

**ORIGINAL RESEARCH**

# The Psychosocial Needs of Patients Participating in Diabetes Shared Medical Appointments

Andrea L. Nederveld, MD, MPH, Dennis Gurfinkel, MPH, Patrick Hosokawa, MS, R. Mark Gritz, PhD, L. Miriam Dickinson, PhD, Phoutdavone Phimphasone-Brady, PhD, Jeanette A. Waxmonsky, PhD, LP, and Bethany M. Kwan, PhD, MSPH

**Background:** Patient reported outcomes (PROs) for diabetes are self-reported and often give insight into outcomes important to people with diabetes. Federally Qualified Health Centers (FQHCs) see patients who may have higher levels of diabetes distress and lower levels of self-care behaviors.

**Methods:** The Invested in Diabetes study is a comparative effectiveness trial of diabetes Shared Medical Appointments (SMAs) in FQHCs and non-FQHC settings. PROs measure outcomes including validated measures on diabetes distress.

**Setting and Participants:** 616 people from 22 practices completed PROs prior to SMAs. At FQHCs, participants were younger (average 57.7 years vs 66.9 years,  $p < 0.0001$ ), more likely to be female (36.8% vs 46.1%,  $p = 0.02$ ), and fewer spoke English (72.7% vs 99.6%,  $p < 0.0001$ ).

**Results:** At FQHCs, diabetes distress was higher (2.1 vs 1.8,  $P = .02$ ), more people were current smokers (14.3% vs 4.7%,  $P = .0002$ ), on insulin (48.9% vs 22.3%,  $P < .0001$ ) and reported food insecurity (52.7% vs 26.2%,  $P < .0001$ ). After controlling for sociodemographic factors, these differences were nonsignificant.

**Conclusions:** Higher numbers of patients at FQHCs report diabetes distress and food insecurity compared with patients in non-FQHC settings, indicating that patient social circumstances need to be considered as part of program implementation. (J Am Board Fam Med 2022;35:1103–1114.)

**Keywords:** Patient-Centered Care, Patient Reported Outcome Measures, Self-Report, Shared Medical Appointments, Social Determinants of Health, Type 2 Diabetes

## Introduction

Shared medical appointments (SMAs), which involve bringing a group of people with the same diagnosis together for treatment and education, are an effective, efficient strategy for improving self-management and subsequent health outcomes.<sup>1,2</sup> Evidence

on SMAs for diabetes generally show improvement in glucose and blood pressure levels<sup>1</sup> and diabetes self-management and disease-related distress.<sup>3–5</sup> However, there is some evidence that SMAs are less likely to be effective in underserved populations.<sup>6,7</sup> This may be because SMAs delivered in underserved communities may not be adequately tailored to the needs, priorities, and characteristics of those with social needs stemming from factors such as food insecurity<sup>7</sup> or low health literacy.<sup>8</sup> People in underserved communities may

necessarily represent the views of PCORI, its Board of Governors, or Methodology Committee.

**Conflict of interest:** The authors declare that they have no conflicts of interest.

**Corresponding author:** Andrea L. Nederveld, MD, MPH, Department of Family Medicine, University of Colorado Anschutz Medical Campus 12631 East 17th Avenue, Box F496, Aurora, CO 80045 (E-mail: andrea.nederveld@cuanschutz.edu).

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From Department of Family Medicine, University of Colorado Anschutz Medical Campus, Aurora, CO (ALN, JAW, BMK); Adult & Child Consortium for Health Outcomes Research & Delivery Science, University of Colorado Anschutz Medical Campus, Aurora, CO (DG, PH, RMG, LMD, JAW, BMK); Eugene S. Farley, Jr. Health Policy Center, University of Colorado Anschutz Medical Campus, Aurora, CO (RMG); Department of Psychiatry, University of Colorado Anschutz Medical Campus, Aurora, CO (PPB).

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also have different priorities for addressing self-management behaviors<sup>9</sup> or sources of disease-related distress.<sup>10–12</sup>

Patient-reported outcomes measures (PROMs) are increasingly used in primary care practice to identify and tailor care to patient needs and characteristics.<sup>13</sup> Patient reported outcomes (PROs) are defined as “any report of the status of a patient’s health condition that comes directly from the patient, without interpretation by a clinician or anyone else.”<sup>14</sup> PROs for people with diabetes can measure levels of diabetes-related distress, self-care behaviors, motivation for maintaining healthy lifestyles, and relevant social determinants of health (SDOH), among other outcomes. Administration of PROMs can help health care providers gain insight into patient self-management skills and priorities beyond traditional clinical measures of disease status, such as hemoglobin A1c in diabetes. This insight can guide patients and providers in adjusting treatment plans and interventions to be more effective and align with patient needs and priorities. There is continued need for research on how PROMs can be used to engage patients in self-management support and inform tailoring of care in real-world health care settings.

The Invested in Diabetes study is a pragmatic comparative effectiveness trial comparing 2 models of SMAs in primary care for diabetes; a patient-driven SMA model (content order and emphasis tailored to patient preferences and delivered by a multidisciplinary care team including behavioral health and peer mentors) and standardized SMA model (content and delivered by a health educator).<sup>15–17</sup> Both models use the Targeted Training in Illness Management (TTIM) curriculum,<sup>18,19</sup> an evidence-based diabetes self-management education program delivered over 6 2-hour sessions. The TTIM curriculum content addresses basic diabetes education as well as content for improving diabetes self-care behaviors, enhancing stress and coping skills, and problem-solving self-management barriers.

Invested in Diabetes involves implementation of SMAs at both federally-qualified health centers (FQHCs) – which primarily serve low-income patients with public insurance—and non-FQHC sites—private practices or health systems serving patients with primarily commercial insurance. FQHCs traditionally care for people who are younger, more likely to be of nonwhite race, and

have less access to health-related resources,<sup>20,21</sup> potentially creating barriers for diabetes management. For example, blood glucose levels have been demonstrated to be higher in low-resource settings and lower in settings where people have stable and continuous insurance coverage;<sup>20–22</sup> psychosocial factors related to SDOH also influence diabetes self-care and outcomes.<sup>20,21,23,24</sup>

This article describes baseline PROs and distinguishing characteristics of patients receiving care in diabetes SMAs in FQHC and non-FQHC settings for the Invested in Diabetes project. Understanding the social and emotional circumstances for patients participating in SMAs allows insight into other factors to consider and address for improved diabetes self-management in addition to group education or as part of the intervention. We hypothesized that people participating in diabetes SMAs at FQHCs would report higher levels of diabetes distress and food insecurity and lower levels of self-care behaviors and health literacy, compared with people participating in SMAs at non-FQHCs.

## Method

### *Study Design*

This analysis represents a cross-sectional correlational design assessing differences in baseline measures of diabetes distress, diabetes self-care, motivational factors (ie, perceived confidence and autonomy support), health literacy, and food security between participants in diabetes SMAs in FQHCs vs non-FQHCs as part of the Invested in Diabetes study. Follow-up PROs were administered after sessions, but are not reported in this analysis. This analysis includes only data from SMA cohorts that began before the COVID-19 pandemic, as there may be substantial differences in PROs after the onset of the pandemic due to related stressors. SMA cohorts included ran between January 2019 and March 2020.

### *Setting and Participants*

Twenty-two primary care practices in Colorado and Kansas participated. Twelve practices were FQHCs and 10 were non-FQHCs. Data from adults aged 18 or over with type 2 diabetes who were willing and able to participate in SMAs and completed baseline PROMs were included in the analysis.

### **Data Collection**

PROMs relevant to diabetes care (diabetes distress, diabetes self-care behaviors and motivation, health literacy, and food security) were administered during sessions 1 (baseline PROMs) and 6 (follow-up PROMs) for both study arms; follow-up timepoints ranged from 6 weeks to 6 months depending on each practice's implementation decisions. These measures were multipurpose, intended to help engage patients in personal goal setting (both SMA models) and content tailoring (patient-driven SMA model only) as part of the intervention as well as to provide outcomes data for the research (eg, changes in diabetes distress between baseline and follow-up serve as the trial's primary patient-centered outcome). PROMs were designed to be administered on article, in English or Spanish. Participants typically completed the measures on their own with article and pencil, with the facilitator assisting those who had difficulty understanding the questions. As an adaptation, some practices had participants complete PROMs before the session due to time restrictions. After the session, practice staff scored the PROMs using an instruction sheet provided by the study team and entered the score into a tracking spreadsheet. On a quarterly basis, the tracking spreadsheet was deidentified and sent to the study team for data monitoring and analysis.

### **Outcomes and Measures**

Diabetes distress, defined as "unique, often hidden emotional burdens and worries that are part of the spectrum of patient experience when managing a severe, demanding chronic disease like diabetes"<sup>25</sup>, was assessed using the 17-item Diabetes Distress Scale (DDS-17).<sup>25–29</sup> The DDS-17 is a validated scale that measures patient-reported distress stemming from the experience of managing diabetes in 4 domains: emotional burden (5 items), health care navigation-related distress (4 items), diabetes self-care regimen-related distress (5 items), and interpersonal distress (3 items).<sup>25–29</sup> Respondents are asked to indicate the degree to which things such as "feeling that diabetes is taking up too much of my mental and physical energy" has bothered or distressed them over the past month. Responses are on a 6-point Likert scale (1 = "not a problem"; 6 = "a very serious problem"), with lower scores indicating less distress.<sup>25–29</sup> The mean of items within each subscale are computed as domain scores and an overall distress score is the mean of all items.

Composite and subscale scores less than 2.0 indicate little to no distress, between 2.0 and 2.9 indicate moderate distress, 3.0 and higher indicate high distress. Diabetes self-care behaviors, including diet, exercise, blood glucose checking, taking medication, smoking, and foot care, were assessed using the Summary of Diabetes Self Care Activities (SDSCA).<sup>30</sup> Respondents report how many days (0 to 7) in the past week they completed relevant health behaviors, with higher scores indicating better self-care. We assessed 2 measures reflecting self-determination theory<sup>31,32</sup> constructs: perceived autonomy support and perceived confidence. The Brief Health Care Climate Questionnaire (HCCQ) is a 6-item scale that assesses autonomy support in the context of health care, for example, "I feel understood by my doctor."<sup>33</sup> Items are assessed on a 7-point Likert scale (1 = "strongly agree"; 7 = "strongly disagree") with lower scores indicating more perceived autonomy support. The Perceived Competence in Diabetes Scale (PCDS) is a 4-item measure of perceived confidence in 1's ability to manage diabetes, for example, "I feel confident in my ability to manage diabetes."<sup>34–36</sup> Items are measured on a 7-point Likert (1 = "not true at all true"; 7 = "very true") with higher scores indicating more perceived competence related to diabetes self-management. Health literacy was assessed using the 3-item Chew Limited Health Literacy Scale, with items scored on a 5-point Likert (1 = "all the time"; 5 = "none of the time") with lower scores indicating worse health literacy.<sup>37</sup> An example question is "How often does someone help you read things your doctor gives you?" Food insecurity was assessed using the USDA 2-item Food Insecurity Screener, which asks "Within the past 12 months, we worried that our food would run out before we had money to buy more" and "Within the past 12 months the food we bought just did not last and we did not have money to get more," with responses assessed on a 3-point scale (1 = "often true" to 3 = "never true"). An average score less than 3 indicated at least some level of food insecurity.<sup>38</sup> See Appendix A for combined PROs used in the study. Participant demographics (race, ethnicity, primary language, age, and gender) were also assessed in the baseline PRO packet.

### **Data Analysis**

Analysis was performed using SAS Version 9.4 (SAS Institute, 2013). We used descriptive statistics

to assess means and standard deviations for continuous variables and frequencies for categorical variables. To account for facility clustering when comparing baseline PRO values between patients participating in diabetes SMAs in FQHCs and non-FQHCs we used a clustered linear model run on values (for parametric values) and value ranks (for non-parametric values). A weighted linear model was used for continuous values, including the nonparametric ranks. DDS-17, HCCQ, SDSCA, PCDS and health literacy scores were analyzed as continuous variables. FQHC/non-FQHC differences in categorical variables - race, ethnicity, primary language, smoking status, insulin use, medication use, and food insecurity (yes/no to any food insecurity) - were assessed using a Rao-Scott test accounting for facility clustering, using a weighted linear model as well. To understand differences in DDS scores between FQHC and non FQHC participants, we conducted multivariable analyses - for example, ANCOVA controlling for potential covariates including age, race, ethnicity, language, whether on insulin, health literacy, and food insecurity.

## Results

### *Sample Characteristics*

As of March 2020, baseline PROs had been collected for 616 participants: 345 from FQHCs and 271 from non-FQHC practices. Overall, participants ranged in age from 18 to 88, majority white and spoke English as a primary language. As shown in Table 1, compared with non-FQHC practices, patients at FQHCs were younger, more likely to be female, more likely to be nonwhite race or Latinx and more likely to speak Spanish as a primary language. More participants from FQHC settings were using insulin as part of their treatment regimen compared with non-FQHC settings. More patients at FQHCs reported food insecurity. Health literacy was not significantly different between the 2 populations.

### *Bivariate Associations*

Table 2 shows the correlation matrix among all PRO measures. As expected, all DDS domain scores correlate positively with the total DDS score. Total distress and all distress domains are all significantly correlated with autonomy support and perceived competence, such that lower scores on the DDS (indicating less distress) are associated with

lower scores on the HCCQ (indicating greater perceived autonomy support by the health care team) and higher scores on the PCS (indicating greater perceived confidence in ability to manage diabetes). Greater health literacy was associated with lower levels of total distress and health care navigation-related distress (but not other distress domains). Lower levels of total distress were significantly associated with better dietary management, exercise, smoking, and foot care behaviors but not glucose monitoring or medication taking. Lower levels of emotional burden were associated with more frequent diabetes diet, exercise, and smoking self-care behaviors. Lower levels of regimen-related distress were associated with better self-care for all behaviors except taking medication. Lower interpersonal distress was associated with better diet. Health care navigation-related distress was not related to any self-care behaviors. More frequent self-care behaviors (except smoking) were associated with more perceived autonomy support, and all but smoking and medication taking were associated with more perceived competence. No self-care behaviors were associated with health literacy.

### *FQHC vs non-FQHC Differences in Diabetes Self-Care Behaviors and Motivation*

As shown in Table 3, diabetes self-care behaviors did not differ significantly between patients in FQHC vs non-FQHC practices, despite higher levels of food insecurity and tobacco use in patients attending sessions at FQHCs. There were also no differences in HCCQ or PCS scores between patients in FQHCs and non-FQHCs.

### *FQHC vs Non-FQHC Differences in Diabetes Distress*

Descriptive statistics for diabetes distress (both total and domain scores) overall and by FQHC and non-FQHC practice type and tests of difference are shown in Table 4. Overall average levels of diabetes distress in people participating in diabetes SMAs were low to moderate at 1.9; however, 30% demonstrated moderate distress (2.0 – 2.9) and 17% demonstrated high distress (3.0 or greater). Overall diabetes distress was significantly higher in participants attending sessions at FQHCs than non-FQHC settings. Examining results by DDS-17 subscale revealed that for all subscales, scores were statistically significantly higher, indicating more distress for participants at FQHCs. In multivariable regression analysis shown in Table 5, the difference

**Table 1. Participant Sociodemographics Overall and by Practice Type**

| Variable                 | All Patients (n = 616) | FQHC (n = 345)   | Non-FQHC (n = 271) | FQHC vs Non-FQHC Difference                |
|--------------------------|------------------------|------------------|--------------------|--|
| Age in years             |                        |                  |                    |  |
| Mean (SD)                | 61.8 (11.0)            | 57.7 (11.1)      | 66.9 (8.6)         | <0.0001* <0.0001 <sup>†</sup>              |
| Min-Max                  | 18 to 88               | 18 to 88         | 31 to 84           | <0.0001 <sup>‡</sup> <0.0001 <sup>§</sup>  |
| Gender N (%)             |                        |                  |                    |  |
| Men                      | 252 (40.9%)            | 127 (36.8%)      | 125 (46.1%)        | 0.02 <sup>  </sup> 0.05 <sup>¶</sup>       |
| Women                    | 364 (59.1%)            | 218 (63.2%)      | 146 (53.9%)        |  |
| Race/Ethnicity N (%)     |                        |                  |                    |  |
| Black                    | 18 (3.9%)              | 10 (5.1%)        | 8 (3.0%)           | <0.0001 <sup>  </sup> 0.002 <sup>¶</sup>   |
| Hispanic                 | 100 (21.6%)            | 76 (38.6%)       | 24 (9.0%)          |  |
| Non-Hispanic White       | 320 (69.0%)            | 90 (45.7%)       | 230 (86.1%)        |  |
| Asian                    | 20 (4.3%)              | 17 (8.6%)        | 3 (1.1%)           |  |
| Other/Declined           | 6 (1.3%)               | 4 (2.0%)         | 2 (0.8%)           |  |
| Primary Language N(%)    |                        |                  |                    |  |
| English                  | 505 (84.2%)            | 250 (72.7%)      | 255 (99.6%)        | <0.0001 <sup>  </sup> n/a <sup>¶</sup>     |
| Spanish                  | 95 (15.8%)             | 94 (27.3%)       | 1 (0.4%)           |  |
| Food availability N (%)  |                        |                  |                    |  |
| No lack of food security | 363 (58.9%)            | 163 (47.3%)      | 200 (73.8%)        | <0.0001 <sup>  </sup> <0.0001 <sup>¶</sup> |
| Health Literacy          |                        |                  |                    |  |
| Median score (IQR)       | 3.66 (3.0 to 3.7)      | 3.3 (2.7 to 3.7) | 3.67 (3.0 to 3.67) | 0.11 <sup>‡</sup> 0.17 <sup>§</sup>        |

Abbreviations: IQR, interquartile range, 25<sup>th</sup>-75<sup>th</sup> percentile; FQHC, Federally Qualified Health Centers; SD, standard deviation.

\**t* test with assumption of normality.

<sup>†</sup>CLM – Clustered linear model with testing FQHC/Non-FQHC flag.

<sup>‡</sup>Wilcoxon Rank Sum.

<sup>§</sup>Clustered linear model with testing FQHC/Non-FQHC flag regressed against value ranks.

<sup>||</sup>  $\chi^2$  test.

<sup>¶</sup>Rao-Scott Categorical test accounting for facility clustering.

in overall distress between FQHCs and non-FQHCs was reduced to nonsignificance when controlling for sociodemographic factors (age, gender, race/ethnicity, and primary language). Accounting for practice type and other sociodemographic factors, older patients, men, patients who speak English as a primary language, and those without food insecurity reported lower levels of total distress. Relative to patients who are White, Asian patients reported less distress while Black patients report slightly but not significantly more distress.

## Discussion

Baseline PROs from the Invested in Diabetes study demonstrated significant differences in diabetes distress on all subscales and as a composite measure between participants in diabetes SMAs at FQHCs compared with those at non-FQHCs. However, in contrast with our hypotheses, self-care behaviors (with the exception of tobacco use) did not differ significantly between those participating in diabetes

SMAs at FQHCs vs non-FQHCs. Health literacy was not significantly different between the 2 populations, but food insecurity was higher in diabetes SMA participants from FQHCs than non-FQHCs.

Multivariable analysis showed that adjusting for age, gender, race/ethnicity, and primary language reduced the FQHC vs non-FQHC difference in total distress to nonsignificance, suggesting, as other studies have found<sup>20,21</sup>, that other factors that differ between populations may in fact explain the differences in distress. For example, previous research has shown that younger age has been shown to be related to higher overall diabetes distress<sup>11,39,40</sup>, possibly related to other life stressors at younger age<sup>41,42</sup>; these data revealed a younger average age at FQHCs. In Invested in Diabetes, FQHCs had more Black and Asian diabetes SMA participants, with diabetes distress higher in Black participants and lower in Asian participants. Thus, stressors associated with systemic racism or life stage may contribute to racial/ethnic and age differences in distress observed.<sup>10-12</sup>

**Table 2. Bivariate Correlations Among Patient-Reported Outcomes Measures**

| PRO Measure                   | DDS-17 Total (L) | DDS-17 Emotional Burden (L) | DDS-17 Health-Care Navigation (L) | DDS-17 Regimen (L) | DDS-17 Inter-Personal (L) | HCCQ Autonomy Support (L) | Perceived Competence (H) | Health Literacy (H) | SDSCA Diet (H)  | SDSCA Exercise (H) | SDSCA Glucose Monitor (H) | SDSCA Smoking (L) | SDSCA Foot Care (H) | SDSCA Med Adherence (H) |
|-------------------------------|------------------|-----------------------------|-----------------------------------|--------------------|---------------------------|---------------------------|--------------------------|---------------------|-----------------|--------------------|---------------------------|-------------------|---------------------|-------------------------|
| DDS-17 Total                  | -                | 0.79 (<0.0001)              | 0.51 (<0.0001)                    | 0.80 (<0.0001)     | 0.68 (<0.0001)            | 0.35 (<0.0001)            | -0.37 (<0.0001)          | -0.06 (<0.0001)     | -0.28 (<0.0001) | -0.19 (<0.0001)    | -0.06 (0.13)              | 0.11 (0.01)       | -0.10 (0.01)        | -0.04 (0.44)            |
| DDS-17 Emotional Burden       | -                | -                           | 0.33 (<0.0001)                    | 0.57 (<0.0001)     | 0.45 (<0.0001)            | 0.22 (<0.0001)            | -0.31 (<0.0001)          | -0.03 (0.44)        | -0.20 (<0.0001) | -0.16 (<0.0001)    | 0.07 (0.07)               | 0.09 (0.03)       | -0.07 (0.07)        | -0.04 (0.33)            |
| DDS-17 Health-care navigation | -                | -                           | -                                 | 0.31 (<0.0001)     | 0.41 (<0.0001)            | 0.39 (<0.0001)            | -0.14 (0.0005)           | -0.09 (0.03)        | -0.06 (0.16)    | -0.02 (0.62)       | -0.04 (0.30)              | -0.03 (0.55)      | -0.07 (0.08)        | -0.04 (0.40)            |
| DDS-17 Regimen                | -                | -                           | -                                 | -                  | 0.47 (<0.0001)            | 0.33 (>0.0001)            | -0.34 (>0.0001)          | -0.04 (0.37)        | -0.35 (>0.0001) | -0.21 (>0.0001)    | -0.20 (>0.0001)           | 0.13 (0.0003)     | -0.15 (0.0003)      | -0.06 (0.16)            |
| DDS-17 Inter-personal         | -                | -                           | -                                 | -                  | -                         | 0.28 (>0.0001)            | -0.24 (>0.0001)          | -0.04 (0.28)        | -0.18 (>0.0001) | -0.09 (0.03)       | 0.00 (0.99)               | 0.06 (0.18)       | -0.06 (0.17)        | 0.01 (0.76)             |
| HCCQ Autonomy support         | -                | -                           | -                                 | -                  | -                         | -                         | -0.21 (>0.0001)          | 0.02 (0.58)         | -0.17 (>0.0001) | -0.09 (0.02)       | -0.09 (0.02)              | 0.04 (0.41)       | -0.17 (>0.0001)     | -0.10 (0.03)            |
| Perceived competence          | -                | -                           | -                                 | -                  | -                         | -                         | -                        | 0.08 (0.04)         | 0.37 (>0.0001)  | 0.21 (>0.0001)     | 0.07 (0.09)               | -0.07 (0.10)      | 0.08 (0.06)         | 0.08 (0.10)             |
| Health Literacy               | -                | -                           | -                                 | -                  | -                         | -                         | -                        | -                   | 0.04 (0.29)     | 0.02 (0.60)        | 0.08 (0.06)               | 0.02 (0.72)       | 0.03 (0.45)         | -0.02 (0.60)            |
| SDSCA Diet                    | -                | -                           | -                                 | -                  | -                         | -                         | -                        | -                   | -               | 0.35 (>0.0001)     | 0.21 (>0.0001)            | -0.06 (0.15)      | 0.19 (<0.0001)      | 0.06 (0.17)             |
| SDSCA Exercise                | -                | -                           | -                                 | -                  | -                         | -                         | -                        | -                   | -               | -                  | 0.07 (0.08)               | 0.05 (0.29)       | 0.10 (0.01)         | -0.02 (0.65)            |
| SDSCA Glucose Monitor         | -                | -                           | -                                 | -                  | -                         | -                         | -                        | -                   | -               | -                  | -                         | 0.03 (0.55)       | 0.24 (>0.0001)      | 0.24 (>0.0001)          |
| SDSCA Smoking (N)             | -                | -                           | -                                 | -                  | -                         | -                         | -                        | -                   | -               | -                  | -                         | -                 | -                   | 0.04 (0.41)             |
| SDSCA Foot Care               | -                | -                           | -                                 | -                  | -                         | -                         | -                        | -                   | -               | -                  | -                         | -                 | -                   | 0.08 (0.09)             |
| SDSCA Med Adherence           | -                | -                           | -                                 | -                  | -                         | -                         | -                        | -                   | -               | -                  | -                         | -                 | -                   | -                       |

Abbreviations: H, higher numbers mean more desirable outcomes; L, lower numbers mean more desirable outcomes; DDS-17, Diabetes Distress Scale; HCCQ, Health Care Climate Questionnaire; SDSCA, Summary of Diabetes Self-Care Activities.

**Table 3. Differences in Patient-Reported Diabetes Self-Care Behaviors and Motivation Measures Overall and Between Patients in Federally Qualified Health Centers (FQHCs) and Non-FQHCs**

| Measure Statistic   | All Patients (n = 616) | FQHC (n = 345)   | non-FQHC (n = 271) | FQHC vs Non-FQHC Difference (p-value)    |
|---|------------------------|------------------|--------------------|--|
| Health Care Climate Questionnaire (HCCQ)                              | 1.7 (1.0 to 2.2)       | 1.7 (1.0 to 2.2) | 1.8 (1.0 to 2.2)   | 0.26*                                    |
| Median score (IQR)  |                        |                  |                    | 0.40 <sup>†</sup>                        |
| Perceived Competence Scale  | 4.3 (3.3 to 6.0)       | 4.0 (3.0 to 6.0) | 4.5 (3.3 to 6.0)   | 0.48*                                    |
| Median score (IQR)  |                        |                  |                    | 0.51 <sup>†</sup>                        |
| Summary of Diabetes Self-Care Activities (SDSCA) - Median score (IQR) |                        |                  |                    |  |
| Diet  | 3.2 (2.0 to 4.2)       | 3.2 (2.0 to 4.2) | 3.3 (2.2 to 4.3)   | 0.81*<br>0.85 <sup>†</sup>               |
| Exercise  | 2.5 (1.0 to 4.0)       | 2.5 (1.0 to 4.0) | 3.0 (0.5 to 4.5)   | 0.52*<br>0.37 <sup>†</sup>               |
| Glucose Monitoring  | 3.5 (0.5 to 7.0)       | 3.5 (1.0 to 7.0) | 3.0 (0.0 to 7.0)   | 0.22*<br>0.23 <sup>†</sup>               |
| Foot Care   | 3.5 (1.0 to 6.0)       | 3.5 (1.0 to 7.0) | 3.0 (1.0 to 4.5)   | 0.02*<br>0.002 <sup>†</sup>              |
| Medication Taking   | 7.0 (5.5 to 7.0)       | 7.0 (5.2 to 7.0) | 7.0 (5.7 to 7.0)   | 0.32*<br>0.67 <sup>†</sup>               |
| Current smoking - yes<br>N (%)  | 57 (10.3%)             | 46 (14.3%)       | 11 (4.7%)          | 0.0002 <sup>‡</sup><br>n/a <sup>§</sup>  |
| Insulin Use - yes<br>N (%)  | 182 (38.0%)            | 138 (48.9%)      | 44 (22.3%)         | <0.0001 <sup>‡</sup><br>n/a <sup>§</sup> |
| Current blood glucose medication - yes<br>N (%)                       | 389 (82.8%)            | 228 (82.0%)      | 161 (83.9%)        | 0.60 <sup>‡</sup><br>0.73 <sup>§</sup>   |

Abbreviation: IQR, interquartile range, 25th-75th percentile.

Notes: For the HCCQ, lower numbers indicate more perceived autonomy support in the health care context. For the Perceived Competence Scale, higher numbers indicate greater confidence in one's ability to manage diabetes (perceived competence). For the SDSCA, numbers represent average number of days per week following the recommended regimen.

\*Wilcoxon Rank Sum.

<sup>†</sup>Clustered linear model with testing FQHC/Non-FQHC flag regressed against value ranks.

<sup>‡</sup> $\chi^2$  test.

<sup>§</sup>Rao-Scott Categorical test accounting for facility clustering.

The high levels of food insecurity in both groups is notable as food insecurity is known to be associated with blood glucose levels, which in turn are associated with diabetes distress.<sup>43,44</sup> In addition to the effects of food insecurity on nutritional quality, many people who experience food insecurity experience other SDOH-related needs<sup>45,46</sup>, which have been shown to affect blood glucose levels and self-management.<sup>47,48</sup> In this sample, however, self-reported self-care behaviors were not different between the 2 groups, despite the higher levels of food insecurity and diabetes distress in FQHC SMA participants. The lack of difference in self-care behaviors contrasts with what has been documented previously in the literature<sup>49,50</sup>, although

this has been found to also be related to health literacy<sup>51</sup>, which was not different between the 2 groups in this study. These findings highlight the need to consider the impact of social needs such as food insecurity when implementing programs aimed at self-management for diabetes. As SMAs tend to focus on development of self-management skills, including diet and exercise, not accounting for these needs may leave participants unable to enact these behavioral changes.<sup>52,53</sup> For example, screening people with diabetes for social needs such as food insecurity and referring those with needs to services may lead to improved ability to enact behaviors associated with diabetes self-care, as has been demonstrated previously.<sup>54</sup> This

**Table 4. Differences in Patient-Reported Diabetes Distress (Total and Domain Scores) Overall and Between Patients in Federally Qualified Health Centers (FQHCs) and Non-FQHCs**

| Construct (Measure)                          | All Patients (n = 616) | FQHC (n = 345)   | non-FQHC (n = 271) | Comparison (p-Value)      |
|--|------------------------|------------------|--------------------|---------------------------|
| <b>Diabetes Distress (DDS) – Total Score</b> |                        |                  |                    |                           |
| Median Score (IQR)                           | 1.9 (1.4 to 2.6)       | 2.1 (1.5 to 2.8) | 1.8 (1.4 to 2.4)   | 0.02* 0.0003 <sup>†</sup> |
| No Distress N (%)                            | 320 (53%)              | 162 (47%)        | 158 (60%)          | <0.0001 <sup>‡</sup>      |
| Moderate Distress N (%)                      | 180 (30%)              | 100 (29%)        | 80 (30%)           |                           |
| High Distress N (%)                          | 106 (17%)              | 81 (24%)         | 25 (10%)           |                           |
| <b>DDS - Emotional Burden</b>                |                        |                  |                    |                           |
| Median Score (IQR)                           | 2.2 (1.4 to 3.2)       | 2.4 (1.4 to 3.5) | 2.0 (1.4 to 2.8)   | 0.04* 0.0012 <sup>†</sup> |
| No Distress N (%)                            | 256 (42%)              | 132 (38%)        | 124 (47%)          | 0.0006 <sup>‡</sup>       |
| Moderate Distress N (%)                      | 158 (26%)              | 80 (23%)         | 78 (30%)           |                           |
| High Distress N (%)                          | 193 (32%)              | 131 (38%)        | 62 (23%)           |                           |
| <b>DDS - Healthcare Navigation</b>           |                        |                  |                    |                           |
| Median Score (IQR)                           | 1.0 (1.0 to 1.5)       | 1.0 (1.0 to 1.8) | 1.0 (1.0 to 1.3)   | 0.01* 0.0004 <sup>†</sup> |
| No Distress N (%)                            | 494 (83%)              | 255 (76%)        | 230 (91%)          | <0.0001 <sup>‡</sup>      |
| Moderate Distress N (%)                      | 47 (8%)                | 36 (11%)         | 11 (4%)            |                           |
| High Distress N (%)                          | 57 (10%)               | 44 (13%)         | 13 (5%)            |                           |
| <b>DDS - Regimen</b>                         |                        |                  |                    |                           |
| Median Score (IQR)                           | 2.4 (1.6 to 3.4)       | 2.6 (1.5 to 3.6) | 2.4 (1.6 to 3.2)   | 0.37* 0.22 <sup>†</sup>   |
| No Distress N (%)                            | 212 (35%)              | 119 (35%)        | 93 (36%)           | 0.04 <sup>‡</sup>         |
| Moderate Distress N (%)                      | 173 (29%)              | 86 (25%)         | 87 (33%)           |                           |
| High Distress N (%)                          | 215 (36%)              | 134 (40%)        | 81 (31%)           |                           |
| <b>DDS - Interpersonal</b>                   |                        |                  |                    |                           |
| Median Score (IQR)                           | 1.3 (1.0 to 2.5)       | 1.3 (1.0 to 2.7) | 1.0 (1.0 to 2.0)   | 0.01* 0.0022 <sup>†</sup> |
| No Distress N (%)                            | 394 (66%)              | 203 (60%)        | 191 (73%)          | 0.0008 <sup>‡</sup>       |
| Moderate Distress N (%)                      | 91 (15%)               | 52 (15%)         | 39 (15%)           |                           |
| High Distress N (%)                          | 115 (19%)              | 82 (24%)         | 33 (13%)           |                           |

Abbreviation: IQR, interquartile range, 25th-75th percentile.

Notes: Diabetes Distress Scale (DDS) categories: No distress = 1-1.9; Moderate distress = 2-2.9; High distress = 3-6.

\*PROC SURVEYREG run on value ranks.

<sup>†</sup>Wilcoxon Rank Sum.

<sup>‡</sup> $\chi^2$  test.

screening and referral to alleviate needs related to SDOH could be done as an important additional component of SMAs or other diabetes-related interventions.

The higher use of insulin at FQHCs compared with non-FQHCs is an interesting finding that deserves more investigation. While it is not possible to say without review of patient clinical information, it is possible that these medication differences are related to ability to afford medications or insurance coverage as well as factors that likely lead to higher blood glucose levels. The effects of nonaffordable medication plans are also thought to be related to the association between food insecurity and diabetes outcomes mentioned above.<sup>48</sup> As newer, more expensive medications are available for management of diabetes, people facing financial

burdens and inability to pay for medications, as many people receiving care at FQHCs experience, are more likely to take sulfonylureas or insulin as they are cheaper.<sup>55</sup> However, these medications are more likely to cause hypoglycemia, which may lead to people reducing or skipping medication, leading to swings in blood glucose and higher HbA1C.<sup>55</sup>

The implications of these results are that context matters in planning for delivery of programs such as diabetes SMAs, and patients in different settings may have different needs. Understanding the perspective of diabetes SMA participants regarding diabetes distress and self-management and life circumstances at the beginning of an intervention allows for consideration of their needs and struggles as well as adjustment of intervention delivery, potentially increasing the impact of the intervention. Evaluating baseline



**Table 5. Multivariable Linear Regression Models Testing Federally Qualified Health Centers (FQHC) vs Non-FQHC Practice Type Differences in Distress with and Without Adjustment for Social Determinants of Health (SDOH)**

| Model Tested  | Coeff (SE)   | Coeff p-Value | F    | Model p-Value |
|---|--------------|---------------|------|---------------|
| Practice type predicting distress: Overall model (n = 605)*                     |              |               | 10.7 | 0.004         |
| Intercept   | 1.94 (0.07)  | <0.001        |      |               |
| FQHC vs Non-FQHC**  | 0.36 (0.11)  | 0.004         |      |               |
| Practice type predicting distress: Overall model (n = 588)                      |              |               | 9.3  | 0.006         |
| Intercept   | 1.95 (0.08)  | <0.001        |      |               |
| FQHC vs Non-FQHC*   | 0.35 (0.12)  | 0.006         |      |               |
| Practice type predicting distress adjusted for SDOH: Overall model (n = 588***) |              |               | 8.2  | <0.001        |
| Intercept   | 3.06 (0.32)  | <0.0001       |      |               |
| FQHC vs Non-FQHC**  | -0.03 (0.10) | 0.74          |      |               |
| Age (per 10 years)  | -0.15 (0.04) | 0.0003        |      |               |
| Women vs Men  | 0.19 (0.08)  | 0.03          |      |               |
| Race/Ethnicity  | -0.44 (0.12) | 0.0006        |      |               |
| Asian vs White  | 0.82 (0.49)  | 0.11          |      |               |
| Black vs White Hispanic vs White Other vs White                                 | -0.02 (0.16) | 0.90          |      |               |
|   | 0.14 (0.10)  | 0.15          |      |               |
| English versus Spanish as Primary Language                                      | -0.29 (0.13) | 0.03          |      |               |
| Food Insecurity (Food Availability < 3)   | -0.36 (0.08) | 0.0003        |      |               |

Abbreviation: SE, standard error.

\*11 have missing DDS-17\_Total so are out of the type only model (605).

\*\*Practice type was dummy coded FQHC=0 and Non-FQHC=1. Adjusted model includes practice type and SDOH variables remaining after reverse selection with alpha = 0.05.

\*\*\*17 have other missing values (16 missing language, 1 missing age) and are removed from the expanded model (588).

PROs was designed to allow both facilitators and participants to understand the lived experience of the cohort, and to adjust the sessions to address these experiences. Ultimately, these findings may indicate a need for different approaches to supporting patients with certain characteristics, including assessing for and offering support and assistance with SDOH-related needs as well as stress and coping in addition to education regarding diabetes self-management. These findings will be important to consider when assessing the outcomes and impact of Invested in Diabetes on clinical diabetes measures such as HbA1C in both FQHC and non-FQHC settings. It is also important to consider when addressing care for diabetes outside of SMAs and argues for policies that support screening for and addressing social needs, such as food availability, as this may decrease diabetes distress and improve long-term diabetes outcomes, benefiting both individuals and whole communities.

Limitations include that PROs are by nature self-reported and therefore we were not able to objectively confirm participants' diabetes self-management. There are likely some nuances that we were not able to uncover with this purely

quantitative evaluation of baseline measures. Not all potentially relevant SDOH factors were measured due to concern over survey length; patient and practice stakeholders prioritized health literacy and food security. In addition, practices included in the study are primarily located in the US state of Colorado, with a few in the Kansas City area, and thus results may not be generalizable to areas that are culturally and geographically different. Finally, people with diabetes who choose to participate in SMAs may be different from people with diabetes who decline participation, and we were unable to track or examine characteristics in those who did not participate. In addition, our assessment of SDOH did not include all SDOH issues that may be important to understand as other determinants of diabetes distress such as health numeracy, lack of stable housing or transportation, or inability to afford medications.

## Conclusion

The FQHC and non-FQHC differences in PROs indicate the need to move beyond focusing primarily on education when implementing interventions like SMAs to improve diabetes outcomes. Many of these

differences require a deeper look at policies and structures that make it more difficult for underserved and low resourced people to manage their chronic health conditions and may help us understand why we observe differences in diabetes distress. We see in our results that participants reported similar self-care activities and perceived competence to manage their diabetes. However, people at FQHCs still report higher levels of distress and experience more social needs like food insecurity and higher tobacco use, both known to contribute to worse diabetes outcomes. When these realities are understood, interventions can be adjusted to address challenges beyond educational gaps, such as connecting people with food or medication assistance resources. Ultimately, our findings demonstrate the need to address SDOH and diabetes distress as factors in diabetes management and for policy changes that will support people in managing chronic disease and lead to better health outcomes.

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