Healthcare Improvement Scotland | SHTG Advice on health technologies

Patient Organisation Submission Form

Subject of SHTG Assessment

Closed loop systems and the artificial pancreas for type 1 diabetes mellitus (T1DM)

Name of patient organisation

IPAG Scotland

Health/medical conditions represented

Type 1 diabetes

Contact name for this submission

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Role of contact person

Chair

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Website

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Date of submission

30/09/2021

Please complete the SHTG Declaration of Interest form.

Please complete this form using the accompanying guide and do not include patient identifiable information.

Accessible Language: Where not specifically required for scientific/technical explanation, please use plain language, explaining acronyms and other non-lay terms.

Please note that the information submitted on this form will be held by the SHTG in accordance with Healthcare Improvement Scotland's policies. This information may be published on the SHTG website or disclosed to third parties in accordance with the Freedom of Information (Scotland) Act 2002 (FOISA).

1. Tell us about the sources you used to gather information for this submission. (See page 6 of guidance.)

500 words maximum

IPAG Scotland is a constituted group of volunteers which was set up in 2008 to campaign for better NHS access to insulin pumps and other diabetes technology. The group's aim was to improve awareness of tech options for both patients and clinical teams, and to ensure equity of access to diabetes technology for all people in Scotland who would benefit from it. The formation of the group resulted from the frustrations our members were experiencing due to extremely limited access to insulin pumps, and lack of familiarity with the various insulin pump technologies among clinical teams.

IPAG administers several tightly moderated, private, social media groups dedicated to Type 1 diabetes and its issues for people with the condition. The most used and most populated

group is Type 1 Diabetes in Scotland (Facebook). In addition to these groups, we have included information from other tightly moderated private Social Media groups whose remit involves Diabetes technology

The IPAG administered groups have a combined membership of over 4,000 members.

The primary sources of data for this submission are as follows:

Patient Information and Feedback

1. **Social media**
   Several social media groups set up by IPAG which are all private groups. Our members are encouraged to ask questions, raise concerns and seek help with no question being considered silly.
   Using members' names and data from our Facebook groups is prohibited and many members do not provide us with information relating to their locations or health board area for privacy reasons.
   We can however provide details of typical questions asked by many which include:
   - *How do I access an insulin pump?*
   - *Can I get CGM funding in Scotland?*
   - *What are the eligibility criteria for pumps/CGM in Scotland?*
   - *I'm due a pump upgrade. What is the best option?*
   - *My clinic says I'm not eligible and don't meet the criteria – but I don't know what the criteria are?*

2. **Diabetes Charities**
   IPAG Scotland has a working relationship with JDRF (Input JDRF) who have campaigned for better access to diabetes technology in other parts of the UK.
   Diabetes Scotland – IPAG Scotland members are involved with the Diabetes Scotland Tech collective which is also campaigning for improved access to diabetes tech.

3.**The Scottish Diabetes Group – (Diabetes in Scotland)**

Data and information sources include:

- The Scottish Diabetes Survey 2019
- Diabetes Improvement Plan – Diabetes Care in Scotland – Commitments for 2021-2026.

4. Patient Enquiries to IPAG

IPAG is contacted directly by people who have approached them seeking help to obtain diabetes technology. IPAG also receives referrals from JDRF.

IPAG Scotland does not carry out surveys, issue questionnaire or collect personal data.

DEFINITIONS:

BG – Blood glucose level. Normal range is conventionally defined as 3.9-10.0 mmol/L.

Hypoglycaemia – low blood glucose (below 3.9 mmol/L)

Hyperglycaemia – high blood glucose (above 10.0 mmol/L)

HbA1c – haemoglobin A1c, a measure related to average BG over the previous 3 months.

Fingerstick testing - A lancet is used to prick a finger to obtain a drop of blood which is applied to a test strip and BG levels are measured using handheld meter

Flash Glucose Monitor – a sensor inserted subcutaneously records interstitial glucose levels continuously. For a record of the readings over the previous 8 hours the user scans the external part of the sensor with a reader or mobile phone.

CGM – *Continuous Glucose Monitor* – a sensor inserted subcutaneously monitors interstitial glucose levels continuously. A small transmitter attached to the external part of the sensor sends readings to a receiver (e.g., insulin pump or mobile phone) in real time.

APS – *Artificial Pancreas System* consisting of an insulin pump, CGM and an algorithm (running on either the pump, a handheld controller or a mobile phone) that regulates insulin delivery automatically. Sometimes referred to as a "Closed Loop".

2. What is the health condition and how does it affect the day-to-day lives of patients and their carers? (See page 7 of guidance.)

500 words maximum

Type 1 diabetes (T1D) is a lifelong, autoimmune condition that can be diagnosed at any age. New diagnoses are equally split between adults and children.

According to the Scottish Diabetes Survey 2019 there were 33,452 people with Type 1 diabetes in Scotland.

Treatment

T1D is treated with insulin which is essential to facilitate the ongoing metabolic activities of the body (basal insulin) and to cover the digestion and absorption of all carbohydrates ingested (bolus insulin).

Insulin can be administered in two different ways:

- **Multiple daily injections** - several insulin injections a day (1 or 2 long acting or basal insulin) and bolus injections of short acting insulin (bolus insulin) at mealtimes. Correction doses may also be required to bring blood glucose levels into range when they rise unacceptably. A person with diabetes will inject a minimum of 5 times a day every day and many inject more often.
- **Insulin pump** – uses a cannula (that is changed by the user every 2-3 days) to deliver insulin. The pump settings are entered by patient with support from their clinical team, to deliver basal insulin at a programmed rate, with additional mealtime doses (boluses) and corrections at the touch of a button.

Insulin must be administered to cover *all* food containing carbohydrates (from a snack to a large meal). People with T1D need to know the carbohydrate content of all foods eaten and understand how quickly different foods are digested.

Blood Glucose Management

Hypoglycaemia is dangerous and inconvenient. Symptoms include sweating, dizziness, shaking or trembling, mood changes, irritability, loss of concentration, and can severely affect ability to carry out normal daily activities. Hypoglycaemia can lead to seizures, accidents and loss of sleep. Driving with low BG can lead to prosecution, with people who have reduced or no hypoglycaemia awareness precluded from some occupations and not permitted to drive.

Hyperglycaemia symptoms include thirst, increased need to urinate, tiredness, blurred vision, nausea, brain fog and muscle weakness.

Long term hyperglycaemia is the main driver of macro and micro vascular damage resulting in diabetes complications such as blindness, kidney disease etc. Hyperglycaemia causes anxiety for patients and their families.

To avoid unwanted BG deviations, patients must test often. “Fingerstick” blood testing only reports the BG level at the current time of testing. Flash Glucose monitoring sensors provide a backwards facing report on BG levels for the previous 8 hours. BG test or scan results often require follow up – e.g., eating carbohydrates (carbs) to raise BG, administration of extra (correction) insulin to reduce BG with follow up testing to confirm that the action taken has been effective. CGM systems send BG readings continuously (in real time) can provide audible advanced warnings if levels are trending towards hypo- or hyperglycaemia.

Theoretically, it might be possible to maintain blood glucose (BG) levels at normal (non-diabetic) levels given an accurate estimate of basal insulin requirements, accurate carb counting and bolus dosing. In practice, few insulin users are able to achieve this. Using carb values and a pre-defined ratio to work out insulin doses by mental arithmetic means errors are likely – especially when BG levels are low and concentration impaired.

Basal insulin requirements are not constant but vary with time-of-day and are strongly impacted by even moderate exercise, hormonal changes, illness, stress and other variables. Exercise can be challenging, requiring careful, time-consuming management involving both insulin adjustments and food

Shockingly, according to the most recent (2019), Scottish Diabetes Survey, only 26.5% of people with T1D achieve an HbA1c) of below 58 mmol/mol, which is considered to represent the *minimum* standard for good control.

Nighttime

Maintaining BG levels within the normal range whilst asleep, particularly avoiding potentially life-threatening hypoglycaemia, is challenging. Many people with diabetes wake themselves once or twice every night to test either with a fingerstick + meter or by manually scanning a Flash glucose sensor.

Prolonged periods of hypoglycaemia overnight can lead to headaches and impaired function the next day. Automated artificial pancreas systems (APS) with their ability to adjust insulin dosing and predictive alarms are vital to facilitate optimal overnight BG levels with minimal intrusion to quality of life.

Paediatrics

Parents provide 24/7 unseen care. To keep children safe and healthy, it is common for parents to get up 2-3 times per night to do a BG test (fingerstick or Flash scan) on a sleeping child. Depending on the outcome, rescue carbohydrates may be necessary to raise blood glucose or an insulin correction dose by injection or by an insulin pump if BG levels are too high. CGM is an important tool with BG levels uploaded to the cloud in real time so that levels can be remotely followed using a smartphone. This allows parents to check their child's levels (and receive alarms) from their own bed. With an APS system, BG levels are automatically adjusted to keep the child safe obviating the need for parental intervention and reducing night-time alarms and loss of sleep for both child and parents. The automatic adjustments carried out by CGM also reduce interruptions in a child's education by keeping their BG stable during the school day and reducing the need for interventions which may require a child to leave class or parents to be called to school.

3. What do patients and carers want from the health technology? (See page 8 of guidance.)

400 words maximum

Every day with Type 1 diabetes is different. A study from Stanford University in 2014 stated that people with diabetes must make 180 extra decisions a day and patients and carers want this to stop. At least 42 different lifestyle, physiological, psychological and social causes affecting BG levels have been identified (https://diatribe.org/42-factors-affect-blood-glucose-surprising-update)

Artificial Pancreas Systems (APS)

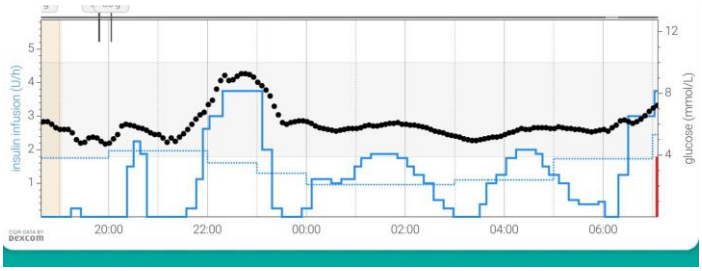
Continuous Glucose Monitoring (CGM) is an integral part of an APS or closed loop system. Insulin pump manufacturers and others have developed advanced algorithms that automate insulin delivery, adjusting insulin delivery in real time whenever changes are detected by CGM. The CGM system provides BG readings at 5-minute intervals so the insulin pump can adjust doses in response to the sensor reading, reducing the need for the patient to act. There are currently tens of thousands of Closed Loop users worldwide. Users still need to bolus for food, but the systems are remarkably efficient at maintaining BG at flat and at non-diabetic levels, particularly overnight.

APS technology helps patients by:

- Simplifying diabetes management by reducing the need for active interventions (e.g., BG tests, correction insulin doses or food)

- Managing their condition continuously in real time with less personal input which reduces disruption to working lives and education
- Enabling patients to live life in the same way as their peers, safely, without fear, and less anxiety and stress
- Allowing a good night's sleep; reducing night-time hypos and post-hypo symptoms such as brain fog or tiredness
- Giving automatic dose adjustments to reduce hypoglycaemic and hyperglycaemic events and adjusting for miscounted carbohydrates
- Alarms and alerts to notify patients/carers and patients of the need to act
- Reducing the requirement for clinic visits which can disrupt working lives (with possible loss of earnings) and education
- Giving parents confidence that their child's diabetes will be safely managed whilst they are at school as well as reducing the need for parents to be on call when BG excursions occur.

The figure below (https://www.diabettech.com/camaps-fx/camaps-a-month-in-review/) shows a snapshot illustrating a single night's use. Black dots show BG and the solid blue line insulin delivery. The number and frequency of changes set by the algorithm are remarkable. Even the most skilled user could not replicate this manually, illustrating the power of automated insulin delivery.



A young IPAG contact commented that he would have to scan a Flash glucose sensor 280 times a day and adjust his insulin doses accordingly to achieve the same result that an APS can achieve automatically. Using only fingerstick or Flash glucose testing to achieve the same result as an APS system is impossible.

In surveys of APS users an overwhelming number identify freedom from overnight hypoglycaemia and unbroken sleep as the most important benefits of these systems.

The ability of APS systems to autocorrect and adjust background insulin dosing in accordance with BG levels is the biggest attraction for prospective users. This hugely reduces the burden for people with diabetes.

4. What difference did the health technology make to the lives of patients that have used it? (Leave blank if you didn't make contact with anyone who had experience of the health technology.) (See page 9 of guidance.)

500 words maximum

1. **With CGM**: Less need to check glucose levels either by manually scanning a sensor or by a fingerstick. Continuous readings to smartphone are available with most systems. The system is working in the background to keep the patient safe.
2. **Fewer fingersticks** – the most popular CGM systems require either no fingersticks or the occasional test to check the sensor.
3. Users can see the often-unanticipated (and otherwise unknown) changes in BG levels and react early to fix problems.
4. **Real-time early warning** when BG is going out of range enabling prevention of highs and lows with remotely and locally accessed historical data and information highlighting anomalies and patterns so that action can be taken to prevent future excursions. Better understanding improves management.
5. **Customisable alerts and alarms** help to keep the user on top of their diabetes management by reducing hypos along with alert sharing with carers and parents.
6. **Time in Range** (TIR) is the length of time a person spends with their blood glucose levels in the target range (conventionally defined as 3.9 – 10 mmol/l).

   Published studies (based on real user data) for the three APS systems available on pump models currently approved for use in Scotland report average TIR figures of 76% for Medtronic 780G; 78% for Tandem C-IQ and 83% for CamAPS (Collins et al, Diabetes Care 2021; Pinckser et al Diabetes Tech & Ther 2021; Fuchs et al BMJ Open 2021). For conventional pump therapy (even with CGM) the numbers were typically 50-55% across the studies.

   Anecdotally, our contacts report not only improved TIR and HbA1c, but notably a greatly reduced need for intervention (no need to constantly micromanage BG levels) and a generally improved level of wellness, ability to work effectively and lead a more normal life. Improved sleep and near normal overnight BG levels are universally identified as one of the most important changes to their wellbeing by APS users.

7. **Education -** Our contacts report that children's performance at school and in exams is greatly improved by the lack of disruption caused by unwanted BG swings.

8. **Mental Health** – Many people with Type 1 diabetes experience issues with their mental health resulting from the overwhelming burden of self-managing their condition.
   The management of diabetes is hard work and "diabetes burn-out" is well known, referenced and can affect many people with the condition. Burn-out may result in people "turning off" from management of their condition, e.g., paying less attention to diet, blood glucose testing and attending diabetes appointments.
   Access to mental health support is limited in Scotland and we believe that by improving access to APS technology with the associated reduction in stress and anxiety for both patients, their carers and their families, there will less need for people to be referred for support with their mental health.

   Patients experience lower levels of anxiety and increased confidence because they know their APS is working in the background and can autocorrect insulin doses without any input or decision making from themselves.

   In summary – easy access to the best technological options improves quality of life.

5. Additional information you believe would be helpful for SHTG to consider. (See page 9 of guidance.)

300 words maximum

1. **Technology currently funded by NHS Scotland**

   Because all insulin pump models on the NHS Scotland Procurement List can either already be used as an integrated APS system or will have that ability soon, no significant investment in more expensive pump technology will be needed.

   Currently, access to CGM via NHS funding in Scotland is restricted to NICE NG17 and NG18 criteria so many people who do not meet the exact criteria feel that they are only receiving half the treatment package. They feel fobbed off because the APS function on their current pumps is effectively denied to them by funding restrictions on CGM.

2. **Health Equality**

   Tech providers are pricing their technology competitively to make it easier to self-fund. Some tech is now being advertised on TV and social media.

Many people opt to pay out-of-pocket for CGM because of the lack of NHS availability, choosing the self-funding option rather than fighting NHS bureaucracy with a high risk of funding refusal.

Effectively, people with insufficient financial resources (typically ~ £2k *per annum*) to fund CGM receive sub-optimal treatment with poorer short and long-term social and health outcomes.

As an example of typical costs, an IPAG member who has self-funded CGM over the past 8 years estimates the total spending at £14,000.

3. Information and Knowledge

At IPAG we have found that a surprising number of people are effectively excluded from access to technology because they are unaware that it exists. Diabetes teams are often reluctant to suggest APS because of the shortage of available funding or clinic resources to carry out training.

The limited access to APS systems reduces the opportunity for Diabetes clinical teams to learn about the technology. Patient experience and knowledge plays an important role in informing clinicians about the way a technology works and its associated benefits. Conversely, patients who achieve improvements in their diabetes control by using APS technology will take up less time and attention by clinical teams. Compared with Flash monitoring, the upfront cost of CGM is higher but only marginally so and an independent study (Roze et al., Diabetes Care 2020) estimates the cost at £9K per QALY, less than half the NICE cutoff.

4. **Scottish Government Commitment**

The Diabetes Improvement Plan (Diabetes Care in Scotland, Commitments for 2021-2026) *explicitly* defines as a stated aim, "… making closed loop technology available to all people who would benefit from these therapies at the earliest opportunity and monitoring equity of access to the most deprived groups.". This aim will not be achievable in the absence of NHS funding for CGM.

6. Please summarise the key points of your submission in up to 5 statements. (See page 9 of guidance.)

Better control – Clinical studies (e.g. Collins et al, Diabetes Care 2021; Pinckser et al Diabetes Tech & Ther 2021; Fuchs et al BMJ Open 2021) of the three APS systems currently available in Scotland report that users achieved average TIR figures of 76-83% (depending on the system). Control groups using CGM with conventional insulin pump therapy only achieved 50-55% in range.

Burden of diabetes for patients, carers and families. The advent of Closed Loop systems demonstrates clearly that the complexities of controlling BG levels are too great to be managed conventionally. This is illustrated by the failure of three quarters of the T1D population in Scotland to achieve even the minimum acceptable measure of control as determined by HbA1c. Only automated systems are capable of making the ongoing changes to insulin delivery needed to achieve good control. Many users attempt to micromanage using conventional systems by spending many hours testing, taking correction insulin doses, eating extra carbs and consulting with diabetes clinical teams all of which has a substantial impact on their daily life and NHS clinical resources.

Reduced anxiety and improved mental health. Fluctuating BG levels do not only have adverse impacts on physical health, they also cause mental health issues for patients, carers and their families. Mental health issues can be a direct symptom of either high or low blood glucose as well as the burden of managing T1D, and also impact on families and carers.

Equity of access. Variations in access. The cost of self-funding CGM effectively excludes the majority of the T1D population from the benefits of APS. This problem is exacerbated by barriers to attending courses, e.g., time off work, lost earnings for structured education, clinic appointments and training; for many people with lower levels of educational achievement lack of confidence is another barrier (Harris et al., Diabet Med 2018).

With no national pathway for access to APS there is a postcode lottery in Scotland with each health board using different criteria for insulin pumps, CGM and APS and with different "approved lists" of available technology.

Cost

Self-funding costs are beyond the budgets of most people with T1D, particularly those from the lower SIMD areas. This is inequitable with lower income patients being excluded from the best treatment options for their condition, reducing their quality of life and putting them at risk of long-term diabetes complications and requiring a higher level of input from their clinical teams.

7. Please give us details of anyone outside your organisation that had a role in preparing your submission. (See page 10 of guidance.)

None

8. Do you consent for your submission to be posted on the SHTG website? (See page 10 of guidance.)

Yes	x	No	

Thank you for completing this form. It will be given to SHTG members to inform their development of an Advice Statement for this technology.