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# 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

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**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*

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## ABSTRACT

### Background

We explored health professionals' views about the training, support and resourcing needed to support people using a closed-loop system in routine clinical care.

### 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. 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 input could result in new challenges; specifically, they had fewer opportunities to reinforce users' diabetes knowledge and skills through ad-hoc contact and to detect potential psychosocial problems. They also noted heightened anxiety amongst some parents due to the constant availability of data and unrealistic expectations. Interviewees suggested that health professionals supporting closed-loop users in routine clinical care will need comprehensive technology training and standardised clinical guidance. They also stressed that all local diabetes teams should be empowered to deliver closed-loop system care, which will require access to training and appropriate resourcing.

### Conclusion

Supporting people to use a closed-loop system will require health professionals to adapt current approaches to offering education and support. To ensure successful rollout of closed-

loop technology, it is vital that healthcare providers reconsider diabetes teams' current training and resourcing.

## BACKGROUND

A closed-loop system is a rapidly evolving technology for the management of type 1 diabetes that 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 commercially available in the United States and Europe, and other systems will follow in due course [1].

To support rollout of this technology, 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 patients' and/or their family members' experiences of using closed-loop systems [2-12]. 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 professionals being appropriately trained and supported is a key mediating factor in patients' access to and experience of using diabetes technologies [13].

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 Figure 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.

< Figure 1 here >

## METHODS

Qualitative methods facilitate exploration of poorly understood topics as they allow findings to emerge from the data rather than from a-priori hypotheses [14]. 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.

The study was informed by Normalization Process Theory, an epistemological position which recognises that the adoption and delivery of a healthcare intervention (including a new technology) may be mediated and informed by individual and contextual factors [15]. Our approach was also informed by earlier work, which has highlighted how unexpected issues, benefits and challenges may arise from introducing and using new diabetes technologies [11,12].

### Recruitment

We recruited health professionals (doctors, diabetes nurses, research nurses) in all seven participating sites: Addenbrooke's Hospital, Cambridge; Leeds Children's Hospital, Leeds; Alder Hey Children's Hospital, Liverpool; Nottingham Children's Hospital, Nottingham; Oxford

Children's Hospital, Oxford; Southampton Children's Hospital, Southampton; and Royal Hospital for Children and Young People, Edinburgh. 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 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 Figure 2. The interviews took place between August 2018 and June 2019, averaged 70 minutes and were digitally recorded and transcribed in full.

< Figure 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 [16,17]. 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. Coded datasets were subject to further analyses to develop more nuanced interpretations of the data. Use of qualitative analysis software package NVivo10 (QSR International, Doncaster, Australia) facilitated data coding and retrieval.

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. We highlight, in particular, their perceptions of what helped or hindered this process and what unanticipated issues may arise for some young people starting out on the technology. We then present their views about what training and resourcing diabetes professionals will need to support people using a closed-loop system in routine clinical care. Finally, we describe their views about who may be best placed to deliver care on the closed-loop system when the technology becomes more widely available.

### 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 a straightforward endeavour. 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 families had needed more extensive teaching input than was required to use other insulin regimens such as MDI or continuous subcutaneous insulin infusion (CSII) therapy. Some reflected on the fact that, because trial participants were newly diagnosed, they only had a rudimentary understanding of diabetes management, which made their education "that little bit harder" (N7). Interviewees also described how providing education on each of the closed-loop system's constituent parts (i.e. insulin pump, sensor, handset and control algorithm) required more time than standard device training. Many interviewees described experimenting with different approaches to delivering this education: "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 to this specific cohort, i.e. individuals naïve to all diabetes technology, worked best when the system's component parts were introduced one-by-one at a pace appropriate to the individual, typically over several weeks, as it "just gives the family time to get used to each element" (N8).

Interviewees further observed that, once people were set up on the closed-loop system, they initially required more support than individuals using other insulin regimens. This was not only due to study equipment occasionally malfunctioning, but also because adolescents and parents needed to become accustomed to the individual devices, their functions and settings, and how to use these effectively. After an initial adjustment period, most felt that the level of support needed was similar to that of people using MDI or CSII. Some, however, suggested that individuals had sought less input over time than was typically requested by people using other insulin regimens. To account for this, these interviewees noted that, when people used a closed-loop system, there was less need to routinely review and adjust basal doses and/or mealtime ratios as the system automatically managed any excessive variability in blood glucose levels:

> "They've done really well with probably, yeah, less support, because…if it was a patient who was just on a pump I think they would need a lot more support from us, looking at downloads and titrating insulin constantly." (N9)

**Unanticipated consequences; implications for workload**

Some interviewees observed that having less contact with closed-loop users to help optimise their blood glucose control could have unanticipated consequences. For example, several discussed how, when individuals started CSII therapy, they would normally use the initial weeks and months of enhanced contact to proactively educate them how to interpret patterns in their blood glucose data and determine appropriate adjustments to basal rates and mealtime ratios. Closed-loop users' reduced need for this type of support, however, meant that health professionals had fewer teaching opportunities, which, in turn, resulted 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 to discuss blood glucose control could affect more holistic aspects of diabetes care and potentially result in support needs emerging further down the line. N7, for example, remarked that closed-loop system users' reduced need for clinical input meant that "we 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 had the potential to 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 the anxieties of some parents, because the greater availability of real-time data allowed minute-by-minute monitoring of their child's blood glucose. 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 and seek reassurance that: "when you're out of range [it] doesn't mean her kidneys are gonna explode and she's gonna go blind and we're gonna have to cut her foot off" (N7). As well as offering education to parents to address misconceptions about the implications of glucose excursions, interviewees also highlighted the importance of proactively managing their expectations of the closed-loop system:

> "I suppose you do have to make it clear that when you're on a closed-loop system 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, delete all lows." (RN5)

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

Interviewees generally considered themselves proficient and confident 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 involved in looking after people using a closed-loop system in routine clinical care 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 training for health professionals 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 to demonstrate one's aptitude before supporting use of the technology in clinical practice. Others highlighted the need for a formal, accredited training scheme:

> "It needs a training scheme of some description and you shouldn't be able to use it unless you've done that training scheme, be it a much more in-depth closed-loop educator scheme or a more loosely affiliated 'you've been on the course' type of affair." (N7)

Regardless of the mode of training delivery, all interviewees emphasised the importance of being given opportunities to familiarise themselves with the technology "in a safe environment, to play, to make your mistakes, to feel confident with the system" (N7) prior to use in clinical practice. As N2 explained:

> "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 a closed-loop system in preparation for this trial. 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).

As the care of individuals using a closed-loop system differs from that of people using other insulin regimens, interviewees suggested that diabetes professionals should be issued with structured guidance on how to advise closed-loop users clinically. This included guidance about more atypical cases, such as how best to manage 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. Ultimately, interviewees acknowledged that learning 'on the job' was key to consolidating their understanding of the closed-loop system:

> "I knew the theory of the closed-loop and I knew what I was looking at, but even now, having dealt with the patients in clinic, I feel I'm in a better position…So even if the information is given at the start, until you've actually had the experience of dealing with it or having to understand it, you don't really take it in." (D2)

**Who should provide closed-loop care?**

All interviewees emphasised 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 tertiary centres with the requisite technological expertise:

> "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 patients' best clinical interest that local diabetes centres have knowledge of closed-loop technology to ensure their appropriate support in times of emergency: "…diabetes is a secondary-level specialty that should be delivered in the centre nearest to the child's home, 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**

This is the first study to explore health professionals' views about the training, support and resourcing needed to support people using closed-loop systems once this technology becomes more widely available in routine clinical care. Interviewees described how, compared to other insulin regimens, teaching and supporting individuals to use a closed-loop system could be initially more time-consuming. They also noted that, after an initial adjustment period, users had less need for initiating contact with the clinical team compared with people using CSII and MDI. Interviewees highlighted how use of the closed-loop system could give rise to new challenges as well as opportunities. Specifically, they noted that, by virtue of the system's ability to keep blood glucose stable, they were presented with fewer opportunities to reinforce users' diabetes knowledge and skills through ad-hoc contact as well as to detect potential psychosocial problems affecting management practices. Heightened anxiety amongst some parents was also noted, due to the constant availability of data and these individuals holding unrealistic expectations. Interviewees recommended that all local diabetes teams should be empowered to deliver closed-loop system care, which will require access to comprehensive technology training, standardised clinical guidance and appropriate resourcing.

Our findings indicate that, when training and supporting new users, the closed-loop system's complexity may lead to an initial increase in health professionals' workloads. However, it should 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. Furthermore, users' need for clinical input and technological support should attenuate as new components become available (e.g. calibration-free CGMs) or are rendered redundant (e.g. by embedding the control algorithm in a smartphone or smartwatch app) [18,19]. (These system modifications are currently being tested in phase 2 of the CLOuD trial.) Having fewer component parts requiring less user input should reduce the potential for equipment malfunctions and user errors, and further alleviate health professionals' workloads.

Our findings also highlight several challenges as well as benefits, which may arise from introducing and using closed-loop technology. Interviewees noted that, because of the system's ability to reduce glycaemic excursions, individuals had needed less clinical input than is typically required by those using CSII and MDI. This led to concerns that individuals might miss out on critical teaching opportunities, such as those needed to make independent adjustments to basal rates and mealtime ratios. Users' inability to manage their blood glucose independently may put them at risk of potentially lengthy, but avoidable, periods of suboptimal glycaemic control and compromise the glycaemic benefits offered by the closed-loop system. This finding therefore highlights the importance of ensuring that people going onto a closed-loop system from diagnosis, like other individuals newly diagnosed with type 1 diabetes, are given access to high-quality, structured education programmes [20].

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 issues, such as poor emotional adjustment or psychosocial problems. Previous studies [21,22] have shown how the closed-loop system can compensate for lax dietary management practices commonly observed among adolescents [23,24]. To date, however, none have reported a potential for unintended psychological consequences to arise from the closed-loop's ability to make these compensations. Others have highlighted how diabetes-related depressive symptoms may lead to adolescents discontinuing use of diabetes technologies [25]. Thus, new users of closed-loop systems, particularly adolescents, might benefit from ongoing psychological assessment and referral to psychological services if required.

Our findings also lend support to others' observations that people who lack knowledge about closed-loop technology may hold unrealistic expectations about the system's capabilities [8,11]. Most families in the current study lacked diabetes experience prior to their child's diagnosis, which may have resulted in some parents being more prone to seeking frequent reassurance about glycaemic excursions. As others have shown, having realistic expectations helps ensure that individuals adopt, and appropriately use, closed-loop technology [26,27]. Hence, to reduce future workload, health professionals should explore people's understanding of the closed-loop system and clarify its capabilities and limitations.

Interviewees highlighted that those training and supporting people to use a closed-loop system must be competent with current pump and sensor technologies. They also raised concerns that some diabetes teams still lacked these skills. In studies of other diabetes technologies, similar shortfalls in expertise have been linked to: time constraints, health professionals having limited device exposure because of prohibitive costs which limit patient access to technology, and a lack of consensus or policy regarding training requirements [13,28]. It has also been noted that a lack of training can result in health professionals being reluctant to recommend closed-loop systems to patients [29]. Hence, health professionals should be encouraged and enabled to access existing technology training to help them acquire the necessary skills and confidence to support closed-loop technology upon its wider rollout. Approaches used to promote staff training in other diabetes technologies might also be considered to support the rollout of closed-loop technology; these include: organisational and managerial support through funding and study time, placements, mentorship schemes, peer support and professional development using videoconferencing facilities [13]. To address interviewees' suggestions regarding competency assessments prior to using closed-loop systems in clinical practice, device manufacturers could provide accredited training options, including online resources that enable flexible access for busy professionals. Interviewees also indicated a need for experiential learning prior to supporting patients using the closed-loop system. Considered an 'ethical imperative' by some [30], 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 [31]. Hence, manufacturers could look to develop simulation closed-loop systems in order to facilitate individual learning and understanding and promote awareness, acceptance and adoption of this technology among the wider community of diabetes professionals.

In addition to training staff in specialist centres, consideration should be given to providing training to health professionals in local diabetes teams who support closed-loop users, as they are typically the first port of call for diabetes-related emergencies. Health professionals in smaller centres often have not just diabetes as their sub-speciality, but may also work in other specialities for which they are required to maintain their professional development and adopt new technologies and learning. This may limit their ability to adopt increasingly more complicated technologies in diabetes. However, there is a need for them to do so to ensure that access to these treatments is equitable and patients can be looked after safely by their local services. Interviewees also highlighted the importance of having robust IT infrastructure in place to facilitate the large data downloads that inform the clinical input and advice given to system users. As others have noted, having limited local expertise and unsupportive service structures and processes can lead to some health professionals limiting their involvement in technology-based diabetes care [29]. In line with recommendations in relation to existing diabetes technologies [13], healthcare providers should consider whether service reconfiguration, reallocation of staffing and resources, or improvements to IT infrastructure may be required to ensure that local teams can deliver care for closed-loop users.

A key study strength is the use of a flexible, open-ended approach, which enabled us identify issues and challenges erstwhile unreported in the literature. A potential limitation is that we focused upon health professionals involved in a clinical trial involving youths newly diagnosed with type 1 diabetes. This might limit the generalisability of our findings and recommendations. Future research 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. All centres running the trial had experience of the use of insulin pumps and CGMs in a wide range of patients with diabetes. Furthermore, interviewees in our study agreed to take part in a trial of closed-loop systems and some had prior experience of supporting individuals using this technology. As such, they are not necessarily representative of the wider community of diabetes professionals. Future studies should thus seek the views of diabetes professionals who have less engagement with treatment technologies to explore the reasons behind this and their expectations, concerns and support needs regarding the rollout of closed-loop technology.

As closed-loop systems become more widely available, diabetes services will need to adapt comprehensively to meet the requirements for delivering this technology. With the future of diabetes management increasingly being dominated by technological solutions, it is imperative that health professionals are given appropriate training, time and support to embrace these developments and ensure that people with type 1 diabetes are able to access, and benefit from, these innovative advances.

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**Figure 1. Details about the CLOuD trial, study device and training provided**

The CLOuD trial aims to determine whether continued intensive metabolic control using a hybrid closed-loop system is better able to preserve beta-cell function in young people newly diagnosed with type 1 diabetes than standard multiple daily injection (MDI) therapy. The automated hybrid closed-loop system used in the first phase of the CLOuD trial, FlorenceM, comprised:

- A modified Medtronic 640G pump
- A Medtronic Guardian 3 sensor
- A locked-down Android smartphone with Medtronic enclosure containing the Cambridge model predictive control algorithm enabling wireless communication with the insulin pump.

Eligibility criteria for the trial included: a diagnosis of type 1 diabetes within the preceding 21 days; aged between 10 and 16.9 years old; a willingness to perform regular capillary blood glucose monitoring (at least 4 blood glucose measurements every day); to wear the study devices; and, to upload pump and sensor data at regular intervals.

*Training and support provided to trial participants*

Pre-randomisation, participants and their families received structured diabetes education and training in accordance with standard clinical practice. All participants received training on the multiple daily injection (MDI) regimen. Participants randomised to the closed-loop arm were additionally trained on the use of the study insulin pump and CGM sensor, and their competency on these devices assessed, prior to starting closed-loop insulin delivery. They were also given a user manual to take away.

The study involved 14 planned visits and 1 telephone/email contact in each arm over the 24-month study period. Participants were contacted by email/telephone within one week after study initiation and subsequently followed up at 3-monthly study visits to: record any adverse events, device deficiencies and changes to insulin doses; take an HbA1c sample; download data from the study devices; and fit participants of both study arms with a blinded CGM sensor to be worn for the next 14 days. Participants also had access to a 24-hour telephone helpline to contact their local study team with any study-related matters. In most sites, the health professionals delivering the trial were also responsible for participants' routine clinical care during the trial.

*Training and support provided to site teams delivering the trial*

Each participating centre received a training visit from two members of the research team, who demonstrated the different study devices (pump, sensor, study handset) and set up a working closed-loop system in real time. They also explained data downloads and the practicalities of the study, including details of the participant visits. The research team also supported the centres on a second visit when they started their first participant on the closed-loop technology. Site teams received a trouble-shooting guide and had access to 24-hour telephone support from the research team throughout the study.

Figure 1. Details about the CLOuD trial, study device and training provided

159x219mm (300 x 300 DPI)

**Figure 2. Key topic areas explored in the interviews**

- Interviewees' clinical background, training and experience; previous involvement (if any) in trials of closed-loop technology.
- Experiences of training study participants to use the closed-loop system; perceived differences to training people using conventional insulin regimens.
- Experiences of providing support to participants using a closed-loop system; perceived differences in the type and amount of support required compared with people using other approaches; perceived sustainability of this level of support upon rollout.
- Experiences of the training and support received to deliver the trial; views about what kind of training, support and resources health professionals will need to support closed-loop users in routine clinical care.
- Views about who should deliver closed-loop routine care.
- Perceived impact of the rollout of closed-loop technology on workloads and wider healthcare resources.

Figure 2. Key topic areas explored in the interviews

158x93mm (300 x 300 DPI)

**Table 1. Participant characteristics**

| | N | % |
|---|---|---|
| **CLOuD sites (n=7)** | | |
| Total number of interviewees | 22 | |
| Interviewees per site - range (mode) | 1-5 (4) | |
| **Role** | | |
| Diabetes Consultants | 7 | 32 |
| Diabetes Nurses | 9 | 41 |
| Research Nurses | 6 | 27 |
| **Number of interviewees with previous closed-loop experience** | 5 | 23 |

Table 1. Participant characteristics

117x93mm (300 x 300 DPI)