Characterization of Patient Activation, Clinical Assessments, and Patient-reported Outcomes in Patients With Type 2 Diabetes Mellitus

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BACKGROUND

- As of 2015, an estimated 30.3 million people in the United States (US; 9.4% of the population) had diabetes[1]
- As with other chronic diseases, patient engagement is an important consideration in the management of diabetes.[2] It is recommended that people with diabetes participate in diabetes self-management education to facilitate the knowledge, skills, and abilities necessary for diabetes self-care and to implement and sustain skills and behaviors needed for ongoing self-management.[3] Furthermore, there is growing evidence to suggest an association between patient activation levels and performance of self-care activities
  - Patient activation specifies the level of patients' involvement with their health care and refers to the extent to which they have the knowledge, motivation, belief, confidence, and skills to manage chronic disease, access health care, and partner with health care providers for disease management[4]
  - The Patient Activation Measure (PAM) is a valid, reliable scale that reflects the developmental model of activation and can be used at the individual patient level to customize interventions and assess changes.[5] An association between patient activation and diabetes self-care activities has been previously demonstrated[5]
- An individual's PAM score is calculated based upon a validated algorithm that is dependent upon responses provided in the instrument. The PAM score correlates with 1 of 4 levels indicating a patient's activation or readiness to self-manage[6]
  - Level 1: disengaged and overwhelmed. Individuals are passive and lack confidence, knowledge is low, goal orientation is weak, and adherence is poor
  - Level 2: becoming aware, but still struggling. Individuals have some knowledge, but large gaps remain. They believe health is largely out of their control, but can set simple goals
  - Level 3: taking action. Individuals have the key facts and are building self-management skills. They strive for best practice behaviors and are goal-oriented
  - Level 4: maintaining behaviors and pushing further. Individuals have adopted new behaviors, but may struggle in times of stress or change. Maintaining a healthy lifestyle is a key focus

OBJECTIVE

- To characterize the baseline clinical and patient-centric characteristics of patients with type 2 diabetes mellitus (T2DM) who met the criteria for a study evaluating an online patient engagement tool

METHODS

Study Design

- This study analyzed pooled baseline data from patients with T2DM identified for a prospective evaluation of an online patient engagement tool at 2 sites: Henry Ford Health System and Northwell Health

Sample Selection

- Potential study participants were identified using electronic medical records (EMRs) and were required to meet the following inclusion and exclusion criteria:
  - Inclusion criteria
    - ≥18 years of age
    - Diagnosis of T2DM (defined using *International Classification of Diseases, 10th Revision* [ICD-10] diagnosis codes at a minimum of 2 consecutive visits within the 13 months prior to enrollment and self-reported patient confirmation of T2DM diagnosis)
    - PAM level of 2 or 3
    - Access to a personal computer or wireless device with supporting internet service
    - Able to provide voluntary, informed consent to participate in the study
  - Exclusion criteria
    - Active malignant disease (defined using ICD-10 diagnosis codes)
    - Major surgical procedure within the last 3 months (patient-reported)
    - End-stage renal disease (defined using ICD-10 diagnosis codes)
    - PAM level of 1 or 4

Study Endpoints

- Eligible patients who provided consent completed online surveys capturing demographics, medical and diabetes history, clinical characteristics, and a series of validated patient-reported outcomes (PROs) at baseline
- Additionally, sites provided EMR and laboratory data for the identification of comorbidities, HbA1c, weight, and body mass index (BMI)
- **Table 1** includes an overview of the PROs included in the study

Table 1. PROs Included in the Study

PRO	Description
PAM	• A 10-question survey that assesses an individual's knowledge, skills, and confidence for managing one's health and health care • Patients are asked to answer questions; based on these answers, scores predictive of health behaviors are calculated • Based on these scores, a PAM level of 1 to 4 is assigned
SF-12[7]	• A 12-question survey that assesses functional health and well-being from the patient's perspective across 8 health domains using PCS and MCS scores • Scores range from 0 to 100, with 0 being the lowest and 100 being the highest level of health • For individual responses, a score of ≥45 indicates at least average overall functioning and a score of <40 indicates impaired functioning in the associated domain (PCS or MCS) • Group mean scores <47 indicate impaired functioning in the associated domain (PCS or MCS)
DDS[8]	• A 17-question survey to assess patient concerns about disease management, support, emotional burden, and access to care • Patients are asked to rate on a 6-point scale the degree to which diabetes has caused them distress, with higher scores indicating increased distress or burden • Mean item scores of ≥3 (moderate distress) are considered a level of distress worthy of clinical attention

SF-12, Short Form-12; PCS, physical component summary; MCS, mental component summary; DDS, Diabetes Distress Scale.

Statistical Analysis

- The primary analysis was descriptive in nature
- Demographics and baseline characteristics (age, gender, race, ethnicity, marital status, education, annual household income, health insurance coverage, employment status, and medical history/comorbidities) were summarized descriptively
- Descriptive statistics, including numbers of patients, means, standard deviations (SDs), medians, minimums, and maximums, were provided for continuous variables
- Frequencies, counts, and percentages were tabulated for categorical variables

RESULTS

Study Attrition

- 792 patients consented to the study, among whom 662 provided complete baseline PAM data and 363 were ultimately eligible for the study. **Figure 1** depicts full sample attrition for the study

Figure 1. Sample attrition.
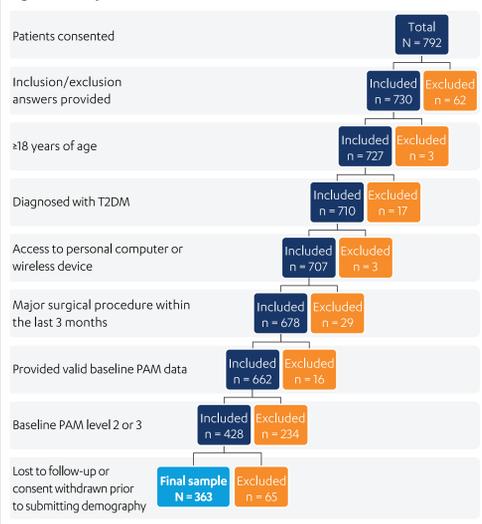
PAM Level

- 662 participants provided valid PAM data, with 15.9% and 48.8% at PAM levels 2 and 3, respectively. **Figure 2** summarizes baseline PAM levels for all participants
- A total of 234 patients with PAM levels 1 (5.4%) and 4 (29.9%) were ultimately ineligible for the full study, and 363 patients met all eligibility criteria for inclusion in this analysis

Figure 2. Distribution of baseline PAM levels among all baseline PAM survey respondents (N = 662).

Level 1 Level 2 Level 3 Level 4
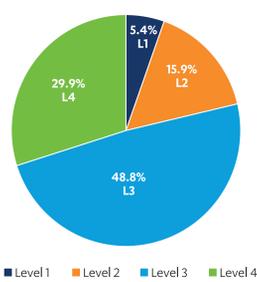
Demographics

- Participants were primarily white (58.4%) and female (59.0%), with a PAM level of 3 (76.6%)
- The mean (SD) age of participants was 57.4 (11.1) years
- The majority of patients were married (61.2%), were employed full time (46.0%), and received health insurance coverage through an employer (54.5%)
- Patient demographics are described in **Table 2**

Table 2. Patient Demographics

	All eligible patients (N = 363)	Baseline PAM level 2 patients (n = 85)	Baseline PAM level 3 patients (n = 278)
Mean (SD) age, y	57.4 (11.1)	55.5 (11.2)	58.0 (11.0)
Age group, n (%)			
18-34 y	10 (2.8)	1 (1.2)	9 (3.2)
35-44 y	39 (10.7)	17 (20.0)	22 (7.9)
45-54 y	84 (23.1)	18 (21.2)	66 (23.7)
55-64 y	115 (31.7)	24 (28.2)	91 (32.7)
65+ y	107 (29.5)	22 (25.9)	85 (30.6)
Data not provided	8 (2.2)	3 (3.5)	5 (1.8)
Gender, n (%)			
Female	214 (59.0)	47 (55.3)	167 (60.1)
Male	142 (39.1)	35 (41.2)	107 (38.5)
Data not provided	7 (1.9)	3 (3.5)	4 (1.4)
Race, n (%)			
White	212 (58.4)	47 (55.3)	165 (59.4)
Black	121 (33.3)	32 (37.6)	89 (32.0)
Asian	15 (4.1)	3 (3.5)	12 (4.3)
American Indian or Alaskan Native	5 (1.4)	0 (0.0)	5 (1.8)
Other	7 (1.9)	2 (2.4)	5 (1.8)
Data not provided	3 (0.8)	1 (1.2)	2 (0.7)
Ethnicity, n (%)			
Hispanic	10 (2.8)	4 (4.7)	6 (2.2)
Non-Hispanic	222 (61.2)	47 (55.3)	175 (62.9)
Other	83 (22.9)	21 (24.7)	62 (22.3)
Unknown	48 (13.2)	13 (15.3)	35 (12.6)
Marital status, n (%)			
Married	222 (61.2)	50 (58.8)	172 (61.9)
Single	67 (18.5)	15 (17.6)	52 (18.7)
Divorced	39 (10.7)	6 (7.1)	33 (11.9)
Live with partner	8 (2.2)	4 (4.7)	4 (1.4)
Separated	5 (1.4)	3 (3.5)	2 (0.7)
Widow/widower	21 (5.8)	7 (8.2)	14 (5.0)
Data not provided	1 (0.3)	0 (0.0)	1 (0.4)
Employment status,* n (%)			
Employed (full time)	167 (46.0)	41 (48.2)	126 (45.3)
Employed (part time)	21 (5.8)	5 (5.9)	16 (5.8)
Unemployed	16 (4.4)	5 (5.9)	11 (4.0)
Retired	81 (22.3)	16 (18.8)	65 (23.4)
Homemaker	8 (2.2)	4 (4.7)	4 (1.4)
Student	1 (0.3)	0 (0.0)	1 (0.4)
Disabled	21 (5.8)	6 (7.1)	15 (5.4)
Data not provided	53 (14.6)	10 (11.8)	43 (15.5)
Health insurance coverage, n (%)			
None	0 (0.0)	0 (0.0)	0 (0.0)
Insurance through employer	198 (54.5)	44 (51.8)	154 (55.4)
Private insurance	24 (6.6)	7 (8.2)	17 (6.1)
Medicaid	28 (7.7)	8 (9.4)	20 (7.2)
Medicare	70 (19.3)	15 (17.6)	55 (19.8)
DoD/veteran's benefits	4 (1.1)	1 (1.2)	3 (1.1)
Other	75 (20.7)	17 (20.0)	58 (20.9)
Highest education level, n (%)			
Did not complete high school	0 (0.0)	0 (0.0)	0 (0.0)
High school diploma or GED equivalent	26 (7.2)	6 (7.1)	20 (7.2)
Some college or certificate program	85 (23.4)	22 (25.9)	63 (22.7)
College or university degree (2-year)	44 (12.1)	17 (20.0)	27 (9.7)
College or university degree (4-year)	77 (21.2)	16 (18.8)	61 (21.9)
Graduate degree	82 (22.6)	13 (15.3)	69 (24.8)
Data not provided	49 (13.5)	11 (12.9)	38 (13.7)
Annual household income, n (%)			
<$35,000	60 (16.5)	23 (27.1)	37 (13.3)
$35,001-$50,000	44 (12.1)	11 (12.9)	33 (11.9)
$50,001-$75,000	67 (18.5)	13 (15.3)	54 (19.4)
$75,001-$100,000	53 (14.6)	9 (10.6)	44 (15.8)
$100,001-$150,000	52 (14.3)	9 (10.6)	43 (15.5)
>$150,000	34 (9.4)	9 (10.6)	25 (9.0)
Data not provided	53 (14.6)	11 (12.9)	42 (15.1)

DoD, Department of Defense; GED, general education diploma.
*Multiple answers were allowed.

Medical History

- The mean (SD) time since diagnosis of T2DM was 10.4 (8.3) years
- The most common comorbidities were hypertension and hypercholesterolemia/hyperlipidemia (20.7% each)
- Patients' medical histories are described in **Table 3**

Table 3. Medical History

	All eligible patients (N = 363)	Baseline PAM level 2 patients (n = 85)	Baseline PAM level 3 patients (n = 278)
Patients with non-missing year of diabetes diagnosis, n (%)	350 (96.4)	80 (94.1)	270 (97.1)
Time since T2DM diagnosis, y			
Mean (SD)	10.4 (8.3)	10.3 (9.1)	10.4 (8.1)
Median	8.5	7.5	9.0
Minimum, maximum	0.0, 43.0	1.0, 43.0	0.0, 42.0
Comorbidities,* n (%)			
Hypertension	75 (20.7)	16 (18.8)	59 (21.2)
Cardiovascular disease	34 (9.4)	7 (8.2)	27 (9.7)
Cerebrovascular disease (including stroke)	5 (1.4)	2 (2.4)	3 (1.1)
Myocardial infarction	6 (1.7)	1 (1.2)	5 (1.8)
Congestive heart failure	3 (0.8)	2 (2.4)	1 (0.4)
Peripheral artery disease	3 (0.8)	1 (1.2)	2 (0.7)
Hypercholesterolemia/hyperlipidemia	75 (20.7)	20 (23.5)	55 (19.8)
Selected diabetes complications			
Neuropathy	27 (7.4)	7 (8.2)	20 (7.2)
Eye conditions/retinopathy	9 (2.5)	2 (2.4)	7 (2.5)
Other (ketoacidosis, gastroparesis)	29 (8.0)	8 (9.4)	21 (7.6)
Arthritis	32 (8.8)	7 (8.2)	25 (9.0)
Peptic ulcer disease/gastroesophageal reflux disease	20 (5.5)	4 (4.7)	16 (5.8)
Pulmonary (asthma/bronchitis/chronic obstructive pulmonary disease)	29 (8.0)	7 (8.2)	22 (7.9)
Thyroid conditions	26 (7.2)	5 (5.9)	21 (7.6)
Any cancer	24 (6.6)	5 (5.9)	19 (6.8)
Depression	17 (4.7)	4 (4.7)	13 (4.7)
Other mental health disorders (anxiety, panic attacks, alcoholism, etc)	37 (10.2)	9 (10.6)	28 (10.1)
Back pain	20 (5.5)	5 (5.9)	15 (5.4)
Liver disease	13 (3.6)	3 (3.5)	10 (3.6)
Any above comorbidity, n (%)	141 (38.8)	34 (40.0)	107 (38.5)

*Not mutually exclusive and based on 180 days before the initial visit.

Clinical Measures

- 39.4% of patients had an HbA1c >8.0%
- Patients' mean (SD) HbA1c was 8.0% (1.8), and mean (SD) BMI fell within the obese range at 36.3 (7.4) kg/m²
- Clinical measures, including HbA1c, weight, and BMI, for eligible patients are described in **Table 4**

Table 4. Clinical Measures: HbA1c, Weight, and BMI

	All eligible patients (N = 363)	Baseline PAM level 2 patients (n = 85)	Baseline PAM level 3 patients (n = 278)
Patients with non-missing HbA1c, n (%)	213 (58.7)	53 (62.4)	160 (57.6)
Mean (SD) HbA1c, %	8.0 (1.8)	8.1 (1.9)	7.9 (1.7)
<7%, n (%)	68 (31.9)	21 (39.6)	47 (29.4)
7%-<8%, n (%)	61 (28.6)	10 (18.9)	51 (31.9)
8%-<9%, n (%)	41 (19.2)	9 (17.0)	32 (20.0)
≥9%, n (%)	43 (20.2)	13 (24.5)	30 (18.8)
Patients with non-missing weight, n (%)	283 (78.0)	63 (74.1)	220 (79.1)
Mean (SD) weight, lb	229.9 (53.6)	244.0 (55.5)	225.8 (52.4)
Patients with non-missing BMI, n (%)	283 (78.0)	63 (74.1)	220 (79.1)
Mean (SD) BMI, kg/m²	36.3 (7.4)	39.0 (8.2)	35.5 (7.1)

PROs

- Mean (SD) PCS and MCS scores from the SF-12 were 40.9 (16.1) and 44.9 (17.1), respectively, indicating impaired functioning in each dimension
- SF-12 survey results are provided in **Table 5**

Table 5. SF-12 Survey Results

	All eligible patients (N = 363)	Baseline PAM level 2 patients (n = 85)	Baseline PAM level 3 patients (n = 278)
Patients with non-missing SF-12 data, n (%)	360 (99.2)	84 (98.8)	276 (99.3)
PCS, mean (SD)	40.9 (16.1)	40.3 (15.4)	41.1 (16.3)
MCS, mean (SD)	44.9 (17.1)	42.7 (16.9)	45.6 (17.1)

- Mean (SD) DDS scores indicated moderate regimen-related distress (3.1 [1.2]) and emotional burden (2.7 [1.2]), suggesting that clinical attention is necessary
- DDS survey results are provided in **Table 6**

Table 6. DDS Survey Results

	All eligible patients (N = 363)	Baseline PAM level 2 patients (n = 85)	Baseline PAM level 3 patients (n = 278)
Patients with non-missing emotional burden score, n (%)	357 (98.3)	84 (98.8)	273 (98.2)
Emotional burden score, mean (SD)	13.5 (5.8)	14.9 (6.3)	13.1 (5.6)
Emotional burden score, median (IQR)	9.0 (17.0)	10.0 (19.0)	9.0 (17.0)
Patients with non-missing physician-related distress score, n (%)	357 (98.3)	84 (98.8)	273 (98.2)
Physician-related distress score, mean (SD)	6.9 (4.1)	7.3 (4.2)	6.7 (4.1)
Physician-related distress score, median (IQR)	4.0 (8.0)	4.0 (9.0)	4.0 (8.0)
Patients with non-missing regimen-related distress score, n (%)	357 (98.3)	84 (98.8)	273 (98.2)
Regimen-related distress score, mean (SD)	15.6 (6.2)	17.8 (6.1)	14.9 (6.0)
Regimen-related distress score, median (IQR)	11.0 (20.0)	13.5 (23.0)	11.0 (19.0)
Patients with non-missing diabetes-related interpersonal distress score, n (%)	357 (98.3)	84 (98.8)	273 (98.2)
Diabetes-related interpersonal distress score, mean (SD)	6.6 (3.9)	7.5 (4.2)	6.3 (3.7)
Diabetes-related interpersonal distress score, median (IQR)	3.0 (8.0)	4.0 (11.0)	3.0 (8.0)

IQR, interquartile range.

Limitations

- The patients in this study were generally well educated, with more than half of patients (55.9%) having at least a 2-year college or university degree. The selection of more educated patients may have introduced bias
- Further, the results of this study may be limited in their generalizability, to the extent that these patients may vary from the general population of US patients
- The inclusion criteria requiring a patient to have access to a personal computer or wireless device with supporting internet service may have led to the exclusion of patients of lower socioeconomic status
- For several of the patient demographic characteristics, including ethnicity, employment status, health insurance coverage, and education level, data were unavailable for >10% of patients
- Because of these limitations, further research is needed to confirm the results of this study

CONCLUSIONS

- With almost 40% of patients indicating inadequate glycemic control with an HbA1c >8% and patients' mean BMI values falling within the obese category, clinical measurements in this population of patients with T2DM with PAM levels 2 and 3 suggest a need for clinical and lifestyle intervention
- Further, the results of the PROs collected in this study support this conclusion, as patients reported impaired physical and mental functioning and moderate regimen-related distress and emotional burden
- Further research is needed to determine appropriate clinical interventions and potential effectiveness of targeted patient engagement tools

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