

Supporting diabetes management to help improve health and lives

Introducing Dexcom ONE Continuous Glucose Monitoring System



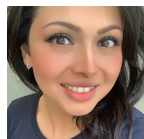
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Foreword



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PCN pharmacist, North Stockton PCN

Diabetes is a complex disease, progressive in nature and unfortunately growing in prevalence.¹ The landscape of diabetes management is evolving and requires a multifactorial approach to prevent or delay complications and maintain health outcomes.²⁻⁴ Glucose measurements are critical to effective diabetes management; however, optimising glucose levels is not always as simple as it appears. Haemoglobin A1C (HbA1c) is the most traditional biomarker, providing a retrospective approximate measure of glycaemic control and is seen as the gold standard for determining glycaemic control.

It is widely documented that reductions in HbA1c reduce complications associated with diabetes.⁴⁻⁶ However, HbA1c fails to reveal acute glycaemic excursions and at times fails to accurately reflect glucose management.⁷ In contrast, Time in Range (TIR) exposes glycaemic fluctuations allowing for a faster assessment and response to treatment adjustments that can otherwise create challenges.^{8,9} It is recommended by an expert panel that TIR should be used to complement HbA1c in defining glycaemic management.^{5,6,10,11}

How can this technology that already exists benefit our patients and revolutionise diabetes care? Continuous

glucose monitoring (CGM) used as a personalised tool can support clinicians and patients to overcome the limitations of HbA1c in diabetes management by providing insight into the direction, magnitude, duration, frequency and causes of glycaemic variability, as well as the impact of lifestyle and medication, particularly when combined with education and support.^{3,10} The monitoring of TIR, alarms/alerts and minimising hypoglycaemia allow delivery of a more personalised approach to improving diabetes management.^{3,6,10}

Barriers that prevent HCPs implementing CGM, include availability of clinical resources, confidence in addressing patient's perceptions, lack of understanding, implication of data, prerequisites to initiations and lack of local guidance. Barriers that prevent patients accessing CGM include accuracy, wear discomfort, and social factors.⁹ The time delay seen by a CGM system can be perceived incorrectly as inaccurate.¹²

From a pharmacist's perspective, data from CGM can prove invaluable, providing trend information and a detailed glycaemic profile allowing for the initiation, monitoring and adjustment of therapies. Using CGM in patients where detailed glycaemic information is required, allows adjustments in therapy and the ability to monitor the impact of newly initiated medication.

Prior to CGM the identification and addressing of glycaemic variability warranted regular monitoring of blood

glucose levels via self-monitoring of blood glucose (SMBG).⁸ In North Stockton primary care network, using CGM in care home patients has enabled us to identify nocturnal hypoglycaemia and facilitate adjustments in insulin therapy to improve glycaemic control. We are supporting an ongoing project involving District Nurses and care home patients where CGM has led to the identification of patients that required changing from NPH insulin to a synthetic ultralong-acting insulin once or twice per day to reduce hypoglycaemia and improve capacity. This would not have been possible previously as SMBG could not have been performed frequently enough (feasibility and pain) to sustain over the long term.⁸

In conclusion, the benefits of CGM are already within our grasp. TIR from CGM can complement HbA1c by offering a detailed insight into glycaemic fluctuations and timely treatment evaluation. Alongside support and education, CGM is an invaluable tool when optimising, initiating and

de-escalating glycaemic therapies. The updated NICE guidelines reflect this in recommending offering CGM to people with type 1 and type 2 diabetes.¹³⁻¹⁵ Using real-time CGM such as the Dexcom ONE actively supports and encourages patient empowerment, allowing for better glycaemic management without finger pricking or active scanning. This booklet is a tool to support pharmacists in realising the benefits of rtCGM and to guide patients to achieve these benefits.

Abbreviations

CGM	Continuous glucose monitoring
isCGM	Intermittent scanning continuous glucose monitoring
rtCGM	Real-time continuous glucose monitoring
T1D	Type 1 diabetes
T2D	Type 2 diabetes
SMBG	Self monitoring of blood glucose

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Introduction

General glucose monitoring plays a role in the diagnosis of diabetes and is an essential part of diabetes management. Avoidance of hypoglycaemia in type 1 diabetes (T1D) and type 2 diabetes (T2D) with insulin requires the consideration of contextual factors such as eating and exercise.¹ Additionally, for those with T2D, long, unnoticed prolonged hyperglycaemic episodes are critical risk factors for long term complications requiring medical intervention or even intensive care.¹

Historically, self-monitoring via finger pricks has been the only option

for patients to manage their diabetes, with some success for improving HbA1c levels.¹ For T2D however, self-monitoring blood glucose (SMBG) only leads to slightly better glycaemic control in the short term, with no significant long-term improvements.^{2,3} Self-monitoring for both T1D and T2D can be perceived as a burden and has been associated with impaired mental health, diabetes-related distress, and a lack of compliance.^{1,4}

The burden of self-monitoring can be overcome with the use of continuous glucose monitoring (CGM). Recently implemented NICE guidance



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Burden of self monitoring blood glucose with finger pricks

Impaired mental health

Lack of compliance



Diabetes-related distress

recommends offering CGM systems to adults and children with T1, and to certain groups of adults with T2 on multiple daily insulin injections.⁵⁻⁷ The guidance includes recommendations for both real-time CGM (rtCGM) and intermittently scanned CGM (isCGM). However, research suggests that HbA1c is improved, the time spent in range (3.9 - 10.0 mmol/L) is higher, time below range and hypoglycaemia distress is lower for people using rtCGM.⁸⁻¹¹

The Dexcom ONE Continuous Glucose Monitoring system is a smart

and easy-to-use diabetes management tool,* continuously measuring glucose levels within the interstitial fluid, and displaying sensor readings on a smartphone[†] or receiver without finger pricks[‡] or scanning.¹² Dexcom rtCGM not only demonstrates improved clinical outcomes, such as lower HbA1c, but has also been seen to improve overall wellbeing, treatment satisfaction and hypoglycaemic confidence, along with a reduced fear of hypoglycaemia and diabetes distress.¹³⁻¹⁷

*Results obtained with Dexcom G6 study, which uses the same applicator, sensor and algorithm as Dexcom ONE

† For a list of compatible devices, visit www.dexcom.com/compatibility

‡ If your glucose alerts and readings from the Dexcom ONE do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions

Importance of tackling diabetes

Diabetes is one of the most common chronic diseases in the UK, with an estimated prevalence of 3.9 million, and almost a million people are estimated to have undiagnosed diabetes.¹⁸ This number is estimated to rise to 5.5 million by 2030.¹⁹ The NHS spends at least £10 billion a year on diabetes, accounting for 10% of its entire budget. Approximately 80% of this total is spent on complications associated with diabetes.¹⁹

There is an exponential relationship between higher HbA1c and diabetes complications, meaning finding treatment options for reducing HbA1c is of great concern.¹⁶ rtCGM has been shown to reduce HbA1c levels especially in patients with higher HbA1c levels at study start, those at the higher risk of diabetes complications.²⁰

The burden of living with diabetes

Diabetes therapy and prognosis are highly dependent on self-management. Self-management of diabetes includes keeping track of administering insulin, maintaining healthy lifestyle habits such as diet and exercise, and instigating proper foot care.¹ Despite self-monitoring of blood glucose showing improvements in HbA1c, this constant self-management can be seen as a burden and can negatively affect mental health.¹

In fact, high levels of negative affect and greater variability in negative affect have been associated with higher glucose levels, higher rates of hyperglycaemia, and greater time out of glucose level range, while higher positive affect was related to lower rates of hyperglycaemia.²¹ Similarly,

in adolescents, positive affect was associated with in-range glucose levels, reduced odds of very low glucose, and reduced daily blood glucose variability.²²

Maintaining optimal quality of life and preventing acute and long-term complications of diabetes requires not only monitoring of glucose but also contextual factors such as mental health, self-care, and sleep.¹

rtCGM systems are a convenient and accurate way to receive a complete picture of the glucose level with a simple glance at a screen mitigating diabetes worry and distress. Within just 3 months of using Dexcom rtCGM, improvements in psychosocial outcomes and improved HbA1c were reported for people with T1D and T2D. These improvements included less diabetes distress and hypoglycaemia fear, as well as greater treatment satisfaction.^{17,23,24}

Compliance

Patient compliance to self-monitoring is essential for successful management of diabetes. Unfortunately, compliance can be quite low, with one study reporting a compliance rate of only 57.6% using SMBG.⁴

Factors associated with reducing patient compliance included a longer course of diabetes and the use of oral anti-diabetic agents.⁴ Poor compliance in patients with a long course of disease may be explained by patients' negative perceptions of the disease as this is seen to affect diabetes self-management.^{4,25} For children and their parents, reasons for



not regularly monitoring glucose included the cost of strips and glucometers, the fear of pain and injection, psychological frustration, lack of availability of information to deal with high readings, no motivation, and challenges in finding appropriate and safe places to perform self-monitoring of blood glucose.²⁶

A general desire to avoid thinking about glucose values and diabetes is a considerable obstacle to self-monitoring; patients who are highly avoidant have lower self-monitoring frequency.²⁷ Furthermore, the degree of avoidance of diabetes and the view that self-monitoring is pointless both significantly impacted how often self-monitoring of glucose data was shared to clinicians.²⁷

It was found that HbA1c was reduced by 0.46% in patients using a Dexcom rtCGM sensor more than 70% of the time, while there was no significant change if used less than 70%.²⁴ Dexcom rtCGM systems have high patient compliance rates of around 70 - 90%, underlining the added convenience of Dexcom rtCGM systems.^{13,14,24,28}

Each week there is an estimated:¹⁹



185

leg, foot, or toe amputations



30

patients with seriously affected sight



700

premature deaths

Guidance on use of CGM



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Previous NICE guidance only recommended CGM technology for adults with T1D under certain circumstances. More recently, the NICE committee have agreed that there is enough evidence in key outcomes, such as HbA1c, time in range, and severe or nocturnal hypoglycaemia, to demonstrate that rtCGM and isCGM provide clinical benefits over standard self-monitoring of blood glucose in T1D and T2D.^{5,7} Updated NICE guidance, published in March 2022, now **recommends** the use of rtCGM and isCGM for adults and children living with T1D, and to **consider** rtCGM next to isCGM for T2D in intensive insulin therapy for the first time.⁵⁻⁷

The guidance emphasises the need to use shared decision making when choosing a CGM device according to the patient's needs and preferences^{5,6,7}

Factors to consider include accuracy of the device, the need for predictive alerts or alarms, access to appropriate software, the need for calibration, fear of hypoglycaemia, and body image concerns.⁵⁻⁷

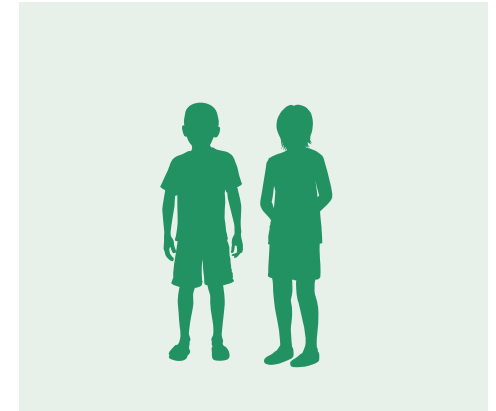
Nevertheless, research has shown that patients have improved HbA1c, spend a greater time in range, and have lower hypoglycaemia distress when using rtCGM compared to isCGM.⁸⁻¹¹

All people with diabetes should be advised that they will still need to take capillary blood glucose measurements if their symptoms do not match their CGM measurements, although this may be less often than with self-monitoring.^{5,7} All key information on CGM must be included in the structured education programme provided by clinicians and people should be empowered to use CGM devices.⁵⁻⁷



NICE recommendations for adults with diabetes

- Recommendation to offer adults with T1D a choice of rtCGM or isCGM based on their preferences and needs⁵
- Offer rtCGM as an alternative to isCGM for adults with insulin treated T2D if it is available for the same or lower cost⁷
- Only offer CGM to T2D if any of the following apply:⁷
 - They have recurrent hypoglycaemia or severe hypoglycaemia
 - They have impaired hypoglycaemia awareness
 - They have a condition or disability (including a learning disability or cognitive impairment) that means they cannot self-monitor their blood glucose by capillary blood glucose monitoring but could use an isCGM device (or have it scanned for them)
 - They would otherwise be advised to self-measure at least 8 times a day



NICE recommendations for children with diabetes

- Offer rtCGM to all children and young people with T1D, before isCGM, alongside education to support them, their families and their carers to use it⁶
- Only offer isCGM to children (>4 years) who are unable to use rtCGM or show a clear preference for isCGM⁶

Meet Chris, a patient with type 1 diabetes



Not a real patient, for illustrative purposes only

Patient profile

Chris is an insurance broker and an assistant coach for his local football club. Intermittently scanning his blood glucose monitor takes up time in his day where he could be working, which is frustrating for Chris. He would like to play football on the weekends but is often tired and worries about having a hypoglycaemic episode if he doesn't scan frequently enough. He tries his best to manage his diabetes with intermittent scanning and insulin but the burden of this interferes with his work and social life, and as a result Chris struggles with his mental health.

Age 34 years old

Height 5' 10"

BMI 22

Current diabetes management isCGM, insulin aspart injection at mealtimes, insulin glargine at night

Medical history Estimated 175 days spent recovering from hypoglycaemic episodes (Juvenile Diabetes Research Foundation, 2022)

Other health conditions Difficulty sleeping

Meet Carol, a patient with type 2 diabetes who takes insulin



Not a real patient, for illustrative purposes only

Patient profile

Carol is a receptionist who enjoys gardening and spending time with her young grandchildren. She finds it difficult to be regularly active and has struggled to maintain a healthy weight over the years. Carol manages her diabetes with diet and exercise, insulin, and finger prick tests, but this leaves her fingers sore and makes it harder to type on a keyboard. Managing her diabetes is distressing and she does not test her blood sugar as often as she should leading to uninformed insulin dosing. Carol is worried about the future and her health long term.

Age 58 years old

Height 5' 4"

BMI 29

Current diabetes management Diet and exercise, finger-prick tests, insulin glargine injection once a day

Medical history Difficulty managing weight

Patient benefits of Dexcom rtCGM

Better quality of life by providing peace of mind

For patients using blood glucose monitoring or isCGM, rtCGM provides an alternative for accurate, automated glucose monitoring without the need for fingerpricks* and scanning, for people with diabetes using insulin.

Transitioning to a Dexcom rtCGM system been shown to significantly

improve subjective well-being and treatment satisfaction, in comparison with conventional therapy.²⁴ For patients living with T1D for over 10 years, rtCGM use reportedly contributed to hyperglycaemic confidence, improved overall wellbeing, and reduced diabetes distress.^{17,24}

Patients with diabetes using Dexcom rtCGM had a lower fear of hypoglycaemia than those using fingerpricks²⁴

Trusted accuracy, reliability, and clinical relevance

Dexcom rtCGM systems demonstrate consistent sensor accuracy, even in instances where glucose levels are rapidly rising or falling, which should give users high device confidence and facilitate persistent use.^{1,12,29,30} Greater patient satisfaction with accuracy is linked to better adherence, more confident and intensive insulin adjustments, improvements in quality of life, reduced reliance on self-monitoring of blood glucose, and may reduce alarm fatigue.³¹

Simple monitoring of glucose levels

Using a Dexcom rtCGM system can improve glycaemic control, which is particularly important for younger patients with diabetes.³² For young

children aged 2 to <8 years old with T1D, percentage time in hypoglycaemia was significantly reduced when using a Dexcom rtCGM compared to blood glucose monitoring (2.5% vs 5.8%).³³ Time spent in range (3.9 - 10.0 mmol/L) for 14 to 24 year-olds with T1D using a Dexcom rtCGM system was greater than for standard blood glucose monitoring (43% vs 35%).³⁴ For adults already using isCGM, time spent in range was higher when using a Dexcom rtCGM system (59.6% vs 51.9%),⁸ and for older adults (60+ years), time spent in range was 8.8% higher using an rtCGM system than standard blood glucose monitoring.³⁵

Dexcom rtCGM systems remove the need for intermittent scanning or finger pricks* and can help patients manage their diabetes by automatically monitoring when their glucose levels

Benefits of Dexcom rtCGM



are in range, below or above, delivering the full picture of their glucose readings. When using Dexcom Clarity,[†] an 8.4% increased time in range has been shown when users engaged with all the Clarity features, such as web-based reports and automated notifications.³⁶

Dexcom Clarity helps prepare patients for conversations with clinicians by giving access to key metrics and reports, which they can share with their healthcare

team. Dexcom Clarity (Professional) also helps healthcare professionals by consolidating their patient's diabetes data in one place, delivering automated reports at a glance, and allows consultations to take place virtually as well as in person. This flexibility allows for more efficient time management when healthcare professionals have limited appointment time per patient.

*If your glucose alerts and readings from the Dexcom ONE do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions

† Results obtained with Dexcom G6 study, which uses the same applicator, sensor and algorithm as Dexcom ONE

‡ An internet connection is required while uploading to Dexcom Clarity. For full detailed instructions always refer to the Dexcom Clarity user guide

CGM can boost the benefits of exercise

Physical activity can help improve glycaemic control, reduce glycaemic variability, and reduce insulin resistance.³⁷ One of the strongest barriers preventing people with T1D from incorporating physical activity into their daily lives is fear of hypoglycaemia.³⁷ Even mild-to-moderate exercise can increase insulin sensitivity for the following 11 to 16 hours and lead to late-onset or nocturnal hypoglycaemia.³⁷

A rtCGM system provides real-time observation of glucose levels allowing patients to quickly detect glycaemic changes that occur during physical activity and its recovery phase.³⁷

The use of CGM and its progress curves offer the possibility to avoid

hypoglycaemia or to react to it at an early stage, especially for people with T1D who are regularly physically active.³⁷ CGM systems can predict further glycaemic courses and consider the influences of sport on glucose levels.³⁷ The simplicity of CGM can help motivate people with diabetes to undertake more physical exercise, which in turn further improves glycaemic control and variability.³⁷ One randomised clinical trial with poorly controlled T2D participants showed using rtCGM for three days per month for 12 weeks resulted in increased physical activity and an additional 1% reduction in HbA1c.³⁸



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Introduction to Dexcom ONE



The Dexcom ONE Continuous Glucose Monitoring system is a smart, effective and easy-to-use diabetes management tool for people with diabetes ages two years and older.^{*,12-14} Dexcom ONE uses a small wearable sensor and transmitter to measure and send real-time glucose values wirelessly to a compatible smart phone[†] or receiver, eliminating the need for painful finger pricks[‡] or active scanning. The app or receiver displays trend arrows to show the speed and direction glucose levels are heading and the customisable alerts indicate whenever glucose levels fall outside of pre-set high and low levels, making treatment decisions easier. There is an option to delay the first high alert. This has been designed to make the high alert even more actionable and relevant for the person living with diabetes. The delay first alert enables users to delay their first high alert for a specific amount of time and only activates if the reading is still at or above the designated alert setting. That specific amount of time can

be set from 15 minutes up to 4 hours. If the glucose level goes up and comes back down within this amount of time, the high alert will not trigger, and this may help to prevent alarm fatigue.

Dexcom ONE makes diabetes management easier, and empowers users to take control of their diabetes:

- Real-time readings with just a glance at the Dexcom ONE smartphone app^{*} or receiver
- Diabetes management with zero fingerpricks,[‡] scanning or calibrations
- Glucose readings the user can trust^{*,12}
- Customisable low and high alerts
- Flexible options for sensor location, convenient, and discreet
- Accurate and easy to use^{*,12}

* Results obtained with Dexcom G6 study, which uses the same applicator, sensor and algorithm as Dexcom ONE

† For a list of compatible devices, visit www.dexcom.com/compatibility

‡ If your glucose alerts and readings from the Dexcom ONE do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions

Using Dexcom ONE

How is it applied?

The sensor is placed on the abdomen or back of the arm, avoiding bones, irritated skin, tattoos, and areas that get bumped easily. For people aged 2-17, the sensor can additionally be placed on the upper buttock.

To apply the Dexcom ONE sensor and transmitter, the patient should wash their hands and clean the sensor site with an alcohol wipe before following the steps below.



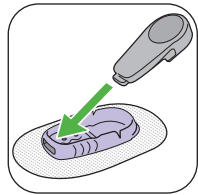
1

Peel off adhesive backing and place the applicator on the skin before breaking off the safety guard (NB: make sure to keep the adhesive backing as this shows the sensor code)



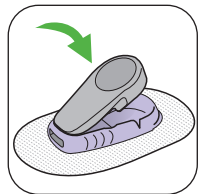
2

Press the button to insert the sensor, then remove the applicator from the skin leaving just the patch and holder



3

Now, clean the transmitter with an alcohol wipe and insert it into the holder with the thinner end first; listen for a click to signal that it is snug in the holder



4

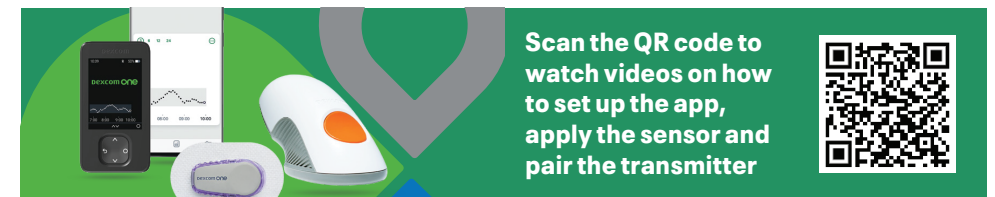
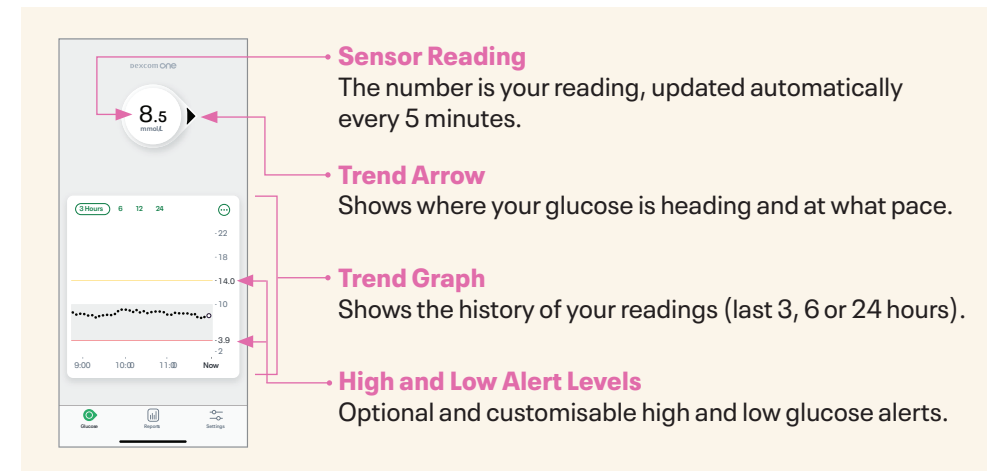
Rub around the patch 3 times to optimise the adhesion (NB: the transmitter lasts up to 3 months)

How is it used?

Once communication is confirmed with the transmitter, a 2-hour sensor warmup will start, after which the first reading will appear on the read-out device (receiver or app). The sensor measures glucose readings from the interstitial fluid every 5 minutes, which are transmitted to the Dexcom ONE read-out device. The app will also store summary reports of glucose information over the last 3, 7, 14, 30 and 90 days, and can be used to identify trends in glucose patterns. The Dexcom ONE receiver will store and allow review of up to 30 days data.

What's on prescription?

Sensors for the Dexcom rtCGM system last for 10 days and can be ordered by prescription on the National Health Service (NHS) if the patient is eligible as per local criteria; pharmacies can order through Alliance Healthcare. Patients will need to order three sensors per month and a new transmitter every three months. Once used, the applicator must be disposed of appropriately in the sharps bin which can be ordered by the patient through their pharmacy.



What's next for Chris and Carol?



Chris' fear of hypoglycaemia during and after exercise and Carol's lack of self-monitoring has caused enough stress to motivate them to talk to their GPs. They each expressed that their anxiety about controlling their diabetes has become overwhelming and asked what their options are.

Carol's GP suggested rtCGM technology to avoid the need for fingerpricks and to provide continuous information on her glucose levels, providing insight to help her with dietary management.

Since Chris is already using isCGM, his GP recommends rtCGM to ensure real-time tracking of glucose levels with customisable alarms during exercise to reduce the burden of intermittently scanning and worry about hypoglycaemia.

What would you choose for Chris and Carol?

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NICE guidance now recommends the use of real-time continuous glucose monitoring (rtCGM) for adults and children living with T1D and to be considered for T2D on intensive insulin treatment⁵⁻⁷



The Dexcom ONE real-time Continuous Glucose Monitoring System makes diabetes management easier, measuring glucose levels automatically in real time and displaying them on your patient's smartphone* or receiver



Compared to self-monitoring and intermittent scanning CGM (isCGM), Dexcom rtCGM use has been shown to be associated with improved glycaemic control, increased time spent in optimal glucose range, and improved HbA1c levels¹³⁻¹⁵



rtCGM use reportedly contributed to hyperglycaemic confidence, improved overall wellbeing, reduced diabetes distress, and high rates of treatment satisfaction^{15,17}



Use of rtCGM and its progress curves offer the possibility to avoid hypoglycaemia or to react to it at an early stage for physically active people³⁷

* For a list of compatible devices, visit www.dexcom.com/compatibility.