Protocol for the Diabetes Technology Network UK and Association of British Clinical Diabetologists' closed-loop insulin delivery audit programme

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Abstract

Background: The Association of British Clinical Diabetologists (ABCD) closed-loop audit aims to capture real-world outcomes from all who use hybrid closed-loop (HCL) insulin delivery systems in routine clinical care. In addition, NHS England has announced a pilot programme this year to expand access to HCL insulin delivery systems to people with type 1 diabetes (T1D) who are already using pump therapy and FreeStyle Libre with a HbA_{1c} ≥ 69mmol/mol (≥ 8.5%). This group is often underrepresented in current randomised control trial evidence and, vitally, the planned audit will capture their data.

Methods: The ABCD nationwide audit programme has Caldicott guardian approval and has also been approved by Confidentiality Advisory Group (CAG). Clinical teams collect anonymised user data using a secure online tool. Baseline characteristics and routinely collected outcome data at follow-up will include: assessment of glycaemic outcomes (HbA_{1c}, time in range, time below range); patient-reported outcome measures (Gold score and diabetes-related distress); and frequency of resource utilisation (hospital admissions, paramedic callouts, diabetic ketoacidosis [DKA] and severe hypoglycaemia).

Discussion: The ABCD closed-loop audit will produce an independent real-world dataset of outcomes in closed-loop users across multiple systems. These data will provide insight into the real-world benefits and challenges of HCL systems used within the NHS in England.

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Introduction

Hybrid closed-loop (HCL) insulin delivery systems combine continuous subcutaneous insulin infusions (CSII, or insulin pump therapy) with real-time continuous glucose monitoring (rtCGM) and an algorithm. The algorithm, which is held on a smartphone or within the insulin pump, receives glucose data from the rtCGM and communicates a decision to sustain, increase, decrease or suspend insulin delivery as needed to maintain glucose within a pre-specified target range.

Randomised control trials (RCTs) demonstrate improvements in HbA_{1c} and time-in-range and reductions in hypoglycaemia on closed-loop therapy compared to sensor-augmented pump therapy with low glucose suspend.[1-3] HCL systems have also been associated with improvements in diabetes distress and other quality of life metrics.[4,5] Though these results are encouraging, the people included in these trials tended to have HbA_{1c} at or close to target levels prior to commencing HCL therapy. Additionally, participants in RCTs are monitored closely for evidence of adverse events and supported at a level that may be more intensive than is generally practicable for most health services. Nonetheless, even outside RCTs HCL usage demonstrates reductions in HbA_{1c} and improvements in time-in-range across a range of currently available systems.[6,7] Whilst these publications feature large cohorts, they do not include people with elevated HbA_{1c} levels at baseline and they may include people upgrading from earlier versions of closed-loop technology (e.g. Basal-IQ to Control-IQ in the Tandem trial). Also, these real-world trials tend not to include data on important outcomes such as hospital admissions, severe hypoglycaemia and patient-reported outcomes.[6,7]

Of the 218,670 people with T1D captured by the National Diabetes Audit in England and Wales, only 1 in 10 were using insulin pump therapy.[8] Data on access to rtCGM are limited and although more than 30% of the population now use FreeStyle Libre for glucose monitoring this cannot at present be used in a commercially available HCL system.[9] It follows that the use of HCL systems until recently was limited to a group of people with diabetes who met the funding criteria for insulin pump therapy (Box 1)[10] and were able to self-fund rtCGM sensors or to meet the previously strict NHS funding criteria for rtCGM. Examples include those with recurrent severe hypoglycaemia and impaired awareness of hypoglycaemia. Real-world evidence for HCL use in a UK context is therefore lacking.

Even amongst individuals who can access pumps and rtCGM on existing criteria, some may remain on older systems where the interaction between pump and rtCGM is limited to suspending glucose in anticipation of low glucose levels – known as predictive low-glucose suspend (PLGS). An overview of HCL systems commonly encountered in UK practice at the time of writing is available for reference.[11]

The ABCD closed-loop audit launched in July 2021, the same year in which NHS England launched their HCL pilot in adults and children with T1D.[12] In line with the published diabetes technology pathway,[13] adults with T1D who were currently using insulin pump therapy and FreeStyle Libre with a HbA_{1c} ≥69mmol/mol (≥ 8.5%) were eligible to access HCL technology as part of the pilot. In addition to those included in the pilot scheme, the audit will also allow data to be collected from all existing and future HCL users, with the potential for further data collection from those who may be granted access to the systems if criteria change in future. This will include those changing from a PLGS system and those commencing HCL with other criteria such as pregnancy. There were no formal exclusion criteria in this audit.

The aim of this audit programme is to capture the routine clinical outcomes of the users of HCL systems to provide real-world insights into the safety and effectiveness of closed-loop systems.

Box 1 Current criteria for NHS insulin pump funding in adults as per NICE[8]

Continuous subcutaneous insulin infusion (CSII or 'insulin pump') therapy is recommended as a treatment option for adults and children 12 years and older with type 1 diabetes mellitus provided that:

Attempts to achieve target haemoglobin A_{1c} (HbA_{1c}) levels with multiple daily injections (MDIs) result in the person experiencing disabling hypoglycaemia. For the purpose of this guidance, disabling hypoglycaemia is defined as the repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life

OR

HbA_{1c} levels have remained high (that is, at 8.5% [69 mmol/mol] or above) on MDI therapy (including, if appropriate, the use of long-acting insulin analogues) despite a high level of care.

Audit development and methods

The ABCD audit has been developed by the ABCD Diabetes Technology Network UK (DTN-UK) steering group with expertise in diabetes technology. The data to be collected were determined by the steering group, who balanced the importance of each covariate or outcome in determining the safety and efficacy of the systems with the data that are likely to be routinely collected within participating diabetes clinics (and therefore available to audit). A secure online tool has been developed to collect the data.

Centres are required to register in order to access the tool, and all individuals who request access are validated before access is granted. Site type is also recorded, which may in future allow differentiation between community and acute hospital-based services. Centre lead details are stored on a secure NHS server and managed by the ABCD audit administrator. The audit has been advertised by ABCD so that any centre with closed-loop insulin system users can choose to participate. As such, the audit has the potential to capture data from a broad range of individuals, which might include people transitioning from PLGS; MDI combined with is/rtCGM sensors or those previously using a pump in isolation.

To ensure anonymization, the patient identifier is encrypted and only the encrypted identifier is stored by the system. Users in the submitting site can search for HCL users from their own service using the NHS number, but they can only access the audit tool from within the secure NHS computer network. Outside the submitting centre, those analysing the data only see the encrypted patient identifier. Further, the date of birth is converted to age by the system and only the age is stored. Data can be collected contemporaneously and entered directly into the online tool or, if more convenient, can also be collected in an editable PDF or paper form for later upload. Data are entered by clinicians at each site, and they are responsible for ensuring the validity of the data. The paper forms are included in appendix 1&2 (online at www.bjd-abcd.com).

Whilst the audit is intended to be prospective from the time of commencing HCL system use, data may also be collected retrospectively should this be required for any existing users. However, patient-reported outcome measures cannot be retrospectively recalled and therefore will only be available if documented in the medical notes at a point contemporaneous to the baseline visit date.

Approvals

The NHS supports clinical audits and mandates them to collect data and outcomes to help improve the service and to evaluate the use of therapies in real-world practice.[9] As a clinical audit, this programme only collects anonymised, routinely available clinical data. Data or tests not performed routinely were not required for this audit. As the audit comprises routinely collected healthcare data only, there is no requirement for approval by a research ethics committee.[14] The ABCD nationwide audit programme, which includes this audit, has Caldicott guardian approval and has also been approved by Confidentiality Advisory Group.[15]

Clinical outcomes – baseline data

A range of clinical parameters will be collected at baseline, prior to HCL initiation. The baseline date will be defined as the date

of HCL commencement. Baseline characteristics include age, ethnicity, diabetes type, diabetes duration and postcode-derived index of multiple deprivation decile as an assessment of socio-economic status,[16] and information about the HCL system and insulin being used. Retinopathy status, including grading where available, will be recorded. The frequency of hospital admissions, paramedic callouts and severe hypoglycaemia (not resulting in paramedic response but requiring third party assistance) in the 12 months before starting the HCL system will be captured alongside HbA_{1c}, weight and height. Two validated, routinely used scoring systems will be utilised: Gold Score to assess hypoglycaemia awareness and the Diabetes Distress Score.[17,18] FreeStyle Libre glycaemic metrics, including time in range, time below range, time above range, glucose management indicator, scan frequency and coefficient of variation, will be recorded at baseline, using ranges defined by international consensus.[19]

Clinical outcomes – follow-up data

The primary measure of interest is change in laboratory-derived HbA_{1c}. Changes in weight, body mass index (BMI), CGM metrics, user-reported outcome measures and frequency of clinical events are reported as secondary outcomes (Table 1). Glucose management indicators (GMI) will not be used in lieu of laboratory HbA_{1c}; GMI is captured as its own data point. Although analysis will be performed at intervals, as an audit of clinical care, follow-up frequency will be determined by the clinical teams responsible, based on clinical need. At follow-up the same clinical outcomes that were captured at baseline will be evaluated where available through patient reporting and review of clinical systems. Sensor glucometrics will be extracted from the relevant HCL system for the 14 days preceding any follow-up.

Statistical analysis

Data will be assessed for accuracy and completeness. Values thought to be erroneous will be flagged for review at the centre submitting the data. Data will be cleaned and analysed using Stata SE 16. Analysis will utilise paired data from individuals with baseline and follow-up at the relevant time interval. The numbers with missing data at baseline and follow-up will be reported.

Stratified analysis by HbA_{1c} level, age, HCL system, type of insulin and ethnicity subgroups (for example) will be performed for each outcome. Where users have changed system or insulin the HCL system or insulin used at follow-up will be used for stratification purposes. Following the initial analysis, further analyses will also include subgroup comparisons between those accessing HCL via the NHS England pilot and those using pre-existing criteria or any new criteria that may be announced in future.

Continuous and numerical variables including event rates, Gold Score and DDS2 will be assessed for normal distribution. Changes in normally distributed continuous covariates will be assessed using paired T-Tests. Wilcoxon Signed Rank tests will be used to assess changes in non-normally distributed data. Stratified analyses will be performed for these outcomes, utilising ANOVA for normally distributed variables or the Kruskal-Wallis test for non-normally distributed variables. Results for pairwise comparisons between subgroups will be Bonferroni-corrected. Comparisons between those switching systems and those remaining on a single system will be performed as a sensitivity analysis.

Adjustment of change in HbA_{1c} and weight from baseline for baseline characteristics and change in other covariates will be performed using a multiple linear regression model to correct for key covariates determined *a priori* as follows: baseline HbA_{1c} /weight, gender, age, duration of diabetes, deprivation level, HCL system and ethnicity.

Table 1. Data collected as part of the Association of British Clinical Diabetologists' closed-loop audit programme

	Data to be collected
User registration *Notes: these details are only collected at baseline*	Age Gender Ethnicity Index of multiple deprivation decile Type of diabetes Date of diabetes diagnosis Date commenced pump therapy
User measurements	HbA_{1c} (mmol/mol) Weight (kg) Body mass index (kg/m$^{2)}$ Height (m)
System details	Date of closed-loop commencement (**baseline only**) Record of any changes/discontinuation of system (**follow-up only**) Funding source • NHS England pilot • Pre-existing criteria (e.g. hypoglycaemia) • Other Closed-loop system details Insulin details • Type • Total daily dose
Clinical events *Note: over the preceding 12-months at baseline and since last review at at follow-up*	Retinopathy • Date of last review • Grading Admissions and paramedic callouts • Hyperglycaemia/diabetic ketoacidosis • Hypoglycaemia • Other diabetes-related (e.g. foot infection) • Other Severe hypoglycaemia (requiring 3rd party assistance but not resulting in admission or paramedic callout)
CGM metrics *Note: over the preceding 14 days, ranges as defined by Battelino et al.[14]*	% Time above range (over 13.9mmol/L) % Time above range (10.1-13.9mmol/L) % Time in range (3.9-10mmol/L) % Time below range (3.0-3.8mmol/L) % Time below range (below 3.0mmol/L) Coefficient of variation Number of scans/day (**baseline only**) % Time in closed-loop (**follow-up only**) Glucose management indicator
User-reported outcome measures	Gold Score for hypoglycaemia awareness[12] Mean Diabetes Distress Score (DDS)[13] User or caregiver opinion of closed-loop system (7-point Likert scales) • Impact on quality of life • Recommendation to other people with diabetes
Free-text responses	Healthcare professional comments User/caregiver comments

Key messages

- The DTN-UK/ABCD Closed-Loop audit builds on established real-world methods
- This audit will aim to capture outcomes in the real-world from Closed-Loop insulin delivery system usage
- Results will be published later this year

The total number of clinical events (admissions, paramedic call-outs, DKA and severe hypoglycaemia) and number of people experiencing these events, at baseline and follow-up (adjusted pro rata) will be compared using Chi-squared tests. Events per person/year rates will be calculated at baseline and follow-up to facilitate comparison. Mean Likert scores for user and caregiver opinions will be reported. The frequency of any reported adverse events will be reported.

Discussion

This ABCD clinical audit will be one of the largest independent audits of routine clinical outcomes to capture real-world data from multiple HCL systems. It builds on the broad expertise and experience of the ABCD audit programme, which has a record of providing novel insights from real-world clinical practice. The group included in the NHS England pilot are of particular interest because they are individuals with higher baseline HbA_{1c} levels, a group often not included in RCTs.

Strengths and limitations

The strengths of this audit and proposed analyses lie in the well-tested design which will produce findings reflective of real-world practice. Local areas will also be able to access their own data to review their outcomes, improve standards and potentially to advocate for access to HCL technology in their area. This will be the first independent audit to incorporate multiple different systems being used in the real world. Our initial analysis will be the first to focus on a cohort with elevated HbA_{1c} levels at baseline, who are poorly represented by the current RCT and observational evidence. It will also capture a broad range of data, including assessment of clinical outcomes such as hospital admission rates and retinopathy data which are not currently reported in other real-world studies. Future analysis featuring a broader range of HCL users, accessing the technology through various criteria, will allow for greater generalisability but will also provide the opportunity to contrast the real-world outcomes in clinically different subgroups.

Despite these strengths, the clinical audit design of this work can introduce problems if there are incomplete or erroneous data. Regular review of the data will allow for troubleshooting of suspected erroneous values or missing key data to minimise this risk. Finally, whilst inclusion and analysis of outcomes in those on the NHS England HCL pilot will produce novel data, it may still fail to answer some questions. Chiefly, because the pilot is only accessible to those already on technology (FreeStyle Libre and an insulin pump) it will not provide an insight of the potential benefits of taking someone with an elevated HbA_{1c} directly from multiple daily injections to HCL or from pump (without sensor) to HCL. However, inclusion of HCL users beyond the NHS pilot should overcome this limitation, by providing data from those transitioning from multiple daily injection therapy to HCL.

Conclusion

This audit programme has the potential to provide a large real-world dataset of HCL therapy in those living with T1D and will be key in informing the future roll-out of this technology. Whilst there are limitations to its design, it will provide a rich data set with a focus on those accessing technology via the NHS England pilot and beyond – groups from whom current data are limited. Ongoing adoption and input into the audit programme will allow future surveillance and reporting of HCL outcomes across the UK and will allow us to compare those accessing the technologies via multiple different criteria.

Conflict of interest TSJC has received speaker fees and/or support to attend conferences from NovoNordisk, Sanofi and Abbott Diabetes Care. TPG has received personal fees from NovoNordisk, Sanofi Aventis, Mundipharma Pharmaceuticals, Dexcom, Abbott Diabetes Care and Eli Lilly. EGW has received personal fees from Abbott Diabetes Care, Dexcom, Eli Lilly, Glooko, Insulet, Medtronic, Novo Nordisk and Sanofi Aventis. PC has received personal fees from Abbott Diabetes Care, Dexcom, Eli Lilly, Insulet, Medtronic, Novo Nordisk, Sanofi Aventis and Glooko. AL has received personal fees from Abbott Diabetes Care, Dexcom, Insulet, NovoNordisk, Sanofi Aventis and research support from Abbot Diabetes Care and Novo Nordisk.

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References

1. Tauschmann M, Thabit H, Bally L *et al*. Closed-loop insulin delivery in suboptimally controlled type 1 diabetes: a multicentre, 12-week randomised trial. *Lancet* 2018;**392**(10155):1321-9. https://doi.org/10.1016/S0140-6736(18)31947-0
2. Collyns OJ, Meier RA, Betts ZL *et al*. Improved glycemic outcomes with Medtronic MiniMed Advanced Hybrid Closed-Loop Delivery: results from a randomized crossover trial comparing automatediInsulin delivery with predictive low glucose suspend in people with type 1 diabetes. *Diabetes Care* 2021;**44**(4):969-75. https://doi.org/10.2337/dc20-2250
3. Brown S, Kovatchev B, Raghinaru D *et al*. Six-month randomized, multicenter trial of closed-loop control in type 1 diabetes. *N Engl J Med* 2019; **381**:1707-17. https://doi.org/10.1056/NEJMoa1907863
4. Adams RN, Tanenbaum ML, Hanes SJ *et al*. Psychosocial and human factors during a trial of a hybrid closed loop system for type 1 diabetes management. *Diabetes Technol Ther* 2018;**20**(10):648-53. https://doi.org/10.1089/dia.2018.0174
5. Beato-Víbora PI, Gallego-Gamero F, Lázaro-Martín L, Romero-Pérez MDM, Arroyo-Díez FJ. Prospective analysis of the impact of commercialized hybrid closed-loop system on glycemic control, glycemic variability, and patient-related outcomes in children and adults: a focus on superiority over predictive low-glucose suspend technology. *Diabetes Technol Ther* 2020; **22**(12):912-9. https://doi.org/10.1089/dia.2019.0400
6. Knoll C, Peacock S, Wäldchen M *et al*. Real-world evidence on clinical outcomes of people with type 1 diabetes using open-source and commercial automated insulin dosing systems: A systematic review. *Diabetic Medicine* 2021:e14741. https://doi.org/10.11111/dme.14741
7. Breton MD, Kovatchev BP. One year real-world use of the Control-IQ ad-

vanced hybrid closed-loop technology. *Diabetes Technol Ther* 2021; **23**(9):601-8. https://doi.org/10.1089/dia.2021.0097
8. NHS Digitial. National Diabetes Audit, 2019-20 , Type 1 Diabetes 2021 [Available from: https://digital.nhs.uk/data-and-information/publications/statistical/national-diabetes-audit/national-diabetes-audit-2019-20-type-1-diabetes.
9. Valabhji JKP, Newbound T. Type 2 diabetes prevention programme and type 1 diabetes glucose monitoring (Letter). NHS England, 2020.
10. National Institute for Health and Care Excellence. TA151. Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus, 2008.
11. Hartnell S, Fuchs J, Boughton CK, Hovorka R. Closed-loop technology: a practical guide. *Practical Diabetes* 2021;**38**(4):33-9. https://doi.org/10.1002/pdi.2350
12. NHS England News. Patients with type 1 diabetes to get artificial pancreas on the NHS 2021 [Available from: https://www.england.nhs.uk/2021/06/patients-with-type-1-diabetes-to-get-artificial-pancreas-on-the-nhs/.
13. Leelarathna L, Choudhary P, Wilmot EG *et al*. Hybrid closed-loop therapy: Where are we in 2021? *Diabetes Obesity Metab* 2021;**23**(3):655-60. https://doi.org/10.1111/dom.14273
14. Oxford University Hospitals NHS Trust. Is my project research? 2021 [Available from: https://www.ouh.nhs.uk/researchers/planning/is-it-research/.
15. Health Research Authority. Confidentiality Advisory Group 2021 [Available from: https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/.
16. Department for Levelling Up HaC. English indices of deprivation 2020 [Available from: https://www.gov.uk/government/collections/english-indices-of-deprivation.
17. Gold AE, MacLeod KM, Frier BM. Frequency of severe hypoglycemia in patients with type I diabetes with impaired awareness of hypoglycemia. *Diabetes Care* 1994;**17**(7):697-703. https://doi.org/10.2337/diacare.17.7.697
18. Fisher L, Glasgow RE, Mullan JT, Skaff MM, Polonsky WH. Development of a brief diabetes distress screening instrument. *Ann Fam Med* 2008;**6**(3):246-52. https://doi.org/10.1370/afm.842
19. Battelino T, Danne T, Bergenstal RM *et al*. Clinical targets for continuous glucose monitoring data interpretation: recommendations from the International Consensus on Time in Range. *Diabetes Care* 2019:dci190028.

Appendix 1.

ABCD Closed-Loop Audit: Baseline Form

Association of British Clinical Diabetologists

In addition to this form please complete a follow-up form at the first visit if the user has been using the system for more than 3 months.

Patient identifiable information in this section will be encrypted to ensure anonymity and only accessible to the submitting centre

Name

NHS Number

Date of Birth

Male ☐ Female ☐ Index of multiple deprivation decile

Please look this up using the persons full UK postcode and enter IMD decile above using the following website: https://www.fscbiodiversity.uk/imd/

Type of diabetes
Type 1 ☐
Type 2 ☐
MODY ☐
Other

Date of Diagnosis ☐ month ☐ year

Date commenced pump therapy (best estimate)
☐ month ☐ year

Ethnicity
White – British ☐
White - Other ☐
Asian ☐
Black ☐
Mixed ☐
Other ☐

Height ☐ m OR ☐ ft/in

Weight ☐ kg OR ☐ st/lb

Is this form being completed before or after commencement?
Before ☐ After ☐ (note: If >3months after commencement please complete follow-up form if data)

Date of commencement of closed-loop (if known)
☐ month ☐ year

Is the system funded under NHS England pilot criteria?
(pump user AND FreeStyle Libre AND HbA1c ⩾69mmol/mol/8.5%)
Yes ☐ No ☐

If no, how is the system funded?
Self-funded ☐
NHS funding under previous criteria ☐ → If NHS funded complete box

Is the pump NHS funded?
Yes ☐ No ☐

Under which criteria is CGM funded
Disabling hypoglycaemia ☐
Pregnancy ☐
Paediatrics ☐
Other

Does this person have retinopathy?
No retinopathy ☐

Is the patient under Ophthalmology care?
No ☐ Yes ☐ → If yes, please comment on current degree of retinopathy

If NHS eye screening programme grading known, please complete the following
Left: R0 ☐ R1 ☐ R2 ☐ R3 ☐ M0 ☐ M1 ☐ Date of screen ☐ *approx. date if not sure*
Right: R0 ☐ R1 ☐ R2 ☐ R3 ☐ M0 ☐ M1 ☐

Has this person undergone structured education (e.g. DAFNE, BERTIE)?
No ☐ Yes ☐ Not to my knowledge ☐

Which system will be used?
Medtronic 670G ☐
Medtronic 780G ☐
Tandem Control IQ ☐
CAMP APS FX ☐
Medtrum ☐
Other

Which insulin will be used?
Novorapid ☐ Fiasp ☐
Humalog ☐ Lyumjev ☐
Apidra ☐
Other

Total daily insulin dose
☐ units

Appendix 1. continued

Healthcare utilisation (please complete in retrospect for the 12 months prior to commencing closed-loop)

	Hyperglycaemia/DKA	Hypoglycaemia	Other (diabetes)	Other
No of hospital admissions				
Dates				
No of paramedic callouts (not resulting in admission)				
Dates				

Number of hypoglycaemic episodes requiring third party assistance but not paramedic call outs ☐ Don't know ☐

Dates

Gold Score (prior to closed-loop, DO NOT enter recollected information, only record if previously documented or if this form is being completed prior to commencement) ADULT USERS ONLY

Ask the person: Do you know when your hypos are commencing?
1=always, 7=never

1 2 3 4 5 6 7

HbA1c (for the 12 months prior to commencing closed-loop)
Note: must have lab HbA1c within 3 months of commencing closed-loop

	Dates	Values (mmol/mol)
Lab HbA1c		

Glucose management indicator (14 days)

Glucose data *from FSL (14 days pre-CL)*

Time >13.9mmol/L %
Time in range % (3.9-10mmol/L)
Time below range % (<3.9mmol/L)
Time <3mmol/L %

Coefficient of variation

Number of scans/day

Diabetes distress scale (prior to closed-loop, DO NOT enter recollected information, only record if previously documented or this form is being completed before commencement)
ADULT USERS ONLY

Question	Not a problem	A slight problem	A moderate problem	A somewhat serious problem	A serious problem	A very serious problem
1. Feeling overwhelmed by the demands of living with diabetes	1	2	3	4	5	6
2. Feeling that I am failing with my diabetes routine	1	2	3	4	5	6

Healthcare professional comments
This box can be used for any additional comments. Please do not include patient identifiable information.

Appendix 2.

ABCD Closed-Loop Audit: Follow-up Form

In addition to this form please complete the baseline form if needed.

Patient identifiable information in this section will not need to be entered into the tool, the previous encrypted baseline entry is stored and can be found using the search function and a new visit created

Name

NHS Number

Date of Birth

Height m OR ft/in
(record height again if Paeds)
Weight kg OR st/lb

Is the patient still using a commercial closed-loop?
Yes ☐ No ☐ → complete box if "No"

Date completed

Reasons for stopping

Current insulin in use?
Novorapid ☐ Fiasp ☐
Humalog ☐ Lyumjev ☐
Apidra ☐ Other ☐

Current closed-loop system? *Please note, if changed to DIY system different options will be presented in the tool*
CAM APS FX ☐ Tandem Control IQ ☐ Medtronic 780G ☐
Medtronic 670G ☐ Medtrum ☐ Other

Healthcare utilisation (since commencing closed-loop if first visit, otherwise since previous review)

	Hyperglycaemia/DKA	Hypoglycaemia	Other (diabetes)	Other
No of hospital admissions				
Dates				
No of paramedic callouts (not resulting in admission)				
Dates				

Number of hypoglycaemic episodes requiring third party assistance but not paramedic call outs — Don't know ☐
Dates

Has this person had updated retinopathy results since last review? No ☐ Yes ☐ → if yes, complete below

No retinopathy on most recent review ☐

Is the patient under Ophthalmology care?
No ☐ Yes ☐ → If yes, please comment on current degree of retinopathy

If NHS eye screening completed and results known since last visit, please enter grading:
Left: R0 ☐ R1 ☐ R2 ☐ R3 ☐ M0 ☐ M1 ☐ Date of screen *approx. date if not sure*
Right: R0 ☐ R1 ☐ R2 ☐ R3 ☐ M0 ☐ M1 ☐

Any other adverse events?
This should include any incidents of failed devices, issues with the personal diabetes manager, worsening of complications

Gold Score ADULT USERS ONLY
Ask the person: Do you know when your hypos are commencing?
1=always, 7=never

1 2 3 4 5 6 7

Appendix 2. continued

HbA1c (since commencing closed-loop, or since previous follow-up)

	Dates	Values (mmol/mol)
Lab HbA1c		

Glucose management indicator (14 days)

Glucose data *for the last 14 days*

Time >13.9mmol/L %

Time in range % (3.9-10mmol/L)

Time below range % (<3.9mmol/L)

Time <3mmol/L %

Coefficient of variation

%time in closed-loop

User/Caregiver opinion of closed-loop

Would they recommend closed-loop to other people with diabetes?

Not recommend at all — Recommend extremely highly

1 2 3 4 5 6 7

What Impact would they rate closed-loop has had on their quality of life?

Extremely negative impact — Extremely positive impact

1 2 3 4 5 6 7

Diabetes distress scale DO NOT enter recollected information, only record if documented or if this form is being completed prospectively. ADULT USERS ONLY

Question	Not a problem	A slight problem	A moderate problem	A somewhat serious problem	A serious problem	A very serious problem
1. Feeling overwhelmed by the demands of living with diabetes	1	2	3	4	5	6
2. Feeling that I am failing with my diabetes routine	1	2	3	4	5	6

Healthcare professional comments

This box can be used for any additional comments. Particularly, in paediatric users, it might be appropriate to comment on concerns around quality of life or hypoglycaemia awareness no assessed using the above if collected during routine clinical practice. Do not enter patient identifiable information in this box.

User/Caregiver comments Do not enter patient identifiable information in this box.