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Designing healthcare information technology to catalyse change in clinical care

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ABSTRACT

The gap between best practice and actual patient care continues to be a pervasive problem in our healthcare system. Efforts to improve on this knowledge–performance gap have included computerised disease management programs designed to improve guideline adherence. However, current computerised reminder and decision support interventions directed at changing physician behaviour have had only a limited and variable effect on clinical outcomes. Further, immediate pay-for-performance financial pressures on institutions have created an environment where disease management

Introduction and background

The failure to effectively apply evidence-based guidelines to the prevention and management of chronic disease has been described as a 'quality chasm' by the Institute of Medicine (IOM) and is well reported in the literature.^{1–4} This disparity between guidelines and practice is pervasive and has been observed for immunisations,^{5,6} cancer prevention,^{7,8} primary prevention⁹ and chronic disease management.^{10,11} Nearly all aspects of the healthcare delivery system have

systems are often created under duress, appended to existing clinical systems and poorly integrated into the existing workflow, potentially limiting their realworld effectiveness. The authors present a review of disease management as well as a conceptual framework to guide the development of more effective health information technology (HIT) tools for translating clinical information into clinical action.

Keywords: clinical reminder systems, electronic medical records, system design

been implicated as important contributors to this 'knowledge–performance gap': time limitations during the clinical encounter,¹² difficulty in managing an increasing burden of clinical data¹³ and sub-optimal medication adherence perhaps related to lack of patient education.¹⁴ According to the IOM, this is a systemic problem: 'The current systems cannot do the job. Trying harder will not work. Changing systems of care will.'

The IOM has identified HIT and evidence-based practice guidelines as key components of a broader strategy to redesign the healthcare system in the USA. Electronic medical records (EMRs), a keystone in the HIT framework, have been recommended as a means to improve safety through error reduction^{17,18} and increase healthcare quality while concurrently decreasing expenditures.^{16,17} Advanced features of EMRs such as disease management (DM) programs have been shown to improve guideline adherence^{19,20} and are an increasingly frequent approach to address the pervasive discrepancy between clinical knowledge and clinical practice.²¹ However, while some interventions directed at changing physician behaviour via computer-assisted decision support systems (CDSSs) and computerised reminders (CRs) have been effective, 2^{2-26} others have had only a limited impact on clinical outcomes.^{21,27–37} With only two-thirds of CDSSs studied actually improving physician performance,²⁹ there is clearly room for improvement in the systems that we design and build.

Healthcare payers are also influencing the shape of our healthcare system through financial pressures such as pay-for-performance (or 'P4P').³⁸ Under P4P compensation models, payers provide financial incentives to physicians, hospitals and other healthcare providers for meeting specific quality and efficiency performance measures.³⁹ If such requirements are not met, typically by the end of an annually renewable contractual relationship, insurers have the right to retain funds that otherwise would have been awarded to providers and healthcare institutions for services rendered. While there is some debate as to whether these efforts are serving the healthcare community well, P4P is already woven into today's healthcare fabric.^{40–42} As a result, healthcare entities are often faced with the harsh reality that the coming year's contractual goals are at risk, resulting in stopgap HIT solutions applied as afterthoughts to existing information systems. As has been observed recently by Crosson *et al*, 43 the mere act of applying a technology to a particular process (such as adding a reminder system to an EMR) does not guarantee improvement. By allowing financial incentives to become the immediate drivers of HIT system development, end-users of HIT (and ultimately healthcare consumers) are potentially short-changed with systems that further fragment existing workflow and consume more healthcare resources. Thus, the challenge is clear: how do we design HIT tools to seamlessly and elegantly prompt the busy physician to 'do the right thing?'

In this paper we review the core elements of DM programs and reflect upon lessons learned by our group over the past decade during the development and implementation of an advanced EMR^{44–46} within our academic health centre. Our goal is to present a conceptual framework to guide the design of innovative informatics tools that can be effectively integrated into clinical processes to change care.

Core elements of disease management programs

Tightly linked with advanced clinical information systems and employing measurable, evidence-based clinical and process-related outcomes, DM programs strive to identify and cost-effectively intervene with high-risk patients with specific disease-based or preventative care programs. Disease management programs have become essential tools as care has made the transition from a one-patient-at-a-time, anecdotal, reactionary and sickness-oriented care model, to one employing a proactive, population and evidence-based risk-management approach. Typically focusing on treating prevalent diseases with well-defined inclusion criteria such as diabetes mellitus, congestive heart failure or chronic obstructive pulmonary disease, DM programs vary widely in implementation and resources used. However, conceptually all DM programs have three main elements: (1) the individual patient (or population) at risk; (2) evidence-based clinical metrics and (3) the clinical effector arm, the final common pathway to affect change.

Identifying the patient and providers: panels and registries

To properly identify and link these at-risk populations with providers who have the ability to effect change, effective DM programs employ two key organisational tools: patient panels and disease registries. Panels identify and link patients with responsible providers while registries facilitate identification and tracking of clinical outcomes.

While there is certainly a fair amount of complexity surrounding the question: 'Who is my patient?',⁴⁷ a panel is, in simplest form, a list of patients being cared for by a particular physician, team or practice. While disease registries can also be simple, manually maintained lists of patients with a particular condition, they may be automated, rule-based systems based on specific disease inclusion criteria. In an automated system, the registry is kept up to date when run against the practice's EMR and laboratory results. This list, when cross-linked with patient panels can uniquely identify both the population at risk and the provider or care team involved in clinical decision making. To be trusted in real-time, panel quality must be high; we suggest enabling panels to be editable by front line users. Otherwise, as data stagnates, a registry becomes another heathcare obstacle instead of being a seamless tool to facilitate workflow.

Evidence-based guidelines

The next core component of a DM program is established practice guidelines for the disease(s) of interest. Not only do these guidelines provide practitioners with evidence-based recommendations for quality care, they serve as ideal process measures (such as screening or vaccination rates) and clinical metrics (such as LDL-cholesterol levels or percentage at goal) by which system effectiveness can be measured. These metrics must be observable and measurable and should be evidence-based or otherwise relate to possible points of intervention.

Applying evidence-based guidelines to panels and registries requires a system (either manual or automated) to collect and monitor clinical data elements for the target population. Automated systems can be used to populate these clinical and process metrics into a dedicated DM data store, or data can be accessed in real time via a service-oriented DM data access layer. While simple, manual registries that require manually entered data may have a lower initial start-up cost, these systems are less likely to be sustainable over the long term because of the additional DM task burden. As time passes, the time cost of manually entering data could quickly overcome the tool's benefits.

Once the essential building blocks listed above are in place, attention can be focused on the design of the most critical element to the success of a DM system: the clinical effector arm.

The clinical effector arm

The final required element of any DM program is the clinical effector arm - the component that actually carries out the intended action. The clinical effector arm, which includes the HIT intervention, the healthcare providers carrying out the intervention (e.g. nurses, case managers, physicians) and the patient, is the most highly variable aspect affecting closure of the DM loop. In is important to note here that the patient in chronic ambulatory care is one of the most important players on the healthcare team, if not the most important. As such, attention should be devoted to design opportunities to help enable productive interactions between informed and activated patients and prepared and proactive providers. Key design considerations affecting the success of this highly critical element of the DM system are described in detail below.

Key design aspects for the clinical effector arm

Elson *et al*⁴⁸ have likened clinical decision making to an industrial process: the main production process is

clinical decision making and the main products are the clinical decisions. There are three key 'raw materials' involved in clinical decision making: the patient's clinical history, the practitioner (and his or her relevant knowledge) and the task at hand. A typical scenario involves a physician being presented with new clinical data. After some review of the patient's medical history and analysis of the risk-benefit balance, the practitioner can take action with an appropriate clinical response. Ideally, the DM system, by providing assistance and support, would streamline this process. Assistance could be in the form of a human agent such as a nurse or medical assistant or in the form of an advanced decision support system. Part of the idea of rendering the physician more efficient is to remove population management from physician workflow completely; practices often employ a 'disease' nurse manager to perform exactly that purpose. Ultimately, the DM system should facilitate closure to the entire clinical workflow and facilitate the transformation of clinical information into action.

Disease management or population management?

Healthcare delivery is under tremendous time pressure. While many practitioners have mastered the fine art of multi-tasking, multiple physician demands within the clinical visit can adversely affect disease prevention and counselling rates⁴⁹ and result in less positive doctor–patient relationships.⁵⁰ Thus, consideration must be given to the venue where the clinical reminder or DM intervention is to be applied. Consider two complementary modalities of healthcare delivery: faceto-face with an individual patient (disease management) and 'asynchronously' for a whole cohort of patients (population management).

Traditional CR systems remain the mainstay of DM interventions and have been used extensively to improve guideline compliance.^{51–53} They are historically 'real-time' clinical tools to support point-of-care physician workflow⁵⁴ and are most effective when physician and patient agendas are aligned. Designed with these constraints in mind, CRs are typically deployed to assist providers during time-pressured patient visits. Unfortunately, the majority of clinicians report simply ignoring *flashing* reminder icons when reviewing a patient's chart during a visit.⁵⁵ Many have concluded that computerised reminder systems are underutilised primarily because of competing physician demands during the clinical encounter.⁵⁶ If a CR does not fit within the visit's agenda or is otherwise considered a lower clinical priority, there is the risk that the intervention may be overlooked altogether.⁵⁷

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Population management approaches the DM task with a broader perspective, focusing on the entire patient cohort with the condition with a given condition rather than on an individual patient.^{58,59} This approach, particularly useful for practices that employ multiple members of a care team or have an expanded locus of care,^{60,61} enables providers to identify patients for further intervention based on acuity and circumvents the time constraints that may limit changes in management during time-constrained individual clinic visits. This approach is most appropriate for interventions that do not require face-to-face visits and facilitates surveillance and intervention for patients without pending follow-up appointments.

Thus, a primary design decision must be made regarding the appropriate locus of intervention for the task at hand: is it most effective to intervene with the patient at the point-of-care or to intervene 'asynchronously' via cohort-based population surveillance and outreach? What is the preferred method for patient involvement that results in the most clinically effective outcome?

Respect provider workflow

Regardless of the mode of intervention, the DM system should reflect and, ideally, improve provider workflow. Quite simply, the tool should make it both quicker and easier for providers to 'do the right thing'. In the following discussion, we consider as a working example our 'Cholesterol FastTrack' system, a computer-assisted physician-directed intervention to improve secondary prevention of hyperlipidemia via interactive and 'actionable' clinical reminders delivered via email external to a clinical visit.^{23–26}

Make it quick

Physician resistance may undermine any new implementation if it takes more time to complete a given task using the newly deployed system. Physicians perceive that there is not enough time in nearly every aspect of their daily work: during ambulatory visits,⁶² when reviewing patient data and laboratory results or when caring for inpatients.^{63,64} Given that a typical full-time primary care physician reviews nearly 50 000 laboratory results per year requiring over an hour of time per day,⁶⁵ efforts must be made to ensure quick data review and efficient action.

The success or failure of a medical information system depends primarily on physician acceptance of its implementation.⁶⁶ Workflow inefficiencies must be directly addressed early and often in the design phase. The essential question relates to the notion of

clinical decision making as an industrial process: what is the information required (the raw materials) to safely and succinctly make a clinical decision (the product)? Attention to the user interface is paramount - information should flow efficiently across the screen and balance must be achieved between too little information and information overload. For FastTrack, which informed providers about patients not meeting clinical guidelines, our intention was to consolidate the most salient information necessary for making a sound decision. We invited feedback from members of our target user group, via physician focus groups. Perhaps most importantly, possible medication choices were rank ordered algorithmically according to each of the key factors affecting medication choice: predicted post-intervention LDL and goal achievement, patient insurance formulary preference and co-pay information (Figure 1).

Make it easy

The management of medical testing and clinical result follow up can be cumbersome: there are as many as 17 individual tasks involved in laboratory testing and reporting⁶⁷ including chart review for risk assessment and therapeutic contraindication, prescription writing within insurance formulary constraints and outreach for patient education and follow-up testing. Unfortunately, few reminder systems actually 'close the loop' and link the reminder with a simple means to affect clinical action.⁶⁸ Ideally, systems should not only report guideline non-compliance, but also catalyse change by facilitating the relevant clinical workflow. In FastTrack, a single 'click' of the physician's mouse automatically initiates the entire work flow chain automatically creating a prescription, updating electronic medication lists and generating tailored patient information letters. However, some tasks, such as creating a handwritten signature on a computer-generated prescription or setting up an infusion, may not be easily automated. It is important to note: the mere act of applying technology to a problem does not predicate that the solution is sound or that it will be adopted.

Choose a technology that can be easily adopted

In thinking about applying information technology (IT) to solve problems in medicine, consider Rogers' Diffusion of Innovation Theory⁶⁹ which identifies five characteristics that correlate with the rate of adoption of an innovation. The innovation should: (1) have a relative advantage over the existing system; (2) be compatible with practice needs; (3) not be too difficult

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to use; (4) have the ability to be tried on an interim basis and (5) have a high degree of visibility among peers. Each of these aspects is described here in the context of HIT:

- 1 Relative advantage In addition to incorporating evidence-based decision support and integrating seamlessly with the existing workflow, the DM system should provide added value for the user. If the system can shorten the steps required to perform a fundamental task, such as faxing an authenticated electronically signed prescription directly to the patient's pharmacy, the overall workflow is streamlined, thereby adding value and saving time. It is this relative advantage that might increase adoption rate or otherwise overcome what resistance might be encountered when moving users to a new system.
- 2 Compatible with physician/user needs The mantra 'If you build it, they will come' should really be 'If you build what they need and it fits, they will come'. This aspect of Rogers' theory helps to frame a potential technological solution with the culture and setting in which the technology will reside. Will the new system fit with the practice's values? Does the system address an issue that clinicians or others consider to be a problem? To address these considerations, the design team should interview individuals from each anticipated user group (physicians, nurses, case managers and patients). In addition to illuminating the work flow from a variety of perspectives, these focus groups often uncover work flow bottlenecks that might impair the usefulness of a new system. Special consideration should be given to aspects of the work flow that are time or labour intensive.
- 3 Non-complex Although intuitively obvious, this concept is worth special note: the greater the complexity of the given system, the less likely the system will be accepted and used. However, because complexity is a relative issue (what may be complex for one user may not be for another), a survey of technological readiness among users during the analysis phase is advised. For FastTrack, all of the physicianusers regularly used email (although not necessarily for direct patient communication). Thus, we concluded that email would be an appropriate delivery medium for interactive reminders. Additionally, because we discovered that our physician-users were familiar with hyperlinks, we felt comfortable sending HTML-rich emails that included embedded 'actionable' links which, when clicked, connected physicians directly to web-enabled EMR services such as note and prescription writing. The best systems are clever behind the screen, not on it.

- 4 **'Trial-ability'** Technologies are more likely to be adopted if they can be experimented with or tried without requiring a large amount of user commitment or risk. By having a testing period, users have an opportunity to discover how a new system improves upon the current work flow or to provide feedback if implementation is logistically awkward. Relatively few systems are 'right first time' and they often have unpredicted effects on the process that they are intended to support. Providing a trial period instills confidence to the users that the team implementing the system is receptive to changes.
- 5 High-visibility At every phase of development and implementation, a high degree of visibility can help stimulate peer discussion and user acceptance. During the project's pre-implementation phases, effort should be made to elicit feedback via meetings with leadership and user focus groups. Prior to a system's release, promotional and training materials should be distributed and practice leaders should be involved in face-to-face discussions with system users. Additionally, if the intervention is to be formally evaluated or published, the results of this analysis should be freely shared with staff.

Preserve physician autonomy

Compliance with clinical guidelines is often adversely affected by physician attitudes reflecting the notion that guidelines undermine physician authority and result in 'cookbook' medicine.⁷⁰⁻⁷² Additionally, physician perception of diminished control has been implicated in the increasingly pervasive sense of inadequate time⁷³ and independently relates to decreasing career satisfaction.⁶⁴ Therefore, in addition to considerations about time and work flow efficiencies, effort should be made to preserve provider autonomy while providing evidence-based decision support. One approach might be by providing a range of evidence-based treatment options within the clinical reminder.⁷⁴ Also, it is important to recognise that there are often good reasons why individual patients are not on 'guideline recommended' regimens. Bates et al⁷⁵ recommend providing a means for physicians to 'opt out' of a particular recommendation and to use these exceptions as a means for follow-up and quality control. These opt outs are essential, as guidelines are not designed to accommodate all possible co-morbidities, or there may be cases where patients are on multiple guidelines and they adversely interact. By preserving physician autonomy, the system provides decision support rather than decision making. This approach may both increase the reminder system's effectiveness and limit physician resistance to change.

Promote the transformation of clinical information into action

Simply presenting clinical information to providers without linking information to action has little to no clinical impact.⁷⁶ To address concerns that information systems introduce work flow inefficiencies,77,78 reminders should be self-contained such that providers can confidently alter therapy without the need to review other information sources (including the EMR). We recommend incorporating end user focus groups to refine the reminder's clinical content and graphical layout. Complete and contextually sensitive data consolidated into a clear and succinct visual presentation will help eliminate labour intensive and error-prone manual chart reviews. By creating 'actionable reminders', Cholesterol FastTrack not only informs providers about poorly controlled patients, but also accelerates care and results in a significant and clinically meaningful impact on pharmacotherapy and subsequent LDL results.²

Involve the patient

A principal challenge in implementing any therapeutic regimen is achieving adequate patient adherence. Even in clinical trials where enrolled patients are educated and engaged, medication non-compliance rates still are significant.⁷⁹ Adherence rates are even lower for routine care where practices lack resources for consistent and proactive patient education. DM programs that incorporate patient education are more effective than physician-directed efforts alone.⁸⁰ Also, if the intervention is population based, it may be appropriate to incorporate automatic mailing of patient education materials to help facilitate patient involvement and an active role in their healthcare decisions. Correspondence should contain material appropriate for a patient's primary language and education level and should address common explanations for patient non-compliance including not believing in the need for treatment, fear of adverse effects and polypharmacy.⁸¹ In many cases, there is an additional layer of complexity hidden within the clinical effector arm that is the true barrier to care: physicians have already attempted to bring the aberrant laboratory result 'in line' with guideline-recommended thresholds by increasing medications, for example, only to find the patient cannot afford them or that there are other competing demands. These barriers to care are often only understood by the physician extenders in the healthcare team with increased patient contact and communication. It is this patient involvement that will guide the team in determining the most clinically effective approach.

Evaluate the system

While many HIT interventions have 'face validity' and are instituted under the presumption that they will indeed improve care, there is enormous historical context for ineffective systems, boycotting doctors^{82–84} and introduction of medical error^{85,86} and relatively few systems are evaluated in clinical trials with clinical measures of effectiveness. We strongly advocate rigorous evaluation of both process measures (such as physician usage patterns) and relative clinical outcomes for all innovative HIT tools. Ideally, outcomes should be assessed using a valid study design such as cluster randomised trials.⁸⁷

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Discussion

As McDonald aptly stated in his 1976 seminal article,⁵⁴ the reduction of practice error would require physicians to spend time in a manner that is unrealistic given the saturation of the physician workday. His hypothesis: computerised clinical information systems would help physicians close this quality gap by performing many of the repetitive, protocol-driven tasks. Over 30 years later we have, for the most part, the same hypothesis. While the idea of applying computers to assist in the practice of medicine (diagnostic support,⁸⁸ online record keeping⁸⁹ and tracking adverse drug reactions⁹⁰) is nothing new, the synergy between computerised clinical systems and evidence-based medicine has remained a promise rather than a reality. Physicians are unwilling to rely on systems deemed slow, cumbersome or unreliable and practices are daunted by adoption costs.⁹¹ Nearly 20 years after the IOM first identified computer-based patient records as an essential healthcare technology,⁹² EMRs are present in less than 25% of US practices.⁹³ While these statistics may sound disheartening, the optimistic among us would consider this a perfect opportunity to build systems that not only improve quality while reducing costs, but also improve clinician workflow. Modern medicine is an information science with a knowledge base that is expanding at a rate beyond that which any provider can sustain. Effective systems should offer 'just-in-time'94 evidence-based decision support and preserve provider autonomy while promoting the transformation of clinical information into action.

With the threat of external forces such as P4P,^{95,96} risk of financial withholds and the physician report card^{97,98} becoming the immediate drivers of HIT system design rather than user-focused iterative design, we are faced with the possibility of continuing to build systems that sit precariously atop existing workflow

rather than improving it. As health care continues to shift from a hospital-based, inpatient model to episodic outpatient and community based care, systems will need more integration, automated surveillance and patient outreach to augment or replace care traditionally given during face-to-face encounters. HIT solutions should be designed with detailed understanding of front-line practitioner and patient needs and developed to seamlessly integrate into existing workflow. If existing workflow will be significantly changed by a new system, the system must provide added value and be technologically elegant or risk being under-used by participating providers. Additionally, interventions with complex systems may have unpredicted effects therefore post-intervention monitoring and follow up is essential. It is important to recognise that the practice of medicine is an ever-changing landscape with evolving front-line practitioner needs and disease management workflow. The need for application evolution never stops. Once designed and implemented, effective computer-assisted DM applications are relatively inexpensive to use and maintain on an ongoing basis and have the potential for significantly improving the efficiency and effectiveness of care for large patient populations.

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CONFLICTS OF INTEREST

None.

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Accepted February 2008