Title: Patient perceptions on the intrusiveness of remote digital monitoring for diabetes

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1. Abstract

Background: Diabetes management requires that patients regularly monitor their blood glucose levels and behavior (physical activity, nutrition) at home. Digital tools such as wearable sensors and smartphone applications could facilitate monitoring. However, they may also be itnrusive to patients' personal life and privacy.

Aim: This study aims to identify the relationship between the characteristics of digital monitoring for diabetes (e.g., monitoring duration, type of monitoring tool) and patients' perceptions of this monitoring.

Methods: This is an international, online vignette-based survey. Our vignettes are short scenarios that describe different ways in which digital monitoring could be used by patients with diabetes. Adults with type 1 or 2 diabetes fluent in french or in English are eligible to participate. The recrutement will take place online via social media and the French e-cohort ComPaRe, and in person by the researchers and associated clinicians. Each participant will be presented with three vignettes chosen at random among the total 36 vignettes. They will be asked to assess how intrusive, reassuring, and acceptable they find each digital monitoring scenario. We will additionally collect information on participant characteristics (e.g., age, gender, frequency of hypoglycemic episodes in past 30 days).

Data analysis: We will present the 36 vignettes classified by their mean intrusiveness score. We will use multilevel regression models with random effects to identify the relationship between vignette factors (e.g., monitoring duration) and participant characteristics and the intrusiveness and acceptability score. We aim to recruit at least 300 participants.

Expected impact: The results of this study could help clinicians and researchers understand how patients perceive digital monitoring in terms of intrusiveness, reassurance and acceptability, and could be used to guide the development of future digital monitoring tools that are adapted to patients' needs and preferences.

2. Background

The use of digital tools (sensor-equipped wearable devices, smart devices, smartphone applications) for the remote monitoring and management of chronic illness could revolutionize how health care is delivered, by whom, and where (1). The continuous monitoring of patients' physiological data, symptoms and behaviors could reduce the number of in-person consultations and related costs, provide clinicians with more fine-grain data than ever before, and allow for real-time, automated intervention in the form of treatment or lifestyle modifications (2, 3). As an example, the Center for Connected Health (MA, USA) developed a remote digital monitoring program that allows patients with type 2 diabetes to upload their glucometer readings to a web portal accessible to both the patient and their physician. The data can be used to observe trends, suggest medication or lifestyle modifications, and determine the need for follow-up visits, offering highly tailored, remote care (4).

The assumption is that as health care shifts away from the clinic and into patients' home, and as patients have access to information about their own health, health care will be increasingly democratized (1). Even though patients are generally thought of as the main winners of the diabetes digital revolution, there are psychosocial and behavioral barriers to adoption that may exclude a proportion of patients (5). Sensors, wearable devices and smartphone applications with real-time feedback loops that move health care from traditional settings into the patients' home, work and leisure spaces may become intrusive on personal privacy (6). The many notifications can lead to alert fatigue, while the need for frequent monitoring and device maintenance adds new tasks to the patients' daily schedule, demanding their physical availability, time and attention, and interfering with their work and social life (7-11). The obtrusive physical presence of the device in combination with audio or visual notifications can 'expose' the patient as ill to the public eye, which may be experienced as a socially undesirable, stigmatizing breach of privacy (10). Disclosure of monitoring data to third parties such as insurers could have tangible consequences for patients, and may therefore be perceived as a particularly undesirable breach of privacy.

Intrusive features of monitoring devices are commonly cited as reasons for continuous glucose monitoring discontinuation, including alert overload and dislike towards having diabetes wearables on their body (each cited by a third of 249 patients who had discontinued CGM use) and disruption of daily functions (e.g., sleep, cited by 20%) (12). Similarly, a reason for discontinuation of insulin pump devices is social stigma (i.e., the visibility of the device triggers others' questions regarding diabetes, cited by 13% of 72 ex-users). Some aspects of intrusiveness may especially affect specific patient subgroups. For example, younger patients report worry about social stigma as

a barrier to adoption twice as frequently as older patients. Similarly, women report the hassle of wearing the device as a barrier more often than men.

Remote digital monitoring can therefore be particularly intrusive, either by disrupting one's daily routine or by breaching the boundaries of privacy through undesirable disclosure of personal information. By contributing to the burden imposed on chronically ill patients, increased perceived intrusiveness could negatively affect uptake and adherence to the prescribed monitoring plan (13, 14). For example, a patient may choose to temporarily remove a monitoring device that is physically obtrusive and easily visible while they are in public transport to avoid attracting attention, in spite of their physicians recommendation to wear it continuously (10). As the responsibility of reporting on their disease is shifted from the patients themselves to the device, such unrecorded data can affect physician-patient communication and complicate their relationship. From a sociological perspective, the adoption and normalization of remote digital monitoring in patients' lives requires complex processes, including the reconfiguration of the caregiver-patient and other social relationships, the redistribution of health care tasks and the respatialization of the care process, that patients may react to by resisting and rejecting the new technology (10, 15). Achieving acceptability may be particularly critical for multimorbid chronically ill patients who often experience increased burden of treatment (8, 16).

However, it is unknown how specific aspects of monitoring determine perceived intrusiveness and its acceptability (e.g., the physical characteristics of the monitoring tool, the duration of monitoring) (17). Identifying perceptions of intrusiveness of digital monitoring, how these relate to acceptability, and for whom is important, as components of digital monitoring will be incorporated in future automated insulin delivery systems and in remote, digital behavior change interventions. Furthermore, barriers to device uptake pertaining to intrusiveness may be modifiable through user-centric design (e.g., by reducing the number of notifications or designing smaller wearable parts).

To further our understanding of intrusiveness in remote digital monitoring in health care, we will conduct a vignette-based survey with patients with diabetes type 1 and 2.

1.1 Objectives

Our aim is to examine the relationship between characteristics of remote digital monitoring and the way patients with type 1 or 2 diabetes mellitus perceive said monitoring in terms of intrusiveness, potential to offer diabetes-related reassurance, and acceptability, compared to their current diabetes monitoring practice.

3. Methods

We will conduct a vignette-based survey. Our vignettes are hypothetical scenarios of digital remote monitoring, in which the presence of key monitoring components is varied systematically.

3.1.Participants

Adult patients diagnosed with type 1 or 2 diabetes mellitus and fluent in French or English are eligible.

3.2.Recruitment procedure

We will recruit patients in person and online:

- By disseminating the study on social media (e.g., francophone and Anglophone patient groups on Facebook),
- By inviting participants with diabetes in the French e-cohort ComPaRe
 (www.compare.aphp.fr). ComPaRe includes patients with chronic conditions who have a
 priori consented to be contacted with invitations to participate in studies on their illness,
- Through clinician associates. We will recruit patients followed at the Jean Verdier hospital (Paris, France) and the Knowledge Evaluation Research Unit (Dir: V. Montori, Mayo Clinic),
- By inviting patients to participate in person in the diabetology ward of hospitals in Paris, France. The researcher (T.O.) will approach patients in the consultation waiting area and the Day Hospital of Cochin hospital. She will verbally explain the purpose of the study.

Patients who wish to participate will be directed to the study website (https://clinicalepidemio.fr/diabete/en/) where they can read and electronically sign the consent form (see Appendix I for consent form).

3.3.Study duration

Participants are required to complete a single questionnaire. Completion takes 10-15 minutes. The total duration of the study (participant recruitment and data analysis) is estimated at 8 months, from February 2019 through August 2019.

3.4. Vignette development

We have developed vignettes presenting the following remote digital monitoring factors: monitoring tool, monitoring duration and feedback, and data management (Table 1). Each factor can take one of several different levels. To create all possible vignettes, we generated all

combinations of the above factors, which resulted to 36 vignettes. Two methodologists screened the vignettes to reject any implausible combinations.

To draft the vignettes, we based the description of the tools on existing devices (for glucose flash monitoring) and apps (for fitness and diet tracking) such as *FreeStyle Libre* (18), *CalorieMama*, *Diet Camera*, *Bitesnap*, *Pedometer Pacer*, *Step Counter*, and *365 Pedometer*.

Table 1. Vignette factors and their levels.

Vignette Factors	Factor Levels
A. Monitoring	1. Continuous glucose monitoring (via adhesive skin sensor) (18) + PA
tool	monitoring via smartphone accelerometer(19)
	2. Continuous glucose monitoring + PA monitoring + diet monitoring
	via smartphone camera-based food recognition (frequency of diet
	monitoring: every 3 days) (20, 21)
	3. Continuous glucose monitoring + PA monitoring + diet monitoring
	(frequency: only at unusual meals)
B. Monitoring	1. Used for one week before appointments only when there is a
duration and	modification in treatment or health complications. The data is sent to
feedback	the patient's electronic health record and used in the next consultation
intervention	to guide treatment adaptation. The physician is not alerted in real
	time.
	2. Used for one week before each appointment with their physician. The
	data is sent to the patient's electronic health record and used in the
	consultations to guide treatment adaptation. The physician is not
	alerted in real time.
	3. Used regularly as the patient's usual monitoring. If an anomaly is
	detected in the collected data, a notification is sent in real time to their
	physician who will decide to contact them if necessary to adapt their
	treatment. No other medical visits are required.
	4. Used regularly as the patient's usual monitoring. If an anomaly is
	detected in the collected data, a notification is sent in real time to a
	carer other than their own physician, who will decide to contact them
	if necessary to adapt their treatment. No other medical visits are
	required.
	5. Used regularly as the patient's usual monitoring. The collected data
	are used to automatically adapt the treatment. This information is sent
	to patients in real time with smartphone notifications. No other
	medical visits are required. The physician is not alerted in real time.
	6. Used regularly as the patient's usual monitoring. The collected data
	are used to automatically adapt the treatment and to create
	suggestions and recommendations for life style changes (e.g.,
	reminders to exercise, personalized nutrition goals). This information
	is sent to patients in real time with smartphone notifications. No other
C Data storage	medical visits are required. The physician is not alerted in real time. 1. Data will be managed by a public sector organization (hospital, the
C. Data storage	
and management	state, etc.) 2. Data will be managed by a private sector organization (insurer,
	pharmaceutical company, etc.)
	pharmaceutical company, etc.)

3.5. Survey description

The 36 vignettes will be individually assessed in our survey (see Appendix II or https://clinicalepidemio.fr/diabete/en/ for survey). The survey begins with a short introduction in which we briefly describe the three digital remote monitoring tools contained in the vignettes. The introduction is followed by demographic and illness related questions (age, gender, education level, type of diabetes, whether they consider their diabetes controlled, current use of continuous flash glucose monitoring) and two questions that assess the patient's current diabetes monitoring (measuring perceived intrusiveness and reassurance on a five-point whole integer scale), and then a randomly selected sample of three vignettes presenting different remote digital monitoring scenarios. Each vignette is presented individually and is assessed with four questions, all of which are assessed on a 5-point Likert scale to avoid cognitive overload and ensure reliability (22).

- Question 1measures perceived intrusiveness of the vignette monitoring (ranging from "Not at all" to "Extremely" intrusive)
- Question 2 measures the degree of reassurance provided by the monitoring (ranging from feeling "Not at all" to "Extremely" reassured)
- Questions 3 and 4 measure acceptability by asking participants about the minimum effectiveness for which they would choose the vignette monitoring over their current diabetes monitoring. Specifically, Question 3 asks how effective the vignette monitoring has to be compared to their current monitoring at reducing hypoglycemic episode frequency ("How effective would this monitoring have to be at reducing the frequency of hypoglycaemic episodes, for you to choose it over your current way of monitoring?"). The 5 point response scale ranges from "It could be much less effective" to "It would have to be much more effective". Question 4 follows the same format but inquires about efficacy in preventing long-term complications.

3.6.Other collected data

At the end of the survey, there are two open-ended questions asking which aspect of the remote digital monitoring vignettes presented in the survey the participant considers most intrusive and why, and how digital monitoring could affect their personal, professional and social life. We also collect three items of the Problem Areas in Diabetes (PAID) scale, the presence of diabetes-related health complications, and the number of hypoglycemic episodes in the past 30 days (23). Lastly we ask participants two additional questions about their current use or the intention of future use of digital monitoring technologies, to determine the stage of behavior change that participants are on according to the Stages of Change behavioral model (not currently using digital monitoring

and not intending to use it in the future, not currently using it but intending to use it, currently using digital monitoring but not regularly, or regularly using digital monitoring) (24). The questions are adapted from measures of change in physical activity behavior (25).

3.7.Study outcomes

We aim to rank the complete vignettes (monitoring scenarios) from most to least intrusive. Outcomes include mean intrusiveness, reassurance and acceptability rating on a 5 point whole integer scale.

3.8. Ethics and data security

This project has been reviewed by the Institutional Review Board of the French institute INSERM (IRB00003888) and has been registered with the French National Institute for Health Data (INDS, www.indsante.fr/fr/repertoire-public/etude-sous-mr-5313131118).

Patients will be informed about the purpose and process of the study and their rights on the website, on a dedicated informed consent page that appears before the beginning of the questionnaire (see Appendix I). Before they proceed in the survey they will consent electronically.

All collected information will be handled with confidentiality. No personal identifiers (patients' names, addresses, email addresses, or full date of birth) will be collected. Data collection and transmission from the participants' computer to the server are secured by HTPPS and SSL (Secure Socket Layer) to ensure confidentiality. The data will be stored in a secure server that is accessible only by the web developer of the research team (Centre of Clinical Epidemiology, Hôtel Dieu Hospital, Paris, France), and will be retained for 2 years after the final publication of the study findings. The dataset will be downloaded for analysis via secure connection and given to researchers in an encrypted USB key. Analysis will be performed by the researchers using computers located in the Hôtel Dieu Hospital in offices accessible only to Research Centre personnel. The principal investigator (T.O.) is responsible for data protection.

3.9. Statistical analysis and sample size

Quantitative data will be presented as means (SD) or proportions. We will present the mean intrusiveness and reassurance ratings of the current diabetes monitoring as a reference point. We will present the vignettes ranked by their mean intrusiveness and reassurance score.

We will additionally use a multilevel logistic regression models to identify the factors that influence acceptability and perceived intrusiveness of digital monitoring, using the following variables:

- The three vignette factors, and
- Patient characteristics (current/intended use of digital monitoring, age, frequency of hypoglycemic episodes, patient perception of their diabetes being well controlled or not, PAID items on anxiety and burnout related to diabetes).

We will use random effects at the respondent level to account for clustering of responses at participant level (26). Because the acceptability questions are rated as relative to the patients' current monitoring, we will adapt the intrusiveness and reassurance score for each vignette to be comparative to that of the current monitoring by subtracting the intrusiveness and reassurance score assigned to each vignette from the scores the participant assigned to their current monitoring.

The data collected in this observational study will be analyzed using multilevel regression models with a maximum of 10 explanatory variables. In simple linear regression, between 10 and 30 observations are required per included variable (27). Taking into account the number of vignettes (n=36), and the fact that each participant will evaluate 3 vignettes in our study, we plan to include a minimum of 300 participants (resulting to 900 vignette evaluations). This number would allow us to perform the planned analysis taking into account the clustering effect at participant level.

For the answers to the open ended question we will use a conventional (inductive) content analysis approach (28). Conventional analysis begins with reading all data repeatedly to obtain a global sense of responses, then reading several responses individually and highlighting the words that capture key concepts in order to generate initial codes. Using these codes the remaining responses are coded and new codes are created if necessary. Codes are sorted into clusters and subclusters, and definitions for each cluster, subcluster, and code are developed and exemplars for each are identified from the data. The approach allows the direct extraction of information without an a priori theoretical framework. All responses will be handled in the original language and at least one proficient speaker will be involved in all stages of the analysis. Each response will be coded by a single researcher and a second researcher will review all coded responses. Any disagreements will be resolved through consensus. We will consider arranging emergent clusters hierarchically by fitting lower-level code clusters under higher-level ones, presented in a tree diagram.

4. Expected results

This study can lead to a better understanding of patients' preferences regarding the use of digital tools to monitor diabetes and to identifying which aspects of digital monitoring affect acceptability and perceived itnrusiveness. This can help clinicians prescribe digital monitoring that is appropriate for patients' expectations and needs.

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Appendix I : Consent form (English version)

Study title: Patient perceptions on the intrusiveness of remote digital monitoring for diabetes

Researchers:

Theodora OIKONOMIDI Prof. Philippe RAVAUD Centre d'Epidémiologie et Statistique Sorbonne Paris Cité (INSERM U1153), Paris, France +33 (0)1.42.34.89.87

Dear participant,

This scientific study aims to describe how patients perceive the use of digital tools (e.g., smartphone applications, continuous glucose monitoring sensors) for the remote monitoring of diabetes. It is run by Public Health researchers of the Center of Epidemiology and Statistics Sorbonne Paris Cité (INSERM U1153, Paris, France).

The information note you are reading describes all the important information relevant to your participation in the study. Please take the time to read it. If you have any questions, do not hesitate to contact the principal investigator to ask for clarifications and further information.

1. Context

Living with diabetes requires that patients regularly monitor their blood glucose and way of life (physical activity, nutrition). That can be complex and time-consuming. Digital tools can help patients monitor their diabetes, but their use could be intrusive in daily life.

2. Study objectives

Our study aims to describe patients' perceptions and preferences regarding the use of digital monitoring for diabetes.

4. Participants and recruitment

Adults with diabetes type 1 or 2 are eligible to participate. Participants will be recruited online (on social media, by invitation to patients already participating in the online cohort ComPaRe) and in hospital diabetology wards (Cochin Hospital). The recruitment period is estimated at 5 months and will include a minimum of 273 participants.

5. Participant engagement

By participating in this study you accept to respond to a single online questionnaire. In this questionnaire, you will be asked to assess three «vignettes» (short scenarios) describing different types of digital monitoring. Completing this questionnaire should take 15 minutes. Once you have completed this questionnaire, your participation in the study is over.

6. Participant rights

a. Anonymity and confidentiality

This questionnaire is anonymous and all collected data are confidential. Only the researchers responsible for this study can have access to the data.

b. Storage and disposal of collected data

The collected data will be stored on a secure server at the facilities of the Centre of Epidemiology and Statistics Sorbonne Paris Cité and deleted 2 years after the publication of the results in a scientific journal.

c. Right to refuse and withdraw participation

Your participation in this study is entirely voluntary. Once you have read this information note you can freely accept or refuse to participate.

If you decide to participate, you can end your participation at any time without providing any justification. This will not affect the quality of care you receive in any way.

7. Risks and benefits

We do not anticipate any risks to you participating in this study.

You will not receive any compensation for your participation. By participating you provide information that can help researchers and doctors make the best use of digital tools in caring for patients with diabetes.

8. Dissemination of the study results

Ready to start the questionnaire?

The results of this study may be published in a scientific journal. No information that could be used to identify you will be made public. A summary of the findings will be available for you on this website.

9. Questions and additional information about the study

You can contact the principal investigator and responsible for data safety with any questions about the study, your participation, and the use of your data: Ms Theodora Oikonomidi / Phone number: (+33) 01.42.34.89.87 / theodora.oikonomidi@inserm.fr.

This study has been reviewed by the Institutional Review Board of INSERM (IRB00003888) on 15/01/2019 and registered with the French National Health Data Protection Institute (INDS).

Ö		T. 1
B.,	I accept to participate.	I do not accept to participate.

Appendix II: Survey (English version)

What is your	age ? years	old					
You are O	A woman C A m	nan Prefer to self-	describe:				
At what age d	At what age did you complete your education? years						
Which type of diabetes do you have?* Type 1 Type 2 Other (please describe)							
Do you use insulin to manage your diabetes? Yes No							
Do you feel yo	our diabetes is wel	l controlled?* [©] Ye	s No				
		ently do to monitor youts, keeping food and ex		s may include finger prick c.			
1. How intrus	ive is your current	monitoring to your da	ily life?				
0	0	0	0	0			
Not at all	A little	Moderately	Very	Extremely			
2. How reassu	red does your curi	rent monitoring make	you feel?				
0	0	0	0	0			
Not at all	A little	Moderately	Very	Extremely			

Imagine that your doctor prescribes that you use the diabetes monitoring below, at no additional financial cost to you.

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- o A glucose sensor and an app to monitor your physical activity.
- An app to monitor your food intake. You will have to take pictures of only themeals, snacks or drinks that are unusual to what you ordinarily consume.

• Monitoring duration:

o This will be your regular monitoring from now on.

• Adapting your treatment:

- o If an anomaly is detected in the data, **your doctor** will receive **a notification in real time.** They will then contact you to adapt your treatment if necessary.
- o **No regular visits** will be required to follow-up on your diabetes, but you will be able to take an appointment with your doctor if you wish to.

• Data handling:

 Your data will be handled by a private organization (an insurance, a pharmaceutical or an informatics company).

1. How intrusive	would this diabetes:	monitoring be to yo	our daily life?	
0	C	0	0	C
Not at all	A little	Moderately	Very	Extremely
2. How reassured	would this monitor	ing make you feel?		
0	C	0	0	C
Not at all	A little	Moderately	Very	Extremely
		_	ucing the frequency of your current way of mor	, , , , , , , , , , , , , , , , , , ,
0	0	0	0	0
It could be much less effective	It could be somewhat less effective	It would have to be just as effective	It would have to be somewhat more effective	It would have to be much more effective
		_	venting eye complicati	ons in the future, for
you to choose it c	over your current wa	y of monitoring?		
0	0	0	0	0
It could be much less effective	It could be somewhat less effective	It would have to be just as	It would have to be somewhat more	It would have to be much more effective

Imagine that your doctor prescribes that you use the diabetes monitoring below, at no additional financial cost to you.

•	Di	gita	l too	ls:
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• A glucose sensor and an app to monitor your physical activity.

Monitoring duration:

o This will be your regular monitoring from now on.

• Adapting your treatment:

- o If an anomaly is detected in the data, **your doctor** will receive **a notification in real time.** They will then contact you to adapt your treatment if necessary.
- o **No regular visits** will be required to follow-up on your diabetes, but you will be able to take an appointment with your doctor if you wish to.

Data handling:

 Your data will be handled by a private organization (an insurance, a pharmaceutical or an informatics company).

1. How intrusive	would this diabetes	monitoring be to ye	our daily life?	
0	0	0	0	0
Not at all	A little	Moderately	Very	Extremely
2. How reassured	would this monitor	ring make you feel?		
0	0	0	0	0
Not at all	A little	Moderately	Very	Extremely
			ducing the frequency of your current way of mo	
O	O	O	0	0
It could be much less effective	It could be somewhat less effective	It would have to be just as effective	It would have to be somewhat more effective	It would have to be much more effective
			eventing eye complicat	ions in the future, for
O CHOOSE IT C	over your current wa	O monitoring:	0	0
It could be much less effective	It could be somewhat less effective	It would have to be just as effective	It would have to be somewhat more effective	It would have to be much more effective

Imagine that your doctor prescribes that you use the diabetes monitoring below, at no additional financial cost to you.

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- A glucose sensor and an app to monitor your physical activity.
- An app to monitor your food intake. You will have to take pictures of only the meals, snacks or drinks that are unusual to what you ordinarily consume.

Monitoring duration:

o This will be your regular monitoring from now on.

• Adapting your treatment:

- Your data will be used to **automatically adapt your treatment**. This information will appear on your smartphone **in real time**.
- No regular visits will be required to follow-up on your diabetes, but you will be able to take an appointment with your doctor if you wish to.
- O Your doctor will **not receive** any real-time notifications.

Data handling:

 Your data will be handled by a private organization (an insurance, a pharmaceutical or an informatics company).

1. How intrusive	would this diabetes	monitoring be to yo	our daily life?	
0	0	0	0	0
Not at all	A little	Moderately	Very	Extremely
2. How reassured	would this monitor	ring make you feel?		
0	0	0	0	C
Not at all	A little	Moderately	Very	Extremely
			lucing the frequency of your current way of mo	
0	0	0	0	0
It could be much less effective	It could be somewhat less effective	It would have to be just as effective	It would have to be somewhat more effective	It would have to be much more effective
		_	eventing eye complicat	ions in the future, for
you to choose it o	ver your current wa	ay of monitoring?		
0	0	0	0	0
It could be much less effective	It could be somewhat less effective	It would have to be just as	It would have to be somewhat more effective	It would have to be much more effective

Finally, plo	ease answer th	e following questions:		
Which asp	ect of the diabe	etes monitoring scenarios	you read did you find most	intrusive and why?
How would	d digital diabe	tes monitoring affect you	ur family, social and prof	essional life?
Have you l	had any of the	following health compli	cations due to your diabe	tes:
		Renal complications Other:	Blindness Amputation	on C
How many	hypoglycaem	ic episodes have you had	l in the last 30 days?	
-	-	sensor or app for your he, nutrition app)? [©] Y	ealth or wellbeing (e.g., fl Yes No	ash glucose sensor,
If no: Do y	ou intend to u	se one in the next 6 mon	ths? O Yes No	
If yes: Do	you use it regu	larly (on several days ar	nd every week)? O Yes	No
For how m	any months h	ave you been using it reg	gularly?	
Which of t	he following d	iabetes issues are currer	ntly a problem for you?	
1. Feelings	of guilt or anxi	ety when you get off trac	k with your diabetes manag	gement?
0	0	•	0	0
Not a problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem
2. Feeling '	'burned out'' by	the constant effort neede	ed to manage diabetes?	
0	0	•	0	0
Not a problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem
3. Worryin	g about the futu	re and the possibility of s	serious complications?	
0	0	•	0	0
Not a problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem