

Deployment of an mHealth Patient Monitoring Solution for Diabetes—Improved Glucose Monitoring Leads to Reduction in Medical Expenditure

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Abstract

Although there is ample evidence that improved glucose control prevents long-term complications of diabetes, few reports have addressed the effect of improved control on short-term healthcare costs. **Methods:** A mobile health (mHealth)-enabled glucose meter combined with a disease management call center was deployed in 143 employees as part of an employer-sponsored diabetes disease management intervention. The program cost was approximately \$50 per member per month over and above the cost of standard care. **Results:** Overall, on an intention-to-treat basis, this program was associated with an annual reduction of \$1,595 (95% confidence interval [CI] −\$2,827 to +\$181) per person in incurred medical claims. A subanalysis documented that those who actively participated in the program (50 %) incurred a year-over-year claims cost decrease of \$3,384 (95 % CI \$643 to \$5,149) compared with an increase of \$282 among those who did not participate. **Conclusions:** These findings suggest that even partial improvement of diabetes testing adherence within an employed population may result in substantial attenuation of employee medical expense. The reduction in healthcare costs, even when considering those who did not comply, outweighed the program costs by several-fold.

Keywords

Diabetes, economics, wireless-health, glucose monitoring, cost-effectiveness

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The preponderance of scientific evidence^{1–3} suggests that monitoring and control of blood glucose prevents vascular complications of diabetes and, consequently, long-term medical costs associated with diabetes.^{4–6} While this effect is widely believed to apply to long-term rather than near-term costs, Sokol and colleagues reported that better medication adherence in diabetes may result in an annual near-term cost reduction of \$4,297 per person.⁷ This methodology was used by the California Public Employees Retirement System to report that people with diabetes were noncompliant with care incurred \$3,384 more in medical costs per year than those who were at least partially compliant.⁸

Individuals with diabetes incur on average \$13,700 per year in medical expenses, more than half (\$7,900) of which is spent directly on treatment of diabetes and its complications.⁶ While health insurers tend to focus on reimbursed medical expenditures associated with illness, employers are also faced with the effects of absenteeism, lost productivity, and worker replacement, currently estimated at \$3,136 per person-year.

The challenge facing the healthcare system is not whether to implement proper glucose monitoring and control, but rather how to motivate people with diabetes to monitor themselves. Behavior-change disease

management (DM) programs have demonstrated efficacy in improving compliance with glucose monitoring and control in patients with diabetes.^{9,10} One such program actually demonstrated a \$3,000 per year increase in employee productivity, providing independent support for the American Diabetes Association (ADA) estimate.⁷ However, the costs of traditional call center-based programs have hindered their widespread implementation.¹¹

In recent years there has been increasing recognition that advances in health information technology, particularly mobile health or ‘mHealth,’ solutions may be vital to the management and control of chronic illness.

Initial studies with prototypes of wireless monitoring solutions have offered encouraging results.^{12,13} Recent advances in cellular radio technology and health information technology have substantially altered this equation. In recent years, the first ‘postage stamp-sized’ cellular radio modules became commercially available, thus making it technologically feasible to insert cellular data transmission capability into a small, inexpensive consumer devices, such as a home-use glucose meter. This technologic advance enables the traditional DM call center to monitor a large population of patients in real time, similar to the manner in which burglar and fire alarms have been monitored for decades—with

Figure 1: Blood Glucose Reading Captured by a Cellular-enabled Glucose Meter



A cellular-enabled glucose meter was used to capture each blood glucose reading, transmit that reading automatically to a care-management server, and return clinical coaching and guidance to the user. Call center personnel made direct contact with the user in the event of out-of-bounds readings and other findings indicative of the need for care identified by a licensed healthcare professional.

Figure 2: Creating an Ecosystem of Care



The wireless blood glucose meter transmits each test result automatically to a Health Information Privacy and Accountability Act-compliant server. From there, the data may be viewed by: physicians and other medical professionals; patients on a secure web portal, workers at disease-management call center, such as the ActiveCare center used in this study; via smartphone apps; and family members of people with diabetes.

resources expended only on those patients who are seen to be out of control or otherwise not complying with care. In 2012, the first US Food and Drug Administration (FDA)-cleared wireless blood glucose meter was made available for commercial use in the US.

Telcare has deployed the first FDA-cleared mHealth glucose meter, and combined that product with ActiveCare's call center-based diabetes management program (see Figures 1 and 2). This study reports the annual medical costs in those who were versus those who were not compliant with glucose monitoring.

Materials and Methods

A mid-sized Southern US employer added a diabetes population management program to its employee health insurance program. Our study was certified as Institutional Review Board (IRB) exempt, since the assessment undertaken was of nonexperimental care involving FDA-cleared products used within the approved labeling and the program was offered to all employees (i.e. no randomization). The clinical coaching and medical management provided was consented to as part of the employee's enrollment in the health plan. In addition, employees verbally consented to receive the wireless glucose meter and be connected to the monitoring software.

Eligible subjects consisted of any employee identified as having diabetes and enrolled the employer's health insurance plan for the last three quarters of 2011. There were no other exclusions from enrollment. An a priori decision was made to exclude those with medical claims in excess of \$100,000 in either year from data analysis on the grounds that costs at that level are generally driven by malignancy, multisystem trauma, and other factors unrelated to diabetes.

The intervention consisted of call center monitoring (ActiveCare, Salt Lake City, Utah) of an FDA-cleared mHealth-enabled glucose meter (Telcare, Inc., Bethesda, Maryland, see Figure 1). The call center identified individuals with abnormally high or low blood glucose values and those individuals were repeatedly encouraged to seek medical care. A registered nurse followed up weekly with willing participants, advising them on recommended eating and exercising habits. The cost of the intervention program was \$25–50 per member per month above the cost of standard care, depending on the frequency with which members tested blood glucose.

Data Analysis

Employee claims data were obtained from the employer's claims administrator and analyzed under a Health Information Privacy and Accountability Act (HIPAA)-compliant business associate's agreement. Statistical analyses were performed using the R analysis package (R Foundation for Statistical Computing, Vienna, Austria). The primary outcome measure was overall change between 2011 and 2012 on an 'intention-to-treat' (ITT) basis. Because of the non-Gaussian distribution of the claims data, this confidence interval (CI) was calculated using Bayesian methods.¹⁴

We also conducted a subanalysis in which the 141 study subjects were stratified by whether or not the subject used the cellular-enabled glucose meter. Use was ascertained based on whether glucose values were transmitted to the cloud server that was linked to the glucose meter.

Table 1: Demographics and Allowed Charges of Study Population

	Eligible But Not Enrolled	Total Enrolled Study Participants	Enrolled and Used Program (Subgroup)	Enrolled and Did Not Use Program (Subgroup)
Number	31	141	71	70
Mean age (SD)	51 (12.6)	51.1 (12.6)	50.6 (11.8)	51.7 (13.4)
Proportion female (male)	0.40 (0.60)	0.41 (0.59)	0.45 (0.55)	0.38 (0.62)
2011 Median claim	Not applicable	10,821	10,735	10,881
2012 Median claim	Not applicable	10,223	9,259	11,188
2011 Average claim (SD)	\$16,758 (\$20,198)	\$17,986 (\$18,536)	\$17,428 (\$18,551)	\$18,570 (\$18,577)
2012 Average claim (SD)	\$16,253 (\$22,230)	\$16,391 (\$16,160)	\$14,044 (\$12,555)	\$18,852 (\$18,971)

SD = standard deviation.

Results

Enrollment and Participation

Of 179 potentially eligible subjects identified from claims data, 148 agreed to participate in the program. Of those, seven were excluded from participation because of claims costs in excess of \$100,000 attributable to conditions other than diabetes. The costs in those individuals were determined to be driven by malignancy, major trauma, and similar conditions unrelated to diabetes. Not all those who initially enrolled in the program actually transmitted glucose readings, thus enabling a comparison of users ($n=71$) compared with nonusers ($n=70$).

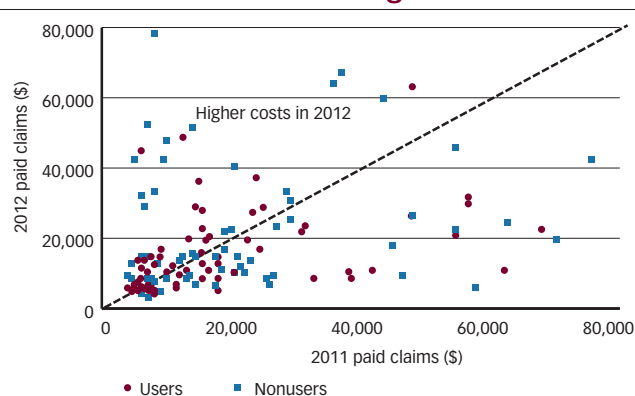
Primary Analysis

Baseline comparison of eligible subjects, enrolled subjects, participating subjects, and nonparticipating subjects is shown in Table 1 and demonstrates the users and nonusers to be comparable. Based on claims data, 8 % of users versus 11 % of nonusers ($p=NS$) were insulin-dependent.

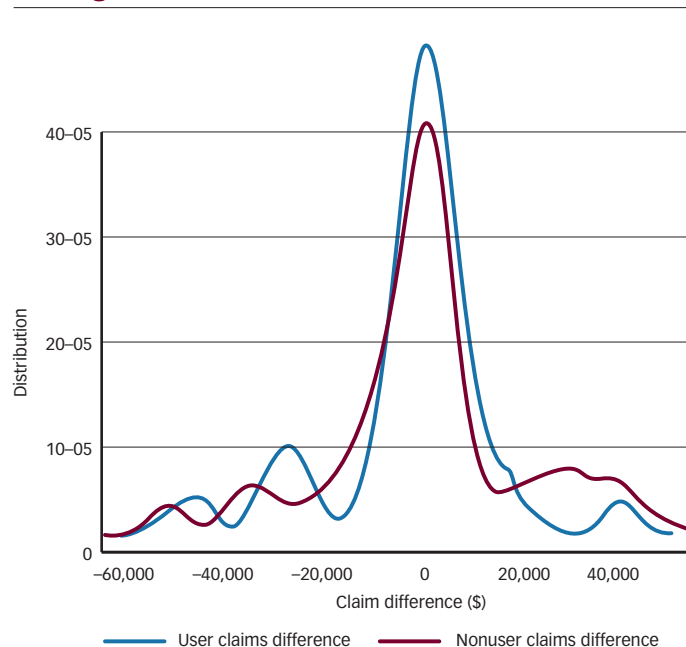
The primary outcome variable was the overall change in allowed claims between 2011 and 2012 on an ITT basis. The null hypothesis was tested based on whether the 95 % CI surrounding the year-over-year change overlapped zero. Because of the non-Gaussian distribution of the claims data (see Figure 3), this CI was calculated using Bayesian mixture models.¹⁵ Overall, the annual incurred claims per person in the diabetes program group decreased by \$1,595 (95 % CI –\$2827 to \$181) from 2011 to 2012. Over the same period of time, a 6.9 % increase in claims costs was experienced nationwide. Thus, while the 95 % CI slightly overlaps zero, the 93 % CI does not. Healthcare costs for those who were deemed eligible, but chose not to enroll in the program demonstrated a negligible and statistically insignificant decrease between 2011 and 2012 (see Table 1, column 1).

The largest difference is observed in the subgroup analysis that compares those who enrolled and used the program ($n=71$) versus those who enrolled and did not use the program ($n=70$) (see Table 1, columns 3,4). Program users experienced an average \$3,384 decrease in incurred medical expenses between 2011 and 2012, whereas nonusers incurred a \$282 increase in costs. The overall difference in incurred medical expenses between users and nonusers was \$3,666 (95 % CI \$643 to 5,149). A scatter plot of the difference in claims costs between 2011 and 2012 (see Figure 2) depicts the actual observations.

General linear modeling was employed in order to further study the claims cost difference between users and nonusers of the technology, while controlling for potential effects of aged and gender. As seen in probability distribution (see Figure 4), claims differences for users and

Figure 3: Scatterplot of Users and Nonusers of the Mobile Health Diabetes Management Intervention

Scatterplot of users and nonusers of the mobile health diabetes management intervention depicts the higher likelihood of nonusers to have increased claims cost in 2012, compared with 2011.

Figure 4: Claims Differences for Users and Nonusers of Mobile Health Diabetes Management Intervention

Claims differences distributions for users and nonusers of mobile health diabetes management intervention depicts the multimodal nature of the claims differences. The bulk of the cost difference between those who used the program and those who did not is associated with the significant ($p<0.01$) increase in the number of claims in the \$20,000–\$55,000 range experienced by nonusers (red curve).

nonusers of the mHealth DM program have multimodal distribution. Using a proportionally weighted t-test based on the mixture model estimates of mean, variability, and mixture proportions, users of the mHealth DM program demonstrated significant claims cost reduction between 2011 and 2012 ($p < 0.001$). The proportionally weighted estimated average cost for high-risk nonusers was \$18,036, with the corresponding average cost for users, within the same model, was \$14,892.

Discussion

Deployment of an mHealth-based population management intervention for diabetes in an employed population of 150 was associated with a year-over-year \$1,595 decrease in allowed employer-funded medical charges, rather than the 6 % increase (approximately \$1,000 per person) in allowed charges that would have been expected based on national averages. When analyzing the results on a subgroup basis, those who enrolled and used the program demonstrated a \$3,384 average decrease in 12 month claims between 2011 and 2012, while those who enrolled but did not use the program (i.e. did not transmit data) demonstrated a \$282 per person increase in costs over the same period of time ($p < 0.001$). The 31 individuals who declined enrollment in the program experienced a slight, but statistically insignificant, reduction in annual charges between 2011 and 2012. While the overall \$1,595 difference in claims on an ITT basis was highly encouraging (i.e. considering all program enrollees), the analysis of program users versus nonusers is particularly telling. All of the overall difference is attributable to year-over-year reduction in medical claims within this subgroup, suggesting that the intervention is highly likely to be causally associated with this reduction in medical claims.

These findings may be surprising to those familiar with multicenter clinical trials that suggest tight control of diabetes reduces long-term, rather than near-term, costs and complications of diabetes.¹⁻³ Those trials, conducted in academic centers, enrolled patients who were already compliant with then-standard blood glucose control and who were motivated to attempt even better control of their condition. The subjects in this study were clearly far less compliant in general and would have been unlikely to meet the stringent enrollment criteria for the National Institutes of Health (NIH)-sponsored trials. Essentially, this study is comparing the effect of some degree of diabetes control versus little to no control in a difficult-to-manage population. No clinical trial has (or could ever) measure the near-term costs of control versus no control for type 2 diabetes, because of the ethical concerns associated with maintaining a control group of people with minimally treated diabetes.

The difference between our approach and previous diabetes DM programs is: 1) data collection is achieved through cost-efficient, cloud-connected cellular devices that cost no more than standard premium glucose meters, 2) artificial intelligence-driven data analytics are used to target the attention of DM personnel, and 3) much of the required coaching and guidance can be delivered automatically to the patient via the mHealth device, rather than by manual phone call. Thus, DM personnel are able to focus their activities on those patients in need of guidance, rather than use costly resources to engage the entire population.

Because this is not a randomized controlled trial, there is no means of controlling the various sources of bias and confounding that may exist

between those who enrolled, but then did not use the intervention and those who both enrolled and used the intervention. At baseline, the claims experience among nonenrollees, enrollees, and the user versus nonuser subgroups was similar, as was their demographic makeup. It is likely that those who used the intervention were more motivated to do something positive to control their diabetes than those who did not use the intervention. This motivation may well have influenced other areas of their lives, such as medication adherence, glucose control, diet, and exercise.

If this self-selection bias plays a major role, the results we observed might not be caused by our intervention, but rather by other behavioral characteristics of the 50 % of the population who complied with (participated in) the mHealth intervention. It is well known that ‘compliers’ typically do better than ‘noncompliers’ in a study of this nature. However, spontaneous, meaningful year-over-year medical cost reduction in diabetic populations has not previously been reported, to our knowledge. Moreover, the significant improvement in medical costs when the study is analyzed on an ITT basis should be highly encouraging, since this analysis includes those initially unwilling to use the technology. Presumably as call center encouragement and increasing levels of employer incentives are directed at the more resistant members of the population, overall results on an ITT basis will improve as well. The initial 50 % adoption of the mHealth technology must be interpreted in light of nationwide compliance with home glucose monitoring at 30 % or less.¹⁶

The findings reported are from phase I implementation in which the cellular-enabled diabetes monitoring technology was distributed to all employees with diabetes who consented to participate. Call center interventions were limited to advice about out-of-range values in order to determine the level of adherence that could be obtained with this level of intervention. The second phase of the deployment (ongoing) targets center outreach toward those not testing or testing infrequently. In phase II, a variety of motivational approaches will be deployed, including gamification and social networking to improve participation.

Our findings are consistent with those of previous peer-reviewed studies that have demonstrated the potential of an mHealth remote monitoring approach for diabetes, but which lacked an ‘all-in-one’ solution to actually implement that approach. Studies involving SMS messaging,¹⁷ attempts to attach a glucose meter to a cell phone,¹⁸ or manual capture of glucose data via a cell phone app have all shown meaningful improvements in adherence and reductions in glycated hemoglobin (HbA_{1c}).¹³

Recently, Toscos and coworkers performed a 12-month trial with a prototype of our device, connecting an external cellular radio to a glucose meter at least once a week, transmitting the data to a central server, and providing the patient and family with a simple trend-monitoring report.¹² Those who were assigned to this technology demonstrated a similar 10 % reduction in average blood glucose (measured by HbA_{1c}), compared with patients who used traditional glucose meters and did not receive automated feedback. These results were both encouraging and statistically significant.

We are struck by the similarity of our findings related to savings, compared with the findings initially reported by the Sokol⁷ and California Public Employees’ Retirement System (calPERS)⁸ studies

on cost savings associated with diabetes care compliance. The study methodologies were quite different in that Sokol and calPERS ascertained compliance based on prescription renewal, whereas our analysis classified those who actually turned on the glucose meter and transmitted test results as adherent. However, given the difference in definitions and ascertainment, the similarity in observed medical cost reduction is remarkable.

In our intervention, the glucose meter and testing supplies are charged to the employer at a price similar to that of the traditional glucose meters

and test strips that are routinely reimbursed under employer-sponsored health insurance. The call center monitoring used in our study cost the employer less than \$500 per year, over and above the cost of standard care. Thus, even with the initial 50 % adoption rate, there is a threefold positive return on investment (ROI) in the first 12 months. Given the difference observed in medical expenses, it is reasonable to assume that there was also a difference in absenteeism and worker productivity, costs that are estimated at \$3,136 per worker. Increased program participation through call center outreach, social networking, and gamification may well increase that ROI. ■

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