BMJ Open Readiness of adults with type 1 diabetes and diabetes caregivers for diabetes distress monitoring using a voice-based digital health solution: insights from the **PsyVoice mixed methods study**

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ABSTRACT

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Objectives Diabetes distress can negatively affect the well-being of individuals with type 1 diabetes (T1D). Voicebased (VB) technology can be used to develop inexpensive and ecological tools for managing diabetes distress. This study explored the competencies to engage with digital health services, needs and preferences of individuals with T1D or caring for a child with this condition regarding VB technology to inform the tailoring of a co-designed tool for supporting diabetes distress management.

Design We used a mixed methods design. We performed a qualitative reflexive thematic analysis of semistructured interviews of people living with T1D or caring for a child with T1D, complemented by quantitative analysis (descriptive statistics).

Setting 12 adults living with T1D who attended diabetes centres or cared for a child with this condition participated in semistructured interviews to collect opinions about voice technology. They also responded to three guestionnaires on sociodemographics and diabetes management, diabetes distress and e-health literacy. Outcome measures Main: Patient experiences and perceptions derived from the coded transcriptions of interview data. Secondary: Quantitative data generated from Socio-Demographic and Diabetes Management questionnaire; Problem Areas in Diabetes Scale and e-Health Literacy Questionnaire.

Results Five major themes were generated from the participants' interview responses: (1) Experience of T1D, (2) Barriers to VB technology use, (3) Facilitators of VB technology, (4) Expectations of VB technology management in T1D, (5) Role of healthcare professionals in implementing VB technology for T1D. Most participants expressed a favourable view of voice technology for diabetes distress management. Trust in technology and healthcare professionals emerged as the predominant sentiment, with participants' current device type impacting anticipated barriers to adopting new technologies. **Conclusion** The results highlighted positive participant views towards VB technology. Device use, previous experience and health professional endorsement were influential facilitators of novel VB digital health solutions.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- \Rightarrow This study applies a robust methodological approach with a comprehensive analytical process, incorporating reflexive field notes and thorough triangulated codebook checks with researchers of varied expertise.
- \Rightarrow The transformative application of patient and public involvement facilitated participatory-led research.
- \Rightarrow The results of this study make a new contribution to understanding the necessary competencies to engage with digital health services and the needs and preferences of people living with type 1 diabetes.
- preferences of people living with type 1 diabetes.
 ⇒ A limitation of this study is the small sample size which might have limited the ability to identify further differences in perspectives on voice-based technological interventions.
 ⇒ Another limitation is that not all ages were represented in the sample of participants.

 Further research involving younger people with T1D could further contribute to the successful development of these tools.
 Trial registration number ClinicalTrials.gov, NCT05517772.
 INTRODUCTION
 Type 1 diabetes (T1D) is a chronic disease that impacts the subjective well-being and quality of life of people living with this condi- \Rightarrow A limitation of this study is the small sample size

quality of life of people living with this condition.¹ Diabetes management poses challenges to daily life, including adherence to a dietary and exercise regimen and glycaemia monitoring activities.^{2 3} Preventing and managing health complications in T1D is associated with psychological comorbidities which can negatively affect self-care behaviours, motivation, perceived well-being and treatment outcomes.² ³ One of the most frequently reported psychological comorbidities in

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people living with T1D is diabetes distress. Diabetes distress is an emotional state in which people experience stress, anger, guilt, denial and frustration resulting from living with the burden of managing the condition and preventing complications.^{2 3} Concerning some symptoms; it may not be separated from other types of stress; however, its cause is different, derived from a complicated diabetes treatment and diabetes complications and how it is assessed (condition-specific questionnaires).⁴ Diabetes distress, therefore, has implications for diabetes management outcomes.⁵

Medical treatment of T1D has evolved in parallel to technological advances, aiming to enhance disease management and reduce its burden.¹ Furthermore, digital resources have gained clinical interest for their potential to address diabetes distress.⁶ Pilot programmes of these digital tools, developed and tested in field conditions, have shown promise in reducing diabetes distress and improving self-management behaviours.⁷⁻⁹

One such digital innovation is vocal biomarker analysis. It refers to detecting acoustic or linguistic changes associated with disease symptoms.^{10 11} Vocal biomarker analysis is a promising technology that would enable continuous, easy and non-invasive disease monitoring at a lower cost than conventional healthcare.¹¹ Since vocal biomarkers do not rely on human-mediated measurements, they are proposed to limit bias in medical judgement, enhance comprehension of disease triggers and facilitate diagnosis and monitoring.¹⁰ However, vocal biomarker analysis has technical challenges, such as, the verification of the sound quality and managing environmental noise which can vary depending on how the voice collection was obtained.¹²

The production of human speech requires close physiological and neurological coordination between the functions of the lungs and the brain.¹³ Therefore, alterations in speech patterns can be indicators of health changes¹²¹⁴ and of psychological states.¹⁵ Vocal biomarker analysis has demonstrated a good discrimination accuracy for depression (89.7%).¹⁵ It involves complex algorithmic methods for processing audio data that may detect subtle voice changes associated with psychological disturbances.^{16 17} The role of vocal biomarkers in detecting psychological conditions is currently studied using artificial intelligence methods for identifying voice characteristics associated with psychological conditions among thousands of voice-derived variables.^{17 18}

For instance, in a case-control study including people with diagnosed depression in ambulatory centres as the cases and relatives of people attending those centres as the controls, voice parameters were able to discriminate between people with and without depression.¹⁹ Another study focused on the utilisation of vocal biomarkers for classifying stress severity in adults using a suicide help-line. They identified 24 vocal patterns with high accuracy (area under the curve 97% (95% CI 96 to 98)) to classify low versus increased psychological distress levels.²⁰

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There is no published research on vocal biomarkers and diabetes distress. To fill this gap, our group, which has already developed voice-based (VB) algorithms for predicting acute (COVID symptoms)^{21–22} and chronic conditions (fatigue),^{22–23} is currently developing algorithms on VB parameters to monitor diabetes distress. This novel VB technology has already been studied for detecting and monitoring other chronic conditions,²⁴ so it may be helpful to diabetes distress management.

VB technologies refer to using the voice in digital health applications.²⁵ Despite the advantages of new technological solutions for disease monitoring, incorporating this technology into patients' daily lives may be challenging.^{5 26} The ability to take advantage of technological resources can differ substantially depending on the age, gender and socioeconomic aspects of the users—creating a phenomenon known as the 'digital divide', where particular demographic groups are excluded from the benefits of technological advances.^{5 27} To reduce the digital divide, it is necessary to tailor digital health interventions to all intended users to increase their acceptability and facilitate adoption.^{26 27} Therefore, a fundamental step is to explore potential users' preferences before defining aspects of VB technology design.^{26 28}

The main objective of this study was to gather information for developing a co-designed VB digital health solution for diabetes distress management based on the competencies necessary to engage with digital health services, needs and preferences of people living with T1D. For that purpose, this study had three sub-objectives: to delineate the properties that a VB digital health solution for diabetes distress management must incorporate to be considered adequate by its intended users; to determine the attributes that would facilitate the integration of this VB technology tool by its end-users into their everyday lives and to identify potential barriers of use.

METHODS

Population

Participants were recruited from the paediatric and adult diabetes clinics of two hospitals in Luxembourg and the Luxembourg Diabetes Association using a convenience sampling strategy. The recruitment process started in June 2022 and finished in May 2023.

Inclusion criteria were having T1D or being a caregiver to a child diagnosed with T1D, being 13 years old or older, living in Luxembourg, being proficient in English, German or French and having internet access. All participants provided informed consent, agreeing to answer online questionnaires, participate in a recorded (video and audio) interview and publish their pseudonymised data. Participants were not compensated for their participation.

Study design and procedures

The study employed a mixed methods design with a concurrent transformative approach, collecting both

quantitative and qualitative data simultaneously.²⁹ Patient and public involvement served as a transformative factor in this study, with a participatory research approach that influenced all methodological decisions. This project emphasised qualitative methods, with quantitative results complementing the qualitative findings. Participation involved completing three online questionnaires (quantitative data) and an online interview (qualitative data).

Participants were informed about the study by their clinicians and in the diabetes association through flyers. Interested people contacted the study's research assistant by telephone or email. Further details were published in the study protocol.³⁰

Online questionnaires

Socio-Demographic and Diabetes Management Questionnaire

We developed an instrument to collect age, educational level and individual diabetes management information. Two volunteers from the Luxembourg Diabetes Association piloted it. It was available in adult and caregiver versions, containing 9 and 11 items.

Problem Areas in Diabetes Scale

This questionnaire is validated and measures diabetesrelated emotional distress. It covers a range of negative emotional states, such as frustration, denial and isolation. It uses a Likert scale (from not a problem to serious problem). We used a 20-item version of the Problem Areas in Diabetes (PAID) questionnaire for adult participants living with T1D (PAID) and a 15-item PAID version for participants caring for a child with T1D (P-PAID-C). The PAID score (standardised scale) is obtained by summing all items \times 1.25 and ranges from 0 to 100, with a cut-off \geq 40 indicating diabetes distress. The P-PAID-C is a scale from 1 to 6, ranging from 15 to 90, with higher scores indicating diabetes distress. We standardised this scale by multiplying the total score by 1.1. There is no cut-off for this scale.^{31 32}

e-Health Literacy Questionnaire

This questionnaire measures people's confidence level when using digital resources to find and use health information, manage their health and communicate with healthcare providers. The instrument comprises 35 items related to seven domains and is scored on a Likert scale.³³ While low scores may reflect a possible weakness in the domain, scores above 2.5 indicate an emerging strength, suggesting increasing competence in the area assessed.

Video interview

We developed an interview guide piloted with two volunteers living with T1D. One researcher (FAV) performed the semistructured interviews. FAV had no prior relationship with the participants before the study.

The guide covered two broad topics: 'previous experiences with technology for diabetes self-management' and 'expectations, preferences, and wishes regarding a voice-based digital health solution for diabetes distress monitoring'. The first part of the interview starts with

exploring the participant's previous knowledge about diabetes distress and vocal biomarkers and clarifying these concepts. Then, the interview continues with three persona-scenario exercises. Based on fictional cases, the interviewer asks the participant's opinion about managing diabetes distress, using new technology and exploring how to integrate vocal biomarkers. A persona scenario is a method for determining the end-user-based requirements a product must fulfil.^{28 34} The second part of the interview is open-ended questions about previous experiences with diabetes monitoring using technology. The third part of the interview also consists of open-ended questions focused on diabetes distress detection Š with vocal biomarkers (online supplemental table 1).

copyrig We recorded audio and video and recordings were transcribed using Amberscript software. FAV created a pseudonymised verbatim transcript. All field notes were listed in a digital notebook. We analysed qualitative data including in MAXQDA software (VERBI Software, 2021). We calculated an average of 70 min of duration for the interview. The transcripts were not returned to the participants.

Patient and public involvement

Two participants provided feedback on the choice of questionnaires, the content of the interviews, the clarity of wording, the duration of questionnaires and video interviews. Therefore, patients influenced methodological decisions.

Statistical analysis

We described demographic and questionnaire data with means and SD. Data obtained from the e-Health Literacy data Questionnaire (eHLQ) and PAID questionnaires were scored using the analysis approach recommended by the respective authors. The PAID scales provided one overall summative score indicating the severity of diabetes distress. The eHLQ provided a score for each scale, training, and reflecting the seven assessed dimensions of digital health literacy.

Qualitative data analysis

We analysed the interview transcripts using a 6-step thematic analysis. 35 We employed inductive thematic analysis with a constructivist approach. This conceptual approach was appropriate to address the lack of knowledge about the acceptability of voice technology and to hnol understand how individuals socially construct and interpret their experiences with voice technology.

Data analysis began with familiarisation through reading interview transcripts and then coding them, creating in-vivo and researcher-derived codes.³⁶ Two coders (FAV, GAA) used MAXQDA, to apply the codes to the transcripts. Codes were organised into themes. The coded transcripts underwent constant comparison and revised theme definitions and names throughout data collection. This process was repeated until consistent coding agreement, confirming the identified themes and arrival at information power, which was based on examining the

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patterns identified in the data against key elements such as the sample specificity and the narrow aim of the study to establish data sufficiency.³⁷ A final codebook was established, outlining five major themes (online supplemental table 2). The codebook was applied to all transcripts by FAV and independently verified by IP using three randomly allocated transcripts for triangulation and final codebook confirmation.

Reflexivity was maintained throughout the process, acknowledging the role the coders' backgrounds played in shaping data analysis. The coders had varied backgrounds in psychology (FAV, female, BSc, IP, female, PhD), medicine (GAA, female, MD, PhD) and diabetes (GAA). The team includes researchers with extensive experience in both diabetes and vocal biomarker research, supported by the insights of members who are clinicians specialising in diabetes management. The team also has artificial intelligence expertise with developers of vocal biomarkers. This experience spans both early career and more experienced team members at the intersection of these fields. This diversity in perspectives assisted in mitigating biases introduced by the coders' backgrounds. This research formed part of FAV Master's thesis project, centred on users' perspectives on VB technology for diabetes distress. FAV initially trained as a clinical psychologist. Given the primarily quantitative expertise of the group, IP joined the team to support the qualitative methodology. IP has a background in health psychology with qualitative research expertise in healthcare communication.

We followed the COREQ (COnsolidated criteria for REporting Qualitative research) Checklist.³⁰

Mixed methods analysis

A description of each participant was created by introducing the self-reported survey data and memos summarising each interview. When data was retrieved by Imini

theme, we could visualise respondents grouped based on age, gender, education, management strategy, relationship to T1D (people living with T1D or caregiver), diabetes distress level and self-reported degree of competence in each e-health literacy-related domain. This data integration served the expected purpose of establishing associations between participants' characteristics and their perspectives on VB technological interventions, allowing for a deeper understanding of how these factors influence their thoughts and attitudes.

RESULTS

Of the 12 individuals who expressed interest in participating, all agreed to participate and complete the study. No one besides the participant or the researcher was present during the video interviews.

Quantitative analysis

Protected by copyright, includi The sample consisted of 12 participants: 11 with T1D and 1 participant was a parent of a child with T1D. 50% were women, with a mean age of 47 (SD 14) years (range of ğ 26–65 years). 50% were married or cohabiting, 67% were employed full or part-time, 17% were retired, 17% were uses relate unemployed and 58% had a bachelor's degree or superior. Additionally, 67% used any insulin pump, with 42% specifically using a hybrid closed loop (HCL) system for diabetes management and 33% using only continuous d to text glucose monitoring device (CGM). Furthermore, 58% of participants used mobile applications to support their health management (table 1). id data

The mean PAID score for the 12 adult participants living with T1D was 31 (SD 17) and ranged from 10 to 70 points. The primary stressors were 'not knowing if your mood or feelings are related to your diabetes' (52%) and

summarising each interview. When data was retrieved by 'Worrying about the future and the possibility of serious Table 1 Demographic characteristics, diabetes management tools and diabetes distress ID Gender Age range T1D management App PAID						
ID	Gender	Age range	T1D management	Арр	PAID	
P1	Male	50–59	CGM+HCL	Yes	35	
P2	Female	40–49	CGM+HCL	No	47	
P3	Male	50–59	CGM	No	10	
P4	Male	60–69	CGM	Yes	24	
P5	Female	50–59	CGM	Yes	40	
P6	Male	40–49	CGM+HCL	Yes	13	
P7	Female	50–59	CGM+SAP	Yes	18	
P8	Female	60–69	CGM+HCL	No	33	
P9	Female	20–29	CGM+HCL	Yes	26	
P10	Female	50–59	CSII	Yes	18	
P11	Male	40–49	CGM	No	43	
P12	Female	30–39	CSII	No	70	

App, application software that performs specific tasks and can be installed and run on a computer, tablet, smartphone or other electronic devices; CGM, continuous glucose monitoring device; CSII, continuous subcutaneous insulin infusion device; HCL, hybrid closed loop insulin delivery system; PAID, Problem Areas in Diabetes; SAP, sensor-augmented pump; T1D, type 1 diabetes.

Table 2 The descriptions of the five analysis-generated themes taken from the final codebook				
Theme	Description			
Experience of type 1 diabetes	Data referring to a participant's descriptions relating to their daily li with T1D, including the burden of the disease, previous experience living with the disease (eg, management in daily life) and where or how they get their information as this can inform their actions.			
Barriers to voice-based technology use	Data encompassing participant views on aspects of novel technology in T1D management that would prevent its use or discourage the integration of it into their condition management.			
Facilitators of voice-based technology	Data encompassing participant views on aspects of novel technology in T1D management that would promote its use or encourage the integration of it into their condition management.			
Expectations of voice-based technology management in type 1 diabetes	Data referring to participant descriptions of their expectations of technology-assisted management of T1D.			
Role of healthcare professionals in implementing voice- based technology for type 1 diabetes	Data encompassing participant views on the role of healthcare professionals concerning their experience of T1D, T1D management and technological developments for T1D management.			
T1D, type 1 diabetes.				

complications' (45%). The standardised P-PAID-C score for the caregiver participant was 47 points. Four participants scored 40 or more (table 1).

The eHealth literacy scores were calculated for each of the seven domains. All participants reported being motivated to interact with digital services (domain 5). 92% of participants showed self-confidence in understanding health-related concepts (domain 2) and 75% felt able to actively engage with digital services, feeling safe and in control when doing so and reported having access to digital services that suited their individual needs (domains 3, 4 and 7, respectively). However, 33% of participants reported limited access to functioning digital services (domain 6) and a lower level of self-confidence in using technology to process health information (domain 1).

Qualitative analysis

Five themes were generated from the coded transcriptions: (1) Experience of T1D, (2) Barriers to VB technologies use, (3) Facilitators to VB technologies, (4) Expectations of VB management technology for T1D and (5) Role of healthcare professionals in the implementation of VB technologies (table 2).

Experience of T1D

T1D held a central role in the participants' lives, dictating how they navigated their daily routines. When describing this experience, participants spoke of the burden of living with this condition and the strategies they have developed to manage their daily lives. Despite this, they also expressed a strong desire to occasionally escape the demands of their diabetes, seeking moments where its presence fades from their thoughts, allowing them to experience life without its constant shadow.

Burden

Participants reported that daily distressing experiences associated with T1D created a significant burden, shaping

their perceptions of life with the condition. This burden **g** for uses most notably when participants tried navigating 'normal' life through social occasions or daily activities. Many expressed feeling unfairly judged due to their T1D diagnosis, citing the challenges of managing their condition in public spaces as stressors.

In the restaurant, you start by stabbing, secondly by calculating, thirdly by injecting in public, because I've never gone to the toilet with my pen to inject insulin. I've always done this inside the restaurant, but the way people commented sometimes, that was madness. (P7)

Some participants perceived their lives as more challenging than those without T1D did because they felt they were centred on glucose in target and preventing severe hypoglycaemia episodes. This extended across multiple domains of life, such as personal relationships, social events and employment.

...Despite working in the medical field, I am always rejected because of my diabetes. That means I'm having trouble finding a job, even now specializing as a diabetology nurse... Although I am affected myself, I have the specialization and nothing works there because everyone is afraid of complications that may arise. (P7)

Participants felt their mental health was notably linked to this management. The glycated haemoglobin results, when they were in target, enhanced participants' self-confidence and competency in self-managing their T1D.

Because I think most diabetics, if the level is too high, you might feel bad...Okay, why is it like this now? Or what did I do wrong? Yes, it's a challenge every day. You always have to reposition yourself, reorient yourself, prepare. Many people probably do not know this or cannot imagine it. (P11)

Developing management strategies

Experiential descriptions of how participants' daily T1D management strategies developed, both behavioural and technological, varied in positive or negative sentiment, illustrating the nuanced nature of these experiences. Once the strategies had been sufficiently developed, however, the positive sentiments were notable.

Well, let's put it this way: until a few years ago, digital technology did nothing for me as a diabetic. But it started very positively and helped greatly with the sensors in my arms. And it's been a huge win for me ever since. (P4)

Most participants reported implementing consistent preventative measures to mitigate complications associated with T1D, including actively pursuing and maintaining metabolic goals.

My current pump is called Lulú, and she keeps my whole metabolism going without that... I only administer bolus for meals. She does the rest on her own. If I go postprandial in hyperglycaemia, she gives me correction boluses. And as such, I no longer have to worry about my diabetes. (P7)

This strategy development was not always successful, as some participants experienced functional impairments or life-threatening situations due to T1D complications. These events were associated with human errors or failures in the T1D management technologies. Some participants suggested while trying to find the best technology for them, some solutions did not function as expected and made management more complex.

...a year ago I had one, then another blood glucose meter... I don't even know what that means to measure... That would be too slow. It took over two hours before it noticed that I was doing an activity. And then I'm high in sugar and the device keeps saying "man you're in hypoglycemia". (P3)

Barriers to VB technology use

Barriers to using VB technology were seen across three subthemes: Mistrust, interpersonal pressures and technological readiness.

Mistrust

For participants, deciding how voice samples will be collected for analysis was crucial. Participants had security and privacy concerns regarding voice-sample collection and its potential use for non-intended purposes.

But it might be worrying, isn't it? Because you would have to know exactly by whom or who wants to use the data... Someone who then uses the data specifically and not a company behind it and then uses the data to do business with it. (P11)

The automatic operation of technologies raised concerns about technology's predictive ability and the infringement on autonomy. Participants noted that technological tools can have inaccuracies in automated insulin dose calculations which can be a life-threatening risk participants want to avoid.

I actually don't use it anymore because the fact that the pump adjusts automatically to your values is something that... I find it kind of scary because it's just a machine and the machine doesn't know everything I have planned... if I do sports, I do know how much my blood sugar needs to be. But since the pump always adjusts to a fixed level of blood sugar, it just doesn't always work. (P12)

When discussing details about VB technologies, participants questioned the impact of the recording environment and user falsification which could potentially impact health professionals' conclusions and the management of their diabetes as a result.

Interpersonal pressures

Participants who had negative personal experiences with T1D carried these experiences into their perceptions of the use of VB technology. Participants expressed concerns in particular involving the dynamic between interpersonal relationships and the glycaemic control behaviours of people living with T1D. It was further suggested that diabetes distress may worsen if the VB technologies' results were directly accessible by loved ones or affected the administration of insulin.

...you see: "Okay, but there he is already three hours at 300" and then you call back and "What's going on there?" and "Don't you want to inject yourself with insulin now?" and so on. That's somehow, I think, not good for the relationship either. (P2)

Participant experience also informed the thoughts of broader social effects of using VB technologies in public, prompting concerns about stigmatisation.

The app might tell him that too, but then the boy isn't that happy with it either. He would say: Now I have to do again something that the others don't have to do, isn't it? (P3)

Technological readiness

Some participants found it difficult to access technological resources for T1D management which impacted their consideration of using VB technologies. Several factors contributed to inaccessibility: product incompatibility with existing devices, unmodifiable default settings, warranty-voiding damage and a lack of self-efficacy when using health technologies.

Participants highlighted that the suitability of VB technologies might differ by age group, with younger

generations described as more comfortable adopting new technologies.

But I think that young people there might find it more interesting. So yes, there are a lot of people who also use these fitness Apps a lot and I think it might be interesting for them to get something else. But now I personally don't think I'll use it. (P2)

Participants' scepticism towards technological resources for health management, including VB technologies, was also based on previous experiences with unreliable devices for T1D management. These experiences were frequently associated with mitigating risks device errors posed to their health.

But I don't trust every device at the moment. I've had issues with an insulin pump and stuff and it always makes me a little suspicious... I still want to decide for myself. That's why I no longer have a pump... As I said, it is a device and a device makes mistakes. (P4)

Facilitators of VB technology

Facilitators for using VB technology were seen across three subthemes; external support; positive management experience and practicalities of diabetes management.

External support

Support in the form of the manufacturer's guarantee and scientific evidence highlighting the product's effectiveness was seen as encouraging for participants when thinking about adopting VB technologies in diabetes distress management.

... I was waiting for a hybrid closed loop system from the manufacturer himself... because the guarantee... It's a guarantee that the system will work. This means that if my pump has a problem now, I call [the company] and they have a new one within 24 hours. That means it will be delivered immediately. And that's reassuring that you can get a replacement at any time. (P7)

This facilitation or support, however, extended to the views of their support network on VB technologies, given the role of the support network in their current management of T1D-specifically their diabetes distress.

Well, I would [use vocal biomarkers]... I think that depends on... my mood. Probably. And at the request of my partner, I would always use it when she says: I should use it... Yes, yes, she knows me very well... She usually determines hypoglycemia before the CGM. (P1)

Positive management experience

Positive experiences with technological T1D management created optimistic expectations for VB technologies. These technologies were used primarily for glucose monitoring, insulin management and physical activity tracking, with some applications allowing for 'followers' to see this activity.

Participants who reported satisfying experiences with their T1D management devices derived experience-based insights about how technological developments could be tailored.

I've had my pump for a good year and a half now. What she learned... She knows that more insulin is needed in summer than in winter. That means she's already reducing my insulin dose in the fall. And I find that insane. And I think that would be for the man now, for example, because he is sporty... and because the pumps can also be adjusted for sport. (P7)

Protected by copyright, including for uses rel Participants stressed the importance of technology that accommodates the individual's lifestyle and allows for relative normalcy without compromising.

Because in turn [technology] gives him some of that thinking "How's my sugar?", "What do I need to inject?"... It takes a bit of the work off of him and he can live a normal life. (P6)

Practicalities of diabetes management

Past experiences of dissonance between participants' needs and the functional ability of technological resources made the practicalities of future voice-analysis-based products more attractive. These practicalities were char-acterised by reducing diabetes distress through easing their management strategies.

I felt more comfortable because the net just looked like a syringe. And it was also easier to inject insulin in public. And then came the pumps and now with all the new technology that means everything is stored on the cell phone. (P7)

and data mining, AI training Further attractive practicalities suggested by participants included health insurance companies' partial or complete financial coverage of the device was seen to

complete financial coverage of the device was seen to g facilitate the integration of novel technologies.
 It's all part of a treatment...That will make treatment easier and I think it would be useful for health insurance companies to contribute. (P5)
 Expectations of VB technology management in T1D
 Participants described a desire for control over the access detection of the device was seen to g, and supported the device was seen to g.

to their voice analysis data and reports. They suggested \overline{g} implementing 'terms and conditions of use' or informed consent that explicitly states the purposes and use of their data. Most participants agreed that sharing their data with their diabetologist or general practitioner would be beneficial. Some participants were willing to donate their anonymised data for research and technology improvement.

Three central aspects made voice analysis technology practical and reliable for participants: technological

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standards, customisable settings and presentation options and a clear final purpose.

Expectations of technological standards

For the participants, flexibility was the most desired property for VB health monitoring devices. The resource should be adaptable to their taste, needs and skills. The participants preferred comfort and fit following flexibility.

It's supposed to be as simple as possible so that I'm not always reminded that I'm sick. And when I count, I don't have to think. I do it and then I get my analysis and that's it. (P4)

Participants expected the product or service to be consistently available and reliable and to provide an integrated and objective view of their health status. They valued a system that avoided failures and respected their autonomy.

Customisable settings for ease of use

The possibility of customising new technological resources plays a central role when evaluating their suitability and acceptability. While many participants advocated for implicit or subtle vocal biomarker recording, under strictly data-protected conditions, they stressed that this was individual and that each person should be able to control the frequency of the feature usage. Participants described appreciation for the use of a non-invasive and subtle device.

Yes, I would try [vocal biomarkers]. I would now... This time I would try it because it's not something that goes into my body. (P5)

Further preferences included integrating VB technologies into their current devices to not interfere with their daily activities and protect against diabetes distress related to social stigmatisation. Examples included incorporating VB technologies into insulin pumps, pens or smartphones, depending on their current glycaemic control regimen.

I would say those things that people carry around with them daily. So, if they have an insulin pump, I would think that it would be very nice to have it integrated in the pump or into the phone... So, things that people do not need to use in addition to what they already use. (P2)

Some participants found integrating this VB technology into smartphones advantageous in monitoring diabetes distress twice to three times weekly through voice if it is done independently from glycaemic control.

And then, in addition, whenever he then... he still has to... if you feel the need and you think you want to check it, you still have to be able to do it. But... But this is not only voluntary, but... somehow, for example twice a week, that you at least have to do it. (P2)

A smartphone application was considered valuable for combining and collecting information from different sources into a single interface and simplifying the integration of additional biomarkers.

Something has to be done at the same time so that you are less stressed. And with the app now, for example, you could then see whether it worked, for example. Has it gotten better or? (P2)

Most participants found it convenient to associate diabetes distress control with daily glycaemic control, suggesting that VB technologies should offer solutions beyond highlighting changes in diabetes distress levels. by copyright, including This included using the collected data to generate prompts for managing stress or health alerts and collecting further data through food diaries.

Now just because the app records it doesn't make you any less stressed... Something has to be done at the same time so that you are less stressed.

Participants also desired concise reports with actionō able insights into diabetes distress management, such as patterns in insulin dosage and physical activity that may uses contribute to blood sugar dysregulation. Some suggested related to text integrating alarms into the technology for hypoglycaemia prevention.

Expectations of voice technology's final purpose

Participants suggested that VB technological tools for diabetes distress management should be designed to improve their well-being by simplifying the management of their condition, allowing a sense of 'normality' in daily life.

I'm pro technologies. I'm happy when something is simplified, for everyday use. It shouldn't just be something I do twice a week... No, it should make my everyday life easier. (P6)

d data mining, Al training They also indicated that the technology should be reli-, and able in alleviating some physical burden of living with T1D. Expectations of what this could look like included VB similar technologies technology built into pens that could assist with data registration and insulin administration. This was described as particularly advantageous for individuals who had visual impairment as a result of diabetes complications.

I'm visually impaired. And sometimes I can't recognize with precision... exactly how much I'm injecting... And if I now have [voice-based technology] in it, then I could always, if I notice "Now the sugar is falling or rising...", then I could call up on the pen "What exactly did I inject there, what time and such". That would be a huge help, especially if you have vision problems. (P4)

One participant saw the benefit of using a VB tool only if it was used for early detection of other health conditions unrelated to T1D.

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Preferences for VB technology

In response to the examples of VB technology provided in the interviews, participants preferred scenarios where technology was integrated into existing smart pens or pumps. This preference was indicated through higher Likert scale ratings and was dependent on device reliability.

Exactly, the device can suggest that to me because it knows more than I do. But conversely, I still need to be able to decide how much the device squirts. With a "yes or no" for example. (P4)

Participants rated more visible or larger technologies, such as smart mirrors or technologies requiring public voice recording, lower on the Likert scale. These technologies were perceived as drawing unwanted social attention or potentially causing additional distress.

I think the general conditions should always be the same. One shouldn't begin to see it once on the street, once at home, once at school. (P6)

Smartwatches or apps were received neutrally or positively, with more emphasis placed on the role of personal preference within these responses.

Role of healthcare professionals in implementing VB technology for T1D

Participants highlighted that healthcare professionals are central to adopting any new T1D management strategy. They suggested that if their family doctors or diabetologists recommended a VB diabetes distress monitoring product, they would consider it medical advice.

When you hear from the doctor himself ... you'll do it... and if you realize that you're maybe more stressed than it's good for you to be, then one could say: "Okay, then you have the device or the app". (P2)

Participants attributed this role to healthcare professionals, citing their face-to-face interactions as allowing healthcare professionals to assess various aspects of patients' lives and conditions. This, in turn, enabled a more comprehensive understanding and informed interventions. As such, healthcare professionals were also seen as the most reliable source for data interpretation from new and existing T1D management devices.

"...I think the most reliable way would be through the doctors... for me, it's always a matter of trust. I got the pump even though I was suspicious of it. You always hear a lot of information that... it's not precise... it was always said that you get something inserted into your body.... That's not true at all! It's put on the body, but you don't have to have surgery or anything like that... (P10)

All participants' primary information sources were health professionals and the patients association (online supplemental table 3).

My contacts are always the diabetologist and the health team in the hospital... So, I always get the first information through them and then also through the diabetics' associations. (P1)

Mixed methods results

Participants' sociodemographic characteristics and T1D treatment were used to explore possible associations between this data and their attitudes toward VB digital health technologies. We observed that age, gender, marital status and educational attainment were not ostensibly associated with their opinions expressed in the interviews. However, the type of technological resources participants used for T1D management at the time of their participation in the study was associated with their envisioned barriers to adopting novel technologies. Participants using more advanced management technology, such as a HCL system or a sensor-augmented pump, raised fewer barriers to VB technologies than participants using simpler devices, such as a pen or single CGM.

We did not observe differences between participants who reported severe diabetes distress levels and those **o** who did not, although all participants alluded to T1D management-related aspects and stressful situations. Exploring potential associations between the interviews ē and the eHLQ did not reveal differences between those ated to participants who were less confident and satisfied using digital health management resources and those who felt more comfortable using them. However, we found that participants who self-reported higher levels of diabetes distress and lower e-health literacy could envision more significant barriers to integrating these technologies. In contrast, participants with lower diabetes distress and higher e-health literacy levels tended to identify as many possible facilitators as barriers to using VB technologies.

At the end of the study, the participants received an infographic with a narrative summary of the results in lay language.

DISCUSSION

l training, and sim We found that the expectations of people living with T1D about the utility that VB technologies may offer for diabetes distress management are closely related to anticipated barriers to and facilitators of the potential use of this technology. If newly developed VB technology tools of fulfil positive expectations, this could increase the likelihood of their integration into T1D management. Furthermore, the reported barriers and facilitators are frequently influenced by previous personal experiences related to the use of other technological developments for T1D management, the burden of diabetes, the self-confidence level when using digital resources and concerns about data management. These factors form the requirements that a VB technological resource must meet to be considered acceptable by its potential users. A notably influential factor of acceptability was the trust in healthcare

professionals' endorsement of a product which could play a role in device integration.

Diabetes distress screening for the study participants did not affect participants' expectations regarding novel VB technologies. They expressed, however, a strong desire for the delivery of solutions, such as suggestions for addressing high levels of diabetes distress. Participants suggested that their primary need was for VB technologies that would assist them with complementary glycaemic monitoring and enable early detection of acute complications which they considered vital. While the fear of complications served as an indicator of diabetes distress, awareness of the diabetes distress level alone was not perceived as useful in health maintenance without accompanying management strategies. There is evidence of the significant positive effect of cognitive behavioural therapy aiming to treat diabetes distress on diabetes distress and depression.³⁹ Novel VB technologies, incorcognitive-behavioural-therapy-based⁴⁰ porating glycaemic management strategies,⁴¹ could help mitigate diabetes distress. Recent research supports this, stating that technology can address the fear of hypoglycaemia by allowing accurate monitoring and responses to glucose levels.42

Our primary purpose was not to analyse the need for hypoglycaemia detection. However, we found that diabetes distress is often exacerbated by the anxiety surrounding hypoglycaemia and T1D complications. A novel voice-based T1D management technology may improve well-being and alleviate diabetes distress through its complementary role in a holistic approach to biomarker and management strategy presentation.

Individual experiences with T1D were also seen to foster participants' anticipated barriers to a novel technology. The barriers primarily concerned privacy, security and the device's reliability. This reflects remote health management technology research where a consistent barrier was data privacy concerns which were suggested to be best addressed through clear communication about good security practices.⁴³ This sentiment was consistently highlighted by our study participants who advocated for clear 'terms and conditions' of data collection and usage. Consequently, when developing the integration of voice technology, clear statements on data collection should be emphasised in the design of the device or application.

Similarly to the participant-anticipated barriers, facilitators of novel technology were also based on previous experiences. Significant facilitation influences were seen in social support, health professional endorsement and ease of integration into daily routine. Social support has been shown to enhance self-care in medical conditions, improve adherence and integrate technology into improving health outcomes.44 However, altered familial and social dynamics in response to disease management can hinder self-management despite contributing supportive factors.⁴⁵ As demonstrated by participant responses, the complexity of the disease and disease experience highlights the individual nature of managing T1D. It confirms the importance of considering not only the physical needs associated with T1D management but also the unique influence of psychosocial needs (on the expectations of technology support for T1D management). Despite these complexities, we identified essential consistencies regarding the ideal development of VB technologies for T1D management. Flexibility, comfort and fit closely align with the facilitating factors of endorsement and reliability because they describe a seamless integration of devices. This integration and ease of use address an influential element of T1D for these participants-the disease burden. The most successful technologies for T1D management, as rated by patients, are found to alleviate some of the psychosocial burden of T1D.46

The burden of T1D and, in particular, diabetes distress is also reflected in the influence of the participants' healthcare professionals. Any novel technology that can impact blood glucose levels-an element of the disease closely linked to adverse outcomes for these participants—requires endorsement by healthcare professionals for peace of mind when integrating new devices into their 👌 regime. Healthcare professionals have been seen to play integral roles in the use of diabetes management technologies-namely within the expectations and experience of integrating these technologies into patient care regimes.⁴⁷ This pattern was seen as a consistent thread throughout the interviews despite individual experience and is therefore seen by study participants as central to successfully integrating any new T1D management tech-pology such as VB technology tools. nology, such as VB technology tools.

Strengths and limitations A strength of this study is its rigorous and robust \overline{a} methodological approach. The qualitative method employed a comprehensive analytical process, incor porating reflexive field notes and thorough triangulated codebook checks with researchers of varied expertise. The transformative application of patient and public involvement facilitated participatory-led research, ensuring active engagement and valuable participant input. This approach should ultimately lead to the development of a representative end product that caters to the necessary competencies to engage with digital health services, needs and preferences of people living with T1D.

nces of people living with T1D. The small sample size might have limited the ability **g** to identify further differences in perspectives on VB technological interventions by sociodemographic factors, relationship to T1D (people living with T1D or caregiver), diabetes distress level and self-reported e-health literacy level in the mixed methods analysis. Although the protocol³⁰ aimed to have young and old participants, we mainly included older participants. There were difficulties in recruiting younger people for this study which may have skewed the representation of perspectives.

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CONCLUSIONS

This mixed methods study provides insights into the needs and preferences of potential users of VB technologies, suggesting that people living with T1D would be open to adopting this new technology if it met specific conditions. The ease of integration into their current device use, previous experience with digital health solutions, secure data management and health professional endorsement were central to the successful integration of VB technologies. This study can guide the development of novel VB T1D management tools based on these criteria. Given our sample's age-based views on technological self-efficacy, future research could incorporate children's or adolescents' perspectives on novel technological methods for T1D management.

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Contributors GF conceived the project. FAV and GAA wrote the analysis plan. FAV performed the interviews. FAV, GAA and IP performed the qualitative and quantitative analysis. GAA performed the text mining. FAV and IP wrote the first draft. MAT and CdB contributed to the data acquisition. CdB, S-MK and TS contributed to the protocol writing. All authors contributed, giving feedback to the draft and approving the last version. GAA is the guarantor of data.

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REFERENCES

- 1 van Duinkerken E, Snoek FJ, de Wit M. The cognitive and psychological effects of living with type 1 diabetes: a narrative review. *Diabet Med* 2020;37:555–63.
- 2 Kiriella DA, Islam S, Oridota O, et al. Unraveling the concepts of distress, burnout, and depression in type 1 diabetes: A scoping review. EClinMed 2021;40:101118.
- 3 Kalra S, Jena BN, Yeravdekar R. Emotional and Psychological Needs of People with Diabetes. *Indian J Endocrinol Metab* 2018;22:696–704.
- 4 Fisher L, Gonzalez JS, Polonsky WH. The confusing tale of depression and distress in patients with diabetes: a call for greater clarity and precision. *Diabet Med* 2014;31:764–72.
- 5 Mathiesen AS, Thomsen T, Jensen T, et al. The influence of diabetes distress on digital interventions for diabetes management in vulnerable people with type 2 diabetes: A qualitative study of patient perspectives. J Clin Transl Endocrinol 2017;9:41–7.
- 6 Bassi G, Mancinelli E, Di Riso D, et al. Parental Stress, Anxiety and Depression Symptoms Associated with Self-Efficacy in Paediatric Type 1 Diabetes: A Literature Review. Int J Environ Res Public Health 2020;18:152.
- 7 Trojanowski PJ, Frietchen RE, Harvie B, *et al.* Internet-delivered eating disorders prevention program for adolescent girls with type 1 diabetes: Acceptable and feasible. *Pediatr Diabetes* 2022;23:1122–32.
- 8 Whittemore R, Coleman J, Delvy R, *et al*. An eHealth Program for Parents of Adolescents With T1DM Improves Parenting Stress: A Randomized Control Trial. *Diabetes Educ* 2020;46:62–72.
- 9 Stenov V, Due-Christensen M, Cleal BR, et al. Significant reduction in diabetes distress and improvements in psychosocial outcomes: A pilot test of an intervention to reduce diabetes distress in adults with type 1 diabetes and moderate-to-severe diabetes distress (REDUCE). Diabet Med 2023;40:e15187.
- 10 Ramanarayanan V, Lammert AC, Rowe HP, et al. Speech as a Biomarker: Opportunities, Interpretability, and Challenges. Perspect ASHA SIGs 2022;7:276–83.
- 11 Fagherazzi G, Fischer A, Ismael M, et al. Voice for Health: The Use of Vocal Biomarkers from Research to Clinical Practice. *Digit Biomark* 2021;5:78–88.
- 12 Sara JDS, Orbelo D, Maor E, et al. Guess What We Can Hear-Novel Voice Biomarkers for the Remote Detection of Disease. Mayo Clin Proc 2023;98:1353–75.
- 13 Zhang Z. Mechanics of human voice production and control. J Acoust Soc Am 2016;140:2614.
- 14 Schöbi D, Zhang Y-P, Kehl J, *et al*. Evaluation of Speech and Pause Alterations in Patients With Acute and Chronic Heart Failure. *J Am Heart Assoc* 2022;11:e027023.
- 15 Zhao Q, Fan H-Z, Li Y-L, et al. Vocal Acoustic Features as Potential Biomarkers for Identifying/Diagnosing Depression: A Cross-Sectional Study. Front Psychiatry 2022;13:815678.
- 16 Zhang L, Duvvuri R, Chandra KKL, et al. Automated voice biomarkers for depression symptoms using an online cross-sectional data collection initiative. *Depress Anxiety* 2020;37:657–69.
- 17 Kappen M, van der Donckt J, Vanhollebeke G, et al. Acoustic speech features in social comparison: how stress impacts the way you sound. Sci Rep 2022;12:22022.
- 18 Alemu Y, Chen H, Duan C, et al. Detecting Clinically Relevant Emotional Distress and Functional Impairment in Children and Adolescents: Protocol for an Automated Speech Analysis Algorithm Development Study. JMIR Res Protoc 2023;12:e46970.
- 19 Silva WJ, Lopes L, Galdino MKC, et al. Voice Acoustic Parameters as Predictors of Depression. J Voice 2024;38:77–85.
- 20 Iyer R, Nedeljkovic M, Meyer D. Using Vocal Characteristics To Classify Psychological Distress in Adult Helpline Callers: Retrospective Observational Study. *JMIR Form Res* 2022;6:e42249.
- 21 Fagherazzi G, Zhang L, Elbéji A, et al. A voice-based biomarker for monitoring symptom resolution in adults with COVID-19: Findings

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from the prospective Predi-COVID cohort study. PLOS Dig Health 2022:1:e0000112

- 22 Higa E, Elbéji A, Zhang L, et al. Discovery and Analytical Validation of a Vocal Biomarker to Monitor Anosmia and Ageusia in Patients With COVID-19: Cross-sectional Study. JMIR Med Inform 2022;10:e35622.
- 23 Elbéji A, Zhang L, Higa E, et al. Vocal biomarker predicts fatigue in people with COVID-19: results from the prospective Predi-COVID cohort study. BMJ Open 2022;12:e062463.
- 24 Ashraf O, Rabold E, Schlichtkrull K, et al. VOICE-BASED SCREENING AND MONITORING OF CHRONIC RESPIRATORY CONDITIONS, Chest 2020:158:A1687.
- 25 Gouda P, Ganni E, Chung P, et al. Feasibility of Incorporating Voice Technology and Virtual Assistants in Cardiovascular Care and Clinical Trials. Curr Cardiovasc Risk Rep 2021;15:13.
- Noorbergen TJ, Adam MTP, Teubner T, et al. Using Co-design 26 in Mobile Health System Development: A Qualitative Study With Experts in Co-design and Mobile Health System Development. JMIR Mhealth Uhealth 2021;9:e27896.
- Saeed SA, Masters RM. Disparities in Health Care and the Digital 27 Divide. Curr Psychiatry Rep 2021;23:61.
- 28 Aguayo GA, Goetzinger C, Scibilia R, et al. Methods to Generate Innovative Research Ideas and Improve Patient and Public Involvement in Modern Epidemiological Research: Review, Patient Viewpoint, and Guidelines for Implementation of a Digital Cohort Study. J Med Internet Res 2021;23:e25743.
- Tashakkori A, Teddlie C. SAGE Handbook of Mixed Methods in Social 29 & Behavioral Research. SAGE Publications, 2010.
- 30 Aguirre Vergara F, Fischer A, Seuring T, et al. Mixed-methods study protocol to identify expectations of people with type 1 diabetes and their caregivers about voice-based digital health solutions to support the management of diabetes distress: the PsyVoice study. BMJ Open 2023;13:e068264.
- 31 Evans MA. Weil LEG. Shapiro JB. et al. Psychometric Properties of the Parent and Child Problem Areas in Diabetes Measures. J Pediatr Psychol 2019;44:703–13.
- 32 Polonsky WH, Anderson BJ, Lohrer PA, et al. Assessment of diabetes-related distress. Diabetes Care 1995;18:754-60.
- 33 Kayser L, Karnoe A, Furstrand D, et al. A Multidimensional Tool Based on the eHealth Literacy Framework: Development and Initial Validity Testing of the eHealth Literacy Questionnaire (eHLQ). J Med Internet Res 2018;20:e36.

- Valaitis R, Longaphy J, Ploeg J, et al. Health TAPESTRY: co-34 designing interprofessional primary care programs for older adults using the persona-scenario method. BMC Fam Pract 2019;20:122
- 35 Braun V, Clarke V. Thematic Analysis: A Practical Guide. SAGE, 2021. 36 Rampin R, Rampin V. Taquette: open-source qualitative data
- analysis. JOSS 2021:6:3522. 37 Malterud K, Siersma VD, Guassora AD. Sample Size in Qualitative
- Interview Studies: Guided by Information Power. Qual Health Res 2016:26:1753-60 38 Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting
- qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care 2007;19:349-57.
- 39 Jenkinson E, Knoop I, Hudson JL, et al. The effectiveness of cognitive behavioural therapy and third-wave cognitive behavioural interventions on diabetes-related distress: A systematic review and meta-analysis. Diabet Med 2022;39:e14948.
- Protected by copyright, including 40 Kannampallil T, Ajilore OA, Lv N, et al. Effects of a virtual voice-based coach delivering problem-solving treatment on emotional distress and brain function: a pilot RCT in depression and anxiety. Transl Psychiatry 2023;13:166.
- Nayak A, Vakili S, Nayak K, et al. Use of Voice-Based Conversational 41 Artificial Intelligence for Basal Insulin Prescription Management Among Patients With Type 2 Diabetes: A Randomized Clinical Trial. JAMA Netw Open 2023:6:e2340232.
- Przezak A, Bielka W, Molęda P. Fear of hypoglycemia-An 42 underestimated problem. Brain Behav 2022;12:e2633.
- 43 Safiee L, Rough DJ, Whitford H. Barriers to and Facilitators of Using eHealth to Support Gestational Diabetes Mellitus Self-management: Systematic Literature Review of Perceptions of Health Care Professionals and Women With Gestational Diabetes Mellitus. J Med Internet Res 2022;24:e39689.
- for uses related to text and data mining, AI training, and similar technologies 44 Arora S, Peters AL, Agy C, et al. A mobile health intervention for inner city patients with poorly controlled diabetes: proof-of-concept of the TEXT-MED program. *Diabetes Technol Ther* 2012:14:492–6.
- Miller TA, Dimatteo MR. Importance of family/social support and 45 impact on adherence to diabetic therapy. Diabetes Metab Syndr Obes 2013;6:421-6.
- Prahalad P, Tanenbaum M, Hood K, et al. Diabetes technology: improving care, improving patient-reported outcomes and preventing complications in young people with Type 1 diabetes. Diabet Med 2018;35:419-29.
- Farrington C. Access to diabetes technology: the role of clinician attitudes. Lancet Diabetes Endocrinol 2018:6:15.