Criteria for Developing Clinical Decision Support Systems

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Abstract

The use of archived information and knowledge derived from data-driven system, both at the point of care and retrospectively, is critical to improving the balance between healthcare expenditure and healthcare quality. Data-driven clinical decision support, augmented by performance feedback and education, is a logical addition to consensus and evidence-based approaches on the path to widespread use of intelligent search agents, expert recognition and warning systems. We believe that these initial applications should (a) capture and archive, with identifiable end-points, complete episode of care information for high-complexity, high-cost illnesses, and (b) utilize large numbers of these cases to drive risk-adjusted "individualized" probabilities for patients requiring care at the time of intervention.

1. Introduction

Successful development and utilization of the next generation of clinical decision support systems (CDSS) require bridging the gap between the challenges faced by these systems' developers and requirements of the systems' clinical, technical, and business users. Current development efforts continue to improve upon medical expert systems that began appearing 25 years ago (e.g., Mycin). We, as CDSS developers, have broadened our definition of these systems to include, in addition to technological development issues, the more practical aspects of knowledge management. Therefore, we believe that the next generation of CDSS tools will include a number of core requirements. Specifically, they will:

- Remain computer mediated but have greater networked and distributive features;
- Become ubiquitous at all organizational levels where decisions are made -- the point of care for patient treatment decisions and at the population level for organizational and clinical management decisions;
- Be used in both real-time and retrospective modes;
- In the near term assist in decision making (e.g., diagnosing a patient), not make or automatically implement actions that follow a decision;[1]
- Utilize clinical data derived from routine patient care stored in large clinical repositories;
- Adjust the data for disease stage, disease severity, co-morbidity and (ultimately) risk;
- Imbed predictive capabilities, initially relying on classical statistics rather than artificial intelligence; and
- Utilize "white box" (openly disclosed, but protected) methodologies for prediction and detailed clinical support due to the high standards of review required for healthcare decision-making.

Developers of advanced CDSS must overcome clear challenges. These challenges range from theoretical (Can computers think? Should computational decisions replace or augment provider judgment?) to psychosocial – overcoming people's fear of computers and aversion to purely electronic record keeping. Organizational development issues within the healthcare user

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base remain significant, including the need to overcome data and expertise silos, the need for codification and recording of common knowledge, as well as clinician computer skills. Practical issues abound in an environment increasingly challenged by new clinical discoveries and technological innovations, shrinking financial margins among the user base, and endemic information technology (IT) issues concerning database and interface standards. Additionally, there are three areas of particular importance to developers of advanced CDSS systems that bear mentioning:

- **Financing development.** Early developers and adopters of current systems have focused on immediate practical problems and have benefited financially through gains in recovered billing and clinically through less redundant and more accurate records in their own institution. Continued CDSS evolution will find it harder, however, to replicate these incentives, since the next generation systems will deal with more subtle issues such as accuracy of diagnosis, improved clinical outcomes over "what would have been," and improved coordination of care. Continued CDSS development will improve the efficiency, effectiveness, and safety of the healthcare *system as a whole,* but may not accrue directly or uniformly to the CDSS users *as individuals*.

- **Appropriate business model.** Developers of future decision support systems must find new solutions for selling as well as integrating these technologies into highly a highly customized technology environment. Successful system deployment will likely require the evolution of a new business model incorporating centralized risk among pools of providers or the government, and/or sophisticated sales strategies that bifurcate CDSS users (those who gain reputation, reduced malpractice exposure, etc.) from CDSS purchasers (those who gain through cost savings, increased billings, etc.).

- **Regulatory efforts.** The use of data critical to patient care, where and when it is needed, is made more difficult through patient confidentiality and data security provisions. Future developers of decision support instruments must focus significant efforts on finding technological solutions that meet regulatory requirements for patient confidentiality as well as patient expectations about healthcare quality. Moreover, the relative level of automation of decision making embedded in the products must be assessed carefully in light of the regulatory criteria of the U.S. Food and Drug Administration (FDA).

Despite the panacea of benefits that can be ascribed to the use of sophisticated CDSS instruments, the financial and regulatory challenges are significant and must be overcome by developers. The regulatory challenges, we believe, are likely to be overcome by newer technologies. It is more difficult, however, to find solutions to the pervasive financial constraints in U.S. healthcare. Clearly the profit centers in healthcare and holders of risk have an incentive to fund the application of sophisticated clinical decision support instruments, but finding an adequate business model will be as challenging as any of the methodological development required to bring their promised benefits into fruition.

There are many other areas critical to the continued evolution and deployment of clinical decision support systems. We will focus on two that appear to offer the greatest leverage for the healthcare industry: The incorporation of non-experimental patient data and the increasing methodological sophistication of CDSS.

2. The increasing value of data-driven approaches

Data driven approaches to CDSS development augment the value currently provided by expert driven, evidence-based approaches. Data driven approaches expand the utility and functionality of CDSS in three key ways:

- They expand CDSS applicability to include a wider spectrum of medical decisions, from individual patients to whole populations;
- They widen the locus where decisions can be made to include point of care or place of service as well as senior managerial levels; and
- They minimize the temporal constraints on decision-making by supporting real-time or retrospective modes of decision-making.

While the utility of controlled double-blinded research trials will doubtlessly persist, particularly for pharmaceutical testing, the proliferation of medical databases (claims, pharmacy, laboratory, and electronic medical records (EMR) data) containing information about large numbers of real patients in the "real" world is being seen as an increasingly valuable source of knowledge. These "field" data have the ability to drive further changes in clinical decision support systems, moving them from systems that utilize traditional care pathways or protocols to guide decision making, to systems which can draw on large data stores to identify actual demonstrated "best pathways" and to dynamically guide clinical decision-making. In addition, these field data provide a valuable tool for organizational development and strategic planning. These field data, when combined with financial, patient satisfaction, human resource and other organizational data, can facilitate organizational decisions that are optimized for cost, access, patient retention, or market share targets, in addition to clinical outcomes. In providing these critical services to users of CDSS, development efforts must focus on:

- Standardizing clinical language terminology, coding, and data capture;
- Developing standards and benchmarks for interventions and outcomes;
- HIPAA patient privacy, confidentiality, and security requirements;
- Infrastructure development that facilitates information sharing;
- Embedding wireless technologies to improve ergonomics of data capture;
- The importance of 24 hour information access from any location; and
- Using meta-analysis to integrate findings captured in industry-accepted guidelines and published studies.

These efforts will further support the information framework development suggested by the National Committee on Quality Assurance (NCQA).[2]

2.1 Point of care for each unique patient – applying CDSS at the 'Archimedean Point'

In healthcare delivery, change is implemented "one patient at a time." This practice demands a mechanism of converting this population-based information into a methodology that can be applied directly to care at the patient level. To meet this demand, patient-specific, real-time, point of care clinical decision support instruments that go far beyond simple flags and alarms are being developed. At the point of care, physicians need to understand their patient's likely clinical outcome trajectory. Additionally, they need to understand the combinations of clinical decisions that will achieve that patient's optimal short-term and long-term clinical outcomes (the "desired course"). This information should enable clinicians to consider "mid-course corrections", (alternative interventions) that address changes in the patient's

presentation, and allow them to model the potential impacts of different clinical decisions as the patient's clinical course changes.

The approach we are advocating "personalizes" evidence-based medicine. Rather than relying on generic protocols with limited decision nodes, CDSS would provide practitioners with scientifically sound and statistically valid information about the impact of their specific clinical decisions on the patient they are treating at the moment, and in addition could model alternative care scenarios.

We believe that the use of information from patient derived data at the point of care can alter the way clinicians create, access and use clinical knowledge. These changes can yield "just-in-time" knowledge through the interpretation of data from real clinical practice including patient risk characteristics, diagnostic and therapeutic interventions, and clinical outcomes. Rather than searching through historical articles of controlled studies for information, physicians can use their own experience with their own patients (compared with a larger population of similar patients), to derive the knowledge they need to make a decision.

2.2 Population-based assessment

Clinical actions that affect organizational outcomes (profitability, resource planning, satisfaction, productivity, quality) can be aggregated and analyzed to create learning environments, optimize trade-offs between care costs and care outcome, and improve the operations of the healthcare enterprise. At the highest level of aggregation, population-based assessment should provide a single value indexed score that is easily interpretable and imbeds multiple measures (such as cost, outcome, satisfaction, health status, and access). In addition, it should provide for the further mining of data on which the score is based. This facilitates performance assessment in multiple dimensions and hierarchies, including geographic locations, care areas, or patient sub-populations. Healthcare organizations must prioritize these elements, and identify the most effective care pathways that maximize the levels of patient satisfaction, health status and clinical outcomes for the acceptable cost level.

Centralizing databases of clinical cases can provide a broad insight into actual clinical practice. Population-level analysis should allow clinicians to compare their actual performance, with their predicted performance, adjusting for their patients' burden of illness. This risk-adjustment methodology should utilize the same clinical data that clinicians use to make patient care decisions in their daily practice. Further, CDSS instruments should enable clinicians to determine the statistical impact of individual clinical decisions upon their patients' risk-adjusted outcomes, and to develop their own "ideal" clinical pathway (that combination of clinical decisions that yield the best outcomes with the most effective use of resources). This process would enable them to compare this ideal to their current practice pattern thus catalyzing an objective, data-driven basis for change management. It can also enable cross-institution and cross-regional comparison of care quality and provider performance.

2.3 Grouping and adjusting mechanisms

We have spoken elsewhere about the value of embedding episodic logic into population healthcare management strategies, and described the widely accepted categories of analysis.[3,4] The ability to collect clinical data electronically will allow us to move from the use of mostly administrative data (claims, patient demographic information) to more detailed clinical data

(vital signs, allergies, etc.), and thus to move beyond simply measuring "episodes of service" toward assessing more complex "episodes of risk."

Moving to episodes of risk will impact healthcare delivery much like the impact of genetic uncoding. Whereas mapping the genetic code helps to identify elements of predisposition (genetic risk) to disease, appropriately designed clinical decision support systems will enable identification of the "environmental code" (risk factors such as diet, exercise, social risks, travel exposure, and air and water standards) that further influences the risk of disease after birth. Increasingly early predictions can occur about events increasingly farther into the future. In the nearer term, linking retrospective analytic capabilities with real time decision support instruments allows clinicians to identify the relationships between cost, outcomes, patient satisfaction, and health status – all current business objectives centered around only episodes of care.

2.4 Attempts to replicate clinical logic

CDSS currently range from data capture systems such as EMRs and clinic management software, to complex medical devices that embed artificial intelligence (AI) to support clinical decisions. We believe that such systems should imbed decision support algorithms, beyond simply flagging and reporting information to the decision maker, but that the healthcare provider must retain the responsibility and accountability for final patient treatment decisions.

We believe that statistical approaches are complementary to many of the AI approaches. However, as developers move their tools closer to the point of care and move to more real time application, they move from the realm of analytical solutions to the realm of medical devices. Medical devices come under greater scrutiny by entities such as the FDA. Moreover, methods that appear to be "black box" by their very nature, i.e. neural nets, might for the present be harder to implement.

In the very near term, we believe that intervention and outcome predictions at the patient level should be based in classical statistics and move increasingly toward being particular to the specific patient being treated, rather than based on generic protocol algorithms. In addition, these data should be provided with critical decision support elements, including field data for similar cases that serve to expand upon the personal practice experience of the physician, industry accepted guidelines, and technical journal articles. Further, we believe that these systems must:

- Appropriately address the provider's concerns about data input, including the specificity of data collected and the resources utilized to input the data;
- Drive value in healthcare through quality improvement and cost reduction; and
- Have sufficiently granular clinical data to enable biostatistics, epidemiology and medical informatics applications to act as foundations for knowledge creation.

2.5 Linking population analysis with real time decision support analysis

Linking population assessment with real-time decision support increases CDSS value by enabling a powerful healthcare delivery improvement methodology. Population assessment can provide on behalf of their organizations sophisticated resource management tools to improve the efficiency and effectiveness of the delivery of care. Nearer term benefits include:

- Benchmarking;

- Identification of centers of excellence;
- Quality improvement initiatives;
- Continuing medical education using clinicians' own population data;
- Resource scheduling;
- Improved coordination and reduced "translation error" between care;
- Consistent information capture; and
- Personnel schedule conflict adjudication.

An expanding data repository fed through real-time interfaces will lead to increasingly stronger predictions of resource use and patient outcomes. It would also support public health initiatives such as the identification of high-risk events (like bio-terrorist incidences), disease outbreaks, and offer much to address the Institute of Medicine's concerns surrounding medical errors and healthcare quality.[5,6]

3. Conclusion

The use of archived information and knowledge derived from data-driven systems, both at the point of care and retrospectively, is critical to improving the balance between healthcare expenditure and healthcare quality over the next decade. Healthcare organizations that use next generation CDSS will benefit from:

- Communities of practice that can share and learn together;
- Monitoring activities at the point of care;
- Performance review with comparable benchmarks;
- Shared consultations between specialists examining the same information without waiting for hard-copies of records in the mail or on fax machines;
- Improved applications that might focus on particular specialty areas or disease states;
- Improved standardization of outcomes;
- Identification of best practices;
- Identification of centers of excellence; and
- Creation and utilization of a standardized terminology.

Additionally these CDSS can act as the foundation for knowledge bases that are more than archived articles and expert testimony. Knowledge bases created through the interpretation of real clinical practice data about patient risk characteristics, diagnostic and therapeutic interventions, and clinical outcomes are possible. Later applications can assist predictions of resource needs, population health trends, and public safety.

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[1] Friedman, C.P. et al., "Enhancement of Clinicians' Diagnostic Reasoning by Computer-Based Consultation: A Multisite Study of 2 Systems", JAMA, November 17, 1999, pp. 1851-1856.

[2] Schneider, E.C., et al., "Enhancing Performance Measurement: NCQA's Road Map for a Health Information Framework", JAMA, September 22, 1999, pp. 1184-1190.

[3] "*Informatics of Physician Profiling*" in Physician Profiling, Background and Practical Experience, Kenneth J. Pechman, PhD, MD (editor) American College of Physician Executives, 2000.

[4] "*Best Clinical Practice: Assessment of Processes of Care and of Outcomes in the US Military Health Services System*" in Physician Profiling and Risk Adjustment, 2nd addition, Norbert Goldfield, MD (editor), Aspen Publishers, Inc, 1999.

[5] *To Err is Human, Building a Safer Healthcare System*, National Academy Press, 2000.

[6] *Crossing the Quality Chasm: A New Health System for the 21st Century*, National Academy Press, 2000.