Struggling to bring clinical prediction rules to the point of care: missed opportunities to impact patient care

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Clinical prediction rules

Clinical prediction rules (CPRs) are a form of evidence-based medicine (EBM) that have emerged to help physicians make personalized, cost-effective decisions that benefit their patients at the point of care. They can be used in a wide variety of clinical settings. They use various components of the history, physical examination and basic laboratory results to stratify a patient in terms of likelihood of having a specific diagnosis, prognosis or response to treatment [1] . CPRs attempt to formally test, simplify and increase the accuracy and consistency of clinicians' diagnostic and prognostic assessments. The content of good CPRs must meet methodological standards that lead to an outcome that is both clearly defined and clinically important. It must be reproducible and make clinical common sense [2-4] . While physician diagnosis and prognosis are primarily based on clinical intuition, reliance on clinical intuition alone can be misleading [2,3] . CPRs can potentially help bridge this gap [4] .

Unfortunately, few clinicians utilize these tools on a day-to-day basis because of barriers such as clinicians' perception of usefulness, poor user interface and lack of integration into workflow [4,5] . Despite industry pressure to improve throughput, reduce cost and enhance the quality of patient care, bringing evidence-based diagnostic tools such as CPRs to the bedside continues to be a challenge.

Clinical decision support systems

Health information technology and informatics is a rapidly growing field that is exponentially expanding to all types of practices. Researchers and health administration alike are starting to harness the electronic heath record (EHR) to study the quality of care their facility is providing and develop strategies to utilize the EHR to improve patient care [6,7] . One such method of improvement are clinical decision support systems (CDSS), which bring clinical decision support (CDS) to a computerized clinical information system such as an EHR [8] .

CDS is defined as anything that directly aids the clinical decision-making process, such as collegial advice, text references, websites or computer systems [9] . Clinical prediction rules (CPRs) are a type of CDS and a CDSS is simply a computerized CDS. CDSS incorporate individual patient data, a rules engine and a medical knowledge base to produce a patient-specific assessment or recommendation for clinicians. CDSS can generate several forms of active decision supports such as alerts, reminders, corollary orders and guidelines [2-4] .

The more successful CDSS have been those implemented at the point of care and that have promoted user acceptance and adherence. Accuracy and simplicity have also been identified as critical elements of a well executed CDSS [10-12] . Successful examples of CDSS have included reductions in the prescribing of brand-name antibiotics [13] , improved lipid management in renal transplant patients [14] , improved compliance with guidelines for treating HIV [15-17] , reduced ordering of tests when costs were displayed [18] and age-specific alerts that reduced inappropriate prescribing in the elderly [19-24] .

*** Development & testing of a clinical prediction rule**

The creation of a well-designed CPR involves three steps:

* Derivation of the rule;

* Internal and external validation of the rule;

* Assessment of the rule's impact on clinical behavior, known as the impact analysis (Figure 1) [1] .

The first phase is the derivation and creation of a model which is typically performed on a retrospective database, but can be done prospectively. The next phase is validation, in which the model is tested preferably in a prospective fashion and in several different sites to demonstrate that the model is transportable and stable across various settings. The third phase is an impact analysis, which evaluates the outcomes as a result of introducing the model into practice.

Numerous CPRs have been derived and validated, including the Heckerling rule for pneumonia to reduce antibiotic use [25] , the Ottawa Ankle Rules for ankle and mid-foot fractures [26] , Walsh for streptococcal pharyngitis [27] , and the Wells rule for deep vein thrombosis (DVT) and pulmonary embolism (PE), in an attempt to reduce unnecessary imaging (Table 1) [28,29] . Impact analysis studies, or the study of integrating CPRs into clinical practice, are currently the most effective way of determining if the rules can improve patient outcomes and reduce the use of healthcare resources [30] . Predictive validity, clinical sensibility and impact potential needs to be considered when determining which CPRs should undergo impact analysis [31] . Ideally, a good CPR can simplify and increase the accuracy and consistency of clinicians' diagnostic and prognostic assessments. Currently, however, only a few impact analysis studies (Level 1) have been conducted and few have demonstrated successful, long-term provider adoption (Table 1) [4,32] .

An example of the underutilization of a CPR

DVT is a common condition with a potentially fatal outcome. Early and accurate diagnosis can reduce the risk of complications, such as PE. DVT and PE morbidity and mortality rates can be improved with an appropriate and timely diagnosis, triage and treatment [33] . The economic burden of DVT and PE in the inpatient setting is substantial, not only due to the initial admission, but also because of the high rate of readmission, particularly within the first 90 days [34] . A recent US model incorporating all sequelae from DVT and PE in a sensitivity analysis estimated that the annual US cost of DVT and PE ranged from US$13.5 to US$27.2 billion [35] . The typical work-up for DVT and/or PE includes the history and physical exam, D-dimer assay and imaging studies [36] . Despite the high sensitivity and negative predictive power of the D-dimer test among lower risk patients, physicians still often order more imaging, such as lower extremity compression ultrasounds or CT pulmonary angiograms (CTPAs) in these patients. As a consequence, 80-90% of PE work-ups are negative and the cost per case diagnosed is excessive [37,38] . Unnecessary work-ups are not without risk to the patient. Over-ordering of CTPAs can result in overdiagnosis and overtreatment of clinically insignificant emboli, which may result in significant increases in complications of anticoagulation both short- and long-term [39] . Inferior vena cava filters can also cause substantial morbidity during both insertion and while in place [40-42] .

Determining the pretest probability can be challenging, and clinicians often fear they are compromising patient safety [2,3] . As a result, a clinician may order a needless test when a high-risk diagnosis is being considered. Well-validated CPRs, such as the Wells DVT/PE scores, have the potential to bring EBM to daily practice, particularly in settings where the decision making is complex, the clinical stakes are high, or there is an opportunity to achieve cost savings without compromising patient care (Table 2) [1] . For example, a low clinical probability of DVT according to the modified Wells score, in conjunction with a negative high-sensitivity assay D-dimer, appears to virtually eliminate the need for additional testing such as ultrasound [43-46] . A recent outpatient retrospective cross-sectional study looking at a higher, age dependent D-dimer cut-off value in the setting of an 'unlikely' DVT Wells score still showed a significant increase in the number of patients in whom DVT could be safely excluded, further supporting this claim [47] . The potential for cost reduction with the use of CPRs cannot be ignored.

Barriers to adoption

There have been a number of barriers to adoption of CPRs identified in the literature at both the infrastructure (old technology) and organizational (importance of CPRs within the culture) levels. As an example of an infrastructural barrier, in 2009, US Congress passed the Health Information Technology for Economic and Clinical Health Act to help stimulate and encourage health systems to integrate EHR, CDSS and tools to reduce medication errors, improve documentation, and diagnosis and treatment of patients [48] . Currently, only 9.6% of US hospitals have computerized physician order entry (CPOE) completely available to their physicians in their EHR [49] . This slow adoption of the EHR as a tool to deliver quality care limits the integration of CPRs by means of CDSS [50] .

At the organizational level, the uptake of CPRs and CDS has been problematic because of difficulties in integrating them into the provider's clinical workflow. Common obstacles cited were loss of efficiency, clinicians' perception of usefulness, information content, user interface and workflow [4,5] . For example, Penaloza *et al.* tested the Wells PE and DVT CPRs with residents in the emergency department and found that the majority of the residents did not use the rule appropriately and misdiagnosed DVT cases [32] . The adoption of electronic CDS, or CDSS, has also been met with resistance from clinicians due to delays caused by alerts, difficulty interpreting alerts or receiving the same alerts repeatedly [51] . This over-triggering or mis-firing of irrelevant alerts can cause fatigue and physicians ignoring or overriding them, and has also been shown to contribute to reduced usability and adherence [52-55] . Override rates were seen to be as high as 89.4% for significant drug-drug interactions and 92.1% for drug-allergy interactions [56] .

Unmet needs & next steps in impact analysis

With the ever increasing demand to make more sound and cost-effective diagnosis and care plans for patients, CPRs and CDS are a potential opportunity to address these issues. Further research is required to look at the process of integration of CPRs and CDS. From here, we can then proceed with more health outcomes type research. Therefore, it is our recommendation that future research focuses on organizational and provider culture, maximizing off-the-shelf technology, and integrating into provider clinical workflow.

*** Organization & provider culture**

Although a research project can have strong results in a controlled setting, it may not translate to a real-life setting. Wallace *et al.* have developed a sequential four-phased framework that we also feel should be adopted by institutions striving to disseminate CPRs (Figure 2) [57] . The framework is collaborative in nature and allows providers and organizations to tailor the integration of the tool to their daily organizational and provider culture in the hope of gaining their support in the process. Phase I is an exploratory phase, which ensures that the rule's components are clinically sensible, comprehensive and appropriate. For example, in a large impact analysis study focusing on the Goldman CPR used in the triage of patients in the emergency department with suspected acute cardiac ischemia, clinicians sought to increase the sensitivity of the rule by adding the presence of an ECG predictor variable to the existing rule [58] . Phase II is the preparation phase that focuses on clinician acceptability and identifies potential organizational, individual and societal barriers to CPR use in a defined setting. Strategies include engaging clinicians in a simulation exercise, finding ways of integrating CPR into the clinical workflow such as the EHR, and providing feedback to clinicians during the trial. Phase III is the experimental phase that measures improvement in clinical care, patient outcome and cost-effectiveness. Phase IV is the dissemination/long-term implementation phase that focuses on strategies of converting the CPR from the research setting into everyday clinical practice delivered by the wider community of clinicians.

*** Maximizing CDSS & off-the-shelf technology to create effective CPRs**

With the introduction of the Health Information Technology for Economic and Clinical Health Act in 2009, hospitals have been purchasing and implementing commercial EHRs with CDS capabilities. When researching different EHRs, it is important to focus not just on its ease of incorporation into clinical practice, but also on its 'meaningful use' by means of CDS and CPR integration. CDS capabilities and utilization vary across commercial EHRs. Not all are customizable to specific hospital or outpatient practice workflow or have all the necessary tools for an effective CDS [59,60] . Tools consist of triggers, calculators or guidelines. For instance, if an EHR does not have a triggering tool such as an alert (e.g., as a result of a specific word being entered into the EHR), physicians may not be notified about drug-drug interactions or annual screenings. Furthermore, even if such tools are available, they may not be easily tailored to the hospital's clinical workflow. In a study conducted by Wadhwa *et al.* , an alert was created to identify patients with congestive heart failure and recommended the ordering of an ACE inhibitor or [beta]-blocker based on the patient's health information. Unfortunately, the EHR was unable to automatically create the recommended list of orders for the CHF alert, requiring physicians to manually place the medication order [61] . This demonstrates the need for hospitals and clinical institutions to select an EHR and CDSS that utilize readily available technology, which allow for easy development and tailoring to institutional and clinical needs. We recommend an EHR with off-the-shelf technology whose back-end CDS features various triggers, alerts, order sets and calculators that can be tailored to clinical workflow and improve uptake and use of CPR and integrated CPR.

*** Integration in clinical workflow**

The integration of CPRs as a form of CDS into the EHR remains largely untested. In 2011, Drescher *et al.* found that an electronic version of the Wells criteria for PE implemented in an emergency department was associated with an improved rate of positive CTPAs [4] . Unfortunately, due to physician resistance and poor utilization rates, the CDSS was removed from the EHR. Despite this, the study highlights the potential for well-validated CPRs to be a means of objectively stratifying a patient's risk without overutilizing healthcare resources. Successful integration of a CPR into clinical workflow has been demonstrated in several studies that used usability testing. Li *et al.* developed a 'near live' usability methodology to integrate a pneumonia and strep clinical prediction rule in the EHR [62,63] . An iterative, low-cost process of monitoring the use of the tool during mock clinical settings, which labeled key success and areas to be tweaked, allowed the tool to be tailored to the clinical workflow for that setting [62,64] . It appears then that the more successful CDSS efforts have been those utilizing usability and workflow integration methodology [10,11,20,65] . Future research studies and efforts to increase the use of EBM and CDS will need to focus on development, pilot testing through focus groups, and usability testing to address barriers. By employing these methodologies, barriers will be identified earlier on in the project, which will hopefully increase the likelihood of a successful end result.

Conclusion

Well-validated CPRs are a means of bringing EBM research, literature, guidelines and tools to the hospital and clinical practice settings. The success of some CDSS is encouraging and suggests there is potential to integrate CPRs into EHRs and make a positive impact on patient care outcomes and healthcare costs. There is a lot of pressure from federal and private healthcare payers, monitoring agencies, EBM researchers, policy makers and others to make this succeed. Continued and expanded efforts will be needed in the areas of impact analysis and integration to make existing, well-validated CPRs part of daily practice [57] .

Future perspective

Over the next decade, the clinical and financial pressures to integrate EBM into daily practice will only escalate. In 2009, the US federal government demonstrated their commitment to health information technology (HIT) by providing US$29 billion for a national HIT infrastructure. The Patient Protection and Affordable Care Act (PPACA), or Obamacare, further encourages the adoption of HIT by requiring the reporting of data to be electronic as a means of demonstrating improvements in healthcare quality, efficiency and overall population health. Clinicians will be required to show that they are using HIT in a meaningful way and especially for quality reporting purposes [66] . This federal push to disseminate HIT and emphasis on quality will hopefully generate more interest in exploring methods to electronically integrate CPRs and other CDS into the provider's clinical workflow and measure impact. It is also likely that as more hospitals and outpatient practices adopt EHRs, the demand for more dynamic and complex CDSS will only intensify. This will presumably be a time-consuming but necessary process that will require additional financial and personnel resources. Developers will need to consider integration methods that are collaborative and tailorable, that consider off-the-shelf technology, and that employ usability and workflow integration methodology.

Table 1. Clinical prediction impact and level of evidence.

Clinical prediction rule	Potential impact	Level of evidence
Heckerling for pneumonia [25]	Reduces unnecessary antibiotic and diagnostic test ordering	Level 2: Derivation and validation complete Need for impact analysis
Ottawa Ankle Rules for ankle and mid-foot fractures [26]	Reduces unnecessary radiography	Level 1: Derivation and validation complete Impact analysis has demonstrated decreased radiography, waiting times, lost productivity and costs
Walsh for streptococcal pharyngitis [27]	Reduces unnecessary antibiotic and diagnostic test ordering, supportive triage step	Level 2: Derivation and validation complete Need for impact analysis
Wells for DVT [28]	Reduces unnecessary ultrasound ordering, supportive triage step	Level 2: Derivation and validation complete Need for impact analysis
Wells for PE [29]	Reduces unnecessary CT angiography ordering	Level 2: Derivation and validation complete Need for impact analysis

CT: Computed tomography; DVT: Deep vein thrombosis; PE: Pulmonary embolism.

Table 2. Modified Wells score.

Clinical characteristic	Score
Active cancer (treatment ongoing or within the previous 6 months or palliative)	1
Paralysis, paresis or recent plaster immobilization of the lower extremities	1
Recently bedridden for 3 days or more, or major surgery within the previous 12 weeks requiring general or regional anesthesia	1
Localized tenderness along the distribution of the deep venous system	1
Entire leg swollen	1
Calf swelling at least 3 cm larger than that on the asymptomatic side (measuring 10 cm below tibial tuberosity)	1
Pitting edema confined to the symptomatic leg	1
Collateral superficial veins (nonvaricose)	1
Alternative diagnosis at least as likely as DVT	-2
Previously documented DVT (part of modified clinical model)	1
Score	
DVT likely	2 or higher
DVT unlikely	<2

DVT: Deep-vein thrombosis.

Data taken from [43] .

Executive summary

Clinical prediction rules

* Clinical prediction rules (CPRs) are a form of evidence-based diagnostic thinking that has emerged to help physicians make evidence-based, personalized, cost-effective decisions that benefit their patients at the point of care.

* CPRs are particularly useful in settings where the decision making is complex, the clinical stakes are high or there is an opportunity to achieve cost savings without compromising patient care.

Clinical decision support systems

* A heavily identified area of opportunity to integrate CPRs into clinical workflow is the electronic health record (EHR) by means of clinical decision support systems (CDSS).

* Successful CDSS are those most sensitive to usability and workflow integration, that promote user acceptance and adherence and are accurate and simple.

Development & testing of a CPR

* The creation of a well-designed CPR involves derivation of the rule, internal and external validation of the rule and assessment of the rule's impact on clinical behavior, known as the impact analysis.

Barriers to adoption

* A number of barriers to adoption have been identified at both the infrastructure and organizational levels.

Unmet needs & next steps in impact analysis

* Developers interested in integrating CPRs into the EHR should consider organizational and provider culture, take advantage of already existing technologies and focus on how to optimally integrate into clinical workflow.

CAPTION(S):

Figure 1. Development and testing of a clinical prediction rule.

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