division of
Medical
Information
Sciences

MEDICAL INFORMATICS REVIEW

Vol. 2 No. 2 *April 2007*

Developing "Safe and Effective" Clinical IT – Lessons from Cognitive Engineering

Summary

The practice of clinical medicine has reached a juncture at which support from information technologies is needed, not just for back office coding and billing or front office scheduling and registration, but for the "central office" cognitive work of clinical providers. There are multiple factors driving this need, including an overwhelming amount of evidence, data, and variables to be synthesized in diagnosis and treatment, as well as an evolution in the roles of patients and clinicians.

There is a broad consensus that transforming healthcare delivery into the next medical era will require the capabilities and productivity provided by clinical informatics. However, early versions of these clinical information systems have met with resistance and frequent implementation failures, as well as criticisms regarding the benefits delivered and unintended consequences for various market stakeholders.

This *Review* edition analyzes one potential cause of these problems: shortcomings in the design of the systems themselves. Drawing from the findings and recommendations of experts in medical informatics system design and a vast experience base accrued from cognitive software development in other complex, variable, and uncertain industries such as aviation and aerospace, we assert that for these efforts to be fully safe and effective, a new generation of cognitive digital systems is needed.

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An Information-Intensive Medical Era

The information intensity and complexity of medical science has begun growing geometrically, and has now reached a level that not infrequently surpasses the abilities of unaided cognition. Accessing, navigating, and applying these ever-increasing data regarding new diagnostic techniques, therapeutic interventions, and their relative effectiveness, require computing support. For example, the National Library of Medicine's Medline archives 31,000 new citations per month, and a clinician must read an estimated 17 articles each day, every day of the year, simply to remain current in his or her field of practice (Pestotnik).

Clearly, clinicians need new tools to help them optimally diagnose, prescribe,

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intervene, partner with patients, and measure results. However, clinical medicine is somewhat late in turning to cognitive support from computers, as virtually all other information and analytically intensive professions now widely utilize information technology to directly support their work.

A number of trends drive this need for technologies that support cognitive clinical work. First, as noted above, clinicians need better ways to manage the onslaught of new clinical results, therapeutic interventions, and diagnostic techniques entering either the published literature or commercial markets each year. Second, due to substantial administrative and regulatory burdens, clinicians have less time available for consuming, analyzing, and applying these data and findings. Third, new information-related demands are being required of clinicians, including patient engagement (despite short encounter windows) and performance measurement and management.

These new information-related functions derive from the enormous shifts now occurring in the healthcare marketplace. The consumer healthcare transformation reflects the demands and needs of patients and purchasers of care for patient involvement and accountability, and the recognition that this requires greater transparency into medical science and decision making. Providers are now being asked to help patients translate and contextualize medical information, as well as to improve treatment adherence by involving patients in their care.

The other major market shift involves movement toward a transparent, value-based purchasing healthcare market, wherein provider results are made public and reimbursement is in part tied to those results. Providers are increasingly being required to measure and report on various aspects of care processes and outcomes. These changes necessitate that providers view their patients not just on an individual basis, but through a population or panel wide lens, as well. More broadly, clinicians must develop new measurement and management tools in addition to new approaches to partnering with patients and systematically managing conditions.

Thus, much as medical providers require new types of surgical and diagnostic instruments as a consequence of medical technologic advances, the emerging era's dependence on information and evidence necessitates Internet and informatics technologies to capture, exchange, analyze, and present clinical information. "Broadly defined, informatics is concerned with the incorporation of IT into the day-to-day workflow and delivery of health care," writes Pestotnik. "To accomplish this, informaticists must deal with the uncertainty of the clinical encounter, the expansion of clinical information, the complexity of the health care delivery setting (clinical and financial), the limited ability of the human mind to simultaneously utilize four to seven data constructs, and the explosion of technology itself." These informatics technologies can be termed "cognitive digital instruments," and are designed to complement the strengths and weaknesses of clinician and patient human cognition and behavior, in order to advance medicine into a new era.

Technologic Support for Clinical Performance

How can information technology best "team" with the clinician to advance care delivery and improve the practice of medicine? The Institute of Medicine's six aims for a new healthcare system articulate key criteria for doing just that. They involve transforming healthcare so that it is safe, effective, efficient, equitable, timely, and patient-centered (Institute of Medicine's Crossing the Quality Chasm: A New Health System for the 21st Century).

To achieve these objectives, there are four major application categories for which clinicians need information management and/or communications support and that can advance performance toward the desired objectives. These applications are:

- External Evidence - Accessing, navigating, and applying the scientific and clinical evidence base
- Internal Evidence - Capturing the clinician's own or group-level clinical experience and results so as to measure clinical performance and generate an internal evidence base
- Streamlining - Standardizing and optimizing task-oriented care delivery processes
- Patient Engagement - Informing, involving, and interacting with the patient as a responsible partner in care

This informatics-enabled, perpetual translator of clinical experience into effectiveness evidence will be game changing.

Navigating the External Evidence Base

The explosion in clinical data and publications that has occurred over the past few decades is in large part the result of the leaps in productivity and publication capabilities provided by computing power. It therefore stands to reason that managing and translating this sea of data into clinically meaningful information would also require computer support.

Marsland and Buchan point out how the field of biologic sciences has undergone a similar transition to informatics: "…We have drawn parallels between health informatics—which is now having to deal with the problem of turning data into useful information that can be used to improve clinical quality—with bioinformatics, which has built up a symbiotic relationship with machine learning over the past few years, and which suffers from many of the same problems—large amounts of noisy data, feedback cycles between genes, and a shortage of temporal resolution."

Generating an Internal Evidence Base: A Revolution in Clinical Knowledge

Many healthcare leaders agree that the most promising and game-changing new capability that could be generated by the broad adoption of optimally designed clinical informatics systems concerns the so-called "secondary uses of clinical data" or "rapid learning." If clinical data regarding patient characteristics, diagnostic tests, treatment interventions, and short- and long-term results can be electronically captured in a structured manner, then informatics systems can analyze de-identified versions of these data across populations within and beyond practice groups to generate a new source of clinical evidence — one based on scientific, observational analyses of real-world clinical experience and intervention effectiveness.

This informatics-enabled, perpetual translator of clinical experience into effectiveness evidence will be game changing in a number of ways. First, it will provide clinicians with feedback regarding the results of their interventions and perhaps best practices regarding procedures. "With large databases and networks, we can learn from real-world experience and eventually do it in real time," writes Etheredge. "In other words, we can rapidly develop new evidence, learn from it, and apply these learnings to medical practice and health policy."

Second, it will enable therapeutic interventions to be selected based on their relative effectiveness for particular, "personalized" groups of patients. In other words, patients will be presented with outcome predictions for different treatment alternatives that are personalized in that they are derived from the clinical experiences of a similar category of patients, as defined by demographic, pathologic, and soon genetic factors. This will define a new era in medicine, as much of the therapeutic trial and error gives way to a more scientific approach to selecting interventions.

Finally, an effectiveness-evidence information engine can power value-based purchasing of medical products and services, a capability critically needed to bring healthcare spending and waste under control and optimally allocate resources projected to be increasingly scarce in the coming decades. Value-based purchasing refers to the act of making reimbursement decisions driven by cost-effectiveness analyses that estimate the clinical and quality-of-life benefits provided by a particular product or service in comparison with the direct and indirect incremental costs associated with that test or intervention. Currently, this approach is hampered by the fact that evidence is limited to "efficacy," meaning how the product or service performed in the rather limited, highly controlled, and thus somewhat artificial context of clinical trials.

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Streamlining Processes

The value-based purchasing movement demands that clinical services and interventions demonstrate higher quality results per unit of resource consumption. Thus, providers need to streamline their operational processes in order to eliminate waste and drive productivity. This is an area for which extensive experience from other industries (even service businesses) demonstrates the advances possible by adopting information technologies.

There are also a number of opportunities to optimize the distribution and execution of tasks, in terms of which resources are applied (including the patient), and how many are automated. Multiple hospital organizations have undergone informatics-supported "lean six sigma" transformations that have substantially improved their patient safety records while decreasing waste and costs. Demographic forecasts regarding future shortages of clinical providers due to rising demand from an aging Baby Boomer cohort emphasize the importance of finding more efficient ways to deliver care services.

Patient Engagement

Market and social forces are reorienting healthcare delivery around the patient, in a manner referred to as "patient-centered care." This means involving the patient as an informed, responsible partner who shares in decision making, is committed to treatment plans, and is financially accountable for some component of care. Given the very limited amount of time available during face-to-face encounters, some sort of informatics and telecommunication technology is necessary to involve the patient in making clinical decisions, following treatment plans, and making behavioral changes as a responsible partner in his or her care. The clinical literature is replete with reports regarding the consequent benefits of engaging patients in this way, including improved outcomes, more satisfied patients, and higher clinical throughput.

Clinical Informatics Design Challenges

To date, efforts to design and implement clinical informatics systems have had very mixed results. Electronic medical records (EMRs) in particular have not been adopted at rates hoped for or projected, and there are wide reports of adoption resistance and missteps. The President of the American Medical Association, William Plested, MD, recently remarked, "There is great interest among many private practice physicians in new technologies that may help increase patient safety and quality of care, but many barriers to adoption remain…. The health information technology field is still young, and while physicians are optimistic about the benefits, more work needs to be done before widespread adoption is possible."

Many have observed that one source of the difficulty rests with the functionality of EMRs and their relative ineffectiveness in supporting clinical cognitive work. "Despite these efforts, clinicians find the records to be a poor match for the kinds of cognitive work that they must perform," observe Nemeth et al. "Electronic medical records have been established that seem to serve everyone except the patient and the physician, as physicians are required to spend more time entering data manually but have few tools for automating manipulation or interpretation of the same data," write Weiner and Biondich.

One researcher has even found that these sorts of design issues can inadvertently negatively affect care; for instance, by interfering with patient interactions: "Given the results of this study and other recent reports assessing the influence of EHRs on the office environment and clinical outcomes, it would be a grave mistake to believe that the effects of EHRs will be automatically and universally positive" (Ventres).

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Why have these early versions of clinical informatics systems encountered such problems? According to professionals with expertise in medical informatics and the design of information technologies that support complex cognitive work, the answer lies in the current design and development of these systems. More specifically, they assert that developing informatics applications that safely and effectively support a domain as complex and variable as clinical care is a challenging endeavor that requires advanced knowledge and a multidisciplinary approach. They also observe that most of the "first generation" clinical informatics systems display basic design mistakes that suggest that the developers have not tapped the experience and knowledge base generated from cognitive computing efforts in other industries, including aviation, aerospace, and genomics.

The past few decades of experience using computer technology for cognitive work across professions have created new expert domains, such as "cognitive engineering" and "human factors." Repeatedly, these trial-and-error software development efforts have shown that the design and functionality of these systems can have varied, significant, and sometimes unintended positive and negative consequences on human performance. In particular, cognitive engineering and human factors experts emphasize the importance of first attaining a deep understanding of the cognitive work performed, its challenges, and its facilitators.

Researchers at the Cognitive Technologies Laboratory at the University of Chicago have concluded that one problem lies in software developers' ignorance of how medical practice functions, in all of its complexity and uncertainty. Nemeth and Cook write, "There really is a problem with healthcare IT… 'many—even most—health care information systems are failures.' The research that our lab has conducted over the past decade indicates that this is the way healthcare IT systems work. With no changes to how IT systems are developed, this is the way they will continue to work in the future. …Healthcare IT systems that are developed without a deep understanding of the healthcare work domain can only reflect a guess of how such systems should be configured."

Unintended Consequences in Clinical Safety and Effectiveness

Information systems not designed based on a deep understanding of the nature and needs of clinical cognitive work can result in unintended safety and effectiveness issues. Many clinicians complain that the design of some EMR systems requires them to take time during the clinical encounter to enter data in a manner that

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interferes with the patient dialogue and slows their processes. Also, most EMR systems cannot support providers' needs regarding data queries to measure and report on quality performance metrics.

In fact, researchers have identified a number of design flaws in current versions of clinical systems: "When human factors practitioners and researchers examine the typical human interface of computer information systems and computerized devices in health care, they are often shocked.…Computer displays, interfaces, and devices in health care exhibit 'classic' human-computer interaction deficiencies" (Woods).

The Institute for Healthcare Communication has studied the situation and reports, "The exam room computer offers new avenues for inviting patients to become active partners in their health care. It also can become a barrier to effective communication. Busy clinicians, whose tasks are now accomplished through the computer, are sometimes drawn immediately to the screen, omitting a critical opportunity to start with a personal connection with the patient."

Finally, one group of researchers convey the gravity of this problem by remarking, "We are concerned that the calls for more use of integrated computerized information systems to reduce error could introduce new and predictable forms of error unless there is a significant investment in user-centered design" (Woods).

A New Generation of Informatics Systems

We, and others, assert that a new approach to designing and deploying informatics technologies is needed for clinicians and patients to derive optimal benefits from their adoption. This next generation of cognitive informatics systems needs to function as a clinical "team member" with complementary capabilities. To achieve this, the design must begin with an intensive analysis and understanding of the human cognitive work of delivering care. The design must also be informed by a system-wide view of the information environment and must apply scientific and technologic methods advanced enough to play an active role in an environment as complex, uncertain, fuzzy, and hazardous as clinical care.

Cognitive engineers describe a "use-centered systems design" for mastering the cognitive work to be supported by an informatics system. This requires a thorough understanding of the specific clinical application domain's goals and constraints; the range of cognitive tasks clinicians perform; the strategies that clinicians currently use to perform tasks; the factors that make tasks complex; and the tools that make it easier for practitioners to accomplish goals effectively and easily.

Because healthcare organizations are widely recognized to operate as complex adaptive systems in which information and activity are highly interconnected and dynamic, clinical informatics applications that affect any one task or function can generate ripple effects across the system and participants, often in unexpected ways.

The Institute of Medicine is among a number of healthcare thought leaders to advocate for the application of complexity science principles in developing novel solutions for 21st century medicine. In their groundbreaking March 2001 report, "Crossing the Quality Chasm: A New Health System for the 21st Century," the authors cite "recent work in understanding complex adaptive systems… A new health system should be based on systems that can organize themselves to achieve a shared purpose by adhering to a few well-thought-out general rules, adapting to local circumstances, and then examining their own performance. In reshaping health care, local adaptation, innovation, and initiative will be essential ingredients for success."

Clinical cognitive instruments must enrich and develop information exchange between clinician and patient, clinician and staff, and specialist and referrer.

This complexity sciences perspective suggests that effective cognitive technologies should be intelligent and flexible enough to adapt with user feedback and system dynamics, changing their functionality and information displays over time and customizing content and functionality employed according to the user and clinical context.

Complexity sciences also emphasize the critical role of interactions between system participants in facilitating a complex system's ability to learn and adapt effectively. Thus, clinical cognitive instruments must enrich and develop information exchange between clinician and patient, clinician and staff, and specialist and referrer. As an internist who has adopted these principles remarks, "Complexity science has taught me that the practice of medicine is in the interactions" (Singhal).

Wherever possible, the instrument should enable data to be captured in a structured format, so that subsequent analytics can be used to generate new knowledge from routine care delivery. For example, an informatics system's ability to recognize patterns in outcomes data collected from scientifically validated patient survey instruments can provide clinicians with vital information regarding which procedures or treatments are most effective under various conditions. This capability to produce reports that detail clinical experience and results, analyzable by intervention and patient profile, is crucial for performance improvement.

In terms of decision-support technology, a rules-based algorithmic approach is likely too rigid and simplistic to be useful to most clinicians. A more promising design might utilize fuzzy pattern-recognition and machine-learning methods (such as neural network software) more applicable to complex and nonlinear domains like medicine. Another manner in which these instruments can support human decisions is through information displays that facilitate human diagnostic and therapeutic thinking by graphically representing trends over time, identifying data sources for benchmarking and alternative possibilities as a safety check.

To illustrate an example of a cognitive instrument, consider a patient engagement application that supports a clinician's patient interactions, including informing the patient outside of the time constraints of office encounters. The "instrument" might be deployed through a secure Internet connection and deliver clinician-prescribed, electronic informational materials to the patient before the encounter, as well as collect medical and intake information using structured online forms.

This application delivers multiple benefits to both clinician and patient, as patients' understanding of their clinical situation empowers their participation and accountability, and providers are able to spend the limited encounter time discussing the trade-offs of alternatives and engaging in supportive dialogues. The clinical database of structured information generated by this sort of instrument supports performance measurement for pay-for-performance programs, as well as internal clinical dashboards for quality improvement programs. "We and others have begun to develop systems that allow patients to enter their own clinical data directly into computer systems, using tools designed for automation and integration. This direct data entry may foster [relationship centered care], by improving the integrity of the data and by providing time for patients and their clinicians to develop dialogue based on findings, rather than dialogue used simply for documentation" (Weiner).

Conclusion

The opportunities that optimally designed cognitive instruments might provide in improving healthcare are numerous. These informatics systems can facilitate informed

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and responsible partnerships, expand the diagnostic and therapeutic capabilities of clinicians, and accelerate the generation of new types of more personalized and predictive clinical knowledge. Such direct benefits would likely help develop patient-centered processes and decisions, greater adherence to treatment plans, improved selection of interventions based on personalized effectiveness predictions, and a return to a more intimate patient-clinician relationship.

A recent report on digital healthcare by The Royal Society summarizes these conclusions quite well: "Information and communication technologies have the potential to transform radically the delivery of healthcare and to address future health challenges. Whether they actually do so will depend on the design and implementation processes sufficiently accounting for the users' needs."

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