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Prevalence of fear of hypoglycemia in adults with type 1 diabetes using a newly developed screener and clinician's perspective on its implementation

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ABSTRACT

Introduction Fear of hypoglycemia (FoH) affects quality of life, emotional well-being, and diabetes management among people with type 1 diabetes (PwT1D). American Diabetes Association's (ADA) guidelines recommend assessing FoH in clinical practice. However, existing FoH measures are commonly used in research and not in clinical practice. In this study, prevalence of FoH was assessed in PwT1D using a newly developed FoH screener for clinical practice; its association with established measures and outcomes was also determined. In addition, healthcare providers' (HCPs) perspectives on implementing FoH screener into real-world practice were explored.

Research design and methods This multiphase observational study used mixed methods in two phases. First, we collected a cross-sectional survey (including the screener) from PwT1D (≥18 years) from T1D Exchange Quality Improvement Collaborative adult clinics. Pearson correlations and regression analyses were performed on diabetes outcome measures using screener scores. Second, we conducted focus groups among HCPs who treat PwT1D and descriptive analysis to summarize results.

Results We included 553 PwT1D. Participants had a mean±SD age of 38.9±14.2 years and 30% reported a high FoH total score. Regression analyses showed that higher A1c and higher number of comorbidities were significantly associated with high FoH ($p<0.001$). High FoH worry and behavior scores were significantly associated with 8-Item Patient Health Questionnaire and 7-Item Generalized Anxiety Disorder Scale scores. Participants with ≥1 severe hypoglycemia event(s) and impaired awareness of hypoglycemia had higher odds of high FoH. Eleven HCPs participated in focus group interviews; they expressed that the FoH screener is clinically necessary and relevant but poses implementation challenges that must be addressed.

Conclusions Our results demonstrate FoH is common in PwT1D and affects their psychosocial well-being and diabetes management. In alignment with ADA position statement, HCP focus group results emphasize importance of screening for FoH. Implementing this newly developed FoH screener may help HCPs identify FoH in PwT1D.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Fear of hypoglycemia (FoH) is common in people with type 1 diabetes (PwT1D) and affects their quality of life and diabetes management.
⇒ Existing patient-reported outcome instruments that assess FoH have been validated for use in PwT1D and are used in the research setting. However, they are not formally used by healthcare providers (HCPs) in clinical practice.

WHAT THIS STUDY ADDS

⇒ Among PwT1D, this newly developed and validated screener found 30% had high FoH.
⇒ Participants with high FoH scores reported higher glycated hemoglobin (A1c), more frequent severe hypoglycemic events, and higher impaired awareness of hypoglycemia.
⇒ The FoH screener, with its clear cut-off values and actionable domains, may facilitate focused clinical conversations between patients and providers about the psychosocial impact of hypoglycemia.
⇒ During focus groups, HCPs expressed that FoH screener is necessary and relevant but posed challenges to implementation that must be addressed.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Focus group results align with the American Diabetes Association's recommendations, emphasizing the importance of screening for FoH.
⇒ This screener may be incorporated in clinical practice flow to help HCPs to identify FoH in PwT1D.

INTRODUCTION

Fear of hypoglycemia (FoH) is specific and extreme fear associated with the risk and/or occurrence of hypoglycemia.[1] In adults with type 1 diabetes (T1D), higher FoH is associated with lower quality of life, impaired emotional well-being, and higher psychological distress.[2] This can lead to compensatory behaviors to avoid future episodes of

hypoglycemia, such as inadequate insulin dosing, more snacking, and low engagement with diabetes management.[3 4] The American Diabetes Association's (ADA) statement on psychosocial care recommends screening for FoH using standardized and validated tools and referring adults with FoH to mental health providers.[5]

Existing patient-reported outcome (PRO) instruments that assess FoH include Hypoglycemia Fear Survey-II (HFS-II), Hypoglycemic Attitudes and Behavior Scale, and Fear of Hypoglycemia Scale.[2 6 7] Common constructs of FoH that have emerged from these instruments are psychosocial distress (ie, fear or worry) due to hypoglycemia, lack of confidence in managing hypoglycemia, and behavioral avoidance of hypoglycemia. These instruments are validated for use in people with diabetes and have been used in the research setting for decades.[8] However, they are not routinely used by healthcare providers (HCPs) for screening in clinical practice.[8 9] A recent systematic review reported that existing FoH instruments lack clear cut-off values informing clinical action.[10] This might restrict the ability of HCPs to assess the burden and impact of FoH in people with type 1 diabetes (PwT1D) in the clinical setting.

Therefore, an easy-to-use, brief, and actionable 9-item screener was developed and validated for use in PwT1D.[8 11] The new screener has demonstrated good validity and internal consistency; its two-factor structure is consistent with existing literature on FoH in PwT1D as it assesses both worry and behavioral avoidance related to hypoglycemia.[12]

The current study aims to assess the prevalence of FoH using a newly developed FoH screener in a sample of PwT1D from adult clinics. We also sought to understand the association of the FoH screener with other established measures of depression and anxiety. In addition, we explored HCPs' perspectives on the importance, relevance, and feasibility of implementing the screener into their practice.

METHODS

Study design

This observational study assessed the prevalence of FoH in a T1D population using a newly validated FoH screener. Screener items were assessed for internal consistency with patient characteristics and common PRO measures (eg, 7-Item Generalized Anxiety Disorder Scale (GAD-7), 8-Item Patient Health Questionnaire (PHQ-8) measure, and HFS-II). Following this, HCPs were interviewed on how the screener could fit within their daily practice. The study used mixed methods: (1) an online quantitative cross-sectional survey (including the screener) with PwT1D (January to February 2022), and (2) two focus groups with HCPs caring for adults with T1D (March 2022).

Study population

In the first part of the study, survey participants were recruited from three T1D Exchange Quality Improvement Collaborative adult clinics in California, Colorado, and New York.[13 14] Eligible participants aged ≥18 years were included if they had been diagnosed with T1D for at least 12 months, had glycated hemoglobin (A1c) measurements available within the last 12 months, resided in the USA, were fluent in reading English, and were not currently pregnant. Eligible participants were identified by clinic personnel via electronic health records. A link to the online survey containing information on self-reported measures was shared through patient portals. Respondents provided their consent to participate before continuing the survey questions.

The second part of the study involved focus groups, which included HCPs from nine clinics who practiced in the USA and had cared for adults with T1D for at least 5 years. An email advertisement was sent to HCPs to inquire about their potential interest in the focus groups (January 2022 to February 2022).[8] Before participating in the focus groups, eligible HCPs completed a preliminary eligibility survey, which included: (1) a consent form; (2) specialty and years of experience; (3) whether they routinely cared for PwT1D; and (4) duration of treatment for PwT1D. Pre-reads of the ADA psychosocial care position statement and the participant survey were shared with the HCPs in an email.[5] Focus group participants were presented with a summary of the patient screener survey results.

Survey measures

Participants reported demographic characteristics (gender, age, race, ethnicity, and insurance type) and general health information (height, weight, and the number of times participants exercised in a week). They also reported diabetes management information such as frequency of their visits to HCPs, T1D duration (years), diabetes-related comorbidities, most recent A1c %, glucose monitoring methods (blood glucose meter and continuous glucose monitor), insulin delivery methods (insulin pump and multiple daily injections), history of hypoglycemia (mild, moderate, and severe) in the past year, and comfortable blood glucose range (lower bound and upper bound). Impaired awareness of hypoglycemia was assessed using the Gold score; participants reported their experience in detecting severe hypoglycemia events with Gold scores ranging from 1 (always aware) to 7 (never aware).[15] To assess prevalence of FoH, a 9-item FoH screener was used for assessment using a 5-point Likert scale, with scores ranging from 1 (strongly disagree) to 5 (strongly agree).[8 11] Item scores were summed to produce a total score as well as worry (6 items) and behavior (3 items) subscale scores (figure 1).

To understand the association between the FoH screener and existing PROs, established measures of anxiety and depression were included. Severity of generalized anxiety disorder was assessed over the preceding

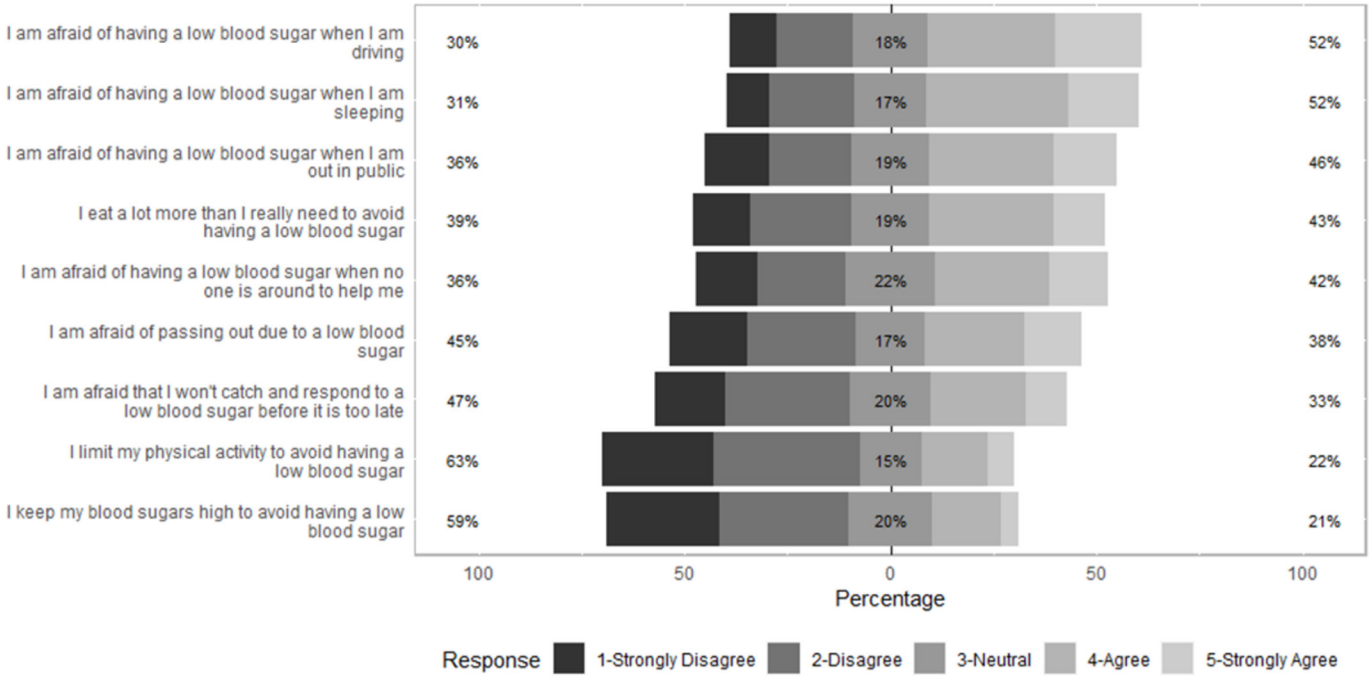

Figure 1 Fear of hypoglycemia screener item distribution by response frequency.

2 weeks using a GAD-7 that assessed the presence of anxiety symptoms with scores ranging from 0 to 21.[16] A PHQ-8 measure was used to assess severity of depressive disorder, with total score ranging from 0 to 24.[17] The HFS-II, a short form that assesses peoples' behavior (5 items) and worry (6 items) related to hypoglycemia in the past 6 months, was used to measure the avoidance behavior and worry components of FoH.[6] Items were rated on a 5-point scale ranging from 0 (never) to 4 (almost always).

Focus group procedures

Semistructured 90 min focus groups were conducted with HCPs. The focus groups were moderated by a diabetes expert from T1D Exchange and conducted using a focus group guide (online supplemental table 1).[8] The audio recordings of focus group interviews were transcribed using TranscribeMe. Each transcript was deidentified and reviewed to identify key topics of interest. Responses were labeled with codes and subcodes to identify common themes discussed across participants using NVivo software.[18] Data from focus groups were categorized into four domains and 12 themes (online supplemental table 2).

Statistical analysis of survey data

Descriptive statistics were performed for all data collected in participant surveys and medical record review. Descriptive statistics included frequencies and percentages for categorical measures and mean, SD for continuous measures.

Psychometric analyses were conducted to further evaluate the reliability and validity of the FoH screener among PwT1D; Cronbach's alpha for internal consistency, correlations between screener scores and GAD-7 score, PHQ-8 score, and HFS-II scores for concurrent validity. Multivariable linear regressions were performed to examine the associations between FoH screener scores and relevant diabetes outcomes (self-reported A1c, number of comorbidities, comfortable blood glucose (lower bound and upper bound), PHQ-8, and GAD-7).

All statistical analyses were performed using R software V.4.0.5 or later (R Core Team, Vienna, Austria). Significance was set at $p<0.05$.

RESULTS

Part 1: survey participant characteristics

Participants who completed the survey (n=533) had a mean±SD age of 39±14 years (table 1). Most participants were female (65%), White (88%), non-Hispanic (92%), enrolled in private health insurance (78%), and exercised at least once a week (82%). Their most recent mean±SD self-reported A1c measurement within the last 12 months was 7±1.2%. A total of 75% of participants used insulin pumps, and 93% used continuous glucose monitors. Participants reported their mean±SD comfortable blood glucose range with lower bound at 85±17 mg/dL and upper bound at 170±44 mg/dL (table 1).

Screener item scores

The distribution of response frequency of the FoH screener items is presented in figure 1. Most participants 'agreed' or 'strongly agreed' that they experienced FoH while driving (52%), sleeping (52%), or when they were out in public (46%). Most participants also 'agreed' or 'strongly agreed' that they ate more than needed to avoid low blood sugar (43%), and that they were afraid of having low blood sugar

Table 1 Characteristics of survey participants

Characteristic	Mean±SD or n (%)
Survey participants (n=553)	
Age, years	
Mean±SD	39±14
Gender	
Female	357 (65)
Male	191 (35)
Other	5 (1)
Race	
White	488 (88)
Asian	23 (4)
Black or African American	12 (2)
American Indian or Alaska Native	2 (<1)
Native Hawaiian or Other Pacific Islander	1 (<1)
Multiracial	11 (2)
Other	15 (3)
Missing	1 (0.2)
Ethnicity	
Hispanic or Latino	46 (8)
Not Hispanic or Latino	506 (92)
Missing	1 (<1)
Health insurance type	
Private insurance	432 (78)
Public insurance	87 (16)
Private and public health insurance	25 (5)
No health insurance	1 (<1)
Do not wish to answer	7 (1)
I do not know	1 (<1)
BMI, kg/m^2 (n=548)	27±5
BMI, categorical	
Underweight (<18.5)	6 (1)
Normal weight (18.5–24.9)	241 (44)
Overweight (25–29.9)	185 (34)
Obesity (≥30)	116 (21)
Missing	5 (1)
Exercise frequency, times/week	
<1	102 (18)
1–3	219 (40)
4–6	182 (33)
>7	50 (9)
HCPs*	
Endocrinologist/diabetologist	525 (95)
CDCES	94 (17)
Diabetes NP or PA	116 (21)
Primary care—physician	101 (18)
Primary care—NP or PA	15 (3)
Psychologist, social worker, therapist, or counselor	29 (5)
Registered dietician	27 (5)
Other	8 (1)
Insulin delivery	
Insulin pump	417 (75)
Multiple daily injections	136 (25)
Blood glucose monitoring method	
Blood glucose meter only	36 (7)
Continuous glucose meter	515 (93)
Missing	2 (0.4)
Self-reported A1c levels (%)	7±1
Comfortable blood glucose range—low (mg/dL)	85±17
Comfortable blood glucose range—high (mg/dL)	170±44
Number of mild hypoglycemia per week	5±6
Number of moderate hypoglycemia per week	2±2
Number of SHEs in the past 12 months	1±6

n=total number of survey participants.
*Primary HCPs of survey participants. HCPs could select more than one option.
A1c, glycated hemoglobin; BMI, body mass index; CDCES, certified diabetes care and education specialist; HCP, healthcare provider; NP, nurse practitioner; PA, physician assistant; SHE, severe hypoglycemic event.

when alone (42%). Of the survey participants, 30% were screened positive for high FoH total score (scores ranging from 31 to 44), 24% screened positive for high FoH worry score (scores ranging from 24 to 30) and 28% screened positive for high FoH behavior score (scores ranging from 10 to 15; online supplemental table 3).

FoH screener associations

Higher FoH screener scores (total, worry, and behavior scores) were associated with female gender (r=0.23, 0.24, and 0.11), higher number of comorbidities (r=0.19, 0.17, 0.18), higher self-reported A1c (r=0.21, 0.15, 0.27), and higher value for the lower bound of 'comfortable low' blood glucose (r=0.15, 0.12, and 0.16) (p<0.05 for all; table 2). Higher FoH total screener scores were also associated with younger age (r=−0.09) and shorter duration of T1D (r=−0.17) (p<0.05; table 2). The 9-item screener showed good internal consistency (total scale, Cronbach's alpha=0.88; online supplemental table 3); the screener scores (total, worry, and behavior scores)

Table 2 Correlation coefficients between FoH screener scores, respondent characteristics and patient-reported outcomes (HFS-II, GAD-7, PHQ-8)

Characteristic/measure	Correlation		
	Total score (r_t)	Worry subscale (r_w)	Behavior subscale (r_b)
Female	0.23*	0.24*	0.11*
Age (years)	−0.09*	−0.08*	−0.07
Duration of T1D (years)	−0.17*	−0.17*	−0.11*
Number of comorbidities	0.19*	0.17*	0.18*
MDI versus pump	−0.08	−0.05	−0.11*
Glucometer use (vs CGM use)	0.02	0.03	0.01
Self-reported A1c (%)	0.21*	0.15*	0.27*
Gold score	0.12*	0.13*	0.03
Number of mild hypoglycemia per week	−0.02	−0.02	−0.01
Number of moderate hypoglycemia per week	0.01	0.02	−0.02
Number of severe hypoglycemia in the past 12 months	0.09*	0.08	0.07
Number of lifetime severe hypoglycemia	0.08	0.09*	0.03
BMI (kg/m^2)	0.09*	0.06	0.13*
Comfortable blood glucose range—low	0.15*	0.12*	0.16*
Comfortable blood glucose range—high	0.05	0.00	0.15*
FoH worry score	0.95*	–	–
FoH behavior score	0.74*	0.49*	–
General anxiety (GAD-7)	0.37*	0.32*	0.33*
Depression (PHQ-8)	0.37*	0.31*	0.35*
HFS total score	0.78*	0.72*	0.61*
HFS worry score	0.74*	0.75*	0.45*
HFS behavior score	0.65*	0.52*	0.69*

Gold score measures impaired awareness of hypoglycemia (responses range from 'Always aware (1)' to 'Never aware (7)'). GAD-7 is a 7-item anxiety scale developed to diagnose generalized anxiety disorder. PHQ-8 is an outcome measure that is used both as a diagnostic and severity measure for depressive disorders in clinical studies. HFS-II (short form) is an 11-item patient-reported outcome measure that assesses adults' behavior (5 items) and worry (6 items) related to hypoglycemia in the past 6 months.
*P<0.05.
A1c, glycated hemoglobin; BMI, body mass index; CGM, continuous glucose monitoring; FoH, fear of hypoglycemia; GAD-7, 7-Item Generalized Anxiety Disorder Scale; HFS-II, Hypoglycemia Fear Survey-II; MDI, multiple daily injections; PHQ-8, 8-Item Patient Health Questionnaire; r_b, correlation coefficient behavior score; r_t, correlation coefficient total score; r_w, correlation coefficient worry score; T1D, type 1 diabetes.

were highly correlated with the 11-item short form of the HFS scores (r=0.78, 0.72, 0.61). Construct validity of the FoH screener (total, worry, and behavior scores) was exhibited with significant moderate positive correlations with depression (PHQ-8, r=0.37, 0.31, 0.35) and anxiety (GAD, r=0.37, 0.32, 0.33; table 2) measures. FoH screener scores were positively correlated with higher GAD-7 score, PHQ-8 score, and HFS total scores (p<0.05; table 2).

Regression analysis

In multiple regression analysis, individuals with high FoH (total FoH score >30) versus low FoH (total FoH score ≤30) reported higher A1c (p<0.001), higher number of comorbidities (p<0.001) and higher value for the lower bound of 'comfortable low' blood glucose (p<0.01) (online supplemental table 4). Participants with high FoH (total FoH score >30) versus low FoH (total FoH score ≤30) reported 0.56% higher A1c (B=0.56, p<0.001) and, on average, one additional comorbidity (B=1.08, p<0.001) (online supplemental table 4).

High FoH worry score was associated with more comorbidities (p<0.001), higher PHQ-8 score (p<0.001), and higher GAD-7 score (p<0.001; online supplemental table 4). High FoH behavior score was significantly associated with higher A1c (p<0.001), higher number of comorbidities (p<0.05), higher blood glucose value for upper bound of 'comfortable high' (p<0.001), higher PHQ-8 score (p<0.001), and higher GAD-7 score (p<0.001; online supplemental table 4).

Individuals who experienced ≥1 severe hypoglycemia event in the past 12 months were more likely to be in the high FoH total group (OR 2.74 (1.70, 4.44); p<0.001)

Table 3 Characteristics of focus group participants

Characteristic	n (%)
Focus group participants (n=11)	
Healthcare provider type	
CDCES	2 (18)
NP or PA	1 (9)
Endocrinologist/diabetologist	6 (55)
Registered dietician	1 (9)
Registered nurse	1 (9)
Years of experience	
5–10	7 (64)
More than 10	4 (36)
State	
Florida	1 (9)
Georgia	1 (9)
Illinois	2 (18)
Massachusetts	2 (18)
New York	4 (36)
Ohio	1 (9)

n=number of healthcare professionals who participated in focus groups.
CDCES, certified diabetes care and education specialist; NP, nurse practitioner; PA, physician assistant.

and the high FoH worry group (OR 2.52 (1.52, 4.17); p<0.001) than those without a severe hypoglycemic event.

Part 2: focus group—participant characteristics

Eleven HCPs participated in focus groups. Most HCPs were endocrinologists/diabetologists (55%), followed by certified diabetes care and education specialists (18%). Most HCPs (64%) had 5–10 years of experience in treating PwT1D (table 3).

Qualitative analysis

Figure 2 presents factors for and against the implementation of the FoH screener in a real-world clinical setting. Focus group participants identified and discussed factors that negatively impact psychosocial well-being and ability to achieve desired health outcomes for PwT1D. These factors include anxiety, diabetes distress, and social determinants of health such as housing instability, food insecurity, and insurance barriers. HCPs expressed concern about the challenges of adopting and implementing a new screener in practice. Endocrinologists quoted staffing shortages and scarcity of social workers and mental health professionals when discussing clinical resources and patient access to care. Delayed access to healthcare, limited capacity within the hospital system, and long wait times were also identified as barriers for individuals who receive internal referrals to mental health providers.

Factors supporting the implementation of the screener during the previsit screening in a clinical setting were: (1) the need for a validated FoH screener to address individual's psychosocial needs; (2) the ability to identify patients who could benefit from referral to education and mental health providers; (3) the need to make informed choices to maximize time and effort by targeting high-risk populations; and (4) the impact of screener results on treatment decisions, as screening would identify people who might not have been predicted or presumed to have FoH.

HCPs discussed several barriers for screener integration into clinical practice during the focus groups. These barriers included: (1) prioritizing adults with high FoH for screening; (2) collecting multiple questionnaires at clinic visits, which was associated with experiencing fatigue or stress for PwT1D; (3) lacking easy patient access to mental healthcare professionals; (4) obtaining information technology (IT) resources to incorporate FoH screener into electronic medical records (EMR) as

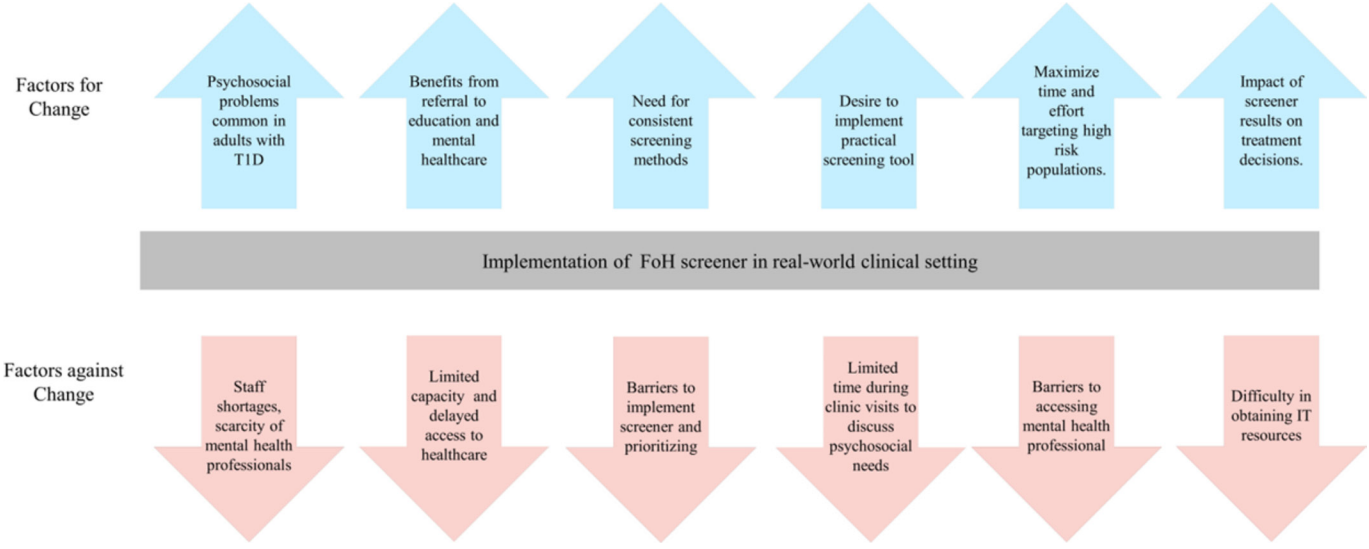

Figure 2 Factors for and against the implementation of FoH screener in real-world clinical setting. FoH, fear of hypoglycemia; IT, information technology; T1D, type 1 diabetes.

structured data; (5) resource limitations in the system; and (6) limited time during clinic visits. Also, it was identified that additional time would be required for staff to ask the screener questions before or during a visit. HCPs discussed that during approximately 20 min clinical encounters, they are tasked with discussing results of screeners with PwT1D; reviewing point-of-care testing results; conducting medication reconciliation; ordering laboratory tests, medications, diabetes device supplies, and behavioral health referrals; discussing patient priorities, treatment goals, and diabetes device data results; and recommending insulin adjustments to increase time in target blood glucose range.

DISCUSSION

We observed strong correlations between the new 9-item screener and well-established FoH measures and moderate positive correlations with psychosocial instruments, as well as associations with clinically meaningful diabetes outcomes.

In the current study, survey participants (n=553) reported mean A1c of 7.0%; most reported using insulin pumps and visiting endocrinologists/diabetologists for their diabetes care. Of the survey participants, 30% had high FoH total score. Higher FoH, as measured by the FoH screener, was associated with higher self-reported A1c and more diabetes-related comorbidities. Individuals comfortable with a higher blood glucose range were identified with higher worry and more frequent behavioral changes to prevent hypoglycemic episodes than participants comfortable with a lower blood glucose range.

Studies have shown that behaviors to avoid hypoglycemia are common in PwT1D, even those who use diabetes technologies and engage in regular self-monitoring of blood glucose.[19] We found that people with higher depression and generalized anxiety were screened for higher FoH. The symptoms of anxiety and/or depression and FoH may co-occur and thus warrant mental health support for this population in alignment with the ADA recommendation for mental health referrals.[5] Given the psychosocial burdens of managing diabetes, combined with high prevalence of FoH, mental health screening and treatment must be integrated into routine diabetes care.[20 21]

The HCP focus group results emphasize the importance of screening for FoH, in alignment with the ADA position statement.[5] Providers expressed interest in implementing the FoH screener into preclinic visits and believed that people who screened high for FoH on the FoH screener could benefit from additional education and/or referrals for mental healthcare.[5] Without an actionable screening tool to assess FoH in clinical practice, HCPs may approach their patients informally with open-ended questions about hypoglycemia. Thus, providers might miss the opportunity to identify potential FoH in PwT1D.[8] Clinicians discussed the barriers in implementation of a new FoH screener such as limited time, burden in modifying the EMR system, staff shortages due to clinical responsibilities, and constraints with IT resources at the health institution.

The brief FoH screener, with its two-factor domain scores and clear cut-offs, can be integrated into routine practice for quick screening of FoH in PwT1D. Its brevity may help overcome barriers of time constraints and staff shortages faced by HCPs in daily clinical practice. Our results demonstrate significant associations between behavior domain scores and higher A1c, highlighting the screener's clinical relevance. Based on domain scores, clinicians might gain insights for targeted interventions to address specific concerns about FoH in PwT1D. The FoH screener stands out from the available FoH instruments because of its clear cut-off and actionable domains. Its scoring thresholds facilitate prompt scoring and identification of patients with high FoH, giving insights into specific behaviors or worries. The FoH screener might also help stimulate clinical conversations between patients and providers about the psychosocial impact of hypoglycemia. Identifying those with severe FoH and referring these patients to mental healthcare services would ultimately benefit the patients and may help distribute mental healthcare resources most efficiently.

This study has limitations. Potential participants for recruitment were identified by each site based on their local Institutional Review Board requirements. These participants may have been more involved in their own diabetes management than the typical PwT1D. This recruitment strategy may have narrowed the sample of survey respondents. Results might also not be representative of all PwT1D, because most survey participants were non-Hispanic White adults who use insulin pumps and continuous glucose monitors, and their self-reported A1c was <7%. The study included self-reported data that can be affected by an external bias caused by social desirability or approval. These results may not be generalizable for HCPs providing care in other treatment settings other than academic medical centers, members of a quality improvement learning health system, and safety net hospitals.

CONCLUSIONS

This validated, easy-to-use, brief, and actionable 9-item FoH screener for in-clinic use may be suitable as an efficient and quick screener to identify FoH in PwT1D, in line with ADA recommendations. Our results suggest that FoH is relevant in adults with T1D and that FoH is associated with negative outcomes (such as higher A1c, more frequent severe hypoglycemia events, more comorbidities, and higher depression and anxiety) that might influence and/or be influenced by psychosocial well-being and diabetes management in this population. This 'fit-for-purpose' screener may aid HCPs to quickly identify people with FoH who can be further evaluated for the root cause of FoH and to have discussions of hypoglycemia risk with referrals to mental health professionals as

needed. In the future, this newly developed screener may be incorporated in real-world clinical practice to help identify FoH in people with diabetes.

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Competing interests JLP, MP-N, and BM are employees and stockholders of Eli Lilly and Company. MEP, NR, KC, WAW, HN, and OE are employees of T1D Exchange. JL was an employee of T1D Exchange at the time of this research. MB and HKA received advisory fees from Eli Lilly and Company.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the WIRB-Copernicus Group (WCG) Institutional Review Board (IRB Protocol No 20214685). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

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