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Safety risks of digital health technologies: current state and a peek into the future

A/Prof. Farah Magrabi

5th Scandinavian Conference on
SYSTEM & SOFTWARE SAFETY
Stockholm, May 22-23, 2017

Outline

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1. Healthcare delivery challenges
2. Evidence and nature of IT risks to patients
3. IT safety initiatives
4. Future risks

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Current safety challenges in healthcare

Patient safety is a major public health crisis

Hospitals

- 10% of admissions associated with patient harm
- UK: 850,000 adverse events per year
- 1 in 5 lead to permanent disability or death
- 50-70% were preventable

Citizens

- 1 in 4 EU citizens affected by medical error
- 18% experienced serious errors in hospital
- 11% prescribed wrong medications

Medical error, third leading cause of death in the USA

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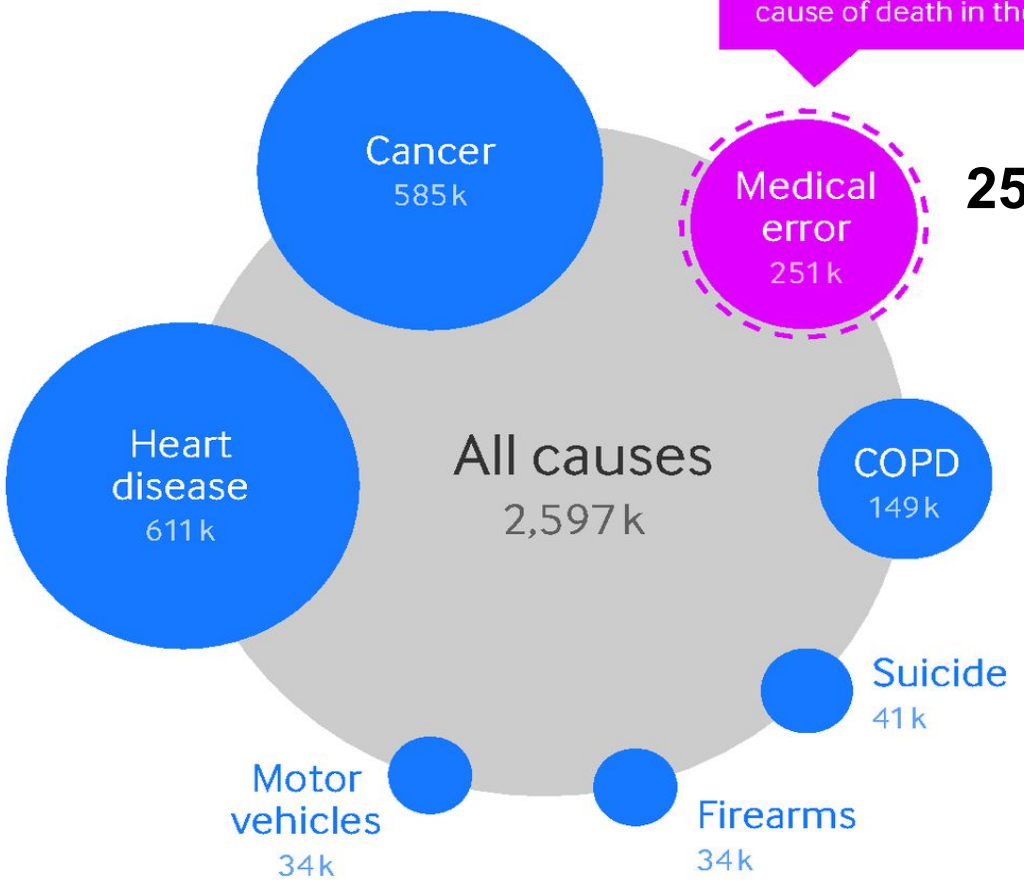
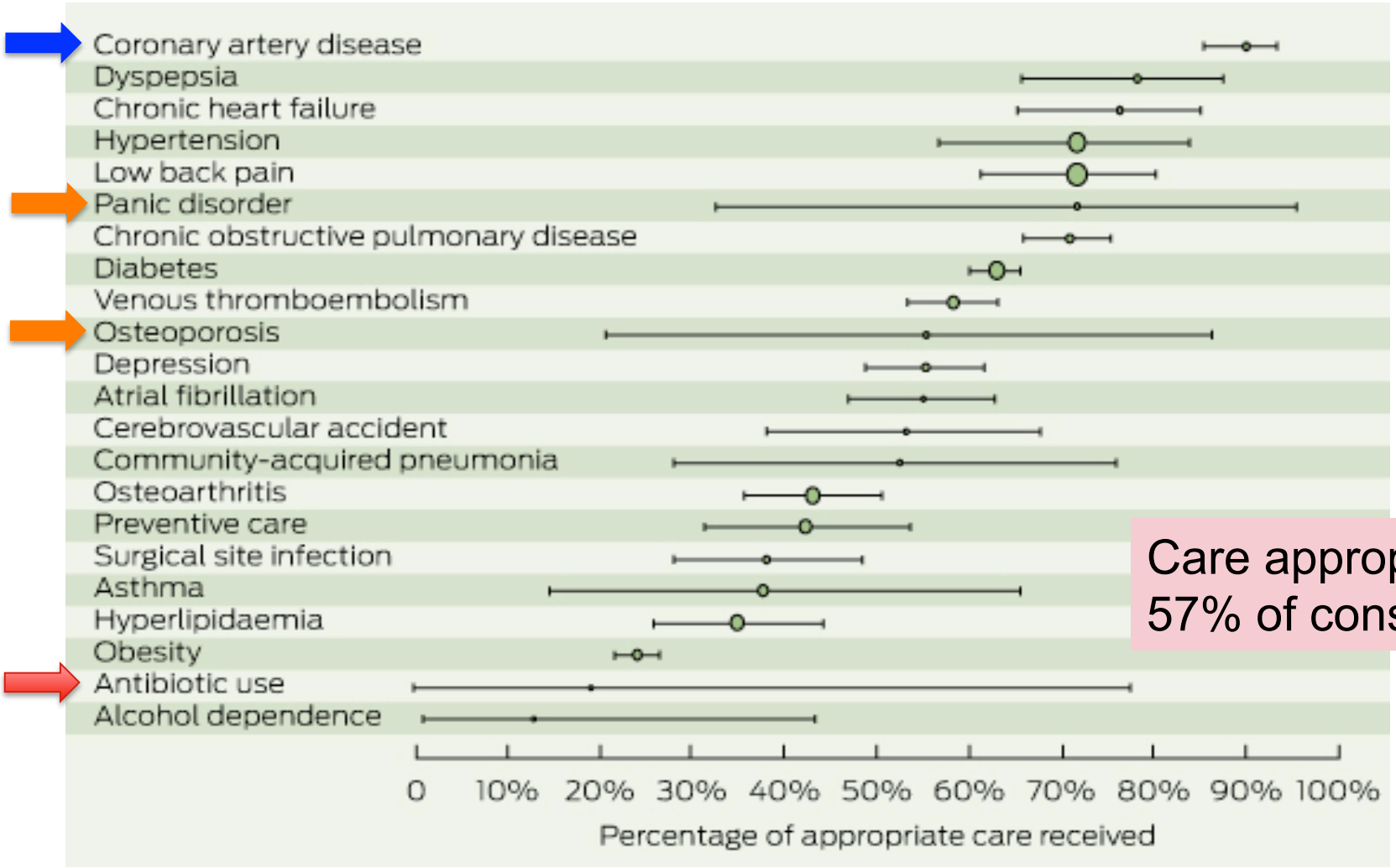


250,000 deaths

However, we're not even counting this - medical error is not recorded on US death certificates

Data source:
http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_02.pdf

Care delivery is highly variable and inappropriate



Care appropriate in 57% of consultations

CareTrack Australia

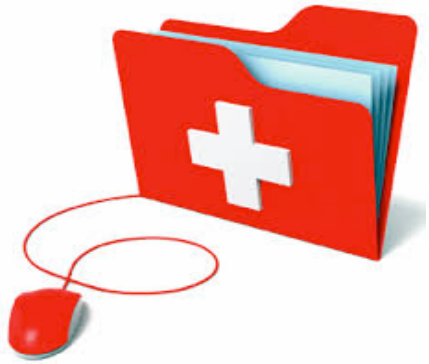
Runciman et al. MJA 2012

Digital health is essential to system reform

decision-making

messaging

record-keeping



IT systems support critical health processes

Pathology testing




test ordered

specimen collected

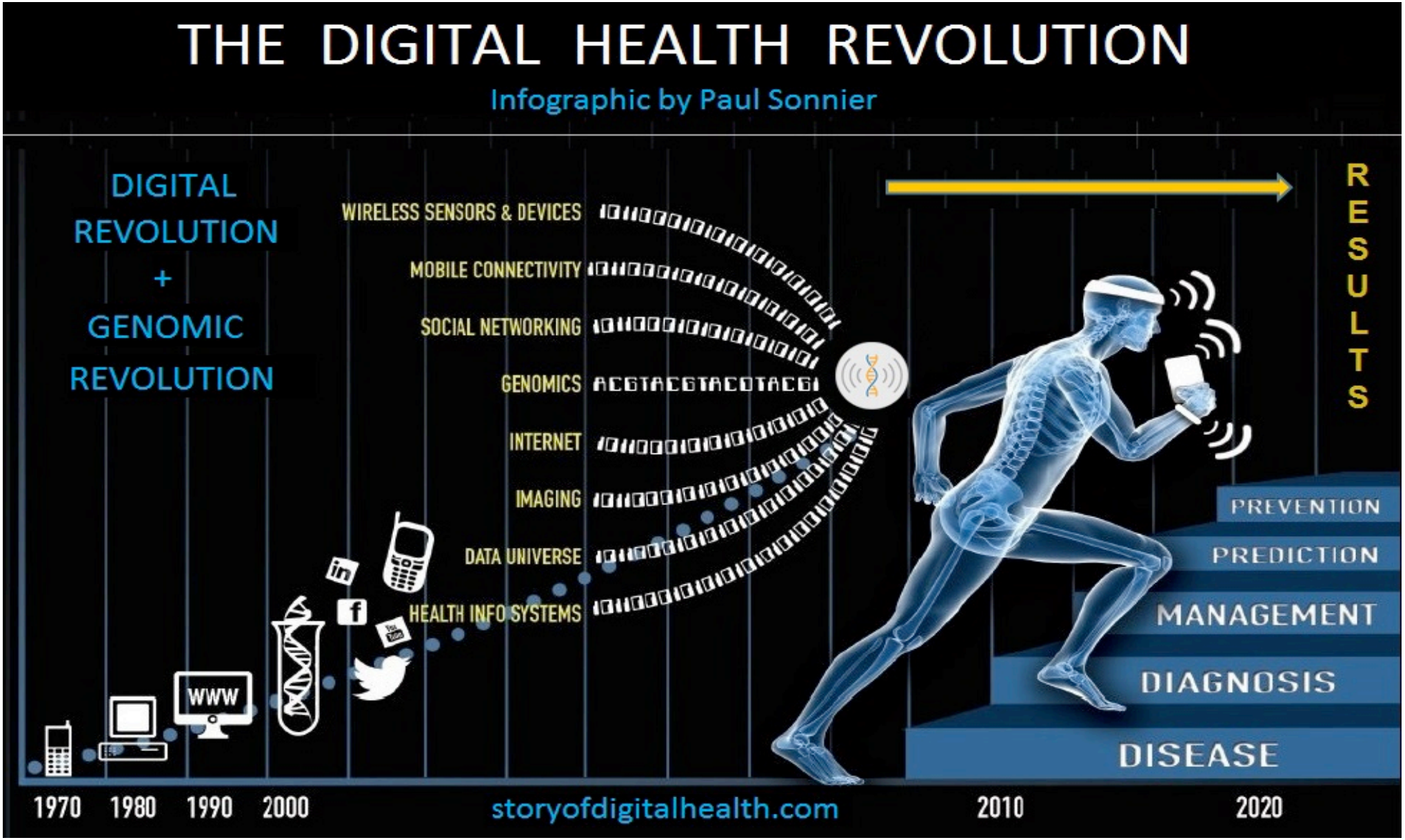
results available

results read

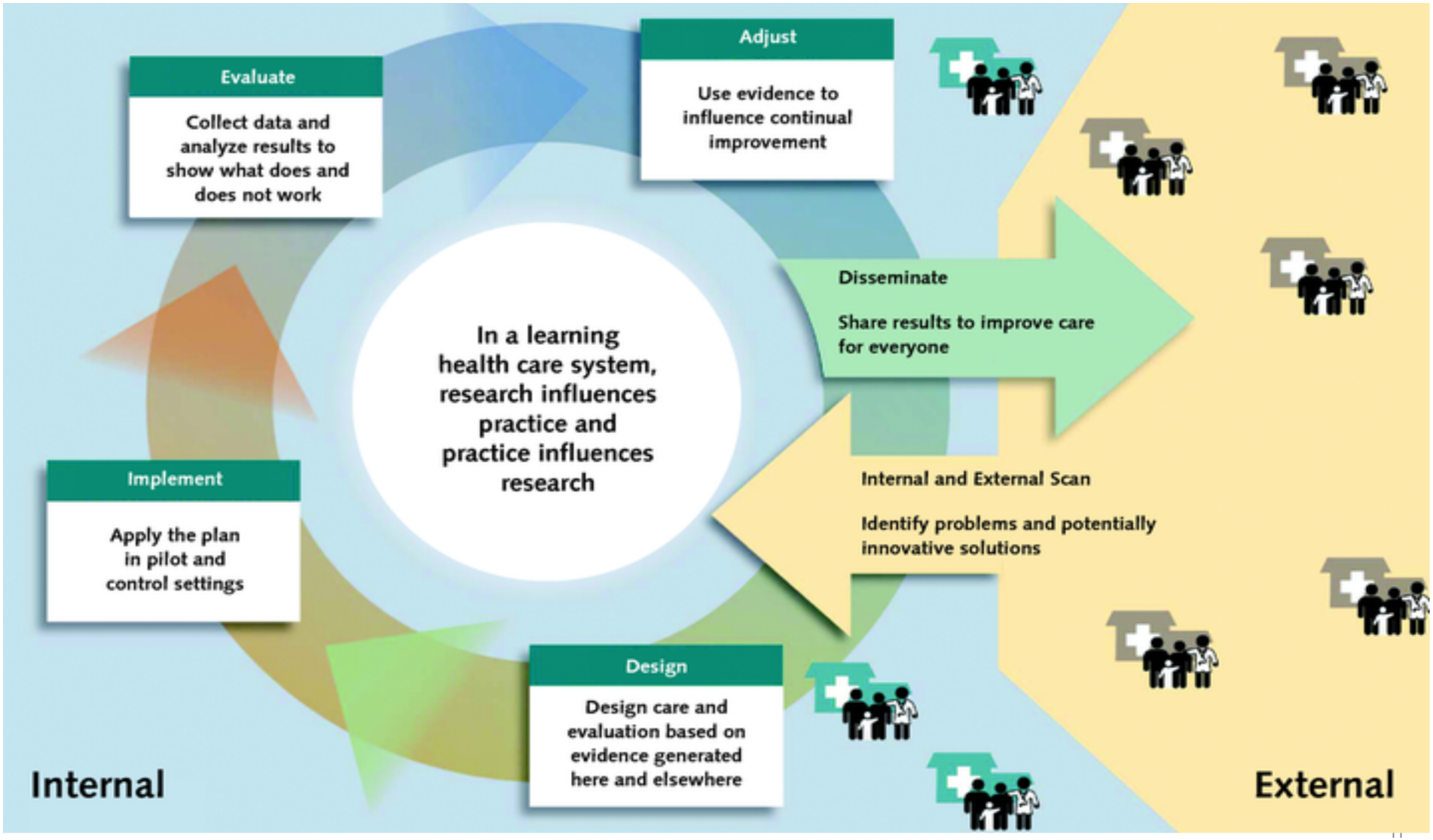
Medical devices are networked

Consumers are more engaged in their health

phoenixchildrens.org


THE DIGITAL HEALTH REVOLUTION
Infographic by Paul Sonnier
DIGITAL REVOLUTION + GENOMIC REVOLUTION
WIRELESS SENSORS & DEVICES
MOBILE CONNECTIVITY
SOCIAL NETWORKING
GENOMICS
ACGTACGTACGTACGT
INTERNET
IMAGING
DATA UNIVERSE
HEALTH INFO SYSTEMS
WWW
RESULTS
PREVENTION
PREDICTION
MANAGEMENT
DIAGNOSIS
DISEASE
1970
1980
1990
2000
storyofdigitalhealth.com
2010
2020

By 2035: a learning health system



Ann Intern Med. 2012;157(3):207

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Digital technologies bring many benefits to health care delivery

…but evidence of patient harm is mounting

Using FDA reports to inform a classification for health information technology safety problems

Farah Magrabi,[1] Mei-Sing Ong,[1] William Runciman,[2,3] Enrico Coiera[1]

► Additional materials are published online only. To view these files please visit the journal online (www.jamia.org/content/19/1.toc).

[1]Centre for Health Informatics, Australian Institute for Health Innovation, University of New South Wales, Sydney, Australia
[2]The School of Psychology, Social Work & Social Policy, University of South Australia, South Australia, Australia
[3]Australian Patient Safety Foundation, Adelaide, South Australia, Australia

Correspondence to
Dr Farah Magrabi, Centre for Health Informatics, University of New South Wales, Sydney 2052, Australia;
f.magrabi@unsw.edu.au

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Published Online First
8 September 2011

ABSTRACT

Objective To expand an emerging classification for problems with health information technology (HIT) using reports submitted to the US Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database.

Design HIT events submitted to MAUDE were retrieved using a standardized search strategy. Using an emerging classification with 32 categories of HIT problems, a subset of relevant events were iteratively analyzed to identify new categories. Two coders then independently classified the remaining events into one or more categories. Free-text descriptions were analyzed to identify the consequences of events.

Measurements Descriptive statistics by number of reported problems per category and by consequence; inter-rater reliability analysis using the κ statistic for the major categories and consequences.

Results A search of 899 768 reports from January 2008 to July 2010 yielded 1100 reports about HIT. After removing duplicate and unrelated reports, 678 reports describing 436 events remained. The authors ide… four new categories to describe problems with s… functionality, system configuration, interface with … and network configuration; the authors' classificat… 32 categories of HIT problems was expanded by … addition of these four categories. Examination of the 436 events revealed 712 problems, 96% were machine-

HIT was listed in the top 10 technology-related hazards identified by the Emergency Care Research Institute among a range of common problems.[9]

Strategies to minimize the risks of HIT need to be based upon a proper understanding of the nature of problems encountered, their contributing factors, and their safety implications.[10] As in other patient safety domains (eg, falls, medication errors) there is no single source of information about HIT problems. A range of information sources, including record reviews, root cause analyses, and observational studies are required (see appendix A, supplementary material at www.jamia.org).[11 12] Reports on patient safety incidents are a valuable source because they facilitate rapid communication about emerging problems[13 14] and have been proposed as one of seven steps to improve safety.[13 14] A definition of a patient safety incident is 'an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient'.[15] In this study we focus on patient safety incidents …ed to …d are …they …lems, contributing factors, and consequences so that the most safety-critical problems can be identified.[17]

- patient harm (n=46)
- four deaths

Reports of IT-related harms are growing

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2010	2011	2012	2013	2014	2015	2016

SA Health

FDA

VA HEALTH CARE

ECRI Institute

Dutch CMR

NHS England

COMMONWEALTH OF PENNSYLVANIA
PATIENT SAFETY AUTHORITY

The Joint Commission

NHS WALES GIG CYMRU

TechWatch

Kim, Coiera & Magrabi JAMIA 2017

The Joint Commission Journal on Quality and Patient Safety

Information Technology

The Contribution of Sociotechnical Factors to Health Information Technology–Related Sentinel Events

Gerard M. Castro, PhD, MPH; Lisa Buczkowski, MS, RN, CPPS; Joanne M. Hafner, MS, RN

120 sentinel events affecting 125 patients

>50% patient death
30% unexpected or additional care
11% permament loss of function

- medication errors
- wrong-site surgery
- treatment delays

health informa-
to sentinel events
nt and use health
ow health IT may
n death or severe

nel events volun-
etween January 1,
keyword queries
T–related events.
d on the basis of
) to determine if
nt, and if so, how

insufficient staff training, lack of time, and limited resources.[6–13]

Health IT–related adverse events occur in the context of complex health care systems that are "sociotechnical" in nature, involving interaction between technology, people, processes, organizations, and the external environment.[14–17] Evaluating the sociotechnical factors that contribute to health IT–related ad-

and why. The contributing factors were classified using a composite of existing classification schemes.

Results: A total of 120 health IT–related sentinel events (affecting 125 patients) were identified. More than half resulted in patient death, 30% resulted in unexpected or additional care, and 11% resulted in permanent loss of function. The

OPEN ACCESS Freely available online PLoS MEDICINE

Effects of Two Commercial Electronic Prescribing Systems on Prescribing Error Rates in Hospital In-Patients: A Before and After Study

Johanna I. Westbrook[1]*, Margaret Reckmann[1], Ling Li[1], William B. Runciman[2], Rosemary Burke[3], Connie Lo[1¤], Melissa T. Baysari[4], Jeffrey Braithwaite[5], Richard O. Day[6]

1 Centre for Health Systems and Safety Research, Australian Institute of Health Innovation, Faculty of Medicine, University of New South Wales, Sydney, Australia, 2 School of Psychology, Social Work & Social Policy, University of South Australia, Adelaide, Australia, 3 Pharmacy Department, Concord Repatriation General Hospital, Sydney, Australia, 4 Aust
Australian Institu
Vincent's Hospit

" use of the system resulted in a decline in errors at Hospital A from **6.25** per admission (95% CI 5.23–7.28) to **2.12** (95% CI 1.71–2.54; p,0.0001) and at Hospital B from **3.62** (95% CI 3.30–3.93) to **1.46** (95% CI 1.20–1.73; p,0.0001)."

"Both hospitals experienced system-related errors (0.73 and 0.51 per admission) which accounted for **35%** of postsystem errors."

Abstra

Backgro many c
interacti
associate
prescribing error rates and their propensities for introducing new types of error.

Methods and Results: We conducted a before and after study involving medication chart audit of 3,291 admissions (1,923
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acted as
after err
errors we
scale, th
"system-
prescribi
(respectively reductions of 66.1% [95% CI 53.9%–78.3%]; 57.5% [33.8%–81.2%]; and 60.5% [48.5%–72.4%]). The use of the system resulted in a decline in errors at Hospital A from 6.25 per admission (95% CI 5.23–7.28) to 2.12 (95% CI 1.71–2.54; $p<0.0001$) and at Hospital B from 3.62 (95% CI 3.30–3.93) to 1.46 (95% CI 1.20–1.73; $p<0.0001$). This decrease was driven by a large reduction in unclear, illegal, and incomplete orders. The Hospital A control wards experienced no significant change (respectively −12.8% [95% CI −41.1% to 15.5%]; −11.3% [−40.1% to 17.5%]; −20.1% [−52.2% to 12.4%]). There was limited change in clinical error rates, but serious errors decreased by 44% (0.25 per admission to 0.14; $p=0.0002$) across the intervention wards compared to the control wards (17% reduction; 0.30–0.25; $p=0.40$). Both hospitals experienced system-related errors (0.73 and 0.51 per admission), which accounted for 35% of postsystem errors in the intervention wards; each system was associated with different types of system-related errors.

Conclusions: Implementation of these commercial e-prescribing systems resulted in statistically significant reductions in prescribing error rates. Reductions in clinical errors were limited in the absence of substantial decision support, but a statistically significant decline in serious errors was observed. System-related errors require close attention as they are frequent, but are potentially remediable by system redesign and user training. Limitations included a lack of control wards at Hospital B and an inability to randomize wards to the intervention.

2012;9:1

IT incidents can lead to large-scale adverse events

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Boston Children's emerges from electronic records shutdown

25 Mar 2015

IT, EHR go dark at 13-hospital system

3 Aug 2015

Data centre outage hits all Queensland hospitals

10 Dec 2014

Cyber attack that paralysed NHS hospitals spreads to at least 75,000 people in 100 countries

14 May 2017

INTERNATIONAL JOURNAL OF MEDICAL INFORMATICS 84 (2015) 198–206

journal homepage: www.ijmijournal.com

Clinical safety of England's national programme for IT: A retrospective analysis of all reported safety events 2005 to 2011

Farah Magrabi[a,*], *Maureen Baker*[b], *Ipsita Sinha*[c], *Mei-Sing Ong*[a], *Stuart Harrison*[b], *Michael R. Kidd*[d], *William B. Runciman*[e,f], *Enrico Coiera*[a]

[a] *Centre for Health Informatics, Australian Institute of Health Innovation, Macquarie University, Australia*
[b] *Health and Social Care Information Centre, Leeds, England*
[c] *Oxford University NHS Trust, England*
[d] *Faculty of Medicine, Nursing and Health Sciences, Flinders University, Australia*
[e] *The School of Psychology, Social Work & Social Policy, University of South Australia, Australia*
[f] *Australian Patient Safety Foundation, Adelaide, Australia*

Large-scale events

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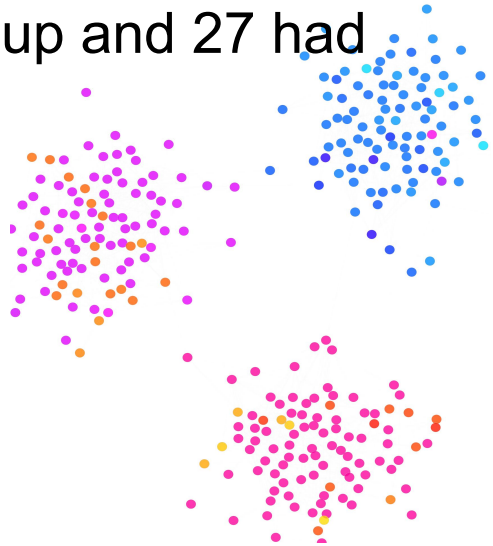
Records: 2500 radiology images used for diagnostic and pre-operative purposes **could not be accessed** due to a database failure.

Workstations: 28 PACS workstations in a trust were **incorrectly configured** and could deliver overdoses of radiation with an error of up to 20%.

Practices: Patient records were **wrongly merged** when **migrated** between practices; 2700 practices had to be followed up and 27 had 900 transactions that needed manual checking.



1 in 4 large-scale events were downtimes

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- Systems: PACS, patient administration system, IT infrastructure
- Problems:
  - unavailable
  - slow
  - power failure
- Duration: 17 min to 6 days
- Scope: up to 66,000 records
- Planned and unplanned events

The **PACS was not available across a trust** because the engineering department decided to do a generator test and switched off the hospital power supply without warning anyone.

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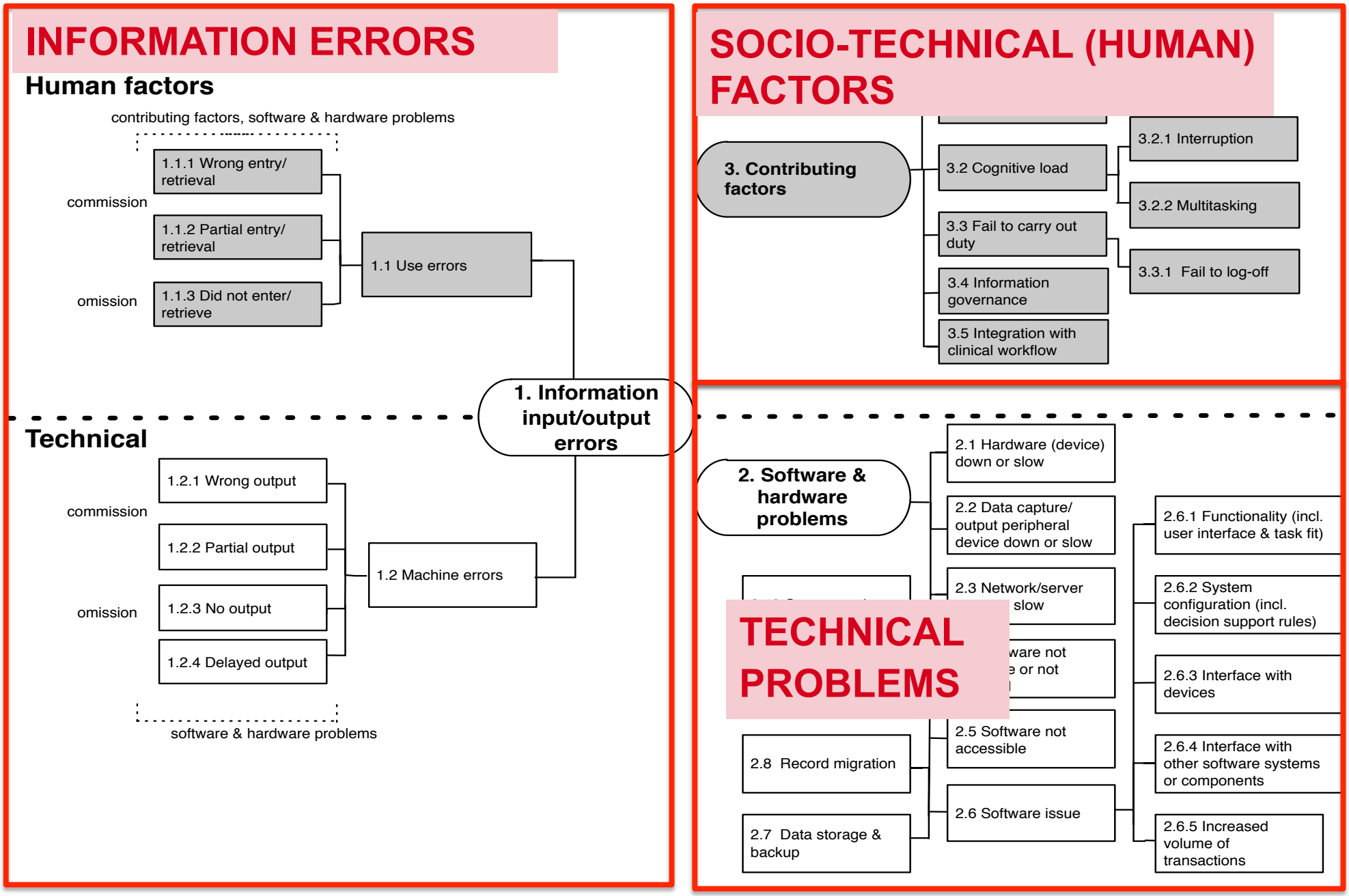
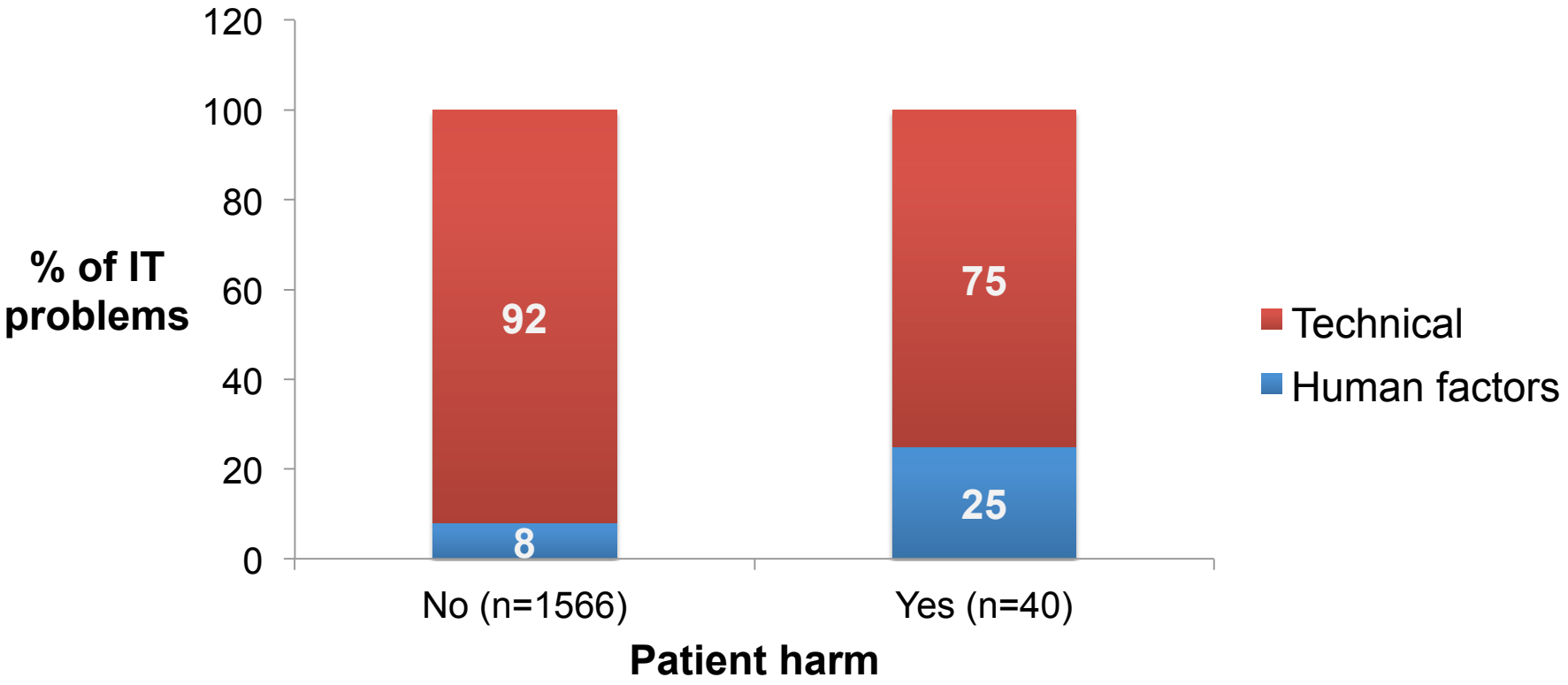
IT-related harms have their origin in system design, implementation or use


INFORMATION ERRORS
Human factors
contributing factors, software & hardware problems
1.1.1 Wrong entry/ retrieval
commission
1.1.2 Partial entry/ retrieval
1.1.3 Did not enter/ retrieve
omission
1.1 Use errors
1. Information input/output errors
Technical
1.2.1 Wrong output
commission
1.2.2 Partial output
1.2.3 No output
omission
1.2.4 Delayed output
1.2 Machine errors
software & hardware problems
SOCIO-TECHNICAL (HUMAN) FACTORS
3. Contributing factors
3.2 Cognitive load
3.2.1 Interruption
3.2.2 Multitasking
3.3 Fail to carry out duty
3.3.1 Fail to log-off
3.4 Information governance
3.5 Integration with clinical workflow
TECHNICAL PROBLEMS
2. Software & hardware problems
2.1 Hardware (device) down or slow
2.2 Data capture/ output peripheral device down or slow
2.3 Network/server slow
2.5 Software not accessible
2.6 Software issue
2.8 Record migration
2.7 Data storage & backup
2.6.1 Functionality (incl. user interface & task fit)
2.6.2 System configuration (incl. decision support rules)
2.6.3 Interface with devices
2.6.4 Interface with other software systems or components
2.6.5 Increased volume of transactions

Human factors problems were proportionally higher in patient harm events



4 times as likely to result in patient harm than technical problems

- 25% vs. 8% (Chi sq =13, df =1, p<0.001)
- Odds ratio 4 (2 to 8)

Magrabi et al. IJMI 2015

Knowledge & skills of users

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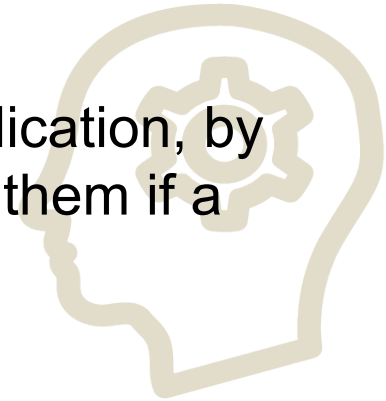
Use error: A patient who was seen with **another patient's records** in general practice was prescribed that patient's medication and died later the same day from taking it. No further details were available.

Use error: A doctor intended to prescribe 4 mg trandolapril for an elderly male patient, but **mistakenly prescribed** Amaryl 4 mg (glimepiride). On taking the medication the patient went into a hypoglycemic coma and had seizures. He was resuscitated in an ICU and admitted to hospital for a week.

System limitations: A doctor prescribed the wrong medication, by **wrongly assuming** that the system would have alerted them if a mistake had been made.



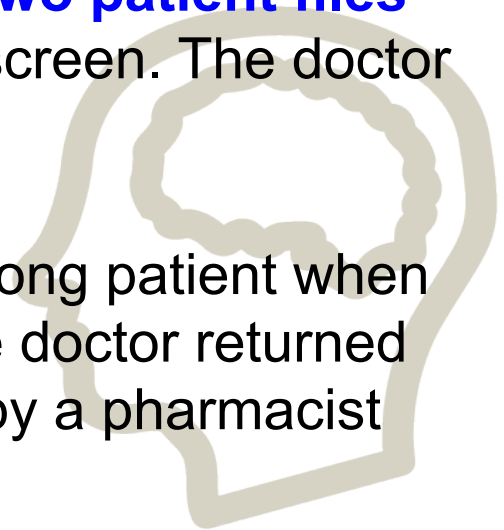
Magrabi et al. IJMI 2015; BMJ Qual Saf 2016

Cognitive resources devoted to system use

Slip of concentration: **Avanza** (mirtazepine) was prescribed instead of **Avandia** (rosiglitazone) due to a slip in concentration. A pharmacist detected the error because the patient did not suffer from diabetes and contacted the doctor to issue a new prescription.

Multi-tasking, multiple patient files open: A doctor mistakenly prescribed a medication for the wrong patient when **two patient files were opened up simultaneously** on the computer screen. The doctor noticed the error and corrected it.

Interruption: A doctor wrote a prescription for the wrong patient when interrupted by a **phone call**. At the end of the call the doctor returned to the wrong patient record. The error was detected by a pharmacist and returned to the doctor.



Magrabi et al. BMJ Qual Saf 2016

Organizational policies & procedures

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Policy for training & system use: A radiologist who missed a training session had been reporting reporting old films and using the new film as a comparison for 6 months.

Access: System access was erroneously given to all users rather than 14 users who had been trained.

Information governance: An **HIV test** ordered during hospital stay was **not followed-up** after discharge. When the patient was re-admitted, the admitting doctors were unable to access the HIV test result because the **test request was hidden** from them. The patient developed and died from pneumonia.

Magrabi et al. IJMI 2015

Safety initiatives

INTERNATIONAL JOURNAL OF MEDICAL INFORMATICS 82 (2013) e139–e148

journal homepage: www.ijmijournal.com

A comparative review of patient safety initiatives for national health information technology

Farah Magrabi[a,*], *Jos Aarts*[b], *Christian Nohr*[c], *Maureen Baker*[d], *Stuart Harrison*[d], *Sylvia Pelayo*[e], *Jan Talmon*[f], *Dean F. Sittig*[g], *Enrico Coiera*[a]

[a] *Centre for Health Informatics, Australian Institute of Health Innovation, The University of New South Wales, Sydney, Australia*
[b] *Institute of Health Policy and Management, Erasmus University Rotterdam, Rotterdam, The Netherlands*
[c] *Danish Centre for Health Informatics, Department of Development and Planning, Aalborg University, Denmark*
[d] *Department of Health Informatics Directorate, Leeds, England, United Kingdom*
[e] *EVALAB – INSERM CIC IT, University Hospital of Lille, University of Lille Nord de France, F-59000 Lille, France*
[f] *Department Medical Informatics, Maastricht University, Maastricht, The Netherlands*
[g] *University of Texas – Memorial Hermann Center for Healthcare Quality & Safety, School of Biomedical Informatics, University of Texas Health Sciences Center, Houston, TX, United States*

Snapshot of current initiatives

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	Standardization			Oversight		
	Guidance	Standard	Regulation	Certification	Regulation	Incident monitoring
Denmark						
Netherlands						

Foundational Guides

High Priority Practices*

Organizational Responsibilities*

Infrastructure Guides

Contingency Planning*

System Configuration*

System Interfaces*

Computerized Provider Order Entry with Decision Support*

Test Results Reporting and Follow-Up*

Clinician Communication*

HealthIT.gov

NHS Digital

- Safety training
- Risk management standards
- Incident monitoring

Current initiatives address safety of software with limited oversight

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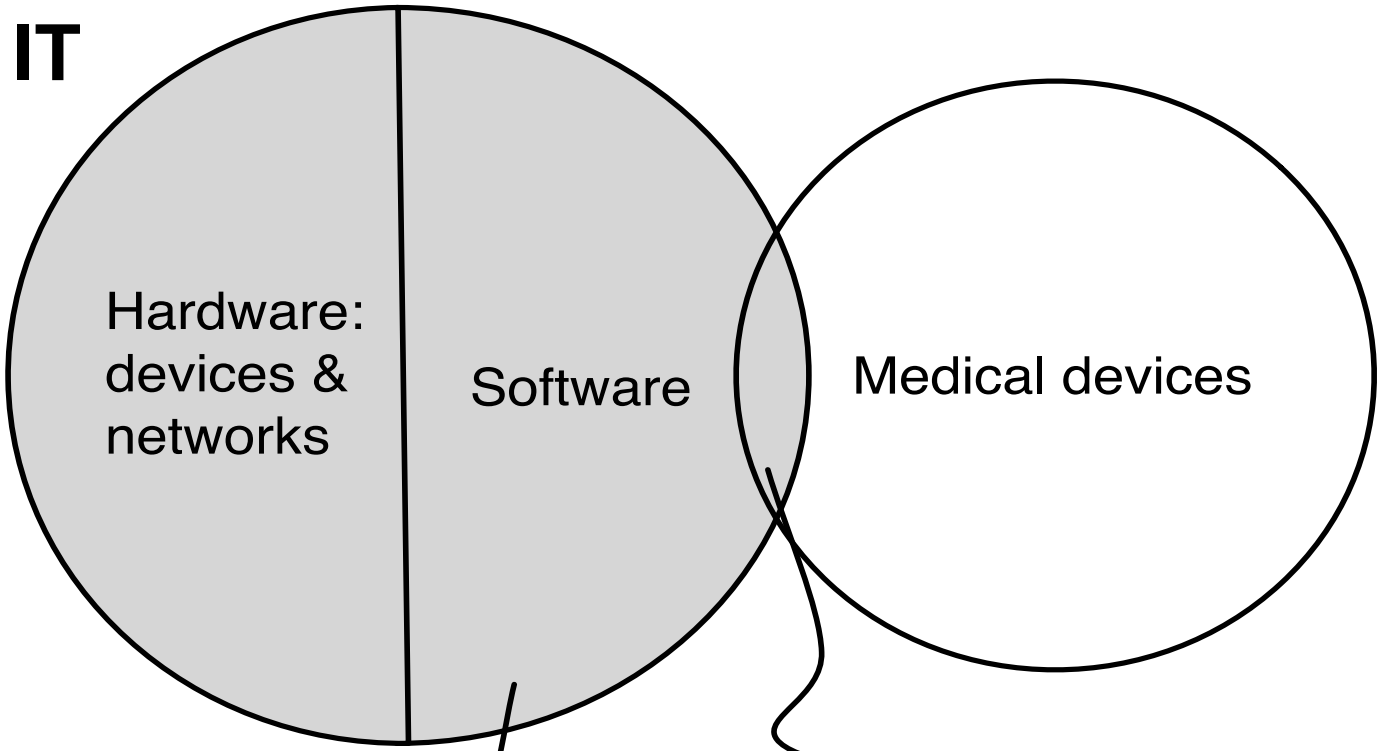

- *Guidelines*
- *Standards*
- *Certification*

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

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The future…

intelligent agents will work alongside humans

Human-computer boundary will blur

	Decision support	Intelligent agents
role	assist human decision-making	+ operate autonomously by reasoning & making decisions
domain	specific clinical area	encompass all health domains
knowledge representation	well-defined, static data	high volume, dynamic data
reasoning methods	-logic-based -statistical -case-based	+ neural networks

Risks of intelligent agents

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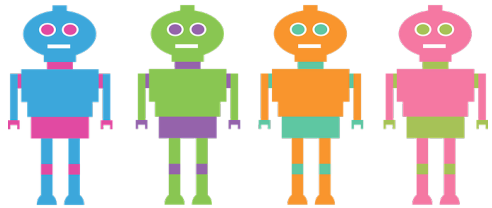
Agents on their own

- knowledge deficiencies: inconsistent, redundant, inaccurate, incomplete, biased



Agents can reinforce bias

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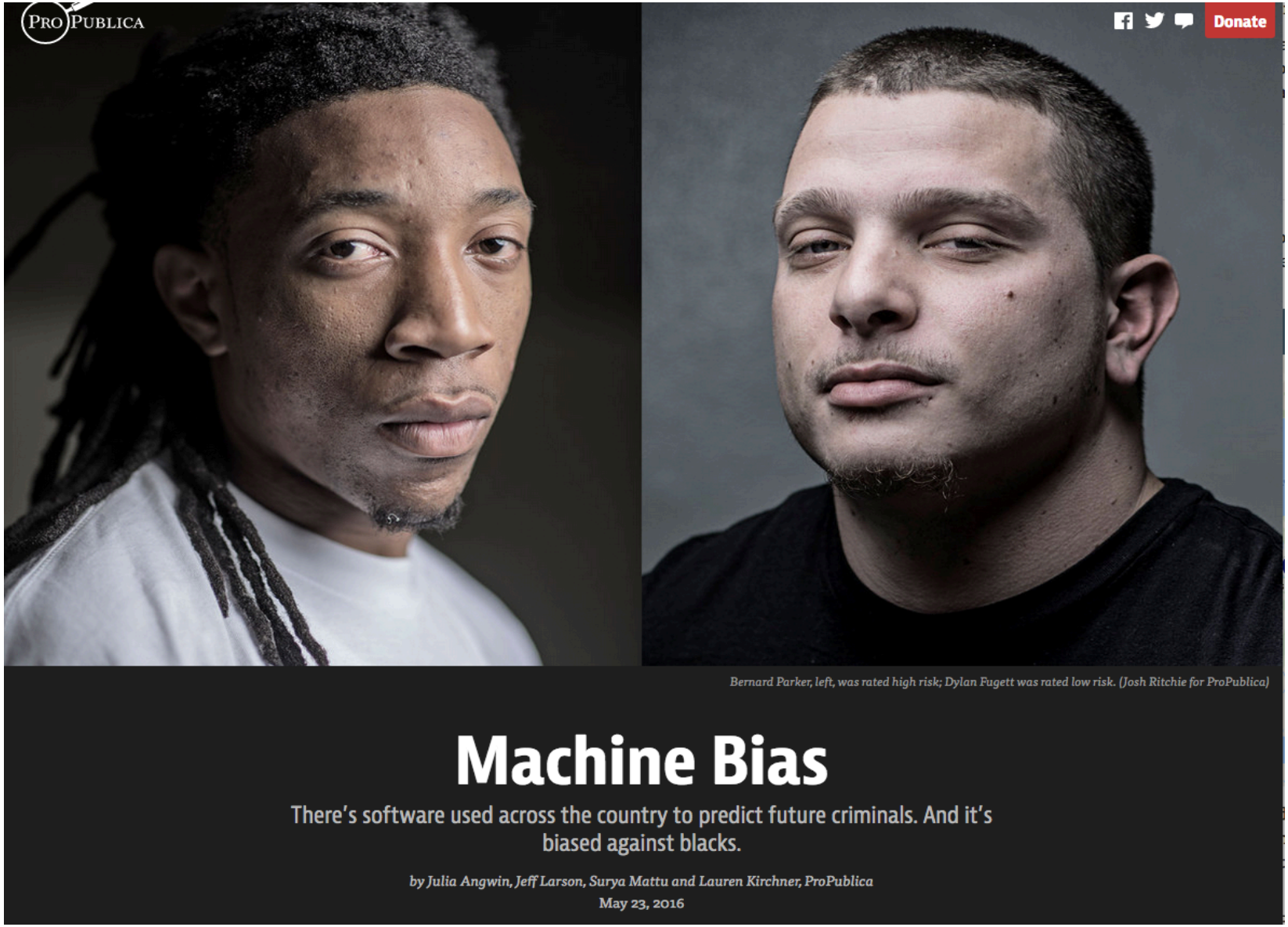
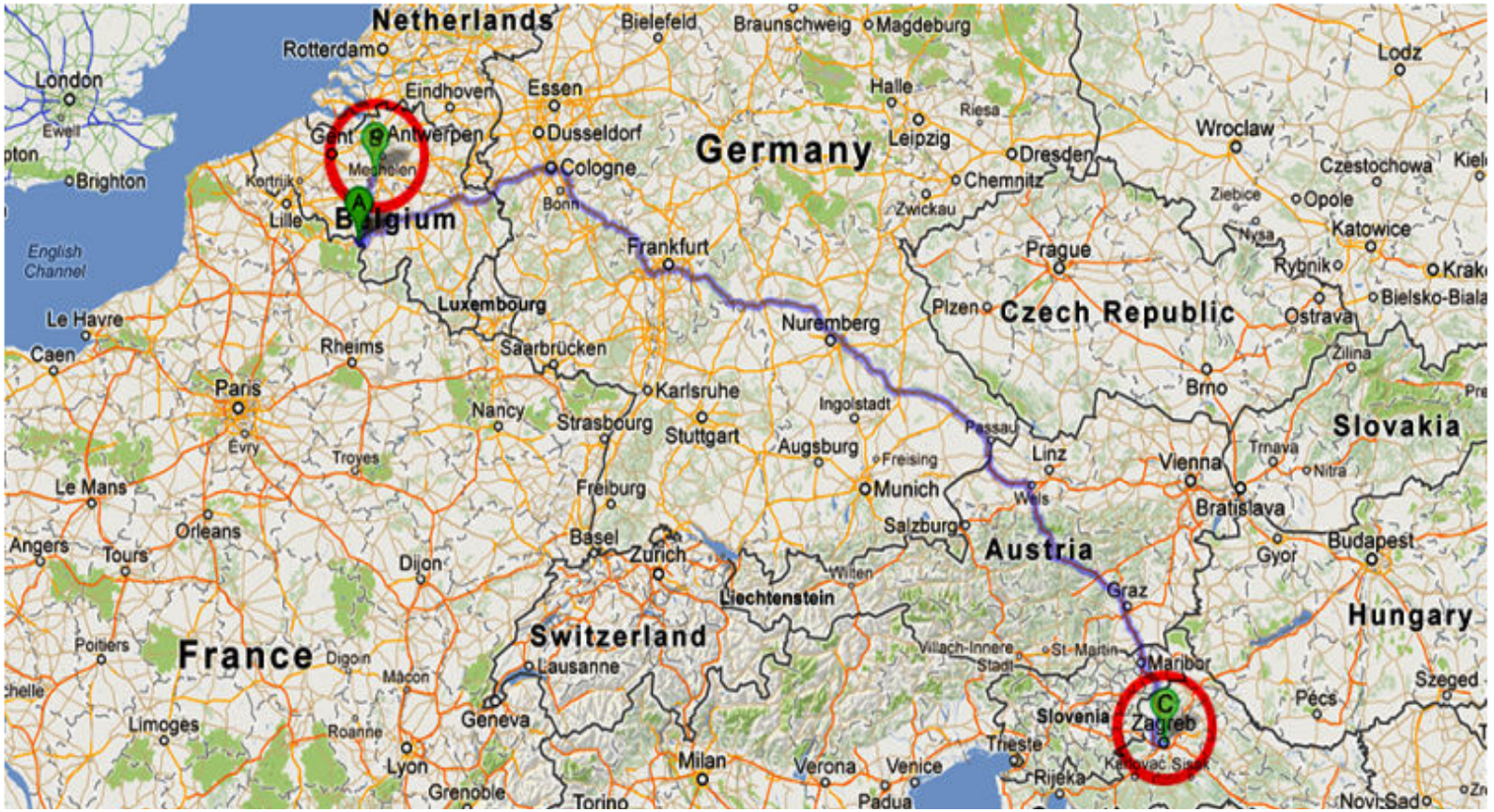


Woman Drives for 900 Miles Instead of 90 Thanks to GPS Error

Jesus Diaz
1/14/13 12:14pm · Filed to: GPS

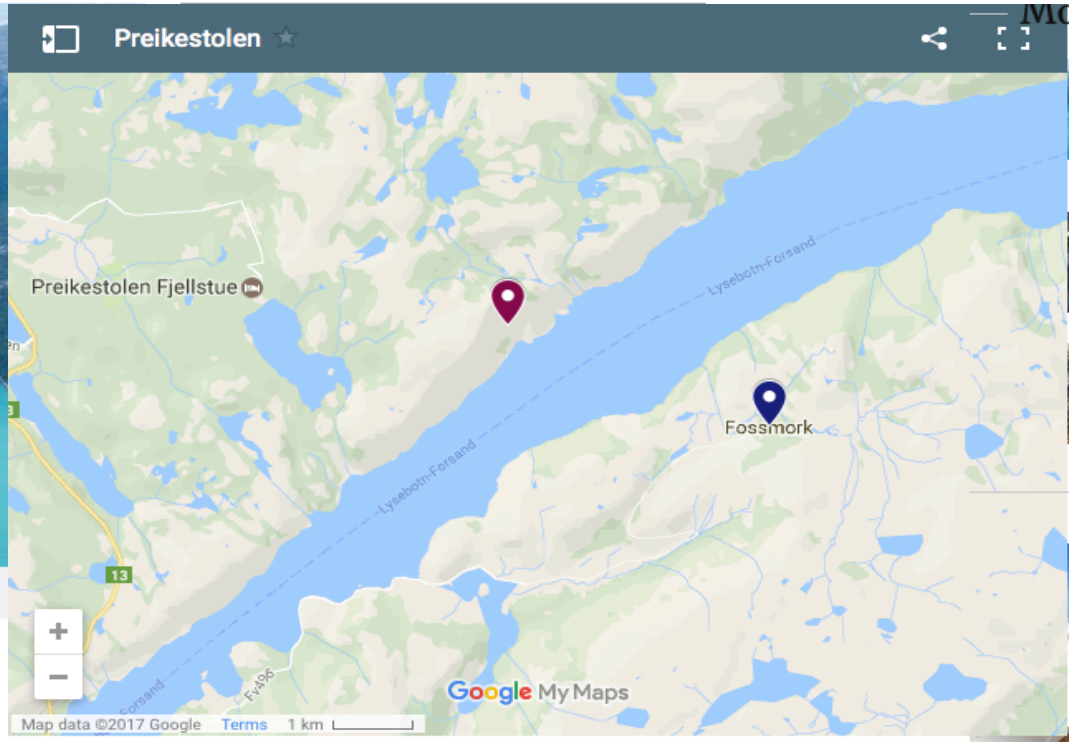
326.6K 483 2



Slide courtesy of D Lyell

Hundreds of tourists directed to nondescript Norwegian village thanks to Google Maps gaffe

The famous Preikestolen cliffs in Norway. Photo: iStock



SMH 14 May 2017

Man killed in Tesla auto-drive crash may have been watching Harry Potter

Barbara Liston and Bernie Woodall

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A digital video disc player was found in the Tesla car that was on autopilot when its driver was killed in a May 7 collision with a truck, Florida Highway Patrol officials said on Friday.

Whether the portable DVD player was operating at the time of the crash has not been determined, however, and witnesses who came upon the wreckage of the 2015 Model S sedan gave differing accounts on Friday about whether the player was showing a movie.

Slide courtesy of D Lyell

Automation bias

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"The tendency to use automated cues as a heuristic replacement for vigilant information seeking and processing"

Mosier & Skitka (1996)

- Arises when automation works well but not perfectly
- Also known as automation induced complacency

Slide courtesy of D Lyell

Automation bias in healthcare

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Table 1: Characteristics of experimental tasks and the reported significance of automation bias

Task	Single or Multi	Subtasks	Task Type	Automation Type	Study	Sample	Trials	Omission Errors	Commission Errors
Mammography, computer-aided detection	Single	Screen mammograms for cancers	D	DS	(14)	19 readers	60 sets of mammograms	$P < .000001^{\#}$	–
					(29)	5 readers	185 sets of mammograms	–	Not reported
					(15)	44 readers	180 mammograms	–	Not reported
EKG, computerized interpretation	Single	Diagnosis of atrial fibrillation	D	DS	(16)	2298 EKGs from 1085 patients		–	Not reported
Clinical decision support system	Single	Prescribe treatment for patient scenarios	T	DS	(30)	26 general practitioners	20 scenarios	–	$P < .05^{\#}$
Clinical decision support system	Single	Answer clinical questions	D	DS	(31)	29 general practitioners	15 questions about clinical cases	–	$P = .031^{\#}$

Slide courtesy of D Lyell

Risks of intelligent agents

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Agents on their own

- knowledge deficiencies: inconsistent, redundant, inaccurate, incomplete, biased data
- situations not previously encountered
- missing context
- mismatched goals, values, preferences

Working with humans

- humans unaware of agent limitations: automation bias
- some reasoning methods lack explanatory power

Working with other AI

Summary

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- Digital health improves safety, but it can also contribute to patient harm.
- IT incidents can mushroom into large-scale adverse events posing risks to numerous patients.
- Magnitude of risk is not known***- tip of the iceberg?***
- Human factors and system use practices are major sources of risk.
- There are significant gaps in safety governance for health IT.
- Current measures are largely focused on software.
- Alongside its benefits, AI will present unique risks.

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Thank you

farah.magrabi@mq.edu.au