NICE advice

Dexcom G6 for real-time continuous glucose monitoring

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is the Dexcom G6 real-time continuous glucose monitoring system. It measures interstitial fluid glucose levels in people with type 1 or type 2 diabetes.
- The **innovative aspects** are that the Dexcom G6 continuously measures glucose levels using a sensor inserted under the skin instead of routine finger-prick blood glucose testing. Glucose measurements can be shared remotely with carers and family members through the connected app. Alerts sound if glucose levels fall outside of a target range. The sensor can be left in place for 10 days.
- The intended **place in therapy** is as an alternative to routine blood glucose monitoring in people (over 2 years old), including pregnant women, with type 1 or type 2 diabetes, who use multiple daily insulin injections or use insulin pumps and are self-managing their diabetes.

- The **main points from the evidence** summarised in this briefing are from 6 studies: 4 randomised controlled trials, 1 prospective multicentre cohort study and 1 retrospective cohort study, including a total of 10,967 people in diabetes clinics. They suggest that using the Dexcom G6 reduces interstitial fluid glucose levels and the time spent in hypoglycaemia compared with self-monitoring of blood glucose using finger-prick testing.
- **Key uncertainties** around the evidence or technology are that there is variable access to continuous glucose monitors, such as Dexcom G6, across clinical commissioning groups.
- The **cost** of Dexcom G6 is between £1,850 and £2,645 per person per year (excluding VAT) depending on the quantity of units bought. One economic study concluded that over each person's lifetime, the total costs of the Dexcom G6 device were £14,234 higher than finger-prick blood glucose testing (£102,468 compared with £88,234). However, improving blood glucose control could lead to cost savings by avoiding the costs of both short-term and long-term clinical outcomes of poorly managed diabetes.

The technology

The Dexcom G6 continuous monitoring system (Dexcom Inc) measures interstitial fluid glucose levels. The G6 system consists of 3 key parts: the sensor wire, a transmitter, and a display device. The display device can be either the Dexcom receiver or an app that can be used on a compatible Android or iOS smart device.

The sensor comprises a water-resistant sensor pod that is worn on the skin, and the sensor wire that is inserted under the skin using the single-use applicator. The sensor can be worn for 10 days and continuously measures glucose levels. All users may wear the sensor on their abdomen or on the back of their upper arm. Children aged 2 to 17 years can also choose to wear it on their upper buttocks.

The transmitter is a multiple-use device that attaches to the sensor pod and sends glucose information to the display device (a smart device or dedicated receiver) using Bluetooth. The transmitter must be discarded after 3 months of use. During normal use, interstitial glucose concentration estimates are sent from the transmitter to the receiving device at 5-minute intervals and can be checked at any time. Alerts can be set to respond when glucose levels or rates of change go outside of the healthy range. This is to help people manage both hyperglycaemia and hypoglycaemia.

The G6 software app is downloaded onto the compatible smart device, which must be paired with the transmitter before use. The app continuously and automatically sends data to the Dexcom remote server, where the data are processed for reporting by the CLARITY diabetes management software. To display the data, the smart device needs to be connected to the transmitter by Bluetooth and have the Dexcom G6 app running. Dexcom receivers store 30 days of readings and need connection to a computer to upload the data to the server periodically.

The user can choose to share glucose levels, trend information and alerts with others such as carers or family members who can view data by downloading the Dexcom Follow app. The Follow app can receive alerts, for example, if the user's glucose level falls outside of the healthy range. The user can also email data reports to healthcare providers or allow them to view their data through the CLARITY software. The Dexcom CLARITY mobile app can send a weekly push notification summarising weekly time-in-range, how the user's current week compares with the previous week, and any high or low glucose patterns.

Innovations

The Dexcom G6 has an alert function. The 'urgent low' alert cannot be deactivated. This alert notifies the user when the glucose level falls to 55 mg/dl or below (defined as a severe hypoglycaemic event). An 'urgent low soon' alert notifies the user if the glucose level is predicted to drop to 55 mg/dl within 20 minutes. This alert can be turned off.

The Dexcom G6 has been designed to communicate with other digitally connected devices (interoperable), including automated insulin pumps. This allows 'hybrid artificial pancreas' systems to be created from separate devices. The Dexcom G6 can work with either the Diabecare R (DANA) insulin pump or the Tandem t:slim X2 (Tandem) insulin pump.

The company states that unlike previous versions of the technology, the Dexcom G6 factory-calibrated sensor does not need daily calibration with finger-prick blood samples. Also, unlike earlier-generation Dexcom systems, G6 readings remain unaffected by routine doses of paracetamol (a maximum of 1,000-mg dose of paracetamol every 6 hours).

Current care pathway

NICE guidelines state that people with diabetes should be empowered to self-monitor their

blood glucose, and be educated about how to measure it and interpret the results. Routine blood glucose testing is typically done using a finger-prick capillary blood sample. Currently, continuous monitoring of interstitial fluid glucose levels using a continuous glucose monitor is not recommended for routine use but can be considered for some people.

The following publications have been identified as relevant to this care pathway:

- NICE's guideline on type 1 diabetes in adults: diagnosis and management
- NICE's guideline on diabetes (type 1 and 2) in children and young people: diagnosis and management
- NICE's guideline on diabetes in pregnancy: management from preconception to the postnatal period
- NICE's guideline on type 2 diabetes in adults: management.

Population, setting and intended user

Dexcom G6 is intended to be an alternative to routine finger-prick blood glucose monitoring for people aged 2 and over, including pregnant women, who have type 1 or type 2 diabetes, have multiple daily injections of insulin or use insulin pumps and are self-managing their diabetes. Dexcom G6 is not indicated for people who are on dialysis or critically ill. Finger-prick blood glucose testing may still be needed if the user's symptoms do not match Dexcom G6 readings or if the user is taking hydroxyurea. The company notes that because the effect of airport scanners on the G6 is unknown, finger-prick blood glucose testing should be used when the user is walking through airport security screening areas. The Dexcom G6 should not be used during MRI, CT or high-frequency electrical heat (diathermy) treatment.

The Dexcom G6 is primarily for people at home as they go about their normal daily activities. Healthcare professionals can review data from the Dexcom G6 remotely using the CLARITY software.

The company provides free access to online training videos, documents and a telephone support service for users. Training and education are also provided free of charge to healthcare professionals, including supplying appropriate supporting materials if needed.

Costs

Technology costs

The company has provided a tiered pricing model for Dexcom G6, based on number of new patients per payer. These costs include all of the sensors and applicators needed for each patient. They do not include the optional Dexcom receiver, which costs £290. In the UK, 6% people using Dexcom G6 use the receiver. Unit costs were not provided.

Dexcom G6 pricing model:

- 1 to 4 new patients: standard price per patient per year £2,645
- 5 to 19 new patients: £2,500 per patient per year (5.5% discount on standard cost)
- 20 to 49 new patients: £2,200 per patient per year (16.8% discount on standard cost)
- more than 50 new patients: £2,000 per patient per year (24.4% discount on standard cost)
- more than 250 new patients: £1,850 per patient per year (30.06% discount on standard cost).

People using the Dexcom G6 may also need occasional use of a blood glucose monitor, with test strips and lancets. The costs for blood glucose monitoring starter kits available through the NHS range from £14.93 for 1 blood glucose meter and 10 glucose strips, lancets and a lancing device, to £107.85 for 1 blood glucose meter and 900 glucose strips and lancets. Blood glucose meters are generally provided to the patient at no cost, whereas test strips and lancets are available on prescription at various tariff prices. Costs of blood glucose test strips to the NHS vary according to the meter used but are typically between £7 and £16 for a pack of 50, with bulk-buy savings available and total cost depending on the meter chosen.

Costs of standard care

Currently, standard blood glucose meters and test strips are used to manage blood glucose levels. Flash glucose monitoring is another technology that is intended as an alternative to routine blood glucose monitoring. As an example of flash glucose monitoring, the company's website for Freestyle Libre advises that FreeStyle Libre costs £48.29 for

the reader. It has a 3-year lifespan, and costs £48.29 for each sensor, which must be replaced every 14 days (equalling £1,271.64 per year). Diabetes UK advises that the current retail cost for FreeStyle Optium blood glucose test strips is £17.10 for 50 strips. FreeStyle Optium blood ketone test strips cost £21.90 for 10 strips. The FreeStyle lancets for taking finger-prick blood cost 3.9p each. Costs are excluding VAT.

Resource consequences

The company states that over 10,000 adults and children across the UK have received NHS funding for Dexcom continuous glucose monitors, and over 5,000 others pay for Dexcom monitors themselves. Access to continuous glucose monitoring (CGM) systems can vary significantly between clinical commissioning groups (Perera et al. 2018).

Resource consequences of the Dexcom G6 device have been reported by Roze et al. (2020). An economic analysis with an NHS perspective was done using the IQVIA CORE Diabetes Model to ascertain the cost effectiveness of real-time CGM with Dexcom G6 compared with self-monitoring of blood glucose alone. Clinical input data were sourced from the DIAMOND trial (Beck et al. 2017) for adults with type 1 diabetes.

Relative to self-monitoring of blood glucose, the use of Dexcom G6 resulted in 1.49 quality-adjusted life years (QALYs) incrementally, and total costs were £14,234 higher than self-monitoring of blood glucose (mean £102,468 compared with £88,234). This gave an incremental cost-effectiveness ratio of £9,558 per QALY gained.

There are no practical difficulties or changes in facilities and infrastructure associated with adopting the technology.

Regulatory information

The Dexcom G6 continuous glucose monitoring system (including the applicator and the app) is a CE-marked class IIb medical device.

The following manufacturer field safety notices or medical device alerts for this technology (Dexcom G5 or G6) have been identified.

- Users of the Dexcom G6 iOS App with versions before 1.54 were alerted that they may not receive their scheduled alerts. Dexcom advised users to update their apps. If the app was not updated, it was blocked from use (on 9 December 2019). Medicine and Healthcare products Regulatory Agency field safety notice (December 2019).
- The notice advised users of Dexcom G5 that the alert about sensor glucose readings not being received did not have an audible prompt. The company advised users to periodically check the app for the status of their sensor glucose readings. Medicines and Healthcare products Regulatory Agency field safety notice (June 2019).

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Pregnant women may particularly benefit from Dexcom G6. People with certain skin conditions or allergies may be unable to wear the sensor. The company notes there may be inequity in access to continuous glucose monitoring (CGM) technologies for people with type 1 diabetes. Type 1 diabetes is classed as a disability under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with NICE's interim process and methods statement for the production of medtech innovation briefings. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Six studies are summarised in this briefing, including up to 10,967 people. The total number of people in the studies is not clear because some of the trials included overlapping populations. These studies were selected because they were the most relevant, had the highest-quality evidence and included the largest patient populations.

One UK randomised controlled trial (RCT) assessed time in target blood glucose range

when using Dexcom G6 compared with self-monitoring of blood glucose (SMBG). Three RCTs using the previous version of the technology, Dexcom G5, were included because they are high-quality studies into relevant clinical outcomes (effect on blood glucose levels and incidence of hypoglycaemic events). Experts suggested that the results from RCTs into Dexcom G5 are generalisable to the G6 version. Welsh et al. (2016) suggested there may be some differences in terms of accuracy, utilisation and number of hypoglycaemic events, with the G6 outperforming the G5 overall. In addition to the 4 RCTs, 1 prospective multicentre cohort study and 1 retrospective cohort study into the Dexcom G6 were included.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

There is an extensive evidence base for Dexcom G5 and G6. This briefing presents a selection of the studies available. Six studies are summarised, including 4 RCTs. In addition, a published economic study was identified, which is reported in the resource consequences section. The evidence base suggests that results provided by the Dexcom G6 are consistent with laboratory-based glucose testing.

Most studies were done in the US, which may affect generalisability of results, but there was 1 RCT done in the UK and economic evidence from a UK NHS perspective. The UK RCT found Dexcom G6 increased the time spent in target blood glucose range compared with SMBG. Several studies suggest that using the Dexcom G6 reduces interstitial fluid glucose levels and the time spent in hypoglycaemia compared with routine SMBG, especially if alerts are turned on. All studies included in this briefing were funded by the company.

There is evidence in different populations including type 1 and type 2 diabetes, young adults and people with limited hypoglycaemia awareness. Other high-quality UK-based studies into other patient subgroups, including children, would further improve the impact of the evidence base.

Thabit et al. (2020)

Study size, design and location

A randomised, controlled crossover trial at 2 UK hospitals of 31 people with type 1 diabetes aged 16 to 24 years old being treated with multiple daily injections or insulin pump therapy. The study ran for 8 weeks and compared time in target blood glucose range (haemoglobin A1c [HbA1c] levels between 3.9 mmol/litre and 10 mmol/litre) using Dexcom G6 compared with SMBG. Measuring HbA1c is a commonly used way to understand a person's blood glucose levels over time. Elevated HbA1c levels are associated with diabetes-related complications.

Intervention and comparator

Intervention: Dexcom G6 (n=31).

Comparator: routine SMBG (n=31). People in the study acted as their own controls.

Reference standard: laboratory blood glucose test.

Key outcomes

Time in target blood glucose range (defined as 70 mg/dl to 180 mg/dl) was significantly higher during Dexcom G6 use compared with control (35.7% plus or minus 13.5% compared with 24.6% plus or minus 9.3%; $p<0.001$). Times spent below range (below 70 mg/dl and below 54 mg/dl) were low and not significantly different during both study periods. The Dexcom G6 was worn 84% of the study period. People reported significantly higher satisfaction levels using Dexcom G6 compared with SMBG.

Strengths and limitations

This was a UK RCT that was adequately powered (at the 80% level) to detect the primary outcome.

The sample size of the study limited any subgroup analyses such as glycemic outcomes in multiple daily injections and pump users. The amount of sensor data available for analysis was not equal between the Dexcom G6 and control periods. The study was funded by the company.

Beck et al. (2017a)

Study size, design and location

A multicentre, randomised controlled trial at 24 endocrinology centres in the US of 158 adults with type 1 diabetes and elevated HbA1c treated with multiple daily insulin injections. The study ran for 6 months and assessed if using the Dexcom G5 reduced HbA1c levels compared with standard methods.

Intervention and comparator

Intervention: Dexcom G5 (n=105).

Comparator: routine SMBG (n=53).

Reference standard: laboratory blood glucose test.

Key outcomes

HbA1c levels were significantly reduced in the Dexcom G5 group compared with SMBG (1.1% at 12 weeks and 1.0% at 24 weeks compared with 0.5% and 0.4%, respectively, p <0.001). Median duration of hypoglycaemia (defined as below 70 mg/dl) was 43 minutes per day in the Dexcom G5 group compared with 80 minutes per day in the SMBG group (p=0.002). There were severe hypoglycaemic events in 2 people in each group (p=0.67). In 102 people in the Dexcom G5 group who completed the trial, median sensor use was 7 days per week at 4, 12, and 24 weeks.

Strengths and limitations

This multicentre RCT was adequately powered to detect a difference in mean blood glucose level between treatment groups (randomised 2:1). The study had a low dropout rate (3 people).

People in the study were unblinded to the group to which they had been assigned (but this is expected with interventions such as Dexcom, which are designed to encourage behaviour change). The study was funded by the company.

Beck et al. (2017b)

Study size, design and location

A multicentre, randomised controlled trial at 25 endocrinology centres in the US of 158 adults with type 2 diabetes treated with multiple daily insulin injections. The study ran for 6 months and assessed if using the Dexcom G5 reduced HbA1c levels compared with standard methods.

Intervention and comparator

Intervention: Dexcom G5 (n=79).

Comparator: routine SMBG (n=79).

Reference standard: laboratory blood glucose test.

Key outcomes

Mean HbA1c levels, which at baseline were 8.5% in both groups. HbA1c levels were significantly reduced in the Dexcom G5 group compared with SMBG (1.0% at 12 weeks and 0.8% at 24 weeks compared with 0.6% and 0.5%, respectively, $p<0.05$). The amount of hypoglycemia was extremely low at baseline (defined as below 70 mg/dl), limiting any assessment of differences in the 2 groups. In 77 people in the Dexcom G5 group who completed the trial, median sensor use was 6.9, 6.7, 6.7 days per week at 4, 12, and 24 weeks, respectively.

Strengths and limitations

This multicentre RCT was adequately powered to detect a difference in mean blood glucose level between treatment groups. The study had a low dropout rate (6 people).

People in the study were unblinded to the group to which they had been assigned (but, as noted above, this is expected with interventions such as Dexcom that are designed to encourage behaviour change). The study was funded by the company.

Heinemann et al. (2018)

Study size, design and location

A multicentre, randomised controlled trial at 12 diabetes centres in Germany of 149 adults with type 1 diabetes treated with multiple daily insulin injections. People who were eligible for the study had a history of impaired hypoglycaemia awareness or severe hypoglycaemia during the previous year. The study duration was 6 months.

Intervention and comparator

Intervention: Dexcom G5.

Comparator: routine SMBG.

Reference standard: laboratory blood glucose test.

Key outcomes

A hypoglycaemic event was defined as glucose values of 3.0 mmol/litre (54 mg/dl) or lower for at least 20 minutes, preceded by a minimum of 30 minutes with glucose values greater than 3.0 mmol/litre (54 mg/dl). The mean number of hypoglycaemic events in the Dexcom G5 group was significantly reduced over 28 days (10.8 at 4-week baseline to 3.5 events at 4-week follow up). There was no significant reduction in the SMBG group. The incidence of all severe hypoglycaemia events among control group participants during follow up was about twice the incidence seen in the Dexcom G5 group (standardised as 1.18 compared with 0.64 events per patient-year). Variability in blood glucose levels fell in the Dexcom G5 group to a greater extent than in the SMBG group. Severe hypoglycaemia events needing third-party assistance without medical assistance for recovery were also less frequent in the Dexcom G5 group than in the control group (19 events compared with 36 events).

Strengths and limitations

This multicentre RCT was adequately powered for the primary outcome of assessing the effect of Dexcom G5 on the number of hypoglycaemic events compared with SMBG. The glucose value in this study is defined as a severe hypoglycaemic event according to experts (below 4.0 mmol/litre defined as hypoglycaemia or a severe hypoglycaemic event).

People were unblinded to the group to which they had been assigned. The study was funded by the company.

Wadwa et al. (2018)

Study size, design and location

A prospective multicentre study of 262 people 6 years or older with type 1 diabetes or insulin-treated type 2 diabetes from 11 sites in the US. The study duration was 10 days.

Intervention and comparator

Intervention: Dexcom G6.

No comparator.

Reference standard: laboratory blood glucose test (Yellow Springs Instrument, YSI).

Key outcomes

There was 10% mean absolute relative difference (MARD) between Dexcom G6 and reference blood glucose measurements. Matched pairs from 134 adults and 128 children and young people aged 6 to 17 years were similar. Dexcom G6 values were within 20% of paired blood glucose values in 92.4% and 91.9% of instances in adults and children and young people. Similarly, MARD was 9.9% and 10.1% respectively. The hypoglycaemia alert was correctly activated in 84.4% of instances within 30 minutes of a hypoglycaemic event (defined as below 70 mg/dl). The corresponding false alert rate was 15.6% and missed detection rate was 15.0%. The 10-day sensor survival rate was 87%.

Strengths and limitations

This is a prospective multicentre site study. There were 28 people excluded from an initial 290 people. This was primarily because of a lack of corresponding blood glucose test data. This was study with a short duration (10 days) in a chronic condition. Larger long-term studies could provide more generalisable results. The study was funded by the company.

Welsh et al. (2019)

Study size, design and location

A study retrospectively comparing the accuracy of Dexcom G5 (n=50) compared with Dexcom G6 (n=159) in people with type 1 or type 2 diabetes from 3 previous separate prospective studies (compared with laboratory tested blood glucose values). The study also compared the clinical outcomes in 10,000 people who switched from the G5 to the G6 system. The location was not reported.

Intervention and comparator

Intervention: Dexcom G6.

Comparator: Dexcom G5.

Reference standard: laboratory blood glucose test.

Key outcomes

The G5 system showed slightly better accuracy than the G6 system in terms of MARD compared with the laboratory blood test, but the statistical significance of this result was not tested. The G6 system had a higher utilisation rates over 30 days compared with the G5 system (95.3% compared with 93.8% respectively, $p<0.001$). Using G6 system was associated with fewer recorded hypoglycaemic glucose values, defined as below 55 mg/dl (3.1 mmol/litre; 0.7% compared with 1.1%, $p<0.001$).

Strengths and limitations

The accuracy of the Dexcom G6 was assessed using data from previous studies (including Wadwa et al. 2018), so there is population overlap. The patient groups were from different studies, so the performance differences may be because of differences in study design. Propensity score matching was used to adjust for differences between G5 and G6 study populations, but it is unclear whether the method was appropriate. The study did not collect data about changes in diabetes treatment, diet, or exercise patterns. The extent to which the switch from G5 to G6 accounted for the changes is therefore uncertain. The glucose value in this study is defined as a severe hypoglycaemic event. The study was funded by the company.

Sustainability

The company suggested that Dexcom G6 could support sustainability by reducing the materials used in the manufacturing of self-monitoring blood glucose test strips and lancets and the use of sharps bins to discard the waste material. There is no published evidence to support these claims.

Recent and ongoing studies

There were 13 recent and ongoing studies identified in the development of this briefing. These included the following 5 UK studies:

- Automated insulin delivery among pregnant women with type 1 diabetes. ISRCTN56898625. Status: recruiting. Indication: pregnant women with type 1 diabetes. Devices: Dexcom G6 continuous glucose monitoring as part of automated closed-loop insulin delivery. Date: January 2022.
- Assessment of the accuracy of continuous glucose sensors in people with diabetes undergoing haemodialysis (ALPHA). ClinicalTrials.gov identifier: NCT03885362. Status: recruiting. Indication: type 1 diabetes. Devices: Dexcom G6 continuous glucose monitoring sensor system compared with FreeStyle Libre. Date: September 2020.
- Assessment of the impact of real-time continuous glucose monitoring on people presenting with severe hypoglycaemia (AIR-CGM). ClinicalTrials.gov identifier: NCT03748433. Status: active, not recruiting. Indication: type 1 diabetes. Devices: Dexcom G6 continuous glucose monitoring as part of automated closed-loop insulin delivery. Date: September 2020.
- Real-time continuous glucose monitoring in young adults at risk of diabetic ketoacidosis (YODA). ClinicalTrials.gov identifier: NCT04039763. Status: suspended because of COVID-19. Indication: diabetes, type 1 diabetes, glucose metabolism disorders, metabolic disease, autoimmune diseases, and endocrine system diseases. Devices: Dexcom G6 continuous glucose monitoring sensor system compared with self-monitored blood glucose. Date: 5 March 2021.
- The impact of a predictive hypoglycaemia alert function in physical activity for people with type 1 diabetes (PACE). ClinicalTrials.gov identifier: NCT04142944. Status: active, not recruiting. Indication: type 1 diabetes. Devices: Dexcom G6 with alert compared with Dexcom G6 without alert. Date: 31 August 2020.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All 3 clinical experts were familiar with the Dexcom G6 device and use it with patients. None felt it had been superseded.

Level of innovation

Three experts agreed that the Dexcom G6 is an innovative technology. One noted that providing a 24-hour glucose profile with hypoglycaemia alerts without the need for calibration represented a unique and significant change. Another noted that while continuous glucose monitoring (CGM) itself is not new, it is significantly different to capillary glucose testing which is the current standard of care. One expert suggested the technology 'shifts the paradigm from invasive monitoring with finger sticks to non-invasive monitoring' with added benefits of alarms at low levels of blood glucose readings. All experts noted that there are alternative companies providing CGM within the UK. Other similar technologies mentioned were the Medtronic Guardian RT and the FreeStyle Libre. Experts noted that, unlike the Dexcom G6, the Medtronic Guardian RT requires finger-prick calibration and the FreeStyle Libre does not have alarms and provides intermittent flash-monitoring rather than continuous monitoring.

Potential patient impact

All 3 experts felt that this technology could offer benefits to people. Benefits included reducing the frequency and severity of hypoglycaemia and better glucose control. One expert highlighted that continuous monitoring of a person's glucose profile can support treatment decisions and enable appropriate adjustments to medication, which would improve clinical outcomes and quality-of-life indicators. Another expert noted that the device's ability to connect to insulin pumps to provide a closed-loop artificial pancreas system may significantly aid monitoring and management.

Two experts felt it was particularly beneficial for people with type 1 diabetes at risk of hypoglycaemia, with 1 expert suggesting children or people operating heavy machinery as specific examples of groups that may benefit. One noted that people who would benefit

should include those who need carer support to manage their diabetes. A third expert highlighted that pregnant women and people who have been unable to achieve target glucose control (after structured education, multiple dose insulin or insulin pump therapy) may benefit.

All experts felt that the technology could change current pathways and clinical outcomes. All experts suggested that the technology could help prevent the need for clinical intervention. For example, 1 expert suggested that recognition and prevention of hypoglycaemia could prevent admission to hospital for severe hypoglycaemia. All experts noted that overall improvement in blood glucose levels could have a positive impact on the development of diabetes-related conditions needing hospital admission and intensive treatment (such as foot disease, diabetes-related eye disease, diabetes nephropathy and dialysis, and cardiovascular disease). One expert also highlighted the potential benefits to mental health.

Potential system impact

Three clinical experts felt that using Dexcom G6 could reduce costs and would benefit the healthcare system. This is because it could improve long-term outcomes, reducing the need for intensive treatment and, in the short term, reducing severe hypoglycaemic events leading to hospital admissions. Remote care may reduce the need for hospital visits.

One expert suggested that managing this technology (including patient support and potential data collection) would need an increase in number of clinicians. Two experts mentioned that training would be needed for staff working with the technology.

General comments

Two experts estimated that between 5% and 20% of people with type 1 diabetes would benefit from CGM.

One expert noted that clinicians working in specialist diabetes care will need training in data analysis and review to provide support to those using the technology. The competency of specialist diabetes centres to provide technologies such as CGM and insulin pump therapy should be standardised to ensure safety in delivering increasingly complex diabetes care.

More research into which subgroups of patients would benefit from this treatment would be valuable and this may allow greater access to the technology. All experts felt that NICE guidance on Dexcom G6 would be very relevant to support decision making and local implementation.

Patient organisation comments

Diabetes UK gave the following comments on the Dexcom G6.

In its experience, Diabetes UK stated that Dexcom represents a significant change from finger-prick blood glucose monitoring, which is presently the most common form of monitoring. It noted that the Dexcom G6 can be used in combination with either the Diabecare R insulin pump or the Tandem t:slim X2 insulin pump to produce a hybrid-closed-loop artificial pancreas system. This represents a significant change in diabetes management.

Diabetes UK noted that continuous glucose monitoring (CGM) devices, such as Dexcom, can improve patient experience and quality of life, particularly in diabetes-related quality-of-life measures such as diabetes distress. The size of the Dexcom sensor allows it to be worn in different locations and this may allow greater flexibility for patients.

The Dexcom sensor alarm function may benefit parents and carers of children with diabetes by reducing the need for blood glucose testing in the middle of the night, and for people with limited hypo-awareness by allowed earlier detection of a hypoglycaemic event then by routine testing. Other groups who may particularly benefit from Dexcom G6 include people with elevated haemoglobin A1c (HbA1c), people who experience frequent hypoglycaemia, people who do regular intensive exercise, and children and young people.

Diabetes UK stated that clinical benefits of CGM for people with diabetes are well documented. This includes the lowering of HbA1c levels, improved neonatal outcomes in mothers with type 1 diabetes and decreasing the number of hypoglycaemic events. They noted that since 2019 the Driver and Vehicle Licensing Agency permits CGM for people with diabetes to establish they are fit to drive, in place of finger-prick monitoring.

Diabetes UK noted the potential benefits of Dexcom on family life because of reducing the diabetes-related anxieties that parents and carers may experience when away from their children. However, the charity also noted that some people using CGM may experience burnout because of alarms or the volume of data CGM can produce. Data from the

Dexcom G6 could be used to offer more tailored, person-centred advice and support around steps to improve diabetes self-management. Training by the healthcare team would be needed and could be given remotely or face-to-face.

Expert commentators

The following clinicians contributed to this briefing:

- Ms Mel Curtis, diabetes specialist nurse, Swindon Integrated Diabetes Service.
- Professor Partha Kar, consultant endocrinologist, Portsmouth Hospitals NHS Trust.
- Dr Parth Narendran, reader in diabetes medicine, University of Birmingham, and consultant diabetologist, The Queen Elizabeth Hospital, Birmingham.

Representatives from Diabetes UK contributed to this briefing.

Development of this briefing

This briefing was developed for NICE by the King's Technology Evaluation Centre (KiTEC). NICE's interim process and methods statement for the production of medtech innovation briefings sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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