

Type 1 diabetes in adults: diagnosis and management – glucose monitoring and diagnosis
Consultation on draft guideline - Stakeholder comments table
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Ascensia Diabetes Care	Guideline	006	007	<p>We welcome the update of the Continuous Glucose Monitoring within 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}.</p> <p>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 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</p> <p>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 al⁴ 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.</p> <p>Data published by Ekhlaspour et al⁵ 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.</p> <p>For T1 people with diabetes (PWD), meter accuracy should be a key concern, since insulin dosing errors could be made</p>	<p>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 1.6.5).</p> <p>Thank you for raising this issue however the quality and accuracy of blood glucose meters is beyond the scope of this guideline update.</p>

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				<p>when using an ISO compliant meter compared with 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 $\pm 15\%$, 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 $\pm 8.4\%$⁶, this range of insulin administered would be reduced to between 3 and 4 units.</p> <p>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 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.</p> <p>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 $\leq \pm 10\%$, 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.</p> <p>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</p>	

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				<p>or, if needed, seek immediate medical attention” Dexcom G6 Instructions For Use Guide (LBL016368 Rev 008 MT25354 Rev Date: 2021/08)</p> <p>3. https://jdrf.org.uk/information-support/treatments-technologies/continuous-glucose-monitors/how-accurate-is-my-blood-glucose-monitor/</p> <p>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</p> <p>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</p> <p>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.</p> <p>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.</p>	
Ascensia Diabetes Care	Guideline	006	013	<p>Under the considerations when choosing a continuous glucose monitoring device, this should be extended to include an additional bullet, that being the accuracy of the device. With there being no ISO standard for CGM or FGM devices to adhere to, the need to consider accuracy should be of paramount importance and even the first bullet in the list. As has been demonstrated by Breton⁷ for capillary blood glucose meters, the probability of missing hypoglycaemic events increases with decreasing levels of meter accuracy. As new CGM enter the UK market there will be no guarantee of the accuracy of these devices and therefore it is extremely important to allow the HCP to make sure the device provided give accurate readings that ensures appropriate self-management for the PWD.</p>	<p>Thank you for your comment. The committee considered this issue and accuracy of the device has added to box 1 as a factor to consider when choosing a continuous glucose monitoring device.</p>

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				7. Breton MD & Kovatchev BP. J Diabetes Sci Technol 2010;4:562–570.	
Association of British Clinical Diabetologists (ABCD)	Guideline	005	001	<p>Not all patients with T1D will be Ab positive and up to 20% will be GAD/IA2/ZnT8 Ab negative. If a clinical diagnosis of T1D is clear, then I would not recommend measuring Abs because a negative result will confuse, risk a revision of the diagnosis, potentially stopping insulin etc, by practicing clinicians not aware of the nuances of these immunology tests. Safer to restrict these tests to those patients where there is diagnostic uncertainty (as per previous guidelines).</p> <p>The rationale for recommending Ab testing is stated as 'The most common misdiagnosis is type 1 diabetes being misdiagnosed as type 2, which could lead to the person not receiving insulin treatment and a subsequent risk of diabetic ketoacidosis'. Recommending Ab testing in those with a clinical diagnosis of TD will not address this problem, rather there is a body of work to be done on the utility of measuring Ab in those with a clinical diagnosis of T2D.</p>	<p>Thank you for your comment. The committee discussed this issue and agreed that the evidence supporting the measurement of diabetes-specific autoantibodies in adults with an initial diagnosis of type 1 diabetes was clear. Measuring diabetes-specific autoantibodies has utility and for the majority this measurement will confirm the correct diagnosis. This recommendation is also in agreement with other international guidelines.</p>
Association of British Clinical Diabetologists (ABCD)	Guideline	005	010	<p>The measurement of C peptide in Ab negative people with a clear clinical diagnosis of T1D will also potentially confuse because C peptide will not have fallen appreciably at the time of diagnosis.</p>	<p>Thank you for your comment. The committee acknowledged the poor quality of studies on the use of c-peptide and the inherent mechanism of action of C-peptide that means it will not function well as a predictor at the time of diabetes presentation. However the committee also agreed that C-peptide along with blood glucose levels was the best reference standard available, but this was only true for a longer time after an initial presentation of diabetes.</p> <p>As a result of this lack of high-quality evidence on the effectiveness of c-peptide, the committee made a research recommendation outlining the need for further research on the effectiveness of c-peptide at correcting misclassification of diabetes diagnosis and what is the optimal timing in distinguishing subtypes of diabetes.</p>

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Association of British Clinical Diabetologists (ABCD)	Guideline	006	007	<p>1.6.10 The term 'evidence based' needs to be inserted before 'real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring'. There are devices coming to market with no published evidence on sensor accuracy, safety or effectiveness. We need to ensure that the devices used are high quality and evidence based – not just cheap to access.</p> <p>In addition these recommendations should be expanded to include people with rarer type of diabetes who may have a similar or greater risk of hypoglycaemia to those living with Type 1 diabetes. For example, those with diabetes secondary to pancreatectomy or pancreatitis, those with insulin treated monogenic diabetes</p>	<p>Thank you for your comment. The committee considered this issue and agreed that we need to ensure that devices are evidence-based. Further detail has been added to the guideline rationale section stating that only CGM devices with a supporting evidence base should be provided to people with type 1 diabetes.</p> <p>The committee discussed this issue and agreed that adults with insulin insufficiency due to other medical causes and conditions would be treated the same as adults with type 1 diabetes. This has been clarified in the guideline and evidence review.</p>
Association of British Clinical Diabetologists (ABCD)	Guideline	007	002	<p>1.6.11 Change to 'Offer the evidence based continuous monitoring device with the lowest cost that meets the person's identified needs and preferences. [2022]'</p>	<p>Thank you for your comment. The committee considered this issue and agreed that we need to ensure that devices are evidence-based. Further detail has been added to the guideline rationale section stating that only CGM devices with a supporting evidence base should be provided to people with type 1 diabetes. Recommendation 1.6.2 has also been amended stating that if multiple continuous glucose monitoring devices meet the person's identified needs and preferences, offer the device with the lowest cost.</p>
Association of British Clinical Diabetologists (ABCD)	Guideline	009	005	<p>Blood glucose targets An additional section is required on glucose targets for those on rCGm/isCGM. This section should recommend that people with access to these technologies align with the international consensus on time in range, aiming for more than 70% time in range and <4% time below range, or if in the high-risk group, >50% time in range and <1% time below range. See: https://care.diabetesjournals.org/content/early/2019/06/07/dci.19-0028</p>	<p>Thank you for your comment. The committee considered this issue but agreed that aligning with the international consensus on time in range was not needed. The committee was concerned how this would be used if this was not achieved and were keen to avoid any barriers in accessing technology.</p>
Association of British Clinical	Guideline	010	012	<p>The most appropriate way to initiate insulin in those with a new diagnosis of T1D is still not clear and there may be a</p>	<p>Thank you for your comment. This area is beyond the scope of this guideline update.</p>

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Diabetologists (ABCD)				benefit to start with bolus only insulin and initiate basal insulin later. This is an important area for research	
Association of British HealthTech Industries (ABHI)	Guideline	General	General	<p>Recommendations</p> <p>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.</p> <p>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.</p>	Thank you for your comment. Recommendation 1.6.1 has been reframed as you suggest considering the person's identified needs and preferences first before cost.
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. The committee considered this issue and agreed this should be included in the continuing programme of education provided to all adults with type 1 diabetes. .
British In Vitro Diagnostics Association (BIVDA)	Guideline	006	General	Although Box 1 (factors to consider when choosing a continuous glucose monitoring device) does detail that calibration requirements should be taken into consideration, we believe this should be expanded upon. Calibration can be difficult to manage, so the ease of this process, alongside the	Thank you for your comment. Your suggested addition acknowledging the ease of the accompanying instructions for use has been added to this factor In box 1

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				ease of the accompanying instructions for use should be added as a consideration when choosing. This is particularly important for children and young people who may be managing this process independently.	
British In Vitro Diagnostics Association (BIVDA)	Guideline	006	General	The ease of extracting and sharing data should be considered.	Thank you for your comment. The way in which data can be extracted and the ease of use with other technologies has been added as a factor in box 1.
Cambridge University Hospitals NHS Foundation Trust	Guideline	General	General	Glucose sensing technology is changing rapidly and there should be some consideration to “future proofing” the wording. At the very least, the terms used to refer to the different technologies should be clearly defined – in places continuous glucose monitoring appears to refer to rtCGM and in other places to rtCGM + isCGM. Increasingly, “isCGM” is converging towards “ rtCGM”. Libre2 already pushes information for alarms and libre 3 will be a rtCGM. Would it be better to refer to all under an umbrella term such as “interstitial fluid glucose monitoring devices” distinct from “continuous glucose monitoring” which in most people’s mind refers to rtCGM? Or perhaps to use a single term “CGM” for clarity but to define clearly at the first point it is used so that readers are clear that this covers all of this technology?	Thank you for your comment. The committee considered this issue and agreed to use the current wording for CGM as these are based on the evidence and how they are described in the studies. The guideline will also clarify that the term continuous glucose monitoring covers both real-time (rtCGM) and intermittently scanned (isCGM) continuous glucose monitoring.
Cambridge University Hospitals NHS Foundation Trust	Guideline	004	005	Rec 1.1.1 – We are broadly in agreement with this but wanted to flag up the growing identification of T1D at the pre-clinical stages (stage 1 and 2) in both adults and children. Currently screening through antibody or genetic risk scores occurs largely in research studies but it is very possible that we may see an increase. Stage 2 may also be picked up serendipitously through occupational screening etc. The strategy for following up stage 1 and 2 T1D are uncertain. It is also uncertain what the best insulin regimen and timing of starting is at the time of transition into early “stage 3” i.e. clinical T1D with a number of advocates for early introduction of prandial insulin with adjustment for carbs rather than background insulin. The committee may want to consider whether these should be acknowledged here and or research	Thank you for your comment and for raising this issue. This area is beyond the scope of this guideline update. The pre-clinical stages of diabetes (stage 1 and 2) are covered by NICE guideline PH38. Type 2 diabetes: prevention in people at high risk which contains recommendations on risk assessment and risk identification.

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				recommendations incorporated? This would also apply to the "Diabetes Type 1 and 2 in children and young adults" NG18 guidelines to ensure consistency.	
Cambridge University Hospitals NHS Foundation Trust	Guideline	005	020	<p>Rec 1.1.9 "people aged 60 and over presenting with weight loss and new-onset diabetes". This recommendation as written may be challenging in practice as weight loss is likely to be extremely common and effectively this may mean that pretty much everyone over the age of 60 with new T1D and many others with T2D will undergo imaging and/or clinicians will be exposed to risk of malpractice accusation if they fail to do so.. Pragmatically, while we wait for further data on how best to filter out new pancreatic cancers (see https://www.lctc.org.uk/research/uk-edi/), we felt that our current approach is to consider alternative pathology in those who fail to regain or halt weight loss shortly after glycaemic control established +/- or with greater weight loss from baseline +/- or presence of additional risk factors for pancreatic cancer such as smoking, family history? Would it be worth Committee reaching out to PI of UK-EDI study above as a European/ World leader in this for advice on how best to word this now?</p> <p><i>A broader point related to this is that people with Type 3c diabetes really aren't covered by current guidelines? 3c is a variable condition, both at service level and potentially for individuals with passage of time. A subset will be markedly insulopenic– e.g. total/subtotal pancreatectomies, chronic pancreatitis and cystic fibrosis/ CFRD. We suggest that "insulopenic diabetes" should be included in the Type 1 guidance including access to continuous glucose monitoring technology. For those who aren't insulopenic we were also concerned that there may not be sufficient guidance in the T2D guidelines NG28- we are aware that these guidelines are also in final stages of preparation and beyond the official consultation period but clearly any changes in NG17 to reflect would need to align with NG28.</i></p>	<p>Thank you for your comment. The committee considered this issue and agreed that this issue cannot be ignored. The current recommendation is consistent with the pancreatic cancer section of the NICE guideline on suspected cancer, recognition and referral.</p> <p>This issue is beyond the scope of this guideline update.</p>

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Cambridge University Hospitals NHS Foundation Trust	Guideline	006	007	1.6.10 Perhaps better written "Offer all adults...?"	Thank you for your comment. The committee considered this and agreed that recommendation 1.6.1 was clear that all adults with type 1 diabetes should be offered a choice of CGM.
Cambridge University Hospitals NHS Foundation Trust	Guideline	007	004	1.6.12 "If a person is unable or does not wish to use any real-time CGM or isCGM device, offer capillary blood glucose monitoring." We recommend that the wording is changed to reflect that SMBG still needs to be available to those who use CGM/ isCGM options. For example, current DVLA requirements mandate this: <i>"Drivers with insulin treated diabetes are advised to take the following precautions • You should always carry your glucose meter and blood glucose strips with you, even if you use a real time glucose monitoring system (RT-CGM) or flash glucose monitoring system (FGM)."</i> Advice from Abbott and Dexcom for example as manufacturers underpins this is to check with SMBG when low and/or when suspicion that reading may not be accurate.	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 1.6.5).
Cambridge University Hospitals NHS Foundation Trust	Guideline	007	006	1.6.13: (though this is not included for comment – it has relevance in the context of the earlier recommendations) Clarity on <i>"Continuous glucose monitoring should be provided by a team with expertise in its use"</i> . Does this imply that all continuous glucose monitoring technology will need specialist initiation? This will require significant resource for training if these now constitute primary choice of glucose monitoring.	Thank you for your comment. The committee considered this issue and agreed that training should be provided by a healthcare specialist in diabetes. The committee also 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 1 diabetes were worth the costs and resources associated in implementing this recommendation and ultimately improving care for people with type 1 diabetes
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 comment. This area is beyond the scope of this guideline update.
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	Thank you for your comment. This area is beyond the scope of this guideline update.

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				infusion devices (pumps) - including sensor augmented pump therapy in an operating theatre – including the use of diathermy – as a top priority. Manufacturers should include 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	CPOC would suggest review of the language used throughout the guideline to bring further in line with the Language Matters recommendations. Terms such as: <i>adults with type 1 diabetes who “achieve” glucose “targets”</i> , blood glucose/glycaemic <i>“control”</i> , may need rephrasing (e.g. adults with type 1 diabetes who manage/maintain their glucose levels within recommended range (specify range or HbA1c numbers); glucose levels or management etc). This is not to say the presented paper doesn't do this very well overall – just some areas for improvement presented themselves. Thank you.	We have checked through the guideline to ensure that all language is in line with the recommendations of Language Matters.
Centre for Perioperative Care	Guideline	004	014	1.1.2 CPOC recommends that clarification is provided as this information is unclear – does this mean that using only BMI <i>OR</i> age to diagnose shouldn't be done? If you use both is that acceptable? (it would be assumed that this is not the case?) If it means that other factors outside of BMI and age that should be considered then add reference to these e.g. if the following points are the factors then add text such as “Other factors should (must?) be considered as per recommendations 1.1.2...x.xx.x” . CPOC would also encourage including a reminder here about atypical presentation are becoming more likely now.	Thank you for your comment. The committee discussed this issue and agreed that age or BMI alone should not be used to diagnose. The evidence showed that no single clinical feature had a sufficient predictive value to make a diagnosis by itself. The committee were particularly concerned that age and BMI might be used in isolation. They noted that the average BMI in people with type 1 diabetes is increasing, and the age at which people are diagnosed with type 2 diabetes is decreasing. This means these clinical features are becoming less useful on their own to differentiate between the subtypes. Despite the growing crossover in age and BMI when people present with type 1 and type 2 diabetes, the committee agreed that these characteristics are still useful for making an initial working diagnosis of diabetes subtype in many people. However, further testing is increasingly needed as previously ‘atypical’ features of type 1 become more commonplace and ‘uncertain’ classifications become more common.

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Centre for Perioperative Care	Guideline	004	016	1.1.3 – CPOC would rephrase this to strengthen the requirement to check again and keep checking e.g., <i>Revisit the diagnosis at all subsequent clinical reviews and consider the possibility of other diabetes subtypes. Carry out further investigations...</i>	Thank you for your comment. The committee considered the feedback and agreed with the current wording of recommendation 1.1.3. Recommendation 1.1.7 also outlines the need to revisit initial diagnosis at subsequent reviews.
Centre for Perioperative Care	Guideline	004	General	1.1 –CPOC would like to highlight that this illustrates that there is a reliance on their being clinical “doubt” or “uncertainty”? e.g., 1.1.7 – who would raise the doubt? Will this guidance make the people who misdiagnose stop and consider the certainty of diagnosis? Is there a step missing to create the opportunity to raise the doubt in the first place? If antibody (or other) testing as routine is not yet a viable option, then should there be some emphasis on closer review of the patient’s progression after diagnosis and even recommendation for review by specialist e.g., diabetes team where not otherwise involved?	Thank you for your comment. As outlined in the guideline rationale further testing is increasingly needed as previously ‘atypical’ features of type 1 become more commonplace and ‘uncertain’ and unclear classifications become more common. Therefore this allows a clinician to explore alternative diagnoses if there is doubt.
Centre for Perioperative Care	Guideline	005	008	1.1.5 – CPOC could not find the <i>evidence review C</i> linked – does this include consideration of https://doi.org/10.1111/dme.14449 and recent change to Scottish guidelines?	Thank you for your comment. The evidence review did not include the study by Foteinopoulou et al (2020) as this study investigated reclassification of initial diagnosis which was different to our research question looking at diagnostic accuracy of tests for initial diagnosis.
Centre for Perioperative Care	Guideline	005	008	1.1.5 – CPOC recommends that this should state that HbA1c should not be used to diagnose Type 1 diabetes	Thank you for your comment. The committee decided that this addition was not necessary. HbA1c was not considered to be a key diagnostic biomarker in the evidence review.
Centre for Perioperative Care	Guideline	005	017	CPOC would like to query if information about testing after 3 years since diagnosis should be added to this? (Research recommendation and statement on pg 013 line 021 noted)	Thank you for your comment. The committee discussed this issue and agreed it was more important to get the initial diagnosis right rather than addressing misclassification after three years. They therefore did not support the approach adopted in Scotland.
Centre for Perioperative Care	Guideline	006	007	1.6.10 – CPOC suggests making it clearer that <i>all</i> people with Type 1 diabetes should be offered CGM as a default position, and, if not offering has to remain an option to HCPs, then make clear that moving to not offering should be very carefully considered ideally working with the person and/or their carer. E.g. older people, people with limited English, learning disability etc often denied access but this is mostly	Thank you for your comment. The committee considered this and agreed that recommendation 1.6.1 was clear that all adults with type 1 diabetes should be offered a choice of CGM. It should not be an option for health care professionals. The inclusion of this recommendation on clinical checklists is an implementation issue and should be considered at a local level.

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				unwarranted and due to incorrect bias/preconceptions. (Could this be further supported by including offer of CGM on clinical checklists?)	
Centre for Perioperative Care	Guideline	006	013	Box 1 – a very welcomed addition. CPOC would suggest adding psychological conditions/concerns e.g. eating disorders, as well as lifestyle and well-being considerations e.g. would it benefit them in terms of work/home priorities?	Thank you for your comment. The committee considered this issue and psychosocial considerations has been added as a factor in box 1.
Centre for Perioperative Care	Guideline	008	General	2 – SMBG and CGM sections come across as mutually exclusive and does not account for the use of SMBG alongside CGM – very few people will SMBG 4x a day if they have CGM, and CGM doesn't fully replace the need for SMBG e.g. calibration, CGM failure etc. Should this be acknowledged and also made clear that the frequency of SMBG does not affect access to CGM (e.g. if not doing 4 tests then this doesn't mean "non-compliance"). This links in with Table 2 – pg 020, items 1.6.10-12 – CPOC is wary that this segregation between SMBG users and CGM users will miss the fact that all CGM users still need to have SMBG available and be trained/monitored in the use of it at least as a back up to CGM and also those circumstances where CGM is not sufficiently reliable. This links in with the inpatient care guidelines also that CGM may not be suitable for clinical decision making and that blood glucose readings may be needed.	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 1.6.5).
Centre for Perioperative Care	Guideline	009	006	1.6.19 – inpatient recommended levels are at a higher range. Individual ranges should also be considered e.g. elderly, in care, end of life etc. (CPOC acknowledges that comments on greyed out sections are not being taken but felt this point important to raise specifically from the inpatient perspective.)	Thank you for your comment. This area is beyond the scope of this guideline update.
Centre for Perioperative Care	Guideline	009	006	1.6.19 – This is correct, but in those undergoing surgery, blood glucose targets should be 6 -10 mmol/l whilst anaesthetised (with up to 12 being acceptable)	Thank you for your comment. This area is beyond the scope of this guideline update.
Centre for Perioperative Care	Guideline	009	006	1.6.19 – This is correct, but those in labour could have glucose between 5 and 8 mmol/l to avoid the risk of intrapartum hypoglycaemia	Thank you for your comment. This area is beyond the scope of this guideline update.

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Chelsea and Westminster Hospital NHS Foundation Trust	Guideline	General	General	<p>Answers to questions:</p> <p>1. <u>Areas with the biggest impact on practice and challenging to implement:</u> The widespread availability of sensors will have the biggest impact in practice, and is likely to be challenging to implement universally without additional time from trained Specialist Nurses. This is because of the sheer number of patients that will have access to a sensor and will require training on its use, and monitoring in the first few weeks post application. Patients that are frail, with learning difficulties, or not as familiar with technology are likely to require more support compared to younger and technology savvy ones.</p> <p>2. <u>Significant cost implications:</u> There is an anticipated cost implication because of the purchasing cost of the sensors, however with achieving improved control and theoretical reduction in diabetes related admissions and long-term complications overall cost-effectiveness is anticipated. Purchasing costs may also be moderated if funding is reviewed for patients that are disengaged from CGM use despite multiple attempts of the Diabetes teams. There is an implementation cost because of the additional appointments that will be required to transition to sensors, this will be predominantly for Specialist Nursing time and Diabetes Doctor time. This cost can be partly offset by using group starts (with possible industry support) for patients who can attend this.</p> <p>3. <u>Resources to help users overcome any challenges:</u> The online resources from the Diabetes Technology Network on the use of isCGM and rCGM, and group education sessions (possibly with industry support due to the current workforce shortages in diabetes teams) are likely to help users</p>	<p>Thank you for your comment and feedback on how our recommendations will impact on the workforce.</p> <p>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.</p> <p>Thank you. Your comments will be considered by NICE where relevant support activity is being planned'</p>

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				<p>using the technology appropriately. For troubleshooting, each company has own advice support line for any technical issues.</p> <p>4. <u>Cost implications in the a choice between real-time and intermittently-scanned continuous glucose monitoring</u>: It is likely that a sizeable proportion of patients currently funded for isCGM will seek funding for rtCGM, especially if the patient's ultimate goal is to initiate a hybrid closed loop system. If a lower price could be negotiated for rtCGM due to the anticipated higher volume of orders expected, then the cost implication may be less substantial.</p> <p><u>Update Research Recommendations</u>: We agree with removing the Research recommendation 2 (Continuous glucose monitoring for adults with type 1 diabetes In adults with type 1 diabetes who have chronically poor control of blood glucose levels, what is the clinical and cost effectiveness of continuous glucose monitoring technologies?) and the Research recommendation 5 (Technologies for preventing and treating impaired hypoglycaemia awareness in adults with type 1 diabetes).</p>	Thank you for your feedback.
Chelsea and Westminster Hospital NHS Foundation Trust	Guideline	007	004	<p><u>Section 1.6.12</u> This recommendation advises offering capillary blood glucose monitoring to people who are unable to or do not wish to use any real-time CGM or isCGM device. In our practice we find that on occasions, sensors (for example isCGM or a brand of CGM) may be less accurate compared to capillary glucose monitoring, especially in the 24hrs post sensor application, and when blood glucose levels are changing quickly. Because of this, maintaining the ability and resources to perform capillary blood glucose monitoring in certain circumstances (for example when changing to a new sensor batch and if symptoms do not match the sensor readings) is important for safety reasons.</p>	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 1.6.5).

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				In addition, some people experience skin reactions at the site of the sensor application to the adhesives used by the manufacturer, and may be unable to tolerate the application or the sensor may result in erroneous readings due to the inflammatory skin changes. Although barrier preparations are available, in our experience often the sensor readings remain inaccurate for clinical use in these circumstances. Therefore, we propose to continue offering capillary blood glucose testing for certain occasions (that is analogous to the frequency of ketone testing) for all patients with type 1 diabetes to enable safe use of sensors.	
Chelsea and Westminster Hospital NHS Foundation Trust	Guideline	011	004	<p><u>Key Recommendation for Research 3.</u> We agree with the recommendation to develop structures that will facilitate examining the effectiveness and cost-effectiveness of CGM devices to improve glycaemic control, as often patients that benefit in clinical practice would not have been eligible to participate in clinical trials, and the technology available changes rapidly.</p> <p>We would also propose research on the proportion of patients who continue to use the technology appropriately, and/or disengage from its use, and research on skin reactions to the adhesives used and available solutions, so that more people can benefit from their application.</p>	Thank you for your comment. This issue was considered by the committee, and they agreed that further research on CGM users was not a priority, Furthermore from their clinical experience sensitivities to glucose monitor sensor adhesives is thankfully rare in adults and didn't warrant an additional research recommendation.
Coeliac UK	Existing Guideline	029	1.12.1	<p>We are pleased to see that the guideline section 1.12.1 on Associated Illness has recently been updated to remove low body mass index (BMI) and that there is a cross reference to NICE guideline NG20 on coeliac disease.</p> <p>We feel this recommendation could be further strengthened by including the following:</p> <ul style="list-style-type: none"> The recommendation to offer serological testing for coeliac disease people with type 1 diabetes, at diagnosis (recommendation 1.1.1 within NG20). This recommendation should be included as it is 	Thank you for your comment. The committee considered these issues and agreed these were beyond the scope of this guideline update.

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				<p>relevant to all adults with type 1 diabetes, at diagnosis.</p> <ul style="list-style-type: none"> The inclusion of other potential symptoms of coeliac disease highlighted by NICE within NG20 (including persistent gastrointestinal symptoms, prolonged fatigue, severe or persistent mouth ulcers and unexplained iron, vitamin B12 or folate deficiency) <p>This guideline provides an opportunity to provide a more timely diagnosis of coeliac disease for adults with type 1 diabetes.</p>	
Dexcom	General	General	General	<p>References</p> <ol style="list-style-type: none"> Visser MM, Charleer S, Fieuws S, De Block C, Hilbrands R, Van Huffel L, Maes T, Vanhaverbeke G, Dirinck E, Myngheer N, Vercammen C. Comparing real-time and intermittently scanned continuous glucose monitoring in adults with type 1 diabetes (ALERTT1): a 6-month, prospective, multicentre, randomised controlled trial. <i>The Lancet</i>. 2021 Jun 2. Beck et al., Effect of Continuous Glucose Monitoring on Glycaemic Control in Adults With Type 1 Diabetes Using Insulin Injections The DIAMOND Randomized Clinical Trial. <i>JAMA</i>. 2017;317(4):371-378 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. <i>Lancet Diabetes Endocrinol</i>. 2017 Sep;5(9):700-708. Lind et al., Continuous glucose monitoring vs conventional therapy for glycemic control in adults with type 1 diabetes treated with multiple daily insulin injections: The GOLD randomized clinical trial. <i>JAMA</i> 2017;317(4):379-387 	<p>Thank you for providing these references. We have checked these against the inclusion criteria of our evidence review.</p> <ol style="list-style-type: none"> This paper was included in our evidence review. This paper was included in our evidence review. This paper did not meet our inclusion criteria as it includes the use of an insulin pump This paper was included in our evidence review. This paper did not meet our inclusion criteria as 94% of the sample were children. and 7. This paper was excluded as it did not have a relevant study design. It was a nonrandomized, prospective, real-life clinical trial. This paper was excluded as the data was not split and presented in a way between children under 18 years and adults over 18 years. This paper was included in our evidence review. This paper did not meet our inclusion criteria as the study population was mixed including participants with type 1 and type 2 diabetes. This study was excluded as it had a mixed population of adults and children, and they did not present data separately for adults and children and young people.

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				<p>5. Mulinacci et al., Glycemic Outcomes with Early Initiation of Continuous Glucose Monitoring System in Recently Diagnosed Patients with Type 1 Diabetes. <i>Diabetes Technol Ther.</i> 2019;21(1):6-10.</p> <p>6. Šoupal J, Petruzelkova L, Flekac M, et al. Comparison of Different Treatment Modalities for Type 1 Diabetes, Including Sensor-Augmented Insulin Regimens, in 52 Weeks of Follow-Up: A COMISAIR Study. <i>Diabetes Technol Ther.</i> 2016;18(9):532-538.</p> <p>7. Šoupal (2019). Glycemic Outcomes in Adults With T1D Are Impacted More by Continuous Glucose Monitoring Than by Insulin Delivery Method 3 Years of Follow-Up From the COMISAIR Study, <i>DIABETES CARE</i> 2019;43(1)37-43</p> <p>8. Laffel, L., et al. (2020). "Effect of Continuous Glucose Monitoring on Glycemic Control in Adolescents and Young Adults with Type 1 Diabetes." <i>JAMA.</i> 323(23):2388-2396</p> <p>9. Pratley, R., et al. (2020). "Effect of Continuous Glucose Monitoring on Hypoglycemia in Older Adults with Type 1 Diabetes." <i>JAMA.</i> 323(23):2397-2406</p> <p>10. 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." <i>Diabetes Technol Ther</i> 20(8): 557-560.</p> <p>11. Thabit, et al (2020). Use of Factory-Calibrated Real-time Continuous Glucose Monitoring Improves Time in Target and HbA1c in a Multiethnic Cohort of Adolescents and Young Adults With Type 1 Diabetes: The MILLENNIALS Study, <i>Diabetes Care</i> 2020 Oct; 43 (10): 2537-2543.</p> <p>12. DiMeglio LA, Kanapka LG, DeSalvo DJ, Anderson BJ, Harrington KR, Hilliard ME, Laffel LM,</p>	<p>12. This paper was excluded as the participants were children and wore masked or blinded continuous glucose monitors which did not meet our inclusion criteria.</p> <p>13. This study was included in the children and young people evidence review and did not meet the population inclusion criteria for this evidence review.</p> <p>14. This paper was included in our evidence review.</p> <p>15. This paper is on the DIAMOND RCT which is included in the evidence review in Beck et al 2017</p> <p>16. This paper did not meet our inclusion criteria as the subjects used an insulin pump.</p> <p>17, 18, and 19. These papers were included in our evidence review.</p> <p>20. This paper did not meet our inclusion criteria as it investigated associations between rebound hyperglycemia and use of real-time continuous glucose monitoring (rtCGM) and an rtCGM system's predictive alert.</p> <p>21. This paper was included in our evidence review.</p> <p>22. This paper did not meet our inclusion criteria as it did not investigate the effectiveness of CGM. It examined the association of glycaemic variability with progression of microvascular outcomes.</p> <p>23. This paper did not meet our inclusion criteria as it examined microvascular and macrovascular complications of diabetes.</p> <p>24. This paper did not meet our inclusion criteria as it is a prospective diabetes study and does not investigate the effectiveness of CGM.</p> <p>25. This paper did not meet our inclusion criteria as it does not investigate CGM and looks at the health care costs of diabetes.</p> <p>26. This paper did not meet our inclusion criteria as it does not investigate CGM and looks at hypoglycaemia.</p> <p>27. This paper did not meet our inclusion criteria as it does not investigate CGM and looks at severe hypoglycaemia.</p>

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				<p>Tamborlane WV, Van Name MA, Wadwa RP, Willi SM. Time spent outside of target glucose range for young children with type 1 diabetes: a continuous glucose monitor study. <i>Diabetic Medicine</i>. 2020 Aug;37(8):1308-15.</p> <p>13. Laffel LM, Kanapka LG, Beck RW, Bergamo K, Clements MA, Criego A, DeSalvo DJ, Goland R, Hood K, Liljenquist D, Messer LH. Effect of continuous glucose monitoring on glycemic control in adolescents and young adults with type 1 diabetes: a randomized clinical trial. <i>JAMA</i>. 2020 Jun 16;323(23):2388-96.</p> <p>14. 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. <i>Lancet</i> 2018;391:1367-1377</p> <p>15. Riddlesworth T, Price D, Cohen N, Beck RW. Hypoglycemic Event Frequency and The Effect of Continuous Glucose Monitoring in Adults with Type 1 Diabetes Using Multiple Daily Insulin Injections. <i>Diabetes Ther</i> 2017; 8:947-51</p> <p>16. Aleppo G, Ruedy KJ, Riddlesworth TD, Kruger DF, Peters AL, Hirsch I, et al. REPLACE-BG: A randomized trial comparing continuous glucose monitoring with and without routine blood glucose monitoring in well-controlled adults with type 1 diabetes. <i>Diabetes Care</i> 2017; 40:538-45.</p> <p>17. Reddy M, Jugnee N, El Laboudi A, Spanudakis E, Anantharaja S, Oliver N: A randomized controlled pilot study of continuous glucose monitoring and flash glucose monitoring in people with Type 1 diabetes and impaired awareness of</p>	<p>28. This paper did not meet our inclusion criteria as it does not investigate CGM and looks at the healthcare costs of hypoglycaemia.</p> <p>29. This paper did not meet our inclusion criteria as it does not investigate CGM and looks at the medical costs of diabetes.</p> <p>30. This paper was excluded as it did not have a relevant RCT study design. It is a prospective cohort study.</p> <p>31. This paper is an NHS England policy document</p> <p>32. This paper did not meet our inclusion criteria as the study population was mixed including participants with type 1 and type 2 diabetes.</p> <p>33. This paper did not meet our inclusion criteria as it investigated associations between rebound hyperglycemia and use of real-time continuous glucose monitoring (rtCGM) and an rtCGM system's predictive alert.</p> <p>34. This paper did not meet our inclusion criteria as it is a non RCT – a retrospective evaluation of device usage and glycaemic control in children.</p> <p>35, 36, and 37 These papers were included in our evidence review.</p> <p>38. This paper did not meet our inclusion criteria as it is a systematic review of HbA1c variables in diabetes complications.</p> <p>39. This paper was included in our evidence review.</p> <p>40. This is the NICE draft guideline</p> <p>41. This paper was included in our evidence review.</p> <p>42. NICE evidence review</p>

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				<p>hypoglycaemia. Diabet Med 2018;20(11):751-757. 2018;20(11):751-757.</p> <p>18. Reddy M, Jugnee N, Anantharaja S, BSc, Oliver N, 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, 2018, DIABETES TECHNOLOGY & THERAPEUTICS, DOI: 10.1089/dia.2018.0252</p> <p>19. Olafsdottir et al. A Randomized Clinical Trial of the Effect of Continuous Glucose Monitoring on Nocturnal Hypoglycemia, Daytime Hypoglycemia, Glycemic Variability, and Hypoglycemia Confidence in Persons with Type 1 Diabetes Treated with Multiple Daily Insulin Injections (GOLD-3). Diabetes Technology & Therapeutics 2018; DOI: 10.1089/dia.2017.0363</p> <p>20. Acciaroli G, Welsh J, Akturk HK, Mitigation of Rebound Hyperglycemia With Real-Time Continuous Glucose Monitoring Data and Predictive Alerts, JDST, 2021 January;</p> <p>21. Pratley RE, Kanapka LG, Rickels MR, Ahmann A, Aleppo G, Beck R, Bhargava A, Bode BW, Carlson A, Chaytor NS, Fox DS. Effect of continuous glucose monitoring on hypoglycemia in older adults with type 1 diabetes: a randomized clinical trial. Jama. 2020 Jun 16;323(23):2397-406.</p> <p>22. Lachin JM, Bebu I, Bergenstal RM, Pop-Busui R, Service FJ, Zinman B, Nathan DM; DCCT/EDIC Research Group. Association of Glycemic Variability in Type 1 Diabetes With Progression of Microvascular Outcomes in the Diabetes Control and Complications Trial. Diabetes Care. 2017 Jun;40(6):777-783</p> <p>23. Fowler JM, Microvascular and Macrovascular Complications of Diabetes, 2008, Clinical Diabetes.</p>	

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				<p>24. Genut, S. Implications of the United Kingdom Prospective Diabetes Study, <i>DIABETES CARE</i>, volume 25, supplement 1, January 2002</p> <p>25. Gilmer, T. P., et al. (2005). "Predictors of health care costs in adults with diabetes." <i>Diabetes Care</i> 28(1): 59-64.</p> <p>26. Frier, B. M. (2014). hypoglycaemia in diabetes mellitus: epidemiology and clinical implications. <i>Nature Reviews Endocrinology</i>, 10(12), 711–722. doi:10.1038/nrendo.2014.170</p> <p>27. Leese, G. P., et al. (2003). "Frequency of severe hypoglycemia requiring emergency treatment in type 1 and type 2 diabetes: a population-based study of health service resource use." <i>Diabetes Care</i> 26(4): 1176-1180.</p> <p>28. McEwan P, <i>et al</i> Healthcare resource implications of hypoglycemia-related hospital admissions and inpatient hypoglycemia: retrospective record-linked cohort studies in England <i>BMJ Open Diabetes Research and Care</i> 2015;3:e000057. doi: 10.1136/bmjdr-2014-000057</p> <p>29. Sharon H. Medical Costs Among Youth Younger Than 20 Years of Age With and Without Diabetic Ketoacidosis at the Time of Diabetes Diagnosis, <i>Diabetes Care</i>, 2019, https://doi.org/10.2337/dc19-1041</p> <p>30. Charleer, S., et al. (2018). "Effect of Continuous Glucose Monitoring on Glycemic Control, Acute Admissions, and Quality of Life: A Real-World Study." <i>J Clin Endocrinol Metab</i> 103(3): 1224-1232.</p> <p>31. NHS England, Long Term Plan, 2019. https://www.longtermplan.nhs.uk/wp-content/uploads/2019/08/nhs-long-term-plan-version-1.2.pdf.</p>	

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				<p>38. Lind M, Odén A, Fahlén M, Eliasson B. A systematic review of HbA1c variables used in the study of diabetic complications. <i>Diabetes & Metabolic Syndrome: Clinical Research & Reviews</i>. 2008 Dec 1;2(4):282-93.</p> <p>39. Bolinder, Jan, Antuna, Ramiro, Geelhoed-Duijvestijn, Petronella et al. (2016) Novel glucose-sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial. <i>Lancet (London, England)</i> 388(10057): 2254-2263</p> <p>40. NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE Guideline Type 1 diabetes in adults: diagnosis and management Draft for consultation, November 2021 ,p15</p> <p>41. Roze, S., et al. "Long-term cost-effectiveness of dexcom G6 real-time continuous 7 glucose monitoring versus self-monitoring of blood glucose in patients with type 1 8 diabetes in the U.K." <i>Diabetes care</i> 2020; 43(10): 2411-2417.</p> <p>42. NICE Type 1 diabetes in adults: diagnosis and management, Evidence reviews for continuous glucose monitoring in adults with type 1 diabetes , 2021, page 39.</p>	
Dexcom	Guideline	006	007	Dexcom would like to place on record our support for the recommendation to offer all people with Type 1 diabetes access to a glucose sensor. Changing the recommendation on the use of rt-CGM from “consider” to “offer” will undoubtedly reduce the variation in access to CGM across NHS England. With regards to rt-CGM, this guideline is now consistent with the significant evidence base ¹⁻²¹ . Offering health care interventions that effectively reduce the probability the long and short term complications associated with diabetes occurring, will improve the efficiency and sustainability of the NHS through a reduction in inpatient costs, hospital admissions, ambulance callouts, and accident	Thank you for your positive comment.

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				& emergency visits related to poor glycaemic control. This may result in improved outcomes and cost reductions to the health care system ²²⁻²⁹ . In addition to this, the proposed update to this guideline is consistent with the NHS England Long Term Plan ³⁰ .	
Dexcom	Guideline	006	013	<p>Dexcom welcomes the recommendation that the choice of device is based on individual patient preferences, needs, characteristics, and importantly the functionality of the devices available. It has been demonstrated that the enhanced functionalities of certain real-time CGM systems such as predictive alarms and the ability to share data with carers and loved ones provide some people with an enhanced layer of support that allows them to better manage their glucose control.</p> <p>This approach is supported by the evidence. An interesting study that considered the digitally displayed predictive low glucose alert available for some real-time CGM devices. This alert was associated with significantly reduced hypoglycaemia and over 93% of CGM users enabled this digital functionality on their devices³². Adding to this body of evidence Acciaroli et al (2020)³³ demonstrated that systems featuring active alerts/alarms that warn users of immediate and/or impending hypoglycaemia or hyperglycaemia, have been shown to reduce the frequency, severity, and duration of rebound hypoglycaemia in people with Type 1 diabetes. This evidence suggests that predictive alarms and alerts are key in supporting the user to maintain good glycaemic control (Puhr 2019, Acciaroli 2020).</p> <p>Parker et al (2017)³⁴ analysed the use of CGMs that provide the user with the ability to share their data with personally selected individuals. It was demonstrated that the use of the CGM Share and Follow digital functionality positively impacted patient outcomes. This study concluded, sharing and following of CGM data is associated with improved device utilization and</p>	Thank you for your comment.

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				glycaemic parameters. The observed association suggests either more timely interventions or higher levels of engagement among the caregivers or the person with diabetes	
Dexcom	Guideline	015	015 - 017	<p>We request that the statement “<i>However, they considered that the evidence for real-time CGM compared with flash was not good enough quality and too low in sample size to clearly show clinical benefits of one technology over the other.</i>” is removed. This statement is factually inaccurate since it is not reflective of the body of evidence regarding the clinical value of rt-CGM.</p> <p>The Type 1 diabetes in adults: diagnosis and management evidence reviews for continuous glucose monitoring in adults with type 1 diabetes document clearly demonstrates that rt-CGM provides superior clinical outcomes vs isCGM in both a head to head RCT and through an indirect comparison of rt-CGM vs isCGM or SMBG.</p> <p>Rt-CGM vs is-CGM ALERTT1 (Visser et al. 2021)¹ and IHART CGM (Reddy et al. 2017)¹⁷ studies were conducted in adults with mean and median ages of 43 and 49 years, respectively. Around one fifth (20%) of patients in the ALERTT1¹ study used pumps for insulin delivery whilst patients in the IHART CGM¹⁷ study were eligible if using a multiple-dose insulin-injection regimen. All (100%) patients in the IHART CGM¹⁷ study experienced a severe hypoglycaemic event in the year prior enrolment or had a Gold score of ≥ 4, whilst in the ALERTT1¹ study, only 10-13% experienced a severe hypoglycaemic event. Both trials enrolled patients with mean HbA1c levels of below 7.5%. Participants in the ALERTT1¹ study had experience with glucose sensors prior enrolment. The I HART CGM¹⁷ study enrolled CGM naïve participants who were in good control (HbA1c) but still struggled with hypoglycaemia problems.</p>	<p>Thank you for your comment. The committee agreed that there was sufficient evidence in key outcomes such as HbA1c, time in range and severe/ nocturnal hypoglycaemia, as discussed in the evidence review, to justify recommending both rtCGM and isCGM over standard self-monitoring of blood glucose.</p> <p>The evidence review did also report evidence from 3 studies comparing rtCGM and isCGM however the evidence review also says - the committee noted that both HbA1c and time in range outcomes had high/ moderate quality results for effectiveness. The committee did note that for HbA1c it was the dichotomous outcome of <7% that showed an effect, while the higher quality outcome of continuous HbA1c at the same timepoint showed no meaningful difference. As a result of this they could not conclude whether HbA1c was more effective in rtCGM or were influenced by these HbA1c findings, Whilst time in range data was both effective as an outcome and had moderate quality evidence at 6 months, the committee noted Visser 2021 (ALERTT1) was not a UK based study. Furthermore, the committee was concerned about the reporting decision in the I-HART CGM study (Avari 2019, Reddy 2018a, Reddy 2018b), as reporting medians over means often suggests a skew in the data, and thus this study was reported as having “some concerns” in the risk of bias assessment.</p> <p>However, they considered that the evidence in pooled and single studies for rtCGM vs isCGM was not of high quality nor adequate enough in sample size to justify recommending one technology over another when combined with cost-</p>

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				<p>Of note, ALERTT1¹ is a randomised controlled trial co-powered to detect differences between the isCGM and real-time CGM in Time in range, HbA1c, Time in level 2 hypoglycaemia, and Hypoglycaemia worry.</p> <p>Baseline characteristics of studies of RT-CGM versus FGM in adults with T1D</p> <table border="1"> <thead> <tr> <th>Study ID</th> <th>Treatment arms</th> <th>N</th> <th>Age (Years)</th> <th>Female (%)</th> <th>Ethnicity</th> <th>CSII (%)</th> <th>Severe hypoglycaemia event in past 12 months (%)</th> <th>HbA1c</th> </tr> </thead> <tbody> <tr> <td rowspan="2">ALERTT1 Vissler, 2021</td> <td>Dexcom G6</td> <td>127</td> <td>Mean 42.8 SD 13.8</td> <td>36</td> <td>NR</td> <td>19</td> <td>13</td> <td>7.4% (0.9)</td> </tr> <tr> <td>FreeStyle Libre</td> <td>127</td> <td>Mean 43.0 SD 14.5</td> <td>40</td> <td>NR</td> <td>20</td> <td>10</td> <td>7.4% (0.9)</td> </tr> <tr> <td rowspan="2">IHA RT IHA RT extension Reddy, 2018</td> <td>Dexcom G5</td> <td>20</td> <td>Median 50.5 IQR 45 to 64.5</td> <td>40</td> <td>NR</td> <td>0</td> <td>100% with severe hypoglycaemia or GOLD score ≥4</td> <td>Mean 7.4% Range 6.6%-7.8%</td> </tr> <tr> <td>FreeStyle Libre</td> <td>20</td> <td>Median 48.5 IQR 34 to 63</td> <td>40</td> <td>NR</td> <td>0</td> <td>100% with severe hypoglycaemia or GOLD score ≥4</td> <td>Mean 7.2% Range 6.5%-8.1%</td> </tr> </tbody> </table> <p>Change in HbA1c Rt-CGM vs isCGM</p>	Study ID	Treatment arms	N	Age (Years)	Female (%)	Ethnicity	CSII (%)	Severe hypoglycaemia event in past 12 months (%)	HbA1c	ALERTT1 Vissler, 2021	Dexcom G6	127	Mean 42.8 SD 13.8	36	NR	19	13	7.4% (0.9)	FreeStyle Libre	127	Mean 43.0 SD 14.5	40	NR	20	10	7.4% (0.9)	IHA RT IHA RT extension Reddy, 2018	Dexcom G5	20	Median 50.5 IQR 45 to 64.5	40	NR	0	100% with severe hypoglycaemia or GOLD score ≥4	Mean 7.4% Range 6.6%-7.8%	FreeStyle Libre	20	Median 48.5 IQR 34 to 63	40	NR	0	100% with severe hypoglycaemia or GOLD score ≥4	Mean 7.2% Range 6.5%-8.1%	<p>effectiveness evidence. This was compounded by the most recent isCGM technologies evolving to become more similar to rtCGM.</p> <p>As a result of the evidence review findings which could not differentiate between the technologies, the committee made a recommendation to offer adults with type 1 diabetes a choice of real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring.</p>
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				<p>In ALERTT1¹, the percentage mean HbA1c level at 6 months was lower in the RT-CGM compared to is-CGM group (7.1% vs. 7.4%, respectively) with a significant difference in means of -0.36% (P<0.0001).</p> <p>It is important to note a reduction 0.3% (3 mmol/mol) in HbA1c is generally considered a clinically meaningful reduction to reduce diabetic long-term complications³⁸.</p> <p>In the IHART CGM¹⁸ study, at week 16 HbA1c remain stable and in the recommended range, RT-CGM (0.5 [-5.5 to 4.5]) and the is-CGM continuing with the additional 8 weeks of RT-CGM (2.0 [0.0 to 3.0]) (P=0.49) were observed.</p> <p>Change in Time in Range rt-CGM vs is-CGM</p> <p>The ALERTT-1¹ study demonstrated a significant difference in the mean difference (95% CI) in the proportion of time spent in range between RT-CGM and is-CGM arms (MD, 6.85%, P<0.0001). For the IHART CGM¹⁸ study, both real time CGM and is-CGM improved the percentage time spent in glucose target (3.9–10 mmol/l) over 4-8 weeks with no significant differences in the median change from baseline between groups, but a larger increase in the percentage of time spent in range during CGM was observed for daytime and night-time endpoints (12.7% and 14.1%, respectively) compared with is-CGM (5.3% and 5.2%, respectively).</p> <p>The IHART¹⁸ extension study demonstrated a significant difference in median (IQR) change from 8 to 16 weeks in time percentage of time spent in range (3.9-10.0 mmol/l) between RT-CGM (-1.0 [-4.4 to 4.1]) and the is-CGM continuing with the additional 8 weeks of RT-CGM (3.5 [-0.4 to 7.2]) (P=0.04).</p> <p><u>Proportion of time spent in range (3.9-10.0 mmol/l) of RT-CGM versus FGM studies in adults with T1D</u></p>	

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Study ID	Timepoint	CGM	FGM	Mean difference (95% CI)	P-value
		Mean (95% CI)	Mean (95% CI)		
ALERTT1	Baseline	52.5% (49.8-55.1)	51.3% (48.7-54.0)	-	-
	6 months	59.6% (56.8-62.4)	51.9% (49.1-54.7)	6.85% (4.36-9.34)	P<0.0001
		Median (IQR)	Median (IQR)		
IHART	Baseline (-2 to 0 weeks)	Daytime: 50.2 (40.8-66.5) Nighttime: 47.8 (39.2-65.9)	Daytime: 54.1 (47.5-64.5) Nighttime: 53.9 (42.3-67.5)	-	-
	Week 4-8	Daytime: 65.9 (53.0-74.8) Nighttime: 62.6 (51.7-72.7)	Daytime: 60.0 (54.5-67.8) Nighttime: 59.5 (52.1-64.2)	-	-
	Change from baseline (95% CI)	Daytime: 12.7 (7.2-15.8) Nighttime: 14.1 (-1.5-23.7)	Daytime: 5.3 (1.1-11.7) Nighttime: 5.2 (0.7-11.6)	NR	P=0.05
				NR	P=0.20

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				<p>Dexcom RT-CGM versus SMBG</p> <p>Overall, there is high-quality evidence from RCTs demonstrating improved outcomes with respect to change in HbA1c, time in range, hypoglycaemic events and QoL. Use of Dexcom CGM devices is supported by numerous RCTs. This evidence suggests that Dexcom CGM devices produce a treatment benefit that exceeds the 0.3% which is considered to be clinically meaningful³⁸).</p> <p>HbA1c outcomes from RCTs of RT-CGM using Dexcom CGM devices and SMBG</p> <table border="1"> <thead> <tr> <th>Study ID</th> <th>Mean difference in ΔHbA1c (95% CI)</th> <th>P-value</th> </tr> </thead> <tbody> <tr> <td>MILLENNIAL</td> <td>-0.76% (-1.1% to -0.4%)</td> <td>P<0.001</td> </tr> <tr> <td>CITY</td> <td>-0.37% (-0.66% to -0.08%)</td> <td>P=0.01</td> </tr> <tr> <td>DIAMOND</td> <td>-0.6% (-0.8% to -0.3%)</td> <td>P<0.001</td> </tr> <tr> <td>GOLD</td> <td>-0.43% (-0.57% to -0.29%)</td> <td>P<0.001</td> </tr> <tr> <td>WISDM</td> <td>-0.3% (-0.4% to -0.1%)</td> <td>P<0.001</td> </tr> </tbody> </table> <p>Note: bolded results are statistically significant (p<0.05)</p> <p>Severe hypoglycaemic events outcomes from RCTs IS-CGM vs SMBG</p> <p>In addition to HbA1c, there is high-quality evidence from demonstrating a reduction in hypoglycaemic events in patients at risk of hypoglycaemic events who treated with RT-CGM compared to SMBG. In particular, the HypoDE¹⁴ trial in patients with impaired hypoglycaemia found that 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)¹⁴.</p> <p>Finally, the RCTs also provide evidence for improved QoL outcomes. Specifically, CGM contributes to significant</p>	Study ID	Mean difference in Δ HbA1c (95% CI)	P-value	MILLENNIAL	-0.76% (-1.1% to -0.4%)	P<0.001	CITY	-0.37% (-0.66% to -0.08%)	P=0.01	DIAMOND	-0.6% (-0.8% to -0.3%)	P<0.001	GOLD	-0.43% (-0.57% to -0.29%)	P<0.001	WISDM	-0.3% (-0.4% to -0.1%)	P<0.001	
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				<p>improvement in diabetes-specific QoL. As shown in the DIAMOND³ study, people using RT-CGM experienced significant improvements in diabetes-related distress, hypoglycaemic confidence and fear of hypoglycaemia relative to SMBG</p> <p>By comparison the Type 1 diabetes evidence review concluded that only one RCT comparing is-CGM and SMBG (Bolinder, 2016)³⁹ was appropriate to assess the clinical benefit of is-CGM. Unfortunately is-CGM failed to demonstrate any statistically significant difference for change in HbA1c</p> <p>The committee seem to make their recommendation regarding the clinical utility of is-CGM vs SMBG purely based on Bolinder 2016 <i>“Based on our definition in the protocol the committee felt the one study comparing isCGM and SMBG (IMPACT) provided sufficient evidence for this comparison”</i> (Type 1 diabetes evidence review, Page 9, line 1). Yet despite ALERTT1¹ having a larger sample size vs Bolinder et al 2016³⁹ (254pts vs 239pts), being judged to having a low risk of bias and HbA1c and time in range outcomes had high to moderate quality results for effectiveness, it was concluded that <i>“the evidence for real-time CGM compared with flash was not good enough quality and too low in sample size to clearly show clinical benefits of one technology over the other”</i>⁴⁰. The wealth and breadth of clinical evidence supporting the use of rt-CGM exceeds the evidence generated in high-quality studies for isCGM. Not only there are more high-quality studies supporting the use of rt-CGM than there are for is-CGM, but these studies also investigate the benefits on a variety of different populations on different glycaemic outcomes. This superiority is further demonstrated through head-to-head studies. The vast difference (favouring rt-CGM) in the evidence base and clinical outcomes of rt-CGM vs is-CGM and SMBG is clearly demonstrated in Appendix F of the Evidence reviews for continuous glucose monitoring in adults with type 1 diabetes (figures 1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20 and 21).</p>	

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				As such the statement “ <i>the evidence for real-time CGM compared with flash was not good enough quality and too low in sample size to clearly show clinical benefits of one technology over the other</i> ” does not reflect the evidence and should not be stated in the final guidelines.	
Dexcom	Health economic report	020	001	<p><u>The base case per patient per year unit cost of £2,000 for rt-CGM is not reflective of the current U.K prices for this technology.</u></p> <p>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.</p> <p>This annual cost is in line with the findings of the committee, which states that when widely available for people with type 1 diabetes, the cost of rt-CGM is expected to be similar to the value cited in Roze et al,(2020),⁴¹ £1,850; “The committee noted that in practice, due to technological developments and the number of different rt-CGM devices available leading to price competition, it was likely that the NHS would be able to procure devices for considerably less than this maximum threshold price.”(NICE 2021 p39).⁴²</p>	<p>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.</p> <p>However, we have now added an additional exploratory scenario in the sensitivity analyses with a lower price for rtCGM at £1,600 as suggested.</p>
Dexcom	Health economic report	022	028	<p><u>Flawed sensitivity analysis</u></p> <p>It is counter-intuitive that the decision was made not to conduct a sensitivity analysis that assessed the impact of price reductions, thereby also failing to meet NICE’ own methodological standards for health economic assessments, which recommend a multi-way sensitivity analysis.</p>	<p>Thank you for your comment. We have now added an additional exploratory scenario in the sensitivity analyses with a lower price for rtCGM at £1,600 as suggested. It is not the role of the Centre for Guidelines at NICE to be involved in price negotiations where multiple devices are available or setting threshold prices, and therefore we do not believe</p>

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				<p>For this reason, it is requested the analysis is re-run to demonstrate the impact of a +/-50% price variation on a base case annual price of £1,600 for rt-CGM. This amendment will improve the robustness and relevance of the CEA for the use of rt-CGM across NHS England.</p> <p>Due to this flaw, it is requested the analysis is re-run to demonstrate the impact of a +/-50% price variation on a base case annual price of £1,600 for rt-CGM. This amendment will improve the robustness and relevance of the CEA for the use of rt-CGM across NHS England.</p>	presenting a wide range of scenario prices would add value to the document.
Diabetes Technology Network - UK	Guideline	General	General	<p>An additional section is required on glucose targets for those on rtCGm/isCGM. This section should recommend that people with access to these technologies align with the international consensus on time in range, aiming for more than 70% time in range and <4% time below range, or if in the high-risk group, >50% time in range and <1% time below range. See: https://care.diabetesjournals.org/content/early/2019/06/07/dci19-0028</p>	Thank you for your comment. The committee considered this issue but agreed that aligning with the international consensus on time in range was not needed. The committee was concerned how this would be used if this was not achieved and were keen to avoid any barriers in accessing technology.
Diabetes Technology Network - UK	Guideline	006	007	<p>1.6.10 The term 'evidence based' needs to be inserted before 'real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring'. There are devices coming to market with no published evidence on sensor accuracy, safety or effectiveness. We need to ensure that the devices used are high quality and evidence based – not just cheap to access.</p>	Thank you for your comment. The committee considered this issue and agreed that we need to ensure that devices are evidence-based. Further detail has been added to the guideline rationale section stating that only CGM devices with a supporting evidence base should be provided to people with type 1 diabetes.
Diabetes Technology Network - UK	Guideline	006	007	<p>1.6.10 In addition these recommendations should be expanded to include people with rarer type of diabetes who may have a similar or greater risk of hypoglycaemia to those living with Type 1 diabetes. For example, those with diabetes secondary to pancreatectomy or pancreatitis (sometimes called type 3c), those with insulin treated monogenic diabetes.</p>	Thank you for your comment. The committee discussed this issue and agreed that adults with insulin insufficiency due to other medical causes and conditions would be treated the same as adults with type 1 diabetes. This has been clarified in the guideline and evidence review.

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Diabetes Technology Network - UK	Guideline	006	007	1.6.10 _ box 1 We are concerned that local funding groups may interpret the current wording as using the cheapest option in all cases. We wonder if the wording be clearer/stronger to recommend who should get real-time CGM – This should include <ul style="list-style-type: none"> - Those with impaired hypoglycaemia or an episode of severe hypoglycaemia in the last year - Those who are unable to self-manage their diabetes Those who will use CGM to connect to an insulin pump as part of automated insulin delivery system such as hybrid closed loop	Thank you for your comment. The committee considered this and agreed that a choice of real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring should be offered based on individual preferences, needs, characteristics, and the functionality of the devices available. The factors raised in your comment are also included in box 1 under factors to consider when choosing a CGM device.
Diabetes Technology Network - UK	Guideline	007	002	1.6.11 Change to 'Offer the evidence based continuous monitoring device with the lowest cost that meets the person's identified needs and preferences. [2022]'	Thank you for your comment. The committee considered this issue and agreed that we need to ensure that devices are evidence-based. Further detail has been added to the guideline rationale section stating that only CGM devices with a supporting evidence base should be provided to people with type 1 diabetes. Recommendation 1.6.2 has also been amended stating that if multiple continuous glucose monitoring devices meet the person's identified needs and preferences, offer the device with the lowest cost.
Diabetes Technology Network - UK	Guideline	008	004	1.6.16 Please change the word "test" to measure – #languagematters	Thank you for your comment. Your suggested amendment has been made in the guideline.
Diabetes Technology Network - UK	Guideline	008	008	1.6.17 Please change the word "test" to measure – #languagematters	Thank you for your comment. Your suggested amendment has been made in the guideline.
Diabetes Technology Network - UK	Guideline	009	006	1.6.19 Please add in time in range targets as per international consensus guidelines Needs a section clarifying the different between GMI and HbA1c, but suggesting they can be used interchangeably.	Thank you for your comment. The committee considered this issue but agreed that aligning with the international consensus on time in range was not needed. The committee was concerned how this would be used if this was not achieved and were keen to avoid any barriers in accessing technology.
Diabetes Technology Network - UK	Guideline	009	010	1.6.20 I wonder where the target of 5-9 post-meal comes from – would it be prudent to align the post meal capillary glucose targets with international Time In Range targets	Thank you for your comment. This area is beyond the scope of this guideline update.

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				This should include the different targets for those with frailty as well as for pregnant women.	
Diabetes UK	Guideline	General	General	<p>Diabetes UK welcomes new and additional guidance on diagnosis to ensure correct and timely treatment, as many people have shared the devastating impact a misdiagnosis has had on their lives with us.</p> <p>We also welcome any recommendations that will increase access to non-invasive blood glucose monitoring systems that are evidenced to improve the clinical outcomes and quality of life for people living with type 1 diabetes.</p> <p><i>“It’s just amazing. As soon as I got it, just to be able to have a look and see exactly what my blood was doing, it was just fantastic. It just completely changed my life. immediately.”</i> [Person living with type 1 diabetes]</p> <p>Intermittent and real-time continuous glucose monitoring (i/RT CGM) has been transforming the lives of some people living with type 1 diabetes for a number of years. However, access to these technologies has been limited, with a postcode lottery in access being present across the UK to greater and lesser degrees.</p> <p>Inequities in access to i/RT CGM amongst people living in areas of high deprivation and from minority ethnic backgrounds is a consistent problem. While we acknowledge that a guideline recommendation for access to this technology for everyone is an important step, we also believe NICE needs to work closely with colleagues from across the health systems to ensure this recommendation is implemented equally and that this specific issue is highlighted in this guideline.</p>	Thank you for your positive feedback.
Diabetes UK	Guideline	004	014	People living with diabetes have shared with us the devastating impact a misdiagnosis has had on their lives.	Thank you for your comment. The committee were in agreement with your feedback. They noted that the average

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				<p>Given that non-diabetes specialists are often the first point of contact upon diabetes diagnosis, it needs to be clear that classification of diabetes type is not always straightforward at presentation and that misdiagnosis is common, particularly as both type 1 and type 2 diabetes can occur in adults and children.</p> <p>Adults do not always present with the classic symptoms seen in children and may experience temporary remission for the need for insulin.</p> <p>Highlighting why BMI is not a useful tool for diabetes type diagnosis could be helpful in this guideline. Specifically, we think this recommendation would benefit from highlighting that increasing BMI across the wider population means it is a less clear indicator of diabetes than previously thought.</p> <p>Reference: https://care.diabetesjournals.org/content/43/Supplement_1/S14</p>	<p>BMI in people with type 1 diabetes is increasing, and the age at which people are diagnosed with type 2 diabetes is decreasing. This means these clinical features are becoming less useful on their own to differentiate between the subtypes.</p>
Diabetes UK	Guideline	007	002 - 003	<p>1.6.11 – The wording of this recommendation risks clinicians and decision-makers pushing people living with type 1 diabetes towards the cheapest available i/RT CGM regardless of their individual preferences and needs. The current wording risks creating a 'race to the bottom'.</p> <p>We suggest reframing this recommendation to place the 'person's identified needs and preferences' at the beginning with cost a second consideration.</p> <p>Flash (iCGM) is not an exact alternative to RT CGM. It is therefore important not to push people living with type 1 diabetes towards the cheapest available option, which may not meet their needs.</p>	<p>Thank you for your comment. Recommendation 1.6.1 has been reframed as you suggest considering the person's identified needs and preferences first before cost.</p>

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Diabetes UK	Guideline	007	004	<p>1.6.12 There is a need for a person-centred approach where the person with diabetes, carers (where relevant) and the clinician can explore options together. This includes providing information about how i/RT CGM could be used – for example, a text talk option with iCGM 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.</p> <p>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 different languages, and appropriate appointment times.</p> <p>Adults with type 1 diabetes with learning disabilities and people from ethnic minority groups, if English is not their first language, should not face barriers to access the technology they are entitled to.</p>	Thank you for your comment. The committee agreed that a person-centred approach is needed. Recommendation 1.6.2 stresses the importance of considering the person's identified needs and preferences. 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.
Diabetes UK	Guideline	007	004	<p>1.6.12 – A recommendation that test strips and meters be prescribed for adults with diabetes using real-time continuous glucose monitoring or intermittently scanned continuous glucose instead of capillary blood glucose testing should be included here.</p> <p>This is because many adults will require them for certain circumstances e.g. driving, change of treatment, technology failure.</p>	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 1.6.5).
Diabetes UK	Guideline	007	009	<p>1.6.14 – We agree that people with type 1 diabetes should routinely be offered education about i/RT CGM. We do not think, however, that education (or lack there-of) should act as a barrier to access. There are large number of people living with diabetes who presently self-fund i/RT CGM and are using it successfully without any formal training from their healthcare team. Many people access information and training online or via peer support.</p>	Thank you for your comment. The committee agreed that education should be provided alongside continuous glucose monitoring and should not be a prerequisite or act as a barrier to accessing technology. The committee also agreed that training should be provided by a healthcare specialist in diabetes.

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				<p>“Once I knew I was funding it then I did my research and went straight onto the Abbott site to look at benefits, gains and also looked at some forums of people who were already using it . I really bought into the benefits and then I went into the costs in terms of expenditure and affordability “ [Person living with type 1 diabetes]</p> <p>While we do not think education should be a prerequisite for i/RT CGM access, we do think this guideline should be explicit in recommending that:</p> <ul style="list-style-type: none"> • adults with type 1 diabetes should be supported by a healthcare professional for their use of technology. • adults with type 1 diabetes (and their carers/supporters) should be offered education so they can best use and be empowered by 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 these technologies offer and to explain the benefits of data sharing with their patients 	
Diabetes UK	Guideline	010	015 - 016	<p>We think evidence on C-peptide screening from the NHS Lothian pilot study can be used to inform this recommendation alongside the outcome data from the recent roll-out of C-peptide testing for all people who have had a type 1 diabetes diagnosis for at least three years in Scotland, as it becomes available.</p> <p>The pilot study showed that about 7% of people who had been diagnosed with type 1 diabetes actually had type 2 diabetes, and about 2% had a form of monogenic diabetes. This meant that 1.5% were able to stop taking insulin and a further 1.9% improved their blood sugar control with the</p>	<p>Thank you for your comment. The committee discussed this issue and agreed it was more important to get the initial diagnosis right rather than addressing misclassification after three years. They therefore did not support the approach adopted in Scotland. The evidence review did not include the study by Foteinopoulou et al (2020) as this study investigated reclassification of initial diagnosis which was different to our research question looking at diagnostic accuracy of tests for initial diagnosis.</p>

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				<p>addition of treatments for type 2 diabetes. Whilst this represents a small percentage of people tested that impact of getting the correct treatment and the improving management of the condition on those is potentially life-changing and important to consider.</p> <p>According to the latest version of the Scottish Diabetes Survey, there are about 35,000 people diagnosed with type 1 diabetes in Scotland, with about 3,000 of those diagnosed less than 3 years ago. Extrapolating from the study this would mean that 2,240 are likely to actually have type 2 diabetes and 640 to have MODY. It would also mean that about 480 people would be able to come off insulin.</p> <p>References: https://onlinelibrary.wiley.com/doi/abs/10.1111/dme.14449 https://www.gov.scot/news/roll-out-of-new-diabetes-test/#:~:text=Scotland%20is%20the%20first%20country%20n%20the%20world,much%20insulin%20</p>	
Diabetes UK	Guideline	010	015 - 016	<p>Consider the ADA recommendations:</p> <ul style="list-style-type: none"> • Screening for type 1 diabetes risk with a panel of islet autoantibodies is currently recommended in the setting of a research trial or can be offered as an option for first-degree family members of a proband with type 1 diabetes. • Persistence of autoantibodies is a risk factor for clinical diabetes and may serve as an indication for intervention in the setting of a clinical trial. <p>Reference: https://care.diabetesjournals.org/content/44/Supplement_1/S15</p>	Thank you for your comment. The committee considered these but agreed they were not relevant for consideration in a clinical setting.
Diabetes UK	Guideline	016	020 - 024	<p>These recommendations are likely to result in broader access but given the currently inequities in access to</p>	Thank you for your comment. The committee were concerned that despite the positive recommendation for

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				technology use amongst those from minority ethnic groups and/or living in areas of high deprivation we feel ongoing research needs to be conducted in this area to understand why these exist and stop them persisting.	CGM in adults with type 1 diabetes 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 who have a lower uptake and making plans to engage with these groups to encourage uptake.
Diabetes UK	Guideline	021	028	It needs to be added that a misdiagnosis of type 1 diabetes (when a person has type 2 diabetes) can delay the option of remission as the evidence suggests the earlier action is taken to achieve remission from diagnosis, the greater the success of any intervention.	Thank you for your comment. This issue of misdiagnosis has been addressed in the guideline rationale. The evidence review also states – ‘In real clinical practice, misdiagnosis is common without antibody testing and patients being offered the wrong treatments might develop diabetic ketoacidosis (DKA) or other fatal complications at a later point, in addition to simply having poorly controlled diabetes due to being given the wrong treatment’.
East of England Priorities Advisory Committee	Evidence Review	General	General	The primary outcome utilised in almost all included studies was change in HbA1c. Overall these changes in HbA1C were small and not statistically significant, which could be attributed to the characteristics of only fairly well controlled patients being included in many studies. The reality is that there is very limited data in patients with less well controlled diabetes and the likely impact of isCGM can only be assumed. The committee also acknowledged that the data in relation to these technologies could have been skewed by operator bias and that users only relied on the readings when they felt well and knew they were going to be within range, using SBMG when they felt unwell.	Thank you for your comment. The committee discussed this issue and agreed that there are benefits of both measures - time in range and HbA1c. They both provide a complete picture of glycaemic control. They can be easily understood, and people can act in response to these measures. However it was the committee's opinion that time in range is used more in clinical practice and considered to be a better measure to assess variability and fluctuations of blood glucose levels. The more time you spend in range, the less likely certain diabetes complications will develop.
East of England Priorities Advisory Committee	Evidence Review	General	General	The secondary outcomes, such as time in range considered as a better marker for effectiveness by the committee are only surrogate markers and may not translate into better outcomes in the real world. More long-term real-world data is required to determine long term cost effectiveness for isCGM and rtCGM.	Thank you for your comment. The committee discussed this issue and agreed that there are benefits of both measures - time in range and HbA1c. They both provide a complete picture of glycaemic control. They can be easily understood, and people can act in response to these measures. However it was the committee's opinion that time in range is used more in clinical practice and considered to be a better measure to assess variability and fluctuations of blood

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					<p>glucose levels. The more time you spend in range, the less likely certain diabetes complications will develop.</p> <p>The committee also agreed that more long-term real-world data is required and they made a research recommendation to encourage the use of routinely collected real-world data to examine the effectiveness and cost effectiveness of continuous glucose monitoring.</p>
East of England Priorities Advisory Committee	Evidence Review	General	General	Utilisation of time in range as a surrogate marker is fundamentally flawed and the possibility of operator bias could have resulted in isCGM only being used when patients knew that their blood sugars would be okay. This was acknowledged by the committee, but the fact remains that this is a confounding factor which may have skewed both the data in the trials and the also the committee deliberations.	Thank you for your comment. The committee discussed this issue and agreed that there are benefits of both measures - time in range and HbA1c. They both provide a complete picture of glycaemic control. They can be easily understood, and people can act in response to these measures. However it was the committee's opinion that time in range is used more in clinical practice and considered to be a better measure to assess variability and fluctuations of blood glucose levels. The more time you spend in range, the less likely certain diabetes complications will develop.
East of England Priorities Advisory Committee	Evidence Review	General	General	<p>In relation to hypoglycaemic events, the data could not differentiate between the technologies. There was only a discernible difference in patients who experience nocturnal hypoglycaemic events which favoured, isCGM and rtCGM, probably because it is easier to monitor without rousing the patient whilst sleeping.</p> <p>There is limited understanding of the likely difference in impact between SMBG, isCGM and rtCGM for overall hypoglycaemic events. In addition, at times of rapidly changing glucose levels, the interstitial levels used by isCGM and rtCGM are unreliable and patients need to use SMBG. Again, this could confound the data.</p>	Thank you for your comment. As a result of the evidence review findings which could not differentiate between the technologies, the committee made a recommendation to offer adults with type 1 diabetes a choice of real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring. The limitations of the studies included were also taken into account by the committee.
East of England Priorities Advisory Committee	Evidence Review	030	001	<p>1.1.7 Summary of included economic evidence: The Healthcare Improvement Scotland Review utilised a cost calculation analysis by Hellmund et al (Diabetes res 2018; 193-200). Whilst the overall methodology utilised in the Hellmund review is recognised as good, the review and consequently the cost effectiveness calculation is</p>	Thank you for your comment. In our economic modelling, we did not take the cost of strips and lancets from Hellmund paper. Instead, we obtained the cost from the average of all the strips and lancets reported as first-line diabetes

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				<p>fundamentally flawed as the average cost of blood glucose testing strips and lancets used in the review is 50% higher than the current average real world costs in the UK, as much cheaper strip and lancets are used in practice; average strip cost in the real world 15.5p and lancet 2.5p vs 29p and 4p in the cost analysis. The study therefore does not reflect real world actual costs and underestimates the cost of isCGM, which in turn affects any QALY calculations based on this data.</p> <p>In relation to isCGM, it is also likely that patients will wish to use the built-in ketone and blood glucose meter, which are significantly higher cost than strips and meters in use across the UK at the moment. This will result in an additional cost pressure, compared to current UK primary care expenditure of blood glucose testing strips.</p>	<p>equipment in the NHS Electronic Drug Tariff at a unit cost of £0.26 for strips and lancets combined.</p> <p>We did not consider the use of built-in ketone and blood glucose meters in our analyses since it is beyond the scope of this update of the guideline. However, given the robustness of the cost-effectiveness results and low price of isCGM, the incorporation of the cost of built-in ketone and blood glucose meter is unlikely to change our recommendations.</p>
East of England Priorities Advisory Committee	Guideline	General	General	<p>National guidance on the use of isCGM (Flash) and real-time CGM is needed to ensure that these technologies are made available in a consistent and fair way to benefit patients.</p> <p>We recognise that as well as reducing the burden of diabetes for patients, there may be long term benefits in terms of improving time in range, outcomes and reducing costs associated with hospital admissions that may not be realised for several years.</p> <p>We accept that affordability is not part of the remit of NICE when developing guidance, however the recommendations made in the draft guidelines will be unaffordable to most health systems within their allocated baselines.</p> <p>CCGs/ICS have a legal responsibility for NHS healthcare budgets and have a duty to live within the budget allocated to them. Individual health systems will make funding decisions based on their local priorities and unless additional funding is provided, it is likely that many will not commission the full recommendations proposed. This will result in a 'post-code'</p>	<p>Thank you for your comment. The committee agreed that the results of the clinical review, and the cost-effectiveness results clearly demonstrated CGM was cost-effective for the full population adults with type 1 diabetes, and therefore agreed it would be inappropriate to restrict the intervention to only a subset of that population.</p> <p>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.</p>

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				<p>lottery which will increase inequalities, as access to these technologies will vary depending on where people live.</p> <p>The guideline produced should acknowledge the reality of affordability and provide clear criteria for prioritising patients with the greatest clinical need, so that access to these technologies can be increased across the country in a fair and sustainable manner within available budgets.</p> <p>The recommendations as they stand will create an expectation that all patients will be offered isCGM or real-time CGM that cannot be fulfilled. This may lead to frustration for people living with Type 1 diabetes when health systems are unable to make these technologies available to all patients as set out in the guideline.</p> <p>More data and a better understanding of the impact on real world outcomes is essential. Despite the comprehensive evidence review conducted by NICE, there is still a lack of robust data regarding impact of these technologies on hospitalisations, healthcare attendance rates and rates of overall hypoglycaemia, which will make proper assessment of the likely impact impossible to ascertain for local systems.</p> <p>At a time where the NHS is under unprecedented financial and operational pressures, clear guidance based on robust evidence is needed to ensure that resources are directed to those with the most need and who will get the greatest benefit, in a consistent way across the country.</p>	
East of England Priorities Advisory Committee	Guideline	006		<p>Box 1 Factors to consider when choosing a continuous glucose monitoring device: Bullet point 5: 'The person's insulin regimen or type of insulin pump, if relevant (taking into account whether a particular device integrates with their pump as part of a hybrid closed loop or insulin suspend function).'</p>	<p>Thank you for your comment. The use of insulin pumps and who they should be recommended for is beyond the scope of this guideline update, so previous recommendations on insulin pumps have been kept. In addition, although the price of rtCGM at £2,000 used in the base case did not consider the cost of insulin pumps, the committee suggested that the price of rtCGM will decrease in the future with widespread</p>

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				<p>The cost of providing rtCGM that integrates with insulin pumps currently exceeds the £2k annual cost assumed in the base case used in the NICE economic evaluation. The cost effectiveness at costs greater than £2k per year is less clear and therefore it is not appropriate to routinely offer integrated rtCGM as an option. Clear criteria are needed to define those patients where an insulin suspend function is essential to their care to ensure resources are targeted to those who will benefit the most.</p> <p>Page 6 line 3 of the guidance states that hybrid closed loop systems are being separately evaluated separately and therefore to offer this technology as a routine option is not appropriate at this time.</p>	<p>use across the NHS, and is very likely to fall below £2,000. The cost-effectiveness analysis only considers the benefits of CGM (not the benefits of insulin pumps) and therefore correctly only considers the costs of CGM (and not insulin pumps).</p> <p>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.</p>
East of England Priorities Advisory Committee	Guideline	006		<p>Box 1 Factors to consider when choosing a continuous glucose monitoring device: Bullet point 5: 'The person's insulin regimen or type of insulin pump, if relevant (taking into account whether a particular device integrates with their pump as part of a hybrid closed loop or insulin suspend function).'</p> <p>There are equity issues to consider where patients are self-funding an insulin pump. Offering a more costly integrated rtCGM system to a patient who is self-funding an insulin pump without a proven clinical need would be inequitable. The choice of device offered needs to be based on objective clinical need.</p>	<p>Thank you for your comment. The use of insulin pumps and who they should be recommended for is beyond the scope of this guideline update, so previous recommendations on insulin pumps have been kept. In addition, although the price of rtCGM at £2,000 used in the base case did not consider the cost of insulin pumps, the committee suggested that the price of rtCGM will decrease in the future with widespread use across the NHS, and is very likely to fall below £2,000. The cost-effectiveness analysis only considers the benefits of CGM (not the benefits of insulin pumps) and therefore correctly only considers the costs of CGM (and not insulin pumps).</p> <p>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.</p>
East of England	Guideline	006	007	To offer all adults with Type 1 diabetes isCGM or real-time CGM will be unaffordable for health systems.	Thank you for your comment. According to the economic analysis, isCGM remains cost effective in the base and

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Priorities Advisory Committee				<p>We are concerned that the evidence on cost effectiveness of isCGM is not sufficiently robust to support the recommendation to offer it to all adults with Type 1 diabetes.</p> <p>Decisions on initiating isCGM or real-time CGM should be based on clinical need. In line with the principles applied to medicines, the most cost-effective device that meets the patients' clinical needs should be used.</p> <p>Real-time CGM is currently at least twice the cost of isCGM. As such, the use of real-time CGM needs to be targeted to patients who have the greatest clinical need where blood glucose testing or isCGM do not meet these needs, e.g. persistent hypoglycaemia unawareness with disabling hypoglycaemia, despite optimised diabetes care. Clear objective criteria based on clinical need are required to ensure consistent provision of this technology to patients with the greatest need within available budgets.</p>	<p>sensitivity analyses (detailed in section HE2.4.1 of the economic report), and therefore the results should be robust enough to support the recommendations.</p> <p>We agree that clinical need should be one factor that informs the choice of device, and this is included in the recommendations. However, the committee also agreed that individual's preferences needed to be taken into account, as the most suitable device would vary for each person. The committee stressed that this freedom of choice is more beneficial than being limited to a specific device, particularly because adherence to the technology is likely to be higher if the device is matched to the person's needs and preferences.</p> <p>The guideline also contains a recommendation that where multiple continuous glucose monitoring devices meet the person's identified needs and preferences, the device with the lowest cost should be offered.</p> <p>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.</p>
East of England Priorities Advisory Committee	Guideline	007		<p>Box 1 Factors to consider when choosing a continuous glucose monitoring device: Bullet point 13: 'Cosmetic factors' We do not think it is appropriate to use the term 'cosmetic factors' in the guidance. Unless in exceptional circumstances, the NHS considers treatment for cosmetic purposes a low priority and does not fund it. The most cost-</p>	<p>Thank you for your comment. Considering feedback from other stakeholders the committee agreed to change cosmetic factors in box 1 to body image concerns. Furthermore, the committee considered that the evidence of clinical and cost effective benefits were strong enough to justify recommending continuous glucose monitoring to adults with type 1 diabetes. Body image concerns should only be considered when choosing a continuous glucose monitoring device.</p>

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				effective device that meets the patients clinical need that they are able to use effectively should be offered.	
East of England Priorities Advisory Committee	Guideline	007	002	The device with the lowest cost that meets the patients clinical need should be offered. Clear objective criteria are needed to define the place in therapy for more expensive technologies.	Thank you for your comment. The committee considered this issue and recommendation 1.6.2 has been amended stating that if multiple continuous glucose monitoring devices meet the person's identified needs and preferences, offer the device with the lowest cost.
East of England Priorities Advisory Committee	Guideline	007	006	We strongly agree that both isCGM and rtCGM 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.	Thank you for your comment.
East of England Priorities Advisory Committee	Guideline	007	009	We strongly agree that patients initiated on isCGM or rtCGM 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.
East of England Priorities Advisory Committee	Guideline	007	015	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 e.g. for isCGM 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, where the patient does not wear a sensor for the minimum time agreed with their diabetes team, where the patient fails to take appropriate action on glucose levels despite the support of their diabetes team. Treatment goals should be agreed with the patient e.g. % improvement in HbA1c, prior to starting therapy and treatment should be discontinued if the goals are not reached despite appropriate support from the diabetes team.	Thank you for your comment. The committee considered this issue and agreed that setting a criterion for discontinuing CGM would be unhelpful and had concerns about technology being taken away. Instead, the committee added to recommendation 1.6.8 stating that if there are any concerns about the way a person is using the device, discuss barriers and concerns and whether there is a way to improve their use of the device, including further emotional and psychological support and education to overcome these.
East of England Priorities	Health economic report	General	General	isCGM: Currently the only isCGM product available in the UK is FreeStyle Libre. As there is no market competition, there is a risk to the NHS around future price rises, the ability of the	Thank you for your comment. Given the robustness of the cost-effectiveness results of the isCGM and its price at the moment, a potential increase in its future price is unlikely to

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Advisory Committee				company to meet the demand that implementing the proposed recommendations would create and ensuring continuity of supply.	change our recommendations. In addition, given the potential price decrease of rtCGM with the widespread use across the NHS, there would be more competition coming from the providers of rtCGM devices, which is likely to restrict the price increases of isCGM.
East of England Priorities Advisory Committee	Health economic report	005	017 - 025	We have concerns that the economic evaluation is based on two cost-utility analyses that were only based on a single RCT. We note that the guideline committee agreed there was value in additional work being undertaken. It seems important to wait for that additional evidence before such wide-reaching adoption with the associated affordability issues is recommended.	Thank you for your comment. Although the base case economic analyses for isCGM were based on a single RCT, the study is assessed to be good quality and the committee agreed that it is sufficient to make the recommendations based on the current evidence. In addition, we have run a series of sensitivity analyses to account for the uncertainty surrounding input parameters. 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.
East of England Priorities Advisory Committee	Health economic report	006	020	We do not believe that it is appropriate to include the “potential to enhance people’s ability to manage their glucose levels and help them regain a sense of personal control over the condition” within the economic model. We are not aware of “potential” (rather than proven) psychological benefits being included in other NICE clinical guidelines.	Thank you for your comment. We have removed the word ‘potential’ from this sentence.
East of England Priorities Advisory Committee	Health economic report	008	037	Table HE002: Baseline cohort characteristics We are concerned that the HbA1c (9.1%) used in the economic model is high and may not be typical of many people with type 1 diabetes. REPOSE was a trial comparing insulin delivered via MDI with insulin delivered via a pump and it is noted in the trial discussion that this HbA1c is high. The authors note, “We therefore powered the trial on the number of participants with a baseline HbA1c of ≥ 7.5% (58 mmol/mol) and in whom a fall would reflect a worthwhile improvement in glycaemic control”. The benefits of reducing HbA1c via isCGM or rtCGM are presumably likely to be less (and hence less cost-effective) in a population with a lower baseline HbA1c. We believe that	Thank you for your comment. According to the committee, people with consistently well-controlled and lower HbA1c is a minority of people with type 1 diabetes, so the committee thought it’s appropriate to use 9.1% as the baseline HbA1c level based on the REPOSE trial to represent an average person with type 1 diabetes. For people with lower HbA1c level, although the benefits in HbA1c are lower, there would still be benefits expected in other domains, such as the control of severe/non-severe hypoglycaemic events. Therefore, the recommendations on rtCGM/isCGM are still applicable to this population group.

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				the NICE recommendations should take the person's baseline HbA1c (when using SMBG) into account.	
East of England Priorities Advisory Committee	Health economic report	014	036	We do not believe that it is appropriate to include people's preferences for using the device (compared with SMBG), over and above the benefits from improved clinical outcomes such as HbA1c and hypoglycaemic events, in the economic analysis. Given the significant cost implications of the draft recommendations, we believe that only hard clinical outcomes should be considered.	Thank you for your comment. NICE has a clear long-term position that our primary interest is in how treatments affect a person's quality of life. Some of this may be as a direct result of hard clinical outcomes, but some can also be a result of process utility (for example, in other evaluations in diabetes we have considered the disutilities associated with having to take a higher number of injections). To not include these factors in the analysis would be to ignore things that directly impact the benefits a person gains from treatment, and NICE views this as something it would be inappropriate to do.
East of England Priorities Advisory Committee	Health economic report	015	024	The guideline committee have noted that there was a potential issue with double counting utility gains when fear of hypoglycaemia (FoH) was included (as utility gains associated with hypoglycaemic events may capture some of the FoH as well). We appreciate that therefore two versions of the base-case analysis were conducted for the rtCGM – one with the utility gains associated with the reduction in FoH included, and one with them excluded. We note that the base case results in scenario 1 showed that isCGM was a cost-effective treatment compared with SMBG under a threshold of £20,000 per QALY, while rtCGM only appeared cost effective at the £30,000 threshold. In scenario 2 rtCGM was cost-effective compared with SMBG at a threshold of £20,000 per QALY. We are therefore concerned that the cost-effectiveness of rtCGM is uncertain and not sufficiently robust to support the recommendations in the draft guideline. In the probabilistic sensitivity analyses, the committee noted that with a lower threshold value at £20,000 per QALY, the probability of rtCGM being cost-effective was around 75%.	Thank you for your comment. You are correct in your description of the two modelling approaches adopted. However, when considering which scenario to place more weight on, the committee made the following points: "They were strongly of the opinion that fear of hypoglycaemia was an important consideration for many people with type 1 diabetes (over and above the harms caused by the hypoglycaemic episodes themselves)" "They discussed whether there was any concern about double counting of benefits with this approach, but agreed that since the Hypoglycaemia Fear Survey specifically asks about worry caused by the potential for hypoglycaemia, not symptoms during a hypoglycaemic event, and that people would spend the large majority of their time not in a hypoglycaemic state, that these should represent separate quality of life gains" Therefore, the committee were confident the correct set of results were used when making their recommendations. NICE is aware that NHS England are currently involved in

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					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.
East of England Priorities Advisory Committee	Health economic report	020	001	<p>We do not think that the assumed £2k (including VAT) per year ceiling price for CGM used in the economic modelling is appropriate. This is based on the pricing structure negotiated with the suppliers of CGM manufacturers (Dexcom, Medtronic and Medtrum) specifically for CGM in pregnancy. The current cost of these technologies on the NHS Supply Chain National Procurement Tower framework when used for indications other than pregnancy, significantly exceed this ceiling e.g. the current price for Dexcom standalone CGM is £2671 per year. It is worth noting that Dexcom is available for self-funders to buy direct from the company at a much lower annual cost of £1908 (including VAT).</p> <p>NB We are aware that a new NHS Supply Chain contract is due to go live in January 2022, but details were not available to us at the time of writing. Commissioners will base their cost pressure and affordability assessments for implementing this guidance on the current prices available to them. It is a risk to assume that the cost of CGM will fall to a maximum of £2k per year based on increased roll out of CGM as this will depend on market forces and is not guaranteed.</p>	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.
East of England Priorities Advisory Committee	Questions	Q1		<p>Q Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why:</p> <p>A. Providing all patients with T1DM the choice of isCGM or real-time CGM will be unaffordable for most health systems.</p> <p>All patients initiated on isCGM or real-time CGM need appropriate training and monitoring to ensure that these technologies are used appropriately and effectively, and that</p>	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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				they are delivering the anticipated improvements in patient care and outcomes to ensure that these technologies provide value for individual patients, the wider community, and the whole NHS, and ensuring the cost effectiveness for these technologies is maximised. 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.	The committee considered this issue and agreed that training should be provided by a healthcare specialist in diabetes. The committee also 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 1 diabetes were worth the costs and resources associated in implementing this recommendation and ultimately improving care for people with type 1 diabetes.
East of England Priorities Advisory Committee	Questions	Q2		<p>Q Would implementation of any of the draft recommendations have significant cost implications?</p> <p>A. isCGM: Based on patient numbers from the National Diabetes Audit 2020/21 numbers, we estimate the cost of providing isCGM to <u>all</u> patients with Type 1 diabetes in England to be £230 million. The current spend on FreeStyle Libre is £88 million, giving an overall cost pressure of £142 million for England. This may be offset by a small reduction in the use of blood glucose testing strips, however our experience is that since NHS England guidance on isCGM was implemented in April 2019, the data does not demonstrate a significant reduction in the use of blood glucose testing and any reduction in costs is mainly due to primary care initiatives to use more cost effective products. Per CCG the cost to implement isCGM alone is a similar order of magnitude to the expected annual uplift to their budget baseline intended to cover increase in costs for all areas of medicines and devices.</p> <p>The Healthcare Improvement Scotland Review utilised a cost calculation analysis by Hellmund et al (Diabetes res 2018; 193-200). Whilst the overall methodology utilised in the Hellmund review is recognised as good, the review is</p>	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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				<p>fundamentally flawed as the average cost of blood glucose testing strips and lancets used in the review is 50% higher than the current average real-world costs in the UK, as much cheaper strip and lancets are used in practice; average strip cost in the real world 15.5p and lancet 2.5p vs 29p and 4p in the cost analysis. The study therefore does not reflect real world actual costs and underestimates the cost of isCGM, which in turn affects any QALY calculations which utilise and are based on this data.</p> <p><u>rtCGM</u>: We estimate the cost of providing rtCGM to <u>all</u> patients with Type 1 diabetes based on the £2k annual maximum cost assumed in the NICE economic evaluation would be in the order of £500 million. This is a conservative estimate as patients who are already using insulin pumps are likely to be offered an integrated CGM system which would exceed the £2k per year cost assumption.</p> <p>Funding the proposed recommendations as they stand will be unaffordable for most health systems and could only be achieved by diverting resources from other health priorities.</p>	
East of England Priorities Advisory Committee	Questions	Q3		<p>Q What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)</p> <p>A Additional funds via a central budget or local budget uplift provided in order to 'invest to save' and to prevent local variations in access to these technologies.</p>	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.
East of England Priorities Advisory Committee	Questions	Q4		<p>Q Would implementation of any of the draft recommendations have significant cost implications?</p> <p>In particular, this guideline recommends offering people a choice between real-time and intermittently-scanned continuous glucose monitoring, and we are aware that currently real-time devices have a higher purchase cost.</p>	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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				<p>Would there be any cost concerns from offering people with diabetes this choice?</p> <p>A. isCGM: Based on patient numbers from the National Diabetes Audit 2020/21 numbers, we estimate the cost of providing isCGM to all patients with Type 1 diabetes in England to be £230 million. The current spend on FreeStyle Libre is £88 million, giving an overall cost pressure of £142 million for England. This may be offset by a small reduction in the use of blood glucose testing strips, however our experience is that since NHS England guidance on isCGM was implemented in April 2019, the data does not demonstrate a significant reduction in the use of blood glucose testing and any reduction in costs is mainly due to primary care initiatives to use more cost effective products. Per CCG, the cost pressure from the proposed type 1 guidance is a similar order of magnitude to the expected annual uplift to their budget baseline intended to cover increase in costs for all areas of medicines and devices.</p> <p>rtCGM: The cost of providing rtCGM to all patients with Type 1 diabetes based on the £2k annual maximum cost assumed in the NICE economic evaluation would be in the order of £500 million. This is a conservative estimate as patients who are already using insulin pumps are likely to be offered an integrated CGM system which would exceed the £2k per year cost assumption.</p> <p>Funding the proposed recommendations as they stand will be unaffordable for most health systems and could only be achieved by diverting resources from other health priorities.</p> <p>Decisions on initiating isCGM or real-time CGM should be based on clinical need. In line with the principles applied to medicines, the most cost-effective device that meets the patients' clinical needs should be used.</p>	

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				Real-time CGM is currently at least twice the cost of isCGM. As such, the use of real-time CGM needs to be targeted to patients who have the greatest clinical need, where blood glucose testing or isCGM do not meet these needs, e.g. persistent hypoglycaemia unawareness with disabling hypoglycaemia, despite optimised diabetes care. Clear objective criteria based on clinical need are required to ensure consistent provision of this technology to patients with the greatest need within available budgets.	
Ideal Diabetes CIC	Guideline	007	009	We are concerned that this lacks sufficient detail. To be effective, empowerment must include education, understanding and effective application of tools to manage the use of glucose monitoring. Critically, although the evidence indicates that CGM improves HbA1c and reduces the frequency of hypos, it does not eliminate the risk of severe hypoglycaemia or the development of hypo unawareness. It is therefore essential that education and empowerment enables the understanding of the importance of rapid and effective response to hypoglycaemia. This requires the education of both healthcare professionals and people with diabetes to ensure the risk hypoglycaemia is effectively mitigated where possible.	Thank you for your comment. The committee considered this issue but agreed that specifying training on rapid and effective response to hypoglycaemia was not needed and would be covered under education provided to all adults with type 1 diabetes.
Juvenile Diabetes Research Foundation (JDRF)	Guideline	005	014	Whilst we are pleased to see the recommendation to revisit the diabetes classification using serum C-peptide if there is doubt, JDRF suggests following the approach Scotland has taken, whereby serum C-peptide is used to check the diagnosis after three years, for everyone with type 1 diabetes. ¹	Thank you for your comment. The committee discussed this issue and agreed it was more important to get the initial diagnosis right rather than addressing misclassification after three years. They therefore did not support the approach adopted in Scotland.
Juvenile Diabetes Research	Guideline	006	007 - 011	JDRF agrees with the recommendation to offer adults with type 1 diabetes a choice of real-time continuous glucose monitoring or intermittently scanned continuous glucose	Thank you for your comment. The committee agreed with your feedback and the need for shared decision making has been added to recommendation 1.6.2.

¹ Roll-out of new diabetes test, Scottish Government, October 2021 <https://www.gov.scot/news/roll-out-of-new-diabetes-test/>

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Foundation (JDRF)				<p>monitoring, based on their individual preferences, needs, characteristics, and the functionality of the devices available.</p> <p>We suggest adding “having first undertaken a process of shared decision making between patient and clinician” after the word “available”.</p> <p>We regularly hear from people with type 1 diabetes about the benefits CGM provides. One supporter recently said “The biggest advantage of the CGM/Flash is that they make my life so much easier than conducting multiple finger prick tests; at least in part, my CGM gives me a sense of freedom. The potential for data sharing is important too.”</p>	
Juvenile Diabetes Research Foundation (JDRF)	Guideline	006	013	As an extra factor to consider, JDRF suggests a point about the way data can be extracted; it's ease of use with other type 1 technologies and the ease at which it can be shared with the patient's clinician.	Thank you for your comment. The way in which data can be extracted and the ease of use with other technologies has been added as a factor in box 1.
Juvenile Diabetes Research Foundation (JDRF)	Guideline	007	002	JDRF suggests re-wording this to “offer the continuous glucose monitoring device that meets the person's identified needs and preferences with the lowest cost.” We are concerned that by “lowest cost” coming before “needs and preferences”, “lowest cost” might be prioritised, which may not be of benefit to the person with type 1.	Thank you for your comments. We have revised the recommendations based on your suggestions. The choice between rtCGM and isCGM will depend on clinical needs and patient preference, and if both devices appear equal from clinical perspective, the one with lower price will be offered.
Juvenile Diabetes Research Foundation (JDRF)	Guideline	007	018	Adults with type 1 diabetes from minority ethnic or socially deprived backgrounds experience higher average blood glucose levels, something that can be reduced through access to technology. ² However people from lower socioeconomic backgrounds are less likely to discuss	Thank you for your comment. The committee were concerned that despite the positive recommendation for CGM in adults with type 1 diabetes inequalities may still occur with uptake of CGM being lower in certain groups. To address this the committee added a recommendation

² NHS Digital, National Diabetes Audit, Type 1 Diabetes, 2019/20 <https://digital.nhs.uk/data-and-information/publications/statistical/national-diabetes-audit/national-diabetes-audit-2019-20-type-1-diabetes>

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				<p>technology with their clinicians, and have lower awareness of the options available to them.³</p> <p>With this in mind, we suggest an extra recommendation be added to the guideline to encourage access to technology amongst groups experiencing health inequalities, by ensuring clinicians proactively discuss technology with patients from hardly reached communities, and monitoring uptake across different groups by local health commissioners.</p>	<p>outlining actions to address this including monitoring uptake, identifying groups who have a lower uptake and making plans to engage with these groups to encourage uptake.</p>
Juvenile Diabetes Research Foundation (JDRF)	Guideline	010	012	<p>JDRF suggests that an additional recommendation for research is made around continuous glucose monitor sensor adhesives to prevent sensitivities, as per the recommendation in NG18. We have heard from adults with type 1 who have experienced itching and blistering due to the adhesive with some sensors and have found the issue has resolved when changing devices.</p>	<p>Thank you for your comment. This issue was considered by the committee, and they agreed that from their clinical experience sensitivities to glucose monitor sensor adhesives is thankfully rare in adults and didn't warrant an additional research recommendation.</p>
Juvenile Diabetes Research Foundation (JDRF)	Guideline	010	018	<p>The following paper, Impact of routine clinic measurement of serum C-peptide in people with a clinician-diagnosis of type 1 diabetes^[1], addresses this question, however it is reasonable to seek more evidence.</p>	<p>Thank you for your comment. The evidence review did not include the study by Foteinopoulou et al (2020) as this study investigated reclassification of initial diagnosis which was different to our research question looking at diagnostic accuracy of tests for initial diagnosis.</p>
King's College Hospital NHS Foundation Trust	Guideline	006	007	<p>In clinical practice, people with type 3c diabetes (e.g. in relation to pancreatitis, pancreatic cancer/pancreatectomy, cystic fibrosis, haemochromatosis) are managed as if they have type 1 diabetes with regards insulin therapy and structured diabetes education. Should these groups of</p>	<p>Thank you for your comment. The committee discussed this issue and agreed that adults with insulin insufficiency due to other medical causes and conditions would be treated the same as adults with type 1 diabetes. This has been clarified in the guideline and evidence review.</p>

³ JDRF, Pathway to Choice, 2020 <https://jdrf.org.uk/wp-content/uploads/2020/02/jdrf-pathway-to-choice-brochure-FINAL.pdf>

^[1] Impact of routine clinic measurement of serum C-peptide in people with a clinician-diagnosis of type 1 diabetes, Foteinopoulou et al; November 2020; <https://onlinelibrary.wiley.com/doi/abs/10.1111/dme.14449>

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				individuals also have the same access to technology being offered in people with autoimmune type 1 diabetes?	
King's College Hospital NHS Foundation Trust	Guideline	006	014	"Whether the device provides predictive alerts or alarms and if these need to be shared with anyone else for example a carer." It should also include consideration of whether a care worker or healthcare professional is needed from a practical perspective to help with the action of monitoring blood glucose.	Thank you for your comment. The committee considered your suggestion but agreed that the example of carer met the needs of those who may need extra support.
King's College Hospital NHS Foundation Trust	Guideline	006	014	"Fear, frequency, awareness and severity of hypoglycaemia" – this statement appears to be less prescriptive than NG17 which is welcome from a patient perspective. It would be useful to have included methods of quantifying fear referenced here (e.g. diabetes distress scale-2, hypoglycaemia fear survey II worry scale etc) in order to be able to assess severity of fear and effectiveness of continuous glucose monitoring in managing this fear.	Thank you for your comment. The committee considered this issue but agreed that due to a lack of standardised measures, it was not possible to list specific measures.
King's College Hospital NHS Foundation Trust	Guideline	007	001	"Cosmetic factors" – whilst it may be an important factor to consider when selecting a particular device, cosmetic factors alone should not be an indication <i>per se</i> for continuous glucose monitoring – it is important that individuals with type 1 diabetes are aware that they may still need to perform capillary glucose monitoring e.g. during sensor failure / error / calibration, confirmation of hypoglycaemia.	Thank you for your comment. Considering feedback from other stakeholders the committee agreed to change cosmetic factors in box 1 to body image concerns. Furthermore, the committee considered that the evidence of clinical and cost effective benefits were strong enough to justify recommending continuous glucose monitoring to adults with type 1 diabetes. Body image concerns should only be considered when choosing a continuous glucose monitoring device.
King's College Hospital NHS Foundation Trust	Guideline	007	015	"Monitor and review the person's use of continuous glucose monitoring as part of reviewing their diabetes care plan". Do criteria for ongoing provision / withdrawal of continuous glucose monitoring need to be included? If there has been no clinical benefit to patient e.g. patient not using continuous glucose monitoring, it would seem appropriate to explore why this has been the case and raise the possibility of withdrawal of continuous glucose monitoring if safe to do so? We feel that it should be open for the healthcare professional working with the patient to decide what this benefit is based on their personalised treatment plan and goals, but that it should be	Thank you for your comment. The committee considered this issue and agreed that setting a criterion for discontinuing CGM would be unhelpful and had concerns about technology being taken away. Instead, the committee added to recommendation 1.6.8 stating that if there are any concerns about the way a person is using the device, discuss barriers and concerns and whether there is a way to improve their use of the device, including further emotional and psychological support and education to overcome these.

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				clear that this benefit needs to be achieved and maintained in order for ongoing provision of continuous glucose monitoring.	
Leeds Teaching Hospitals NHS Trust and NHS Leeds CCG	Guideline	General	General	In the section on diagnosis, it would be really useful to have an algorithm like the algorithm in the ADA guidelines by Holt et al. https://care.diabetesjournals.org/content/early/2021/09/27/dci.21-0043	Thank you for your comment. Your comment will be considered by NICE where relevant support activity is being planned.
Leeds Teaching Hospitals NHS Trust and NHS Leeds CCG	Guideline	005	001	Rec 1.14 – We believe that ideally you would take GAD and if negative then test for IA2 or ZnT8 if there is still a high level of suspicion for type 1 diabetes. Unless locally it is more economical to run the antibody tests at the same time.	Thank you for your comment. The committee discussed this issue and agreed that availability of autoantibody tests vary by laboratory. They acknowledged a regional variation. Therefore the committee decided not to specify specific autoantibody tests.
Leeds Teaching Hospitals NHS Trust and NHS Leeds CCG	Guideline	005	008 - 012	Rec 1.15/1.16 – only offer C-peptide testing immediately if antibody negative and person is <35 years old and there are features of monogenic diabetes	Thank you for your comment. The committee disagreed with your suggested cut off of <35 years old as from their clinical experience a majority of patients are diagnosed over 35 years.
Leeds Teaching Hospitals NHS Trust and NHS Leeds CCG	Guideline	005	008 - 012	Rec 1.15/1.16 – we were wondering what the rationale was behind the use of serum C-peptide vs. urinary C-peptide?	Thank you for your comment. The committee noted that serum C-peptide is more appropriate in individual clinical diagnosis settings as it can be paired with blood glucose, while urine C-peptide is mainly used in epidemiological studies. The two measures of serum c-peptide and blood glucose are needed together to interpret the serum c-peptide value. Low levels of c-peptide and high blood glucose levels can be an indicator of type 1 diabetes. This comparison cannot be carried out with urine c-peptide.
Leeds Teaching Hospitals NHS Trust and NHS Leeds CCG	Guideline	005	014	Rec 1.17 - we wondered if this should give a more specific indication of time frame for example after >3 years	Thank you for your comment. The committee considered this issue and agreed that setting a specific timeframe would not be useful. This should be carried out as soon as there is clinical doubt or at subsequent clinical reviews.
London Diabetes Clinical Network	Guideline	General	General	As sensors can fail, recommendation that blood test strips to be prescribed alongside sensors to enable users to self-manage by using capillary blood glucose testing.	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

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					CGM and isCGM and to ensure they have enough test strips to do this (rec 1.6.5).
London Diabetes Clinical Network	Guideline	007	002-003	Rec 1.6.11 – More emphasis to be placed on offering the continuous monitor device that meets the person's identified needs and preference first rather than the one with the lowest price to ensure there is equity of access.	Thank you for your comment. Recommendation 1.6.1 has been amended with the ordering changed to state 'considering the person's identified needs and preferences' first before cost.
London Diabetes Clinical Network	Guideline	007	009 - 014	Rec 1.6.14 – Agree with ensuring education is a part of using continuous glucose monitoring, more focus needed preparing patients on understanding the continuous glucose monitoring data. High quality education needs to be on offer for a period of months. The financial implication of this will be costly but essential for successful use and improved long term outcomes.	Thank you for your comment. The committee also recognised and acknowledged this implementation issue and agreed this was needed for successful use and for improved long-term outcomes.
London Diabetes Clinical Network	Guideline	007	009 - 014	Agree with the offer of structured education, but peer support is needed. Current diabetes technology users can share valuable experiences and learning. This is an untapped resource and many people happy to mentor and help.	Thank you for your comment. The inclusion of this peer support with education is an implementation issue and should be considered at a local level.
London Diabetes Clinical Network	Guideline	009	021-022	Rec 1.6.22 Agree with teaching self-monitoring skills at the time of diagnosis and the start of insulin therapy, however, teaching these skills also needs to be a continuous offer as managing blood glucose levels is an ongoing learning process.	Thank you for your comment. This area is beyond the scope of this guideline update.
Medtronic Ltd	Evidence review	034	006	<p><i>The committee also highlighted TIR to be a better measure than HbA1c as it captures variation and can be more directly linked to risk of complications. They also predicted that TIR would be the more appropriate measure going forward and will be used to assess the clinical effectiveness of CGM interventions</i></p> <p>We disagree that "TIR is a better measure than HbA1c and can be more directly linked to risk of complications". TIR is complimentary – see consensus statement – recommended to be used in combination..... HbA1c is the validated, gold standard predictor of long-term diabetes complications The association between HbA1c and long-term vascular</p>	Thank you for your comment. The committee discussed this issue and agreed that there are benefits of both measures - time in range and HbA1c. They both provide a complete picture of glycaemic control. They can be easily understood, and people can act in response to these measures. However it was the committee's opinion that time in range is used more in clinical practice and considered to be a better measure to assess variability and fluctuations of blood glucose levels. The more time you spend in range, the less likely certain diabetes complications will develop.

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				<p>complications in diabetes was established by the Diabetes Control and Complications Trial (DCCT).</p> <p>We agree that TIR is an important measure as it highlights glycaemic variability however it has not been validated as a surrogate marker for risk of complications and the evidence linking this measure to long-term complications has not been established. TIR also has a large standard deviation relative to HbA1c which leads to less certainty of effect.</p>	
Medtronic Ltd	Evidence review	036	037	<p><i>“The committee, when considering clinical and cost-effectiveness evidence, found themselves in a position of equipoise between rtCGM (more effective less cost-effective) and isCGM (less effective more cost effective), the range of personal factors to consider when choosing a CGM device (highlighted in box 1) and the continuing progression towards similarity of the two device types, they decided to recommend both evenly”.</i></p> <p>We disagree with the conclusion that isCGM is more cost effective than real-time CGM.</p> <p>In the economic analyses of rtCGM versus SMBG, and isCGM versus SMBG, both were found to be cost effective.</p> <p>An economic analysis directly comparing rt-CGM to is-CGM was not conducted therefore a conclusion re relative cost effectiveness of rt-CGM and isCGM cannot be determined by indirect comparison of ICERs. The ICER is a 'pairwise' measure that must be calculated between two interventions and a higher or lower ICER does not necessarily imply that one intervention is more or less cost-effective than another. An intervention can be cost effective in a range of circumstances e.g. technology might be more effective and</p>	<p>Thank you for your comment. We agree with you that this paragraph was poorly phrased, and we have removed it from the evidence review. The committee's reasoning for their recommendation that both devices should be available as options is explained in the documents as follows:</p> <p>“They considered that the evidence for real-time CGM compared with intermittently scanned CGM flash was neither high quality enough nor adequate enough in sample size to clearly show clinical benefits of one technology over the other.”</p> <p>“The committee considered whether a preference should be specified between isCGM and rtCGM in the recommendations. They noted that there was limited evidence directly comparing rtCGM and isCGM, that the technologies were rapidly evolving, with newer versions being released over time, and that although isCGM monitoring was currently cheaper than rtCGM, there was no guarantee this would remain the case in the future. They considered whether a comparison between these two options in the economic modelling, would help to address these concerns, and agreed that such a comparison would provide limited value. In particular, they noted that for various parameters data was only available for one type of device or the other (for example, fear of hypoglycaemia data only</p>

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				<p>more costly or less effective and less costly, within the ceiling willingness to pay.</p> <p>The determination that isCGM was more cost effective than real-time CGM seems to have been a factor in determining that real-time CGM and isCGM should be recommended evenly. We ask that the committee reconsider this in light that superior cost effectiveness has not been determined (and cannot be determined) by this economic model.</p> <p>We ask that Section 1.6.10 be changed to “offer real-time continuous glucose monitoring to all adults with Type 1 diabetes”, with isCGM offered for those who are unable to use rtCGM or express a preference for isCGM.</p>	<p>being available for rtCGM, and ‘process’ utility data only being available for isCGM). Whilst this was not a major limitation when comparing to SMBG, as the committee were happy in places to extrapolate data from one type of device to the other, it would make modelling comparisons between the two devices less useful, as in places they would be based on the same set of effectiveness data.</p> <p>Additionally, the committee noted that different devices may be more appropriate for different individuals, based on their characteristics and the features of those devices, and that matching the correct device to the correct person would be likely to improve adherence, and therefore cost-effectiveness. They therefore agreed that both rtCGM and isCGM should be made available within the NHS and people and clinicians should be able to choose between them according to their preference and needs. They did also note, however, that the overall cost impact of introducing these technologies could be high (due to the large number of people with type 1 diabetes) and that therefore if there were multiple different devices available that would meet the person’s needs, the cheapest of those available devices should be used.”</p> <p>We believe this reasoning remains an entirely valid basis on which the committee can make decisions.</p> <p>This wording of this recommendation has been modified to make clear that in circumstances where multiple CGM devices are suitable to meet a person’s needs and preferences the cheapest device be used, as this is most likely to provide the same clinical benefits to the individual, as well as free up resources that can be used elsewhere in the healthcare system.</p> <p>On the point about no comparison being conducted between rtCGM and isCGM, it is true the committee decide this would</p>

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					provide limited value based on the points above. However, it should be noted it is entirely valid methodologically to compare the estimated costs and QALYs for isCGM and rtCGM reported, as they are both based on a comparison to the same SMBG data, and therefore form a valid indirect comparison. Undertaking such an analysis would show rtCGM as not being cost-effective compared to isCGM.
Medtronic Ltd	Guideline	007	002	<p><i>“Offer the continuous glucose monitoring device with the lowest cost that meets the person’s identified needs and preferences”.</i></p> <p>Cost effectiveness analysis is imbedded in NICE reviews to provide an objective method of assessing whether the additional benefits of a technology, justify the additional costs, when assessed against a “ceiling willingness to pay”. This methodology has allowed us to move away from arbitrary recommendations based on lowest acquisition costs. A recommendation from NICE to “use the device with the lowest cost” without a comparison of cost effectiveness will drive the use of the lowest cost device regardless of patient needs or preferences and is at odds with NICE methods of assessing cost effectiveness.</p> <p>We ask that that section 1.6.11 be removed and a statement added to the guidance to indicate that both real-time CGM and isCGM have been assessed as cost effective interventions and that the comparative cost effectiveness of real-time CGM and isCGM has not been assessed.</p>	Thank you for your comment. This wording of this recommendation has been modified to make clear it is referring to circumstances where multiple CGM devices are suitable to meet a person’s needs and preferences. In those circumstances it is both appropriate and entirely in keeping with NICE’s methodology to recommend that the cheapest device be used, as this is most likely to provide the same clinical benefits to the individual, as well as free up resources that can be used elsewhere in the healthcare system.
Medtronic Ltd	Guideline	015	015	<p><i>“The committee..... considered that the evidence for real-time CGM compared with flash was not good enough quality and too low in sample size to clearly show clinical benefits of one technology over the other”.</i></p>	Thank you for your comment. The committee agreed that there was sufficient evidence in key outcomes such as HbA1c, time in range and severe/ nocturnal hypoglycaemia, as discussed in the evidence review, to justify recommending

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				<p>We thank the Committee for their careful consideration of the evidence.</p> <p>We disagree with the committee's conclusion that there is not enough evidence in key outcomes, such as HbA1c, time in range and severe or nocturnal hypoglycaemia to clearly show benefits of real-time CGM over isCGM.</p> <p>The evidence from studies directly comparing real-time CGM vs isCGM and from indirect comparison of real-time CGM vs SMBG and isCGM vs SMBG clearly demonstrate superior efficacy of real-time CGM.</p> <p>The NICE evidence review of real-time-CGM vs isCGM (evidence from 3 studies) concluded superior efficacy of real-time CGM for HbA1c <7%, % TIR, glycaemic variability, nocturnal hypoglycaemia and high-quality evidence on reduction of severe hypoglycaemia favouring RT-CGM. <i>NB: None of the outcomes reviewed favoured isCGM.</i></p> <p>The evidence review of real-time-CGM vs SMBG (evidence from 16 studies) concluded superior efficacy of real-time CGM for HbA1c >6 months, HbA1c <7.5%, HbA1c <7%, %TIR, glycaemic variability, hypoglycaemia event duration, severe hypoglycaemia, nocturnal hypoglycaemia.</p> <p>The evidence review of isCGM vs SMBG concluded superior efficacy of isCGM vs SMBG only in %TIR, glycaemic variability and time in nocturnal hypoglycaemia (evidence from 1 study).</p> <p>The Visser RCT comparing real-time CGM to isCGM reported that 28% vs 15% of participants achieved >70% TIR and 49% vs 33% achieved HbA1c <7% at 6 months with 40% vs 22% achieving HbA1c<7% with <1% of time</p>	<p>both rtCGM and isCGM over standard self-monitoring of blood glucose.</p> <p>The evidence review did also report evidence from 3 studies comparing rtCGM and isCGM however the evidence review also says - the committee noted that both HbA1c and time in range outcomes had high/ moderate quality results for effectiveness. The committee did note that for HbA1c it was the dichotomous outcome of <7% that showed an effect, while the higher quality outcome of continuous HbA1c at the same timepoint showed no meaningful difference. As a result of this they could not conclude whether HbA1c was more effective in rtCGM or were influenced by these HbA1c findings, Whilst time in range data was both effective as an outcome and had moderate quality evidence at 6 months, the committee noted Visser 2021 (ALERTT1) was not a UK based study.</p> <p>However, they considered that the evidence in pooled and single studies for rtCGM vs isCGM was not of high quality nor adequate enough in sample size to justify recommending one technology over another when combined with cost-effectiveness evidence. This was compounded by the most recent isCGM technologies evolving to become more similar to rtCGM.</p> <p>As a result of the evidence review findings which could not differentiate between the technologies, the committee made a recommendation to offer adults with type 1 diabetes a choice of real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring.</p>

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				<p><3.0mmol/l. Visser also reported a statistically significant reduction in HbA1c of 0.38%.</p> <p>In the evidence review page 36, line 37, the committee found that rtCGM was more effective and less cost-effective) than isCGM and a higher utility value is assigned to real-time CGM in the economic model. This is at odds with the statement on page 15, line 15 of the guidance.</p> <p>We ask the committee to specify, in their recommendations, a preference for real-time CGM based on the superior efficacy, in line with the evidence review, particularly with respect to people who have high glycaemic variability, are hypo unaware or have episodes of severe hypoglycaemia, as the evidence base does not support equivalence of isCGM in these populations.</p> <p>We ask that Section 1.6.10 be changed to “offer real-time continuous glucose monitoring to all adults with Type 1 diabetes”, with isCGM offered for those who are unable to use rtCGM or express a preference for isCGM.</p>	
Medtronic Ltd	Guideline	015	018	<p><i>“The committee also acknowledged that CGM technologies were <u>changing very quickly</u>, with increasing overlap between real-time CGM and flash as features such as predictive alerts are being added to newer flash devices”.</i></p> <p><i>“This was compounded by the most recent isCGM technologies evolving to become more similar to rtCGM”. (evidence review p36, line 35)</i></p> <p><i>“... and the continuing progression towards similarity of the two device types, they decided to recommend both evenly”</i></p> <p><i>“The committee.....noted that there was limited evidence directly comparing rtCGM and isCGM, that the technologies</i></p>	Thank you for your comment. The committee considered this issue and decided to keep this wording in order to future proof the guideline.

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				<p><i>were rapidly evolving, with newer versions being released over time” (evidence review p 39, line 30)</i></p> <p><i>“.. the committee stated that glucose-monitoring devices are being released on the market and evolving so quickly that making recommendations for a specific device is not desirable” (evidence review p37, line 6)</i></p> <p>References to emerging devices and overlap between real-time CGM and isCGM are made throughout the evidence review and the draft guidance and may be influencing assumptions and recommendations of equivalence between real-time CGM and isCGM. These “newer devices” are not yet launched in the UK and therefore should not be part of the decision-making process as the evidence relating to claimed benefits of overlap between “newer flash devices” and real-time CGM, has not been assessed as part of this process.</p> <p>We ask the Committee to remove comments relating to claimed benefits of flash devices, not yet launched, from the draft guidance, and to base recommendations only on the evidence for the currently available Freestyle Libre 2 flash device. It took over 2 years from CE mark to availability of the current Freestyle Libre 2 in the UK and many factors can delay the launch of new products.</p> <p>When new devices are launched with real-time CGM features, they may fall under the recommendations for real-time CGM in this guidance rather than the currently defined isCGM so we believe it is important that this guideline makes recommendations based on the efficacy of the currently assessed isCGM device to avoid confusion.</p>	
National Nurse Consultant	Guideline	006	007	People with type 3c are managed as if they have type 1 diabetes with regards insulin therapy and structured diabetes	Thank you for your comment. The committee discussed this issue and agreed that adults with insulin insufficiency due to

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Diabetes Group				education. Therefore we think that they should have the same access to technology as people with type 1	other medical causes and conditions would be treated the same as adults with type 1 diabetes. This has been clarified in the guideline and evidence review.
National Nurse Consultant Diabetes Group	Guideline	006	014	"Fear, frequency, awareness and severity of hypoglycaemia" – Do we need to have any ways of measuring these so that we are consistent?	Thank you for your comment. The committee considered this issue but agreed that due to a lack of standardised measures, it was not possible to list specific measures.
National Nurse Consultant Diabetes Group	Guideline	007	015	"Monitor and review the person's use of continuous glucose monitoring as part of reviewing their diabetes care plan". This sounds like there needs to be measurable criteria to ensure everyone is clear about ongoing provision or withdrawal of technology. We would like there to be mention that a health care professional has discussed the technology with the person with diabetes, and has made a clinical decision that the person would not be safe to have the treatment withdrawn.	Thank you for your comment. The committee considered this issue and agreed that setting a criterion for discontinuing CGM would be unhelpful and had concerns about technology being taken away. Instead, the committee added to recommendation 1.6.8 stating that if there are any concerns about the way a person is using the device, discuss barriers and concerns and whether there is a way to improve their use of the device, including further emotional and psychological support and education to overcome these.
NEL Commissioning Support Unit	Guideline	006	007 - 012	Paragraph 1.6.10. Previous guidance says to consider CGM. The new guidance says to offer CGM (or Flash), albeit with considerations regarding fear of hypoglycaemia, lack of awareness etc. These are not quantified despite there being opportunities through validated scales such as Gold and Clarke to set quantifiable criteria for use of CGM and Flash. We are concerned that the new guidance may lead to a significantly greater use of CGM and Flash and be a significant cost to CCGs.	Thank you for your comment. We agree this guidance is likely to lead to an increase in the use of continuous glucose monitoring, and a consequent increase in costs. However, as these technologies were assessed as being a cost-effective use of NHS resources compared to capillary blood glucose monitoring, the committee agreed it was still appropriate to broaden the recommendations for their use. 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.
NEL Commissioning Support Unit	Guideline	016	020	"These recommendations are likely to result in broader access to flash and real-time CGM devices." We are concerned that this broader access is not quantified and may risk pressure on the workforce. Whether a CCG sets a policy that CGM/ Flash should be initiated by a Specialist or GP or	Thank you for your comment. The committee also 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 1 diabetes were worth the costs and resources

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				GP with special interest, there may not be sufficient flex in the workforce to both initiate patients on devices and to monitor their progress in a timely and proper way. This could be a barrier to implementation.	associated in implementing this recommendation and ultimately improving care for people with type 1 diabetes.
NEL Commissioning Support Unit	Health economic report	020	001	"For real-time CGM our base case assumes an annual cost of £2,000. This is the ceiling price listed in the NHS England and NHS Improvement funding document (September 2020)." This price refers to CGM in pregnancy. Outside the scope of pregnancy, we calculate that the cost of CGM ranges from £1,606 to £3,502 per person per year, and an average of £2,320. We are concerned about the cost pressure on CCGs. If CGM in pregnancy can be provided against a ceiling cost, should CCGs in their own commissioning policies set a ceiling price? Will NHSE or NHSI set a ceiling price for CGM and Flash under NG17?	<p>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.</p> <p>The guideline also contains a number of sensitivity analyses looking at different rtCGM prices, ranging from £1,600 per year to £3,000 per year.</p>
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Evidence Review	General	General	Limited data available for isCGM in patients who are not very well controlled wrt HbA1c. Should also be noted that when patients are not well, they rely more on SMBG rather than isCGM which is less reliable. How has this been factored into cost-effectiveness calculations?	Thank you for your comment. We take this subgroup of population into account in the sensitivity analysis, by including a scenario with a higher frequency of SMBG use to represent people who rely more on SMBG than the average, even when using other monitoring devices (for example, people who continue to test at mealtimes). Specifically, this included people using SMBG 10 times per day if that was their primary form of monitoring, or 3 days per day if they were also using CGM (as opposed to averages of 4.6, 0.46 and 0.15 times per day with SMBG, isCGM and rtCGM respectively in our primary analysis).
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Evidence Review	General	General	Time in range is a surrogate marker and hence whether that will lead to better clinical outcomes is unknown. Therefore more data is required on this aspect to be able to make a more robust decision on wide usage.	Thank you for your comment. The committee discussed this issue and agreed that there are benefits of both measures - time in range and HbA1c. They both provide a complete picture of glycaemic control. They can be easily understood, and people can act in response to these measures. However it was the committee's opinion that time in range is used more in clinical practice and considered to be a better measure to assess variability and fluctuations of blood

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					glucose levels. The more time you spend in range, the less likely certain diabetes complications will develop.
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Evidence Review	General	General	Time in range is a surrogate marker as people in the clinical trials may have only used isCGM when they were well controlled. This is a confounding factor which may have skewed both the data in the trials and also the committee deliberations	Thank you for your comment. The committee discussed this issue and agreed that there are benefits of both measures - time in range and HbA1c. They both provide a complete picture of glycaemic control. They can be easily understood, and people can act in response to these measures. However it was the committee's opinion that time in range is used more in clinical practice and considered to be a better measure to assess variability and fluctuations of blood glucose levels. The more time you spend in range, the less likely certain diabetes complications will develop.
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Evidence Review	General	General	There is limited understanding of the likely difference in impact between SMBG, isCGM and rtCGM for overall hypoglycaemic events. In addition, at times of rapidly changing glucose levels, the interstitial levels used by isCGM and rtCGM are unreliable and patients need to use SMBG. Again, this could confound the data.	Thank you for your comment. As a result of the evidence review findings which could not differentiate between the technologies, the committee made a recommendation to offer adults with type 1 diabetes a choice of real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring. The limitations of the studies included were also taken into account by the committee.
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Evidence Review	030	001	Costs of test strips & lancets used by most CCGs are far cheaper than those quoted from the Hellmund paper, please review and change the costs used in the cost-effectiveness analysis. In relation to isCGM, it is also likely that patients will wish to use the built-in ketone and blood glucose meter, which are significantly higher cost than standard strips and meters in use across the UK at the moment. This will result in an additional cost pressure, compared to current UK primary care expenditure of blood glucose testing strips. Please factor this into the cost-effectiveness analysis.	Thank you for your comment. In our economic modelling, we did not take the cost of strips and lancets from Hellmund paper. Instead, we obtained the cost from the average of all the strips and lancets reported as first-line diabetes equipment in the NHS Electronic Drug Tariff at a unit cost of £0.26 for strips and lancets combined. We did not consider the use of built-in ketone and blood glucose meters in our analyses since it is beyond the scope of this update of the guideline. However, given the robustness of the cost-effectiveness results and low price of isCGM, the incorporation of the cost of built-in ketone and blood glucose meter is unlikely to change our recommendations.

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NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Guideline	General	General	<p>NHS BSW CCG agrees with the comments being made on this guidance by the PresQIPP organisation that we are subscribers to.</p> <p>National guidance on the use of isCGM (Flash) and real-time CGM is needed to ensure that these technologies are made available in a consistent and fair way to benefit patients as currently each CCG will have their own policy & criteria within that.</p> <p>We understand that affordability is not part of the remit of NICE, however the recommendations made in the draft guidelines will be unaffordable to most health systems within their allocated baselines. Individual health systems will make funding decisions based on their local priorities and prioritised against all other funding pressures within the system. Therefore, unless additional funding is provided, it is likely that many will not commission the full recommendations proposed. This will result in a 'post-code' lottery which patients and their support groups dislike and it increases inequalities.</p> <p>The guideline produced should acknowledge the reality of affordability and provide clear criteria for prioritising patients with the greatest clinical need.</p>	<p>Thank you for your comment. The committee agreed that the results of the clinical review, and the cost-effectiveness results clearly demonstrated CGM was cost-effective for the full population adults with type 1 diabetes, and therefore agreed it would be inappropriate to restrict the intervention to only a subset of that population.</p> <p>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.</p>
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Guideline	006		<p>Box 1</p> <p>Integrated CGM needs to be dealt with differently as it is higher cost than standard CGM and so needs clear criteria as to why it might be needed ahead of standard CGM. If they are being considered in a different piece of guidance then this guidance needs to state that integrated CGM is not included in the recommendations of this guideline.</p>	<p>Thank you for your comment. The use of insulin pumps and who they should be recommended for is beyond the scope of this guideline update, so previous recommendations on insulin pumps have been kept. In addition, although the price of rtCGM at £2,000 used in the base case did not consider the cost of insulin pumps, the committee suggested that the price of rtCGM will decrease in the future with widespread use across the NHS, and is very likely to fall below £2,000. The cost-effectiveness analysis only considers the benefits of CGM (not the benefits of insulin pumps) and therefore correctly only considers the costs of CGM (and not insulin pumps).</p>

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					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 and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Guideline	006		Box 1 Need to include something about patients who are self-funding a pump as any offer of CGM should be based on their clinical need and not offered integrated CGM as that would go well with their self-funded pump.	<p>Thank you for your comment. The use of insulin pumps and who they should be recommended for is beyond the scope of this guideline update, so previous recommendations on insulin pumps have been kept. In addition, although the price of rtCGM at £2,000 used in the base case did not consider the cost of insulin pumps, the committee suggested that the price of rtCGM will decrease in the future with widespread use across the NHS, and is very likely to fall below £2,000. The cost-effectiveness analysis only considers the benefits of CGM (not the benefits of insulin pumps) and therefore correctly only considers the costs of CGM (and not insulin pumps).</p> <p>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.</p>
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group	Guideline	006	007	We have concerns that the current evidence base does not support the use of isCGM in all type 1 diabetes patients. Patients should try the most cost-effective system first & only use higher cost systems if they are clinically warranted	Thank you for your comment. The committee considered this and agreed that recommendation 1.6.1 was clear that all adults with type 1 diabetes should be offered a choice of CGM. However further detail has been added stating that if multiple continuous glucose monitoring devices meet the person's identified needs and preferences, offer the device with the lowest cost.

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g Group (NHS BSW CCG)					
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Guideline	007		Box 1 Do not use the term cosmetic factors in bullet point 13. Need is established on clinical parameters only.	Thank you for your comment. Considering feedback from other stakeholders the committee agreed to change cosmetic factors in box 1 to body image concerns. Furthermore, the committee considered that the evidence of clinical and cost effective benefits were strong enough to justify recommending continuous glucose monitoring to adults with type 1 diabetes. Body image concerns should only be considered when choosing a continuous glucose monitoring device.
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Guideline	007	002	Use most cost-effective option first with clear criteria as to why a patient might need more expensive technology.	Thank you for your comment. The committee agreed that based on the clinical and cost-effectiveness evidence, both devices should be made available within the NHS. The choice between them depends on a number of factors, such as clinical needs, characteristics and preferences. They agreed there would be inefficiencies and wasted staff time associated with trialling everyone on a particular device first without taking account of these factors, and then only switching at a later point if issues were identified.
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Guideline	007	006	Agree specialist teams only to assess and provide technology.	Thank you for your comment.
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Guideline	007	009	Agree that regular training and support is essential for patients to use the technology properly.	Thank you for your comment.

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NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Guideline	007	015	Monitoring of the way that the patient is using the technology is needed along with discontinuation criteria if its not being used properly.	Thank you for your comment. The committee considered this issue and agreed that setting a criterion for discontinuing CGM would be unhelpful and had concerns about technology being taken away. Instead, the committee added to recommendation 1.6.8 stating that if there are any concerns about the way a person is using the device, discuss barriers and concerns and whether there is a way to improve their use of the device, including further emotional and psychological support and education to overcome these.
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Health economic report	General	General	As we only have one manufacturer of isCGM currently, the price could change in the future. There could also be difficulties with that one manufacture being able to keep up with demand if so many more people are able to access this on the NHS? Will their supply be sustainable & affordable in the future?	Thank you for your comment. Given the robustness of the cost-effectiveness results of the isCGM and its price at the moment, a potential increase in its future price is unlikely to change our recommendations. In addition, given the potential price decrease of rtCGM with the widespread use across the NHS, there would be more competition coming from the providers of rtCGM devices, which is likely to restrict the price increases of isCGM.
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Health economic report	005	017-025	Huge cost impact guidance based on 1 RCT of economic evidence. More caution is needed for such a huge cost impact and therefore recommendations should be down-scaled until further supportive evidence from further trials are available.	Thank you for your comment. Although the base case economic analyses for isCGM were based on a single RCT, the study was assessed to be good quality and the committee agreed that it is sufficient to make the recommendations based on the current evidence. In addition, we have run a series of sensitivity analyses to account for the uncertainty surrounding input parameters. 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.
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical	Health economic report	006	020	Refers to <i>potential</i> psychological benefits, which are not usually included in NICE modelling.	Thank you for your comment. We have removed the word 'potential' from this sentence.

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NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Health economic report	008	037	Table HE002: Baseline cohort characteristics The benefits of reducing HbA1c via isCGM or rtCGM are presumably likely to be less (and hence less cost-effective) in a population with a lower baseline HbA1c. We therefore think that the NICE recommendations should take the person's baseline HbA1c (when using SMBG) into account.	Thank you for your comment. According to the committee, people with consistently well-controlled and lower HbA1c is a minority of people with type 1 diabetes, so the committee thought it's appropriate to use 9.1% as the baseline HbA1c level based on the REPOSE trial to represent an average person with type 1 diabetes. For people with lower HbA1c level, although the benefits in HbA1c are lower, there would still be benefits expected in other domains, such as the control of severe/non-severe hypoglycaemic events. Therefore, the recommendations on rtCGM/isCGM are still applicable to this population group.
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Health economic report	014	036	Patient preference for technology should not be part of the considerations, it should be based on the clinical benefits required to improve the control of their condition.	Thank you for your comment. NICE has a clear long-term position that our primary interest is in how treatments affect a person's quality of life. Some of this may be as a direct result of hard clinical outcomes, but some can also be a result of process utility (for example, in other evaluations in diabetes we have considered the disutilities associated with having to take a higher number of injections). To not include these factors in the analysis would be to ignore things that directly impact the benefits a person gains from treatment, and NICE views this as something it would be inappropriate to do.
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Health economic report	015	024	We have concerns about the cost-effectiveness of rtCGM, especially in the scenarios where fear of hypoglycaemia were included and not included. Given the very conservative cost of CGM used in the cost analyses, the cost-effectiveness of rtCGM is questionable.	Thank you for your comment. When considering which scenario to place more weight on, the committee made the following points: "They were strongly of the opinion that fear of hypoglycaemia was an important consideration for many people with type 1 diabetes (over and above the harms caused by the hypoglycaemic episodes themselves)" "They discussed whether there was any concern about double counting of benefits with this approach, but agreed

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					<p>that since the Hypoglycaemia Fear Survey specifically asks about worry caused by the potential for hypoglycaemia, not symptoms during a hypoglycaemic event, and that people would spend the large majority of their time not in a hypoglycaemic state, that these should represent separate quality of life gains"</p> <p>Therefore, the committee were confident the correct set of results were used when making their recommendations. Furthermore, the committee agreed those results demonstrated that rtCGM was a cost-effective technology, compared to capillary blood glucose monitoring, with an ICER below £30,000/QALY, and the results robust to a number of sensitivity analyses undertaken. 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.</p>
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Health economic report	020	001	Please review the cost of CGM used in the cost-effectiveness analysis which is lower than that being paid by CCGs currently.	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 and North East Somerset, Swindon and Wiltshire Clinical	Questions	Q1		<p>Q Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why:</p> <p>A: Affordability will be the greatest challenge, alongside explaining to patients why we can only afford it for certain</p>	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

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Commissioning Group (NHS BSW CCG)				cohorts, and deciding what not to fund if we divert budgets to this technology. The other major issue is that of ensuring there are enough staff within the diabetes teams to train & support patients with this technology to ensure they get the most out of it. It takes a long time to train diabetes specialist nurses and so having the right staff in place will take some time. Patients might not adhere to using the technology properly over time and so it should be recognised that patients may well need regular on-going support.	the concerns about affordability of the recommendations that have been raised through this consultation. The committee considered this issue and agreed that training should be provided by a healthcare specialist in diabetes. The committee also 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 1 diabetes were worth the extra costs and resources associated in implementing this recommendation and ultimately improving care for people with type 1 diabetes.
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Questions	Q2		Q Would implementation of any of the draft recommendations have significant cost implications? Yes, this guideline would be unaffordable for our health economy alongside other priorities for our population so we could not implement it fully. In practice we have not found that reduction in use of test strips for those able to access Freestyle Libre has resulted in any reduction of costs overall. NICE need to look at how much test strips and lancets are costing CCGs in practice as the study used in the cost calculations is far higher than the prices we are paying (Hellmund et al). CGM costs also look to be far lower than what we are paying for as a CCG. Integrated CGM is being used far more widely now for new patients which costs much more than what has been used in the cost analysis.	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 and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group	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 from NHSE to cover the extra costs, or tighter criteria to aim technology at those most in need. Plus discontinuation criteria are needed.	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

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g Group (NHS BSW CCG)					<p>the concerns about affordability of the recommendations that have been raised through this consultation.</p> <p>The committee also considered this issue and agreed that setting a criterion for discontinuing CGM would be unhelpful and had concerns about technology being taken away. Instead, the committee added to recommendation 1.6.8 stating that if there are any concerns about the way a person is using the device, discuss barriers and concerns and whether there is a way to improve their use of the device, including further emotional and psychological support and education to overcome these.</p>
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Questions	Q4		<p>Q Would implementation of any of the draft recommendations have significant cost implications? In particular, this guideline recommends offering people a choice between real-time and intermittently-scanned continuous glucose monitoring, and we are aware that currently real-time devices have a higher purchase cost. Would there be any cost concerns from offering people with diabetes this choice?</p> <p>A The current offer is unaffordable to our health system. Patients should try the most cost-effective system first & only use higher cost systems if they are clinically warranted, according to agreed criteria.</p>	<p>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.</p>
NHS Herefordshire and Worcestershire CCG	Evidence review	General	General	<p>The primary outcome utilised in almost all included studies was change in HbA1c. Overall these changes in HbA1C were small and not statistically significant, which could be attributed to the characteristics of only fairly well controlled patients being included in many studies. The reality is that there is very limited data in patients with less well controlled diabetes and the likely impact of Flash can only be assumed. The committee also acknowledged that the data in relation to these technologies could have been skewed by operator bias and that users only relied on the readings when they felt well</p>	<p>Thank you for your comment. The committee discussed this issue and agreed that there are benefits of both measures - time in range and HbA1c. They both provide a complete picture of glycaemic control. They can be easily understood, and people can act in response to these measures. However, time in range is used more in clinical practice and considered to be a better measure to assess variability and fluctuations of blood glucose levels.</p>

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				and knew they were going to be within range, using SBMG when they felt unwell.	
NHS Herefordshire and Worcestershire CCG	Evidence review	General	General	The secondary outcomes, such as time in range considered as a better marker for effectiveness by the committee are only surrogate markers and may not translate into better outcomes in the real world. More long-term real-world data is required to determine long term cost effectiveness for Flash and rtCGM.	<p>Thank you for your comment. The committee discussed this issue and agreed that there are benefits of both measures - time in range and HbA1c. They both provide a complete picture of glycaemic control. They can be easily understood, and people can act in response to these measures. However it was the committee's opinion that time in range is used more in clinical practice and considered to be a better measure to assess variability and fluctuations of blood glucose levels. The more time you spend in range, the less likely certain diabetes complications will develop.</p> <p>The committee also agreed that more long-term real-world data is required and they made a research recommendation to encourage the use of routinely collected real-world data to examine the effectiveness and cost effectiveness of continuous glucose monitoring.</p>
NHS Herefordshire and Worcestershire CCG	Evidence review	General	General	Utilisation of time in range as a surrogate marker is fundamentally flawed and the possibility of operator bias could have resulted in Flash only being used when patients knew that their blood sugars would be okay. This was acknowledged by the committee, but the fact remains that this is a confounding factor which may have skewed both the data in the trials and the also the committee deliberations.	<p>Thank you for your comment. The committee discussed this issue and agreed that there are benefits of both measures - time in range and HbA1c. They both provide a complete picture of glycaemic control. They can be easily understood, and people can act in response to these measures. However it was the committee's opinion that time in range is used more in clinical practice and considered to be a better measure to assess variability and fluctuations of blood glucose levels. The more time you spend in range, the less likely certain diabetes complications will develop.</p>
NHS Herefordshire and Worcestershire CCG	Evidence review	General	General	In relation to hypoglycaemic events, the data could not differentiate between the technologies. There was only a discernible difference in patients who experience nocturnal hypoglycaemic events which favoured, Flash and rt CGM, probably because it is easier to monitor without rousing the patient whilst sleeping. There is limited understanding of the likely difference in impact between SMBG, Flash and rtCGM for overall	<p>Thank you for your comment. As a result of the evidence review findings which could not differentiate between the technologies, the committee made a recommendation to offer adults with type 1 diabetes a choice of real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring.</p>

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				hypoglycaemic events. In addition, at times of rapidly changing glucose levels, the interstitial levels used by Flash and rCGM are unreliable and patients need to use SMBG. Again, this could confound the data.	
NHS Herefordshire and Worcestershire CCG	Evidence review	030	001	<p>1.1.7 Summary of included economic evidence: The Healthcare Improvement Scotland Review utilised a cost calculation analysis by Hellmund et al (Diabetes res 2018; 193-200). Whilst the overall methodology utilised in the Hellmund review is recognised as good, the review and consequently the cost effectiveness calculation is fundamentally flawed as the average cost of blood glucose testing strips and lancets used in the review is 50% higher than the current average real world costs in the UK, as much cheaper strip and lancets are used in practice; average strip cost in the real world 15.5p and lancet 2.5p vs 29p and 4p in the cost analysis. The study therefore does not reflect real world actual costs and underestimates the cost of Flash, which in turn affects any QALY calculations based on this data. In relation to Flash, it is also likely that patients will wish to use the built-in ketone and blood glucose meter, which are significantly higher cost than strips and meters in use across the UK at the moment. This will result in an additional cost pressure, compared to current UK primary care expenditure of blood glucose testing strips.</p>	<p>Thank you for your comment. In our economic modelling, we did not take the cost of strips and lancets from Hellmund paper. Instead, we obtained the cost from the average of all the strips and lancets reported as first-line diabetic equipment in the NHS Electronic Drug Tariff at a unit cost of £0.26 for strips and lancets combined.</p> <p>We did not consider the use of built-in ketone and blood glucose meter in our analyses, since it's beyond our scope. However, given the robustness of the cost-effectiveness results and current price of isCGM, the incorporation of the cost of built-in ketone and blood glucose meter is unlikely to change our recommendations.</p>
NHS Herefordshire and Worcestershire CCG	Guideline	General	General	<p>National guidance on the use of FlashGM and real-time CGM is needed to ensure that these technologies are made available in a consistent and fair way to benefit patients.</p> <p>We recognise that as well as reducing the burden of diabetes for patients, there may be long term benefits in terms of improving time in range, outcomes and reducing costs associated with hospital admissions that may not be realised for several years.</p> <p>We accept that affordability is not part of the remit of NICE when developing guidance, however the recommendations</p>	<p>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.</p>

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				<p>made in the draft guidelines will be unaffordable to most health systems within their allocated baselines.</p> <p>CCGs/ICS have a legal responsibility for NHS healthcare budgets and have a duty to live within the budget allocated to them. Individual health systems will make funding decisions based on their local priorities and unless additional funding is provided, it is likely that many will not commission the full recommendations proposed. This will result in a 'post-code' lottery which will increase inequalities, as access to these technologies will vary depending on where people live.</p> <p>The guideline produced should acknowledge the reality of affordability and provide clear criteria for prioritising patients with the greatest clinical need, so that access to these technologies can be increased across the country in a fair and sustainable manner within available budgets.</p> <p>The recommendations as they stand will create an expectation that all patients will be offered Flash or real-time CGM that cannot be fulfilled. This may lead to frustration for people living with Type 1 diabetes when health systems are unable to make these technologies available to all patients as set out in the guideline.</p> <p>More data and a better understanding of the impact on real world outcomes is essential. Despite the comprehensive evidence review conducted by NICE, there is still a lack of robust data regarding impact of these technologies on hospitalisations, healthcare attendance rates and rates of overall hypoglycaemia, which will make proper assessment of the likely impact impossible to ascertain for local systems.</p> <p>At a time where the NHS is under unprecedented financial and operational pressures, clear guidance based on robust evidence is needed to ensure that resources are directed to</p>	

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				those with the most need and who will get the greatest benefit, in a consistent way across the country.	
NHS Herefordshire and Worcestershire CCG	Guideline	006	007	<p>To offer all adults with Type 1 diabetes Flash or real-time CGM will be unaffordable for health systems.</p> <p>We are concerned that the evidence on cost effectiveness of Flash is not sufficiently robust to support the recommendation to offer it to all adults with Type 1 diabetes.</p> <p>Decisions on initiating a Flash or real-time CGM should be based on clinical need. In line with the principles applied to medicines, the most cost-effective device that meets the patients' clinical needs should be used.</p> <p>Real-time CGM is currently at least twice the cost of Flash. As such, the use of real-time CGM needs to be targeted to patients who have the greatest clinical need where blood glucose testing or Flash do not meet these needs, e.g. persistent hypoglycaemia unawareness with disabling hypoglycaemia, despite optimised diabetes care. Clear objective criteria based on clinical need are required to ensure consistent provision of this technology to patients with the greatest need within available budgets. rtCGM should only be considered after a trial with Flash had failed to deliver required benefits.</p>	<p>Thank you for your comment. According to the economic analysis, isCGM remains cost effective in the base and sensitivity analyses, and therefore the results should be robust enough to support the recommendations.</p> <p>We agree that clinical need should be one factor that informs the choice of device, and this is include in the recommendations. However, the committee also agreed that individual's preferences needed to be taken into account, as the most suitable device would vary for each person. The committee stressed that this freedom of choice is more beneficial than being limited to a specific device, particularly because adherence to the technology is likely to be higher if the device is matched to the person's needs and preferences.</p> <p>The guideline also contains a recommendation that where multiple continuous glucose monitoring devices meet the person's identified needs and preferences, the device with the lowest cost should be offered.</p> <p>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.</p>
NHS Herefordshire and Worcestershire CCG	Guideline	006	Box 1	<p>Factors to consider when choosing a continuous glucose monitoring device:</p> <p>Bullet point 5: 'The person's insulin regimen or type of insulin pump, if relevant (taking into account whether a particular device integrates with their pump as part of a hybrid closed loop or insulin suspend function).'</p>	<p>Thank you for your comment. The use of insulin pumps and who they should be recommended for is beyond the scope of this guideline update, so previous recommendations on insulin pumps have been kept. In addition, although the price of rtCGM at £2,000 used in the base case did not consider the cost of insulin pumps, the committee suggested that the</p>

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				<p>The cost of providing rtCGM that integrates with insulin pumps exceeds the £2k annual cost assumed in the base case used in the NICE economic evaluation. The cost effectiveness at costs greater than £2k per year is less clear and therefore it is not appropriate to routinely offer integrated rtCGM as an option. Clear criteria are needed to define those patients where an insulin suspend function is essential to their care to ensure resources are targeted to those who will benefit the most.</p> <p>Page 6 line 3 of the guidance states that hybrid closed loop systems are being separately evaluated separately and therefore to offer this technology as a routine option is not appropriate at this time.</p>	<p>price of rtCGM will decrease in the future with widespread use across the NHS, and is very likely to fall below £2,000. The cost-effectiveness analysis only considers the benefits of CGM (not the benefits of insulin pumps) and therefore correctly only considers the costs of CGM (and not insulin pumps).</p> <p>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.</p>
NHS Herefordshire and Worcestershire CCG	Guideline	006	Box 1	<p>Factors to consider when choosing a continuous glucose monitoring device:</p> <p>Bullet point 5: 'The person's insulin regimen or type of insulin pump, if relevant (taking into account whether a particular device integrates with their pump as part of a hybrid closed loop or insulin suspend function).'</p> <p>There are equity issues to consider where patients are self-funding an insulin pump. Offering a more costly integrated rtCGM system to a patient who is self-funding an insulin pump without a proven clinical need would be inequitable. The choice of device offered needs to be based on objective clinical need.</p>	<p>Thank you for your comment. According to the economic analysis, isCGM remains cost effective in the base and sensitivity analyses, and therefore the results should be robust enough to support the recommendations.</p> <p>We agree that clinical need should be one factor that informs the choice of device, and this is include in the recommendations. However, the committee also agreed that individual's preferences needed to be taken into account, as the most suitable device would vary for each person. The committee stressed that this freedom of choice is more beneficial than being limited to a specific device, particularly because adherence to the technology is likely to be higher if the device is matched to the person's needs and preferences.</p> <p>The guideline also contains a recommendation that where multiple continuous glucose monitoring devices meet the person's identified needs and preferences, the device with the lowest cost should be offered.</p>

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					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 Herefordshire and Worcestershire CCG	Guideline	007	002	The device with the lowest cost that meets the patients clinical need should be offered. Clear objective criteria are needed to define the place in therapy for more expensive technologies. rtCGM should only be considered after a trial with Flash had failed to deliver required benefits.	Thank you for your comment. The committee considered this issue and recommendation 1.6.2 has been amended stating that if multiple continuous glucose monitoring devices meet the person's identified needs and preferences, offer the device with the lowest cost.
NHS Herefordshire and Worcestershire CCG	Guideline	007	006	We strongly agree that both Flash and rtCGM 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. However this proposed guidance means patient numbers will swamp current specialist service and service capacity will need to be increased with the associated costs.	Thank you for your comment. The committee considered this issue and agreed that training should be provided by a healthcare specialist in diabetes. The committee also 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 1 diabetes were worth the extra costs and resources associated in implementing this recommendation.
NHS Herefordshire and Worcestershire CCG	Guideline	007	009	We strongly agree that patients initiated on Flash or rtCGM 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.
NHS Herefordshire and Worcestershire CCG	Guideline	007	015	We agree that the use of Flash 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 e.g. for Flash 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, where the patient does not wear a sensor for the minimum time agreed with their diabetes team, where the patient fails to take appropriate	Thank you for your comment. The committee considered this issue and agreed that setting a criterion for discontinuing CGM would be unhelpful and had concerns about technology being taken away. Instead, the committee added to recommendation 1.6.8 stating that if there are any concerns about the way a person is using the device, discuss barriers and concerns and whether there is a way to improve their use of the device, including further emotional and psychological support and education to overcome these.

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				action on glucose levels despite the support of their diabetes team. Treatment goals should be agreed with the patient e.g. % improvement in HbA1c, prior to starting therapy and treatment should be discontinued if the goals are not reached despite appropriate support from the diabetes team.	
NHS Herefordshire and Worcestershire CCG	Guideline	007	Box 1	Factors to consider when choosing a continuous glucose monitoring device: Bullet point 13: 'Cosmetic factors' We do not think it is appropriate to use the term 'cosmetic factors' in the guidance. Unless in exceptional circumstances, the NHS considers treatment for cosmetic purposes a low priority and does not fund it. The most cost-effective device that meets the patients clinical need that they are able to use effectively should be offered.	Thank you for your comment. Considering feedback from stakeholders the committee agreed to change cosmetic factors in box 1 to body image concerns. Furthermore, the committee considered that the evidence of clinical and cost effective benefits were strong enough to justify recommending continuous glucose monitoring to adults with type 1 diabetes. Body image concerns should only be considered when choosing a continuous glucose monitoring device.
NHS Herefordshire and Worcestershire CCG	Health economic report	General	General	Flash: Currently the only Flash product available in the UK is FreeStyle Libre. As there is no market competition, there is a risk to the NHS around future price rises, the ability of the company to meet the demand that implementing the proposed recommendations would create and ensuring continuity of supply.	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 Herefordshire and Worcestershire CCG	Health economic report	005	017-025	We have concerns that the economic evaluation is based on two cost-utility analyses that were only based on a single RCT. We note that the guideline committee agreed there was value in additional work being undertaken. It seems important to wait for that additional evidence before such wide-reaching adoption with the associated affordability issues is recommended.	Thank you for your comment. Although the base case economic analyses for isCGM were based on a single RCT, the study is assessed to be good quality and the committee agreed that it is sufficient to make the recommendations based on the current evidence. In addition, we have run a series of sensitivity analyses to account for the uncertainty surrounding input parameters. 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. Regarding the clinical evidence, the single RCT (Bolinder et al 2016) was rated as "some concerns" in risk of bias assessment (due to lack of information on allocation

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					concealment), the committee accepted this study was of sufficient quality and large enough to be used to judge the effectiveness of isCGM vs SMBG alongside the rtCGM evidence. The study reported no meaningful difference in HbA1c outcomes. However, the committee judged the reported increase in time in range and decrease of time below range, as well as decrease in glycaemic variability (moderate quality evidence) to be evidence of an effect.
NHS Herefordshire and Worcestershire CCG	Health economic report	006	020	We do not believe that it is appropriate to include the “ <i>potential</i> to enhance people’s ability to manage their glucose levels and help them regain a sense of personal control over the condition” within the economic model. We are not aware of “potential” (rather than proven) psychological benefits being included in other NICE clinical guidelines.	Thank you for your comment. We have removed the word ‘potential’ from this sentence.
NHS Herefordshire and Worcestershire CCG	Health economic report	008	037	Table HE002: Baseline cohort characteristics We are concerned that the HbA1c (9.1%) used in the economic model is high and may not be typical of many people with type 1 diabetes. REPOSE was a trial comparing insulin delivered via MDI with insulin delivered via a pump and it is noted in the trial discussion that this HbA1c is high. The authors note, “We therefore powered the trial on the number of participants with a baseline HbA1c of $\geq 7.5\%$ (58 mmol/mol) and in whom a fall would reflect a worthwhile improvement in glycaemic control”. The benefits of reducing HbA1c via Flash or rtCGM are presumably likely to be less (and hence less cost-effective) in a population with a lower baseline HbA1c. We believe that the NICE recommendations should take the person’s baseline HbA1c (when using SMBG) into account.	Thank you for your comment. According to the committee, people with consistently well-controlled and lower HbA1c is a minority of people with type 1 diabetes, so the committee thought it’s appropriate to use 9.1% as the baseline HbA1c level based on the REPOSE trial to represent an average person with type 1 diabetes. For people with lower HbA1c level, although the benefits in HbA1c are lower, there would still be benefits expected in other domains, such as the control of severe/non-severe hypoglycaemic events. Therefore, the recommendations on rtCGM/isCGM are still applicable to this population group.
NHS Herefordshire and Worcestershire CCG	Health economic report	014	036	We do not believe that it is appropriate to include people’s preferences for using the device (compared with SMBG), over and above the benefits from improved clinical outcomes such as HbA1c and hypoglycaemic events, in the economic analysis. Given the huge cost implications of the draft recommendations, we believe that only hard clinical outcomes should be considered.	Thank you for your comment. NICE has a clear long-term position that our primary interest is in how treatments affect a person’s quality of life. Some of this may be as a direct result of hard clinical outcomes, but some can also be a result of process utility (for example, in other evaluations in diabetes we have considered the disutilities associated with having to take a higher number of injections). To not include these

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					factors in the analysis would be to ignore things that directly impact the benefits a person gains from treatment, and NICE views this as something it would be inappropriate to do.
NHS Herefordshire and Worcestershire CCG	Health economic report	015	024	<p>The guideline committee have noted that there was a potential issue with double counting utility gains when fear of hypoglycaemia (FoH) was included (as utility gains associated with hypoglycaemic events may capture some of the FoH as well). We appreciate that therefore two versions of the base-case analysis were conducted for the rtCGM – one with the utility gains associated with the reduction in FoH included, and one with them excluded.</p> <p>We note that the base case results in scenario 1 showed that Flash was a cost-effective treatment compared with SMBG under a threshold of £20,000 per QALY, while rtCGM only appeared cost effective at the £30,000 threshold. In scenario 2 rtCGM was cost-effective compared with SMBG at a threshold of £20,000 per QALY. We are therefore concerned that the cost-effectiveness of rtCGM is uncertain and not sufficiently robust to support the recommendations in the draft guideline.</p> <p>In the probabilistic sensitivity analyses – the committee noted that with a lower threshold value at £20,000 per QALY, the probability of rtCGM being cost-effective was around 75%.</p>	<p>Thank you for your comment. You are correct in your description of the two modelling approaches adopted. However, when considering which scenario to place more weight on, the committee made the following points:</p> <p>“They were strongly of the opinion that fear of hypoglycaemia was an important consideration for many people with type 1 diabetes (over and above the harms caused by the hypoglycaemic episodes themselves)”</p> <p>“They discussed whether there was any concern about double counting of benefits with this approach, but agreed that since the Hypoglycaemia Fear Survey specifically asks about worry caused by the potential for hypoglycaemia, not symptoms during a hypoglycaemic event, and that people would spend the large majority of their time not in a hypoglycaemic state, that these should represent separate quality of life gains”</p> <p>Therefore, the committee were confident the correct set of results were used when making their recommendations.</p> <p>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.</p>
NHS Herefordshire and	Health economic report	020	001	We do not think that the assumed £2k (including VAT) per year ceiling price for CGM used in the economic modelling is appropriate. This is based on the pricing structure negotiated with the suppliers of CGM manufacturers (Dexcom,	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,

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Worcestershire CCG				<p>Medtronic and Medtrum) specifically for CGM in pregnancy. The current cost of these technologies on the NHS Supply Chain National Procurement Tower framework when used for indications other than pregnancy, significantly exceed this ceiling e.g. the current price for Dexcom standalone CGM is £2671 per year. It is worth noting that Dexcom is available for self-funders to buy direct from the company at a much lower annual cost of £1908 (including VAT).</p> <p>NB We are aware that a new NHS Supply Chain contract is due to go live in January 2022, but details were not available to us at the time of writing. Commissioners will base their cost pressure and affordability assessments for implementing this guidance on the current prices available to them. It is a risk to assume that the cost of CGM will fall to a maximum of £2k per year based on increased roll out of CGM as this will depend on market forces and is not guaranteed.</p>	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 Herefordshire and Worcestershire CCG	Questions	Q1		<p>Q Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why: Providing all patients with the choice of Flash or real-time CGM will be unaffordable for all health systems, and the current service struggles to manage the small cohort already using Flash.</p> <p>All patients initiated on Flash or real-time CGM need appropriate training and monitoring to ensure that these technologies are used appropriately and effectively, and that they are delivering the anticipated improvements in patient care and outcomes to ensure that these technologies provide value for individual patients, the wider community, and the whole NHS, and ensuring the cost effectiveness for these technologies is maximised. 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</p>	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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				over time and the level of nursing time needed to keep them on track with their individual treatment targets currently remains unknown.	
NHS Herefordshire and Worcestershire CCG	Questions	Q2		<p>Q Would implementation of any of the draft recommendations have significant cost implications?</p> <p>A <u>Flash</u>: Based on patient numbers from the National Diabetes Audit 2020/21 numbers, we estimate the cost of providing Flash to <u>all</u> patients with Type 1 diabetes in England to be £230 million. The current spend on FreeStyle Libre is £88 million, giving an overall cost pressure of £142 million for England. This may be offset by a small reduction in the use of blood glucose testing strips, however our experience is that since NHS England guidance on Flash was implemented in April 2019, the data does not demonstrate a significant reduction in the use of blood glucose testing and any reduction in costs is mainly due to primary care initiatives to use more cost effective products. Per CCG the cost to implement Flash alone is a similar order of magnitude to the expected annual uplift to their budget baseline intended to cover increase in costs for all areas of medicines and devices.</p> <p>The Healthcare Improvement Scotland Review utilised a cost calculation analysis by Hellmund et al (Diabetes res 2018; 193-200). Whilst the overall methodology utilised in the Hellmund review is recognised as good, the review is fundamentally flawed as the average cost of blood glucose testing strips and lancets used in the review is 50% higher than the current average real world costs in the UK, as much cheaper strip and lancets are used in practice; average strip cost in the real world 15.5p and lancet 2.5p vs 29p and 4p in the cost analysis. The study therefore does not reflect real world actual costs and underestimates the cost of Flash, which in turn affects any QALY calculations which utilise and are based on this data.</p>	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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				<p><u>rtCGM</u>: The cost of providing rtCGM to <u>all</u> patients with Type 1 diabetes based on the £2k annual maximum cost assumed in the NICE economic evaluation would be in the order of £500 million. This is a conservative estimate as patients who are already using insulin pumps are likely to be offered an integrated CGM system which would exceed the £2k per year cost assumption.</p> <p>Funding the proposed recommendations as they stand will be unaffordable for all health systems and could only be achieved by diverting resources from other health priorities.</p>	
NHS Herefordshire and Worcestershire CCG	Questions	Q3		<p>Q What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.)</p> <p>Additional funds via a central budget or local budget uplift provided in order to 'invest to save' and to prevent local variations in access to these technologies. This needs to take in necessary service costs to implement the change.</p>	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 Herefordshire and Worcestershire CCG	Questions	Q4		<p>Q Would implementation of any of the draft recommendations have significant cost implications? In particular, this guideline recommends offering people a choice between real-time and intermittently-scanned continuous glucose monitoring, and we are aware that currently real-time devices have a higher purchase cost. Would there be any cost concerns from offering people with diabetes this choice?</p> <p>Flash: Based on patient numbers from the National Diabetes Audit 2020/21 numbers, we estimate the cost of providing Flash to all patients with Type 1 diabetes in England to be £230 million. The current spend on FreeStyle Libre is £88 million, giving an overall cost pressure of £142 million for England. This may be offset by a small reduction in the use of blood glucose testing strips, however our experience is</p>	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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				<p>that since NHS England guidance on Flash was implemented in April 2019, the data does not demonstrate a significant reduction in the use of blood glucose testing and any reduction in costs is mainly due to primary care initiatives to use more cost effective products. Per CCG, the cost pressure from the proposed type 1 guidance is a similar order of magnitude to the expected annual uplift to their budget baseline intended to cover increase in costs for all areas of medicines and devices.</p> <p>rtCGM: The cost of providing rtCGM to all patients with Type 1 diabetes based on the £2k annual maximum cost assumed in the NICE economic evaluation would be in the order of £500 million. This is a conservative estimate as patients who are already using insulin pumps are likely to be offered an integrated CGM system which would exceed the £2k per year cost assumption.</p> <p>Funding the proposed recommendations as they stand will be unaffordable for most health systems and could only be achieved by diverting resources from other health priorities.</p> <p>Decisions on initiating Flash or real-time CGM should be based on clinical need. In line with the principles applied to medicines, the most cost-effective device that meets the patients' clinical needs should be used.</p> <p>Real-time CGM is currently at least twice the cost of Flash. As such, the use of real-time CGM needs to be targeted to patients who have the greatest clinical need, where blood glucose testing or Flash do not meet these needs, e.g. persistent hypoglycaemia unawareness with disabling hypoglycaemia, despite optimised diabetes care. Clear objective criteria based on clinical need are required to ensure consistent provision of this technology to patients with the greatest need within available budgets. rtCGM should</p>	

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				only be considered after a trial with Flash had failed to deliver required benefits.	
NHSE	General	General	General	We would suggest including Type 3c Diabetes in this cohort as the pathophysiology of Type 3c diabetes is the same as Type 1- ergo lack of beta cells- with the difference being Type 1 is due to an autoimmune process while Type 3c is due to a locally destructive process such as pancreatitis or pancreatic surgery. The reasoning for Type 1 Diabetes having access to this technology should there by apply to Type 3c diabetes too	Thank you for your comment. The committee discussed this issue and agreed that adults with insulin insufficiency due to other medical causes and conditions would be treated the same as adults with type 1 diabetes. This has been clarified in the guideline and evidence review.
Northern Lincolnshire & Goole NHS Foundation Trust	Guideline	009	005 - 014	A well written document. Our only suggestion is below: These targets described may be appropriate for many but are very arbitrary. We suggest a statement around the need for individualisation / personalisation of treatment approaches and targets based on a broader, more holistic risk versus benefit analysis. For example, older, frailer with Type 1 diabetes those with reduced awareness of hypoglycaemia or significant past issues with hypoglycaemia, those with hazardous occupations etc.	Thank you for your comment. The committee agreed that a person-centred approach is needed. Recommendation 1.6.2 stresses the importance of considering the person's identified needs and preferences. The guideline also highlights that people using continuous glucose monitoring devices should be empowered to do so.
Northumbria Healthcare NHS Foundation Trust - DAFNE Executive Board	Guideline	005	001	Not all patients with T1D will be Ab positive and up to 20% will be GAD/IA2/ZnT8 Ab negative. If a clinical diagnosis of T1D is clear, then we would not recommend measuring Abs because a negative result will confuse, risk a revision of the diagnosis, potentially stopping insulin etc, by practicing clinicians not aware of the nuances of these immunology tests. It would be safer to restrict these tests to those patients where there is diagnostic uncertainty (as per previous guidelines). The rationale for recommending Ab testing is stated as 'The most common misdiagnosis is type 1 diabetes being misdiagnosed as type 2, which could lead to the person not receiving insulin treatment and a subsequent risk of diabetic ketoacidosis'. Recommending Ab testing in those with a clinical diagnosis of T1D will not address this problem, rather	Thank you for your comment. The committee discussed this issue and agreed that the evidence supporting the measurement of diabetes-specific autoantibodies in adults with an initial diagnosis of type 1 diabetes was clear. Measuring diabetes-specific autoantibodies has utility and for the majority this measurement will confirm the correct diagnosis. This recommendation is also in agreement with other international guidelines.

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				there is a body of work to be done on the utility of measuring Ab in those with a clinical diagnosis of T2D.	
Northumbria Healthcare NHS Foundation Trust - DAFNE Executive Board	Guideline	005	010	1.1.6 The measurement of C peptide in Ab negative people with a clear clinical diagnosis of T1D will also potentially confuse because C peptide may not have fallen appreciably at the time of diagnosis.	<p>Thank you for your comment. The committee acknowledged the poor quality of studies on the use of c-peptide and the inherent mechanism of action of C-peptide that means it will not function well as a predictor at the time of diabetes presentation. However the committee also agreed that C-peptide along with blood glucose levels was the best reference standard available, but this was only true for a longer time after an initial presentation of diabetes.</p> <p>As a result of this lack of high-quality evidence on the effectiveness of c-peptide, the committee made a research recommendation outlining the need for further research on the effectiveness of c-peptide at correcting misclassification of diabetes diagnosis and what is the optimal timing in distinguishing subtypes of diabetes..</p>
Northumbria Healthcare NHS Foundation Trust - DAFNE Executive Board	Guideline	006	007	<p>The term 'evidence based' needs to be inserted before 'real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring'. There are devices coming to market with no published evidence on sensor accuracy, safety or effectiveness. We need to ensure that the devices used are high quality and evidence based – not just cheap to access.</p> <p>In addition, these recommendations should be expanded to include people with rarer type of diabetes who may have a similar or greater risk of hypoglycaemia to those living with Type 1 diabetes. For example, those with diabetes secondary to pancreatectomy or pancreatitis, those with insulin treated monogenic diabetes.</p>	<p>Thank you for your comment. The committee considered this issue and agreed that we need to ensure that devices are evidence-based. Further detail has been added to the guideline rationale section stating that only CGM devices with a supporting evidence base should be provided to people with type 1 diabetes.</p> <p>Thank you for your comment. The committee discussed this issue and agreed that adults with insulin insufficiency due to other medical causes and conditions would be treated the same as adults with type 1 diabetes. This has been clarified in the guideline and evidence review.</p>
Northumbria Healthcare NHS	Guideline	007	002	Change to 'Offer the evidence based continuous monitoring device with the lowest cost that meets the person's identified needs and preferences. [2022]'	Thank you for your comment. The committee considered this issue and agreed that we need to ensure that devices are evidence-based. Further detail has been added to the

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Foundation Trust - DAFNE Executive Board					guideline rationale section stating that only CGM devices with a supporting evidence base should be provided to people with type 1 diabetes. Recommendation 1.6.2 has also been amended stating that if multiple continuous glucose monitoring devices meet the person's identified needs and preferences, offer the device with the lowest cost.
Northumbria Healthcare NHS Foundation Trust - DAFNE Executive Board	Guideline	007	009	The targets for those using continuous glucose monitoring needs to be emphasised so that we know people are gaining the most benefit they can from this technology. This section should recommend that people with access to these technologies are encouraged to align with the international consensus on time in range , aiming for more than 70% time in range and <4% time below range, or if in the high-risk group, >50% time in range and <1% time below range. See: https://care.diabetesjournals.org/content/early/2019/06/07/dci.19-0028	Thank you for your comment. The committee considered this issue but agreed that aligning with the international consensus on time in range was not needed. The committee was concerned how this would be used if this was not achieved and were keen to avoid any barriers in accessing technology.
Northumbria Healthcare NHS Foundation Trust - DAFNE Executive Board	Guideline	010	009	Recommendations for research. The most appropriate way to initiate insulin and incorporate newer technologies in those with a new diagnosis of T1D is still not clear. This is an important area for research.	Thank you for your comment. This area is beyond the scope of this guideline update.
Northwood Group Practice	Guideline	General	General	The guidance opens up the use of both real time CGM and isCGM to all with Type 1 diabetes. There will be significant implications for commissioning and service delivery. Will any additional funding be made available centrally to fund the implementation e.g. additional service capacity required, education and resources? This would be across primary, secondary and intermediate care as well as for district nurses and in all care settings e.g. care homes.	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.
Northwood 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 evidence that on-going use of flash glucose is demonstrably improving an individuals	Thank you for your comment. The committee considered this issue and agreed that setting a criterion for discontinuing CGM would be unhelpful and had concerns about technology being taken away. Instead, the committee added to recommendation 1.6.8 stating that if there are any concerns

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				diabetes self management. Are NICE planning to introduce any of these requirements? We would welcome further guidance on this within the guideline to ensure that those who are receiving isCGM are benefitting from use.	about the way a person is using the device, discuss barriers and concerns and whether there is a way to improve their use of the device, including further emotional and psychological support and education to overcome these.
Northwood Group Practice	Guideline	General	General	For individuals with pancreatic diabetes, we manage as if they have type 1 diabetes (with regards to insulin). Would this group of individuals fit within this guidance?	Thank you for your comment. The committee discussed this issue and agreed that adults with insulin insufficiency due to other medical causes and conditions would be treated the same as adults with type 1 diabetes. This has been clarified in the guideline and evidence review.
Northwood Group Practice	Guideline	006	014	Fear, frequency, awareness and severity of hypoglycaemia – we would welcome a quantitative measure for this to support both a baseline measure and assessing improvement post CGM	Thank you for your comment. The committee considered this issue but agreed that due to a lack of standardised measures, it was not possible to list specific measures.
Novo Nordisk	Guideline	General	General	<p>We welcome the use of an established cost-effectiveness modelling approach</p> <p>We welcome the modelling approach used for this NG17 guideline update, which is based on the CORE diabetes model. As stated in the Health Economics Report, this is an established method for modelling the complexity of diabetes, for both type 1 and type 2 diabetes.</p> <p>This is a validated method to access cost-effectiveness in diabetes modelling¹⁻⁴, and accounts for the key outcome measures across all aspects of treatment.</p> <p>References:</p> <ol style="list-style-type: none"> 1. Capehorn M, Hallén N, Baker-Knight J, Glah D, Hunt B. Evaluating the Cost-Effectiveness of Once-Weekly Semaglutide 1 mg Versus Empagliflozin 25 mg for Treatment of Patients with Type 2 Diabetes in the UK Setting. <i>Diabetes Ther.</i> 2021 Feb;12(2):537-555. doi: 10.1007/s13300-020-00989-6. Epub 2021 Jan 9. PMID: 33423240; PMCID: PMC7846640. 	Thank you for your comment, and your support for the model used in this particular update of the guidance.

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				<p>2. Viljoen A, Hoxer CS, Johansen P, Malkin S, Hunt B, Bain SC. Evaluation of the long-term cost-effectiveness of once-weekly semaglutide versus dulaglutide for treatment of type 2 diabetes mellitus in the UK. <i>Diabetes Obes Metab.</i> 2019 Mar;21(3):611-621. doi: 10.1111/dom.13564. Epub 2018 Nov 28. PMID: 30362224; PMCID: PMC6587509.</p> <p>3. Bain SC, Hansen BB, Malkin SJP, Nuhoho S, Valentine WJ, Chubb B, Hunt B, Capehorn M. Oral Semaglutide Versus Empagliflozin, Sitagliptin and Liraglutide in the UK: Long-Term Cost-Effectiveness Analyses Based on the PIONEER Clinical Trial Programme. <i>Diabetes Ther.</i> 2020 Jan;11(1):259-277. doi: 10.1007/s13300-019-00736-6. Epub 2019 Dec 12. PMID: 31833042; PMCID: PMC6965564.</p> <p>4. Johansen P, Chubb B, Hunt B, Malkin SJP, Sandberg A, Capehorn M. Evaluating the Long-Term Cost-Effectiveness of Once-Weekly Semaglutide Versus Once-Daily Liraglutide for the Treatment of Type 2 Diabetes in the UK. <i>Adv Ther.</i> 2020 May;37(5):2427-2441. doi: 10.1007/s12325-020-01337-7. Epub 2020 Apr 18. PMID: 32306244; PMCID: PMC7467468.</p>	
Novo Nordisk	Guideline	006	007 - 014	<p>We support the recommendation to offer CGM and isCGM as standard care and we suggest this guideline is future-proofed to recognise existing, emerging and new technologies that will inform decision-making on CGM/isCGM choice.</p> <p>We support the recommendation that all adults with type 1 diabetes should be offered a choice of real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring (isCGM), to support increased access to these technologies that can help people in managing their diabetes.</p>	Thank you for your comment. We have added your suggested text to box 1 in the guideline.

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				<p>We support the reference in the draft guideline to a person's individual preferences needing to be taken into account in offering them a choice with regards to which glucose-monitoring technology they may wish to use, noting the committee's acknowledgment on page 16 of the guideline that</p> <p><i>"this freedom of choice is more beneficial than being limited to a specific device, particularly because adherence to the technology is likely to be higher if the device is matched to the person's needs".</i></p> <p>In recognition of the different ways in which people use their data from CGMs/isCGMs, for example linking with their smartphone, and in anticipation of future technologies with additional capabilities for shared data platforms with insulin dosing data alongside CGM data, we recommend a small change to the wording in Box 1, Factors to consider when choosing a continuous glucose monitoring device:</p> <p><i>"The ways in which data can be extracted, its ease of use with other technologies and whether it can be shared with the person's healthcare provider."</i></p>	
Novo Nordisk	Guideline	007	003	<p>Guidelines should include reference to the need for shared decision making between clinicians and patients in determining which glucose monitoring device to use</p> <p>We welcome reference in the guidance that a person's individual preferences and needs should be taken in to account when choosing a glucose monitoring device and note that page 15 of the guidance states the committee's view in reaching its overall recommendations that <i>"the specific functionality of flash versus real-time CGM devices should be discussed between the person and their healthcare professional"</i>.</p>	<p>Thank you for your comment. The committee agreed with your feedback and the need for shared decision making has been added to recommendation 1.6.2. Further detail has also been added stating that if multiple continuous glucose monitoring devices meet the person's identified needs and preferences, offer the device with the lowest cost.</p>

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				<p>To ensure that patients have sufficient opportunity to express their needs and preferences and that cost does not become the determining factor in deciding which type of glucose monitoring device to offer a person, we recommend that line 3 on page 7 is amended to make explicit reference to the need to adhere to a process of shared decision making between patients and clinicians in deciding which device is right for them. We recommend that the line is amended as follows:</p> <p><i>“Offer the continuous glucose monitoring device with the lowest cost that meets the person’s identified needs and preferences, having first undertaken a process of shared decision-making between clinician and patient.”</i></p>	
Oxford Centre for Diabetes, Endocrinology and Metabolism	Guideline	General	General	There should be an attempt to avoid discrepancies between the CYP and adult guidelines for glucose monitoring in order to prevent practice changes being suggested when young people move to the adult clinic.	Thank you for your comment. We will try to ensure that the children and young people and adult guidelines are aligned.
Oxford Centre for Diabetes, Endocrinology and Metabolism	Guideline	006	007 - 012	<p>In a resource limited system, where there is a currently a significant cost differential between isCGM and the commonest used rtCGM, to offer a free choice of devices without considering cost may not be the best use of resource. We should use the most suitable AND cost-effective device for the individual patient situation, taking into account the factors listed in Box 1.</p> <p>Although the next section says “offer the device with the lowest cost which meets their preferences”, if the patient prefers rtCGM because it communicates with their Apple Watch - is that a good enough reason to spend £60 per month more??</p>	<p>Thank you for your comment. We agree that clinical need should be one factor that informs the choice of device, and this is include in the recommendations. However, the committee also agreed that individual’s preferences needed to be taken into account, as the most suitable device would vary for each person. The committee stressed that this freedom of choice is more beneficial than being limited to a specific device, particularly because adherence to the technology is likely to be higher if the device is matched to the person’s needs and preferences.</p> <p>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</p>

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					affordability of the recommendations that have been raised through this consultation.
Roche Diabetes Care, Ltd	Guideline	General		Aligned with the NHS Long Term Plan we support the use of digital tools for people with diabetes. Increasing numbers of mobile phone applications that can support blood glucose monitoring are available and have a varied evidence base. It is important that healthcare professionals are provided with guidance relating to recommending these solutions to be able to advise patients accordingly.	Thank you for your comment. NICE will consider whether the use of digital tools for people with diabetes should be prioritised for future updates.
Roche Diabetes Care, Ltd	Guideline	007	004	<p>We fully support the recommendation that people who do not wish or who are unable to use any real-time CGM or isCGM devices are offered capillary blood glucose monitoring. Capillary blood glucose monitoring is an important precursor and back-up to real-time CGM and isCGM. People requiring capillary blood glucose monitoring devices must not be impacted by the cost of providing real-time CGM and isCGM to others. Evidence demonstrates that structured monitoring using a connected meter and data management system can increase satisfaction and glycaemic outcomes (1,2). We believe pragmatic recommendations to healthcare professionals around connected devices and diabetes management solutions should be included in the guidelines.</p> <p>1. Mora P et al, Use of a novel, remotely connected diabetes management system is associated with increased treatment satisfaction, reduced diabetes distress and improved glycaemic control in individuals with insulin-treated diabetes: first results from the Personal Diabetes Management Study. <i>Diabetes Technol Ther</i> 2017; 19(12): 715-722</p> <p>2. Weissmann J et al, Improving the Quality of Outpatient Diabetes Care Using an Information Management System: Results From the Observational VISION Study. <i>J Diabetes Sci Technol</i>. 2015 Jul 29; 10(1): 76-84</p>	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 1.6.5).
Royal College of General Practitioners	Guideline	General	General	When diagnosing Type 1 DM it would be useful for a flow diagram/ pictorial view of which tests to use and when to bring the guidance together for clarity. This should include	Thank you for your comment. Your comment will be considered by NICE where relevant support activity is being planned.

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				HBa1C, fasting glucose, autoantibodies and C peptide. This would help primary care and would enable commissioners to see, at a glance, which tests need to be commissioned across the ICS to enable accurate diagnosis to be made. The flow diagram could also point out with weight loss to consider the differential for pancreatic cancer and include the risk factors in recommendation 1.1 and 1.1.2	
Royal College of Nursing	Guideline	006 - 007	013 -014	This guidance will likely provide people with type 1 diabetes with greater access to hybrid closed loop systems. This in turn should improve care outcomes.	Thank you for your comment.
Royal College of Nursing	Guideline	006	007 -011	We agree that individual preferences, needs, characteristics and functionality of the devices should be considered when offering adults with type 1 diabetes a choice of rt/isCGM.	Thank you for your comment.
Royal College of Nursing	Guideline	010	009	Suggestions for research are pertinent and important given the increasing complexity of definitive diagnosis in some cases and the need for a standardised approach.	Thank you for your comment.
Royal College of Nursing	Guideline	011	001	Ongoing analysis of real-world data is paramount to understand the cost effectiveness of CGM – this analysis should be made over 5-10 years to account for impact on long term complications of diabetes.	Thank you for your comment.
Royal College of Nursing	Guideline	019	003	This revision is effective to highlight the need for ongoing review of diagnosis during initial stages	Thank you for your comment.
South Asian Health Foundation	Guideline	005	001	Not all patients with T1D will be Ab positive and up to 20% will be GAD/IA2/ZnT8 Ab negative. If a clinical diagnosis of T1D is clear, then we would not recommend measuring Abs because a negative result will confuse, risk a revision of the diagnosis, potentially stopping insulin etc, by practicing clinicians not aware of the nuances of these immunology tests. Safer to restrict these tests to those patients where there is diagnostic uncertainty (as per previous guidelines). The rationale for recommending Ab testing is stated as 'The most common misdiagnosis is type 1 diabetes being misdiagnosed as type 2, which could lead to the person not receiving insulin treatment and a subsequent risk of diabetic ketoacidosis'. Recommending Ab testing in those with a clinical diagnosis of TD will not address this problem; rather	Thank you for your comment. The committee discussed this issue and agreed that the evidence supporting the measurement of diabetes-specific autoantibodies in adults with an initial diagnosis of type 1 diabetes was clear. Measuring diabetes-specific autoantibodies has utility and for the majority this measurement will confirm the correct diagnosis. This recommendation is also in agreement with other international guidelines.

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				there is a body of work to be done on the utility of measuring Ab in those with a clinical diagnosis of T2D	
South Asian Health Foundation	Guideline	005	010	The measurement of C peptide in Ab negative people with a clear clinical diagnosis of T1D will also potentially confuse because C peptide will not have fallen appreciably at the time of diagnosis.	<p>Thank you for your comment. The committee acknowledged the poor quality of studies on the use of c-peptide and the inherent mechanism of action of C-peptide that means it will not function well as a predictor at the time of diabetes presentation. However the committee also agreed that C-peptide along with blood glucose levels was the best reference standard available, but this was only true for a longer time after an initial presentation of diabetes.</p> <p>As a result of this lack of high-quality evidence on the effectiveness of c-peptide, the committee made a research recommendation outlining the need for further research on the effectiveness of c-peptide at correcting misclassification of diabetes diagnosis and what is the optimal timing in distinguishing subtypes of diabetes.</p>
South Asian Health Foundation	Guideline	010	012	The most appropriate way to initiate insulin in those with a new diagnosis of T1D is still not clear and there may be a benefit to start with bolus only insulin and initiate basal insulin later. This is an important area for research	Thank you for your comment. This area is beyond the scope of this guideline update.
University Hospitals Birmingham NHS Foundation Trust	Guideline	005	001	<p>Not all patients with T1D will be Ab positive and up to 20% will be GAD/IA2/ZnT8 Ab negative. If a clinical diagnosis of T1D is clear, then we would not recommend measuring Abs because a negative result will confuse, risk a revision of the diagnosis, potentially stopping insulin etc, by practicing clinicians not aware of the nuances of these immunology tests. Safer to restrict these tests to those patients where there is diagnostic uncertainty (as per previous guidelines).</p> <p>The rationale for recommending Ab testing is stated as 'The most common misdiagnosis is type 1 diabetes being misdiagnosed as type 2, which could lead to the person not receiving insulin treatment and a subsequent risk of diabetic ketoacidosis'. Recommending Ab testing in those with a clinical diagnosis of TD will not address this problem; rather</p>	<p>Thank you for your comment. The committee discussed this issue and agreed that the evidence supporting the measurement of diabetes-specific autoantibodies in adults with an initial diagnosis of type 1 diabetes was clear. Measuring diabetes-specific autoantibodies has utility and for the majority this measurement will confirm the correct diagnosis. This recommendation is also in agreement with other international guidelines.</p>

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				there is a body of work to be done on the utility of measuring Ab in those with a clinical diagnosis of T2D.	
University Hospitals Birmingham NHS Foundation Trust	Guideline	005	010	The measurement of C peptide in Ab negative people with a clear clinical diagnosis of T1D will also potentially confuse because C peptide will not have fallen appreciably at the time of diagnosis.	<p>Thank you for your comment. The committee acknowledged the poor quality of studies on the use of c-peptide and the inherent mechanism of action of C-peptide that means it will not function well as a predictor at the time of diabetes presentation. However the committee also agreed that C-peptide along with blood glucose levels was the best reference standard available, but this was only true for a longer time after an initial presentation of diabetes.</p> <p>As a result of this lack of high-quality evidence on the effectiveness of c-peptide, the committee made a research recommendation outlining the need for further research on the effectiveness of c-peptide at correcting misclassification of diabetes diagnosis and what is the optimal timing in distinguishing subtypes of diabetes.</p>
University Hospitals Birmingham NHS Foundation Trust	Guideline	010	012	The most appropriate way to initiate insulin in those with a new diagnosis of T1D is still not clear and there may be a benefit to start with bolus only insulin and initiate basal insulin later. This is an important area for research	Thank you for your comment. This area is beyond the scope of this guideline update.
University Hospitals of North Midlands NHS Trust	Guideline	General	General	What time frame of newly diagnosed T1DM should we use to review if these technologies are offered?	Thank you for your comment. The committee considered this issue and agreed that a review timeframe is difficult to define as it should be based on individual need. They therefore did not include this in the guideline.
University Hospitals of North Midlands NHS Trust	Guideline	General	General	Will this be facilitated by primary care? Or all expected to be done by secondary care?	Thank you for your comment. The committee considered this issue and agreed that training should be provided by a healthcare specialist in diabetes to take account of different models of care delivery.
University Hospitals of North	Guideline	006	013	The persons insulin regimen - more clarity in here - basal-bolus, BD biphasic, OD basal all included?	Thank you for your comment. The committee considered this issue and agreed that extra detail on insulin regimen is not needed and would be too prescriptive.

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Midlands NHS Trust					
University Hospitals of North Midlands NHS Trust	Guideline	006	013	Hybrid closed loop – is the team able to choose the CGM device that will provide this function if patient is already on a specific insulin pump?	Thank you for your comment. Box 1 outlines that the person's type of insulin pump should be considered when choosing a CGM device.
University Hospitals of North Midlands NHS Trust	Guideline	007	002	1.6.11 Does this mean we will offer CGM/isCGM to anyone newly diagnosed with T1DM? Or should we still be offering capillary blood glucose monitoring first?	Thank you for your comment. The committee considered this issue and agreed that adults newly diagnosed with type1 diabetes should be offered CGM first and not capillary blood glucose monitoring. The committee were keen to avoid any delays in access to this technology.

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27	British In Vitro Diagnostics Association (BIVDH)	BIVDA represents approximately 200 organisations within the IVD industry including start-up companies, SMEs, UK developers and manufacturers as well as subsidiaries of the global IVD corporations. We also represent some distributors and other economic operators. Our response is therefore submitted on behalf of this membership and reflects the general views of companies within the IVD sector.	Thank you for your comment.

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

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