

The Safety and Quality of Decision Support Systems

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Summary

Objectives: The use of clinical decision support systems (CDSS) can improve the overall safety and quality of health care delivery, but may also introduce machine-related errors. Recent concerns about the potential for CDSS to harm patients have generated much debate, but there is little research available to identify the nature of such errors, or quantify their frequency or clinical impact.

Methods: A review of recent literature into electronic prescribing systems, as well as related literature in decision support.

Results: There seems to be some evidence for variation in the outcomes of using CDSS, most likely reflecting variations in clinical setting, culture, training and organizational process, independent of technical variables. There is also preliminary evidence that poorly implemented CDSS can lead to increased mortality in some settings. Studies in the US, UK and Australia have found commercial prescribing systems often fail to uniformly detect significant drug interactions, probably because of errors in their knowledge base. Electronic medication management systems may generate new types of error because of user-interface design, but also because of events in the workplace such as distraction affecting the actions of system users. Another potential source of CDSS influenced errors are automation biases, including errors of omission where individuals miss important data because the system does not prompt them to notice them, and errors of commission where individuals do what the decision aid tells to do, even when this contradicts their training and other available data. Errors of dismissal occur when relevant alerts are ignored. On-line decision support systems may also result in errors where clinicians come to an incorrect assessment of the evidence, possibly shaped in part by cognitive decision biases.

Conclusions: The effectiveness of decision support systems, like all other health IT, cannot be assessed purely by evaluating the usability and performance of the software, but is the outcome of a complex set of cognitive and socio-technical interactions. A deeper understanding of these issues can result in the design of systems which are not just intrinsically 'safe' but which also result in safe outcomes in the hands of busy or poorly resourced clinicians.

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Keywords

Decision support systems, safety, error, automation bias, electronic prescribing

Introduction

There is now clear consensus that computer based decision support (CDSS) can be a potent intervention to improve the quality, safety and effectiveness of clinical decisions, can result in improved patient outcomes and in more effective clinical services [1-4]. Nonetheless, the uptake of CDSS remains low in many settings, probably because the introduction of CDSS is often believed to require the prior implementation of electronic health records (EHR) - a substantial organizational challenge itself. In settings such as primary care, where the task of introducing such records is less complex, the rates of CDSS use, such as electronic prescribing, have now reached significant levels in many countries [5, 6]. Consequently, it seems that the message that CDSS are an important component of clinical services, and indeed, are probably essential to much of modern practice, has finally started to break through.

However, while we know that CDSS can improve clinical outcomes, we still know relatively little about the specific impact of CDSS on clinicians. How do we know when a CDSS provides its advice safely and in a format which will encourage use [7]? Even the simplest paper-based decision tools frequently lead to the wrong answer being generated [8], with serious consequences for patient care. Does the same happen with CDSS? Do all clinicians get the same benefit from using a CDSS? Do some clinicians use CDSS more effectively than others or do some face challenges

[7] and require specific training prior to using a CDSS? Are there specific work settings in which certain CDSS designs are problematic? Currently most research comes from single institutions that have pioneered their own decision support systems, and as a consequence they usually have strong local ownership and clinical acceptance of the system. Where there have been cross-institutional studies, it seems there is indeed wide variation in CDSS use [9, 10], often because of organizational and cultural factors [11, 12].

This variation should be unsurprising, since clinical software is just one component of a clinical service. It is the totality of interaction between users, clinical settings, and technology that shapes the final outcome. Clinical services are socio-technical systems, meaning that we recognize that social and cultural variables are as likely to affect service performance as are individual cognitive variables, or specific aspects of the design of a technology [13]. Such socio-technical systems are complex, and a feature of all complex systems is unexpected emergent behavior.

One unexpected outcome of introducing CDSS into clinical settings is that, while we can improve the overall safety and quality of existing practices, a paradoxical side effect may be the creation of new kinds of machine-related error. In 2004, by bringing together results from qualitative studies in three countries, Ash et al provided anecdotal accounts that clinical use of CDSS in some circumstances actually lead to new types of errors. Since then,

there has been a flurry of editorial comment and concern about the safety and quality of decisions support systems. Some raise concerns that CDSS technology has yet to deliver on its promises [14], that CDSS systems may not be 'team players' in a setting that demands collaborative actions [15], or that rapid adoption of CDSS may be a risk [16]. Others are anxious that over-emphasis on CDSS generated errors will delay the implementation of a crucial technology that has the very real opportunity to save many lives [17].

Use of Electronic Medication Management Systems May Generate New Types of Error

Unfortunately the current literature on the use of decision support systems in clinical practice is not rich or large enough to answer clearly key questions about the situations in which the safety or effectiveness of a CDSS may be compromised. Carrying out a laboratory

impact study, in which users record their decisions about a case both before and after seeing the advice from the CDSS [18], is a useful step beyond the ubiquitous studies of the accuracy of CDSS advice. However, such studies need to be carefully designed to control bias, and their results will not necessarily predict those from a rigorous field trial [19]. Perhaps the area that is best studied is medication management, and we can garner some clues about CDSS safety from this specific literature. Several recent publications have identified the potential of electronic prescribing systems (e-PS) to create medication errors (See Box 1) [20-25]. Qualitative studies have highlighted examples of system design flaws, poor decision support rules and lack of training in the functionality of systems that could conceivably result in errors. Using focus groups, interviews and direct observation of clinicians, Koppel et al [26] identified a range of electronic prescribing system features at one US hospital that were reported as increasing the occurrence of specific error types.

Yet the specific system they studied was a very old one, originating in the 1960s, requiring multiple screens for many activities, and therefore leading to errors not necessarily associated with more modern designs [17]. Further, the actual frequency of these prescribing system-induced errors in clinical practice was not measured, nor was the extent to which any such errors actually resulted in patient harm. Yet the broad literature on clinical error emphasizes that a single error in isolation will rarely be the cause of an adverse outcome, and most adverse events or poor outcomes result from a string of errors in succession [27]. Consequently, it remains completely unclear how often a single error that occurs in electronic prescribing translates to an error in the treatment the patient actually receives. Of concern, several studies have now shown that commercial e-PSs often fail to alert users to clinically significant drug-drug interactions that should be known to the system, and as a result generate inappropriate prescriptions that have the potential to harm patients. In a

Table 1 Examples of 'new errors' introduced by the use of electronic prescribing systems

- Substitution errors: eg two similar drug names are located together on a scroll down list and the incorrect drug is selected [23]. A US clinician reported *"I was ordering Cortisporin, and Cortisporin solution and suspension comes up. The patient was talking to me, I accidentally put down the solution, realized that's not what I wanted.. I would not have made that mistake if I have been writing it out because I would have put down what I wanted."* [24]
- Selection of the wrong patient from scroll down menus or placing orders for the wrong patient because a previous record was not closed [23], or because patients' names are listed in alphabetical order [26]. Koppel et al found 55% of 261 clinicians in one hospital reported that they had difficulty being able to quickly tell which patients they were ordering for because of poor screen display.
- System delays in transfer of information: eg a patient had a severe hypoglycaemic episode following a system delay in notifying a doctor's order to cancel an insulin dose for this diabetic patient who was fasting for a procedure [21].
- Inability to view all relevant information – eg a patient's entire medication list may go over several screens and is not able to be reviewed as easily as a paper chart resulting in missed information, or multiple screens scrolled too quickly result in missing information [26]. Seventy-two percent of survey clinicians at one hospital reported they were often uncertain about patients' medications and doses because of the difficulty of viewing all medications on one screen [26]. Popup screens may hide important information.
- Inflexible systems: eg systems which fail to allow non-standard drug orders, *"...nonformulary medication to prevent organ rejection was not listed among medications in CPOE, was not sent to the pharmacy, and was ignored for 6 days"* (page 1201) [26]. Ninety-two percent of surveyed clinicians at one hospital reported having difficulty in ordering non-standard and off-formulary medications in the previous three months.
- Over-reliance on drug dose options: eg an e-PS system allowed doctors to order large doses of IV potassium without specifying it be given in divided doses leading to a 3.5 fold increase in the rate of intercepted, life-threatening ADEs [20]. A hospital prescribing system displayed drug doses in terms of doses available in pharmacy stock. These doses were often interpreted by clinicians as the "minimally effective" or as a basis for calculating the range of doses, potentially producing errors in drug dosing. In a survey Koppel et al found 73% of clinicians in one hospital reported that they had used computer dose displays in this way for drugs they infrequently prescribed in the previous three months [26].
- Failure of system to alert clinicians to carry out specific actions: An absence of alerts to remind doctors to gain approval for a renewal of certain antibiotics led to gaps in therapy [26]. In one hospital 83% of clinicians surveyed reported that they were aware of at least one such unintended gap in therapy during the last three months.

nationwide field-test of e-PS systems in the US, data generated by mock patients and taken from actual prescriptions that had led to death or serious injury were entered into 307 electronic prescribing systems. Over 60% of systems tested failed to detect four of the five fatal drug orders entered, and among those systems that did detect them a large percentage (in most cases over 60%) allowed users to override the alerts without making a note [23].

Fernando et al. [28] tested four commercial e-PS in the UK using 18 test cases that should have generated an alert that the prescription was unsafe. The best system only generated seven out of 18 possible alerts. Two systems generated four alerts and the fourth generated only three. An Australian study by the National Prescribing Service of four e-PS widely used in general practice found that of 32 drug combinations that should have created an alert of significant risk of drug interaction, the commercial systems identified only between eight and 16 of them [29]. While little is known about the specific causes of such failures to alert, the most likely culprit is a CDSS knowledge base which is inaccurate or out of date.

Errors May Arise from the Setting in which the CDSS Is Used

More recently Han et al. have reported an unexpected and statistically significant increase in mortality from 2.80 to 6.57% after implementing a commercial electronic prescribing system in a hospital [44]. Assigning the blame for this startling outcome is complicated, and the study identifies many factors that might have contributed. The software certainly increased the complexity and time taken to prescribe, and altered

traditional work patterns. Clinicians who might have routinely discussed prescribing decisions face to face with colleagues over a paper form were required to work at a computer, removed from the immediate bedside, thus reducing the opportunity for their decisions to be critiqued by colleagues. Before e-PS implementation, physicians and nurses converged at the patient's bedside to stabilize the patient. After implementation, while one physician continued to direct medical management, a second physician was often needed solely to enter orders into the computer during the first 15 minutes to 1 hour if a patient arrived in extremis. The process of implementing the new system itself occurred over just six days, which seems an extremely short time to introduce a complex new organizational process and expect it to work smoothly. Many of these forced alterations to existing organizational work practices, which seemingly might increase the risks of error, could have been identified and rectified during a more gradual implementation process.

Sometimes, it is the organizational setting itself that may be the primary cause of errors associated with the use of a decision support system. Self reported error data from over 570 US hospitals published in 2005 [25] revealed that 20% of hospital medication errors in 2003 involved computerization or automation, but less than one percent of the errors that occurred at the time of prescribing using an electronic system resulted in harm to patients. A large proportion of these were due to computer data entry errors, which were the fourth leading cause of medication errors. Most data entry errors occurred after the initial medication orders had been placed in the system, and included incomplete or incorrect information. User distraction accounted for nearly 60% of all data entry errors. This high-

lights the way in which the clinical environment can contribute to what is otherwise seen as a CDSS 'error'. Should we blame a CDSS if a clinician is distracted by an event in their workplace while using the system? Should we recognize that CDSS need to be 'fit-for-purpose' and that software designed for quiet use may become unsafe when applied in busy, interruptive workplaces? In such settings do we blame the CDSS for being unsafe, or the decision to implement it in a setting in which it became unsafe?

Indeed, a crucial feature of safety-critical systems seems to be the presence of systems to cross-check decisions, and one might wonder if a workplace that relies totally on the output of a CDSS is inherently unsafe, independent of the performance of a specific CDSS. For example, Bates et al's 1999 study reported that poor user interface design in an electronic prescribing system resulted in a 350% increase in the rate of intercepted, but potentially life-threatening adverse drug events at a US hospital. The system allowed doctors to order large doses of IV potassium without specifying it must be given in a sequence of divided doses [20]. However, the presence of parallel checking systems meant that all the CDSS errors were intercepted and no patients were harmed, even though the problem was not rectified for two years following system implementation.

Automation Biases May Generate Decision Errors

Although little studied in clinical settings, one type of error found to be associated with decision support systems is known as *automation bias*, where people using an automated decision aid act as the aid directs them to, irrespec-

tive of the correctness of the suggested action [30]. For example, individuals may be less vigilant in checking drug orders that are generated by a computer because they assume the computer will have already done the work, or continue with a dangerous drug order because the computer did not alert them that the order was unsafe. Thus use of a CDSS could lead to *errors of omission* where individuals miss important data because the system does not prompt them to notice them, or to *errors of commission* where individuals do what the decision aid tells or allows them to do, even when this contradicts their training and other available data.

In a laboratory experiment looking for automation bias, Skitka et al. [31] gave users a simulated flight task. Some users had the additional benefit of a CDSS that monitored system states and made decision recommendations. When the aid worked perfectly, users of the system outperformed those who did not use it. However when the computer aid was not perfectly reliable, and occasionally failed to prompt the user when action was needed, or incorrectly made a prompt to carry out an action when none was needed, the situation changed. Users without the aid outperformed their counterparts with the aid - those using an aid only had 59% accuracy on the omission error events, compared to 97% for the non-computer users, and performed even worse with commission errors, with an accuracy of only 35%. There are many possible explanations for automation bias. It has been suggested that humans who trust a computer system shed responsibility for tasks, and devolve them to the computer. Computer users may as a result develop an 'out of loop unfamiliarity' with the system they are meant to be monitoring, because they have delegated the task of monitoring data to the automated aid, effectively taking themselves out

of the decision loop [32]. If an urgent event were to occur, the consequence of out of loop unfamiliarity may be that it takes much longer to become familiar with the current state of the patient, and to develop the mental model needed to solve the problem. In contrast, without a decision aid, the human has no choice but to maintain an active mental model of the state of the system being monitored. Recent evidence suggests that explicit training in automation bias has a short term benefit only, but that making individuals personally accountable for their decisions does seem to reduce automation bias. Specifically, if individuals are told that their actions are socially accountable, because the data of their performance are being recorded, and that they will be held accountable for the outcome of their performance, then individuals spend more time verifying the correctness of the decision aid's suggestions by checking data, and therefore make fewer errors [33].

A form of anti-automation bias also exists, which we might label *errors of dismissal*, where computer advice is ignored. Clinicians routinely disable or ignore the alarms or alerts on clinical monitoring devices [34] for a variety of genuine reasons (e.g. high false alarm rates [35, 36] or repetition of the same alarms) and for some not so valid reasons (e.g. not wanting to be interrupted). This behavior is likely to occur much more widely, and it does seem that clinicians ignore the alerts generated by CDSS in other settings [37, 38]. For example, Weingert et al. [38] looked at physicians' decisions to override computerized drug alerts in primary care, and found that physicians overrode 91.2% of drug allergy and 89.4% of high-severity drug interaction alerts generated by a common computerized physician order entry system for prescription writing. They found no adverse

events amongst the physicians who followed the alert and three among patients with alert overrides, but the difference was not statistically significant. In a hospital setting, similar high rates of alert overrides were reported by Hsieh et al [39] where 80% of alerts in a order entry system were overridden, six percent of which led to adverse drug events (ADEs). However all these ADEs were judged to be nonpreventable because the clinical need for the drug outweighed the risk of a serious allergic reaction. One study of two diagnostic CDSS showed that the system advice added the correct diagnosis to the doctor's differential in 12% of patient scenarios but led to them deleting it in a further 6%, giving a net benefit in 6% of cases [40].

Understanding the extent to which automation bias in all its forms plays a role in creating new errors in clinical practice from using CDSS is an important new area of scientific investigation and few empirical studies have yet been conducted.

Using Evidence-retrieval Systems May Lead to Decision Errors

There are various different forms of decision support available to clinical users. In many situations a clinician is interested in accessing text-based resources like clinical guidelines, research papers and systematic reviews to help form an opinion about a clinical problem. On-line evidence retrieval systems that allow clinicians to search for and access such resources are sometimes characterized as passive CDSS, to contrast their performance with decision support systems that try and formulate a specific recommendation or alert.

In one laboratory study, experienced

clinicians were asked to provide their answers to clinical problems before and after using search engines to find supporting clinical evidence [41]. While the group of clinicians had an overall improvement of 21% in their decision making after using the retrieval system, performance declined for a small subgroup. For 7% percent of clinical problems reviewed, clinicians had initially provided a correct answer, but after using the system to review the evidence, changed their answer to an incorrect one. It is not clear what factors contributed to this result, but clearly reading misleading, old or conflicting evidence all may play a part in altering a clinician's decision, highlighting the importance of providing high quality and up to date evidence through clinical information retrieval systems. Interestingly, more recent analysis has shown that despite seeing the same evidence, clinicians can arrive at very different conclusions, strongly influenced by their prior beliefs [42]. This result suggests that well known human cognitive biases, in addition to the new automation biases, remain a challenge even when humans are supported by machines, and that system designers cannot assume that any two individuals will react in the same way to what may appear clear guidance provided by the machine.

Conclusion

There is now growing evidence that when poorly designed, implemented or used, decision support systems may lead to harm. Just like any other effective and powerful clinical intervention, we must recognize that it is the very capacity for decision support systems to influence clinical outcomes that requires us to treat them with professional respect. The repeated demonstrations in

different countries that commercial electronic prescribing systems often fail to detect significant drug interactions should be a major cause for concern, and raises questions about the best mechanisms to ensure that clinicians and patients can have confidence in the quality of such systems.

While the integrity of the software itself may sometimes be of concern, the effectiveness of decision support systems, like all other health IT, cannot be assessed purely by evaluating the usability and performance of the software. System performance is the outcome of a complex set of cognitive and socio-technical interactions within which the computer system is enmeshed. One needs to consider the extent to which the clinical users have been trained to use a system safely and effectively, the extent to which the working environment is conducive to safe work practices, and the appropriateness of the decision support system for the clinical tasks to which it is being applied.

Recognizing that the use of a decision support system can result in errors because of poor user training, human error, disruption of system use because of interruptions by work colleagues, or because the software was used in ways its designers never intended is important because it tells us about the importance of establishing safe organizational practices and cultures when using decision support.

A deeper understanding of these issues should result in the design of systems which are not just intrinsically 'safe' but which also result in safe outcomes in the hands of busy or poorly resourced clinicians [43].

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