

## Research: Care Delivery

# A qualitative study exploring the expectations of people living with type 1 diabetes regarding prospective use of a hybrid closed-loop system

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### Abstract

**Aim** To identify the expectations of a diversified sample of informed adults with type 1 diabetes on their prospective use of a hybrid closed-loop system.

**Methods** Semi-structured interviews were conducted with 16 adults with type 1 diabetes who shared their expectations on an experimental hybrid closed-loop system after receiving information on its design, functioning and capability. The sample had equal representation of genders and diabetes management methods and was diversified according to age, education and occupation when possible. Qualitative content analysis of the interview transcripts with MaxQDA was used to identify expected benefits, expected inconveniences and concerns, expected improvements to design and functionalities, and interest and trust in the system.

**Results** Participants expected benefits regarding diabetes management, clinical outcomes, psychosocial aspects of their lives, nutrition and meals, and physical activity. Participants expected inconveniences or shared concerns regarding wearability, costs and technical limitations. According to participants, improvements could be made to the system's physical appearance, practical convenience, functionalities, and software integration. Overall, 12 participants would use the system. While participants' trust could be immediate or grow over time, it could ultimately be conditional on the system's performance.

**Conclusion** Prospective users' general enthusiasm and trust foster the clinical and commercial success of hybrid closed-loop systems. However, poor user satisfaction caused by unrealistic expectations and plausible inconveniences and concerns may limit this success. Providing prospective users with comprehensive information while validating their understanding could mitigate unrealistic expectations. Improvements to design and coverage policies could favour uptake.

### Introduction

Multiple new therapeutic options, such as continuous glucose monitoring (CGM) and continuous subcutaneous insulin delivery (CSII), have been developed and commercialized to improve type 1 diabetes management [1]; however, people with type 1 diabetes still struggle to reach glycaemic goals while continuing to face frequent acute (e.g. severe hypoglycaemia) and chronic (e.g. retinopathy) complications [2]. Closed-loop systems, also known as artificial pancreases, are being developed to improve diabetes management. These systems aim to automatically tailor CSII to glycaemic data provided by a CGM using an algorithm [3].

Since they still require user intervention for administration of bolus insulin, notably to account for meals and exercise, current closed-loop systems are hybrid [3].

The first commercially available hybrid closed-loop system is the Medtronic MiniMed™ 670G (Medtronic, Northridge, CA, USA), which was approved by the US Food and Drug Administration and Health Canada in 2018. In Canada, the MiniMed™ 670G can only be accessed through out-of-pocket payments or some private insurers because of the current lack of public reimbursement policies. Hybrid closed-loop systems increase the safety and effectiveness of type 1 diabetes management in free-living conditions by reducing the occurrence of hypoglycaemic and hyperglycaemic episodes and by improving time in target by a mean of 2.5 h/day [4,5].

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**What's new?**

- Few studies have explored in depth the expectations of a diversified sample of informed adults with type 1 diabetes on their prospective use of hybrid closed-loop systems.
- Prospective users were generally enthusiastic towards an experimental hybrid closed-loop system and could learn to trust it, based on its performance. Participants had expectations regarding benefits, inconveniences and concerns, and potential improvements.
- Prospective users' enthusiasm and trust foster the clinical and commercial success of hybrid closed-loop systems. Providing prospective users with more comprehensive information while validating their understanding could mitigate unrealistic expectations. Improvements to design and coverage policies could favour uptake of these systems.

In accordance with patient-centred care, uptake of hybrid closed-loop systems will jointly depend on clinical effectiveness and considerations of patient preferences [6,7]. To this end, several qualitative studies report on appreciation of experimental hybrid closed-loop systems for adults with type 1 diabetes [8-16]. Users were generally satisfied with these systems. They experienced simpler and safer diabetes management [12,16], improved glycaemic control resulting in a reduced number of hyperglycaemic and hypoglycaemic events [10-12,14-16], and psychosocial benefits such as reassurance and peace of mind [10,14-16], normalcy [14], increased flexibility in schedules and lifestyles [15,16] and improved sleep [10,12,14,15]. Participants were dissatisfied with size, visibility or cumbersomeness [10-11,14,15], technical issues and glitches [10,14,15], and alarm intrusiveness and frequency [10-11,13-15]. While some participants dedicated less time to thinking about diabetes, others experienced the opposite [12,14,16]. A limitation common to these studies is that participants were not diversified based on sociodemographic characteristics or prior diabetes management strategies [8-16].

Hybrid closed-loop systems could be clinically and commercially successful if they spark prospective users' interest, fulfil their expectations, and gain their trust. Barnard *et al.* [7] and Naranjo *et al.* [17] studied prospective users' expectations and trust in hybrid closed-loop systems. The qualitative results reported in these studies suggest that prospective users expected benefits and inconveniences consistent with those reported for system users above [7-17]. Prospective users suggested improvements to the design and functionalities of these systems: they should be small and discreet [7,17], they should merge infusion and sensor sites [7], they should be performant [7,17], and they should be easy to use [7]. Prospective users were concerned about

trusting these systems and were ambivalent about their projected level of involvement in their diabetes care [7,17]. Most importantly, some participants held unrealistic expectations for a 'set and forget' [17] or 'all-in-one' [7] system that would require minimal involvement and maintenance [7,17], enable users to live a normal life [7,17], or improve mood and relationships [17]. These unrealistic expectations, ambivalence, and issues of trust could stem from poor knowledge [17] or limited education [7] about these systems. Prospective users interviewed by Naranjo *et al.* [17] were diversified, which may have helped capture a broader range of expectations, but the diversification procedure is not specified. Together, these observations highlight the need to conduct an in-depth qualitative investigation of expectations for and interest and trust in hybrid closed-loop systems among a clearly diversified sample of adults with type 1 diabetes educated on the design, functioning and capabilities of this system.

Hence, the general objective of this qualitative study was to identify the in-depth expectations of a diversified sample of informed adults with type 1 diabetes on their prospective use of a hybrid closed-loop system. The study had three specific aims: to identify prospective users' expectations regarding the benefits and inconveniences of the system, in addition to their concerns; to identify their expectations on improvements that they would like to be made to the design and functionalities of the system; and to assess their interest and trust in using the system once it is commercially available.

## Participants and methods

### Recruitment

#### *Recruitment from a parallel online survey study*

A parallel online survey study exploring the perceptions and expectations of French-speaking adults with type 1 diabetes regarding the use of hybrid closed-loop systems, with and without glucagon addition, served as a recruitment tool for the present interview study. The interview study was designed to explore some of the topics raised by the survey in greater detail. The survey study was advertised by two Quebec diabetes associations on Facebook. To ensure a diverse sample of respondents, the survey study was subsequently sent to patients of the Diabetes Clinic at the *Institut de recherches cliniques de Montréal* (IRCM) to recruit patients whose demographic characteristics or clinical characteristics were underrepresented among initial survey respondents. At the end of the survey, respondents could volunteer to participate to the interview study. Results from the survey study will be discussed in an upcoming publication.

#### *Invitation and diversification of participants*

Interview candidates were selected from volunteers based on their sociodemographic characteristics and the diabetes

management methods they reported in the survey study. The interviewee sample was designed to have equal representation of genders, insulin infusion method used [multiple daily injections (MDI) or CSII], and glycaemic monitoring method used (CGM or not), and interviewees were diversified according to age, education and occupation when possible [17]. Interview candidates received an email invitation including the consent form and an explanatory document. The latter was designed to foster good understanding of an experimental hybrid closed-loop system among participants prior to the interview. The document initially introduced CSII and CGM. Then, it distinguished the hybrid closed-loop system from these methods by describing its design, functioning and capability (Appendix S1).

### Semi-structured interviews

#### *Development of the interview guide*

The interview guide and the explanatory document were developed with input from members of the Metabolic Diseases Research Unit and the Pragmatic Health Ethics Research Unit, both located at the IRCM. Semi-structured interviews were carried out by the first author, a graduate student in bioethics member of the latter unit, with a research interest in the views of people with type 1 diabetes on upcoming hybrid closed-loop systems. The interview guide was tested with five pilot interviews [18,19].

#### *Interview setting and content*

At the beginning of each interview, the interviewer discussed the explanatory document with the participant. She ensured that the participant understood the hybrid closed-loop system's design, functioning and capability, and how it differed from the combined use of CSII and CGM. The interview guide included 40 questions and nine sub-questions (Appendix S2). The interview was divided into five sections: (a) introductory questions; (b) lived experience with type 1 diabetes; (c) expectations for the artificial pancreas, notably regarding benefits and inconveniences; (d) ethical and social issues, and (e) characteristics of an ideal closed-loop system. Some results mostly pertaining to the sections (c) and (e) are reported in the present publication. The remaining results will be discussed in a forthcoming publication. Participants chose the location of their interview for convenience. Interviews were audio-recorded and transcribed by a professional transcription service. Transcriptions were reviewed in parallel with the recruitment process in order to end recruitment at theoretical saturation, i.e. when no significantly new content emerged from the interview transcripts [20].

#### *Choice of experimental hybrid closed-loop system featured in the interviews*

Given that all interviews were conducted before any commercial hybrid closed-loop systems were approved in

Canada, an experimental hybrid closed-loop system was featured in the explanatory document (Appendix S1). This system was constituted of CSII and CGM versions that were commercially available in Canada when the interviews were conducted (i.e. the Medtronic MiniMed Paradigm Veo and the Medtronic Enlite Sensor, respectively), in addition to a smartphone on which a software and algorithm are installed. This experimental hybrid closed-loop system was featured in the interview on the grounds of prudence and grounded speculation [21]. Commercially available components were included to avoid anchoring the study in flawed assumptions about future closed-loop systems, and participants were informed that the experimental system could evolve over time. Participants were told that user intervention would be required for administration of bolus insulin to account for meals and exercise and that the system could reduce the incidence of hypoglycaemic and hyperglycaemic events.

### Qualitative content analysis

Qualitative content analysis was conducted on interview transcripts [22-24]. MaxQDA (Berlin, Germany) was used to develop a coding guide comprising primary codes, secondary codes, tertiary codes, and quaternary codes in some cases. An initial draft of the coding guide was designed deductively based on the interview guide structure [24]. The primary codes reflected the main headings and secondary headings of the interview guide (Appendix S2). The secondary codes and some tertiary codes when applicable initially matched the interview questions and sub-questions. The other tertiary codes and quaternary codes corresponded to results put forward by participants that were relevant to the study objective or aims, but were not addressed in the interview guide [23]. Secondary codes, tertiary codes, and quaternary codes were refined iteratively and inductively as transcripts were read [24]. Text excerpts were linked to relevant tertiary or quaternary codes with MaxQDA [23] and the number of text excerpts associated with each lower-level code was noted [22]. The analysis focused on manifest content (i.e. content explicitly put forward by participants) [24].

While developing and applying the coding guide to all transcripts, the first author documented the procedure used. A research assistant applied the coding guide to four transcripts following this procedure to validate the first author's consistent application of the coding guide. Discrepancies were discussed by the first author and the research assistant and resolved through consensus, which led to minor changes to the coding guide and its application. The research assistant was a member of the Pragmatic Health Ethics Research Unit.

### Reporting of results

Participants' clinical and sociodemographic data, presented in Table 1, were obtained through the survey study.

**Table 1** Participants' sociodemographic and clinical data

Age range	Pseudonym	Gender	Highest level of education	Occupational status	Insulin administration	Glucose monitoring	Self-reported HbA <sub>1c</sub> , mmol/mol (%)
20–29 years	Jonathan	Man	CÉGEP*	Student	MDI	Glucometer	54–59 (7.1–7.5)
	Erika	Woman	University	Employed	CSII	CGM	43–48 (6.1–6.5)
	Andréanne	Woman	University	Employed	CSII	CGM	49–53 (6.6–7.0)
30–39 years	Geneviève	Woman	University	Maternal leave	MDI	CGM	43–48 (6.1–6.5)
	Valérie	Woman	CÉGEP*	Employed	CSII	CGM	71–75 (8.6–9.0)
	Sébastien	Man	University	Employed	CSII	CGM	54–59 (7.1–7.5)
	Nathalie	Woman	High school	Stay-at-home mother	MDI	Glucometer	43–48 (6.1–6.5)
40–49 years	Victoria	Woman	University	Employed	MDI	Glucometer	49–53 (6.6–7.0)
	Mario	Man	High school	Employed	MDI	Glucometer	54–59 (7.1–7.5)
	Étienne	Man	University	Employed	CSII	CGM	76–80 (9.1–9.5)
	Isabelle	Woman	Canadian Forces Diploma	Employed	CSII	Glucometer	Did not know
	Denis	Man	University	Unable to work due to medical reasons	MDI	Glucometer	54–59 (7.1–7.5)
50–59 years	Benoit	Man	University	Employed	CSII	CGM	43–48 (6.1–6.5)
	Mireille	Woman	University	Retired	MDI	Glucometer	54–59 (7.1–7.5)
60–70 years	Claude	Man	High school	Employed	MDI	Glucometer	Did not know
	Arthur	Man	University	Retired	CSII	CGM	54–59 (7.1–7.5)

CGM, continuous glucose monitoring; CÉGEP, collège d'enseignement général et professionnel; CSII, continuous subcutaneous insulin infusion; MDI, multiple daily injections.

\*Post-secondary education institutions exclusive to Quebec, which typically offer 2-year preparatory programmes for university studies or 3-year programmes for trades.

Interview quotations were translated from Canadian French to English and the accuracy of the translation was validated by the last author. Pseudonyms were used to protect participants' confidentiality. Gender and treatment method used are indicated when the result predominantly emerged from participants with a common characteristic. In accordance with qualitative content analysis, general frequencies (e.g. 'several', 'a few', etc.) or specific frequencies (e.g. 'two') for each result are provided when informative [22].

## Ethics

All participants signed the informed consent form and read the explanatory document before the interview. This interview study was approved by the research ethics board of the IRCM (file number: 2016-853). The study complied with the Tri-Council Policy Statement 2 – Ethical Conduct for Research Involving Humans and the Standards of the *Fonds de recherche du Québec – Santé* on Research Ethics and Scientific Integrity.

## Results

### Participant profiles

Of the 128 participants who completed the online survey study, 32 were invited to participate in the interview study, and 16 participated. Table 1 presents participants' sociodemographic and clinical characteristics obtained from the survey study. An equal number of men and women, MDI and CSII users, and glucometer and CGM users participated in the interview study.

### Expected benefits of the hybrid closed-loop system

Participants' expected benefits of the hybrid closed-loop system are summarized in Table 2. Benefits regarding diabetes management, clinical outcomes, psychosocial aspects, nutrition and meals, and physical activity were expected. Among notable results, participants stressed that diabetes management would be simpler and safer with the system. Several participants believed that the system would alleviate some of their questions and uncertainties and the need for frequent calculations, as well as prevent mistakes. Victoria said, 'I would be freed, for example, from what regularly poisons my life', when referring to forgetting to self-inject.

All participants expected improvements in glycaemic control with a hybrid closed-loop system. For example, Arthur, a CSII and CGM user, believed that hypoglycaemic and hyperglycaemic events 'would be over, once and for all'. Benoit agreed that the system would better mitigate the effects of stress on his glycaemia than his current strategy of 'always wait[ing] to see what will happen for one, two, three days before taking action and changing basal insulin ratios'. Mireille, who used MDI, hoped that the system would allow her to 'perhaps live a little bit longer (...) with a better quality of life and dignity'.

Several participants expected that the hybrid closed-loop system would improve their psychological well-being and their relationships with others. Victoria believed that the system's automated glycaemic management would make it more reliable, and that she would therefore be more at peace and reassured when using it. Jonathan, who used MDI, would expect 'greater self-confidence' through improved

**Table 2** Expected benefits of the hybrid closed-loop system

Category of expected benefits	Expected benefits
Diabetes management	Simpler management (fewer uncertainties and calculations) Optimized insulin dosing Continuous access to glycaemic data Safer management (e.g. avoids problems that arise when forgetting whether a self-injection was made for MDI users) Less time-consuming Does not require additional supplies throughout the day Eliminates the need for self-injections and their disadvantages, for people currently using MDI Eliminates the need for glycaemic self-monitoring
Clinical outcomes	Improved glycaemic control: -e.g. prevention of hyperglycaemia or hypoglycaemic events; -glycaemia in target range; -improved control during physiological variations (e.g. stress, infections, fatigue, temperature variations or extremes, or daily level of activity). Prevention of long-term complications
Psychological and social functioning	Greater personal well-being (e.g. peace of mind, confidence, emotional stability) Living a more normal life Improved accommodation for professional context Less reliance on others Greater flexibility for unexpected activities
Nutrition and meals	No impact on meal content or no impact on the need to count carbohydrates Improved accommodation for meals with unknown carbohydrate content or unplanned meals More flexibility for meal schedules More diverse meals More energy to dedicate to other aspects of diabetes management (e.g. diet quality, carbohydrate counting) Eliminate the need for snacks to correct hypoglycaemic events
Physical activity	No impact on the ability or motivation to exercise Improved glycaemic control during physical activity Greater confidence when exercising

MDI, multiple daily injections.

glycaemic management. A few participants added that the system would allow them to live more normal lives. For example, Andréanne explained that the system's greater flexibility regarding carbohydrate intake would 'facilitate [her] activities and relationships'.

On this topic, some participants, like Andréanne, believed that the hybrid closed-loop system could better accommodate unknown meal contents (e.g. when eating out) or

unplanned food intake. A few participants using MDI highlighted that the system would free up time and energy to be invested in other aspects of diabetes management, such as carbohydrate counting, diet quality, or physical activity. In contrast, more than half of the participants believed that the system would not influence their nutrition habits. Moreover, half of the participants believed that the system would not impact their ability to exercise, notably because they were either already physically active or would not feel bothered by the cumbersomeness of the device. However, three participants, including two men using CSII and CGM, suggested that the system would further maintain their glycaemia in target ranges during exercise. Mario, an MDI user, expected that he would feel more confident in his ability to exercise.

### Expected inconveniences of the hybrid closed-loop system and concerns

Participants expected inconveniences regarding the hybrid closed-loop system or were concerned about its wearability, financial implications and technical limitations. More than half of the participants, the majority of whom were MDI users, were concerned about the system's cumbersomeness during everyday activities and physical work. Mario explained: 'I work with equipment, a large vest, tools a belt, therefore a catheter [...] is not necessarily convenient'. Five women were preoccupied by the system's visibility. They disliked the idea of wearing two devices at once or were concerned with the restrictions it would impose on clothing choices (e.g. dresses, some skirts). Two men using CSII and CGM were preoccupied with poor sensor adherence to the skin during physical activity.

Furthermore, four participants worried about the hybrid closed-loop system's potentially high costs in the advent of insufficient coverage. Andréanne said that she would 'be more hesitant [to acquire the system] if it is really more expensive' than her current combined use of CSII and CGM. Some participants were concerned about potential alarms in addition to technical issues that could arise with the system. Technical issues mentioned were inadequate hypoglycaemia prevention or inaccurate calculation of the required insulin doses, infection at the infusion site, and impaired insulin administration due to pressure on the infusion site or obstruction of the catheter.

### Improvements to the design and functionality of the hybrid closed-loop system

Participants were generally satisfied with the hybrid closed-loop system's design, sometimes noting that it was physically equivalent to the combined use of CSII with CGM. Only Isabelle was dissatisfied with the system's design. Being the only participant using an Omnipod, she was worried about wearing a catheter and a sensor given that

she had never tried a CGM device. Participants expected forthcoming improvements to the design and functionalities of the system, that are described below and summarized in Table 3.

#### Suggestions for design

Most participants desired that the size of the system, and ideally, its number of components, be minimized. Two MDI users believed that a system adhering to the skin (e.g. with an Omnipod-style insulin pump) would be less cumbersome than the experimental system presented to them. Three participants suggested combining the infusion and CGM sites. Andréanne believed that the system's practical convenience in daily life should be improved. Based on her previous experience with CGM, she highlighted that the 'sensor's efficacy is at its lowest during rapid glycaemic variations' and should better account for situations like physical exercise, 'because this is where it is the most critical'. She believed that the closed-loop system should tolerate reasonable distance variations between its components, otherwise she found that it would be 'limiting, and somewhat uninteresting', for example in 'more private, intimate situations'.

#### Suggestions for functionalities

A few participants stated that they would like to be able to override the system's decisions, notably by interrupting an insulin infusion if desired. Geneviève, a CSII user, suggested integrating the system's application with existing lifestyle applications (e.g. Fitbit, MyFitnessPal) to better estimate her insulin needs based on a more precise assessment of her carbohydrate consumption and level of physical activity. Participants' divergent preferences on alarms suggest that their volume and frequency should be customizable. Arthur explained that he would not mind hearing the alarm at night so that he could correct his glycaemia. However, Arthur and Isabelle would like to be able to mute the alarm when attending a concert or a professional meeting, respectively. Andréanne would dislike too many alarms. Participants had equal preferences for controlling the system's interface through a smartphone (as described in the explanatory document) or on the insulin pump's screen.

#### Overall interest and trust in the hybrid closed-loop system

Overall, participants were highly in favour of the hybrid closed-loop system. When asked not to take into account cost

**Table 3** Suggestions for improvements to the design and functionality of the hybrid closed-loop system

Characteristics of the hybrid closed-loop system	Suggestions to improve design or functionality
Physical appearance	As small as possible, not cumbersome, discreet Thinner Limited number of components when possible Robust (i.e. sturdy and impact-resistant) A single site for glucose monitoring and insulin infusion
Practical convenience	Tolerance for greater acceptable distance variations between components Replaceable components (i.e. insulin cartridge, glucose sensor, catheter) could have an equal lifespan so that they can be replaced all at once Improved performance of the glucose sensor (e.g. better capture rapid glycaemic fluctuations, fewer or no calibrations needed) Sufficiently long battery life Simple to use
Software functionality	Suspension of insulin infusion (e.g. when prompted if a meal is not finished, in the case of a hypoglycaemic event) Software integration with current exercise and carbohydrate counting applications (e.g. MyFitnessPal, Fitbit) Alarms could be customized to fit user preferences: -useful notifications (e.g. imminent hypoglycaemic events, loss of connections between components); -issues with frequent alarms; -different needs with respect to frequency and volume according to the user and its/her environment.
Software integration	Using the closed-loop systems' interface on a smartphone: -not an inconvenience to always carry a smartphone, as this is already the case; -its larger screen facilitates interface use and data visualization; -its internet connection would facilitate troubleshooting. Using the closed-loop systems interface on an insulin pump: -constantly having to carry a smartphone is an inconvenience (i.e. it can be lost, forgotten, or out of battery, not everyone has a smartphone, inappropriate in some situations); -would eliminate the need to carry an additional component; -enhancements to the insulin pump's screen could be made to facilitate its use (e.g. touch screen, colours).

considerations, 12 participants (75%) said they would want to use the system once it was commercialized. Some participants explained that their interest stemmed from greater expected benefits than expected inconveniences, while acknowledging that the system was not a flawless solution for diabetes management. Four participants stated interest in being given the option to try the system for a certain time before acquiring it. For 10 participants, trust in the system would depend on its performance. While half of these participants thought they would immediately trust the system, the other half believed that they would learn to trust it over time. Several participants also trusted closed-loop systems immediately given their own trust in biomedical developments and regulatory oversight.

## Discussion

This qualitative study explored in depth the expectations of a diverse sample of adults with type 1 diabetes about their prospective use of a hybrid closed-loop system through semi-structured interviews. The study participants were educated regarding an experimental hybrid closed-loop system's design, functioning and capability in preparation for the interviews. Overall, participants expressed interest in the system. While participants expected to trust the system quickly or over time, their trust could ultimately be conditional on the system's performance. These results suggest that this experimental hybrid closed-loop system could be perceived as a desirable type 1 management technique by its prospective users.

Several factors can impact the clinical and commercial success of hybrid closed-loop systems aside from prospective users' prior interest. First, when provided comprehensive information on these systems, prospective users will more likely make informed decisions to use or not use these systems in clinical encounters. Better informed prospective users, more cognisant of the system's limitations, may also be more satisfied. The information provided on design, functioning and capability indeed fostered realistic expectations among participants, mirroring those reported in experimental trials: simpler diabetes management, improved glycaemic control through reduction of hypoglycaemic and hyperglycaemic events [10-12,14-16], greater personal well-being [10,14-16], normalcy [14], and improved accommodation for meals and unexpected activities [15,16]. Participants also expected realistic inconveniences and concerns which resembled those reported by those who participated in experimental trials pertaining to visibility or clumsiness [10-11,14,15] and technical issues or glitches [10,14,15].

Yet, it is possible that more comprehensive information on hybrid closed-loop systems would have helped foster even more realistic expectations on the system's capabilities. Despite being told that the system could reduce (as opposed to eliminate) hypoglycaemic and hyperglycaemic events, Arthur expected that they 'would be over, once and for

all'. While his wish is understandable given the daily burden of type 1 diabetes, Arthur could easily be disappointed with the system's imperfect performance. This finding reiterates the need for clinicians to validate prospective users' understanding of information on a new treatment method, such as a hybrid closed-loop system, in clinical practice. A few participants also expected that they would not need to self-monitor their glycaemia anymore or eat snacks to correct hypoglycaemic events (Table 1). These unrealistic expectations could be lessened by providing additional information on these specific topics to prospective users in clinical encounters. Moreover, a few participants, including Jonathan, expected improvements in their confidence and emotional stability with system use. His expectation, which is reminiscent of the improvements in mood expected by some prospective users of the insulin delivery system examined in the study by Naranjo *et al.* [17], speaks to the emotional burden posed by type 1 diabetes. While sensor-augmented insulin pump therapy has been shown to reduce diabetes distress [25], it is not yet known whether this benefit will result from the use of hybrid closed-loop systems or translate to improved confidence and emotional well-being. Prospective users should therefore be warned that these systems may not necessarily enhance confidence and emotional well-being, and if needed, be offered appropriate educational interventions to reduce their diabetes distress [26]. Overall, despite some unrealistic expectations, participants' understanding that the system would not be flawless illustrates that information on design, functioning, and capability of the system generally helps foster realistic expectations. Their expectations were more realistic than those reported in other studies (e.g. a 'set and forget' device requiring limited user involvement) conducted with prospective users who were, at best, minimally informed on hybrid closed-loop systems [7,17]. Furthermore, the authors of these previous studies did not identify unrealistic expectations that would need to be corrected through comprehensive patient education.

Key inconveniences and concerns highlighted in this study may need to be mitigated to further favour the clinical and commercial success of hybrid closed-loop systems. Inconveniences and concerns linked to wearability and alarms, also reported by some of the prospective users interviewed by Barnard *et al.* [7] and Naranjo *et al.* [17], make the system less attractive. These concerns could be alleviated by implementing some of the suggested improvements that are compatible with upcoming technological developments [5], namely, reducing the system's size, merging components, and customizing alarms. The plausible high cost of the system, which was a concern shared by our participants and those in the study by Barnard *et al.* [7], could significantly limit uptake. Health technology assessment agencies should eventually reflect on the usefulness of recommending public coverage for hybrid closed-loop systems through an assessment of their cost-effectiveness and the satisfaction of their

users. Mitigating inconveniences and concerns linked to wearability and affordability is necessary, from a standpoint of justice, to avoid the system's benefits being unevenly distributed across sociodemographic groups. For example, the preoccupations held by several women regarding the system's visibility could hinder its uptake among this group unless its design is improved. Similarly, without proper public coverage, access to the systems could be restricted to those with greater financial resources.

While this study targeted prospective users of hybrid closed-loop systems – an important group distinct from groups who have tried these systems during experimental trials – its main limitation is that it did not assess their appreciation of these systems after trying them. Another limitation is that the participant sample was not analogous to an average clinical population. For example, participants were generally educated to quite a high level and had above average HbA<sub>1c</sub> readings. They may have also had prior interest in these systems given that they volunteered to participate in this study through an online survey on the topic. To mitigate this bias, participants had been diversified according to sociodemographic characteristics (including education and age) and treatment method currently used.

To conclude, the hybrid closed-loop system is well positioned to attain clinical and commercial success as illustrated by prospective users' enthusiasm. Providing prospective users with comprehensive and rigorous information on the system beyond design, functioning and capability may further foster user satisfaction. Addressing inconveniences and concerns pertaining to the system's wearability and alarms through key improvements to design and functionality may make it more desirable for prospective users. Appropriate public coverage policies, notably in Canada, may ultimately be necessary to ensure clinical uptake.

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### Competing interests

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Roche, Sanofi-Aventis and Takeda, has received honoraria for conferences by Abbott, Astra-Zeneca, Eli Lilly, Janssen, Medtronic, Merck, Novo-Nordisk and Sanofi-Aventis, and has received in kind contributions related to closed-loop technology from Animas, Medtronic and Roche. R.R.L. also benefits from unrestricted grants for clinical and educational activities from Eli Lilly, Lifescan, Medtronic, Merck, Novo Nordisk and Sanofi and holds intellectual property in the field of type 2 diabetes risk biomarkers, catheter life and the closed-loop system. R.R.L. and V.M. have received purchase fees from Eli Lilly in relation with closed-loop technology. A.Q. and E.R. do not have any competing interests to declare.

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### References

- McGibbon A, Adams L, Ingersoll K, Kader T, Tugwell B. Glycemic management in adults with type 1 diabetes. *Can J Diabetes* 2018; 42: 80–87.
- Pettus JH, Zhou FL, Shepherd L, Preblich R, Hunt PR, Paranjape S et al. Incidences of severe hypoglycemia and diabetic ketoacidosis and prevalence of microvascular complications stratified by age and glycemic control in US adult patients with type 1 diabetes: a real-world study. *Diabetes Care* 2019; 42: 2220–2227.
- Saunders A, Messer LH, Forlenza GP. MiniMed 670G hybrid closed loop artificial pancreas system for the treatment of type 1 diabetes mellitus: overview of its safety and efficacy. *Expert Rev Med Devices* 2019; 16: 845–853.
- Taleb N, Tagougui S, Rabasa-Lhoret R. Single-Hormone artificial pancreas use in diabetes: clinical efficacy and remaining challenges. *Diabetes Spect* 2019; 32: 205.
- Weisman A, Bai J-W, Cardinez M, Kramer CK, Perkins BA. Effect of artificial pancreas systems on glycaemic control in patients with type 1 diabetes: a systematic review and meta-analysis of outpatient randomised controlled trials. *Lancet Diabetes Endocrinol* 2017; 5: 501–512.
- Institute of Medicine. *Crossing the quality chasm: a new health system for the 21st century*. Washington, DC: National Academy Press, 2001.
- Barnard KD, Pinsker JE, Oliver N, Astle A, Dassau E, Kerr D. Future artificial pancreas technology for type 1 diabetes: what do users want? *Diabetes Technol Ther* 2015; 17: 311–315.
- Farrington C. Psychosocial impacts of hybrid closed-loop systems in the management of diabetes: a review. *Diabet Med* 2018; 35: 436–449.
- Barnard KD, Wysocki T, Ullly V, Mader JK, Pieber TR, Thabit H et al. Closing the loop in adults, children and adolescents with

- suboptimally controlled type 1 diabetes under free living conditions: A psychosocial substudy. *J Diabetes Sci Technol* 2017; **11**: 1080–1088.
- 10 Barnard KD, Wysocki T, Thabit H, Evans ML, Amiel S, Heller S *et al*. Psychosocial aspects of closed- and open-loop insulin delivery: closing the loop in adults with type 1 diabetes in the home setting. *Diabet Med* 2015; **32**: 601–608.
  - 11 Kovatchev B, Cheng P, Anderson SM, Pinsky JE, Boscaro F, Buckingham BA *et al*. Feasibility of long-term closed-loop control: a multicenter 6-month trial of 24/7 automated insulin delivery. *Diabetes Technol Ther* 2017; **19**: 18–24.
  - 12 Iturralde E, Tanenbaum ML, Hanes SJ, Suttiratana SC, Ambrosino JM, Ly TT *et al*. Expectations and attitudes of individuals with type 1 diabetes after using a hybrid closed loop system. *Diabetes Educ* 2017; **43**: 223–232.
  - 13 Tanenbaum ML, Iturralde E, Hanes SJ, Suttiratana SC, Ambrosino JM, Ly TT *et al*. Trust in hybrid closed loop among people with diabetes: perspectives of experienced system users. *J Health Psychol* 2020; **25**: 429–438.
  - 14 Farrington C, Stewart ZA, Barnard K, Hovorka R, Murphy HR. Experiences of closed-loop insulin delivery among pregnant women with type 1 diabetes. *Diabet Med* 2017; **34**: 1461–1469.
  - 15 Farrington C, Stewart Z, Hovorka R, Murphy H. Women's experiences of day-and-night closed-loop insulin delivery during type 1 diabetes pregnancy. *J Diabetes Sci Technol* 2018; **12**: 1125–1131.
  - 16 Lawton J, Blackburn M, Rankin D, Allen JM, Campbell FM, Leelarathna L *et al*. Participants' experiences of, and views about, daytime use of a day-and-night hybrid closed-loop system in real life settings: longitudinal qualitative study. *Diabetes Technol Ther* 2019; **21**: 119–127.
  - 17 Naranjo D, Suttiratana SC, Iturralde E, Barnard KD, Weissberg-Benchell J, Laffel L *et al*. What end users and stakeholders want from automated insulin delivery systems. *Diabetes Care* 2017; **40**: 1453–1461.
  - 18 Mann PH. *Methods of social investigation. 2nd edn*. Oxford: Blackwell Publishers, 1985.
  - 19 Turner IDW. Qualitative interview design: a practical guide for novice investigators. *Qual Rep* 2010; **15**: 754–760.
  - 20 Guest G, Bunce A, Johnson L. How many interviews are enough? An experiment with data saturation and variability. *Field Methods* 2006; **18**: 59–82.
  - 21 Racine E, Martin Rubio T, Chandler J, Forlini C, Lucke J. The value and pitfalls of speculation about science and technology in bioethics: the case of cognitive enhancement. *Med Health Care Philos* 2014; **17**: 325–337.
  - 22 Morgan DL. Qualitative content analysis: a guide to paths not taken. *Qual Health Res* 1993; **3**: 112–121.
  - 23 Graneheim UH, Lundman B. Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. *Nurse Educ Today* 2004; **24**: 105–112.
  - 24 Elo S, Kyngäs H. The qualitative content analysis process. *J Adv Nurs* 2008; **62**: 107–115.
  - 25 Rubin RR, Peyrot M. Health-related quality of life and treatment satisfaction in the Sensor-Augmented Pump Therapy for A1C Reduction 3 (STAR 3) trial. *Diabetes Technol Ther* 2012; **14**: 143–151.
  - 26 Schmidt CB, van Loon BP, Vergouwen AC, Snoek FJ, Honig A. Systematic review and meta-analysis of psychological interventions in people with diabetes and elevated diabetes-distress. *Diabet Med* 2018; **35**: 1157–1172.

## Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

**Appendix S1.** Explanatory document on T1D management technologies.

**Appendix S2.** Interview guide.