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Authors:

Affiliation:

Abstract: Clinical decision support systems are interactive software systems designed to assist clinicians with decision making tasks, such as determining a diagnosis or recommending a treatment for a patient. Clinical decision support systems are a widely researched topic in the Computer Science community but their inner workings are less well understood by and known to clinicians. In this article we provide a brief explanation of clinical decision support systems and provide some examples of real world systems. We also describe some of the challenges to implementing these systems in clinical environments and posit some of the reasons for limited adoption of decision support systems in practice. We aim to engage clinicians in the development of decision support system that can meaningfully help with their decision making tasks and open up a discussion about the future of automated clinical decision support as a part of healthcare delivery.

Context

Information technology (IT) is now commonplace in almost every branch of healthcare. Electronic health records (EHR), e-prescribing and digital medical imaging are now well known to clinicians and have been implemented with varying degrees of success [1]. In addition clinicians increasingly make use of online repositories such as PubMed and Google Scholar [2], or specialised search engines such as FindZebra [3] to help answer clinical questions. One often overlooked set of IT tools are Clinical Decision Support Systems (CDSSs), which have been defined as systems that 'provide clinicians or patients with computer-generated clinical knowledge and patient-related information, intelligently filtered or presented at appropriate times, to enhance patient care' [4]. CDSSs have been the subject of academic Computer Science research for over 50 years [5], and offer the potential for better supported clinician decision making, improved compliance with medical standards and improved clinical efficiency and safety [6, 7]. Nonetheless, CDSS utilization remains limited and most healthcare IT systems do not include robust CDSS functions that can be widely employed across organizations, clinical presentations and domains [8].

Some of the challenges to CDSS implementation relate to the volume of high quality data required for state-of-the-art systems, the translation of such data to machine readable states, and the mapping of CDSS processes so that they fit with existing clinical workflows. As a result successful CDSSs implementations

have tended to be site and domain specific and there have been major difficulties in replicating these successes more extensively throughout healthcare systems [9]. This is in contrast to commercial fields such as finance where decision support technologies have been widely deployed. For example, risk profiling tools for financial experts have been developed as easy-to-use programs that can assimilate information and guide users through complex financial information and associated decisions tailored to individual customer needs. Healthcare decision making is significantly more complex than financial planning, however some of the challenges in both domains are similar; large quantities of data that need to be linked, integrated and translated to machine readable formats, and expert knowledge required to contextualize and apply the data in a meaningful way. In the following sections we discuss some reasons for limited dissemination and adoption of CDSSs to date and reflect on the major barriers that need to be overcome for wider adoption of these useful tools.

A Brief Taxonomy of CDSSs

CDSSs vary widely in their type and complexity. Systems can be passive (the user explicitly makes a request for support); semi active (watchdog systems that are invoked automatically and present information when the user requests it); or active (triggered automatically and present information without it being requested and in some cases make decisions without the intervention of the clinician).

CDSSs have been implemented to support clinicians across the spectrum of medical specialities, as well been abstracted for different levels of clinical expertise from novice (e.g. student nurses) [10], to non-specialist (e.g. in community hospital settings) [11], and highly specialist healthcare professionals (e.g. digital pathology) [12].

In terms of complexity, CDSSs vary widely. Simple CDSSs usually check the input provided by a clinician and verify whether it is an allowable value or within a specified range, or if there are any predefined contra-indications. The output of the CDSS is usually in the form of an alert or reminder. Examples of such CDSS are usually embedded in order entry systems and include functions for drug-allergy checking, basic dosing guidance, duplicate therapy checking and drug–drug interaction checking [13].

CDSS of mid-level complexity include prognostic calculators and automated clinical practice guideline systems. Prognostic calculators are used to automatically determine prognosis usually by implementing established clinical scoring systems. Examples include the GBM (glioblastoma multiforme) Calculator which implements the EORTC (European Organisation for Research and Treatment of Cancer) Scoring System [14] and Adjuvant Online which is a tool to assist with decisions about adjuvant therapy in patients with early invasive breast cancer [15].

Automated clinical practice guideline systems represent clinical knowledge from practice guidelines in one of a number of guideline modelling languages which

allows a CDSS to execute extracted guideline rules or algorithms to compute decisions about possible diagnoses or interventions. By coupling a computer-based guideline system with an EHR, recommendations can be personalized to the individual patient. Guideline based CDSSs have been developed for a range of clinical specialities [16] and are also widely used as a basis for helplines where less expensive or experienced clinical staff perform triage services, or in Telemedicine services where diagnoses are performed remotely [17]. These systems are also gaining traction in the consumer health informatics arena as the basis for online self-assessment tools for patients e.g. NHS Direct [18].

Complex CDSSs use Artificial Intelligence (AI), data mining, or statistical methods to reason about the classification or prediction of a disease or patient state. These methods automatically identify key features that are important for the clinical classification or prediction problem and use mathematics to determine the way in which the these features should be combined to create an output representing the classification or prediction [19]. Commonly used techniques include logistic regression, artificial neural networks and support vector machines. These complex methods have been applied to a wide range of clinical decision making problems including diagnosis of prostate cancer [20], screening for obstructive sleep apnea in persons with ischemic heart disease [21], and identifying psychiatric problems [22].

In systems of simple or mid-level complexity, the decision computed by the CDSS can usually be easily explained to the clinician (e.g. by showing a trace of the rules used to compute the outcomes). However in complex systems decisions are computed using advanced mathematics and non-linear transformations and it is therefore difficult to document how specific decisions are reached and thus explain the output to clinicians. However, these complex CDSSs better mirror clinicians' decision making processes by integrating and reasoning over multiple facets of patient data and computing a likely outcome for a specific patient state.

Challenges to Implementation and Adoption of CDSSs

Most literature focuses on operational aspects that act as a barrier to CDSS implementation [23]. In particular, slowly emerging standards for healthcare IT and poor interoperability between clinical systems limits the development of generic, reusable and scalable CDSSs. However, valuable work is being carried out to remedy these technical gaps by standards agencies such as HL7 [24] as well as on-going work on developing comprehensive biomedical terminologies such as SNOMED-CT [25]. Furthermore the increasing prevalence of EHRs should improve accuracy and standardization in data collection as well as link disparate parts of patient records. These developments have important implications for CDSSs - for CDSSs to operate optimally they require accurate and comprehensive data, and to operate in different settings they require standardized data. We posit that these developments will ease practical development of CDSSs; however, there remain other significant issues not related to technology that will still present challenges. These challenges are

related to so-called "softer" elements and include vendors and users of systems as well as organizational, legal and ethical challenges.

A survey of the CDSS capabilities of major commercial Clinical Information Systems (CISs) in the USA found that the majority have small-scale in-built functionalities mostly comprised of alerts and reminders with scant support for more complex decision-making tasks [26]. The reasons for the emphasis on simpler functionality is clear: in order for commercial systems to be viable, they need to scale to different contexts and work environments and thus providers focus on simpler tasks that are homogeneous across institutions (e.g. computerized order entry). The development of CDSSs to support more complex decision making (e.g. prediction of patient states or classification of diseases), is significantly more difficult and time consuming and such efforts have remained largely confined to academic environments, where researchers possess the time required and advanced computational expertise to create appropriate solutions. However the nature of these academic projects is such that they are funded for relatively short periods of time and, if deployed clinically, they usually remain standalone small-scale systems used only by the clinicians who were involved in their development. This is exacerbated by the fact that complex CDSSs are difficult to customize to different tasks and contexts (e.g. different CDSS are often required for paediatric and adult conditions, or systems may not generalize for similar patient cohorts from different countries [15]), as they use specific learning algorithms that have been trained to achieve optimal accuracy on a specified set of patient attributes and states. Wider deployment of any CDSS will also include the requirement to tailor the system to the local clinical setting including the established clinical workflow, the site-specific clinical vocabulary and locally installed hardware and software IT systems. In addition maintenance presents a significant challenge both in the face of rapidly advancing clinical knowledge and a lack of standardized institutional guidelines on periodic review of CDSSs. The maintenance dilemma is also intensified by the fact that many graduates who develop academic CDSSs tend to find limited opportunities in the healthcare domain and find more lucrative opportunities in developing decision support tools for finance or industry.

A common criticism of CDSSs is their poor usability [27]. Clinicians work in busy environments under demanding time and other pressures and any system that adds to those burdens will not be accepted. Reviews of clinicians' information seeking behaviour show that a lack of time and formal training with IT systems, as well as having to distract from the current workflow and clinical task at hand because decision making software is often not embedded directly within relevant CISs resulted in clinicians using colleagues as their first source when seeking information about decisions [28].

As already mentioned, the most commonly available CDSSs are alert and reminder systems and even such rudimentary systems are frequently ill-designed, for example providing alerts that appear too frequently, or alerts that are not sufficiently specific and thus impede the clinical workflow. More complex

CDSSs, for example those that employ so-called "black-box" methods such as neural networks from AI, come with a different set of usability issues; these include a lack of understanding of these methods on the part of clinicians and an associated lack of comprehensibility about how the CDSS has computed its decision. However, these methods are necessary for the successful development of robust CDSSs that can reason over large clinical datasets as well as incorporate clinical knowledge in order to compute accurate outputs. These methods will gain in importance as complex high volume genomic data becomes commonplace in clinical practice and application of these techniques will play an important role in achieving the benefits of personalized medicine [29].

An important tenet of Human Computer Interaction, the domain of Computer Science that deals with the interaction between users and computers, is to design with the end user in mind. In the case of CDSSs, computer scientists are often developing software for the manipulation of complex clinical concepts that they do not fully understand, for clinicians who clearly understand these concepts but who may not well understand the technologies and methodologies that underpin CDSSs. It is clear that the most effective CDSSs will be developed via close collaboration between computer scientists and clinicians, where computer scientists require better understanding of the real clinical needs that CDSSs should satisfy, and clinicians need to better understand the "inner workings" of CDSSs. Sophisticated CDSSs, beyond alerts and reminders, require better informed end users, and with the growing prevalence of computers in medicine, clinicians must be better supported so that their informatics training needs are met, thereby fostering understanding and trust in computerized knowledge used to generate decisions. Better motivation on the part of clinicians to use CDSSs would also drive commercial development, and vendors of CIS would be forced to expend more investment in CDSS technologies.

Whilst closer collaboration between the medical and computer science communities is required for useful and usable CDSSs, it must be recognised that these communities have different foundations. Medicine is a long established, highly regulated discipline when compared to Computer Science. In Computer Science no licence is required to practice the profession although possible computer system errors could have a direct impact on patient safety. Whilst the US Food and Drug Administration has developed guidance regarding medical software and other safety critical health care IT systems, software validation is not usually subject to such stringent protocols as for other healthcare interventions (e.g. Randomized Controlled Trials for new therapies). Furthermore computer scientists usually work in teams who collectively develop software, whereas it is often the individual clinician that is solely responsible for medical decisions related to patients' health. Questions therefore arise about the legal risks to clinicians when relying on decisions generated by a CDSS, particularly when these systems use complex "black box" methods. On the other hand there is also the potential for CDSSs to be used to decrease medical litigation. If CDSSs embed best practices, clinical guidelines and recommended standards of care, they could be used as a focus for quality control, including auditing of

clinical decisions.

It is worth noting that until recently the vast majority of CDSS development has been aimed at clinicians; however the increasing rate of patient engagement with online medical content is giving rise to a new market for consumer-oriented CDSSs. A recent survey of 1132 patients in the United States showed that 67% were favourably disposed to using online health resources as a complement to in-person doctor visits and 47% would use them as a substitute [30]. On the one hand consumer-oriented CDSSs have the potential to encourage patients to become more involved in and informed about their care and can encourage them to make healthy choices to improve or maintain their health. It may also be possible to use these systems to relieve pressures on front line services by allowing patients to self-manage some conditions. On the other hand there are justifiable concerns about patients' ability to interpret medical information correctly as well as the quality of health information online. A recent study that assessed the quality of 60 mobile phone "apps" providing health promotion in the areas of 'healthy diet', 'obesity', 'smoking cessation', and 'cancer prevention' found that less than 5% of the apps indicated that the educational material was peer reviewed by appropriate clinical parties [31]. CDSSs for consumer health informatics clearly opens up many questions for both the medical and computer science communities and is an area where collaboration between both parties is essential to ensure the safe delivery of services within this new healthcare paradigm.

Questions for CDSSs' stakeholders

From a technical standpoint, the time is now ripe for developing CDSSs that can offer meaningful support for clinical decision-making. The growing prevalence of healthcare IT, including EHR, standards such as HL7 for sharing and integrating patient data, and mobile applications to aid with point of care consultations lend themselves to the development of CDSSs that can support complex decision making as part of clinical workflow. However, there remain other important challenges and we conclude with some food for thought on the future of CDSSs:

- The computerization of healthcare is something that is only going to increase and hence the clinician's educational needs must include generally relevant areas of IT. Should clinicians also be educated in the specific computer science methodologies that underpin CDSSs?

- If clinicians gain more knowledge of, and trust in, CDSSs, are vendors of CISs ready to change their approach and to focus on decision support needs of clinicians in addition to operational tasks?

- The decisions computed by complex CDSSs using techniques from AI are often not transparent and there is a lack of institutional guidance on decision-making supported by CDSSs. Should developers of CDSSs bear some responsibility for decisions taken by clinicians starting from CDSS suggestions?

- Finally, if all challenges outlined in this viewpoint were addressed and it became possible to develop CDSSs such that their performance was on a par with the expert clinician, would clinicians want to use them?

List of abbreviations used

IT: Information Technology
EHR: Electronic Health Records
CDSS: Clinical Decision Support System
AI: Artificial Intelligence
CIS: Clinical Information System

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