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ABSTRACT

Introduction Type 2 diabetes is a chronic condition associated with impaired glucose tolerance and a high prevalence of comorbidity, polypharmacy and medication safety incidents. Little is known about the patient work associated with using diabetes management technologies by patients and their informal caregivers at home. This study aims to apply a systems engineering approach to better understand this work.

Methods and analysis This is a qualitative focused ethnographic study using interview and photography. Adults, living independently at home, with type 2 diabetes who have been using insulin as part of their treatment regimen for a minimum of 6 months and who are using at least one diabetes management technology without support of a professional at home are eligible for inclusion. Participants will be recruited through advertisements on social media, in diabetes clinics and by contacting associations of persons living with diabetes and diabetes specialists. Participant consent will be taken, interviews will be undertaken in the participant's home, audio-recorded and photographs securely saved. The Systems Engineering Initiative for Patient Safety (SEIPS) model will frame the data coding and we will develop new codes to accommodate data outside the SEIPS model. Results will be interpreted to produce a description of work processes, work system elements and interactions that support or jeopardise the achievement of safety. This protocol will follow the consolidated criteria for reporting qualitative research checklist for the reporting of qualitative research interviews.

Ethical considerations and dissemination This protocol was approved by the University of Lille's Behavioural Sciences Ethics Committee. The study will comply with data protection legislation: the protocol has been declared by the Data Protection Officer of the University of Lille to the National Commission on Informatics and Liberty. We plan to disseminate our findings via presentations at relevant patient/public, professional, academic and scientific meetings, and publish in a peer-reviewed journal.

STRENGTH AND LIMITATIONS OF THIS STUDY

⇒ This exploratory study is novel because the work of people experiencing type 2 diabetes (PT2D) using diabetes technology at home has never been studied using a systems engineering approach.
⇒ The data collection methods are rigorous, combining on-site interviews and photographs, which have proven valuable to get detailed insights on patient work at home.
⇒ The recruitment of a Patient and Public Involvement panel, enabling patients to collaborate with researchers working with and for them, caregivers, diabetologists and community pharmacists, will enable us to cross-fertilise viewpoints on study findings and interpretation.
⇒ This study is limited by the purposive sampling approach which, although best suited to in-depth qualitative analyses aimed at understanding a complex phenomenon, does not support transferability of the results beyond the study population.

INTRODUCTION

Problem statement

Type 2 diabetes is a chronic condition associated with impaired glucose tolerance and a high prevalence of comorbidity and polypharmacy. It is estimated that by the year 2030, greater than 500 million people worldwide will experience type 2 diabetes and between 7% and 15% of these will use insulin as part of their management.[1] People with type 2 diabetes (PT2D) have been reported to spend between 1 and 2 hours per day managing their condition at home, which would represent 1–2 years of life if they lived 50 years with this disease.[2–4] Diabetes management can be considered as real patient work ('exertion of effort and investment of time on the part of

patients or family members to produce or accomplish something'[5]) in the same way as paid work or hobbies, with the difference that an insulin dosage error can put the patient's health or life at risk. Indeed, managing diabetes with insulin therapy is a risk management situation. Patients and/or their informal caregivers must regularly measure their blood glucose levels to inject the necessary dose of insulin to keep their glucose levels in the target range. Not enough insulin will prevent regulation of blood sugar levels, leading to hyperglycaemia and, if sustained, complications (eg, cardiovascular diseases).[6 7] An overdose of insulin can lead to hypoglycaemia, with the potential for minor (eg, lipothymia) to major (eg, vigilance disorders, coma, death) consequences.[8 9]

Diabetes technologies are offering opportunities to improve self-management and glycaemic control.[10] They are intended to help to measure glucose levels more easily (eg, finger pricker, continuous glucose monitor—CGM), calculate and inject the right dose of insulin safely (eg, automated bolus calculators, autoinjector pens), and manage and communicate health data (eg, mobile apps). Although research on these technologies has focused primarily on people living with type 1 diabetes, it is increasingly recognised that PT2D face similar challenges and could therefore benefit from these advances to achieve the recommended glycaemic standards.[11] In summary, these technologies are expected to reduce the diabetes management burden on PT2D and their caregivers, and improve glycaemic control and quality of life.[12]

However, while the use and impact of these technologies have been evaluated in the professional setting, relatively little is known about their use in the home setting.[13] It is now acknowledged that diabetes technologies, when used by PT2D or informal caregivers, may jeopardise safety and the expected improvement in glycaemic control. For example, certain misuses have been observed in the use of CGMs which can distort glucose measurement (eg, incorrect sensor position and calibration, sensor disinsertion or age) or discourage users (eg, poor alarm setting).[14] Similarly, several problems have been identified in insulin injection by PT2Ds (eg, skipping injection, needle reuse, incorrect rotation of injection sites leading to lipodystrophy).[15] Yet, from a systems engineering perspective, patient work (eg, managing diabetes) is shaped by the interactions between the elements that compose their work system.[16] Following this approach, if PT2Ds and their caregivers behave in a way that has negative consequences in terms of safety or suboptimal treatment, it is not seen as a failure of the people but as the consequence of a poorly designed work system. In this perspective, interventions to improve safety and compliance are not just based on the education or motivation of PT2D and caregivers but rather on the redesign of the work system.[17]

Background: systems engineering approach

Carayon *et al* proposed the Systems Engineering Initiative for Patient Safety (SEIPS) model,[18 19] enhanced by Holden *et al*,[20] to investigate the complexity of the causes of patient safety incidents by looking at the interactions between the elements of the patient's system (eg, technologies, environments, persons) to understand decisions and behaviours rather than analysing them in isolation. This model is one of the most widely used systems engineering models for the study of patient safety. It is based on a three-interdependent-section structure (figure 1): the sociotechnical work system (on the left of the figure) produces a work process(es) (in the centre) which gives rise to outcomes (on the right). The sociotechnical work system is made up of six interacting elements that shape the behaviour of the patient and their caregivers: (1) the people (eg, patient, formal or informal caregivers), (2) the tasks these people perform (eg, related to medication management or not), (3) the work or home organisation in which these tasks are performed (eg, work and life schedules, resources, social support), (4) the internal environment in which these tasks are performed (eg, physical environment, distractions), (5) the tools and technologies used to perform the tasks (eg, information technologies, physical tools), and (6) the external environment governing the performance of these tasks (eg, community, regulatory, policy). A work process emerges when two or more elements of this work system interact. This work process may be performed by the patient, their caregiver or by their cooperation. It leads to intended or unintended outcomes that may concern the patient (eg, safety, workload, satisfaction) or the caregivers (ditto).

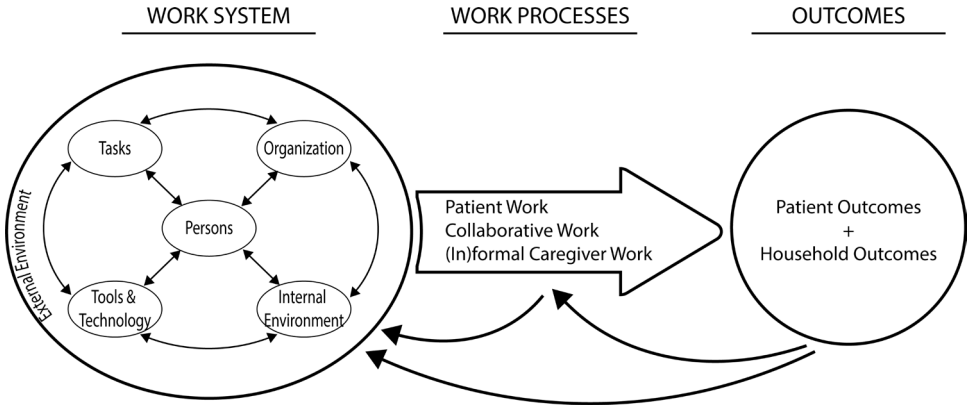

Figure 1 The Systems Engineering Initiative for Patient Safety (SEIPS) adapted to the household context (from [20]).

The SEIPS models have been used successfully to understand the work system elements that can be influenced to improve the safety of different patient population conditions,[21] the older people taking more than 4 medications,[22] people who are polymedicated and living with a chronic disease,[23] and people living with asthma or chronic obstructive pulmonary disease.[24]

The present need for research and objectives

PT2Ds' work has received little research attention. Some research has investigated patient work's evolution over time or in exceptional circumstances (COVID-19) to inform the design of digital support interventions,[25 26] PT2D's work to access and benefit from formal diabetes care,[27] or treatment burden.[28] However, it did not adopt a work system perspective and did not focus on the home setting.

Very few studies investigated PT2D work using a system engineering approach.[21] Werner *et al* studied personal health information management, a subtask of diabetes management.[29] Novak *et al* investigated the role of everyday objects in the construction and maintenance of routines among PT2Ds.[30] Although those papers analysed part of the patient work, they did not investigate the use of diabetes technologies and their integration within the home work system. Wahbeh *et al* investigated the strengths and weaknesses of mobile apps dedicated to diabetes self-management based on apps users' reviews not on the actual observed use of those technologies.[31] None of those studies distinguished between type 1 and type 2 diabetes despite differences in their management and their risks, and in the patients' demographic, age of starting insulin therapy, and morbidity profiles.

To the best of our knowledge, no studies have investigated the actual use of diabetes technologies within PT2D's and informal caregiver's work at home using a systems engineering approach. Our study aims to fill this gap by investigating the patient work associated with the use of diabetes technologies. For this purpose, we will ask the following question:

- What are the work processes of PT2D and informal caregivers that include diabetes technologies?
- What are the elements within the PT2D work system that are important to understand the work processes?
- What are the consequences of these work processes?
- What are the elements of the work system that, if modified, could facilitate and improve the use of diabetes technologies?

Study context: type 2 diabetes in France

Almost 4 million people are identified as diabetic (national prevalence 5.6%).[32] In the Hauts-de-France region, to which the European Metropolitan area of Lille belongs, the prevalence of diabetes rises to 6.2%. For comparison, in 2021, the number of people living with diabetes was estimated at 537 million worldwide (global prevalence 9.8%) and 61.42 million in Europe (7% prevalence in Europe).[33] 90% of people living with diabetes have type 2 diabetes.[33] Insulin injection therapy is the last option for PT2D after following a healthy lifestyle and other pharmaceutical treatments (eg, metformin). It is estimated that 23% of PTD2 in metropolitan France are treated with insulin.[34]

In the French healthcare system, general practitioners (GP) are responsible for monitoring adult PT2D. Nurses may also be involved in the treatment and management (eg, injections, therapeutic patient education). Despite a few local experiments, community pharmacists' contractual obligations do not yet include consultations to improve diabetes management.[35 36] In the event of complications (eg, uncontrolled diabetes), the GP refers the patient to appropriate specialists for more specialised assessments, often in hospital. Although GPs are responsible for coordinating care and monitoring their patients, patient information is not systematically shared between GPs, hospitals and medical laboratories. The responsibility for sharing this information generally lies with the patient.[37 38]

France has a statutory health insurance system that provides universal coverage for its residents. This health insurance finances 83% of total healthcare expenditure, the remainder being covered by private insurance and out-of-pocket payments.[39] Diabetes is acknowledged as a long-term condition. As a consequence, examinations, treatments and devices related to this disease (eg, blood glucose metre, lancets, CGM flash) are covered at 100% by the statutory health insurance (within the limit of reimbursement rates).[40 41]

METHODS AND ANALYSIS

Patient and public involvement

People living with a health condition and their (formal and informal) caregivers are often in a better position than a researcher to know what research should be performed to improve their quality of life. Therefore, they can help adapt the research question and identify the most meaningful and relevant outcomes to measure. Overall, Patient and Public Involvement (PPI) helps improve the relevance and the value of research for patients and society.[42–44] Additionally, members of the public may include stakeholders involved in the topic under study, who can also contribute meaningfully to enhance the research validity and integrity.

The PPI panel will be formed of PT2D, informal caregivers, a diabetologist and a community pharmacist. The panellists cannot be recruited from the sample of participants. They will be invited to participate on a continuous basis throughout the research project, similar to a previous study.[45] Before the study commences, the PPI panel will review and revise the participant facing materials (eg, participant information leaflet). They will comment on the protocol in order to optimise observation of key issues. During the research, they will be actively involved in the data analysis, interpretation of the results, and will comment on the impact of the findings on patient work

systems and processes, technology design or healthcare provider decision-making. They will be engaged and will contribute to the co-creation of outputs (especially the publication of the results in reports and scientific publications) and the development of public facing information. They will also help with dissemination and outreach of these materials (eg, engaging with patient advocacy groups, healthcare providers, technology designers or vendors).

A suitable level of engagement will be decided jointly with the PPI panellists on each occasion depending on their preferences, availability and resources at each step. Panellists will be trained to support their learning needs required to meet the tasks.

Design

An exploratory qualitative focused ethnographic study design is adopted to understand the complex phenomenon of self-managing diabetes with diabetes technology. Focused ethnography is a branch of classical ethnography used in applied science, such as technology impact investigation or the study of medication communication.[46 47] In focused ethnography, the researcher focuses on a specific research question. Data collection is less experience-intensive and time-extensive. It is rather data-intensive: data collection is performed during shorter periods of time and is supported by recording devices.[48 49] Semistructured interviews with PT2D and informal caregivers supported by photos of their life environment are planned.

Participants

The inclusion and non-inclusion criteria for participants are summarised in table 1.

Inclusion criteria

We will target adult participants (over 18), living independently at home, with type 2 diabetes who have been using insulin as part of their treatment regimen for a minimum of 6 months and who are using at least one diabetes technology, defined as a CE marked medical device indicated to support diabetes management, without the support of a professional at home. Participants must be fluent in French. They will not be excluded if they refuse to show parts of their home or to allow photos of their home setting to be taken. The participants should not be known to the interviewers prior to study recruitment.

Exclusion criteria

People with any type of diabetes other than type 2 (eg, type 1, gestational, MODY) or with type 2 diabetes not using insulin or for less than 6 months, children, people under legal protection (eg, guardianship, curatorship) are not eligible for inclusion. Patients who reside in a care facility or whose insulin treatment within the home is managed, even partly, by healthcare professionals are not included. Because this study requires home visits, patients are not included if they live outside Lille metropolitan area.

Sampling strategy

Non-probabilistic approaches are well suited to in-depth qualitative research aiming at understanding complex phenomena.[50] Precisely, a purposive sampling method is 'used to select respondents that are most likely to yield appropriate and useful information' about a phenomenon of interest.[51] Therefore, a purposive non-probabilistic sampling approach is chosen to recruit participants for our exploratory qualitative research. The criteria for purposive selection are: people who live independently at home in the Lille metropolitan area, experiencing type 2 diabetes, using insulin for at least the previous 6 months and using diabetes technology in the self-management of their diabetes.

A sample size of 30 was chosen due to anticipated diversity to support having sufficient information power.[52] This size is in line with the range of sample sizes recruited in qualitative systems engineering studies of patient work (eg, chronic condition or medication management) at home.[23 29 53–55] This sample size does not include caregivers who may take part in the interviews. As this study is exploratory, we will not be seeking data saturation.[56]

Recruitment

Participants will be recruited through advertisements on social media, and by contacting associations of PT2D, diabetes specialists and healthcare practitioners' networks. At this stage, prospective participants will be able to self-check their eligibility against the study's inclusion

Table 1 Summary of inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Adult PT2D (over 18)	People living with other kinds of diabetes or under 18
Insulin as part of their regimen (for over 6 months)	PT2D not using insulin or for less than 6 months
At least one CE marked medical device for diabetes	No diabetes medical device used
No professional support for insulin use	Insulin use supported by a professional even partly
Living independently at home	Living in a care facility or outside Lille metropolitan area
Fluent in French	People known to the interviewer prior to the study

CE, Conformité Européenne; PT2D, people with type 2 diabetes.

criteria, which will be outlined in the participant information leaflet downloadable through a QR code included in the advertisement and in hard copy. Persons interested in taking part in the study should contact the researcher by e-mail or telephone. They will be called back by e-mail or telephone, depending on the contact details given and their preferences. At participant's contact, details of the study are explained (eg, only non-identifying elements will be photographed or if some were photographed, they would be blurred on the saved pictures), the patient information leaflet is sent to the prospective participant, and eligibility criteria are checked. If patients agree to participate (oral consent expression; no written consent required for this type of study in France) and the eligibility criteria are met, an appointment is made for an interview at home. During this contact interview, participants will be also asked if they feel that in their daily life a non-healthcare professional in their network actively helps them to manage their diabetes (eg, spouse, child, neighbour). If so, then participants may invite this person to participate in the study with them. A caregiver information leaflet will be sent to the participant to pass on to his/her caregiver. Participants and their informal caregivers will not be compensated for participation in the study.

To ensure maximum variation in this sample, efforts will be made to include participants different in gender, age or home situations. A matrix of participant demographic characteristics will be employed to support iterative recruitment of less well-represented groups.[45]

Data collection

Data are collected through semistructured interviews and photography. PT2D interviews will be conducted individually; if the PT2D invites an informal caregiver, the dyad will be interviewed together. Interviews will take place in the home of the PT2D to facilitate recall of their activities and access to their daily routine and environment. The interviews will last around 1h30 and will be entirely audio-recorded on an encrypted dictaphone, then transcribed verbatim.

The interviews will be conducted in French by two human factors experts, both trained in ethnographic methods including interviewing. In the following sections, the human factors experts are referred to as the interviewers. To improve inter-interviewer reliability, they will train together to carry out these interviews. The first interview will be carried out by one of them under the other's observation, then the second by the other expert under their colleague's supervision. In the event of discrepancies in the way interviews are conducted, a conciliation meeting will be organised. Subsequent interviews will rotate between both interviewers. Interviewers will adopt a neutral, benevolent stance towards the participant to free their speech.

On arrival at the PT2D's home, the interviewer reminds them of the detailed purpose of the study and invites them and, if necessary, their informal caregiver, to express their oral consent. They will be reminded that they can interrupt the interview and withdraw from the study at any time and that if any identifying elements were photographed, they would be blurred.

The interview takes place in two stages, followed by a debriefing (cf. online supplemental material: interview guide).

First phase: general characteristics of the participant

In this phase, the interviewer collects data on participant's: age, gender, lifestyle (living alone or not), type of home, employment status (number of work hours, proportion of teleworking), duration of insulin and diabetes technology use, and relationship and distance to the informal caregivers. In order not to bias the interviewer's perception, no questions are asked about serum glucose or glycated haemoglobin levels or other measures of diabetes control.

Second phase: daily diabetes self-management

In this second phase, the interviewer asks the PT2D/caregiver to explain how they manage their diabetes at home on a daily basis and then asks questions to get a detailed understanding of each task. The interviewer explains that even tasks that the PT2D/caregiver finds negligible are interesting and should be presented. In order to gather as much information as possible about the context of these tasks, the interviewer asks the PT2D/caregiver to show where in their home these tasks are carried out. If the PT2D agrees, the interviewer therefore follows them around the various rooms in the house where tasks are performed, as required.

After the PDT2/caregiver has described their diabetes management, for each task, the interviewer will ask them to name it and describe it in detail; to do this, the researcher will ask them questions (in no strict order) about:

- Who performs the task? Why this person?
- At what time(s) of day is the task performed, and why
- What precedes and/or triggers the task
- What needs to be prepared, and how, to perform this task?
- The role of this task in overall diabetes management
- Where the task is performed and why?
- Precise description of how and why the task is performed (task miming if needed)
- What is done after the task is completed, and why?
- The artefact/furniture/tools/technologies used, and why
- Where and how the elements used to carry out this task are stored and serviced, how they are procured

For each task, the interviewer asks the P2TD/caregiver to describe remarkable situations: difficulties in carrying out the task and how they are overcome, errors, omissions and their consequences.

As the interview progresses, the interviewer ensures that all the steps in the diabetes insulin management process are explained by the P2TD/caregiver (acquisition

of materials/medication, storage, preparation for monitoring, monitoring, preparation of insulin, use of insulin, entry or interpretation of monitoring data, cleaning/maintenance of materials, disposal of materials/insulin). If a step was not mentioned, the interviewer would name it and ask the P2TD/caregiver to explain it.

Photography

During the interviews, PT2D-led photo walkabouts will be conducted.[57] As the interview progresses through the tasks' description, PT2D/caregivers will be asked, if they agree, to show where those tasks are performed. For each task described, and with the participant's agreement, photographs will be taken to collect visual information on behaviours, tools and places of use to support, explain and illustrate the interview data. Photographs will be taken with digital cameras. The photographs will be immediately transferred to an encrypted hard disk along with the audio recordings for transcription, anonymisation and analysis. Photographs are not the main source of data but rather will complement the interview data by helping the investigators to refine their understanding and discuss the collected data within the research team.[58] No photographs of PDT2/caregivers are taken. In the event of personal data being photographed (eg, name on medicine bottle), these will be blurred on the photos.

Debriefing

At the end of each interview, the researcher will let the PDT2/caregiver express themselves freely on the study (eg, their feelings), will take note of their remarks on it and will answer as many of their questions about the study as possible (eg, on data analysis, exploitation and access to results).

Data analysis

After leaving the PDT2's home, initial thoughts about the way the PDT2/caregiver manages their diabetes at home will be summarised in notes.

General characteristics of the participant

Descriptive statistics will be used to describe the sample of participants in numbers and percentages (eg, gender, home lifestyle) and in median and interquartile ranges (eg, age, duration of insulin and technology use). Statistics will be generated with Jamovi software.

Daily diabetes self-management

Interview transcripts, notes and photos will be analysed using both deductive and inductive content analysis approaches.[59] Qualitative analyses will be supported by using a qualitative research software, NVivo. Initially, the two interviewers will read the transcripts and summary notes and view the photos of the first three interviews, to get an overall idea of their content. Then, they will reread the transcripts and notes and review the photos in detail to deductively apply, independently of each other, a coding scheme based on the SEIPS 2.0 model.[20] Their codes include the three main parts of the SEIPS 2.0 model, as described in the introduction and in figure 1. If necessary, other codes will be inductively developed to reflect data diversity.

Each code will be defined and illustrated with an excerpt from the interview, and code patterns will be developed. After this first coding stage, the two researchers will meet to discuss disagreements over coding, code definition and grouping into patterns. Disagreements will be discussed with a third researcher to produce an illustrated and shared codebook. This codebook will then be discussed with the PPI panel. Subsequent interviews will be coded by a unique interviewer and cross-checked by a second: disagreements will be discussed between three researchers.

Then, for each task of the diabetes self-management process, prototypical work processes will be identified along with the elements of the work system that model them. The consequences described by the PT2Ds/caregivers will be analysed in relation to the work process in which they occur. Work processes will be categorised according to the valence of their consequences (positive, negative) and what they affect (eg, satisfaction, workload, socialisation, therapeutic adherence), and will be linked to their causes in the work system.

The findings will be discussed within the research team, including the PPI panel, to produce the final description of the relevant patient work, including work system elements and work processes, with a list of their consequences. The research team and PPI panel then co-interpret these findings to co-produce a descriptive list of the elements of the work system that, if modified, could facilitate and secure the safer and more efficient use of type 2 diabetes technologies.

Ethics and dissemination

Compliance with ethical standards

This protocol has been approved by the University of Lille's Behavioural Sciences Ethics Committee (reference: 2023–723 S120). This study will be performed in accordance with the 1964 Helsinki declaration and later amendments. Informed consent will be obtained from all study participants and they will be reminded that they can withdraw at any time.

We will collect nominative data to organise data collection (eg, participants' identity and address) and non-nominative data during the interviews (eg, health condition, home lifestyle). Therefore, this protocol has been declared by the Data Protection Officer of Lille University to the National Commission on Informatics and Liberty (reference: 2023–203). Shortly after inclusion, nominative data will be erased and interview records will be transcribed: identifying data will be hidden (eg, specific events) and records erased after transcription checking. No correspondence table will be used: a code will be attributed to each participant and used for all related data sources (interview transcript, photos, sociodemographic data form, analysis files). In sum, only

non-nominative non-identifying data will be used for analysis and stored.

Strengths and limitations of this study

Due to the sampling approach, we may not uncover all existing patterns relevant to the use of technology to self-manage type 2 diabetes at home and we may not be able to generalise the results to the French PT2D population. However, the aim of the study is to provide an in-depth analysis of the patient work system rather than aiming for process exhaustiveness without detailed analysis. Another limitation is that we do not collect measures of diabetes control, preventing us from connecting observed patterns with clinical consequences. However, we will be able to relate patterns of use to consequences as perceived and reported by participants.

The protocol has several strengths. First, the combination of on-site interviews and photographs has already proved very valuable in obtaining detailed information about how patients manage their health at home.[57 58] In addition, the recruitment of a PPI panel, enabling human factors and pharmacy researchers to work jointly with a PT2D, caregiver, diabetologist and community pharmacist, will enable us to cross-fertilise viewpoints on methods, data interpretation and findings. This will improve the uptake and translation of this research into sustainable practice.

Dissemination

The results will be made available to relevant patient, medical, nursing and pharmaceutical diabetes associations in French and English (eg, written reports, presentations). We will produce a lay summary of our findings. In addition, this study will be reported according to the consolidated criteria for reporting qualitative research checklist[60] and results will be published open access in a peer-reviewed journal indexed in MEDLINE. This will make it freely accessible to the public and possible for other researchers, clinicians, health authorities, diabetes technology vendors and diabetes federations to understand the PT2D work system and adapt their research, orders, regulations and development accordingly or to help improve PT2Ds'/caregivers' agency.

Key milestones and timeframe

The study will start in March 2024. The interviews are expected to take 8 months to complete. Data analysis will be conducted as interviews are performed. The research is scheduled to end in December 2024, after the results, interpretation and dissemination phase.

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Contributors RM and TG designed the protocol. PQ, ML, AB, CH and EA reviewed and amended the protocol. RM and TG drafted the initial manuscript. RM, TG, PQ, EA, ML, AV, AB, CH and JBB critically reviewed and revised the manuscript. JBB acquired the funding and PQ administered them. All authors approved the final manuscript as submitted. RM is the guarantor.

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