Continuous Glucose Monitoring Adoption in the United Kingdom – An Economic and Policy Perspective

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Continuous glucose monitoring (CGM) technology provides real-time glucose concentration data to people with diabetes. The data enable timely treatment decisions that can lead to avoidance or mitigation of hypoglycaemia, with potential cost savings. This commentary discusses CGM implementation and funding policies in the UK, and regional disparities that confront many people with diabetes who could benefit from the technology.

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People with type 1 diabetes are at risk of diabetes-specific microvascular complications of retinopathy, nephropathy and neuropathy, and face an increased risk of cardiovascular disease compared with the general population.[1] These risks can be modified by optimising glucose self-management,[2] commonly measured by glycated haemoglobin (HbA1c), and achieved through appropriate selection of insulin preparation,[3] structured education programmes,[4] insulin pump therapy,[5] capillary blood glucose monitoring, and continuous glucose monitoring (CGM).

CGM devices display contemporaneous glucose concentration, glucose direction and rate of change, and a graphical representation of the preceding glucose trend. They also provide alerts and alarms for glucose values outside of defined thresholds, and for rapid rates of change. Randomised controlled trials have demonstrated that, compared with intermittent self-monitoring, CGM improves HbA1c, reduces time spent in hypo- and hyperglycaemia, improves fear of hypoglycaemia and quality of life, and lowers the risk of severe hypoglycaemia.[6–10]

With the publication, in 2015, of the National Institute for Health and Care Excellence (NICE) guidelines for type 1 diabetes,[11,12] CGM was advocated as a therapeutic option for children and adults living with type 1 diabetes in England (*Table 1*). The NICE guidance for children supports offering CGM to children with frequent severe hypoglycaemia, to those with impaired awareness of hypoglycaemia associated with adverse consequences (such as seizures or anxiety), or where there is inability to recognise, or communicate about, symptoms of hypoglycaemia due to cognitive or neurological disabilities. In addition, CGM should be considered in neonates, infants and pre-school children with type 1 diabetes, in children and young people who undertake high levels of physical activity (for example, sport at a regional, national or international level), and in children and young people who have comorbidities (for example anorexia nervosa) or who are receiving treatments (such as corticosteroids) that can make blood glucose control difficult.

The adult guideline supports consideration of CGM for adults with type 1 diabetes who meet one or more of the following criteria: more than one episode a year of severe hypoglycaemia with no obvious preventable precipitating cause; complete loss of awareness of hypoglycaemia; frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities; extreme fear of hypoglycaemia; hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite self-monitoring of capillary blood at least 10 times a day.[11] Adults accessing CGM should commit to using the system for at least 70% of the time and it must be provided by a centre with expertise in its use, as part of strategies to optimise HbA1c and reduce the frequency of hypoglycaemia. The NICE guidelines are stricter than those in other territories and may prevent some groups from accessing CGM, such as those with impaired awareness of hypoglycaemia and a Gold score between 4 and 6. In order to change this in future guidance, further evidence may be required.

Table 1: Summary of the indications for continuous glucose monitoring in the 2015 NICE guidelines

Adult guideline (aged ≥18 years and over)	Paediatric guideline (aged <18 years)
Consider real-time continuous glucose monitoring for adults with type 1 diabetes who are willing to commit to using it at least 70% of the time and to calibrate it as needed	
More than one episode a year of severe hypoglycaemia with no obviously preventable precipitating cause	Offer ongoing real-time continuous glucose monitoring with alarms to children and young people with type 1 diabetes who have frequent severe hypoglycaemia
Complete loss of awareness of hypoglycaemia	Offer ongoing real-time continuous glucose monitoring with alarms to children and young people with type 1 diabetes who have impaired awareness of hypoglycaemia associated with adverse consequences (for example, seizures or anxiety)
Frequent (more than two episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities	Offer ongoing real-time continuous glucose monitoring with alarms to children and young people with type 1 diabetes who have inability to recognise, or communicate about, symptoms of hypoglycaemia (for example, because of cognitive or neurological disabilities)
Extreme fear of hypoglycaemia	Consider ongoing real-time continuous glucose monitoring for neonates, infants and pre-school children
Hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day. Continue real-time continuous glucose monitoring only if HbA1c can be sustained at or below 53 mmol/mol (7%) and/or there has been a fall in HbA1c of 27 mmol/mol (2.5%) or more	Consider ongoing real-time continuous glucose monitoring for children and young people who undertake high levels of physical activity (for example, sport at a regional, national or international level)
For adults with type 1 diabetes who are having real-time continuous glucose monitoring, use the principles of flexible insulin therapy with either a multiple daily injection insulin regimen or continuous subcutaneous insulin infusion (CSII or insulin pump) therapy	Consider ongoing real-time continuous glucose monitoring for children and young people who have comorbidities (for example anorexia nervosa) or who are receiving treatments (for example corticosteroids) that can make blood glucose control difficult
Real-time continuous glucose monitoring should be provided by a centre with expertise in its use, as part of strategies to optimise a person's HbA1c levels and reduce the frequency of hypoglycaemic episodes	Consider intermittent (real-time or retrospective) continuous glucose monitoring to help improve blood glucose control in children and young people who continue to have hyperglycaemia despite insulin adjustment and additional support

CSII = continuous subcutaneous insulin infusion; HbA1c = glycated haemoglobin; NICE = The National Institute for Health and Care Excellence.

For both adults and children, the use of CGM is an adjunct to education and support, and randomised clinical trials support CGM use independent of the insulin delivery modality (pump or multiple dose injection).[7,9,13] Importantly, NICE guidelines advocate an overall HbA1c target of 48 mmol/mol (6.5%), supporting people with type 1 diabetes to achieve near normoglycaemia without disabling or problematic hypoglycaemia. The recommendations in the guidelines all support this overarching target, including implementation of CGM to optimise glucose.

The conditions of access in the adult guideline reflect the evidence assessed by the panel at the time. Benefit accrues from the use of CGM in a dose-dependent fashion, and a minimum of 6 days out of 7 use-per-week was the threshold for benefit in young adults in the landmark Juvenile Diabetes Research Foundation (JDRF) study.[8] The guidance also reflects the outcome of an economic analysis published alongside the NICE guidance which assessed the net monetary benefit of CGM compared with capillary blood glucose testing 2, 4, 6, 8 and 10 times per day. From these data, the required HbA1c improvement for CGM, and the threshold where self-monitoring may be considered to have failed, were set.[11] Since publication of the guidance, additional data from randomised, controlled trials has been published, confirming the benefits of CGM for people with type 1 diabetes using multiple dose injection regimens, both in reducing HbA1c by a clinically significant margin, and in addressing time spent below hypoglycaemic thresholds.[7,9] Data suggest CGM is now sufficiently accurate to replace capillary blood glucose testing in most scenarios,[14] but there remains a legal requirement in the United Kingdom to assess blood glucose (not interstitial fluid) prior to driving.

Despite the support for CGM in the adult and paediatric guidance, routine implementation into treatment pathways has not been achieved, reflecting, in part, challenges with provider arrangements. Across England there are around 200 clinical commissioning groups (CCGs), to whom local provision of care is devolved. The National Health Service (NHS) England, the executive public body of the Department of Health which oversees the budget, planning, delivery and operation of the NHS, state that CCGs must be mindful of NICE guidance but guidance documents are not mandated and local adoption, interpretation, and implementation is possible. This situation allows for geographical variation in the availability of some technologies. This contrasts with NICE technology appraisal documents which are mandated by law, and which support insulin pump use in England.

Some areas of England have successfully adopted the NICE guidance including North West London, where a group of eight CCGs, covering a population of around 2 million people, has implemented access to CGM for adults with type 1 diabetes who meet the NICE criteria. This co-ordinated implementation arose from collaboration between specialists, commissioners, and primary care, and supports people with challenging glycaemia to access appropriate technologies, enabling effective self-management of type 1 diabetes. Following a stakeholder meeting between commissioners, specialists, primary care physicians and business managers, a business case was prepared that included an evidence review, and defined access criteria, duration of use and monitoring processes. The business case included emergency response data for hypoglycaemia in North West London, provided by the London Ambulance Service. The final business case was presented to the Collaboration Board of CCGs where it was approved, along with a short application form for initial funding and a renewal form including monitoring data to be completed at 6 month intervals.

However, equity of access to CGM remains a challenge across the NHS and the use of individual funding requests, designed for access

to therapies only in exceptional circumstances, remains common for CGM. Conservatively, 25% of people with type 1 diabetes have impaired awareness of hypoglycaemia and the frequency of severe hypoglycaemia is around 0.5 episodes per patient year,[15–17] suggesting that the NICE criteria are not exceptional and many people with type 1 diabetes would meet these requirements if broadly applied. In 2011, the estimated cost of a single episode of severe hypoglycaemia requiring healthcare professional support is £377–1,306, suggesting significant potential for cost savings for people at highest risk of severe hypoglycaemia.[18] Furthermore, only 29.2% of people with type 1 diabetes in England and Wales achieve an HbA1c below 58 mmol/mol (7.5%)[19] and access to a wider array of intensification strategies including CGM is likely to increase this number over time.

The National Insulin Pump Audit has collected data across the NHS for insulin pump usage, and will continue annually to assess this, enabling longitudinal benchmarking.[20] This audit will now include the use of CGM technologies, allowing year-on-year assessment of uptake of CGM in the NHS. The presented data in this survey paper assess the state of CGM in the UK in 2017, including the views of people using it and adoption outside of the NHS; data that have not previously been reported. While this survey should not be considered comprehensive it offers some insight into the use of CGM and the benefits as reported by patients.

Adoption of new technologies into a resource-limited public health system is challenging and requires evidence for clinical, and cost, effectiveness. CGM is not unique but the evidence-base moves rapidly in line with product cycles, and it is important that guidelines and access criteria are able to move in parallel with this, to ensure people with type 1 diabetes are able to access interventions that are clinically relevant, and offer potential long-term cost savings. CGM can be rapidly adopted by people with diabetes and benefit can be measured over a short period of time, often with existing resources. It is clear that use of CGM, at present, extends beyond NHS provision, and that those people who are self-funding technologies, perceive benefit. The survey data support development of more flexible guidance that is able to take this into account, and which ensures safe implementation of CGM with demonstration of clinically meaningful outcomes, including psychosocial wellbeing and quality of life. ❑

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