

**Living With Diabetes Project: Draft Final Project Report to the
Center for Health Management Research**

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Introduction:

More than half of the nation's health care spending is on behalf of patients with multiple chronic diseases, but current health care delivery systems are not producing acceptable results. To improve health care outcomes, the Living with Diabetes (LWD) project evaluated whether a traditional pharmacist outreach program or Internet-based computer application could be employed to manage the care of patients with diabetes in between clinic visits. The short-term economic impacts of improved patient care were estimated. Member organizations were surveyed regarding their readiness to implement provider-centered electronic medical records (EMR) and patient-centered Internet-based co-management modules.

Executive Summary

- The LWD project undertook three specific research tasks:
- Evaluate the short-term economic impact of improved type 2 diabetes outcomes using a traditional pharmacist outreach program
 - Pilot test an Internet-based co-management module. If the results of the pilot study are positive, conduct a randomized controlled trial to determine the module's efficacy in lowering HbA1c levels
 - Survey members to assess Information Technology (IT) and security readiness for both traditional provider-centered Electronic Health Records (EHR) functionality and patient-centered exchange of data from home in between office visits

To evaluate the economic impact of a traditional computerized diabetes registry and telephone reminder system employed within a pharmacist outreach program, we examined the care provided to 185 patients with diabetes who regularly used the Family Medicine Center (FMC) at the University of Washington's (UW). This three-year CQI program, conducted by the research team, succeeded in lowering the percentage of diabetic patients with an HbA1c level of > 8% (the ADA's definition of "unacceptable" treatment) from 37% to 21%, and lowered utilization rates by reducing symptoms and complications. Average monthly ambulatory visits among participants declined from 133 to 112 per 100 patients over the two years following the conclusion of the program, a relative reduction of 16%. The improvement in glycemic control, however, reversed over the following two years when the outreach program was discontinued due to declines in revenue. Even "simple" applications like computerized registries -- when tied to outreach -- can have substantial positive effects on the provision of health care, but scheduling times to communicate over the telephone can be a nightmare.

We next developed a Web-based diabetes care module to test the feasibility of allowing patients to co-manage their disease from home, completing a six-month alpha test in 2002. "Proof-of-concept" was demonstrated by the pilot participants who were the module's most active users. For example, over a four-month period one newly diagnosed patient achieved control of his diabetes on an oral hypoglycemic with two upward dose adjustments (HbA1c declined from 8.0% to 6.1%). His treatment was monitored by exchanging 14 e-mails based on the 231 glucose-meter readings he sent from home without requiring in-person follow-up visits.

Based on this positive experience, a randomized control trial is being conducted at the UW's General Internal Medicine Clinic (GIMC). Preliminary results of this trial suggest a decline in HbA1c levels of 1.2% over 12 month period. Thus, Internet-based chronic disease management may be an especially powerful tool for improving patient care. Its asynchronicity appears to offer a distinct advantage over traditional outreach programs.

Results from a CHMR-member survey indicate that members are developing the computer infrastructures necessary for implementing EHRs, but only a few are ready to host an Internet-based chronic disease management

application. Members are aware, however, that patient records need to be maintained behind institutional firewalls, with patient access to their information and linkage to their provider by email via the Web. Security concerns are consistently being addressed in all IT models.

Our findings argue for member organizations adopting Internet co-management modules as a routine component of chronic disease care.

Project Background

Over 120 million Americans currently suffer from chronic diseases. This number will grow over the next two decades as the baby boom generation retires. More than half of the nation's health care spending is on behalf of patients with multiple chronic diseases. (1) Yet, current health care delivery systems are not producing acceptable results. Less than half of patients with hypertension adequately control their blood pressure (<130/80 mm Hg). Only 37% of adults with type 2 diabetes meet the American Diabetes Association's optimal target HbA1c level of < 7% (2). Even modest improvements in chronic disease management would have immediate economic as well as clinical consequences.

To improve chronic disease management, the Institute of Medicine's report "Crossing the Quality Chasm" recommends a shift from care based on office visits towards care based on continuous healing relationships. (3) Wagner's Chronic Care Model has further highlighted the need to move away from the current focus on short and infrequent clinic visits towards involving patients in the daily management of their own health care. (4) Co-management health care programs based on a social cognitive view of self-regulated learning are feasible. Such programs should enhance patients' health care knowledge, and enable the processes of self-observation, self-judgment and self-reaction. The process of self-regulation must be incorporated into patients' daily lives. For example, patients with diabetes need to be able to observe and judge the influence of diet, exercise and medication on blood sugar in order to self-manage their disease by adjusting food intake, level of physical activity, and medications. Provider feedback and coaching that are relatively immediate and ongoing have the greatest likelihood of enhancing self-regulated learning. Perceptions of self-efficacy, the extent to which people believe they can successfully complete specific tasks in a given situation, serve as a "thermostat" of the self-regulation process (5).

Complex EHRs have yet to definitively demonstrate returns on investment in either the short or long run under many scenarios. (6) One innovative medical record "sub-system" exhibiting promise as a "value-added" component is the computerized disease management module. Because this class of software can usually interface with legacy registration, laboratory, and pharmacy computer systems, initial capital required for implementation is minimal. However, few hospital information systems are Web-based, and the opportunity for patients to access at home the same electronic information used by health care providers has gone largely unrealized. If such "cyber" communications were to become more common, improved outcomes might be realized by having patients and providers exchange clinical information as a substitute for routine clinic visits. This Internet-based exchange of information might also improve long-term control of chronic diseases, thereby reducing costs associated with patient hospitalizations due to end-stage organ disease. It is crucial that this alternative approach to chronic disease care be evaluated.

In order to have available the longitudinal, real-time data required to monitor and improve the quality of patient primary care, this research team led in the UW's creation of the nation's first Web-based EHR. The system is composed of the Medical Information Networked Database (MIND), its results reporter (MINDscape), and its SQL query engine, the MIND Access Project (MAP). We published a letter in *The Lancet* in 1998 -- reasoning where better to publicly announce the development of medical records accessible from anywhere in the world than in the world's oldest international medicine journal. MIND presently stores the records of 612,000 UWAMC patients in over 500 tables and 624,000,000 rows -- a total of 115 gigabytes of data. Each month, 4000 users generate over 1.5 million MINDscape Web-page "hits." Since 1997, over 600 referring physicians have enrolled in the pilot program "U-link" that enables them to remotely view the records of their patients. Discharge summaries, for example, can now be read online as they are transcribed, often weeks before the receipt of hard copies through the mails. To date, referring physicians from as far away as Ketchikan, Alaska have followed the care of over 16,000 patients hospitalized in Seattle. (7) Like most clinical computing systems, however, MINDscape was originally designed to improve providers' ability to deliver office-based care.

Specific Research Questions

1) Evaluate the short-term economic impact of a traditional pharmacist outreach program to improve type 2 diabetes. If impact is substantive, management should consider adopting such practices as a quality improvement issue in addition to considering "bottom line" impact under capitation versus fee-for-service (FFS) scenarios.

Research Methodology

To evaluate the economic impact of a traditional computerized diabetes registry and telephone reminder system employed within a pharmacist outreach program, we examined the care provided to the 185 patients with diabetes who regularly used the Family Medicine Center (FMC) at the UW. The pharmacist's activities were informed by computerized feedback consisting of monthly reports on each provider's panel of diabetic patients. Rates of compliance with recommended process measures -- such as every-six-month HbA1c determinations and yearly retinal examinations -- were reported along with interim visit dates and corresponding HbA1c levels. Patients who were not adequately controlling their disease or who were lost to follow-up were called and encouraged to make appointments. Where appropriate, meetings with the FMC's nurse educator and/or nutritionist were also scheduled. Primary physicians, along with the pharmacist, received special training in the use of standardized diabetes treatment algorithms and provided oversight.

Findings

Over a three-year period, the program increased recommended glycohemoglobin (HbA1c) testing by 50% (P=0.02) and reduced the number of

patients who inadequately controlled their diabetes by 43% ($P < 0.01$). The average number of monthly ambulatory visits declined from 133 to 112 per 100 patients over the approximately two years following the conclusion of the program, a relative reduction of 16% ($P = 0.04$). This corresponds to an annualized per-patient “savings” of 2.5 visits. Declines in patient primary and specialty care visits, however, demonstrated only statistical trends. Patients averaged 6.8 FMC visits per year during the length of the study, and at the end of the study, had reduced their annual primary care visit rate by 22% ($P = 0.15$). Specialty visits declined 11% ($P = 0.15$). Average hospital visits did not significantly change following the withdrawal of the trial intervention, remaining stable at approximately one day per patient per year ($P = 0.48$).

These results are similar to the reported experience of Group Health Cooperative of Puget Sound, the largest HMO in western Washington, from a non-interventional cohort comparing diabetics whose outcomes had improved versus not improved. (8) Four years following an improvement in HbA1c levels of 1.0%, patients with diabetes made 1.3 fewer ambulatory visits annually than did patients with diabetes who had not improved. Hospital utilization (percent admitted) was (analogous to the FMC experience) unchanged. The FMC outcome improvement, however, was reversed over the subsequent two years when staffing austerities forced by declines in revenue caused the withdrawal of trial interventions given the FFS nature of the clinic.

Even “simple” applications like registries -- when tied to outreach -- can have substantive effects, but the synchronicity imposed by telephoning was a bit of a scheduling nightmare. CQI programs will likely never flourish, however, until quality improvement and reimbursement mechanisms become better aligned (9).

2) Pilot test an Internet co-management module. If the results are positive, conduct a randomized controlled trial to determine its efficacy in lowering HbA1c. If results of the trial are positive, management should consider adopting such practices as a quality improvement issue in addition to considering the “bottom line” impact under capitation versus FFS scenarios.

Research Methodology

We developed and pilot tested an Internet-based diabetes care module, compatible with MINDscape that would allow patients with type 2 diabetes to co-manage their disease from home. The disease-management module comprised five Web sites that enabled patients to:

- View their entire electronic medical record, the same record used by providers,
- Upload blood glucose readings stored in a digital meter,
- Manually enter medication, nutrition, and exercise information into an online daily diary,
- Communicate with providers regarding treatment recommendations or other questions using a clinical e-mail service, and

- Obtain additional information from an on-line education site whose content and links were endorsed by the Medical Director of the UW's Diabetes Care Center (DCC).

Nurse-practitioners case managers reviewed all information weekly.

Findings

Proof-of-concept was clearly demonstrated by the three pilot participants who were the module's most active users. Over a four-month period, one newly diagnosed patient achieved control of his diabetes on an oral hypoglycemic with two upward dose adjustments (HbA1c declined from 8.0% to 6.1%). His treatment was monitored by exchanging 14 e-mails based on the 231 glucose-meter readings he sent from home without requiring in-person follow-up visits. A second patient being treated with insulin lived on an island in Puget Sound. He appreciated being able to negotiate changes in insulin dosages and view lab values immediately from home versus making a four-hour ferry and bus. His HbA1c levels, which had averaged 7.3% during the previous year, dropped to 6.1%, the lowest value during his five-years of care. The third participant suffered from obesity and sleep apnea. By entering the serving sizes of her meals into her online daily diary, grams of carbohydrate intake could be automatically tracked over time. This helped her to lose 20 pounds and lowered her HbA1c level from 7.8% to 6.4%.

These cases illustrate the feasibility of involving patients and providers in collaboratively managing patients' chronic diseases between office visits. The asynchronicity of Internet-based interactions offers a distinct advantage over telephone-based interventions. Because of these positive results, we are conducting a randomized controlled trial of the module versus usual care within the GIMC. The number of subjects in the trial (n=84) is adequate to detect an effect size of approximately 0.5% change in HbA1c levels. Preliminary results from 40% of patients who have completed the study suggest a decline in HbA1c levels of 1.2% (n=4.0 to 6.0%) over a 12-month period. If these results are confirmed at the trial's conclusion, such a compelling improvement in glycemic control would warrant use of Internet-based co-management modules as a quality improvement measure -- even in the absence of a compelling business case (10).

3) Survey members to assess IT and security capabilities regarding both a traditional provider-centered EHR and a patient-centered exchange of data from home. Such information can assist managers in deciding whether to adopt an Internet-based co-management module as a routine component of chronic disease care.

Research Methodology

We designed three surveys over the grant period and sent them to the UW IT Services and Patient Data Services departments (benchmark), and 7 CHMR members. The surveys were designed to:

- Determine if a basic IT infrastructure was present that was capable of supporting an Internet-based chronic disease management application
- Identify the general progress toward a functional EHR environment including basic software applications necessary to feed an enterprise clinical data repository (CDR), i.e., the kind of large relational database capable of storing all patient data and records.
- Identify any changes within a preliminary and follow-up time frame
- Secure information on participants' awareness of the Health Insurance Portability and Accountability Act (HIPAA)

The first two surveys were conducted as a preliminary review with participants surveyed again six months later. Preliminary and follow-up survey findings were presented at CHMR meetings. Announcements and details on the survey process were provided through a "Living With Diabetes" List Serve set up through the project. Additional research was done to identify benchmark cases that addressed similar goals and objectives for the grant. Literature search findings were provided to the participants. Key features and applications that reflected a similar focus on exploring chronic disease management and patient access to their health information were included in the presentations and materials prepared for CHMR sessions. Of note during the project, national initiatives were announced to advance work on electronic health records. The Health Information Management Systems Society published a position paper on the topic in 2003 (11). The Centers for Medicare and Medicaid Services asked the Institute of Medicine (IOM) for guidance on care delivery functions and the IOM Committee on Data Standards for Patient Safety began work on care delivery functions in June, 2003. The IOM and HL7 Standards Organization were directed to coordinate development of a national EHR Functional Model in 2003. This EHR standard is to be:

- National model for the next decade
- Key component of the National Health Information Infrastructure
- Acceleration process for the adoption of EHR systems
- Value to vendors and purchasers (12)

An initial letter report was issued in July, 2003. The framework recommendations and their inclusion of the co-management role of patients in accessing their personal health information were included in the benchmark information provided to the project participants.

The draft survey on security was presented to participants at the CHMR meeting in October, 2003. The draft was revised to conform to the latest security assessment information reflecting national standards and the Health Insurance Portability and Accountability Act (HIPAA) security requirements, and sent to CHMR participants in April, 2004.

Findings

Across both the benchmark and CHMR-member organizations, basic infrastructure is established and key inpatient, administrative and outpatient

applications are largely in place. While Web-based technologies are underway, limited organizational Web infrastructure hinders on-line chronic disease management options; and more work is needed on Internet technologies generally. Use of Institutional data repositories and clinical data dictionaries still fall short of benchmark standards.

It is notable that, regardless of the stage of development in information systems generally, new technology is being explored in most sites with 5 of 7 sites exploring wireless options.

Most (6 out of 7) sites have all the EHR infrastructure needed in place or in development; and 5 out of 7 member participants report that they have applications in place or planned that contain 50% or more of the EHR content recommended in national publications such as the American Health Information Management Association Definition of the Health Record for Legal Purposes Content. (13) Content is drawn from basic applications such as pharmacy, laboratory, radiology which feed results applications, bedside documentation applications and others. However, significant work is still needed to define the overall EHR content. Related institutional policy updates that address changes to computerized health records need more attention.

Less than 50% of the member organizations report they are working to bring technology to managing diabetes care. Still, more than half of those surveyed reported a readiness to adopt one of the key premises of the project – enhanced patient role in their care. Further, the online capability for chronic disease management featured in this project is included in the national direction in EHR standards which call for increasing information for patients in self-management and specific capability for electronic patient/provider communication. (14) From a health information management perspective, this project clearly demonstrated that patients would engage with their own data and contribute to their medical record. As already noted, patients in this project stepped up to a co-management role in the project.

Security policies and procedures were followed from the beginning of the project. Necessary consents for participation and patient agreement on use of secure access tools and procedures were obtained at the beginning of the project. The care team followed institutional policies and procedures in accessing patient information. Security assessment surveys which offer HIPAA security assessment for participants to aid in their preparation for upcoming HIPAA security rules have been sent to participants. (15) Results are pending.

Recommendations for Dissemination

The UK Prospective Diabetes Study (UKPDS) is the largest RCT (3687 patients over 10 years) that has provided the clinical evidence for treating type 2 diabetes with oral hypoglycemics and/or insulin, versus diet therapy alone. The drug-therapy group demonstrated a 0.9% decline in HbA1c levels versus the diet-therapy group, and a resulting 25% risk reduction in microvascular endpoints, including the need for retinal photocoagulation (16). If the preliminary results of our Internet-based co-management randomized controlled trial are

confirmed at the trial's end, a 1.2% HbA1c sustained decline would result in a 33% reduction in end-organ damage. Such a compelling clinical finding would argue strongly for member organizations to adopt an Internet-based co-management module as a routine component of chronic disease care. The majority of members have IT capacities sufficiently mature to support this activity when the module, or others like it, becomes commercially available.

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