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Factors associated with persistent poorly controlled diabetes mellitus: Clues to improving management in patients with resistant poor control

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Abstract

Objectives: Patients with persistent poorly controlled diabetes mellitus (PPDM), defined as an uninterrupted hemoglobin A1c >8.0% for ≥1 year despite standard care, are at high risk for complications. Additional research to define patient factors associated with PPDM could suggest barriers to improvement in this group and inform the development of targeted strategies to address these patients' resistant diabetes.

Methods: We analyzed patients with type 2 diabetes from a multi-site randomized trial. We characterized patients with PPDM relative to other patients using detailed survey data and multivariable modeling.

Results: Of 963 patients, 118 (12%) had PPDM, 265 (28%) were intermittently poorly controlled, and 580 (60%) were well-controlled. Patients with PPDM had younger age, earlier diabetes diagnosis, insulin use, higher antihypertensive burden, higher low-density lipoprotein cholesterol, and lower statin use relative to well-controlled patients. Among patients with objective adherence data (Veterans Affairs patients), a larger oral diabetes medication refill gap was associated with PPDM.

Discussion: Strategies are needed to target-specific barriers to improvement among patients whose diabetes is resistant to standard diabetes care. Our data suggest that strategies for targeting PPDM should accommodate younger patients' lifestyles, include medication management for insulin titration and comorbid disease conditions, and address barriers to self-management adherence.

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Introduction

The prevalence of type 2 diabetes is growing and poor glycemic control is a substantial public health problem.[1] Among poorly controlled patients, complications and costs rise as hemoglobin A1c (HbA1c) increases.[2,3] Improving glycemic control reduces diabetes complications,[4] even when improvements are not permanent.[5] Even compared with those with temporary improvements in glycemic control, individuals maintaining a persistently elevated HbA1c over time are at especially high risk for complications.

Many with persistent HbA1c elevations maintain poor control despite standard, clinic-based diabetes management. We have classified patients with a continually above-goal HbA1c despite diabetes care with a Primary Care Provider (PCP) or Endocrinologist as having ''persistent poorly controlled diabetes mellitus'' (PPDM). Because patients with PPDM have ongoing hyperglycemia that increases their risk for complications over time, and because their diabetes is resistant to standard diabetes management, this population is a particularly important target for care innovations.

Many factors at the patient, provider, and system levels likely interact to perpetuate suboptimal control in PPDM. At the patient level, individuals with PPDM may have unique barriers to improvement that help explain their insufficient response to standard care. Better understanding patient factors associated with PPDM could point to common barriers to improvement in this population, and guide the development of effective strategies to target these barriers. While various demographic, socioeconomic, clinical, and psychosocial factors associated with elevated HbA1c are recognized,[1,6–11] these data have two key limitations pertaining to PPDM. First, studies have typically examined HbA1c only cross-sectionally or at two longitudinal time points (e.g. at baseline and 1 year without accounting for interval values), so are not designed to identify those highest risk patients whose poor glycemic control persists uninterrupted. Although one recent study did characterize a cohort with truly persistent HbA1c elevation,[11] it used administrative data and examined a limited number of patient factors. Second, studies have generally not accounted for the diabetes care that poorly controlled patients receive. Individuals whose poor control results from inadequate access to care likely differ significantly from those with PPDM, who have already proven resistant to standard care; studies that fail to distinguish between these populations are therefore not well-designed to characterize patients with PPDM. Given these limitations, additional research exploring factors associated with PPDM is needed in order to better understand possible barriers that perpetuate poor control in the face of standard care.

To address this evidence gap, we used detailed data from a randomized trial conducted within two high-quality health care systems to identify patient factors associated with persistent poorly controlled type 2 diabetes. Because having PPDM by definition suggests resistance to standard care, we also described our cohort's care utilization. By identifying patient factors associated with insufficient response to standard, clinic-based diabetes care, this post-hoc analysis sought to inform strategies to more effectively target possible barriers to improvement in PPDM.

Materials and methods

Adherence and Intensification of Medications Trial

The Adherence and Intensification of Medications (AIM) Trial (NCT00495794, ClinicalTrials.gov) was a prospective, multi-site trial, with cluster randomization of 16 primary care teams at 3 Veterans Affairs (VA) and 2 Kaiser Permanente (KP) medical centers to a 14-month hypertension intervention or usual care.[12] The intervention and randomization process are described in detail elsewhere.[13] Briefly, all patients had type 2 diabetes and poor blood pressure (BP) control. Study exclusion criteria included impaired decision-making (e.g. dementia), pregnancy, and age $\leq$18 or $\geq$100. KP patients were also excluded if they were hospitalized, receiving nursing facility, hospice, or home health care, or had <12 months of an active drug benefit in the past year.

The AIM intervention's goal was to improve BP. Intervention patients achieved earlier lowering of systolic BP than usual care during the study, though usual care achieved equal reduction by 6 months after the intervention period.[12] The AIM intervention did not explicitly address diabetes and had no significant impact on diabetes control. Because the AIM intervention targeted hypertension and not diabetes, all study patients received standard diabetes care through the KP or VA systems.

Definition of patients with PPDM

We chose HbA1c >8.0% as indicating suboptimal control because, even for patients with a history of hypoglycemia, multiple comorbidities, or advanced diabetes complications, the American Diabetes Association recommends targeting an HbA1c below this level for the large majority of patients.[14]

We examined the last pre-enrollment HbA1c and all HbA1cs during the 12-months post-enrollment in order to define patients as "PPDM," "intermittent poorly controlled diabetes mellitus" (IPDM) or "well-controlled" (Figure 1). We defined patients with PPDM as having a last pre-enrollment HbA1c >8.0% and all post-enrollment HbA1c measurements >8.0%. PPDM patients therefore maintained an HbA1c continuously >8.0% for $\geq$1 year despite standard diabetes care. Well-controlled patients had a pre-enrollment HbA1c $\leq$8.0% and all post-enrollment HbA1c measurements $\leq$8.0%, so maintained an HbA1c continuously $\leq$8.0% for $\geq$1 year with standard diabetes care. IPDM patients had HbA1cs neither continuously >nor $\leq$8.0% during the 12-month observation period, so had intermittent poor control despite standard diabetes care, but met neither PPDM nor well-controlled criteria. PPDM status could not be defined for patients with fewer than 2 HbA1cs available during the observation period.

Patient factors evaluated

We analyzed patients completing the baseline AIM trial survey (1151 of 2319 intervention arm patients) and had a determined PPDM status (963 of 1151 patients with survey data). Using all available demographic/socioeconomic, clinical, psychosocial, and health care utilization data, we characterized patients in all three PPDM status groups.

Demographic/socioeconomic factors included age, age at diabetes diagnosis, diabetes duration, sex, race/ethnicity, education level, marital status, income, and study site.

Clinical factors included disease control markers (HbA1c, BP, and low-density lipoprotein cholesterol (LDL-C)), insulin use, BP medication use, statin use, and self-reported general health status. We also included two measures of medication adherence: self-reported medication adherence,

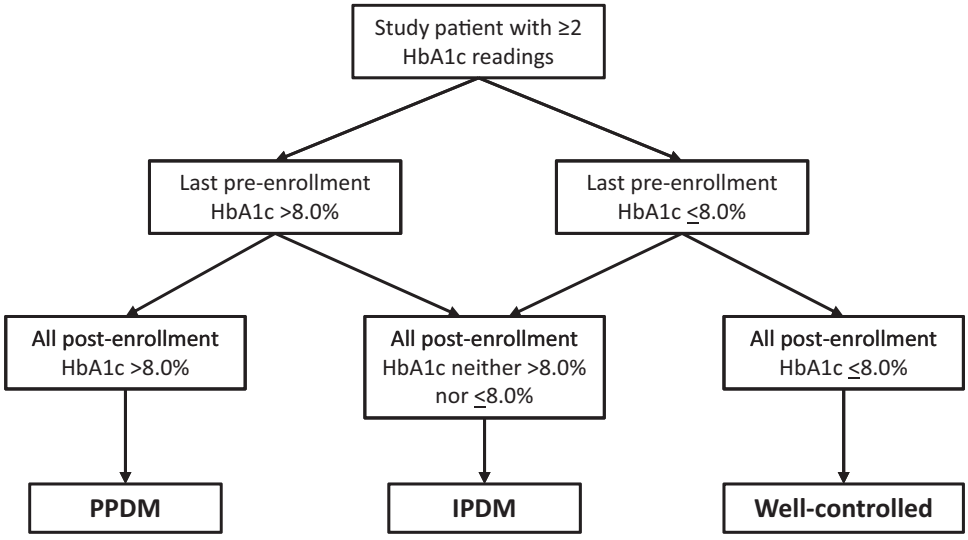

Figure 1. Framework for determining PPDM status for AIM study patients.
HbA1c: hemoglobin A1c; IPDM: intermittent poorly controlled diabetes mellitus; PPDM: persistent poorly controlled diabetes mellitus; AIM: Adherence and Intensification of Medications.

assessed by the Reported Adherence to Medication scale (Table 1);[15] and objectively assessed adherence to oral diabetes and BP medications, measured by refill gaps (refill gaps available for VA patients only).[13]

Available psychosocial data included the Patient Health Questionnaire-2 (PHQ-2) depression screen,[16] Patient Activation Measure-13 for self-management,[17] Perceived Competence Scale for self-efficacy,[18] and components of the patient activation and goal-setting subscales of the Patient Assessment of Chronic Illness Care (PACIC) scale (Table 1).[19] We also included an internally developed Health Care Satisfaction scale and a single-item measure evaluating the extent to which patients feel listened-to by providers.

Available health care utilization information used to characterize our study cohort's standard diabetes care included number of HbA1c values, PCP visits, diabetes-oriented Endocrinology visits (VA patients only), and emergency room (ER) visits.

Statistical analysis

For categorical data, we used chi-square analysis to compare the three PPDM status groups and directly compare the PPDM and well-controlled groups. For normally distributed continuous data, we used analysis of variance to compare means across all groups and a *t*-test to compare means between the PPDM and well-controlled groups. For ordinal data we used the Kruskal–Wallis test to compare means across all groups and the Mann–Whitney test to compare means between the PPDM and well-controlled groups.

We also compared the PPDM and well-controlled groups using multivariable logistic regression. Models included covariates measured at baseline with bivariate

Table 1. Description of relevant patient-reported scales included in baseline AIM survey.

Scale	Description	Reference
Reported Adherence to Medication scale	4-item measure for assessing self-reported medication adherence (final score range 4–20; higher score indicates greater adherence)	Horne and Weinman[15]
Patient Health Questionnaire-2	2-item screening tool to ascertain depressive symptoms (each item scored 0–3; combined score $\geq$3 considered positive)	Arroll et al.[16]
Patient Activation Measure-13	13-item measure for assessing an individual's knowledge, skill, and confidence for managing health and health care (final score transformed to range 0–100; higher score indicates greater knowledge, skills, and confidence)	Hibbard et al.[17]
Perceived Competence Scale	4-item measure for assessment of patient self-efficacy (final score transformed to range 0–100; higher score indicates greater perceived competence)	Williams et al.[18]
Patient Assessment of Chronic Illness Care	5 items from patient activation and goal-setting subscales (final scores for patient activation and goal setting each transformed to 0–100; higher score indicates greater patient activation or collaborative goal setting)	Glasgow et al.[19]
Health care Satisfaction Scale	4-item measure for assessing satisfaction with different domains of health care (final score transformed to range 0–100; higher score indicates greater dissatisfaction)	N/A

AIM: Adherence and Intensification of Medications.

associations with PPDM (vs. well-controlled) to $p < 0.20$. For missing data, multiple imputations were performed on included covariates. We developed two models. The first included all patients categorized as PPDM or well-controlled. The second model included VA patients categorized as either PPDM or well-controlled; this was done specifically to include refill gap data for oral diabetes medications and antihypertensive medications, which were available only for VA patients. All analyses used STATA 12.1 (College Station, Texas, 2011).

Results

Patient population

Of 963 patients (449 KP and 514 VA), 118 (12%) had PPDM, 265 (28%) had IPDM, and 580 (60%) were well-controlled. On bivariate analysis, VA patients were more likely to have PPDM than KP patients (14% vs. 10%, $p = 0.01$) (Table 2). The number of HbA1c measurements during the study period differed significantly on bivariate analysis between groups; PPDM patients had 3.2 ± 1.2 measurements, IPDM patients 3.7 ± 1.1, and well-controlled patients 3.0 ± 1.0 ($p < 0.0001$).

Bivariate associations with PPDM

With respect to demographic/socioeconomic factors, individuals with PPDM were significantly younger than other patients, both at study enrollment and at diabetes diagnosis (Table 2). PPDM patients were more likely to be non-White, unmarried, and to have attended at least some

Table 2. Characteristics of PPDM, IPDM, and well-controlled patients at baseline AIM study assessment ($n = 963$).

Measure	PPDM ($n = 118$)	IPDM ($n = 265$)	Well-controlled ($n = 580$)	p-value (3-way)	p-value (PPDM vs. well-controlled)
Demographic/socioeconomic data					
Mean age (SD)	60.3 (9.8)	63.3 (10.1)	67.4 (10.4)	<0.001	<0.001
Age diabetes diagnosed (SD)	47.1 (10.9)	50.4 (12.7)	55.6 (12.1)	<0.001	<0.001
Years with diabetes (SD)[a]	13.9 (8.3)	13.1 (10.4)	12.3 (11.1)	0.28	0.15
Male	76%	75%	70%	0.17	0.15
Non-White race	37%	34%	34%	0.59	0.27
At least some college[a]	65%	54%	55%	0.13	0.06
Unmarried[a]	47%	36%	38%	0.12	0.07
Strong social support[a]	51%	58%	58%	0.33	0.16
Annual income[a]				0.38	0.58
<$30 K	53%	50%	54%		
$30–50 K	20%	26%	22%		
$50–80 K	12%	16%	14%		
>$80 K	15%	8%	10%		
Shared cost problems with provider[a]	20%	29%	25%	0.16	0.22
AIM study site				0.01	0.01
KP	37%	43%	50%		
VA	63%	57%	50%		
Clinical data					
General health status[a]				0.06	0.08
Excellent/v. Good	13%	13%	20%		
Good	40%	48%	43%		
Fair/Poor	47%	39%	37%		
Mean baseline:					
HbA1c (SD)	9.8 (1.5)	8.3 (1.4)	6.6 (0.7)	<0.001	<0.001
SBP (SD)	151.4 (10.4)	151.5 (10.0)	149.9 (10.3)	0.08	0.16
DBP (SD)	78.2 (8.5)	77.5 (8.9)	76.8 (8.8)	0.02	0.02
LDL-C (SD)	103.1 (38.8)	90.1 (32.7)	87.8 (30.2)	<0.001	<0.001
Use of insulin	62%	45%	19%	<0.001	<0.001
Mean BP meds (SD)	2.7 (1.5)	2.5 (1.6)	2.4 (1.5)	0.10	0.05
Use of statin	62%	71%	70%	0.18	0.10
Mean RAM (SD)[a]	14.9 (3.5)	15.3 (3.3)	16.0 (3.1)	<0.001	<0.001
Refill gaps (SD)[b]					
Oral diabetes meds	0.20 (0.24)	0.20 (0.21)	0.14 (0.18)	0.01	0.01
Hypertension meds	0.33 (0.23)	0.28 (0.24)	0.27 (0.23)	0.14	0.05
Psychosocial/survey data					
Positive PHQ-2 screen[a]	34%	27%	21%	0.01	<0.001
Mean PAM-13 (SD)[a]	71.0 (13.5)	70.1 (13.1)	70.5 (13.9)	0.82	0.74
Mean PCS (SD)[a]	63.1 (21.1)	61.3 (22.1)	61.9 (20.5)	0.75	0.57
Mean PACIC (SD)[a]					
Patient activation	54.7 (30.3)	57.0 (29.0)	54.1 (27.0)	0.40	0.81
Goal setting	61.1 (30.0)	59.1 (28.8)	55.1 (29.7)	0.06	0.05

(continued)

Table 2. Continued.

Measure	PPDM ($n = 118$)	IPDM ($n = 265$)	Well-controlled ($n = 580$)	p-value (3-way)	p-value (PPDM vs. well-controlled)
Mean health care satisfaction (SD)[a]	30.4 (22.2)	26.8 (19.2)	25.9 (17.9)	0.07	0.02
Feels that providers often do not listen[a]	18%	18%	13%	0.13	0.08

AIM: Adherence and Intensification of Medications; BP: blood pressure; DBP: diastolic blood pressure; DM: diabetes mellitus; HbA1c: hemoglobin A1c; IPDM: intermittent poorly controlled diabetes mellitus; KP: Kaiser Permanente; LDL-C: low-density lipoprotein cholesterol; PACIC: Patient Assessment of Chronic Illness Care; PAM-13: Patient Activation Measure-13; PCS: Perceived Competence Scale; PHQ-2: Patient Health Questionnaire-2; PPDM: persistent poorly controlled diabetes mellitus; RAM: Reported Adherence to Medication; SBP: systolic blood pressure; VA: Veterans Affairs.
[a]Obtained from AIM baseline survey (all other data obtained from electronic medical records).
[b]Available for VA patients only ($n = 514$; 74 for PPDM, 152 for IPDM, and 288 for well-controlled).

Table 3. Health care utilization during observation period for PPDM, IPDM, and well-controlled patients.

Measure	PPDM ($n = 118$)	IPDM ($n = 265$)	Well-controlled ($n = 580$)	p-value (3-way)	p-value (PPDM vs. well-controlled)
Mean PCP visits (SD)	5.6 (6.4)	6.9 (5.8)	6.0 (5.5)	0.05	0.57
Seeing Endocrinology for diabetes[a]	24%	24%	10%	<0.001	<0.001
Mean Endocrinology visits for diabetes (SD)[a]	1.0 (2.0)	0.8 (1.8)	0.2 (0.6)	<0.001	<0.001
Mean ER visits (SD)	0.4 (1.2)	0.6 (1.3)	0.4 (0.8)	0.03	0.51
Mean hemoglobin A1c tests (SD)	3.2 (1.2)	3.7 (1.1)	3.0 (1.0)	<0.001	0.047

AIM: Adherence and Intensification of Medications; ER: emergency room; IPDM: intermittent poorly controlled diabetes mellitus; PCP: Primary Care Provider; PPDM: persistent poorly controlled diabetes mellitus.
[a]Available for Veterans Affairs patients only ($n = 514$; 74 for PPDM, 152 for IPDM, and 288 for well-controlled).

college, and were less likely to report strong social support; however, these trends did not achieve statistical significance.

For clinical factors, patients with PPDM had significantly higher mean HbA1c, BP, and LDL-C at study baseline compared with others (Table 2). PPDM patients were far more likely to use insulin than other patients, and used more BP medications than well-controlled patients. PPDM patients also had significantly lower self-reported and objectively measured adherence (higher refill gaps) than well-controlled patients.

Regarding psychosocial factors, PPDM patients were significantly more likely than others to have a positive PHQ-2 depression screen (Table 2). Compared with well-controlled patients, PPDM patients had a significantly higher score on the PACIC goal-setting subscale and lower general health care satisfaction.

Patients in all three groups had frequent PCP contact during the study period, and ER utilization was similar between groups (Table 3). PPDM patients had a significantly higher likelihood of seeing Endocrinology for their diabetes than did other patients,

and diabetes-related Endocrinology visits were more frequent for PPDM patients than for others.

Multivariable model results

With the well-controlled group as a comparator, we determined adjusted odds ratios for associations between baseline patient factors and having PPDM during the observation period (Table 4). Factors significantly associated with PPDM on multivariable modeling included younger age, younger age at diabetes diagnosis, insulin use, higher antihypertensive medication burden, higher LDL, lower statin use, and a higher score on the PACIC goal-setting subscale. Of note, study site, self-reported medication adherence, and positive depression screen were not associated with PPDM status after adjustment for other factors. Since refill gap data were not available for KP patients, we evaluated a second model that included VA patients only ($n = 362$). In addition to confirming the association between PPDM and insulin use, antihypertensive medication burden, and the PACIC goal-setting subscale (not shown), this model demonstrated that higher oral diabetes medication refill gaps were significantly associated with PPDM (odds ratio 1.23 (1.06–1.43) for each additional 10% increase in refill gap).

Discussion

Summary of findings

Because patients with PPDM have not responded to standard diabetes management, they remain at high risk for diabetes complications. Consequently, PPDM is an important target for care innovation. Our incomplete understanding of patient factors associated with PPDM currently hinders the enhancement of existing services and development of new intervention strategies targeting barriers to improvement in this population. Using data from a randomized trial, we identified a sizeable population with persistent poorly controlled type 2 diabetes (12% of our cohort), and described associated patient factors. Key factors associated with PPDM in our principal multivariable model included younger age both during the study period and at diabetes

Table 4. Results of multivariable logistic regression modeling to determine adjusted associations between baseline patient factors and PPDM, with well-controlled group as referent.

Factor	Odds ratio for PPDM [95% CI]
Full model ($n = 698$)	
Patient age (per year >40)*	0.95 [0.92–0.99]
Age at diabetes diagnosis (per year >40)†	0.97 [0.95–1.00]
Use of insulin*	7.07 [4.17–11.99]
Baseline antihypertensive burden (for each additional medication)†	1.19 [1.01–1.41]
LDL-C (for every point >100)†	1.01 [1.00–1.02]
Use of a statin medication†	0.58 [0.35–0.98]
PACIC goal-setting subscale (for each additional point)*	1.02 [1.01–1.03]
VA-only model ($n = 362$)	
Each additional 10% increase in refill gap (oral diabetes meds)*	1.23 [1.06–1.43]

BP: blood pressure; CI: confidence interval; LDL-C: low-density lipoprotein cholesterol; PACIC: Patient Assessment of Chronic Illness Care; PPDM: persistent poorly controlled diabetes mellitus; VA: Veterans Affairs.
*$p < 0.01$, †$p < 0.05$.

diagnosis, insulin use, higher antihypertensive medication burden, higher LDL, lower statin use, and a higher score on the PACIC goal-setting subscale. A secondary model analyzing patients with refill gap data demonstrated that lower medication adherence was also associated with PPDM. Of note, our PPDM cohort remained poorly controlled despite ample primary care and higher utilization of Endocrinology diabetes care.

This analysis is distinct from prior studies in that our PPDM definition captures all HbA1c values from the observation period and focuses exclusively on individuals with poor control despite standard diabetes care by omitting patients with minimal health care contact. As a result, we have identified a truly resistant group that is at high risk for diabetes complications despite standard care within high-functioning health care systems. An additional strength of our analysis is its use of detailed, prospectively collected patient data to thoroughly characterize patients with PPDM. This analysis addresses an important knowledge gap by enhancing our understanding of factors underlying persistent poor diabetes control and informing strategies to better target possible patient-level barriers to improvement in PPDM.

Clues to improving management of PPDM

Patients with PPDM appear to be younger than better controlled patients, which is consistent with reports linking age and HbA1c.[1,6–8] However, our finding that patients with PPDM are diagnosed younger than well-controlled patients – at 47 years old, on average – is novel and noteworthy. Individuals with poor glycemic control throughout their early course appear to develop ''metabolic memory'' that predisposes them to future complications.[20] Because patients with PPDM are prone to poor glycemic control and develop diabetes earlier than others, they likely acquire deleterious metabolic memory at a younger age, which then impacts their prognosis over a longer period of time. The resulting high lifetime complication risk in PPDM particularly warrants aggressive and targeted intervention for this population. Age-related demands from employment and greater social engagement may represent barriers to improvement among younger patients with PPDM, so early intervention utilizing well-tolerated strategies to accommodate busier lifestyles (e.g. telemedicine, mHealth, and eHealth) may be more effective than clinic-based care in PPDM.

Like prior studies linking insulin use to poor glycemic control,[1,7,8] we found that insulin use was strongly associated with PPDM. Although the present analysis cannot establish causation, insulin use likely generates multiple barriers to improvement in PPDM. For example, medication adherence appears to be more challenging with insulin-based regimens.[21] As our analysis indicates that patients with PPDM have suboptimal oral diabetes medication adherence, it can be inferred that non-adherence to the insulin-based regimens common in PPDM may help perpetuate poor glycemic control. Additionally, insulin use may contribute to PPDM via clinical inertia. Many providers lack comfort managing insulin-based diabetes regimens,[22] which could hinder treatment intensification and promote PPDM. Of note, standard diabetes care appears less effective than dedicated group diabetes clinics for insulin-using patients.[23] As insulin use is common in PPDM, PPDM patients may benefit from care strategies capable of effectively delivering robust medication management and self-management education to enhance treatment intensification and self-management adherence.

We found that patients with PPDM have higher antihypertensive medication burdens, higher LDL-C, and lower statin use

compared with other diabetes patients. These findings may indicate that self-managing medications for comorbid medical conditions may represent a relevant barrier in PPDM. Given the importance of comprehensive cardiovascular risk factor management in improving long-term outcomes in diabetes,[24] these findings highlight the need for intervention strategies that not only improve glycemic control in PPDM but also provide effective management for other cardiovascular risk factors. PPDM patients scored higher on the PACIC goal-setting subscale, indicating more collaborative goal setting for chronic conditions. This may suggest that clinic providers are trying to engage these resistant patients but not achieving adequate HbA1c lowering, further supporting the need for strategies to improve engagement of PPDM patients.

Several noteworthy factors were not associated with PPDM on multivariable analysis. Although our analysis showed a bivariate association between PPDM and depression, this association lost significance on multivariable modeling. This finding is important in the context of numerous reports linking depression and poorly controlled diabetes.[9,10] Because affective symptoms wax and wane over time, it is possible that depression exacerbates diabetes control during discrete periods but in many cases does not lead to persistent poor control over longer intervals. Others have questioned the long-term relationship between depression and glycemic control,[25] and our analysis identifies this as an important area for further research. Our model results further suggest that PPDM affects patients regardless of sex, race, income, health system, or other psychosocial factors such as patient activation and self-efficacy.

Limitations

Although we evaluated a broad set of prospectively collected patient factors for association with PPDM, our analysis was limited to the measures collected for the AIM trial baseline survey. As a result, we were unable to evaluate other possible patient-level determinants of PPDM such as disease-specific features (e.g. glycemic variability and hypoglycemia susceptibility), personality, and health beliefs. Similarly, assessing provider- and system-level associations with PPDM was beyond our scope, and will be an important area for future research. Finally, although we hypothesize about barriers to improvement indicated by the associated factors, the present analysis cannot establish causation between these factors and PPDM.

We examined only patients with type 2 diabetes, so our findings may not generalize to PPDM in patients with type 1 diabetes. Further, our cohort comprised patients with reliable access to high-quality care, which may also affect generalizability; the standard diabetes care provided at the centers analyzed may differ from other locations, and may likewise vary between and within centers studied. Although we attempted to characterize care utilization in our cohort, we were unable to evaluate the proportion of patients utilizing ancillary services such as diabetes self-management education and support. Despite these limitations, deriving our sample from high-functioning health care systems does lessen the likelihood that the PPDM group's poor control resulted from suboptimal standard care.

Along with PPDM and well-controlled patients, we identified a third population labeled "IPDM." With respect to many factors, such as age, insulin use, and adherence, IPDM patients fell in between the other two groups. IPDM patients may represent a true intermediate-risk population, a heterogeneous group comprising patients that have not yet progressed to one of the other groups, or both. Although IPDM individuals could potentially benefit from more aggressive intervention to improve their diabetes

control, further study of these patients was beyond the scope of this analysis.

Implications for future research/clinical practice

Because patients with PPDM have high risk for complications but have not responded to standard diabetes care over time, they likely require care strategies that target their barriers to improved glycemic control. We describe key patient factors associated with persistent poor control, which in turn point to possible barriers to improvement in the PPDM population. Our findings suggest that an intervention targeting PPDM should utilize a flexible delivery strategy to accommodate younger patients' lifestyles, include medication management capable of addressing insulin titration and comorbidities such as hypertension and dyslipidemia, and address deficits in medication and self-management adherence.

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Conflict of interest

None declared.

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