Edinburgh Research Explorer

What training, support and resourcing do health professionals need to support people using a closed-loop system?

What training, support and resourcing do health professionals need to support people using a closed-loop system? A qualitative interview study with health professionals involved in the Closed Loop from Onset in type 1 Diabetes (CLOuD) trial

Running title: Closed-loop training for health professionals

Kimbell Barbara[1], Rankin David[1], Ashcroft Nicole L[2], Varghese Lidiya[3], Allen Janet M[2,4], Boughton Charlotte K[2], Campbell Fiona[5], Ghatak Atrayee[6], Randell Tabitha[7], Besser Rachel EJ[8], Trevelyan Nicola[9], Hovorka Roman[2,4], Lawton Julia[1] on behalf of CLOuD Consortium

[1]Usher Institute, Medical School, University of Edinburgh, Edinburgh, UK

[2]Wellcome Trust – Medical Research Institute of Metabolic Science, University of Cambridge, Cambridge, UK

[3]Cambridge Clinical Trials Unit, Cambridge, UK

[4]Department of Paediatrics, University of Cambridge, Cambridge, UK

[5]St James's University Hospital, Leeds, UK

[6]Alder Hey Children's NHS Foundation Trust, Liverpool, UK

[7]Nottingham Children's Hospital, Nottingham, UK

[8]NIHR Oxford Biomedical Research Centre, John Radcliffe Hospital, Oxford University Hospitals NHS Foundation Trust, Oxford, UK and Department of Paediatrics, University of Oxford, Oxford, UK

[9]Southampton Children's Hospital, Southampton, UK

Corresponding author:

Dr Barbara Kimbell, Usher Institute, University of Edinburgh, Teviot Place, Edinburgh EH8 9AG. Tel: 0131 650 6675; Email: barbara.kimbell@ed.ac.uk

Diabetes Professional Care conference, London, 29/10/2019

ABSTRACT

Background

We explored health professionals' views about the training, support and resourcing needed to support people using closed-loop technology in routine clinical care to help inform the development of formal guidance.

Methods

Interviews with health professionals (n=22) delivering the Closed Loop from Onset in type 1 Diabetes (CLOuD) trial after they had ≥6 months experience of supporting participants using a closed-loop system. Data were analysed descriptively.

Results

Interviewees described how, compared to other insulin regimens, teaching and supporting individuals to use a closed-loop system could be initially more time-consuming. However, they also noted that, after an initial adjustment period, users had less need for initiating contact with the clinical team compared with people using pumps or multiple daily injections. Interviewees highlighted how a lessened need for ad-hoc clinical input could result in new challenges; specifically, they had fewer opportunities to reinforce users' diabetes knowledge and skills and detect potential psychosocial problems. They also observed heightened anxiety amongst some ~~individuals~~ parents due to the constant availability of data and unrealistic expectations about the system's capabilities. Interviewees noted that all local diabetes teams should be empowered to deliver closed-loop system care, but stressed that health professionals supporting closed-loop users in routine care will need comprehensive technology training and standardised clinical guidance.

Conclusion

These findings constitute an important starting point for the development of formal guidance to support the rollout of closed-loop technology. Our recommendations, if actioned, will help limit the potential additional burden of introducing closed-loop systems in routine clinical care and help inform appropriate user education and support.

BACKGROUND

A closed-loop system is a rapidly evolving technology, which is predominantly used in for the management of type 1 diabetes, but is also being tested for use in type 2 diabetes. that It combines a continuous glucose monitor (CGM), an insulin pump and a control algorithm that interprets, in real time, CGM glucose data and calculates the amount of insulin needing to be administered by the pump. The first hybrid closed-loop system has recently become is now commercially available in the United States and Europe, and other several more systems will follow in due course are expected to be launched within the year [1]. The absence of available approved commercial systems has also prompted the use of do-it-yourself (DIY) closed-loop systems, presenting healthcare professionals with additional ethical, regulatory and practical challenges [2].

To support rollout, it is important to learn from the perspectives and experiences of those who have already used, or supported the use of, closed-loop systems. To date, most studies have focused on the experiences of people with type 1 diabetes and/or their family members when using closed-loop systems [2-12-3-13]. Health professionals' perspectives have only received limited attention, including their views about the training, support and resourcing needed to support individuals using the technology in routine clinical care. This is an important omission, given the evidence that a key mediating factor in people's access to and experience of using diabetes technologies is professionals being appropriately trained and supported [1314].

To address this gap, we report findings from an interview study with health professionals involved in the Closed Loop from Onset in type 1 Diabetes (CLOuD) study. CLOuD is an open-label, multi-centre, randomised controlled trial, which is assessing the effect of closed-loop insulin delivery on residual beta-cell function in young people (aged 10-16 years) newly diagnosed with type 1 diabetes. In the first phase of the trial, participants were randomised to receive 24 months of treatment using either conventional multiple daily injection (MDI) therapy

or closed-loop insulin delivery. Health professionals trained the adolescents and their families to use the closed-loop system and provided all study-related support. In most cases, the health professionals delivering the trial were also responsible for participants' routine clinical care. (See Box 1 for further information about the trial, the study equipment and the training and support provided to professionals delivering the trial and trial participants.) Key aims of the interview study were to: (a) explore health professionals' experiences of providing training and support to individuals using the closed-loop system during the trial and lessons learnt for supporting future users; and, (b) seek their views about the training and resourcing health professionals will need to support people using closed-loop systems in routine clinical care to help inform development of formal guidance.

<Box 1 here>

METHODS

Qualitative methods facilitate the exploration of poorly understood topics as they allow findings to emerge from the data rather than from a-priori hypotheses [1415]. We used semi-structured interviews informed by topic guides to help ensure the discussion remained relevant to the study aims, while allowing participants to raise issues they considered important. Data collection and analysis took place concurrently to allow (unanticipated) findings from early interviews to be explored in later ones.

Our epistemological position was informed by the literature on the evaluation of complex health interventions [1516] as well as earlier work, which has highlighted how unexpected issues, benefits and challenges may arise from introducing and using new diabetes technologies [11,1212,13].

Recruitment

We recruited health professionals (doctors, diabetes nurses, research nurses) in all seven participating trial sites (see Box 1 for details). Health professionals were invited to opt in to the interview study after they had at least six months experience of supporting people using closed-loop systems during the trial. Recruitment continued until there was good representation of staff involved in trial delivery from across all sites (specifically, we sought representation from at least one doctor, one diabetes nurse and one research nurse from each site) and data saturation was reached (i.e. no new findings were identified in new data collected).

Data collection and analysis

BK, an experienced, non-clinical qualitative researcher, conducted the interviews using a topic guide informed by literature reviews, inputs from clinical co-investigators and revised in response to emerging findings. Key topic areas relevant to the reporting in this paper are outlined in Box 2. The interviews took place between August 2018 and June 2019, averaged 70 minutes and were digitally recorded and transcribed in full.

<Box 2 here>

We undertook qualitative descriptive data analysis, which produces 'low-inference' descriptions of views and experiences and is particularly suited to understanding and illuminating issues relevant to policy and practice [16,1717,18]. BK and JL undertook independent analyses, which involved repeatedly reading and cross-comparing individual transcripts and writing separate reports, before meeting to discuss their interpretations of the data and agreeing a coding frame that captured key areas of relevance to clinical practice development. Use of qualitative analysis software package NVivo10 (QSR International, Doncaster, Australia) facilitated data coding and retrieval. Coded datasets were subject to further analysis to develop more nuanced interpretations of the data and identify representative quotations. Informed by a 'What? So what? Now what?' approach to facilitating

collaborative working between practitioners and researchers [~~18~~19], study findings were presented to members of the wider CLOuD trial consortium to generate realistic and practical recommendations appropriate for a range of diabetes professionals and clinical settings.

The Usher Research Ethics Group (UREG), University of Edinburgh, granted ethical approval for the study (approval date: 08 February 2018). To safeguard anonymity, we use unique identifiers in the reporting below (i.e. D=doctor; N=diabetes nurse; RN=research nurse).

RESULTS

The sample comprised 22 health professionals (7 doctors, 9 diabetes nurses and 6 research nurses). Further details are provided in Table 1.

<Table 1 here>

Below, we report interviewees' experiences of training and supporting young people and their families to use the closed-loop system, their views about what training and resourcing diabetes professionals will need to support people using the system in routine clinical care; and, their views about who would be best placed to deliver this support when the technology becomes more widely available. As responses were not found to differ according to health professionals' roles or previous experience with closed-loop system trials, individual characteristics are not separated out in the reporting below.

Teaching and supporting people to use the closed-loop system

Interviewees reported that they had found teaching families how to use the closed-loop system to be straightforward (see Box 1 for information about the training provided to closed-loop

participants). Some attributed this to individuals' growing familiarity and competency with technologies in everyday life:

"They all seem to take to it really well. I don't know whether it's now with younger ones being into technology more than I would have been. You know, I would have maybe struggled, but even the parents have all commented about how quickly they've picked up the use of the closed loop." (RN1)

However, all interviewees noted that participants had needed more extensive teaching input than was typically required by individuals commencing use of MDI or continuous subcutaneous insulin infusion (CSII) therapy. Some reflected on the fact that trial participants were newly diagnosed and so only had a rudimentary understanding of diabetes management, which could require the inclusion of more general diabetes education alongside their closed-loop system training. Interviewees also observed how providing education on the closed-loop system's multiple constituent parts (i.e. insulin pump, sensor, handset interface) required more time than single device training. Many interviewees described experimenting with different educational delivery approaches: "I tried to do as much as possible within just one visit and failed epically, so after that I've been a lot more structured and have split things up" (N5). All interviewees concluded that delivering closed-loop education had worked best when the system's component parts were introduced one by one at a pace appropriate to the individual, typically over several weeks, "so they have time to get used to one thing before they get the next" (N3).

Interviewees further observed that occasional technical glitches with the prototype equipment, and adolescents and parents needing to become accustomed to the individual devices and how to use these effectively, resulted in them initially needing more support than individuals using other insulin regimens. However, several described how these ~~teething~~ technical problems and early confidence issues were quickly overcome and how many users had

subsequently sought less clinical input than was typically requested by people using other treatment approaches. To account for this, these interviewees noted that, because the closed-loop system automatically managed any excessive variability in blood glucose levels, "there's very little, you know, background basal rates, compliance, insulin-to-carb ratio correction, target glucose, exercise, there's not that much that I need to do" (D7). As a result, interviewees noted how the initial increased effort required to set up newly-diagnosed individuals on a closed-loop system was offset by reduced requirements for clinical intervention thereafter:

> "There's so much equipment to get used to…So at the start, definitely they need more support, no question…I think after the support is…if they're using the closed loop well, support in terms of adjusting insulin is virtually nil." (D2)

Unanticipated consequences; implications for workload

Some interviewees observed that this reduced contact could have unanticipated consequences. They explained that, when individuals started CSII therapy, they would normally use the initial weeks and months of enhanced contact to proactively educate users how to interpret patterns in their (or their child's) blood glucose data and determine appropriate adjustments to basal rates and mealtime ratios. Closed-loop users' reduced need for this type of support thus meant that there were fewer teaching opportunities, which could result in individuals "missing out really on the sort of basic education of what to do if things weren't going as well" (N9).

Interviewees also observed how reduced contact could affect more holistic aspects of diabetes care and potentially result in support needs emerging further down the line. N7, for example, remarked that diabetes professionals might "drop the ball in other areas, you know, psychosocial stuff that we'd pick up if we were speaking to them more regularly" (N7). Several interviewees also suggested that the system's efficiency at controlling glycaemic excursions could delay some individuals coming to terms with their diagnosis by masking the true burden

of having diabetes. Similarly, some noted that the system's ability to counteract neglectful self-management practices, such as lax carbohydrate-counting or missed mealtime boluses, could mask underlying issues, such as a poor emotional adjustment to diabetes, which was consequently "probably being picked up later than it could have been" (D3).

Several interviewees observed that the closed-loop system could heighten some parents' anxieties due to the greater availability of real-time data. They described how having access to this information compelled some anxious parents to micromanage by overriding some of the closed-loop's automated adjustments and administering their own correction doses, thereby interfering with the system's ability to adapt to the user's individual insulin requirements. Some worried parents were also reported to have made frequent contact with clinicians to discuss what they erroneously perceived as dangerous blood glucose digressions, because "they don't have any experience of what usual type 1 diabetes glucose levels are like" (D5). As well as offering education to parents to address these kinds of misconceptions, interviewees highlighted the importance of proactively managing their expectations of the closed-loop system:

> "I suppose you do have to make it clear that…it will do its best, but you are diabetic. You will have highs still and you will have lows still. Because I think they think that this will delete them full stop." (RN5)

Training and resources needed to support closed-loop users in routine care

Interviewees generally considered themselves proficient with pump and sensor technology, so their main training needs to support people using a closed-loop system cohered around the handset containing the system's algorithm, which they found "reasonably straightforward, it's not difficult to learn" (N6). Interviewees felt that, while it was not necessary for everyone to be trained to educator level, all team members should have at least some understanding of the system: "I think all the clinicians…should be aware and understand the functionalities and

know a little bit of troubleshooting" (D4). They also offered suggestions for how future health professional training might be delivered. This included training videos, Webinars, recorded TED talks and in-depth training from device manufacturers "to provide specific competencies that we have proven to the company trainers that we are able to follow" (N5). Similarly, several interviewees recommended a competency assessment on completion of training, while others highlighted the need for a formal, accredited training scheme. Regardless of the mode of training delivery, all interviewees emphasised the importance of being given opportunities to familiarise themselves with the technology prior to use in clinical practice:

"I think webinars have their place…and recorded training. But you'd need to hold the kit…to actually have the kit in your hands and to manipulate it yourself…We wouldn't expect that the patients, you know, learn about how to do an injection from watching a video." (N2)

Several interviewees also described how they would routinely test new insulin pumps and sensors on themselves to further their own understanding or demonstrate their use to families, but how this had not been logistically feasible with the closed-loop system. Consequently, they suggested that, upon wider rollout, health professionals should have access to simulation equipment to aid their own learning as well as a demonstration system to support education sessions with families. Interviewees also noted that having a manual available for ongoing reference was helpful, because "sometimes it's quite a gap between…someone going on closed-loop and when your next one goes onto it…so you need to go back and refer to it" (N8).

Interviewees also suggested that diabetes professionals should be issued with guidance on how to advise closed-loop users clinically. This included advice about more atypical cases, such as how best to support a very active person, and non-routine events such as travel across time zones. Additionally, D3, like others, suggested that guidance should highlight the clinically most important areas within the system's extensive data outputs, because "there are I think at least like 40, 50 pages of download that happen and…we've got to go through all of it, or the

most pertinent aspects of it, in a flash, so knowing what bits will be useful and why in a clinic setting would be helpful" (D3). Relatedly, all interviewees emphasised that centres will require robust IT systems with good internet connectivity to facilitate these large data downloads.

Who should provide closed-loop care?

All interviewees stressed that, to be able to appropriately advise and support closed-loop users, health professionals needed to be proficient in the use of insulin pumps and sensors:

> "I think the prerequisite should be complete familiarity with pumps and CGM…because it's a closed-loop and it will do pretty much all the work itself, it cannot be delivered by people who are not completely conversant with the parts of the loop." (D2)

Some, however, noted that this expertise was currently lacking in some diabetes centres and, hence, that closed-loop system care should, at least initially, be managed by specialised centres of excellence:

> "I've worked in quite a few different diabetes centres and have often been the only person with any pump experience there…I think getting everybody comfortable with delivering training for patients on closed-loop is probably a bit of a step too far, so at least starting with specialised centres is probably the most economical way of delivering it in the future." (D5)

Conversely, many interviewees agreed with N6's sentiment that "there's no reason why every specialist diabetes team in every centre can't take on that role. It's not any more rocket science than what people are managing with the pumps…and the CGM that's routine now" (N6). Indeed, several argued that it was in users' best clinical interest that local diabetes centres have knowledge of closed-loop technology to ensure their appropriate support in times of emergency, because "unfortunately lots of children do have emergencies with their

diabetes…unless the local service is able to understand their insulin regimen it is dangerous"
(D6).

DISCUSSION

We report on health professionals' perspectives regarding the issues, opportunities and
challenges that may arise from the introduction and mainstreaming of closed-loop technology
in routine clinical care. Our findings provide an important starting point for the development of
formal guidance to support the rollout of closed-loop technology in routine clinical care,
particularly with regard to health professionals' training and resource requirements. Below, we
discuss and put forward our recommendations for potential next steps (see Box 3 for a
summary of these recommendations).

<Box 3 here>

Interviewees emphasised that health professionals training and supporting people to use a
closed-loop system must be proficient with current pump and CGM technologies. However,
some indicated that not all diabetes teams currently have this level of competency. In studies
of other diabetes technologies, similar shortfalls in expertise have been linked to: time
constraints, health professionals having limited device exposure, and a lack of consensus or
policy regarding training requirements [~~13,19~~14,20]. In light of potential shortages in the
requisite expertise, some interviewees in the current study suggested that, at least initially,
only specialist centres should deliver closed-loop system care. Conversely, others highlighted
the importance of local diabetes teams having the necessary technological know-how, as they
are typically the first port of call for diabetes-related emergencies. To address these issues,
we propose that each service delivery hub should have at least one health professional with
formal training in closed-loop technology to act as an 'expert' resource for their local diabetes
team. Additionally, as suboptimal user education and support can compromise both user
safety and the system's clinical benefits and cost-effectiveness, any health professional

wishing to provide closed-loop system care should undergo accredited training and evidence relevant continued professional development. Finally, the development of formal standards, which set out the core competencies expected of health professionals delivering closed-loop system education and care, should be considered.

Interviewees expressed preferences for a range of modes of learning, which included competency assessments, accredited training routes and a need for experiential learning. Considered an 'ethical imperative' by some [2021], simulation-based learning in medical education is recognised as enhancing health professionals' knowledge and skills (and thus patient safety) as well as benefitting wider organisational outcomes, such as staff retention and positive culture change [2122]. Interviewees also suggested that health professionals should be provided with guidance to support closed-loop system consultations in routine clinical care. In response to these findings, we propose that closed-loop system training for professionals should be made available using different media, such as YouTube, TED talks and written materials, to accommodate different learning styles and flexible access. This should include competency assessments and formal accredited options, which, for quality assurance, have been endorsed by relevant learned organisations. Given the range of commercial closed-loop systems about to enter the market [1], training for health professionals should also include up-to-date guidance on available models and their suitability for different types of user. To facilitate experiential learning, we recommend that device manufacturers provide demonstration systems to help health professionals understand closed-loop system functionality and modes of use. Finally, we suggest that clinical guidance should be developed to support professionals delivering closed-loop system consultations. As interviewees highlighted, this resource should provide advice on: basic troubleshooting; how to advise users clinically, including the consideration of atypical cases and non-routine events; and, which data fields to prioritise during time-pressured clinic appointments. This guidance could also be tailored to the specific needs of different age groups such as young children, adolescents and adult users.

Interviewees described how delivering closed-loop system education had worked best when using a structured approach that introduced each component in turn. However, it must be noted that the CLOuD trial involved newly-diagnosed individuals; hence, users with prior experience of pumps and/or sensors are likely to have fewer training needs. Interviewees further observed that, once set up on the system, its ability to reduce glycaemic excursions lessened users' need for ad-hoc clinical input compared with people using CSII and MDI. This prompted concerns about having fewer opportunities to reinforce critical diabetes management skills, such as how to independently adjust basal rates and mealtime ratios in the event of device failures. Resonating with others' observations, interviewees also described how some people had held unrealistic expectations about the system's capabilities [8,119,12] and could feel overly anxious due to the greater availability of real-time blood glucose data [2223]. To address these concerns, we recommend the development of a structured, stepwise education package. This resource should instruct users how to safely manage blood glucose in the event of device failure, set realistic expectations about time in range and glycaemic excursions when using a closed-loop system and, to help minimise potential data burden, outline which aspects of the available data users should focus on.

Interviewees also noted how reduced contact with users, alongside the system's ability to rectify (and therefore mask) poor self-management practices (e.g. meal boluses being miscalculated or omitted), might compromise timely detection of psychosocial problems. Previous studies [23,2424,25] have shown how the closed-loop system can partially compensate for lax dietary management practices commonly observed among adolescents [25,2626,27]. To date, however, none have reported a potential for unintended psychological consequences to arise from the system's ability to make these compensations. Others have highlighted how diabetes-related depressive symptoms may lead to adolescents discontinuing use of diabetes technologies [2728]. Thus, we recommend that health professionals regularly assess users of closed-loop systems, particularly adolescents, in line with existing clinical

practice for the psychological support of people with type 1 diabetes. Furthermore, integrating validated psychological tools such as INSPIRE [2829] into users' initial teaching package could help clarify their expectations, anxieties and hopes regarding closed-loop systems and highlight issues that may need to be addressed to ensure safe and effective long-term use of this technology.

A key study strength is the use of a flexible, open-ended approach, which enabled us to identify issues and challenges erstwhile unreported in the literature. A potential limitation is that all centres running the trial were experienced in the use of insulin pumps and CGMs, which may not be representative of other sites delivering diabetes care. Furthermore, studies have shown that health professionals may hold erroneous views regarding individuals' capabilities and suitability for diabetes technologies [30,14]. Such preconceptions, as well as their experience of working on a clinical trial, may have biased the professionals in this study; indeed, we described how these professionals acknowledge such prejudices, and the trial's influence on their views, in a companion article [31]. Similarly, their perspectives may reflect a more traditional, paternalistic stance towards healthcare delivery and a difficulty accepting increased patient autonomy [32]. We also focused on the experiences of health professionals working on a clinical trial, involvingwith a specific participant group (newly-diagnosed adolescents) and using one type of prototype closed-loop system. Future research could explore the perspectives of health professionals working in adult diabetes care or with different types of closed-loop technology. It should also be noted that, in the event of the CLOuD trial demonstrating clear clinical benefits to people using closed-loop technology from diagnosis, the number of newly-diagnosed individuals being moved onto closed-loop systems will likely increase, thereby strengthening the generalisability of our findings. Consequently, future work should consider longer-term follow-up of newly-diagnosed closed-loop system users to establish whether health professionals' concerns regarding a delayed emergence of support needs are realised.

The above recommendations constitute an important and timely starting point for informing the mainstreaming of closed-loop systems in routine clinical care. If actioned by the relevant stakeholders, such as industry, healthcare providers and pertinent learned societies, they will help limit the potential additional burden of introducing closed-loop systems in routine clinical care and help inform appropriate user education and support.

Author disclosure statement

RH reports having received speaker honoraria from Eli Lilly and Novo Nordisk, serving on advisory panel for Eli Lilly and Novo Nordisk, receiving licence fees from BBraun and Medtronic. RH reports patent patents, patent applications, shareholding and directorship at CamDiab. TR reports having received speaker honoraria from Novo Nordisk and consultancy fees from Abbott Diabetes Care. FC reports having received travel expenses and honorarium to attend the Advisory Boards of Medtronic, Dexcom, Ypsomed and Eli Lilly. RB reports having received speaker honoraria from Eli Lilly and Springer Healthcare. BK, DR, JMA, NLA, LV, CKB, NT, GA and JL – No competing financial interests exist.

REFERENCES

[1] Allen N, Gupta A. Current diabetes technology: Striving for the artificial pancreas. Diagnostics (Basel). 2019;9:31.

[2] Lewis D. History and perspective on DIY closed looping. Journal of Diabetes Sci Technol. 2019;13:790-793.

[3] Barnard KD, Wysocki T, Ully V, 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.

[4] Hendrieckx C, Poole L, Sharifi A, et al. "It is definitely a game changer": A qualitative study of experiences with in-home overnight closed-loop technology among adults with type 1 diabetes. Diabetes Technol Ther. 2017;19:410-416.

[5] Barnard KD, Wysocki T, Allen JM, et al. Closing the loop overnight at home setting: Psychosocial impact for adolescents with type 1 diabetes and their parents. BMJ Open Diabetes Res Care. 2014;2:e000025.

[6] Barnard KD, Wysocki T, Thabit H, 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.

[7] Young AJ, Thabit H, Heller SR, et al. Holistic impact of closed-loop technology on people with type 1 diabetes. J Diabetes Sci Technol. 2015;9:932-933.

[8] Farrington C, Stewart ZA, Barnard K, et al. Experiences of closed-loop insulin delivery among pregnant women with type 1 diabetes. Diabet Med. 2017;34:1461-1469.

[9] Iturralde E, Tanenbaum ML, Hanes SJ, et al. Expectations and attitudes of individuals with type 1 diabetes after using a hybrid closed loop system. Diabetes Educ. 2017;43:223-232.

[910] Tanenbaum ML, Iturralde E, Hanes SJ, et al. Trust in hybrid closed loop among people with diabetes: Perspectives of experienced system users. J Health Psychol. 2017:1359105317718615.

[1011] Iturralde E, Tanenbaum M, Naranjo D, et al. Partner perspectives on closed loop systems. PLAID. 2016;2:30-38.

[1112] Lawton J, Blackburn M, Rankin D, 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.

[1213] Lawton J, Blackburn M, Rankin D, et al. The impact of using a closed-loop system on food choices and eating practices among people with type 1 diabetes: A qualitative study involving adults, teenagers and parents. Diabet Med. 2019;36: 753–760.

[1314] James S, Perry L, Gallagher R, et al. Diabetes educators: Perceived experiences, supports and barriers to use of common diabetes-related technologies. J Diabetes Sci Technol. 2016;10:1115-1121.

[1415] Pope C, Mays N. Qualitative research: Reaching parts other methods cannot reach: An introduction to qualitative methods in health and health services research. BMJ. 1995;311:42-45.

[1516] Medical Research Council. A framework for the development and evaluation of RCTs for complex interventions to improve health. London: MRC, 2000.

[1617] Sandelowski M. Whatever happened to qualitative description? Res Nurs Health. 2000;23:334-340.

[1718] Sandelowski M. What's in a name? Qualitative description revisited. Res Nurs Health. 2010;33:77-84.

[1819] Breckenridge JP, Gianfrancesco C, de Zoysa N, et al. Mobilising knowledge between practitioners and researchers to iteratively refine a complex intervention (DAFNEplus) pre-

trial: Protocol for a structured, collaborative working group process. Pilot Feasibility Stud. 2018;4:120.

[1920] Perry L, James S, Gallagher R, et al. Supporting patients with type 1 diabetes using continuous subcutaneous insulin infusion therapy: Difficulties, disconnections, and disarray. J Eval Clin Pract. 2017;23:719-724.

[2021] Ziv A, Root Wolpe P, Small SD, et al. Simulation-based medical education: An ethical imperative. Acad Med. 2003;78:783-788.

[2122] Gaba DM. The future vision of simulation in health care. Qual Saf Health Care. 2004;13 (Suppl 1):i2-10.

[2223] Pickup JC, Ford Holloway M, Samsi K. Real-time continuous glucose monitoring in type 1 diabetes: A qualitative framework analysis of patient narratives. Diabetes Care. 2015;38:544-550.

[2324] Elleri D, Maltoni G, Allen JM, et al. Safety of closed-loop therapy during reduction or omission of meal boluses in adolescents with type 1 diabetes: A randomized clinical trial. Diabetes Obes Metab. 2014;16:1174-1178.

[2425] Chernavvsky DR, DeBoer MD, Keith-Hynes P, et al. Use of an artificial pancreas among adolescents for a missed snack bolus and an underestimated meal bolus. Pediatr Diabetes. 2016;17:28-35.

[2526] Olinder AL, Kernell A, Smide B. Missed bolus doses: Devastating for metabolic control in CSII-treated adolescents with type 1 diabetes. Pediatr Diabetes. 2009;10:142-148.

[2627] Vanderwel BW, Messer LH, Horton LA, et al. Missed insulin boluses for snacks in youth with type 1 diabetes. Diabetes Care. 2010;33:507-508.

[2728] Wong JC, Dolan LM, Yang TT, et al. Insulin pump use and glycemic control in adolescents with type 1 diabetes: Predictors of change in method of insulin delivery across two years. Pediatr Diabetes. 2015;16:592-599.

[2829] Weissberg-Benchell J, Shapiro JB, Hood K, et al. Assessing patient-reported outcomes for automated insulin delivery systems: The psychometric properties of the INSPIRE measures. Diabet Med. 2019;36:644-652.

[30] Lawton J, Kirkham J, Rankin D, et al. Who gains clinical benefit from using insulin pump therapy? A qualitative study of the perceptions and views of health professionals involved in the REPOSE (Relative Effectiveness of Pumps over MDI and Structured Education) Trial. Diabet Med. 2016; 33:243-251.

[31] Lawton J, Kimbell B, Rankin D, et al. Health professionals' views about who would benefit from using a closed-loop system: qualitative study. Diabet Med. *In press*.

[32] Beverly EA, Ritholz MD, Brooks KM, et al. A qualitative study of perceived responsibility and self-blame in type 2 diabetes: Reflections of physicians and patients. J Gen Intern Med. Sep 2012;27:1180-1187.