Effectiveness of Mobile Health Solutions in Lowering Glycated Hemoglobin and Resulting Economic Effects—A Review of the Current Literature

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Abstract

Background: In recent years, a variety of innovative solutions have been introduced that are designed to improve adherence to blood sugar testing among patients with diabetes, lower glycated hemoglobin (HbA_{1c}), and decrease complications associated with diabetes mellitus. The value of lowering HbA_{1c} in preventing long-term complications of diabetes is broadly recognized. The purpose of this review is to provide an overview of the peer-reviewed literature documenting both the efficacy of mobile health (mHealth) solutions in improving adherence and lowering HbA_{1c}, along with the impact of lowering HbA_{1c} on near-term cost and complications of diabetes. **Methodology:** An extensive search of Index Medicus was performed in order to identify studies documenting the effectiveness of mHealth solutions in reducing HbA_{1c} and documenting the effectiveness of reducing HbA_{1c} in lowering near-term medical costs. **Results:** Six randomized controlled trials were identified in which the use of mobile monitoring solutions for blood glucose was tested against standard care. All demonstrated a reduction in HbA_{1c}, ranging from 0.35–1.9 percentage points. Ten studies, primarily longitudinal and retrospective in nature, were identified, which evaluated the effectiveness of HbA_{1c} reduction on reducing near-term medical costs. Overall, moderate reduction in HbA_{1c} appears to reduce medical costs by 10 % on average in commercially insured populations and 7 % on average in Medicare-age populations. **Conclusions:** mHealth interventions for diabetes show promise in reducing HbA_{1c} across multiple settings and achieving this clinical result is likely to result in reduction of near-term medical costs.

Keywords

Diabetes, mHealth, mobile health, eHealth, remote monitoring, glucose monitoring, wireless communication, cellular communication, economic analysis, cost-effectiveness

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In recent years, a variety of innovative solutions have been introduced that are designed to improve adherence to blood sugar testing among patients with diabetes, lower glycated hemoglobin (HbA_{1c}), and decrease complications associated with diabetes mellitus. The value of lowering HbA_{1c} in preventing long-term complications of diabetes is broadly recognized. The purpose of this review is to provide an overview of the peer-reviewed literature documenting both the efficacy of mobile health (mHealth) solutions in improving adherence and lowering HbA_{1c}, along with the impact of lowering HbA_{1c} on near-term costs and complications of diabetes. There are multiple variables to be considered when estimating the financial impact of an mHealth solution on preventing complications of diabetes and lowering medical costs within a healthcare organization. Those variables include, but are not limited to:

- An organization's current population, diabetes prevalence, and overall medical costs;
- An organization's current population with diabetes compliance with treatment protocols at baseline;
- An organization's current diabetes-management programs;
- The percentage of the population with diabetes willing to participate in the program; and
- The proposed treatment interventions associated with the glucose monitoring data that will be generated by the mHealth system.

However, no estimate of cost-effectiveness for a proposed model can be generated without supportable assumptions on efficacy of such interventions in lowering HbA_{1c} and, hence, near-term costs.

mHealth Solutions for Improving Control of Diabetes

Concommitant with the introduction of the first data-capable cell phones, innovators have sought to connect physicians and patients around the measurement and control of blood glucose. Initial solutions were based around connecting cellular radio devices to traditional blood glucose meters,[1] fashioning blood glucose meters that could attach directly to early cell phones (typically called feature-phones as distinguished from smartphones),[2] and relying on the patient to manually enter data via a cell phone application.[3] Other mHealth programs have relied on home telemonitoring devices[4,5] or web-based solutions.[6] The most recent approach to mHealth for Diabetes has implemented cellular data communication capability within a glucose meter.[7] This has the dual advantages of not imposing extra actions or cost on the patient, beyond those already associated with fingerstick glucose monitoring on the one hand, and providing the patient with immediate caregiver feedback on the other. Embedded cellular solutions typically consist of a blood glucose meter capable of cellular data transmission, a back-end cloud server that is capable of receiving data, interpreting and displaying it to patients and caregivers, and ancillary mobile apps that may be used by authorized friends and relatives to assist the patient in managing his or her condition (see *Figure 1*). Although the US Food and Drug Administration (FDA) has recently relaxed its degree of regulation around mobile medical apps, mHealth systems that connect to regulated medical devices, such as blood glucose meters, and provide clinical guidance to patients remain regulated by the FDA.

Studies on the Impact of mHealth Solutions on Glycated Hemoglobin Reduction

The published studies that measure the feasibility and efficacy of diabetes blood glucose telemonitoring on HbA$_{1c}$ results are primarily small, randomized controlled trials (RCTs), which vary based on participant selection criteria (population age, gender, diabetes type, and baseline HbA$_{1c}$), study duration, and intensity of treatment interventions (see *Table 1*). For example, telemedicine interventions that resulted in real-time modifications to a patient's diabetes medications were associated with higher HbA$_{1c}$ reductions. The following table summarizes recently published studies regarding the efficacy of telemonitoring on reducing HbA$_{1c}$ results. The mean decline in HbA$_{1c}$ based on the above studies varied from –0.35 to 1.9 percentage points. As indicated, study variations, such as diabetes type, baseline HbA$_{1c}$, patient age, and the intensity of the associated treatment interventions, may have an impact on the results.

Studies Evaluating the Impact of Reduction in Glycated Hemoglobin on Medical Costs

There are a number of studies that evaluate the association between diabetes costs and glycemic control. Many of these studies compare the medical costs of the population with diabetes with poor glycemic control to those with sustained glycemic control. There is a sizable body of research evaluating the long-term impact of controlled HbA$_{1c}$ on medical costs; however, this model addresses the near-term medical cost impact.

Table 2 summarizes published studies that have evaluated the impact of improved HbA$_{1c}$ control on medical costs.

The studies above reflect evidence that lower HbA$_{1c}$ and diabetic medication adherence are associated with reduced inpatient and overall medical costs in the short term, with the savings timeframe varying from 1 to 3 years. The studies included in this review did not distinguish the extent to which the decrease in HbA$_{1c}$ was associated with better testing adherence (such as via an mHealth intervention) versus better medication adherence. As indicated above, this research did not include studies that evaluate the long-term impact of sustained HbA$_{1c}$ compliance on reductions in diabetic complications and healthcare costs. The long-term Diabetes Control and Complications Trial (DCCT) and the Epidemiology of Diabetes Intervention and Complications (EDIC) studies identified that interventions aimed at achieving glycemic control as close to nondiabetic range as safely as possible reduced all of the microvascular and cardiovascular complications of diabetes.[1,17] In researching the estimated cost savings, we have assumed that there is a direct correlation between improved blood glucose monitoring and improvement in medication adherence and HbA$_{1c}$ results. The studies differ in the assumptions regarding starting HbA$_{1c}$ levels or medication

Figure 1: Components of an mHealth Solution for Diabetes

Embedded cellular solutions, which consist of a blood glucose meter capable of transmitting clinical values and receiving messaging from a back-end cloud server, thus completing the feedback loop between patient and caregiver.

adherence levels, diabetes type, study duration, service types measured, and the population base (e.g. staff model Managed Care Organization, employer group, large payer). As a result, the medical cost savings estimates for these studies vary from approximately 3–17 % of total medical costs for diabetes patients. (In some studies, for extreme changes, such as for those patients with the highest baseline blood glucose level, e.g. over 10 %, showing sustained improvement, the medical cost savings were measured to be well over 20 %.) The midrange of the studies estimated the savings total medical costs for patients with diabetes to be within the 7–13 % range. This includes the sometimes increased drug cost of improved medication adherence. Savings associated with deployment of an mHealth program are likely to be higher if the population is relatively higher cost; for example, if the program targeted patients with diabetes with the largest potential savings. Also, the savings would be higher for more aggressive monitoring and intervention programs. Several of the analyses were retrospective summaries of costs for patients with better versus worse levels of HbA$_{1c}$ or medication adherence, without a specific diabetes program involved. Their results could be exceeded by an effective, targeted program. Based on our review of the studies described above, a reasonable midpoint assumption of medical cost savings associated with meaningful HbA$_{1c}$ reduction might be 10 % of medical cost for a commercial population and 7 % for a Medicare population. Again, these should be adjusted to reflect the population being analyzed. Lower and higher savings assumptions are reasonable. For example, one analysis measuring one deployment of Telcare's system resulted in a 20 % reduction in the first year of use compared to the claim costs incurred in the base period.[9]

Additional Components of Savings

Aside from direct medical savings associated with improved blood glucose monitoring and lower HbA$_{1c}$, Medicare Advantage insurance plans should also consider the potential impact of such interventions on their star quality ratings. Under current Medicare regulations, improved quality ratings under this system trigger direct financial benefits through rebates and bonuses from the Medicare program. Higher star ratings and resulting revenue allow the plan to either decrease member premiums or provide additional supplemental benefits. Additionally, if a plan achieves a five-star rating, it permits them to

Table 1: Published Studies on the Impact of mHealth Solutions in Lowering Glycated Hemoglobin

Authors/Date	Study Methodology/Intervention	Diabetes Type	Study Length	Outcomes	Limitations
Toscos et al. (2012)[1]	RCT: Children >1 year and <12 years old (n=48) Intervention group: wireless, automated blood glucose monitor system collected results automatically, sent real-time alerts of BG after docking, and emailed 21-day BG trends daily to parents	1	12 months	Intervention group HbA_{1c}: 7.44 % (–0.35 from baseline) Control group HbA_{1c}: 8.31 % (+0.15 from baseline)	Type 1 diabetes only, children only, small study size
Kim and Kim (2008)[2]	RCT: Obese patients with diabetes (n=34) Intervention group: participant requested to record their BG, diabetes drugs/dosages on website. Based on results, researcher sent optimal recommendations to each patient by both cell phone and internet weekly (e.g. change drug dosage)	2	12 months	Intervention group: Statistically significant improvement in HbA_{1c} 6.67 % (–1.49 mean percentage points from baseline)	Type 2 diabetes only, small study size Obese population only
Quinn et al. (2011)[3]	RCT conducted in primary care offices (n= 163) Participants 18–64 years old with diabetes >6 months and HbA_{1c} >7.5% within past 3 months Three intervention groups: maximal intervention group included mobile- and web-based self-management patient coaching system and provider decision support. Patients received individualized automated real-time education based on results. Providers received quarterly patient reports summarizing glycemic control and medication management and evidence-based treatment options	2	12 months	HbA_{1c} decrease from baseline: intervention groups: • Group 4 (maximal interventions): –1.9 % • Group 3: –1.2 % Group 2: –1.6 % Control group: –0.7%	Type 2 diabetes only Small study size
Stone et al. (2010)[4]	RCT: Veterans receiving care at VA Pittsburgh clinics <80 years old, received diabetes drugs ≥12 months and most recent HbA_{1c} ≥7.5 % (n=150) Intervention group: received daily home telemonitoring device, transmit BG, blood pressure and weight NP reviews/adjusts medications, contacts participants as needed, including self-management education based on high-risk reports and monthly calls for individual counseling on self-management based on transmitted data	2	6 months	Intervention group HbA_{1c} decreased from 9.6 (baseline) to 7.9 at 6 months (–1.7) Control group decrease from 9.4 (baseline) to 8.6 at 6 months (–0.8)	6-month study, type 2 diabetes only Females under-represented
Wakefield et al. (2011)[5]	RCT: Veterans with Diabetes and Hypertension being treated by VA primary care providers (n=302) Intervention groups: Home telehealth device and care management. Nurses monitor results and provided early intervention • High intervention—(n= 93) DM algorithms based on ADA and AHA guidelines–prompts sent daily • Low intervention—(n=102) Prompts but no DM algorithms	2	6 months	High intervention group HbA_{1c} (–0.44 from baseline) Low intervention group HbA_{1c} (–0.40 from baseline). Control group HbA_{1c} (–0.07 from baseline)	6-month study, uncertain if reduced HbA_{1c} sustainable Type 2 diabetes only Females under-represented
Ralston et al. (2009)[6]	RCT conducted at General Internal Medicine Clinic: Criteria: Patients with diabetes 18–75 years old with most recent HbA_{1c} ≥7.0 % in the prior 12 months and home web access (n=83). Intervention group–(n=42) Usual care plus web-based program w/patient access to electronic medical records, secure email with providers, feedback on glucose readings, education website, and interactive diary for entering info on diet, exercise, and medication (includes web-based care manager interaction, promotes self-management, ability to modify medical prescription regime, primary care involvement, etc.)	2	12 months	Intervention Group HbA_{1c} = 7.3 (change –0.9) Control Group HbA_{1c} = 8.1 (change 0.2) No difference noted in use of primary care, specialty care, or inpatient services between the intervention and control groups.	Small study size Type 2 diabetes only
Javitt et al. (2013)[7]	Employees with diagnosis of diabetes and enrolled in health plan for last 3 quarters with <$100K in annual claims costs (n=141) Intervention—Call center called those with abnormally high/low values and repeatedly encouraged them to seek medical care. RN followed up weekly with willing participants to advise on eating/exercise Measured the change in allowed claims between 2011 and 2012 on intention to treat basis	Not defined	1 year	From 2011 to 2012 for the 141 participants: annual claims/person decreased $1,595 Same time 6.9 % increase in claims costs nationwide Subgroup analysis: • Employees that used the system (n=71): average claims cost per person decrease $3,384 • Did not use the system (n=70): average claims cost per person increased $282 Net difference $3,666	Employees only Small study size Telcare shareholder authored

ADA = American Diabetes Association; AHA = American Heart Association; BG = blood glucose; DM = data mining; HbA_{1c} = glycated hemoglobin; NP = nurse practitioner; RCT = randomized controlled trial; RN = registered nurse.

Table 2: Studies on the Effect of Improved Glycated Hemoglobin Control on Medical Costs

Authors/ Date	Study Methodology	Diabetes Type	Study Length	Outcomes	Limitations
Juarez (2013)[8]	Retrospective administrative data analysis of diabetes patients with poor HbA_{1c} control (starting ≥9 % at beginning of study) n=1,304. Examined reduced HbA_{1c} values and costs in same year and impact of sustained HbA_{1c} control (<7 %) for 3 years on changes in healthcare costs	Not defined	3 years	In patients with sustained HbA_{1c} <7 % for 3 years, direct increase medical costs decreased $2,207 versus $3,006 for patients without sustained control (net difference of $5,214) Cross-sectional analysis at baseline shows higher medical costs in those with HbA_{1c} <7 % ($14,821 versus $12,108: difference = $2,713)	Single health plan in HI In 2006, only 8 % of the plan's patients with diabetes had an HbA_{1c} ≥9 % (national average was 12.4 %)
Shetty et al. (2005)[9]	Retrospective database analysis of large MCO (5.4 million members) medical claims, pharmacy claims, lab data Two groups: • 'At target'—Type 2 diabetes continuously controlled with HbA_{1c} ≤7 %(n=3,121) • 'Above target'—Type 2 diabetes continuously with HbA_{1c} >7 % (n=3,659)	Type 2	1 year	At target HbA_{1c}: total diabetes-related costs $1,171 Above target HbA_{1c}: total diabetes-related costs $1,540 (32 % higher) Conclusion—Members with type 2 diabetes with continuously controlled HbA_{1c} ≤7% over 1 year period incurred lower diabetes-related costs	Excludes type 1 diabetes Managed care population only Only included members continuously above or below HbA_{1c} target. Only included diabetes-related costs defined as: medical claims with primary diagnosis diabetes and pharmacy claims for diabetic drugs
Wagner et al. (2001)[10]	Group Health Puget Sound staff model HMO (500,000 members) All patients >18 years old continuously enrolled 1992 to 1996 and HbA_{1c} measured at least 1 x per year in 1992 to 1994 (n=4,744) Improved cohort—Patients with diabetes with HbA_{1c} a decrease of 1 % or more between 1992 to 1993 and sustained decline through 1994 (n=732) Not improved cohort (n=4,012)	Not defined	5 years	Improved cohort had higher HbA_{1c} at baseline compared with the group without improvement (baseline HbA_{1c} 10.0 % versus 7.7 %) Improved cohort—Mean total healthcare costs were $695–$950 less each year Savings were only statistically significant among those with the highest baseline HbA_{1c} ≥10.0 % Differences in hospital admission rates were not statistically significant in any year Patients in improved cohort experienced a somewhat lower rate of ED use, but only statistically significant in 1 year Conclusion—Sustained reduction in HbA_{1c} is associated with significant cost savings within1–2 years of improvement	Staff mode only
Menzin et al. (2010)[11]	Retrospective cohort review—3-year study (1994–1998). Fallon Clinic adults diagnosed with diabetes (n=2,394) assigned to cohort based on mean HbA_{1c}: Good control: <8 % Fair control: 8–10 % Poor control: >10 %	Not defined	3 years	IP treatment and mean adjusted charges over 3 years: • Good control (<8 %); 13/100 patients, $970 • Fair control (8–10 %); 16/100 patients, $1,380 • Poor control (>10 %); 31/100 patients, $3,040 For 30 % of population with long-term complications more marked over 3 years: • Good control <8 %; 30/100 patients, $2,610 • Fair control 8–10 %; 38/100 patients, $3,810 • Poor control >10 %; 74/100 patients, $8,320	Study duration 3 years
Oglesby et al. (2006)[12]	Longitudinal analysis of large health plan database (1998–2003). Used first date of diabetes diagnosis and individuals having at least two HbA_{1c} values (n=10,780) Patients stratified based on HbA_{1c} as follows: Good: ≤7 (n=6,069) Fair: >7 and ≤9 (n=3,586) Poor: >9 (n=1,125)	Type 2	5 years	Type 2 direct medical costs: • Good control = $1,505 (16 % lower than fair; 20 % lower than poor) • Fair control = $1,801 • Poor control = $1,871 Prescription drugs costs • Good = $377 • Fair = $465 • Poor = $423 Almost 44 % of patients with type 2 diabetes had suboptimal glycemic control	One health plan in south-east US. Type 2 diabetes only Unable to control for time from initial diagnosis (same for the other studies) Funding provided by Eli Lily–competing interests 5-year study duration
Fitch et al. (2013)[13]	Used NHANES survey data (2005–2006 and 2007–2008 combined) to identify persons with type 2 diabetes: Commercial: n=392 Medicare: n=466 Based on NHANES risk factors: HbA_{1c}; blood pressure, HDL, and total	Type 2		Type 2 diabetes prevalence: 6.1 % in commercially insured (20–64 years old) 19.4 % in Medicare ≥65 years old 47 % commercially insured and 38 % Medicare found to have HbA_{1c} ≥7 % Type 2 diabetes: Commercial PPPM $1,090 (versus average PPPM	Hypothetical model Medicare model does not include prescription drugs Additional costs for pharmaceutical treatment and care management to improve were not included

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	cholesterol used UKPDS modeling tool to project rates of seven diabetes complications under status quo risk factors and better management (three improvement scenarios) Used MarketScan and Medicare 5 % sample data to develop PPPM costs for patients with diabetes and the incremental costs of the 7 diabetes-related complications Created hypothetical cohorts based on NHANES diabetic population and modeled 3 improvement scenarios			$448 without diabetes) Cost of complications contributed 20 % to diabetes costs ($214) Medicare PPPM $1,565 (compared with average PPPM $668 without diabetes and $858 total Medicare population) (Does not include prescription drugs) UKPDS complications contributed 21 % of total spend Scenario 1 savings—decrease HbA_{1c} 1 %: Commercial $99 PPPM; $2.06 PMPM Medicare $74.55 PPPM; $4.35 PMPM Scenario 2 savings—decrease HbA_{1c} 1.25 % Commercial $129 PPPM; $2.67 PMPM Medicare $100.38 PPPM; $5.86 PMPM Scenario 3 savings—decrease HbA_{1c} 1.5 % Commercial $158 PPPM; $3.28 PMPM Medicare $126 PPPM; $7.38 PMPM	in the models Savings specific to 7 diabetes-related complications.
Sokol et al. (2005)[14]	Evaluated the impact of diabetic medication adherence on medical costs Retrospective cohort observation of patients continuously enrolled in combined medical/drug plans for 1997–1999 Used claims to identify patients with chronic conditions, including diabetes during first 12 months of, the study measured medical/drug utilization during 12-month period after identification	Not defined	1 year	For diabetes, a high level of medication adherence was associated with lower disease-related medical costs and risk for hospitalization For patients with diabetes, a significant increase in medication adherence rates (from 1–19 to 80–100) was associated with reduction in all-cause medical and pharmacy costs from $15,186 and $1,312, respectively, to $6,377 and $2,510. And, all-cause hospital risk was reduced from 55 to 30 %	Studied impact of medication adherence. Under 65 population
Encinosa et al. (2010)[15]	Developed a model using 2001–2002 Marketscan data to evaluate the impact of diabetic medication adherence on hospital and emergency room utilization and hospital costs for patients with type 2 diabetes (n=56,744)	Type 2	1 year	Shifting the MPR from 50 to 100 % was estimated to reduce hospitalization rates by 23.3 % and emergency room visits by 46.2 % The cost of adherence was projected to increase diabetic drug cost by $776 per year, but it would be offset by averted hospital visits	Commercial data only Studied impact of medication adherence
Fera et Al. (2009)[16]	Quasi-experimental observational analysis, pre-post comparison Employers in 10 regions provided-value based benefit models to employees with diabetes Participants with diabetes enrolled voluntarily (n=573) Used community-based pharmacist coaching, evidence-based care guidelines and patient self-management strategies	Not defined	1 year	Statistically significant reduction in HbA_{1c} from 7.5 at baseline to 7.1 (–0.4 %) employer promotion Average total healthcare costs reduced $1,079 (7.2 %) per year compared with projected costs	Voluntary health benefit through May have included healthier, more-motivated participants.

ED = emergency department; HbA_{1c} = glycated hemoglobin; HDL = high-density lipoprotein; HI = Hawaii; IP = inpatient; MCO = managed care organization; MPR = medication possession ratio; NHANES = National Health and Nutrition Examination Survey; NP = nurse practitioner; PPPM = savings per participant/per month; PMPM = savings per member/per month across all plan members (with and without diabetes); UKPDS = UK Prospective Diabetes Study.

market year round as opposed to only during open enrollment and special election periods. Employers who are considering the implementation of mHealth programs for diabetes should also consider the economic impact of decreased worker absenteeism and increased worker productivity that may be driven by reduced complications of diabetes. In some employed populations, these factors may be as important as the projected savings in direct medical cost.In summary, although the impact of mHealth solutions on lowering HbA_{1c} is widely assumed to reduce only long-term complications of diabetes, a rapidly emerging literature suggests that meaningful financial and medical impact may be realized in the short term as well. ■

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patient, beyond those already associated with fingerstick glucose monitoring on the one hand, and providing the patient with immediate caregiver feedback on the other. Embedded cellular solutions typically consist of a blood glucose meter capable of cellular data transmission, a back-end cloud server that is capable of receiving data, interpreting and displaying it to patients and caregivers, and ancillary mobile apps that may be used by authorized friends and relatives to assist the patient in managing his or her condition (see *Figure 1*). Although the US Food and Drug Administration (FDA) has recently relaxed its degree of regulation around mobile medical apps, mHealth systems that connect to regulated medical devices, such as blood glucose meters, and provide clinical guidance to patients remain regulated by the FDA.

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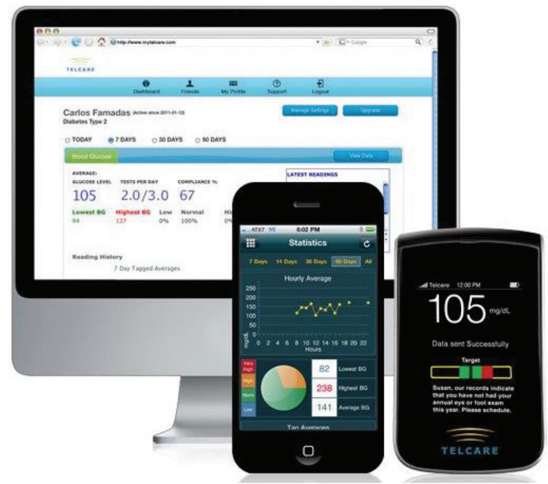

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Authors/Date	Study Methodology/Intervention	Diabetes Type	Study Length	Outcomes	Limitations
Toscos et al. (2012)[1]	RCT: Children >1 year and <12 years old (n=48) Intervention group: wireless, automated blood glucose monitor system collected results automatically, sent real-time alerts of BG after docking, and emailed 21-day BG trends daily to parents	1	12 months	Intervention group HbA_{1c}: 7.44 % (–0.35 from baseline) Control group HbA_{1c}: 8.31 % (+0.15 from baseline)	Type 1 diabetes only, children only, small study size
Kim and Kim (2008)[2]	RCT: Obese patients with diabetes (n=34) Intervention group: participant requested to record their BG, diabetes drugs/dosages on website. Based on results, researcher sent optimal recommendations to each patient by both cell phone and internet weekly (e.g. change drug dosage)	2	12 months	Intervention group: Statistically significant improvement in HbA_{1c} 6.67 % (–1.49 mean percentage points from baseline)	Type 2 diabetes only, small study size Obese population only
Quinn et al. (2011)[3]	RCT conducted in primary care offices (n= 163) Participants 18–64 years old with diabetes >6 months and HbA_{1c} >7.5% within past 3 months Three intervention groups: maximal intervention group included mobile- and web-based self-management patient coaching system and provider decision support. Patients received individualized automated real-time education based on results. Providers received quarterly patient reports summarizing glycemic control and medication management and evidence-based treatment options	2	12 months	HbA_{1c} decrease from baseline: intervention groups: • Group 4 (maximal interventions): –1.9 % • Group 3: –1.2 % Group 2: –1.6 % Control group: –0.7%	Type 2 diabetes only Small study size
Stone et al. (2010)[4]	RCT: Veterans receiving care at VA Pittsburgh clinics <80 years old, received diabetes drugs ≥12 months and most recent HbA_{1c} ≥7.5 % (n=150) Intervention group: received daily home telemonitoring device, transmit BG, blood pressure and weight NP reviews/adjusts medications, contacts participants as needed, including self-management education based on high-risk reports and monthly calls for individual counseling on self-management based on transmitted data	2	6 months	Intervention group HbA_{1c} decreased from 9.6 (baseline) to 7.9 at 6 months (–1.7) Control group decrease from 9.4 (baseline) to 8.6 at 6 months (–0.8)	6-month study, type 2 diabetes only Females under-represented
Wakefield et al. (2011)[5]	RCT: Veterans with Diabetes and Hypertension being treated by VA primary care providers (n=302) Intervention groups: Home telehealth device and care management. Nurses monitor results and provided early intervention • High intervention—(n= 93) DM algorithms based on ADA and AHA guidelines–prompts sent daily • Low intervention—(n=102) Prompts but no DM algorithms	2	6 months	High intervention group HbA_{1c} (–0.44 from baseline) Low intervention group HbA_{1c} (–0.40 from baseline). Control group HbA_{1c} (–0.07 from baseline)	6-month study, uncertain if reduced HbA_{1c} sustainable Type 2 diabetes only Females under-represented
Ralston et al. (2009)[6]	RCT conducted at General Internal Medicine Clinic: Criteria: Patients with diabetes 18–75 years old with most recent HbA_{1c} ≥7.0 % in the prior 12 months and home web access (n=83). Intervention group–(n=42) Usual care plus web-based program w/patient access to electronic medical records, secure email with providers, feedback on glucose readings, education website, and interactive diary for entering info on diet, exercise, and medication (includes web-based care manager interaction, promotes self-management, ability to modify medical prescription regime, primary care involvement, etc.)	2	12 months	Intervention Group HbA_{1c} = 7.3 (change –0.9) Control Group HbA_{1c} = 8.1 (change 0.2) No difference noted in use of primary care, specialty care, or inpatient services between the intervention and control groups.	Small study size Type 2 diabetes only
Javitt et al. (2013)[7]	Employees with diagnosis of diabetes and enrolled in health plan for last 3 quarters with <$100K in annual claims costs (n=141) Intervention—Call center called those with abnormally high/low values and repeatedly encouraged them to seek medical care. RN followed up weekly with willing participants to advise on eating/exercise Measured the change in allowed claims between 2011 and 2012 on intention to treat basis	Not defined	1 year	From 2011 to 2012 for the 141 participants: annual claims/person decreased $1,595 Same time 6.9 % increase in claims costs nationwide Subgroup analysis: • Employees that used the system (n=71): average claims cost per person decrease $3,384 • Did not use the system (n=70): average claims cost per person increased $282 Net difference $3,666	Employees only Small study size Telcare shareholder authored

ADA = American Diabetes Association; AHA = American Heart Association; BG = blood glucose; DM = data mining; HbA_{1c} = glycated hemoglobin; NP = nurse practitioner; RCT = randomized controlled trial; RN = registered nurse.

Table 2: Studies on the Effect of Improved Glycated Hemoglobin Control on Medical Costs

Authors/ Date	Study Methodology	Diabetes Type	Study Length	Outcomes	Limitations
Juarez (2013)[8]	Retrospective administrative data analysis of diabetes patients with poor HbA_{1c} control (starting ≥9 % at beginning of study) n=1,304. Examined reduced HbA_{1c} values and costs in same year and impact of sustained HbA_{1c} control (<7 %) for 3 years on changes in healthcare costs	Not defined	3 years	In patients with sustained HbA_{1c} <7 % for 3 years, direct increase medical costs decreased $2,207 versus $3,006 for patients without sustained control (net difference of $5,214) Cross-sectional analysis at baseline shows higher medical costs in those with HbA_{1c} <7 % ($14,821 versus $12,108: difference = $2,713)	Single health plan in HI In 2006, only 8 % of the plan's patients with diabetes had an HbA_{1c} ≥9 % (national average was 12.4 %)
Shetty et al. (2005)[9]	Retrospective database analysis of large MCO (5.4 million members) medical claims, pharmacy claims, lab data Two groups: • 'At target'—Type 2 diabetes continuously controlled with HbA_{1c} ≤7 %(n=3,121) • 'Above target'—Type 2 diabetes continuously with HbA_{1c} >7 % (n=3,659)	Type 2	1 year	At target HbA_{1c}: total diabetes-related costs $1,171 Above target HbA_{1c}: total diabetes-related costs $1,540 (32 % higher) Conclusion—Members with type 2 diabetes with continuously controlled HbA_{1c} ≤7% over 1 year period incurred lower diabetes-related costs	Excludes type 1 diabetes Managed care population only Only included members continuously above or below HbA_{1c} target. Only included diabetes-related costs defined as: medical claims with primary diagnosis diabetes and pharmacy claims for diabetic drugs
Wagner et al. (2001)[10]	Group Health Puget Sound staff model HMO (500,000 members) All patients >18 years old continuously enrolled 1992 to 1996 and HbA_{1c} measured at least 1 x per year in 1992 to 1994 (n=4,744) Improved cohort—Patients with diabetes with HbA_{1c} a decrease of 1 % or more between 1992 to 1993 and sustained decline through 1994 (n=732) Not improved cohort (n=4,012)	Not defined	5 years	Improved cohort had higher HbA_{1c} at baseline compared with the group without improvement (baseline HbA_{1c} 10.0 % versus 7.7 %) Improved cohort—Mean total healthcare costs were $695–$950 less each year Savings were only statistically significant among those with the highest baseline HbA_{1c} ≥10.0 % Differences in hospital admission rates were not statistically significant in any year Patients in improved cohort experienced a somewhat lower rate of ED use, but only statistically significant in 1 year Conclusion—Sustained reduction in HbA_{1c} is associated with significant cost savings within1–2 years of improvement	Staff mode only
Menzin et al. (2010)[11]	Retrospective cohort review—3-year study (1994–1998). Fallon Clinic adults diagnosed with diabetes (n=2,394) assigned to cohort based on mean HbA_{1c}: Good control: <8 % Fair control: 8–10 % Poor control: >10 %	Not defined	3 years	IP treatment and mean adjusted charges over 3 years: • Good control (<8 %); 13/100 patients, $970 • Fair control (8–10 %); 16/100 patients, $1,380 • Poor control (>10 %); 31/100 patients, $3,040 For 30 % of population with long-term complications more marked over 3 years: • Good control <8 %; 30/100 patients, $2,610 • Fair control 8–10 %; 38/100 patients, $3,810 • Poor control >10 %; 74/100 patients, $8,320	Study duration 3 years
Oglesby et al. (2006)[12]	Longitudinal analysis of large health plan database (1998–2003). Used first date of diabetes diagnosis and individuals having at least two HbA_{1c} values (n=10,780) Patients stratified based on HbA_{1c} as follows: Good: ≤7 (n=6,069) Fair: >7 and ≤9 (n=3,586) Poor: >9 (n=1,125)	Type 2	5 years	Type 2 direct medical costs: • Good control = $1,505 (16 % lower than fair; 20 % lower than poor) • Fair control = $1,801 • Poor control = $1,871 Prescription drugs costs • Good = $377 • Fair = $465 • Poor = $423 Almost 44 % of patients with type 2 diabetes had suboptimal glycemic control	One health plan in south-east US. Type 2 diabetes only Unable to control for time from initial diagnosis (same for the other studies) Funding provided by Eli Lily–competing interests 5-year study duration
Fitch et al. (2013)[13]	Used NHANES survey data (2005–2006 and 2007–2008 combined) to identify persons with type 2 diabetes: Commercial: n=392 Medicare: n=466 Based on NHANES risk factors: HbA_{1c}; blood pressure, HDL, and total	Type 2		Type 2 diabetes prevalence: 6.1 % in commercially insured (20–64 years old) 19.4 % in Medicare ≥65 years old 47 % commercially insured and 38 % Medicare found to have HbA_{1c} ≥7 % Type 2 diabetes: Commercial PPPM $1,090 (versus average PPPM	Hypothetical model Medicare model does not include prescription drugs Additional costs for pharmaceutical treatment and care management to improve were not included

Authors/ Date	Study Methodology	Diabetes Type	Study Length	Outcomes	Limitations
	cholesterol used UKPDS modeling tool to project rates of seven diabetes complications under status quo risk factors and better management (three improvement scenarios) Used MarketScan and Medicare 5 % sample data to develop PPPM costs for patients with diabetes and the incremental costs of the 7 diabetes-related complications Created hypothetical cohorts based on NHANES diabetic population and modeled 3 improvement scenarios			$448 without diabetes) Cost of complications contributed 20 % to diabetes costs ($214) Medicare PPPM $1,565 (compared with average PPPM $668 without diabetes and $858 total Medicare population) (Does not include prescription drugs) UKPDS complications contributed 21 % of total spend Scenario 1 savings—decrease HbA_{1c} 1 %: Commercial $99 PPPM; $2.06 PMPM Medicare $74.55 PPPM; $4.35 PMPM Scenario 2 savings—decrease HbA_{1c} 1.25 % Commercial $129 PPPM; $2.67 PMPM Medicare $100.38 PPPM; $5.86 PMPM Scenario 3 savings—decrease HbA_{1c} 1.5 % Commercial $158 PPPM; $3.28 PMPM Medicare $126 PPPM; $7.38 PMPM	in the models Savings specific to 7 diabetes-related complications.
Sokol et al. (2005)[14]	Evaluated the impact of diabetic medication adherence on medical costs Retrospective cohort observation of patients continuously enrolled in combined medical/drug plans for 1997–1999 Used claims to identify patients with chronic conditions, including diabetes during first 12 months of, the study measured medical/drug utilization during 12-month period after identification	Not defined	1 year	For diabetes, a high level of medication adherence was associated with lower disease-related medical costs and risk for hospitalization For patients with diabetes, a significant increase in medication adherence rates (from 1–19 to 80–100) was associated with reduction in all-cause medical and pharmacy costs from $15,186 and $1,312, respectively, to $6,377 and $2,510. And, all-cause hospital risk was reduced from 55 to 30 %	Studied impact of medication adherence. Under 65 population
Encinosa et al. (2010)[15]	Developed a model using 2001–2002 Marketscan data to evaluate the impact of diabetic medication adherence on hospital and emergency room utilization and hospital costs for patients with type 2 diabetes (n=56,744)	Type 2	1 year	Shifting the MPR from 50 to 100 % was estimated to reduce hospitalization rates by 23.3 % and emergency room visits by 46.2 % The cost of adherence was projected to increase diabetic drug cost by $776 per year, but it would be offset by averted hospital visits	Commercial data only Studied impact of medication adherence
Fera et al. (2009)[16]	Quasi-experimental observational analysis, pre-post comparison Employers in 10 regions provided-value based benefit models to employees with diabetes Participants with diabetes enrolled voluntarily (n=573) Used community-based pharmacist coaching, evidence-based care guidelines and patient self-management strategies	Not defined	1 year	Statistically significant reduction in HbA_{1c} from 7.5 at baseline to 7.1 (–0.4 %) employer promotion Average total healthcare costs reduced $1,079 (7.2 %) per year compared with projected costs	Voluntary health benefit through May have included healthier, more-motivated participants.

ED = emergency department; HbA_{1c} = glycated hemoglobin; HDL = high-density lipoprotein; HI = Hawaii; IP = inpatient; MCO = managed care organization; MPR = medication possession ratio; NHANES = National Health and Nutrition Examination Survey; NP = nurse practitioner; PPPM = savings per participant/per month; PMPM = savings per member/per month across all plan members (with and without diabetes); UKPDS = UK Prospective Diabetes Study.

market year round as opposed to only during open enrollment and special election periods. Employers who are considering the implementation of mHealth programs for diabetes should also consider the economic impact of decreased worker absenteeism and increased worker productivity that may be driven by reduced complications of diabetes. In some employed populations, these factors may be as important as the projected savings in direct medical cost.In summary, although the impact of mHealth solutions on lowering HbA_{1c} is widely assumed to reduce only long-term complications of diabetes, a rapidly emerging literature suggests that meaningful financial and medical impact may be realized in the short term as well. ■

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