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Abbott Diabetes Care	Evidence Review	171	001	We are delighted by the draft recommendation for isCGM / Flash use in type 2 diabetes, as specified in the guideline document. Evidence included shows improvement in hypoglycaemia in people with type 2 diabetes, with Flash use, which is also discussed in the rationale for the guideline. The Yaron RCT demonstrates a significant improvement in HbA1c but was excluded with the reason cited as 'retrospective CGM' – please could you clarify this point. This was not a study with retrospective CGM, meaning a blinded system, so data accessible only for the HCP during consultation. The participants in the intervention group used the FreeStyle Libre system for 10 weeks and were instructed to scan with a reader at least every 8 hours so they would see the data themselves. When using a reader data is not automatically uploaded to the cloud so desktop software was used so the data was stored centrally and also to share the data with the consulting physician during the visits. We feel there may have been a misunderstanding around this point leading to the conclusion of 'retrospective CGM'	Thank you for your comment. The committee considered your feedback and the NICE technical team looked again at the Yaron RCT (2019). It was agreed that there has been a misunderstanding and the Yaron RCT did meet our inclusion criteria and has been added to our evidence review.
Ascensia Diabetes Care	Guideline	005	021	We welcome the inclusion of Continuous Glucose Monitoring into these guidelines, however believe the guidance should be extended under this section, to also include that capillary blood glucose monitoring should still be provided to support the person with diabetes with all the tools necessary to manage their condition. Materials for two of the commonly utilised systems on the market in the UK, the Abbott Freestyle Libre 2 and Dexcom's G6, state the continued need for capillary SMBG under certain circumstances[1,2]. At these times when SMBG testing may be needed, it is paramount to obtain an accurate reading, however the current regulations in place to market a capillary SMBG meter in the UK is such that there is no independent assessment. This concern has been voiced by the JDRF	Thank you for your comment. In response to stakeholder feedback the committee agreed to add a recommendation acknowledging the importance of capillary blood glucose monitoring and that it is still needed as a back up to real-time CGM and isCGM and to ensure they have enough test strips to do this (rec 1.6.20). Thank you for raising this issue however the quality and accuracy of blood glucose meters is beyond the scope of this guideline update.

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				which on their website states "It's a surprise to most people, including doctors and nurses, that a blood glucose meter doesn't have to be independently assessed to be placed on the market in the EU, including the UK."[3] In reality current meters marketed with a CE mark are no guarantee of quality or accuracy, which has been demonstrated via published data by Klonoff et al[4] in 2018, this study assessed 18 meters marketed in the US but also used in the UK, against both the ISO 15197:2015 and the FDA guidelines and found that only 6 out of the 18 meters evaluated met those standards, with 12 failing to meet the standards. Data published by Ekhlaspour et al[5] also evaluated 17 meters against the ISO 15197:2015 standards and they found just 2 of the meters met the standard with the other 15 meters failing to meet the standards. Again all 17 meters had a CE mark. For those T2 people with diabetes (PWD) utilising multiple daily injections of insulin, meter accuracy should be a key concern, since dosing errors could be made when using an ISO compliant meter compared a highly accurate meter like the Contour® Next One & Contour® Plus Blue. As an example, a patient looking to reduce their blood glucose level from 14mmol/L down to 7mmol/L, using a meter that meets the ISO standard of ±15%, would give them a range of between 2 and 5 units to administer. Whereas with a highly accurate meter such as the Contour® Next One with an accuracy of ±8.4%[6], this range of insulin administered would be reduced to between 3 and 4 units. The example demonstrates the impact of the meter accuracy and the resultant variance of the PWD's blood glucose levels. This greater variance of a less accurate SMBG meter could impact the PWD's ability to manage their blood glucose levels and the impact it has on achieving their target	

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				HbA1c level. This makes the assumption the meter meets the ISO15197:2013 standards which based on published data outlined above is not the case for a significant number of meters currently available and that any further increased error range of these meters would have a magnified effect on the insulin calculations. Our proposal would be to include in the guidance the specific need to also support the PWD with capillary blood glucose testing and that the HCP should utilise a meter and strip which demonstrates an accuracy level <±10%, to ensure in those situations when the PWD requires a blood glucose readings, the value obtained is accurate to support informed self-management and accurate insulin dosing. 1. Abbott Freestyle Libre 2 "Finger pricks are required if your glucose readings and alarms do not match symptoms or expectations." (https://www.freestylelibre.co.uk/libre/) 2. Dexcom G6 CGM states "If your glucose alerts and G6 readings do not match what you are feeling, use your blood glucose meter (meter) to make diabetes treatment decisions or, if needed, seek immediate medical attention" Dexcom G6 Instructions For Use Guide (LBL016368 Rev 008 MT25354 Rev Date: 2021/08) 3. https://jdrf.org.uk/information-support/treatments-technologies/continuous-glucose-monitors/how-accurate-is-my-blood-glucose-monitor/ 4. D Klonoff et al, Investigation of the Accuracy of 18 Marketed Blood Glucose Monitors, Diabetes Care 2018;41:1681–1688, https://doi.org/10.2337/dc17-1960 5. L. Ekhlaspour et al, Comparative Accuracy of 17 Point-of-Care Glucose Meters, Journal of Diabetes Science and Technology, 2017; Volume: 11 issue: 3, page(s): 558-566, DOI: 10.1177/1932296816672237	

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				5 Example based on an actual blood glucose level of 14.0mmol/L targeting to achieve a BG value of 7.0 mmol/L, with an insulin sensitivity of 2.0. 6 Christiansen M et al. Accuracy and user performance evaluation of a new blood-glucose monitoring system in development for use with CONTOUR™NEXT test strips. Poster presented at the 15th Annual Meeting of the Diabetes Technology Society (DTS); 22-24 October, 2015; Bethesda, Maryland. USA.	
Association of British HealthTech Industries	Guideline	General	General	It is important that people living with diabetes, their families and carers have access to diabetes management technology that enables effective glucose control based on their individual preferences and needs. Furthermore, the need for education and training, and to empower people to self-manage cannot be underestimated or overlooked. The ABHI welcomes these recommendations. However, ABHI wishes to express caution over a recommendation that advocates for use of 'lowest cost' medical technology. This is a general comment on behalf of the medical devices industry, and not limited to diabetes therapy. In this instance, whilst the recommendation makes clear that technology of choice does need to meet the person's identified needs and preferences, there have been many instances across our health system where the opportunity to drive patient access based on low cost is sought ahead of individual preference and patient outcomes. We suggest that any implementation tools published reiterate that clinical decision making should not be dictated by price alone.	Thank you for your comment and support of the guideline. Cost is an important consideration in NICE guidelines. Because of the additional cost associated with CGM and the large number of adults with type 2 diabetes, the committee used both the evidence and their clinical experience to decide who would gain the most benefit from using CGM. We agree however that it is important that considerations about cost are not made in isolation, but linked to clinical benefits and patient preferences, and we would agree this needs to be done as part of implementation and clinical decision making, as well as being a part of guidance.
Association of Chartered Physiotherapists in Cardiovascular	Guideline	General	General	This guideline does not include the routine prescription of capillary blood glucose monitoring equipment for people with T2DM on insulin secretagogues (particularly sulphonylureas) in relation to physical activity and exercise. This is a notable omission given that exercise training can enhance blood glucose control.	Thank you for your comment. This specific issue is beyond the scope of this guideline update.

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Rehabilitation (ACPICR)				Within a cardiac rehabilitation and/or physical activity environment, this makes exercise prescription difficult. Often rehabilitation teams don't have easy access to the equipment, and they are often not provided by primary care due to limited guidance. For the individual, the immediate impact is risk of hypoglycaemia, which reduces confidence for exercise. Compared to those on Insulin, the hypoglycaemia is often more resistant to treatment, causing a more prolonged interruption to delivery of the exercise session. Ultimately, the more long-standing impact is that the individual is less likely to become a safe, independent exerciser.	
Boehringer Ingelheim UK	Guideline	General	General	Dear NICE Team, Boehringer Ingelheim welcomes the opportunity to comment on these guidelines. Boehringer Ingelheim fully supports any opportunities for patient empowerment to enable them to better monitor and manage their Type 2 Diabetes. We agree with the principle that people with diabetes have the right to be involved in the decisions regarding their treatment and the management of their condition. These draft Guidelines introduce for the first time the opportunity for appropriate patients with Type 2 diabetes to be offered intermittently-scanned continuous glucose monitoring which we see as a real benefit for patients, their carers and families and as an Organisation we support the recommendations in this Guideline draft. Thank you Kind Regards	Thank you for your comment and support for this guideline.
British Association for	Guideline	005	021	The guidance for T2DM does not mention the specific need for blood glucose monitoring to be done when someone	Thank you for your comment. Due to the high number of people who have type 2 diabetes, and the costs associated

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Cardiovascular Prevention and Rehabilitation				with T2DM is using an insulin secretagogue (especially the sulphonylureas) and begins to be more active or increase their exercise. Clinically, this means that this population are put under unnecessary risk of hypoglycaemia episodes at home when they become more active independently. From discussing with colleagues around the country, we have found GPs are often reluctant to prescribe CBG monitors for these individuals as it is not specifically mentioned in the NICE guidance. See our recent statement https://bjsm.bmj.com/content/bjsports/55/13/709.full.pdf	with the use of CGM, the committee decided to recommend CGM for those who they thought would benefit the most from its use. Although people who use an insulin secretagogue and become more active may be at greater risk of hypoglycaemic episodes, this is something that they could be made aware of as part of the education recommended in the Type 2 diabetes in adults guideline (NG28). More information on how the committee decided which groups should be offered CGM is available in the committee discussion section of the evidence review.
British In Vitro Diagnostics Association (BIVDA)	Guideline	General	General	The guidance should encourage that only products bearing a UKCA or CE mark should be provided to patients (while the CE mark continues to be recognised within the UK market). Users should also be made aware of how to report issues with their continuous glucose monitor with their healthcare professional and through the MHRA Yellow Card reporting scheme.	Thank you for your comment. NICE recommendations apply to products that are licensed for use in the UK, and so would not include those that do not meet UKCA or CE standards. Recommendation 1.6.20 states that CGM should be provided by a team who have expertise in its use, and recommendation 1.6.22 includes education about the use of CGM as part of education provided to people who have type 2 diabetes. These recommendations will give people an awareness of what to do if they have issues with their monitor.
Centre for Perioperative Care	Guideline	General	General	The title of the guideline should be changed to reflect the fact that this refers to the person in the community, and not to hospitalised people- we would not want anyone to misread these documents and assume that the correct CBG zone for hospitalised people is 4-7.	Thank you for your comments. This is an update to sections of an existing guideline and so we cannot modify the title. The updated sections do not refer to treatment in hospital and so we believe that this should be clear to people who are using the guideline.
Centre for Perioperative Care	Guideline	General	General	CPOC suggests that NICE should add the following to future research- the use and safety of continuous glucose monitoring devices and continuous subcutaneous insulin infusion devices (pumps) - including sensor augmented pump therapy in an operating theatre – including the use of diathermy – as a top priority. Manufacturers should include	Thank you for your comment. This specific issue is beyond the scope of this guideline update.

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				this data when bringing out new devices and the MHRA / device regulators should insist on this data being available	
Centre for Perioperative Care	Guideline	General	General	Other drug combinations that should be researched – SGLT2is and GLP-1RAs given together	Thank you for your comments. The guideline update is looking specifically at the use of CGM for people with type 2 diabetes. The use of different combinations of drugs was beyond the scope of this update and so we could not make research recommendations for this area.
Centre for Perioperative Care	Guideline	005	004	1.6.14 – it is suggested that NICE should state who should teach the use of the glucose meter otherwise this recommendation will not be carried out in practice. Whilst this is something that is advocated for in the JBDS steroid guideline (Steroid use for inpatients with diabetes | ABCD (Diabetes Care) Ltd), it is not stated do not say who will teach the use of the glucose meter – if this recommendation is carried over to other specialities [respiratory, gastro, dermatology, rheumatology, oncology, etc) who commonly use oral or intravenous corticosteroids (as it should be), then diabetes services will be overwhelmed - primary care will not do this either, so this recommendation will not be adopted in practice (even though it says 'consider'). This is the aspirational ideal, but if no money or resources accompany this, then it is felt that it will be difficult for this to be introduced into everyday practice. CPOC recommends that it should be clearly stated whose role it is to teach this.	Thank you for your comment. These recommendations are beyond the scope of this guideline update.
Dexcom	General	General	General	References 1. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med. 1993;329(14):977-986.	Thank you for the supporting references. We have responded to these in relation to any other comments you have made. We have also included a list below of whether a reference was included in the review, and if not then why they were not included: 1. This study focuses on people with type 1 diabetes and does not contain the outcomes of interest for our review 2. This study focuses on people with type 1 diabetes and does not use CGM as the intervention 3. This study does not use CGM as the intervention

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				2. Reichard P, Pihl M, Rosenqvist U, Sule J. Complications in IDDM are caused by elevated blood glucose level: the Stockholm Diabetes Intervention Study (SDIS) at 10-year follow up. Diabetologia. 1996;39(12):1483-1488. 3. UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet. 1998;352(9131):837-853. 4. Gerstein HC, et al. Effects of intensive glucose lowering in type 2 diabetes. N Engl J Med. 2008;358(24):2545-2559. 5. Khunti K, et al. Rates and predictors of hypoglycaemia in 27 585 people from 24 countries with insulin-treated type 1 and type 2 diabetes: the global HAT study. *Diabetes Obes Metab.* 2016;18(9):907-915. 6. American Diabetes Diabetes Technology (ADA): Standards of Medical Care in Diabetes-2021, Diabetes Care 2021;44(Suppl. 1):S85–S99 7. Danne, T et al. (2017). International Consensus on Use of Continuous Glucose Monitoring.	4. This study does not use CGM as the intervention 5. This study does not use CGM as the intervention 6. These are recommendations on diabetes technology and not a relevant study design 7. This is a summary of recommendations and not a relevant study design 8. This study was excluded as it wasn't an RCT. It is an exploratory retrospective cohort study 9. This is an article commentary and not a relevant study design 10. This is a summary of CGM and not a relevant study design 11. This is a review of CGM and not a relevant study design 12. This study focuses on people with type 1 diabetes 13. This is a retrospective study that compared people who were hypoglycaemic to people who were not, and did not compare CGM to self-monitoring 14. Published after completion of the evidence review. Also see response to comment 1. 15. This is the same as the 1st reference provided 16. Study investigated the effects of discontinuing CGM rather than its effectiveness 17. Post-hoc analysis of an existing included study (Beck 2017) that does not include any additional relevant information 18. Already included in the review 19. This is a non-comparative observational study 20. This study focuses on people with type 1 diabetes 21. This study focuses on people with type 1 diabetes 22. The included link is to a report which is not in English

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				Diabetes Care, 40(12), 1631–1640.doi:10.2337/dc17-1600 8. Karter, A. J., et al. (2021). "Association of Real-time Continuous Glucose Monitoring With Glycemic Control and Acute Metabolic Events Among Patients With Insulin-Treated Diabetes." JAMA 325(22): 2273-2284 9. T. Haak et al Continuous Glucose Monitoring Versus Usual Care in Patients With Type 2 Diabetes Receiving Multiple Daily Insulin Injections, Ann Intern Med 2018 Vol. 168 Issue 7 Pages 525-526 Accession Number: 29610904 DOI: 10.7326/l17-0705 10. Burge MR, Mitchell S, Sawyer A, Schade DS. Continuous glucose monitoring: the future of diabetes management. Diabetes Spectr 2008; 21:112-19. 11. Verheyen N, Gios J, De Block C. Clinical aspects of continuous glucose monitoring. Eur Endocrinol 2010; 6:26-30. 12. Heinemann, L, Freckmann, G, Ehrmann, D, Faber-Heinemann, G, Guerra, S, Waldenmaier, D, Hermanns, N. Real-time continuous glucose monitoring in adults with type 1 diabetes and	23. Post-hoc analysis of an existing included study (Beck 2017) that does not include any additional relevant information

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				impaired hypoglycaemia awareness or severe hypoglycaemia treated with multiple daily insulin injections (HypoDE): a multicentre, randomised controlled trial. *Lancet* 2018;391:1367-1377 13. Ishikawa, Tet al. (2017). Continuous glucose monitoring reveals hypoglycemia risk in elderly patients with type 2 diabetes mellitus. Journal of Diabetes Investigation, 9(1), 69–74.doi:10.1111/jdi.12676 14. T. Martens, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Patients With Type 2 Diabetes Treated With Basal Insulin: A Randomized Clinical Trial, JAMA 2021 Vol. 325 Issue 22. 15. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med. 1993;329(14):977-986. 16. G. Aleppo, R. et al. The Effect of Discontinuing Continuous Glucose Monitoring in Adults With Type 2 Diabetes Treated With Basal Insulin, Diabetes Care 2021 Pages dc211304	

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				17. Billings, L.K et al, Baseline Glycated Hemoglobin Values Predict the Magnitude of Glycemic Improvement in Patients with Type 1 and Type 2 Diabetes: Subgroup Analyses from the DIAMOND Study Program. Diabetes Technol Ther, 2018. **20**(8): p. 561-565 18. Ehrhardt, N. M et al. (2011). *The Effect of Real-Time Continuous Glucose Monitoring on Glycemic Control in Patients with Type 2 Diabetes Mellitus. Journal of Diabetes Science and Technology, 5(3), 668–675.*doi:10.1177/193229681100500320 19. Pazos-Couselo, M et al. (2015). High Incidence of Hypoglycemia in Stable Insulin-Treated Type 2 Diabetes Mellitus: Continuous Glucose Monitoring vs. Self-Monitored Blood Glucose. Observational Prospective Study. Canadian Journal of Diabetes, 39(5), 428–433.doi:10.1016/j.jcjd.2015.05.007 20. Beck et al., Effect of initiating use of an insulin pump in adults with type 1 diabetes using multiple daily insulin injections and continuous glucose monitoring (DIAMOND): a multicentre, randomised controlled trial. Lancet Diabetes Endocrinol. 2017 Sep;5(9):700-708.	

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				21. Heinemann, L, Freckmann, G, Ehrmann, D, Faber-Heinemann, G, Guerra, S, Waldenmaier, D, Hermanns, N. Real-time continuous glucose monitoring in adults with type 1 diabetes and impaired hypoglycaemia awareness or severe hypoglycaemia treated with multiple daily insulin injections (HypoDE): a multicentre, randomised controlled trial. Lancet 2018;391:1367-1377 22. Gemeinsame Bundesausschus (G-BA); Joint Committee on a change in the methodology directive Contract medical care: Continuous interstitial glucose measurement with real-time measuring devices (rtCGM) for Therapy control in patients and Patients with insulin-dependent diabetes mellitus, June 16, 2016 (https://www.g-ba.de/downloads/39-261-2623/2016-06-16_MVV-RL_rtCGM_BAnz.pdf) 23. Puhr, S., et al. (2018). "The Effect of Reduced Self-Monitored Blood Glucose Testing After Adoption of Continuous Glucose Monitoring on Hemoglobin A1c and Time in Range." Diabetes Technol Ther 20(8): 557-560.	

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Dexcom	Guideline	005	020	Due to the above it is requested that the recommendation to offer is-CGM to people with Type 2 diabetes on multiple daily insulin injections if any of the following apply: **is amended to "offer rt-CGM".** • they have recurrent or severe hypoglycaemia • they have impaired hypoglycaemia awareness • they have a condition or disability that means they cannot self- monitor their blood glucose by intermittent capillary blood glucose monitoring but could use an isCGM device (or have it scanned for them) • they would otherwise be advised to self-test at least 8 times a day.	Thank you for your comment. Because of the additional cost associated with CGM and the large number of adults with type 2 diabetes, the committee used both the evidence and their clinical experience to decide who would gain the most benefit from using CGM. There was no evidence that real-time CGM was cost effective for people with type 2 diabetes, so the committee agreed it could not be recommended for all adults with type 2 diabetes, or for the subpopulation of adults with type 2 diabetes using insulin. For intermittently scanned CGM, there was evidence that it was cost effective for adults with type 2 diabetes using insulin, but no evidence for populations not using insulin, so the committee agreed to restrict their recommendations to that subpopulation.
Dexcom	Guideline	005	021	People that require insulin to manage their diabetes (Type 1 or Type 2) are at risk for developing hypoglycaemia. Numerous randomized clinical trials (RCTs) have shown that intensive diabetes therapy, which aims to achieve lower average blood glucose, increases the risk of severe hypoglycaemia by 2- to 3-fold in patients with T1D and T2D[1-4]. Nocturnal hypoglycaemia, which are severe hypoglycaemic events occurring at night, are particularly dangerous. Nocturnal hypoglycaemia is estimated to be a contributing factor to patients dying while asleep, which has been found to occur at an incidence of 2.5 events/patient-year inT2D patients[5]. Interestingly at a point where an individual is required to use insulin to control their diabetes, the American Diabetes Association's (ADA) 2021 Standards of Medical Care in Diabetes[6] do not differentiate between people with insulin dependent Type 2 diabetes and Type 1 diabetes in regard to the use of CGM. The ADA recommend that CGM should be used for insulin	Thank you for your comment. The committee agreed that hypoglycaemic events are one of the most important and concerning outcomes for adults with type 2 diabetes, and so the potential to reduce these events are crucial. The evidence showed reductions in nocturnal hypoglycaemic events and nocturnal time spent in hypoglycaemia with isCGM, although it only showed small reductions in the number of total hypoglycaemic events, with effects less than the minimal important difference. However, in the committee's experience, advances in isCGM technology that have taken place since the evidence was published mean that the use of isCGM is a good way to monitor and reduce the number of hypoglycaemic events. In the committee's experience, isCGM was also an effective method for people with impaired hypoglycaemic awareness to monitor their blood glucose levels, and so this group were also listed as people who should be offered isCGM.

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				dependent diabetics, without differentiating between Type 1 and Type 2 diabetes. As the guidance is mainly focused on providing intensive insulin using Type 2 diabetic people with the appropriate technology to avoid severe hypoglycaemic events, the guidance should recommend a class of product that is proven to reduce severe hypoglycaemic events and improve glycaemic control in insulin dependent diabetics, this being rt-CGM. The alarm functionality is key to prevent the occurrence of hypoglycaemia, particularly if the patient does not recognise the symptoms of the impending event. This recommendation was first made in 2017 in the ATTD International Consensus on Use of Continuous Glucose Monitoring statement[7] , recommending that "*CGM should be considered in conjunction with HbA1c for glycemic status assessment and therapy adjustment in all patients with type 1 diabetes, and patients with type 2 diabetes treated with intensive insulin therapy who are not achieving glucose targets,* ***especially if the patient is experiencing problematic hypoglycaemia****."* (Danne et al 2017, p1631-1640). Similarly to the ATTD consensus, rt-CGM is recommended and funded within the German health care system for patients on intensive insulin therapy, regardless of whether it is a person with Type 1 or Type 2 diabetes[22].	
Dexcom	Guideline	007	023	NICE guideline NG17 Evidence reviews underpinning recommendations 1.7.3 to 1.7.7 and research recommendations in the NICE guideline NICE may also consider the developing evidence base demonstrating the clinical value of using rt-CGM in the wider insulin using Type 2 diabetic population. **Clinical Evidence** Martens et al (2021)[14] published a multicentre, randomized, open-labelled, parallel group clinical trial to determine the	Thank you for your comment. Because of the additional cost associated with CGM and the large number of adults with type 2 diabetes, the committee used both the evidence and their clinical experience to decide who would gain the most benefit from using CGM. There was no evidence that real-time CGM was cost effective for people with type 2 diabetes, so the committee agreed it could not be recommended for all adults with type 2 diabetes, or for the subpopulation of adults with type 2 diabetes using insulin. For intermittently scanned CGM, there was evidence that it was cost effective for adults with type 2 diabetes using

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				effectiveness of CGM in adults with T2D treated with basal insulin without prandial insulin in a **primary care setting**. This study included 175 T2D patients with HbA1c levels between 7.8% and 11.5% [mean 9.1%] who used 1-2 daily injections of long- or intermediate-acting basal insulin for at least 6 months. This study demonstrated that CGM users achieved a -0.4% decrease in HbA1c levels vs SMBG users [8.0% vs 8.4%, respectively, at 8-months]. A far greater proportion of CGM users (63%) obtained an HbA1c of <8% at 8-months compared to SMGB users (39%). In addition, Martens and colleagues also found 63% of CGM users compared to 41% of the SMBG group achieved a ≥10% improvement in HbA1c, a 54% relative greater improvement, which based on the DCCT trial, for example this equates to a 40% reduction in the development of retinopathy[15]. Aleppo et al[16] conducted a 6-month follow-up analysis to Marten study that assessed the clinical value for sustained use for rt-CGM in insulin using type 2 diabetics, This analysis re-randomised rt-CGM using participants, to either continue or discontinue rt-CGM. The participants that discontinued CGM were placed on blood glucose monitoring (BGM). The results of this analysis clearly demonstrated that a significant proportion of the benefits such as time in range (TIR) derived through use of CGM were lost when CGM was withdrawn. The study findings clearly demonstrate that with the use of rt-CGM, poorly controlled patients with T2D on basal insulin can improve glycaemic control in the primary care setting. Billings et al[17] (2018) conducted a post hoc analysis to investigate whether the DIAMOND study participants at progressively higher baseline HbA1c levels benefit from using rt-CGM. In this analysis, 120 T2D patients (rt-CGM, n=63; control, n=57) with baseline HbA1c ≥ 8.0% – 10%	insulin, but no evidence for populations not using insulin, so the committee agreed to restrict their recommendations to that subpopulation. Thank you for suggesting these studies for consideration: This new Martens et al study (2021) with outcome data for rtCGM was published after the evidence review search cut-off date. The committee did consider the findings from this study but agreed that it would not affect the recommendations. The study be Alepoo et al (2021) was not included in the evidence review as it investigated the effects of discontinuing CGM rather than its effectiveness. Billings et al (2018) is a post-hoc analysis of an existing included study (Beck 2017) that did not include any additional relevant information. The study by Ehrhardt et al (2011) is already included in our evidence review. Pazos- Couselo et al (2015) is a non-comparative observational study which did not meet the inclusion criteria of our evidence review.

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				were included. The study observed that change in HbA1c was significantly greater among participants in the rt-CGM group compared to SMBG at all predefined HbA1c thresholds at 12 and 24 weeks. Reductions in HbA1c ranged in magnitude from 0.8% to 1.4% (8 to 15 mmol/mol) depending on baseline HbA1c with the greatest change being in ≥ 9.0% subgroup. This is a significant finding as it demonstrates that using of rt-CGM, significant reductions in HbA1c can be achieved among elevated baseline HbA1c levels. Ehrhardt et al (2011)[18] conducted a prospective, 52-week, two-arm, randomized trial comparing rt-CGM versus self-monitoring of blood glucose (SMBG) in 50 people with T2D not taking prandial insulin. Baseline HbA1c was 8.4% (68 mmol/mol) and 8.2% (66 mmol/mol) respectively. Mean reduction in HbA1c at 12 weeks was 1.0% in the rt-CGM group and 0.5% in the SMBG group. The participants who used the rt-CGM for ≥48 days reduced their HbA1c by 1.2% versus 0.6% in those who used it <48 days. The finding suggests that the real-time feedback provided by rt-CGM enables people with T2D to see the glycaemic effects of meals and exercise, which may teach lifestyle skills. Pazos-Couselo[19] et at (2015) conducted an observational prospective study. Included in the study were 63 stable, insulin treated patients with type 2 diabetes. The results showed significantly higher percentages of hyperglycaemic and hypoglycaemic episodes detected by CGM than by capillary blood glucose measurements 61.1% vs. 50.8% and 3.8% vs. 1.7% respectively. A total of 33% patients experienced nocturnal hypoglycaemia, and 19% of patients who had no hypoglycaemia data recorded in the capillary blood glucose diary, had experienced hypoglycaemia as measured by CGM. Hypoglycaemia occurred mainly during the nocturnal period.	

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Dexcom	Guideline	009	008	NICE guideline NG17 Evidence reviews underpinning recommendations 1.7.3 to 1.7.7 and research recommendations in the NICE guideline The literature search failed to identify Karter et al (2021)[8]. This retrospective propensity match cohort study included 344 Type 2 intensive insulin using rt-CGM naïve diabetic patients. This study demonstrated that using rt-CGM, rates of hospital admissions due to hypoglycaemia were reduced by 4% (95%CI, −7.8%to −0.2%; P = .04). In addition to reducing hospital admissions, the use of rt-CGM in an insulin dependent Type 2 population also demonstrated a reduction in mean HbA1c from 8.20% to 7.64% (difference, −0.56%) (−0.72 to −0.41; P = <.001). It should be considered that while Haak[9] et al proposed that is-CGM was associated with a reduction in severe hypoglycaemic events, these events were derived through sensor readings where at least two consecutive measurements, at 15 minute intervals below 3.9 mmol/L [70 mg/dL], and 3.1 mmol/L [55 mg/dL]) were defined as an event. In addition to this, people that had suffered a severe hypoglycaemic event requiring third party assistance in the previous 6 months were excluded from this analysis. As such, this data may not be reflective of a patient group that suffer from recurrent severe hypoglycaemic episodes or impaired awareness to hypoglycaemia in which Is-CGM is recommended. Systems which provide predictive and standard alarms and alerts to inform patients when blood glucose is exceeding or falling below specified thresholds[10,11] have proven to significantly reduce time spent in hypoglycaemia[23.] In addition, rt-CGM are the only systems that are proven to be effective in a diabetic population with impaired awareness to hypoglycaemia (IAH). The HypoDE[12] trial found that in a	Thank you for your comment. Karter et al (2021) was not included in our evidence review and it was not an RCT. It is an exploratory retrospective cohort study. Thank you for your comment. Because of the additional cost associated with CGM and the large number of adults with type 2 diabetes, the committee used both the evidence and their clinical experience to decide who would gain the most benefit from using CGM. There was no evidence that real-time CGM was cost effective for people with type 2 diabetes, so the committee agreed it could not be recommended for all adults with type 2 diabetes, or for the subpopulation of adults with type 2 diabetes using insulin. For intermittently scanned CGM, there was evidence that it was cost effective for adults with type 2 diabetes using insulin, but no evidence for populations not using insulin, so the committee agreed to restrict their recommendations to that subpopulation.

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				population with problematic hypoglycaemia, rt-CGM reduced the incidence of hypoglycaemic events by 72%, the incidence of nocturnal hypoglycaemic events by 65% and the incidence of severe hypoglycaemic events by 64% (Heinemann, 2018). This data highlights that insulin using diabetic people can significantly benefit from an rt-CGM to alert them to potentially dangerous glucose excursions. Preventing rt-CGM access to these patients may negatively impact patient safety. This was further highlighted by Ishikawa et al (2018)[13]. The author concluded that patients aged ≥ 65 years with T2D have a higher glucose variability and lower average glucose levels indicating a greater hypoglycaemia risk. It is therefore necessary to ensure comprehensive blood glucose control in such patients to prevent hypoglycaemia. Just as the guideline for Type 1 diabetes notes, that the choice of appropriate sensor technology should be based on individual needs, characteristics, and the functionality of the devices available, these considerations are the relevant ones to guide interventions for Type 2 diabetes as well. Such as: Whether the device provides predictive alerts or alarms and if these need to be shared with anyone else, for example a carer Fear, frequency, awareness, and severity of hypoglycaemia It would be prudent for the type 2 diabetes in adults guidelines to be consistent with the Type 1 diabetes in adults guidelines and recommend technology that has a proven effect for the given population, this being rt-CGM.	

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Dexcom	Health economic report	017	Severe hypoglycaemic events	The economic report refers to the fact that no severe hypoglycemic events were experienced by rt-CGM or SMBG patient cohorts during Beck et al 2017. This is significant as Beck et al[20] was one of the two studies included in the meta-analysis. NICE rightly assessed Type 1 data sources to determine the reduction of severe hypoglycaemic events through the use of rt-CGM, however, the most appropriate data source is HypoDE[21]. HypoDE demonstrated that rt-CGM reduced the incidence of hypoglycaemic events by 72%, the incidence of nocturnal hypoglycaemic events by 65% and the incidence of severe hypoglycaemic events by 64% (Heinemann, 2018).	*Thank you for your comment. The committee agreed the evidence bases for type 1 and type 2 diabetes should be reviewed separately; this study focuses on people with type 1 diabetes, and was therefore not included in the review for this guideline.*
Dexcom	Health economic report	019	HE 2.3.3.3	NICE referenced annual rt-CGM costs of £2,000 in their Cost Effectiveness Analysis (CEA), significantly overestimating the current annual cost of this technology in the UK, resulting in an inflated ICER. By using the value of £2,000 Cost Effectiveness Analysis (CEA) significantly overestimates the current unit cost of rt-CGM in the UK, and hence the resulting ICER. With widespread use of rt-CGM across NHS England, as per the new guideline recommendation, the Dexcom G6 would be available for £1,600 per patient per year based on Dexcom volume related pricing options. As a result, it is imperative that the CEA base case utilize the appropriate annual cost of £1,600 to establish a more accurate assessment of the cost effectiveness of rt-CGM.	*Thank you for your comment. The committee were not convinced £1,600 represented the full average costs currently involved with using rtCGM – for example when people require receivers as well, which will increase the cost above this baseline value.* *However, we have now added an additional exploratory scenario in the sensitivity analyses with a lower price for rtCGM at £1,600 as suggested, and the device still does not appear to be cost-effective under the threshold of £20,000-£30,000 per QALY.*
Dexcom	Health economic report	023	Sensitivity analyses	A significant weakness of this analysis is that no attempt was made to assess the influence which CGM pricing variations would have on the ICER. As highlighted above, the base case annual price of rt-CGM is 20% above the actual annual price of the Dexcom G6. A sensitivity analysis of the annual cost of rt-CGM base case would provide transparency into the direct relationship between product pricing and the ICER. Additionally, when the potential influence of both a significant reduction in the annual cost of rt-CGM and reduction in hypoglycaemic	*Thank you for your comment. The committee were not convinced £1,600 represented the full average costs currently involved with using rtCGM – for examples when people require receivers as well, which will increase the cost above this baseline value.* *However, we have now added an additional exploratory scenario in the sensitivity analyses with a lower price for rtCGM at £1,600 as suggested, and the device still does*

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				events are considered, the rt-CGM ICER would be demonstrably reduced.	*not appear to be cost-effective under the threshold of £20,000-£30,000 per QALY.*
Diabetes Technology Network UK	Guideline	General	General	There are many rarer types of diabetes which will not get their own specific guidance from NICE. We recommend that these proposed changes should apply to all people with diabetes other than type 1 diabetes, rather than specifically to type 2 diabetes.	Thank you for your comments. This guideline is specifically for people with Type 2 diabetes. Other forms of diabetes were beyond the scope of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.
Diabetes Technology Network UK	Guideline	005 - 006	021 – 004	**Recommendation 1.6.17** We recommend offering isCGM to all people with type 2 diabetes treated with multiple daily injections. The RELIEF trial demonstrated a 40% reduction in hospitalisations for diabetes related conditions in a population including 40 000 people with type 2 diabetes. 88% of the overall trial population of 74 000 people were using MDI or CSII.	Thank you for comment and for providing this data. The RELIEF study was published after the evidence review search cut-off date – the committee did consider the findings from this study. This study is a not an RCT and is a retrospective study on hospitalisations for acute diabetes complications in people with type 1 and type 2 diabetes. It was agreed these findings would not affect the recommendations,
Diabetes Technology Network UK	Guideline	005 - 006	021 – 004	**Recommendation 1.6.17** We recommend that the assessment of hypoglycaemia should be explicitly mentioned in the assessment of people with diabetes treated with insulin,and should include assessment of whether there is impairment or complete absence of awareness of hypoglycaemia. This should be assessed using a validated method such as the Gold Score. This assessment will support identification of those who will particularly benefit from CGM technologies.	Thank you for your comment. The committee were aware of methods to assess impaired hypoglycaemic awareness, such as the use of the GOLD or Clarke scores. However, although these tools are validated for use with people with type 2 diabetes, the committee were aware that they are not always accessible in primary care. As such, they decided against recommending specific methods of assessing impaired hypoglycaemic awareness.
Diabetes Technology Network UK	Guideline	005 - 006	021 – 004	**Recommendation 1.6.17** We recommend that isCGM should be offered to all people with type 2 diabetes (diabetes of any type) treated with insulin who are undergoing haemodialysis. This is in line with current recommendations for the use of isCGM.	Thank you for your comment. The committee agreed with your statement.
Diabetes Technology Network UK	Guideline	005	021 - 022	**Recommendation 1.6.17** We recommend that rtCGM be considered for people with type 2 diabetes treated with insulin who are at highest risk – meaning those experiencing severe/recurrent hypoglycaemia and those with complete loss of awareness of hypoglycaemia. 10% of people with type 2 diabetes experience severe	Thank you for your comment. The committee agreed that hypoglycaemic events are one of the most important and concerning outcomes for adults with type 2 diabetes, and so the potential to reduce these events are crucial. The evidence showed reductions in nocturnal hypoglycaemic events and nocturnal time spent in hypoglycaemia with

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				hypoglycaemia, and severe hypoglycaemia is associated with an increased risk of cardiovascular events. This adjusted recommendation would be consistent with recommendation 1.3.19 from NICE NG3 Diabetes in pregnancy: management from preconception to the postnatal period.	isCGM, although it only showed small reductions in the number of total hypoglycaemic events, with effects less than the minimal important difference. However, in the committee's experience, advances in isCGM technology that have taken place since the evidence was published mean that the use of isCGM is a good way to monitor and reduce the number of hypoglycaemic events. In the committee's experience. IsCGM is also an effective method for people with impaired hypoglycaemic awareness to monitor their blood glucose levels, and so this group were also listed as people who should be offered isCGM.
Diabetes Technology Network UK	Guideline	006	003	Recommend use "self-monitor blood glucose" rather than "self-test"	Thank you for your comment. This has been updated as suggested.
Diabetes Technology Network UK	Guideline	006	015 - 018	**Recommendation 1.6.22** We believe that information around Time in Range should be explicitly included in the education around continuous glucose monitoring which empowers people with diabetes in the use of continuous glucose monitoring in line with international (https://doi.org/10.2337/dci19-0028) and national (https://doi.org/10.1111/dme.14433) recommendations.	Thank you for your comment. Recommendation 1.6.23 outlines ensure continuous glucose monitoring is part of the education provided to adults with type 2 diabetes who are using it (see the section on patient education in the existing guideline) and that people using CGM devices are empowered to do so. The committee agreed that the content of training should be determined at a local level.
Diabetes Technology Network UK	Guideline	006	019 - 022	**Recommendation 1.6.23** We believe that information about Time in Range should be explicitly included in the review of a person's use of continuous glucose monitoring as part of their diabetes care plan in line with international (https://doi.org/10.2337/dci19-0028) and national (https://doi.org/10.1111/dme.14433) recommendations.	Thank you for your comment. Recommendation 1.6.23 outlines ensure continuous glucose monitoring is part of the education provided to adults with type 2 diabetes who are using it (see the section on patient education in the existing guideline) and that people using CGM devices are empowered to do so. The committee agreed that the content of training should be determined at a local level.
Diabetes UK	Guideline	General	General	Diabetes UK welcomes new and additional guidance on monitoring that will increase access to diabetes technology, which we know can be beneficial in the short- and long-term for people living with type 2 diabetes. We note that in type 1 diabetes, where use of these devices is more common, there are stark inequities in access – data shows those from minority ethnic groups and	Thank you for your comment and support for the guideline. Despite the positive recommendation for the use of CGM in adults with insulin-treated type 2 diabetes, tThe committee were concerned that inequalities may still occur with uptake of CGM being lower in certain groups. To address this the committee added a recommendation outlining actions to address this including monitoring uptake, identifying groups

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				people living in areas of high deprivation are the least likely to be accessing isCGM and rtCGM. It is important that the committee considers within this guideline how any recommendations can be strengthened to ensure the same inequities are not experienced by people living with type 2 diabetes. Further, we hope NICE will work closely with colleagues across the health system to ensure these guidelines, when published, are adopted in an equitable way across the country.	who have a lower uptake and making plans to engage with these groups to encourage uptake.
Diabetes UK	Guideline	005	020	The NICE guidelines 'Diabetes in pregnancy' [NG3] states CGM should be considered for pregnant women who are on insulin therapy but do not have type 1 diabetes, if: *"They have problematic severe hypoglycemia (with or without impaired awareness of hypoglycemia) or* *They have unstable blood glucose levels that are causing concern despite efforts to optimize glycemic control."* (page 15) We feel this guideline update should include a clear cross-reference to this.	Thank you for your comment. A cross reference will be added to the NICE diabetes in pregnancy guideline.
Diabetes UK	Guideline	005	021 - 028	1.6.17 - We welcome this recommendation, which we believe will help ensure many more people living with type 2 diabetes are empowered to self-manage their condition effectively. However, we feel that the recommendation could go further and we think all people living with type 2 diabetes who use insulin intensively should be given access to isCGM. This is particularly important in the context of the COVID-19 pandemic, where technologies like isCGM can offer people with type 2 diabetes the possibility of better self-management at a time when access to care is understandably limited. Indeed, this technology can also	Thank you for your comment. Recommendation 1.6.17 outlines to offer isCGM to adults with type 2 diabetes on multiple daily insulin injections. The evidence showed reductions in nocturnal hypoglycaemic events and nocturnal time spent in hypoglycaemia with isCGM, although it only showed small reductions in the number of total hypoglycaemic events, with effects less than the minimal important difference. However, in the committee's experience, advances in isCGM technology that have taken place since the evidence was published mean that the use of isCGM is a

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				help facilitate more high-quality remote diabetes care, meaning healthcare professionals are also able to deliver a continuity of care they may otherwise be unable to. We also believe people with type 2 diabetes should be considered for access to isCGM, whether or not they use insulin if: • they are experiencing problematic hypoglycaemia episodes more than twice a week or problematic hyperglycaemia (over 8.5% HbA1c) • they are pregnant • they need monitoring by a third party • physical, psychosocial, or occupational reasons preclude finger prick monitoring Reference: https://diabetes-resources-production.s3.eu-west-1.amazonaws.com/resources-s3/public/2021-10/Position%20statement%20on%20Flash%20glucose%20monitoring%20211021.pdf	good way to monitor and reduce the number of hypoglycaemic events. The findings of the cost effectiveness modelling were also in agreement. A cross reference will be added to the NICE diabetes in pregnancy guideline. Recommendation 1.6.17 also outlines that isCGM be offered to adults with type 2 diabetes on multiple daily insulin injections and who have a condition or disability, including learning disability that means they cannot self-monitor their blood glucose.
Diabetes UK	Guideline	006	005 - 007	1.6.18 - NHSE recommend all people on a GP learning disability register who use insulin have access to isCGM and we suggest this is mirrored in this guidance.	Thank you for your comment. Learning disability has been added to recommendation 1.6.17.
Diabetes UK	Guideline	006	010 - 012	1.6.20 - Healthcare professionals need the necessary knowledge and skills and access to training to be able to support people living with type 2 diabetes to use this technology. This means having the necessary training to be able to interpret their patient's data and to encourage patients to share this. They also need to be aware of the benefits of using this technology for people living with type 2 diabetes. We think it is important to note that many people living with type 2 diabetes who use insulin receive clinical support for their condition in a primary or community care setting. We	Thank you for your comment. The committee discussed this issue and agreed that the expertise of the team providing support is more important than the setting. This should be provided through local arrangements.

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				therefore think this recommendation should be explicit about which competencies healthcare professionals working in these settings will need and how they can access to relevant resources to learn this. If the expectation is that healthcare professionals working in primary and community care should be supporting people with type 2 diabetes to use isCGM – which we believe should be the case – it is important to make that clear in this guidance.	
Diabetes UK	Guideline	006	013	1.6.21 We are concerned that the recommendation to not offer CGM to those who are "unable" or "do not wish to use" it may further exacerbate the inequitable access to diabetes technology experienced by some. People with type 1 diabetes face stark inequities in access to diabetes technology, particularly individuals living in areas of high deprivation and those from minority ethnic groups. We consider it likely that similar inequalities could emerge in isCGM access for people with type 2 diabetes. There is a need for a person-centred approach for the person with diabetes, carers (where relevant) and the clinician to explore options together, through structured care and support planning. This includes providing information about how is and rtCGM could be used – for example, a text talk option with isCGM which may help people living with sight loss - and working with the person with diabetes to better understand and address any concerns they might have. To do this, reasonable adjustments may be required in accordance with the Equality Act 2010, including resources in appropriate format e.g., Easy read and language, and appropriate appointment times. Adults with type 2 diabetes with learning disabilities and people from ethnic minority	Thank you for your comment. The committee agreed that a person-centred approach is needed. The guideline also highlights that people using continuous glucose monitoring devices should be empowered to do so. This includes making reasonable adjustments in accordance with the Equality Act 2010

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				groups, if English is not their first language, should not face barriers to access the technology they are entitled to.	
Diabetes UK	Guideline	006	013	1.6.21 - A recommendation that test strips and meters be prescribed for adults with diabetes using isCGM and rtCGM instead of capillary blood glucose testing should be included here. This is because many adults will require them for certain circumstances e.g. driving, change of treatment, technology failure.	Thank you for your comment. In response to stakeholder feedback the committee agreed to add a recommendation acknowledging the importance of capillary blood glucose monitoring and that it is still needed as a back up to real-time CGM and isCGM and to ensure they have enough test strips to do this (rec 1.6.20).
Diabetes UK	Guideline	006	015	1.6.22 - The following additional information needs to be included in this guidance: • adults with type 2 diabetes should have not just education but support from healthcare professionals to optimise their use of isCGM • ensure adults with type 2 diabetes (and their carers/supporters) have access to relevant education so they can best use the information these devices provide to improve management of their blood glucose levels • healthcare professionals must be trained to be able to interpret the data and to support patients to share the data too. They could, for example, access the Diabetes Technology Network's Academy Programme. We do not think a lack of access to education should routinely act as a barrier to access to isCGM. We are aware of people living with type 2 diabetes who self-fund isCGM and use it successfully without formal training or education, but through website learning, peer support and other educational resources.	Thank you for your comment. Recommendation 1.6.23 outlines ensure continuous glucose monitoring is part of the education provided to adults with type 2 diabetes who are using it (see the section on patient education in the existing guideline) and that people using CGM devices are empowered to do so. The committee agreed that the content of training should be determined at a local level. Finally the committee did not consider the evidence base for structured education training so were unable to make research recommendations.
Diabetes UK	Guideline	008	007 - 011	We also recommend further research on the use of CGM in the preconception period as data is lacking due to the limited research in this area for women with type 2	Thank you for your comment. Pregnant women with Type 2 diabetes were out of scope for this guideline update as recommendations and research recommendations for this

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				diabetes. A 2020 audit showed women with type 2 diabetes now make up 54% of diabetes' pregnancies, compared to 47% in 2014 and it is vital that we improve our knowledge concerning optimising glycaemic control to help reduce poor maternal and neonatal outcomes. Reference: https://files.digital.nhs.uk/4D/0ABE7F/National%20Pregnancy%20in%20Diabetes%20Audit%202020%20Report.pdf	group are provided in the NICE guideline for diabetes in pregnancy (NG3).
Diabetes UK	Guideline	008	007 – 011	We also suggest that further research into the benefits of rtCGM and isCGM for people not on insulin but taking multiple oral medications and/or injectables that put them at greater risk of hypos is needed to understand the maximum potential benefit of these technologies for people living with diabetes.	Thank you for your comment. The evidence review did not contain studies of people not on insulin but taking multiple oral medications and/or injectables. However the use of this technology is anticipated in this group.
East of England Priorities Advisory Committee	Guideline	005	023	Further clarity is needed on what constitutes multiple daily injections i.e. are NICE recommending use in patients who are managed on two daily insulin injections?	Thank you for your comment. A terms used in the guideline section has been added which contains a definition for multiple daily injections.
East of England Priorities Advisory Committee	Guideline	005	027	'they have a condition or disability that means they cannot self-monitor their blood glucose by intermittent capillary blood glucose monitoring but could use an isCGM device (or have it scanned for them)' We support this recommendation where it empowers the patient to manage their diabetes independently or with the help of their family/support network, without input from an external care worker or healthcare professional. The NICE guidance should include a statement to this effect.	Thank you for your comment. The committee discussion (benefits and harms section) in the evidence review discusses the reasons behind this recommendation in more detail. This includes the potential for a person to become more independent if they no longer have to rely on external support for blood glucose monitoring.
East of England Priorities Advisory Committee	Guideline	006	003	'they would otherwise be advised to self-test at least 8 times a 3 day' It needs to be made clear that the recommendations apply only to clinically appropriate testing as recommended by the diabetes team involved in the patient's care. Suggest including the wording used in NHS England Flash Glucose Monitoring: National Arrangements for Funding of	Thank you for your comment. The committee considered this issue and decided that the term clinically appropriate testing was too prescriptive and not needed in the guideline.

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				Relevant Diabetes document: 'Patients are clinically indicated as requiring intensive monitoring >8 times daily, as demonstrated on a meter download/review over the past 3 months'	
East of England Priorities Advisory Committee	Guideline	006	005	'Offer isCGM to adults with insulin-treated type 2 diabetes who would otherwise need help from a care worker or healthcare professional to monitor their blood glucose.' We support this recommendation where it empowers the patient to manage their diabetes independently or with the help of their family/support network, without input from an external care worker or healthcare professional. The current wording of this recommendation is too open and implies that isCGM should be offered to all patients who are being cared for in a care home setting, which would not be appropriate.	Thank you for your comment. The committee discussed this issue and felt that recommendation 1.6.18 was not too open. Giving these people access to isCGM may increase their independence and improve control of their diabetes.
East of England Priorities Advisory Committee	Guideline	006	010	We strongly agree that both isCGM should be initiated and monitored by specialist teams to ensure that the patient receives appropriate training and advice on how to use, interpret and take action on information to optimise their glucose control.	Thanks for your comments and support for this guideline.
East of England Priorities Advisory Committee	Guideline	006	015	We strongly agree that patients initiated on isCGM should receive education to ensure that the technology is utilised correctly and that they are able to interpret and act upon information to optimise their glucose control.	Thank you for your comment. Recommendation 1.6.23 outlines ensure continuous glucose monitoring is part of the education provided to adults with type 2 diabetes who are using it (see the section on patient education in the existing guideline) and that people using CGM devices are empowered to do so.
East of England Priorities Advisory Committee	Guideline	006	019	We agree that the use of isCGM and rtCGM should be regularly monitored to ensure that it is being used correctly and that it is delivering the patient outcomes anticipated. The NICE guidance should include criteria for discontinuing treatment for isCGM e.g. if the patient does not undertake the agreed number of minimum scans per day required to give them and their diabetes team the information necessary to make positive changes to their care or where the patient fails to take appropriate action on glucose levels despite the support of their diabetes team.	Thank you for your comments. The committee decided not to specify specific criteria for discontinuing isCGM because there is no specific evidence on how frequently a monitor should be scanned, or the results reported, to be effective. They were also aware that there may be a variety of reasons that people are not using their monitor as frequently as expected, and thought it was important for this to be addressed on an individual basis, rather than one rule for all. This is discussed in more detail in the evidence review.

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				Treatment goals should be agreed with the patient prior to starting therapy and treatment should be discontinued if the goals are not reached despite appropriate support from the diabetes team.	
East of England Priorities Advisory Committee	Questions	Q1		Q. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why. A. All patients initiated on isCGM need appropriate training and monitoring to ensure that it is used appropriately and effectively. This needs to be undertaken by specialist diabetes teams who are already under resourced, and this may be a barrier to implementation. There is also a lack of long-term data beyond 12-24 months. This could be important if patient engagement with the technology wanes over time and the level of nursing time needed to keep them on track with their individual treatment targets currently remains unknown.	Thank you for your comment. The committee also recognised and acknowledged this as an implementation issue. However, they agreed that the clinical and cost-effective benefits associated with the promotion of CGM in adults with insulin treated type 2 diabetes were worth the costs and resources associated in implementing this recommendation and ultimately improving care for adults with type 2 diabetes.
East of England Priorities Advisory Committee	Questions	Q2		Q. Would implementation of any of the draft recommendations have significant cost implications? A. The cost of implementing these recommendations is unknown and is potentially significant due to the high number of patients diagnosed with Type 2 diabetes. Assuming approximately 10% of patients with Type 2 diabetes are managed on insulin, this equates to 322,000 patients in England, which exceeds the number of patients diagnosed with Type 1 diabetes. Exact number of T2DM patients on insulin who would be offered treatment under the proposed guideline is unknown, but the cost of providing isCGM to a conservative estimate 10% of these patients would be approximately £29 million per year. The proposed criteria are too open and could result in a much higher percentage of patients managed on insulin being eligible for isCGM, with a maximum potential annual cost pressure of approximately £300 million.	Thank you for your comment. NICE is aware that NHS England are currently involved in discussions about pricing with various manufacturers of continuous glucose monitoring devices. Whilst we are not involved in those conversations, we hope that whatever results will prove useful in reducing the concerns about affordability of the recommendations that have been raised through this consultation.

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				This is likely to be unaffordable to some health systems and may result in variation in access to this technology across the country. It is highly likely that in order to commission this guidance in full, significant budget cuts will be needed in other clinical pathways.	
East of England Priorities Advisory Committee	Questions	Q3		Q. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.) A. Additional funds via a central budget or local budget uplift provided and clearly communicated to finance and medicines optimisation teams, in order to 'invest to save' and to prevent local variations in access to these technologies.	Thank you for your comment. NICE is aware that NHS England are currently involved in discussions about pricing with various manufacturers of continuous glucose monitoring devices. Whilst we are not involved in those conversations, we hope that whatever results will prove useful in reducing the concerns about affordability of the recommendations that have been raised through this consultation.
King's College Hospital NHS Foundation Trust	Guideline	005	023	Whilst we welcome the introduction of recommendations for use of Flash glucose monitoring in people living with type 2 diabetes on multiple daily insulin (MDI) injections, we feel that there needs to be some clarity as to what an MDI regimen is in the guidance. MDI in most diabetes clinics, and clinical research, would usually refer to a basal bolus insulin regimen using separate rapid acting insulin for meals, and once/twice daily long acting insulin for background cover. However, patients with type 2 diabetes may be taking twice daily pre-mixed insulin, or twice daily long acting insulin alone (without rapid acting insulin) and the user may interpret this to also mean multiple (i.e. more than one) daily insulin injections.	Thank you for your comment. A terms used in the guideline section has been added which contains a definition for multiple daily injections.
King's College Hospital NHS Foundation Trust	Guideline	005	025	Please could recurrent or severe hypoglycaemia be defined (usual definition of severe hypoglycaemia would be loss of consciousness or requiring 3rd party assistance. Existing NG17 for type 1 diabetes refers to more than 1 episode a year of severe hypoglycaemia, complete loss of hypoglycaemia awareness, frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily living). Should fear of hypoglycaemia be included as well (to achieve parity with type 1 diabetes)?	Thank you for your comment. A terms used in the guideline section has been added which contains a definition for recurrent and severe hypoglycaemia.

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King's College Hospital NHS Foundation Trust	Guideline	005	026	Please could "impaired hypoglycaemia awareness" be defined?	Thank you for your comment. The committee were aware of methods to assess impaired hypoglycaemic awareness, such as the use of the GOLD or Clarke scores. However, although these tools are validated for use with people with type 2 diabetes, the committee were aware that they are not always accessible in primary care. As such, they decided against recommending specific methods of assessing impaired hypoglycaemic awareness.
King's College Hospital NHS Foundation Trust	Guideline	006	003	NHS England have approved the use of Flash glucose monitoring for patients with any form of diabetes and on dialysis, being treated with insulin therapy. Will this no longer be the case within this guidance?	Thank you for your comment. We understand that this policy will continue to apply. The committee also considered this population would be covered by recommendations 1.6.17 and 1.6.18 in having a condition that means they cannot or need help to self-monitor their blood glucose.
King's College Hospital NHS Foundation Trust	Guideline	006	010	Whilst we agree that continuous glucose monitoring should be provided by a team with expertise in its use, that vast majority of patients with type 2 diabetes on multiple daily insulin injections are not seen in secondary care, but either in community diabetes clinics or by primary care, who may not have such expertise in continuous glucose monitoring. This may put pressure on secondary care services to provide continuous glucose monitoring, unless appropriate training of existing type 2 diabetes services in this technology is provided, either from local hospitals, ICS/CCG, nationally or through industry.	Thank you for your comment. The committee discussed this issue and agreed that the expertise of the team providing support is more important than the setting. This can be determined at a local level.
King's College Hospital NHS Foundation Trust	Guideline	006	015	Structured education for type 2 diabetes does not currently include continuous glucose monitoring. Research into how this is best delivered (the medium of education, group size etc) or translation from type 1 diabetes research will be required to inform changes to type 2 diabetes structured education curriculum.	Thank you for your comment. Recommendation 1.6.23 outlines ensure continuous glucose monitoring is part of the education provided to adults with type 2 diabetes who are using it (see the section on patient education in the existing guideline) and that people using CGM devices are empowered to do so. The committee agreed that the content of training should be determined at a local level. Finally the committee did not consider the evidence base for structured education training so were unable to make research recommendations.

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King's College Hospital NHS Foundation Trust	Guideline	006	019	Does there need to be a statement of what needs to have been achieved for continuous glucose monitoring to continue? At present, NHS England guidance have listed indications for flash glucose monitoring and the requirements for ongoing use e.g. evidence of utilisation (people are actually scanning the sensors) and benefit (e.g. reduction in HbA1c, hypoglycaemia, "psychosocial" measures etc). If criteria for evidence of benefit are proposed for ongoing provision of this technology, it would need to be clear that this might always be relevant e.g. HbA1c reduction may not be appropriate if the indication for introducing continuous glucose monitoring was for patients requiring help from a care worker or health care professional to monitor blood glucose.	Thank you for your comments. The committee decided not to specify specific criteria for discontinuing isCGM because there is no specific evidence on how this should be determined, such as how frequently a monitor should be scanned to be effective, or what criteria for benefit should be used. They were also aware that there may be a variety of reasons that people are not using their monitor as frequently as expected, and thought it was important for this to be addressed on an individual basis, rather than one rule for all. This is discussed in more detail in the evidence review.
Leeds Teaching Hospitals NHS Foundation Trust and NHS Leeds CCG	Guideline	General	General	We are concerned that no recommendations have been made for review and appropriate cessation of the technology e.g., should the appropriateness of the technology be explored with a person using the technology if the person is not scanning at least 3 times a day	Thank you for your comments. The committee decided not to specify specific criteria for discontinuing isCGM because there is no specific evidence on how frequently a monitor should be scanned, or the results reported, to be effective. They were also aware that there may be a variety of reasons that people are not using their monitor as frequently as expected, and thought it was important for this to be addressed on an individual basis, rather than one rule for all. This is discussed in more detail in the evidence review.
Leeds Teaching Hospitals NHS Foundation Trust and NHS Leeds CCG	Guideline	General	General	We would be grateful if NICE would consider including a statement saying that you may wish to use isCGM as a tool to solely inform a clinical decision rather than using it as a permanent method of monitoring. In some people this may be more appropriate and more importantly in some it may be more acceptable.	Thank you for your comment. The committee were aware that temporary, rather than permanent, use of CGM can be beneficial for some people. More detailed information about this is included in the evidence review, and additional details have now been added to the rationale and impact section of the guideline.
Leeds Teaching Hospitals NHS Foundation Trust and NHS Leeds CCG	Guideline	General	General	It would be useful to have some guidance on reducing the prescribing of CBG testing strips in those using isCGM as their main mechanism of monitoring (recognising they will still require some strips)	Thank you for your comment. In response to stakeholder feedback the committee agreed to add a recommendation acknowledging the importance of capillary blood glucose monitoring and that it is still needed as a back up to real-time CGM and isCGM and to ensure they have enough test strips to do this (rec 1.6.20).

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Leeds Teaching Hospitals NHS Foundation Trust and NHS Leeds CCG	Guideline	General	General	We would like to raise that although we support the guidance that the pressures of the training and development of staff to support the roll out of the technology is of concern. It is felt there is huge potential for inequality as we know different practices vary in their ability to handle new technology and diabetes in general. There is a real risk that the patients in affluent areas being more likely to get the opportunity for this technology.	Thank you for your comment. The committee also recognised and acknowledged this as an implementation issue. However, they agreed that the clinical and cost-effective benefits associated with the promotion of CGM in adults with insulin treated type 2 diabetes were worth the costs and resources associated in implementing this recommendation and ultimately improving care for adults with type 2 diabetes.
Leeds Teaching Hospitals NHS Foundation Trust and NHS Leeds CCG	Guideline	005	021	Rec 1.6.17 We would ask that the committee considers adding in those who are enterally fed to the list of people with type 2 diabetes qualifying for this technology.	Thank you for your comment. The committee considered this population would be covered by recommendations 1.6.17 and 1.6.18 in having a condition that means they cannot or need help to self-monitor their blood glucose.
Leeds Teaching Hospitals NHS Foundation Trust and NHS Leeds CCG	Guideline	005	021	Rec 1.6.17 We would ask that the committee considers adding in those who are preparing for surgery where good glycaemic control is required are added to the list of people with type 2 diabetes qualifying for this technology	Thank you for your comment. The committee considered this population would be covered by recommendations 1.6.17 and 1.6.18 in having a condition that means they cannot or need help to self-monitor their blood glucose.
Leeds Teaching Hospitals NHS Foundation Trust and NHS Leeds CCG	Guideline	005	021	We would like to ask the committee that those who might have to test more than 8 times in a day for occupational reasons may be considered for isCGM if they are on insulin or SU e.g. taxi driver on a SU or insulin	Thank you for your comment. Recommendation 1.6.17 outlines to offer isCGM to adults with type 2 diabetes on multiple daily insulin injections and if they would otherwise be advised to self-test at least 8 times a day.
Leeds Teaching Hospitals NHS Foundation Trust and NHS Leeds CCG	Guideline	005	025	We are concerned that recurrent or severe seems a little vague and should better defined and state recurrent and severe hypoglycaemia	Thank you for your comment. A terms used in the guideline section has been added which contains a definition for recurrent and severe hypoglycaemia.
Leeds Teaching Hospitals NHS Foundation	Guideline	005	026	Rec 1.6.17 We are concerned regarding impaired hypoglycaemia awareness; traditionally this is poorly explored with people and hence the requirement now to do	Thank you for your comment. The committee were aware of methods to assess impaired hypoglycaemic awareness, such as the use of the GOLD or Clarke scores. However, although these tools are validated for use with people with

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Trust and NHS Leeds CCG				a gold score for patients. Could NICE consider looking to add in requesting a Gold score.	type 2 diabetes, the committee were aware that they are not always accessible in primary care. As such, they decided against recommending specific methods of assessing impaired hypoglycaemic awareness.
Leeds Teaching Hospitals NHS Foundation Trust and NHS Leeds CCG	Guideline	006	008	Offering real time CGM for people with T2DM would be in exceptions circumstances as it currently stands. We would need to make that clear to primary care who will be concerned about the isCGM. We appreciate that NICE is future proofing however it is very possible this, even conceptually will be a cause for concern.	Thank you for your comment. The guideline only recommends real-time CGM as an alternative to isCGM if it is available for the same or lower acquisition cost (rec 1.6.19)
London Diabetes Strategic Clinical Network	Guideline	General	General	Decision on who would gain the most from using CGM is based on evidence and clinical experience. Voices of people with lived experienced is not mentioned.	Thank you for your comment. NICE guideline committees always include lay members. The lived experiences and opinions of people who have type 2 diabetes are therefore reflected in the development of this guideline and the discussions that informed the recommendations.
London Diabetes Strategic Clinical Network	Guideline	008 009	022 001 002 003	Although the committee were confident that people who have type 2 diabetes can benefit from the use of CGM, because of the large number of people who have type 2 diabetes and the cost implications associated with offering everyone the use of CGM, it was recommended to not offer this to everyone. Concerned that this will cause inequity of access and that the cost implications has been calculated based on initial costs rather than long term cost savings and quality of life.	*Thank you for your comment. The evidence base identified only demonstrated the value of isCGM for people with type 2 diabetes using insulin, and therefore the recommendations were restricted to this patient population.* *The time horizon of the economic model for type 2 diabetes is lifetime (80 years), and we have considered long-term costs and quality of life associated with all types of diabetes complications. As a large proportion of the benefits were accrued through reductions in hypoglycaemic events, and the average rate of hypoglycaemic events is lower for people with type 2 diabetes than people with type 1 diabetes, the committee agreed it was reasonable to reprioritise use of the devices in people who have large problems with hypoglycaemia, as they would be expected to derive the most benefit.*
Medtronic	Evidence review	030	033	The evidence review states: *"while there was evidence for both HbA1c and time in range for comparisons between*	Thank you for your comment and for highlighting this study. This study was published after the evidence review search

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				isCGM and SMBG, there was no evidence for time in range for comparisons between rtCGM and SMBG". We ask the committee to consider the recent 2021 RCT including 175 adults with type 2 diabetes, published in JAMA after the evidence review was completed, reported significant improvements in time in range. In the rtCGM group, compared with the BGM group, the mean percentage of time at 70 to 180 mg/dL was 59% vs 43% (adjusted mean difference, 15% [95% CI, 8% to 23%]; P < .001; equivalent to 3.6 hours more per day *[Effect of Continuous Glucose Monitoring on Glycemic Control in Patients With Type 2 Diabetes Treated With Basal Insulin JAMA. 2021 Jun 8; 325(22): 1–11].*	cut-off date – the committee did consider the findings from this study but agreed that it would not affect the recommendations, which is also based on cost effectiveness evidence and modelling.
Medtronic	Guideline	005	021	We disagree with the recommendation 1.6.17 to "offer intermittently scanned continuous glucose monitoring to adults with type 2 diabetes on multiple daily insulin injections…" as the evidence does not support superior efficacy of isCGM over real-time CGM (rtCGM). There is no head-to-head clinical evidence comparing isCGM with rtCGM in a Type 2 population so efficacy estimates are from indirect comparison of rtCGM vs SMBG and isCGM vs SMBG. The evidence review for **isCGM vs SMBG** found no difference in HbA1c, no difference in Time in range (70 – 180 mg/dl) and no difference in hypoglycaemia events. The only evidence difference found to favour isCGM vs SMBG, was for time in hypoglycaemia and one of the measures of glycaemic variability, for a sub population of participants on insulin, in a single study (Haak 2017). The Haak study was powered at 90% to detect a difference of 3.8 mmol/mol (0.35%) in HbA1c between the intervention and control group at 6 months. The study failed to meet the	Thank you for your comment. Because of the additional cost associated with CGM and the large number of adults with type 2 diabetes, the committee used both the evidence and their clinical experience to decide who would gain the most benefit from using CGM. There was no evidence that real-time CGM was cost effective for people with type 2 diabetes, so the committee agreed it could not be recommended for all adults with type 2 diabetes, or for the subpopulation of adults with type 2 diabetes using insulin. For intermittently scanned CGM, there was evidence that it was cost effective for adults with type 2 diabetes using insulin, but no evidence for populations not using insulin, so the committee agreed to restrict their recommendations to that subpopulation. The committee agreed that there was no robust evidence comparing the effectiveness of isCGM and rtCGM, but agreed such evidence was not necessary in order to make recommendations, given the known current price differential between the two systems, and the fact isCGM was found to be cost-effective compared to SMBG, and rtCGM was not. In the absence of such evidence, the

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				primary endpoint therefore all of the secondary endpoints used for efficacy conclusions in the evidence review and for utility values in the economic model, including hypoglycaemia event rates, glycaemic variability and patient satisfaction scores, are only exploratory and cannot be used to base recommendations re comparator efficacy. The author states in the publication that ***"no adjustment was made for multiple testing of secondary endpoints"*** and ***"no adjustments were made for multiple testing by subgroup"*** *and* ***"further work is required to confirm this observation"*** and ***"many of the endpoints, particularly those derived from sensor glucose values, are highly inter-related and should not be considered in isolation"*** In contrast, the evidence review for **rtCGM vs SMBG** found a statistically significant reduction in HbA1c for real-time CGM vs SMBG, based on evidence of statistically significant reductions in HbA1c from 4 RCTs. A recent 2021 RCT including 175 adults with type 2 diabetes, published in JAMA after the evidence review was completed, reported a significantly greater decrease in HbA_{1c} level over 8 months with rtCGM compared to blood glucose meter monitoring (−1.1% vs −0.6%). They also reported significant improvements in TIR. In the rtCGM group, compared with the BGM group, the mean percentage of time at 70 to 180 mg/dL was 59% vs 43% (adjusted mean difference, 15% [95% CI, 8% to 23%]; P < .001; equivalent to 3.6 hours more per day). The mean percentage of time at greater than 250 mg/dL was 11% vs 27% (adjusted mean difference, −16% [95% CI, −21% to −11%]; P < .001; equivalent to 3.8 hours less per day). There was a downward shift in mean glucose levels throughout the 24 hours of the day, with the means of mean glucose level of 179 mg/dL vs 206 mg/dL (adjusted difference, −26 mg/dL [95% CI, −41 to −12]; P < .001) in	committee agreed it was therefore not appropriate to make r ecommendations in favour of rtCGM, as this would create known additional costs without evidence that it would generate significant additional clinical benefits. However, the committee did make a future proofing recommendation to enable rtCGM to be used, if it was available for the same price as isCGM in the future.

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				the rtCGM group compared with the BGM group. *[Effect of Continuous Glucose Monitoring on Glycemic Control in Patients With Type 2 Diabetes Treated With Basal Insulin JAMA. 2021 Jun 8; 325(22): 1–11].* This study adds significantly to the evidence base for superior effectiveness of rtCGM compared with SMBG. In light of the lack of efficacy evidence for isCGM vs SMBG , as outlined above, and the significant evidence supporting rtCGM vs SMBG in terms of HbA1c reduction and time in target glucose range, we ask the committee to reconsider recommendation 1.6.17 to "offer intermittently scanned continuous glucose monitoring to adults with type 2 diabetes on multiple daily insulin injections…" and to offer adults with Type 2 diabetes a choice of rtCGM or isCGM based on their individual preferences, needs, characteristics and the functionality of the devices available.	
Medtronic	Guideline	005	026	We suggest that this recommendation for isCGM in people with impaired hypoglycaemic awareness is not supported by any evidence. We ask the committee to consider that isCGM, as defined in the review protocol, requires users to scan the sensor to obtain information on glucose levels and that people with impaired hypoglycaemic awareness may be unable to recognise symptoms of hypoglycaemia. People using real-time CGM automatically receive real-time glucose values every 1-5 minutes. Real-time CGM also has predictive alarms to alert users to the potential risk of impending hypo- or hyperglycaemia. The I HART CGM study in adults with type 1 diabetes, reported that rtCGM has greater beneficial impact on hypoglycaemia than isCGM in adults with type 1 diabetes (T1D) at high risk. An extension phase of this study looked	Thank you for your comment. The committee agreed that hypoglycaemic events are one of the most important and concerning outcomes for adults with type 2 diabetes, and so the potential to reduce these events are crucial. The evidence showed reductions in nocturnal hypoglycaemic events and nocturnal time spent in hypoglycaemia with isCGM, although it only showed small reductions in the number of total hypoglycaemic events, with effects less than the minimal important difference. However, in the committee's experience, advances in isCGM technology that have taken place since the evidence was published mean that the use of isCGM is a good way to monitor and reduce the number of hypoglycaemic events. In the committee's experience. IsCGM is also an effective method for people with impaired hypoglycaemic awareness to monitor their blood glucose levels, and so this group were also listed as people who should be offered isCGM.

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				at adults with impaired awareness of hypoglycaemia or recent episode of severe hypoglycaemia concluded that that switching from flash to rt-CGM has a significant beneficial impact on hypoglycaemia outcomes and that continued use of rt-CGM maintains hypoglycaemia risk benefit in this high-risk population. *[Reddy M, Jugnee N, El Laboudi A, et al. A randomized controlled pilot study of continuous glucose monitoring and flash glucose monitoring in people with type 1 diabetes and impaired awareness of hypoglycaemia. Diabet Med 2018;35:483–490, Reddy M et al. Switching from Flash Glucose Monitoring to Continuous Glucose Monitoring on Hypoglycemia in Adults with Type 1 Diabetes at High Hypoglycemia Risk:The Extension Phase of the I HART CGM Study. Diabetes Technology & Therapeutics. Volume 20, Number 11, 2018]* We ask the committee to add a recommendation that hypoglycaemia risk, including frequency, severity, and awareness, should be assessed when considering the appropriate glucose monitoring device.	
Medtronic	Health economic model	General	General	In the economic model, all utility inputs for isCGM come from a single study, Haak 2017. This study was powered at 90% to detect a difference of 3.8 mmol/mol (0.35%) in HbA1c between the intervention and control group at 6 months. The study failed to meet the primary endpoint therefore the secondary endpoints used for utility values for this review, are only exploratory and cannot be used to base conclusions re comparator efficacy. The author states in the publication that "no adjustment was made for multiple testing of secondary endpoints" and **"no adjustments were made for multiple testing by subgroup and further work is required to confirm this observation"** and **"many of the endpoints, particularly those derived from sensor glucose values, are highly inter-related and should not be considered in isolation".**	*Thank you for your comment. The committee pre-specified which blood glucose values they felt were most appropriate to use as proxies for severe and non-severe hypoglycaemic events, and these data were the ones included in our analysis. Whilst these may not always match what were chosen as the primary outcomes for the underlying studies, they represent the committee's view of the most appropriate outcomes to use. The fact these decisions were pre-specified should also reduce any concerns about, multiple outcomes being included in the studies, as not all of those outcomes were deemed relevant to use in the modelling.* *In addition, we have run a series of sensitivity analyses to account for the uncertainty surrounding input parameters.*

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				We ask that the base case in the model be adjusted to indicate no difference between isCGM and SMBG in event rates of severe and non-severe hypoglycaemic events, glycaemic variability, patient satisfaction scores and any other utility value obtained from the Haar study, as these values are exploratory as outlined above. We ask that the outcomes data for rtCGM from the new study be explored in the base-case and sensitivity analysis to explore the effects on the ICER.	*isCGM remained to be cost-effective under the threshold of £20,000 per QALY in the sensitivity analysis, which supports the internal validity of our analysis.* This new Martens et al study (2021) with outcome data for rtCGM was published after the evidence review search cut-off date. The committee did consider the findings from this study but agreed that it would not affect the recommendations.
National Nurse Consultant Diabetes Group	Guideline	005	023	Clarification or be specific of what meant by 'multiple injections'. Majority of people with type 1 will be on basal bolus insulin that currently have access to continuous glucose monitoring. People with type 2 diabetes could be basal twice a day, biphasic insulin to TDS and basal bolus.	Thank you for your comment. A terms used in the guideline section has been added which contains a definition for multiple daily injections.
National Nurse Consultant Diabetes Group	Guideline	006	005	Including people who would require help from health care professional or carer to check blood glucose readings, is a welcome addition. Community teams have patients under district nurses' caseloads that will benefit, especially as currently blood sugars readings usually taken after meals and not fasting so not always clear what hypo risks are when titrating insulin.	Thank you for your comment and support for this guideline.
National Nurse Consultant Diabetes Group	Guideline	006	010	Offering a wider group of patients with Type 2 Diabetes access to continuous blood glucose monitoring is a positive step. The question is who will be delivering this service/care? Currently continuous blood glucose monitoring is provided within secondary care. If plans for community diabetes services or PCN to deliver these services as this new groups of patients will be on their caseloads, there needs consideration that not only the technology is funded but also the workforce. Funding for training of staff, commissioning extra services/time and infrastructure in place to deliver this. Since the draft consultation being out community services have been undated with queries from existing caseload as well as	Thank you for your comment. The committee decided to highlight that CGM should be provided by a team who have expertise in its use. To ensure that CGM is effective, healthcare professionals need to have the skills to interpret and communicate the data effectively. As well as healthcare professionals having a clear understanding of CGM, it is also crucial that people with type 2 diabetes who are using CGM have education about the technology. This will increase the likelihood that people will scan and report the results frequently, allowing people to understand and manage their diabetes effectively. The committee recognised and acknowledged this implementation issue However, they agreed that the clinical and cost-effective benefits associated with the promotion of

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				increased referrals from primary care requesting Libre. It will also require training of not just specialist services but supporting services such as District Nurses and Pharmacists etc as more people than currently will be prescribed them	CGM in adults with type 2 diabetes were worth the costs and resources associated in implementing this recommendation and ultimately improving care for adults with type 2 diabetes.
NHS Bath & North East Somerset, Swindon and Wiltshire CCG	Guideline	005	023	Further clarity is needed on what constitutes multiple daily injections i.e. are NICE recommending use in patients who are managed on two daily insulin injections?	Thank you for your comment. A terms used in the guideline section has been added which contains a definition for multiple daily injections.
NHS Bath & North East Somerset, Swindon and Wiltshire CCG	Guideline	006	003	'they would otherwise be advised to self-test at least 8 times a 3 day' It needs to be made clear that the recommendations apply only to *clinically appropriate testing* as recommended by the diabetes team involved in the patient's care.	Thank you for your comment. The committee considered this issue and agreed that the term clinically appropriate testing was too prescriptive and not needed in the guideline.
NHS Bath & North East Somerset, Swindon and Wiltshire CCG	Guideline	006	010	We strongly agree that both isCGM should be initiated and monitored by specialist teams to ensure that the patient receives appropriate training and advice on how to use, interpret and take action on information to optimise their glucose control.	Thanks for your comment and support for this guideline.
NHS Bath & North East Somerset, Swindon and Wiltshire CCG	Guideline	006	019	Regular monitoring and support for patients by a well-staffed service will be essential. Discontinuation criteria are very important- e.g. using the sensors for isCGM >70% of the time. Please include such criteria.	Thank you for your comments. The committee decided not to specify specific criteria for discontinuing isCGM because there is no specific evidence on how frequently a monitor should be scanned, or the results reported, to be effective. They were also aware that there may be a variety of reasons that people are not using their monitor as frequently as expected, and thought it was important for this to be addressed on an individual basis, rather than one rule for all. This is discussed in more detail in the evidence review.
NHS Bath & North East Somerset, Swindon and Wiltshire CCG	Questions	Q1		NHS BSW CCG agrees with the comments being made on this guidance by the PresQIPP organisation that we are subscribers to.	Thank you for your comment. Despite the positive recommendation for the use of CGM in adults with insulin-treated type 2 diabetes, the committee were concerned that inequalities may still occur with uptake of CGM being lower in certain groups. To address this the committee added a recommendation outlining actions to address this including

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				Q. Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why. A. All patients initiated on isCGM need on-going training and monitoring to ensure that it is used appropriately and effectively. This needs to be undertaken by specialist diabetes teams who are already under resourced, so staffing may be a barrier to implementation. There is also a lack of long-term data beyond 12-24 months. This could be important if patient engagement with the technology wanes over time and the level of nursing time needed to keep them on track with their individual treatment targets currently remains unknown.	monitoring uptake, identifying groups who have a lower uptake and making plans to engage with these groups to encourage uptake.
NHS Bath & North East Somerset, Swindon and Wiltshire CCG	Questions	Q2		Q. Would implementation of any of the draft recommendations have significant cost implications? A. Absolutely, the cost impact of this guidance will be unaffordable for our healthsystem and so will lead to a postcode lottery in terms of availability which is not good for patients and leads to inequity. The proposed criteria are too open and could result in a much higher percentage of patients managed on insulin being eligible for isCGM. It is highly likely to in order to commission this guidance in full, significant budget cuts will be needed in other clinical pathways.	Thank you for your comment. NICE is aware that NHS England are currently involved in discussions about pricing with various manufacturers of continuous glucose monitoring devices. Whilst we are not involved in those conversations, we hope that whatever results will prove useful in reducing the concerns about affordability of the recommendations that have been raised through this consultation.
NHS Bath & North East Somerset, Swindon and Wiltshire CCG	Questions	Q3		Q. What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.) A. Additional funds via a central budget or local budget uplift provided. Clear criteria for use in order to allow CCGs to be able to aim technology at the most in need of it and discontinuation criteria so that it can be removed if the patient is unable to use it properly or they are not achieving the desired results with it.	Thank you for your comment. NICE is aware that NHS England are currently involved in discussions about pricing with various manufacturers of continuous glucose monitoring devices. Whilst we are not involved in those conversations, we hope that whatever results will prove useful in reducing the concerns about affordability of the recommendations that have been raised through this consultation.

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NHS England Diabetes team	Guideline	General	General	Please see below the comments from the NHS England Diabetes team on this guideline: We would suggest extending the groups eligible to the following: a) Women with Type 2 Diabetes planning pregnancy, irrespective of current treatment, as so many will go on to require insulin during pregnancy anyway, and we may have missed the window for pre-conception improvement in glycaemia otherwise This is approx. 2500 patients/ year- and similar to existing NICE guidelines around Type 1 Diabetes and pregnancy. b) Genetic Diabetes or MODY -being treated with Insulin	Thank you for your comment. This guideline is specifically for people with Type 2 diabetes. Other forms of diabetes were beyond the scope for this guideline. Recommendations for women with diabetes planning a pregnancy are provided in the NICE guideline for diabetes in pregnancy (NG3). For women planning a pregnancy with insulin treated type 2 diabetes, the CGM recommendations in NG28 would apply.
NHS London Procurement Partnership	Guideline	005	025	1.6.17 - Please define how many episodes "recurrent" covers or eludes to.	Thank you for your comment. A terms used in the guideline section has been added which contains a definition for recurrent and severe hypoglycaemia.
NHS London Procurement Partnership	Guideline	005	025	1.6.17- Please quantify what severe hypoglycaemia is, for example what is the range you have considered?	Thank you for your comment. A terms used in the guideline section has been added which contains a definition for recurrent and severe hypoglycaemia.
NHS London Procurement Partnership	Guideline	005	027	1.6.17 - Please could you clarify what the list of conditions might be?	Thank you for your comment. The conditions could include those such as a physical or cognitive impairment. This is outlined in the committee discussion section of the evidence review.
NHS London Procurement Partnership	Guideline	006	010	1.6.20 – is there a standard to define expertise?	Thank you for your comment. The committee discussed this issue and agreed that expertise should be defined as a local implementation issue.
North Wood Group Practice	Guideline	General	General	Current NHS England recommendations advise that there is a requirement for individuals to wear a isCGM device 70% or the time, scan at least 8 times per day and continuation of therapy is only warranted if there is	Thank you for your comment. The committee decided not to specify specific criteria for discontinuing isCGM because there is no specific evidence on how frequently a monitor should be scanned, or the results reported, to be effective.

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				evidence that on-going use of flash glucose is demonstrably improving an individuals diabetes self management at a 6-9month point. Are NICE planning to introduce any of these requirements? We we would welcome further guidance on this within the guideline to ensure that those who are receiving isCGM are benefitting from use	They were also aware that there may be a variety of reasons that people are not using their monitor as frequently as expected, and thought it was important for this to be addressed on an individual basis, rather than using one stopping rule for all. This is discussed in more detail in the evidence review.
North Wood Group Practice	Guideline	General	General	We would welcome the groups thoughts on use of isCGM where we need to establish glucose patterns across the day e.g. to identify the most appropriate insulin regime to be used or where there appears to be significant variation in glucose readings across the day/night	Thank you for your comment. The committee discussed the practicalities of isCGM, including how it does not always need to be a permanent solution and how temporary use of isCGM may be useful for some people. Using isCGM for a short period of time may help people to understand when they have hypoglycaemic episodes, thereby helping them to develop a more effective treatment plan. By developing this understanding of their blood glucose patterns, they can still benefit from isCGM even if is decided that they do not want to use the device on a long-term basis.
North Wood Group Practice	Guideline	General	General	Currently NHS England recommend use of Flash glucose in patients with any form of diabetes and on haemodialysis, being treated with insulin. Under this current draft guidance, this cohort of patients would not routinely be eligible unless other criteria are met. Is this the case?	Thank you for your comment. NHS England recommendations are stand-alone to NICE guidelines.
North Wood Group Practice	Guideline	005	023	We would be grateful if the committee were able to define 'multiple daily injections'. Traditionally this has referred to basal bolus however we have been asked if two injections a day e.g. twice daily mixed insulin or twice daily basal insulin would count as multiple daily injections given more than one injection is given daily	Thank you for your comment. A terms used in the guideline section has been added which contains a definition for multiple daily injections.
North Wood Group Practice	Guideline	005	025	We would be grateful if the committee were able to define 'recurrent hypoglycaemia' e.g number of episodes/timeframe otherwise if people have had two episodes of hypoglycaemia on insulin over the past 5 years, this could be seen as recurrent and they would then be eligible	Thank you for your comment. A terms used in the guideline section has been added which contains a definition for recurrent and severe hypoglycaemia.

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North Wood Group Practice	Guideline	005	026	We would be grateful if the committee could suggest a standardised way of identifying impaired hypoglycaemia awareness e.g. GOLD or Clarke score, otherwise this could be a subjective assessment	Thank you for your comment. The committee were aware of methods to assess impaired hypoglycaemic awareness, such as the use of the GOLD or Clarke scores. However, although these tools are validated for use with people with type 2 diabetes, the committee were aware that they are not always accessible in primary care. As such, they decided against recommending specific methods of assessing impaired hypoglycaemic awareness.
North Wood Group Practice	Guideline	006	008	In section 1.6.19 - Consider real-time CGM as an alternative to isCGM if it is available for the same or lower acquisition cost'. As far as the group are aware rtCGM is more expensive than isCGM and this statement would not currently allow any options for use of rtCGM. If people with type 2 diabetes clinically require rtCGM, would an individual funding request need to still be made to the CCG? We would be grateful for further clarity within the guideline.	Thank you for your comment. NICE is aware that NHS England are currently involved in discussions about pricing with various manufacturers of continuous glucose monitoring devices. Whilst we are not involved in those conversations, we hope that whatever results will prove useful in reducing the concerns about affordability of the recommendations that have been raised through this consultation.
North Wood Group Practice	Guideline	006	010	The statement 'continuous glucose monitoring should be provided by a team with expertise in its use, as part of supporting people to self- manage their diabetes' - currently it is mainly secondary care teams that initiate Libre given existing eligible patient populations. The draft criteria suggest a much wider cohort than currently eligible. Whilst patients with severe hypos or recurrent hypos for example are likely to be under a specialist team (intermediate or secondary care team), a number of patients will be under their GP practice. GP practices are unlikely to have expertise in use of isCGM and as such would necessitate a referral to either an intermediate care team or secondary care for initiation. Even if specialist teams initiate isCGM, it is likely that GP practices would need to review data and review patients with isCGM. There will be significant implications for commissioning and service delivery for secondary, intermediate and primary care teams. Will any additional funding be made available centrally to fund the	Thank you for your comment. The committee discussed this issue and agreed that the expertise of the team providing support is more important than the setting. This can be determined at a local level. The committee decided that people who have poorly managed diabetes and need help from a care worker or other healthcare professional to administer their insulin injections should also be offered intermittently scanned CGM, even if they only use once-daily insulin injections.

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				implementation e.g. additional service capacity required, education and resources? The guidance also suggests those who would need help from a care worker or healthcare professional to monitor their blood glucose would be eligible if on insulin. This would include a number of patients who are housebound or in care settings. This would require a home visit to initiate flash glucose and arrangements to be made with a carer or in some cases a healthcare professional to change the sensor every two weeks. Will any funding be made available centrally to support implementation e.g. training of all district nurses, care home workers? Whose responsibility is it to train staff members in care settings in the use of these devices to ensure they are used to the full potential in helping with the management of diabetes	Intermittently scanned CGM will help care workers to record a person's blood glucose levels quickly. And for people who have multiple home care visits per day, blood glucose levels can be recorded at each visit. This should ensure that there are sufficient recordings against which a person's insulin schedule can be adjusted to reduce the risk of hypoglycaemic events between home visits. It may also reduce the number of hospital admissions for this group as it will be easier for them to monitor their blood glucose levels and reduce their number of hypoglycaemic or hyperglycaemic episodes. The committee also recognised and acknowledged this implementation issue The committee recognised and acknowledged this implementation issue However, they agreed that the clinical and cost-effective benefits associated with the promotion of CGM in adults with type 2 diabetes were worth the costs and resources associated in implementing this recommendation and ultimately improving care for adults with type 2 diabetes.
North Wood Group Practice	Guideline	006	013	The statement 1.6.21 - 'if a person is unable or does not wish to use any real time CGM or isCGM device, offer capillary blood glucose monitoring' could be read as a separate statement that we need to offer CGM to all (regardless of medication) and only then if they don't want it, we offer capillary testing. To avoid confusion with this statement, this needs to sit within bullet point 1.6.17 and 1.6.18 rather than a separate point which could be read that anyone with type 2 diabetes can have flash glucose	Thank you for your comment. In response to stakeholder feedback the committee agreed to add a recommendation acknowledging the importance of capillary blood glucose monitoring and that it is still needed as a back up to real-time CGM and isCGM and to ensure they have enough test strips to do this (rec 1.6.20).
North Wood Group Practice	Guideline	006	015	Structured education for type 2 diabetes is usually undertaken early in diagnosis with some accessing refresher sessions. Structured education sessions do not currently include continuous glucose monitoring within the training package. Research into how this is best delivered e.g., virtual 1:1, groups, online learning etc needs to be reviewed and learning taken from use in T1DM	Thank you for your comment. Recommendation 1.6.23 outlines ensure continuous glucose monitoring is part of the education provided to adults with type 2 diabetes who are using it (see the section on patient education in the existing guideline) and that people using CGM devices are empowered to do so. Finally the committee did not consider the evidence base for structured education

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					training so were unable to make research recommendations.
Northern Lincolnshire & Goole NHS Foundation Trust	Guideline	005	023	This guideline is well written, informative workable in 'real-life' clinical practice. Our only comment is below: Suggest add in 'or less intensive insulin regimes if MDI not deemed appropriate or acceptable.	Thank you for your comment. A terms used in the guideline section has been added which contains a definition for multiple daily injections.
Novo Nordisk	Guideline	General	General	**We welcome the recommendation for wider access to continuous glucose monitoring for specific groups of people with type 2 diabetes.** The economic analysis was based on a paucity of available evidence, but it is clear that clinical experts support the use of this technology as providing quality of life and clinical benefits for certain groups of people living with type 2 diabetes.	Thank you for your comment and support for this guideline.
Novo Nordisk	Health economic report	General	General	**Inconsistency in cost-effectiveness modelling approach for different NG28 guideline updates on glucose monitoring and type 2 diabetes management.** The Health Economics (HE) Report suggests the IQVIA CORE diabetes model was selected as it is suitable given the complexity of Type 2 diabetes (with the model accounting for the long-term complications of diabetes within a lifetime time horizon) and due to the time constraints associated with this clinical guideline development. While the use of this established cost-effective modelling approach for this NG28 partial guideline update in relation to glucose monitoring is welcomed, what is the justification for selecting a different model here to assess the cost-effectiveness of glucose monitoring, compared to the recent NG28 guideline update on type 2 diabetes management that was published for consultation in September?	*Thank you for your comment. The modelling approaches used for these two guideline updates were considerably different, due to differences in the underlying decision problems. In particular, the update of pharmacological treatments for diabetes was significantly influenced by modelling direct benefits on cardiovascular outcomes, derived directly from RCTs, rather than proxy outcomes such as HbA1c. No such direct cardiovascular outcome data was available for evaluating CGM.* *The UKPDS model was assessed as having considerable advantages for the cardiovascular modelling approach. In particular, the greater transparency refenced means it is possible to generate individual patient trajectories and life histories from the UKPDS model, something which is not practical from the CORE model. Whilst his was not considered to be a particular limitation for this analysis of CGM, it was agreed it was a significant limitation for the pharmacological analysis, and hence a different approach to modelling was selected.*

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				The HE report published as part of the consultation on the partial NG28 guideline update in September, provided the following justifications for not using the IQVIA CORE diabetes model when updating the guideline at that point: (page 9, lines 29-32), "*Whilst recognising that models funded by industry could still be robust for decision making the committee felt it was most appropriate to use a non-industry funded model in the first instance*". The report also stated (page 10, lines 18-19) "*The committee noted that the mechanisms of the CORE model were less transparent than those of the UKPDS".* Whilst we agree with the approach of using the IQVIA CORE diabetes model, the rationale is inconsistent across the NG28 guideline updates and would ask what the reason is for this inconsistency.	
Obesity Group of the British Dietetic Association	Guideline	006	010 - 012	We would like specific inclusion on the team of a dietitian specialist in this area of work, to ensure that the diabetes is well controlled but also that nutritional needs are being met in line with expert recommendations.	Thank you for your comment. The committee considered this issue and agreed that support should be provided by a healthcare specialist in diabetes which could include a state registered dietitian specialist.
Oxford Centre for Diabetes, Endocrinology and Metabolism	Guideline	General	General	The testing guideline should also cover other forms of "non-type 1 diabetes" that don't have their own guideline e.g. Monogenic, mitochondrial, pancreatic etc	Thank you for your comments. This guideline is specifically for people with Type 2 diabetes. Other forms of diabetes was beyond the scope for this guideline. Recommendations for women with diabetes planning a pregnancy are provided in the NICE guideline for diabetes in pregnancy (NG3).
Oxford Centre for Diabetes, Endocrinology and Metabolism	Guideline	005	021 - 024	We recommend specifically including women with Type 2 diabetes who are pregnant. The testing load is very high in pregnancy, but crucial for good outcomes, so a time limited prescription of isCGM would be beneficial	Thank you for your comment. Pregnant women with Type 2 diabetes were out of scope for this guideline update as recommendations for this group are provided in the NICE guideline for diabetes in pregnancy (NG3).
Oxford Centre for Diabetes, Endocrinolog	Guideline	005	023	What is the definition of "multiple daily injections" – it probably should be specific that this is basal bolus	Thank you for your comment. A terms used in the guideline section has been added which contains a definition for multiple daily injections.

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y and Metabolism					
Oxford Centre for Diabetes, Endocrinology and Metabolism	Guideline	006	010 - 012, 015 - 021	It should be clear how training and follow-up will be organised when the majority of people with type 2 diabetes on insulin are cared for in primary care	Thank you for your comment. The committee discussed this issue and agreed they could not be prescriptive on this and should be provided through local arrangements and use of a specialist service.
Oxford Centre for Diabetes, Endocrinology and Metabolism	Guideline	011	016 - 017	There would be a resource impact associated with education and monitoring because primary care teams do not routinely provide this.	Thank you for your comment. The committee also recognised and acknowledged this as an implementation issue. The committee recognised and acknowledged this implementation issue However, they agreed that the clinical and cost-effective benefits associated with the promotion of CGM in adults with type 2 diabetes were worth the costs and resources associated in implementing this recommendation and ultimately improving care for adults with type 2 diabetes.
Roche Diabetes Care, Ltd	Guideline	General	General	Aligned with the NHS Long Term Plan we support the use of digital tools for people with diabetes. Blood glucose meters have evolved from a device that simply generates a blood glucose value to having connectivity capabilities. Tools that collect data from meters can be used to improve efficiencies and enable remote care. Transferring structured self-monitored blood glucose data from patients to healthcare professionals allows for more timely adjustments to diabetes management and improves outcomes. The guidelines should include recommendations relating to structured monitoring, connected meters and remote care. Examples of relevant references: 1. Polonsky WH et al A structured self-monitoring of blood glucose approach in type 2 diabetes encourages more frequent, intensive, and effective physician interventions: results from the	Thank you for raising this issue however the use of blood glucose meters is beyond the scope of this guideline update and therefore these references are not included in the evidence review.

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				STeP study. Diabetes Technol Ther. 2011 Aug;13(8):797-802. doi: 10.1089/dia.2011.0073. 2. Bosi E et al PRISMA Study Group. Intensive structured self-monitoring of blood glucose and glycemic control in noninsulin-treated type 2 diabetes: the PRISMA randomized trial. Diabetes Care. 2013 Oct;36(10):2887-94. doi: 10.2337/dc13-0092. 3. Chircop J et al Systematic Review of Self-Monitoring of Blood Glucose in Patients with Type 2 Diabetes. Nurs Res. 2021 Jul 20. doi: 10.1097/NNR.0000000000000542. Epub ahead of print. PMID: 34292228. 4. Mannucci E et al Effects of Structured Versus Unstructured Self-Monitoring of Blood Glucose on Glucose Control in Patients With Non-insulin-treated Type 2 Diabetes: A Meta-Analysis of Randomized Controlled Trials. J Diabetes Sci Technol. 2018 12(1):183-189. 5. Machry RV et al. Self-monitoring blood glucose improves glycemic control in type 2 diabetes without intensive treatment: A systematic review and meta-analysis. Diabetes Res Clin Pract. 2018 142:173-187 6. Di Molfetta S et al PRISMA STUDY GROUP. Structured self-monitoring of blood glucose is associated with more appropriate therapeutic interventions than unstructured self-monitoring: a novel analysis of data from PRISMA. Diabetes Res Clin Pract. 2021 7. Ceriello A et al Diabetes as a case study of chronic disease management with a personalized approach: the role of a structured feedback loop. Diabetes Res Clin Pract. 2012 Oct;98(1):5-10. doi: 10.1016/j.diabres.2012.07.005.	

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Roche Diabetes Care, Ltd	Guideline	General	General	A significant body of evidence exists to support use of structured self-monitoring of capillary blood glucose to improve glycaemic outcomes in people with non-insulin treated Type 2 diabetes as part of a holistic care plan. The guidelines relating to non-insulin treated diabetes should be reviewed next and updated to reflect this and to match existing clinical guidelines such as those from TREND. People who are not eligible for isCGM must still be able to access the required technology to carry out capillary blood glucose monitoring effectively. Examples of evidence includes (though is not limited to): 1. Sia HK, Kor CT, Tu ST, Liao PY, Wang JY. Self-monitoring of blood glucose in association with glycemic control in newly diagnosed non-insulin-treated diabetes patients: a retrospective cohort study. Sci Rep. 2021 Jan 13;11(1):1176. 2. Sarol Jr J, Nicodemus Jr N, M Tan K, B Grava M. Self-monitoring of blood glucose as part of a multi-component therapy among non-insulin requiring type 2 diabetes patients: A meta-analysis (1966-2004)2005. 173-84 p. 3. Schwedes U, Siebolds M, Mertes G. Meal-related structured self-monitoring of blood glucose: effect on diabetes control in non-insulin-treated type 2 diabetic patients. Diabetes Care. 2002;25(11):1928-32. 4. Guerci B, Drouin P, Grange V, Bougneres P, Fontaine P, Kerlan V, et al. Self-monitoring of blood glucose significantly improves metabolic control in patients with type 2 diabetes mellitus: the Auto-Surveillance Intervention Active (ASIA) study. Diabetes & metabolism. 2003;29(6):587-94.	Thank you for your comment. This specific issue is beyond the scope of this guideline update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.

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				5. Montero AR et al, Implications of remote monitoring Technology in Optimizing Traditional Self-Monitoring of blood glucose in adults with T2DM in primary care. BMC Endocr Disord. 2021 Nov 10;21(1):222. doi: 10.1186/s12902-021-00884-6. 6. Ngaosuwan K & Osataphan S. Diabetes Mellitus Treated with Medical Nutritional Therapy and Self Blood Glucose Monitoring: A Randomized Controlled Trial. J Med Assoc Thai. 2015 Nov;98 Suppl 10:S66-73. 7. Parsons SN et al, Effect of structured self-monitoring of blood glucose, with and without additional TeleCare support, on overall glycaemic control in non-insulin treated Type 2 diabetes: the SMBG Study, a 12-month randomized controlled trial. Diabet Med. 2019 May; 36(5): 578-590 8. Polonsky WH et al A structured self-monitoring of blood glucose approach in type 2 diabetes encourages more frequent, intensive, and effective physician interventions: results from the STeP study. Diabetes Technol Ther. 2011 Aug;13(8):797-802. doi: 10.1089/dia.2011.0073. Bosi E et al PRISMA Study Group. Intensive structured self-monitoring of blood glucose and glycemic control in noninsulin-treated type 2 diabetes: the PRISMA randomized trial. Diabetes Care. 2013 Oct;36(10):2887-94. doi: 10.2337/dc13-0092.	
Roche Diabetes Care, Ltd	Guideline	006	013	We support the recommendation to offer capillary blood glucose monitoring to those who are unable or do not wish to use any real-time CGM or isCGM device. Capillary blood glucose self-monitoring is most beneficial when carried out in a structured manner and this should be included in the	Thank you for your comment. In response to stakeholder feedback the committee agreed to add a recommendation acknowledging the importance of capillary blood glucose monitoring and that it is still needed as a back up to real-time CGM and isCGM and to ensure they have enough test strips to do this (rec 1.6.20).

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				recommendation. This is an important precursor and back up to real-time CGM and isCGM.	
Roche Diabetes Care, Ltd	Guideline	008	007	We support the recommendation to use routinely collected real-world data to assess the effectiveness of CGM. We believe this should be expanded to assess the effectiveness of structured capillary blood glucose monitoring for all people with Type 2 diabetes to ensure the evidence-base is complete.	Thank you for your comment and support for the guideline. The committee did not consider the evidence base for structured capillary blood glucose monitoring for all people with Type 2 diabetes as a stand-alone intervention so are unable to recommend further research in this area.
Roche Diabetes Care, Ltd	Guideline	011	013	It is not clear why healthcare professionals would not need to meet with people using CGM technology as frequently as those who are self-monitoring. If this relates to the ability of CGM data to be reviewed remotely then a connected blood glucose meter would also support this approach. Data can be seen without requiring a physical appointment and data download therefore also optimising clinic time and improving the quality of consultations. Kulzer B et al 2018 Integrated personalized diabetes management improves glycemic control in patients with insulin-treated type 2 diabetes: Results of the PDM-ProValue study program. Diabetes Research and Clinical Practice Oct; 144: 200-212	Thank you for your comment. The committee acknowledged that healthcare professionals do not have to meet people who are using CGM as often as people who use capillary blood glucose monitoring. However the committee have not considered the evidence for connected blood glucose meters (this is beyond the scope of this update) so are unable to comment on the use of this device.
Royal College of General Practitioners	Guideline	006	1.6.18	The RCGP welcomes the addition of continuous blood glucose monitoring in people with type 2 DM using insulin and in particular with those who require care worker or health care professional to monitor their blood glucose. This will enable our district nursing teams and care/nursing home teams to monitor these patients in a much easier way. We hope that commissioners will ensure this is funded across the ICS, being aware that increased costs associated with the device, will be offset by reductions in care/ social care costs.	Thank you for your comment and support for this guideline. NICE is aware that NHS England are currently involved in discussions about pricing with various manufacturers of continuous glucose monitoring devices. Whilst we are not involved in those conversations, we hope that whatever results will prove useful in reducing the concerns about affordability of the recommendations that have been raised through this consultation.
Royal College of Nursing	Guideline	005 - 006	025 - 028; 001 - 009	We agree with the criteria provided to offer isCGM to people with type 2 diabetes using multiple daily injections or those using insulin who would otherwise require support for glucose monitoring.	Thank you for your comments and support for this guideline.

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Royal College of Nursing	Guideline	005	021	This guideline for CGM provision is key in improving the management of people with T2D at risk of hypoglycaemia, with difficult to manage diabetes and those for which cap blood glucose monitoring is problematic for physical or cognitive reasons.	Thank you for your comments and support for this guideline.
Royal College of Nursing	Guideline	006	015	Is further detail – specific to patient education in relation to technology required in the existing guidance?– principles for the need for education is discussed however some thought required about use of tech, digital literacy, equity of access to internet as this is a factor alongside the use of these devices themselves especially with reference to remote monitoring and clinical consultation.	Thank you for your comment. Recommendation 1.6.23 outlines ensure continuous glucose monitoring is part of the education provided to adults with type 2 diabetes who are using it (see the section on patient education in the existing guideline) and that people using CGM devices are empowered to do so. The committee agreed that the content of training should be determined at a local level.
Royal College of Nursing	Guideline	015	022	Important to clarify the use of capillary blood glucose rather than CGM	Thank you for your comment. The capillary blood glucose recommendations were beyond the scope of this guideline update.
University Hospitals of North Midlands NHS Trust	Guideline	General	General	The Libre initiation will still need to have 6 month trial?	Thank you for your comment. This specific issue is beyond the scope of this guideline update.
University Hospitals of North Midlands NHS Trust	Guideline	General	General	Do patients need to be under specialist care to initiate Libre? Can this be done in primary care? Can GPs make the decision of initiating someone on it.	Thank you for your comment. The committee considered this issue and agreed that support should be provided by a healthcare specialist in diabetes. They also noted that the expertise of the team providing support is more important than the setting. This can be determined at a local level.
University Hospitals of North Midlands NHS Trust	Guideline	General	General	More clarification regards the insulin regimen – can Libre be initiated in any person on insulin or does it need to be people on more than 2 injections a day?	Thank you for your comment. Recommendation 1.6.17 outlines to offer isCGM to adults with type 2 diabetes on multiple daily insulin injections. This is defined as two or more daily insulin injections.
University Hospitals of North Midlands NHS Trust	Guideline	General	General	Will patients require capillary glucose monitoring alongside Libre monitoring?	Thank you for your comment. In response to stakeholder feedback the committee agreed to add a recommendation acknowledging the importance of capillary blood glucose monitoring and that it is still needed as a back up to real-time CGM and isCGM and to ensure they have enough test strips to do this (rec 1.6.20).

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None of the stakeholders who commented on this clinical guideline have declared any links to the tobacco industry.