

Diabetes Information Technology: Designing Informatics Systems to Catalyze Change in Clinical Care

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Abstract

Current computerized reminder and decision support systems intended to improve diabetes care have had a limited effect on clinical outcomes. Increasing pressures on health care networks to meet standards of diabetes care have created an environment where information technology systems for diabetes management are often created under duress, appended to existing clinical systems, and poorly integrated into the existing workflow. After defining the components of diabetes disease management, the authors present an eight-step conceptual framework to guide the development of more effective diabetes information technology systems for translating clinical information into clinical action.

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Introduction

The failure to effectively apply evidence-based guidelines to the management of chronic diseases such as diabetes has been described as a “quality chasm” by the Institute of Medicine (IOM).¹⁻⁴ According to the IOM, this gap is the result of a systematic problem that requires redesigning the overall system of care delivery. The need for systematic redesign is particularly apparent in diabetes care,⁵ with less than 10% of U.S. adults with diabetes simultaneously attaining recommended goals for glycemic, blood pressure, and cholesterol control.⁶ The application of health information technology (HIT) represents a key component of a broader strategy to redesign the health care system in the United States. Electronic medical records (EMRs), a keystone in the HIT framework, have been recommended and are used increasingly⁷ as a means to improve safety through error

reduction⁸ and to increase health care quality while concurrently decreasing expenditures.^{9,10}

Diabetes care is particularly complex: patients’ physicians have multiple different test results to track and simultaneous risk factors to control and patients have complex medical regimens and may encounter multiple members of a diabetes care team. While some EMRs have been shown to improve rates of missing clinical information,¹¹ improve guideline adherence and diabetes clinical decision making,¹²⁻¹⁴ and improve the health care coordination of care among care team members,¹⁵ current HIT implementations have yet to demonstrate the transformational change promised. While some interventions directed at changing physician behavior via computer-assisted decision support (CDSS) and clinical

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Abbreviations: (CDSS) computer-assisted decision support, (CRs) clinical reminders, (DM) disease management, (EMRs) electronic medical records, (HIT) health information technology, (IOM) Institute of Medicine, (PDSA) Plan-Do-Study-Act

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reminders (CRs) have been effective,¹⁶⁻²⁰ others have had only a limited impact on clinical outcomes.^{7,21-31} Evidence shows that only two-thirds of CDSS systems actually improve physician performance²³; there is clearly room for improvement in the systems that are designed and built. As has been observed by Crosson *et al.*,³² the mere act of applying a technology to a particular process (such as using an EMR to help improve diabetes care) does not guarantee improvement.

Thus, in our efforts to improve care for our patients with diabetes—as providers of care (and the consumers of HIT), as practice managers considering the implementation of a system to help improve practice efficiency, or as HIT system designers—the challenge is clear: How do we seamlessly and elegantly help the diabetes care team “do the right thing?” This article reviews the core elements of disease management and reflects upon lessons learned by our group over the past decade during the development and implementation of an advanced EMR system³³⁻³⁵ within our academic health center. This article outlines the core elements of disease management programs and provides an eight-step conceptual framework to guide the design of innovative medical informatics applications that can be effectively integrated into HIT systems for diabetes care.

Core Elements of Disease Management Programs

Broadly speaking, diabetes-related disease management (DM) is the concept of improving health care quality for patients with diabetes by preventing or minimizing the effects of the disease while decreasing health care expenditures. Tightly linked with advanced clinical information systems and employing measurable, evidence-based clinical and process-related outcomes, diabetes disease management programs have become essential tools as care has transitioned 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. The key elements to a functional DM program include (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.

Patients and Populations at Risk

To properly identify and link diabetes patient populations with providers who have the ability to affect change, effective DM programs employ two key organizational tools: patient panels and disease registries. Patient panels

identify and link patients to the clinicians directly responsible for their care, while registries facilitate identification and tracking of clinical outcomes for all patients served within a health care network.

While there is certainly a fair amount of complexity surrounding the question: “Who is my patient?,”³⁶ a panel is, in simplest form, a list of patients being cared for by a particular physician, team, or practice. While diabetes registries can be simple, manually maintained patient lists, they may also be automated, rule-based systems based on specific 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 can then be cross-linked with patient panels to 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 recommend that frontline clinicians be able to edit the lists. Otherwise, as data stagnate, a registry becomes another health care obstacle instead of being a seamless tool to facilitate workflow.

Evidence-Based Clinical Metrics

The next core component of a DM program is evidence-based practice. Not only do these guidelines provide practitioners with evidence-based recommendations for quality care, they serve as ideal process measures (such as screening rates) and clinical metrics (such as low-density lipoprotein cholesterol levels or percentage at goal) by which system effectiveness can be measured. These metrics must be directly measurable and should be evidence based or, in the case of workflow improvement, should relate to possible points of intervention (such as turnaround time for laboratory result review).

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 diabetes 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 start-up cost initially, 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 entering data manually can quickly overcome the benefits of the tool. Once these essential building blocks 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 both the HIT intervention and the health care providers carrying out the intervention (e.g., nurses, case managers, physicians), is the most highly variable aspect affecting closure of the DM loop.

Elson *et al.*³⁷ 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. Three key “raw materials” are involved in clinical decision making: the patient’s clinical history, the practitioner, 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 “diabetes 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?

Health care delivery is under tremendous time pressure. While many practitioners have mastered the fine art of multitasking, multiple physician demands within the clinical visit can adversely affect disease prevention and counseling rates³⁸ and result in less positive doctor–patient relationships.³⁹ Thus, consideration must be given to the venue where the clinical reminder or DM intervention is to be applied. Consider two mutually complementary modalities of health care delivery: face to face with an individual patient (classically defined as disease management) and “asynchronously” for a whole cohort of patients (population management).

Traditional CR systems remain the mainstay of HIT interventions and have been used extensively to improve guideline compliance.^{26,40,41} They are historically “real-time” clinical tools to support point-of-care physician

workflow⁴² 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.⁴³ Many have concluded that computerized reminder systems are underutilized primarily because of competing physician demands during the clinical encounter.⁴⁴ 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.⁴⁵

Population management approaches the DM task with a broader perspective utilizing elements of traditional DM, such as evidence-based guidelines and clinical metrics, but instead focuses on an entire patient cohort rather than on an individual patient.^{46,47} This approach, particularly useful for practices that employ multiple members of a care team or have an expanded locus of care,^{48,49} enables providers to identify diabetes 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?

Eight Rules for Designing Informatics Systems to Catalyze Change in Diabetes Care

With component elements of diabetes disease management in mind, we present the following eight concepts as a guide for designing effective informatics systems to support diabetes management.

1. Respect Provider Workflow

Regardless of the mode of intervention, the 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.” The reality is that when existing processes are changed, there may be unpredicted effects on the process that they are

intended to support. Relatively few attempts actually get it “right the first time.” Because interventions to complex systems may have unpredicted effects, postintervention monitoring and follow-up are essential.

2. 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,⁵⁰ when reviewing patient data and laboratory results, or when caring for inpatients.^{51,52} 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*,⁵³ 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.⁵⁴ 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 information is 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.

3. 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 reporting,⁵⁵ including chart review for risk assessment and therapeutic contraindication and prescription writing within insurance formulary constraints, as well as 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.¹⁶ Ideally, systems should not only report guideline noncompliance, but catalyze change by facilitating the relevant clinical workflow. However, some tasks, such as creating a handwritten prescription signature, simply cannot be automated.

4. Choose a Technology That Can Be Adopted Easily

When applying information technology to solve problems in medicine, consider Rogers’ diffusion of innovation theory,⁵⁶ which identifies five characteristics that correlate with an innovation’s rate of adoption. The innovation should (i) have a relative advantage over the existing system, (ii) be compatible with practice needs, (iii) not be

too difficult to use, (iv) have the ability to be tried on an interim basis, and (v) have a high degree of visibility among peers. Each of these aspects is described here in the context of HIT.

i. 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 the same 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 the adoption rate or otherwise overcome what resistance might be encountered when moving users to a new system.

ii. 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 Roger’s theory helps 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). In addition to illuminating the workflow from a variety of perspectives, these focus groups often uncover workflow bottlenecks that might impair the usefulness of a new system. Special consideration should be given to aspects of the workflow that are time- or labor-intensive.

iii. Noncomplex. Although intuitively obvious, this concept is worth special note: the higher 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.

iv. “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 workflow or provides feedback if implementation is logistically awkward. Additionally, providing a trial period instills confidence that the team implementing the system is receptive to changes.

v. 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 preimplementation 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 evaluated formally or published, the results of this analysis should be shared freely with staff.

5. Preserve Physician Autonomy

Compliance with clinical guidelines is often affected adversely by physicians' attitudes reflecting the notion that guidelines undermine physician authority and result in "cookbook" medicine.⁵⁷⁻⁵⁹ Additionally, physician perception of diminished control has been implicated in the increasingly pervasive sense of inadequate time⁶⁰ and relates independently to decreasing career satisfaction.⁵² Therefore, in addition to considerations about time and workflow 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.⁶¹ Also, it is important to recognize that there are often good reasons why individual patients are not on "guideline-recommended" regimens. Bates *et al.*⁶² 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. This approach may both increase the reminder system's effectiveness and limit physician resistance to change.

6. 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.⁶³ To address concerns that information systems introduce workflow inefficiencies,^{64,65} 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 labor-intensive and error-prone manual chart reviews.

7. 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 noncompliance rates still are significant.⁶⁶ 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.⁶⁷ Also, if the intervention is population based, it may be appropriate to incorporate automatic mailing of patient education materials. 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.⁶⁸ 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 that 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 health care team with increased patient contact and communication. It is this patient involvement that will guide the team in determining the most clinically effective approach.

8. 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,⁶⁹⁻⁷¹ and introduction of medical error,^{72,73} and relatively few systems are evaluated in clinical trials with clinical measures of effectiveness. We strongly advocate for 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-randomized trials.⁷⁴

Barriers to System-Wide Implementation of Diabetes Informatics Systems

Following the aforementioned "eight rules" will ideally lead to the design or selection of an effective informatics system for diabetes population management. The final steps to success, however, are the actual implementation and wide adoption of the new technology within the target health care system (e.g., group practice, academic health center, and provider organization). According to a review by Bodenheimer and colleagues,⁷⁵ the top five

barriers to system adoption are lack of institutional resources, a reimbursement structure that does not reward high quality, inadequate HIT, physician resistance, and physicians being too busy. Intraorganizational factors such as leadership and culture are variable factors and may be either a facilitator or a barrier to HIT implementation.⁷⁵

Building Success

If you are involved in developing the HIT that makes up the diabetes informatics system, the first critical barrier that needs to be overcome is actually producing the system that you intend. Software projects are notorious for being overbudget, lacking features, late, or canceled altogether. A report from the Standish group⁷⁶ cited that only 28% of software projects are considered truly successful, while nearly half of all projects were in some way handicapped by being substantially late, significantly overbudget, or simply lacking the intended features. Even worse, 23% of projects studied in this report were canceled before they were even completed. To help beat these odds, we need to carefully consider and monitor the project's main constraints: scope, time, cost, and quality. All four constraints are interrelated and must be addressed to have a successful project. The overarching goal is to meet the project's objectives while maintaining a balance among these inherent project limitations.

The Plans Are Fixed, the World Is Not

In some ways, the practice of medicine is a lot like project management. Take the management of diabetic ketoacidosis as an example: After diagnosis, we plan our attack. We have algorithms to help us manage a patient's hydration, insulin, and electrolyte imbalances. While at the initial diagnosis, we have a well-defined problem and evidence-based strategies for management, sometimes along the way things can change as complications emerge and we have to modify our original plan. If we do not account for these variations, we sacrifice care. Applying this analogy to project management terms, after our initial diagnosis of "inadequate HIT," we devise a plan or a set of features (or scope) of our HIT intervention. From here we can derive the project's other constraints: time, cost, and quality. If one of the four project constraints is modified, such as recognizing that our analysis failed to include a needed feature, we need to reassess and work these changes into our plan. For example, increasing the scope of the project usually requires some adjustment in the costs and/or the schedule while cutting back on expenditures calls for modifying the project's scope or calendar. Is it more important to maintain the budget and deliver on time, while possibly sacrificing features,

or is it more important to build out the complete feature set, while potentially sacrificing budget and schedule?

Promote, Evaluate, Discuss, Iterate

When we talk about barriers to implementation, in addition to ensuring that we have support from institutional leadership, we need to consider strategies to help promote the adoption of the tools we build by the people who actually use them. In thinking about this, I am reminded of the old question that starts with "If a tree falls in the forest and no one is there to hear it..." Clearly, promotional, marketing, and training materials need to be considered along with any deployment schedule. After the development team has worked out the final project specifications, yet well before the team has delivered the final product, project leadership should integrate the distribution of promotional and training materials into their deployment plan. Additionally, users may benefit from dedicated training sessions where in addition to seeing a demonstration of the useful features, they will have protected time to ask questions or try the new system. Also, during the rollout, it is important to be visible "on the floors" to solicit feedback via face-to-face discussions with users of the system. It is important to evaluate the system relative to the design objectives. We recommend using an iterative Plan-Do-Study-Act (PDSA) cycle to measure the impact of a workflow change. While not as rigorous as randomized clinical trials, PDSA cycles are quasi-experiments that can be done on very small scales and, most importantly, very quickly.^{77,78} Key questions include the following: Does the system provide relative advantages? Is it easy to use? What are the remaining bottlenecks? What unforeseen obstacles have cropped up or otherwise make the system less than ideal?

Conclusion

Systems used to assist practitioners in the management of diabetes systems should offer "just-in-time"⁷⁹ evidence-based decision support and preserve provider autonomy while promoting the transformation of clinical information into action. It is important to recognize that the practice of medicine is an ever-changing landscape with evolving frontline practitioner needs and disease management workflow. Successful HIT solutions require the sustained understanding of workflow requirements. By automating and streamlining the informational needs of the busy practitioner, computer-assisted DM applications have the potential to curb health care costs while significantly improving care for large patient populations.

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