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Remote glucose monitoring and HbA1c improvement among persons with newly diagnosed diabetes mellitus type 2: A multi-center community-based study

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ABSTRACT

Aims: Remote monitoring can support patients with Type II diabetes. Still, evidence for improved glucose outcomes in broad community practice patients is extremely limited. We examined remote glucose monitoring in newly diagnosed patients with diabetes to identify its impact on diabetes outcomes.
Methods: In a retrospective cohort study of all adults (age 18–75) with newly diagnosed Type II diabetes February 2020–December 2021 in a large integrated health system, we compared HbA1c (units: percentage, %) outcomes in remote monitoring users to non-users in their first year with diabetes, using propensity-weighted analyses.
Results: Among 35,958 patients, patients age 45+ (vs. age 18–34), who were Asian/Pacific Islander or Hispanic (compared to White), living in more deprived neighborhoods, not using the patient portal, or with baseline HbA1c ≤ 8 were significantly ($p < 0.001$) less likely to use remote glucose monitoring. After adjustment, remote monitoring use was associated with a 23 % (95 % CI: 17–29 %) higher rate of reaching the HbA1c ≤ 8 % (vs. non-users). In patients starting with HbA1c > 8, remote glucose monitoring use was associated with 0.93 % greater absolute improvement in HbA1c value (vs. non-users, $p < 0.05$).
Conclusions: Remote glucose monitoring was associated with improved HbA1c among newly diagnosed patients with Type II diabetes.

1. Introduction

The number of patients with Diabetes Mellitus (DM) has been rising globally, along with Diabetes related mortality [1]. DM management is labor intensive for clinical care teams and patients. This, along with health care interruptions during the COVID-19 pandemic, has led DM control to suffer [2,3], requiring clinicians and health care systems to explore new frontiers in management. Virtual care, particularly remote monitoring, has clear potential to offer both patients and clinicians a way to collect and analyze detailed patient health measures and to use these data together to support patient engagement and clinical interventions [4,5].

Without digital remote glucose monitoring, conventional diabetes glucose self-monitoring requires cumbersome patient self-tracking of blood sugars, often multiple times a day, on log sheets. Then, the data is relayed to their providers either verbatim, by sending pictures or transcribing the readings into a message. A small number of prior studies have suggested that remote glucose monitoring may be associated with great HbA1c control; however these studies have had small or biased, non-community-based samples or lacked comparison groups for assessing remote glucose-monitoring's impact on outcomes [6–8]. There are currently no studies that rigorously assess the association between remote glucose monitoring and patient outcomes among a diverse set of patients in real-world clinical settings.

To evaluate real-world remote glucose monitoring use and outcomes in clinical care for patients with diabetes, we examined a large integrated delivery system offering remote glucose monitoring in patients newly diagnosed with DM during the COVID-19 pandemic. We compared patients enrolled in the remote glucose monitoring program with those not using remote glucose monitoring, with propensity weighting to balance these groups based on a wide set of clinical and socio-demographic characteristics. We examined patient characteristics associated with remote glucose monitoring use and studied clinical benefits using HbA1c measures. We hypothesized that remote glucose

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monitoring use would differ by patient characteristics and would be associated with lower HbA1c levels.

2. Methods

2.1. Setting

This study was conducted within Kaiser Permanente Northern California, an integrated health care system with 21 inpatient and outpatient medical centers providing comprehensive medical services to more than 40% of insured Californians in the geographical area. The patient population is racially and ethnically diverse, and represents the demographics of the Northern California population, except at the extremes of income [9].

At KPNC, DM management uses a team-based approach led by physicians in partnership with clinical pharmacists. Clinical pharmacists independently follow guideline driven protocols to manage patient's long term. All patients with newly diagnosed diabetes were eligible for enrollment in the remote glucose monitoring program, with referral from their diabetes care manager or any physician. Once invited to enroll, patients needed to download the remote glucose monitoring smartphone application, create an account, and sync their glucometer.

Table 1
Baseline characteristics of patients with new diabetes, by users and non-users of remote glucose monitoring.

Characteristic	Overall	Remote glucose monitoring user	Non-user	p-value[b]
	N = 35,958[a]	N = 1,928[a]	N = 34,030[a]	
Age at diagnosis (years)				<0.001
18-34	2004 (5.6 %)	211 (10.9 %)	1793 (5.3 %)	
35-44	4939 (13.7 %)	449 (23.3 %)	4490 (13.2 %)	
45-54	9289 (25.8 %)	588 (30.5 %)	8701 (25.6 %)	
55-64	11,388 (31.7 %)	491 (25.5 %)	10,897 (32.0 %)	
65-75	8338 (23.2 %)	189 (9.8 %)	8149 (23.9 %)	
Biological sex				0.2
Male	19,710 (54.8 %)	1086 (56.3 %)	18,624 (54.7 %)	
Female	16,245 (45.2 %)	842 (43.7 %)	15,403 (45.3 %)	
Race/ethnicity				<0.001
White	11,279 (31.4 %)	709 (36.8 %)	10,570 (31.1 %)	
Hispanic	9840 (27.4 %)	481 (24.9 %)	9359 (27.5 %)	
Black	3475 (9.7 %)	197 (10.2 %)	3278 (9.6 %)	
Asian/Pacific Islander	9546 (26.5 %)	449 (23.3 %)	9097 (26.7 %)	
Other	1,818 (5.1 %)	92 (4.8 %)	1726 (5.1 %)	
Limited English proficiency	2,950 (8.2 %)	43 (2.2 %)	2907 (8.5 %)	<0.001
Neighborhood deprivation index				<0.001
Q1(low deprivation)	5891 (16.4 %)	398 (20.6 %)	5493 (16.1 %)	
Q2	9653 (26.8 %)	558 (28.9 %)	9095 (26.7 %)	
Q3	10,423 (29.0 %)	548 (28.4 %)	9875 (29.0 %)	
Q4(high deprivation)	9991 (27.8 %)	424 (22.0 %)	9567 (28.1 %)	
Low neighborhood internet access	8475 (23.6 %)	417 (21.6 %)	8058 (23.7 %)	0.024
Portal use in prior year	31,307 (87.1 %)	1879 (97.5 %)	29,428 (86.5 %)	<0.001
Care manager: high remote glucose monitoring use	26,841 (74.6 %)	1521 (78.9 %)	25,320 (74.4 %)	<0.001
Baseline BMI				<0.001
Not obese	14,194 (39.5 %)	527 (27.3 %)	13,667 (40.2 %)	
Obese	20,996 (58.4 %)	1363 (70.7 %)	19,633 (57.7 %)	
Insulin				<0.001
No Insulin Use	34,361 (95.6 %)	1713 (88.8 %)	32,648 (95.9 %)	
Used Insulin	1597 (4.4 %)	215 (11.2 %)		

[a] n (%).
[b] Pearson's Chi-squared test.

2.2. Study design, data, population

We conducted a retrospective cohort study of all newly diagnosed adults (age 18–75) with Type II diabetes, who newly entered the clinical diabetes registry (also used for quality reporting) [10] between February 1, 2020 (the first month that the user administrative data was available) to December 31, 2021, comparing remote glucose monitoring users with patients not using remote glucose monitoring. Since the diabetes registry is generated from automated clinical and quality-driven criteria, we classified a patient as newly diagnosed at the timing that they first entered the registry. Each patient's study period lasted for one year after newly entering the clinical diabetes registry (index date).

Study data was derived from KPNC's comprehensive Electronic Health Record (EHR) system (including inpatient, outpatient, pharmacy, lab etc.), research virtual data warehouse, and The Permanente Medical Group's Clinical Diabetes Registry. To capture clinical characteristics at baseline, we excluded patients who were not continuously enrolled in the health plan for 12 months before their diabetes diagnosis. Additionally, we excluded pregnant individuals, and those with End Stage Renal Disease (ESRD) during the 365 days preceding the diagnosis.

The Institutional Review Board of the The Institutional Review Board of the Kaiser Foundation Research Institute approved the study protocol and materials and waived the requirement for written informed consent for participants. This cohort study followed the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) reporting guideline.

2.3. Exposure and outcomes

We defined patients as remote glucose monitoring users if they completed at least 2 device uploads within 90 days of enrollment in the diabetes registry.

The primary study outcome was HbA1c (%), measured starting at least 90 days after their initial remote glucose monitoring enrollment and exposure. The post-intervention HbA1c outcome was determined by calculating the average of all the HbA1c measurements obtained throughout the 6-month follow-up period. HbA1c was categorized as >8 mmol/l vs. ≤ 8 mmol/l) [11].

As a secondary outcome, we also examined Body Mass Index (BMI), measured throughout the same follow-up period. If multiple BMI measures were available during the follow up period, the mean BMI was used as the study outcome. BMI was categorized as "not obese" if less than 30 kg/m^2, and "obese" if 30 kg/m^2 or higher, based on Centers for Disease Control and Prevention (CDC) guidelines.

2.4. Covariates

For each patient, we defined their baseline covariates and HbA1c based on the 12 months prior to entering the clinical diabetes registry. We extracted patient socio-demographic and clinical covariates including socio-demographics (age, sex, self-reported race, self-reported

Table 2
Unadjusted baseline (pre-intervention) and outcome (post-intervention) HbA1c, by users and non-users of remote glucose monitoring.

Characteristic	Overall	Remote glucose monitoring user	Non-user	p-value[b]
	N = 35,958[a]	N = 1,928[a]	N = 34,030[a]	
Baseline: Overall HbA1c, %	7.1 (6.5, 9.2)	10.0 (7.7, 11.6)	7.0 (6.5, 8.8)	<0.001
Baseline: HbA1c subgroup, N (%)				<0.001
≤8	20,947 (58.3 %)	537 (27.9 %)	20,410 (60.0 %)	
>8	10,262 (28.5 %)	1330 (69.0 %)	8932 (26.2 %)	
Missing	4749 (13.2 %)	61 (3.2 %)	4688 (13.8 %)	
Outcome: Overall Post-intervention HbA1c, %	6.7 (6.2, 7.4)	6.5(6.0, 7.1)	6.7 (6.2, 7.4)	<0.001
Outcome: Post-intervention HbA1c, N (%)				<0.001
≤8	22,581 (62.7 %)	1428 (74.0 %)	21,153 (62.1 %)	
>8	4149 (11.5 %)	138 (7.1 %)	4011 (11.8 %)	
Missing	9228 (25.8 %)	362 (18.9 %)	8866 (26.1 %)	

[a] Median (IQR); n (%).
[b] Wilcoxon rank sum test; Pearson's Chi-squared test.

English-language proficiency, Neighborhood deprivation index [NDI]), technology access and use (Neighborhood internet access, KP portal use [any login within 1 year prior to index date]), clinical characteristics (Charlson comorbidity score, baseline HbA1c,baseline BMI, and baseline insulin use) and their diabetes care manager's overall rate of using remote glucose monitoring in their own managed patients. English language proficiency was determined using self-reported need for an interpreter. Neighborhood internet access was defined using US Census's American Community Survey data on the types of computers and internet subscriptions, linked to the geocoded residential addresses of the participants (US Census, 2020) [12]. NDI quartiles were calculated based on the KPNC population, NDI is a composite measure of neighborhood characteristics such as poverty and unemployment [13].

Baseline HbA1c (units: percentage, %) and BMI (categorized as <30 kg/m^2 vs ≥ 30 kg/m^2) were defined using the most recent measurement within 365 days prior to the index date. Since patients in the diabetes clinical registry are also managed by a chronic care manager, who may encourage patients to use remote glucose monitoring, we defined participants as being managed by a care manager with higher overall use of remote glucose monitoring (highest quartile) vs. lower care manager use of remote glucose monitoring in their full set of patients managed.

2.5. Statistical analysis

To investigate the association between patient characteristics and exposure to remote glucose monitoring, we utilized Generalized Estimating Equations (GEE) with a log link function and robust standard errors. The hierarchical model accounted for the clustering effect of medical facilities. The model included the following covariates: age, sex, race, baseline HbA1c, baseline BMI, insulin use, English proficiency, NDI, Neighborhood internet access, portal use in prior year, Charlson comorbidity score, and care manager use of remote glucose monitoring.

To address baseline imbalances between the exposed and unexposed groups, we developed a propensity score weighting model by fitting a generalized linear mixed effects model with enrollment status as the outcome variable. Covariate adjustments were made for age, sex, race, baseline HbA1c, baseline BMI, insulin use English proficiency, NDI, neighborhood internet access, portal use in prior year, Charlson comorbidity score, and Care manager use of remote glucose monitoring.

To evaluate the association between remote glucose monitoring intervention and post-intervention HbA1c outcome or post-intervention BMI, we used separate propensity-weighted models. We also explored statistical interactions between patients' baseline HbA1c levels (>8% or ≤8%) and the remote glucose monitoring intervention on the primary outcome using a weighted GEE model with interaction term [10]. Covariates chosen for inclusion both in the propensity score and analytic models were based on clinical importance and previously published evidence. Based on model results, we calculated the adjusted percentage of remote glucose monitoring use across all subgroups using marginal standardization.

3. Results

We identified 35,958 total eligible patients newly diagnosed with type 2 diabetes for the study sample, comprised of 1928 individuals in the remote glucose monitoring user intervention group and 34,030 individuals in the non-user comparison group. The distribution of baseline sociodemographic characteristics by intervention status is presented in Table 1. Among all patients, 26,730 patients had post-intervention HbA1c measurements, and 22,689 patients had post-intervention BMI measurements. Table 2 presents the baseline and post-intervention clinical characteristics of the cohort.

3.1. Patient characteristics associated with remote monitoring use

After multivariate adjustment, patients age over age 45 were statistically significantly less likely to enroll in remote glucose monitoring than patients age 18–35 (age 45–54 33 % less likely, RR = 0.67, 95 % CI: 0.56–0.79; age 55–64 51 % less likely, RR = 0.49, 95 % CI: 0.41–0.59; age 65–75 68 % less likely, RR = 0.32, 95 % CI: 0.26–0.40; Fig. 1). We did not find statistically significant differences in remote monitoring use by sex. Patients with Asian/Pacific Islander race/ethnicity (21 % less likely, RR = 0.79, 95 % CI: 0.70–0.90) and patients with Hispanic race/ethnicity (37 % less likely, RR = 0.63, 95 %, CI: 0.56–0.72) were statistically significantly less likely to enroll in remote glucose monitoring than White patients. The participants who reported needing a language interpreter were 65 % less likely to enroll in remote glucose monitoring than those who needed an interpreter (RR = 0.35, 95 % CI: 0.25–0.49).

After adjustment, patients living in neighborhoods with lower socioeconomic status were less likely to use remote glucose monitoring. For example, patients living in the neighborhoods with the highest quartile of deprivation were 43 % (RR = 0.57, 95 % CI: 0.49–0.67) less likely to enroll in remote glucose monitoring than patients in the least deprived neighborhoods. We did not observe differences by neighborhood internet access. Active patient portal users were 447 % (RR = 5.47, 95 % CI: 3.92–7.63) more likely to enroll in remote glucose monitoring than non-users.

Adjusting for all patient characteristics, patients with baseline HbA1c > 8 were 343 % (RR = 4.43, 95 % CI: 3.96–4.96) more likely to enroll in remote glucose monitoring than those who started with HbA1c ≤ 8. Those who were obese were 53 % (RR = 1.53, 95 % CI: 1.38–1.69) more likely to enroll in remote glucose monitoring than those who were not obese.

3.2. Association between remote monitoring use and HbA1c outcomes

After adjustment, 81.4 % of remote glucose monitoring users achieved a HbA1c ≤ 8 outcome, compared to 66.4 % of non-users. Remote glucose monitoring use was associated with an overall 23 % (RR = 1.23, 95 % CI: 1.17–1.29) higher rate of reaching the HbA1c ≤ 8 outcome, compared to non-remote glucose monitoring users (Fig. 2). When stratifying by patients' baseline HbA1c levels, in patients who started with baseline HbA1c > 8, remote glucose monitoring use was associated

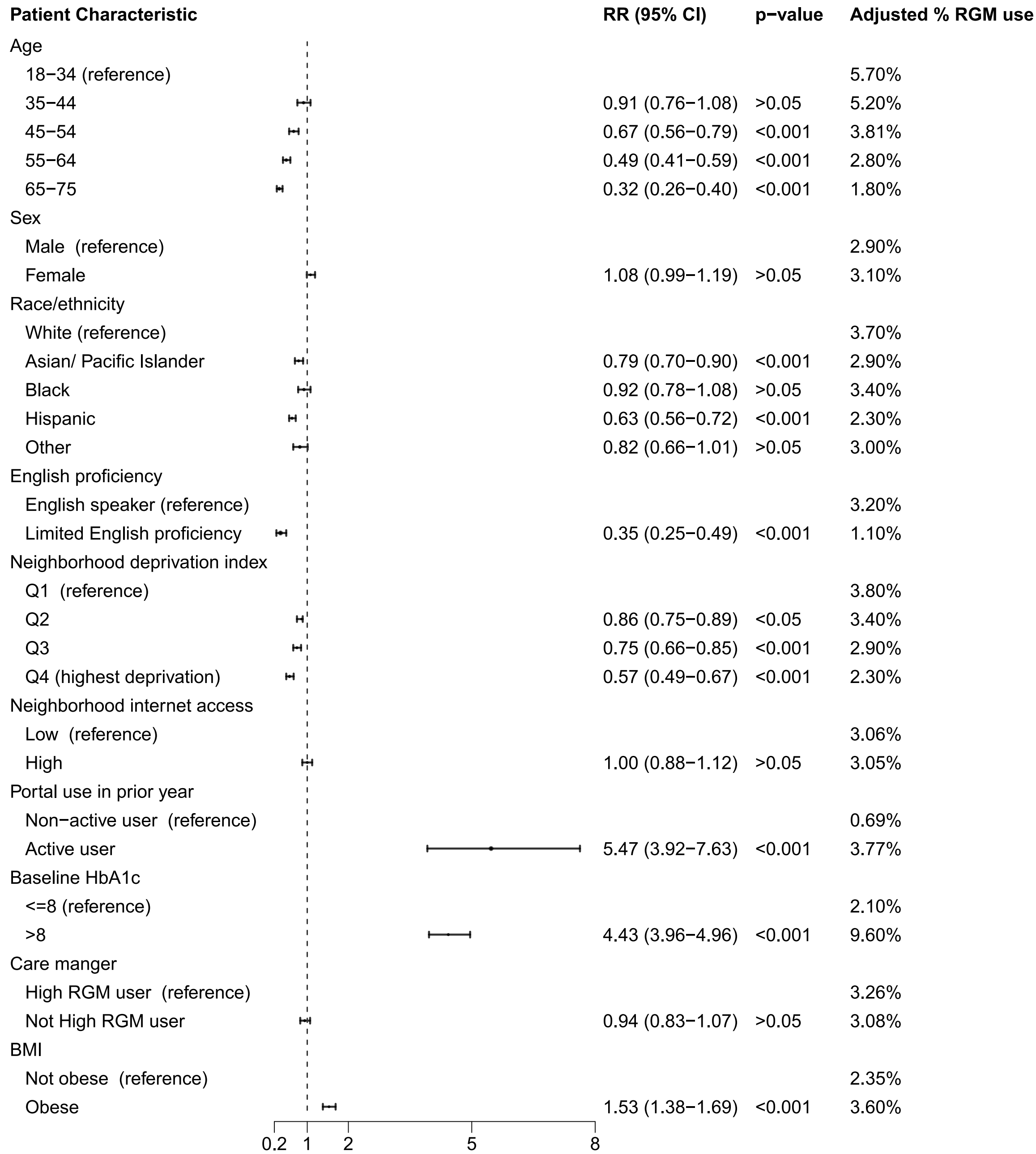

Fig. 1. Adjusted association between patient characteristics and remote glucose monitoring (RGM) use (N = 35,958).

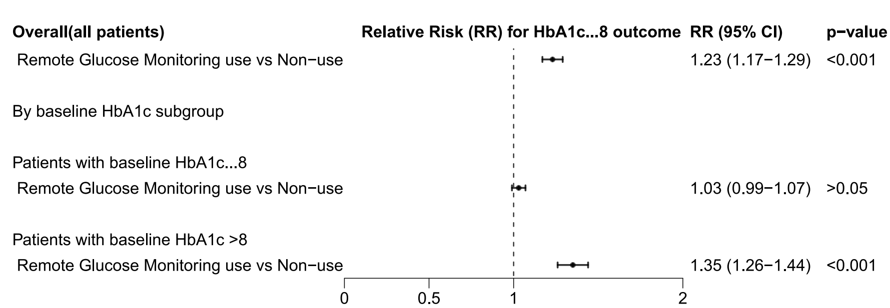

Fig. 2. Adjusted association between Remote Glucose Monitoring use and HbA1c … 8 outcome, by baseline HbA1c (N = 26,730).

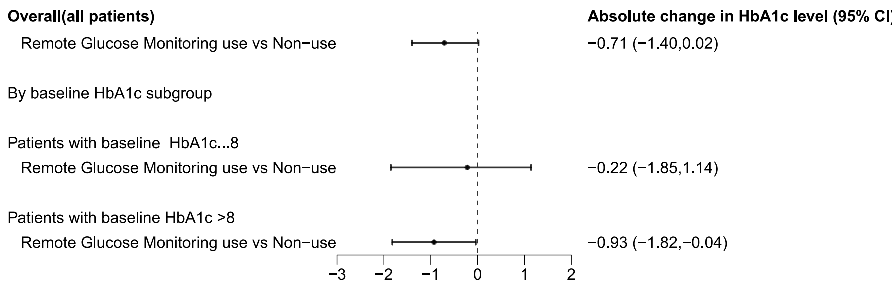

Fig. 3. Adjusted association between Remote Glucose Monitoring use and HbA1c as continuous outcome, by baseline HbA1c (N = 26,730).

with even greater likelihood of reaching an outcome of HbA1c ≤ 8 (remote glucose monitoring RR = 1.35, 95%CI: 1.26–1.44), compared with remote glucose monitoring use in those who started with baseline HbA1c already ≤8 (remote glucose monitoring RR = 1.03, RR = 1.03, 95 % CI: 0.99–1.07).

When examining the absolute HbA1c values as an outcome, patients with HbA1c> 8 at baseline and using remote monitoring had 0.93 % greater absolute reduction in HbA1c value (95 % CI: 0.04–1.82 reduction in HbA1c value) than patients who did not use remote glucose monitoring (Fig. 3). We found no evidence of an association between the use of remote glucose monitoring and BMI (RR = 1.00, 95 % CI: 0.97–1.02).

4. Discussion

In real-world clinical use of remote glucose monitoring in a large, diverse, community-based population of patients newly diagnosed with type 2 diabetes, patients starting with a baseline HbA1c >8% had an absolute 0.93% greater improvement in their HBA1c value improvement compared to non-users, with improvements that did not reach statistical significance in in patients with lower HbA1c at baseline. Remote glucose monitoring use was associated with younger age, White race/ethnicity, English language proficiency, active patient portal use history, and higher baseline HbA1c values. These findings support the potential clinical utility of remote glucose monitoring in patients with newly diagnosed diabetes, with potential to improve reach of the intervention across patient groups.

The current study substantially extends prior evaluations of remote glucose monitoring and improvements in HbA1c, which were mostly in small or in highly selected populations. For example, a randomized trial of less than 80 patients found remote patient monitoring was associated with larger HbA1c improvements and weight loss [7]. Another trial in 90 patients showed remote monitoring combined with coaching reduced the gap in HbA1c between black and white patients, though substantial disparities remained [8]. An observational study of approximately 900 hospitalized patients found remote glucose monitoring was associated with significant improvement in HbA1c during the 3 months after hospital discharge, with greater improvements in men and those with higher patient activation [6]. The current study is, to our knowledge, the first to examine an extremely large, demographically diverse, community-based population of newly diagnosed patients with diabetes using remote patient monitoring within a primary care chronic conditions management program. We extend the prior evidence in identifying remote glucose monitoring associated HbA1c improvements over 6 months in a broad community population of patients with diabetes.

The study-identified remote glucose monitoring-associated HbA1c outcomes may be attributed to increased engagement by remote glucose monitoring users with their primary care teams. Patients using remote glucose monitors could view their own blood glucose data trends on the smartphone application and no longer needed to keep tedious blood sugar logs. Anecdotally, this supported more effective and efficient interactions between these patients and their diabetes care teams, including clinical pharmacists who support diabetes care alongside primary care providers. This is a low cost, high yield intervention that supports engagement between the patients and their care team. Still, non-English speakers, and patients with Asian or Hispanic race/ethnicity were less likely to enroll. Further operational work is ongoing in the study setting to improve outreach to close these care gaps and increase the consistent offering of remote glucose monitors to all eligible patients.

A strength of our study is the community primary care setting with a large sample of study enrollees spanning over a large geographic setting with diverse race/ethnicities, ages, neighborhood deprivation indexes and language preferences. The robust electronic health record-derived study data allowed for identification of additional characteristics like BMI, use of Insulin, and baseline HbA1c's. As such, the findings may not necessarily generalize well to other clinical settings, particularly settings without well-developed diabetes population management programs. Even in the study setting, the remote glucose monitoring program did have initial technical challenges in implementation which may have limited potential enrollment or continued engagement. Given this is an observational, retrospective study there could be unknown underlying confounders, including in variation in the workflow for offering patients remote glucose monitoring enrollment, or in oral diabetes medication use rates. Reassuringly, however, patients' care manager population remote glucose monitoring use rate was not significantly associated with individual patient-level use likelihood. While our study measures a wide range of patient covariates and balanced these differences though propensity score weighting, we cannot rule out unmeasured differences between remote glucose monitoring users and non-users and these observational data should not be interpreted to be causal.

5. Conclusions

Remote patient monitoring in newly diagnosed patients with diabetes was linked to greater HbA1c improvement compared to patients who did not use remote glucose monitoring, with even larger improvements in patients with higher baseline clinical need. Remote monitoring may have particular benefit when used in patients with poor glycemic control/Further outreach and intervention in patient groups with lower remote monitoring adoption, such as those who are older, socioeconomically deprived, or with language barriers, could support increased engagement to further realize remote glucose monitoring benefits.

CRediT authorship contribution statement

Mehreen Khan: Writing – original draft, Funding acquisition, Conceptualization. **Lusine Gigoyan:** Visualization, Validation, Methodology, Formal analysis, Data curation. **Mary Reed:** Writing – review & editing, Supervision, Project administration, Investigation.

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