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Missing Elements Revisited: Information Engineering for Managing Quality of Care for Patients with Diabetes

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Abstract

Introduction:
Advances in information technology offer new avenues for assembling data about diet and care regimens of diabetes patients "in the field." This creates a challenge for their doctors and the diabetes care community—how to organize and use new data to produce better long-term outcomes for diabetes patients.

Methods:
iAbetics approaches the challenge as a quality management problem, drawing on total quality concepts, which in turn are grounded in application of the scientific method. We frame the diabetes patient's quality-of-care problem as an ongoing scientific investigation aimed at quantifying and predicting relationships between specific care-management actions and their outcomes for individual patients in their ordinary course of life.

Results:
Framing diabetes quality-of-care management as a scientific investigation leads to a seven-step model termed "adaptive empirical iteration." Adaptive empirical iteration is a deliberate process to perfect the patient's choices, decisions, and actions in routine situations that make up most day-to-day life and to systematically adapt across differences in individual patients and/or changes in their physiology, diet, or environment. The architecture incorporates care-protocol management and version control, structured formats for data collection using mobile smart phones, statistical analysis on secure Web sites, tools for comparing alternative protocols, choice architecture technology to improve patient decisions, and information sharing for doctor review.

Conclusions:
Adaptive empirical iteration is a foundation for information architecture designed to systematically improve quality-of-care provided to diabetes patients who act as their own day-to-day care provider under supervision and with support from their doctor. The approach defines "must-have" capabilities for systems using new information technology to improve long-term outcomes for diabetes patients.

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Abbreviations: (app) application program, (BG) blood glucose, (HbA1c) hemoglobin A1c

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Introduction

In September 2009, *Journal of Diabetes Science and Technology* published "The Missing Element of Telemedicine for Diabetes: Decision Support Software," by David C. Klonoff and Mark W. True.[1] The editorial notes that information technology enables better ways to collect diabetes patients' data "in the field" and to communicate data to doctors via electronic medical records. The essay argues that the diabetes-care community needs decision support software to help use new data effectively.

We agree. It is not the goal to *record* blood glucose (BG) test results; the goal is to *improve* them. Improving results means influencing decisions—if patients do not make better decisions about their diabetes care regimens, there is little likelihood that their medical outcomes will improve.

However, we frame the diabetes-care management problem differently. We see diabetes management not as a decision-support problem, but as a quality management problem. This article outlines our perspectives and describes a framework for organizing and using information to support sustained improvement in patient quality of care, with implications for "must-have" features of effective information systems seeking to improve health care for diabetes patients.

State of the Application

At one level, this article is premature—we do not have clinical research results to report. Advances in information technology are outpacing clinical research about its effectiveness as a tool to improve diabetes health care. Since the introduction of Apple App Store in July 2008, at least 50 different information collection application programs (apps) for diabetes patients have been introduced; dozens more are offered on Google's Android and other platforms (including Windows). Precise information is not public, but anecdotal evidence suggests that over 100,000 diabetes patients have downloaded a smart phone diabetes-management application.

While the wide-open app marketplace fosters entrepreneurial innovation, there is simply no way to track who is using what product and what success or issues they find. To our knowledge, there is as yet no reliable clinical study on the effectiveness of smart-phone-based data collection systems for diabetes patients. Further, it is likely to be several years before anyone generates acceptable clinical research to answer critical questions about the adoption, sustainability, and effectiveness of the new technologies in day-to-day use by real patients in the field.

The rapid—and largely uncontrolled—adoption of new information collection technologies for diabetes patients presents a dilemma for the diabetes-care community:

- Does the doctor withhold judgment regarding the relative merits of alternative apps pending development of reliable clinical research studies (which may be years away), leaving patients to experiment on their own without doctor guidance?

  or

- Does the doctor formulate design perspectives regarding desirable app features and characteristics judged most likely to support long-term effectiveness based on first-principle understanding and reasoning not yet supported by research rising to clinical standards?

We favor the latter option, even though formulating design perspectives at this stage is an inherently conceptual and theoretical discussion. We would argue that discussion at a conceptual level today is timely—in fact, essential, for these reasons:

- Ready or not, diabetes patients in the field are experimenting with a great number of new information collection and data-management tools without much guidance from the medical community. They are not waiting for proper clinical research—they are acting now.

- Not all data are equally useful—organizing, collating, and analyzing data to extract usable information and then using them to act appropriately does not happen automatically. Information architecture matters. We stand at the brink of exciting new potential for improving diabetes quality of care. It would be a shame to blow it by haphazardly assembling data that we cannot use to effect sustained improvement in diabetes quality of care.

- There is not much potential harm lurking in the patient's premature adoption of technology advances—

> yet. If advanced technology simply facilitates record keeping that reflects the doctor's advice and counsel, then "no harm done." But as advances in technology inevitably move toward evaluating and prescribing rather than simply recording actions, then the potential for unintended harm increases.

The time for framing the future information architecture for smart-phone-based diabetes-care-management systems is upon us. Simply put, if the doctor and the diabetes-care community are not ready to offer guidance, then patients will act on their own—perhaps unwisely.

Engaging the conceptual information-architecture discussion at this early stage also implies a leap of faith—that advances in smart phone and Web technology can and will resolve the many practical implementation difficulties associated with data collection, retrieval, and usage by diabetes patients in the field. As anyone who has tried will know, it is not easy to maintain meticulous daily health-care records, especially about what one eats. But there are 50 million iPhone users today who seem to think that the data management and retrieval capabilities of the device are game changing, and we are among them.

Notwithstanding technology advances, it always requires discipline and effort to collect data, even with advanced new smart phones. The critical question is whether the effort "is worth it." In our view, the core challenge is not ease of use; the core challenge is value of information.

The iAbetics system—indeed as with any care-management system for diabetes patients or other chronic patients—must be designed to focus not just on data collection, communication, and retrieval, but rather on the patient's care-management decisions and the underlying cause-and-effect relationships. Rather than recounting the well-known ease-of-use and implementation-related benefits of the new technology (i.e., how to collect and store information), we focus our article on what information to collect and how to use it. It seems to us that this is the more important question today.

"Quality" Perspective on Diabetes Information Management Systems

As mentioned earlier, we frame diabetes care as a quality-management problem.

Treatment of diabetes relies on the patient to act as their own day-to-day care provider, without continuous supervision by their doctor. Day to day, the patient is responsible for monitoring his or her physical condition, recognizing situations that require action, determining the correct dose of insulin or other drugs, and properly administering the necessary medication at the right time.

In clinical settings, these tasks are performed by trained professionals working under the doctor's direct supervision, with disciplined processes to prevent mistakes and ensure quality of care. But this quality-assurance infrastructure does not extend to the patients acting as their own day-to-day care provider because systems that safeguard quality of care in the clinic do not apply to patients in the field. As a result, mistakes happen and patient care is compromised.

There is no practical alternative to relying on the patient as day-to-day care provider—it is not possible for patients to report to clinics four times a day for meals, BG tests, and insulin injections. But that does not mean that we should accept unreliable patient monitoring, destructive diets, and mismanaged drug dosages. We need to help patients do better, so we ask, "What tools can we provide to help doctors ensure that patients deliver high quality of care when acting as their own care providers operating "outside the system"?

Quality Management and the Scientific Method

Over past decades, leaders in many fields have sought to reduce defects in delivery of products and services and to meet customer needs more efficiently and elegantly. This has spawned a rich body of knowledge about quality management, including statistical process control, total quality, ISO 9000, and Six Sigma. Space does not permit a thorough review of the extensive quality literature or even a review of successful quality management initiatives in health care or diabetes management. We will assert, however, that well-designed quality management initiatives have proven capability to drive sustained improvement in outcomes across a wide range of applications, including diabetes care management.

The core quality philosophies directly relevant to the problem of patients acting as care providers are as follows:

- Put real-time measurement and evaluation tools at the point of contact,
- Prevent rather than correct unexpected variance and errors,

- Focus on managing “the process,”
- Drive for continuous improvement, and
- Provide executive engagement—or in the case of diabetes management, doctor engagement.

Technical Architecture and Communications

Details about technical architecture and communications protocols are outside the scope of this article, beyond noting that our design integrates functions operating within two coordinated domains (smart phone devices and Internet Web sites; **Figure 1**). This architecture allows both real-time measurements at the point of contact for patients and remote data sharing for oversight by doctors and their staff.

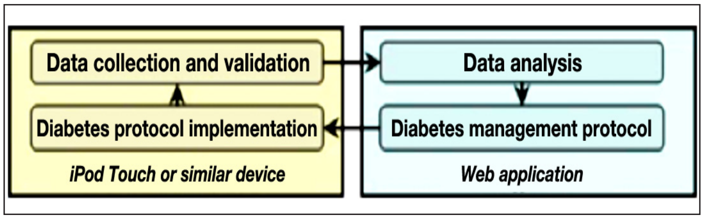

Figure 1. Our design integrating functions operating within two coordinated domains (smart phone devices and Internet Web sites).

Information Architecture

Perhaps surprisingly to some, modern quality-management processes are grounded in the scientific method. Quality management programs are systematic and structured approaches to evidence-based analysis of cause-and-effect relationships designed to discover and manage sources of unintended failure. The scientific method, of course, also underlies medical standards of care—also a systematic and structured approach to evidence-based analysis of cause-and-effect relationships designed to discover and manage sources of unintended failure.

This common foundation is the bridge between modern quality management systems used in industry and the quality-of-care needs of diabetes patients acting as their own care providers. So we frame the diabetes patient’s quality-of-care challenge as an ongoing scientific investigation:

- Each care-management action is a testable hypothesis about underlying cause-and-effect relationships for a specific individual, given specific conditions.
- Each day consists of repetitions of experiments testing whether a specific hypothesis holds.
- The outcome of each experiment is the measured change in BG after a defined time.

For review of a successful program integrating quality management principles in diabetes-care practices in Germany, see Reference 2. For a similar study in Japan, see Reference 3.

Applying principles of the scientific method leads us to a quality-of-care management strategy we call “adaptive empirical iteration.” Adaptive empirical iteration is a deliberate process to perfect the patient’s decisions and actions in routine situations and to systematically adapt across differences in individual patients and/or changes in their individual physiology, diet, or environment.

Because it is grounded upon the scientific method, the process is empirical and structured around compliance with predefined protocols. Decisions and actions reflect objective data, building on medically accepted cause-and-effect relationships between food intake, insulin absorption, activity, and BG levels. There are no unproven medical theories or technologies in our approach, only a more effective way for diabetes patients to use data they have.

The core mechanism for improving BG is iteration. The user defines a plan (with the doctor’s support and supervision), collects results, and then evaluates whether the plan is working (again, with the doctor’s guidance). Iteration is already the *de facto* standard-of-care for patient-care providers managing diabetes: the doctor suggests rules of thumb, the patient attempts to follow them, the doctor reviews the patient’s hemoglobin A1c (HbA1c) and recent BG data, and then suggests new, modified rules of thumb. Our information architecture formalizes and optimizes a previously haphazard process.

Finally, the process is adaptive. If the patient’s food changes, their mean change in BG will also change, and they will iterate to a new insulin dose. If unknown factors change, the user automatically adapts without external intervention. If a different person uses the system, that patient will iterate to their own personalized correct diabetes care regimen.

Framework for Applying Quality Management Principles to Diabetes Care Management

We define seven steps to our process—Seven Steps to Managing Quality of Care for Diabetes Patients (**Figure 2**).

Step 1: Set the Goal

We start by stating goals, which link strategic objectives to quantitative measurements of actionable cause-and-effect relationships.

Our objective is to reduce long-term complications while avoiding hypoglycemia. Lower HbA1c reduces incidence of complications, and HbA1c reflects BG levels, so BG tests are used as our key performance measurement. Actions affecting BG usually play out over a few hours, so we break the day into 2–3 h time blocks—long enough to see net effects of food intake or insulin doses but short enough to give actionable feedback. Control means elimination of unexpected variance, so we target zero change in BG levels over each time block.

Of course, it makes no sense to target zero change if the patient starts with an unacceptably high or low BG level. In these cases, the appropriate goal is a reduction or an increase in BG level sufficient to restore results to an acceptable target range. However, we focus on *preventing* rather than correcting undesirable variation in results so that out-of-range results do not occur in the first place. Accordingly, we emphasize development of behavior that reduces change in BG to zero for a given patient in the course of ordinary day-to-day life, recognizing that day-to-day reality also calls for special-purpose plans tailored to correcting undesired highs or lows.

Scientific research requires recognition of *all* underlying causal factors. If we do not account for factors that we know affect achievement of the goal, then we undermine success. We know that food intake increases BG, insulin reduces it, and exercise affects the rate at which these happen. This implies that we must integrate not only information about BG tests and insulin doses, but also food intake and exercise as essential actions within the diabetes patient's care regimen.

We define our goal as follows: prevent errors by balancing insulin, food, and activity so that change in BG equals zero (over a predefined time subject to predefined conditions, including the condition that the starting BG reading is within the patient's desired target range).

We see each BG test as both the starting point for a new set of decisions/actions *and* the ending point for prior decisions/actions. As a starting point, each BG test provides information for deciding what to do next. But importantly, as an ending point, each BG test provides information for evaluating the outcome of prior actions and considering what to do the next time we face a similar situation.

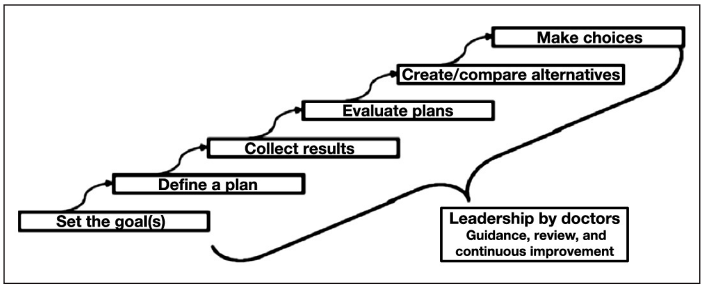

Figure 2. Seven steps to managing quality of care for diabetes patients.

Step 2: Define a Plan

Quality management emphasizes defining (and refining) the "process"—steps the operator takes to produce a desired product or service. Health care emphasizes the "protocol"—steps taken to produce a desired health-care outcome. Scientific researchers emphasize the "hypothesis"—steps in an experiment together with a prediction stating the expected outcome.

Similarly, the diabetes patient acting as a care provider needs well-defined processes, protocols, and hypotheses, what a layman might call "plans," for what to do to get the result they want. Just as processes, protocols, and hypotheses are the heart of their disciplines, plans are the heart of the iAbetics quality-of-care management system.

A "plan" at iAbetics typically covers a 2–3 h time block and includes the following:

- what you are going to do (what insulin, what food, and what activities),
- when you are going to do it (under what conditions), and
- what you expect to happen (to your BG level after a specified time).

A plan can be stated as a testable experimental hypothesis: if I take these actions, then the change in my BG will be zero at time *t*, subject to [conditions].

Each plan starts and ends with a BG test (patients can also record interim tests). The plan describes specific insulin doses, food intake, and activities and includes a prediction about the effect those actions have on this patient's BG level (typically, that the change over the defined time will be zero, assuming that the time block starts with BG level within the acceptable target range).

We know that people do not like tightly defined constraints governing what they do and when they do it, even if those constraints are important to their health. To provide variety and flexibility, we help patients create a library of alternative plans based on the their personal preferences and lifestyle: (1) to cope with different situations (e.g., breakfast versus dinner, weekday versus weekend) and (2) to provide desirable variety (e.g., turkey sandwich instead of chicken Caesar salad at lunch).

Further, because of physiological and measurement variability, we cannot analyze plans without repetition. We cannot get repetition from actions that change every day, especially without precise records of what the actions were. We also cannot measure compliance without planned protocols, because compliance *is* conformance with prior planning.

Fortunately, most people are creatures of habit—many time blocks over a week are near-exact repetitions of the same actions. A patient might eat the same breakfast at the same time on Monday, Wednesday, and Friday; take the same insulin dose; and then attend the same morning class or schedule. We build from the routine and the familiar.

We provide an array of tools to create plans:

- Activity planner, to plan and measure activities and exercise levels;
- Meal builder, to construct and assess the nutritional profile of food items and meals;
- Alerts, to remind patients when to eat, test, or medicate; and
- Plan maker, to put the pieces together.

Step 3: Collect Results

We see each day as a series of experiments testing the hypothesis embedded in the plans. We do not ask patients to "conduct experiments and observe outcomes;" we ask them to "collect results." A "result" at iAbetics includes the following:

- what plan you chose (and the conditions under which you chose it),
- what you actually did (compared to what the plan calls for), and
- what actually happened (to your BG level after a specified time).

We use "care cycles" to link actions to specific "before" and "after" BG readings. A common label is attached to the data items that make up a cycle, using one standard data format. Each variable tracked is measured quantitatively. We use standard monitors for BG data. Insulin doses are recorded, including type, units, and injection site, whether delivered by injection or pump. We capture time spent exercising, converting to a common measure of caloric burn. Finally, data is collected about the type and quantities of food eaten and tie that to nutritional databases to produce detailed records of a patient's intake of calories, carbohydrates, glycemic load, fat, protein, and other measures.

We use smart phones and our Islet^{TM} application for quick, intuitive capture of data as actions occur. The data collected are comprehensive, but the system used to collect them is efficient and easy to use, employing touch-screen interfaces, "quick-pick" menus, and automatic population of default values. We provide capability to either confirm action in compliance with the plan or to note deviations.

Asking nonprofessionals to capture detailed data in real time has been raised as a potential blocking issue in almost every quality management program since Deming's work in Japan in the 1950s. However, the record in industry shows that frontline nonprofessionals are capable of collecting and using detailed process data, given proper tools, training, and motivation.

Step 4: Evaluate Plans

We synchronize data collected on the smart phone with the iAbetics database on the Internet, providing secure private storage and enhanced analytical capabilities. We aggregate and organize data, identifying favorite plans that the user repeats from day to day. We provide analytic tools and reports looking at averages, trends, and standard deviations for results from specific plans. An evaluation is made at to what is "good" and what is "bad," and various plans are rated based on their capability to deliver results consistent with our goal to produce zero change in BG (or to produce a predefined increase or decrease if required).

We also monitor compliance with protocols contained in the plans, noting data entry time stamps, and deviations from the plan. We track incidence of deviations and report outcomes of plans that were strictly followed compared to plans that were not strictly followed, so patients can see the benefits of their efforts.

Step 5: Create and Compare Alternatives

Next we use empirical data and analysis to make deliberate, purposeful adjustments to the plans. If our analysis of results shows that the average change in BG for a specific plan is not equal to zero (or equal to another predefined target result), then the patient-care provider may increase or decrease insulin to iterate toward a solution that keeps BG constant over the defined time.

Insulin adjustment is not the only path to improved results. The patient-care provider could also adjust the food intake associated with a plan, substituting food with lower glycemic index (an apple) for food with higher glycemic index (apple juice). By integrating information about critical underlying casual factors, including food intake, the iAbetics data design creates potential to control BG using the full array of available levers, not just "more medication."

Tools provided for comparing alternative plans and ways to track the various alternatives the patient creates are:

- Iteration manager with version control and
- RECAP—our tool to help patients and their doctors Review, Evaluate, and Compare Alternative Plans.

Step 6: Choose

Next is implementation or plan deployment. Once the patient makes a new plan, it is put into action by downloading plans to our Islet smart phone application for ready access by patients.

The iAbetics system incorporates techniques intended to influence patients toward choices with the best outcomes by structuring the patient's choice architecture and providing simple system rewards and discouragements (e.g., "good choice" or "are you sure?").

Step 7: Review and Improve

The final challenge is continuous improvement. Because continuous improvement focuses on things that have been overlooked, external review is critical. We drive this with doctor-led reviews assessing how well the quality management system is helping patients learn what care regimen works best for them, followed by adjustments that focus on setting new goals and coaching the patients on ways to use the system to best effect.

Our tools enable the doctor to access the iAbetics database to see records and reports related to their patients (with patient permission). We provide summary reporting capabilities that let the doctor quickly understand what is going on and decide where to focus continuous improvement energies.

Patients who achieve good balance over 2–3 h cycles may experience interim BG spikes or crashes, so we provide for multiple BG tests at different times within a cycle. Once a patient masters 2–3 h cycles, for example, we may shift focus to changes in BG 30–45 min after food intake, addressing short-term spikes by reducing intake of high-glycemic foods or better managing the timing of insulin doses.

Finally, the system design provides for access by researchers to anonymous patient data (with prior patient permission). Sharing results across patient populations supports best-practices research. Detailed data revealing blood-glucose effects from specific food intake, exercise, and insulin regimens for large groups of patients will, we hope, lead to new insights in diabetes standards of care.

A final note: no diagram of information flows can adequately convey what we view as the essential role of the doctor in the diabetes care management process. We see the doctor and his staff as fully integrated partners and coaches at each step in the process, inviting patients to consider using a diabetes information management system; helping them through initial setup and developing the first plans with sound nutritional, exercise, and medication strategies; encouraging compliance for those who falter; and challenging patients to continue strive for excellence in the quality of care they provide themselves.

Conclusion

It is possible that *any* system asking patients to observe and record *any* diabetes-care data will produce some measure of improvement. Scientists have long known that even simple observation and record keeping affect the behavior of human subjects, at least for a short time.

The question is whether simple observation and record keeping comprise an effective and sustainable system for managing the quality of care that diabetes patients acting as their own care providers deliver for themselves in the field on a day-to-day basis. We think not. The historical record of scientific progress is clear—a structured, systematic approach to evidence-based analysis of cause-and-effect relationships produces far more sustained progress than haphazard observation.

What then are the indispensable elements of an effective information system to support health care for diabetes patients? Here is our summary:

- The system must address food intake and exercise. What the patient eats is the critical source of variation in outcomes over daily care cycles. Unmanaged food intake and lack of exercise vastly complicate the problem of diabetes control. Further, poor diets and sedentary lifestyles fail to safeguard long-term health even for persons without diabetes.

- The system must embrace plans. If there are no prior plans to guide actions, there can be no compliance, no repetition, and no foundation for analysis of cause-and-effect relationships. A system that does not embrace plans does not provide a foundation for systematic scientific investigation and cannot deliver long-term progress as if it did.

- The system must build around data structures that link specific plans with actual actions and then to empirical results. If the data architecture is unable to link actions (including food and exercise) both to predefined plans and to before-*and*-after blood-glucose test results, then it cannot analyze cause-and-effect relationships or predict what course of action is "right."

- The system must define a specific mechanism for adaptation to accommodate differences across individual patients or changes in the diet, physiology, or other characteristics of specific individuals. It is not enough to simply hope that data magically transforms into better decisions and new behavior. If not systematic iteration, then what other mechanism of improvement?

- The system must focus on helping patients learn what care regimens are most successful for their personal physiology, situation, and environment. Advances in information technology will improve long-term outcomes for diabetes patients, if—and only if—patient-care providers see real value in the information they invest time and energy to collect and use to improve their day-to-day quality of care.

- The system must facilitate doctor engagement and review. It requires discipline and effort to collect and use new information; the issue is whether the effort is worth it. Without the doctors' endorsement, support, encouragement, and challenge, it is hard to imagine that patients will sustain the motivation and engagement essential to the long-term successful management of chronic disease.

References:

1. Klonoff DC, True MW. The missing element of telemedicine for diabetes: decision support software. J Diabetes Sci Technol. 2009;3(5):996–1001.
2. Rothe U, Müller G, Schwarz PE, Seifert M, Kunath H, Koch R, Bergmann S, Julius U, Bornstein SR, Hanefeld M, Schulze J. Evaluation of a diabetes management system based on practice guidelines, integrated care, and continuous quality management in a Federal State of Germany: a population-based approach to health care research. Diabetes Care. 2008;31(5):863–8.
3. Yamamoto M, Isomura Y, Satoh Y, Yasuda K. Application of total quality management (TQM) for diabetes patient primary care: improvement of blood glucose levels for patients and knowledgement for faculties. Diabetes Res Clin Pract. 2000;50(Suppl 1):1.