Web-Based Collaborative Care for Type 2 Diabetes

A pilot randomized trial

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OBJECTIVE — To test Web-based care management of glycemic control using a shared electronic medical record with patients who have type 2 diabetes.

RESEARCH DESIGN AND METHODS — We conducted a trial of 83 adults with type 2 diabetes randomized to receive usual care plus Web-based care management or usual care alone between August 2002 and May 2004. All patients had GHb $\geq 7.0\%$, had Web access from home, and could use a computer with English language–based programs. Intervention patients received 12 months of Web-based care management. The Web-based program included patient access to electronic medical records, secure e-mail with providers, feedback on blood glucose readings, an educational Web site, and an interactive online diary for entering information about exercise, diet, and medication. The primary outcome was change in GHb.

RESULTS — GHb levels declined by 0.7% (95% CI 0.2−1.3) on average among intervention patients compared with usual-care patients. Systolic blood pressure, diastolic blood pressure, total cholesterol levels, and use of in-person health care services did not differ between the two groups.

CONCLUSIONS — Care management delivered through secure patient Web communications improved glycemic control in type 2 diabetes.

Health care limited to clinic visits does not meet the needs of many patients with diabetes. Care systems that use Web-based communication provide an opportunity to shift the focus in health care away from the office and toward patients' daily lives at home. Patient interaction with online care plans and electronic medical records may further enhance the effectiveness of chronic care (1,2). Little is known, however, about the impact of using Web communications and shared electronic medical records in the primary care of patients with diabetes.

We present the results of a randomized trial examining a Web-based diabetes support program that aimed to improve glycemic control for patients with type 2 diabetes. The program consisted of access from home to the electronic medical record, secure electronic communications between patients and providers, and interactive disease management tools. We hypothesized that glycemic control would improve in the group receiving the intervention.

RESEARCH DESIGN AND METHODS — Between August 2002 and May 2004, we enrolled participants in a 12-month open, randomized, single-center, controlled trial with a parallel group design. Patients with type 2 diabetes were randomly assigned to a group receiving usual care or a group receiving usual care plus Web-based care management. Participants, physicians, and care managers could not be feasibly blinded to group assignment after randomization. The study was approved by the University of Washington (UW) Institutional Review Board.

We conducted the trial at the UW General Internal Medicine Clinic (GIMC), a teaching clinic that provides care to 7,707 patients. The clinic is staffed by 25 faculty and 48 resident providers and employs a nurse practitioner to provide case-management services to chronic-disease patients.

Electronic medical record data were used to identify potential participants 18 to 75 years old, whose most recent GHb in the prior 12 months was $\geq 7\%$, and who had made at least two visits to GIMC during the prior year. We excluded patients who had participated in the pilot study of the intervention, had major psychological illness, were non–English speaking, had a resident as a primary physician, or were followed primarily in a specialty clinic.

Following an invitation letter, the study coordinator contacted potential participants by phone to assess study eligibility. Exclusion criteria assessed during the phone interview included lack of Internet access and cognitive, language, or hearing impairment severe enough to preclude participation. At the end of the recruitment phone call, the study coordinator invited eligible participants to participate. Participants initially provided oral consent over the phone.

Allocation to the study group was concealed from the study coordinator and the participant until after the recruitment phone call. Following initial oral consent, the study coordinator consulted the allocation assignment table. Participants were randomly assigned in equal numbers to the two groups. The study's statistician used a computer random number generator to create a random number table in a nonblocked sequence. For participants in

Table 1—*Design of Web-based collaborative care intervention*

Domain (ref. 4)	Intervention
Self-management support	Promoted patient review of the electronic medical record at home over the Web through "My Health Record," a real-time view of the same record and interface used by providers and containing all clinical data since January 1994
	Provided remote collaboration and interactive feedback on automatically uploaded blood glucose readings over the Web through "My Upload Meter"
	Provided remote collaboration and interactive feedback on nutrition, medications, and exercise using a Web-based self-management tool, "My Diabetes Daily Diary"
	Promoted and integrated secure e-mail into ongoing care with diabetes case manager
	Provided general diabetes educational Web site with links to information endorsed by the medical director of the UW Diabetes Care Center
Delivery system design	Used case manager model
	Provided initial weekly follow-up over the Web for blood glucose levels and other self-management needs
	Provided subsequent proactive follow-up based on patient needs
	Promoted and integrated secure e-mail exchanges into ongoing care
	Promoted and integrated patients' blood glucose and lifestyle information into ongoing care
Clinical information systems	Provided ongoing tracking and documentation of patients' needs and care
	Used secure e-mail integrated as part of the record
Decision support	Used an interactive electronic medical record for collaborative decision support shared by both patient and provider:
	Clinical reminders visible to both patient and provider
	Single-page summary of patients' clinical information relevant to diabetes
	Established provider decision support through patients' remote transmission of blood glucose readings, daily diary inputs, and secure e-mail exchanges

the intervention group, the study coordinator arranged for in-person, follow-up written consent and an intake visit. Participants in the intervention and usual-care groups did not receive additional incentive for participation in the study. Baseline data for all participants were from automated data in the electronic medical record.

Intervention
The study aimed to improve glycemic control, used a care manager (3), and targeted four key domains in Wagner's Chronic Care Model (4): self-management support for patients, delivery system design, clinical information systems, and clinical decision support (Table 1). A complete description of the module is elsewhere (1,5).

Participants in the care management group met with the care manager for a 1-h visit. The care manager used a collaborative-care approach consisting of four components: *1*) defining problems, *2*) setting goals, *3*) providing access to services that teach skills needed to carry out medical regimens, guide health behavior change, and provide emotional support, and *4*) following up actively. The care manager and patient reviewed the patient's electronic medical record and collaboratively created an action plan.

The care manager introduced participants to the Web-based program and encouraged them to review online medical records, send blood glucose readings weekly, and send secure e-mail as needed. She responded to patients' messages Monday through Friday, reviewed blood glucose levels at least once per week, adjusted hypoglycemic medications, and conferred with the primary care provider as needed.

All participants received primary care from a physician who was board certified in internal medicine at the UW GIMC. All providers used the same electronic medical record, which included patient-specific reminders for measurement of GHb to <7.0%.

Outcomes measures
The primary outcome was the absolute change in GHb between baseline and end of the 12-month study period. Secondary outcomes included total plasma cholesterol and systolic and diastolic blood pressure. The most recent GHb in the 12 months before randomization was used for baseline measurements. Participants were called 12 months after randomization for a GHb test if one had not been obtained between 9 and 12 months postrandomization. We used the GHb measure closest to 12 months after randomization and no earlier

than 9 months or later than 15 months after randomization. GHb values were rapid immunoassay tests from a Bayer Laboratories DCA-2000+ analyzer (Siemens Medical Solutions Diagnostics, Tarrytown, NY). Secondary analysis examined the percent of individuals with GHb <7%.

Post hoc analyses evaluated secondary outcomes related to overall care of diabetes but not targeted by the intervention, including blood pressure and total cholesterol, which were collected as part of usual care. Total cholesterol was used instead of LDL cholesterol measurements because of its more common availability; values were measured using enzymatic analytic chemistry on a Beckman Synchron. Blood pressure was measured using an aneroid sphygmomanometer at GIMC. To maximize the power, absolute change in systolic and diastolic blood pressure and total cholesterol was evaluated between the groups. Exploratory analysis investigated the relationship of GHb with number of participants' page views of the electronic medical record and number of blood glucose level uploads.

Health care utilization was measured by total number of outpatient encounters with health care providers and inpatient days at the UW Medical Center and affiliated hospitals and clinics during a 2-year period that included the 12 months be-
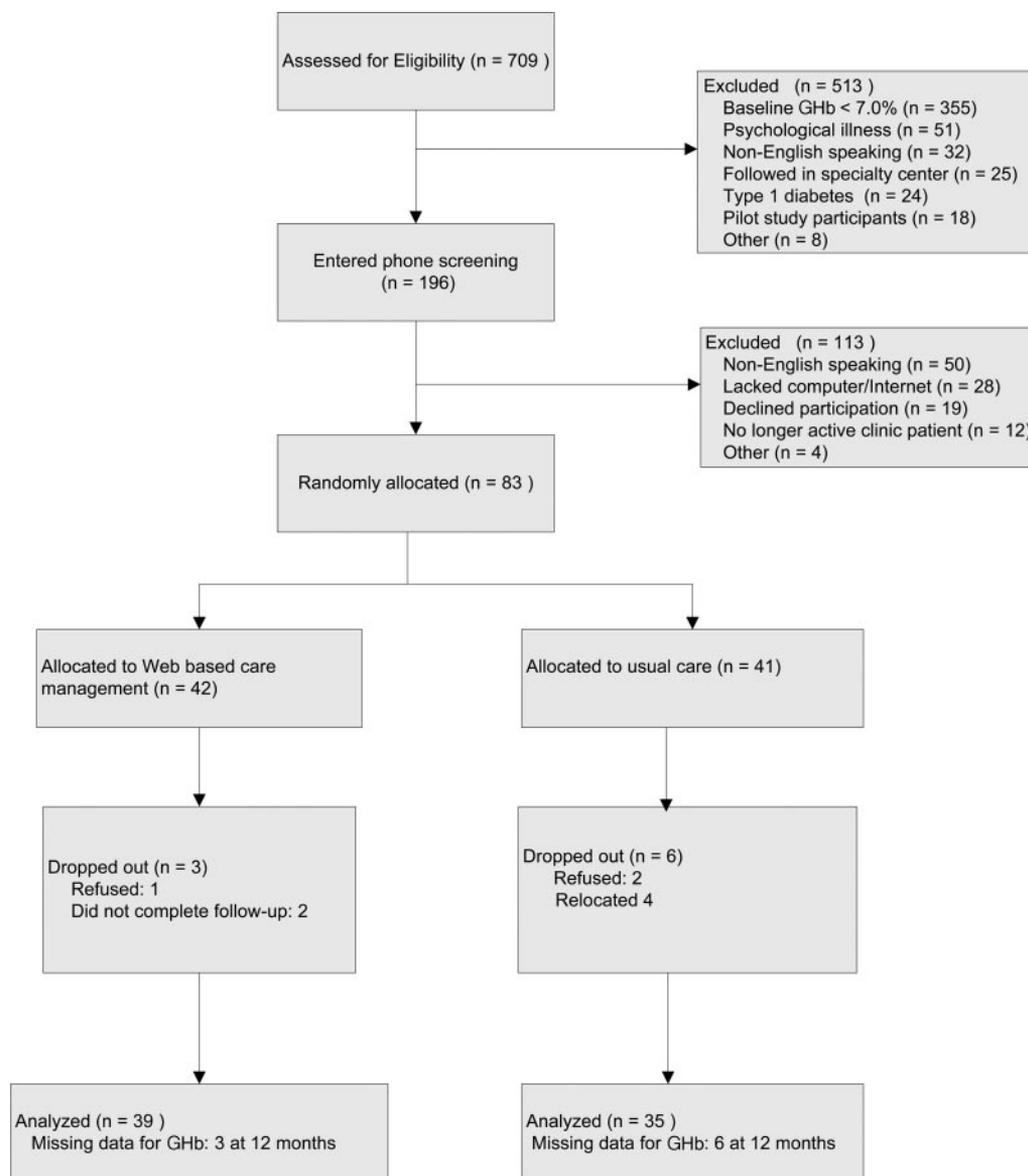
Figure 1—*Study flow diagram.*

fore study enrollment and the 12-month intervention period. Outpatient encounters were further divided into specialty and primary care encounters.

Electronic medical record access was measured by the number of page views by section of the Web-based medical record. E-mail use by a participant was defined as one or more messages initiated to or in reply to the case manager (6). Individual counts of e-mails were not available for analysis. Study staff collecting outcomes were not blinded to group assignment.

Statistical analysis
The trial was designed to have 80% power to detect a difference of 0.5% in GHb concentration (two-sided significance level of $P < 0.05$; SD of mean GHb 1.26; mean

change in Z score SD in GHb levels 0.87) (7). Intention-to-treat analysis of the main trial outcome included all randomly allocated participants with available outcome data. Three participants in the intervention group and six in the usual-care group did not have a follow-up GHb. Primary analysis used linear regression with change in GHb as the dependent variable, adjusted for age and sex and for baseline GHb (8). Sensitivity analyses included a single imputation method for missing GHb follow-up measures using the baseline GHb observation carried forward, an average of baseline GHb among all participants carried forward, and an average of all available post GHb by study group.

Secondary outcomes used the same analysis procedure as in the primary anal-

ysis. Utilization analyses used Student's t tests to compare differences in utilization between intervention and usual-care groups, including differences at baseline and follow-up, and in the changes from baseline to follow-up.

RESULTS — The initial screening criteria for age and diabetes diagnosis were met by 709 patients, of whom 626 were excluded before and during the phone screen: 355 had GHb <7%, 82 were non–English speaking, 28 lacked computer access, and 19 declined participation (Fig. 1). Those excluded were not significantly different from those enrolled by sex (49.5 vs. 47.8% male, respectively), race (80 vs. 75% nonwhite) or age (59.4 vs. 57.9 mean years of age). Among the 83 indi-

Table 2—*Baseline characteristics of patients with type 2 diabetes before intervention by randomization group*

	Usual-care group	Intervention group
n	41	42
Age (years)	57.6	57.0
Female (%)	51.2	47.6
Non-Hispanic white (%)	73.0	89.7
Insulin use (%)	39.0	38.1
Baseline values of outcomes		
GHb (%)	7.9	8.2
Systolic blood pressure (mmHg)	133.0	133.3
Diastolic blood pressure (mmHg)	76.0	76.3
Total cholesterol (mg/dl)	192.7	188.8
Outpatient visits (*n*)	10.3	9.6
Primary care, annual (*n*)	3.3	4.3
Specialty care, annual (*n*)	7.0	5.3
Inpatient days (*n*)	0.7	0.3

Data are means unless otherwise indicated.

viduals randomized to the usual-care and intervention groups (Table 2), the difference in percentage of Caucasians between groups approached significance (73.0% usual care vs. 89.7% intervention group; $P = 0.06$); 54 participants (65%) had all three diagnoses of diabetes, hyperlipidemia, and hypertension. Six individuals in the usual-care group and three individuals in the intervention group did not have follow-up GHb measurements. By the end of the trial, no adverse events were attributed to study participation.

Primary outcomes
GHb declined significantly in the intervention group compared with the usual-care group (change -0.7%; $P = 0.01$) at 12 months after adjusting for age, sex, and baseline GHb (Table 3). Unadjusted analysis increased the effect size (-1.1%; $P = 0.003$). The different approaches for imputing missing GHb data did not change effect size, and adjustment for non-Hispanic white race/ethnicity also did not change effect size.

Secondary outcomes
More participants in the intervention group than in the usual-care group had GHb <7% after 12 months (33 vs. 11%; $P = 0.03$ for difference between groups; Table 3). Intervention and usual-care groups did not differ in baseline systolic blood pressure (133.0 vs. 133.3 mmHg; $P = 0.93$), diastolic blood pressure (76.0 vs. 76.3 mmHg; $P = 0.91$) or total cholesterol (192.7 vs. 188.8 mg/dl; $P = 0.70$). At 12 months, mean changes in

systolic blood pressure (-0.9 mmHg; $P = 0.84$), diastolic blood pressure (0.1 mmHg; $P = 0.96$), and total cholesterol (7.6 mg/dl; $P = 0.38$) were not significantly different between groups. These results did not change in sensitivity analyses.

Process of care: health care utilization and medication changes
None of the differences between groups in the utilization measures were statistically significant (Table 3). The care manager self-reported an average of four hours per week spent updating care plans and communicating over the Web with patients in the intervention group.

In the intervention group, 76% of participants accessed their electronic medical record, 69% e-mailed, 43% uploaded blood glucose readings, and 33% entered medication, nutrition, or exercise data. Participants viewed 1,146 Web pages of the electronic medical record distributed as follows: transcribed notes (26%), lab results (20%), problem lists (9%), reminders to receive indicated care (6%), cardiology diagnostic reports (4%), and radiology reports (4%). Number of page views of the electronic medical record ($n = 1,146$) was not related to GHb improvement. Uploads of blood glucose levels ($n = 189$) showed a trend toward improvement with each additional 10 uploads associated with an estimated 0.4% reduction in GHb ($P = 0.09$).

Participants in the intervention group with a follow-up GHb <7% were older (mean age 62 years) than those with fol-

low-up GHb ≥7% (56 years) ($P < 0.05$). Mean age, baseline GHb, and percent non-Hispanic white were similar among those with follow-up GHb <7% compared with those with follow-up GHb ≥7%. Comparisons within the intervention group were limited by small sample sizes.

CONCLUSIONS— Web-based collaborative care of diabetes with a shared electronic medical record was effective at improving glycemic control in patients with type 2 diabetes. The 0.7% decrease in GHb in the intervention group is concordant with telephone and in-person interventions using care managers integrated with primary care teams (3,9), focused on self-management support (10), and able to modify a patient's medication regimen (9,11). Prior Web-based and telemedicine studies of care management have shown modest improvements in GHb (0.3–0.6%) and have lacked full integration with primary care teams (12–14). Our intervention's use of Web-based communications to extend the connection to primary care outside the office is consistent with the vision of the Institute of Medicine (2) and the Patient-Centered Advanced Medical Home (15).

To our knowledge, this is the first trial of Web-based support for diabetes care that included complete patient access to the same electronic medical record used by a patient's providers. Several studies have shown the value of promoting patient review of the paper medical record as part of multifaceted interventions in diabetes and other chronic diseases (16–18). This study extends this work by connecting patients and providers through a shared electronic medical record. Active review of the electronic medical record in the study is consistent with other studies showing that patients value medical test results when available online (1,19,20). Future studies should continue to determine how best to share electronic records with patients who have diabetes.

No differences were found in the use of primary care, specialty care, or inpatient services in the intervention group compared with the usual-care group, suggesting that the intervention did not lead to marked changes in health care utilization. The study, however, was not designed to reduce utilization or powered to detect changes in utilization and costs. Measure of utilization also did not include

Table 3—*Study outcomes and service use at 12 months after intervention by randomization group*

	Usual-care group	Intervention group	Mean group difference	*P*
n	35*	39*		
Mean GHb (%)				
Baseline	7.9	8.2	0.3	0.12
Follow-up	8.1	7.3	−0.8	0.01
Change	0.2	−0.9	−1.1	<0.01
Adjusted analysis†	—	—	−0.7	0.01
GHb <7% (%)				
Baseline	0	0	0	—
Follow-up	11	33	22	0.03
Change	11	33	22	0.03
Any contacts (%)				
E-mail with case manager	0.0	69	NA	
Blood glucose level uploads	0.0	43	NA	
Review of electronic medical record	0.0	76	NA	
Outpatient visits				
Pre	10.3 ± 7.7	9.6 ± (9.6)	−0.7	0.71
Post	8.2 ± (9.1)	10.2 ± (10.1)	2	0.36
Change	−2.1 ± (7.0)	0.6 ± (10.7)	2.7	0.18
Primary care provider visits				
Pre	3.3 ± 2.2	4.3 ± 3.8	1	0.15
Post	3.1 ± 3.0	4.3 ± 4.5	1.2	0.16
Change	−0.2 ± 2.8	0.0 ± 2.9	0.2	0.76
Specialty physician visits				
Pre	7.0 ± 7.9	5.3 ± 7.1	−1.7	0.30
Post	5.1 ± 8.7	5.9 ± 7.4	0.8	0.66
Change	−1.9 ± 5.9	0.6 ± 9.0	2.5	0.14
Inpatient days				
Pre	0.7 ± 1.8	0.3 ± 1.5	−0.4	0.31
Post	0.4 ± 1.2	0.5 ± 2.0	0.1	0.77
Change	−0.3 ± 1.8	0.2 ± 2.6	0.5	0.32

Data are mean, mean ± SD, or % unless otherwise indicated. *Six subjects in the usual-care group and three subjects in the intervention group did not have follow-up GHb measures at 12 months. †Analysis adjusted for age, sex, and baseline GHb.

the additional 4 h per week of management time devoted to the 42 individuals in the intervention group, and we did not include the costs of the electronic medical record and Web technology. Compared with other trials of care management outside the office-based setting (14), the Web technology behind our intervention was relatively low cost and already in use by many patients in other aspects of their daily lives. Future interventions may also become more efficient as care managers' skills further develop. If larger trials determine that collaborative care management over the Web is cost-effective, reimbursement for providers will need to be reformed to support electronic communication.

Interpretation of these results should take into account several limitations. The study used a single case manager whose individual characteristics may limit generalizability. The study did not control for greater attention paid by the care manger to intervention participants or distinguish the relative effectiveness or efficiency of Web-based care management compared with traditional care management. Outcome measurements in the study were not blinded to investigators, but GHb and total cholesterol were based on objective, laboratory-based measures; blood pressure measures were taken by medical staff not involved in the study. Primary care providers were not blinded to the assignment of intervention and usual-care groups; primary care providers were not an intervention target. Baseline measures of outcomes varied from 12 months to the day before randomization, which may have affected the size of the intervention effect; some participants may not have been eligible (GHb <7.0%) if GHb was measured at the time of randomization.

This should either underestimate or have no impact on the effect size of the intervention. We were not able to distinguish which components were most important for the effectiveness of the intervention. No exit interviews were done with participants to identify potential mediators of the intervention. Small sample size limited the ability to detect particular patient groups who may have benefited from the intervention (e.g., those taking insulin or of non-Hispanic white decent). The study population also had limited ethnic, racial, and socioeconomic diversity. Many with type 2 diabetes and its complications are in resource-poor environments with limited health literacy and access to care and technologies. Although interventions similar to this study may uniquely address some existing disparities in access to care, they may also fail to address or may even exacerbate other disparities (21).

Current health care systems do not sufficiently support the needs of patients with diabetes and other chronic conditions. Patients suffer the consequences in morbidity and mortality. In keeping with the vision of the Institute of Medicine and the Patient-Centered Advanced Medical Home, this study improved glycemic control with Web-based care management using a shared electronic medical record. Should this intervention prove generalizable and cost effective, it will support the case for reimbursement reform.

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