Diabetes (type 1 and type 2) in children and young people: diagnosis and management – glucose monitoring

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Abbott Diabetes Care	Guideline	009	001	We appreciate the robustness and expert opinion included in this guideline review. There is a research recommendation made to collect real-world data yet the methodology of the guideline assessment did not allow for inclusion of real world/ observational evidence. We are aware that NICE is examining the approach to technology evaluation with potential for such evidence sources to be considered in the future, we welcome this. Real-world evidence demonstrates the value of medical devices in everyday clinical practice, rather than in a clinical trial setting, this is especially the case with data rich technologies such as FreeStyle Libre for which there is an extensive body of real world evidence that should be considered as complementary supporting evidence. There is such a body of data for children and young people demonstrating efficacy, improved user satisfaction and quality of life. We hope to see in the future that this could be included for review so Flash sensing technology could be considered on a par with rtCGM as a choice for the child or young person with diabetes dependant on their needs.	Thank you for your comment and support of our research recommendation on the use of real-world data. Yes, NICE is currently exploring how real-world data can feed into our future guideline updates.
Ascensia Diabetes Care	Guideline	004	008	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]. 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	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 1.1.7). Thank you for raising this issue however the quality and accuracy of blood glucose meters is beyond the scope of the guideline update.

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				nurses, that a blood glucose meter doesn't have to be independently assessed to be placed on the market in the EU, including the UK."[3] In reality current meters marketed with a CE mark are no guarantee of quality or accuracy, which has been demonstrated via published data by Klonoff et al[4] in 2018, this study assessed 18 meters marketed in the US but also used in the UK, against both the ISO 15197:2015 and the FDA guidelines and found that only 6 out of the 18 meters evaluated met those standards, with 12 failing to meet the standards. Data published by Ekhlaspour et al[5] also evaluated 17 meters against the ISO 15197:2015 standards and they found just 2 of the meters met the standard with the other 15 meters failing to meet the standards. Again all 17 meters had a CE mark. For T1 people with diabetes (PWD), meter accuracy should be a key concern, since insulin dosing errors could be made 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 ±15%, would give them a range of between 2 and 5 units to administer. Whereas with a highly accurate meter such as the Contour® Next One with an accuracy of ±8.4%[6], this range of insulin administered would be reduced to between 3 and 4 units. The example demonstrates the impact of the meter accuracy and the resultant variance of the PWD's blood glucose levels. This greater variance of a less accurate SMBG meter could impact the PWD's ability to manage their blood glucose levels and the impact it has on achieving their target HbA1c level. This makes the assumption the meter meets the	

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

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				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.	
Ascensia Diabetes Care	Guideline	005	003	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 Breton[7] 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. 7. Breton MD & Kovatchev BP. J Diabetes Sci Technol 2010;4:562–570.	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.
Barking Havering and Redbridge University Hospital NHS Trust	Guideline	004	009	1.2.63: This will need investment in the current MDT workforce. As quality of training in use of CGMS is crucial to achieve success. Do we need a section on when to check capillary blood glucose when using realtime CGMS or isCGMS?……..	Thank you for your comment. The committee recognised and acknowledged this implementation issue However, they agreed that the clinical and cost-effective benefits associated with the promotion of CGM in children and young people with type 1 diabetes were worth the costs and resources associated in implementing this recommendation and ultimately improving care for children and young people with type 1 diabetes. 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 (rec 1.1.7). The

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					recommendation also provides examples when capillary blood glucose monitoring should be used although this is not an exhaustive list.
Barking Havering and Redbridge University Hospital NHS Trust	Guideline	004	017	1.2.65: Choice of RT CGM. Does this cover Cam APS for hybrid closed loop system for children>age 1 year? It would help both clinicians and commissioners.…	Thank you for your comment. The committee discussed this issue and the choice of real-time CGM would include the Cam APS for hybrid closed loop system for children>age 1 year.
Barking Havering and Redbridge University Hospital NHS Trust	Guideline	006	017	1.2.70: at what stage the CGMS is to be replaced by finger prick blood glucose testing if additional support does not improve adherence?	Thank you for your comment. The committee discussed this issue and agreed that rather than replace CGM with capillary blood monitoring, if the child or young person is not using their device at least 70% of the time, discuss with them any possible barriers or problems in using the device and offer further emotional and psychological support and education to overcome these (rec 1.1.11).
Barts Health NHS Trust - Paediatric Diabetes Team	Guideline	General	General	Rec 1.2.81 (2015 guideline) – In our practice, we have identified that children and young people do not require oral complex long-acting carbohydrate to prevent further episodes of hypoglycaemia once glucose levels rise/normalise. However, we do recommend that children and young people have a meal or snack if it is due or if they are hungry (with insulin). We recognise that this advice will differ when considering physical activity or exercise. We would suggest that this recommendation be investigated further or identified as an area for research.	Thank you for your comment. The issue that you have raised is beyond the scope of this guideline update.
Barts Health NHS Trust - Paediatric Diabetes Team	Guideline	General	General	Rec 1.3 (2015 guideline) – We are concerned that the updated guideline does not provide recommendations on frequency of glucose monitoring or type of glucose monitoring for children and young people with Type 2 diabetes. The 2015 guideline only specifies HbA1c targets.	Thank you for your comment. The issue that you have raised is beyond the scope of this guideline update. The committee has also made a research recommendation on the effectiveness and cost effectiveness of continuous glucose monitoring devices in children and young people with type 2 diabetes.
Barts Health NHS Trust - Paediatric Diabetes Team	Guideline	General	General	Rec 1.2.80 (2015 guideline) – We agree that that school nurses should be trained in giving glucagon injections. However, school nurses are not always based on site at schools. We suggest that the working be changed to 'Train	Thank you for your comment. The issue that you have raised is beyond the scope of this guideline update.

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				and equip families, carers, and (if appropriate) school nurses, *school staff trained in diabetes care,* and other carers to give intramuscular glucagon for severe hypoglycaemia in an emergency'.	
Bolton NHS Foundation Trust	Guideline	005		Bottom Line in box 1 - We feel the word 'Cosmetic' trivialises the very real body image concerns that some young people have regarding wearing technology	Thank you for your comment. Following discussion with the committee, this factor in box 1 has been changed to body image concerns.
Bolton NHS Foundation Trust	Questions	Q1		1.Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why. Most challenging for DSNs in terms of offering CGM to more families - initial discussions, education prior to CGM start, starts, ongoing monitoring	Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned.
Bolton NHS Foundation Trust	Questions	Q2		2. Would implementation of any of the draft recommendations have significant cost implications? We currently don't have issues with CCG funding of Dexcom but we would want to be sure that CCGs are adequately funded for this situation to continue DSN staffing levels will need to be increased as referred to above	Thank you for your comment and for raising concerns around funding. 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. The committee recognised and acknowledged this implementation issue However, they agreed that the clinical and cost-effective benefits associated with the promotion of CGM in children and young people with type 1 diabetes were worth the costs and resources associated in implementing this recommendation and ultimately improving care for children and young people with type 1 diabetes. Your comments will be considered by NICE where relevant support activity is being planned.
Bolton NHS Foundation Trust	Questions	Q3		3. What would help users overcome any challenges? Increased staffing time again to ensure adequate interaction with families	Thank you for your comment. The committee recognised and acknowledged this implementation issue However, they agreed that the clinical and cost-effective benefits associated with the promotion of CGM in children and young people with type 1 diabetes were worth the costs and resources associated in implementing this recommendation and

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					ultimately improving care for children and young people with type 1 diabetes.
British In Vitro Diagnostic Association (BIVDA)	Guideline	005	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 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.	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.
British In Vitro Diagnostic Association (BIVDA)	Guideline	005	General	The ease of extracting and sharing data should be considered.	Thank you for your comment. Considering feedback from other stakeholders, the committee added the following factor to box 1 - the ways in which data can be extracted, its ease of use with other technologies and whether it can be shared with the child or young person's healthcare provider to help inform treatment.
British In Vitro Diagnostic 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 children and young people with type 1 diabetes and their families or carers.
Children and Young People's Wales Diabetes Network	Guideline	General	General	The Children and Young People's Wales Diabetes Network welcomes the latest iteration of the NICE guidance on use of CGM in children and young people. It is clear from the NPDA data, and other evidence including the experience of international colleagues, that using technology, including CGM, leads to improved short and long-term outcomes. Our network supports the advice within the revised guideline, and would be keen to see it published as soon as possible.	Thank you for your positive comment.
Dexcom	General	General	General	References 1. Nirantharakumar K, et al. Clinically meaningful and lasting HbA1c improvement rarely occurs after 5	Thank you for providing these references. We have checked these against the inclusion criteria of our evidence review.

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				years of type 1 diabetes: an argument for early, targeted and aggressive intervention following diagnosis. Diabetologia 2018;61:1064–1070. 2. Livingstone SJ, Levin D, Looker HC, Lindsay RS, Wild SH, Joss N, Leese G, Leslie P, McCrimmon RJ, Metcalfe W, McKnight JA. Estimated life expectancy in a Scottish cohort with type 1 diabetes, 2008-2010. Jama. 2015 Jan 6;313(1):37-44. 3. Lawton J, Waugh N, Barnard KD, Noyes K, Harden J, Stephen J, McDowell J, Rankin D. Challenges of optimizing glycaemic control in children with Type 1 diabetes: a qualitative study of parents' experiences and views. Diabetic Medicine. 2015 Aug;32(8):1063-70. 4. Patton SR, Dolan LM, Henry R, Powers SW. Fear of hypoglycemia in parents of young children with type 1 diabetes mellitus. Journal of Clinical Psychology in medical settings. 2008 Sep;15(3):252-9. 5. Haugstvedt A, Wentzel-Larsen T, Graue M, Søvik O, Rokne B. Fear of hypoglycaemia in mothers and fathers of children with Type 1 diabetes is associated with poor glycaemic control and parental emotional distress: a population-based study. Diabetic Medicine. 2010 Jan;27(1):72-8.	References 1, 2, 3, 4, 5, 6, 10, 11 and 12 did not meet our inclusion criteria as these are not RCT studies to assess what is the most effective method of glucose monitoring to improve glycaemic control in children and young people with type 1 diabetes. 7. Thabit H,et al – this study was considered under the duplicate paper by Prabhu et al (2020) please see excluded studies list in Appendix J in our evidence review. This study was excluded as it had a mixed population of adults and children and was excluded as: o data has not been reported for the subgroup of children AND o ≤50% of people were aged <18 years 8. This paper was included in our evidence review. 9. This paper was excluded as the participants wore masked or blinded continuous glucose monitors which did not meet our inclusion criteria. 13. This paper was included in our evidence review.

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				6. Fleming M et al, Educational and Health Outcomes of Children Treated for Type 1 Diabetes: Scotland-Wide Record Linkage Study of 766,047 Children, Diabetes Care, 2019 7. Thabit H, Prabhu JN, Mubita W, Fullwood C, Azmi S, Urwin A, Doughty I, Leelarathna L. 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. Diabetes Care. 2020 Oct 1;43(10):2537-43. 8. 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. JAMA. 2020 Jun 16;323(23):2388-96 9. DiMeglio LA, Kanapka LG, DeSalvo DJ, Anderson BJ, Harrington KR, Hilliard ME, Laffel LM, 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	

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				glucose monitor study. Diabetic Medicine. 2020 Aug;37(8):1308-15. 10. MSAC 1663 report. Review of Continuous Glucose Monitoring Products (June 2021), Table 49 and table 86 11. MSAC 1663 report. Review of Continuous Glucose Monitoring Products (June 2021), Table 52 and table 89 12. MSAC 1663 report. Review of Continuous Glucose Monitoring Products (June 2021), Table 53 and pg. 187 13. Burckhardt MA, Roberts A, Smith GJ, Abraham MB, Davis EA, Jones TW. The use of continuous glucose monitoring with remote monitoring improves psychosocial measures in parents of children with type 1 diabetes: a randomized crossover trial. Diabetes Care 2018;41(12):2641-3.	
Dexcom	Guideline	004	009	Dexcom would like to place on record our support for the recommendation to offer all children and young people with type 1 diabetes (T1D) access to a rt-CGM. As a result of this update the guideline is now consistent with the significant evidence base presented below.	Thank you for your comment. We are pleased that our recommendations are consistent with the evidence base that you have presented.

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<tr><td></td><td></td><td></td><td></td><td>In addition to the recommendation to offer all children and young people with T1D access to a rt-CGM now being reflective of the evidence it is also in line with the American Diabetes Association, the endocrine society and the Advanced Technology and Treatments for Diabetes (ATTD) consensus statements

Table 1 Professional Society & Consensus Recommendations on CGM
<table><tr><td>American Diabetes Association (Fonseca 2017)</td><td>"CGM is useful tool for improving
pregnant women; children & adole</td></tr><tr><td>The Endocrine Society (Peters 2016)</td><td>• Recommend CGM for adults wit
• Recommended for children & ad
• Short-term intermittent use reco</td></tr><tr><td>Advanced Technology and Treatments for Diabetes (ATTD, Danne et al 2017)</td><td>"CGM should be considered in co
assessment and therapy adjustm
2 diabetes treated with intensive i
targets, especially if the patient is</td></tr></table>
The publication of this guideline will provide children and young people with T1D, an enhanced ability to achieve optimal glycaemic control as early as possible which has been shown to be critical in establishing good long-term HbA1c[1] levels. As such the provision of health care</td><td></td></tr>
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				interventions that enable the user to achieve good glucose control in the early years of the condition is of prime importance. This was demonstrated in a study of death rates based on a large Scottish registry of people with T1D[2]. This study found that at age 20 years, the average man with T1D subsequently had an estimated life expectancy loss of about 11 years and women about 13 years. In the general population without T1D, 76% of men and 83% of women survived to age 70 years compared with 47% of men and 55% of women with T1D. This data suggested that 40% of the differential in life expectancy was attributable to circulatory disease. However, people with T1D appeared more likely to die early for a wide range of other reasons including malignancy, renal failure and respiratory disease. All of which has been associated with poorly controlled diabetes. Deaths due to diabetic coma or DKA were the primary reported cause of death associated with the loss in life expectancy occurring before age 50 years in men. In the younger age group, parents/ caregivers of children with diabetes worry about their child's ability to detect and communicate symptoms of hypoglycaemia and factors that can impact their child's blood glucose levels[3]. Fear of hypoglycaemia is common among the parents of children	

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				with diabetes. Evidence suggest that parents / caregivers may maintain slightly higher than optimal glucose levels in their children to avoid the emergence of hypoglycaemia[4,5]. While the parents' / caregivers' desire to prevent hypoglycaemia is understandable, it may lead to an increase in the probability of the individual developing the long-term complications associated with poor glycaemic control. In addition to health outcomes, it has also been demonstrated that people with T1D with poorly controlled HbA1c attending school have suboptimal educational outcomes in comparison to people without diabetes[6]. It is therefore imperative that young T1Ds have access to evidence based technology to support them and their network to achieve optimal glycaemic control ***Type 1 diabetes in children and young people change in HbA1c*** Of the studies presented below two studies reported a significant difference in mean HbA1c levels between the rt-CGM groups compared to SMBG. In the crossover RCT (MILLENNIAL)[7], young people achieved a significantly larger	

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Mean change in HbA1c levels of RT-CGM vs SMBG studies in children and young people with T1D is presented in Table 2.

Table 2 Mean HbA1c levels in studies of RT-CGM versus SMBG in children or young people with T1D [10]
<table>
<tr><th>Study ID</th><th>Timepoint</th><th>CGM Mean (SD or 95% CI)</th><th>SMBG Mean (CI)</th></tr>
<tr><td>MILLENNIAL</td><td>Change from baseline to Week 8</td><td>-0.53% (0.74%)</td><td>0.24%</td></tr>
<tr><td>CITY</td><td>Baseline</td><td>8.9% (1.0%)</td><td>8.9% (</td></tr>
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	Week 26	8.5% (1.2%)	8.9% (1.2%)	-0.37% (-0.66% to -0.08%)	P=0.01
	Change from baseline	-0.4% (1.0%)	0.1% (0.8%)	-	NR
SENCE	Baseline	8.2% (0.8%)	8.2% (0.7%)	-	-
	Week 26	8.2% (0.8%)	8.1% (0.8%)	0.1% (-0.2% to 0.3%)	P=0.58
Burckhardt, 2018	NR	NR	NR	NR	NR

Type 1 diabetes in children and young people Time in range

The proportion of time spent in range (3.9-10.0 mmol/l) among patients across RT-CGM versus SMBG studies in children and young people with T1D is presented in Table 3. Of the studies that reported the proportion of time spent in range, the MILLENNIAL[7] and CITY[8] studies reported a significant increase in the percentage of time spent in range with rt-CGM versus SMBG (MD, 11.1% and 6.9%, respectively; P<0.001). The SENCE[9] study reported a small numerical increase in time spent in range with rt-CGM versus SMBG, but this was not significant (MD, 0.5%; P=0.75). Aging it should be noted that this study was in a very young

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Table 3 Proportion of time spent in range (3.9-10.0 mmol/l) in studies of RT-CGM versus SMBG in children and young people with T1D [11]
<table>
<tr><th>Study ID</th><th>Timepoint</th><th>CGM Mean (SD or 95% CI)</th><th>SMBG Mean (SD CI)</th></tr>
<tr><td>MILLENNIAL</td><td>8 weeks</td><td>35.7% (13.5)</td><td>24.6% (9.3</td></tr>
<tr><td>CITY</td><td>Baseline</td><td>37% (13)</td><td>36% (12)</td></tr>
<tr><td></td><td>Follow up at 13 and 26 weeks pooled</td><td>43% (15)</td><td>35% (12)</td></tr>
<tr><td>SENCE</td><td>Baseline</td><td>41% (10)</td><td>41% (10)</td></tr>
<tr><td></td><td>Follow up at 6 months</td><td>41% (9)</td><td>40% (9)</td></tr>
<tr><td>Burckhardt, 2018</td><td>NR</td><td>NR</td><td>NR</td></tr>
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Type 1 diabetes in children and young people
Hypoglycaemic events

The number of hypoglycaemic events among patients across rt--CGM versus SMBG studies in children and young people with T1D is presented in Table 4.

In general, most RCTs were not designed to detect differences in the rates of hypoglycaemic events.

The SENCE[9] study in children aged <8 years found a significant reduction in the number of severe hypoglycaemic events for patients managed with rt-CGM compared to those managed with SMBG. It should be further noted that the arm of this study that included rt-CGM plus a behavioural intervention experienced no severe hypoglycaemic events.

Table 4 Hypoglycaemic events among patients in studies of RT-CGM versus SMBG in children and young people with T1D [12]

Study ID	Measure	CGM n/N (%)	SMBG n/N (%)
MILLENNIAL	Severe	0/30 (0%)	0/30 (0%)
CITY	Severe	3/74 (4%)	2/79 (3%)
SENCE	Severe	1/44 (1%)	5/49 (5%)
Burckhardt, 2018	NR	NR	NR

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				Type 1 diabetes in children and young people Quality of life The quality of life measures reported in studies of rt-CGM versus SMBG in children and young people with T1D is presented in Table 5. Burckhardt (2018) was designed to assess psychosocial measures in parents of children with T1D. While there were no significant differences in general (PedsQL Generic) and diabetes specific (PedsQL Diabetes) parent-proxy scores, scores for the Family Impact module (total, parent health-related quality of life, family functioning) were significantly higher in the rt-CGM group compared with the SMBG group. Parental Hypoglycaemia Fear Survey scores were lower while the child was using rt-CGM with remote monitoring (P<0.001). Furthermore, parental HRQoL and family functioning, stress, anxiety, and sleep measures also improved significantly after intervention. The SENCE study reported no significant differences at 26 weeks between rt-CGM and SMBG in the WHO-5 Well-Being Index scores (P=0.66) or in the Diabetes Family Impact Score (P=0.79). Due to this compelling evidence base, it is clear the decision to offer rt-CGM to children and adolescents with Type 1 diabetes is consistent with the evidence.	

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Diabetes UK	Guideline	004	009 - 012	1.2.63 - We broadly welcome this recommendation but do not believe structured education, or lack thereof, should act as a barrier to technology access. A recent report highlighted only 39% of people with diabetes had attended a diabetes education course, despite 70% being interested in doing so and the pandemic has exacerbated this situation with people facing delays in accessing vital education. It is important that education is discussed, including the various routes to learn about how to use CGM (e.g., manufacturer website or Diabetes Technology Network showroom). We suggest NICE makes clear that the recommendation is not for structured education alone, as this implies face to face group education which is not always available, but for a child or young person with diabetes and their parent or carer to be supported to use the technology by a healthcare professional and signposted to the various education routes available. Reference: https://www.diabetes.org.uk/resourcess3/2017-11/1111B%20The%20future%20of%20diabetes%20report_FINAL_.pdf	Thank you for your comment. The guideline refers to a continuous programme of education. This should not be used as a barrier to technology access. We outline in recommendation 1.1.9 that a continuing programme of education is provided to all children and young people with type 1 diabetes. Furthermore recommendation 1.2.2 highlights the importance of tailoring the education programme to meet the needs of each child or young person with type 1 diabetes and their families and carers.
Diabetes UK	Guideline	004	013 - 019	Where a child or young person does express a preference for isCGM, we suggest this guideline should recommend a facilitated conversation to understand why and to highlight the benefits of rtCGM. We recommend that a decision about which technology should be used should be a joint decision with the young person with diabetes and their family/carer and should include documentation of current problems and anticipated outcomes. Reference: https://www.diabetes.org.uk/resources-s3/2019-03/Nikki%20diabetic%20medicine%20article.pdf)	Thank you for your comment. Recommendation 1.1.4 outlines that children and young people with type 1 diabetes should be offered a choice of real-time CGM device based on their individual preferences, needs, characteristics, and the functionality of the devices available. Box 1 in the guideline provides factors to consider as part of this discussion. Recommendation 1.1.5 also refers to using shared decision making to identify the child or young person's needs and preferences and offer them an appropriate device.
Diabetes UK	Guideline	006	017 - 020	1.2.70 - We welcome this recommendation but feel it can be strengthened by explicitly stating that technology should not	Thank you for your comment. The committee were in agreement. Rather than setting a criterion for discontinuing

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				be removed if a child or young person does not use it at least 70% of the time without further discussion about possible problems and barriers. In its current format, we are concerned that this recommendation may inadvertently deny children and young people access to this technology. Furthermore, we would recommend that these guidelines stipulate that access to appropriate emotional and psychological support should be provided and should be integral to the diabetes multi-disciplinary team. Living with diabetes is relentless and emotional or psychological problems are experienced by at least four in ten people with diabetes at any one time, yet less than a quarter of people with diabetes have access to appropriate emotional and psychological support which reduces their ability and motivation to self-manage. This can result in technology not always being worn or being used optimally. Reference: Perera R, Oliver N, Wilmot E, Marriott C. Variations in access to and reimbursement for continuous glucose monitoring systems for people living with Type 1 diabetes across England. Diabetes Medicine 2018 ; 35:1617 –1618) https://www.diabetes.org.uk/resources-s3/2017-10/Revised%20Emotional%20and%20psychological%20support_DUK%20position%20statement_%28For%20web%20-%20without%20info%20prescrip%20text%29%20-%20Revised%20reference%203%2010%202017.pdf	treatment, if a child or young person is not using their device 70% of the time to use this as an opportunity to discuss with them any possible barriers or problems in using the device and offer further emotional and psychological support and education to overcome these (recommendation 1.1.11). The committee were in agreement and we also added your suggested wording of emotional and psychological support to recommendation 1.1.11.
Diabetes UK	Guideline	009	009 - 010	We also welcome further research into the best CGM sensor adhesive to prevent sensitivities to the device given that our support Helpline and forum receive queries concerning this problem and we know it can be a significant barrier to the use of technology.	Thank you for your comment and useful feedback that sensor adhesive sensitivities are a barrier to the use of this technology. We hope our research recommendation will promote further research to address these issues.

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Diabetes UK	Guideline	General	General	Diabetes UK considers this draft guideline a welcome step towards more children and young people living with diabetes having access to continuous glucose monitors (CGM) – something we know can transform glycaemic control and vastly improve quality of life for both the child and their parents/carers. However, we note that data from the National Paediatric Diabetes Audit shows stark inequities in diabetes technology access in children and young people. Children and young people with diabetes who live in areas of high deprivation and from minority ethnic groups are least likely to be using diabetes technology and, alarmingly, this inequality is growing in some areas. We urge NICE and the committee to make reference to this issue within the guideline and to recommend that healthcare professionals and decision makers take this into account as they deliver diabetes care to children and young people.	Thank you for your comment. The committee were concerned that despite the positive recommendation for CGM in CYP 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	General	General	We strongly disagree with the decision not to recommend isCGM use for children and young people with type 2 diabetes. This often vulnerable cohort of patients often see rapid disease progression, with many children with type 2 diabetes requiring treatment intensification and potentially insulin use much more quickly that adults. Whether or not a child with type 2 diabetes is using insulin, iCGM can help shine a light on blood glucose fluctuations and, in turn, allow them and their parents/carers to better understand their condition. We note that draft guideline update for 'Type 2 diabetes in adults' [NG28] calls for some adults with type 2 diabetes being given access to iCGM. This guideline should, at the very least, reflect these recommendations.	Thank you for your comment. The effectiveness and cost-effectiveness of CGM in children and young people with type 2 diabetes was beyond the scope of this guideline update. However the committee discussed this population and acknowledged the lack of evidence. They therefore made a research recommendation to address this gap in the evidence base. With more evidence we hope to address this in future updates.

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				While we accept that more research is needed into this area, we think NICE is missing a huge opportunity here to make a recommendation that could improve the life chances of children and young people who develop type 2 diabetes.	
Diabetes UK	Guideline	General	General	We suggest an additional research recommendation which looks at inequities in technology use amongst children and young people from minority ethnic groups and/or living in areas of high deprivation. This is a growing issue and something that needs to be better understood in order for it to be addressed. A research recommendation on this issue would help support the case for this area to be prioritised.	Thank you for your comment. The committee were concerned that despite the positive recommendation for CGM in CYP 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.
East Kent Hospitals University Foundation NHS Trust	Guideline	004 - 006	General	This is a very welcome update to NICE guidance. In our experience of caring for >400 children and young people (CYP) with diabetes we have found the existing CGMS guidance does not match the needs for CYP: even those who meet criteria normally have another more important reason for using CGMS; these updated criteria therefore create a much fairer provision of CGMS. In particularly this guidance brings potential to provide integrated pump systems to teenagers with high HbA1c; in the few cases we have been able to do this we have seen dramatic reductions in HbA1c.	Thank you for your comment.
East Kent Hospitals University Foundation NHS Trust	Guideline	006	017	This is a very helpful recommendation for children and young people (CYP); the requirement to use the system 70% of the time is understandable from existing research, but it is a particular concern for young people that they may be penalised for the actions of parents, and also that within this age group there are specific cases who are unable to tolerate 70% use but still benefit from use when it is possible.	Thank you for your comment. The committee agreed with your sentiment and added to recommendation 1.1.11 that If the child or young person is not using their device at least 70% of the time, discuss with them any possible barriers or problems in using the device and **offer further emotional and psychological support** and education to overcome these.
East Kent Hospitals University Foundation NHS Trust	Guideline	General	General	This update will bring a significant cost to commissioners in Kent and Medway who have only recently agreed a policy to provide CGMS according to previous guidance, and are not clear about the funding stream. Currently the majority of CYP locally use isCGM. Switching to CGM will not be offset by stopping isCGM as this is funded centrally under the NHSE	Thank you for your comment. The committee agreed that the results of the clinical review, and the cost-effectiveness results extrapolated from the adult type 1 diabetes population, clearly demonstrated rtCGM was cost-effective for the full population of children and young people with type 1 diabetes,

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				arrangement, so unless a central funding arrangement is made for CGM, or a very clear mandate (including specification of funding stream) accompanies this guidance, it is very likely that CYP in Kent and Medway will continue to be disadvantaged.	and therefore agreed it would be inappropriate to restrict the intervention to only a subset of that population. In contrast, the review found no evidence of benefits from isCGM in children and young people. The committee agreed that isCGM has a number of limitations in its functionalities, which made it difficult to be managed by CYP or their parents and therefore often has a lower adherence rate, making it less cost-effective overall. 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	Evidence review	026	003	We are concerned that the evidence on cost effectiveness of rtCGM is not sufficiently robust to support the recommendation to offer it as a first line option to all children and young people with Type 1 diabetes. The committee decided that the adult cost effectiveness study could be extrapolated to apply to children and young people. The adult assessment concludes that rtCGM is only cost effective if fear of hypoglycemia is factored in. This is a subjective measure and therefore this evidence, from a commissioning perspective, is not adequate and not robust enough to support routine commissioning for all patients and the financial commitment needed by system.	Thank you for your comment. In the absence of any economic evidence specific to children and young people with type 1 diabetes, and with clinical evidence showing benefits for rtCGM in children and young people, the committee agreed that the technology should be at least as cost-effective in children and young people as in adults. This was because there are some situations where the same outcomes would be expected in children and adults (for example, the direct quality of life impact of a hypoglycaemic event) and some where the benefit might be larger in children (for example fear of hypoglycaemia, where both the child and their parents/guardians may experience this fear), but nothing where the impact in children would be expected to be less. The committee also agreed that fear of hypoglycaemia is a factor to consider in the economic evaluation among children and young people. Previous studies showed that the use of rtCGM would significantly improve the sleeping quality of CYP and their carers by reducing their fear of hypoglycaemia.

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					Therefore, the benefit of rtCMG for CYP would be larger than for the adult population due to more utility gains related with fear of hypoglycaemia. We agree that fear of hypoglycaemia is a subjective measure, but we do not agree this is a reason to consider it less important. The studies used established, validated scales to measure fear of hypoglycaemia, and there is a validated relationship between fear of hypoglycaemia and quality of life. The fact this is patient reported a subjective measure therefore is not reason to discount the accuracy or importance of these results.
East of England Priorities Advisory Committee	Guideline	004	009	We are concerned that the evidence on cost effectiveness of rtCGM is not sufficiently robust to support the recommendation to offer it as a first line option to all children and young people with Type 1 diabetes. Offering rtCGM as a first line option to all children with T1DM will be unaffordable for most health systems. The use of rtCGM should be reserved for patients with the greatest clinical need e.g. children with persistent severe hypoglycaemia where a trial of isCGM has failed or children diagnosed with T1DM aged below age 2 years. NICE should provide clear criteria to define these patients to ensure equitable access to these technologies.	Thank you for your comment. The committee agreed that the results of the clinical review, and the cost-effectiveness results extrapolated from the adult type 1 diabetes population, clearly demonstrated rtCGM was cost-effective for the full population of children and young people with type 1 diabetes, and therefore agreed it would be inappropriate to restrict the intervention to only a subset of that population. In contrast, the review found no evidence of benefits from isCGM in children and young people. The committee agreed that isCGM has a number of limitations in its functionalities, which made it difficult to be managed by CYP or their parents and therefore often has a lower adherence rate, making it less cost-effective overall. 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	Guideline	005	003	Box 1 Factors to consider when choosing a continuous glucose monitoring device	Thank you for your comment. The use of insulin pumps and who they should be recommended for is beyond the scope of

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Advisory Committee				Bullet point 4: The child or young 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). 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 for adults which concluded that rtCGM was cost effective, and which the committee agreed was appropriate to extrapolate to apply to use of rtCGM in children and young people. The cost effectiveness at costs greater than £2k per year is less clear and therefore it would not appropriate to routinely offer integrated rtCGM as an option. Clear criteria are needed to define those children and young people for whom an insulin suspend function is essential to their care, to ensure resources are targeted to those who will benefit the most. The draft guideline for glucose monitoring in adults with Type 1 diabetes states that NICE diagnostics guidance on integrated sensor-augmented pump therapy systems for managing blood glucose levels in type 1 diabetes is being updated and will assess hybrid closed loop systems. It is therefore not appropriate to offer this technology as a routine option at this time.	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). 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	Guideline	005	003	Box 1 Factors to consider when choosing a continuous glucose monitoring device: Bullet point 4: '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).' 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	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

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				pump without a proven clinical need would be inequitable. The choice of device offered needs to be based on objective clinical need.	correctly only considers the costs of CGM (and not insulin pumps). 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	Guideline	005	003	Box 1 Factors to consider when choosing a continuous glucose monitoring device: Bullet point 12: '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 child or young person's clinical need and that they are able to use effectively should be offered.	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 all children and young people with type 1 diabetes. Body image concerns should only be considered when choosing a continuous glucose monitoring device.
East of England Priorities Advisory Committee	Guideline	005	003	The guidance should contain a statement that 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 have added a recommendation stating that if multiple continuous glucose monitoring devices meet the child or young person's identified needs and preferences, offer the device with the lowest cost.
East of England Priorities Advisory Committee	Guideline	006	001	We strongly agree that both isCGM and rtCGM should be initiated and monitored by specialist teams to ensure that the child or young person, parents or carers receive 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	006	007	We strongly agree that children and young people 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. Recommendation 1.1.9 outlines that continuous glucose monitoring should be included in the continuing programme of education provided to all children and young people with type 1 diabetes and their families or carer, and to ensure that children and young people using it are empowered to do so.

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East of England Priorities Advisory Committee	Guideline	006	013	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.	Thank you for your comment. The committee were in agreement and recommended in 1.1.0 that the child or young person's use of continuous glucose monitoring should be monitored as part of reviewing their diabetes care plan and explain to them the importance of continuously wearing the device.
East of England Priorities Advisory Committee	Guideline	006	017	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, or 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 your feedback and agreed that rather than setting a criterion for discontinuing treatment, if a child or young person is not using their device 70% of the time to use this as an opportunity to discuss with them any possible barriers or problems in using the device and offer further emotional and psychological support and education to overcome these (recommendation 1.1.11).
East of England Priorities Advisory Committee	Guideline	General	General	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 children and young people. 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. 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	Thank you for your comment. The committee agreed that the results of the clinical review, and the cost-effectiveness results extrapolated from the adult type 1 diabetes population, clearly demonstrated rtCGM was cost-effective for the full population of children and young people with type 1 diabetes, and therefore agreed it would be inappropriate to restrict the intervention to only a subset of that population. 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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				technologies will vary depending on where children and young people live. 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. The recommendations as they stand will create an expectation that all children and young people will be offered real-time CGM that cannot be fulfilled. This may lead to frustration for children and young people living with Type 1 diabetes and their family and carers, when health systems are unable to make these technologies available as set out in the guideline. 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.	
East of England Priorities Advisory Committee	Questions	Q1		Q Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why: A. Providing children and young people with the real-time CGM as a first line option will be unaffordable for most health systems. All children and young people initiated on isCGM 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 children and young people, the wider community, and the whole NHS, and ensuring the cost	Thank you for your comment and for raising concerns around funding. 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. The committee recognised and acknowledged this implementation issue However, they agreed that the clinical and cost-effective benefits associated with the promotion of CGM in children and young people with type 1 diabetes were worth the costs and resources associated in implementing

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				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.	this recommendation and ultimately improving care for children and young people with type 1 diabetes. Your comments will be considered by NICE where relevant support activity is being planned.
East of England Priorities Advisory Committee	Questions	Q2		Q Would implementation of any of the draft recommendations have significant cost implications? A. The National Paediatric Diabetes Audit 2019/20 reported that approximately 20% of children and young people are using rtCGM, and that there is variation across the country. As the cost of rtCGM is a minimum of twice the cost of isCGM, offering rtCGM first line to the remaining 80% of the population will have a considerable cost impact and may not be affordable for some health systems. The use of rtCGM should be reserved for patients with the greatest clinical need e.g., children with persistent severe hypoglycaemia where a trial of isCGM has failed or children diagnosed with T1DM aged below age 2 years. NICE should provide clear criteria to define these patients to ensure equitable access to these technologies. 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.	Thank you for your comment and for raising concerns around funding. 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	Q3		Q What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.) A. Additional funds via a central budget or local budget uplift provided in order to 'invest to save' and to prevent local variations in access to these technologies.	Thank you for your comment and for raising concerns around funding. 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.
Families with Diabetes National Network	EIA	General	General	FWD were worried to see on the NPDA how inequalities in CGM access existed to the detriment of those from lower socio-economic groups & BAME groups. It is important that	Thank you for your comment. The committee were concerned that despite the positive recommendation for CGM in CYP with type 1 diabetes, inequalities may still occur with uptake of CGM being lower in certain groups. To address this the

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				barriers to rtCGM use are looked at eg language, access to technology.	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.
Families with Diabetes National Network	Guideline	004	009	Important that this is for all children. Important that education is given alongside. (In our FWD CGM survey of families in 2016 76% of those using CGM were self taught. This in itself means that access is unequal)	Thank you for your comment. Your suggested addition of all has been added to recommendation 1.1.9.
Families with Diabetes National Network	Guideline	004	013	Important to have the option of flash if rtCGM is unsuitable for any reason	Thank you for your comment.
Families with Diabetes National Network	Guideline	004	017	Choice of rtCGM is really important. Agree with all the factors in the Box 1. Some sensors work better for some people. Some insulin pump /CGM combinations are more suitable.	Thank you for your comment and agreement with the factors in box 1.
Families with Diabetes National Network	Guideline	006	001	Agree that a team with expertise is important. Diabetes teams should ensure training in use of CGM is available & kept updated for all healthcare professionals involved.	Thank you for your comment.
Families with Diabetes National Network	Guideline	006	004	There should still be the option of using capillary BG monitoring. It is also important that those using CGM are allowed capillary BG tests as these are still necessary at times eg if CGM fails , if CGM appears inaccurate & for checking when hypoglycemic to judge if hypo treatment has been sufficient in view of the lag in CGM. Undoubtedly will need less capillary strips but it is important that strips are not restricted.	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 1.1.7).
Families with Diabetes National Network	Guideline	006	007	Important that all patients know about CGM & what it does & the benefits, & that barriers are not there such that some groups do not know about it.	Thank you for your comment. Recommendation 1.1.9 outlines that continuous glucose monitoring should be included in the continuing programme of education provided to all children and young people with type 1 diabetes and their families or carer, and to ensure that children and young people using it are empowered to do so.

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Families with Diabetes National Network	Guideline	006	013	Agree that CYP are empowered to use CGM effectively	Thank you for your comment.
Families with Diabetes National Network	Guideline	006	017	Really important that > 70% use of CGM is supported in a positive & encouraging way & that judgements are not made on why CYP are not using as much	Thank you for your comment. The committee agreed with your sentiment and added to recommendation 1.1.11 that If the child or young person is not using their device at least 70% of the time, discuss with them any possible barriers or problems in using the device and **offer further emotional and psychological support** and education to overcome these.
Families with Diabetes National Network	Guideline	008	027	Agree it is important to research use in Type 2 diabetes	Thank you for your comment.
Families with Diabetes National Network	Guideline	009	001	Agree use of real world data should be used. In the past studies have been too limited.	Thank you for your comment. NICE is currently exploring how real-world data can feed into our future guideline updates.
Families with Diabetes National Network	Guideline	009	007	Agree need research, pooling of knowledge, investment & openness by CGM companies into sensor adhesive sensitivities & then easy widespread access to information on strategies for Families /CYP to deal with, rather than currently those affected having to rely on social media advice.	Thank you for your comment and useful feedback.
Families with Diabetes National Network	Guideline	010	001	Agree with & commend the well thought out rationale for rtCGM use. It cannot be underestimated the quality-of-life benefits to families/CYP of using rtCGM - Alarms & remote monitoring give back sleep to both parents & CYP, enable access to education & residential trips, participating in sports & activities while relieving parents anxiety with remote monitoring. - Alarms help with both CYP & family fear of hypoglycemia. - Families & CYP are better able to see trends & what factors influence their BG & use that information to manage their diabetes. CGM helps with exercise & at times of illness	Thank you for your comment. The committee agreed with the sentiment outlined in your feedback.

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				- In our FWD Outcomes survey in 2014 severe hypos & hypos at night were the things that worried families & also CYP the most. In our CGM survey 88% of parents felt their anxiety was reduced with CGM use, 96% felt they had more independence, 78% had an improved HbA1c, majority of families had improved sleep with use of CGM & also in use of remote monitoring	
Families with Diabetes National Network	Guideline	012	016	Broader access & funding is vital. In the past we agree those families that can advocate for their CYP +/or can self fund CGM have gained access & seen the benefits.	Thank you for your comment. The committee were in agreement. By offering rtCGM to all CYP with type 1 diabetes this should broaden access to this technology.
Families with Diabetes National Network	Guideline	General	General	We wholeheartedly agree with the new recommendations based on real lived experience of use of rtCGM in CYP (children & young people).	Thank you for your positive comment.
Families with Diabetes National Network	Guideline	General	General	These are a few comments from our CGM survey "I won't have to finger prick all the time"; "So I can feel safer when I'm high or low and it can be caught before it gets bad"; "I would get less worried about diabetes" ; "I wouldn't worry about going low and dying when I'm asleep" ; " to help me look after my diabetes better and more independently"; "my mum and dad can do my night-time tests without waking me"; "because my fingers are sore"; "I do not have any hypo awareness and can feel anxious about losing control of my body because of a low"; "to help manage my condition"; "I would have more freedom".	Thank you for providing feedback from your CGM survey.
Families with Diabetes National Network	Questions	Q1		Q1. Increased access to rtCGM will hopefully have a massive impact on families. Challenges will be time taken to train families & CYP & it is important that CYP can get timely access to CGM & not be waiting for months or years. It is also important that there is a clear pathway to funding that is equal to all families & not dependent on families being able to navigate the funding pathway.	Thank you for your comment and for raising the issue of funding. 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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Families with Diabetes National Network	Questions	Q2		There will be a cost to provision of CGM & training/education but in the longer term we would hope that better outcomes in better blood glucose management & time in range, less stress in managing BG, hypo fear, reduced DKA & reduced complications will outweigh those costs	Thank you for your comment. The committee were in agreement. The committee recognised and acknowledged this implementation issue However, they agreed that the clinical and cost-effective benefits associated with the promotion of CGM in children and young people with type 1 diabetes were worth the costs and resources associated in implementing this recommendation and ultimately improving care for children and young people with type 1 diabetes.
Families with Diabetes National Network	Questions	Q3		Training time - streamlining education, group training, use of device company staff to help with training.	Thank you for your comment. The committee recognised and acknowledged this implementation issue However, they agreed that the clinical and cost-effective benefits associated with the promotion of CGM in children and young people with type 1 diabetes were worth the costs and resources associated in implementing this recommendation and ultimately improving care for children and young people with type 1 diabetes.
Juvenile Diabetes Research Foundation (JDRF)	Guideline	004	009 - 016	JDRF agrees with the recommendation to offer all children and young people with type 1 diabetes a choice of real-time continuous glucose monitoring alongside education, and intermittently scanned CGM if they are unable to use real-time CGM or express a clear preference for isCGM.	Thank you for your positive comment.
Juvenile Diabetes Research Foundation (JDRF)	Guideline	004	017 - 019	JDRF agrees with the recommendation to offer children and young people a choice of real-time CGM based on their individual preferences, needs, characteristics, and the functionality of the devices available; We suggest adding "having first undertaken a process of shared decision making between patient and clinician" after the word "available".	Thank you for your comment. The committee agreed with your feedback. Recommendation 1.1.5 refers to using shared decision making to identify the child or young person's needs and preferences and offer them an appropriate device.
Juvenile Diabetes Research Foundation (JDRF)	Guideline	005	004	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. Considering feedback from other stakeholders, the committee added the following factor to box 1 - the ways in which data can be extracted, its ease of use with other technologies and whether it can be shared with the child or young person's healthcare provider to help inform treatment.
Juvenile Diabetes Research	Guideline	006	007	JDRF agrees with the recommendation to ensure continuous glucose monitoring is included in the continuing programme	Thank you for your comment.

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Foundation (JDRF)				of education provided to children and young people with type 1, and their families and carers.	
Juvenile Diabetes Research Foundation (JDRF)	Guideline	006	021	The most recent National Paediatric Diabetes Audit showed that children from minority ethnic or socially deprived backgrounds have lower uptake of technology to help manage their type 1 diabetes, and children living in socially deprived areas experienced higher average blood glucose levels than those in less deprived areas.[1] This could lead to further disparity in health outcomes given the benefits that technology can provide, meaning all who could benefit from it should be able to access it if they choose. We suggest an extra recommendation should be added to the guideline to encourage access to technology amongst groups experiencing health inequalities such as above, with local health commissioners responsible for monitoring this to prevent the gap widening.	Thank you for your comment. The committee were concerned that despite the positive recommendation for CGM in CYP 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.
Manchester University Hospitals NHS Foundation Trust	General	General	General	We did wonder whether NICE might produce a shorter, easier to read, illustrated version of the new guidelines aimed for children and families explaining the options that they have, why the guidelines have been changed and how they might continue to evolve with research and advances in technology.	Thank you for your response. Your comments will be considered by NICE where relevant support activity is being planned.
Manchester University Hospitals NHS Foundation Trust	Guideline	General	General	The Draft Guidelines have been shared for comment across the Children's Diabetes Services in the Trust, Royal Manchester Children's Hospital, Wythenshawe Hospital and North Manchester General Hospital with the Consultants, Diabetes Specialist Nurses and Paediatric Dieticians. We unanimously welcomed these new guidelines in offering support and flexibility to children and young people in choosing the most appropriate device and method of glucose monitoring. We agree that there does need to be high level support from teams in interpreting the data from devices in an ongoing way to optimise blood glucose control. As the largest	Thank you for your positive feedback.

[1] RCPCH, National Paediatric Diabetes Audit, 2019/20

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				service in terms of total patient numbers at the Trust we have already set up a technology guidelines group across the 3 sites to produce local guidelines on how to make the best offer of CGMS, insulin pumps and closed loop systems for children and their families and we consider that the new guidelines will strongly support our plans. Thank you.	
Medtronic Ltd	General	General	General	We thank the committee for their careful consideration of the evidence and we agree that the draft recommendations reflect the evidence base.	Thank you for your comment.
NEL Commissioning Support Unit	Guideline	004	009 - 012	Paragraph 1.2.63. We are concerned that implementing the guidance would be a significant cost pressure for CCGs. This will be a challenge to implementation.	Thank you for your comment. The committee agreed that the results of the clinical review, and the cost-effectiveness results extrapolated from the adult type 1 diabetes population, clearly demonstrated rtCGM was cost-effective for the full population of children and young people with type 1 diabetes, and therefore agreed it would represent an efficient use of NHS resources to fund this technology. 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	004	009 - 012	Paragraph 1.2.63. CCGs will need to be convinced of the scaling of benefits of CGM for children. For example, what is the extent of benefit of CGM to patients without recent and severe hypoglycaemia (low-risk cohort) compared to patients with impaired awareness/ recent and severe hypoglycaemia (high-risk cohort), and what might be the (possibly higher) discontinuation rate in the low-risk cohort?	Thank you for your comment. The committee considered that the evidence of clinical and cost effective benefits were strong enough to justify recommending continuous glucose monitoring to all children and young people with type 1 diabetes regardless of whether they are low or high risk.
NEL Commissioning Support Unit	Guideline	010	014 - 018	We are concerned regarding the proportionate use of evidence. The committee notes that for Flash monitoring, no clinically meaningful effect was seen for any of the outcomes that were looked at in the evidence review. Yet the committee (see line 26-28, page 10) agree that Flash should be used by	Thank you for your comment. The committee agree that the evidence review found that where there was an effect it consistently favoured the use of rtCGM. Furthermore, the evidence showed key outcomes favoured rtCGM over the self-monitoring of blood glucose, the committee

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				children who are unable to use or do not want to use CGM and would prefer Flash. We think that in this situation there should be, in relation to the lack of evidence, an indication of higher need at the least.	recommended rtCGM use first in all children and young people with type 1 diabetes, only offering isCGM if rtCGM is not preferred or contraindicated. However, the committee also agreed that for the small number of people who want to use CGM but are unable to use any of the available rtCGM devices, it would not be appropriate to deny them access to the technology. In particular, because the key reason rtCGM was found to be more beneficial in children was because of concerns around adherence, they agreed that children or young people who express a clear, informed preference for isCGM over rtCGM were more likely to adhere to using the technology, and therefore achieve benefits from it.
NEL Commissioning Support Unit	Guideline	010	019 - 022	"Because the evidence showed similar benefits of real-time CGM for children and young people as for adults, the committee extrapolated the cost-effectiveness from adults, concluding that real-time CGM was cost effective in this population." We are concerned about this because it may apply extrapolation beyond the point at which we would be comfortable. Children and young people are a different population with, potentially, different rates of capillary testing, different adherence and a different impact on quality of life – for both children and parents. We would be interested in seeing the economic model.	Thank you for your comment. The committee agreed there would be limited value in additional modelling specific to children and young people because of the extra uncertainties in the CORE diabetes model for that population. In the absence of any economic evidence specific to children and young people with type 1 diabetes, and with clinical evidence showing benefits for rtCGM in children and young people, the committee agreed that the technology should be at least as cost-effective in children and young people as in adults. This was because there are some situations where the same outcomes would be expected in children and adults (for example, the direct quality of life impact of a hypoglycaemic event) and some where the benefit might be larger in children (for example fear of hypoglycaemia, where both the child and their parents/guardians may experience this fear), but nothing where the impact in children would be expected to be less. The committee also made specific recommendations around addressing adherence, given their experience that this may be an issue for some children and young people using continuous glucose monitoring.

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NEL Commissioning Support Unit	Guideline	General	General	We are concerned about pressure on workforce. Whether a CCG adopts the new guidance with initiation by a consultant or a GP / GP with specialist interest, the workforce implications may be significant in terms of initiation of CGM to a wider population and monitoring progress in a timely and effective manner. This is a challenge to implementation.	Thank you for your comment. The committee recognised and acknowledged this implementation issue However, they agreed that the clinical and cost-effective benefits associated with the promotion of CGM in children and young people with type 1 diabetes were worth the costs and resources associated in implementing this recommendation and ultimately improving care for children and young people with type 1 diabetes.
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Evidence review	026	003	We are concerned that the evidence on cost effectiveness of rtCGM extrapolated from the adult population is not sufficiently robust to support the recommendation to offer it as a first line option to all children and young people with Type 1 diabetes. The adult assessment concludes that rtCGM is only cost effective if fear of hypoglycemia is factored in. This is a subjective measure and therefore this evidence, from a commissioning perspective, is not adequate and not robust enough to support routine commissioning for all patients and the financial commitment needed by the system.	Thank you for your comment. In the absence of any economic evidence specific to children and young people with type 1 diabetes, and with clinical evidence showing benefits for rtCGM in children and young people, the committee agreed that the technology should be at least as cost-effective in children and young people as in adults. This was because there are some situations where the same outcomes would be expected in children and adults (for example, the direct quality of life impact of a hypoglycaemic event) and some where the benefit might be larger in children (for example fear of hypoglycaemia, where both the child and their parents/guardians may experience this fear), but nothing where the impact in children would be expected to be less. The committee also agreed that fear of hypoglycaemia is an factor to consider in the economic evaluation among children and young people. Previous studies showed that the use of rtCGM would significantly improve the sleeping quality of CYP and their carers by reducing their fear of hypoglycaemia. Therefore, the benefit of rtCMG for CYP would be larger than for the adult population due to more utility gains related with fear of hypoglycaemia. We agree that fear of hypoglycaemia is a subjective measure, but we do not agree this is a reason to consider it less important. The studies used established, validated scales to measure fear of hypoglycaemia, and there is a validated relationship between fear of hypoglycaemia and quality of life.

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					The fact this is patient reported a subjective measure therefore is not reason to discount the accuracy or importance of these results.
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Guideline	004	009	We are concerned that the evidence on cost effectiveness of rtCGM is not sufficiently robust to support the recommendation to offer it as a first line option to all children and young people with Type 1 diabetes. rtCGM should be offered to children with the most need such as those who have persistent severe hypoglycaemia where a trial of isCGM has failed or children diagnosed with T1DM aged below age 2 years.	Thank you for your comment. The committee agreed that the results of the clinical review, and the cost-effectiveness results extrapolated from the adult type 1 diabetes population, clearly demonstrated rtCGM was cost-effective for the full population of children and young people with type 1 diabetes, and therefore agreed it would be inappropriate to restrict the intervention to only a subset of that population. In contrast, the review found no evidence of benefits from isCGM in children and young people. The committee agreed that isCGM has a number of limitations in its functionalities, which made it difficult to be managed by CYP or their parents and therefore often has a lower adherence rate, making it less cost-effective overall. 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	005	003	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 would not be appropriate to routinely offer integrated rtCGM as an option. The cost of £2k per year for CGM is below the average cost that CCGs pay currently and so if used does not provide an accurate cost-effectiveness assessment. Should integrated CGM be included in this guidance as it is noted that such systems are being considered in other	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

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				guidance that is being updated by NICE? If so, there should be a statement in this guidance that it does not include integrated CGM.	correctly only considers the costs of CGM (and not insulin pumps). 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	005	003	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.	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 the factors to consider when choosing a continuous glucose monitoring device outlined in Box 1 it includes the child or young person's insulin pump and whether a particular device integrates with their pump as part of a hybrid closed loop or insulin suspend function. This reflects your identified clinical need.
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Guideline	005	003	We do not think it is appropriate to use the term 'cosmetic factors' in the guidance. The NHS considers treatment for cosmetic purposes a low priority and does not fund it. The most cost-effective device that meets the child or young person's clinical need and that they are able to use effectively should be offered.	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 all children and young people 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	Guideline	005	003	The guidance should contain a statement that 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. We have added a recommendation (rec 1.1.5) to say that when multiple devices are identified as meeting the child or young person's identified needs and preferences, the device with the lowest cost should be used.

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Group (NHS BSW CCG)					
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Guideline	006	017	Discontinuation criteria are needed to ensure that technology being provided is being used appropriately and is beneficial.	Thank you for your comment. The committee considered your feedback and agreed that rather than setting a criterion for discontinuing treatment, if a child or young person is not using their device 70% of the time to use this as an opportunity to discuss with them any possible barriers or problems in using the device and offer further emotional and psychological support and education to overcome these (recommendation 1.1.11).
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Guideline	General	General	NHS BSW CCG agrees with the comments being made on this guidance by the PresQIPP organisation that we are subscribers to. 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 children and young people. 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. 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 children and young people live. The guideline produced should acknowledge the reality of affordability and provide clear criteria for prioritising patients	Thank you for your comment. The committee agreed that the results of the clinical review, and the cost-effectiveness results extrapolated from the adult type 1 diabetes population, clearly demonstrated rtCGM was cost-effective for the full population of children and young people with type 1 diabetes, and therefore agreed it would be inappropriate to restrict the intervention to only a subset of that population. 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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				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. 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.	
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Questions	Q1		Q Which areas will have the biggest impact on practice and be challenging to implement? Please say for whom and why: Providing rtCGM to every child with type 1 diabetes will be unaffordable to most CCGs. Families need a huge amount of support from specialist teams to be able to get the most out of this technology and we do not have trained staff available to suddenly join the teams to increase their ability to support such a large number of patients.	Thank you for your comment and for raising concerns around funding. 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. The committee recognised and acknowledged this implementation issue However, they agreed that the clinical and cost-effective benefits associated with the promotion of CGM in children and young people with type 1 diabetes were worth the costs and resources associated in implementing this recommendation and ultimately improving care for children and young people with type 1 diabetes. Your comments will be considered by NICE where relevant support activity is being planned.
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 the recommendations are unaffordable to our health system and could only be funded by removing funding from other areas. rtCGM is far more expensive than isCGM and for some patients, isCGM will be all that they need. We need to offer rtCGM to those patients that clinically need the more expensive technology due to their clinical circumstances. There needs to be criteria available to distinguish between	Thank you for your comment and for raising concerns around funding. 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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				those patients that could use isCGM vs those that need rtCGM.	
NHS Bath and North East Somerset, Swindon and Wiltshire Clinical Commissioning Group (NHS BSW CCG)	Questions	Q3		Q What would help users overcome any challenges? (For example, existing practical resources or national initiatives, or examples of good practice.) Additional funds via a central budget or local budget uplift provided. Discontinuation criteria as well as clear criteria for who should access the technologies according to their clinical need.	Thank you for your comment and for raising concerns around funding. 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 England – Diabetes Team	Guideline	General	General	Please see below the comments from the NHS England Diabetes team on this guideline: 'No comments from our end- thank you for an excellent overview and recommendations'	Thank you for your positive comment.
Novo Nordisk	Guideline	004	008 - 019	**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.** We support the recommendation that real-time continuous glucose monitoring (CGM) should be offered to all children and 10 young people with type 1 diabetes and that intermittently scanned continuous glucose monitoring (isCGM) should be offered to those aged 4 and over who are unable to use a real-time CGM or where an isCGM is their preference. We support increased access to these technologies that can help children and young people in managing their type 1 diabetes. In recognition of the different ways in which people children and young people and their families/carers use their data from CGMs/isCGMs, for example linking this to their smartphone, and in anticipation of future technologies with additional capabilities for shared data platforms which can	Thank you for your comment. We have added your suggested text to box 1 in the guideline.

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				include insulin dosing data alongside CGM data, we recommend a small addition to the wording in Box 1, Factors to consider when choosing a continuous glucose monitoring device: *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 to help inform treatment.* This is in line with ensuring patient choice and preferences that are in line with their individual needs.	
Novo Nordisk	Guideline	005	002 - 003	**Guidelines should include reference to the need for shared decision making between clinicians, children and young people and their families in determining which glucose monitoring device to use** 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. To ensure that children and young people and families and carers have sufficient opportunity to express their needs and preferences in deciding which type of glucose monitoring device to offer, we recommend that an additional line on page 5 (between lines 2 and 3) should be inserted to make explicit reference to the need to adhere to a process of shared decision making between children and young people/ families and carers and clinicians in deciding which device is right for them. We recommend that the line is inserted as follows: *"Offer the continuous glucose monitoring device that meets the children or young person's identified needs and preferences, having first undertaken a process of shared decision-making between the clinician and child or young person living with type 1 diabetes and their family or carer."*	Thank you for your comment. The committee agreed with your feedback. Recommendation 1.1.5 refers to using shared decision making to identify the child or young person's needs and preferences and offer them an appropriate device.

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Novo Nordisk	Guideline	006	020 - 021	**The guidelines should reference the need for clinicians to adopt a proactive approach in offering access to glucose monitoring devices to children and young people who could benefit from them, particularly taking in to account evidence of existing inequalities in access** We believe the NHS should take steps to ensure that all children and young people living with type 1 diabetes are proactively offered a choice of continuous glucose monitoring device, should they wish to use one, to help improve access and to help support the implementation of this guideline recommendation. The most recent National Paediatric Diabetes Audit found that while the number of children and young people in England and Wales using a real time continuous glucose monitor in 2019/20 had increased compared to the previous year, with one-fifth of children using the technology, the data showed that use was lowest in children and young people from socially deprived areas and from ethnic minority communities.[1] To help address this particular disparity, we recommend that an additional section is added to the guidelines between lines 20 and 21 on page 6, requiring local health commissioners to support clinicians to proactively identify those children and young people from socially deprived areas and ethnic minority communities living with type 1 diabetes and that commissioners should be required to regularly monitor their uptake of and access to glucose monitoring devices. **Reference:** Royal College of Paediatrics and Child Health (2021), National Paediatric Diabetes Audit – National Report 2019/20: Care Processes and Outcomes.	Thank you for your comment. The committee were concerned that despite the positive recommendation for CGM in CYP 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. Thank you. The committee were concerned that despite the positive recommendation for CGM in CYP 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.

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Obesity Group of the British Dietetic Association	Guideline	006	001 - 003	We agree that a team should be involved but would like this to specify inclusion of a dietitian specialised in working in this area with children and young people. This is needed to ensure that diabetes is controlled and monitored but also to ensure that energy and nutritional needs for growth, development and wellbeing are met.	Thank you for your comment. The committee considered this issue and agreed that training should be provided by a healthcare specialist in diabetes which could include a state registered dietitian specialist.
Obesity Group of the British Dietetic Association	Guideline	008	012 - 016	We agree that research is needed on the impact on children and young people of dietary advice based on glycaemic index.	Thank you for your comment.
Royal College of Nursing	Guideline	014	016	It is pertinent to revise the wording of the guideline to reflect evidence of the benefit for rtCGM and that access to this technology is now broadly equitable and not driven by severe clinical presentation such as severe or frequent hypoglycaemia	Thank you for your comment. By offering real-time continuous glucose monitoring to all children and young people with type 1 diabetes alongside education to support them and their families and carers we hope this will address these barriers and will not be driven by severe clinical presentation.
Royal College of Nursing	Guideline	015	003	Important to still offer guidance toward the continued use of capillary blood glucose monitoring	Thank you for your comment. In response to stakeholder feedback the committee agreed to add a recommendation acknowledging the importance of capillary blood glucose monitoring and that it is still needed as a back up to real-time CGM and isCGM and to ensure they have enough test strips to do this (rec 1.1.7).
Royal College of Paediatrics and Child Health	Guideline	General	General	Although CGM delivers blood glucose readings automatically at short intervals, twice-daily finger sticks are usually necessary to calibrate the CGM for accuracy.	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 backup and to calibrate CGM (rec 1.1.7).
Royal College of Paediatrics and Child Health	Guideline	General	General	CGM machines are prescription-only and expensive. The ADA's Standards of Medical Care in Diabetes notes that there is no "one-size-fits-all" approach to technology use in people with diabetes. *Reference: What to Know About Continuous Glucose Monitoring* *By Caroline Messer, MD Updated on September 14, 2021* *Medically reviewed by Do-Eun Lee, MD*	Thank you for your feedback.

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Royal College of Paediatrics and Child Health	Guideline	General	General	Advise finger stick glucose test if symptoms don't match sensor reading. Especially at night as there may be compression lows.	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 1.1.7).
Royal College of Paediatrics and Child Health	Guideline	General	General	Patients may over treat hyperglycaemia (repeatedly giving insulin because the glucose levels do not fall rapidly enough, a phenomenon known as stacking), as well as over treat low glucose levels (because the glucose levels rise slowly with ingestion of carbohydrates). *Reference: What are the limitations of continuous glucose monitors (CGMs) for the treatment of type 1 diabetes mellitus (DM)?* *Updated: Oct 08, 2021* *Author: Romesh Khardori, MD, PhD, FACP; Chief Editor: George T Griffing, MD*	Thank you for your comment.
Royal College of Paediatrics and Child Health	Guideline	General	General	The reviewer is happy with this comprehensive diabetes guideline for children.	Thank you for your comment.
South East Coast and London Children and Young People's Diabetes Partnership	Guideline	004	009	We welcome the changes to 1.2.63 to 70. These changes will ensure access to technology for more individuals in an equitable manner and improve overall outcomes	Thank you for your positive feedback.
South East Coast and London Children and Young People's Diabetes Partnership	Guideline	004	010	There are other causes of diabetes than autoimmune Type 1 where there is absolute insulin deficiency such as cystic fibrosis related diabetes where there is clear evidence linking glycaemic control to lung function. Autoimmune diabetes and cystic fibrosis related diabetes both share loss of beta cells so it seems unfair to exclude cystic fibrosis related diabetes just because it does not have an autoimmune basis but shares exactly the same end result loss of beta cells. In addition the	Thank you for your comment. The committee discussed this issue and agreed that children and young people with insulin insufficiency due to other medical causes and conditions would be treated the same as children and young people with type 1 diabetes. The committee also acknowledged the challenges of treating these populations.

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				finger clubbing in cystic fibrosis precludes the use of finger prick blood glucose testing.	
South East Coast and London Children and Young People's Diabetes Partnership	Guideline	015	003	The current published data suggests that better control is attained with a minimum of 7 finger prick blood glucose tests per day	Thank you for your comment. Recommendation 1.2.71 on the number of capillary blood glucose checks per day was beyond the scope of this guideline update.
University College London Hospital NHS Foundation Trust	Evidence review	General	General	Please consider Johnson SR, Holmes-Walker DJ, Chee M, Earnest A, Jones TW. Universal subsidized continuous glucose monitoring funding for young people with type 1 diabetes: uptake and outcomes over 2 years, a population based study. Diabetes Care 2021 *https://doi.org/10.2337/dc21-1666*	Thank you for your comment. The study is based on Australian data and shows that the uptake of CGM can be as high as 79%, which is in line with our evidence. Whilst this study does not meet the criteria for inclusion in the guidance (as it is neither a randomised controlled trial nor a cost-utility study), we do not believe there is anything in the findings of it that contradicts any of the recommendations made.
University College London Hospital NHS Foundation Trust	Guideline	004	009	1.2.63 We agree with this recommendation, we would like to see some clarity around the use of CGMS in under 2 years of age to enable teams who may have concerns about off licence use have the confidence to use CGMS in this younger age group or make referrals to centres with experience to support the use.	Thank you for your comment. The committee considered that off-license use of continuous glucose monitoring (and indeed some insulins) in children under 2 years is a common practice for paediatric healthcare professionals and that further clarification was not needed.
University College London Hospital NHS Foundation Trust	Guideline	006	021	1.2.71 We do not believe that 5 capillary glucose checks a day is sufficient to achieve optimal outcomes and target HbA1c of below 48mmol/L. Where children, families and young people choose to use capillary glucose monitoring they should not be disadvantaged by limitations on numbers of strips prescribed. We believe current evidence suggests that 7-8 capillary glucose tests are required a day for optimal outcomes.	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 1.1.7). Recommendation 1.2.71 on the number of capillary blood glucose checks per day was beyond the scope of this guideline update.
University College London Hospital NHS	Guideline	007	003	1.2.73 – we would encourage the committee to consider strengthening this recommendation to include the provision of bolus calculators to optimise blood glucose management and reduce diabetes burden and hypoglycaemia risk	Thank you for your comment. The provision of bolus calculators was beyond the scope of this guideline update.

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Foundation Trust					
University College London Hospital NHS Foundation Trust	Guideline	012	026	Context – please update to support continuation of therapy in adult services to include continuation of funding of CGMS or flash	Thank you for your comment. The update of the adults with type 1 diabetes guideline recommends offering a choice of real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring so this should support continuation of therapy to adult services.
University College London Hospital NHS Foundation Trust	Guideline	013	006	We believe the statement that much of the general Type 2 diabetes care is similar to type 1 diabetes to be incorrect and does not reflect current management of Type 2 Diabetes in children and adolescents.	Thank you for your comment. The management of type 2 diabetes in children and young people was beyond the scope of this guideline update.
University College London Hospital NHS Foundation Trust	Guideline	General	General	We agree with the conclusions and recommendations of the guideline and believe that CGMS should be the first line strategy for CYP living with Type 1 Diabetes provided they are able to use the technology.	Thank you for your positive comment.
University College London Hospital NHS Foundation Trust	Guideline	General	General	We believe that the use of Type 1 and Type 2 diabetes should be expanded so that those children and young people who effectively have Type 1 Diabetes due to other treatments e.g., pancreatectomy are clearly covered by this guideline.	Thank you for your comment. The committee discussed this issue and agreed that children and young people with insulin insufficiency due to other medical causes and conditions would be treated the same as children and young people with type 1 diabetes. The committee also acknowledged the challenges of treating these populations. This issue has been clarified in the guideline.
University College London Hospital NHS Foundation Trust	Questions	Q1		Implementation - This guideline will have impact on trust finances if funding is not received from the CGG/ICS with whom the funding responsibility lies. Pathways for funding will need to be clearly identified so that money transfers appropriately. Decreased use of glucose test strips and prescriptions by GP will offset a significant proportion of the cost of use of CGMS.	Thank you for your comment and for raising concerns around funding. 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.
University College London Hospital NHS	Questions	Q1		Implementation - A potential challenge of implementation will be use of CGMS and/or Flash from diagnosis and hospital systems for in patient management will require review.	Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned.

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University College London Hospital NHS Foundation Trust	Questions	Q4		Research Recommendations - We agree with the removal of research recommendations 1 to 6	Thank you for your comment.

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