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Update on approaches to the review and investigation of health IT-related patient safety incidents

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Preface

This document has two components.

The first section provides an update to the 2017 *Literature Review and Environmental Scan on Approaches to the Review and Investigation of Health IT-Related Patient Safety Incidents* (the 2017 literature scan), that was prepared by the Australian Institute of Health Innovation at Macquarie University for the Australian Commission on Safety and Quality in Health Care (the Commission).[1]

The literature update was undertaken in mid-2018 by the Australian Government Department of Health library, to review the literature published in this area since the 2017 literature review. The review sought to identify notable developments that might alter the findings of the first literature review, especially regarding the classification of health IT-related events.

The second section of this document focuses on a recent environmental scan investigating the literature on data breach incidents relating to hospital clinical information systems, electronic medical records, and electronic health records. This follows passage of the *Privacy Amendment (Notifiable Data Breaches) Act 2017*.[*] Changes outlined in this legislation require health care providers to notify patients or others affected when there is a serious data breach. These breaches may result in unauthorised access to personal health information, including through the national electronic health record system (the My Health Record).[2,3]

[*] *Privacy Amendment (Notifiable Data Breaches) Act 2017* (An Act to amend the *Privacy Act 1988*, and for related purposes) See: https://www.legislation.gov.au/Details/C2017A00012

Update to the literature review and environmental scan on approaches to the review and investigation of health IT-related patient safety incidents

RCA^2

The first literature review identified root cause analysis (RCA) as the key method to investigate patient safety incidents. This is a systematic process used in New South Wales (NSW), and other states and territories of Australia, that attempts to identify and analyse the root causes and any other factors contributing to an incident.[4]

Incidents have varying degrees of severity, and in Australia are assigned severity assessment codes (SACs) or similar risk rating scales. In NSW, the most serious types are rated SAC1, and are the most likely to undergo an RCA investigation.[5] After identifying what, how and why an incident or event occurred, recommended actions are directed at preventing a recurrence.

In 2015, the (US) National Patient Safety Foundation (now part of the Institute for Healthcare Improvement) coordinated and published a report examining best practices around RCA and offering guidelines to help health professionals standardise the RCA process and improve the way they investigate medical errors, adverse events, and near misses[6]. The updated RCA process is referred to as RCA^2 (RCA 'squared'). The RCA^2 report provided guidance on issues including identifying events suitable for RCA, timing of RCA, RCA team size and composition, RCA process, steps, tools, actions, measurements, leadership, and effectiveness and sustainability.

The resource was endorsed by many organisations, including the Canadian Patient Safety Institute, Children's Health Queensland Hospital and Health Service, ECRI Institute, Institute for Healthcare Improvement, Institute for Safe Medication Practices, The Joint Commission, Kaiser Permanente, and the National Association for Healthcare Quality. For more information, see *RCA2: Improving Root Cause Analyses and Actions to Prevent Harm* (see: www.ihi.org/resources/Pages/Tools/RCA2-Improving-Root-Cause-Analyses-and-Actions-to-Prevent-Harm.aspx).

Literature review update

The literature search for the 2017 literature review was undertaken by the Australian Institute of Health Innovation. The Commission requested the Australian Government Department of Health library re-perform the literature search for the period May 2016 to May 2018 using Pubmed, Cochrane Library, Embase, Medline, Business Source Premier, Health Policy Reference Center and Cinahl.

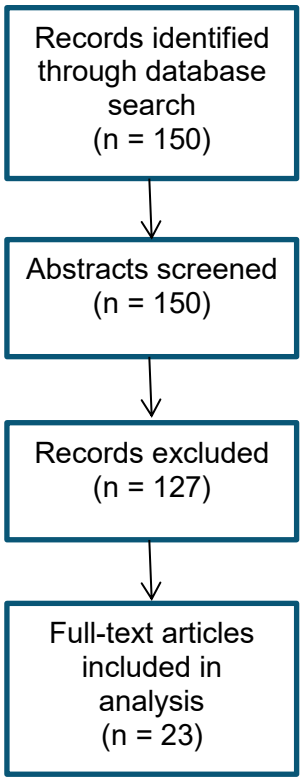
The search query was ('health information technology' OR HIT OR 'health IT' OR 'electronic health record' OR 'electronic medical record' OR 'decision support' OR CPOE OR 'technology induced' OR 'computer related') AND ('medication error*' OR error* OR incident* OR 'unintended adverse consequence*' OR consequence* OR 'incident report*' OR 'patient outcome') AND (data OR analysis OR qualitative OR quantitative).

Only English-language case studies were included. Duplicates were removed. The literature search identified 150 articles.

Two reviewers independently reviewed the abstracts for relevance to the first literature review subject area. A consensus approach was used to judge relevance for inclusion. Items

that were recommended for inclusion by only one reviewer were reviewed by a separate adjudicator. Twenty-three items were included for full review. The two reviewers read all papers and created a summary record in the same format as used in the original 2017 literature scan. A flow diagram detailing the paper search and selection process is shown in Figure 1.

Figure 1: Flow diagram of the paper search and selection process



The combined summary is provided at Attachment 1.

Findings

Within the included studies there were relatively few examples of existing taxonomies being applied to classify events. In a number of papers there were ad hoc classifications based on the subject of the discussion; for example, clinical area, harm, reason for pharmacist intervention. Several papers used classifications for particular types of event; for example, medication errors. Existing published classifications cited included the (US) Agency for Healthcare Research and Quality Common Formats, health information technology (health IT) unintended consequences, and so on. The existing published taxonomy of health IT events that was commonly cited was Magrabi et al.[7] One paper, Palojoki et al[8], observed that 'the health IT-specific taxonomy developed by Magrabi et al. is more widely used and was developed specifically to classify health IT-related incidents', thereby allowing the comparison of health IT events in an international context. Palojoki et al go on to suggest that Magrabi et al's taxonomy could be used as a starting point for developing standard international incident reporting classifications of machine-related incidents. The development of standard classifications, with clear category descriptions, would not only make data more valuable but also support international comparison.

Conclusion

Despite a marked number of reported investigations into health IT-related patient safety incidents, no notable developments for using existing taxonomies to classify these events were found. Instead, most articles reviewed used ad hoc classification systems. Several of the articles identified in this literature review concluded that more standardised safety reporting of health IT-related events using a common taxonomy would be of great benefit to healthcare systems and would allow the implementation of prevention strategies.

Data breach incidents in the health literature relating to hospital clinical information systems, electronic medical records and electronic health records

The Commission explored the literature for data breach incidents relating to electronic health information in a hospital setting, with a particular focus on how these breaches are classified.

A data breach is defined by the Office of the Australian Information Commissioner (OAIC) as 'an unauthorised access or disclosure of personal information or loss of personal information'.[9] Data breaches can cause substantial harm to both individuals and companies.[10] The health and welfare of the affected individual can be reduced, along with their financial situation and reputation. Similarly, data breaches can also lead to reputational and financial harm for the organisation involved, and may undermine confidence in the health system. Although health data are considered the most sensitive of personal data and therefore of a higher risk category[2], the processes around maintaining the confidentiality, integrity and security of health data are not clearly understood or followed.[11]

Mandatory data breach notification is becoming the norm across the world, and reports of data breaches within healthcare organisations are becoming more common.[3,11] Despite this, the reporting and analysing of health data breaches was not consistent in the health literature examined. Only one published classification system was found within this environmental scan – the US Office for Civil Rights system. This system classifies health data breaches into seven categories: IT/hacking incident, improper disposal, loss and theft, unauthorised access, unauthorised disclosure and other/unknown.[11] The OAIC also groups data breaches within the health sector into three categories: malicious or criminal attack, system fault, and human error.[12] It is clear that more categories or expanded definitions, or indeed a detailed standardised classification system, are likely to be needed in the future, because the current categories are not sufficiently broad to encompass all situations. For example, usability of health information technology is a documented challenge for clinicians and can result in the use of privacy-compromising system workarounds to avoid work disruption.[13] These workarounds can include sharing accounts, not logging off computers, and copying patient information to personal devices. It is therefore key that IT staff understand clinical workflows to allow the optimisation and successful implementation of electronic health record systems within hospitals.

A limitation of searching the health literature databases for the term 'data breach' as an 'incident' is that 'data breach' is not a Medical Subject Heading (MeSH) at present.[14] Therefore, retrieving articles about electronic medical record (EMR)-related data breach incidents in hospital is difficult. In the literature, the term 'incident', in the hospital setting, is aligned with medically induced errors and not EMRs.

Conclusion

The literature did not contain examples of data breach incidents relating specifically to EMR design, build and use being routinely recorded and reported. This may be because a standardised classification system for collecting such data breaches is not available.

The Commission's response

Healthcare systems around the world have taken up the challenge to detect and prevent adverse events within the acute and primary care environments.[15–18]

The development of standardised taxonomies and classification systems is integral for managing patient safety information.[19,20]

Health information technologies (health IT), such as clinical information systems (CIS) and electronic medication management (EMM) systems, are known to heighten the need to monitor patient safety in healthcare.[21] Health IT-related safety risks continue to be unintended consequences from implementation of CIS.

Most states and territories, and some private hospitals, have implemented or are implementing EMM systems. Complex and difficult issues, to which implementation teams must be alert, are arising, and little is known about the types of errors that may be associated with:

- EMM-related work practice changes
- Clinicians working across multiple sites and settings, and remote ordering
- Hybrid environments in which EMM and hard-copy documentation for prescribing and administration of medicines, are both used
- Multiple EMM systems, such as separate ICU or oncology systems
- Multiple patient EMM records being open at the one time
- Selection errors associated with use of 'drop-down' medicine lists when prescribing
- Dosing errors associated with on-screen presentation of medicines information
- Decision support information not being used, not readily accessible for use, or not considered relevant (interaction alerts) by clinicians
- Planned and unplanned downtime.

The Commission continues to disseminate information to help organisations refine their approaches to health IT safety. This information aims to assist organisations to meet the requirements of the National Safety and Quality Health Service Standards, especially those relating to governance and managing risk associated with implementation and use of technology (for example, EMM).

Following publication of the 2017 literature scan reporting on the methods used in health IT safety science for monitoring hazards and investigating incidents, the Commission convened an EMM incident classification roundtable in December 2017 and another in December 2018.

Participants at both roundtables recommended that EMM safety be improved by national development of a system for classifying adverse events and incidents pertaining to the implementation and use of EMM systems.

This 2019 update on the literature review and investigation of health IT-related patient safety incidents is an important addition to the national conversation. Reference to data breach notifications has been an important inclusion, given the increasing concern within health care and the potential for substantial harm to individuals and organisations. A recent Australian report examines the trends over the first 12 months of mandatory reporting obligations under the *Privacy Amendment (Notifiable Data Breaches) Act 2017,* and includes a breakdown of causes.[22] In health, human error accounted for 55% of 206 reported data breaches.

This update has informed development and testing of potential health IT/CIS incident classification systems and accompanying guidance.

A recent international qualitative study, first published in March 2019, identified a set of activities or tasks that organisations should perform to minimise health IT/CIS-related patient safety risks.[23] This latest study will also inform the Commission's guidance.

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Attachment 1: Summary of studies combined

Authors (year)	Study period	Source/ case study	Country	Settings	HIT types	N	Case study/incident analyses methods R: reporting format HIT: problem categories C: consequences	Summary of findings
Adams et al (2017)[1]	2009 to 2016	Pennsyl-vania PA-PSRS; 1.735 million reports; 2,625 health IT reports	USA	Large healthcare system Mid-Atlantic US	EHR Inter-operability	209	Identify patient safety events reflecting EHR interoperability issues R: Self-reporting to the PA-PSRS HIT: Customised: 4 categories (1. clinical areas of interoperability-related events; 2. sending–receiving information and interoperability-related events; 3. Provider sites and interoperability-related events; 4. Harm scores of interoperability-related events) C: Harm	8% of HIT reports related to interoperability. Most common EHR interoperability issues involved pharmacy, laboratory and radiology systems. Medication, laboratory and radiology events comprised 76% (n = 158) with 68% (n = 107) occurring when information was sent into the EHR. 51 (32%) occurred when EHR sent information to another system (e.g. radiology) Potential or actual harm due to: • Unsafe condition: 38 (18%) • Did not reach patient – no harm: 55 (26%) • Reached patient – no harm: 111 (53%) • Patient harm: 5 (2%) (No deaths reported)
Alhanout et al (2017)[2]	5 May 2015 to 1 Dec 2015	Retro-spective study. CPOE PharmInt to deal with paediatric	France	Paediatric department	Pharma; CPOE	302	R: Clinical pharmacist checks the Pharma CPOE daily to identify any errors (raises a PharmInt) HIT: Not entirely clear; it could be that the pharmacist classifies the	11 types of errors were identified in the 302 PharmInts. The most common errors in CPOE entries for paediatrics were: incomplete information about dosing frequency (most common);

Authors (year)	Study period	Source/ case study	Country	Settings	HIT types	N	Case study/incident analyses methods R: reporting format HIT: problem categories C: consequences	Summary of findings
		prescrip-tion errors in CPOE system					error or the researchers developed the classification from the PharmInt C: The reason for pharmacist intervention (e.g. wrong dosing regimen)	missing body weight; and excessive doses
Amato et al (2017)[3]	6 months for 10 CPOE systems at 6 sites, Jan to Dec 2013	Medication errors in CPOE systems: CPOE Medication Safety study	USA	Inpatient and outpatient	CPOE	2,522; 1,308 (51.9%) related to CPOE; 171 CPOE facili-tated; 1,137 CPOE could potent-ially prevent	R: Voluntary self-reporting HIT: CPOE medication error taxonomy[4] (and revised in this work) – 16 codes for what happened to the patient; 64 for what happened in CPOE; 73 codes for why it occurred. Australian-authored[5] classification cited AHRQ Common Formats for Event Reporting contains a classification for HIT[6] C: CPOE-related 171 (13.1%) directly facilitate or caused the error, 1,137 (86.9%) failed to prevent the error. 33.9% delay in medicines reaching the patient; 16.2% received/potentially	Errors related to CPOE commonly involved transmission errors, erroneous dosing, and duplicate orders. More standardised safety reporting using a common taxonomy could help health care systems and vendors learn and implement prevention strategies

Authors (year)	Study period	Source/ case study	Country	Settings	HIT types	N	Case study/incident analyses methods R: reporting format HIT: problem categories C: consequences	Summary of findings
							duplicate medicine; 10.6% patients received or nearly received a dose higher than indicated; 6.7% risk of not receiving a medicine; 5.4% risk of not receiving the medicine	
Bristol et al (2018)[7]	Not specified	Responses to qualitative survey questions	USA	Variety: (medical–surgical, , intensive care, ambulatory setting, floats between units, other)	EHR work-arounds	Not reported	Qualitative question responses	144 nurses completed an online questionnaire. Nurses engaged in workarounds, sometimes in positively deviant ways (atypical actions performed by individuals during difficult situations, which result in better outcomes than others in similar circumstances). EHR users need support and training (UX/UI); importance of communications
Brown et al (2017)[8]	1 Jan 2004 to 22 June 2015	Systematic review focused on 34 studies	USA, Canada, Spain, Sweden, The Nether-lands, Australia, Denmark	Primary and secondary care	CPOE pre-scribing errors	Not reported	Systematic review, but no explicit classification system used for identifying themes	Qualitative data sought to identify the types and causes of CPOE-related errors. The review identified 8 key themes (computer screen display; drop-down menus and auto-population; wording; default settings; non-intuitive ordering of information transmission; repeat prescription and automated processes; users' work processes; CDSS). Human factors can help improve UI and better CDSS can perform checks

Authors (year)	Study period	Source/ case study	Country	Settings	HIT types	N	Case study/incident analyses methods R: reporting format HIT: problem categories C: consequences	Summary of findings
Chaparro et al (2017)[9]	24 months (Feb 2008 to Dec 2010)	Evaluation tool results for 41 paediatric hospitals	USA	Paediatric hospitals	CPOE and CDSS in EHRs	Not applic-able	HIT: Leapfrog paediatric CPOE evaluation tool	CPOE systems can intercept most potential medication errors. Repeated evaluations improved identification of potential errors. In this study the tool intercepted 62% of potential medication errors
Howe et al (2018)[10]	Up to 36 months (2013 to 2016)	Patient safety reports within the Pennsyl-vania PA-PSRS; 1.735 million reports; 1,956 with EHR vendor	USA	Hospital	EHR usability (UX/UI)	557	Identify patient safety events reflecting EHR usability issues R: Voluntary reporting to the PA-PSRS HIT: Synthesised taxonomy of 7 usability topics; Clinical process C: 1. Reached the patient and potentially required monitoring to preclude harm 2. Potentially caused temporary harm 3. Potentially caused permanent harm 4. Could have necessitated intervention to sustain life or could have resulted in death	Understatement of issue because patient safety reports contain limited information. 1956 (0.11%) mentioned EHR and possible patient harm; 557 (0.03%) had language explicitly suggesting EHR usability contributed to possible patient harm. Harm reached patient (n=557): • Potentially requiring monitoring 468 (84%) • Potential temporary harm 80 (14%) • Potential permanent harm 7 (1%) • Intervention to sustain life or death 2 (<1%) 7 usability categories: data entry (27%, n = 152); alerting (22%, n = 122); interoperability (18%, n = 102); visual display (9%, n = 52); availability of information (9%, n = 50); system automation

Authors (year)	Study period	Source/ case study	Country	Settings	HIT types	N	Case study/incident analyses methods R: reporting format HIT: problem categories C: consequences	Summary of findings
								and defaults(8%, n = 43); and workflow support (7%, n = 36). EHR clinical processes: usability challenges occurred during order placement (37%, n = 207); review of results (16%, n = 87); documentation (9%, n = 50)
Howlett et al (2018)[11]	Not specified (conference abstract)	Delphi process	UK	Paediatric intensive care units	PICU HIT errors	19 scenarios	Delphi process with 37 participants	Delphi process can be used to gain agreement on classifying novel errors
Huang and Gramo-padhye (2016)[12]	4 months (May to Aug 2012)	Observ-ational study	USA	1 US rural hospital	EHR/ CPOE bar coding system: leading to medication adminis-tration process issues	1	Observational study mapping medication administration	Paper's focus is on implementation rather than classifying events. Implementation must consider people, tasks, tools, environment and organisation. The study observed the changes made to workflow (and violations against work standards) following implementation of EHR/CPOE/barcode scanning systems
Kalish (2016)[13]	Not specified	News item reporting on present-ation	USA	All	Not applic-able	Nil	News item	Plan to reduce EHR risks
Kim et al (2017)[14]	Review Jan 2014 to Dec 2015	34 studies	Various	Various	Not applic-able	20 to 90,876	Systematic review – categorisation of sociotechnical factors[15] and classification of impact:[5]	Much of the literature is qualitative; potential for systematic study (using standard taxonomy)

Authors (year)	Study period	Source/ case study	Country	Settings	HIT types	N	Case study/incident analyses methods R: reporting format HIT: problem categories C: consequences	Summary of findings
							• Potential or actual harm to patient • Interrupted sequence or near miss • IT issue but no patient harm • IT issue but no consequence • Hazardous event or circumstance	
Korb–Savoldelli et al (2018)[16]	Review Mar 1982 to Aug 2017; studies used published 2006 to 2016; study durations 5 days to 7 years	Systematic review of 14 studies of CPOE-related medication prescriptio n errors	Europe, USA, Australia, Singapore	Hospital	CPOE	Medic-ation error rate due to CPOE 6.1 to 77.7%; median 26.1%	Systematic review HIT: NCCMERP taxonomy; Ohio State University Medical Center Adverse Drug Assessment Tool; Pharmacy and Provider e-prescribing Experience Reporting Tool. 7 of the 14 prospective and retrospective studies, did not use published taxonomy and 3 studies used published taxonomies: French Clinical Pharmacy Society and NCCMERP	Mixed results. Medication error rate due to CPOE 6.1 to 77.7%; median: 26.1% 'Wrong dose' and 'Wrong drug' were the most commonly reported errors
Kuziemsky et al (2016)[17]	Literature review 2000 to 2015	Literature review of 18 studies of UICs linked to organisatio	US, Australia, Canada, Denmark, Israel, The	Not specified	A variety studied; e.g. bar-code medication	Not reported	HIT: Classification of unintended consequences[18–20]	Lack of consensus on classification of UICs. No formal definition for positive or negative UICs.

Authors (year)	Study period	Source/ case study	Country	Settings	HIT types	N	Case study/incident analyses methods R: reporting format HIT: problem categories C: consequences	Summary of findings
		nal and social issues (subset of issues)	Nether-lands, Norway		adminis-tration, CPOE, EHR, CDSS, UICs			Focus on organisational and social issues rather than technological. Suggests framework for studying UICs
Larsen et al (2017)[21]	36 months (1 Jan 2013 to 10 Jan 2016)	Mid-Atlantic US Health care single event reporting system; 80,381 reports; 76 safety events with EHR downtime	USA	A large multi-site health system with urban, suburban and rural hospitals with 6 different EHRs, 1 EHR from a major vendor for inpatient services	EHR downtime	76	R: Voluntary reporting HIT: Downtime events categorised by clinical process: laboratory, medication, imaging, registration, patient handoff, documentation, history viewing, delay of procedure, general delay of care C: Identified through use of grounded theory	Authors focused on the free text descriptions in the incident reports. Majority (48.7%) of downtime safety events related to laboratory orders/results followed by medication ordering/administration (14.5%). Downtime procedures not well followed or in place in 46% of the incidents (n = 21)
Palojoki, Borycki et al (2017)[22]	Literature review period not specified	Compara-tive study of character-istics of 2 means of monitoring HIT errors	EU and USA	Not specified	All	Not applic-able	R: Mandatory reports to EU Medical Device Vigilance System (Oversight) and voluntary reporting to patient safety incident reporting system HIT: Not reported C: Not reported	No classification. Descriptive comparison of 2 systems, oversight vs patient incident reporting systems, for technology-induced errors

Authors (year)	Study period	Source/ case study	Country	Settings	HIT types	N	Case study/incident analyses methods R: reporting format HIT: problem categories C: consequences	Summary of findings
Palojoki, Makela et al (2017)[23]	24 months, 23 hospitals (Dec 2011 to Nov 2013)	EHR-related patient safety incidents reported into the Finnish patient safety incident reporting tool (HaiPro)	Finland (with com-parisons)	Hospitals	EHR-related patient safety incident reports	2,379 incident reports	R: Voluntary reports to HaiPro HIT: Magrabi et al classification[5,24,25] and Finnish HaiPro classification C: not reported	Since 2007 the hospital district (21,000 employees, 500,000 patients) fully paperless. EHR-related patient safety incidents are more common than previously reported. Human–computer interaction problems most reported. They note: 'Magrabi et al's taxonomy constitutes a basis for patient safety incident reporting recommended for use as a starting point for international reporting classifications of machine-related incidents'
Palojoki, Pajunen et al (2016)[26]	1 month in 2015, 23 hospitals	Mixed methods. EHR safety concerns (of users)	Finland	Hospitals	EHR	2,864 respond-ents	R: Survey responses HIT: Based on Sittig and Singh work:[27] 1. Incorrect patient identification 2. Extended EHR unavailability (either planned or unplanned) 3. Failure to heed a computer-generated warning or alert 4. System-to-system interface errors 5. Failure to find or use the most recent patient data	Finnish survey tool developed based on the literature and piloting. Pilot testing aimed to measure end users' perceptions of common EHR-related safety concerns; users' views of EHR safety concerns or events of highest clinical risk. For instance, incorrect patient identification and extended EHR downtime perceived highest risks

Authors (year)	Study period	Source/ case study	Country	Settings	HIT types	N	Case study/incident analyses methods R: reporting format HIT: problem categories C: consequences	Summary of findings
							6. Translational challenges in EHR time measurement 7. Incorrect item selected from a list of items 8. Open, incomplete or missing orders C: Not reported	
Palojoki, Pajunen et al (2017)[28]	Not specified	Tool to measure EHR users' percept-ions of common EHR-related safety concerns	Finland	Hospitals	EHR	2,864 respond-ents	R: Survey responses HIT: Based on Sittig and Singh work[27] (see above) C: Not applicable	Tool (FIN-TIERA) for assessing EHR users' views of technology-induced errors
Prgomet et al (2017)[29]	Jan 2000 to Jan 2016	Systematic review/ meta-analysis of CPOE and CDSS on ICU medication errors, LOS, and mortality; 20 studies	US (11), UK (4), Belgium, Canada, Israel, Saudi, Spain (1 each)	ICUs	Medication errors – CPOE and CDSS	Various	R: Not reported HIT: Not reported C: Medication errors; ICU mortality; hospital mortality; and LOS. Studies with a p value of <0.05 reported 5.96 LOS median days[30]; medication errors (zero[31], 76[32], 2,070[33] and 44[30])	Overall evidence of impact of introduction of CPOE and CDSS on ICU – 85% reduction in medication prescribing errors and 12% reduction in ICU mortality. However, there were unexpected increase in hospital deaths:[34] 36 hospital deaths (p value <0.05). Of the 20 studies, 19 were rated as weak to moderate according to the reviewers methodology

Authors (year)	Study period	Source/ case study	Country	Settings	HIT types	N	Case study/incident analyses methods R: reporting format HIT: problem categories C: consequences	Summary of findings
Russ et al, (2017)[35]	Not specified	Study of CTA to investigate medication safety incidents	USA	Veterans Affairs Medical Center outpatient/ inpatient	Medication safety events	80 incidents 60 inter-views	R: Voluntary reports HIT: 1. Side effect, adverse reaction or allergy; 2. drug–drug interaction; 3. drug–disease interaction involving low renal function C: Not reported	Use of CDM interview (a CTA method) to study medication safety incidents: EHR not integrated with CDM and no categorisation of EHR incidents is performed, other than for testing CTA
Sittig and Singh (2017)[36]	Not applicable	Various	Inter-national	Healthcare	EHR	Not reported	No data	This was a chapter in Key Advances of Clinical Informatics. It provided an overview of the 8-dimension sociotechnical model as well as the 5 major types of EHR-related safety concerns and the Safer Guides
Tolley et al (2018)[37]	Review 1946 to 2017	Systematic review of 47 studies	US, Iran, UK, Canada, The Nether-lands, Sweden, France, Spain, Israel, Singapore, Taiwan	Various – e.g. adult and paediatric hospitals, ambulatory care clinics, emergency depart-ments, pharma-cies, PICU, national pre-scription repository	Medication errors using CPOE	Various	R: Not reported HIT: Thematic analysis of studies C: Not reported	Thematic and sub-thematic analyses of 47 papers to identify factors contributing to medication errors in CPOEs in paediatrics. Identified 5 factors contributing to errors using CPOE: 1. Lack of dosing alerts 2. Generation of inappropriate dosing alerts 3. Inappropriate duplicate medicine alerts 4. Drop-down menu selection errors 5. System design issues

Authors (year)	Study period	Source/ case study	Country	Settings	HIT types	N	Case study/incident analyses methods R: reporting format HIT: problem categories C: consequences	Summary of findings
Zheng et al (2016)[38]	24 months (1 Jan 2014 to 31 Dec 2015)	Survey/ review of 34 papers on unintended conse-quences of HIT	US, Norway, Australia, Saudi, UK, Argentina, Canada	Ambulatory care, emergency department	UICs associated with imple-mentation of EHR, CPOE, PACS	Not specified	R: The articles listed the following data sources: surveys; observations; interviews; incident reports; human resources records, charts. HIT: Unintended consequences affect: patient safety; time efficiency and workflow; documentation quality; clinician performance and quality of care; communication and coordination; workarounds; financial impact; privacy and confidentiality; methods	Review paper of unintended consequences of HIT suggests greater breadth of unintended consequences being reported

AHRQ = Agency for Healthcare Research and Quality (USA); CDM = critical decision method; CDSS = clinical decision support system; CPOE = computerised prescriber (or physician) order entry; CTA = cognitive task analysis; EHR = electronic health record; HIT = health information technology; EU = European Union; ICU = intensive care unit; LOS = length of stay; NCCMERP = National Coordinating Council for Medication Error Reporting and Prevention; PACS = picture archiving and communication system; PA-PSRS = Pennsylvania Patient Safety Reporting System; PharmInt = pharmacist intervention; PICU = paediatric intensive care unit; UI = user interface; UIC = unintended consequence; UX = user experience

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