Refereed paper

Clinicians were oblivious to incorrect logging of test dates and the associated risks in an online pathology application: a case study

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ABSTRACT

Background UK primary care physicians receive their laboratory test results electronically. This study reports a computerised physician order entry (CPOE) system error in the pathology test request date that went unnoticed in family practices.

Method We conducted a case study using a causation of risk theoretical framework; comprising interviews with clinicians and the manufacturer to explore the identification of and reaction to the error. The primary outcome was the evolution and recognition of and response to the problem. The secondary outcome was to identify other issues with this system noted by users.

Results The problem was defined as the incorrect logging of test dates ordered through a CPOE system. The system assigned the test request date to the results, hence a blood test taken after a therapeutic intervention (e.g. an increase in cholesterol-lowering therapy) would appear in the computerised medical record as though it had been

tested prior to the increase in treatment. This case demonstrates that: the manufacturers failed to understand family physician workflow; regulation of medical software did not prevent the error; and inherent user trust in technology exacerbated this problem. It took three months before users in two practices independently noted the date errors.

Conclusion This case illustrates how users take software on trust and suppliers fail to make provision for risks associated with new software. Resulting errors led to inappropriate prescribing, follow-up, costs and risk. The evaluation of such devices should include utilising risk management processes (RMP) to minimise and manage potential risk.

Keywords: computerised medical records systems, general practice, medical informatics, medical order entry systems, safety management

Introduction

Computerised medical records (CMR) and computerised physician order entry systems (CPOE) systems are increasingly used in clinical practice.[1] Information and communication technology is changing society[2] and supporting healthcare professionals[3] by standardising communication protocols.[4] Such systems are

beneficial for laboratory work processes,[5–7] improving the efficiency of laboratories[8] and healthcare delivery.[3,9,10] However, there is limited data on patient outcomes when using these applications, which may be due to the potential for adverse events in clinical practice.[11]

Strict regulation,[12] validation and verification processes ensure that software is tailored to user requirements and ensure patient safety.[13] Clinicians rely on medical software to deliver information, however, these devices are associated with inherent hazards such as functional errors, being unreliable, user-unfriendly or if the primary setting is unprepared to accommodate the required working processes.[14] Such failures can negatively affect working processes and the decisions of healthcare providers, resulting in harm for patients.[13,15]

Risk management processes (RMP) aim to reduce error, and utilising these is the responsibility of both users and service providers (Box 1).[16–18] There should be systems in place to facilitate communication and action if errors arise. This is particularly relevant for CPOE systems, as their introduction can have unexpected consequences requiring early detection and action.[19] Research to date highlights the need for risk avoidance through the continual evaluation of systems; ensuring optimal useability[11] and intrinsic safety that will persist, even in the hands of busy clinicians.[20]

Box 1 Risk theory application to software implementations

Possible causes of failure
- **Task perception**: Failure of users and service providers to realise responsibility; mistaken priorities by developers.
- **Capability and experience**: Lack of appreciation of the consequences of actions or appropriate training.
- **Work environment**: Information overload in a difficult work environment may make it difficult for users to identify problems with the application.
- **Mistake**: Random slips may occur at any stage of development or use.
- **Motivation**: The designers may have had a lack of incentive to produce a high-quality application; the users may not feel motivated to report and look out for problems/errors with the medical devices they use.
- **Actions of others**: The failure to communicate errors or problems between users/providers could lead to on-going increased clinical risk when using the application.

Case description

A CPOE pathology test-ordering system within UK primary care enables better tracking of specimens and results. This allows community based clinicians to request tests and view patient results. Family doctor users identified a problem with this CPOE system; test requests were logged as taken on the date of request, instead of, as intended, on the date the sample was taken. This was not recognised by all users, and may have led to errors when interpreting these results. The identification of this problem has consequently been evaluated, using a risk management framework to identify potential sources of error from each stakeholder group. This case study aims to raise awareness of potential risk associated with medical software devices used in clinical practice.

Method

Overview

We evaluated the application using a risk theory framework.[16–18] Data was collected through interviews with key stakeholders using the system. The primary outcome was to explore the evolution and recognition of and response to the problem. The secondary outcome was to identify other issues with this system as noted by users.

Literature review

We carried out a literature review using PubMed, Medline and Web of Science. We searched using the medical subject heading (MeSH) *Medical Order Entry Systems* combined with either *Safety management* or *General Practice.*

Timeline

The timeline begins with the installation of the software, and then highlights the timespan between recognition and reporting of the problem, and the manufacturer's response. All correspondence between the manufacturer, affiliated CMR software providers, the laboratory and users was recorded and included.

Data collection

Data was collected through face-to-face interviews with primary care staff (five general practitioners, a

practice nurse and practice manager) who identified the problem. Telephone interviews with the manufacturer, CMR system vendor support team and the pathology laboratory support team were conducted to explore existing regulatory frameworks, user requirements, and review responses to the user experience with this CPOE system.

Causation of the risk and risk management

These findings were indexed and charted through use of Chapman and Ward's causation of risk theoretical framework (Box 1).[16–18] The framework provided a formal structure for identifying the source, extent and consequences of the error(s) and understanding how the resultant risks were managed by the key stakeholder groups involved. This application of the risk framework provided a systematically derived insight into the prevention of similar events in future practice.

Ethical considerations

This investigation meets the National Research Ethics Service (NRES) criteria of a service evaluation (www. nres.nhs.uk/applications/is-your-project-research/).

Results

Primary outcome

Problem definition

The software incorrectly logged the test date as though the test had been done on the date it was requested, rather than the date the sample was taken and the test done. In primary care, tests are commonly requested in advance. These results were inaccurately stored with dates corresponding to when they were requested; creating discrepancies in the order of test results. This created confusion and may have compromised patient safety; particularly with regards to drug monitoring.

Examples of where interpretation difficulties could have clinical implications are given below.

- A GP reduces a statin dose (a medicine that lowers blood cholesterol) and prepares a laboratory cholesterol request form. A printout is issued and the patient books to attend an outpatient appointment in a month. The test result is filed on the date the request form was printed, before the statin dose was reduced. This complicates interpretation of results

and leads to repeat testing and inadequate treatment.
- With warfarin (an anticoagulant) dosing and international normalised ratio (INR) measurements of clotting, day-to-day accurate results are needed to titrate doses, therefore, errors in INR test dates may have significant clinical implications for patients on warfarin.

In practice, the final test request form should have allowed the clinician to differentiate between a test to be performed straight away and one to be carried out later (Figure 1). However, when clinicians deferred test dates, the software presumed that the test was performed on the date of the request.

Timeline

After installation in October 2010, it took until January 2011 for only two of the family practices using the software to recognise this problem (Figure 2).

The initial response was to retrain the doctors, as the practice managers considered that they were responsible for incorrectly logging dates. It soon became apparent that this was an inbuilt error. When users reported this error to the manufacturer, the response time was slow and inappropriate in relation to the risk posed. The maufacturer initially offered impractical solutions, such as a change in software or parallel recording of dates. After six months of emails and telephone calls relating to this problem, the manufacturer finally offered a solution.

Figure 1 Screenshot of initial test-ordering screen
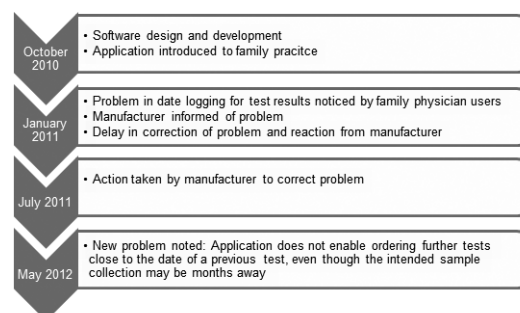

Figure 2 Timeline

Causation of the risk

Responses from the manufacturer of this application, CMR system vendor, the pathology laboratory service and practitioners recognising the problem suggest that the focus of individual actors was on their domain of responsibility only rather than minimising risk across the system as a whole (Table 1).

Risk management

The discrepancy between the manufacturer and front-line clinicians regarding the perceived risk may have explained the delay in reaction time and initial dismissive approach from the manufacturer. A delay in finding a solution resulted in months of inaccurate dating of results with subsequent knock-on effects on clinical care.

Secondary outcomes

First, the family physicians interviewed considered the interface to be 'user-unfriendly'. Second, subsequent to the difficulties with recording dates, a block was introduced into the CPOE that prevented a second request being made for the same test shortly after the first (Figure 3). In practice workflow, a family physician often sees a patient, adjusts therapy and requests a pathology test just before the next time they meet for a review. However, the introduction of the block during 2012 – presumably to prevent unnecessary duplicate tests – means that either the patient has to be seen an extra time or some workaround such as issuing a paper request form (with the inherent increased inherent risks of transcription or other errors) has to be put in place. Although it appears to be a check that can be overridden, the alert cannot be cancelled.
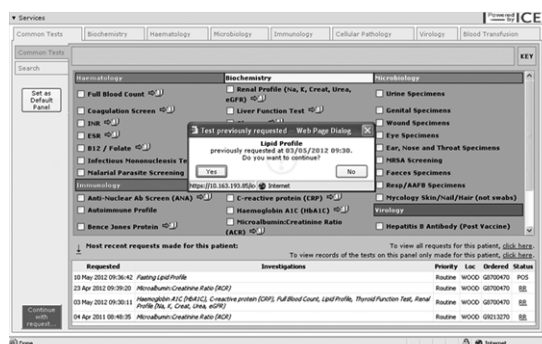

Figure 3 Screenshot of refused second lipid profile

Discussion

Principal findings

This case describes the incorrect logging of dates for tests ordered through the CPOE system. It highlights how users trusted the software and failed to identify risks associated with incorrect test dates, and how providers of this system failed to understand family physician workflow. Regulation of medical software does not appear to have prevented this type of error.

Implications of the findings/ implications for practice

This risk may have significantly compromised patient safety. Delays in correction meant that results continued to be logged incorrectly, increasing the chance of adverse events from reviewing incorrectly dated results. Because this error was not noted earlier during product development or applied performance testing, this raises questions of whether the software underwent adequate user pilot testing ahead of general release. There is as a result a need for improved quality assurance of software ensuring accuracy and safety of devices.

Although noted by two practices, the problem was not obvious to other practices using the system; implying either incorrect use of the system, or failure to recognise the error. This is important because if the other users were not aware of this problem, they may be at greater risk of misinterpreting sample results. Therefore, this case should assist in heightening clinician's suspicion of medical support tool accuracy used in clinical decision making.

Furthermore, the impact of such errors may include: (1) unwarranted tests or therapies, (2) the risk of physicians branding a patient non-adherent, (3) the opportunity cost of correcting errors, (4) the financial costs of serious errors, and (5) the cost of addressing the supposed error rather than the actual error, by 'retraining users of the device' prior to recognising the inbuilt nature of the error.

Comparison with the literature

There are many calls for improved evaluation of clinical support tools;[4,13,21] incorporating usability engineering principles into software design to help identify interface problems that may lead to adverse events.[11] Heuristic evaluations of usability should take place early in the process of designing CPOE systems[6] and successful CPOE implementation requires a solid understanding of the organisational, communication,

Table 1 Sources of risk inefficiency in the key stakeholder groups

Factors	Family practice users recognising the problem	Pathology laboratory	Computerised medical record (CMR) system vendor	Software manufacturer
Task perception	(1) Failure to realise responsibility (2) Mistaken priorities due to difficulty using system 'overcomplicated' and 'user-unfriendly'	Following instructions incorrectly	(1) Mistaken priorities (2) Failure to realise responsibility 'it appears like it's a training issue or it could be there is a fault on the desktop or perhaps the wording should be made clearer' '... manufacturer, please can this issue be looked into urgently.' Closed the case when they transferred problem to manufacturer	(1) Mistaken priorities (2) Failure to realise responsibility 'I think you are probably best to contact CMR system vendor with regards to how they handle sample collection dates, they are in a better position to advise.' When responsibility was realised – the response: 'The system is working by design.' 'This is both a known and national issue.' Then they offered some workarounds.
Capability and experience	Lack of training/skills in identifying risk and having an index of suspicion	Lack of training/skills	Jumping to conclusions	(1) Jumping to conclusions about the nature of a situation and the impact (2) Lack of appreciation of the consequences of actions
Work environment	Information overload makes it difficult to identify important information			Inadequate work environment – increasing risk of mistakes
Mistake		Incorrect assessment of situation	(1) Incorrect assessment of situation (2) Failure to detect problem	
Motivation		(1) Lack of incentive for high-level performance (2) Personal objectives		
Actions of others	Failure to communicate information	Frustration of others	Failure to communicate information	Failure to communicate information If it was an inbuilt problem – why were the users not made aware of this? Incorrect components supplied

and temporal circumstances within which the system will operate.[22]

Effective decision-support systems cannot be assessed purely by evaluating the usability and performance of the software, the system testing needs to include cognitive and socio-technical interactions.[22] We need to generate a deeper understanding of these issues to design intrinsically 'safe' systems that minimise risk in the hands of clinicians, who are often poorly resourced.[22]

We should evaluate these types of applications in practice.[15,23,24] However, identified barriers to the evaluation of such devices include: insufficiently available evaluation guidelines and support, inadequate collaboration, cost and innate organisational resistance.[4,25] The barriers for clinicians include motivation and the complexity of the evaluation object.[24]

The emphasis on raising awareness among clinicians should be reinforced by suggesting that evaluation of health informatics systems should have the same role in medical informatics as evidence and audit have in clinical practice.[15]

Limitations

This was a small case study making it hard to be certain of generalisability. However, safety literature is often based on reporting of critical incidents to help raise awareness and inform others.

Call for further research

Further research is needed to reduce the margin for error, raise awareness and ensure that products in use meet user requirements. We recommend carrying out on-site pilots with users in advance of general release, and the promotion of widespread use of systematic risk frameworks and RMPs such as *Shape Harness and Manage Project Uncertainties* (SHAMPU)[16] to formalise risk management. Video is acceptable and a useful media to observe workflow and can be combined with other data gathering approaches.[26] Video studies could be used to capture current ways of working and the impact and risk associated with the introduction of new technologies on it.[27]

Conclusion

This case study describes how medical software utilised for ordering online tests had an inbuilt design error resulting in the incorrect logging of dates for test results. This case study highlights how current systems should consider making greater use of risks assess-

ment and management processes during the implementation of a new software application.

CONFLICTS OF INTEREST

None.

REFERENCES

1 de Lusignan S and van Weel C. The use of routinely collected computer data for research in primary care: opportunities and challenges. *Family Practice* 2006; 23:253–63.

2 Haux R, Knaup P, Bauer AW *et al.* Information processing in healthcare at the start of the third millennium: potential and limitations. *Methods of Information in Medicine* 2001;40:156–62.

3 Maurette P. To err is human: building a safer health system. *Annales Françaises d'Anesthésie et de Réanimation* 2002;21:453–4.

4 Ammenwerth E, Brender J, Nykänen P, Prokosch HU, Rigby M and Talmon J. HIS-EVAL Workshop Participants. Visions and strategies to improve evaluation of health information systems. Reflections and lessons based on the HIS-EVAL workshop in Innsbruck. *International Journal of Medical Informatics* 2004;73:479–91.

5 Ali J, Barrow L and Vuylsteke A. The impact of computerised physician order entry on prescribing practices in a cardiothoracic intensive care unit. *Anaesthesia* 2010;65:119–23.

6 Chan J, Shojania KG, Easty AC and Etchells EE. Usability evaluation of order sets in a computerised provider order entry system. *BMJ Quality and Safety* 2011;20: 932–40.

7 Georgiou A, Williamson M, Westbrook JI and Ray S. The impact of computerised physician order entry systems on pathology services: a systematic review. *International Journal of Medical Informatics* 2007;76: 514–29. Epub 2006 Mar 29.

8 Georgiou A, Lang S, Rosenfeld D and Westbrook JI. The use of computerized provider order entry to improve the effectiveness and efficiency of coagulation testing. *Archives of Pathology & Laboratory Medicine* 2011;135:495–8.

9 Georgiou A, Westbrook J, Braithwaite J and Iedema R. Multiple perspectives on the impact of electronic ordering on hospital organisational and communication processes. *Health Information Management Journal* 2006;34:130–5.

10 Westbrook JI, Georgiou A and Rob MI. Computerised order entry systems: sustained impact on laboratory efficiency and mortality rates? *Studies in Health Technology and Informatics* 2008;136:345–50.

11 Graham TA, Kushniruk AW, Bullard MJ *et al.* How usability of a web-based clinical decision support system has the potential to contribute to adverse medical events. *AMIA Annual Symposium Proceedings* 2008:257–61.

12 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0042:EN:HTML (accessed 2 July 2012).

13 Rigby M, Forsström J, Roberts R and Wyatt J. Verifying quality and safety in health informatics services. *BMJ* 2001;323(7312):552–6.

14 Southon G, Sauer C and Dampney K. Lessons from a failed information systems initiative: issues for complex organisations. *International Journal of Medical Informatics* 1999;55(1):33–46.

15 Ammenwerth E and Shaw NT. Bad informatics can kill – is evaluation the answer? *Methods of Information in Medicine* 2005;44:1–3.

16 Chapman CB and Ward SC. *Project Risk Management: processes, insights and techniques.* (2e). London: John Wiley and Son Ltd, 2006.

17 Ward SC. *Risk Management: organisation and context.* London: Witherby & Co. Ltd, 2005.

18 Borodzicz EP. *Risk, Crisis and Security Management.* Chichester: John Wiley & Sons Ltd, 2005.

19 Georgiou A, Morse W, Timmins W *et al.* The use of performance metrics to monitor the impact of CPOE on pathology laboratory services. *Studies in Health Technology and Informatics* 2008;136:291–6.

20 Coiera E, Westbrook J and Wyatt J. The safety and quality of decision support systems. *Yearbook of Medical Informatics* 2006:20–5.

21 Haux R, Ammenwerth E, Herzog W and Knaup P. Health care in the information society: a prognosis for the year 2013. *International Journal of Medical Informatics* 2002;66(1–3):3–21.

22 Georgiou A, Westbrook J and Braithwaite J. What effect does electronic ordering have on the organisational dynamics of a hospital pathology service? *Studies in Health Technology and Informatics* 2010;160(Pt 1):223–7.

23 Gell G. Side effects and responsibility of medical informatics. *International Journal of Medical Informatics* 2001;64(2–3):69–81.

24 Ammenwerth E, Gräber S, Herrmann G *et al.* Evaluation of health information systems – problems and challenges. *International Journal of Medical Informatics* 2003;71(2–3):125–35.

25 Rigby M. Evaluation: 16 powerful reasons why not to do it – and 6 over-riding imperatives. *Studies in Health Technology and Informatics* 2001;84(Pt 2):1198–202.

26 de Lusignan S, Kumarapeli P, Chan T *et al.* The ALFA (Activity Log Files Aggregation) toolkit: a method for precise observation of the consultation. *Journal of Medical Internet Research* 2008;10(4):e27.

27 Pflug B, Kumarapeli P, van Vlymen J *et al.* Measuring the impact of the computer on the consultation: an open source application to combine multiple observational outputs. *Informatics for Health and Social Care* 2010; 35(1):10–24. PubMed PMID: 20302436.

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