**Continuous Glucose Monitoring**

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Glucose monitoring in individuals with Type 1 diabetes mellitus who meet one or more of the following criteria for whom flash glucose monitoring is one potential option to support patient centred diabetes care leading to improved blood glucose control:-

1. More than 1episode a year of severe hypoglycaemia with no obviously preventable precipitating cause.
2. Complete loss of awareness of hypoglycaemia.
3. Frequent (more than 2episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities.
4. Extreme fear of hypoglycaemia.
5. Hyperglycaemia (HbA1c level of 75mmol/mol [9%] or higher) that persists despite testing at least 10times a day
6. Hyperglycaemia (HbA1c level of 84mmol/mol (10%) or higher in an individual and/or recurrent hospital admissions with DKA who is not achieving recommended traditional SBGM testing frequency but with flash glucose monitoring is able to achieve and maintain a drop in HbA1c of at least 12mmol/mol and/or a reduction in hospital admissions due to DKA.

Criteria 1-5 are NICE guidance criteria for real-time continuous glucose monitoring and align closely with the criteria for CSII (continuous subcutaneous insulin infusion) therapy. Please see attached flowchart outlining the expected therapeutic pathway to be followed by the specialist team at Hull & East Yorkshire NHS Hospitals Trust in supporting such patients.

Criteria 6 is a locally agreed criteria which identifies a group at very high risk of costly diabetes complications in whom flash glucose monitoring enables them to achieve much tighter glucose control thereby reducing significantly the risk of complications and offsetting the cost of future complications and hospital admissions.

NICE guidance for Type 1 Diabetes Mellitus (nice.org.uk/guidance/ng17) recommends the person with diabetes should monitor blood glucose as a minimum 4 times every day and up to 7-10 times a day in order to achieve recommended target HbA1c of 48mmol/mol and detect and manage potential hypoglycaemia.

The guidance also states – “Advise adults with type1 diabetes to aim for: a fasting plasma glucose level of 5–7mmol/litre on waking and a plasma glucose level of 4–7mmol/litre before meals at other times of the day”.

Some individuals find such frequent finger pricking painful and extremely intrusive and for a variety of reasons are not able to maintain such a testing regimen. Others experience loss of hypoglycaemia warning signs and/or extreme fear of hypoglycaemia and may be compelled to self-test 10 or more times a day to keep themselves safe and manage anxiety. NICE guidance has recommended that real-time continuous glucose monitoring should be considered in selected cases as defined in this document.

The Freestyle Libre flash glucose monitoring system differs from full continuous glucose monitoring systems in that it does not provide an automatic alert to the wearer that the glucose level is moving outside of a pre-set target range. In contrast to other CGMS systems the Freestyle Libre does not require calibration with capillary finger prick glucose tests. The system has been reviewed by HEY Near Patient Testing committee and approved for patient use. The wearer has to flash scan the device to obtain a glucose reading at any given time point and will also then get a trend indicator arrow and graph of the glucose levels over the preceding 8 hours on the screen. Scanning is done using the handset scanner provided with the sensor starter pack and/or with the persons own Android smartphone and suitable app. Downloading the scanner provides the user and HCP with full 24 hours continuous glucose data and a wealth of data that can be used to adjust insulin doses to support tight glucose control.

There is limited randomised controlled trial evidence regarding therapeutic use of continuous glucose monitoring. The Association of British Clinical Diabetologists (ABCD) Position statement[[1]](#footnote-1) summarises the current evidence base and recommends its use for “the protection against recurrent disabling hypoglycaemia; and for those with hypoglycaemia unawareness or debilitating fear of hypoglycaemia”. The largest RCT to date using CGMS in adults is the JDRF CGM study[[2]](#footnote-2) which studied 83 adults and demonstrated a significant reduction in episodes of severe hypoglycaemia which was maintained and reduced further during the 6 month extension phase of the trial that followed the initial 6month trail phase. Scaramuzza[[3]](#footnote-3) found similar reduction in hypoglycaemia rates in a real world survey of children and teenagers using CGMS combined with insulin pump therapy.

More recently an abstract was presented at the American Diabetes Association meeting in June 2016 in which 241 adults with Type 1 diabetes were randomised to either the Abbott Freestyle Flash glucose sensor or traditional glucose monitoring for a 6 month period[[4]](#footnote-4). This was a group with good glycaemic control at randomisation (HbA1c 50.1+/-6.1mmol/mol) and average duration of diabetes 22+/-12years. The group randomised to sensor use had a reduction in hypoglycaemia (glucose <4.0mmol) of 38% which translated to 1.24hrs less spent in hypoglycaemia per day. Hypoglyceamia below 2.4mmol was reduced by 65% (p<0.0001) and nocturnal hypoglycaemia was also reduced by 39.8%. On average users scanned the sensor 15 times a day and reduced the number of traditional SMBG tests to 0.1 per day compared to strip use prior to the trial of median 5.4 tests per day and control group strip use of 5.6 per day. This highly significant drop in hypoglycaemia frequency and duration was achieved without any rise in mean glucose or HbA1c. Further analysis of this data is expected with data on the impact on emergency department attendances but not yet published.

The ability to quickly and simply scan the sensor even through clothing provides the user with knowledge of their blood glucose level on which they can act if required to correct hyperglycaemia or hypoglycaemia. For individuals who experience frequent hypoglycaemia with impaired warning signs and/or fear of hypoglycaemia this system provides rapid reassurance that the person is safe or that they need to take steps to stop a falling glucose level before it becomes dangerous. The ability to collect much more data about blood glucose levels throughout the 24hrs with the Ambulatory Glucose Profile enables the person with diabetes supported by HCP to make decisions about diet, exercise and insulin doses to achieve recommended target blood glucose control.

A download can easily be performed in the clinic but also on a home PC and then emailed to the diabetes team as a pdf file to enable remote support between clinic visits so that patients are not waiting for traditional outpatient clinic appointments to trouble shoot an issue with their glucose control that the download has identified. A particular feature is the ambulatory glucose profile (AGP) which is a summative presentation of the glucose control pattern over the period of sensor wear. As can be readily seen from the example this is relatively easy to interpret and identify problem areas of glucose control – for example hyperglycaemia overnight is evident as well as tendency towards hypoglycaemia in the late afternoon.

Two real world local example cases we have supported who have self-funded the Libre sensor demonstrate the very different ways this technology can help patients.

The first case aligns with the Impact study abstract being a person who was experiencing frequent hypoglycaemia and had an Hba1c of 67mmol/mol. This individual was doing traditional SBGM tests 8-10 times a day. Using the sensor they scanned on average 15 times a day and episodes of hypoglycaemia dropped from 7-10 per week to just 2 per week. Just as importantly for the person with diabetes they reported much improved sleep and greater self-confidence.

The second example is completely different being a young man with type 1 diabetes since early childhood but who has had extremely high Hba1c (generally >130mmol/mol) for several years despite all the efforts of the team to support him to use his evident knowledge and understanding of his diet and diabetes to get his diabetes under control. He was very reluctant to make changes to his insulin, had a fear of hypoglycaemia but was not testing his glucose more than once a day if that. With the Libre sensor he is now scanning around 15 times a day and with that knowledge and confidence that he knows what his glucose is he is now giving his insulin consistently and brought his Hba1c down to 80mmol/mol within 4-6 weeks. In the last few weeks he has even decided to change his morning insulin to split basal and quick –acting insulin which we have been trying to persuade him to do for at least 3 years without success. Having seen what the ambulatory glucose profile shows about his glucose control over the morning he has now made the decision for himself that this is the next step to getting his diabetes under control.

**Proposed number of patients anticipated to be treated via CGM**

For each CCG if 50 individuals were using this system continuously throughout the year the cost would be £65,200 to each CCG. Offset against this is a reduction in traditional strip costs and reduction in lancets used for any period of sensor wear (note strip use is not eliminated as in some situations a traditional capillary test is still advised); reduction in YAS call outs and ED attendances for hypoglycaemia and over the longer term a reduction in complication costs.

**Estimated annual cost per patient**

Costs are calculated assuming no discounting available, though some work is progressing on reduced cost sensor purchasing.

Continuous wear of sensor 52 weeks of the year £1304

Sensor wear average 26 weeks a year £628.

Note - offset against this cost is the reduction in traditional strip costs and lancets so net additional cost per patient based on 52 week continuous use would be estimated to be closer to £650 per annum assuming a drop of 90% in traditional strip use which would be in line with evidence from real patient data collected by Abbott but awaiting publication. NICE type 1 guidance estimates a paramedic call-out for hypoglycaemia to cost the health economy £240 and the tariff for an admission for hypoglycaemia or DKA are both well in excess of £650 so a single prevented admission per year would equate to a cost saving to the NHS.

These costs compare to:-

* Real-time CGMS eg Medtronic or Dexcom - 52 weeks a year wear approx £3000
* CSII average costs per annum are £2500 for pump and consumables

Traditional SBGM strips and lancets testing average 7 tests per day using advanced meter systems such as Roche bolus advisor at £15 per 50strip box and 0.04pence per lancet would be £742 pa and average 4 tests a day would be £425per annum.

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| **Intervention** | **Estimated cost per patient per annum (£)** |
| Libre sensor continuous use 52 weeks | 1304 |
| Libre sensor 50% use 26 weeks | 628 |
| Libre sensor net additional cost assuming SBGM drops by 90% | 650 |
| Full CGMS eg Dexcom/Medtronic | 3000 |
| Traditional SBGM 7 tests per day - depending on strips/meter eg bolus advisor meter | 500 to 800 |
| Average insulin pump and consumables cost | 2400 |

1. Hammond PJ et al. ABCD position statement on continuous glucose monitoring: use of glucose sensing in outpatient clinical diabetes care. Practical Diabetes Interventions 2010; 27: 66-68 [↑](#footnote-ref-1)
2. JDRF CGM study group. Sustained benefit of continuous glucose monitoring on A1c, glucose profiles and hypoglycaemia in adults with type 1 diabetes. Diabetes Care 2009; 32: 2047-9 [↑](#footnote-ref-2)
3. Scaramuzza AE et al. Use of integrated real-time continuous glucose monitoring/insulin pump system in children and adolescents with Type 1 diabetes: a 3 year follow-up study. Diabetes Technology Therapy 2011; 13: 99-103 [↑](#footnote-ref-3)
4. Bolinder J et al. Using novel flash glucose-sensing technology reduces hypoglycaemia in individuals with type 1 diabetes. Impact Study. Poster 868P. [↑](#footnote-ref-4)