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Integrating Telehealth Technology into a Clinical Pharmacy Telephonic Diabetes Management Program

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Abstract

Background:

Use of home monitoring technologies can enhance care coordination and improve clinical outcomes in patients with diabetes and other chronic diseases. This study was designed to explore the feasibility of incorporating a telehealth system into an existing telephonic diabetes management program utilizing clinical pharmacists.

Methods:

This observational study was conducted at three Providence Medical Group primary care clinics. Adults with a diagnosis of diabetes and a recent hemoglobin A1c (HbA1c) >8% were referred by their primary care provider to participate in the study. Participants utilized the telehealth system developed by Intel Corporation and were followed by clinical pharmacists who provide telephonic diabetes management. The primary clinical outcome measure was change in mean HbA1c. Secondary outcomes included blood glucose levels, participant self-management knowledge, and the degree of participant engagement.

Results:

Mean HbA1c level decreased by 1.3% at the study end (p = .001). Based on participant satisfaction surveys and qualitative responses, participants were satisfied with the telehealth system. Mean blood glucose values decreased significantly over the 16-week study period from 178 mg/dl [standard deviation (SD) 67] at week 1 to 163 mg/dl (SD 64) at week 16 (p = .0002). Participants entered the study with moderate to good knowledge about managing their diabetes based on three questions, and no statistically significant improvement in knowledge was found post-study.

Conclusion:

Telehealth technology can be a positive adjunct to the primary care team in managing diabetes or other chronic conditions to improve clinical outcomes.

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Abbreviations: (A1C) hemoglobin A1c, (EMR) electronic medical record, (PAM) Patient Activation Measure, (PHS) Personal Health System, (SD) standard deviation

Keywords: diabetes, disease management, home monitoring, pharmacy, primary care, telehealth

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Introduction

Today, 7.8% of the population in the United States have diabetes.[1] If current trends continue, one in three Americans will develop diabetes sometime in their lifetime, and those with diabetes will lose, on average, 10 to 15 years of life.[2,3] Diabetes has a significant impact on the health and functioning of the individual with the disease. Engaging in effective self-management activities is essential to achieving good control of diabetes. This typically includes a working relationship between the individual and the health care team. For many patients with diabetes, the health care team mainly consists of their primary care provider.

Incorporating clinical pharmacists into the primary care setting to provide diabetes management is a way to expand and strengthen the primary care team. Several studies have demonstrated the effectiveness of clinical pharmacists in improving glycemic control in primary care.[4,5] In many states, under collaborative drug therapy management agreements, clinical pharmacists can initiate, modify, and discontinue medications. Clinical pharmacists can serve as a conduit to connect primary care teams with patients by providing interim diabetes management between office visits.

Due to the large number of patients with diabetes, primary care teams are pressed to practice more effectively and efficiently. New strategies and resources must be identified to support patients with diabetes. A number of studies have shown that the use of telehealth technologies can enhance care coordination, improve clinical outcomes, and increase satisfaction with care.[6,7] Few studies are available showing the utility of integrating telehealth services including home monitoring into the primary care setting. These limited results are promising, showing reductions in hemoglobin A1c (HbA1c) levels and high levels of acceptance by patients and providers.[8–10]

This 4-month observational study explored the feasibility of incorporating a home monitoring telehealth system into an existing telephonic diabetes management program utilizing clinical pharmacists in a primary care setting. Outcomes evaluated included HbA1c levels, blood glucose values, participant self-management knowledge, and participant engagement in self-management activities.

Methods

Study Setting

The study was conducted at three Providence Medical Group primary care clinics located within the Oregon Region of Providence Health and Services, a large integrated health system. The study was approved by the Providence Health and Services Institutional Review Board. Providence Medical Group primary care providers in the Portland metropolitan area are supported by clinical pharmacists who provide a telephonic diabetes management program for patients.

Eligibility

To qualify for participation in the study, patients had to be established with a provider at one of the designated clinics, have diabetes (International Classification of Diseases-9 codes 250.xx on problem list), be at least 18 years old, and have a HbA1c >8% on the most recent test result within the previous 12 months. Patients living in a nursing home or on hospice care were excluded from the study. Lists of patients meeting the entry criteria were distributed to their primary care physicians who then eliminated any patients they felt could not participate (e.g., memory impairment or other condition impairing participation). A total of 258 eligible patients were identified, and research staff was able to contact 117.

Telehealth System Description

The telehealth system (**Figure 1**) was developed by Intel Corporation (Santa Clara, CA) and is called Intel® Health Guide System. It is a Food and Drug Administration-cleared

Figure 1. Data flow through the telehealth system.

system comprising a (1) Personal Health System (PHS) 6000, a touch-screen, remote, stand-alone patient management unit placed in the patient's home, and a (2) Health Care Management Suite, a clinician–user interface accessible via a secure Internet link through a broadband connection in the patient's home. For this study, two peripheral devices, a glucometer (Breeze 2, Bayer Healthcare) and a blood pressure monitor (UA-767PC, A&D Medical), were connected to each PHS 6000 unit. The PHS 6000 alerts a patient to scheduled health sessions by audio and visual alarm. A health session prompts the patient to test and transmit blood glucose and/or blood pressure reading(s). The timing and frequency of health sessions are individualized to the patient. A health session also contains individually tailored assessment questions and prompts the participant to view brief educational videos on hypoglycemia, hyperglycemia, hypertension, and hypotension as appropriate. The clinician–user interface includes a triage page for blood glucose and blood pressure measurements that exceed preset individualized thresholds. During the study, threshold violations were reviewed, evaluated, and acted upon by the clinical pharmacist as appropriate.

Design

During this 4-month study, eligible participants attended an initial office visit with the clinical pharmacist to establish care. If needed, a broadband Internet connection was installed at the participant's home at no charge. An information technology technician and clinical pharmacist conducted a home visit to install the telehealth system, to teach the participant how to use the PHS 6000, glucometer, and blood pressure monitor, and to arrange scheduling of health sessions. Participants were provided free test strips throughout the study in quantities appropriate to their testing regimen and were permitted to keep the glucometer and blood pressure monitor after the study was completed.

Following the procedure established in the existing telephonic diabetes management program, the clinical pharmacist scheduled telephone follow-up to review blood glucose and blood pressure values at patient-appropriate intervals (e.g., 1, 2, or 3 weeks). Prior to the telephonic visit, the clinical pharmacist reviewed the blood glucose and blood pressure data in the clinician–user interface. During the call, appropriateness of frequency, timing, and content of the health session were assessed and modified as necessary. The clinical pharmacist provided routine components of collaborative drug therapy management, such as education and/or support on therapeutic lifestyle changes, and adjusted diabetes and hypertension medications as needed.

Data Collection and Measurements

Patient demographics, including age, gender, and primary insurance, were extracted from the electronic medical record (EMR) and used to characterize study participants. The primary clinical outcome measure was change in mean HbA1c. The study entry HbA1c levels were used as baseline values. The follow-up HbA1c was extracted from the EMR if the test was done within ±14 days of the final PHS 6000 use. If there was no follow-up HbA1c value recorded in the EMR, an intention-to-treat approach was used by carrying the baseline value forward.

Secondary outcomes included blood glucose levels, participant self-management knowledge, and the degree of participant engagement. Change in blood glucose levels over time was evaluated based on the patient-transmitted information from the telehealth device. Participant self-management knowledge was assessed by a questionnaire completed at baseline and study completion. A multi-disciplinary expert team consisting of researchers, a health educator, and a clinical pharmacist developed knowledge questions following the main principles of survey design and reviewed the survey for face and content validity. Degree of participant engagement was measured pre- and post-study using the 13-item validated Patient Activation Measure (PAM) tool for patients with chronic conditions.[11] Scores ranged from 0 to 100, which were converted to one of four activation stages per published PAM methodology.

Device utilization was determined by dividing the number of days the participant had the PHS 6000 by the number of days the PHS 6000 was used. Participant adherence to the health session blood glucose and blood pressure testing regimen was calculated based on the number of completed health sessions divided by the number of scheduled health sessions.

Participant perception of the program and the telehealth technology was evaluated with two surveys developed for the study. The first survey focused on participant satisfaction and was administered via the PHS 6000 at the end of the study. The second survey targeted participant usability and was administered by a research assistant pre- and post-study. Similar to the knowledge survey, this survey was developed by the expert team utilizing the main principles of the survey design. All questions used a Likert-type five-point scale in

which two ends of the continuum were balanced by a middle category.

Clinical pharmacist satisfaction with the telehealth technology was evaluated using both quantitative and qualitative methods. A group discussion was held that probed deeper into themes identified in a paper survey administered to the clinical pharmacists.

Statistical Analysis

Continuous data were described by mean [standard deviation (SD)] and were compared using paired *t*-test. Categorical data were described by percentages and were compared by chi-square tests or McNemar test for the paired proportions. Significance level was set at 0.05. Analyses were completed using SAS version 9.1.3.

For the PAM, all responses to each of the 13 questions (based on a four-point Likert scale) were added to calculate a raw score, which can range from 13 to 52 points. A Rasch score table was used to convert curvilinear raw scores to linear scores of the measure of activation.

Results

A total of 258 patients were determined eligible for the study, 117 (45%) were contacted, and 45 (38.5%) consented to participate. Of the participants who consented, 30 had the PHS 6000 installed in their homes and 28 participated in the study. **Table 1** displays characteristics of the participants as compared with the total eligible population. Study participants were statistically different from the total eligible population; they were more likely to be females, younger, and with no insurance.

Table 1.
Baseline Characteristics

	Total eligible (n = 258)	Participants (n = 28)	P value
Mean age (SD), years	56 (15)	50.4 (13.4)	0.03
Gender, female (%)	51.6	78.6	0.002
Mean baseline HbA1c (SD)	9.7% (1.6)	9.8% (2.08)	0.73
Insurance, (%)			0.03
Commercial	48.5	54.2	
Financial assistance	1.3	4.1	
Medicaid	4.9	4.2	
Medicare, advantage	22.0	12.5	
Medicare, traditional	16.3	8.3	
Self-pay, uninsured	7.1	16.7	

There was no difference in baseline mean HbA1c between participants and the total eligible population. The study participants predominantly had type 2 diabetes (89%). Four of the 28 participants failed to provide data for all 16 weeks of the study.

Utilization of the Telehealth System

On average, participants used the PHS 6000 97 out of 116 days, for an 83% utilization rate. Adherence, measured as completion of scheduled health sessions, was 78%.

Clinical Outcomes

Mean HbA1c at baseline for the 28 study participants was 9.8% (SD 2.08). Mean HbA1c decreased to 8.5% (SD 2.20) at study end. This was a statistically significant reduction (Δ = -1.3%, p = .001). The percentage of participants with a HbA1c > 9% (poor control) decreased from 50% to 29%, and 21% achieved the American Diabetes Association HbA1c goal of <7%. In contrast to the study participants, mean HbA1c increased for the 17 patients who consented but did not participate in the study (Δ = 0.1%).

The 28 participants measured their blood glucose values multiple times per day for the duration of the study. A total of 8149 measures were recorded with the telehealth system for analysis. Participants tested blood glucose values an average of 18 times per week (two to three times per day) and persisted in this frequency of testing throughout the study (**Figure 2**). Mean blood glucose values decreased significantly over the 16-week study period from 178 mg/dl (SD 67) at week 1 to 163 mg/dl (SD 64) at week 16 (p = .0002). Median and SD values demonstrated similar trends. In addition, percentages of blood glucose values between 70 and 180 mg/dl increased over the 16-week period from 50% to 70%, while incidence of hypoglycemia remained low (**Figure 3**).

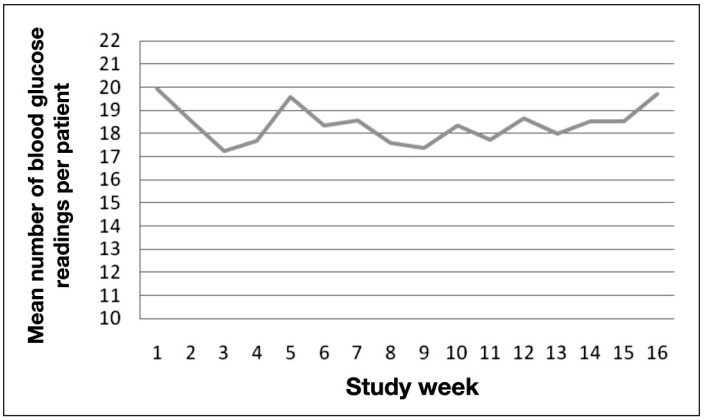

Figure 2. Mean number of glucose readings per patient per week.

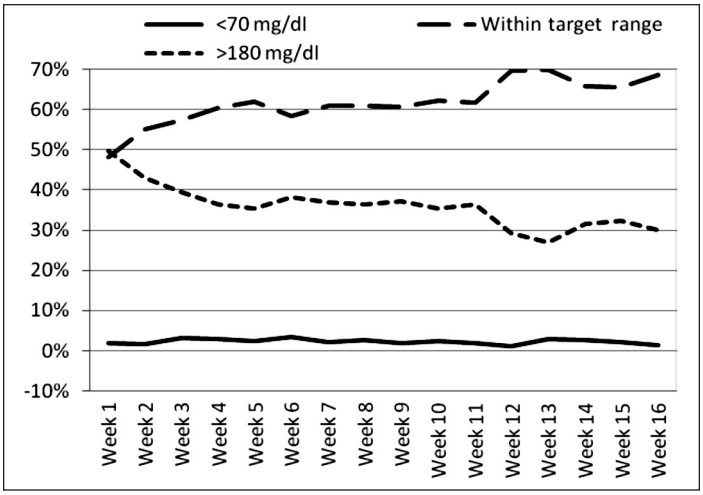

Figure 3. Weekly blood glucose level trend.

Knowledge Surveys and Patient Activation Measure Scores

Participants entered the study with moderate to good knowledge about managing their diabetes based on three questions. No statistically significant improvement in knowledge was found post-study. The PAM score increased from baseline to follow-up, but this difference did not achieve statistical significance at 0.05 level of significance (p = .09). See **Table 2** for details.

Patient Satisfaction

Survey questions administered via the PHS 6000 addressed satisfaction for usability, training, perception of privacy, and comfort using the telehealth system. A majority of participant responses were positive (either "agree" or "strongly agree") for all categories (**Table 3**).

The telephone survey indicates that participants were very satisfied with the educational content on the PHS 6000 and the interactions with the clinical pharmacist. There was a lower level of satisfaction with ease of information transmission, which may have been due to problems experienced with glucometers (**Table 4**).

Clinical Pharmacist Satisfaction and Efficiency

In general, the clinical pharmacists found the Health Guide System easy to use. Some efficiency was gained, for example, not having to wait while the participant reported blood glucose values over the telephone. However, these efficiencies were generally lost because of extra steps needed to integrate the information from the clinical–user interface into the EMR system. As a result, the average duration of the telephonic visits was 30 minutes in the study compared with 20 minutes in the existing program.

Table 2.
Knowledge Survey and Patient Activation Measure Results for Study Participants

	Pre	Post	p value
Knowledge Survey			
What should you not do if blood glucose is low? (% accurate responses)	72.7	77.3	0.7
What should you not do if blood glucose is high? (% accurate responses)	85.7	100	0.5
Ideal blood pressure for people with diabetes is 130/80? (% accurate responses)	92.3	92.5	0.5
PAM			
Mean score (SD)	68 (15)	72 (16)	0.09
Stages of activation (% responders)			0.2
1. Does not yet believe they have an active/important role	3.6	7.1	
2. Lacks confidence and knowledge to take action	10.7	7.1	
3. Beginning to take action	35.7	25.0	
4. Maintaining behaviors over time	50.0	60.7	

A sampling indicates that an average of eight telephonic visits per participant was completed by the clinical pharmacists during the study, which was similar to the number of visits per patient in the existing program. The majority of the telephone visits were preplanned. Telephonic visits that were not preplanned were initiated by the participant or the pharmacist and were related to hypoglycemia or hyperglycemia.

Discussion

Results demonstrate that a home monitoring telehealth system incorporated into an existing telephonic diabetes management program with clinical pharmacists is feasible and could improve quality of care for patients with diabetes. We found a decrease in mean HbA1c level of 1.3% (p = .001). This improvement is generally consistent with other telemedicine studies that reported improved glycemic control. McMahon and colleagues[12] demonstrated a 1.6% reduction in HbA1c for the intervention group who had an HbA1c above 9% at the start of the study. Whitlock and associates[8] had similar outcomes for patients receiving telemedicine home consultations with nurse case managers. Smaller but also

significant improvements in HbA1c were reported by Shea and coworkers[6] and Cho and colleagues.[13]

Both patients and pharmacists in our study found the units beneficial for monitoring and improving glycemic control. Based on participant satisfaction surveys and qualitative responses, participants were satisfied with the telehealth system. Several other studies have also demonstrated high acceptance rates and satisfaction by patients using telehealth programs.[10,14,15] Utilization and adherence rates were higher than anticipated during the study period. Even participants who encountered technical problems said that the device was beneficial in keeping them accountable.

Table 3.
Health Guide System Satisfaction Surveys (*n* = 26)

	Strongly disagree		Disagree		Neutral		Agree		Strongly agree	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%
I feel that this program made me more comfortable in the care I am receiving	1	4%	0	0%	2	8%	10	38%	13	50%
I felt comfortable using the equipment	1	4%	0	0%	0	0%	12	46%	13	50%
I felt my privacy was sufficiently protected	1	4%	0	0%	2	8%	9	35%	14	54%
It was easy to follow the instructions from the health guide	1	4%	0	0%	0	0%	8	31%	17	65%
If I had problems, someone was available to help me	1	4%	0	0%	3	12%	7	27%	15	58%
It was easy to see and read the questions, answers, and health tips	1	4%	0	0%	0	0%	9	35%	16	62%
The equipment was easy to use	1	4%	0	0%	0	0%	9	35%	16	62%
The training I received prepared me to use the equipment	1	4%	0	0%	0	0%	10	38%	15	58%
The verbal questions were easy to hear	1	4%	0	0%	0	0%	7	27%	18	69%
I would recommend this program to others	1	4%	1	4%	1	4%	8	31%	15	58%

Table 4.
Telephone Satisfaction Survey (*n* = 28)

	Very difficult		Difficult		Neither		Easy		Very easy	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%
How easy to take and send blood pressure results?	0	0	2	7.4	0	0	11	40.7	14	51.9
How easy to use glucose meter and send results?	0	0	1	3.8	0	0	13	46.4	14	50
	Very unhelpful		Somewhat unhelpful		Neither		Somewhat helpful		Very helpful	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%
How helpful was educational content on the device?	0	0	2	7.1	0	0	5	17.9	21	75
How helpful was provider?	0	0	0	0	0	0	2	7.1	26	92.9
	Very difficult		Difficult		Neither		Easy		Very easy	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%
How easy to comply with home monitoring plan?	0	0	2	7.1	0	0	13	46.4	13	46.4
	Very little value		Little value		Average value		Valuable		Very valuable	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%
How valuable is the device in management of diabetes?	0	0	3	10.7	1	3.6	6	21.4	18	64.3
	Very dissatisfied		Dissatisfied		Neither		Satisfied		Very satisfied	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%
Overall satisfaction with device?	0	0	2	7.1	0	0	11	39.3	15	53.6

An attempt was made to enroll participants who did not use the computer and/or Internet. Early recruitment calls determined that a majority of the patients were regular computer users, so this inclusion criterion was removed. Despite regular computer use, 15 (54%) participants required broadband Internet to be installed for purposes of the study. Given the overall high acceptance of the PHS 6000, a lack of experience with computers and the Internet did not appear to be a barrier.

At the beginning of the study, clinical pharmacists instructed participants on the use of the telehealth system in their home. This communication also allowed the clinical pharmacists to determine an appropriate health session schedule for each individual. Through the course of the study, clinical pharmacists determined that some efficiency was lost because of the time involved with setup. Other inefficiency included a lack of integration into the EMR and time spent fielding technical questions from participants.

Due to recruitment staff availability, patients were called only during business hours, which limited the opportunity to speak with potential candidates. Of those patients who were reached and declined participation, a variety of reasons were cited. While issues with technology were mentioned by a small number of individuals, it was not a strong reason for declining to participate.

The study exposed several areas for continued development with the telehealth technology, which is available with the current version of the product but was not available at the time of the study. For example, using wireless data transmission of data instead of broadband Internet would circumvent the need for broadband installation.

Most participants had not previously used the designated study glucometer, which meant additional participant training and participant adaptability to using a new meter. Newer technology allows a greater number of brands of glucometers to work with the PHS 6000. Ensuring the compatibility and usability of peripherals is important to reduce error messages and increase reliability.

The telehealth technology had a built-in video option that was not used during this study. Video capability is another potential enhancement that could have increased knowledge scores and activation levels. Video capability would have provided the opportunity to visually verify techniques for blood glucose testing, blood pressure monitoring, or insulin administration. Use of video conferencing may have provided an efficient alternative to the clinical pharmacist's visit to the patient's home.

Customization to the Health Care Management Suite, (e.g., whether a blood glucose value was taken before or after meal and which meal and if/when/how much insulin was administered) were submitted for consideration in a future release. Inclusion of these features coupled with EMR integration capabilities could provide the infrastructure needed to enable efficiency gains. Improved clinical outcomes and efficiency gains might be greater for organizations without an existing telephonic diabetes management program or collaborative drug management therapy program already in place.

Limitations

Our study demonstrated the baseline mean PAM score was 10 points higher than previously published for populations with chronic conditions.[16] This could be an indication of self-selection bias as more activated patients would be more likely to participate in the study. Study participants were also more likely to be uninsured and receive financial assistance. It is possible that patients who agreed to participate in the study may have been influenced by free broadband and/or test strips. It is difficult to estimate the degree to which this potential bias may have affected utilization of and adherence to the telehealth system or the improvement in HbA1c and blood glucose values.

Because the study was not designed with a control group, efficacy of the telehealth system on clinical outcomes over routine telephonic management was not evaluated. A convenience sample from the existing telephonic diabetes management program found a mean HbA1c reduction similar to that found in this study.[17] Additional HbA1c reduction may have been observed in this study with a longer duration of follow-up.

Conclusions

The Intel Health Guide System was successfully integrated into an existing telephonic diabetes management program. The system was well accepted by participants, and HbA1c values improved significantly during the study. Integrating telehealth technology into an existing diabetes management program can provide greater standardization and predictable data collection compared with self-report. Patient adherence and satisfaction with this telehealth program was excellent. Telehealth technology can be a

positive adjunct to a primary-care-based clinical pharmacist diabetes management program.

Disclosure:

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