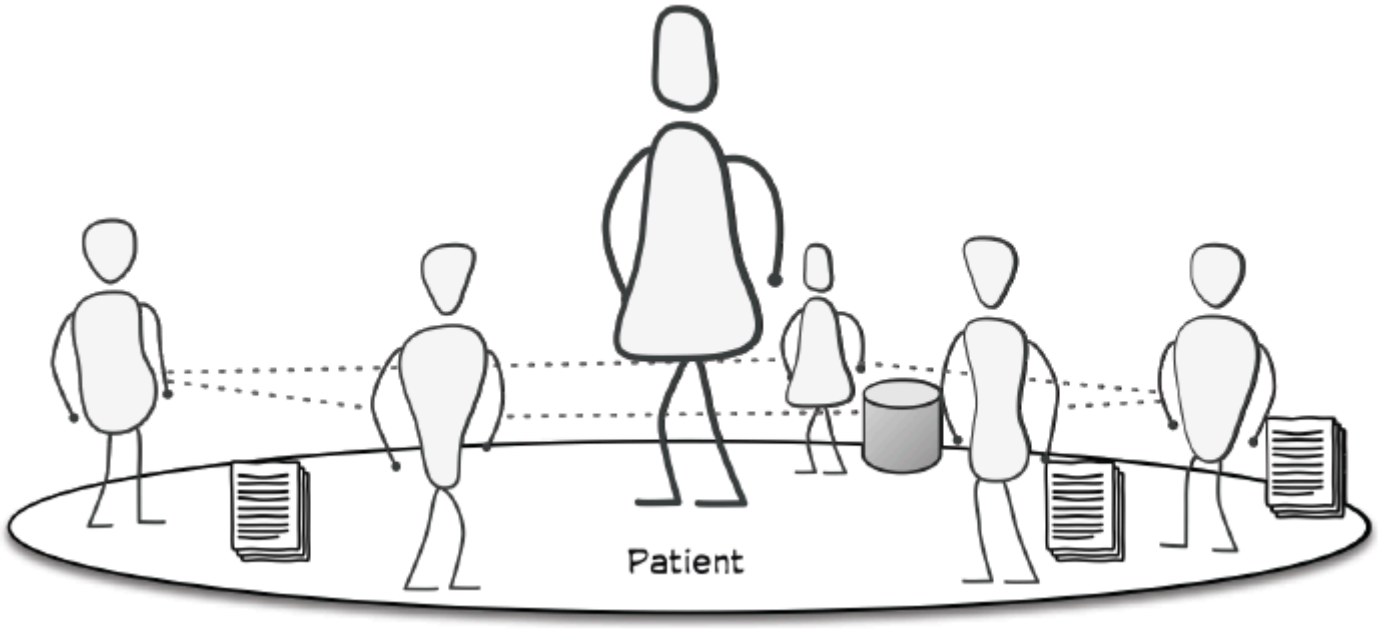
George Arthur Akerlof

(Nobel Prize 2001)

Race to the bottom

Learnt Intermediary Doctrine - does it apply?

[HIT Software] <---> [Clinician] <---> [Patient]



Price, M. (2010)

[Clinician] <---> [HIT Software] <---> [Clinician/Patient]

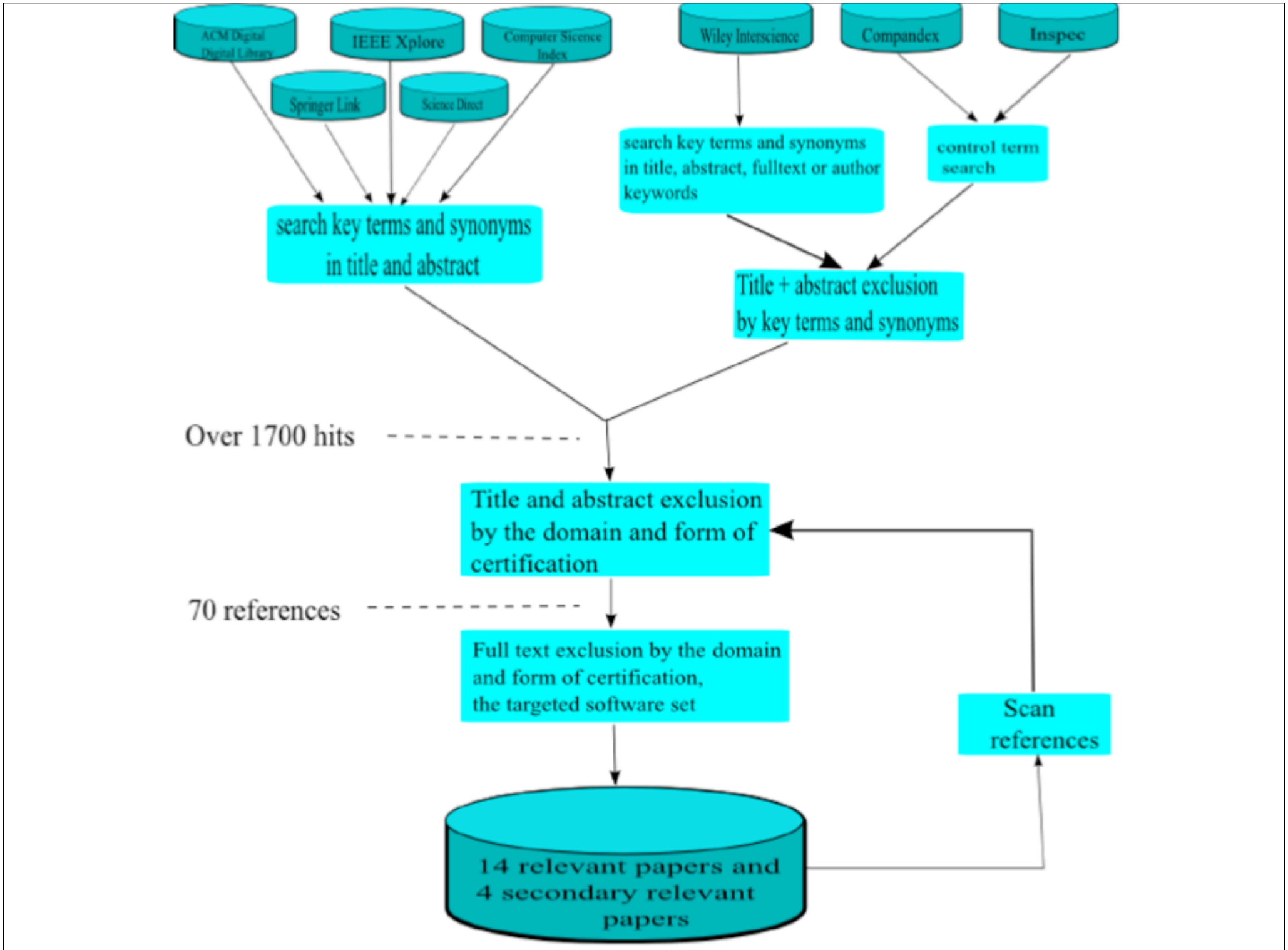
HIT Software is a "conduit" for knowledge

Some Observations

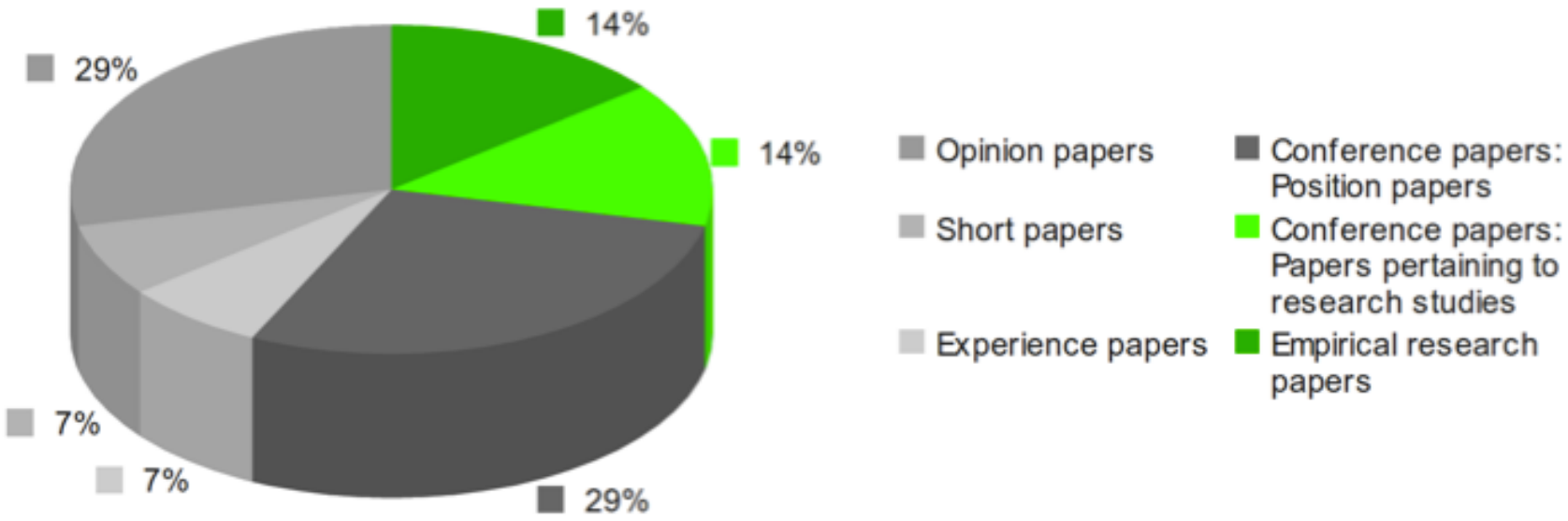
- Grave safety concerns with Commercial HIT Software
- Current legal stipulations "*defeat patient safety efforts and are contrary [...] principles of good engineering.*" Health Care Renewal
  http://hcrenewal.blogspot.com/2009/03/health-care-information-technology.html
- Call for adapted regulation/legislation (certification is now mandatory in Canada)
  - However, main issues of HIT software not sufficiently covered: *Knowledge Aspect*

A Systematic Literature Review on Medical SW Certification

- RQ1. How much research activity is in the area of medical software certification?
- RQ2. What issues/topics of medical software certification have been studied?
- RQ3. What research approaches, techniques, methods and tools are used by researchers to address these issues?
- RQ4. Does this research contribute to practice by providing guidelines or frameworks for medical software certification?
- RQ5. What are the limitations of the current research?


ACM Digital Digital Library
IEEE Xplore
Computer Sicence Index
Springer Link
Science Direct
Wiley Interscience
Compandex
Inspec
search key terms and synonyms in title, abstract, fulltext or author keywords
control term search
search key terms and synonyms in title and abstract
Title + abstract exclusion by key terms and synonyms
Over 1700 hits
Title and abstract exclusion by the domain and form of certification
70 references
Full text exclusion by the domain and form of certification, the targeted software set
Scan references
14 relevant papers and 4 secondary relevant papers

Distribution of Results



J. Forsström. **Why certification of medical software would be useful?** *International Journal of Medical Informatics* 47 (1997) 143–152

- The distinction between device-related (certifiable) software and other HIT software is becoming obscure.
- For historical reasons, medical software is evaluated similar to medical devices: *Technical*. No focus on medical knowledge included and updated.
- Evaluation of drugs as a model for medical software
  - *serverovigilance* analog to *pharmacovigilance*
- Beneficiaries: Users, developers, insurers, device manuf., patients
- Guidance on registration

J. Niinimäki **Approaches for certification of electronic prescription software** *International Journal of Medical Informatics 47 (1997) 175–182*

- Software directly operating a device connected to a patient or making unattended decisions about medical care **should naturally be certified** and supervised to avoid health-threatening error situations.
- Exclude software when competent humans are interpreting the results before decisions concerning care are made.

Example MAUDE Report #2

Company *** CORP.
Device Type CPOE
EventInjury
Event Date 1/24/2007
FDA Received1/8/2010
Days to Report 1,080
Outcome Life Threatening
Description Electronic order entered in to the cpoe contrivance ordering the holding of sliding scale insulin at night time. The order was delivered to an electronic file on the nurse's module. This order was not seen by the nurse. Insulin was given. Hypoglycemia with severe symptoms ensued. Orders are delivered without notification to electronic files of the nurse's module. There is a design flaw consisting of failures of the contrivance to link free text orders to specific treatments and medications and to notify health care professionals of new or stat orders. User error is invariably extended as cause to cover-up the design defect facilitating such error.

J. Wyatt **Quantitative evaluation of clinical software, exemplified by decision support systems** *International Journal of Medical Informatics 47 (1997) 165–173*

- Knowledge in CDSS most difficult to certify
- Randomized Controlled Trials (RCT) suggested, *but*...
  - Checklist effect
  - Contamination effect (randomize providers, not patients)
  - Hawthorne effect
  - knowledge evolution

D. C Classen et al. **Evaluation and Certification of Computerized Provider Order Entry Systems**

JAMIA 14: 48-55 (2007)

- Certification of CPOE Software
- Certification Commission for Healthcare Information Technology (CCHIT)
- Leapfrog approach to CPOE testing: estimate safety risk (frequency/severity) based on random sample from "gold standard"

RX 08.09	Support for drug interaction and error checking	The system shall provide the ability to set the severity level at which drug interaction warnings should be displayed.	2009	N		**AM 19.05**	**ADM.06**
RX 08.10	Support for drug interaction and error checking	The system shall provide the ability to check for dose ranges based on patient age and weight.	2009	N	CCHIT	**Source is public comments and WG discussion related to MIPPA.**	**1.23**
RX 08.13	Support for drug interaction and error checking	The system shall facilitate selection of the preferred route(s) for a medication or alert if an inappropriate route is selected that is not appropriate for the medication/form.	2009	N	This criterion is excluded for compounded and text-based medications.	**AM 11.11**	**1.29**

Category	Description
Therapeutic duplication	Therapeutic overlap with another new or active order; may be same drug, same drug class, or components of combination products
Single and cumulative dose limits	Specified dose that exceeds recommended dose ranges; will result in a cumulative dose that exceeds recommended ranges; can also include dose limits for each component of a combination product
Allergies and cross allergies	Allergy has been documented or allergy to other drug in same category exists
Contraindicated route of administration	Order specifying a route of administration that is not appropriate for the identified medication
Drug–drug and drug–food interactions	Results in known dangerous interaction when administered together with a different medication or results in an interaction in combination with a drug or food group
Contraindications/ dose limits based on patient diagnosis	Contraindication based on patient diagnosis or diagnosis affects recommended dosing
Contraindications/dose limits based on patient age or weight	Contraindication based on age or weight

D. C Classen et al. **Evaluation and Certification of Computerized Provider Order Entry Systems**

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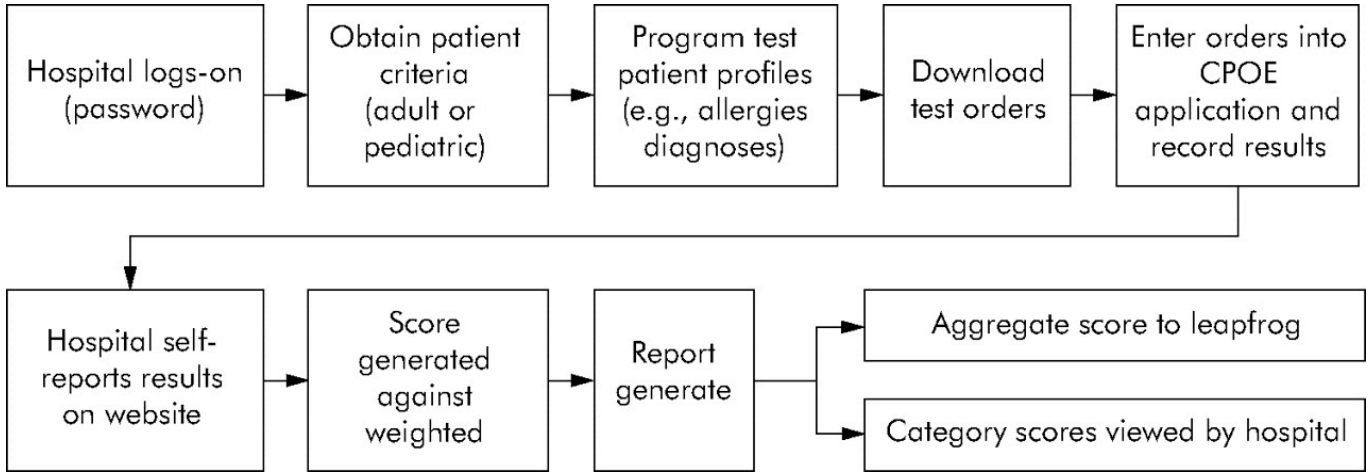
Leapfrog



M.M. Abdeen et al. **FDA: Between Process & Product Evaluation** *Joint Workshop on High Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability (2007)*

- Critical view at FDA approach to certification
  - process vs. product
  - absence of explicit criteria and measures
  - comparison with Common Criteria

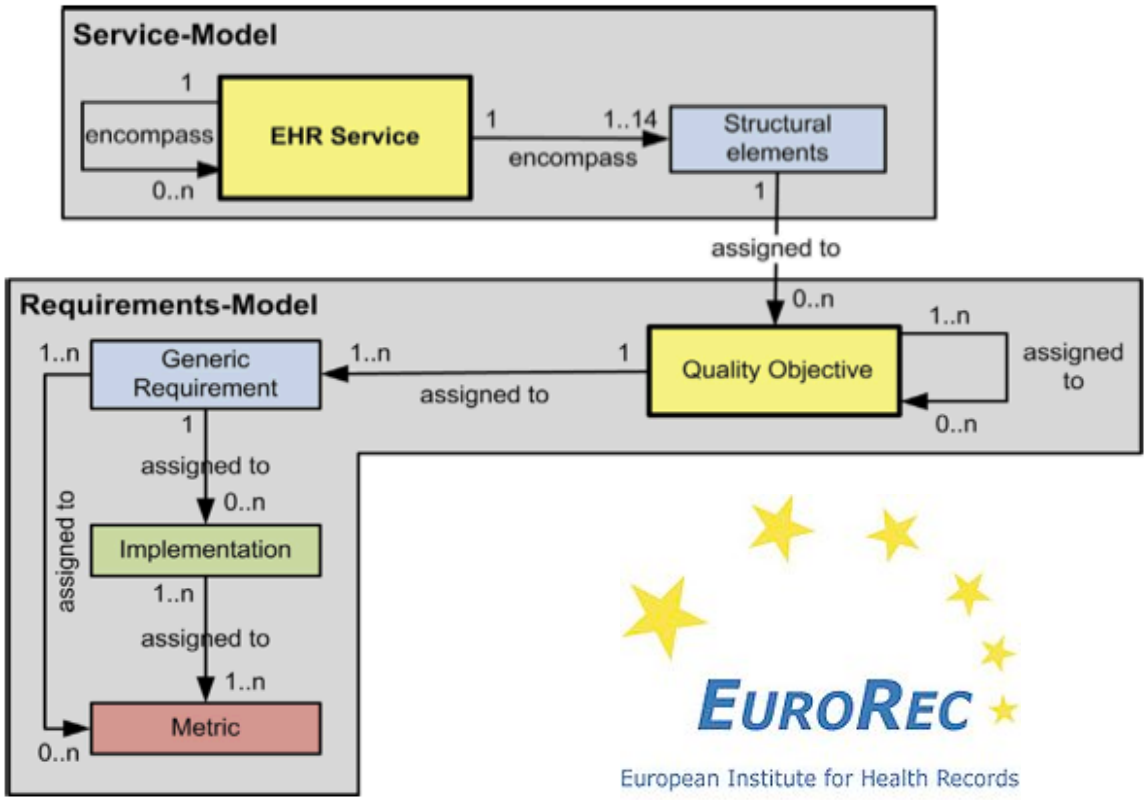
K. Rohloff et al. **Software Certification for Distributed, Adaptable Medical Systems: Position Paper on Challenges and Paths Forward** *Joint Workshop on High Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability (2007)*

How to certify medical devices for PnP and ad hoc adaptation?

- Idea of 'Continuous certification'

A. Hoerbst et al. **A Structural Model for Quality Requirements regarding Electronic Health Records – State of the art and first concepts** ICSE *Workshop on Software Engineering in Health Care,2009*

"Common Criteria" for EHR software?



EuroRec
European Institute for Health Records

Requirements Portal Service – User Interface
QO - The interface should be user friendly (UI57)
GR - The user interface should be context sensitive (UI12)
QO - Forms should be user friendly (UI32)
GR - Forms should be structured (UI39)
GR - The user interface should be consistent (UI19)
IP - Icons should be unambiguous and conform to industry standards (UI86)
IP - The fonts should be consistent and easily readable (UI124)
IP - Screen item placement should be predictable (UI432)
GR - The user interface should be customizable (UI213)
IP - Font size should be customizable (UI17)
IP - Icon placement should be customizable (UI83)

Conclusion

- Need for certification/regulation
  - investment policies informed by studies of carefully groomed HIT systems
  - HIT Goldrush - Commercial systems have many issues
  - Market asymmetry creates "market of lemons"
  - learnt intermediaries / gag orders defeat safety and are contrary to good engineering
- Empirical safety issues with HIT largely deal with issues of knowledge communication/transformation/processing
- Current research body on certifying (medical) software does not respond to these issues
  - process-based approach does not catch data/knowledge/issues
  - Traditional formal methods don't help much