Impact of a diabetes remote monitoring program on medication adherence

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What is already known about this subject

- Diabetes remote monitoring (DRM) programs have proliferated and been implemented at scale as mobile health technologies have evolved over the past decade.
- DRMs have reported glycemic improvements; however, the effect of remote monitoring and mobile health technologies on adherence has been mixed.
- Most studies have been conducted among small samples of patients using different technologies and often with adherence estimated using self-reported questionnaires.

What this study adds

- DRM participation and engagement were associated with higher medication adherence among people with diabetes compared with those not participating in a DRM program.
- Longer engagement in a DRM program were associated with greater improvements in medication adherence.
- Study findings have important implications for payers and patients related to improved health outcomes through digital health solutions.

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ABSTRACT

BACKGROUND: Medication nonadherence in diabetes is well documented to be associated with inadequate glycemic control. Through remote blood glucose (BG) monitoring, unlimited test strip and lancet supplies, personal coaching, and online access to clinical information and educational resources, diabetes remote monitoring (DRM) programs may provide a solution.

OBJECTIVE: To examine the relationship between patient participation in a DRM solution and adherence to oral antidiabetic drugs (OAD).

METHODS: A retrospective, propensity score-matched cohort study was conducted

using deidentified administrative claims data from a large pharmacy benefit manager. Commercially insured patients aged 18 years or older and having 2 or more 30-day adjusted OAD claims comprised the target sample. Patients enrolled in insurance plans that implemented DRM, who had at least 1 BG check (ever engaged) between April 1, 2015, and March 31, 2018 (exposure) were matched to patients enrolled in insurance plans that did not implement DRM (nonexposure). After a 1:2 matching on baseline demographics, disease burden proxy, total pharmacy out-of-pocket costs, previous adherence and insulin use, nonexposure group participants were assigned the same first BG check date as their matched DRM participants. Medication

adherence measured as proportion of days covered (PDC) in the 365 days following first BG check was examined as a continuous and binary outcome measure (PDC > 80% or adherent vs < 80% or nonadherent). Multivariable linear and logistic regression were conducted to examine differential magnitude in adherence and likelihood of being adherent, respectively.

RESULTS: The final sample consisted of 6,002 exposure and 12,004 nonexposure group patients. DRM participants who were ever engaged had a 4.5% higher adherence rate ($P < 0.001$) and 42% higher odds of being adherent ($P < 0.001$) in the period after engagement compared with non-DRM participants. Sensitivity analyses showed that patients engaged continuously (>1 BG check

per week) for 3, 6, and 12 months had 5.1%, 5.2%, and 6.4% higher adherence rates, respectively ($P < 0.001$), and 52%, 64%, and 98% higher odds of being adherent, respectively ($P < 0.001$), compared with non-DRM participants.

CONCLUSIONS: The study findings offer evidence that DRM engagement is associated with higher odds of medication adherence. DRM solutions that provide access to glucose test results, personalized coaching, educational resources, and lower testing supply cost can also influence adherence. Our findings have important implications for payers and patients related to improved health outcomes due to higher medication adherence.

Over 120 million US adults are living with diabetes or pre-diabetes, with diabetes being the seventh leading cause of death in the United States in 2017.^{1,2} As a chronic condition highly dependent on self-management, nearly half of all individuals with diabetes are reported to have poor glycemic control.³ Optimal management of type 2 diabetes mellitus (T2DM) involves a variety of therapies that involve changes in lifestyle, including diet and physical activity, as well as pharmacotherapy, to improve metabolic control in most individuals.^{4,5}

Treating T2DM typically often requires multiple medications, and medication adherence has been associated with improved risk factor management, lower hospitalization rates, lower total health care costs, and improved longevity.^{6–11} However, many individuals with T2DM lack tools for and knowledge about self-management of their diabetes and medications, resulting in suboptimal medication management. Diabetes remote monitoring (DRM) programs have proliferated and been implemented at scale as mobile health technologies have evolved over the past decade to address these gaps in self-management for people with diabetes.¹² DRM programs have reported glycemic improvements; however, outcomes vary by program, age, and sex.^{13–16} Evidence is increasing regarding the effect of DRM programs on medication adherence¹⁷; however, the effect of remote monitoring and mobile health technologies on adherence has been mixed, with some trials showing improvements in adherence, while others have not found statistically significant improvements.^{18,19} Most studies have been conducted among small samples of patients using different technologies and often with adherence estimated using self-reported questionnaires.

We are unaware of previously published studies in a large population of people with T2DM to examine the influence of these technologies on oral antidiabetic drug (OAD) medication adherence using pharmacy claims data. As a result,

we sought to examine the association between participation in a DRM digital health service—which incorporated a cellular connected glucometer, free strips and supplies, a smartphone application, and access to virtual sessions with certified diabetes educators (CDEs)—and medication adherence.

Methods

STUDY DESIGN AND SAMPLE

This study was a retrospective, propensity score-matched cohort study that used deidentified member enrollment and pharmacy administrative claims from a large national pharmacy benefit manager for 2014–2019. Inclusion was limited to commercially insured adults and retirees aged 18 years or older as of their index dates during which they were included in the study. Members enrolled in the DRM program who submitted at least 1 blood glucose (BG) check between April 13, 2015, and March 31, 2018, were included in the study. The date of the first BG check reported was defined as the index date, and the index period was defined as a 90-day period from the index date.

Members were included if they filled 2 or more 30-day adjusted OAD prescription claims in the index period (herein referred to as people with diabetes or participants). The diabetes therapy classes included in this study were metformin, sulfonylureas, thiazolidinediones, meglitinides, alpha-glucosidase inhibitors, dipeptidyl peptidase-4 inhibitors, and sodium glucose co-transporter inhibitors. Participants who were not continuously enrolled in their health plans for a period of 180 days before and 365 days after the index date, and those who filled only insulin or noninsulin injectable drug claims were excluded from the study. The 180-day pre-index period was referred to as the lookback index period, and the 365-day period was the measurement period (Figure 1).

Members enrolled in commercial insurance plans contracted to receive DRM services who had a confirmed diagnosis of T2DM were offered the opportunity to opt into the program. All participants in the DRM program received a 2-way cellular connected glucometer with unlimited strips and testing supplies, a smartphone application (iOS and Android) that provided information on the results of BG checks, and health literacy information related to T2DM. This diabetes-related content was accredited by the American Diabetes Association and the Association of Diabetes Care and Education Specialists (ADCES), and participants had access to unlimited virtual live coaching by CDEs who had clinical backgrounds as nutritionists, dietitians, or exercise therapist/physiologists. Specific program

FIGURE 1 Study Timeline

OAD=oral antidiabetic drug; Rx=prescription claim.

aspects built on the ADCES 7 Self Care behaviors practice guidelines to promote medication adherence were included and accredited by ADCES in the DRM program.⁸

The comparison group included commercially insured adults and retirees who were enrolled in a health plan that did not implement any DRM program through the pharmacy benefit manager. An 8:1 propensity score matching was conducted to match the DRM enrollees with the comparison group members on demographic variables (age, sex, and geographic region). The matched comparison group members were then assigned the index date of the DRM enrollees they matched to, and further inclusion and exclusion criteria were applied. The final sample of comparison group members with 2 or more 30-day adjusted OAD prescription claims in the index period and continuous eligibility were then matched once again to the DRM enrollees on all covariates listed in the next section using a 2:1 propensity score-matching approach.

STUDY VARIABLES

Medication adherence, measured as proportion of days covered (PDC), was the outcome of interest. PDC measures the proportion of the study duration during which patients had their OADs on hand. PDC was calculated as both continuous and binary measures, where a PDC of less than 80% was considered suboptimal (reference variable), and patients with PDC of 80% or more were considered adherent.

The covariates examined in this study were age (in years) as of index date, sex (women [reference variable], men),

region, previous medication adherence, disease burden proxy score, total pharmacy out-of-pocket costs, number of OAD classes filled during the index period, and number of insulin drugs filled during the study period. The region variable was based on the geographic census regions of Northeast (reference variable), Midwest, South, and West.

Previous medication adherence was the PDC for each patient in the study calculated over the 180-day lookback period. This variable was included in our analyses to account for previous adherence behavior effect, since past behavior is a good marker for predicting future behavior.²⁰

Patient overall disease burden was a proxy calculated from prescription claims data and was defined as the number of unique 2-digit Generic Product Identifiers indicating drug therapy classes used by the patient. Number of index OAD classes and number of insulin medications were included to account for differential severity of diabetes between the 2 study groups.

ANALYSIS

Bivariate comparison of outcomes in the propensity score-matched study groups was conducted using the t-test (continuous variables) and McNemar's test (categorical variables). Differences in continuous PDC were analyzed using multivariable linear regression, while multivariable logistic regression was used for the binary PDC measure to estimate the odds of being adherent. SAS version 9.4 was used for data processing and analyses (SAS Institute).

FIGURE 2 Sample Selection

DRM=diabetes remote monitoring; OAD=oral antidiabetic drug; Rx=prescription.

SENSITIVITY ANALYSIS

We conducted 3 sets of analyses among patients with varying levels of engagement with the DRM program. Adherence was examined among DRM patients who were continuously engaged with the DRM program for at least 3 months, at least 6 months, and at least 12 months. Continuous engagement was defined as reporting at least 1 BG reading per week during all weeks in the month. The hypothesis was that longer engagement with the DRM program would be associated with stronger associations with increase in medication adherence.

Results

A total of 16,818 DRM enrollees and over 76 million members in the comparison group were examined for inclusion in this analysis. The final 2:1 propensity score-matched sample included 6,002 DRM participants who

reported at least 1 BG check during the study period and 12,004 non-DRM participants (Figure 2). The demographic and health characteristics of the study groups are displayed in Table 1. After propensity score matching, the 2 study groups did not have any statistically significant differences for these characteristics. Average age of the study sample was over 54 years, and more than 57% of patients in each group were women.

Participants were mostly prevalent users of OADs (≥1 OAD claim in lookback period), and about 40% of patients in both groups were from the South. Average disease burden proxy score was over 6.6 and previous adherence of 60.7%, while both groups of participants had more than \$770 on average in total out-of-pocket pharmacy costs in the lookback period. They filled 1.59 OAD classes during the index period, and about 1 insulin drug during the study period.

Table 2 displays the bivariate analysis results. Average adherence in the measurement period was higher by nearly 5% for DRM participants compared with non-DRM participants (85.11% vs 80.69%, $P<0.001$). A difference of 6.1% between DRM and non-DRM groups was observed when examining the proportion of participants who were adherent ($PDC\geq 80\%$). While 73.8% of people with diabetes were adherent in the DRM group, only 67.7% were adherent in the non-DRM group ($P<0.001$).

Multivariable regression analyses results are displayed in Table 3. After adjusting for all demographic and health characteristics, average adherence was higher by 4.5% among the DRM group compared with the non-DRM group ($P<0.001$). When examining the likelihood of being adherent, the DRM group was found to have 42% higher odds of being adherent to OADs after participating in the DRM program compared with the matched non-DRM counterparts over the same time period (odds ratio=1.42, 95% CI=1.32-1.53; $P<0.001$).

Our sensitivity analyses indicated that participants engaged for longer periods in the DRM program had higher improvements in adherence ([Supplementary Figure 1](#), available in online article). We examined adherence among a subset of DRM participants who were enrolled continuously for at least 3 months ($n=4,246$), at least 6 months ($n=2,632$), and at least 12 months ($n=1,019$). The adherence was compared with their 2:1 propensity score-matched non-DRM group participants. Participants engaged continuously for at least 3, at least 6, and at least 12 months in the DRM program had 5.0%, 5.2%, and 6.4% higher adherence, respectively, compared with matched non-DRM participants. Similarly, the odds of being adherent were 52%, 64%, and

TABLE 1 Demographic and Health Characteristics of Study Sample

Characteristics	DRM group (n=6,002)		Non-DRM group (n=12,004)		P value ^a
	n or mean	% or SD	n or mean	% or SD	
Age (in years)	54.17	8.83	54.43	9.10	0.070
Sex					
Women	3,450	57.48	6,932	57.75	0.733
Men	2,552	42.52	5,072	42.25	
New user					
No	5,634	93.87	11,265	93.84	0.948
Yes	368	6.13	739	6.16	
Disease burden proxy	6.65	4.12	6.75	4.15	0.128
Region					
Northeast	987	16.44	2,052	17.09	0.541
Midwest	1,970	32.82	3,853	32.1	
South	2,408	40.12	4,784	39.85	
West	637	10.61	1,315	10.95	
Patient OOP cost	\$793.00	\$959.20	\$771.50	\$1,067.70	0.187
Previous adherence	60.66	29.35	60.90	29.28	0.600
Index drug classes, n	1.59	0.74	1.59	0.76	0.733
Insulins, n	1.21	2.82	1.20	3.32	0.783

^aA P value of <0.05 indicated that differences between DRM and non-DRM participants were statistically significant.

DRM=diabetes remote monitoring; OOP=out of pocket.

TABLE 2 Bivariate Analysis of Unadjusted Medication Adherence Outcomes

Characteristics	Groups	DRM group (n=6,002)		Non-DRM group (n=12,004)		P value ^a
		n or mean	% or SD	n or mean	% or SD	
PDC, %		85.11	20.66	80.69	24.27	<0.001
Adherent ^b	No	1,575	26.24	3,883	32.35	<0.001
	Yes	4,427	73.76	8,121	67.65	

^aP value of <0.05 indicated that differences between DRM and non-DRM groups were statistically significant.

^bPeople with diabetes were considered adherent if they had an average PDC of 80% or higher.

DRM=diabetes remote monitoring; PDC=proportion of days covered.

almost twice higher for the DRM group engaged continuously for at least 3, at least 6, and at least 12 months, respectively, compared with

the matched non-DRM counterparts. All of these differences were statistically significant between both groups ($P<0.001$).

Discussion

To our knowledge, our findings represent the largest, real-world study of the effect that an integrated DRM has on improving medication adherence at 12 months. We found that, compared with a control group of matched individuals, those who enrolled in DRM had 4.5% higher adherence, with 42% higher odds of adherence to OADs in a period of 1 year after engagement. Longer engagement in the program led to higher adherence rates, suggesting a time dependent positive response to the DRM program as it relates to medication use. These findings suggest that a digital solution that offers a cellular connected glucometer, free strips and testing supplies, access to diabetes content through a smartphone application, and access to CDEs may also improve patient medication-taking behavior, beyond the direct effect on BG.

The World Health Organization notes that increasing adherence may have a greater effect on health than improvements in specific medical therapy.⁹ With about 37% of commercially insured people with diabetes being nonadherent to their medications, nonadherence is a serious challenge to chronic disease management and a driver of significant costs and comorbidity.^{10,21}

The underuse of evidence-based therapies for chronic conditions imposes a substantial clinical and economic burden on patients and health care systems.²²⁻²⁴ For people with T2DM, this lack of adherence has dramatic effects on health and a substantial increase in mortality.²⁵⁻²⁸ Jha et al found that patients with T2DM with improved medication adherence had a 13% reduction in the risk of hospitalization or emergency department (ED) visits, while a 15% increase in hospitalization and ED visits was associated with worsening adherence

TABLE 3 Multivariable Analysis Examining Average Adherence and Odds of Being Adherent Among DRM and Non-DRM Groups^a

Groups	Absolute difference in PDC (%)				Adherent (PDC ≥80%)			
	Beta estimate	95% CI		P value ^b	Odds ratio	95% CI		P value ^b
Non-DRM	–	–	–	–	–	–	–	–
DRM	4.54	3.88	5.19	<0.001	1.42	1.32	1.53	<0.001

^aAll regression analyses were adjusted for age, sex, region, disease burden proxy, new user indicator, previous adherence, total pharmacy costs, number of index diabetes drug classes and number of concomitant insulins.

^bP value of <0.05 indicated that differences between DRM and non-DRM groups were statistically significant.

DRM=diabetes remote monitoring; PDC=proportion of days covered.

over time.²⁹ A systematic review of the economic impact of medication adherence and/or persistence on the overall cost of T2DM care found that the average total annual cost per patient ranged from \$4,570 to \$17,338, and medication adherence was inversely associated with total health care and hospitalization costs.³⁰

Our study leveraged a multimodal approach to address the multiple barriers that exist. Before enrollment in the DRM program, there was little difference in the PDC rates between non-DRM and DRM participants, and both groups had similar adherence rates at 61%, which is similar to previous estimates.¹⁷ Clients of enrollees in both arms had access to similar utilization management programs and clinical solutions. The intervention group received full and unlimited access to the DRM program. At the end of 12 months, there was a clinically meaningful and statistically significant additional increase in medication adherence in those individuals engaged in the DRM program.

The multimodal aspect of the DRM program to assist individuals with medication rituals and reminders probably contributed to the observed improvement in adherence relative to the non-DRM cohort. In addition, providing free strips as part of the DRM program (where after 90 strips, most coverage plans require individuals

to pay out of pocket for additional strip refills within 90 days) could have served to offset financial barriers to paying for oral diabetes medications.³¹

The longitudinal nature and need for continuous monitoring in chronic disease management with concomitant reductions in the costs of technology and sensors has accelerated developments in telehealth and remote monitoring. Many of these innovations are starting to demonstrate the ability to improve clinical outcomes and reduce costs; however, the effect on medication adherence has been mixed.^{18,32,33} Studies have shown the positive effect of virtual health tools such as text messaging and telephonic support for medication adherence in diabetes, but there have not been high quality studies with suitable concurrent controls to examine how other technologies improve medication adherence.¹⁸ This limited observed efficacy may reflect the fact that many interventions do not adequately address each individual's unique barriers to adherence and/or only do so at a single point in time.³⁴

In addition, among those interventions demonstrating success, many have not been widely adopted because of the substantial human resources required to sustain them.³⁵ Choudhry et al conducted a cluster randomized trial of a multicomponent intervention to improve medication adherence

in individuals with hypertension, diabetes, and hyperlipidemia.¹⁷ Their program randomized patients to a multicomponent intervention using telephone-delivered behavioral interviewing by trained clinical pharmacists, text messaging, pillboxes, and mailed progress reports and found that the intervention group improved PDC by 4.7% at 12 months compared with usual care.¹⁷ Our results in the DRM group compared with the control group resulted in similar findings despite differences in the approach, suggesting that multicomponent interventions that address different barriers are required to provide meaningful improvements in medication adherence rates in people with diabetes.

LIMITATIONS

Our study has some limitations. The retrospective study design examined associations and not established causality. Also, given the opt-in nature of the DRM program, more motivated and healthier individuals could have introduced selection bias into the DRM group. However, through propensity matching, balancing the analysis of the endpoints of interest and the observation that both groups had similar trajectories of improvement in PDC at 12 months, we reduced the influence of this bias in our reported results.

We did not include injectables or

insulin in our analysis of medication adherence given the difficulty using claims data to monitor adherence and the dispensing nature and variable administration that is often required in patients self-managing their diabetes medications. Moreover, claims-based adherence estimation is not able to verify that patients have consumed their medications as prescribed. However, this method is widely used and accepted as a measure for adherence in health services research.

Our findings are important and provide timely evidence on the effect of a DRM program, given the proliferation of these solutions and the wider adoption and implementation of digital health technologies by payers and providers. They also highlight the need for ensuring longer engagement on an ongoing basis for achieving greater improvements in outcomes such as medication adherence.

Conclusions

Our study shows that engagement in a scalable, multicomponent DRM program is associated with clinically meaningful improvements in medication adherence in T2DM using oral diabetes medications. Future studies should examine the relationship of the DRM program's medication adherence improvement to clinical outcomes and cost reductions.

DISCLOSURES

Funding for this study was provided by Express Scripts. Munshi, Amelung, Carter, and Henderson are employed by Express Scripts. James and Shah are employed by Livongo, which provided the DRM solution.

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