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RESEARCH ARTICLE



Implementation of fully closed-loop insulin delivery for inpatients with diabetes: Real-world outcomes

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Abstract

Aims: Fully closed-loop insulin delivery has been shown in clinical trials to be safe and improve glucose control compared with standard insulin therapy in the inpatient setting. We investigated the feasibility of implementing the approved CamAPS HX fully closed-loop system in a hospital setting.

Methods: This implementation project was conducted in a large teaching hospital in Cambridge, UK. Healthcare professional training was multimodal including face-to-face workshops, online learning modules and supported by standard operating procedures. Set-up and maintenance of closed-loop devices were undertaken by the inpatient diabetes team. Selection of suitable patients was multidisciplinary and prioritised those with more challenging diabetes management. Demographic and clinical data were collected from electronic health records and diabetes data management platforms.

Results: In the 12 months since the closed-loop system was implemented, 32 inpatients (mean \pm SD age 61 \pm 16 years, 8 females, 24 males) used closed-loop insulin delivery during their admission, across medical and surgical wards in the hospital with a total of 555 days of closed-loop glucose control (median [IQR]: 14 [6, 22] days per inpatient).

The time spent in target glucose range 3.9-10.0 mmol/L was $53.3 \pm 18.3\%$. Mean glucose was $10.7 \pm 1.9 \text{ mmol/L}$ with $46.0 \pm 18.2\%$ of time spent with glucose >10.0 mmol/L. Time spent with sensor glucose below 3.9 mmol/L was low (median [IQR]: 0.38 [0.00, 0.85]). There were no episodes of severe hypoglycaemia or diabetic ketoacidosis during closed-loop use.

Conclusions: We have demonstrated that the fully closed-loop system can be safely and effectively implemented by a diabetes outreach team in complex medical and surgical inpatients with challenging glycaemic control.

K E Y W O R D S

closed-loop, continuous glucose monitoring, implementation, in-patient diabetes, therapy, type 2 diabetes

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1 | INTRODUCTION

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Making hospitals safe for people with diabetes is a key priority.¹ Providing high-quality diabetes care during a hospital admission is important as both hyper- and hypoglycaemia are associated with worse outcomes including increased risk of infection and admission to the intensive care unit, longer length of stay and mortality.^{2,3} Achieving the recommended target glucose levels in hospital is challenging with current approaches.⁴ The impact of the acute illness, medication changes and alterations to meal timings and intake can all affect glucose levels. Attempts to achieve target glucose levels can increase the risk of hypoglycaemia, and require increased workload for healthcare professionals.

A closed-loop system automatically delivers insulin via a subcutaneous insulin pump in response to real-time sensor glucose levels. Automation of insulin delivery removes the need for frequent insulin dose adjustments by healthcare professionals, and continuous glucose monitoring allows for alerts to identify hypoglycaemia and significant hyperglycaemia. Randomised controlled trials using the Cambridge fully closed-loop system in hospital showed that the closedloop system achieves superior glucose control compared to standard insulin management, without increasing the risk of hypoglycaemia.^{5–8} Participants who used the closed-loop system during their admission spent an additional 6h each day with glucose in the target range compared to those who continued with standard insulin therapy (66% vs. 42%). In a study including inpatients requiring nutrition support (enteral/parenteral nutrition) during their admission, participants in the closed-loop group spent an additional 8h each day with glucose in the target range compared to the control group (68% vs. 36%), without any increase in hypoglycaemia. We aimed to investigate the feasibility of implementing the approved CamAPS HX fully closed-loop system at a tertiary hospital, to improve outcomes for inpatients with diabetes and to inform widespread adoption.

2 | RESEARCH DESIGN AND METHODS

This implementation project was conducted at a large teaching hospital in Cambridge, UK. Participants included adult inpatients on medical or surgical wards requiring insulin therapy for glucose control. People with type 1 diabetes were excluded as per the manufacturer's instructions.

2.1 | Pre-implementation

Funding for the project was awarded in August 2020 from the local hospital charitable trust. The award was used to

What's new?

- Fully closed-loop insulin delivery has been shown in clinical trials to be safe and improve glucose control in the hospital.
- We have shown that the fully closed-loop system can be safely and effectively implemented by a diabetes outreach team in complex medical and surgical inpatients with challenging glycaemic control in a real-world setting.
- These real-world data support increased adoption of this technology in routine inpatient diabetes care.

procure the approved devices and consumables to operate three fully closed-loop systems for 12 months within the hospital.

Approvals were obtained from local Departmental and Divisional leads and governance committees, the Medical Device Approval Group, new interventional procedures committee, Joint Drugs and Therapeutics Committee, the finance committee and the quality improvement committee.

Healthcare professional training was multimodal. Standard operating procedures, tip-sheets and troubleshooting flow sheets were developed for both diabetes specialist staff and non-specialist ward staff to support implementation. A free online competency-based training module was created and hosted on the CamAPS online training platform (https://hx.camdiabtraining. com). The module takes about 30 min to complete. Workshops (online and face-to-face) lasting approximately 1h were held for diabetes nurses and dieticians working in the diabetes outreach team. Diabetes consultants and trainees undertook project awareness training. Non-specialist ward staff were supported with face-toface and remote reviews of inpatients using the system, and resource packs were kept at the patient bedside with advice on how to monitor the system and escalate as required including out of hours.

2.2 | Implementation

The CamAPS HX closed-loop app (CamDiab) resides on an unlocked Android phone, receives sensor glucose data from a Dexcom G6 transmitter (Dexcom) and uses the Cambridge adaptive model predictive control algorithm (version 0.3.71) to direct insulin delivery on a Dana Diabecare RS pump (Diabecare). Every 8–12 min, and based on sensor glucose data, the Cambridge adaptive control algorithm calculates an insulin infusion rate that is communicated wirelessly to the insulin pump. Sensor glucose and insulin data are automatically uploaded to the Diasend (https://diasend.com//en) data management platform. The control algorithm is initialised using the participant's weight and total daily insulin dose and gradually adapts its insulin dosing based on observed glucose patterns. The nominal glucose target is 5.8 mmol/L and can be adjusted as required between 4.4 and 11.0 mmol/L. In this project, the glucose target was set based on individual clinical circumstances. Low glucose alarms were customised at a threshold to suit the user. Fiasp insulin (Novo Nordisk) was used in the closed-loop system.

Inpatient selection, set-up and maintenance of closed-loop devices was undertaken by the diabetes outreach team (a consultant led inpatient diabetes specialist nurse and specialist dietician team). Selection of suitable patients did not use specific glycaemic criteria but prioritised those with diabetes or stress hyperglycaemia that was difficult to manage with standard insulin therapy including requirement for enteral/parenteral nutrition, use of corticosteroids and those receiving haemodialysis.

Standard operating procedures for both non-specialist ward staff and trained members of the diabetes outreach team describe details of glucose monitoring, management of the closed-loop system around scans and surgery, management of hypoglycaemia and hyperglycaemia while using the closed-loop system and processes for escalating issues or system faults including outside of usual working hours. These are in Supporting Information.

Closed-loop system data were reviewed remotely every 1–3 days depending on the complexity of the patient and duration of use. Insulin infusion set changes were undertaken every 2–3 days and sensor changes every 10 days by the diabetes outreach team. Non-specialist ward staff were responsible for reviewing and documenting sensor glucose levels up to four times a day, checking that a capillary glucose measurement aligned with the sensor glucose reading once a day, responding to any system alerts and administering hypoglycaemia treatment or supplemental insulin when required, and escalating any issues including radiology scans, surgery or imminent discharge.

2.3 | Outcome measures

Demographic and clinical data of users were collected from electronic health records. For each user, glucose metrics and insulin requirements were collected from Diasend and calculated using GStat software, version 2.3 (University of Cambridge). Safety events including hypoglycaemia events (defined as glucose <3.9 mmol/L as measured by either fingerstick capillary testing or sensor glucose reading), blood ketone measurements and system issues were collected from electronic health records.

3 | RESULTS

Initial application of the fully closed-loop system in the hospital following attainment of all approvals was in August 2021.

3.1 | Training

Face-to-face training was completed by 21 healthcare professionals within the diabetes outreach team. Twelve healthcare professionals completed the online training module with high post-completion evaluation ratings for knowledge about the closed-loop system (4.64/5), confidence in using the closed-loop system (4.45/5) and familiarity with troubleshooting and management guidelines (4.64/5). Further training was cascaded ad hoc as on-the-job training between trained healthcare professionals and trainees.

3.2 | Closed-loop system usage

Between August 2021 and July 2022, the three closedloop systems have been used for a total of 555 days (53% of available days). The first system implemented was used for 267 days (76% of available days), while the other two systems implemented subsequently were used for 156 and 132 days (44% and 38% of available days).

3.3 | Patient characteristics

The closed-loop systems have been used by a total of 32 inpatients (mean \pm SD age 61 ± 16 years, 8 females, 24 males, BMI 28.9 ± 8.4 kg/m², HbA1c 71 ± 24 mmol/mol ($8.6\pm2.2\%$); Table 1). The median (IQR) duration of closed-loop system use per inpatient was 14 days (6, 22).

Twenty-four users (75%) had type 2 diabetes, four had diabetes secondary to pancreatic disease (inflammation or previous surgery), three had feed induced hyperglycaemia and one had steroid induced hyperglycaemia.

Just over half of the patients (56%) were on medical wards with the most common reasons for admission being a stroke or neurological issue, haematological including transplant, diabetic foot infection or sepsis (Table 2). The most common reasons for surgical inpatient admission

were abdominal surgery and transplant or intestinal failure. Approximately half (47%) of inpatients using the closed-loop system required nutrition support with enteral and/or parenteral nutrition. Corticosteroids were used by 11 patients (34%) and three patients (9%) required haemodialysis during their admission (Table 2). The median (IQR) Charlson comorbidity index was 6.^{4,9} The median (IQR) duration of hospital admission was 38 (22, 124) days.

3.4 | Glycaemic outcomes

The mean \pm SD time spent in target glucose range 3.6–10.0 mmol/L with the closed-loop system was 53.3 \pm 18.3% (Table 3). Mean sensor glucose was 10.7 \pm 1.9 mmol/L. Time spent in hyperglycaemia >10.0 mmol was 46.0 \pm 18.2% and >16.7 mmol/L was 7.6 (2.2, 15.1)%. Median (IQR) time spent in hypoglycaemia <3.9 mmol/L was 0.38% (0.00, 0.85) and <3.0 mmol/L was 0.01% (0.00, 0.19) (Table 3). The standard deviation of glucose was 3.6 \pm 1.0 mmol/L and the coefficient of variation of glucose was 33.7 \pm 6.5%. The median (IQR) total daily insulin dose was 16.2 (8.5, 33.5) units/day (Table 3).

An example of glucose control of a patient on parenteral nutrition and parenteral hydrocortisone is shown in Figure S1 during treatment with different insulin regimens.

3.5 | Safety

There were no episodes of severe hypoglycaemia or diabetic ketoacidosis in patients using the fully closed-loop

TABLE 1 Patient characteristics.

	Overall $(n=32)$
Age (years)	61 ± 16
Female sex— $n(\%)$	8 (25)
Ethnicity—n (%)	
White	23 (72)
Asian	3 (9)
Not reported	6 (19)
Body mass index (kg/m ²)	28.9 ± 8.4
HbA1c (mmol/mol) ^a	71 ± 24
HbA1c (%) ^a	8.6 ± 2.2
Duration of diabetes (years)	11 (1, 20)
Duration on insulin therapy (years)	2 (1, 14)
Charlson comorbidity index	6 (4, 9)

Note: Data are presented as mean \pm SD or median (IQR) unless otherwise stated.

^aHbA1c data were only available in 29 patients.

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TABLE 2 Admission details.

	Overall $(n=32)$
Reason for admission, n (%)	
Medical	18 (56)
Stroke/neurological	4 (13)
Haematology including transplant	4 (13)
Diabetic foot	3 (9)
Infection/sepsis	3 (9)
Cardiac	2(6)
Renal	2(6)
Surgical	14 (44)
Abdominal	8 (25)
Transplant/intestinal failure	3 (9)
Neurosurgical	1(3)
Vascular/amputation	1(3)
Orthopaedic	1(3)
Complicating factors, <i>n</i> (%)	
Nutrition support (enteral/parenteral nutrition)	15 (47)
Corticosteroids	11 (34)
Dialysis	3 (9)
Duration of admission (days)	38 (22, 124)

Note: Data are presented as n (%) or median (IQR).

TABLE 3Glucose outcomes.

	(n=32)
Time with glucose 3.9–10.0 mmol/L (%)	53.3 ± 18.3
Mean glucose (mmol/L)	10.7 ± 1.9
Time with glucose >10.0 mmol/L (%)	46.0 ± 18.2
Time with glucose >16.7 mmol/L (%)	7.6 (2.2, 15.1)
Time with glucose <3.9 mmol/L (%)	0.38 (0.00, 0.85)
Time with glucose $<3.0 \text{mmol/L}$ (%)	0.01 (0.00, 0.19)
Standard deviation of glucose (mmol/L)	3.6 ± 1.0
Coefficient of variation of glucose (%)	33.7 ± 6.5
Total daily insulin dose (units/day)	16.2 (8.5, 33.5)
Total daily insulin dose (units/kg/day)	0.22 (0.12, 1.35)
Days of closed-loop use	14 (6, 22)

Note: Data are presented as mean ± SD or median (IQR).

system (Table 4). There was one episode of ketonaemia (ketones >1.5 mmol/L) in a patient with diabetes secondary to necrotising pancreatitis and previous recurrent diabetic ketoacidosis (Table 4). The insulin pump ran out of insulin overnight and the patient was switched to intravenous insulin infusion. There were 38 episodes of glucose

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	Closed-loop $(n=32)$
Episodes of severe hypoglycaemia	0
Episodes of diabetic ketoacidosis	0
Episodes of ketonaemia >1.5 mmol/L	1
No. of patients with ketonaemia, <i>n</i> (%)	1(3)
Documented episodes of glucose <3.9 mmol/L ^a	38
No. of patients with documented glucose <3.9 mmol/L, n (%)	14 (44)
Episodes of insulin injection administration	43
No. of patients with insulin injection administration, n (%)	15 (47)

^aDocumented episodes of glucose <3.9 mmol/L measured by either fingerstick capillary testing or sensor glucose reading.

<3.9 mmol/L which occurred in 14 patients recorded in the electronic health records (Table 4). There were 43 episodes of corrective insulin injection administration which occurred in 15 patients (Table 4).

3.6 | System interruptions and discontinuations

The system was interrupted on 34 occasions during its use which occurred in 16 patients (50%). The reasons for interruptions included MRI/CT scan (n=9), transfer to the operating theatre (n=1), sensor failure or connectivity issue (n=4), insulin pump or phone battery running out (n=5), insulin pump occlusion or the pump running out of insulin (n=5), accidental device removal (n=10). The system was re-started after the cause for the interruption was resolved.

Seventeen patients (53%) discontinued using the system due to imminent discharge home, repatriation or death. Five patients (16%) discontinued closed-loop due to transfer to surgery or the intensive care unit. Closedloop was stopped in four patients (13%) as the devices kept being removed accidentally by the patient due to confusion. Three patients (9%) stopped as per patient preference (did not like having the devices attached or disliked the alarms associated with the system) and two (6%) discontinued due to low/no insulin requirements. Closed-loop was stopped in one patient (3%) due to the presence of ketones.

3.7 | Healthcare professional contacts

In total, there were 263 face-to-face contacts by the diabetes outreach team (average of 8 contacts per user) over the 12 months of closed-loop system use. These included setting up devices, replacement of devices, for example, after MRI scan, and removal of devices prior to discharge. Face-to-face contacts were predominantly for device maintenance (infusion set changes, top-up of insulin, pump battery replacement and glucose sensor changes) and also included adjustments to system settings (change to personal glucose target, non-specialist staff and/or patient education). There were 32 remote contacts made by the diabetes outreach team which included advice about managing the closed-loop system during X-ray, CT or MRI scans and plans for procedures, advice regarding changes in feeding regimens and providing reassurance regarding system status.

There were ten contacts made to a doctor which related to the closed-loop system and required remote review. There were no contacts requiring face-to-face review by a doctor.

4 | DISCUSSION

We report on the feasibility of implementing the CamAPS HX fully closed-loop system in a large teaching hospital with a dedicated diabetes outreach team in the UK.

The time to the first application of the closed-loop system was approximately 12 months from when funding was received, demonstrating some of the challenges associated with implementing new technologies within the NHS infrastructure. Training was multimodal (faceto-face workshops, online modules and by cascading within the diabetes outreach team) and there have been no concerns regarding the competency of the healthcare professionals implementing the closed-loop system. One unanticipated benefit of this project was the upskilling of diabetes nurses and dieticians not previously familiar with insulin pump and sensor technology. It was observed that training needed to be completed within a short period prior to implementation to ensure that skills were not forgotten. It is evident from the patient characteristics including a high proportion of patients receiving nutrition support and corticosteroids, the high average Charlson comorbidity index and the average length of stay of 38 days, that those patients selected to use the closed-loop system by the diabetes outreach team were those with more challenging diabetes management and/or comorbidity profile. This was done intentionally to get the most benefit from the closed-loop system both in terms of glycaemic control and also to reduce the amount of diabetes outreach team input required with insulin dose adjustments.

Although the time spent in target glucose range in this real-world implementation project was lower than that achieved in the previous clinical trials, this likely reflects the more challenging cohort of patients using the closed-loop system in this project. Furthermore, implementation in the real-world setting relies on busy ward staff noticing and escalating potential system issues (e.g. pump batteries and insulin running out) to the diabetes outreach team who work between 9AM and 5PM, compared to a research team who are able to rectify any system issues within a shorter space of time maximising system operation time. Importantly, the time spent with glucose <3.9 mmol/L was low (0.38%) and there were no episodes of severe hypoglycaemia associated with closed-loop use supporting safety of this approach in a real-world setting. Recent data from a randomised controlled trial evaluating continuous glucose monitoring (CGM) in the inpatient setting report higher rates of hypoglycaemia than we observed in our cohort with particularly challenging glucose control (patients using CGM: 0.69% time with glucose <3.9 mmol/L and 0.32% time with glucose <3.0 mmol/L; patient using finger-stick glucose: 2.15% time with glucose <3.9 mmol/L and 1.00% time with glucose <3.0 mmol/L).⁹

Informal feedback from non-specialist ward staff was positive regarding the perceived benefits on workload burden with reduced need for finger-stick glucose monitoring, ketone checks and the need to escalate glucose levels out of target range. Non-specialist ward staff were keen to be involved and learn more about the system with increased practical management such as infusion set changes and insulin refills in future phases. From our experience, an improved method of implementation of closed-loop technology may be for non-specialist ward staff to be trained to set up and manage the closed-loop devices (akin to a variable rate insulin infusion or syringe driver) to avoid delays in any device issues being resolved, and to optimise the time the system is in operation. This is being explored for the next phase.

Due to the adaptive nature of the closed-loop algorithm which learns and adjusts based on the needs of the user, patients who used the system for less than 3 days had less optimal glycaemic control than those using the system over a longer period. Patients with confusion who frequently removed devices gained the least in terms of glycaemic benefit and required the greatest input from healthcare professionals to replace devices and so consideration should be given to patient's tolerability of devices prior to commencement of closed-loop therapy.

The strengths of our project include the implementation of a regulatory-approved device in a real-world setting, delivered by the diabetes outreach team and nonspecialised ward nurses. Healthcare professional contacts were documented in a systematic way on an Electronic Health Record. The main limitation is the lack of a control group. Despite this limitation, we feel that with ongoing use of closed-loop insulin delivery and increasing experience, the glycaemic benefits and the positive impact on reducing healthcare professional burden support wider adoption of this technology in the hospital setting.

We have demonstrated that the CamAPS HX fully closed-loop system can be safely and effectively implemented in a large teaching hospital by the diabetes outreach team in complex medical and surgical inpatients with challenging glycaemic control.

AUTHOR CONTRIBUTIONS

Charlotte K Boughton, Sara Hartnell, Andrea Lake, Katy Davenport, Roman Hovorka and Vishakha Bansiya co-designed the implementation project. Charlotte K Boughton, Sara Hartnell, Aideen Daly and Candice Ward generated training material for healthcare professionals. Charlotte K Boughton, Sara Hartnell, Nicola Hobday, Andrea Lake, Katy Davenport, Aideen Daly and Vishakha Bansiya provided patient care. Roman Hovorka designed and implemented the glucose controller. Caroline Taylor and Andrea Lake supported data collection. Charlotte K Boughton undertook data analysis and wrote the report. All authors contributed to the interpretation of the results and critically reviewed the manuscript. Charlotte K Boughton and Vishakha Bansiya had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data and analyses.

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CONFLICT OF INTEREST STATEMENT

CKB has received consulting fees from CamDiab and speaker honoraria from Ypsomed. SH has served as a member of Medtronic and Dexcom advisory boards, is a director of Ask Diabetes Ltd providing training and research support in healthcare settings, and reports having received training honoraria from Medtronic and Sanofi and consulting fees for CamDiab. CW is the training and outreach manager for CamDiab and director of Edify Ltd providing e-learning functionality for the CamAPS online training platforms. RH reports receiving speaker honoraria from Eli Lilly, Dexcom and Novo Nordisk, receiving license and/or consultancy fees from B. Braun and Abbott Diabetes Care; patents related to closed-loop, and being director at CamDiab. NH, AL, KD, AD, CT and VB declare no competing financial interests exist.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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SUPPORTING INFORMATION

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

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