Chapter 53. Clinical Decision Support Systems

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Background

Integrating medical knowledge and advances into the clinical setting is often difficult due to the complexity of the involved algorithms and protocols. Clinical decision support systems (CDSS) assist the clinician in applying new information to patient care through the analysis of patient-specific clinical variables.[1] Many of these systems are used to enhance diagnostic efforts and include computer-based programs such as Dxplain™ that provide extensive differential diagnoses based on clinical information entered by the clinician.[2] Other forms of clinical decision support systems, including antibiotic management programs and anticoagulation dosing calculators, seek to prevent medical errors and improve patient safety.[3-5]

Practice Description

Clinical decision support systems vary greatly in their complexity, function and application.[1] These clinical tools differ from practice guidelines (Chapter 51) and critical pathways (Chapter 52) in that they require the input of patient-specific clinical variables and as a result provide patient-specific recommendations. Guidelines and pathways, in contrast, may not require the input of such information and provide more general suggestions for care and treatment. Although many clinical decision support systems are now computer-based, some are relatively simple, with no inherently complex internal logic systems. Among the most common forms of support systems are drug-dosing calculators, computer-based programs that calculate appropriate doses of medications after clinicians input key data (eg, patient weight, indication for drug, serum creatinine). These calculators are especially useful in managing the administration of medications with a narrow therapeutic index (see Chapter 9). More complex systems include computerized diagnostic tools that, although labor intensive and requiring extensive patient-specific data entry, may be useful as an adjunctive measure when a patient presents with a confusing constellation of symptoms and an unclear diagnosis. Other systems, both simple and complex, may be integrated into the point-of-care and provide accessible reminders to clinicians regarding appropriate management based on previously entered data. These systems may be most practical when coupled with computerized physician order entry and electronic medical records (see Chapter 6). Finally, through their integration with practice guidelines and critical pathways, decision support systems may provide clinicians with suggestions for appropriate care, thus decreasing the likelihood of medical errors. For example, a guideline for the management of community-acquired pneumonia may include a clinical tool that, after the input of patient-specific data, would provide a recommendation regarding the appropriateness of inpatient or outpatient therapy.[6]

Prevalence and Severity of the Target Safety Problem/Opportunities for Impact

A great variety of patient safety issues may be affected by clinical decision support systems. Since the systems are typically intercalated at the point-of-care, they are likely to have their greatest effect on problems related to the individual patient. Some of the best studied applications of decision support systems are those that seek to prevent adverse drug reactions and inappropriate drug dosing as well as those that facilitate the appropriate use of effective prophylactic measures, such as those for venous thromboembolic disease (see Chapter 31).[4,5] Decision support systems may also help ensure a minimum standard for quality of care as part of the implementation of practice guidelines by providing patient-specific recommendations after the input of certain clinical variables. This combination of decision support systems and guidelines may be especially effective in conjunction with the use of the electronic medical record.[7] To date no high quality studies have examined the impact of widespread institution of decision support, but local studies suggest that it may be substantial. An evaluation of an antibiotic management system in a single 12-bed Intensive Care Unit over a 3 year period revealed that use of the system resulted in 24 fewer adverse drug reactions and 194 fewer cases of antibiotic-susceptibility mismatch.[4] These results and others suggest that national implementation of decision support systems could markedly improve patient safety.

Study Design

The functionality and effectiveness of clinical decision support systems has been evaluated in a number of systematic reviews. The seminal review, last updated in 1998, investigated the use of computer-based systems in all clinical settings.[3] The authors completed an exhaustive search of electronic databases and the bibliographies of pertinent articles and found 68 prospective trials on the subject. The vast majority of these studies (90%) were randomized trials. The articles were rated on a 10-point scale for quality. The scale assessed the design features of the trials, including method of randomization, baseline comparability of the study groups, allocation unit, outcome measures, and degree of follow-up. The mean score on this validity scale was 6.4 for studies published prior to 1992 and 7.7 for subsequent studies.

Another systematic review evaluated the use of computer-based decision aids in the provision of outpatient preventive care.[8] This study, which was based on a search of electronic databases including MEDLINE, found 16 trials that met the pre-defined inclusion criteria. Only randomized controlled studies were included. Those that used only historical controls were excluded. The acceptable studies were then evaluated using weighted mixed effects model regression analysis.

Yet another systematic review investigated the utility of computer systems in the primary care setting.[9] A detailed search of several electronic databases and a hand search of bibliographies and conference proceedings yielded 30 studies that met criteria for inclusion. These papers were ranked by the same validity score utilized in the systematic review of computer-based decision supports systems described above. The average validity score of the included trials was 6.7 on the 1-10 scale.

Most relevant to patient safety *per se* is a fourth systematic review of the utility of computers in medication dosing.[10] This review, which located studies in the Cochrane Collaboration on Effective Clinical Practice, was also based on an extensive search of electronic databases, supplemented by a bibliography search and consultation with experts. Of 16 relevant studies, all but one were randomized controlled clinical trials. Time series studies were not included. The included trials were then evaluated using a random effects model.

A final systematic review analyzed the utility of computers in the implementation of practice guidelines which, in such a setting, may be considered clinical decision support systems.[11] A structured search of MEDLINE, CINAHL, bibliographies and books found 25 papers detailing the use of 20 such systems. In this group, there were 10 time series studies (all without external controls) and 10 controlled trials, 9 of which were randomized.

Two well-designed studies have been published since the above systematic reviews. One is a cluster randomized trial of the use of a decision support system in the treatment of patients with hypertension.[12] The second is a prospective time series investigation of a decision support system for the prevention of thromboembolic disease in post-surgical patients.[4]

Study Outcomes

Most of the reviewed studies reported results in terms of patient outcomes and provider performance. The most common clinical outcomes (Level 2) included the relative adherence to specific recommendations and the degree to which prospectively described tenets of "appropriate practice" were followed. Examples of such principles included whether clinicians followed medication dosage recommendations and delivered appropriate preventive health care measures. Several studies reported even more definitive clinical data (Level 1) including the degree of blood pressure reduction, the incidence of adverse drug reactions, the control of postoperative pain and percentage of patients with therapeutic drug blood levels.

Evidence for Effectiveness of Practice

The majority of the systematic reviews portray clinical decision support systems in a positive light. The seminal systematic review of computer-based decision support systems, for example, found that 43 of the 65 investigated studies showed at least some benefit in either the process of care or patient outcomes.[3] Most impressively, 74% of the studies of preventive health care reminder systems and 60% of the evaluations of drug dosing models reported a positive impact. In addition, 6 of the 14 studies that reported actual patient outcomes reported a beneficial effect. However only one of the five diagnostic aids, a model used to predict postoperative pulmonary complications, showed encouraging results. The others, including systems designed to aid diagnostic efforts in patients with chest and abdominal pain, were ineffective. This review was rigorously conducted and only those papers with robust study design were included. Overall it provides compelling evidence for the effectiveness of specific decision support systems.

These results are supported by the review of systems to aid the delivery of preventive health care.[8] By applying weighted mixed effects model regression analysis to the 16 identified studies, the authors found decision support systems resulted in significantly improved rates of delivery of preventive health care (OR 1.77, 95% CI: 1.38-2.27). Computer systems, however, were not statistically superior to manual reminder systems. Although this study reviewed many of the same papers that were evaluated in the reviews discussed above, it provides further evidence of the utility of these systems in improving the process of care.

The review of clinical decision support systems in the outpatient setting provided similarly encouraging results.[9] All of the 21 studies that examined processes of care found improvements. Results were somewhat less impressive in the articles reporting more definitive clinical outcomes including level of blood pressure reduction and patient satisfaction. Only one of three such studies found significant benefit.

The systematic review of the use of computer models to determine drug doses provides some of the most compelling evidence for application of decision support systems to patient safety and error avoidance efforts.[10] Seven of the 11 studies showed a beneficial effect on drug

dosing, and more significantly, 4 of 6 showed a decrease in adverse drug effects. Five of six also reported direct positive effects on the patient, including one that reported improved control of postoperative pain. Since the majority of the analyzed studies were randomized controlled trials, this review provides powerful evidence that decision support systems may prevent medical errors and other adverse events. A more recent study of an antibiotic management program also supports this contention.[5] In this prospective before-after trial, the use of the decision support system resulted in a substantial and significant decrease in the incidence of adverse drug reactions ($p=0.018$) and prescriptions for medications contraindicated by allergy ($p<0.01$). The system was also popular among the health care providers, cut costs and saved time (see also Chapter 6).

Finally, clinical decision aids were useful in implementing practice guidelines. The systematic review of this subject found favorable effects on guideline adherence in 14 of the 18 papers studied.[11]

The impact of decision support systems on the outcomes of care for discrete disorders has also been studied. These results are mixed. For example, the recent randomized controlled trial of a computer-based system in the treatment of patients with hypertension failed to show any benefit, and the system was actually out-performed by a paper-based system.[12] These findings corroborated those of a systematic review that questioned the utility of CDSS for treating hypertension.[13]

In summary, clinical decision support systems may provide significant benefits in the process of care, preventing medical errors and prompting physicians to provide appropriate preventive care measures. Their utility in guiding the treatment of individual clinical disorders (such as hypertension) remains a matter of study.

Potential for Harm

Most studies show no major adverse effects from the use of CDSSs. Although one study demonstrated that they may increase a physician's consultation time (thus decreasing the time spent on direct patient care),[14] others suggest that they may improve efficiency, especially in terms of data recall.[5] The usefulness and efficiency of such systems is clearly dependent on the programmed logic. As such they must be with developed with extremely high quality control standards. A system that provides erroneous information and guidance, for example, has the potential to cause broad deleterious impact.

Costs and Implementation

Very few studies specifically address the cost of developing and implementing decision support systems. We posit that the costs may be substantial as the majority of systems are now computer-based and require significant hardware, most commonly placed at the point-of-care. In addition, many of the successful systems were integrated with computerized medical record systems and physician order entry (Chapter 6), which are not yet in universal use. The development and frequent updating of system software is also likely to be very expensive. Despite these concerns, the widespread implementation of successful systems is feasible and will likely become even more so as providers and systems increasingly shift to computerized medical record systems.

Comment

The preponderance of evidence suggests that clinical decision support systems are at least somewhat effective. Their highest utility has been demonstrated in the prevention of medical errors, especially when coupled with a computerized medical record and directly intercalated into the care process. Unlike more passive methods such as education and feedback, decision support systems are generally able to modify physician behavior and affect the process of care. Although the results of support systems have been far less positive when used in the ongoing care of patients with chronic diseases or to help with diagnostic decision making, these capabilities may improve with further technological advances.

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