

An Electronic Case Manager for Diabetes Control

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OBJECTIVE — To evaluate the usage and safety of an electronic case manager (ECM) system designed to facilitate the task of glycemic control. Sustained improvement in blood glucose control is the proven treatment outcome that will reduce or eliminate the long-term complications of diabetes.

RESEARCH DESIGN AND METHODS — A customized microcomputer system served as the ECM. Located at the clinic, this voice-interactive system required the remote patient to need only a touch-tone telephone. Patients accessed the system to report daily self-measured glucose levels or hypoglycemic symptoms together with associated lifestyle events. System beta-testing was in an open-case series ($n = 184$) in an academic diabetes center with the goal of evaluating the ECM in terms of utilization, frequency of crises, and fiscal matters.

RESULTS — Of the patients, 58% ($n = 107$) actively used the ECM for their daily diabetes care, accumulating 788 patient-months of follow-up. Over 45,000 telephone calls were received by the ECM during the start-up year. Each call was processed instantly and automatically. Patients benefited from having 24-h access to the ECM. Prevalence of diabetes-related crises (hyperglycemia >400 mg/dl [22 mmol/l] or hypoglycemia <50 mg/dl [2.8 mmol/l]) decreased approximately threefold ($P < 0.05$), with a concomitant statistically significant decrease in HbA_{1c} of 0.8% at 6 months ($n = 45$, $P = 0.024$) and 0.9% at 12 months ($n = 30$, $P = 0.044$). The ECM provided 24-h on-line assistance in adjusting daily insulin and/or tablet therapy, automatic generation of standardized medical reports, electronic medical-legal documentation, as well as a marked reduction in the time spent on the phone with patients. Clinic visits in managing complex diabetes were reduced approximately twofold ($P < 0.0001$), and the effort spent by case managers was estimated.

CONCLUSIONS — Patients with diabetes who accessed the ECM system received timely, cost-effective, and reliable medical intervention. This reduced the incidence of diabetic crises and the need for frequent clinic visits. The ECM empowers case managers to provide safer and superior diabetes care.

Frequent intervention and increased contact between a health care team and the patient was key to improving metabolic control in diabetes in the Diabetes Control and Complications Trial (DCCT) (1). It is possible to facilitate intervention by using either telephone, modem, or fax machine (2–4). According to this method, patients were instructed to measure their blood glucose each day and to call in (modem, fax, phone) a report of their

results, in some cases several times a day. A case manager (nurse or clerk) received these transmissions and passed a written note to the patient's doctor who reviewed the new data in reference to the patient's medical history of previous results, activity level, diet patterns, etc. Decisions regarding medication dosing, diet, or exercise were then made and noted in the medical chart, and pertinent instructions were returned to the case manager for transmission back to

the patient, usually by phone. This manual method, supplemented by greater frequency of clinic visits as relied on by the DCCT health care team, could achieve the goal of frequent intervention. However, because it is extraordinarily time-intensive, the method is usually not attractive to either patient or doctor and, realistically, is not feasible outside a clinical research setting. As a consequence, it is rarely extended to many patients or even practiced for long periods of time in the general population with diabetes.

Recognizing both the need for frequent intervention and the problems of the manual methods, we evaluated an electronic case manager (ECM) (4) capable of data collection, processing, and management. Because the ECM is automatic, it greatly reduces the time and effort inherent in such interactions.

RESEARCH DESIGN AND METHODS

Computer platform

The ECM is based on a personal computer (PC) platform. Two interfaces are provided: one for the physician or case manager and one for the patient.

Health care professional interface. The health care professional interface permits an on-screen review of patient-entered blood glucose measurements, lifestyle events (such as changes in diet, exercise, stress, etc.), and other indexes (such as intercurrent illness, fever, loss of appetite, vomiting, ketonuria, etc.). Electronic reports derived from these data are automatically prepared and available at any time to the health care professional. All reports are standardized in format. Furthermore, the health care professional can activate a virtual recorder and using a microphone, leave voice messages for the patient regarding specific instructions. All interactions by the health care professional are documented in electronic medical chart notes with the annotations for time and effort spent as required for the legal medical record. Together these interactions form the basis for prolonged evaluation and management (Current Procedural Terminology [CPT] code 99358) claims against

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Abbreviations: CPT, Current Procedural Terminology; DCCT, Diabetes Control and Complications Trial; ECM, electronic case manager.

Advanced User Guide					
Blood Glucose Example					
To explain a blood glucose of 47, due to less food and more exercise; You should enter blood glucose as 47**1**23A					
	Factor Code	Suffix Codes			
Factor		1	2	3	8 to 9
Hypoglycemia	**0	mid	typical	strong	undefined
Carbohydrates	**1	less	typical	more	undefined
Activity	**2	less	typical	more	undefined
Stress	**3	less	usual	more	undefined
Fever	**4	mid	moderate	high	undefined
Menstrual	**5	less	usual	more	undefined
Steroids	**6	less	same	more	undefined
Medication	**7	enter the supplement dose in Units or Tablets			
Nasser	**8	mid	moderate	varying	undefined
Ketones	**9	trace	moderate	large	undefined

Figure 1—Advanced user guide.

the patient's health insurance. A facility is included to forward courtesy reports automatically by fax to referring physicians. Summary reports can be printed immediately or are generated automatically at intervals, as ordered by the physician.

Patient interface. The patient interface is located within the same hardware, realized through a voice-interactive, hardware link to an analog telephone line. Patients may use any available touch-tone telephone as a terminal through which to enter each glucose measurement, crisis event, lifestyle factor, and self-administered medication in response to verbal instructions given by the ECM. To these ends, the ECM system talks, generating a humanlike voice to relay instructions and messages over the telephone when the patient calls. However, it only deciphers key-press tones that are interpreted as the digits 0 through 9 and the symbols * and # on the touch-tone keypad. Lifestyle events such as changes in activity, food intake, stress level, health status, or medications were communicated by the patient to the ECM via additional keypad presses as dictated by an advanced user guide (Fig. 1). With experience, the transaction time for a patient to report a blood glucose measurement and associated lifestyle event is <30 s; each additional entry done during the same call takes ~20 s. The ECM is programmed to confirm that the information and designated instructions have been delivered to the patient and to document confirmation of patient understanding of the instructions. The responsibility of entering blood glucose readings and lifestyle events was assumed entirely by the patients; no clerical positions for data entry were needed.

Data storage. Patients access their data file in the ECM through a password or personal identification number (PIN) that is unique and easy to remember. Every number entered by the patient is verified before being accepted (see CONCLUSIONS). Only the physicians (or the designated case manager) can make changes in medication, direct instructions, and leave messages to patients. The ECM accumulates the number of telephone calls made, the number of blood glucose readings entered, the number of crises (which includes the number of hyperglycemic and hypoglycemic events), and the number of days used over the month. These data collected over the 1st year constitute the substance of this study.

Expert subsystem (insulin-dosage computer). The patient interface includes a rule-based expert subsystem that, if enabled by the physician, must be interactively programmed for each particular patient (5–8,16,17). If engaging the expert subsystem, the physician is responsible for customizing each individual patient's treatment plan by inputting the appropriate insulin types, doses and timing, target blood glucose, and rates of adjustments and supplements. When the rule-based expert subsystem is disabled, the health care professional must revert to empirical methods of diabetes management (9). In all cases, the system allows the patient to make their own decisions, but documents the decisions for the physician to review. The Food and Drug Administration, Center for Devices and Radiological Health has determined that this ECM is a medical device (10) and an expert system as defined under section 201(h) of the Federal Food, Drug

and Cosmetic Act (11). Accordingly, any changes to the ECM must be traceable and fully documented and checked for safety.

Methods

System evaluation was done using a study design with multiple end points. Patients were included under broad criteria and participated in the use of the ECM after a simple registration procedure and brief instructions for the user. Using the ECM is much like many telephone banking or credit card systems.

Study design and specific end points addressed

Study design is an open and ongoing case series. The set of specific questions addressed deals with the system's utilization statistics, the fiscal and administrative aspects of the implementation, and ongoing use. Included are the following: 1) the number of patients registered, 2) the proportion who were actively using the ECM, 3) how many telephone calls (reporting blood glucose measurements, lifestyle or crisis events) were handled over the 1st year, 4) the average rate of calls by patient by month of use, 5) how many on average were hyper- or hypoglycemic events, 6) whether use of each data file engendered changes in the incidence of hyper- and hypoglycemia, 7) whether users adhered to the ECM (i.e., was there an evanescent or novelty effect to using the ECM), 8) what the costs were for providing access to each data file and for providing the associated medical care, 9) the frequency of clinic visits before and after using the ECM, and finally, 10) what reimbursements were received from third-party providers. A subgroup of active users, for which HbA_{1c} data was available, was retrospectively evaluated in terms of change in HbA_{1c} over time. Paired *t* test was performed for statistical analysis, and results were reported as means ± SD. *P* < 0.05 was considered statistically significant.

Inclusion criteria

Entrance criteria were unrestricted with respect to sex, age, socioeconomic class, geographic location, type of diabetes, method of treatment, type(s) of medication (over 94% were insulin users), method of glucose self-measurement, etc. No additional laboratory tests were done for the purposes of the study beyond those usually ordered in clinical practice. Mainly, difficult-to-manage diabetic patients participated solely on the physician's judgment of the patient's need for

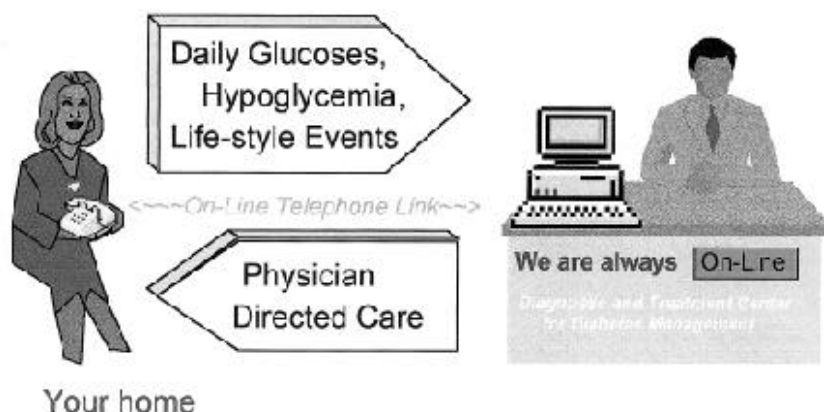


Figure 2—System diagram showing remote patient (possibly at home or elsewhere) accessing on-line computer system for daily diabetes care. Physician and case manager provide expert intervention in response to reported blood glucose readings, hypoglycemia, lifestyle events (diet, exercise, stress, ketonemia, illness, etc.) rendered daily, or preferably at each measurement.

increased intervention, specifically, 1) to improve blood glucose control, 2) to lower glycated hemoglobin, 3) to stabilize diabetes, 4) to reduce frequent hypo- and/or hyperglycemia. In this way, complicated patient populations representative of this clinical practice site were included.

Diabetes crisis events were identified by the ECM and immediately flagged. Crisis events included reported intercurrent illness, ketonuria, hypoglycemia, and hyperglycemia. Hyperglycemia in the crisis range was defined as any blood glucose entry >400 mg/dl (22 mmol/l) or moderate-to-large ketones. Hypoglycemia in the crisis range was defined as either symptoms of hypoglycemia (without measurement) or any reported blood glucose <50 mg/dl (2.8 mmol/l).

Registration and patient instruction

Patients directed by their physicians to use the ECM were registered into the computer database. Registration involved about 5 min of time and could be done by case managers. After registration, the patient was instructed in the use of the ECM, given a basic user guide and, as appropriate, an advanced user guide (Fig. 1). Patient instruction took an additional 10–15 min and could also be done by case managers. Besides specifying algorithm rules (i.e., blood glucose targets, slope of insulin dose adjustments and supplements, etc.), physicians directed patients how often to access the ECM daily.

Fiscal considerations

A cost analysis was done to estimate the effort expended to serve the active users of the ECM. Estimates included the physicians'

time to provide prolonged evaluation and management services (CPT 99358), voice messages, and all documentation (for medical-legal and billing purposes) as well as time needed to handle any additional direct telephone calls from patients regarding these services. Effort by the case manager(s) included the times to register patients into the ECM and instruct them in its use as well as the ongoing effort to relay messages to the patients (via the ECM or otherwise) and to document their activities for medical-legal and billing purposes. Effort for billing, finance/invoicing, filing, copying, and related mailings was estimated. Also, direct costs for lease of the ECM and use of telephone lines (local and 1–800) were calculated (Table 3). Finally, the frequency of clinic visits was ascertained in a subset of active users.

RESULTS — Figure 2 illustrates the various components of the ECM. Patients electronically access the ECM remotely via touch-tone telephone. On-site in the clinic, the physician and case manager(s) have direct control over the ECM through its graphical user interface.

The usage data for the ECM were collected continuously over the 1st year of observation. The numbers reflect a cross-sectional representation of a 12-month period, during which time patients were continually enrolled in the program. Thus during the year of observation, some patients used the ECM for the full 12 months, while others used it for shorter periods of time. After 1 year, registered users totaled 184. Active users were a majority, representing some 58% of registrants; they

Table 1—Annual system usage for ECM

Period	1 year
Registered Users	184
Active Users	107 (58%)
Nonusers	77 (42%)
Total telephone calls to system	45,882
Total calls reporting hyperglycemia	589
Total calls reporting hypoglycemia	1,087

generated 45,882 telephone calls to the ECM. Total calls reporting hyperglycemia totaled 589, while total calls reporting hypoglycemia totaled 1,087 (Table 1).

As shown in Table 2, patients had been instructed to self-measure blood glucose and call in their results daily or 7 days per week. The cumulative beta-testing experience was 788 patient-months. Specific usage on average was 58 ± 34 (mean \pm SD) calls per patient per month. Out of a maximum of 31 days, patients accessed the ECM on 29 ± 9 days per month. The average rate (\pm SD) of crises (hypo- and hyperglycemia) was 2.1 ± 3.6 crises per patient per month. Among the crises, the mean rate of hypoglycemia was 1.4 ± 2.5 events per patient per month. We were unable to identify any events of severe hypoglycemia (requiring assistance or hospitalization) among any of the active users.

Specific rates of hyperglycemia were followed. As shown in Fig. 3, the nonlinear regression line fitted to the data revealed a significant downward slope ($P < 0.01$), which led to a approximately twofold fall in the percentage of calls reporting hyperglycemia.

Reports of hypoglycemia represented some 3% of calls in the first 2 months of the

Table 2—Specific usage and rates of diabetic crises and hypoglycemia

Patients instructed to use system	~ 7 days/week
Using expert subsystem	Yes
Usage (patient-months)	788
Rate of calls made	58 ± 34
Rate of days used (maximum = 31)	22 ± 9
Rate of crises reported	2.1 ± 3.6
Rate of hypoglycemia	1.4 ± 2.5
Reports of severe hypoglycemia	0

Data are means \pm SD and are per patient per month.

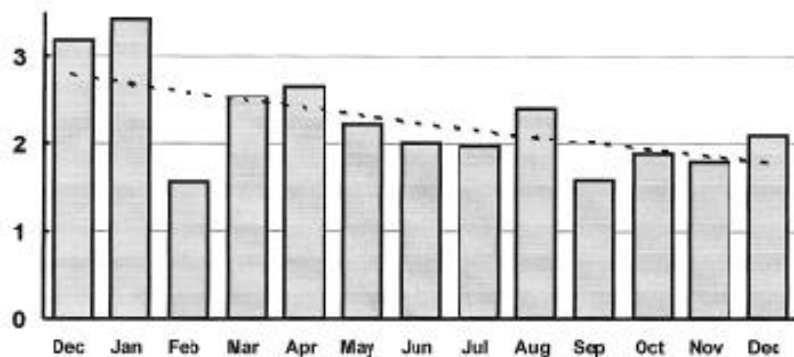


Figure 3—Percentage of total calls to system each month reporting hyperglycemia (blood glucose >100 mg/dl or 22 mmol/l) over a period of 1 year.

study, as shown in Fig. 4. By December, 1 year later, the fraction of calls reporting hypoglycemia was down 33% to an average rate of 2% per month. The nonlinear regression line fitted to the data indicate that the reduction in hypoglycemia is statistically significant ($P < 0.05$). For patients in whom HbA_{1c} data was available at baseline and 6 months and at baseline and 12 months, there was a statistically significant and consistent fall in HbA_{1c} from 9.8 ± 1.97 to $9.0 \pm 1.46\%$ ($n = 45$, $P = 0.024$) and $9.8 \pm 1.71\%$ to $8.9 \pm 1.76\%$ ($n = 30$, $P = 0.044$), respectively. When the patients were separated with regard to diabetes type, the differences in HbA_{1c} from baseline were even more evident for type 2 (9.2 ± 1.46 vs. $8.2 \pm 1.01\%$, $n = 22$, $P = 0.005$ at 6 months and 9.7 ± 1.03 vs. $8.6 \pm 1.54\%$, $n = 18$, $P = 0.003$ at 12 months) than for type 1 diabetes (10.5 ± 2.28 vs. $9.7 \pm 1.37\%$, $n = 22$, $P = 0.03$ at 6 months and 10.0 ± 2.45 vs. $9.4 \pm 2.00\%$, $n = 12$, $P = 0.09$ at 12 months).

The average number of telephone calls (per patient per month) is shown in Fig. 5. Call rates tended to decline from some 62 ± 31 per patient per month in July to 53 ± 32 in December ($P = 0.15$). Patient use and adherence is averaged over the year of observation of the ECM. During that year, patients were continuously enrolled in the ECM, some remaining active through the period of observation, some using it only for a limited period, and others still never participating (nonusers). As shown in Fig. 6, there were a consistent number of active users through the 1st year of observation. The usage statistics we report were based on this cohort of patients.

The fiscal issues encountered are summarized in Table 3. These were based on the stated number of active users. Average effort by case managers/health care professionals

was 33 min per patient per month. This effort included physician and nurse time. The unit costs for billing, postage, and phone services are listed. Total costs rose \$12.00 with the added lease of a (1–800) telephone service for the convenience of patients outside the local calling area.

Annual clinic visits decreased twofold ($P < 0.001$). A subgroup of 20 patients who had been followed at the clinic for a minimum of 1 year before enrolling in the ECM program was used for these calculations. The number of physician visits during the 1st year of ECM use were compared with the number of visits for the year preceding ECM enrollment. The patients served as their own control for this comparison of clinic use; the results reported in Table 4 are based on this subgroup of active users (nonusers were not considered for this assessment).

Reimbursement matters were resolved with each patient's insurance. Of third-party providers, 72% (representing 49% of submitted claims) honored the monthly CPT 99358 (prolonged physician service without direct patient contact) fee billed for

the system services. When third-party payers accepted to cover the expenses of the ECM, they actually reimbursed 48–100% of the submitted fee of \$179 (CPT 99358). Reviewing the clinic collections from health maintenance organizations (HMOs) and indemnity insurance companies for use of the ECM over the year of operation, this translates into approximately \$50.00 per patient per month. The cost of running one ECM (Teledoc) system is approximately \$1,000 per month; this would mean that to break even, each system would need to enroll 20 patients for which partial reimbursement is available (the system as it stands should be able to accommodate approximately 150–200 patients). Alternatively, the patients can choose to pay a set out-of-pocket fee for continued use of the ECM.

CONCLUSIONS — It is now widely held that sustained improvement in blood glucose control is the only treatment outcome that will prevent or reduce the long-term complications of diabetes. We have tested an ECM designed to facilitate this task. To evaluate its potential, a representative initial experience was accumulated. This testing included some 788 patient-months of follow-up. This study primarily focuses on the utilization statistics, along with fiscal and administrative aspects of the technology.

System usage by the patients was significant. Over 45,000 telephone calls for diabetes care were received by the ECM during the start-up year. Each of these calls was processed instantly and, in most cases, automatically. The higher incidences of hyper- and hypoglycemia noted in patients at the beginning of the use of the ECM reflected the registration of patients with complex

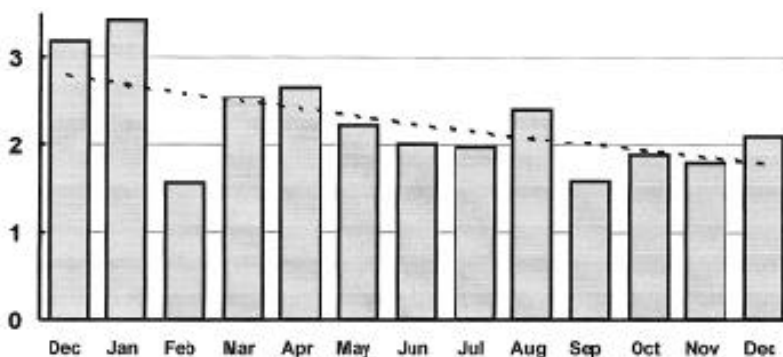


Figure 4—Percentage of total calls to system each month reporting hypoglycemia (blood glucose <50 mg/dl [2.8 mmol/l] or symptoms) over a period of 1 year.

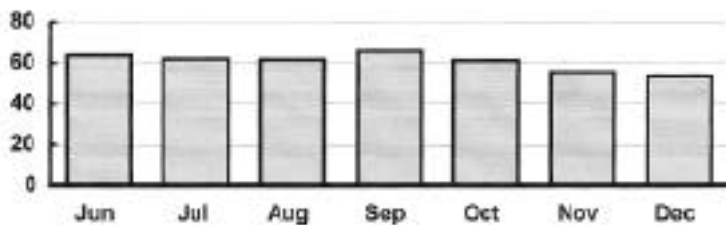


Figure 5—Average number of calls per patient per month.

and difficult-to-manage diabetes. After 1 year, the overall rate of occurrence of hypoglycemic events was reduced to between 1 and 2% of calls, and rates of hyperglycemia were decreased twofold, both events being statistically significant. In a subset of patients where metabolic data (HbA_{1c}) were available, we also noted a statistically significant decrease in HbA_{1c}, both at 6 months and at 12 months when compared with paired baseline results (no control population data available). Interestingly, but not surprisingly, the greatest benefit in terms of HbA_{1c} was seen in patients with insulin-requiring type 2 diabetes. Among active users of the ECM, clinic visits also decreased twofold, reflecting changes in the needs of patients with complex diabetes. We attribute this favorable outcome to the effects of the daily intervention that this system engenders. Others (20) using manual methods (versus the rule-based expert subsystem) failed to realize a change in metabolic control after 1 year, but noted a reduction in nurse task-time with a modem system for receiving blood glucose readings transmitted every 2 weeks.

In effect, the ECM provides an innovative tool that allows for automation of various aspects of daily diabetes patient care. It serves as a locus of up-to-date data collec-

tion, analysis, and processing. Although the ECM is geared toward reducing human error in data entry by asking the patient to reconfirm the actual data inputted (blood glucose, lifestyle description, insulin dose), inaccurate entry of data in the ECM can originate either from an unintentional error in the collection and reporting of capillary blood glucose or from a willfully misleading report. Nothing prevents the patient from purposefully entering fabricated data, just as they could using empirical methods of reporting data, e.g., handwritten log-book. The accuracy of this data would be equivalent, whether collected by the ECM or by a face-to-face encounter with a health care professional. In any case, the values obtained from the ECM are periodically compared with both the patient's HbA_{1c} results and glucose meter memory log, when available.

The system-produced electronic reports are standardized and complete and include the added documentation necessary for medical-legal and billing purposes. The data in the reports are presented to the physician and health care team in a user-friendly and easily interpreted form, resulting in more efficient and accurate interpretations. This also saves time and facilitates medical deci-

Table 3—Fiscal issues: case manager effort per patient and ancillary unit costs*

Case manager time (min)†	33
Billing services time (min)	29
Postage	\$0.96
Lease of local telephone line(s)	\$0.71 (3)
Lease of telephone line (1-800)	\$12.00

*Based on 100 active users. †Case manager time includes physician, nurse-educator, and support-staff effort spent.

sion making as well as patient instruction. The health care providers did not need to call back for clarification of information any more than they would have, had the data been collected by log-book or other empirical methods. However, the providers did have the advantage of leaving succinct, specific instructions, or even encouragement, to the patients via voice-recorded messages. Since this did not involve an actual conversation with the patient, the time needed for this remote interaction was minimal (30–45 s on the average).

The rule-based expert subsystem was used continuously in a majority of patients (only 5% used the ECM without the expert subsystem). It provided safe, reliable, and immediate feedback with regard to insulin dose adjustments and supplements. Empirical methods were used to supplement or override the expert system occasionally. The expert subsystem assists in tightening the loop between patient and health care provider, which in fact was the key ingredient to the success of the DCCT. This automated system for daily diabetes care can become the essential tool in helping to bridge the tremendous gap between current conventional diabetes care and what the DCCT clearly demonstrated should be the gold standard for diabetes management.

Another key question was that of adherence, or whether patients would abandon this method of care after the initial enthusiasm. The data suggest an adher-

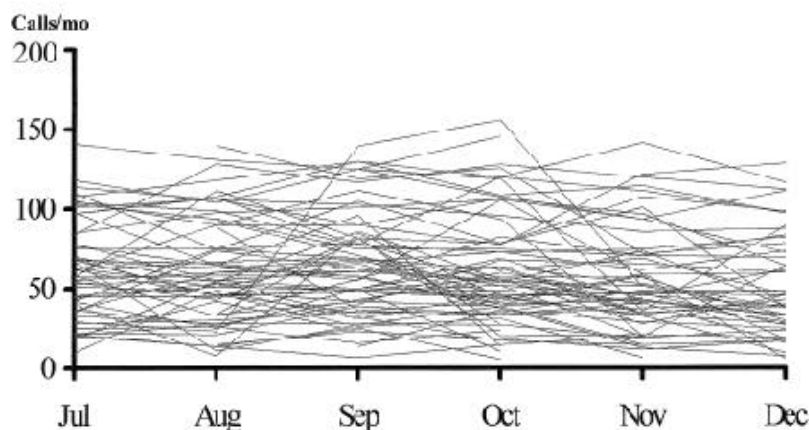


Figure 6—Adherence: active users (specific calls per patient per month).

Table 4—Average clinic visit frequency*

Clinic visits per year (before)	6.3 ± 1.9
Clinic visits per year (after)	3.2 ± 1.3

*Based on a subgroup of 20 active users. Data are means ± SD over the year or more before introduction of the ECM or over the year after introduction of the ECM ($P < 0.001$, $n = 20$).

ence to the process. Although they ranged widely, the specific number of telephone calls remained constant month by month in the majority of patients. Strikingly, a considerable number of registered patients dropped out because third-party providers would not pay for the medical services they were receiving. The remaining nonusers never made a single call. Why this occurs and what ought be done to change these adherence failures is not at all clear. The psychological underpinnings, possible system dependencies, and personality traits contributing to the various behaviors clearly require further study.

Recent in-depth reviews of the application of computers in diabetes care (13-15) showed that effort has been directed 1) to developing information systems, 2) to database formation and interpretation, 3) to fiscal decision support, and 4) to education. The present ECM is different. It includes the patient as an active participant in the care process and empowers the physician to increase intervention and advance his/her unique skills for improving metabolic control. It extends to the outpatient setting previous work done with a bedside, computer-assisted, closed-loop control system (16,17) and broadens the experience gained with hand-held devices for daily self-management (6,8,18). Although successful for hospital or independent outpatient use, these earlier devices were too expensive (\$45,000 and \$2,500, respectively) and less well suited for wide-scale use. In the present design (12,19), there are no communication or computer devices needed by the patient and, therefore, no device costs to the patient who is only responsible for the medical fees associated with the increased intervention and case management or care plan oversight services he or she may require. Where third-party insurance existed, the costs of providing services (19) were adequately covered.

In conclusion, patients with diabetes who accessed the ECM received timely, cost-effective medical intervention, which resulted in a significant reduction of diabetic crises. This reported case series attempts to define the safety and feasibility of diabetes management via a computer. Although much work has been done in the

field of computers for diabetes management, there still is a lack of well-controlled, prospective clinical studies in the field. Hopefully, this preliminary description will garner enough interest for the continued application and testing of computers in diabetes management. This new electronic system can empower case managers to provide safer and superior diabetes care and possibly provide the tools to realistically bridge the gap between conventional and intensified diabetes care. This unique diabetes management tool awaits further validation studies in clinical practice.

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