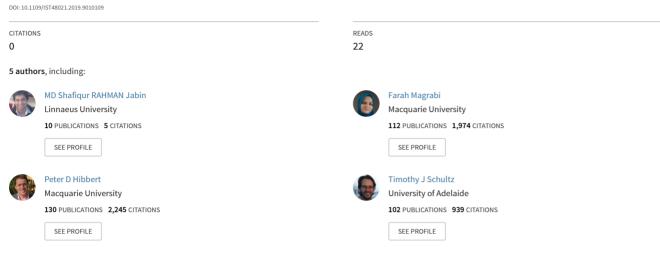
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Identifying and Classifying Incidents Related to Health Information Technology in Medical Imaging as a Basis for Improvements in Practice

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Identifying and classifying incidents related to health information technology in medical imaging as a basis for improvements in practice

Md Shafiqur Rahman Jabin Australian Centre for Precision Health University of South Australia Adelaide, Australia <u>rahmy027@mymail.unisa.edu.au</u>

> Tim Schultz Adelaide Nursing School University of Adelaide Adelaide, Australia tim.schultz@adelaide.edu.au

Farah Magrabi Australian Institute of Health Innovation Macquarie University Sydney, Australia farah.magrabi@mq.edu.au

William Runciman Australian Centre for Precision Health University of South Australia Adelaide, Australia william.runciman@unisa.edu.au Peter Hibbert Australian Institute of Health Innovation Macquarie University Sydney, Australia peter.hibbert@mq.edu.au

Abstract—The Joint Commission in the United States disseminated a Sentinel Event Alert because of the number of adverse outcomes from problems with health information technology (HIT). The HITs were trading off safety and quality against throughput or efficiency. The Alert urged healthcare providers to improve process measurement and provide leadership in mitigating the risks. In order to understand what problems compromise safety and efficiency, this study has accessed, deconstructed, categorized and analyzed Australian patient safety incident reports of the things that go wrong in medical imaging, and their impact on both patients and the medical imaging acquisition and processing systems. Data Sources comprised two sets of voluntary incident reports and convenience samples of interviews with radiology staff. A special targeted search was undertaken for identifying HIT related incidents so that they could be deconstructed with the health information technology classification system. This resulted in 436 HIT related incidents. Within these incidents, 623 HIT related issues were found. These included use or human factor related issues (40%), software and hardware related issues (30%) and machine related issues (30%). Although many technical problems and deficiencies were detected in the reports identified, we did not anticipate that more than half of the incidents would have involved failures of human performance. Identifying and characterizing the things that are going wrong, related to HIT through the lens of medical imaging incident reports can provide a basis for preventing issues and improving clinical practice.

Keywords—medical imaging, health information technology, incident reports, classification system, safety and quality

I. INTRODUCTION

Healthcare comprises a complex socio-technical system and undergoes change continuously [1]. Whenever change is introduced, new and often unforeseen problems emerge that need attention. Thus, new challenges arise continuously in setting priorities for safety and quality. Assessing the nature and impact of patient safety incidents, characterizing them, and developing preventive and corrective strategies must be a high priority in rapidly changing, complex healthcare systems [2]. The ever-increasing range of what is possible, due to advances in areas such as medical imaging, and the rapid, widespread deployment of health information technology (HIT), has led to better ways of doing things, but also to a whole range of new problems [3].

The comprehensive adoption and implementation of HIT in the US healthcare system was encouraged to increase cost effectiveness, and reduce incidents and their cost [4]. HIT adoption was encouraged by the Health Information and Management Systems Society (HIMSS) by implementing reimbursement incentives [5]. These investments were predicted to reduce medical expenditures and related federal spending by \$19 billion by the Congressional Budget Office [6]. However, a major issue faced by radiology departments is sub-optimal work efficiency caused by limitations in PACS systems and their implementation, resulting in care delivery not meeting performance expectations with respect to speed of response and ability to transmit imaging data. Recent research conducted in Australia by Gulati in 2013 found similar problems [7]. It is therefore important to realize the promise of HIT by identifying, understanding and responding to the problems that are being encountered.

Counting things that go wrong can draw attention to what is going wrong, but to respond requires an understanding of how and why they go wrong. The process of reporting allows reflection on what happened, what could have happened and what might have mitigated or ameliorated what happened, and captures both near misses and adverse events [8]. Involvement in incident reporting, with local follow-up of incidents, may play an important role in improving the safety culture of an organization [9].

To address issues relevant to HIT, a classification tailored for HIT was used for this study [10]. This took a "bottom-up" approach, developed by Magrabi et al to categorize the problems (Magrabi et al. 2015). Problems were divided into human factors or technical problems, and then allotted to one or more subclasses, software and hardware problems.

II. THE NEED FOR RESEARCH INTO THE PROBLEMS ARISING FROM HIT

The Joint Commission (TJC) in the USA disseminated a Sentinel Event Alert because of the number of adverse outcomes from problems with HIT, reflecting an imbalance between safety, quality and throughput. Healthcare providers were urged to improve process measurement and provide leadership in mitigating the risks associated with HIT. It was pointed out that the chance of a problem may increase due to heavy workloads, workforce deficiencies or a combination of both [11], and that some of these risks may be addressed by using the appropriate criteria at the time of entry of patient data and ensuring correct imaging technique, whilst aiming for ALARA (as low as reasonably achievable) risk [12].

Anecdotally, healthcare organizations in Australia are experiencing the same types of incidents as those being reported in the USA and elsewhere, with the need to address them being increasingly recognized. For example: missed fractures in the emergency medicine [13]; medicolegal claims arising from medical imaging [14]; and handover and communication related incidents in medical imaging [15].

It was therefore decided to collect, collate, deconstruct, classify and analyze incident reports in medical imaging, with a particular focus on HIT, with a view to devising preventive and corrective strategies and recommendations to implement them [16].

III. METHODS

In order to understand what problems compromise safety and efficiency, the studies included in this thesis have accessed, deconstructed, categorized and analyzed for Australian patient safety incident reports of the things that go wrong in medical imaging, and their impact on both patients and the image acquisition and processing systems.

A. Collecting Reports of Medical Imaging Incidents

Sources of information about things that had gone wrong in relation to medical imaging were identified. These comprised two sets of voluntary incident reports and convenience samples of interviews with radiology staff.

The free-text narratives from 4,963 incident reports and 100 interviews were collected; 4,915 were included for analysis and 48 were excluded. Inclusion criteria were that they involved medical imaging and had patient safety or quality implications. Exclusion criteria were inadequate details for coding or no free text description. For example, if an incident could not be classified into at least one incident type, it was excluded.

B. Identifying HIT Incidents from the Collected Incident Reports

A special targeted search was undertaken for identifying health information technology (HIT) related incidents so that they could be subjected to classification by the HIT classification system (HIT-CS). A set of keywords thought to be indicative of incidents involving HIT was identified. The bulk of the keywords was drawn from the work of Farah Magrabi (FM) [17]. This was supplemented by contributions from the principal investigator and other authors of this study, making 100 keywords. The keywords are:

<u>Hardware</u>

Input Devices (12) – keyboard, type, typing, mouse, click, pointer, touch, screen, stylus, digitiser/digitizer, scanner, OCR

Output Devices (5) – Terminal, VDU, printer, print out, printout

Networking (10) – Internet, web, network, cable, server, crash, glitch, bug, system down, system unavailable

Fixed Computers (7) – Computer, information system, information technology, health IT, ICT, workstation, IT system

Mobile device (6) – Mobile, portable, tablet, handheld, palm, digital assistant

Main power supply (6) – Power supply, power failure, power outage, power interruption, power disruption, power cut

<u>Software</u>

Generic name (26) – Electronic, EHR, EMR, Computer aided diagnosis/CAD, order entry, CPOE, patient administration, EPAS, prescribing package, laboratory information system/LIS, Picture archiving/PACS, radiology information system/RIS, teleradiology, health record, patient monitoring system, clinical order, medical order, communication system, digital imaging system/DIS, estop/estop, emergency management, EDIS, efilm/e-film, voice recognition, speech dictation, speech recognition

Manufacturer (14) – Oasis, Kestral, Impax/Impacs, ARIA, Homer, HASS, Cerner, iSOFT, Toshiba, GE Health, Philips, Siemens, Voyager, ComRad

Input feature (5) – Pick list, menu, drop down, data entry, typing

Software component (7) – Database, knowledge base, decision support, dose suggestion, drug suggestion, warning, alert

Output display (2) – Information display, information presentation

Incident narratives were then searched for these keywords, and the incidents that contained one or more of them were subjected to an algorithm to discern if they were HIT related or not (see Fig. 1). This algorithm had been used by The Joint Commission (TJC) by following the definition used by the Agency for Healthcare Research and Quality [18] for identifying HIT-related incidents [19, 20]. The HIT related incidents were identified by reading the incidents containing the keywords and using the algorithm.

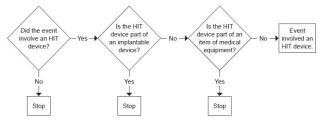


Fig. 1 The algorithm for identifying HIT related events. Adapted from [21]

An incident was included if HIT was involved. Incident reports that contained a keyword were rejected if they related to an implantable medical device, a part of medical equipment, or were found not to be relevant to HIT.

C. Classify the HIT Incidents using the HIT-CS

Incident reports were aggregated and recorded in Microsoft Excel Spreadsheets. Incident analysis consisted of coding according to the HIT-CS by reading the incidents and extracting relevant concepts relating to the codes.

The principal coder then examined the free-text descriptions of HIT related incidents and classified them using the HIT-CS. The interrater reliability was calculated for the information related problems for 8% of the 436 HIT related incidents by the principal coder and Farah Magrabi. If there was disagreement, the incident was re-examined, and a consensus was reached by discussion.

IV. RESULT

A search of the 4,915 incidents using 100 selected keywords involving safety and/or quality of care, HIT and imaging, identified 1,565 incident reports with one or more of these keywords. Applying an algorithm for identifying HIT incidents amongst these yielded 436 incidents. They were then classified using the HIT-CS (see Fig. 2). Cohen's kappa (k) statistic for interrater coding reliability for use or human factors related problems using HIT-CS (n= 35) was reasonable, k = 0.68, p<0.00.

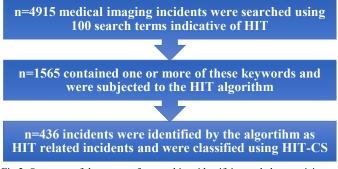


Fig 2. Summary of the process for searching, identifying and characterizing HIT related incidents

A. Classification of HIT Incidents using the HIT-CS

HIT related issues were categorized as:

- 1. Information related issues
 - **a.** use related (human factors) issues
 - **b.** machine (technical) related issues
- 2. Software or hardware (technical) issues

Of the 436 HIT related incidents, 623 HIT related issues were suitable for classification using HIT-CS. "Use related

issue" (1.a) refers to staff with a direct interaction (interface) with the HIT system causing an incident. Table I illustrates the types of issues for HIT incidents using the HIT-CS, the majority (40%) of which were "use related issues".

TABLE I. TYPES OF ISSUES FOR HIT INCIDENTS USING THE HIT-CS

Types of issues	n	%
Use related issue (1.a)	252	40
Software or hardware issue (2)	187	30
Machine related issue (1.b)	184	30
Total	623	

1) Use (human) related issues (1.a): Of all use related issues, over 93% were 'wrong entry or retrieval' (n=154, 61%) or 'did not enter or retrieve' (n=80, 32%) (Table II). Examples of each type of use related issues are given in Table III.

TABLE II. TYPES OF HUMAN OR USE (INPUT) RELATED ISSUES

Information (use) related issue	n	%
Wrong entry or retrieval	154	61
Did not enter or retrieve	80	32
Partial entry or retrieval	15	6
Delayed entry or retrieval	3	1
Total	252	

TABLE III. TYPES OF USE RELATED ISSUES AND RELEVANT EXAMPLES

Use related issue	Example
Wrong entry or retrieval	Radiographer selected the incorrect code for a hip x-ray. The image was registered as a chest x- ray and displayed on PACS under chest.
Did not enter or retrieve	Request forms not scanned into PACS for several patients.
Partial entry or retrieval	Consent scanned into Aria was incomplete (no consent circled for tattoos).
Delayed entry or retrieval	Electronic order submitted 90 minutes late.

2) Software and/ or hardware (technical) issues (2): Issues have been allocated to one or the other category. In some cases, this allocation was somewhat arbitrary, as the exact nature of the problem may not have been evident to the reporter or was not reported in the incident report.

Of all software related issues, 68% comprised 'interface with device' (n=34, 28%), 'software functionality' (n=28, 23%) or system configuration (n=21, 17%) (Table IV). Examples of each type of software issues are in Table V.

TABLE IV. TYPES OF SOFTWARE (TECHNICAL) RELATED ISSUES

Software issue	n	%
Interface with devices	34	28
Software functionality	28	23
System configuration	21	17
Interface with other software system or components	13	10
Network server down or slow (software issue)	11	9
Software not accessible	7	6
Software not available or not licensed	5	4
Record migration	3	2
Increased volume or transactions	1	1
Total	123	

TABLE V. TYPES OF SOFTWARE ISSUES AND RELEVANT EXAMPLES

Software issue	Example
Interface with devices	Reconstructed CT angiogram images were not available for review in e-film.
Software functionality	PACS program malfunctioned during neuroradiology meeting.
System configuration	New computer installed last week. Not set up properly, cannot push studies into e-film to be read.
Interface with other software system or components	Patient having a PET scan had an image acquisition error when moving from CT to PET. Acquisition 'bombed out' and was unable to be retrieved.
Network server down or slow (software issue)	Radiology IT server malfunction. PACS sufficiently slow as to be unusable.
Software not accessible	Unable to log into computer in radiology library, had to move rheumatology meeting to a suboptimal location.
Software not available or not licensed	Computer had no software installed for reporting images.
Record migration	A new RIS system was put into place. The data was transferred from the old system. The problem was that the data did not come up with accurate descriptions in the new RIS system.
Increased volume or transactions	Study has 770 images. Not all studies automatically loading into e-film. Manual loading rate about 1 image every 2 seconds.

Of all hardware related issues, 50% (n=32) were 'device down or slow' (Table VI). Examples of each type of hardware issue are in Table VII.

TABLE VI. TYPES OF HARDWARE (TECHNICAL) RELATED ISSUES

Hardware issues	n	%
Device down or slow	32	50
Data capture or output peripheral down or slow	14	22
Problems with data storage & backup	11	17
Power failure	7	11
Total	64	

TABLE VII. TYPES OF HARDWARE ISSUES AND RELEVANT EXAMPLES

Hardware issue	Examples	
Device down or	Technical issue leading to the non/mal function	
slow	of the PACS system.	
Data capture or	CT scanner had an "error" part way through	
output peripheral	the CT acquisition which required the scan to	
down or slow	be repeated.	
Problems with	Medical Imaging equipment in Emergency	
data storage &	Resus Room 1 and 2 not working correctly.	
backup	Backup imaging equipment in Resus failed.	
Power failure	Interrupted power supply. Delay in reporting.	

3) Information (machine) related issues (1.b): Of all machine related issues, 87% were 'no output' (n=120, 65%) or 'delayed output' (n=41, 22%) (Table VIII). Examples of each type of machine related issue are given in Table IX.

TABLE VIII. TYPES OF MACHINE (OUTPUT) RELATED ISSUES

Information (machine) related issue	n	%
No output	120	65
Delayed output	41	22
Wrong output	21	12
Partial output	2	1
Total	184	

TABLE IX. TYPES OF MACHINE RELATED ISSUES AND RELEVANT EXAMPLES

Machine related issue	Examples
No output	Technical error leading to inability to review patient imaging during grand rounds when images and patient plans are supposed to be reviewed.
Wrong Output	Chest x-ray of patient A superimposed onto a chest x-ray film of patient B, both ICU patients. Repeat x-ray required.
Delayed Output	MRI spine performed at 1500 hours. No images were received for more than 2.5 hours. MRI demonstrated cord compression.
Partial Output	Only the latent image appeared, and the fully processed image failed to deliver/save onto the system.

V. DISCUSSION

For this study, we examined things that had gone wrong with medical imaging, particularly in relation to HIT, as a basis for trying to determine what is going wrong and what should be done to prevent and manage similar problems in the future. Embarking on examining what had gone wrong over seven years, through the lens of nearly 5000 incident reports, we expected to find a host of mainly technical problems. Indeed, a statement in the executive summary of a document on "Challenges faced by Australian Radiologists while Working with Conventional Imaging Workflow Solutions" reinforced this notion at the start of this study [7]. "The most severe obstacle for Australian radiologists is data fragmentation and inefficient information management tools and protocols. Lack of interoperability, differences in file formats and inefficient data communication standards and protocols lead to time pressures for radiologists. Furthermore, medical imaging systems are unable to communicate with other hospital information systems or even the patient's electronic medical record, creating a significant gap in the radiologists' knowledge and understanding. Imaging quality, ability to integrate multiple modalities and system speed and performance were identified as other areas of (sic) improvement. With radiology becoming an increasingly important component of emergency care, the above inefficiencies can be critical in delivering quality care" [7].

However, medical imaging is a socio-technical system [22] in which human behavior, performance and culture have an intimate relationship with technical devices and systems; they can synergistically improve the safety and quality of practice whist simultaneously causing harm and disrupting healthcare processes in new and unforeseen ways, sometimes affecting large number of patients [23]. Castro, in his conclusion on the contribution of socio-technical factors to HIT-related sentinel events, states "health IT-related events are primarily associated with the sociotechnical dimensions of human-computer interface, workflow and communication, and clinical content. Improved identification of health ITrelated contributing factors in the context of sociotechnical dimensions may help software developers, device manufacturers, and end users in health care organizations proactively identify vulnerabilities and hazards, ultimately reducing the risk of harm to patients" [20].

A. Human Factors

Although many technical problems and deficiencies were detected in the reports identified, which will be discussed below, we did not anticipate that more than half of the incidents (n=252; 58%) would involve failures of human performance.

When these HIT incidents were subjected to the HIT-CS (to classify the type of technical factors, these would be more than one incident type or characteristic per report), human (use) problems were identified for 252 incidents and made up 40% of the problems amongst the 623 HIT issues identified. No or wrong data entry or retrieval accounted for 93%, and partial or delayed data entry or retrieval for 7%, consistent with the findings in the workflow analysis above.

Human errors are normal and inevitable and play a role in the genesis of over 80% of problems in most complex systems [24]; seniority and experience provide no immunity [25]. They are also difficult to prevent because they are unintended, and the cognitive mechanisms by which they originate are usually obscure. Prevention may be possible by the introduction of 'forcing functions' [26], such as being required to log that certain mandatory checks have been done, but process based interventions should be used very judiciously, as "over-proceduralization" may detract from vigilance and situational awareness. It is better for equipment or systems to be designed so as to prevent certain errors from being possible (in anaesthesia, for example, anti-hypoxia rotameters for gas delivery, pin-indexing for attaching gas cylinders to gas delivery systems). Exhortations to "be more careful" are not a solution. Considerable thought and ingenuity will be required, ideally backed up by observational and ethnographic studies, to devise ways of preventing the occurrence and/or propagation of errors in the contexts of the various steps at which they occur.

The Royal Australian and New Zealand College of Radiologists (RANZCR) teaches a protocol, introduced in 2004, that radiology practices should have a system for identifying all patient records (such as referrals, images and reports) at all stages of patient care to ensure correct patient, date of birth and medical record number, as well as the date, time of study and practice name. The 3Cs protocol (correct patient, correct site and correct procedure) should also be checked by radiology personnel at a 'time out' immediately before any imaging or other procedure, and any mismatch should be dealt with and documented in the patient's record [27, 28].

However, a wrong patient is more likely to be detected at a "downstream" re-check than a wrong body part, side, or procedure, as questions checking the patient identity are often repeated at several stages of the procedure, whereas it seems that questions relating to these other issues are less likely to be. Once erroneous information is in the system, there is a tendency for it to be regarded as correct, due to "automation bias", manifesting as a "tendency to use automated cues as a heuristic replacement for vigilant information seeking and processing" [29]. Considerable ingenuity will be required to come up with crosschecking mechanisms which are sufficiently robust to prevent or detect these errors.

As pointed out by The Joint Commission, assiduous adherence to protocols, double checking that the input and output of data to and from IT systems is correct and complete, using interpreters for foreign language patients, and trying to keep the big picture in mind, can all help to prevent and detect errors, as well as ensuring that the staff are properly trained and aware that human error is the major cause of problems [21].

B. Technical Factors

Upon classifying incidents using the HIT-CS, it was found that software/ hardware issues accounted for 30% and machine related issues for another 30% of technical incidents. Most of the software issues, which made up 60% of the hardware/ software issues, involved interface, functionality and configuration problems, whereas most of the hardware related issues, which made up 40%, were 'device down or slow', with some additional problems due to data storage, backup and power failures. Inability to retrieve old images and to compare them to new ones creates the conditions for missed diagnosis. The acquisition devices were fairly reliable, but the systems supporting the manipulation and flow of information and images, including PACS, were much less so.

C. Obscure Mechanisms

Although the immediate (or sometimes late) consequences of human errors and technical failures were evident in most reports, the underlying mechanisms which may have led to them are usually not reported, and the reporter may indeed not have understood or even been aware of them. It may be easy to determine, for example, that access could not be obtained to a system such as PACS, or that an image was lost or corrupted, but exactly where the underlying problem in the system is and what the exact mechanisms were, is usually obscure. A problem of this nature is facing the Boeing Aircraft Corporation, who apparently built a software "fix" into their new "737 Max" aircraft to counteract a tendency to pitch nose-up, and in spite of the imperative imposed by the deaths of 346 people in two accidents, it seems that the exact mechanism of the problem has been hard to pinpoint and fix.

D. Strength and Limitations of the HIT-CS

The HIT-CS was developed from bottom-up to help to deconstruct incidents involving information technology, and to delineate problems arising from human use, hardware, software and machine failures [10]. At the level used in this study it had insufficient granularity to provide a detailed picture which could be used to properly understand what had happened. Although it is useful for deconstructing incidents and providing cues to reporters, in the form used in this study, its main value lay in being able to validate and triangulate the findings of the other classifications we used.

E. Further Work Identified in this Study

What follows is a description of what a good system could look like, based on our findings in this study and an appraisal of the literature. This should be done using a convenient, easy-to-use on-line system as exists in most jurisdiction, but ideally reporters should try to ensure that the "cues" in the HIT-CS are used to ensure completeness of the reports, and that the stages in the workflow process at which the incident was caused and was detected are included. This would comprise a structured "mini" root cause analysis rather than an informal narrative which may not contain the information an analyst might like. The database in which this information is collected could be augmented by a mechanism for collecting additional information from medicolegal files, complaints, and root cause analyses of sentinel events [30]. Lists of relevant key concepts should be generated, either by highlighting these at the stage of receipt of the narratives or before analysis and used for identifying clusters of incidents that are thought to be important or topical. Use of frameworks such as the HIT-CS can be very valuable for providing cues to reporters and people following up problems.

VI. CONCLUSION

Medical imaging is an essential part of modern medicine and, with health information technology (HIT) for managing both images and workflow, has become a truly complex socio-technical system. Although efficiency has improved, if these systems are not properly planned, designed, implemented and managed, unforeseen consequences such as delays, corruption of information, and harm to patients can ensue. It was therefore important to identify and characterize, through the lens of medical imaging incident reports, the things that are going wrong, with a particular focus on HIT, to provide a basis for improvements for preventing issues and improving clinical practice.

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