Diabetes in children and young people (update)

Consultation on draft guideline - 10/12/14 to 05/03/15
Stakeholder comments table

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Psychological Society	FULL	General	General	The Society's view is that psychological adjustment and adherence issues are similar in children and young people across all types of long-term and life-limiting conditions because the psychological processes underpinning them are not disease-specific. There is therefore a rationale for including a review of the evidence for psychological interventions in children with long-term conditions as a whole within this scope, particularly given the limited literature on psychological interventions in diabetes in children. There is also a rationale for broadening the scope to include relevant diabetes research conducted in adult populations, albeit that they should be interpreted with care. Not including the broader, existing and relevant literature has led to a skewed view of the evidence and inappropriately narrow recommendations.	Thank you for this comment. The guideline development group acknowledge the points made in relation to the extrapolation of evidence from other long-term conditions and adult populations. At the time of protocol development the option of including studies that enrolled participants with other conditions was considered, but the guideline development group concluded that there were issues specific to children and young people with diabetes that were not present in other conditions. Also, due to concerns around the interpretation of such data and their reliability for informing national recommendations, indirect evidence is typically sought only if there is no evidence available in the population of interest. The need for more data directly relevant to this population has been reflected in research recommendations
British Psychological Society	FULL	General	General	General point that arises first on p3 (Introduction): Use of the term 'chronic' which is now being replaced with 'long-term' as the colloquial meaning of 'chronic' has distorted its use and is more negative than the intended original term.	Thank you for this comment. The term chronic has been changed to long-term in the introductions to the NICE and full guidelines to avoid any unintended negativity in phrasing in these prominent parts of the guidance. There are no other occurrences of chronic in the NICE guideline (short version). The term chronic has however been retained elsewhere in

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					the full guideline for consistency between the 2004 guideline text and the 2015 update text
British Psychological Society	FULL	General	General	There appears to be some confusion in the terminology to describe patient-reported outcome measures in the guidelines. Well-being is mentioned on many occasions, sometimes where it would be more appropriate to refer to quality of life. Well-being is not the same thing as quality of life Well-being can be measured over a shorter time period and questionnaires typically include items to measure mood states such as depressed, anxious mood and feeling stressed, as well as positive mood states and feeling energetic. Quality of life is assessed over a period of months or more and has been defined as how good or bad an individual feels their life to be. If someone is depressed or anxious their quality of life (QoL) is unlikely to be good but even in the absence of depression or anxiety, QoL might be severely affected by an inflexible and demanding treatment regimen that interferes with family life and activities that are important to the individual. (Pouwer F, et al, 2001) showed that routine assessment and discussion of well-being with a nurse improved mood compared with the standard care group. There is every reason to expect that similar benefits would be found for routine monitoring of well-being in children and teenagers. The Society advises caution when selecting a well-being measure for use with children and young people with diabetes. Generic measures of depression include symptoms that can be confounded with symptoms of diabetes. The W-BQ for adults was designed for use in diabetes and avoids using confounding symptoms. (Bradley, C. et al, 1994) References: Bradley, C., and Gamsu, DS: St. Vincent Declaration Action Programme for	Thank you for this comment. In the NICE guidelines manual, health-related quality of life is considered an important measure of effect for health economic evaluation. "The QALY is the measure of health effects preferred by NICE, based on patient-reported changes in health-related quality of life" and is thus always prioritised for inclusion in the systematic reviews. The terminology used in the evidence reviews is led by the reporting in individual articles. The guideline development group recognise that the use of the terms health-related quality of life and well-being in diabetes research has historically been inconsistent (Speight 2009). The protocols in Appendix E do not specify particular measures as the reviews aim to report whatever data are available. The validity and reliability of the scales is taken into consideration when evaluating the quality of the evidence and at the time of making recommendations. Please note evidence for routine monitoring of well-being was outside the

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				Diabetes (1994). Guidelines for encouraging psychological well-being: Report of a working group of the World Health Organisation Regional Office for Europe and International Diabetes Federation European Region St. Vincent Declaration Action Programme for Diabetes. Diabetic Medicine, 11, 510-516. http://www.ncbi.nlm.nih.gov/pubmed/8088133 Pouwer, F., Snoek, F.J., Henk, M., van de Ploeg, Ader, H.J., Heine, R.J. (2001) Monitoring of psychological well-being in outpatients with diabetes. Diabetes Care 24: 1929-35	scope of the guideline and therefore the guideline development group are unable to comment on that evidence **Speight 2009** Speight J, Reaney MD, Barnard K, Not all roads lead to Rome—a review of quality of life measurement in adults with diabetes, Diabetic Medicine, 26, 315–327, 2009
British Psychological Society	FULL	General	General	The Society notes that a psychologist was a member of the Guideline Development Group (GDG) in 2004, and, that, although a research health psychologist is an advisor to the 2015 panel, there is no clinical psychology representation on or advice to the GDG. We strongly recommend the addition of clinical psychology representation as well as health psychology within the core membership of the GDG for future NICE Guidelines for children with diabetes and other long-term conditions.	Thank you for this comment. Feedback on the proposed constitution of the guideline development group is sought at the stakeholder workshop before positions are advertised on the NICE website and other places such as NICE Twitter, social media and websites of stakeholders, medical Royal Colleges and professional organisations. Registered stakeholders are notified of the advertisements and the composition of the group for all NICE guidelines. Recruitment is conducted in accordance with NICE's policy and procedure for recruitment and selection to advisory bodies and topic expert groups. In this case, expert advice on the mental health literature was sought from an external adviser on an 'as-required basis', in line with the process outlined in the NICE guidelines manual.

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					The guideline content is subject to a public consultation and takes into consideration the feedback obtained from all stakeholders equally
British Psychological Society	FULL	General	General	Terminology around 'therapy' and 'intervention' is inaccurate throughout the document and particularly page 30 Line 23, Point 108. . • Behavioural intervention therapy – This is not a recognised therapy. • Cognitive Behavioural Therapy – this is not a behavioural intervention. Behaviour is a component of the model of therapy. It also does not focus on quality of life per se. CBT has been evidenced to be effective in multiple RCTs and reported in NICE guidance as the core intervention for anxiety disorders (including panic attack and post-traumatic stress), bipolar disorder, depression, OCD, chronic fatigue, chronic pain, eating disorders. • Multi-systemic therapy – This is not an evidence based intervention in diabetes. Evidence has only been growing in juvenile offenders and looked after children. • Mentoring – This is not a therapy or an intervention. • Motivational interviewing – this is not a behavioural intervention.	Thank you for this comment which highlights the inconsistent use of many of these terms within the field of study, not just the guideline. In the absence of clear definitions, the content of the interventions have been described in Table 37 in the full guideline. The guideline development group have amended the terminology in this section where required for clarity. Please note that the inclusion of interventions in the systematic review has been led by the evidence, regardless of whether the interventions are currently available in the UK, e.g. multi-systemic therapy
Coeliac UK	FULL	General	General	NICE guidelines for the treatment and management of coeliac disease are currently under consultation with publication anticipated in September 2015. The diabetes in children and young people update and coeliac disease update should be harmonised to ensure consistency within guidelines.	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (coeliac disease in this case). In the case of coeliac disease the guideline development group recognise that NICE

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					has produced separate guidance and so the recommendations in this guideline have been amended to cross-refer to the NICE coeliac disease guideline for guidance on monitoring for coeliac disease in children and young people with type 1 diabetes
Faculty of Pharmaceutical Medicine	FULL	General	General	Add a page near start of document for a list of abbreviations used. For example, BMI is not defined in the document as 'body mass index'. DKA is defined once as diabetic ketoacidosis.	NICE style is to define abbreviations at first use in each section, although certain abbreviations (such as BMI) are considered to be sufficiently well recognised by the general readership that they do not need to be defined. The full guideline does, however, include a list of abbreviations used
HQT Diagnostics	FULL	General	General	General Practitioners should test and supplement Fatty Acids to achieve: • Omega-3 Index: >8% • Omega-6/3 Ratio: <3:1 Re-test after 3 months Omega-3 Poly Unsaturated Fatty Acids (PUFA) are involved in glucose level control and insulin sensitivity More at: www.expertomega3.com/omega-3-study.asp?id=2 http://jama.jamanetwork.com/article.aspx?articleid=2088851 http://www.ncbi.nlm.nih.gov/pubmed/?term=phinney+SD www.hqt-diagnostics.com	Thank you for submitting comments in response to the stakeholder consultation. Please note that the consideration of dietary supplements is excluded from the 2015 update scope and as evidence related to this topic has not been reviewed the guideline development group cannot make recommendations in this area

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HQT Diagnostics	FULL	General	General	General Practitioners should test and supplement Vitamin D 25(OH)D to be between 100-150 nmol/L and re-test after 3 months Vitamin D - with co-factors such as Calcium and Magnesium – helps to prevent and treat Diabetes This should also reduce fatty deposition in the liver and also improve vascular reactivity. More at: www.vitamindwiki.com/Overview+Diabetes+and+vitamin+D http://www.eurekaselect.com/72897/article	Thank you for submitting comments in response to the stakeholder consultation. Please note that the consideration of dietary supplements is excluded from the 2015 update scope and as evidence related to this topic has not been reviewed the guideline development group cannot make recommendations in this area
National Children and Young People's Diabetes Network	FULL	General	General	Glycaemic Index: our dietitians agree with the principles of a low Glycaemic Index diet so that seems reasonable, but we would not usually write it down as such for patients, but consider it within our general healthy eating advice. i.e. not using the GI figures with patients for calculations to avoid confusion. Would it need to consider glycaemic load?	Thank you for this comment. The guideline development group considered this suggestion, but did not change the recommendations. Some children and young people with type 1 diabetes are familiar with the concept of glycaemic index. The recommendations are to advise taking account of glycaemic index. How that is explained to the child or young person should be based on their individual circumstances
Neonatal and Paediatric Pharmacists Group	FULL	general	General	The term "saline" is not an approved synonym – see above. The correct term is sodium chloride. The word saline appears numerous times on numerous pages throughout the FULL NICE Guideline	The phrase hypertonic saline has been changed to hypertonic sodium chloride as suggested
Royal College of Paediatrics and Child Health	FULL	general	general	The 2015 guideline is very comprehensive and has been carefully constructed. However, it is confusing in places and could be considerably condensed. For example much of the guidance for type 1 and type 2 diabetes is the same. It would be easier for the reader top have one guideline covering both type 1 and 2 and	Thank you for this comment. The guideline development group felt there was a strong rationale for keeping the recommendations for type 1 diabetes and type 2 diabetes

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				point out where there are differences in the guidance for the different type of diabetes.	separate: in practice the two sets of recommendations will be read as stand-alone documents; the separation makes the guidance more patient-focused; and the link to the separate guidelines on diagnosis and management of type 1 and type 2 diabetes in adults further emphasises the relevance of having separate sets of recommendations for the different conditions
Royal College of Paediatrics and Child Health	FULL	General	General	Hypoglycaemia section was not reviewed in detail	Thank you for submitting comments in response to the stakeholder consultation. Please note that the part of the guideline that deals with management of hypoglycaemia is excluded from the 2015 update and the evidence has not been reviewed since the original (2004) guideline
South West Paediatric Diabetes Network	FULL	General	General	Lots of the recommendations for type 2 diabetes are the same for type 1 therefore it is hard to spot what is different. Would it be worth just stating what is different for type 2?	Thank you for this comment. The guideline development group felt there was a strong rationale for keeping the recommendations for type 1 diabetes and type 2 diabetes separate: in practice the two sets of recommendations will be read as stand-alone documents; the separation makes the guidance more patient-focused; and the link to the separate guidelines on diagnosis and management of type 1 and type 2 diabetes in adults further emphasises the relevance of having

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					separate sets of recommendations for the different conditions
Families with Diabetes National Network	FULL	1.2.1	15	Education: In reference to this, FwDNN feel that a structured education programme needs to be in place from diagnosis. Families with children with diabetes spend just three hours (maybe less) a year in clinical settings with their team and over 8,000 hours caring for our children in a family and school setting.	There was no evidence identified to support structured education from diagnosis (structured here meaning a formal training or education package with a recognised curriculum and approaches to delivery). The guideline recommendations do, however, list core topics that should be covered as part of (unstructured) education
				We welcome the recommendations that advocate home care at diagnosis and especially 24 hour access; families need to feel supported. Clinicians need to instil confidence and offer timely and appropriate education for extended families, schools and HCP's (especially primary care) .	Thank you for this comment in support of the guideline. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (care setting at diagnosis and 24-hour access to the diabetes team in this case)
				We welcome the suggestion of peer led training, which is especially pertinent for teenagers and throughout transition. However we feel that topics such as dose adjustments and corrections should be included in education and information as a priority.	The reference to peer-led education is a recommendation for further research as no evidence was identified to support this practice currently. The guideline development group do, however, believe it has the potential to be effective for children and young people with type 1 diabetes. The additional topics suggested

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					in the comment as priorities for education are implicit in the list of core topics for education. Insulin dose-adjustment is recognised as being important and so it has been added to the first bullet in the list of core topics for children and young people with type 1 diabetes
Families with Diabetes National Network	FULL	1.2.18	18	Regimens: FwDNN feel that regimens advocated at diagnosis should reflect the very best that diabetes care has to offer. The inclusion of mixed insulin seems somewhat dated in light of the developments in insulin pump therapy and continuous glucose monitoring and the success that can be achieved by using such regimes. FwDDNN are also disappointed to see the omission of hyperglycaemia as a criteria for CGM use. The impact of high blood sugar levels are well documented in the long term health of individuals with Type 1 Diabetes. We therefore recommend the inclusion of persistent hyperglycemia as criteria for continuous glucose monitoring.	Thank you for this comment. The guideline development group did not feel that use of insulin regimens other than multiple daily injections (or insulin pump therapy if a multiple daily insulin injection regimen is not appropriate) was appropriate at diagnosis hence the strong recommendation to offer multiple daily injection regimens from diagnosis. The later recommendation referring to mixed insulin is included to cover those children and young people who might be using such a regimen although these are not recommended strongly The guideline development group made consensus recommendations about continuous glucose monitoring in children and young people with type 1 diabetes as they found very little evidence in the systematic review. They agreed that 'real-time' continuous glucose monitoring should be offered because it allows

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				FwDNN also strongly advise that recommendations are included that present families with a full range of choice of regimens at diagnosis.	immediate recognition of changes in blood glucose concentrations in relation to treatments and activities which should lead to more effective treatment choices. They also agreed that there was sufficient reason to justify considering the use of continuous glucose monitoring for some children and young people in whom tight glycaemic control might be of particular concern. They felt that the previous strong recommendation to offer continuous glucose monitoring to children and young people with recurrent hypo- or hyperglycaemia was still justified. The recommendations in the guideline emphasise individualised targets, informed choice and taking the 'whole child' into account. However, the specific recommendations reflect the evidence base identified through the systematic reviews conducted as part of guideline development and this has led to a preference for multiple daily insulin injection regimens (or insulin pump therapy if multiple daily injections are not suitable) from diagnosis as reflected in the recommendations
Families with Diabetes	FULL	1.2.59	25	Blood glucose testing: Of utmost concern to our Members is the proposal of the reduction of the current HbA1c target from 7.5% to 6.5%. It is felt that the revised	Thank you for this comment. The views expressed by stakeholders with regard to

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National Network				target is not achievable, especially with regard to the guideline proposals of just 5 blood glucose tests per day FwDNN, therefore, advocate that a minimum of 7 blood glucose tests be undertaken per day. FwDNN are also concerned that no mention has been made of night testing our children which forms a substantial area of care and contributes hugely to the safety, wellbeing, short and long term health of our children. We would therefore like a reference explicitly made in reference to night testing. We welcome outlining the upper limit and timing for blood glucose measurements after meals for children and young people with Type 1 diabetes, however strategies to achieve good postprandial blood glucose numbers should be explored thoroughly between the families, young people and their clinicians and teams, especially dieticians.	targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to

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					avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to makeUltimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline The reference in the comment to the minimum number of times per day that

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					blood glucose monitoring should be performed has been considered carefully. The revised recommendations emphasise that more frequent testing is often needed, and examples of situations where this would apply are provided in the recommendations. The minimum number of 5 tests per day is, however, based on the available evidence; there is no evidence to support an added clinical benefit of setting the minimum number at a higher level for all children and young people with type 1 diabetes. The guideline development group did not consider it necessary to make a specific recommendation about night-time testing, but the recommendations do not prevent this, since the timing of the minimum number of 5 tests that should be performed each day is not prescribed in the recommendations. The reference in the comment to exploring strategies for optimising postprandial blood glucose control is covered by the recommendations about education and dietary advice
Families with Diabetes National Network	FULL	1.2.68	27	HbA1c: It is overwhelmingly felt that the reduction in HbA1c target to 6.5% will adversely affect families, children and young people. It is felt that the lower target will be detrimental the wellbeing, not only of the child, but of their carer(s). We cannot emphasise just how strongly it is felt in the wider diabetes community that	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour

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				such decrease in the target would be unacceptable. It is felt that such a target could only be met with an increased frequency of lower range blood glucose levels , increasingly likelihood of hypoglyecimia This seems to contradict the recommendations that outline strategies for avoiding and managing hypoglyecimia. FwDNN therefore propose a target of 7%, and ask that the roll out of the amended target be handled sensitively. With this in mind, FwDNN welcome the commentary that highlights that children and young people should not experience problematic hypoglycaemia or undue emotional stress when attempting to achieve or maintain blood glucose and HbA1c targets. We are happy with the attempt to individualise care, by proposing to work with families to agree achievable HbA1c targets, taking into account life goals. FwDNN also are pleased with the section that highlights the awareness of the possible negative psychological impact of setting targets that are difficult to achieve and maintain.	the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these

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					specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline
Families with Diabetes National Network	FULL	1.2.78	28	Glucagon: FwDNN are ardent supporters of the prescription and training in the use of Glucagon from diagnosis; the recommendations should capture the training of all individuals who are involved in the care of our children (not just school nurses, but Teaching Assistants, for example).	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015

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					update, where the evidence has not been reviewed since the original (2004) guideline (recognition and management of hypoglycaemia in this case). The guideline development group do agree with the view expressed in the comment but feel that the recommendation about offering education about recognising and managing hypoglycaemia to children and young people with type 1 diabetes, their family members, carers, and schoolteachers addresses this
Families with Diabetes National Network	FULL	1.2.81	29	Glucogon: The prescription of Glucagon should be available from diagnosis as ongoing training given to those involved in the care of our children.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (recognition and management of hypoglycaemia in this case)
Diabetics with Eating Disorders	FULL	10.4	General	It is common knowledge that anorexia has the highest mortality rate of any mental illness but while the mortality rate for AN is 7 per 1000 and for type 1 Daiabetes is 2.2, combine the conditions and that mortality rate jumps to a truly depressing 34.6 per 1000 (Nielsen, Emborg &Mølbak 2002)	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (eating disorders in this case)
Diabetics with	FULL	10.4	217	Unlike anorexia, bulimia and binge eating disorder, insulin omission is not named	Thank you for submitting comments in

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Eating Disorders				as a mental health condition in its own right in the Diagnostic and Statistical Manual of Mental Disorders (DSM). Instead, insulin omission appeared in the DSM-IV subsumed under the criteria for bulimia. This reference has been built upon only slightly in the recently published DSM-5 by the additional inclusion of insulin omission under the criteria for anorexia nervosa Although another mention of insulin omission as clinically relevant is a welcome addition to the DSM-5, the position of DWED is that the failure to identify chronic insulin omission as a mental health condition in its own right is problematic. Under these diagnostic criteria, one may ask: "what is the difference between people with diabetes and anorexia and those with diabetes and bulimia?" Simply put, the answer is weight; however, determining eating disorder severity by weight is not relevant to people with type 1 diabetes who omit insulin. The measure of severity for this demographic would more accurately be HbA1c. Furthermore, these diagnostic criteria propagate the idea that one simply has anorexia or bulimia with diabetes as a footnote. We know that there are diabetes-specific environmental factors that contribute to the development of diabulimia and, perhaps more importantly, that eating disorder treatment programmes that do not address the diabetes-related factors fail abjectly (Rodin et al, 1991; Smith et al, 2008; Ismail et al, 2010). Currently, individuals who are identified as omitting insulin are usually referred to their local eating disorder service. The difficulty is that eating disorder professionals are not experts in diabetes or the psychological implications of diabulimia, often seeing the problem as one of food alone rather than one of food, insulin and all the other stresses of the diabetes	response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (eating disorders in this case)

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				regimen. This leads to inappropriate use of NHS resources and, therefore, increased costs, not only in the initial ineffective treatment, but also in the costs of dealing with people with seriously uncontrolled diabetes over the long term. There is also an impact on the individuals themselves, which include failure to maintain employment, reliance on benefits, deterioration in mental wellbeing and relationships and, at its worst, death . A person with type 1 diabetes who has an eating disorder, particularly insulin omission, cannot be dealt with in isolation by an eating disorder team. What DWED has observed to be effective is the patients' DSNs being proactive in collaborating with both the individuals and their eating disorder teams to guide and educate them as to how diabetes can be managed whilst the eating disorder is being treated. A multidisciplinary approach is the only effective way to treat a person with type 1 diabetes and an eating disorder. Taken from Allan & Nash (2015) Guidelines must take this into consideration. It is really important that treatment is able to address the often diabetes specific roots of eating disorders, simply palming these patients off to ED services that do not understand insulin omission is a waste of everyone's time and money. It is imperative that those treating Diabetics with Eating Disorders take a multi-disciplinary approach. It doesn't matter if a type 1 who omits insulin is 15 stone or 7 stone in DKA the risk is the same and somebody somewhere has to start protecting us regardless of weight.	
Diabetics with Eating Disorders	FULL	10.4	218	Signs and Symptoms collated from patients and published on the dwed website www.dwed.org.uk	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not

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				Signs and Symptoms Recurrent episodes of DKA/ Hyperglycaemia Recurrent episodes of Hypoglycaemia High HbA1c Frequent hospitalisations for poor blood sugar control Delay in puberty or sexual maturation or irregular menses / amenorrhea Frequent trips to the Toilet Frequent episodes of thrush/ urine infections Nausea and Stomach Cramps Loss of appetite/ Eating More and Losing Weight Drinking an abnormal amount of fluids Hair loss Delayed Healing from infections/ bruises. Easy Bruising Dehydration – Dry Skin Dental Problems Blurred Vision Severe Fluctuations in weight/ Severe weight loss/Rapid weight Gain/Anorexic BMI Fractures/ Bone Weakness Anaemia and other deficiencies Early onset of Diabetic Complications particularly neuropathy, retinopathy, gastroperisis & nephropathy Co – occurrence of depression, anxiety or other psychological disturbance i.e. Borderline Personality Disorder. Anxiety/ distress over being weighed at appointments Frequent Requests to switch meal plans Fear of hypoglycaemia Fear of injecting/ Extreme distress at injecting Continually requesting new meters (for the b.s. Solution) Injecting in private	able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (eating disorders in this case)

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				Insisting on having injected out of view Avoidance of Diabetes Related Health Appointments Lack of BS testing /Reluctance to test Over/ under - treating Hypoglycaemic episodes A fundamental belief that insulin makes you fat Assigning moral qualities to food (i.e. good for sugars/ bad for sugars) An encyclopaedic knowledge of the carbohydrate content of foods Persistent requests for weight loss medications If T1 is concurrent with hypothyroidism – abuse of levothyroxine Metformin abuse	
Diabetics with Eating Disorders	FULL	10.4.24	217	Since the 1980s researchers have investigated the rate of eating disorders in the Type 1 Diabetic population. Prevalence rates have varied wildly however and papers have been fraught with methodological problems. One of the main issues of contention is whether or not insulin omission for weight loss purposes is included as a feature of an eating disorder. In order to investigate these issues further it is necessary to look at how changing definitions in the Diagnostic Statistical Manual (DSM) have affected the diagnostic criteria for eating disorders and the role of insulin omission within them. The DSM III (1980) has no mention of Insulin omission in the guidelines for Eating Disorders and neither does the revised version (1987). Insulin Omission is first mentioned in the Eating disorders section in the DSM IV (1994) within the notes for bulimia, the same is published in the DSM IV revised (2000) 'Individuals with diabetes mellitus and bulimia nervosa may omit or reduce insulin doses in order to reduce the metabolism of food consumed during eating binges.' (p546)[i] Insulin omission may be viewed as a form of purging within the bulimia framework. In its most recent incarnation, the DSM V (May 2013) Insulin omission is included as a clinical feature of both Anorexia and Bulimia, in the clinical features of	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (eating disorders in this case)

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				Anorexia the following is written 'Individuals with anorexia nervosa may misuse medications, such as by manipulating dosage, in order to achieve weight loss or avoid weight gain. Individuals with diabetes mellitus may omit or reduce insulin doses in order to minimize carbohydrate metabolism' (p376) And the following on Bulimia which is an exact replica of earlier revisions 'Individuals with diabetes mellitus and bulimia nervosa may omit or reduce insulin doses in order to reduce the metabolism of food consumed during eating binges. (p381) The changing status of insulin omission as significant may contribute to the widely fluctuating estimates in prevalence. Some studies have reported a non-significant difference between type 1 diabetic females and their non-diabetic counterparts, some have reported a slightly elevated prevalence (please see table 1) and others have reported as much as a 4 times higher risk (Rukiye 2005). However there are further issues with methodology such as the demographics of the sample used, the diagnostic criteria applied, the scale of measurement used, control groups and self-report vs structured interviewing Please see appendix for table 1	
Royal Cornwall Hospitals NHS Trust	FULL	11	General	Explain to children and young people with type 1 diabetes and their family members or carers (as appropriate) that an HbA1c target level of 48 mmol/mol (6.5%) or lower is ideal to minimise the risk of long-term complications. [new 2015] [1.2.68] [1.2.25] We believe as a team that this is too low and there is a possibility that the child will have lots of hypos and potentially lose hypo awareness. I think if it has to be	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing

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				lowered from 58(7.5%) to 53mmol/mol (7.0%)	children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some

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					stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline
South West Paediatric Diabetes Network	FULL	18	39	Need to further define what is meant by 'Level 3' Carbohydrate counting.	Thank you for this comment. Level 3 carbohydrate counting is the use of carbohydrate counting with the adjustment of insulin dosage according to carbohydrate content of meals and blood glucose levels, using an insulin:carbohydrate ratio. This has been

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					clarified in a footnote to the recommendation
Roche Diagnostics	FULL	19 26 195	9 13 1 5 18 22	Roche Diabetes Care welcomes recommendations to offer ongoing unblinded ('real-time') continuous glucose monitoring (CGM) with alarms to children and young people with type 1 diabetes and consideration for ongoing unblinded ('real-time') continuous glucose monitoring for neonates, infants and pre-school children and children and young people who undertake high levels of physical activity. Patients with continued hyperglycaemia could also benefit from CGM: Patients not achieving adequate glycaemic control using self-monitoring of blood glucose (SMBG) and MDI or CSII. A study by Lynch et al. (Lynch P, Attvall S, Persson S, Barsoe C, Gerdtham U. Routine use of personal continuous glucose monitoring system with insulin pump in Sweden. Diabetologia 2012; 55:432.) shows a significant reduction in HbA1c in real-life use of CGM, whilst the frequency of severe hypoglycaemic events was slightly but significantly reduced (medical records: 0.10 vs. 0.02 events/month in 6 months before and after CGM start, respectively, p=0.0021). It could also be considered that as the draft guideline for adults, children should also have access to CGM in case of: • frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities • extreme fear of hypoglycaemia.	Thank you for this comment. The conference abstract mentioned in the comment does not meet the inclusion criteria specified in the review protocol. This is now reflected in the excluded studies list for the review question
National Children and Young People's Diabetes Network	FULL	19	23 27	This statement is inaccurate and stating that children and young people should be offered access to 'mental health professionals' does not follow from the Best Practice Criteria stated in the Department of Health, (2012) guidance that psychology should be "integral to the multi-disciplinary team" and that each patient should have an annual assessment by their MDT as to whether input to their care by a psychologist is needed. The Global ISPAD Consensus Guidelines (2000) stated that "psychosocial factors	The guideline development group consider that the recommendations are complementary to the Best Practice Tariff and do not prevent an annual assessment to determine the need for psychological support or inclusion of psychologists as a part of the multidisciplinary team. The

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				are the most important influences affecting the care and management of diabetes" and made the following three recommendations: (i) Psychologists should be part of the interdisciplinary health care team (ii) Overt psychological problems should receive support from the diabetes care team and expert attention from psychology (iii) The diabetes care team should receive training in the recognition, identification, and provision of information on psychosocial problems related to diabetes	linking evidence to recommendations section of the review has been amended to clearly state this. Please note that the 2004 review on behavioural interventions, which included the ISPAD guideline as a source of evidence, has been updated in 2015. The ISPAD guideline did not meet the inclusion criteria for the review and therefore is not used to inform the 2015 recommendations
British Psychological Society	FULL	19 29 30	24 33 40 6	The Society welcomes the recognition of the need for access to mental health professionals, where necessary. However, children, young people and families need access to paediatric clinical or health psychology services integrated within a diabetes MDT, so that psychological difficulties associated with their physical health and its management (that do not warrant a mental health label) can be identified and treated in a timely, non-stigmatising setting. Routine review by paediatric clinical or health psychologists in the hospital setting is important to facilitate adaptive coping and functioning with treatment regimens and invasive procedures (see British Psychological Society 2010 Guidelines on Managing Invasive Procedures in Children). We recommend changing this statement to read: "timely and ongoing access to paediatric clinical or health psychology and mental health professionals" This would be consistent with the Global ISPAD Consensus Guidelines (ISPAD Clinical Practice Consensus Guidelines Compendium, 2009) which stated that "psychosocial factors are the most important influences affecting the care and management of diabetes" and made the following three recommendations: (i) Psychologists should be part of the interdisciplinary health care team	The guideline development group use the term 'mental health professional' so that the recommendation covers access to a wide range of professional services including psychologists, family therapists, psychiatrists, etc. A sentence has been added to the linking evidence to recommendations section of the full guideline to explain this more clearly Please note that the 2004 review on behavioural interventions, which included the ISPAD guideline as a source of evidence, has been updated in 2015. The ISPAD guideline did not meet the inclusion criteria for the review and therefore is not used to inform the 2015 recommendations

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				(ii) Overt psychological problems should receive support from the diabetes care team and expert attention from psychology The diabetes care team should receive training in the recognition, identification, and provision of information on psychosocial problems related to diabetes. <u>References:</u> ISPAD Clinical Practice Consensus Guidelines Compendium (2009). Psychological Care of children and adolescents with diabetes. Pediatr Diab; 10 (Suppl 12): 175-184	
South West Paediatric Diabetes Network	FULL	19	36	The greater difficulty of obtaining an early morning urine sample for microalbuminuria outweigh the relatively low false positive rate from samples obtained during clinic. Where a clinic sample shows a raised albumin/creatinine ratio further early morning urine samples should be obtained to confirm abnormal renal albumin excretion.	Thank you for this comment. The discussion about the risks and benefits of using an early morning sample are discussed in Section 17.4.6.5 of the full guideline. On balance, the guideline development group believe a morning sample should be used in the first instance
South West Paediatric Diabetes Network	FULL	20	7	I understand that most children with diabetes have Type 1 (as determined by National Audit), however, in my experience, families want and are reassured by the pretty definitive evidence of their / child's type of diabetes that antibody-specific testing of more recent years provides..	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis (specifically evidence for distinguishing between type 1 and type 2 diabetes) and concluded that diabetes-specific autoantibody titres should not be measured to distinguish type 1 diabetes from type 2 diabetes. However, the recommendations emphasise that measuring C-peptide after initial presentation should be considered if there is difficulty distinguishing type 1 diabetes from other types of diabetes and that

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					genetic testing should be performed if atypical disease behaviour, clinical characteristics or family history suggest monogenic diabetes
National Children and Young People's Diabetes Network	FULL	20	34	Please see comments from Andrew Hattersley about other types of diabetes, and note that Neonatal Diabetes has been missed from these guidelines.	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis (specifically evidence for distinguishing between type 1 and type 2 diabetes) and concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the

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					young (MODY) and neonatal diabetes. The term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY
Institute of Child Health	FULL	20	40	Optic atrophy could be added as another ocular feature observed in monogenic diabetes. The presence of optic atrophy or retinitis pigmentosa in children and young people with suspected diabetes suggests the possibility of types of diabetes other than types 1 or 2 ie secondary to other underlying conditions.	Thank you for this comment. The suggested change has been made
National Children and Young People's Diabetes Network	FULL	20	42	Pancreatic antibodies have been shown to differentiate between type 1 diabetes and MODY (maturity onset diabetes of the young) at diagnosis and can indicate type 2, see comments from Andrew Hattersley for reference. They should therefore be removed from this recommendation.	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes (including maturity onset diabetes in the young (MODY)) was excluded from the 2015 update. The recommendations have been revised to clarify that C-peptide and diabetes-specific autoantibody titres should not be measured at initial presentation to distinguish type 1 diabetes from type 2 diabetes (this recommendation previously referred to distinguishing type 1 diabetes from other forms of diabetes, which as the comment indicates is

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					incorrect as C-peptide can be used to distinguish between type 1 diabetes and MODY)
South West Paediatric Diabetes Network	FULL	20	42	We would prefer not to use term 'do not' – perhaps it is not usually necessary – to measure C-peptide or diabetes specific antibodies at presentation – there are a number of scenarios when you should at presentation to stop needless use of insulin for weeks or months– examples – babies in first year of life when they might have rare neonatal forms of diabetes, adolescents with acanthosis, raised BMI and no ketonuria, thin children with a strong (across 3 generations) family history of diabetes presenting in early life (MODY) – making a quick accurate diagnosis in these scenarios with those test is undoubtedly helpful.	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis (specifically evidence for distinguishing between type 1 and type 2 diabetes) and concluded that C-peptide and diabetes-specific autoantibody titres should not be measured at initial presentation to distinguish type 1 diabetes from type 2 diabetes. However, the revised recommendations emphasise that measuring C-peptide after initial presentation should be considered if there is difficulty distinguishing type 1 diabetes from other types of diabetes and that genetic testing should be performed if atypical disease behaviour, clinical characteristics or family history suggest monogenic diabetes. The 'do not use' form of recommendation reflects the strength of the evidence base
National Children and Young People's Diabetes Network	FULL	21	1.2.37	Offer level 3 carbohydrate-counting education – we have no idea what this means. Needs to be more specific, i.e. teach insulin adjustment for carb content of meals (or whatever level 3 means)	Thank you for this comment. Level 3 carbohydrate counting is the use of carbohydrate counting with the adjustment of insulin dosage according to carbohydrate content of meals and blood glucose levels, using an insulin:carbohydrate ratio. This has been

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					clarified in a footnote to the recommendation
BD UK	Full	21	10 23	We welcome the recommendation to provide young people with type 1 diabetes and their family members or carers a continuing program of education on managing diabetes, including education on insulin therapy. We also welcome that the GDC have included practical skills in injection as part of education programmes on diagnosis (page 76). We believe that ensuring people on insulin therapy use good injection technique is important in order to minimise pain and discomfort for patients and to ensure consistency in insulin dose delivery and minimisation of insulin wastage.[1-3] It can also lead to better glucose control, which can prevent long-term complications of diabetes.[4] Injection technique covers a number of important factors to consider. Injection site rotation is only one element of good injection technique. Other important factors to consider include correct skin fold technique (if using longer needles), angle and duration of injection, injection site care, storage of insulin, the correct use of syringes, pens and needles, where to inject, proper skin fold technique, and how to detect lipohypertrophy.[4] Lipohypertrophy is a common complication of insulin injection[1,3] and injection into lipohypertrophy lesions may cause delayed or erratic insulin absorption. A study of the effect of lipohypertrophy at injection sites on insulin absorption found the mean clearance of insulin from lipohypertrophy sites to be significantly slower ($p<0.05$) than from the non-lipohypertrophy control sites, however the impact on glycaemic control is uncertain.[5] Lipohypertrophy is fairly common, reported in >70% of patients with type I diabetes and >50% of patients with type 2 diabetes in an observational study conducted in Spain.[3] The main risk factor was lack of, or incorrect, injection site rotation ($p< 0.0001$); needle reuse was also strongly associated with lipohypertrophy ($p < 0.008$). People with confirmed lipohypertrophy consumed more insulin on average per day than those without	Thank you for submitting comments in response to the stakeholder consultation and for your general comments in support of the guideline. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (insulin injection techniques and needle choice in this case)

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				lipohypertrophy, and the authors of this study estimated the incremental cost to the Spanish health care system for this excess insulin consumption at more than 122 million Euros.[3] Although this was an observational study, we consider this to be compelling evidence that correct injection site rotation is a critical factor in optimising insulin therapy. A cross-sectional, observational study conducted in China, which was recently presented at the Advanced Technologies and Treatments for Diabetes conference, reported that patients with lipohypertrophy had significantly higher daily insulin doses than patients without lipohypertrophy (0.54U/kg vs 0.41U/kg; p<0.001) and significantly greater HbA_{1c} levels (8.2% vs 7.7%; p=0.003).[6] The cost of excess insulin consumption in patients with lipohypertrophy was estimated as >$630 million per year.[7] The Injection Technique Questionnaire surveyed 4,352 insulin-injecting patients with type 1 and type 2 diabetes across 16 countries including the UK and found large numbers of patients had deficiencies with injection technique, including incorrect site rotation and a high incidence of injection related complications.[8] The survey also found that the education provided to patients on injection technique was frequently inadequate as it was either not provided or did not cover all aspects of the technique.[8] Given the importance of injection technique in the successful administration of insulin therapy, more widespread structured education regarding injection technique for people with diabetes about good practice in the UK could make an important contribution in improving health outcomes and controlling diabetes-related costs. A study which investigated the impact of targeted and individualised training in injection technique, including a switch to the shortest insulin needle (4mm), in diabetes patients who had been receiving insulin therapy for more than 4 years identified a mean reduction of HbA_{1c} of 0.58% (p<0.05) and a reduction in insulin consumption of 2 units per day across the whole cohort within three months.[9] Although we recognise this is a prospective non-controlled study, this is a	

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				potentially important finding that supports the conclusions of Blanco et al, described above[3]. Furthermore, to demonstrate this effect more robustly, two randomised controlled studies are currently planned in the UK and France comparing outcomes and healthcare resource use in type 1 and 2 diabetes patients receiving structured education on injection technique as recommended by the TITAN workshop, compared with those receiving standard advice.[1] In our experience we find that education on injection technique needs regular periodic reinforcement. As well as being part of an education programme on diagnosis we believe that practical skills in injection technique should be part of an ongoing programme of education. We suggest that the wording of recommendation 26 is modified to specify some of the subjects on insulin therapy that should be included in a programme of continuous education, and that this should include structured practical skills in injection technique. 1. Frid, A. et al. New injection recommendations for patients with diabetes. Diabetes & metabolism 36 Suppl 2, S3-18, doi:10.1016/S1262-3636(10)70002-1 (2010). 2. Hansen, B., Kirketerp, G., Ehlers, G., Nordentoft, E. & Hansen, G. Evidence-based clinical guidelines for injection of insulin for adults with diabetes mellitus. Available at http://www.dsr.dk/artikler/documents/english/evidence-based_clinical_guidelines_for_injection.pdf Accessed February 2015 (2006). 3. Blanco, M., Hernandez, M. T., Strauss, K. W. & Amaya, M. Prevalence and risk factors of lipohypertrophy in insulin-injecting patients with diabetes. Diabetes & metabolism 39, 445-453, doi:10.1016/j.diabet.2013.05.006 (2013). 4. The Forum for Injection Technique. The First UK Injection Technique Recommendations. 2nd Edition Available at http://www.fit4diabetes.com/files/2613/3102/3031/FIT_Recommendations	

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				_Document.pdf Accessed February 2015 (2011). 5. Young, R. J., Hannan, W. J., Frier, B. M., Steel, J. M. & Duncan, L. J. Diabetic lipohypertrophy delays insulin absorption. Diabetes care 7, 479-480 (1984) 6. Hirsch, L. et al. Lipohypertrophy - prevalence, risk factors, and clinical characteristics of insulin-requiring patients in China. Diabetes technology & therapeutics 17 (2015). 7. Hirsch, L. et al. Lipohypertrophy - prevalence, risk factors and clinical characteristics of insulin-requiring patients in China. Poster presented at the 8th International Conference on Advanced Technology and Treatments for Diabetes, February 18-21 2015, Paris, France Data on file (2015). 8. De Coninck, C. et al. Results and analysis of the 2008-2009 Insulin Injection Technique Questionnaire survey. Journal of diabetes 2, 168-179, doi:10.1111/j.1753-0407.2010.00077.x (2010). 9. Grassi, G., Scuntero, P., Trepiccioni, R., Marubbi, F. & Strauss, K. Optimizing insulin injection technique and its effect on blood glucose control. J Clin Trans Endocrinol 1, 145-150 (2014).	
National Children and Young People's Diabetes Network	FULL	22	48	See FIT guidelines for latest evidence re needle length.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (needle choice in this case)
National Children and Young People's	FULL	23	45	What is level 3 carbohydrate counting?is clarification needed.	Thank you for this comment. Level 3 carbohydrate counting is the use of carbohydrate counting with the adjustment of insulin dosage according to

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Diabetes Network					carbohydrate content of meals and blood glucose levels, using an insulin:carbohydrate ratio. This has been clarified in a footnote to the recommendation
National Children and Young People's Diabetes Network	FULL	25	1.2.59	Rather than just saying 5 tests, should it recommend timings of tests, I.e. before meals and bedtime, pre and 2-3 hrs post meals?	Thank you for this comment. The guideline development group discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that should be recommended, but also the timing at which the tests should be performed. They concluded that at least 5 tests should be performed routinely, and emphasised in the revised recommendations that it is often necessary to conduct more than 5 tests. They did not, however, wish to specify an upper limit for the number of tests, nor the exact timing for the minimum number of tests because to do so would remove some flexibility that is otherwise available to the child or young person and their family members or carers (as appropriate)
National Children and Young People's Diabetes Network	FULL	25	6	Fast acting carbohydrate should be available during exercise and intermediate/long acting carbohydrate post exercise.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004)

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					guideline (exercise in this case)
Roche Diagnostics	FULL	25	47 50	Roche Diabetes Care welcomes the recommendation for at least 5 capillary blood glucose tests per day. The frequency of daily testing and the most suitable blood glucose meter used should be considered on a case-by-case basis, with healthcare professionals and patients/carers working together to develop and agree on an individual care plan, with specific focus on improving clinical outcomes, for example testing more appropriately and achieving their individual agreed HbA1c target level. For children and young people, this can prove difficult in school settings, with recent Government legislation setting out to support children with long-term conditions, including diabetes, in schools. Children and young people often come up against restrictions on when and where they can test at school, along with access to clinical waste sharps bins for the safe disposal of test strips. Access to discreet strip free blood glucose meters and an amendment to the Children and Families Act 2014 which requires governing bodies to make arrangements for supporting pupils at school with medical conditions, including diabetes, has sought to address these challenges. "Advise children and young people with type 1 diabetes and their family members or carers (as appropriate) that more frequent testing may be needed in some circumstances, for example during intercurrent illness. [new 2015]": This statement should be expanded to healthcare commissioners, to ensure there is appropriate supply of test strips based on individual testing targets and during intercurrent illness. If the test strips supply is planned on 5 tests per day, it is based on a minimum level and there is a significant risk this will be interpreted as the average/maximum daily amount required, resulting in cases where there may not be enough strips available based on individual patient lifestyle/needs or at times of intercurrent illness with respective risks for patient safety and costs for treating unstable situations and emergencies eg. A&E attendances and admissions for	Thank you for this comment. The guideline development group discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that should be recommended, but also the timing at which the tests should be performed. They concluded that at least 5 tests should be performed routinely, and emphasised in the revised recommendations that it is often necessary to conduct more than 5 tests. They did not, however, wish to specify an upper limit for the number of tests, nor the exact timing for the minimum number of tests because to do so would remove some flexibility that is otherwise available to the child or young person and their family members or carers (as appropriate) The remit of the guideline development group did not extend to making recommendations for schools, while the recommendations already included should raise awareness with healthcare commissioners of the need to have enough test strips available to meet the child or young person's needs, as reflected in the revised recommendations

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				hypos.	
South West Paediatric Diabetes Network	Full	26	22 37	Whilst I agree that we should aim for the lowest, safely attainable, HbA1c, I wonder how many of our patients will be able to safely achieve an HbA1c of 48 mmol/mol or lower without the use of pumps, and maybe even continuous glucose monitoring. I suspect very few, particularly those who have been diagnosed for more than a couple of years who didn't benefit from early carbohydrate counting and therefore have a 'poor' metabolic memory. Whilst I accept you have added recommendations that HbA1c targets should be individualised and for us to be aware of the possible negative impacts of setting targets that might be difficult to achieve (page 28, lines 44-46), doesn't there also need to be a change in the NICE TAG for insulin pumps, and a new NICE TAG for continuous glucose monitoring, to allow more patients to benefit from this? It seems unfair that children aged 12 years and above, who haven't got disabling hypoglycaemia, can only get a pump if their HbA1c remains above 69mmol/mol.	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the

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					risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline

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					Your comment has been passed to the NICE Technology Appraisals team
Roche Diagnostics	FULL	27	1 4	It is also important blood glucose tests are used before the 'use-by' date.	The guideline development group agree with the comment but this is already widely understood by healthcare professionals, patients and families and does not need to be stated in a recommendation. The recommendation that mentions use-by dates for ketone strips is included because these have a short shelf life and are expensive
National Children and Young People's Diabetes Network	FULL	27	1.2.68	As so few of our children nationally achieve the current target of 58mmols/mol, is it realistic to now say should be achieving 48mmols/mol. This just makes even more parents and children feel that they have failed.	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people

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					and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1

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					diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline
National Children and Young People's Diabetes Network	FULL	27	7	Add "discuss actual (low) risk of severe hypo in order to minimise fear of hypoglycaemia	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case)
South West Paediatric Diabetes Network	FULL	27	23	No blood glucose concentration is given to define hypoglycaemia. Tighter blood glucose targets will increase the frequency of pre-prandial blood glucose levels between 3.5-4.0mmol/l. Often these will be asymptomatic. Guidance on the need to treat hypoglycaemia in this context is required.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case)
National	FULL	27	25	Change 10-20 g to "5-20 g"	Thank you for submitting comments in

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Children and Young People's Diabetes Network					response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case)
National Children and Young People's Diabetes Network	FULL	27	30	Change to Recheck blood glucose levels "after 10-15 minutes and repeat fast-acting glucose if level below 5.6 mmol/L" (see ISPAD 2014 guidelines)	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case). However, to maintain the safety of the recommendations the suggestion to repeat fast-acting glucose if hypoglycaemia persists has been added to this recommendation
South West Paediatric Diabetes Network	FULL	28	82	Having age and weight can be confusing guidance for dose determination and results in administration errors. Suggest weight only is necessary ie weight more than / less than 25kg.	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case). Moreover, there are several

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					recommendations in the parts of the guideline that are covered by the 2015 update that allow weight or age for dosage, and we have retained this flexibility to allow for various clinical scenarios (where weight may not be known or the child or young person may be markedly under or over weight for their age)
South West Paediatric Diabetes Network	FULL	28	86	I thought recent evidence had aligned cognitive impairment to hyperglycaemia and not hypoglycaemia, as previously thought.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case)
British Psychological Society	FULL	29	24	Assessment of emotional and psychological well-being should not be focused only on children who present with diabetes ketoacidosis. Ketoacidosis is a serious complication of diabetes and steps need to be taken to intervene regarding maladaptive adjustment before such a serious complication arises. The Best Practice for Commissioning Diabetes Services Guidelines, (Department of Health, 2012) stipulate that psychology should be "integral to the multi-disciplinary team" and that each patient should have an annual assessment by their MDT as to whether input to their care by a clinical or health psychologist is needed.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (assessment of emotional and psychological wellbeing of young people with type 1 diabetes who present with frequent episodes of diabetic ketoacidosis in this case)

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British Psychological Society	FULL	29	27	Children with type 1 diabetes are at higher risk for adjustment problems during the initial period of adaptation after diagnosis. When adjustment problems exist children are at higher risk for continuing difficulties (Kovacs, M., et al, 1996.). There is growing evidence that young people with diabetes have a greater incidence of psychosocial problems including depression, eating disorders, and anxiety disorders, all of which are associated with sub-optimal glycaemic control and the development of long-term complications, (Northam, E et al, 1996) References: Kovacs, M., Charron-Prochownik, D., Obrosky, D.S. (1996). A longitudinal study of biomedical and psychosocial predictors of multiple hospitalizations among young people with insulindependent diabetes mellitus. Diabetic Medicine, 12, 142–148. Northam, E.A., Matthews, L.K., Anderson, P.J., Cameron, F.J., and Werther, G. A. (1996) Psychiatric morbidity and health outcome in Type 1 diabetes – perspectives from a prospective longitudinal study, Diabetic Medicine, 22(2), 52–157	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (adjustment and adaptation following diagnosis in this case)
National Children and Young People's Diabetes Network	FULL	29	27	This point is inaccurate and lacks evidence base. Children with type 1 diabetes are at higher risk for adjustment problems during the initial period of adaptation after diagnosis. When adjustment problems exist children are at higher risk for continuing difficulties (Kovacs, Ho & Pollock, 1995). There is a growing evidence that young people with diabetes have a greater incidence of psychosocial problems including depression, eating disorders, and anxiety disorders, all of which are associated with poor glycaemic control and long term complications (Northam et al., 2004).	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (adjustment and adaptation following diagnosis in this case)
British Psychological Society	FULL	29	31	There is good evidence on the psychological impact of diabetes both on the individual and the family (see below). There is no evidence that diabetes leads to 'conduct disorder.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not

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				Rates of depression have been reported to be double in adults with diabetes compared to the general population. Anderson, R.A., et al, 2001) The 'costs' of (untreated) depression in diabetes are high. It is associated with poor engagement in self-management; sub-optimal glycaemic control; an increased risk of micro-vascular complications, cardiovascular disease, hospitalisations and medical costs; loss of productivity (work days/days in bed) and increased mortality (Egede et al, 2003 and Katon et al, 2005). Adolescents with type 1 diabetes have worse glycaemic control than any other age group with type 1 diabetes (Ambler, G.R et al, 2006.) putting them at high risk of developing diabetes-related complications. Around 30-40% of youth with type 1 diabetes are 'lost' to specialist diabetes care each year, most frequently during the transition from paediatric to adult services. (Kipps, S et al, 2002) Type 1 Diabetes is also regarded as a risk factor for disordered eating in adolescents. Research strongly suggests there is an increased prevalence of eating disorders, particularly Bulimia Nervosa and Eating Disorder Not Otherwise Specified (EDNOS), in girls with Type 1 diabetes (Colton, P et al, 2004). Half of adolescent girls with type 1 diabetes have disturbed eating patterns, of which 10% qualify as an eating disorder (double the rate of their peers without type 1 diabetes) (Jones, J.M. et al, 2000) The prevalence of General Anxiety Disorder (GAD) in people with diabetes is higher than in the general population. Anxiety can have a negative impact on glycemic control (HbA1c) both through the disruptive effects of high levels of stress hormones and the avoidance behaviours and dysfunctional coping strategies that people may use to cope with anxiety. In addition, young people with type 1 diabetes are at risk of diabetes specific anxieties, including:	able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (conduct disorders, anxiety and depression, eating disorders and cognitive function in this case)

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				• Needle phobia and fear of self-injecting and or self-testing, which is associated with poor glycaemic control (High HBA1c) and is often accompanied by serious psychological co-morbidity such as depression and/or other phobias (Mollema, E.D. et al, 2001). • Fear of hypoglycaemia (low blood glucose levels), which has an increased risk with elevated trait anxiety and hypoglycaemia 'unawareness' (Snoek, F.J. et al, 2000). • Fear of hyperglycaemia (high blood glucose levels) and future complications is associated with abnormal frequent self-testing, adjustment of insulin, and severe hypoglycaemia. • There is evidence for the effects of relaxation training on lowering blood glucose, (Bradley, C et al, 1998) Studies of neuro-cognitive functioning indicate that diabetes can impact on academic achievement particularly in children with poor metabolic control. References: Ambler, G.R., Fairchild, J., Craig, M.E., Cameron, F.J. (2006) Contemporary Australian outcomes in childhood and adolescent type 1 diabetes: 10 years post the Diabetes Control and Complications Trial. J Pediatric Child Health; 42(7-8):403-10 Anderson, R.A., Freeland, K. E., Clouse, R. E. and Lustman, P. J. (2001). The Prevalence of Comorbid Depression in Adults with Diabetes: A meta-analysis. Diabetes Care, 24(6), 1069-1078 Bradley C, Pierce, M.B., Hendrieckx, C., Riazi, A., Barendse, S. (1998) Diabetes Mellitus. In M Johnston and DW Johnston (Eds) Health Psychology, 8, in Bellack,	

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				A.S., and Hersen, M. (Eds) Comprehensive Clinical Psychology, Oxford: Elsevier Science, 277-304 Colton, P. Olmsted, M., Daneman, D., Rydall, A. and Rodin, G. (2004) Disturbed Eating Behavior and Eating Disorders in Preteen and Early Teenage Girls With Type 1 Diabetes: A case-controlled study. Diabetes Care, 27(7), 1654-1659 Gonder-Frederick, L.Z., Bauchowitz, J., Lee, J., et al (2009). Cognitive function is disrupted by both hypo- and hyperglycaemia in school-aged children with type 1 diabetes: a field study. Diabetes Care, 32: 1001-1006. Jones, J.M., Lawson, M.L., Daneman, D., Olmsted, M.P., Rodin, G. (2000) Eating disorders in adolescent females with and without type 1 diabetes: cross sectional study. BMJ. 10; 320(7249):1563-6 Kipps, S., Bahu, T., Ong, K., Ackland, F.M., Brown, R.S., Fox, C.T. (2002) Current methods of transfer of young people with Type 1 diabetes to adult services. Diabetes Med; 19(8):649-54. Snoek, F.J., Pouwer, F., Welch, G.W. & polansky, W.H. (2000). Diabetes-related emotional distress in Dutch and U.S. diabetic patients: cross-cultural validity of problem areas in diabetes scale. Diabetes Care, 23: 1305-1309 Mollema, E.D., Snoek, F.K., Ader, H.J. et al. (2001). Insuline-treated diabetes patients with fear of self-injecting or fear of self-testing: psychological comorbidity and general well-being. Jorunal of Psychosomatic research, 51: 665-672. Naguib, J.M., Kulinskaya, E., Lomax, C.L. & Garralda, M.E. (2009). Neuro-cognitive performance in children with type-1 diabetes – a meta-analysis. Journal of Pediatric Psychology, 34(3): 271-282.	

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				Snoek, F.J., Pouwer, F., Welch, G.W. & polansky, W.H. (2000). Diabetes-related emotional distress in Dutch and U.S. diabetic patients: cross-cultural validity of problem areas in diabetes scale. Diabetes Care, 23, 1305-1309	
National Children and Young People's Diabetes Network	FULL	29	40	The Best Practice Tariff criteria (Department of Health, 2012) stipulate that psychology should be "integral to the multi-disciplinary team". Having 'access' to mental health care is not sufficient or adequate.	The guideline development group consider that the recommendations are complementary to the Best Practice Tariff and do not preclude an annual assessment to determine the need for psychological support, nor the inclusion of psychologists as part of the multidisciplinary team. The linking evidence to recommendations section of the review has been amended to clearly state this
British Psychological Society	FULL	29	43	NHS Diabetes, Best Practice for Commissioning Diabetes Services: An integrated care framework (2012) states that all children and young people with a diagnosis of diabetes should have an annual assessment by their MDT as to whether input to their care by a clinical psychologist is needed, and access to psychological support.	The guideline development group consider that the recommendations are complementary to the Best Practice Tariff and do not preclude an annual assessment to determine the need for psychological support. The linking evidence to recommendations section of the review has been amended to clearly state this
National Children and Young People's Diabetes Network	FULL	29	43	The BPT criteria (Department of Health, 2012) clearly state that all children and young people with a diagnosis of diabetes should have an annual assessment by their MDT as to whether input to their care by a clinical psychologist is needed, and access to psychological support.	The guideline development group consider that the recommendations are complementary to the Best Practice Tariff and do not preclude an annual assessment to determine the need for psychological support. The linking

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					evidence to recommendations section of the review has been amended to clearly state this.
				The use of the term 'conduct disorder' is inappropriate.	Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (conduct disorders in this case)
				The use of the term 'mental health professional' is inaccurate. The DoH have clearly recommended psychology professionals in their 2012 guidance.	The guideline development group use the term 'mental health professional' so that the recommendation covers access to a wide range of professional services including psychologists, family therapists, psychiatrists, etc. A sentence has been added to the linking evidence to recommendations section of the full guideline to explain this more clearly
British Psychological Society	FULL	29	46	It is not clear who should carry out the screening. Screening only children who have poor glucose control is not clinically appropriate. The DOH 2012 guidance state that ALL children should have an annual assessment by their MDT as to whether input to their care by a psychologist is needed, and access to psychological support.	Thank you for this comment. This recommendation is complementary to the Best Practice Tariff which requires an annual assessment to determine the need for psychological support. In this case it highlights the need for screening in a population at high risk of anxiety and depression. As with all of these recommendations, the intervention should be performed by an appropriately skilled

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					professional
National Children and Young People's Diabetes Network	FULL	29	46	Screening only children who have poor glucose control is inappropriate and has not been recommended. This statement is unclear. It is not stated 'who' should carry out the screening. The DOH 2012 guidance and Best Practice Tariff guidance have clearly stated that ALL children should have an annual assessment by their MDT as to whether input to their care by a psychologist is needed, and access to psychological support.	The guideline development group consider that the recommendations are complementary to the Best Practice Tariff and do not preclude an annual assessment to determine the need for psychological support. The linking evidence to recommendations section of the review has been amended to clearly state this. This recommendation highlights the need for screening in a population at high risk of anxiety and depression. As with all of these recommendations, the intervention should be performed by an appropriately skilled professional
South West Paediatric Diabetes Network	FULL	29	94	Is there any reason why they have not added that children having minor procedures could managed in a day surgery unit ?(as per ACDC / ISPAD guidance)	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (surgery for children and young people with diabetes in this case)
British Psychological Society	FULL	30	1	See order numbers 12 above. Children and young people with diabetes are at risk of anxiety, depression, eating disorders, and neuro-cognitive difficulties.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been

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					reviewed since the original (2004) guideline (anxiety and depression, eating disorders and cognitive function in this case)
National Children and Young People's Diabetes Network	FULL	30	1	As above. This point is misleading and does not reflect the DoH 2012 guidance. The risk of 'anxiety/or depression' is inaccurate and not in line with current evidence base (see order number 5 above) Children and young people with diabetes are at risk of anxiety, depression, eating disorders, and neuro-cognitive difficulties. All children should have access to a yearly assessment by their MDT as to whether clinical psychology input is needed.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (anxiety and depression, eating disorders, cognitive function and general aspects of care delivered by mental health professionals in this case)
National Children and Young People's Diabetes Network	FULL	30	1.2.85	Diabetes teams should consider referring children and young people with type 1 diabetes who have frequent hypoglycaemia and/or recurrent seizures for assessment of cognitive function, particularly if these occur at a young age. [2004] May be referring a lot of CYP if we aim for new targets! Were do we refer to?	Thank you for this comment. The guideline development group have not specified the referral details as these might differ depending on the local service configuration. The recommendations about HbA1c targets emphasise the need to take individual circumstances into account and that safely achievable targets should be set. This should reduce the risk of hypoglycaemia, especially given the clinical benefits of modern insulin regimens
British	FULL	30	5	The use of 'child mental health professionals' is misleading and inaccurate. See	The guideline development group use the

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Psychological Society			17	order number 9 above. The evidence for eating disorders also states the need for a psychologist to lead on interventions.	term 'mental health professional' so that the recommendation covers access to a wide range of professional services including psychologists, family therapists, psychiatrists, etc. A sentence has been added to the linking evidence to recommendations section of the full guideline to explain this more clearly. The evidence for the review on eating disorders was not updated in 2015, so the guideline development group are unable to specify who should lead the intervention
National Children and Young People's Diabetes Network	FULL	30	5	The use of 'child mental health professionals' is misleading and inaccurate. Current DoH guidance has clearly requested the presence of psychology as core member of the diabetes MDT and all children and young people with type 1 diabetes should have access to psychological intervention via a clinical psychologist.	Thank you for this comment. The term 'child mental health professionals' is terminology that was used in the 2004 guideline. The guideline development group consider that the recommendations are complementary to the Best Practice Tariff and do not preclude an annual assessment to determine the need for psychological support. The linking evidence to recommendations section of the review has been amended to clearly state this
British Psychological Society	FULL	30	20	We believe that 'specific family-based behavioural interventions' do not exist. 'Behavioural family systems therapy' is not an evidence-based therapy. There is a growing evidence base for Family Therapy using systemic models and theory (Delamater, 2001; Wysocki et al., 2007).	Thank you for your suggestions. The terminology used within the review of psychological interventions reflects the descriptions contained in the studies that meet the inclusion criteria set out in the

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				There is some evidence for the use of Motivational Interviewing to improve long-term glycaemic control and psychosocial outcomes (ISPAD, https://www.ispad.org/content/ispad-clinical-practice-consensus-guidelines-2009). References: A.M., Alan M. Jacobson, A.M, Anderson, B., Cox, D., Fisher, L. Patrick Lustman, P., Rubin, R. and Wysocki, T. (2001) Psychosocial Therapies in Diabetes: Report of the Psychosocial Therapies Working Group. Diabetes Care, 24(7), 1286-1292 Wysocki' T., Harris' M. A., Buckloh' L. M. Mertlich' D., Sobel Lochrie' A Taylor' A., Sadler, M. and White, N.H. (2007) Randomised, Controlled Trial of Behavioral Family Systems Therapy for Diabetes: Maintenance and Generalization of Effects on Parent-Adolescent Communication. Behavior Therapy, 39, 33–46.	systematic review protocol (Appendix E). More generally, the terminology has been broadened so that the review refers to psychological, and not just behavioural, interventions
British Psychological Society	FULL	30	23	Suggest re-wording to: "..cognitive behavioural and systemic interventions…" or "psychological interventions" As the examples cited include cognitive-behavioural and systemic therapy interventions, not just behavioural interventions. The term 'behavioural' only is misleading.	The recommendation has been amended to refer to behavioural intervention therapy or behavioural techniques
National Children and Young People's Diabetes Network	FULL	30	23	See order number 9. 'Behavioural intervention therapy' is inaccurate terminology. CBT does not focus on quality of life. This is inaccurate. Multi-systemic therapy is not a behavioural intervention. There is no evidence of its effectiveness in diabetes. Mentoring is not a behavioural intervention and is not a therapy. There is no adequate evidence base for the use of mentoring in diabetes. NICE guidance has clearly stated that CBT is the recommended intervention for	Please note the following responses to each point raised in the comment. • The terminology referring to 'behavioural interventions' has been amended throughout the guideline to 'psychological interventions' as required. • In this instance, 'CBT focussing on

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				depression based on RCTs and current evidence base. Recommending motivational interviewing is inaccurate and goes against current gold standards of care. The evidence base for motivational interviewing is in adherence and shown to improve long-term glycaemic control and psychosocial outcomes (ISPAD, 2009).	quality of life' is how the paper described the intervention, which is further explained in Table 37 of the full guideline and in the evidence tables contained in Appendix I (de Wit 2008). • Six studies were included in the review which considered the effectiveness of multi-systemic therapy interventions for children and young people with type 1 diabetes. The evidence was found to be in favour of treatment with this therapy when compared with standard care. • The terminology referring to 'behavioural interventions' has been amended to 'psychological interventions' and evidence for mentoring is presented in the systematic review. • The recommendation has been amended so that it cross-refers to the existing NICE guidance on the treatment of depression in children and young people. The previous version of the recommendation reflected the association between improved depression and motivational interviewing that was found in the evidence specific to those with type 1 diabetes.

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					• The evidence for motivational interviewing referred to here is from Channon 2007 in the ISPAD 2009 guidance which is included in the systematic review of psychological interventions. As only p values were presented in the article they could not be used in the evidence review. The results that were included were not adjusted for baseline and did not demonstrate the same pattern of efficacy.
Royal College of Paediatrics and Child Health	FULL	30 240 246	35 13 18	Motivational Interviewing is a useful tool for behaviour change but is not a treatment for depression.	The evidence underpinning this recommendation found a reduction in depression at 12 months compared with those patients who received support visits only. However, the guideline development group refer the reader to the updated NICE guideline on depression in children and young people and have amended the recommendation to include this cross-reference to existing NICE guidance
South West Paediatric Diabetes Network	FULL	30	113	Coeliac screening advice should be aligned to / informed by National guidance document BSPGHAN	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (coeliac disease in this case). In

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					the case of coeliac disease the guideline development group recognise that NICE has produced separate guidance and so the recommendations in this guideline have been amended to cross-refer to the NICE coeliac disease guideline for guidance on monitoring for coeliac disease in children and young people with type 1 diabetes
Royal College of Paediatrics and Child Health	FULL	31	1 2	Coeliac and thyroid disease screening: both these conditions are recognised association with type 1 diabetes and the risk of developing them is life-long, not just at diagnosis. There is much anecdotal evidence to support this. Both conditions are treatable and both have significant differences in outcome if treated. It seems bizarre therefore that NICE only recommend celiac disease screening at diagnosis and not thereafter. Coeliac disease is actually more common than thyroid disease and much is diagnosed post the diagnosis of type 1 diabetes. Much celiac disease is 'asymptomatic' until diagnosed and often once the diagnosis is made there is a realisation that the patient had unrecognised symptoms for a while. We believe the NICE guidance on celiac disease currently undergoing updating is going to recommend continued screening for those with type 1 diabetes. The NPDA urge NICE to continue to support continued celiac screening lifelong. There will never be a RCT in this area and it is not clear whether the advisory committee have sought consensus opinion from stakeholders.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (coeliac disease and thyroid disease in this case). In the case of coeliac disease the guideline development group recognise that NICE has produced separate guidance and so the recommendations in this guideline have been amended to cross-refer to the NICE coeliac disease guideline for guidance on monitoring for coeliac disease in children and young people with type 1 diabetes
South West Paediatric Diabetes Network	FULL	31	1	Coeliac disease may present after a diagnosis of T1DM. It does not therefore make sense to only screen for coeliac disease at diagnosis.	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the

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					guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (coeliac disease in this case). However, the guideline development group recognise that NICE has produced separate guidance on coeliac disease and so the recommendations in this guideline have been amended to cross-refer to the NICE coeliac disease guideline for guidance on monitoring for coeliac disease in children and young people with type 1 diabetes
Institute of Child Health	FULL	31	4	The guideline only addresses one part of the review question (starting age) and has not commented on any evidence for the frequency of the screening. The guideline later states that 'The aim of this review was to determine when screening for retinopathy should start and how frequently it should be repeated in children and young people with type 1 diabetes' (Full version, page 251, lines 9-10). We assume that given that the low quality of the evidence the group decided to maintain this feature of the screening strategy, but explaining the rationale behind this decision would have been a useful addition to the guideline.	Thank you for this comment. The recommendations state that monitoring should be conducted annually for children and young people with type 1 diabetes and those with type 2 diabetes. The rationale behind the decision is discussed in Sections 11.4.1.6 and 17.3.6 of the full guideline
National Children and Young People's Diabetes Network	FULL	31	27	Need to specify what is blood glucose should be raised up to i.e. Consistent with ISPAD Guidance to treat Hypoglycaemia up to 5.6mmol. Relevant for consistent standardised management across England including in school plans and to prevent over treatment of hypoglycaemia which is also important for improving HbA1C's and long term outcomes.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been

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					reviewed since the original (2004) guideline (management of hypoglycaemia in this case)
South West Paediatric Diabetes Network	FULL	31	44	Why does the guidance not offer a recommendation on treatment with ACE inhibitor or ARB drug in management of established microalbuminuria?	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that the scope of this guideline covers only the detection of long-term complications of diabetes and not their subsequent management
Institute of Child Health	FULL	32	11 17	The aim of this eye examination or the pathways for abnormal results are not explained in the guideline. No evidence for this recommendation is presented in the guideline. Additionally, this does not fit with any current RCOphth guidance on community optometric care for children. We advise that this should be changed to 'Parents should be advised that their child is entitled to a free NHS eye examination with an optometrist up to the age of 16 (19 if in full time education)' (page 5 on RCOphth guidance on "Ophthalmic Services for Children". http://www.rcophth.ac.uk/page.asp?section=293)	Thank you for this comment. The pathway of care beyond the identification of an abnormal retinopathy screening result was outside the scope of the guideline. The evidence supporting the screening recommendations is presented in Sections 11.4.1 and 17.3 of the full guideline. The recommendations are in line with the National Screening Programme for Diabetic Retinopathy. The consensus recommendation from 2004 about the frequency of routine eye tests reflects good clinical practice and that section of the guideline was not updated in 2015
South West Paediatric Diabetes Network	FULL	32	16	We are not convinced of the value of a biennial optician review in addition to retinopathy screening. What is the rationale for this recommendation?	Thank you for this comment. The rationale for the recommendation on screening for retinopathy is discussed in Section 11.4.1 of the full guideline. The consensus recommendation from 2004 about the frequency of routine eye tests reflects good clinical practice and that section of

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					the guideline was not updated in 2015
British Psychological Society	FULL	32	18	The National Service Framework For Children, Young People And Maternity Services - Type 1 Diabetes In Childhood And Adolescence (DoH 2010) states that the provision of information, education and psychological support that facilitates self-management is the cornerstone of diabetes care. Psychological wellbeing should be part of the programme of education from diagnosis. Psychological well-being and QoL also need to be monitored systematically.	The guideline development group agree that the psychological well-being and quality of life of all children and young people with diabetes is a very important consideration and have therefore included a recommendation that children, young people and their family members or carers receive access to mental health professionals with an understanding of diabetes. The evidence review did not consider the effectiveness of systematic monitoring of psychological well-being and quality of life
National Children and Young People's Diabetes Network	FULL	32	18	The NSF (2001) has stated that the provision of information, education and psychological support that facilitates self-management is the cornerstone of diabetes care. Psychological wellbeing should be part of the programme of education from diagnosis.	The guideline development group agree that the psychological well-being and quality of life of all children and young people with diabetes is a very important consideration and have therefore included a recommendation that children, young people and their family members or carers receive access to mental health professionals with an understanding of diabetes. The evidence review did not consider the effectiveness of systematic monitoring of psychological well-being and quality of life
Institute of Child Health	FULL	32	38 44	As explained in the previous comment, we advise that this should be changed to 'Parents should be advised that their child is entitled to a free NHS eye examination with an optometrist up to the age of 16 (19 if in full time education)'	Thank you for this comment. The pathway of care beyond the identification of an abnormal retinopathy screening result was

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				(page 5 on RCOphth guidance on "Ophthalmic Services for Children". http://www.rcophth.ac.uk/page.asp?section=293)	outside the scope of the guideline. The evidence supporting the screening recommendations is presented in Sections 11.4.1 and 17.3 of the full guideline. The recommendations are in line with the National Screening Programme for Diabetic Retinopathy. The consensus recommendation from 2004 about the frequency of routine eye tests reflects good clinical practice and that section of the guideline was not updated in 2015
South West Paediatric Diabetes Network	FULL	32	121	Document should make it clear that this eye examination by an optician every 2 yrs is independent of the retinal screening (ie does not replace retinal screening) and is standard eye screening.	Thank you for this comment. The 2004 recommendation for eye screening was developed by consensus methods in the absence of evidence and a sentence has been added to Section 11.4.1.6 which discusses its relationship to the 2015 recommendation for annual monitoring for diabetic retinopathy
British Psychological Society	FULL	33	1.2.103	The Society recommends regular and routine assessment of a young person's adjustment to living with diabetes as a life-long condition, requiring extensive behavioural self-management. There will be an emotional consequence as the young person gains more self-awareness, as they increasingly take on the task of self-monitoring and as their own awareness of the impact of living with diabetes changes over time, according to their cognitive ability, developmental stage and emotional resources. This is a continual process of adjustment and adaption for the child and their family. There needs to be ongoing systematic monitoring of the impact of diabetes on quality of life (using e.g. the ADDQoL-Teen McMillan et al 2004 HQLO 2; 61) as	The guideline development group agree that the psychological wellbeing and quality of life of all children and young people with diabetes is a very important consideration and have therefore included a recommendation that children, young people and their family members or carers receive access to mental health professionals with an understanding of diabetes. The evidence reviewed did not consider the effectiveness of systematic

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				well as monitoring of well-being (to include depressed and anxious mood). Reference: McMillan, C.V., Honeyford, R.J., Datta, J., Madge, N.J.H., Bradley, C. (2004) The development of a new measure of quality of life for young people with diabetes mellitus: the ADDQoL-Teen. Health and Quality of Life Outcomes, 2, 61 http://www.hqlo.com/content/2/1/61	monitoring of psychological wellbeing and quality of life
National Children and Young People's Diabetes Network	FULL	34	1.2.108	coeliac disease at diagnosis – to also test annually as for thyroid. We've had children diagnosed with cd who were negative at diagnosis	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (coeliac disease and thyroid disease in this case). In the case of coeliac disease the guideline development group recognise that NICE has produced separate guidance and so the recommendations in this guideline have been amended to cross-refer to the NICE coeliac disease guideline for guidance on monitoring for coeliac disease in children and young people with type 1 diabetes
Royal College of Paediatrics and Child Health	FULL	34	1.2.108	Coeliac disease at diagnosis – to also test annually as for thyroid. We've had children diagnosed with cd who were negative at diagnosis	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not generally able to accept comments on parts of the guideline that are excluded

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					from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (coeliac disease and thyroid disease in this case). In the case of coeliac disease the guideline development group recognise that NICE has produced separate guidance and so the recommendations in this guideline have been amended to cross-refer to the NICE coeliac disease guideline for guidance on monitoring for coeliac disease in children and young people with type 1 diabetes
National Children and Young People's Diabetes Network	FULL	34	46	This point is identical to the one on page 29 – In view of the differences in aetiology and medical management between type 1 and type 2 diabetes, it is unlikely the will have the same identical psychological needs. This is therefore misleading.	Thank you for this comment. The guideline development group recognise that the aetiology and medical management of type 1 and type 2 diabetes are different and that the psychological needs of the children and young people in each of these groups will therefore be different. The recommendation is not prescriptive about what these needs might be
National Children and Young People's Diabetes Network	FULL	35	1.2.11 1	Never been certain what is magic about the age 12. Should there be some advice re length of diagnosis as well? A child diagnosed at 11 months will have had diabetes for almost 12 years before being screened, yet a child diagnosed at 12 will be screened within a year.	Thank you for this comment. The guideline development group noted that studies commonly reported only the presence or absence of retinopathy, with little emphasis on severity. Therefore, it was difficult for them to determine the prevalence of retinopathy requiring treatment at any given age. Of the studies which commented on

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					severity of retinopathy at different ages, 5 reported no incidence of proliferative retinopathy in children and young people under the age of 13 years (Cerutti 1989; Frank 1982; Goldstein 1993; Johansen 1994; Klein 1989). This was consistent with the clinical experience of the guideline development group, which was that retinopathy requiring treatment is extremely rare in children and young people under the age of 12 years. They therefore recommended that screening for significant diabetic retinopathy should begin at the age of 12 years. This threshold is consistent with the National Screening Programme
South West Paediatric Diabetes Network	FULL	35	38	What about monitoring of liver function tests in males and females and PCOS type features in females – both are very common in type 2 diabetes in adolescence	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (adolescence in this case)
South West Paediatric Diabetes Network	FULL	35	154	Poor control should be quantified. (i.e. above 69mmols/l?)	This recommendation has been revised to state that screening for anxiety and depression should be offered to children and young people with type 1 diabetes who have persistently suboptimal blood glucose control. This phrasing allows for

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					clinical judgement to be used, taking account of individualised targets and personal circumstances. This recommendation is, however, in part of the guideline that is not covered by the 2015 update scope and so the evidence to specify what constitutes suboptimal control in this context has not been reviewed and the recommendation cannot be made more specific
South West Paediatric Diabetes Network	FULL	36	9 11	Should we be using a BP cut off of the 90th centile, rather than the 95th centile, for investigating and treating hypertension in children with diabetes? That's what our tertiary nephrologist recommends.	Thank you for this comment. The view of the guideline development group was that it was preferable to use the 95th percentile. Using the 90th percentile would result in many more children and young people being subjected to additional testing with no evidence of clinical benefit
Institute of Child Health	FULL	36	31 33	We suggest that referring these children to the local diabetic eye screening programme would be preferable to direct referral to an ophthalmologist because (1) this maintains a central register of screened diabetic children, (2) pathways for normal/abnormal results are already established and (3) it is likely to be more cost-effective.	Thank you for this comment. The recommendation does not specify local referral but the guideline development group felt that it was necessary to consider a retinal examination in this selected group of younger children and young people with type 2 diabetes via an ophthalmologist
South West Paediatric Diabetes Network	FULL	36	168	Indicate / suggest time interval for repeat sample and affirm if first sample random, second should be fasting sample before determining management strategy.	Thank you for this comment. The test should be repeated on an early morning urine sample (as described in the recommendation) which would therefore require a minimum of 24 hours in between samples. Please note that fasting is not

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					required for a urine test
South West Paediatric Diabetes Network	FULL	37	179	Quantify 'elevated level' of concern ie 3Fmmols/l	The guideline development group's view is that a specific level for ketones should not be specified in the recommendation that triggers sending a child or young person with possible diabetic ketoacidosis to hospital. This is because the evidence reviewed for the guideline does not support ketone testing as being a specific test for diabetic ketoacidosis, and the recommendation should not risk preventing the child or young person being sent to hospital by including an arbitrary threshold that may not quite be met in individual circumstances. This recommendation is not for diagnosing diabetic ketoacidosis (this will be done in the hospital) and a child or young person with known diabetes should already have ketone testing equipment and advice about seeking help plus an individualised sick-day management plan so they will be able to detect elevated ketones
National Children and Young People's Diabetes Network	FULL	40	4	This will be quite difficult for non diabetes specialists to follow and may lead to errors. Is it not better to subtract all resuscitation bolus from 48 hour requirement?	The difference between the 'consider' recommendation here (ketone monitoring during management of diabetic ketoacidosis) and the stronger 'offer' or 'use' recommendation elsewhere (ketone self-monitoring during management of intercurrent illness) is that there is a lack of

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					specific evidence of cost effectiveness of near-patient testing of ketones in the hospital setting. The reason that resuscitation boluses are not subtracted from the 48-hour fluid calculation is that the fluid quantities recommended in the guideline are already less than in previous guidance and only rarely will a child or young person with diabetic ketoacidosis be given more than 20 ml/kg of intravenous fluid
South West Paediatric Diabetes Network	FULL	40	4	Earlier guidance limits fluid boluses to 10ml/kg in severe DKA but reference is made here to larger volumes (20+ml/kg) being given. Current guidance is that all fluid boluses are subtracted from total volume of fluid to be given over 48 hours, this guidance seems to suggest that this should only be done when fluid boluses of 20+ml/kg have been given during resuscitation. Why is this if a general cautious approach to IV fluid therapy is recommended?	The reason that resuscitation boluses are not subtracted from the 48-hour fluid calculation is that the fluid quantities recommended in the guideline are already less than in previous guidance and only rarely will a child or young person with diabetic ketoacidosis be given more than 20 ml/kg of intravenous fluid
South West Paediatric Diabetes Network	FULL	43	3	Whilst home based care has been shown to be as effective as hospital based care at diagnosis it is also places increased demands on health care professional resource. Most children's diabetes teams are not well enough resourced to deliver home-based care at diagnosis. Furthermore research has shown that whatever their initial preferences families are adaptable with regards the locus of initial care and recognise the benefits of each. Location of care at diagnosis cannot solely be determined by family preference.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (care setting at diagnosis in this case)
Royal College of Paediatrics	FULL	43	9	Home-based care at diagnosis is not appropriate for the initiation of MDI and carbohydrate counting or insulin pumps.	Thank you for submitting comments in response to the stakeholder consultation.

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and Child Health		373	14		Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (care setting at diagnosis in this case).
Royal College of Paediatrics and Child Health	FULL	43 377	46 40	Joint transition clinics with staff from paediatric and adult services should be offered for at least one year prior to transfer.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (transition from paediatric to adult services in this case)
South West Paediatric Diabetes Network	FULL	43	241	This statement might considerably raise expectation. Access to 24 hour advice, yes. Advice from a health care professional who is following diabetes team guidance, yes realistic expectation .....actually from their diabetes team is probably unrealistic for most services.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (24-hour access to the diabetes team in this case)
British Psychological Society	FULL	44	General	Commissioning of systematic review(s) of the paediatric diabetes psychology literature is recommended. Psychology research recommendations appear to be based on 2004 Guidelines. There appears to be a lack of systematic reviews in some areas of the psychology literature, which limits the scope upon which the GDG can come to conclusions. In reviewing the clinical psychology literature it is	The broad research recommendation highlighting the need for further studies to evaluate the effectiveness of behavioural and social interventions on anxiety and depression, eating disorders, behavioural

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				important to know both what is known (RCTs) and not yet known from the emerging clinical literature in order to make specific recommendations for future research on the psychosocial aspects of diabetes. The Society recommends that the GDG consider a NICE recommendation for secondary research in the area of systematic reviews of the clinical psychology literature. For example: Recommendation for secondary research: A systematic review of the literature on the effectiveness of psychological interventions to improve outcomes in children and young people with type 1 diabetes is recommended to review the emerging literature and make recommendations for future research. This recommendation would assist in supporting bids for funding for clinical psychology systematic reviews to be carried out in order to address this significant gap. This in turn would facilitate the availability of systematic reviews of the psychology literature for future NICE guideline reviews.	and conduct disorders, and adherence to therapy in children and young people with type 1 diabetes, especially in adolescence, from diagnosis and in established diabetes which was included in the original (2004) guideline has been retained in the 2015 update. As several specific topics related to psychological and psychosocial issues affecting children and young people with type 1 diabetes are excluded from the 2015 update (for example, anxiety and depression, eating disorders and behavioural and conduct disorders) it has not been possible to be more specific about the form this research should take. The guideline development group agree, however, that systematic reviews to complement those already undertaken for topics included in the update could form part of these further research studies
National Children and Young People's Diabetes Network	FULL	44	General	There are no recommendations for research on the effectiveness and/or impact of psychological interventions. This is in spite of DoH stating that psychology is a core member of the MDT and The Global ISPAD Consensus Guidelines (2000) stating that "psychosocial factors are the most important influences affecting the care and management of diabetes"	The broad research recommendation highlighting the need for further studies to evaluate the effectiveness of behavioural and social interventions on anxiety and depression, eating disorders, behavioural and conduct disorders, and adherence to therapy in children and young people with type 1 diabetes, especially in adolescence, from diagnosis and in established diabetes which was included in the original (2004)

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					guideline has been retained in the 2015 update. As several specific topics related to psychological and psychosocial issues affecting children and young people with type 1 diabetes are excluded from the 2015 update (for example, anxiety and depression, eating disorders and behavioural and conduct disorders) it has not been possible to be more specific about the form this research should take. The guideline development group agree, however, that systematic reviews to complement those already undertaken for topics included in the update could form part of these further research studies
Roche Diagnostics	FULL	44	6 8	"What is the optimal upper limit and timing for blood glucose measurements after meals for children and young people with type 1 diabetes to achieve an HbA1c level of 48 mmol/mol 8 (6.5%) without unacceptable hypoglycaemia?" For patients to achieve an HbA1c level of 48 mmol/mol 8 (6.5%) without unacceptable hypoglycaemia, please consider that a sufficient amount of test strips should be available so that there are no preventable cases of hypoglycaemia and related hospitalisations eg reducing A&E attendances and admissions or even death.	Thank you for this comment. The recommendation about often needing to perform blood glucose testing more than 5 times per day has been amended to emphasise to children and young people with type 1 diabetes and their family members or carers (as appropriate) that they should ensure that they have enough test strips to meet these needs
Roche Diagnostics	FULL	44 138	25 27 10	As this topic was addressed by the NICE TA151 and as there is substantial evidence of a significant HbA1c effect on this topic (Misso, Egberts et al. 2010), please specify which concrete research question could be further investigated.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015

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			12 15 16		update, where the evidence has not been reviewed since the original (2004) guideline (insulin pump therapy in this case). Moreover, the indications for insulin pump therapy are determined by the NICE Technology Appraisal (TA) guidance mentioned in the comment and the guideline development group are unable to change the TA guidance or to draw conclusions about specific requirements for future research in this area
British Psychological Society	FULL	45	10	The following relevant NICE guidelines for children and young people are missing: • Managing overweight and obesity mong children and young people • Promoting physical activity for children and young people • Improving children and young people's health	Thank you for this comment. The guideline on overweight and obesity mentioned in the comment has been replaced by the updated guideline 'obesity: identification, assessment and management of overweight and obesity in children, young people and adults'. This is already included in the list of related NICE guidance, as is the similar guidance about prevention of overweight and obesity in children and adults. The public health guidance on promoting physical activity for children and young people has now been included in the list of related NICE guidance. Specific guidance on improving children and young people's health (other than in children and young people with cancer) could not be identified and so this has not been added to the list of related

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					NICE guidance
Royal College of Paediatrics and Child Health	FULL	45	17	This research question on the correlation of BMI and A1c could be addressed by using data collected by the NPDA.	Thank you for this comment. The evidence to recommendations section that precedes this research recommendation has been expanded to note the possibility of data from the National Paediatric Diabetes Audit being used for this research
Royal College of Paediatrics and Child Health	Full	46	12	The sentence here states that much of the care for type 1 and 2 in paediatric practice is the same…….therefore why not combine the guidance as already previously suggested.	Thank you for this comment. The guideline development group felt there was a strong rationale for keeping the recommendations for type 1 diabetes and type 2 diabetes separate: in practice the two sets of recommendations will be read as stand-alone documents; the separation makes the guidance more patient-focused; and the link to the separate guidelines on diagnosis and management of type 1 and type 2 diabetes in adults further emphasises the relevance of having separate sets of recommendations for the different conditions
National Children and Young People's Diabetes Network	FULL	46	37	Clinical psychologists are stated as one of the professionals for whom this guidance may be relevant. To make this statement accurate all prior mentions of 'child mental health workers' should be corrected to 'clinical psychologists'.	The guideline development group use the term 'mental health professional' so that the recommendations cover access to a wide range of professional services including psychologists, family therapists, psychiatrists, etc. A sentence has been added to the linking evidence to recommendations section of the full guideline to explain this more clearly. The

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					statement about the professionals for whom the guideline may be relevant has been revised accordingly
British Psychological Society	FULL	47	General	Specific outcome measures for psychological factors have omitted to include the following: • Adherence (Evidence of adherence to treatment and higher levels of attendance at clinic appointments has already been evidenced. (Lemanek et al., 2001) • Adjustment • Depression (Rates of depression have been reported to double in people with diabetes compared to controls. (Anderson et al., 2001)) • Anxiety (including diabetes specific anxieties such as needle phobia, fear of hypoglycaemia, fear of hyperglycaemia) • Diabetes-related distress (which may account for a large proportion of the variance in depressive symptoms reported by people with diabetes.(Gonzalez, J.S., et al, 2008) Most research studies would have included outcomes on one or more of the above (rather than 'quality of life' as the only outcome). The use of the term 'quality of life' as an umbrella term to capture all patient-reported (or psychological) outcomes is not recommended as it is not informative and can lead to inappropriate selection of measures and misinterpretation of findings (Speight, J., et al, 2009.) Reference: Anderson, R.J., Freedland, K.E., Clous, R.E. & Lustman, P.J. (2001). The prevalence of comorbid depression in adults with diabetes: A meta-analysis. Diabetes Care, 24(6): 1069-1078.	The selected outcome measures are specified in each individual review protocol in Appendix E. The guideline development group believe the text referred to in the comment is from methods of the 2004 guidance. In the 2015 update, psychological outcomes including adherence, depression and anxiety were considered important outcomes for inclusion. These outcomes were considered in addition to quality of life, which is a requirement by NICE as it is used to inform health economic evaluation. Please refer to individual review protocols for details relevant to each systematic review. Unfortunately, the outcomes prioritised for inclusion were not often reported in the literature

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				Gonzalez, J.S., Peyrot, M., McCarl, L.A., Collins, E.M., Serpa, L., Mimiaga, M.j> & Safren, S.A. (2008). Depression and diabetes treatment nonadherence: A meta-analysis. Diabetes Care, 31(12). 2398-2403. Lemanek, K.L., Kamps, J. & Chung, N.B. (2001). Empirically supported treatments in pediatric psychology: Regimen adherence. Journal of Pediatric Psychology, 26(5): 253-275. Speight, J., Reaney, M.D., Barnard, K.D. (2009) Not all roads lead to Rome – a review of quality of life measurement in diabetes. Diabetic Medicine, 26(4), 315-327.	
National Children and Young People's Diabetes Network	FULL	47	General	The following relevant NICE guidelines for children and young people are missing: - Managing overweight and obesity among children and young people - Promoting physical activity for children and young people - Improving children and young people's health	Thank you for this comment. The guideline on overweight and obesity mentioned in the comment has been replaced by the updated guideline 'obesity: identification, assessment and management of overweight and obesity in children, young people and adults'. This is already included in the list of related NICE guidance, as is the similar guidance about prevention of overweight and obesity in children and adults. The public health guidance on promoting physical activity for children and young people has now been included in the list of related NICE guidance. Specific guidance on improving children and young people's health (other than in children and young people with cancer) could not be identified and so this has not been added to the list of related

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					NICE guidance
Royal College of Paediatrics and Child Health	FULL	47	General	The following relevant NICE guidelines for children and young people are missing: - Managing overweight and obesity among children and young people - Promoting physical activity for children and young people - Improving children and young people's health	Thank you for this comment. The guideline on overweight and obesity mentioned in the comment has been replaced by the updated guideline 'obesity: identification, assessment and management of overweight and obesity in children, young people and adults'. This is already included in the list of related NICE guidance, as is the similar guidance about prevention of overweight and obesity in children and adults. The public health guidance on promoting physical activity for children and young people has now been included in the list of related NICE guidance. Specific guidance on improving children and young people's health (other than in children and young people with cancer) could not be identified and so this has not been added to the list of related NICE guidance
British Psychological Society	FULL	51	9	Fears and anxieties should be identified by someone with expertise in this area, preferably the clinical psychologist embedded within the MDT (as described in the DoH 2012 guidance). Depression is often undetected in diabetes clinics by health professionals and the diagnosis of depression is missed in 30 - 50% of the cases in primary and secondary care. (Egede et al, 2003) For this reason it is important to monitor psychological well-being using a	Thank you for this comment. The guideline development group recognise the importance of identifying depression early in this patient group, but did not consider the effectiveness of monitoring psychological well-being in the clinical setting. Making a recommendation about regular screening in this population is therefore outside the remit of the guidance

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				questionnaire with a subscale to measure depressed and anxious mood to identify children and young people at risk of depression to enable early intervention. References: Egede, L.E. (2007). Failure to recognize depression in primary care: Issues and Challenges. Journal of General Internal Medicine, 22(5), 701-703.	
Royal College of Paediatrics and Child Health	FULL	56	3.2.5	The NPDA would support this action of trying to make recommendations that will influence outcome. Therefore it is not clear why annual screening for celiac disease is no longer considered as affecting outcome when there is evidence that living with celiac disease affects QoL. Furthermore, dyslipidaemia screening is not recommended by NICE in children yet it is in adults – why the difference? This is a lifelong condition and dyslipidaemia affects outcomes. It is a very useful screening tool used by many paediatricians to help educate patients and families on the importance and relationship between diabetes control and dyslipidaemia. In childhood we are trying to prepare children for a lifelong condition and why a screening tool should suddenly change at transition is unclear!	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (coeliac disease and dyslipidaemia in this case). In the case of coeliac disease the guideline development group recognise that NICE has produced separate guidance and so the recommendations in this guideline have been amended to cross-refer to the NICE coeliac disease guideline for guidance on monitoring for coeliac disease in children and young people with type 1 diabetes
Royal College of Paediatrics and Child Health	FULL	57	3.2.7	Clearly the expert committee are highly recognised experts in the field of paediatric diabetes but do not necessarily represent consensus views across the speciality. It seems that some issues where there was lack of evidence such as the use of osmotic agents for cerebral oedema, the expert committee were allowed to influence the guidance which might reflect the committee's membership. However, in other areas such as those stated above (celiac and	Thank you for submitting comments in response to the stakeholder consultation. The draft guideline was subjected to extensive consultation with a wide range of stakeholder organisations representing healthcare professionals and patient

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				dyslipidaemia screening) the committee made decisions that are not necessarily representative of the expert beliefs. A wider consultation needs to be made on some of these gray areas. For lipids there is also extrapolation from adult studies.	support groups. The breadth of opinions and views expressed as part of this process have been taken into account in the final recommendations. Please note, however, that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (coeliac disease and dyslipidaemia in type 1 diabetes in this case) and this is why the corresponding sections of the guideline have not generally been modified as part of the 2015 update. In the case of coeliac disease the guideline development group recognise that NICE has produced separate guidance and so the recommendations in this guideline have been amended to cross-refer to the NICE coeliac disease guideline for guidance on monitoring for coeliac disease in children and young people with type 1 diabetes
South West Paediatric Diabetes Network	FULL	73	14 16	I would argue that consideration of MODY in children is of greater importance than type 2 diabetes as although MODY is rare, it is harder to differentiate from type 1 (see later comments) and to miss it would mean someone being on insulin unnecessarily with quality of life and probably cost implications. Has Andrew Hattersley from Exeter been asked to comment?	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was

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					excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The revised recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY. However, the limitations of the scope for the 2015 update prevent the guideline development group from providing more detail about the diagnosis

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					or management of forms of diabetes other than type 1 or type 2
South West Paediatric Diabetes Network	FULL	75	20 27	In terms of thinking of a diagnosis of MODY: - 'Rarely or never produces ketone bodies during times of hyperglycaemia' isn't very easy to identify. - 'Have associated features, such as retinitis pigmentosa, deafness, or another systemic illness or syndrome.' doesn't cover all MODY. - shouldn't strong family history of diabetes be in there?	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The revised recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together

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					these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY. Additionally the recommendations have been revised to include family history of diabetes. However, the limitations of the scope for the 2015 update prevent the guideline development group from providing more detail about the diagnosis or management of forms of diabetes other than type 1 or type 2
South West Paediatric Diabetes Network	FULL	75	28 30	Re measuring antibodies at diagnosis: - We took part in the UNITED study with Andrew Hattersley and if GAD or IA2 were positive then patients were not tested for MODY, which presumably means that the negative predictive value of a positive antibody for MODY is high? - According to your evidence, in children <11y, 63% will have positive GAD or IA2 and 93% will have ≥1 antibody if check GAD, IA2 and IAA/ZnT8. In young people and adults, 75% will have positive GAD or IA2. Therefore if these antibodies were checked at diagnosis you wouldn't need to worry about MODY in those who had at least one positive antibody and I think it alerts you to the possibility of MODY in the negative antibody patients.	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis (specifically evidence for distinguishing between type 1 and type 2 diabetes) and concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic

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					or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY
British Psychological Society	FULL	76	29	Focusing solely on the evidence base of interventions specific to type 1 diabetes is a limitation. There is a wealth of evidence for the effectiveness of psychological interventions across long-term health conditions. Furthermore, there is evidence of the detrimental impact of type 1 diabetes on parental well-being and therefore the need to assess anxiety and depression in parents and families, not just children and young people with the diagnosis of type 1 diabetes. (Streisand et al, 2009) <u>References:</u> Streisand, R., Mackey, E.R. & Herge, W (2009). Associations of parent coping, stress and well-being in mothers of children with diabetes: Examination of data from a national sample, Maternal and Child Health Journal, 14(4): 612-617.	Thank you for this comment. The guideline development group considered the inclusion of studies from other long-term health conditions at the time of protocol development and agreed that it was not appropriate to extrapolate from evidence beyond the population of children and young people with type 1 diabetes when making national recommendations. The review protocol (Appendix E) specified that the satisfaction reported by the children and young people's families was of interest for inclusion in this review but that the assessment and management of their

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					psychological condition was outside the scope of the guideline. The NICE process required prioritisation of the outcomes for inclusion and limits the number that can be considered. An excerpt from each protocol has been added to the beginning of each evidence review, clearly stating which outcomes were prioritised for inclusion. In this review they were as follows. Physical: • HbA1c (minimum follow-up 6 months after completion of primary intervention) • adherence to diabetes management • adverse events (for example, severe hypoglycaemic episodes, diabetic ketoacidosis (DKA) or self-harm) Psychosocial: • health-related quality of life • children and young people's and families' satisfaction with the intervention • depression or anxiety • school performance or attendance

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					• risk-taking behaviours
National Children and Young People's Diabetes Network	FULL	76	29	Fears and anxieties should be identified by someone with expertise in this area, preferably the clinical psychologist embedded within the MDT (as prescribed in the DoH 2012 guidance). Depression is often undetected in diabetes clinics by health professionals and the diagnosis of depression is missed in 30 - 50% of the cases in primary and secondary care (Egede et al, 2003)	Thank you for this comment. The guideline development group recognise the importance of identifying depression early in this patient group, but did not consider the effectiveness of monitoring psychological well-being in the clinical setting. Making a recommendation about regular screening in this population is therefore outside the remit of the guidance
British Psychological Society	FULL	78	5.2.4	This study appears to focus on psychological intervention in relation to adjustment to diagnosis. This demonstrates emerging and promising evidence for the benefits of early psychological intervention in adjusting to diagnosis on adherence and family functioning.	Thank you for this comment on the evidence presented in Section 5.2.4. Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (psychological support in this case)
National Children and Young People's Diabetes Network	FULL	78	5.2.4	Focusing on evidence base of interventions specific to type 1 diabetes is flawed. There is a wealth of research and evidence base of psychological interventions across chronic health conditions. Flawed outcome criteria in the search for evidence base has led to lack of evidence (see point made in order number 20 above) Furthermore, there is evidence base of the impact of type 1 diabetes on parents (e.g. Streisand et al., 2008) and therefore the need to focus on anxiety and depression in parents and families, not just children and young people with the diagnosis of type 1 diabetes.	Thank you for this comment. The guideline development group acknowledge the points made in relation to the extrapolation of evidence from other long-term conditions and adult populations. At the time of protocol development the option of including studies that enrolled participants with other conditions was considered, but the guideline development group concluded that there were issues specific to children and young people with diabetes that were not present in other conditions.

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					Also, due to concerns around the interpretation of such data and their reliability for informing national recommendations, indirect evidence is typically sought only if there is no evidence available in the population of interest. The need for more data directly relevant to this population is captured in a research recommendation. In addition, the guideline development group carefully considered, and decided to focus on, the impact of type 1 diabetes on the child or young person only, given the available resources
British Psychological Society	FULL	78	8 15	It is also important to consider parents' preferences as education will not be effective for those who cannot attend, even if it is highly effective for those few who do attend. There is evidence to suggest that specialist diabetes nurses need communication skills training and training in the assessment and recognition of the emotional impact of diabetes from appropriately trained psychologists with expertise in child development and family dynamics (Lowes et al., 2015). As there is no evidence that structured education has an impact on HbA1c, (Christie et al, 2014) education needs to take place in a therapeutic/collaborative context with more individualised interventions so that treatment can be matched to lifestyle preferences and treatment preferences. References: Christie, D., Thompson, R., Sawtell, M., Allen, E., Cairns, J., Smith, F., Jamieson,	There was no evidence identified to support structured education from diagnosis (structured here meaning a formal training or education package with a recognised curriculum and approaches to delivery). The guideline recommendations do, however, list core topics that should be covered as part of (unstructured) education An individualised approach to education is already covered in the recommendations and the guideline development group's remit did not include consideration of who delivers care and training to deliver education

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				E., Hargreaves, K., Ingold, A., Brooks, L., Wiggins, M., Oliver, S., Jones, R., Elbourne, D., Santos, A., Wong, I.C., O'Neill, S., Strange, V., Hindmarsh, P., Annan, F., Viner, R. (2014). Structured, intensive education maximising engagement, motivation and long-term change for children and young people with diabetes: a cluster randomised controlled trial with integral process and economic evaluation - the CASCADE study. Health Technology Assess, 18(20):1-202 Lowes, L., Eddy, D., Channon, S., McNamara, R., Robling, M., Gregory, J.W. (2015) The Experience of Living with Type 1 Diabetes and Attending Clinic from the Perception of Children, Adolescents and Carers: Analysis of Qualitative Data from the DEPICTED Study. J Pediatr Nurs, 30(1), 54-62.	
British Psychological Society	FULL	80	5	There is no reference to psycho-education on the emotional impact on or coping of parents of a diagnosis of type 1 diabetes on their child e.g., • Mood and its effects on blood glucose levels (and vice versa) • Impact of diagnosis of a long term condition on relationships and education around adjustment • Impact of blood glucose levels on cognitive function • Stress in children, young people and their families and ways to cope and manage it	Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (universal principles of education in this case)
National Children and Young People's Diabetes Network	FULL	80	5	A lot of weight has been placed on what and how parents feel education should be delivered to the dismissal of the evidence base and what has been found to have the greatest clinical impact. There is strong evidence base to suggest that specialist diabetes nurses need communication skills training and training in the assessment and recognition of the emotional impact of diabetes from appropriately trained psychologists with expertise in child development and family dynamics (e.g. Lowes et al., 2015).	There was no evidence identified to support structured education from diagnosis (structured here meaning a formal training or education package with a recognised curriculum and approaches to delivery). The guideline recommendations do, however, list core topics that should be covered as part of (unstructured) education

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				Evidence for psychological group interventions with children and young people have been shown to improve adherence and adjustment (e.g. Greco et al., 2001)	An individualised approach to education is already covered in the recommendations and the guideline development group's remit did not include consideration of who delivers care and training to deliver education Thank you for this comment. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (non-adherence and adjustment to diagnosis in this case).
British Psychological Society	FULL	81	General	Educational aims for parents of pre-school and primary school children should also include education on changes in their child's mood and behaviour (e.g. anxiety, depression, and anger) and the possible impact on peer relationships and activities, and how to manage these. School staff awareness and understanding certainly needs to improve and develop, and there are many possibilities which could help this. A particular area is that of managing the transition between primary and secondary school. The Society believes that there is currently very little in the way of psychological support for CYP with diabetes and their families.	There was no evidence identified to support structured education from diagnosis (structured here meaning a formal training or education package with a recognised curriculum and approaches to delivery). The guideline recommendations do, however, list core topics that should be covered as part of (unstructured) education. The guideline development group's view is that the core topics and the recommendations to tailor education to the individual and add other topics as needed cover much of the stakeholder's comment. Moreover, the majority of children and young people with

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					diabetes will not have anxiety or depression anyway, despite being at increased risk, and so these do not need to be listed as core topics The guideline development group's remit did not include consideration of who delivers care and training to deliver education, nor did it cover school-based care
British Psychological Society	FULL	81	General	Adolescence is a period of high risk for all young people (regardless of whether or not they live with a long term condition) due to physiological and psychosocial changes, including cognitive neuro-development. Living with Type 1 diabetes places adolescents at higher risk for problems such as diabetes-related distress, anxiety, depression, disordered eating, and deterioration of adherence to their diabetes regimen.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (adolescence in this case)
National Children and Young People's Diabetes Network	FULL	81	General	There is no mention of education for the emotional impact on parents of a diagnosis of type 1 diabetes on their child.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on topics that are outside the scope of the guideline, which applies in the case of this comment
National Children and Young People's Diabetes Network	FULL	81	General	Educational aims for infants and preschool children should also include education on changes in their child's mood and behaviour (e.g. anxiety, depression, and anger) and how to manage these.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been

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					reviewed since the original (2004) guideline (education according to age group in this case).
National Children and Young People's Diabetes Network	FULL	81	General	Educational aims for primary school children should also include education on changes in their child's mood and behaviour (e.g. anxiety, depression, and anger) and the possible impact on peer relationships and activities, and how to manage these.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (education according to age group in this case). Moreover there was no evidence identified to support structured education from diagnosis (structured here meaning a formal training or education package with a recognised curriculum and approaches to delivery). The guideline recommendations do, however, list core topics that should be covered as part of (unstructured) education. The guideline development group view is that the core topics and the recommendations to tailor education to the individual and add other topics as needed cover much of the stakeholder's comment. The majority of children and young people with diabetes will not have anxiety or depression anyway, despite being at increased risk, and so these do not need to be listed as core topics

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National Children and Young People's Diabetes Network	FULL	81	8	Change to or add "hyperglycaemia"	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (education according to age group in this case)
Royal College of Paediatrics and Child Health	FULL	81 206	29 22	Add "without inducing fear of hypoglycaemia"	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (education according to age group in this case)
British Psychological Society	FULL	81	43 46	There is no evidence that conflict resolution and bargaining techniques constitute 'coping skills training'. 'Coping skills training' is a phrase used to denote a range of skills which are chosen by the researcher/therapist (e.g. coping skills in a standardised CBT intervention, in group interventions ranging from coping with pain, coping with diagnosis of personality disorder, treating substance abuse, etc.,) The use of the term 'coping skills training' suggests a standardised intervention, which is inaccurate and is not supported by evidence base.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (education according to age group in this case)
National Children and Young	FULL	81	43 46	The wording on this statement is inappropriate and pathologises and belittles young people's experiences of the transition into adolescence.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not

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People's Diabetes Network				Adolescence is a period of high risk for all young people (regardless of whether or not they live with a chronic illness) due to physiological and psychosocial changes, including cognitive neuro-developments. Living with Type 1 diabetes places adolescents at higher risk for problems with anxiety, depression, disordered eating, and deterioration of adherence to their diabetes regimen.	able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (adolescence in this case)
British Psychological Society	FULL	82	6 8	Recommendations should include education for children and young people as well as parents and family members about identifying and coping with anxiety and low mood as well as ways to improve well-being and energy. This is in line with The Global ISPAD Consensus Guidelines (https://www.ispad.org/content/ispad-clinical-practice-consensus-guidelines-2009)., which state that "psychosocial factors are the most important influences affecting the care and management of diabetes"	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (education according to age group in this case).
National Children and Young People's Diabetes Network	FULL	82	6 8	There is no evidence base for conflict resolution and bargaining techniques as 'coping skills training'. 'Coping skills training' is not a standardised intervention. 'Coping skills training' is a phrase used to denote a range of skills which are chosen by the researcher/therapist (e.g. coping skills in a standardised CBT intervention, in group interventions ranging from coping with pain, coping with diagnosis of personality disorder, treating substance abuse, etc…) The use of the term 'coping skills training' is misleading and inaccurate and is not supported by evidence base.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (education according to age group in this case)
Royal College of Paediatrics and Child	FULL	96 100	5.4.6.2	I don't think anyone would disagree that ongoing structured education is important despite the lack of evidence from RCT's to support it. NICE need to therefore be consistent with their approach ie happy to recommend structured education	There was no evidence identified to support structured education from diagnosis (structured here meaning a

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Health			15	despite no evidence form RCT's, happy to support thyroid screening on the basis of expert opinion but not happy to support celiac of dyslipidaemia screening based on expert opinion. This is not a consistent approach.	formal training or education package with a recognised curriculum and approaches to delivery). The guideline recommendations do, however, list core topics that should be covered as part of (unstructured) education. The guideline development group's view is that the core topics and the recommendations to tailor education to the individual and add other topics as needed will ensure that effective education is provided for children and young people with diabetes. In the absence of evidence of clinical and cost effectiveness of structured education programmes as defined above, the recommendations for (unstructured) education were based on the expertise and experience of the guideline development group. This is consistent with the NICE guideline development process in which evidence of clinical and cost effectiveness must be sought, but if no evidence is available (or if there is insufficient evidence) then the guideline development group may use their clinical and patient experience and expertise to reach a consensus on what constitutes

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					good practice. In the case of structured education programmes there would be significant cost implications in setting up and delivering the programmes, and the absence of evidence of cost effectiveness was an important consideration for this review question. In some other areas covered by the 2015 update the guideline development group wished to recommend current practice and provided this is not expected to result in ineffective or unsafe care and there will be no significant uplift in resource use formal evidence of cost effectiveness is not always required. Please note that the specific topics other than structured education that are mentioned in the comment (monitoring for coeliac disease, thyroid disease and dyslipidaemia in children and young people with type 1 diabetes) were excluded from the scope of the 2015 update and so the guideline development group were not able to change the recommendations in those areas in any case

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British Psychological Society	FULL	100	General	"Take particular care" does not specify what resources need to be used to communicate with children and/or families with physical and sensory, and/or where English is not the first language. Accessible communication options could be listed (e.g. written information or audiotaped material and professional interpreters should be sought for those whose preferred language is not English).	Thank you for this comment. The guideline guideline development group deliberately left these recommendations broad as they did not look at evidence as part of the 2015 update to allow specific individual circumstances to be considered (because this part of the guideline was excluded from the 2015 update) and so no specific resources are recommended. Although the guideline development group were unable to amend the phrasing or content of these recommendations they selected them as key priorities for implementation (key recommendations) because of the importance of the content
				There are several references to increased rates of type 2 diabetes among people from black and ethnic minorities and yet no recommendations for ensuring that services are accessible to black and ethnic minority members of the community.	This issue was discussed at length during development of the guideline, but no specific evidence was found regarding improving access for different ethnicities. The recommendations about education for children and young people with type 1 diabetes and those with type 2 diabetes do include tailoring to individual circumstances, including taking into account cultural considerations. In response to the stakeholder comments the recommendations about diet for both type 1 and type 2 diabetes have been revised to include taking account of social and

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					cultural considerations to allow for different ethnicities
National Children and Young People's Diabetes Network	FULL	100	General	Recommendations should include education on psychological wellbeing in children and young people as well as parents and family members. This is in line with The Global ISPAD Consensus Guidelines (2000), which state that "psychosocial factors are the most important influences affecting the care and management of diabetes"	There was no evidence identified to support structured education from diagnosis (structured here meaning a formal training or education package with a recognised curriculum and approaches to delivery). The guideline recommendations do, however, list core topics that should be covered as part of (unstructured) education. The guideline development group's view is that the core topics and the recommendations to tailor education to the individual and add other topics as needed cover much of the stakeholder's comment. The majority of children and young people with diabetes will not experience psychological or psychosocial issues, despite being at increased risk, and so these do not need to be listed as core topics
Royal Cornwall Hospitals NHS Trust	FULL	100	General	Family members or carers and, where appropriate, school nurses and other carers should be trained and equipped to give intramuscular glucagon for severe hypoglycaemia in an emergency [1.2.78] We do not teach teachers at school as we believe that they will rarely use Glucagon and then not be competent when required. If however a child was going on a residential trip we would train a relevant member of staff.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case). School-based care is outside

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					the scope of the 2015 update and so the part of the 2004 recommendation that refers to school nurses has not been updated
British Psychological Society	FULL	100	40 43	The research recommendations do not highlight the need to explore the benefits of education on well-being and/or what aspects of the education have the greatest benefits.	Thank you for this comment. The evidence for components and topics of an education package is presented in Section 5.2 and includes a Health Technology Appraisal which examined the effects on psychosocial outcomes. This evidence review was not updated in the 2015 guideline as it was not included in the scope of the update
	Full	100		There is growing evidence that successful education programmes, and indeed successful insulins (such as lispro and glargine) like DAFNE and X-pert patients improve treatment satisfaction and quality of life and not just HbA1c. There are multiple references to papers showing improved QoL following education or change of insulin regimen on the list of selected references to the ADDQoL measure of the impact of diabetes on quality of life on the following website www.healthpsychologyresearch.com under the Guidelines tab and multiple references to interventions that improve DTSQ treatment satisfaction scores in the list of selected refs to the DTSQ. There is a DTSQ-Teen for teenagers and a DTSQ-Parent for parents of children with diabetes of all ages as well as a DTSQ for adults but most of the published research is with adults.	The guideline development group have made several recommendations for further research and they have selected research related to peer-led education as the top priority for research to evaluate education for children and young people with type 1 diabetes. The list of outcomes that could be evaluated as part of this research has been revised in the light of the comment to include quality of life
National Children and Young People's Diabetes	FULL	100	40 43	"Take particular care" does not specify what resources need to be used to communicate with children and/or families with physical and sensory and/or where English isn't the first language. This section should be removed if not amended appropriately.	Thank you for this comment. The guideline development group deliberately left these recommendations broad as they did not look at evidence as part of the 2015 update to allow specific individual

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Network				Accessible communication options should be listed (e.g. written information or audiotaped material and professional interpreters should be sought for those whose preferred language is not English).	circumstances to be considered (because this part of the guideline was excluded from the 2015 update) and so no specific resources are recommended. Although the guideline development group were unable to amend the phrasing or content of these recommendations they selected them as key priorities for implementation (key recommendations) because of the importance of the content
British Psychological Society	FULL	101	General	We recommend the guidelines, avoid using the term Health Related Quality of Life or HRQoL as it is widely misused in the literature where health status measures that don't measure QoL of any description are commonly and wrongly referred to as HRQoL measures. Consequently much of the literature is highly misleading in suggesting interventions improve QoL when in fact they only improve health status and QoL isn't measured (see Bradley, C. (2001) References: Bradley C (2001) Importance of differentiating health status from quality of life. The Lancet, 357, 7-8. http://www.ncbi.nlm.nih.gov/pubmed/11197385	In the NICE guidelines manual health-related quality of life is considered an important measure of effect for health economic evaluation. "The QALY is the measure of health effects preferred by NICE, based on patient-reported changes in health-related quality of life" and is thus prioritised for inclusion in the systematic reviews. In the 2015 update, each review specifies how quality of life has been measured and reported within the evidence. The guideline development group acknowledge the challenges associated with the use of this term in diabetes, i.e. measures of health status versus wellbeing. The protocols in Appendix E do not specify particular measures as the review aims to report whatever data are available. The validity and reliability of the scales is taken into

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					consideration when evaluating the quality of the evidence and at the time of making recommendations
National Children and Young People's Diabetes Network	FULL	101	General	Research recommendations do not highlight the need to explore the benefits of education in wellbeing and/or what aspects of the education have the greatest benefits.	Thank you for this comment. The evidence for components and topics of an education package is presented in Section 5.2 and includes a Health Technology Appraisal which examined the effects on psychosocial outcomes. This evidence review was not updated in the 2015 guideline as it was not included in the scope of the update
National Children and Young People's Diabetes Network	FULL	117	17	Change "dietary" to "insulin" regimen	Thank you. This typographical error in the full guideline has been corrected
Novo Nordisk Ltd	FULL	120	29 30	The guideline states that for insulin aspart (NovoRapid®) the pharmacodynamic profile differs for children and young people from adults. However a clinical trial comparing preprandial soluble human insulin with post-prandial insulin aspart was performed in small children (20 patients aged 2-6 years, studied for 12 weeks, amongst those were four patients younger than 4 years old) and a single dose PK/PD trial was performed in children (6-12 years) and adolescents (13-17 years). The pharmaco-dynamic profile of insulin aspart in children was similar to that seen in adults (NovoRapid® SPC). Novo Nordisk suggests that this is corrected. It should be noted that insulin aspart is licensed for patients from the age of 2 years – please include a statement reflecting this information.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (insulin preparations in this case)
Novo Nordisk	FULL	121	8	Novo Nordisk suggests highlighting the fact that BIAsp 30 (insulin analogue) has a	Thank you for submitting comments in

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Ltd				faster onset of action than biphasic human insulin and should generally be given immediately before a meal. When necessary, BIAsp30 can be given soon after a meal (NovoMix® 30 SPC). This flexibility in dosing is an advantage over human insulin in this age group and so we suggest it is included within the guideline.	response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (insulin preparations in this case)
Novo Nordisk Ltd	FULL	123	35 44	Insulin aspart has been shown to significantly reduce the rate of major nocturnal hypoglycaemia in a double blind cross over trial in 155 adults with type 1 diabetes. Risk of minor hypoglycaemic episodes was significantly lower with insulin aspart and there was no difference in glycaemic control observed between treatments (Heller et al. Diabet Med 2004;21:769–75). Novo Nordisk requests this data also be added to this section to demonstrate the clinical advantage of insulin aspart over human insulin.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (insulin preparations in this case)
Novo Nordisk Ltd	FULL	123	45	The studies that have been included in the patient preference section, when comparing rapid-acting insulin analogues with soluble human insulin include only insulin lispro. Novo Nordisk suggests to ensure that the data is fair and balanced, the following randomised trials should be considered: ➢ A 6-month study by Bott et al. (2003) compared quality of life (QoL) and treatment satisfaction in 424 patients with Type 1 diabetes receiving the rapid-acting insulin analogue, insulin aspart (NovoRapid®), with that in patients receiving soluble human insulin. After 6 months, insulin aspart was associated with significantly greater improvement in treatment satisfaction than human insulin in two different scales ($P < 0.01$), and in QoL with respect to diet restrictions ($P < 0.01$). Improved satisfaction was mainly due to increased dietary and leisure time flexibility ($P < 0.0001$). ➢ Another 6 month multi-centre, randomised open-labelled, parallel group	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (insulin preparations in this case)

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				study in 1070 subjects with type 1 diabetes used the DTSQ8. A significant difference in treatment satisfaction with insulin aspart was shown with the largest differences between treatments related to the convenience, flexibility and satisfaction-to continue-present-treatment criteria. (Home et al. Diabetic Medicine 2000; 17: 762-770). ➢ A 12 week, cross-over trial, (in 26 children, 17 boys and 9 girls; aged 2.4-6.9yrs), which compares insulin aspart and regular human insulin, assessed treatment satisfaction, the treatment satisfaction score tended to be better for insulin aspart and reached statistical significance regarding the parental satisfaction with continuing insulin aspart treatment (P<0.05). (Danne T et al. Pediatr Diabetes 2007; 8:278-285).	
Novo Nordisk Ltd	FULL	126	8 9	NovoNordisk requests that as part of the overall question 'What is the most appropriate intermediate or long-acting insulin for children and young people?' the clinical trial data assessing insulin degludec (Tresiba®) in children and adolescents should be included: ➢ A study has compared insulin degludec with insulin detemir both in combination with bolus insulin aspart in children and adolescents with type 1 diabetes. Insulin degludec dosed once daily showed similar reduction in HbA_{1c} at week 52 at lower dose and significantly greater reduction in FPG from baseline versus insulin detemir dosed once or twice daily. The rates of severe, confirmed and nocturnal hypoglycaemia were not statistically significantly different with insulin degludec versus insulin detemir. The rate of hyperglycaemic episodes with ketosis was significantly lower for insulin degludec reconfirming the clinical benefits of the long duration of action of insulin degludec. (Thalange et al. Diabetologia 2014; 57 (Suppl 1): S395 Abstract 964). The full manuscript has now been published, as Thalange et al. Pediatric Diabetes, 2015.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (insulin preparations and insulin delivery systems in this case)

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				DOI: 10.1111/pedi.12263. Insulin degludec is a basal insulin with a -long duration of action and stable action profile that results in a glucose lowering effect beyond 42 hours and a lower day-to-day variability in glucose-lowering effect compared with insulin glargine (Tresiba® SPC). Insulin degludec enables patients who miss a scheduled dose to administer it when it is discovered (ensuring a minimum of 8 hours between injections of insulin degludec) without increasing the risk of hypoglycaemia (Tresiba® SPC). This is a particularly important benefit for children and young people. The delivery device for insulin degludec (FlexTouch®), has shown consistency and accuracy of dose delivery with significantly lower injection force than comparator pens (Hemmingsen H, Diabetes Technol Ther 2011; 13:1207–1211).	
Novo Nordisk Ltd	FULL	126	11	The section on insulin glargine includes data in adults. Since this is a guideline for children, then the section should only cite data in children which is relevant. Novo Nordisk suggests the data on adults using insulin glargine is not relevant in this guideline and should be removed. Alternatively the guideline should also cite the data in adults with insulin detemir and other insulins in order to be balanced, for example: In long-term trials in adult patients with type 1 diabetes receiving basal-bolus insulin therapy, fasting plasma glucose was improved with insulin detemir compared with NPH insulin. Glycaemic control with insulin detemir was comparable to NPH insulin, with a lower risk of nocturnal hypoglycaemia and no associated weight gain (Levemir® SPC).	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (insulin preparations in this case)
Novo Nordisk Ltd	FULL	127	22	Novo Nordisk requests that the section on insulin detemir is expanded to also reflect the data in children and highlight that it is licensed for children aged 2 years and above. The time action profile of insulin detemir is statistically significantly less variable and therefore more	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been

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				predictable than for NPH (Neutral Protamine Hagedorn) insulin. The duration of action is up to 24 hours depending on dose providing an opportunity for once or twice daily administration (Levemir® SPC). There is data in children which the guideline does not seem to acknowledge. Please see below. ➢ 26 weeks of treatment with insulin detemir or NPH insulin once daily or twice daily in combination with insulin aspart in children and adolescents (aged 6–17 years) resulted in: similar HbA_{1c} control in both treatment groups, a similar proportion of subjects experiencing hypoglycaemic episodes during the maintenance period with both treatment groups, a significantly lower risk of having a nocturnal hypoglycaemic episode with insulin detemir than with NPH insulin and a significantly lower baseline-adjusted BMI with insulin detemir than with NPH insulin (Robertson et al. Diabet Med 2007;24:27–34). ➢ Another study compared the safety and efficacy of insulin detemir with NPH insulin in young patients (aged 2–16 years) with type 1 diabetes after 1 year of treatment (Thalange et al. Diabet Med 2013;30:216–25; Thalange et al. Pediatr Diabetes 2010;11(Suppl. 14):83). After 52 weeks, insulin detemir provided glycaemic control comparable to NPH insulin, with significantly lower nocturnal hypoglycaemia and significantly less weight gain. A 12 month extension in the 2-5 years old subgroup showed similar glycaemic control with significantly less hypoglycaemia including nocturnal hypoglycaemia with insulin detemir and lower weight Z scores vs NPH. Treatment with insulin detemir had no correlation between antibody levels and HbA_{1c} or insulin dose (Thalange et al. Paedietric Diabetes 2011;12:632-41)	reviewed since the original (2004) guideline (insulin preparations in this case)

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				This data is very relevant for this guideline and should be included. We would also request that the benefits in relation to weight are reflected in this guideline.	
Novo Nordisk Ltd	FULL	129	9	This is incorrect. There is randomised controlled trial data for insulin detemir in children which shows advantages in reducing nocturnal hypoglycaemia. The guideline should be updated to reflect this.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (insulin preparations in this case)
BD UK	Full	137	32	Becton Dickinson (BD) would like to thank the guideline development group for the opportunity to comment on the draft guideline for the diagnosis and management of type 1 and type 2 diabetes in children and young people. BD is a leading manufacturer of both syringes and pen needles for insulin injection devices, with considerable experience in research and education on insulin injection technique, and as such would like to provide feedback on the guideline recommendations regarding needle choice and injection technique. 26. Provide children and young people with type 1 diabetes with insulin injection needles that are of an appropriate length for their body fat. [2004, amended 2015] The recommendation to use needles in children and younger people that are of an appropriate length for their body fat suggests that there might be theoretical circumstances where a longer needle provides better glycemic control, or a shorter needle option might be inappropriate, for example in children with obesity, due to potential risk of intradermal injection. We would advise that this is not consistent with current clinical evidence. We would also advise that the RCT reviewed by the GDC, comparing 8mm and 12.7mm needles, [1] is not suitable to form the basis of this guidance as needles of these lengths are no longer considered part of clinical practice and guidance for children. In 2010 the	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (insulin injection techniques and needle choice in this case)

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				advisory board for the Third Injection Technique Work Shop found that there is no medical reason for recommending needles longer than 6 mm for children and adolescents.[2] Since then, further evidence has emerged and we now strongly believe that only 4mm needles should be used (at least, initially) in children and young people. The evidence available indicates that the risk of intradermal injection with 4, 5 and 6 mm needles is extremely low, particularly in children where the skin thickness is slightly less than in adults.[3] As has been identified in the draft guideline on type 1 diabetes in adults, Gibney et al studied skin thickness in 388 patients at four different sites, concluding that skin thickness is rarely greater than 3–3.2 mm, even in obese adults.[4] Lo Presti et al investigated subcutaneous skin and (SC) tissue thickness in 100 children with type 1 diabetes divided into three groups according to age: 2–6, 7–13, and 14–17 years. They found that the mean skin thickness varied from 1.58 ± 0.23 mm in the arm of the youngest children to 2.29 ± 0.41 mm in the buttocks of adolescents age 14-17, slightly less than the dimensions in adults reported by Gibney etal.[3,5] Additionally, Bergenstal et al prospectively demonstrated the safety and equivalent efficacy of a 4mm pen needle vs 8 and 12.7 mm needles in obese adult patients.[6] This finding is supported by the studies identified in the guideline on type 1 diabetes in adults showing equivalence in outcomes with needles longer and shorter than 5mm in length.[7-9] There are two important clinical benefits associated with shorter needles: 1) a reduction in perceived pain and 2) a reduction in the risk of intramuscular (IM) injection. In fact, since the risk of IM injection is directly related to needle cannula length, and several studies demonstrate equivalent glycaemic control with shorter vs longer needles, we suggest it is logical that 4 mm needles be considered the preferred length of pen needle for use in children and young people with diabetes, at least initially.	

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				Shorter pen needles carry a lower risk of intramuscular (IM) injection than longer needles. Gibney et al, 2010 reported that the estimated risk of IM injection is 0.4%, 1.8%, 5.7% and 15% with 4, 5, 6 and 8 mm needles, respectively – pooled across the four common injection sites.[4] Data are now available showing the site-specific estimated risks of IM injection with needles of different length.[9] There are large differences in the risk of IM injection by needle length, injection site (thigh 2–4X higher risk than abdomen), BMI and gender. Shorter needles have a lower risk of IM injection than longer needles at all injection sites.[10] These findings appear to be particularly applicable to children. In a similar study, Birkebaek et al found that 44% of girls and 95% of boys had less than 8mm of skin + subcutaneous (SC) thickness at the thigh, and 16% of girls and 50% of boys had skin + SC thickness of less than 6mm on the thigh and buttocks.[11] Lo Presti et al found that the mean skin + SC thickness at the arm ranged from 4.9 ± 1.47 mm to 6.3 ± 1.94 mm in the 2-6 year and 14-17 year paediatric subgroups respectively.[5] The mean skin + SC thickness at the buttocks in 14-17 year old group was found to be 8.1mm ± 2.81.[3] In patients aged 14-17 years the risk of IM injection was estimated to be 66.1%, 16.1% and 2.4% with 8, 5 and 4 mm needles respectively.[5] In patients age 2-6 years with 8, 5,and 4 mm needles the risk was estimated to be 83.9%, 46.0% and 20.2% respectively.[5] In another study, Birkebaek et al compared the performance of 4 and 6 mm needles in children and lean adults after giving injections straight in without a pinch-up. They found that more patients injected SC using the 4-mm needle than using the 6-mm needle in the abdomen ($p=0.032$) as well as in the thigh ($p \leq 0.001$).[12] This is important because when injected IM, insulin is absorbed at variably higher rates as when injected subcutaneously, the degree of change largely dependent on muscle exertion or exercise, which can result in glycaemic variability and hypoglycaemia.[13-17] Hypoglycaemia represents a substantial cost to the NHS with the cost of managing moderate and severe hypoglycaemia for type 1 diabetes patients estimated to be in excess of £33 million in 2010/2011.[18]	

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				Although the GDC found no studies that evaluated patient preference or long-term complications in relation to needle length in children, in adults there are a number of studies suggesting that shorter needles provide some benefits in terms of pain perception, patient acceptability.[6-9,19] In particular, Bergenstal et al reported that pain was significantly less as measured by VAS with 4 mm needles compared with 8 mm and 12.7 mm needles (both $p<0.05$).[6] Similarly Hirsch et al compared 4, 5, and 8 mm needles in a randomized non-inferiority cross-over trial, showing equivalence between needles in percent absolute change in serum fructosamine.[7] Using a comparative VAS ranging from -75 mm (much less painful) through 0 mm (equally as painful) to +75 mm (much more painful), pain scores were 23.3 mm less for the 4 mm Vs the 8 mm pen needle ($p<0.001$) and 11.9 mm less for the 4 mm vs the 5 mm pen needle ($p=0.019$); both clinically meaningful differences.[7] Although these studies are not in children we believe they are clinically relevant to this patient group as pain is as important, if not more so, for children as well as adults. Patients who are receiving insulin for the treatment of diabetes typically need to inject themselves between 2–4 times per day in order to achieve adequate glycaemic control.[20] Correct insulin administration is crucial in the management of diabetes as it prevents the occurrence, and reduces progression of long-term complications;[21] however, non- adherence is a common problem which can contribute to poor glycaemic control, with immediate adverse consequences.[22] In a survey of over 500 patients with type 1 and type 2 diabetes, 57% of patients skipped insulin injections they knew they should take, while 20% of patients 'sometimes' or 'often' skipped their insulin injections.[23] Injection pain was an independent and significant risk factor for omitting insulin injections.[23] Another survey of 500 patients receiving insulin injections reported that almost 30% consider the injection of insulin to be the hardest part of their diabetes care, and 47% of patients said they would be more adherent to their treatment regimen if they knew about a way to ease the pain and discomfort associated with their insulin injections.[24]	

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				In younger patients the risk of IM injection appears to be very high, particularly in very young patients, but also in adolescents. Using shorter needles may also be less painful than longer ones. Including recommendation 26 in the guideline could lead clinicians to erroneously believe that there may be times when using a longer needles in children is appropriate. We find the evidence sufficiently compelling to consider the use of needles longer than 4mm in children to be a questionable practice. We therefore suggest that recommendation 26 be revised to include a recommendation that only 4 mm needles should be used initially in children, in line with current international consensus. Should this not provide the desired outcomes, only then should a longer needle length be recommended. Indeed, in very young children ages 2-6, the available evidence indicates that a 4mm length needle should be used with a lifted skin-fold. 1. Tubiana-Rufi N, Belarbi N, Du Pasquier-Fediaevsky L, Polak M, Kakou B, Leridon L, et al. Short needles (8 mm) reduce the risk of intramuscular injections in children with type 1 diabetes. Diabetes Care. 1999;22:1621–5. 2. Frid, A. et al. New injection recommendations for patients with diabetes. Diabetes & metabolism 36 Suppl 2, S3-18, doi:10.1016/S1262-3636(10)70002-1 (2010) 3. Smith CP, Sargent MA, Wilson BP, Price DA. Subcutaneous or intramuscular insulin injections. Arch Dis Child 1991;66:879-82. 4. Gibney, M. A., Arce, C. H., Byron, K. J. & Hirsch, L. J. Skin and subcutaneous adipose layer thickness in adultwith diabetes at sites used for insulin injections: implications for needle length recommendations. Current medical research and opinion 26, 1519-1530, doi:10.1185/03007995.2010.481203 (2010) 5. Lo Presti D, Ingegnosi C, Strauss K. Skin and subcutaneous thickness at	

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				injecting sites in children with diabetes: ultrasound findings and recommendations for giving injection.Pediatric Diabetes 2012: 13: 525–533 6. Bergenstal, R. M. et al. Safety and Efficacy of Insulin Therapy Delivered via a 4mm Pen Needle in Obese Patients With Diabetes. Mayo Clinic proceedings, doi:10.1016/j.mayocp.2014.12.014 (2015). 7. Hirsch, L. J. et al. Comparative glycemic control, safety and patient ratings for a new 4 mm x 32G insulin pen needle in adults with diabetes. Current medical research and opinion 26, 1531-1541, doi:10.1185/03007995.2010.482499 (2010). 8. Miwa, T. et al. Comparison of the effects of a new 32-gauge x 4-mm pen needle and a 32-gauge x 6-mm pen needle on glycemic control, safety, and patient ratings in Japanese adults with diabetes. Diabetes technology & therapeutics 14, 1084-1090, doi:10.1089/dia.2012.0170 (2012). 9. Hirsch, L. J., Gibney, M. A., Li, L. & Berube, J. Glycemic control, reported pain and leakage with a 4 mm x 32 G pen needle in obese and non-obese adults with diabetes: a post hoc analysis. Current medical research and opinion 28, 1305-1311, doi:10.1185/03007995.2012.709181 (2012). 10. Hirsch, L., Byron, K. & Gibney, M. Intramuscular risk at insulin injection sites-measurement of the distance from skin to muscle and rationale for shorter-length needles for subcutaneous insulin therapy. Diabetes technology & therapeutics 16, 867-873, doi:10.1089/dia.2014.0111 (2014). 11. Birkebaek NH, Johansen A, Slovig J. Cutis/subcutis thickness at insulin injection sites and localization of simulated insulin boluses in children with type 1 diabetes mellitus: need for individualization of injection technique? Diabet Med 1998: 15: 965–971 12. Birkebaek NH, Solvig J, Hansen B, Jorgensen C, Smedegaard J,	

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				Christiansen JS. A 4-mm needle reduces the risk of intramuscular injections without increasing backflow to skin surface in lean diabetic children and adults. Diabetes Care 2008: 31: e65. doi: 10.2337/dc08-0977 13. Frid, A., Ostman, J. & Linde, B. Hypoglycemia risk during exercise after intramuscular injection of insulin in thigh in IDDM. Diabetes care 13, 473-477 (1990). 14. The Forum for Injection Technique. The First UK Injection Technique Recommendations. 2nd Edition Available at http://www.fit4diabetes.com/files/2613/3102/3031/FIT_Recommendations_Document.pdf Accessed February 2015 (2011). 15. Thow, J. C., Johnson, A. B., Fulcher, G. & Home, P. D. Different absorption of isophane (NPH) insulin from subcutaneous and intramuscular sites suggests a need to reassess recommended insulin injection technique. Diabetic medicine : a journal of the British Diabetic Association 7, 600-602 (1990). 16. Vaag, A. et al. Variation in absorption of NPH insulin due to intramuscular injection. Diabetes care 13, 74-76 (1990). 17. Karges, B., Boehm, B. O. & Karges, W. Early hypoglycaemia after accidental intramuscular injection of insulin glargine. Diabetic medicine : a journal of the British Diabetic Association 22, 1444-1445, doi:10.1111/j.1464-5491.2005.01654.x (2005). 18. Hex, N., Bartlett, C., Wright, D., Taylor, M. & Varley, D. Estimating the current and future costs of Type 1 and Type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs. Diabetic medicine : a journal of the British Diabetic Association 29, 855-862, doi:10.1111/j.1464-5491.2012.03698.x (2012). 19. McKay, M., Compion, G. & Lytzen, L. A comparison of insulin injection needles on patients' perceptions of pain, handling, and acceptability: a randomized, open-label, crossover study in subjects with diabetes.	

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				Diabetes technology & therapeutics 11, 195-201, doi:10.1089/dia.2008.0054 (2009). 20. De Coninck, C. et al. Results and analysis of the 2008-2009 Insulin Injection Technique Questionnaire survey. Journal of diabetes 2, 168-179, doi:10.1111/j.1753-0407.2010.00077.x (2010). 21. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. The New England journal of medicine 329, 977-986, doi:10.1056/NEJM199309303291401 (1993). 22. Morris, A. D. et al. Adherence to insulin treatment, glycaemic control, and ketoacidosis in insulin-dependent diabetes mellitus. The DARTS/MEMO Collaboration. Diabetes Audit and Research in Tayside Scotland. Medicines Monitoring Unit. Lancet 350, 1505-1510 (1997). 23. Peyrot, M., Rubin, R. R., Kruger, D. F. & Travis, L. B. Correlates of insulin injection omission. Diabetes care 33, 240-245, doi:10.2337/dc09-1348 (2010). 24. American Association of Diabetes Educators. Injection Impact Report. Availabe at http://www.injectionimpact.com/surveyresults.html Accessed February 2015 (2008).	
South West Paediatric Diabetes Network	FULL	146	2 4	Re metformin: - I agree further research is needed, but is the fact that there is a lack of evidence regarding the effectiveness of metformin at the moment a reason not to use it unless it is part of a research study? - It definitely seems to help patients requiring high insulin doses, not just in terms of blood glucose levels, but also to stop weight increasing. - I have not witnessed any harm from using it. Your evidence review says that some studies showed increased mild hypoglycaemia, but that is not necessarily a bad thing and we should be monitoring that routinely and adjusting insulin doses accordingly.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (metformin combined with insulin for the management of type 1 diabetes in this case). The guideline development

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					group have, however, retained the 2004 research recommendation related to this topic
National Children and Young People's Diabetes Network	FULL	149	23 46	Carbohydrate counting: We understand that 'level 3 carbohydrate counting' derives from an American system in 1998, where Level 1 is basic looking at meal volume, Level 2 is advanced learning – identifying carbohydrate- and Level 3 is what we would usually consider as carbohydrate counting. We don't believe there is any robust evidence that this is required from diagnosis. We wonder if it may be unrealistic as families have so much to take on board when adjusting to the diagnosis. Level 1 certainly seems important with a view to working towards Level 3. We wonder what the psychology view on this would be as recent presentations suggest that there is too much to learn at diagnosis.	Thank you for this comment. Level 3 carbohydrate counting is the use of carbohydrate counting with the adjustment of insulin dosage according to carbohydrate content of meals and blood glucose levels, using an insulin:carbohydrate ratio. This has been clarified in a footnote to the recommendation. There is evidence of the effectiveness of using level 3 carbohydrate counting and its use is in keeping with common practice in the UK, which the guideline development group felt was justification for recommending it from diagnosis
Royal College of Paediatrics and Child Health	FULL	169	40	Unless I've missed it the only reason that the GDG have set a tighter target of 6.5% is to fall into line with the adult guideline. The evidence for the adult target is not presented. It would be useful to have a summary of this evidence. Although many caveats to reaching this target for CYP are presented – 'such as the best A1c achievable should be sought', it is important to emphasise this a little more. We know from the recent families with diabetes survey that one of the biggest short term concerns amongst them and their parents is hypoglycaemia. Pushing a target to a potentially unachievable low level raises concern in their eyes about hypoglycaemia. I don't think the lack of evidence reassures them that this is not the case. The wording around the 6.5% needs careful thought so as not to disillusion stakeholders.	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group

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					considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term

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					complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested, as here, that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline
Roche Diagnostics	FULL	170 181	3 17 19 40	The included studies date from 1986 to 1997 and most probably do no longer represent clinical practice, especially because the clinical standard for dosing insulin is SMBG not urine testing. It is a regulatory requirement to use insulin in conjunction with SMBG not with urine testing. SMBG gives immediate, quantitative regulation of blood glucose (see intended use in package inserts), while urine blood glucose only permits a semi-quantitative estimation - and this only, if there is an urge to urinate. Please consider that the timing of insulin dosing necessity and the urge to urinate may not be in synchronicity. Consequently, urine monitoring and visually read stick are not an option for a	These comments are about how to perform capillary blood or urine glucose testing (i.e. what sort of test strip to use) and whether to use urine glucose testing at all. The parts of the guideline referred to in the comment are excluded from the 2015 update which deals only with the frequency of self-monitoring of blood glucose and so the guideline development group are unable to amend them. They do not, however, impact on the recommendations which are specific to

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				flexible insulin management regime which resides upon a flexible insulin application based on the quantitative – not semi-quantitative- determination of blood glucose.	blood glucose testing
Roche Diagnostics	FULL	171 178	25 28 19 27	Glucose monitoring enables safe application of insulin. Therefore, in insulin dependent patients the safe insulin application may be considered as a higher priority than HbA1c reductions. As HbA1c and hypoglycaemia are interrelated, clinical relevance should not be determined by a stand-alone 0.5 HbA1c reduction. Thus, setting a clinical relevance threshold of 0.5% reduction in HbA1c may not be appropriate to assess the value of SMBG for the following reasons: • According to Clar et al. (Clar, Barnard et al. 2010) setting a relevance threshold of 0.5% reduction in HbA1 appears to be "somewhat arbitrary" as there is also a lack of scientific justification of this clinical relevance threshold, especially in diagnostics. • The UKPDS investigators found that every 1.0% reduction in HbA1c was associated with a 37.0% decrease in risk for microvascular complications and a 21.0% decrease in the risk of any end point or death related to diabetes. Furthermore, they did not observe any thresholds of glycaemia for any type of complication of diabetes. This suggests that there is no specific target value of haemoglobin HbA1c for which one should aim but that the nearer to normal the haemoglobin HbA1c concentration the better. (Stratton, Adler et al. 2000). Thus, a statistically significant reduction of HbA1c 0.25 % at 6 months reported in the meta-analysis should not be dismissed at all as a clinically not significant improvement in patient care. • That the DCCT trial shows that a 1 percentage point deceases in HbA1c halved the risk of diabetes-related complications, does not mean that a smaller HbA1c reduction leads to complication reductions that are not	The guideline development group did not consider that the benefit of safe insulin application would be an important determinant of the cost effectiveness of different frequencies of capillary blood glucose monitoring. This was not highlighted as a priority outcome by the guideline development group. The group did consider that a 0.5 percentage point reduction in HbA1c would constitute a clinically important benefit of the various management strategies considered in the guideline. Although this is clearly an arbitrary threshold it was one that the group felt justified in using in terms of interpreting evidence identified in the systematic reviews conducted for the guideline as required by the GRADE approach used by NICE. However, the recommendations emphasise that in clinical practice any reduction in HbA1c level reduces the risk of long-term complications

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				worthwhile to pursue.	
Royal College of Paediatrics and Child Health	FULL	172	29 30	It seems to make little sense that the adult guidance has set a lower A1c target of 6.5% but a higher lower limit of acceptable blood glucose level of 5mmol/l as opposed to 4 mmol/l in CYP. This is a contradiction in terms!	The recommended targets for blood glucose and HbA1c have been determined through an evaluation of available evidence in both the children and young people's guideline and the adult guideline. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline. In addition, each guideline took account of specific considerations relevant to the target population for the recommendations. These included the duration of diabetes during the lifetime of a person who receives the diagnosis as a child or young person, and in whom tighter targets from the outset may help to reduce the risk of long-term complications in the future, as compared to an adult who receives such a diagnosis at a later stage in their life and in whom the tighter targets might not be as relevant. Another consideration specific to the different guidelines was whether or not the person with diabetes is likely to drive; this is more likely to be the case in the guideline for adults

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Roche Diagnostics	FULL	174 178	12 19 38 45	What should be the incentive to conduct and invest into a study of 5 vs. 4 SMBG tests per day? Why should an intervention be investigated at this small increment?	This comment relates to the review question considered for the guideline, which was designed to compare the effectiveness of up to 4 tests per day with 5 or more tests per day (not exactly 4 tests versus exactly 5 tests as implied by the comment). The reason the guideline development group were interested in this comparison was that the original (2004) guideline recommended 4 tests per day and it was considered important to evaluate the effectiveness of this monitoring strategy compared to more frequent monitoring
Roche Diagnostics	FULL	174 175 177	20 24 35 18	• "As depicted in Fig. 1, the effect of a more frequent SMBG on HbA1c-reduction was more pronounced in patients on intensified conventional (≥ 4 daily injections) or continuous subcutaneous insulin infusion therapy (HbA1c-reduction of 0.32% for one additional measurement/day) compared to patients on conventional (1–3 daily injections) therapy (HbA1c-reduction of 0.16% for one additional measurement/day)." (Schutt, Kern et al. 2006)	Thank you for this comment. The guideline development group considered the articles mentioned in the comment for potential inclusion in the review but found that they did not meet the required criteria. • Schutt 2006: mixed population (type 1 and type 2 diabetes) and results were not stratified according by either type 1 diabetes or type 2 diabetes • Wilkinson 2010: participants over the age of 18 years were included and results were not stratified by age • Shalitin 2010: participants over the age of 18 years were included and the results were not stratified by age • Hansen 2009: participants over the age

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				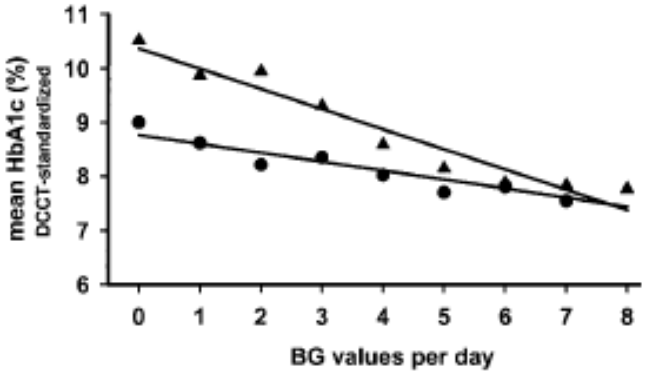 Figure 1: Effects of self-monitoring of blood glucose in type 1 and type 2 diabetes. (Schutt, Kern et al. 2006) • "The purpose of this study was to evaluate factors associated with insulin pump therapy resulting in lower HbA1c levels in young people with Type 1 diabetes mellitus. … Using cross-sectional data, lower HbA1c values correlated with use of more frequent daily insulin boluses (r=-0.46, P<0.0001) and more frequent blood glucose checks/day (r=-0.35, P<0.0001). Young people with HbA1c levels <7.5% (58 mmol/mol) vs. values of 7.5-9.0% (58-75 mmol/mol) or greater equal 9.0% (75 mmol/mol) tested blood glucose more frequently/day (P<0.0001), bolused more frequently/day (P<0.0001), reported more grams of carbohydrates eaten/day (P<0.05) and had a higher per cent bolus insulin/day (P<0.05) compared with the ≥9.0% of youth. Using longitudinal data, 48 of 85 patients had a change in HbA1c level of greater equal 0.5% (6 mmol/mol) between downloads (24 improved). …This study emphasizes the importance of blood glucose testing, of bolus insulin	of 18 years were included and the results were not stratified by age This has been reflected in the excluded studies list for the review question

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				administration and of an increase in the time of temporary basal rate use in relation to improving glycaemic control." (Wilkinson, McFann et al. 2010) • "Switching patients to CSII resulted in a sustained decrease in HbA1c and improved glycaemic control in patients with high HbA1c. Young age, frequent SBGM and lower HbA1c at pump initiation were identified as predictors of achieving glycaemic targets with CSII." (Shalitin, Gil et al. 2010) • "Lower HbA1c was associated with more frequent testing." (Hansen, Pedersen-Bjergaard et al. 2009)	
Roche Diagnostics	FULL	179 180	44 17	Is there any evidence that the "possibility of excessive monitoring" actually happens? Even with an absolute number of test strips used, it is most probably not known how many were excessive and how many were necessary to take care of an unstable glucose situation. Furthermore, as SMBG includes finger pricking, the incentive to excessively test is most probably a negative one. This section is contradictory to p.19 lines 6-8 which states "Advise children and young people with type 1 diabetes and their family members or carers (as appropriate) to routinely perform at least 5 capillary blood glucose tests per day.". "recommending 5 tests per day would improve access to strips": This statement cannot be followed as it may lead to an inappropriate shortage of strips in the hands of some patients, based on individual testing targets, when they need them for controlling unstable glucose situations. This shortage may lead to harm of patients, unnecessary consecutive hospitalisation and thus increased cost beyond the level of test strip cost to CCGs and the NHS.	These comments are about how to perform capillary blood or urine glucose testing (i.e. what sort of test strip to use) and whether to use urine glucose testing at all. The parts of the guideline referred to in the comment are excluded from the 2015 update which deals only with the frequency of self-monitoring of blood glucose and so the guideline development group are unable to amend them. They do not, however, impact on the recommendations which are specific to blood glucose testing
National Children and Young People's	FULL	179	50 51	Blood sugar tests: 5 blood tests a day – where is the evidence for this and why a change from four per day? When would the 5th one be? – if NICE stick to this, they should specify when the tests should be taken. We think that one extra during the night may be ok initially but sets a precedent and anxiety that families may not	Thank you for this comment. The guideline development group discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that

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Diabetes Network				be able to break. Guidance should state a minimum of 4 blood sugar tests per day. The pre-prandial targets set seem reasonable, not sure where the post-prandial targets come from, but again seem reasonable. The guidance should state a target for before bed.	should be recommended, but also the timing at which the tests should be performed. The evidence reviewed for the guideline demonstrated that glycaemic control improves with the number of capillary tests performed up to 5 five tests per day. The guideline development group concluded, therefore, that at least 5 tests should be performed routinely, and emphasised in the revised recommendations that it is often necessary to conduct more than 5 tests. They did not, however, wish to specify an upper limit for the number of tests, nor the exact timing for the minimum number of tests because to do so would remove some flexibility that is otherwise available to the child or young person and their family members or carers (as appropriate)
Juvenile Diabetes Research Foundation	FULL	186 188	7.5.10	JDRF urges the Institute to include the results from additional randomised controlled trials examining the efficacy of continuous glucose monitoring in children and young people with type 1 diabetes. Specifically, we urge the Institute to include evidence published in 2012 by Battelino et al (Battelino T, Conget I, Olsen B, et al. The use and efficacy of continuous glucose monitoring in type 1 diabetes treated with insulin pump therapy: a randomised controlled trial. Diabetologia 2012: 3155-3162). The randomised controlled trial reported on by Battelino et al. was a multicentre,	Thank you for this comment. The guideline development group have considered the evidence suggested, however none of the articles met the inclusion criteria in the review protocol for the question about continuous glucose monitoring (CGMS) compared with capillary (finger-prick) testing. The articles were excluded because: • Battelino 2012 assesses the effectiveness of CGMS combined with

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				randomised, controlled crossover study to determine the efficacy of adding continuous glucose monitoring (CGM) to insulin pump therapy in type 1 diabetes. The primary endpoint of the trial was change in HbA1c level between sensor on and sensor off arms after 6 months of follow-up. The trial enrolled both children and adults who were randomised to one of two continuous glucose monitoring arms – sensor on/sensor off sequence or sensor off/sensor on sequence. In the sensor on/sensor off sequence arm, participants wore unblinded real-time CGM for 6 months, followed by a 4 month washout period, and then 6 months of blinded CGM. In the sensor off/sensor on sequence arm, participants work blinded CGM for 6 months, followed by a 4 month washout period, and then 6 months of real-time CGM. Results were reported separately for children. The mean difference in HbA1c between sensor on and sensor off arms was -0.46% (-5.0 mmol/mol) (95% CI -0.26%, -0.66% [-2.8, -7.2 mmol/mol]; p<0.001) in paediatric participants. Based on study results, the authors conclude that in paediatric participants with type 1 diabetes using insulin pump therapy alone, the addition of CGM results in an improvement in HbA1c and the removal of CGM resulted in a loss of benefit. JDRF understands that the study design utilised to conduct this trial differs from those included in the Institute's evidence review. The crossover study design, however, is rigorous and results are consistent with findings from other trials, which indicate that CGM is effective at reducing HbA1c and that success with CGM is determined by consistent CGM sensor use. JDRF also urges the Institute to include evidence from Bergenstal 2010. (Bergenstal RM, Tamborlane WV, Ahmann A, et al. Effectiveness of sensor-augmented insulin-pump therapy in type 1 diabetes. N Engl J Med 2010: 311-320) Data from this study was included in the systematic review identified for inclusion in the guideline review (Langendam 2012), but was not considered by the Institute. Below, we provide additional detail regarding the study described by Bergenstal et	insulin pump therapy compared with pump therapy alone • Bergenstal 2010 assesses the effectiveness of insulin pump therapy compared with insulin injection therapy • Poolsup 2013 is a systematic review whose studies were already included in this review with the exception of Battelino 2012, which did not meet the review criteria • Pickup 2011 enrolled participants whose age exceeded 18 years in all of its included studies; there were no separate results reported for children and young people aged less than 18 years. These exclusions have now been reflected in the list of excluded studies

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				al 2010. The 1 year, multicentre, randomised, controlled trial reported on by Bergenstal et al. compared the efficacy of sensor-augmented pump therapy (pump + CGM) to the efficacy of multiple daily injections (MDI + SMBG) in adults and children with inadequately controlled type 1 diabetes. The primary endpoint was the change from baseline HbA1c. Among children, the baseline mean HbA1c had decreased -0.5 percentage points (95% CI, -0.8 to -0.2; p<0.001) at 1 year. JDRF understands that the study design utilised to conduct the trial described by Bergenstal et al. differs from those included in the Institute's evidence review. The study design, however, is rigorous and results are consistent with findings from other trials, which indicate that CGM is effective at reducing HbA1c and that success with CGM is determined by consistent CGM sensor use. Moreover, this study demonstrates that the benefits associated with CGM are sustained at 1 year. JDRF urges the Institute to include in its evidence review a systematic review of the effectiveness of continuous glucose monitoring on glucose control by Poolsup, Suksomboon, and Kyaw (2013). This systematic review and meta-analysis looks specifically at the evidence related to the effectiveness of CGM in children and young people with type 1 diabetes. The meta-analysis related to real-time CGM included five studies (Battelino 2012, Bergenstal 2010, JDRF 2008, Kordonouri 2010, and Mauras 2012). The results of the meta-analysis indicate that glycaemic control (HbA1c) is better with real-time CGM compared with self-monitoring of blood glucose (SMBG) [mean difference -0.18% (95% CI, -0.35% to -0.02%, p=0.02). Moreover, although the studies included in the meta-analysis have clinical and methodological differences, the heterogeneity of the model specific to real-time CGM vs SMBG as assessed by the I^2 statistic was only 48% - indicating	

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				only some heterogeneity. (Poolsup N, Suksomboon N, Kya AM. Systematic review and meta-analysis of the effectiveness of continuous glucose monitoring (CGM) on glucose control in diabetes. Diabetology & Metabolic Syndrome 2013. 5:39.) Finally, JDRF urges the Institute to consider the results of an individual patient data ("IPD") meta-analysis in its review of the clinical evidence for use of CGM in children and young people with type 1 diabetes. (Pickup JC, Freeman SC, Sutton AJ. Glycaemic control in type 1 diabetes during real time continuous glucose monitoring compared with self-monitoring of blood glucose: meta-analysis of randomised controlled trials using individual patient data. BMJ 2011;343:d3805.) Although not specific to children and young people, this IPD meta-analysis does include data for this population and is a unique examination of the impact of real time continuous glucose monitoring compared with self-monitoring of blood glucose. IPD meta-analyses are considered the gold standard of systematic reviews. Results from IPD meta-analyses are regarded as more reliable and interpretable than results from other types of systematic reviews. Because reviewers have access to raw data, IPD meta analyses allow for more detailed analyses such as subgroup analyses. For example, Pickup et al. were able to test the effect of baseline HbA1c, sensor usage, age, and other covariates on CGM outcomes because they utilised individual patient data. These types of analyses are not possible using aggregate or summary data from published trials – the type of approach utilised in the 2012 Cochrane Review or the 2013 systematic review described by Poolsup, Suksomboon, and Kyaw. The results of this IPD indicate that CGM reduces HbA1c and that reductions are greatest in those with higher baseline HbA1c and those who use CGM consistently. Moreover, the analysis indicates that age has only a small effect on	

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				the efficacy of CGM compared with self-monitoring of blood glucose. The specific effect is 0.002%. The authors provide a concrete example to describe the effect – "…continuous glucose monitoring would be expected to reduce the HbA1c level by only an extra 0.05% in a 40 year old with diabetes compared with a 15 year old with diabetes." Because of the valuable insights offered by this IPD meta-analysis, JDRF urges the Institute to consider this evidence in its review.	
British Psychological Society	FULL	189	33 41	Recommend changing to: "…assessment and monitoring…" A child's cognitive and neuropsychological development needs to be monitored throughout development if they have a history of hypoglycaemia and/or recurrent seizures, particularly in early childhood. For example, a neuropsychological difficulty with executive function associated with early hypoglycaemic episodes, may not be apparent in assessments carried out in early childhood but may emerge in adolescence. A child's neuropsychological development needs to be considered within the context of the developing brain. Monitoring of development is important.	Thank you for this comment, but it is unclear which section of the guideline the comment refers to
Royal College of Paediatrics and Child Health	FULL	195	7	Include blood glucose meters with bolus advisor function	There was no evidence identified for inclusion in the guideline systematic review that would allow the guideline development group to recommend use of blood glucose meters with a bolus adviser function. This aspect was not a specific criterion identified for consideration in the systematic review and so no recommendation has been made to address this
South West Paediatric Diabetes	FULL	195	18 29	Re indications for considering/offering unblinded (real time) CGM: – By including these indications in this NICE guideline, do the GDG feel that commissioning groups should fund CGM for these indications?	NICE guidelines do not have the same funding directive (mandatory implementation) that applies to NICE

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Network				– At the moment, as far as I'm aware, the only way of getting CGM is by submitting individual applications to commissioning groups which is very time consuming. Should there be a NICE TAG produced for CGM, as there is for pumps, so that funding is easier to obtain?	Technology Appraisal guidance, but it is expected that services will be commissioned to implement the guideline recommendations. By including a recommendation about offering real-time continuous glucose monitoring as a key priority for implementation (key recommendation) the guideline development group have emphasised the importance of this recommendation for clinical practice
Royal College of Paediatrics and Child Health	FULL	206	78	This could be interpreted as school teachers as well. The need for usage of IM glucagon is rare. Even patients/parents feel uncomfortable about its administration let alone a school teacher. This needs careful wording to avoid an avalanche of burden being placed on PDSN's to provide continuous training programmes to schools about IM glucagon. I couldn't see any evidence for this recommendation.	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (recognition and management of hypoglycaemia in this case). The guideline development group do agree that the 2004 recommendation covers schoolteachers (and other stakeholders strongly welcomed this), but this part of the guideline is not within the scope of the 2015 update and so it has not been revised
National Children and Young	FULL	213	General	Behavioural interventions are rarely used in isolation (e.g. cognitive behavioural therapy, CBT uses behavioural interventions as one component of the therapy but rarely on its own).	Thank you for this comment. The literature search for the guideline was sufficiently broad that it would have captured the

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People's Diabetes Network				A review of behavioural interventions is a very narrow view of the evidence base and outcomes research in psychological interventions in paediatric diabetes.	literature covering interventions that were assessed in combination with each other. The guideline development group recognise that these interventions often comprise multiple parts, but this was not reflected in the literature. A systematic review of behavioural interventions was specified as part of the scope of the guideline update
National Children and Young People's Diabetes Network	FULL	213	General	This whole section is badly written and psychological terminology is used incorrectly throughout. The section needs re-writing for it to be accurate and have meaning. In its current status, it is meaningless.	Thank you for this comment. The guideline development group have reviewed the terminology and amended it where appropriate
National Children and Young People's Diabetes Network	FULL	213	10	Cognitive disorders is a term used inaccurately.	Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (cognitive disorders in this case)
British Psychological Society	FULL	213	16	We believe that this indicates the need to address parental emotional and mental health well-being in addition to the child. This point needs to be addressed in the NICE version. Consider addition: 'The diagnosis of pre-school children increases the psychosocial burden for	Thank you for this suggestion. The current recommendations offer family members or carers 'timely and ongoing access to mental health professionals with an understanding of diabetes". Treatment specific to people aged 18 years or over was outside the remit of the guideline

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				parents. Consider offering psychological support and intervention to parents to aid their own mental wellbeing, adjustment and coping'. This should read 'Avoidant coping strategies'.	Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline
British Psychological Society	FULL	213	29 31	The following appear to be missing from the list of potential psychosocial issues: • Adjustment to diagnosis • Family adaptation / functioning • Managing fear / distress of needles / invasive procedures • School and peer relationships and functioning • Involving young people in decision making about their health • Transition to adult services These are all aspects of clinical psychology practice in a medical setting and in diabetes multi-disciplinary teams.	Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (emotional and behavioural problems in this case)
Royal College of Paediatrics and Child Health	FULL	213	29 31	The Global ISPAD Consensus Guidelines (2000) stated that "psychosocial factors are the most important influences affecting the care and management of diabetes".	Thank you for this comment recognising the importance of psychosocial factors in children and young people with diabetes
National Children and Young People's Diabetes Network	FULL	213	33	'Conditions such as depression, and eating..' – This sentence is grammatically and conceptually incorrect. Eating is not a condition!	This is a matter of punctuation in a section of the guideline that is excluded from the 2015 update (emotional and behavioural problems). The phrase continues as follows: 'Conditions such as depression, and eating, cognitive and behavioural disorders …' and the sense is that eating appears in in conjunction with disorders (i.e. the reference is to eating disorders). No change has been made in response to this comment

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National Children and Young People's Diabetes Network	FULL	213	36	'Severe conduct or attachment difficulties' – Conduct difficulties is a meaningless term. Behaviour difficulties and conduct disorder are appropriate terms (for different concepts) and are not the same as attachment difficulties. This sentence in its current form is meaningless.	Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (emotional and behavioural problems in this case)
National Children and Young People's Diabetes Network	FULL	213	39	This sentence is unclear: 'in a partnership between paediatric and child mental health services' Does this refer to paediatric psychologists working in partnership with Child and Adolescent Mental Health services? Or Does this refer to paediatric health professionals working in partnership with clinical psychologists to address mental health issues?	Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (emotional and behavioural problems in this case)
National Children and Young People's Diabetes Network	FULL	213	40 42	The sentence: 'Diagnosis of a chronic condition such as type 1 diabetes may be accompanied by a period of denial followed by gradual acceptance during which feelings of grief, stress and difficulty in coping may be experienced'. This is a poor description of the process of adjustment to a chronic illness. There are multiple and varying models of adjustment to chronic illness, none of which are well represented by the sentence above. The word 'denial' is a pathologising term.	Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (emotional and behavioural problems in this case)
British Psychological Society	FULL	214 21	33 34 38	Clinically, addressing the role of the parents and family is crucial, but the intervention needs to be individualised (based on a formulation), and effective. Anecdotally, most of my clinical interventions are working to decrease anxiety/PTSD and depression in the main carer, and booster their approach-based coping strategies, by using a range of therapeutic models and interventions based on a Formulation. The Full guideline (pg. 214) acknowledges the impact on parents, but this in not translated in the NICE document.	Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (emotional and behavioural problems in this case)

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		214	38	Consider a re-word as follows: 'Offer a formulation based approach to assess the role of parent and family factors. Offer specific family/parent based interventions, if there are difficulties with diabetes related-family conflict, parent anxiety or mental health difficulties including parental PTSD'.	
National Children and Young People's Diabetes Network	FULL	215	3	'In the medically ill' is a pathologising term and should be removed.	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (anxiety and depression in this case). In this case, it has, however, been possible to amend the terminology of the introductory sentence to replace 'in the medically ill' with 'when associated with other medical conditions'
National Children and Young People's Diabetes Network	FULL	215	8 11	These statistics are not relevant to the NICE guidance for children and young people with type 1 diabetes.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (anxiety and depression in this case)

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National Children and Young People's Diabetes Network	FULL	215	14	Does the term 'sex' denote 'gender'? If so, this should be amended appropriately.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (anxiety and depression in this case)
British Psychological Society	FULL	215	21 22	The NICE guidance 'Depression in children and young people: Identification and management in primary, community and secondary care' is comprehensive and highlights the importance of psychological intervention, using CBT. Focusing on evidence of CBT for depression in children with type 1 diabetes is not appropriate. The existing evidence base for interventions targeting depression has been done with children and young people who have symptoms of depression, regardless of their chronic health condition. Managing depression with antidepressants is not the first line of treatment for children and young people. There are risks to extrapolating from research done with adult populations to children and young people, especially if this is with regards to medication, although there is relatively little research with children with diabetes compared with adults with diabetes and children would be seriously disadvantaged if we could not extrapolate at all from research. This section has omitted to report on the management of children and young people with suicidal ideation and/or intention despite discussing research that highlights the risk of self-harm and suicide in this population.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (anxiety and depression in this case)

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British Psychological Society	FULL	216	General	There is no gold standard method of diagnosing or detecting 'depressive symptoms'. What does exist are tools that aid in the detection of depressive symptoms (e.g. the CDI and the BDI) with cut-off scores that identify those more or less at risk. Clinical depression can be diagnosed using DSM-IV criteria by psychiatrists and/or psychologists. The impact of depressive symptoms on daily functioning is the most important factor. The BDI includes symptoms that are confounded by symptoms of hyperglycaemia (see ref and comment above in first General point).	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (anxiety and depression in this case)
British Psychological Society	FULL	216	General	Significant care needs to be taken in the interpretation of and potential extrapolation of adult studies of treatment for depression in diabetes to children. Reference to the NICE Guidelines on depression in childhood is more relevant here. Psychological interventions are the therapy of choice for the majority of presentations of depression in childhood.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (anxiety and depression in this case)
National Children and Young People's Diabetes Network	FULL	216	General	The NICE guidance 'Depression in children and young people: Identification and management in primary, community and secondary care' is comprehensive and highlights the importance of psychological intervention, using CBT. Focusing on evidence of CBT for depression in children with type 1 diabetes is not appropriate. The existing evidence base for interventions targeting depression has been done with children and young people who have symptoms of depression, regardless of their chronic health condition. Managing depression with antidepressants is not the first line of treatment for	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (anxiety and depression in this case)

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				children and young people. Research done with adult populations cannot be extrapolated or generalized to children and young people, especially if this is with regards to medication. This section has omitted to report on managing children and young people with suicidal ideation and/or intention despite discussing research that highlights the risk of self-harm and suicide in this population.	
National Children and Young People's Diabetes Network	FULL	216	23 27	Poorly written section with gross inaccuracies. It also offers an interpretation for the risk of depression. This is a rudimentary way of conceptualising depressive symptoms and does not highlight that a diagnosis of type 1 diabetes places children, young people and their families at greater risk of depressive symptoms.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (anxiety and depression in this case)
British Psychological Society	FULL	216	28 37	The Society believes that 'Encouragement to seek help from a child mental health professional' should refer to the evidence base for CBT or Family Interventions for depression in children and young people, not simply 'seek help'	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (anxiety and depression in this case)
British Psychological Society	FULL	216	46 47	'Studies' do not tend to advise on which health professionals give treatment or intervention on depression. There are numerous professionals who can advise children and young people on depression, including: • GP	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the

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				• Clinical psychologists in CAMHS • Paediatric clinical or health psychologists embedded within the Diabetes MDT • Child psychiatrists • Child and adolescent mental health care professionals	guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (methods of managing depression in this case)
British Psychological Society	FULL	217 218	General	The title 'Behavioural and Conduct Disorders' is potentially misleading. 'Behavioural disorders' is a term that encompasses diagnosis such as Oppositional Defiant Disorder, Conduct Disorder, and Attention Deficit Hyperactivity Disorder. Behavioural problems and conduct disorders are very different things. Discussing both in parallel is inappropriate and misrepresents the evidence base. Conduct disorder is a diagnostic term from DSM-IV that is characterised by fighting and physical cruelty, destructiveness, lying and stealing, truancy and running away from home. Psychiatrists and clinical psychologists can help to diagnose conduct disorder. Behavioural problems can occur in children of all ages and include temper tantrums and occasional outbursts of aggressive behavior. These do not meet criteria for a diagnosis of conduct disorder.	The phrase in this title (behavioural and conduct disorders) is what was used in the original (2004) guideline. Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (the section titled behavioural and conduct disorders in this case)
National Children and Young People's Diabetes Network	FULL	217 218	General	Section 10.4 on Eating Disorders confuses evidence on the prevalence of eating disorders in type 1 diabetes with research on interventions for the management of eating disorders in this population. Research strongly suggests there is an increased prevalence of eating disorders, particularly Bulimia Nervosa and Eating Disorder Not Otherwise Specified (EDNOS), in girls with Type 1 diabetes (Colton et al., 2004). Insulin omission ('purging') is most frequently reported (10% skip injections; 7.5% under dose	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (eating disorders in this case)

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				insulin). 'NICE guidance: Eating disorders: Core interventions in the treatment and management of anorexia nervosa, bulimia nervosa and related eating disorders' specifies that all children and young people with Type 1 diabetes and poor adherence should be screened and assessed for the presence of an eating disorder. Evidence base interventions recommended by the NICE guidance above include cognitive analytic therapy (CAT), cognitive behaviour therapy (CBT), interpersonal psychotherapy (IPT), focal psychodynamic therapy and family interventions focused explicitly on eating disorders all of which need to be carried out by an appropriately trained professional in psychological therapies.	
National Children and Young People's Diabetes Network	FULL	217	12 20	'Studies' do not tend to advise on what health professionals give treatment or intervention on depression (e.g. I equally do not know of any studies that specify who should lead the medical healthcare of children with type 1 diabetes) There are numerous professionals who can advise children and young people on depression, including: - GP - Clinical psychologists in CAMHS - Paediatric clinical psychologists embedded within the MDT - Child psychiatrists - Child and adolescent mental health care professionals Furthermore: The Global ISPAD Consensus Guidelines (2000) made the following three recommendations: (i) Psychologists should be part of the interdisciplinary health care team (ii) Overt psychological problems should receive support from the diabetes care	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (methods of managing depression in this case)

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				team and expert attention from psychology (iii) The diabetes care team should receive training in the recognition, identification, and provision of information on psychosocial problems related to diabetes	
National Children and Young People's Diabetes Network	FULL	219	General	The term 'cognitive disorders' is inaccurate and misleading. Cognitive disorders is a term used in DSM-IV diagnostic manual to specifically denote mental health disorders that affect memory, learning, perception and problem solving (including amnesia, dementia and delirium). Studies of neuro-cognitive functioning indicate that young people with diabetes are at increased risk for information processing weaknesses and learning problems, especially with early diabetes onset and history of sever hypoglycaemia or chronic hyperglycaemia. There is also evidence to suggest that diabetes can impact on academic achievement particularly in children with poor metabolic control (Naguib et al., 2009)	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (cognitive disorders in this case)
British Psychological Society	FULL	219	2 5	Evidences nocturnal hypoglycaemia as a risk factor for low mood and therefore the need for embedding early identification of psychological issues in routine care There is also a need to avoid nocturnal hypoglycaemia which may be caused by excessively low HbA1c and associated with risk of death. See General point about the lack of a lower limit for HbA1c above.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (cognitive disorders in this case)
British Psychological Society	FULL	219	10.5	'Subtle neurocognitive dysfunction', whilst correct in terms of the evidence, underplays the potential significant impact on the trajectory of cognitive development. Suggest re-wording to "specific neurocognitive dysfunction".	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been

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					reviewed since the original (2004) guideline (cognitive disorders in this case)
British Psychological Society	FULL	219	29 30	The other implications, missing from this summary, are that poor glycaemic control affects behaviour and that conduct problems affect adherence and therefore that a vicious cycle of adherence and behavioural difficulties is likely to explain the findings. The implications for treatment are that a functional analysis and that behavioural / family interventions are indicated.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (cognitive disorders in this case)
British Psychological Society	FULL	221	40 49	The consistent reporting in the guidelines of a lack of systematic reviews in the literature on psychosocial aspects of diabetes suggests a strong secondary research recommendation for such reviews to be carried out.	The broad research recommendation highlighting the need for further studies to evaluate the effectiveness of behavioural and social interventions on anxiety and depression, eating disorders, behavioural and conduct disorders, and adherence to therapy in children and young people with type 1 diabetes, especially in adolescence, from diagnosis and in established diabetes which was included in the original (2004) guideline has been retained in the 2015 update. As several specific topics related to psychological and psychosocial issues affecting children and young people with type 1 diabetes are excluded from the 2015 update (for example, anxiety and depression, eating disorders and behavioural and conduct disorders) it has not been possible to be more specific about the form this research should take.

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					The guideline development group agree, however, that systematic reviews to complement those already undertaken for topics included in the update could form part of these further research studies
British Psychological Society	FULL	222	42	Behavioural interventions are a specific type of intervention that is based on behavioural theory and behavioural models (e.g. operant conditioning, classical conditioning, reinforcement, extinction and reward). The research evidence summarised in this section is overall not in line with behavioural interventions. This heading and review question is therefore problematic.	Thank you for this comment. The guideline development group have amended the terminology where appropriate
British Psychological Society	FULL	223	General	Motivational Interviewing is not a behavioural intervention. It is a conversational tool that leads to behaviour change. Motivational interviewing is a collaborative, goal-oriented style of communication with particular attention to the language of change. It is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person's own reasons for change within an atmosphere of acceptance and compassion (Channon, S. J. et al, 2007) References: Channon, S. J., Huws-Thomas, M. V., Rollnick, S., Hood, K., Rebecca L. Cannings-John, R. L., Rogers, C. and Gregory, J.W (2007) A Multicenter Randomized Controlled Trial of Motivational Interviewing in Teenagers With Diabetes. Diabetes Care, 30(6), 1390-1395.	Thank you for this comment. The guideline development group have amended the terminology where appropriate
British Psychological Society	FULL	223	2 14	The Society believes that a research question on "Psychological interventions" would have been more appropriate here.	Thank you for this comment. The terminology has been amended throughout

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				This should be more accurately called 'Psychological Interventions' rather than behavioural interventions. Review question. This should more accurately be: 'What is the effectiveness of Psychological Interventions to improve outcomes…?' The description of these therapies is unhelpful and confusing. It is probably beyond the scope of this document to be clear about different therapeutic agreed with young person, family and health professional and that they need to take into account the wider psychosocial factors and lifestyle choices of the young person to ensure that they are achievable and owned. Needs relating to point 1.2.70	
British Psychological Society	FULL	223 241	10.8	Only including RCTs will miss some pertinent evidence, given the small samples available for study of specific psychological issues within this specific disease cohort. A Systematic Review would capture emerging literature and smaller studies other than RCTs.	The protocol for this review question (Appendix E) states that study designs other than randomised controlled trials (RCTs) will be considered for any of the prioritised interventions only if no RCT evidence is identified for inclusion for that intervention. The review was conducted according to the systematic review methodology specified in the NICE guidelines manual
British Psychological Society	FULL	223	24 27	Behavioural family systems therapy (BFST) is not widely used in paediatric settings, outside of eating disorders. Only one RCT has been carried out in diabetes with this model. It is inadequate to base evidence in this guidance based on one paper only. (Wysocki, T. et al, 2009) References: Wysocki, T., Harris, M.A., Buckloh, L.M., Mertlich, D., Lochrie, A.S., Taylor, A.	Thank you for this comment. The purpose of the review is to determine the effectiveness of behavioural family systems therapy in children and young people with type 1 diabetes. The extent of this therapy's application in other settings and disease areas is not relevant to the review. The recommendation states that the healthcare professional should

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				(2009). Randomized controlled trial of behavioral family systems therapy for diabetes: Maintenance and generalisation of effects on parent-adolescent communication. Behavior Therapy, 39, 33–46	consider its application in this setting and is accompanied by a recommendation for further research
National Children and Young People's Diabetes Network	FULL	223	24 27	Motivational Interviewing is not a behavioural intervention. It is a conversational tool that leads to behaviour change. Motivational interviewing is a collaborative, goal-oriented style of communication with particular attention to the language of change. It is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person's own reasons for change within an atmosphere of acceptance and compassion (Miller & Rollnick).	Thank you for this comment. The guideline development group have amended the terminology where appropriate
National Children and Young People's Diabetes Network	FULL	223	28 30	CBT is by its title not a behavioural intervention as its cognitive component is central to the model of therapy. CBT explores thoughts and feelings and how these impact on behavior.	Thank you for this comment. The terminology has been amended throughout to more accurately reflect the content of the interventions
Royal College of Paediatrics and Child Health	FULL	223	28 30	CBT is by its title not a behavioural intervention as its cognitive component is central to the model of therapy. CBT explores thoughts and feelings and how these impact on behavior.	Thank you for this comment. The terminology has been amended throughout to more accurately reflect the content of the interventions
National Children and Young People's Diabetes Network	FULL	223	31 32	Counselling is not a behavioural intervention. Counselling is a type of talking therapy that uses empathy at its core. Advice is rarely given and behavioural strategies are not part of the counselling model.	Thank you for this comment. The terminology has been amended throughout to more accurately reflect the content of the interventions
Royal College of Paediatrics and Child	FULL	223	31 32	Counselling is not a behavioural intervention. Counselling is a type of talking therapy that uses empathy at its core. Advice is	Thank you for this comment. The terminology has been amended throughout to more accurately reflect the

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Health				rarely given and behavioural strategies are not part of the counselling model.	content of the interventions
National Children and Young People's Diabetes Network	FULL	223	33	Family therapy is not a behavioural intervention. Family therapy is based on systemic theory. It explores relationships within families and recognises and builds on relational resources. Its main focus is not on behavioural change but on changes within relationships.	Thank you for this comment. The terminology has been amended throughout
Royal College of Paediatrics and Child Health	FULL	223	33	Family therapy is not a behavioural intervention. Family therapy is based on systemic theory. It explores relationships within families and recognises and builds on relational resources. Its main focus is not on behavioural change but on changes within relationships.	Thank you for this comment. The terminology has been amended throughout
National Children and Young People's Diabetes Network	FULL	223	35	Family-based teamwork is not a model of therapy or an evidence based intervention.	Thank you for this comment. The terminology has been amended throughout to more accurately reflect the content of the interventions. The review is led by the evidence identified in the systematic review
British Psychological Society	FULL	223	41	See point 2 above. The evidence base for psychological interventions for Medically Unexplained Symptoms and Self Harm is relevant here and should be cross-referenced.	Thank you for this comment. This statement in the guidance aims to describe the therapy rather than all instances of its application
National Children and Young People's Diabetes Network	FULL	223	41	Behavioural family systems therapy is a variation on the family therapy model used at the Maudsley Hospital for eating disorders, where most of the evidence base lies. BFST is not widely used in paediatric settings, outside of eating disorders. Only one RCT has been carried out in diabetes with this model (Wysocki et al., 2007). It is inadequate to base evidence in this guidance based on one paper only.	Thank you for this comment. The purpose of the review is to determine the effectiveness of behavioural family systems therapy in children and young people with type 1 diabetes. The extent of this therapy's application in other settings and disease areas is not relevant to the review. The recommendation states that

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					the healthcare professional should consider its application in this setting and is accompanied by a recommendation for further research
National Children and Young People's Diabetes Network	FULL	223	45	Multisystemic Therapy (MST) is not a behavioural intervention. MST is an intensive family and community based intervention that has good evidence base for young people at risk in either care or custody due to their offending or having severe behaviour problems. The training for MST comes from the USA and is expensive. To my knowledge it has not been used in paediatric diabetes settings in the UK and there is no evidence base for its effectiveness in this population.	Thank you for this comment. The terminology has been amended throughout to more accurately reflect the content of the interventions
National Children and Young People's Diabetes Network	FULL	224	General	Description of included studies – this section is not coherent. It is not valid to campare the interventions listed as they all derive from different therapeutic models. It is also misleading to focus on 'behavioural outcomes' and HBA1c for these interventions as none of the interventions included in this section can be defined as purely behavioural interventions. There is a large evidence base on the effectiveness of CBT on depression, anxiety, and eating disorders. Focusing on 'quality of life' as the only outcome is not an adequate report of the evidence base. There is a large evidence base on the effectiveness of Motivational Interviewing on adherence to treatment. Focusing on HBA1C as the main outcome is under reporting of the evidence base.	Thank you for this comment. The guideline development group have amended the terminology throughout this section so that it reflects the content of the interventions. The systematic review sought all available evidence in this population and did not directly compare the interventions via any quantitative analysis. The guideline development group discussed the heterogeneity of the evidence in the linking evidence to recommendations section of the review. Please note that the outcomes prioritised for inclusion in this systematic review (Appendix E) included depression, anxiety and adherence in addition to health-related

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					quality of life. These outcomes were included in the evidence base when they were reported in the included studies
National Children and Young People's Diabetes Network	FULL	224	1 3	Mentoring is not a behavioural intervention. It is a supportive relationship where young people are able to share and participate in activities with their mentor and get help to reach their goals (e.g. write a CV). "Mentoring is to support and encourage people to manage their own learning in order that they may maximise their potential, develop their skills, improve their performance and become the person they want to be." Eric Parsloe, The Oxford School of Coaching & Mentoring	Thank you for this comment. The terminology has been amended as required
National Children and Young People's Diabetes Network	FULL	224	4 5	Peer support is not a behavioural intervention. Peer support can be defined as people supporting each other on an equal basis, to offer something based on shared experiences. This is usually provided informally via groups.	Thank you for this comment. The terminology has been amended throughout to more accurately reflect the content of the interventions
British Psychological Society	FULL	224	9 10	Addressing the role of the parents and family is crucial, however the intervention also needs to be individualised (based on a formulation). The Full guideline (pg. 214) acknowledges the impact on parents, but this in not translated in the NICE document. Consider a re-word as follows: 'Offer a formulation based approach to assess the role of parent and family factors. Offer specific family/parent based interventions, if there are difficulties with diabetes related-family conflict, parent anxiety or mental health difficulties including parental PTSD'.	Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (emotional and behavioural problems in this case)
National Children and	FULL	235	General	An overall summary of the evidence base on these interventions is not satisfactory as they cannot be compared to each other.	Thank you for this comment. The interventions have not been compared to

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Young People's Diabetes Network					each other, but rather considered in the context of their clinical and cost effectiveness
National Children and Young People's Diabetes Network	FULL	239	General	The Global ISPAD Consensus Guidelines (2000) stated that "psychosocial factors are the most important influences affecting the care and management of diabetes" HBA1c is a medical measure and is not a fit outcome for psychological interventions that focus on exploring and working on relationships, overall mood and quality of life. Thus, placing HBA1C as the highest priority outcome of psychological interventions dismisses a large part of the evidence base.	Thank you for this comment. The guideline development group recognise the importance to children, young people and their family members or carers the need for improving psychological outcomes which is why the protocol for this review question included a set of six psychological outcomes (health-related quality of life; children and young people's and families' satisfaction with intervention; depression; anxiety; school performance or attendance; and risk-taking behaviours). In addition to this, HbA1c provides a valid and reliable measure of clinical benefit
National Children and Young People's Diabetes Network	FULL	239 240	General	Consideration of clinical benefits and harms section is not based on adequate evidence. The evidence base, as has been presented, cannot be summarised coherently as is discussed in order point 59 above.	The consideration of clinical benefits and harms section of the review reflects the evidence that was identified in the systematic review. The guideline development group acknowledge that there was heterogeneity amongst the identified studies and they discussed how this might impact interpretation of the body of evidence in this section of the full guideline
Royal College of Paediatrics	FULL	239	General	Consideration of clinical benefits and harms section is not based on adequate evidence. The evidence base, as has been presented, cannot be summarised	The consideration of clinical benefits and harms section of the review reflects the

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and Child Health		240		coherently as is discussed in order point 59 above.	evidence that was identified in the systematic review. The guideline development group acknowledge that there was heterogeneity amongst the identified studies and they discussed how this might impact interpretation of the body of evidence in this section of the full guideline
British Psychological Society	FULL	239	31 34	The Society welcomes this as it demonstrates the need to consider the evidence base for treatments for adherence and depression, which is not necessarily disease specific, see point 2 above.	The guideline development group are unclear what statement this refers to
British Psychological Society	FULL	239	38 41	The Global ISPAD Consensus Guidelines (https://www.ispad.org/content/ispad-clinical-practice-consensus-guidelines-2009)., state that "psychosocial factors are the most important influences affecting the care and management of diabetes" HbA1c should not be the only outcome or even the main outcome, although it is appropriate that it be one outcome for a psychological intervention, just as it is entirely appropriate to have QoL as an outcome, and sometimes even a primary outcome, in a study of a medical intervention. We recognise that if HbA1c is not included as an outcome there is a risk that short-term gains to QoL may be valued without recognising the risk of long-term damage to QoL that will be associated with long-term complications, but it should not be the only outcome or even main outcome for a psychological intervention.	Thank you for this comment. The guideline development group recognise the importance to children, young people and their family members or carers the need for improving psychological outcomes which is why the protocol for this review question included a set of six psychological outcomes (health-related quality of life; children and young people's and families' satisfaction with intervention; depression; anxiety; school performance or attendance; and risk-taking behaviours). In addition to this, HbA1c provides a valid and reliable measure of clinical benefit
British Psychological Society	FULL	240	34 37	Psychological intervention has been shown to significantly reduce the number of readmissions into hospital. High levels of parental anxiety have been shown to increase use of health care resources and therefore increase the cost of treatment (Goldman, S.L. and Owen,	Thank you for this comment. The systematic review conducted in the 2015 guideline update demonstrates a positive association between psychological intervention and patient benefit, including a

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				M.T, 1994). In addition, children with Type 1 diabetes who have associated low mood have higher utilisation of health services (Cote et al., 2003). Integrated psychology into paediatric diabetes is likely to offset medical costs, including: • Better adherence to treatment and higher levels of attendance at clinic appointments (Lemanek et al., 2001). This will reduce medical costs through the prevention of long-term complications and reduced number of DNA's at clinic appointments. • Psychological interventions for procedural fear or anxiety can reduce the number of cancelled blood tests and medical procedures and maximise resources. • Indirect cost benefits of improved staff retention and reduction of staff sick days as a result of staff feeling well supported by having a clear referral route for complex psychological cases. The Department of Health has stipulated that transition from paediatric to adult services should be a purposeful, planned process that addresses the medical, psychosocial, educational and vocational needs of adolescents and young adults with diabetes (DOH, 2012). Holmes et al, 2007, demonstrated that the cost of providing a transition care programme was covered by the cost savings made through fewer admissions to hospital. References: Cote, M., Mullins, L., Hartman, V., Hoff, A., Balderson, B., Chaney, J. and Domek, D. (2003). Psychosocial correlates of health care utilisation for Children and adolescents with Type 1 Diabetes mellitus. Children's Health Care, 32, 1-16) Finney, J., Eiley, A., Cataldo, M. (1991) Pediatric psychology in primary care:	reduction in diabetic ketoacidosis (DKA)-related admissions to hospital (Ellis 2007). The transition from paediatric to adult services is outside the scope of this guideline, but is the focus of a NICE guideline currently in development: http://www.nice.org.uk/guidance/indevelopment/gid-scwave0714 The references listed in the comment have not been checked for relevance to this part of the guideline because it is outside the scope of the guideline update

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				effects of brief targeted therapy on children's medical care utilisation. Journal of Pediatric Psychology, 16, 447-461. Goldman,S.L. and Owen, M.T. (1994). The impact of parental trait anxiety on the utilisation of health care services in infancy: A prospective study. Journal of Pediatric Psychology, 19(3): 369-381. Holmes-Walker, D. J., Llewellyn, A. C. and Farrell , K. (2007) A transition care programme which improves diabetes control and reduces hospital admission rates in young adults with Type 1 diabetes aged 15-25 years. Diabetes Medicine. 24(7):764-9 Lemanek, K., Kamps, J. and Chung, N. (2001) Empirically supported treatments in pediatric psychology: Regimen adherence. Journal of Pediatric Psychology, 26, 253-75	
National Children and Young People's Diabetes Network	FULL	240	34 37	The BPT criteria (Department of Health, 2012) stipulate that psychology should be "integral to the multi-disciplinary team" and that each patient should have an annual assessment by their MDT as to whether input to their care by a clinical psychologist is needed, and access to psychological support as appropriate. The GDG considering whether or not to offer psychological interventions to families based on whether they consider it to be 'burdensome' is inappropriate. This implies a subjective opinion on whether children and families should have access to psychology and is discriminatory (i.e. only the children and families who shout loudest will have access to psychological support). Furthermore, attending 4x clinic appointments to meet Best Practice Tariff criteria (and ensure the trust in question gets the financial reward) also impacts on school attendance and family functioning, particularly for those children and young people who have good adherence and well controlled blood glucose levels. All children and young people with type 1 diabetes should have equal access to psychological assessment and support as stipulated by the DoH guidelines and the ISPAD guidelines. Some children and their families may decline or chose not	The guideline development group consider that the recommendations are complementary to the Best Practice Tariff and do not preclude an annual assessment to determine the need for psychological support. The linking evidence to recommendations section of the review has been amended to clearly state this. The statement that behavioural interventions could be inconvenient or even burdensome for some reflects the diversity of attitude toward the uptake of psychological interventions by children, young people and their families which may affect decision-making. It should not

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				to engage with psychology services and this will be at the choice and discretion of the families, while their needs should continue to be monitored by the wider MDT.	influence the offering of, or availability of access to services. The statement has been revised to clearly reflect this intention
National Children and Young People's Diabetes Network	FULL	240	38 45	The GDGs reflections on who is best placed to deliver psychological interventions is moot. Most of the interventions listed in the guidance can only be carried out by trained professionals who would only have access to training if they are professionally qualified to do so (with the exception of counselling, mentoring, peer support and family-based teamwork).	Thank you for this comment. Not all of the interventions require delivery by an appropriately skilled professional and therefore the guideline development group have not amended the text
British Psychological Society	FULL	241	General	It is of concern that the key conclusions and recommendations do not take into consideration the wider literature for psychological interventions with children with long-term health conditions and mental health problems (e.g. There are BPS Guidelines for the use of psychological interventions in the management of invasive procedures in children as well as NICE Guidelines on the treatment of depression and suicidal behaviour, PTSD etc.,).	Thank you for this comment. The guidance was developed using systematic review methodology defined in the NICE guidelines manual. The protocol for the review was agreed by the guideline development group, who felt that consideration of a wider body of literature was not appropriate in this case. Where relevant, the guideline cross-refers to other NICE guidance
National Children and Young People's Diabetes Network	FULL	241	General	The quality of the evidence is impacted by the choice of outcomes in the review process and the lack of understanding about psychological concepts such as: behavioural interventions, conduct disorder, behaviour disorder, quality of life, counselling etc… (see numerous points above) Key conclusions are flawed and lack evidence base in view of the above. There is extensive evidence base on the impact of motivational interviewing for adherence in children and young people The key recommendation for depression is CBT as per NICE gold standard guidance. There are no conclusions or recommendations for self-harm and suicidal risk despite this being highlighted in previous sections of the guidance.	The guideline development group acknowledge the concerns highlighted in this comment and have responded to each point individually in the previous comments and made amendments to the guideline where appropriate. No data on self-harm were identified in the evidence reviewed for psychological interventions. The discussion about suicidal risk was in the 2004 guidance which was not updated in 2015

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National Children and Young People's Diabetes Network	FULL	241	5 7	Psychological intervention has proved to significantly reduce number of readmissions into hospital (Martin et al., 2013). High levels of parental anxiety have been shown to increase use of health care resources and therefore increase the cost of treatment (Goldman and Owen, 1994). In addition, children with Type 1 diabetes who have associated low mood have higher utilisation of health services (Cote et al., 2003). Integrated psychology into paediatric diabetes is likely to offset medical costs, including: • Better adherence to treatment and higher levels of attendance at clinic appointments (Lemanek et al., 2001). This will reduce medical costs through the prevention of long-term complications and reduced number of DNA's at clinic appointments. • Psychological interventions for procedural fear or anxiety can reduce the number of cancelled blood tests and medical procedures and maximise resources. • Indirect cost benefits of improved staff retention and reduction of staff sick days as a result of staff feeling well supported by having a clear referral route for complex psychological cases. The Department of Health has stipulated that transition from paediatric to adult services should be a purposeful, planned process that addresses the medical, psychosocial and educational and vocational needs of adolescents and young adults with diabetes (DOH, 2012). Holmes, Walker, Llewellyn and Farrell (2007) showed that the cost of providing a transition care programme was covered by the cost savings made through fewer admissions to hospital	Thank you for this comment. The systematic review conducted in the 2015 guideline update demonstrates a positive association between psychological intervention and patient benefit, including a reduction in diabetic ketoacidosis (DKA)-related admissions to hospital (Ellis 2007). None of the studies cited in this comment met the inclusion criteria for the review as set out in the review protocol (Appendix E). The guideline development group discuss the benefits of psychological interventions in the evidence to recommendations section of the full guideline following the evidence review and, while they agree with many of the points raised in the comment, the evidence was limited with regard to some key outcomes The transition from paediatric to adult services is the focus of a NICE guideline currently in development: http://www.nice.org.uk/guidance/indevelopment/gid-scwave0714
British Psychological Society	FULL	241	23	No systematic reviews appear to have been identified in response to the RQ. This is of concern, as the NICE Guideline review will have only considered RCTs. Given that the psychological literature is emerging in this area, there will be gaps in what is known and not known in the literature and where future research is to be directed.	Thank you for this comment. As outlined in the systematic review protocol that was agreed by the guideline development group, systematic reviews of non-randomised comparative studies would

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					only be included if insufficient randomised controlled trial (RCT) evidence was identified. In this case, RCT evidence was identified, and therefore the lower level of evidence was not interrogated. RCT evidence is prioritised for inclusion so that national recommendations are based on the most reliable evidence available. The review conducted by the guideline development group is systematic and is not intended to be exploratory. The guideline development group take input from stakeholders into consideration at the time of scoping to identify areas for improvement in current practice
British Psychological Society	FULL	241	23	The Society recommends that 'mental health professionals' should be replaced by psychological intervention by appropriately trained practitioner psychologists to facilitate coping and emotional well-being Children and young people with type 2 as with type 1 require timely and ongoing access to clinical/health psychology input which is delivered by appropriately trained and experienced clinicians to facilitate coping, in addition to assessment of mental health difficulties.	The guideline development group used the term 'mental health professional' so that the recommendation covers access to a wide range of professional services including psychologists, family therapists, psychiatrists, etc. A sentence has been added to the linking evidence to recommendations section of the full guideline to explain this more clearly
British Psychological Society	FULL	246 242	101 12	There is little reference to anxiety. It is referred to in the recommendations but there is little in the text. Anxiety is at least as important as depression; in general, related to fear of complications and particularly fear of hypoglycaemia, and affecting both the individual and their family. Clinically, fear of hypoglycaemia is a significant problem for parents of young children.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been

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		246	15 96 101	Major risks should include pregnancy. Disordered eating and body image concerns are prevalent in young people with diabetes, which they can manipulate through non-adherence. Greater emphasis should be given to assessing these as they are significant contributors to poor control and DKA admissions.	reviewed since the original (2004) guideline (anxiety and depression and eating disorders in this case). The guideline development group include a reference to the related NICE guideline on the management of diabetes in pregnancy in both the full and short guidelines
Coeliac UK	FULL	249	10	The guidelines state that "Definitive diagnosis is made by jejunal biopsy". Joint guidelines published by the British Society of Paediatric Gastroenterology, Hepatology and Nutrition (BSPGHAN) and Coeliac UK (2013) recommend that children who have symptoms of coeliac disease, and results of tTG blood test which show levels of antibodies ten times greater than the normal upper limit may not require a biopsy to confirm diagnosis. Instead, a further blood sample to check IgA-EMA and HLA-DG2/DQ8 typing can be used to confirm diagnosis.	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (coeliac disease in this case). However the guideline development group recognise that NICE has produced separate guidance and so the recommendations in this guideline have been amended to cross-refer to the NICE coeliac disease guideline for guidance on monitoring for coeliac disease in children and young people with type 1 diabetes
Royal College of Paediatrics and Child Health	FULL	249	37 41	Considering the evidence in support of celiac disease screening it seems bizarre that this was amended in 2009. I understand the celiac disease guideline is also being updated and is likely to recommend screening again. I assume the diabetes guidance will be adjusted to take this into account.	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004)

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					guideline (coeliac disease in this case). However the guideline development group recognise that NICE has produced separate guidance and so the recommendations in this guideline have been amended to cross-refer to the NICE coeliac disease guideline for guidance on monitoring for coeliac disease in children and young people with type 1 diabetes
Institute of Child Health	FULL	259	2 26	A key definition in any screening is the relevant/valuable outcome considered as the main aim of the programme. The relevant outcome defines the screening strategy and pathways for positive results. The GDG appear to consider that treatment is not necessary for background retinopathy (BDR). This could either be because: by 'treatment', they mean ophthalmic intervention (which is an unsuitable main aim as laser / intra-vitreal treatments are associated with a risk of visual morbidity) rather than conservative / systemic treatment to improve disease control and reduce the morbidity associated with microvascular complications or that BDR does not require systemic treatment (ie improvement of blood sugar control). This reading of their intended meaning is supported by their statements that: 'the incidence of microaneurysms in people of this age who do not have diabetes is unknown and it is difficult, therefore, to ascertain whether the identification of background retinopathy is specifically associated with diabetes' (Full version, page 259, lines 8-11) 'background retinopathy may fluctuate' (Full version, page 259, line 35), although the GDG also later state that 'background retinopathy is often found through	Thank you for this comment. In the clinical experience of the guideline development group, although background retinopathy can fluctuate, it remains an important indicator of progression to further damage. This view was neither confirmed nor disproved by the data As patient outcomes are largely driven by improvements in blood glucose control, the recommendation does not intend to suggest that background retinopathy does not require systemic treatment. The guideline development group believe this is clearly stated in the recommendation which advises that 'background retinopathy is often found through monitoring and improving blood glucose control will reduce the risk of this progressing to significant diabetic retinopathy'

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				monitoring, and improving blood glucose control will reduce the risk of this progressing to serious forms of diabetic retinopathy' (Full version, page 273, lines 25-27) Whilst there is no evidence on the prevalence of retinal microaneurysms in non-diabetic children, the evidence from studies in adults shows that although microaneurysms are not specifically associated with diabetes in the elderly population (because they are also present in vasculopathies, e.g. hypertension), the presence of retinal microaneurysms in working age non-diabetic adults predicts a future diagnosis of diabetes (Klein et al. 2006. The relationship of retinopathy in persons without diabetes to the 15-year incidence of diabetes and hypertension: Beaver Dam Eye Study. Trans Am Ophthalmol Soc.104:98-107). This supports the prognostic importance of the finding of BDR in children diagnosed with diabetes, and the importance of intervention at this early stage. BDR may fluctuate in severity but there is no evidence that it fluctuates in the absence of medical intervention. The proportion of children who show signs of regression is unknown and more studies are needed to examine the natural history of BDR and more advanced stages of the disease. Without evidence about the natural history of BDR, the relationship between benefits and harms is difficult to calculate.	
Institute of Child Health	FULL	260	37 38	Related to the previous comment, we also feel it is important for the GDG to define what they mean by 'significant retinopathy', as used in the following statements: 'annual screening from the age of 12 years is important because, if significant diabetic retinopathy is found, early treatment will improve the outcome'. (Full version, page 260 lines 37-38 and Full version, page 31, line 29-31) We suggest that any degree of retinopathy including BDR is significant retinopathy (for the reasons outlined in the previous comment), and that the main aim of eye examination in children with type 1 and 2 diabetes is to identify those at risk of both visual impairment due to retinopathy and further systemic morbidity due to microvascular complications. This would fall under screening rather than	Thank you for this comment. Significant diabetic retinopathy is defined in Section 11.4.1.6.2 of the full guideline as retinopathy that requires intervention. The guideline development group agree that the identification of background retinopathy is important because it can encourage children and young people to improve their blood glucose control which may prevent progression of damage.

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				monitoring, although once BDR is detected, further examinations would constitute monitoring in order to detect worsening of retinopathy which would justify referral to hospital eye services. We support the recommendation that in children with type 2 diabetes 'the identification of any grade of retinopathy (even that which is not immediately sight threatening) may be of importance' (Full version, page 316, lines 16-17).	The term 'monitoring' has been used to maintain continuity with the terminology in previous reviews. However, as is rightly pointed out, the term screening is most appropriate until the point when background retinopathy has been detected. The guideline development group acknowledge this subtle difference and have taken it into consideration when developing the review
Royal College of Paediatrics and Child Health	FULL	271	32 38	This is poor evidence. It seems a poor excuse to say we shouldn't measure lipid profiles as this places a burden on the family. Clearly and logically screening helps guide the family and patient about their overall diabetes control. Furthermore, the guidance in the adult diabetes is to screen lipids – so what changes at transition? Diabetes is for life so it seems illogical to think that just because you are a child that screening should be different. High cholesterols can be treated by improving diabetes control. ISPAD suggests screening at diagnosis and 5 yearly thereafter but no evidence for this timescale.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (lipid monitoring in children and young people with type 1 diabetes in this case)
National Children and Young People's Diabetes Network	FULL	295	12 16	HbA1c target: Where is the evidence for this target? We don't doubt the principle of aiming for the best HbA1c possible for the individual, but think this target is too much of a jump and will be demotivating for individual patients and their teams. A change to less than or equal to 53mmol/mol (7%) seems reachable. If NICE persist with the target of <48mmol/mol (6.5%), they should state what is safe in terms of frequency and severity of hypoglycaemia.	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider

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					the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development

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					group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group of this guideline strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline
Roche Diagnostics	FULL	295	28 30	To safely achieving and maintaining the lowest attainable HbA1c: • within insulin-dependent T2 diabetes it is necessary that patients have appropriate access to SMBG that even considers higher testing needs in phases of intercurrent illness, • within non-insulin-dependent T2 diabetes the benefits of structured testing should be used in clinical practice and within education of patients	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not able to accept comments on topics that are excluded from the scope of the 2015 update (self-monitoring of blood glucose for children and young people with type 2 diabetes in this case). The only measure of glycaemic control prioritised for

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				and healthcare providers: The STeP study was a large prospective, cluster-randomised, multi-centre trial evaluating the use of structured SMBG in 483 poorly controlled (HbA1c ≥7.5%, insulin-naïve T2DM patients from 34 US primary care practices (Polonsky 2011). The primary endpoint was change in HbA1c over time. Patients in the structured testing group used a simple paper tool that facilitates collection and interpretation of 7-point glucose profiles over 3 consecutive days. These patients completed the tool on a quarterly basis, brought the completed tools to medical visits, and discussed findings with their physicians. Structured testing group patients received training in blood glucose measurement, including instructions for how to identify problematic glycaemic patterns and how best to address such problems through changes in physical activity, portion sizes, and/or meal composition; structured testing group physicians received an algorithm describing various pharmacologic/lifestyle treatment strategies that could be used in response to the specific SMBG patterns identified. Active control group patients received enhanced usual care only and were instructed to use their meter following their physicians' recommendations but received no additional SMBG prompting, training, or instruction. At 12 months, intent-to-treat (ITT) analysis revealed that structured testing group patients (n=256) experienced significantly greater improvement in mean HbA1c than active control group patients (n=227): -1.2% vs. -0.9%; P=0.04. Per protocol (PP) analysis revealed an even greater HbA1c reduction (- 0.5%) in the experimental (n=130) vs. control (n=161) patients (-1.3% vs. -0.8%; P<0.003). Further analyses of data from the STeP study have revealed improvements in several other parameters, including clinicians' intensification of treatment; depression and diabetes-related distress; and patient self-efficacy and autonomous motivation in managing their diabetes. Similar findings were seen in a pilot study by Franciosi et al. (Franciosi, Lucisano et al. 2011) evaluating the efficacy of a structured SMBG-based intervention with T2DM patients treated with	consideration in the 2015 update with regard to type 2 diabetes was HbA1c

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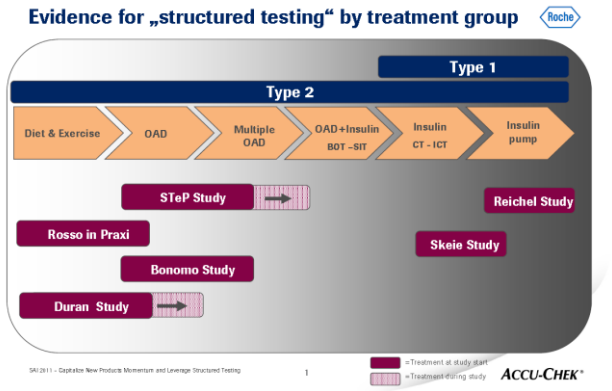
				oral agents. Parkin et al. have published a review article that provides more detailed descriptions of these studies (Parkin, Hinnen et al. 2009).  Figure 2: Evidence for "structured testing" by treatment (Roche Diabetes Care) Further studies have proven the effective contribution of structured SMBG within different treatment regimens (Skeie, Kristensen et al. 2009, Bonomo, De Salve et al. 2010, Duran, Martin et al. 2010, Kempf, Kruse et al. 2010, Reichel 2010, Kempf, Kruse et al. 2012). Within the STeP study over an one year period, introducing a structured SMBG approach according to STeP versus unstructured SMBG without education beyond the regular instructions of the practitioner is cost-neutral even if treatment is intensified (Myers, Berndt et al. 2011).	

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				An explorative analysis of the STeP data showed that structured SMBG in non-active testers before the start of the study was associated with higher reductions in HbA1c compared to standard SMBG use. The use of structured SMBG may be especially cost-effective in terms of HbA1c reduction per test strips used in patients with poorly controlled non-insulin-dependent diabetes mellitus who do not show a history of consistent SMBG use (Berndt, Jelsovsky et al. 2011). According to Schramm combining STeP-outcomes with U.S.-costs (in USD) of diabetes and its consequences utilising a well-established Markov model diabetes treatment using structured vs. unstructured SMBG according to STeP represents a cost-effective approach to improve diabetes care from the perspective of U.S. third party payers over a life-time (Schramm 2012). "Improved glycaemic control achieved through the STeP approach demonstrates that a simple, validated program that prompts greater interaction between physicians and patients can significantly improve the management of diabetes… The patient and physician educational components of STeP broadly enable a standardised approach, which is, in our opinion, one of the program's most valuable characteristics. One aspect of the educational component of STeP that should not be overlooked is that it provides physicians with a glucose pattern management guideline. The treatment algorithm in the program allows simple pattern recognition to occur, which assisted physicians in the structured testing group intervention to improve their assessment of glycaemic control and promote specific treatment changes. The result is that through the use of the ACCU-CHEK 360° View tool, patients' and physicians' appreciation of blood glucose patterns appeared to more readily prompt collaborative decision making on the optimisation of lifestyle changes and pharmacologic management. STeP provides an impetus for this vital collaboration between physicians and patients and empowers patients to help manage their own care."…"By observing what happens when patients use STeP and monitor	

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				their blood glucose levels, it becomes possible to identify those individuals who have the most difficulty with self-management and might most benefit from additional focused interventions through disease or case management. Although simple in design, the program may help segment the patient population and help focus both resources and interventions to improve patient care and control of HbA1c. To fully realise the potential benefits of STeP for patient care, endocrinologists can be engaged to work with the primary care providers and physician extenders who use and understand the program in order to identify patients who need more complex educational and case management interventions, as well as those who need the benefit of endocrinologist consultation. Furthermore, its simplicity makes it well suited for introduction into pharmacies to be used to support medication therapy management programs. Treatment adjustments in diabetes have always been an issue for both physicians and patients and it is frequently difficult to convince patients of the necessity of changing their medications, especially when that change involves the prescription of an additional oral agent or the initiation of insulin. The data indicate that increased testing is not required; rather, periodically concentrating the testing appears to be effective as a diabetes management tool. The STeP study authors noted that these results suggest the focus of SMBG testing should shift from quantity to quality (Polonsky, Fisher et al. 2011). STeP leads to more effective and efficient use of resources already covered by health insurance benefits (eg, testing strips, supplies), as well as contributing to the behavioural motivation necessary to adhere to an optimized treatment regimen. STeP offers an intervention that reduces HbA1c through better utilization of existing management principles. This program shows us how to more effectively use an existing benefit (test strips, supplies) for added value.	

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				STeP is a simple program that can be used by practitioners at many levels, including physicians, pharmacists, health educators, and nurse practitioners, all of whom seem destined to become more involved in diabetes management as a consequence of the impending changes proposed for the US healthcare delivery system. In addition, these provider organisations are expected to have endocrinologists available to help manage their most complex patients, guide the primary care physicians and physician extenders, support primary care interventions, and even engage in case management and disease management programs. Accountable care organisations, particularly those being developed by large, experienced medical groups, could also successfully deploy STeP. In this case, the program presents the opportunity for medical groups to better manage patients with diabetes, improve their HEDIS scores, and enhance their collective financial performance. Implementation of STeP would also yield significant benefits for patient-centred medical home programs, which are often focused on the management of chronic diseases, such as diabetes. Recent evidence indicates that patient-centred medical homes have had success in improving patient outcomes and decreasing costs associated with diabetes (Grumbach and Grundy 2010) and this setting seems ideal for implementing STeP. Compensation models move toward an outcomes and performance basis and away from production-based systems, it seems likely that physicians will become more receptive to mastering new approaches that can help reach targets such as HbA1c reductions. In fact, the program's simplicity makes it adoptable across a broad range of healthcare providers, and there are likely many potential innovative ways in which smaller practices and even local health departments can utilize this practical clinical approach" (Lonigro and Sredzinski 2011).	

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British Psychological Society	FULL	301	8 12	Diabetes teams should have integrated clinical/health psychology input, as this is recommended in DoH (2012) guidance. Psychological assessment and intervention is more purposeful and meaningful than 'psychosocial support'.	The guideline development group consider that the recommendations are complementary to the Best Practice Tariff and do not preclude an annual assessment to determine the need for psychological support. The linking evidence to recommendations section of the review has been amended to clearly state this. The phrase psychological support includes psychological assessment and intervention. The phrase has been retained for consistency throughout the guideline
British Psychological Society	FULL	301	13 15	Screening for emotional difficulties and problematic coping should not be restricted to only those children and young people with persistently poor blood glucose control, which also a very loosely defined and pejorative term. We recommend 'difficulties with managing blood glucose levels' be used instead'.	The recommendation has been amended so that 'poor' is replaced with 'suboptimal'
British Psychological Society	FULL	301	16 18	Children and young people with type 2 as with type 1 require timely and ongoing access to clinical/health psychology input which is delivered by appropriately trained and experienced clinicians to facilitate coping, in addition to assessment of mental health difficulties.	The guideline development group agree with the views expressed in the comment and have reflected this in the recommendations which state that timely and ongoing access should be given to 'mental health professional with an understanding of diabetes'. This broad definition includes clinical/health psychology input from appropriately skilled professionals

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British Psychological Society	FULL	301	22 24	The Society recommends that greater clarity in distinguishing between psychological services and "mental health professionals". In terms of service provision, a simple distinction would be that Child and Adolescent Mental Health Services work within mental health, while Paediatric/Health Psychology Services provide psychological/psychosocial services for children and young people within physical health. Similarly, a diabetes team may have an applied psychologist (health/clinical/counselling psychologist) specifically employed within its team.	The guideline development group use the term 'mental health professional' so that the recommendation covers access to a wide range of professional services including psychologists, family therapists, psychiatrists, etc. A sentence has been added to the linking evidence to recommendations section of the full guideline to explain this more clearly
Royal College of Paediatrics and Child Health	FULL	323	166	It is noted that annual screening for dyslipidaemia is recommended for type 2 and not type 1 despite the low level of evidence for type 2. The GDG however agreed that monitoring for type 2 was appropriate. It is not clear why the GDG approve this for type 2 but not type 1?	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline. This applies to monitoring for dyslipidaemia in children and young people with type 1 diabetes (which means that the guideline development group are unable to update that section of the guideline), whereas monitoring for dyslipidaemia in children and young people with type 2 diabetes is covered by the scope of the 2015 update
Roche Diagnostics	FULL	408 419	9 24	As increased frequency of capillary blood glucose (finger-prick) testing comes along with the inconvenience of testing for the children and young people, it is highly improbable that the frequency of finger-prick testing actually exceeds the necessary amount.	The guideline development group did not agree that the benefits of safe insulin application would need to be included in the analysis. This was not included in the review protocol as a priority outcome. The

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				Better control of blood glucose is not the only aim of SMBG testing in type 1 diabetes. The benefits of safe insulin application would need to be included in the analysis. Including these benefits in the analysis would be advisable before considering conclusions like "the cost effectiveness of increased testing is overstated in this analysis". As part of an individual care plan developed with their healthcare professional, patients should have the amount of blood glucose testing available that is necessary for the safe application of insulin, based on their individual testing target and in situations of intercurrent illness.	guideline development group did not think that safe insulin application would result in a requirement for an increased frequency of daily testing in the long term. The guideline development group did not conclude that 'the cost effectiveness of increased testing is overstated in this analysis'. This statement was making a technical observation that estimating effectiveness from correlational studies could potentially cause the cost effectiveness to be overstated if there were confounders. The guideline development group did consider that plausible confounders could exist and therefore this is an important caveat to be aware of in interpreting the results of this study
Roche Diagnostics	FULL	408	10 27	It is pivotal that the benefit of safe insulin application is considered in the context of cost effectiveness of different frequencies of capillary blood glucose monitoring. As there are always reasons why particular evidence does exist eg. no incentives or even requests to generate appropriate evidence, alternatively it could be argued that the decision should be in the hands of the patients and their treating physicians because they know their particular situation best and their health needs shall not depend upon the intricacies evidence development. Therefore, it is pivotal that the requirement "it is important to remember that the demands of a child or young person's lifestyle at certain times maybe such that it makes sense to test more frequently than routinely recommended in the guideline" should not be	The recommendation was for a minimum of 5 tests per day, not an average of 5 tests per day. However, the guideline development group were concerned that commissioners might interpret their recommendation as meaning an average of 5 tests per day and therefore the recommendations have been amended to reflect that additional testing may often be important and that the child or young person should have sufficient test strips

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				hindered by healthcare commissioning and planning based on average tests of 5 per day which inevitably would lead to shortages in the supply of test strips, thus potentially leading to harm and unnecessary cost burden to CCGs and the NHS.	available to meet the needs of additional testing. While the guideline development group are not familiar with the specific term 'safe insulin application' they believe that the process of ensuring safe treatment with insulin (if that is the intended meaning) encompasses more than just the frequency of testing. T the impact of other factors (such as insulin preparations and method of delivery of insulin) are discussed in detail in Section 6 of the full guideline and captured in the outcomes that were prioritised for inclusion in the evidence review and health economic modelling.
Roche Diagnostics	FULL	408	30 31	Testing frequencies depend on the individual situation of the patients. Randomised studies that would compare different frequencies of finger-prick testing may be difficult to conduct because patients with different testing frequencies needs differ from a medical viewpoint which would make a valid comparison difficult or forcing patients to differing testing frequencies than their actual needs could be unethical or impractical. This kind of trial would be for sure very difficult to recruit for as it would be difficult to motivate patients to participate.	We agree that there could be difficulties in conducting randomised studies to assess the optimal frequency of finger-prick testing, which may reflect why such studies were not found, and why the modelling used observational/correlation studies to estimate effect. However, that does not mean that there are no limitations with such an approach
Roche Diagnostics	FULL	408	37 41	Still, withdrawing the access to blood glucose control tests could negatively impact the motivation of the patients.	The updated guideline has increased the recommended frequency of daily testing, as previously more than four or more tests per day was recommended only for

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					children and young people with type 1 diabetes trying to optimise their glycaemic control and/or with intercurrent illness. Furthermore the recommendations in this guideline have been amended following the stakeholder consultation to reflect that 5 tests per day is a minimum, and that sufficient test strips should be available for more frequent testing when necessary
Roche Diagnostics	FULL	409	14 17	While taking the decision of assessing the frequency of monitoring blood glucose levels up to 5 times per day, please consider that the underlying reference lines out that this primarily applies for conventional therapy not for flexible treatment esp. when used with CSII: "The finding that the effect of numerous SMBG on the HbA1c was smaller in the group with conventional therapy could possibly be explained by a more strict treatment regimen overall. With constant meals and insulin doses, the reflection on SMBG and consecutive adaptation to treatment are uncommon, and therefore an increase in frequency of SMBG results only in limited improvement of metabolic control. On the contrary, patients using CSII will adjust their insulin treatment ideally with each blood glucose measurement. This may account for the observation that an increase in SMBG frequency beyond 5/d was associated with a decrease in average HbA1c only in the CSII group."(Ziegler, Heidtmann et al. 2011)	The authors of this study concluded that "Increasing the SMBG above 5 times per day did not result in further improvements of metabolic control" and therefore the guideline development group did not think there was an evidence-based justification for recommending more than 5 tests per day as a minimum, especially given the limitations in assuming causation from correlation
Roche Diagnostics	FULL Appendix K	527 533	General	Could the GDG please explain if and to which extend a lack of blinding has contributed to low quality ratings considering the feasibility of blinding in medical technologies like glucose monitoring?	Outcomes from studies that are included in the reviews have been assessed according to the NICE checklists for methodological limitations. The outcomes have been assessed for risk of bias (including any study blinding issues) accordingly and the guideline development

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					group's conclusions have been reflected in the footnotes under each GRADE table. Where there is no risk of bias, this means that the outcome is not affected by any selection, performance, attrition or detection bias and it has not been downgraded. For questions related to glucose monitoring (GRADE Tables 40, 41, 42 and 43 in Appendix K7), included studies were assessed and lack of blinding (due to the nature of the intervention) was taken into account in the limitations checklist for each study, but were not downgraded for risk of bias in GRADE
Alder Hay Children's NHS Foundation Trust	General	General	General	Dr Ghatak – I found the guidance very difficult to navigate. I was obliged to read entire guidance each time to find information but I appreciate this may be standardised format of NICE Guidance.	Thank you for this comment
Alder Hay Children's NHS Foundation Trust	General	General	General	Dr Ghatak - Points in the guidance to be commended: 1. Guidance directs towards intensive therapy from the word go and mentions pumps as routine early care. 2. Promotes carbohydrate counting from the start. 3. Recommends 5 blood tests a day. 4. Lays out clear guidance for stand-alone CGM use. 5. Lower HbA1c targets. 6. Blood ketone monitoring	Thank you for this comment in support of the guideline. The strengths highlighted in the comment are preserved in the revised guideline after taking account of all stakeholder comments

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				7. Psychosocial Health	
Association of School and College Leavers	General	General	General	No comments	No response required
Bayer	General	General	General	No comments	No response required
British Psychological Society	General	General	General	There are no recommendations for research on the effectiveness and/or impact of psychological interventions. This is in spite of DoH stating that psychology is a core member of the MDT and the Global ISPAD Guidance (https://www.ispad.org/content/ispad-clinical-practice-consensus-guidelines-2009) stating that "psychosocial factors are the most important influences affecting the care and management of diabetes"	The broad research recommendation highlighting the need for further studies to evaluate the effectiveness of behavioural and social interventions on anxiety and depression, eating disorders, behavioural and conduct disorders, and adherence to therapy in children and young people with type 1 diabetes, especially in adolescence, from diagnosis and in established diabetes which was included in the original (2004) guideline has been retained in the 2015 update. As several specific topics related to psychological and psychosocial issues affecting children and young people with type 1 diabetes are excluded from the 2015 update (for example, anxiety and depression, eating disorders and behavioural and conduct disorders) it has not been possible to be more specific about the form this research should take. The guideline development group agree, however, that systematic reviews to complement those already undertaken for

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					topics included in the update could form part of these further research studies
Department of Health	General	General	General	No comments	No response required
Heart UK	General	General	General	No comments	No response required
Merck, Sharp and Dohme UK Ltd	General	General	General	No comments	No response required
National Children and Young People's Diabetes Network	General	General	General	Screening for coeliac disease should just say 'follow latest NICE guidelines on coeliac disease' rather than specifying 'test only at diagnosis', so that if NICE guidelines change for CD, our guidelines won't be immediately out of date.	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (coeliac disease in this case). However the guideline development group recognise that NICE has produced separate guidance and so the recommendations in this guideline have been amended to cross-refer to the NICE coeliac disease guideline for guidance on monitoring for coeliac disease in children and young people with type 1 diabetes
National Children and Young People's Diabetes	General	General	General	Hypoglycaemia section was not reviewed in detail	Thank you for submitting comments in response to the stakeholder consultation. Please note that the part of the guideline that deals with management of hypoglycaemia is excluded from the 2015

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Network					update and the evidence has not been reviewed since the original (2004) guideline
National Children and Young People's Diabetes Network	General	General	General	Intercurrent Illness was not reviewed but urinary ketones needs to be changed to blood ketones.	This section describes the content of consensus guidance reviewed for the 2004 guideline. This does not form part of the 2015 update and so the text has not been superseded by a new evidence review. The explanatory text added as part of the 2015 update has now been revised to clarify that blood ketone testing (rather than urine ketone testing) should be performed during intercurrent illness
National Children and Young People's Diabetes Network	General	General	General	Transition from paediatric to adult care has not been reviewed yet this is an area where services and guidelines are rapidly being developed and much research has been undertaken in recent years.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (transition from paediatric to adult services in this case) Please note that the NICE guideline on tTransition from children's to adult services is currently under development and is expected to publish in February 2016
NHS Choices	General	General	General	No comments	No response required
NHS England	General	genera	Gener	An issue requiring consideration is the age threshold for moving the goals of care	Thank you for submitting comments in

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		l	al	from what is contained in this guideline, to that which is contained in the separate guidelines for adult Type 1 diabetes and adult Type 2 diabetes. The recognition that quite a different outpatient service, the transition service, can span the ages of 13 through to 25 - variable currently, but increasingly recognized across the country as necessary - needs to be acknowledged in some way. Information should be given around, for example, benefits from government disability support (1.2.8) and how entitlements may change at the legal age of adulthood, which of course is buried within the age span of the transition service. Perhaps a statement, or at least some acknowledgement around the potential issues, of whether an inpatient episode for a young person around the age of 16 should be delivered on a paediatric ward or an adult ward; this could be individualized within a care plan for each young person, rather than being specified purely by age.	response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (transition from paediatric to adult services in this case) The guideline development group recognise the importance of the separate NICE guidance on transition that is being developed but note that it is not completed at present
NHS England	General	genera l	Gener al	1.1.5 Outside the acute presentation, another useful set of parameters to help differentiate those with Type 2 diabetes from those with Type 1 are lipid values, with low HDL cholesterol and high triglyceride suggestive of a degree of insulin resistance and hence Type 2 diabetes.	Thank you for this comment. The guideline development group reviewed the evidence for distinguishing between type 1 and type 2 diabetes using C-peptide or diabetes specific autoantibody titres, whereas evidence for other approaches to distinguishing between type 1 and type 2 diabetes were not prioritised for consideration in the 2015 guideline update. The approaches mentioned in the comment have, therefore, not been evaluated as part of the update and are consequently not included in the recommendations
NHS England	General	genera l	Gener al	2. 1.2.8 - as outlined above, information should also be given around the change in entitlements at the legal age of adulthood.	Thank you for this comment. NICE is not able to accept comments on parts of the

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					guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (transition from paediatric to adult services in this case) The guideline development group recognise the importance of the separate NICE guidance on transition that is being developed but note that it is not completed at present
NHS England	General	general	General	Also under 1.2 - education and information, recommendations around driving should be included (from age 17), and advice included on contraception, conception and pregnancy (though perhaps any age threshold for this should be individualized).	There was no evidence identified to support structured education from diagnosis (structured here meaning a formal training or education package with a recognised curriculum and approaches to delivery). The guideline recommendations do, however, list core topics that should be covered as part of (unstructured) education. The guideline development group's view is that the core topics and the recommendations to tailor education to the individual and add other topics as needed will allow issues such as those listed in the comment to be covered effectively when needed. Please note, however, that the guideline remit did not include consideration of contraception, conception and pregnancy as these are covered by the NICE guideline on diabetes

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					in pregnancy. The diabetes in pregnancy guideline is included in the list of related NICE guidance
NHS England	General	general	General	1.5.2 - "24 hour access to advice from their diabetic team". Has any evaluation been performed of how well this has been implemented since 2004? Are teams remunerated for such out of hours activity, or has cover, where provided, been provided informally? Is there any cost-effectiveness evaluation around provision of 24/7 access to "their own" diabetes team. To provide legal rotas, teams would have to be large, probably unrealistically so given that there are 177 different providers of paediatric diabetes services in England and Wales. Perhaps consideration should be given to rotas covering larger areas/regions.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (24-hour access to the diabetes team in this case)
NHS England	General	General	General	For Type 2 diabetes, there is a great deal of emphasis on measurement, but virtually nothing on the subsequent actions to be taken if measurements are abnormal. Aside introducing metformin from diagnosis, there are no additional therapeutic suggestions, despite suggesting 3 monthly checks of HbA1c with a target of 48 mmol/mol (the suggestion being that further moves to achieve target can be achieved by lifestyle interventions alone, which is somewhat unrealistic). What should second line drug treatment be? Given that the younger age of onset of Type 2 diabetes is being driven by weight gain, should there be a greater emphasis on weight neutral or weight loss promoting therapies after metformin? Similarly, there is a section on measuring blood pressure (1.3.42-44), even 24 hour blood pressure monitoring, without any suggested action on the basis of abnormal results - which first line anti-hypertensive would the guideline suggest? Similarly a section on dyslipidaemia (1.3.45-47) and its regular assessment gives no suggested actions on the basis of abnormality. If there is no evidence on which to guide recommendations, this might at least be stated. An issue requiring consideration is the age threshold for moving the goals of care from what is contained in this guideline, to that which is contained in the separate	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that the part of the guideline that considers type 2 diabetes in children and young people is constrained by the scope for the 2015 update to cover metformin but no other pharmacological treatments after metformin, and to cover monitoring for long-term complications, such as hypertension and dyslipidaemia but not their subsequent management. The consideration of evidence that would lead to recommendations as suggested is outside the scope of the guideline

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				guidelines for adult Type 1 diabetes and adult Type 2 diabetes. The recognition that quite a different outpatient service, the transition service, can span the ages of 13 through to 25 - variable currently, but increasingly recognized across the country as necessary - needs to be acknowledged in some way. Information should be given around, for example, benefits from government disability support (1.2.8) and how entitlements may change at the legal age of adulthood, which of course is buried within the age span of the transition service. Perhaps a statement, or at least some acknowledgement around the potential issues, of whether an inpatient episode for a young person around the age of 16 should be delivered on a paediatric ward or an adult ward; this could be individualized within a care plan for each young person, rather than being specified purely by age.	Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (transition from paediatric to adult services in this case). It should be noted that NICE is currently developing a guideline on the transition from children's to adult services
Roche Diagnostics	General	General		References Berndt, K., Z. Jelsovsky, C. Rees and O. Mast (2011). "Effectiveness and self-monitoring of blood glucose (SMBG) frequencies in poorly-controlled patients with non-insulintreated diabetes (NITDM) who were not active testers prior to the step study." Value in Health 14(7): A245. Bonomo, K., A. De Salve, E. Fiora, E. Mularoni, P. Massucco, P. Poy, A. Pomero, F. Cavalot, G. Anfossi and M. Trovati (2010). "Evaluation of a simple policy for pre- and post-prandial blood glucose self-monitoring in people with type 2 diabetes not on insulin." Diabetes Res Clin Pract 87(2): 246-251. Duran, A., P. Martin, I. Runkle, N. Perez, R. Abad, M. Fernandez, L. Del Valle, M. F. Sanz and A. L. Calle-Pascual (2010). "Benefits of self-monitoring blood glucose in the management of new-onset Type 2 diabetes mellitus: the St Carlos Study, a prospective randomized clinic-based interventional study with parallel groups." J Diabetes 2(3): 203-211. Franciosi, M., G. Lucisano, F. Pellegrini, A. Cantarello, A. Consoli, L. Cucco, R. Ghidelli, G. Sartore, L. Sciangula and A. Nicolucci (2011). "ROSES: role of self-monitoring of blood glucose and intensive education in patients with Type 2 diabetes not receiving insulin. A pilot randomized clinical trial." Diabet Med 28(7):	This comment lists references cited in other comments submitted by the stakeholder. The articles listed have been considered when addressing those comments and responses regarding their relevance to the guideline reviews are provided where appropriate

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				789-796. Grumbach, K. and P. Grundy (2010) "Outcomes of Implementing Patient Centered Medical Home Interventions: A Review of the Evidence From Prospective Evaluation Studies in the United States." Hansen, M. V., U. Pedersen-Bjergaard, S. R. Heller, T. M. Wallace, A. K. Rasmussen, H. V. Jorgensen, S. Pramming and B. Thorsteinsson (2009). "Frequency and motives of blood glucose self-monitoring in type 1 diabetes." Diabetes Res Clin Pract 85(2): 183-188. Kempf, K., J. Kruse and S. Martin (2010). "ROSSO-in-praxi: a self-monitoring of blood glucose-structured 12-week lifestyle intervention significantly improves glucometabolic control of patients with type 2 diabetes mellitus." Diabetes Technol Ther 12(7): 547-553. Kempf, K., J. Kruse and S. Martin (2012). "ROSSO-in-praxi follow-up: long-term effects of self-monitoring of blood glucose on weight, hemoglobin A1c, and quality of life in patients with type 2 diabetes mellitus." Diabetes Technol Ther 14(1): 59-64. Lonigro, R. and M. Sredzinski (2011). "Implications of step for improved diabetes control: A payer perspective." American Journal of Pharmacy Benefits 3(5): 257-262. Misso, M. L., K. J. Egberts, M. Page, D. O'Connor and J. Shaw (2010). "Continuous subcutaneous insulin infusion (CSII) versus multiple insulin injections for type 1 diabetes mellitus." Cochrane Database Syst Rev(1): CD005103. Myers, J., K. Berndt, N. Wegmann, C. Rees, O. Mast and R. Wagner (2011). "Analysis of cost drivers in structured smbg in poorly controlled, non-insulin treated type-2 diabetes: Results from the step study." Value in Health 14(3): A82. Parkin, C. G., D. Hinnen, R. K. Campbell, P. Geil, D. L. Tetrick and W. H. Polonsky (2009). "Effective use of paired testing in type 2 diabetes: practical applications in clinical practice." Diabetes Educ 35(6): 915-927. Polonsky, W., Fisher, L, Schikman, CH, Hinnen, DA, Parkin, CG, Jelsovsky, Z, Petersen, B, Schweitzer, M, Wagner, RS (2011). "Structured self-monitoring of	

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				blood glucose significantly reduces A1C levels in poorly controlled, noninsulin-treated type 2 diabetes: results from the Structured Testing Program study." Diabetes Care 34(34(2)): 262-267. Polonsky, W. H., L. Fisher, C. H. Schikman, D. A. Hinnen, C. G. Parkin, Z. Jelsovsky, M. Axel-Schweitzer, B. Petersen and R. S. Wagner (2011). "A structured self-monitoring of blood glucose approach in type 2 diabetes encourages more frequent, intensive, and effective physician interventions: results from the STeP study." Diabetes technology & therapeutics 13(8): 797-802. Reichel, A. (2010). Improved A1c and less hypoglycemia by self-analysis of graphically depicted SMBG. Poster. 70th Scientific Session of the American Diabetes Association. Orlando, Florida (USA). Schramm, W. (2012). The Economics of Structured Self-Monitoring of Blood Glucose (SMBG) in Non-Insulin-Dependent Type 2 Diabetes Mellitus - Lessons to be Learned from the Structured Testing Program (STeP) Study. Gac Sanit 9th HTAi Annual Meeting "HTA in Integrated Care for a Patient Centered System" Bilbao, Spain. 26 (espec Congr 2): 193 (Abtr.-No. 465). Schutt, M., W. Kern, U. Krause, P. Busch, A. Dapp, R. Grziwotz, I. Mayer, J. Rosenbauer, C. Wagner, A. Zimmermann, W. Kerner and R. W. Holl (2006). "Is the frequency of self-monitoring of blood glucose related to long-term metabolic control? Multicenter analysis including 24,500 patients from 191 centers in Germany and Austria." Exp Clin Endocrinol Diabetes 114(7): 384-388. Shalitin, S., M. Gil, R. Nimri, L. de Vries, M. Y. Gavan and M. Phillip (2010). "Predictors of glycaemic control in patients with Type 1 diabetes commencing continuous subcutaneous insulin infusion therapy." Diabet Med 27(3): 339-347. Skeie, S., G. B. Kristensen, S. Carlsen and S. Sandberg (2009). "Self-monitoring of blood glucose in type 1 diabetes patients with insufficient metabolic control: focused self-monitoring of blood glucose intervention can lower glycated hemoglobin A1C." J Diabetes Sci Technol 3(1): 83-88. Wilkinson, J., K. McFann and H. P. Chase (2010). "Factors affecting improved glycaemic control in youth using insulin pumps." Diabet Med 27(10): 1174-1177.	

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				Ziegler, R., B. Heidtmann, D. Hilgard, S. Hofer, J. Rosenbauer, R. Holl and D. P. V. W. Initiative (2011). "Frequency of SMBG correlates with HbA1c and acute complications in children and adolescents with type 1 diabetes." Pediatr Diabetes 12(1): 11-17.	
Royal College of Nursing	General	General	General	Royal College of Nursing welcomes the update of the diabetes in children and young people guideline. It is timely. The comments below are based on feedback from members who care for children and young people in Paediatric and Adolescent Diabetes Services.	Thank you for this comment in support of the guideline
Royal College of Nursing	General	General	General	In the introduction the guideline authors state: " A variety of genetic conditions (such as maturity-onset diabetes in the young) and other conditions (such as cystic fibrosis-related diabetes) may also lead to diabetes in children and young people, but the care of these diverse conditions is beyond the scope of this guideline" however in the previous paragraph they outline that for Type 2 diabetes "These differences in management and complications need guidance specific to type 2 diabetes, which is included here for the first time." We accept that the guideline group needs to limit their scope and cannot include every rare subtype but would ask that they consider including the commonest subtypes where there is very strong evidence that a diagnosis will alter management as much as it does in Type 2 diabetes. The key subtypes would be glucokinase MODY – the commonest cause of incidental hyperglycaemia in the paediatric age range, HNF1A the commonest from of symptomatic MODY which have a clear sensitivity to low dose sulphonylureas (hence a difference in treatment from Type 1 and Type 2) and neonatal diabetes which has dramatically different treatment and can be diagnosed solely on the age of diagnosis).	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected

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				There is insufficient information included in the guidelines about monogenic diabetes. A good summary is provided in the ISPAD guidelines on monogenic diabetes which is a good source of evidence. There is published evidence that in the UK in the paediatric age range monogenic diabetes is as common as Type 2 diabetes (Ehtisham S, Hattersley AT, Dunger DB, Barrett TG; British Society for Paediatric Endocrinology and Diabetes Clinical Trials Group. First UK survey of paediatric type 2 diabetes and MODY. Arch Dis Child. 2004 Jun; 89(6):526-9. PMID: 15155395). This report is over 10 years old and now there is evidence that both Type 2 and monogenic diabetes are much more recognized. In the UK there are over 353 cases of molecularly diagnosed MODY or neonatal diabetes who are still under 18 years and a further 623 cases that were diagnosed in the paediatric age range but are now older (source Professor Ellard, Head of Diagnostic Testing for Monogenic Diabetes in the UK, Royal Devon and Exeter NHS FT). In the USA the minimum prevalence of genetically proven MODY diabetes was 1.2% (Pihoker C, et al (2013) Prevalence, characteristics and clinical diagnosis of maturity onset diabetes of the young due to mutations in HNF1A, HNF4A, and glucokinase: results from the SEARCH for Diabetes in Youth. J Clin Endocrinol Metab. 2013 Oct; 98(10):4055-62. PubMed PMID: 23771925 ;). In the UK the UNITED study http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=9408 has unpublished information from seven UK paediatric clinics of a minimum prevalence of 1.8% in UK paediatric clinics.	diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY. However, the limitations of the scope for the 2015 update prevent the guideline development group from providing more detail about the diagnosis or management of forms of diabetes other than type 1 or type 2

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				The importance is that the diagnosis is often not made correctly (only 8% were correctly diagnosed (Pihoker et al, 2013) and like Type 2 diabetes they need very different treatment from Type 1 diabetes.	
Royal College of Nursing	General	General	General	The guidelines should include information on neonatal diabetes. It is a new subtype to be recognized since the 2004 guidelines. At present there is no information on neonatal diabetes. This subtype is important as: 1. There are over 200 cases diagnosed in the UK (Source Professor Ellard, Exeter with 90 having potassium channel mutations). 2. These patients can be recognised clinically and the correct diagnosis can greatly alter treatment leading to a massive change in outcome and quality of life. 3. They present with Diabetic Ketoacidosis (DKA) so can be easily misdiagnosed as Type 1 if the significance of the age of diagnosis is not appreciated. The key thing is that a diagnosis less than 6 months is neonatal diabetes and not type 1 diabetes. (Edgehill et Diabetes 55:1895–1898, 2006). This is very important as 50% of these patients will have a potassium channel mutation and despite being insulin dependent 90% can get greatly improved control without hypoglycaemia on a sulphonylurea (Pearson ER et al N Engl J Med 2006; 355:467-77). A recent review is in the ISPAD guidelines of monogenic diabetes.	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another

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					systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY. However, the limitations of the scope for the 2015 update prevent the guideline development group from providing more detail about the diagnosis or management of forms of diabetes other than type 1 or type 2
Royal College of Paediatrics and Child Health	General	General	General	Screening for coeliac disease should just say 'follow latest NICE guidelines on coeliac disease' rather than specifying 'test only at diagnosis', so that if NICE guidelines change for CD, our guidelines won't be immediately out of date.	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (coeliac disease in this case). However the guideline development group recognise that NICE has produced separate guidance and so the recommendations in this guideline have been amended to cross-refer to the NICE coeliac disease guideline for guidance on monitoring for coeliac disease in children and young people with type 1 diabetes
Royal College	General	Gener	Gener	Intercurrent Illness was not reviewed but urinary ketones needs to be changed to	This section describes the content of

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of Paediatrics and Child Health		al	al	blood ketones.	consensus guidance reviewed for the 2004 guideline. This does not form part of the 2015 update and so the text has not been superseded by a new evidence review. The explanatory text added as part of the 2015 update has now been revised to clarify that blood ketone testing (rather than urine ketone testing) should be performed during intercurrent illness
Royal College of Paediatrics and Child Health	General	General	General	Transition from paediatric to adult care has not been reviewed yet this is an area where services and guidelines are rapidly being developed and much research has been undertaken in recent years.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (transition from paediatric to adult services in this case). Please note that the NICE guideline on transition from children's to adult services is currently under development and is expected to publish in February 2016
Royal College of Paediatrics and Child Health	General	General	General	No comments	No response required
Royal College of Physicians	General	General	General	Endorse comments made by Association of British Clinical Diabetologists	Thank you for this comment
Staffordshire University	General	General	General	No comments	No response required

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Alder Hay Children's NHS Foundation Trust	General	14	1.1.7	Dr Ghatak – I feel it is useful to have if diagnosis of Type of DM in doubt. Absent/very low C Peptide can be useful information. Slightly contentious	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis (specifically evidence for distinguishing between type 1 and type 2 diabetes) and concluded that C-peptide and diabetes-specific autoantibody titres should not be measured at initial presentation to distinguish type 1 diabetes from type 2 diabetes. However, the revised recommendations emphasise that measuring C-peptide after initial presentation should be considered if there is difficulty distinguishing type 1 diabetes from other types of diabetes and that genetic testing should be performed if atypical disease behaviour, clinical characteristics or family history suggest monogenic diabetes. The 'do not use' form of recommendation reflects the evidence base
Alder Hay Children's NHS Foundation Trust	General	18	1.2.19	Dr Ghatak – Unclear, are we suggesting use BD regime sometimes? Slightly contentious	Thank you for this comment. The guideline guideline development group did not feel that use of insulin regimens other than multiple daily injections (or insulin pump therapy if a multiple daily insulin injection regimen is not appropriate) was appropriate at diagnosis hence the strong recommendation to offer multiple daily injection regimens from diagnosis. The later recommendation referring to mixed

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					insulin is included to cover those children and young people who might be using such a regimen although these are not recommended strongly
Alder Hay Children's NHS Foundation Trust	General	21	1.2.32	Dr Ghatak – Metaformin use in Type 1 restricted only to research settings? Slightly contentious	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (metformin combined with insulin for the management of type 1 diabetes in this case). The guideline development group have, however, retained the 2004 research recommendation related to this topic
Alder Hay Children's NHS Foundation Trust	General	23	1.2.55	Dr Ghatak – Fasting BG targets 4-7mmol/l? all recent data seems to suggest 4-6, especially in light of new HbA1c target. Slightly contentious	The upper limit for the blood glucose target range was chosen after discussion with the guideline guideline development group for the other NICE guidelines on diabetes, via a process coordinated by NICE. It is the same as the upper limit which is recommended for adults with type 1 diabetes, and this will ease transition from paediatric to adult services. The lower limit for the target range remains lower for children and young people with type 1 diabetes because they are likely to have the condition for many years and setting a

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					lower target aims to reduce the risk of long-term complications in this group
Royal College of Paediatrics and Child Health	General	26	25	For most individuals a target of 48mmol/mol is setting them up to fail. The NPDA in 2012/13 found only 3.8% of CYP with diabetes to have an A1c <48 (this included all types of diabetes and there were even les when only type 1 is considered). The evidence for targets at this low level does not exist and for most this level of control is aspirational and never achievable. The best level of control (A1c) should always be sought but targeting all to a level of 48mmol/mol is unrealistic. All other European and American guidance set 7.5% (58mmol/mol) which is the inflection point where the risk of complication reduces dramatically. Unless NICE can provide evidence that moving from 58 to 48 mmol/mol makes any difference to risk then they should be cautious advocating this for all.	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48

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					mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations

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					section in the full guideline
Royal College of Paediatrics and Child Health	General	27	30	Change to Recheck blood glucose levels "after 10-15 minutes and repeat fast-acting glucose if level below 5.6 mmol/L" (see ISPAD 2014 guidelines)	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case). However to maintain the safety of the recommendations the suggestion to repeat fast-acting glucose if hypoglycaemia persists has been added to this recommendation
Royal College of Paediatrics and Child Health	General	27 207	32 7	Omit "give" and change to "Oral complex long-acting carbohydrate may be required to maintain blood glucose levels if: Mixed insulin is being used Prolonged exercise has been taken Alcohol has been ingested Blood glucose was initially lower"	This change has not been made because it would involve inserting a new recommendation in part of the guideline that is excluded from the 2015 update (management of hypoglycaemia)
Faculty of Pharmaceutical Medicine	General	28	1.2.77	suggest give examples of source of 'fast acting glucose'	The guideline development group considered fast-acting glucose to be the clearest description of the product to be given and they did not wish to use the trade name for that product
National Children and Young People's Diabetes	General	30 240 246	35 13 18	Motivational Interviewing is a useful tool for behaviour change but is not a treatment for depression.	Thank you for this comment. The recommendation has been amended so that it cross-refers to the existing NICE guidance on the treatment of depression in children and young people. The previous

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Network					version of the recommendation reflected the association between improved depression and motivational interviewing that was found in the evidence specific to those with type 1 diabetes
National Children and Young People's Diabetes Network	General	31 273	1 3	Add "and if any symptoms, e.g. poor growth, gastrointestinal symptoms, anaemia or post-prandial hypoglycaemia".	Thank you for this comment. The symptoms referred to in the comment are quoted from the 2000 ISPAD consensus guideline recommendations on the diagnosis of coeliac disease in children and young people with diabetes. The recommendations have been amended to cross-refer to the NICE coeliac disease guideline on monitoring for coeliac disease in children and young people with type 1 diabetes
National Children and Young People's Diabetes Network	General	40	1.3.17	1.3.17 Talking about healthy eating at EACH contact. 'Regularly' would suffice	This recommendation relates to children and young people with type 2 diabetes and the guideline development group felt it was important to discuss healthy eating at every visit, whereas regularly would be ambiguous and potentially much less frequent
National Children and Young People's Diabetes Network	General	43 373	9 14	Home-based care at diagnosis is not appropriate for the initiation of MDI and carbohydrate counting or insulin pumps.	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004)

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					guideline (care setting at diagnosis in this case).
National Children and Young People's Diabetes Network	General	43 377	38 32	Preparation for Transition should start around 12 years of age. Ensure that the young person has the knowledge and skills to self-manage their diabetes prior to transfer to young adult or adult services (unless physical or learning disabilities prevent this). This should be documented on an individual Transition Plan.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (transition from paediatric to adult services in this case)
National Children and Young People's Diabetes Network	General	43 377	46 40	Joint transition clinics with staff from paediatric and adult services should be offered for at least one year prior to transfer.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (transition from paediatric to adult services in this case)
National Children and Young People's Diabetes Network	General	46 56	General	Should not include urinary ketone measurement as should use blood ketone measurement. Is the current DKA guideline going to be reviewed to ensure it is in line with NICE? DKA - new the fact that can be treated with oral fluids/s/c insulin if patient alert, nou nauseous/vomiting or clinically dehydrated. - calculations allow 10% dehydration if pH,7.1and only subtract boluses at more then 20 mls/kg from total fluid calculations. - Mainatenance fluids more restricted.	Measurement of blood ketones (ketonaemia) or urine ketones (ketonuria) are both allowed for in the recommendations about diagnosis of diabetic ketoacidosis, although blood ketones are to be preferred if near-patient testing is available. Whether or not existing (non-NICE) guidance is updated to reflect the guideline recommendations will be at the discretion of the organisations that

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					publish such guidance
				Probably these changes in fluid management will lead to a total less fluids in total.	The guideline development group agree that this is likely to be the case
				Noted Insulin starting at 0.05-0.1 Units/kg/hour, reflcting the idea that insulin can be started at lower dose.	The guideline development group acknowledge the recognition of the potential for a lower starting dose of intravenous insulin as indicated in the comment
National Children and Young People's Diabetes Network	General	47 50	General	Management of Diabetic Ketoacidosis: We are disappointed to see changes to this with no evidence to support it. Adapting to the previous guidance took a lot of effort of education and some of the changes seem to go back.	The guideline development group sought evidence for each of their review questions related to the scope of the 2015 update, including the section on diabetic ketoacidosis. Where evidence is lacking they have used their clinical expertise and experience to formulate recommendations and this is discussed in the linking evidence to recommendations section of the full guideline
				The principle of restricting fluids is appropriate, but why change to not taking the fluid boluses into account having previously taken them off the 48 hour total? It will cause further confusion. Should there be a restriction on number of boluses given?	The reason that resuscitation boluses are not subtracted from the 48-hour fluid calculation is that the fluid quantities recommended in the guideline are already less than in previous guidance and only rarely will a child or young person with diabetic ketoacidosis be given more than 20 ml/kg of intravenous fluid

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				The restriction of maintenance fluids to 40mls/hour for bigger children seems random and will cause increased hypoglycaemia on 0.1 units/kg/hour insulin infusion (we already see more than previously). We note the change to 0.05-0.1 units/kg/hour – if there is a need to change back, it should specify when to use which rate. Also 1.4.44 gives a range for infusion rate but surely should either recommend starting at highest or lowest and then titrate up or down depending on rate of fall of blood sugar. No oral fluid at all unless ketones <1 – again, where is the evidence? Should patients follow this principle at home? It seems extreme.	The restriction of fluids to 40 ml/hour does not tend to increase the risk of hypoglycaemia (this is based on the expertise and experience of the guideline development group) and the guideline recommends relatively low doses of insulin (as low as 0.05 units/kg/hour) It is not possible to choose between 0.05 units/kg/hour and 0.1 units/kg/hour based on the available evidence and so the recommendation allows for any dosage in that range The recommendation about restricting oral fluids has been changed to avoid specifying a value for ketones and now states that oral fluids should not be given to a child or young person who is receiving intravenous fluids for diabetic ketoacidosis unless ketosis is resolving, the child or young person is alert, and there is no nausea or vomiting
Alder Hay Children's NHS Foundation Trust	General	49	1.4.17	Dr Ghatak – is this always practical with HDU bed space availability?	Thank you for this comment. The recommendation referred to in the comment has been changed to state that children and young people with diabetic ketoacidosis should be cared for with one-to-one nursing either on a high-dependency unit (preferably a paediatric

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					unit), or on a general paediatric ward with one-to-one nursing. This change clarifies and emphasises that 1:1 care is most important and the revised recommendation allows for care in an adult high dependency unit if there is no other option
Alder Hay Children's NHS Foundation Trust	General	50	1.4.25	Dr Ghatak - I understand not stopping IV fluids/insulin treatment till Ketosis is below 1mmol/litre but are oral fluids not allowed at all?	The recommendation referred to in the comment has been changed to state that oral fluids should not be given to a child or young person who is receiving intravenous fluids for diabetic ketoacidosis unless there is no nausea or vomiting and ketosis is resolving. These changes avoid the specification of a threshold for ketosis below which oral fluids may be given, and they clarify the circumstances in which oral fluids may be given (in terms of there being no nausea or vomiting)
National Children and Young People's Diabetes Network	General	58	General	Consideration of transition to adult services: there should be care that the guidance links to adult guidance. I understand that the adult guideline is likely to say that metformin should be used in combination with insulin for those with insulin resistance due to obesity. It has been beneficial in some young people, so our guidance should be more flexible. In Type 2 diabetes, should we always use metformin from diagnosis or might there be some who benefit from lifestyle changes?	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (transition from paediatric to adult services in this case). This guideline emphasises that some aspects of diabetes care will change at transition. Moreover, the scope for the 2015 update did not

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					include pharmacological treatments other than metformin for children and young people with type 2 diabetes, and this is why insulin is not considered for type 2 diabetes in this guideline. The guideline development group's view is that metformin should be offered to children and young people with type 2 diabetes from diagnosis, but there are also recommendations about lifestyle advice (diet, physical activity and weight loss)
National Children and Young People's Diabetes Network	General	81 206	29 22	Add "without inducing fear of hypoglycaemia"	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (education according to age group in this case)
National Children and Young People's Diabetes Network	General	91		Sick day rules: reviewing these annually with patients seems a reasonable standard. Previously, there had been suggestions e.g. how much extra insulin to give and we think these basic principles should still be included.	Thank you for this comment in support of the guideline. The recommendations which mention sick-day rules also include adjustments to insulin regimens, which is broad enough to cover the issues highlighted in the comment
National Children and Young People's	General	99		Calculating Body Mass Index at each clinic visit? We do that when recording on our database, but unsure that is helpful information for every patient – we already see some insulin mismanagement as a form of eating disorder. Measuring and plotting height and weight at each clinic visit should be enough.	We agree that it is not necessary to measure BMI at every clinic visit for children and young people with type 1 diabetes and so the bullet about BMI

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Diabetes Network					measurement has been deleted from the corresponding recommendation. However, BMI is the most important measure of response to treatment in children and young people with type 2 diabetes and so the bullet about BMI measurement has been retained in the recommendation for that group
Royal College of Paediatrics and Child Health	General	171	6	No mention of harms of large fluctuations in blood glucose or of severe hypoglycaemia	The guideline development group did not include a specific recommendation about this based on their understanding and interpretation of the available evidence
British Psychological Society	General	240	5 10	The BPT criteria (Department of Health, 2012) stipulate that psychology should be "integral to the multi-disciplinary team" and that each patient should have an annual assessment by their MDT as to whether input to their care by a clinical psychologist is needed, and access to psychological support as appropriate. All children and young people with type 1 diabetes should have equal access to psychological assessment and support as stipulated by the DoH guidelines and the ISPAD guidelines. Some children and their families may decline or chose not to engage with psychology services; however, their needs should continue to be monitored by the wider MDT.	The guideline development group consider that the recommendations are complementary to the Best Practice Tariff and do not preclude an annual assessment to determine the need for psychological support. The linking evidence to recommendations section of the review has been amended to clearly state this
Abertawe Bro Morgannwg University NHS Trust (HQ)	NICE	General	General	5 glucose tests a day are suggested but not suitable times for these tests	Thank you for this comment. The guideline development group discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that should be recommended, but also the timing at which the tests should be performed. They concluded that at least 5 tests should be performed routinely, and emphasised in the revised

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					recommendations that it is often necessary to conduct more than 5 tests. They did not, however, wish to specify an upper limit for the number of tests, nor the exact timing for the minimum number of tests because to do so would remove some flexibility that is otherwise available to the child or young person and their family members or carers (as appropriate)
Abertawe Bro Morgannwg University NHS Trust (HQ)	NICE	General	General	HbA1c target of 48 mmol/mol (6.5%) or lower I have multiple concerns about this: 1. There is limited / no evidence to support this target instead of 7.5% 2. ISPAD 2014 guidelines specify a target of 58 mmol/mol (7.5%) or lower. If we adopt this draft guidance, the UK will be out of step with the global paediatric diabetes community 3. Although not mentioned in the text, some of the justification for setting a target of 6.5% mmol/mol is that evidence shows patients often achieve 0.5-1% higher than the set target. I have significant issues with "lying" to my patients and think this is an antiquated paternalistic approach. If the target is 7.5%, we should look at the factors that cause failure to achieve this rather than set 6.5% in the hope of achieving 7.5% 4. Whilst the guidance mentions individualised targets, as clinicians we know families who will see 6.6% as failure, even if we have agreed an individualised target of 7.5%. 5. A recent study demonstrated zero (0%) microvascular complications after 20y in patients with a mean HbA1c of 7.6%. I do not understand the justification for aiming for 6.5% 6. I am unconvinced that this is safe and will not lead to patient harm. 2 adult studies of type 2 diabetes showed increased CVS mortality in elderly patients aiming for very tight control.	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected

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				In younger people, I am concerned this change will lead to harm from severe or recurrent hypoglycaemia.	by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that

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					lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline
Abertawe Bro Morgannwg University NHS Trust (HQ)	NICE	General	general	All the above is personal opinion, not representing my organisation, but my own views	Thank you for this comment and explanation
Abertawe Bro Morgannwg University NHS Trust (HQ)	NICE	General	General	The overall tone and changes made are excellent and I am very supportive of almost all of the recommendations	Thank you for this comment in support of the guideline
Alder Hay Children's NHS Foundation Trust	NICE	General	General	Diabetes Team Dieticians - The lack of a complete review means that some areas of the updated guideline are out of sync with current clinical practice and international guidelines. This may create confusion and increase the amount of variability in practice nationally.	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline. It is recognised that future updates may need to be considered for all NICE guidelines, and NICE has a rolling programme of surveillance reviews to facilitate the prioritisation of areas for update

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Association of British Clinical Diabetologists	NICE	General	General	Within diabetes transition clinics (joint between paediatrics and adult services) adherence to the principles outlined in NHS Diabetes Transition document in 2013 (Ref 1) has led to adherence to treatment and care process measures, improved levels of HbA1c, reduced non attendances at clinic and emergency hospital admissions, and qualitative measures of self efficacy in reports from several services that have examined transition, in comparison to baseline, as well as from evidence from the national peer review of CYP services (Ref 2) . There is unlikely to be a randomised trial of different support models, and in reality little basis for such an approach. The NHS DM working group agreed that there was no merit in a -1 size fits all approach to transition and transfer. However a dedicated young adult clinic from the age of 19-21 or to 25-30 was considered necessary and is often not provided in many adult services. The key principle of transition of diabetes care being a process over time with supported joint input from paediatric and adult services rather than consultation on at most 1-2 occasions appears key to best prospect of handover. Recommendations and principles for best transition care of diabetes were produced by NHS Diabetes in 2013 and complement the generic recommendations using the traffic light 'Ready Steady Go 'system (Reference 3) that both encapsulate the principles of a continuum of care over time in the transition setting . Factors supporting best care through the work of the regional CYP diabetes networks include single integrated managed diabetes database information system , access to the full MDT in the transition service through use of the best practice tariff , effective in patient diabetes services to ensure care of transition cases admitted under adult services and flexible outreach clinical engagement using open non judgemental questions and patient focused priorities covered through consultations. Local initiatives that that been successful have been introduced in EN Herts. , Northumbria , Yeovil, Portsmouth, Newham , Nottingham , Southwark and Belfast	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (transition from paediatric to adult services in this case)

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				. Innovations include a linked transition service to University health services, and enhanced education of primary care teams, particularly around earlier diagnosis of diabetes. A non traditional model of care involving youth workers and preliminary data analysis from Newham where diabetes nurses utilising telehealth communication including Skype and text messaging has been piloted have shown better adherence to care planning, reduced emergency admissions and lower measures of HbA1c. Full resourced MDT team appears critical to implementation of best practice standards and a named nurse supporting both transition care and transfer of any individual patient. Local audits have shown that whilst transition services operate to offer good care with the BpT standards applied the major pressure point is after or at the time of transfer to adult services where audits have shown the fall off in accessing specialist care can be as high as 25-35%. There is anecdotal evidence that flexibility not rigidity in transfer to young adult services helps the process. Given the high prevalence of 19-25 yr old diabetes patients and the fact that many young patients present at this age without prior paediatric input the major challenge remains the care of this so called 'lost tribe'. The MDT supporting best practice tariff ceases at the age of 19 and psychology support as well as the staff patient ratio and available clinical slots ceases in the vast majority of services from the age of 19 onwards (Ref 4) . There has been a recent survey confirming a major challenge in the access to training even amongst specialist medical staff in transitional care of diabetes (Ref 5) Young adult care requires the same level of commitment form adult diabetes services (and the same resources) as those made available to the transition services. The semantics of this issue are important – transition often refers to the process of joint care – although there is significant variation in how joint services operate (transfer may be at age of 19-21 or beyond) the major challenge is in the	

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				care of those aged > 19 at transfer. Most ambulatory out patient services have a discharge policy and clinic services that are inflexible for adults aged over 19 and with out the outreach out of hospital-primary care settings that have been suggested to improve care and contact of young adults. All adult services should have at least 1 lead consultant and DSN to support transition and ensure continuity in a young adult service after transfer. References 1. Diabetes transition. Assessment of current best practice and development of a future work programme to improve transition processes for young people with diabetes. NHS Diabetes 2012 2. National Children and Young People's Diabetes Peer Review Programme. Measures for Children and Young People's Diabetes 2014 3. Ready Steady Go Documentation 2014. Accessed at www.uhs.nhs.uk/readysteadygo 4. Care of adolescents and young adults with diabetes .-much more than transitional care – a personal view . Winocour PH . Clinical Medicine 2014 ;14:3:1-5 . 5. Training Needs in Adolescent & Young Adult Health and Transition in Paediatric and Adult Higher Specialist Trainees in Endocrinology & Diabetes in the UK. RJ Wright, S Chapman, K Cheer, REJ Besser, CA Steele, S Sankar, P Dimitri, P Winocour, H Gleeson , on behalf of the Young Adult and Adolescent Special Interest Group . Submitted for publication 2015	
British Psychological Society	NICE	General	General	Quality of life is at least as important an outcome of diabetes care as HBA1c and yet is currently poorly considered. The first mention of measuring quality of life appeared on page 59 of the NICE draft guidance. If quality of life is to be	Thank you for this comment. The guideline development group agree that the consideration of quality of life is an

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				preserved in spite of demanding treatment regimens, then it needs to be measured at least annually and when changes are made to treatment regimens. An individualised diabetes-specific quality of life measure for teenagers has been designed, developed and used in the UK (McMillan, C.V. et al 2004) References: McMillan, C.V., Honeyford, R.J., Datta, J., Madge, N.J.H., Bradley, C., (2004) The development of a new measure of quality of life for young people with diabetes mellitus: the ADDQoL-Teen. Health and Quality of Life Outcomes, 2, 61	important outcome for patients, and have reflected this in the systematic review protocols (Appendix E). The effectiveness of regularly and systematically monitoring quality of life was not a focus of the evidence review and therefore cannot be considered for recommendation
British Psychological Society	NICE	General	General	The terms 'exercise' and 'physical activity' are used interchangeably. Exercise is typically planned and structured, such as a PE lesson, or swimming lengths of a swimming pool, whereas physical activity is part of daily life and refers to active events that might be spontaneous or just part of general living such as running to the shop, walking to school or doing some housework. Physical activity has been shown to be beneficial for children with type 1 diabetes (Quirk et al, 2014). Healthcare professionals are in a unique position to promote active lifestyles in children with Type 1 Diabetes, and educate children and families on the guidelines for physical activity, yet research suggests that there is limited physical activity encouragement in current care (MacMillan et al., 2014). Concurrent with the promotion of physical activity should be recommendations to reduce sedentary behaviour (e.g., sitting watching TV, on the computer, and playing video games). The current guidance gives very little attention to sedentary behaviour, which is surprising given the current attention to it being a major public health concern. Discussions around physical activity and sedentary behaviour (rather than structured exercise and sports) at routine clinic appointments should be encouraged. Healthcare professionals could be advised to utilise behaviour change techniques during clinic appointments, such as those from Motivational	Exercise for children and young people with type 1 diabetes is excluded from the 2015 update and so the terminology there has not been changed. In the new section on type 2 diabetes, the broader term physical activity is used and the NICE guidance on physical activity for children and young people has been added to the list of related NICE guidance

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				Interviewing, to uncover potential barriers to an active lifestyle and develop patient-centred action plans and goals. Whilst the current guidance does recommend a programme of behavioural intervention therapy (section 1.2.101) for children whom there are concerns about psychological wellbeing, it might be effective to utilise brief versions of these techniques as part of routine care. References: MacMillan, F., Kirk, A., Mutrie, N., Moola, F. and Robertson, K. (2014) Building physical activity and sedentary behavior support into care for youth with type 1 diabetes: patient, parent and diabetes professional perceptions. Pediatric Diabetes doi: 10.1111/pedi.12247. Quirk, H, Blake, H., Tennyson, R., Randell, T. and Glazebrook, C., (2014). Physical activity interventions in children and young people with Type 1 Diabetes Mellitus: A systematic review with meta-analysis Diabetic Medicine. 31(10), 1163-73 HB/HQ	
British Psychological Society	NICE	General	general	Clinically, the term 'blood glucose tests' sets up an expectation where the child/young person feels that they have 'failed' the 'test' if their numbers are out of the target range, triggering feelings of anxiety/ frustration/ guilt/ distress. Young people and families report clinically that changing the language is helpful (without reference to 'passing' or 'failing' 'tests') to 'checking blood glucose' or 'blood glucose monitoring'. We recommend this subtle but important change of language be promoted through this document to reach all health professionals. We would like to refer the GDG to the Diabetes Australia Position Statement: 'A new language for diabetes: Improving communications with and about people with diabetes' References:	The guideline development group felt that in the medical context the term test is widely understood to mean an investigation performed by a doctor. It is also simpler than the use of terms such as monitoring. Also it would be difficult to rephrase the many uses of test, such as testing strips (for glucose), which is widely understood by children and young people with type 1 diabetes and their families and carers (as appropriate). We have, therefore, not altered the terminology in the recommendations

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				Speight, J., Conn, J.J., Dunning, T., Skinner, T.C., (2012) Diabetes Australia position statement: A new language for diabetes: improving communications with and about people with diabetes. Diabetes Research and Clinical Practice, 97, 425-431.	
British Psychological Society	NICE	General	General	Consideration should be given within the document to supporting a CYP's choices within school surrounding their management in order to promote their independence and confidence with diabetes and to reduce stigma associated with diabetes care. This should be done in consultation with the young person and their parents and supported by the diabetes team, documented in their school care plan and reviewed regularly. Failure to do so can result in young people's diabetes management and quality of life being significantly compromised due to diabetes-related stigma and feelings of difference.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (school-based diabetes management in this case)
HQT Diagnostics	NICE FULL	General	General	The primary objective of treatment or prevention for Diabetes should be to reduce the amount of Insulin that the body produces from carbohydrates and certain proteins. Refer patient to Dietitian or Nutritional Therapist for advice about Diet & Lifestyle (www.bda.uk.com or www.bant.org.uk) More at: http://www.ncbi.nlm.nih.gov/pubmed/?term=phinney+SD http://www.ncl.ac.uk/magres/research/diabetes/documents/Diabetes-Reversaloftype2studyJune14.pdf https://www.youtube.com/watch?v=FcLoaVNQ3rc https://www.youtube.com/watch?v=mAwgdX5VxGc http://www.biznews.com/category/lchf-health-summit/	Thank you for this comment. Level 3 carbohydrate counting is the use of carbohydrate counting with the adjustment of insulin dosage according to carbohydrate content of meals and blood glucose levels, using an insulin:carbohydrate ratio. This has been clarified in a footnote to the recommendation. There is evidence of the effectiveness of using level 3 carbohydrate counting and its use is in keeping with common practice in the UK, which the guideline development group felt was justification for recommending it from diagnosis

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National Children and Young People's Diabetes Network	NICE	General	General	In the introduction the authors say that " A variety of genetic conditions (such as maturity-onset diabetes in the young) and other conditions (such as cystic fibrosis-related diabetes) may also lead to diabetes in children and young people, but the care of these diverse conditions is beyond the scope of this guideline" however in the previous paragraph they outline that for Type 2 diabetes "These differences in management and complications need guidance specific to type 2 diabetes, which is included here for the first time" We accept that the committee needs to limit their scope and cannot include every rare subtype but would ask that they consider including the commonest subtypes where there is very strong evidence that a diagnosis will alter management as much as it does in Type 2 diabetes. The key subtypes would be glucokinase MODY – the commonest cause of incidental hyperglycaemia in the paediatric age range, HNF1A the commonest from of symptomatic MODY which have a clear sensitivity to low dose sulphonylureas (hence a difference in treatment from Type 1 and Type 2) and neonatal diabetes which has dramatically different treatment and can be diagnosed solely on the age of diagnosis) There is insufficient information included in the guidelines about monogenic diabetes. A good summary is provided in the ISPAD guidelines on monogenic diabetes which is a good source of evidence. There is published evidence that in the UK in the paediatric age range monogenic diabetes is as common as Type 2 diabetes (Ehtisham S, Hattersley AT, Dunger DB, Barrett TG; British Society for Paediatric Endocrinology and Diabetes Clinical Trials Group. First UK survey of paediatric type 2 diabetes and MODY. Arch Dis Child. 2004 Jun;89(6):526-9. PMID: 15155395) This report is over 10 years old and now there is evidence that both Type 2 and monogenic diabetes are much more recognized. In the UK there are over 353 cases of molecularly diagnosed MODY or neonatal diabetes who are still under 18 years and a further 623 cases that were diagnosed in the pediatric age range but are now older (source Prof Ellard head of diagnostic testing for Monogenic diabetes in the UK, Royal Devon and Exeter NHS FT). In the USA the	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the

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				minimum prevalence of genetically proven MODY diabetes was 1.2% (Pihoker C, et al Prevalence, characteristics and clinical diagnosis of maturity onset diabetes of the young due to mutations in HNF1A, HNF4A, and glucokinase: results from the SEARCH for Diabetes in Youth. J Clin Endocrinol Metab. 2013 Oct;98(10):4055-62. PubMed PMID: 23771925;). In the UK the UNITED study http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=9408 has unpublished information from 7 UK paediatric clinics of a minimum prevalence of 1.8% in UK paediatric clinics. The importance is that the diagnosis is often not made correctly (only 8% were correctly diagnosed in Pihoker et al) and like Type 2 diabetes they need very different treatment from Type 1 diabetes.	young (MODY) and neonatal diabetes. The term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY. However, the limitations of the scope for the 2015 update prevent the guideline development group from providing more detail about the diagnosis or management of forms of diabetes other than type 1 or type 2
National Children and Young People's Diabetes Network	NICE	General	General	This guidance document should include information on neonatal diabetes. It is a new subtype to be recognized since the 2004 guidelines. At present there is no information on neonatal diabetes. This subtype is important as 1) there are over 200 cases diagnosed in the UK (information from Prof Ellard, Exeter with 90 having potassium channel mutations) 2) these patients can be recognized clinically and the correct diagnosis can great alter treatment leading to a massive change in outcome and quality of life 3) they present with DKA so can be easily misdiagnosed as Type 1 if the significance of the age of diagnosis is not appreciated. The key thing is that a diagnosis less than 6 months is neonatal diabetes and not type 1 diabetes. (Edgehill et Diabetes 55:1895–1898, 2006). This is very important as 50% of these patients will have a potassium channel mutation and despite being insulin dependent 90% can get greatly improved control without hypoglycaemia on a sulphonylurea (Pearson ER et al N Engl J Med 2006;355:467-77.). A recent review is in the ISPAD guidelines of monogenic diabetes.	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes,

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					monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY. However, the limitations of the scope for the 2015 update prevent the guideline development group from providing more detail about the diagnosis or management of forms of diabetes other than type 1 or type 2
Royal College of Paediatrics and Child Health	NICE	General	General	In the introduction the authors say that " A variety of genetic conditions (such as maturity-onset diabetes in the young) and other conditions (such as cystic fibrosis-related diabetes) may also lead to diabetes in children and young people, but the care of these diverse conditions is beyond the scope of this guideline" however in the previous paragraph they outline that for Type 2 diabetes "These differences in management and complications need guidance specific to type 2 diabetes, which is included here for the first time" We accept that the committee needs to limit their scope and cannot include every	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was

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				rare subtype but would ask that they consider including the commonest subtypes where there is very strong evidence that a diagnosis will alter management as much as it does in Type 2 diabetes. The key subtypes would be glucokinase MODY – the commonest cause of incidental hyperglycaemia in the paediatric age range, HNF1A the commonest from of symptomatic MODY which have a clear sensitivity to low dose sulphonylureas (hence a difference in treatment from Type 1 and Type 2) and neonatal diabetes which has dramatically different treatment and can be diagnosed solely on the age of diagnosis) There is insufficient information included in the guidelines about monogenic diabetes. A good summary is provided in the ISPAD guidelines on monogenic diabetes which is a good source of evidence. There is published evidence that in the UK in the paediatric age range monogenic diabetes is as common as Type 2 diabetes (Ehtisham S, Hattersley AT, Dunger DB, Barrett TG; British Society for Paediatric Endocrinology and Diabetes Clinical Trials Group. First UK survey of paediatric type 2 diabetes and MODY. Arch Dis Child. 2004 Jun; 89(6):526-9. PMID: 15155395) This report is over 10 years old and now there is evidence that both Type 2 and monogenic diabetes are much more recognized. In the UK there are over 353 cases of molecularly diagnosed MODY or neonatal diabetes who are still under 18 years and a further 623 cases that were diagnosed in the pediatric age range but are now older (source Prof Ellard head of diagnostic testing for Monogenic diabetes in the UK, Royal Devon and Exeter NHS FT). In the USA the minimum prevalence of genetically proven MODY diabetes was 1.2% (Pihoker C, et al Prevalence, characteristics and clinical diagnosis of maturity onset diabetes of the young due to mutations in HNF1A, HNF4A, and glucokinase: results from the SEARCH for Diabetes in Youth. J Clin Endocrinol Metab. 2013 Oct;98(10):4055-62. PubMed PMID: 23771925;). In the UK the UNITED study http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=9408 has unpublished information from 7 UK paediatric clinics of a minimum prevalence of 1.8% in UK paediatric clinics. The importance is that the diagnosis is often not made correctly (only 8% were	concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY. However, the limitations of the scope for the 2015 update prevent the guideline development group from providing more detail about the diagnosis or management of forms of diabetes other

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				correctly diagnosed in Pihoker et al) and like Type 2 diabetes they need very different treatment from Type 1 diabetes.	than type 1 or type 2
Royal College of Nursing	NICE	General	1.2.35	Add "… eating foods with 'naturally' low Glycaemic index…	Thank you for this comment. The evidence supporting this recommendation did not differentiate between 'natural' or otherwise occurring low glycaemic index foods, therefore this has not been added to the recommendation
Royal College of Nursing	NICE	21/22	1.2.37	Within this recommendation we feel the words "Repeat the offer" is vague; is this the original offer for level 3 carbohydrate- counting training or regular updates? If so at what frequency? Not everyone would automatically what level 3 education is.	Thank you for this comment. Repeating the offer of level 3 carbohydrate counting is a pragmatic recommendation to ensure that a child or young person who does not take up the approach at diagnosis has opportunities to consider doing so later. The guideline development group did not identify any evidence to specify the timing and frequency of repeating the offer and so this is not specified in the recommendation Level 3 carbohydrate counting is the use of carbohydrate counting with the adjustment of insulin dosage according to carbohydrate content of meals and blood glucose levels, using an insulin:carbohydrate ratio. This has been clarified in a footnote to the recommendation
Association of Children's	NICE	1.2.108	34	We believe that screening for coeliac disease should occur at diagnosis and at intervals after diagnosis? Interval to be agreed by experts……? Annually or	Thank you for submitting comments in response to the stakeholder consultation.

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Diabetes Clinicians				every 3 years	Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (coeliac disease in this case). However the guideline development group recognise that NICE has produced separate guidance and so the recommendations in this guideline have been amended to cross-refer to the NICE coeliac disease guideline for guidance on monitoring for coeliac disease in children and young people with type 1 diabetes
Association of Children's Diabetes Clinicians	NICE	1.4.25	52	Committee also felt that they did not agree that oral fluids would not be given until ketosis is markedly improved below 1 mmol as this would prolong admission. Suggested that oral fluids can be given if acidosis improves and there are significant improvements in clinical symptoms	The recommendation referred to in the comment has been changed to state that oral fluids should not be given to a child or young person who is receiving intravenous fluids for diabetic ketoacidosis unless there is no nausea or vomiting and ketosis is resolving. These changes avoid the specification of a threshold for ketosis below which oral fluids may be given, and they clarify the circumstances in which oral fluids may be given (in terms of there being no nausea or vomiting)
Association of Children's Diabetes Clinicians	NICE	1.1.7	14	Members concerned about guidance of not measuring diabetes specific antibodies at diagnosis as we now obese patients where this may be useful in coming to final diabetes	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis (specifically evidence for distinguishing between type 1 and type

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					2 diabetes) and concluded that C-peptide and diabetes-specific autoantibody titres should not be measured at initial presentation to distinguish type 1 diabetes from type 2 diabetes. However, the revised recommendations emphasise that measuring C-peptide after initial presentation should be considered if there is difficulty distinguishing type 1 diabetes from other types of diabetes and that genetic testing should be performed if atypical disease behaviour, clinical characteristics or family history suggest monogenic diabetes. The 'do not use' form of recommendation reflects the evidence base
Association of Children's Diabetes Clinicians	NICE	1.4.46	55	Concern about guidance to delay change from IV insulin to SC insulin only when ketones less than 0.6 mmol…….again this may delay discharge	Two recommendations have been revised in response to the comment. The first now states that healthcare professionals should think about stopping intravenous fluid therapy for diabetic ketoacidosis in a child or young person if ketosis is resolving, they are alert, and they can take oral fluids without nausea or vomiting. The second recommends not changing from intravenous insulin to subcutaneous insulin until ketosis is resolving and the child or young person with diabetic ketoacidosis is alert and can take oral fluids without nausea or vomiting. These changes

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					acknowledge that setting a limit (even as an example) for defining ketosis as being resolved may delay restarting oral fluids and/or insulin and it may be too restrictive (the revised recommendations allow clinical judgement and will not result in the child or young person being kept in hospital for longer than necessary)
British Psychological Society	NICE	1.2.68		The guidelines have changed to recommend an HbA1c target of 48 mmol/mol (6.5%) or lower and no indication is given anywhere in the NICE draft that there is a safe lower limit (Note that on p85 of the NICE draft it says that the old section 1.26,4 which mentioned the risk of hypoglycaemia with low HbA1c has now been cut). The guidelines currently suggest that ANY level lower than 48 is ideal or even that lower levels would be even better. There is a real risk of death from hypoglycaemia if HbA1c is too low. In DAFNE the one death from nocturnal hypoglycaemia was in the patient who had the lowest HbA1c obtained – 5.9. Other patients were advised to keep their HbA1c above 6 and there were no further fatalities.	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the

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					recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the

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					previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline The reference in the comment to hypoglycaemia is covered by the individualised targets (with safely achievable for the individual being a key consideration) and recommendations elsewhere in the guideline. The guideline development group was also of the view that modern insulin regimens reduce the risk of hypoglycaemia compared to those in place when, for example, the Diabetes Control and Complications Trial was undertaken. This is also documented in the evidence to recommendations section in the full guideline
Association of Children's Diabetes Clinicians	NICE	1.2.68	41	- concerns were received by members that a target set below 6.5% was too low or may be demotivating. Committee feels that this is an aspirational target and if this was approve, then it should go in line with NPDA statistics of comparisons	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or

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					carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c

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					targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline
Association of British Clinical Diabetologists	NICE	3	3	The clear intention in this summarised introduction of achieving near normoglycaemia and an HbA1c in the normal range sets an unrealistic starting point that will be alien to the vast majority managing the care of children and young people up till the age of 19. The extended document of course makes the vital need (as in all diabetes care) for individualisation of care and in turn HbA1c targets and in the interests of best care and credibility for the rest of the document it would be sensible to add this important statement at this stage of the document	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider

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					the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development

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					group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline
National Children and Young People's Diabetes Network	NICE	3	3	The clear intention in this summarised intro of achieving near normoglycaemia and an HbA1c in the normal range sets an unrealistic starting point that will be alien to the vast majority managing the care of children and young people up till the age of 19. The extended document of course makes the vital need (as in all diabetes care) for individualisation of care and in turn HbA1c targets and in the interests of best care and credibility for the rest of the document it would be sensible to add this important statement at this stage of the document	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to

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					fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c

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					level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline
The Royal College of Pathologists	NICE	3	28	'glycosylated haemoglobin' should more correctly read 'glycated haemoglobin'	Thank you for this comment. The suggested change has been made
Abertawe Bro Morgannwg University NHS Trust (HQ)	NICE	10	General	"Level 3 Carbohydrate counting training" is mentioned but nowhere in the document does it specify what this is	Thank you for this comment. Level 3 carbohydrate counting is the use of carbohydrate counting with the adjustment of insulin dosage according to carbohydrate content of meals and blood glucose levels, using an insulin:carbohydrate ratio. This has been clarified in a footnote to the

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					recommendation
Association of British Clinical Diabetologists	NICE	10	General	Mentioned in more detail in full version and later in the NICE document, but the implication here is MDI or CSII are the only options from diagnosis . Premixed bd-tds insulin or split pm insulin (premix , quick acting and bed time basal) should also be stated options. Intensification of control and complexity of regime may naturally follow after loss of the honeymoon phase , more independent self management or the impact of puberty.	Thank you for this comment. The guideline development group did not feel that use of insulin regimens other than multiple daily injections (or insulin pump therapy if a multiple daily insulin injection regimen is not appropriate) was appropriate at diagnosis hence the strong recommendation to offer multiple daily injection regimens from diagnosis. The later recommendation referring to mixed insulin is included to cover those children and young people who might be using such a regimen although these are not recommended strongly
Association of British Clinical Diabetologists	NICE	10	General	'routinely perform at least 5 times a day' – this and the HbA1c are a counsel of perfection , based on a research study of a self selected highly motivated cohort with considerable sustained specialist support . Apart from the gulf between the research protocol and best clinical care, the recommendation is impractical at best and if the intention is to generalise this there would be serious concern this would demotivate this challenging group of young people. Individualised frequency of testing is deliverable.	Thank you for this comment. The guideline development group discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that should be recommended, but also the timing at which the tests should be performed. The evidence reviewed for the guideline demonstrated that glycaemic control improves with the number of capillary tests performed up to 5 five tests per day. The guideline development group concluded, therefore, that at least 5 tests should be performed routinely, and emphasised in the revised recommendations that it is often necessary

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					to conduct more than 5 tests. They did not, however, wish to specify an upper limit for the number of tests, nor the exact timing for the minimum number of tests because to do so would remove some flexibility that is otherwise available to the child or young person and their family members or carers (as appropriate), and this is supported by the individualised testing suggested in the comment
British Psychological Society	NICE	10	General	The Society recommends offering children and young people with type 1 and type 2 diabetes and their family members or carers (as appropriate) timely and ongoing access to psychological services as they may experience mental health difficulties (such as anxiety, depression, behavioural and conduct disorders and family conflict) OR psychosocial difficulties that can impact on diabetes self-management and well-being. (changes italicised) References: Speight, J., Conn, J.J., Dunning, T., Skinner, T.C., (2012) Diabetes Australia position statement: A new language for diabetes: improving communications with and about people with diabetes. Diabetes Research and Clinical Practice, 97, 425-431.	Thank you for this suggestion. The individual recommendations have been amended where appropriate following the stakeholder consultation, however, the comment seems to refer to the guideline development group's selection of key priorities for implementation and this has not been changed
National Children and Young People's Diabetes Network	NICE	10	General	Mentioned in more detail in full version and later in the NICE document but implication here is MDI or CSII as the only options from diagnosis . Premixed bd-tds insulin or split pm insulin (premix , quick acting and bed time basal) should also be stated options not least as the principle of intensification of control and complexity of regime may naturally follow loss of honeymoon phase , more independent self management or the impact of puberty.	Thank you for this comment. The guideline development group did not feel that use of insulin regimens other than multiple daily injections (or insulin pump therapy if a multiple daily insulin injection regimen is not appropriate) was appropriate at diagnosis hence the strong

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					recommendation to offer multiple daily injection regimens from diagnosis. The later recommendation referring to mixed insulin is included to cover those children and young people who might be using such a regimen although these are not recommended strongly
Abbott Diabetes Care	NICE	10	1.2.59	We agree that regular blood glucose testing is important and that routinely performing 5 capillary tests per day could support certain treatment regimens. We also suggest that differing and potentially increased levels of blood glucose testing appropriate to the age and treatment regimen agreed with the child/parent/ adolescent are embraced within the guidance supporting transition to adult services. This would also bring alignment to the current draft NICE guidelines for type 1 diabetes 2015 which supports further testing where desired/warranted by the person with diabetes.	Thank you for this comment. The guideline development group discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that should be recommended, but also the timing at which the tests should be performed. The evidence reviewed for the guideline demonstrated that glycaemic control improves with the number of capillary tests performed up to 5 five tests per day. The guideline development group concluded, therefore, that at least 5 tests should be performed routinely, and emphasised in the revised recommendations that it is often necessary to conduct more than 5 tests. They did not, however, wish to specify an upper limit for the number of tests, nor the exact timing for the minimum number of tests because to do so would remove some flexibility that is otherwise available to the child or young person and their family members or carers (as appropriate), which supports the

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					individualised approach to testing suggested in the comment, and will promote continuity of approach during transition to adult services
Juvenile Diabetes Research Foundation	NICE	10 19	9	Similarly, we strongly support making it a priority for children and young people to be offered continuous glucose monitoring for frequent severe hypoglycaemia and impaired awareness of hypoglycaemia. We would also recommend that the GDG consider the benefits of low glucose suspend systems to reduce the risk of nocturnal hypoglycaemia and diabetic coma, particularly in light of the forthcoming NICE Diagnostic Assessment Programme for the Medtronic MiniMed Paradigm Veo (due October 2015).	Thank you for this comment in support of the guideline. The guideline development group identified very little evidence on which to base recommendations about continuous glucose monitoring in children and young people with type 1 diabetes. Their consensus view was that 'real-time' continuous glucose monitoring should be offered because it allows immediate recognition of changes in blood glucose concentrations in relation to treatments and activities and this in allows for more effective treatment choices to be made. The group felt that the previous strong recommendation to offer continuous glucose monitoring to children and young people with recurrent hypo- or hyperglycaemia remained justified. The group also felt there was sufficient reason to justify the consideration of continuous glucose monitoring for some children and young people in whom tight glycaemic control might be of particular concern. However, the group did not identify any evidence to support a specific recommendation to offer devices

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					incorporating glucose suspend systems
Medtronic	NICE	10	10	We welcome the recommendation on insulin pump therapy as a key priority for implementation within the guideline. Insulin pump therapy has been approved as a clinical and cost-effective technology, and although uptake of this therapy in children is around 19% - approaching the target levels set out in the NICE Technology Appraisal 151 - these levels are considerably lower than those in other comparable countries across Europe (UK Insulin Pump Audit, 2013).	Thank you for this comment. The guideline development group did not feel that use of insulin regimens other than multiple daily injections (or insulin pump therapy if a multiple daily insulin injection regimen is not appropriate) was appropriate at diagnosis hence the strong recommendation to offer multiple daily injection regimens from diagnosis. Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (insulin pump therapy in this case). Moreover, the indications for insulin pump therapy are determined by the NICE Technology Appraisal (TA) guidance
National Children and Young People's Diabetes Network	NICE	10	10	Consider including alternative insulin regimes e.g. Twice daily fixed, mixed insulin if indicated by patient need.	Thank you for this comment. The guideline development group did not feel that use of insulin regimens other than multiple daily injections (or insulin pump therapy if a multiple daily insulin injection regimen is not appropriate) was appropriate at diagnosis hence the strong recommendation to offer multiple daily injection regimens from diagnosis. The later recommendation referring to mixed insulin is included to cover those children

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					and young people who might be using such a regimen although these are not recommended strongly
National Children and Young People's Diabetes Network	NICE	10	18	Consider defining 'Level 3' of carbohydrate counting or reference definition	Thank you for this comment. Level 3 carbohydrate counting is the use of carbohydrate counting with the adjustment of insulin dosage according to carbohydrate content of meals and blood glucose levels, using an insulin:carbohydrate ratio. This has been clarified in a footnote to the recommendation
Royal College of Paediatrics and Child Health	NICE	10	18	Consider defining 'Level 3' of carbohydrate counting or reference definition	Thank you for this comment. Level 3 carbohydrate counting is the use of carbohydrate counting with the adjustment of insulin dosage according to carbohydrate content of meals and blood glucose levels, using an insulin:carbohydrate ratio. This has been clarified in a footnote to the recommendation
National Children and Young People's Diabetes Network	NICE	10	27	Team would recommend 'At least 4 tests' but wonder why the number 5 had been arrived at- when would the 5th be placed in the day?	Thank you for this comment. The guideline development group discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that should be recommended, but also the timing at which the tests should be performed. The evidence reviewed for the guideline demonstrated that glycaemic control improves with the number of

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					capillary tests performed up to 5 five tests per day. The guideline development group concluded, therefore, that at least 5 tests should be performed routinely, and emphasised in the revised recommendations that it is often necessary to conduct more than 5 tests. They did not, however, wish to specify an upper limit for the number of tests, nor the exact timing for the minimum number of tests because to do so would remove some flexibility that is otherwise available to the child or young person and their family members or carers (as appropriate)
Juvenile Diabetes Research Foundation	NICE	10 18	31	JDRF strongly supports improving access to diabetes technologies for children and young people and their families. We know that NICE technology appraisal 151 is frequently under-implemented so ensuring that children and young people have access to an insulin pump if it would be of use is vital.	Thank you for this comment. The guideline development group did not feel that use of insulin regimens other than multiple daily injections (or insulin pump therapy if a multiple daily insulin injection regimen is not appropriate) was appropriate at diagnosis hence the strong recommendation to offer multiple daily injection regimens from diagnosis. Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (insulin pump therapy in this case). Moreover, the indications for insulin pump therapy are

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					determined by the NICE Technology Appraisal (TA) guidance
Association of British Clinical Diabetologists	NICE	11	General	'48 mmol/mol or lower' – similarly to the BG monitoring frequency and BG targets are derived from DCCT – not replicable in NHS clinical practice . Individualised Hba1c targets stated in all other NICE DM guidance should be applicable to children and young people with 58 mmol/mol as in last CYP guidance still retained as legitimate target , not least as this was the mean achieved in DCCT so by definition even in that trial setting 50% could not attain that level of control .	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48

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					mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations

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					section in the full guideline
British Psychological Society	NICE	11	General	In the guidance, healthcare professionals are advised to encourage children and their families to monitor blood glucose before, during and after exercise, which is acceptable if the exercise is planned and structured, and resources could be provided to facilitate this such as a log sheet. However, different advice may be needed when children, quite typically, engage in spontaneous or sporadic activity. The current guidance gives no recommendations around spontaneous or unplanned physical activity, which research has demonstrated that parents perceive difficulty in managing (Quirk et al., 2014a). Further, recent qualitative research exploring the perceptions of parents has shown that parents of children with type 1 diabetes have concerns about exercise-induced hypoglycaemia and delayed onset hypoglycaemia after exercise (Fereday et al., 2009; MacMillan et al., 2014; Quirk et al., 2014a). In the sections covering exercise, the guidance gives very little attention to the potential psychological effect of physical activity and concerns about its side-effects. Little research has explored the potential psychological effect of regular physical activity for this population (Quirk et al., 2014b). Healthcare professionals could be advised to explore and elicit parental or family concerns around physical activity and/or hypoglycaemia, as fear of hypoglycaemia in children and their parents has been identified as a barrier to physical activity (Johnson et al., 2013). References: Fereday, J., MacDougall, C., Spizzo, M., Darbyshire, P. and Schiller, W. (2009) "There's nothing I can't do - I just put my mind to anything and I can do it": a qualitative analysis of how children with chronic disease and their parents account for and manage physical activity. BMC Pediatrics 9: 1(1). Johnson, S. R., Cooper, M. N., Davis, E. A. and Jones, T. W. (2013)	Much of this comment relates to management of type 1 diabetes in children and young people who are undertaking exercise or physical activity. Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (exercise in this case) The guideline development group have, however, discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that should be recommended, but also the timing at which the tests should be performed. They concluded that at least 5 tests should be performed routinely, and emphasised in the revised recommendations that it is often necessary to conduct more than 5 tests. They did not wish to specify an upper limit for the number of tests, nor the exact timing for the minimum number of tests because to do so would remove some flexibility that is otherwise available to the child or young person and their family members or carers (as appropriate) The recommendations have been revised

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				Hypoglycaemia, fear of hypoglycaemia and quality of life in children with Type 1 diabetes and their parents. Diabetic Medicine 30(9): 1126-1131. MacMillan, F., Kirk, A., Mutrie, N., Moola, F. and Robertson, K. (2014) Building physical activity and sedentary behavior support into care for youth with type 1 diabetes: patient, parent and diabetes professional perceptions. Pediatric Diabetes doi: 10.1111/pedi.12247. Quirk, H., Blake, H., Dee, B. and Glazebrook, C. (2014a) "You can't just jump on a bike and go": a qualitative study exploring parents' perceptions of physical activity in children with type 1 diabetes. BMC Pediatrics 14(1), 313. Quirk, H., Blake, H., Tennyson, R., Randell, T. Glazebrook, C. (2014b) Physical activity interventions in children and young people with Type 1 diabetes mellitus: a systematic review with meta-analysis. Diabetic Medicine 31(10): 1163-1173. HB/HQ	to emphasise the need to have enough test strips available to meet the child or young person's needs, and this will support more frequent testing during periods of physical activity which is also reflected in the revised recommendations
Dexcom	NICE	11	general	Real time CGM (unblinded) should be presented as a therapy tool option for children that experience hypoglycaemia unawareness, nocturnal hypoglycaemia, or sports programs.	The guideline development group identified very little evidence on which to base recommendations about continuous glucose monitoring in children and young people with type 1 diabetes. Their consensus view was that 'real-time' continuous glucose monitoring should be offered because it allows immediate recognition of changes in blood glucose concentrations in relation to treatments and activities and this allows for more effective treatment choices to be made. The group felt that the previous strong recommendation to offer continuous

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					glucose monitoring to children and young people with recurrent hypo- or hyperglycaemia remained justified. The group also felt there was sufficient reason to justify the consideration of continuous glucose monitoring for some children and young people in whom tight glycaemic control might be of particular concern. However, the group did not identify other factors such as nocturnal hypoglycaemia as specific indications for offering or considering continuous glucose monitoring (although the reference to devices with alarms would cover their use in the case of nocturnal hypoglycaemia)
National Children and Young People's Diabetes Network	NICE	11	General	'48 mmol/mol or lower' – similarly to the BG monitoring frequency and BG targets are derived from DCCT – not replicable in NHS clinical practice . Individualised Hba1c targets stated in all other NICE DM guidance should be applicable to children and young people with 58 mmol/mol as in last CYP guidance still retained as legitimate target , not least as this was the mean achieved in DCCT so by definition even in that trial setting 50% could not attain that level of control .	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is

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					achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that

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					the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline
Medtronic	NICE	11	1	Again we welcome the positive inclusion of continuous glucose monitoring (CGM) as a key priority for implementation in certain patient groups.	Thank you for this comment in support of the guideline
National Children and Young People's Diabetes Network	NICE	11	1	Unsure as to how the number '48' has been arrived at. Is this based on particular evidence, is this in the hope that setting a strict guideline will 'shift' patient behaviour towards better control? Wonder if it might be better to refer to 'as close to normal/non-diabetic' range rather than suggest 1 particular number.	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48

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					mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations.

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					Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline
Association of British Clinical Diabetologists	NICE	12	General	No explicit recommendations re treatment but stated that 'early treatment will improve outcome' – presumably ACE inhibitor therapy. I am not aware there is such outcome data yet in children and young people but there is clearly evidence of reversability of microalbuminuria in type 1 diabetes in the younger age cohort which is not mentioned in the document .	Thank you for submitting comments in response to the stakeholder consultation. Please note that the scope of this guideline covers only the detection of long-term complications of diabetes and not their subsequent management. The guideline development group view is, however, that appropriate management of such complications will be beneficial Evidence for the natural history, including potential reversibility of microalbuminuria, was not evaluated by the guideline development group

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Diabetes UK	NICE	13	1.1.1	We recommend the addition of excessive tiredness.	Thank you for this comment. The recommendation is not strictly included in the scope of the 2015 update, but excessive tiredness is well recognised as being associated with diabetes, and as the corresponding change has been made in the section about recognition of diabetic ketoacidosis (which is covered by the 2015 update) the requested change has been made
National Children and Young People's Diabetes Network	NICE	13	1.1.2	Refer children and young people with suspected type 1 diabetes immediately (on the same day) to a multidisciplinary paediatric diabetes team with the competencies needed to confirm diagnosis and to provide immediate care. [2004, amended 2015] This confuses the need for same day referral by GP to acute paediatric services with the BPT measure of ensuring discussion with a senior member of the paed diabetes team within 24hrs of presentation & being seen by a senior member of the specialist paed diabetes team on the next working day.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (referral to the diabetes team at diagnosis in this case)
Association of British Clinical Diabetologists	NICE	14	General	MODY – remarkable no mention here of family history of DM in young adulthood as necessary basis to consider this possible diagnosis	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes

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					should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The revised recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY. Additionally the recommendations have been revised to include family history of diabetes. However, the limitations of the scope for the 2015 update prevent the guideline development group from providing more detail about the diagnosis or management

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					of forms of diabetes other than type 1 or type 2
National Children and Young People's Diabetes Network	NICE	14	1.17	We would strongly recommend that the measurement of antibodies is removed from this recommendation, There is very clear evidence that autoantibodies can differentiate at diagnosis from MODY with a difference in prevalence of 80% v 1% McDonald T et al Islet autoantibodies can discriminate maturity-onset diabetes of the young (MODY) from Type 1 diabetes. Diabet Med. 2011Sep;28(9):1028-33. PMID: 21395678 In addition in the USA screening patients who were antibody negative at diagnosis identified MODY Pihoker C, et al Prevalence, characteristics and clinical diagnosis of maturity onset diabetes of the young due to mutations in HNF1A, HNF4A, and glucokinase: results from the SEARCH for Diabetes in Youth. J Clin Endocrinol Metab. 2013 Oct;98(10):4055-62. PubMed PMID: 23771925). The data reviewed to support this statement has not included IA2 antibodies which greatly increase the detection rate in Type 1 diabetes and do not contribute false positive results. In addition at present Prof Barrett uses the absence of antibodies in his definition of Type 2 diabetes in children.	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis (specifically evidence for distinguishing between type 1 and type 2 diabetes) and concluded that C-peptide and diabetes-specific autoantibody titres should not be measured at initial presentation to distinguish type 1 diabetes from type 2 diabetes. However, the revised recommendations emphasise that measuring C-peptide after initial presentation should be considered if there is difficulty distinguishing type 1 diabetes from other types of diabetes and that genetic testing should be performed if atypical disease behaviour, clinical characteristics or family history suggest monogenic diabetes. The 'do not use' form of recommendation reflects the evidence base
Diabetes UK	NICE	14	1.1.6	We feel that the characteristics monogenic diabetes are not fully represented in this point and recommend that ISPAD guidelines are used https://www.ispad.org/sites/default/files/resources/files/4-the_diagnosis_and_management_of_monogenic_diabetes_in_children_and_adolescents.pdf	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was

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					excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The revised recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY. Additionally the recommendations have been revised to include family history of diabetes. However, the limitations of the scope for

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					the 2015 update prevent the guideline development group from providing more detail about the diagnosis or management of forms of diabetes other than type 1 or type 2
National Children and Young People's Diabetes Network	NICE	14	1.1.6	rarely or never produce ketone bodies in the urine (ketonuria) during episodes of hyperglycaemia ? blood ketones	Thank you for this comment. The second bullet of the recommendation has been changed as suggested and it now refers to rarely or never developing ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia
National Children and Young People's Diabetes Network	NICE	14	1.1.6	This section needs modifying it should give the other diagnoses in the order of prevalence in the paediatric population maturity-onset diabetes of the young is the most common 1-2%, then neonatal diabetes (0.4%), then syndromic diabetes (0.4%) then insulin resistant syndromes (<0.3%)	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes,

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					monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY. However, the limitations of the scope for the 2015 update prevent the guideline development group from providing more detail about the diagnosis or management of forms of diabetes other than type 1 or type 2, and from examining the relative prevalence of types of diabetes other than type 1 and type 2
National Children and Young People's Diabetes Network	NICE	14	1.1.6	The clinical feature if rarely or never produce ketone bodies is not correct and should be removed: Neonatal diabetes presents in ketoacidosis (Gloyn et al NEJM 2004), ketones do occur in MODY and although very rare ketoacidosis can occur (like in Type 2 diabetes)	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of

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					diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The revised recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The bullet about having diabetes in the first year of life has been included in the revised recommendations specifically to cover neonatal diabetes which is not otherwise captured by the characteristics listed. Moreover, the term monogenic

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					diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY
National Children and Young People's Diabetes Network	NICE	14	1.1.6	The important clinical features that should be included in this section are: 1. Diagnosis less than 6 months as this is neonatal diabetes and not type 1 diabetes. (Edgehill et Diabetes 55:1895–1898, 2006). This is very important as 50% of these patients will have a potassium channel mutation and despite being insulin dependent 90% can get improved control on a sulphonylurea (Pearson ER et al N Engl J Med 2006;355:467-77.) 2. Parental diabetes (especially when an extended family and the absence of obesity) as this suggests MODY rather than Type 1 or Type 2 diabetes. 3. Incidental hyperglycaemia that is mild (the commonest cause >50% is glucokinase MODY) in at least 3 national surveys Lorini R et al Maturity-onset diabetes of the young in children with incidental hyperglycemia: a multicenter Italian study of 172 families. Diabetes Care. 2009 Oct;32(10):1864-6.PMID: 19564454: Codner E, et al Pediatr Diabetes. 2009 Sep;10(6):382-8. PMID: 19309449; Feigerlová E, Et al . Aetiological heterogeneity of asymptomatic hyperglycaemia in children and adolescents. Eur J Pediatr. 2006 PMID: 16602010. 4. Absence of autoantibodies (discussed below McDonald T et al Islet autoantibodies can discriminate maturity-onset diabetes of the young (MODY) from Type 1 diabetes. Diabet Med. 2011Sep;28(9):1028-33. PMID: 21395678 This approach has been proven to be successful in identifying MODY in the paediatric population (Pihoker C, et al Prevalence, characteristics and clinical diagnosis of maturity onset diabetes of the young due to mutations in HNF1A, HNF4A, and glucokinase: results from the SEARCH for Diabetes in Youth. J Clin Endocrinol Metab. 2013 Oct;98(10):4055-62. PubMed PMID: 23771925) 5. Acanthosis nigricans in a slim child (suggests a genetic disorder of insulin resistance)	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The revised recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another

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					systemic illness or syndrome. The bullet about having diabetes in the first year of life has been included in the revised recommendations specifically to cover neonatal diabetes which is not otherwise captured by the characteristics listed. Moreover, the term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY. Additionally the recommendations have been revised to include family history of diabetes. However, the limitations of the scope for the 2015 update prevent the guideline development group from providing more detail about the diagnosis or management of forms of diabetes other than type 1 or type 2
National Children and Young People's Diabetes Network	NICE	14	1.1.6	Recommend the addition of autosomal dominant history of diabetes including gestational diabetes.	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are

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					strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The revised recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY. Additionally the recommendations have been revised to include family history of diabetes. However, the limitations of the scope for the 2015 update prevent the guideline development group from providing more detail about the diagnosis or management of forms of diabetes other than type 1 or

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					type 2, including consideration of autosomal dominant history of gestational diabetes
Royal College of Nursing	NICE	14	1.1.6	We consider that this section needs modifying. It should give the other diagnoses in the order of prevalence in the paediatric population, maturity-onset diabetes of the young is the most common 1-2%, then neonatal diabetes (0.4%), then syndromic diabetes (0.4%) then insulin resistant syndromes (<0.3%).	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another

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					systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY. However, the limitations of the scope for the 2015 update prevent the guideline development group from providing more detail about the diagnosis or management of forms of diabetes other than type 1 or type 2, and from examining the relative prevalence of types of diabetes other than type 1 and type 2
Royal College of Nursing	NICE	14	1.1.6	The clinical feature of "rarely or never produce ketone bodies in the urine" is not correct and we suggest should be removed: Neonatal diabetes presents in ketoacidosis (Gloyn et al NEJM 2004), ketones do occur in MODY and although very rare ketoacidosis can occur (like in Type 2 diabetes).	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The revised recommendations

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					emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The bullet about having diabetes in the first year of life has been included in the revised recommendations specifically to cover neonatal diabetes which is not otherwise captured by the characteristics listed. Moreover, the term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY
Royal College of Nursing	NICE	14	1.1.6	The important clinical features that should be also included in this section are: 1. Diagnosis less than 6 months as this is neonatal diabetes and not type 1 diabetes. (Edgehill et Diabetes 55:1895–1898, 2006). This is very important as 50% of these patients will have a potassium channel	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas

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				mutation and despite being insulin dependent 90% can get improved control on a sulphonylurea (Pearson ER et al N Engl J Med 2006; 355:467-77.) 2. Parental diabetes (especially when an extended family and the absence of obesity) as this suggests MODY rather than Type 1 or Type 2 diabetes. 3. Incidental hyperglycaemia that is mild (the commonest cause >50% is glucokinase MODY) in at least 3 national surveys Lorini R et al (2009) Maturity-onset diabetes of the young in children with incidental hyperglycemia: a multicenter Italian study of 172 families. Diabetes Care. 2009 Oct; 32(10):1864-6.PMID: 19564454: Codner E, et al Pediatr Diabetes. 2009 Sep; 10(6):382-8. PMID: 19309449; Feigerlová E, et al (2006) Aetiological heterogeneity of asymptomatic hyperglycaemia in children and adolescents. Eur J Pediatr. 2006 PMID: 16602010. 4. Absence of autoantibodies (discussed below McDonald T et al (2011) Islet autoantibodies can discriminate maturity-onset diabetes of the young (MODY) from Type 1 diabetes. Diabet Med. 2011Sep; 28(9):1028-33. PMID: 21395678. This approach has been proven to be successful in identifying MODY in the paediatric population. (Pihoker C, et al (2013) Prevalence, characteristics and clinical diagnosis of maturity onset diabetes of the young due to mutations in HNF1A, HNF4A, and glucokinase: results from the SEARCH for Diabetes in Youth. J Clin Endocrinol Metab. 2013 Oct; 98(10):4055-62. PubMed PMID: 23771925). 5. Acanthosis nigricans in a slim child (suggests a genetic disorder of insulin resistance).	distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The revised recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. The bullet about having diabetes in the first year of life has been included in the revised recommendations specifically to cover neonatal diabetes which is not otherwise captured by the characteristics listed. Moreover, the term monogenic diabetes has been used in the revised

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					recommendations so that neonatal diabetes is covered as well as MODY. Additionally the recommendations have been revised to include family history of diabetes. However, the limitations of the scope for the 2015 update prevent the guideline development group from providing more detail about the diagnosis or management of forms of diabetes other than type 1 or type 2
Royal College of Paediatrics and Child Health	NICE	14	1.1.6	Recommend the addition of autosomal dominant history of diabetes including gestational diabetes.	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The revised recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in

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					children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY. Additionally the recommendations have been revised to include family history of diabetes. However, the limitations of the scope for the 2015 update prevent the guideline development group from providing more detail about the diagnosis or management of forms of diabetes other than type 1 or type 2, including consideration of autosomal dominant history of gestational diabetes
Royal College of Paediatrics and Child Health	NICE	14	1.1.6	This section needs modifying it should give the other diagnoses in the order of prevalence in the paediatric population maturity-onset diabetes of the young is the most common 1-2%, then neonatal diabetes (0.4%), then syndromic diabetes (0.4%) then insulin resistant syndromes (<0.3%)	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas

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					distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY. However, the limitations of the

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					scope for the 2015 update prevent the guideline development group from providing more detail about the diagnosis or management of forms of diabetes other than type 1 or type 2, and from examining the relative prevalence of types of diabetes other than type 1 and type 2
Royal College of Paediatrics and Child Health	NICE	14	1.1.6	The clinical feature if rarely or never produce ketone bodies is not correct and should be removed: Neonatal diabetes presents in ketoacidosis (Gloyn et al NEJM 2004), ketones do occur in MODY and although very rare ketoacidosis can occur (like in Type 2 diabetes)	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The revised recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone

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					bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The bullet about having diabetes in the first year of life has been included in the revised recommendations specifically to cover neonatal diabetes which is not otherwise captured by the characteristics listed. Moreover, the term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY
Royal College of Paediatrics and Child Health	NICE FULL	14	1.1.6	Rarely or never produce ketone bodies in the urine (ketonuria) during episodes of hyperglycaemia ? blood ketones	Thank you for this comment. The second bullet of the recommendation has been changed as suggested and it now refers to rarely or never developing ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia
National Children and Young People's Diabetes Network	NICE	14	1.1.8	Consider measuring C-peptide after initial presentation if there is difficulty distinguishing type 1 diabetes from other types of diabetes. Be aware that C-peptide concentrations have better discriminative value the longer the interval between initial presentation and the test. [new 2015] Comment: antibodies not requested at diagnosis in less then 11 years; in older	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE does not include links to external organisations in its recommendations unless these provide definitive information or guidance that has been reviewed by the guideline

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				children if strong suspicion of Type 2 these can be done later. ? include hyperlink to relevant website e.g. Exeter	development group of the guideline in accordance with the NICE process
Royal College of Paediatrics and Child Health	NICE FULL	14	1.1.8	Consider measuring C-peptide after initial presentation if there is difficulty distinguishing type 1 diabetes from other types of diabetes. Be aware that C-peptide concentrations have better discriminative value the longer the interval between initial presentation and the test. [new 2015] Comment: antibodies not requested at diagnosis in less then 11 years; in older children if strong suspicion of Type 2 these can be done later. ? include hyperlink to relevant website e.g. Exeter	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE does not include links to external organisations in its recommendations unless these provide definitive information or guidance that has been reviewed by the guideline development group in accordance with the NICE process.
Abbott Diabetes Care	NICE	15	1.2.1	We support the new recommendation on patient education and information for children and young people with diabetes which embraces glucose variability, managing excursions and ketosis. We believe that to support this educational journey, use of easy to read reports from download capabilities of blood glucose meters should also be encouraged and integrated in to patient education in order to support good treatment decisions.	Thank you for the comment in support of the guideline. There was no evidence identified to support structured education from diagnosis (structured here meaning a formal training or education package with a recognised curriculum and approaches to delivery). The guideline recommendations do, however, list core topics that should be covered as part of (unstructured) education. The guideline development group's view is that the core topics and the recommendations to tailor education to the individual and add other topics as needed cover the issues raised in the comment
Alder Hay Children's	NICE	15	1.2.1	Diabetes Team Dieticians - Strongly agree with this recommendation	Thank you for this comment in support of the guideline

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NHS Foundation Trust					
Dexcom	NICE	15	1.2.1	CGM should be presented as an option for child or families as an alternative therapy for blood glucose monitoring	The recommendations about education for children and young people with type 1 diabetes include items related to insulin therapy and blood glucose monitoring. The guideline development group do not view continuous blood glucose monitoring as a form of therapy and so the suggestion in the comment is not reflected in the recommendations; continuous blood glucose monitoring is, however, included in the recommendation via the broad interpretation of the bullet about blood glucose monitoring
Diabetes UK	NICE	15	1.2.1 1.2.2	We welcome the detail on content of a continuing education programme and that this should be tailored to the individual.	Thank you for this comment in support of the guideline
Juvenile Diabetes Research Foundation	NICE	15 100	1.2.1 5.7 11	JDRF strongly supports the recommendation to ensure core diabetes education is provided to children, young people and their family or carers on an ongoing basis from the point of diagnosis.	Thank you for this comment in support of the guideline
Juvenile Diabetes Research Foundation	NICE	15 100	1.2.2 5.7 12	We also support tailoring education to the needs of each child or young person and their family or carer and believe that emotional and mental health should be a key focus of support for children and young people as it is a major factor in the self-management of the condition, particularly through the teens and early twenties when control often becomes poorer leading to early onset complications.	Thank you for the comment in support of the guideline. There was no evidence identified to support structured education from diagnosis (structured here meaning a formal training or education package with a recognised curriculum and approaches to delivery). The guideline

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					recommendations do, however, list core topics that should be covered as part of (unstructured) education. The guideline development group's view is that the core topics and the recommendations to tailor education to the individual and add other topics as needed cover the issues raised in the comment
Royal College of Paediatrics and Child Health	NICE	16 1.2.4	General	Unclear why role for optician if 12+ enrolled in retinal screening separately – this may lead to confusion as evidence base to have separate optician checks is not apparent to me	Thank you for this comment. The rationale for the recommendation on screening for retinopathy is discussed in Section 11.4.1 of the full guideline. The consensus recommendation from 2004 about the frequency of routine eye tests reflects good clinical practice and that section of the guideline was not updated in 2015
Royal College of Nursing	NICE	16	1.2.3	We feel that the wording relating to clinic appointments may unintentionally limit the frequency of clinic appointments offered to Children & Young People (CYP). We suggest the wording be changed to 'minimum number'. There also needs to be clarification as to the type of appointment being referred to – i.e. multidisciplinary clinics.	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (clinic appointments and attendance in this case). With regard to clinic appointments and attendance, the 2004 recommendations have, however been amended to complement the Best Practice Tariff

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Diabetes UK	NICE	16	1.2.9	We feel that this point should be expanded to recommend accessible communication methods for these groups of people eg. written/audio information, use of interpreters etc.	Thank you for this comment. The guideline guideline development group deliberately left these recommendations broad as they did not look at evidence as part of the 2015 update to allow specific individual circumstances to be considered (because this part of the guideline was excluded from the 2015 update) and so no specific resources are recommended. Although the guideline development group were unable to amend the phrasing or content of these recommendations they selected them as key priorities for implementation (key recommendations) because of the importance of the content
Alder Hay Children's NHS Foundation Trust	NICE	17	1.2.10	Diabetes Team Dieticians - There is no such thing as a restricted sport. This is factually incorrect.	Thank you for submitting comments in response to the stakeholder consultation. Please note NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (information for children and young people with type 1 diabetes in this case). The guideline development group do, however, agree that the term 'restricted sport' has no meaning and so the recommendation has been amended to state that children and young people with type 1 diabetes wishing to participate in sports that may

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					have particular risks for people with diabetes should be offered comprehensive advice by their diabetes team
Diabetes UK	NICE	18	1.2.19	We welcome the recommendation to consider family circumstances and personal preference when choosing an insulin regimen.	Thank you for this comment in support of the guideline
Juvenile Diabetes Research Foundation	NICE	18 136 137	1.2.19 6.1.5 19	JDRF strongly welcomes the guideline recommendation to take into account the personal preferences and family circumstances of children, young people and their families in choosing an insulin regimen.	Thank you for this comment in support of the guideline
Royal College of Nursing	NICE	18	1.2.19	This sentence is a better wording of 1.2.18 – having both sentences is repetitive.	Recommendation 1.2.18 in the consultation draft (which has now been moved as requested in another stakeholder comment) is about insulin delivery systems. Recommendation 1.2.19 in the consultation draft is about insulin regimens which is a different issue. Both recommendations have, therefore, been retained
Alder Hay Children's NHS Foundation Trust	NICE	19	1.2.20	Diabetes Team Dieticians - Strongly agree with this recommendation	Thank you for this comment in support of the guideline
Diabetes UK	NICE	19	1.2.20	We agree with the recommendation of personalizing the injection regimen for newly diagnosed children and young people and that generally multiple daily insulin injections from diagnosis should be offered. However we feel that the guidance should address insulin regimens for children and young people with established diabetes and recognise that in certain circumstances neither MDI nor CSII would be appropriate, and a BD regimen may	Thank you for this comment. The guideline guideline development group did not feel that use of insulin regimens other than multiple daily injections (or insulin pump therapy if a multiple daily insulin injection regimen is not appropriate) was

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				be necessary to gain compliance with treatment.	appropriate at diagnosis hence the strong recommendation to offer multiple daily injection regimens from diagnosis. The later recommendation referring to mixed insulin is included to cover those children and young people who might be using such a regimen although these are not recommended strongly
Juvenile Diabetes Research Foundation	NICE	19 137	1.2.20 6.1.5 20	JDRF notes that children and young people should be advised to aim for a target HbA1c of 48 mmol/mol (6.5%) or under (new 2015, 1.2.68) and suggests that this lower level should be taken into account when discussing an insulin regimen with families. Consequently, although outside the immediate remit of this consultation, we believe the GDG should recommend that the criteria for NICE TA151 should be revised so that children and young people over the age of 12 qualify for continuous subcutaneous insulin infusion (CSII) when HbA1c levels remain above 7.5% rather than 8.5% despite a high level of care. This is likely to greatly assist children and young people in meeting recommended HbA1c targets.	Thank you for this comment. The reference to the Technology Appraisal guidance has been brought to the attention of NICE by the guideline development group
National Children and Young People's Diabetes Network	NICE	19	1.2.20	Those going straight onto CSII should also be taught the skill of injecting insulin with a pen device in the event of pump failure. This skill should regularly be reviewed.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (insulin pump therapy in this case). Moreover, the indications for and other aspects of the use of insulin pump therapy are determined by the NICE Technology Appraisal (TA) guidance mentioned in the comment and the

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					guideline development group are unable to change the TA guidance
Royal College of Nursing	NICE	19	1.2.20	Those going straight onto continuous subcutaneous insulin infusion (CSII or insulin pump) should also be taught the skill of injecting insulin with a pen device in the event of pump failure. This skill should regularly be reviewed.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (insulin pump therapy in this case). Moreover, the indications for and other aspects of the use of insulin pump therapy are determined by the NICE Technology Appraisal (TA) guidance
Royal College of Nursing	NICE	19	1.2.20	We are pleased that this guideline clearly recommends multiple daily insulin injection as a treatment therapy – but we feel that the order of the recommendations should be changed so that it comes before 1.2.18 & 1.2.19. This seems logical.	Recommendation 1.2.18 in the consultation draft has now been moved to later in this section of the guideline. Recommendation 1.2.19 in the consultation draft refers to the individual child or young person's personal and family circumstances and this has been retained before the recommendation to offer multiple daily injection regimens to emphasise the importance of taking account of the individual's circumstances (because multiple daily injection regimens are not suitable for all children and young people with type 1 diabetes)
Diabetes UK	NICE	19	1.2.22	We recommend that what constitutes a specialist team in terms of CGMS should be specified.	The guideline development group did not prioritise a review question on whether or

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					not continuous glucose monitoring should be supported by a specialist team. The recommendation in the guideline that refers to a specialist team is that for continuous subcutaneous insulin infusion (CSII or insulin pump) therapy and the reason that is included is because it comes from the related NICE Technology Appraisal guidance to which the guideline refers
National Children and Young People's Diabetes Network	NICE	20	1.2.25	…..48 mmol/mol (6.5%). General feeling is that this will be very hard to attain for families (currently those that do achieve it manage diabetes with all available technical & canine support & still suffer hypos/hypo unawareness). Are we being unrealistic and ensuring our patients will rarely achieve this goal so feel that it is not worth trying? Longitudinal studies post DCCT suggest that current targets are appropriate to reduce complications. ISPAD (2009) suggests: HbA1c targets. A target range for all age-groups of <7.5% is recommended These targets are intended as guidelines. Each child should have their targets individually determined with the goal of achieving a value as close to normal as possible while avoiding severe hypoglycemia as well as frequent mild to moderate hypoglycemia.	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of

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					personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline

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					development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline
Royal College of Nursing	NICE	20	1.2.27	"…insulin injection needles that are an appropriate length for their body fat" Please consider adding to this "…taking into account the variable depth at different injection sites and between different age groups". (In the 2-6 year old age group the upper outer quadrant is recommended with the shortest needle available which is currently 4mm" (Lo Presti et al in Pediatric Diabetes 2012.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (insulin injection techniques and needle choice in this case)
Royal College of Nursing	NICE	20	1.2.29	Consider amending wording to..."Support CYP with Type 1 diabetes and their family members or carers to develop a good working knowledge of lipohypertrophy, how to detect and how it can affect their diabetes. Offer CYP a review of injection sites at each clinic visit" Blanco et al 2013 Diabetes & Metabolism.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (insulin injection techniques and needle choice in this case)
National Children and Young	NICE	20	1.2.30	Please add wording "and detailed instructions in its use".	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not

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People's Diabetes Network					able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (insulin injection techniques and needle choice in this case)
Royal College of Paediatrics and Child Health	NICE	20	1.2.30	Please add wording "and detailed instructions in its use".	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (insulin injection techniques and needle choice in this case)
Royal College of Nursing	NICE	20	1.2.31	Include a comprehensive assessment of injection technique and examination for lipohypertrophy in the list.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (insulin injection techniques and needle choice in this case)
Royal College of Ophthalmologists	NICE	20	34 40	5. Recommendation about diagnosis of diabetes mellitus (page 20, lines 34-40) 'Think about the possibility of types of diabetes other than types 1 or 2…in children and young people with suspected diabetes (with)…associated features, such as retinitis pigmentosa, [2004, amended 2015]' Comment: In version 2004 the recommendation was "associated features, such as	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes,

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				eye disease, deafness, or another systemic illness or syndrome. (1.1.1.3)". The reason for the change was that "the GDG felt that 'eye disease' was not specific enough and could be mistaken for diabetic retinopathy." (Appendices page 23). Some monogenic causes of diabetes mellitus display among their features retinitis pigmentosa (e.g. Alström syndrome, Sheck L et al. 2011. Alström syndrome--an uncommon cause of early childhood retinal dystrophy. BMJ Case Rep. doi: 10.1136/bcr.06.2011.4388) and we agree with Ms Pilling's suggestion that optic atrophy could be added as another feature observed in monogenic DM.	type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. The revised recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The term monogenic diabetes has been used in the revised recommendations. However, the limitations of the scope for the 2015 update prevent the guideline development group from providing more detail about the diagnosis or management of forms of diabetes other than type 1 or type 2
National Children and	NICE	21	1.2.32	Metformin in combination with insulin is suitable for use only within research studies because the effectiveness of this combined	Thank you for submitting comments in response to the stakeholder consultation.

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Young People's Diabetes Network				treatment in improving blood glucose control is uncertain. [2004] This is effective treatment in those CYP with type 1 diabetes & insulin resistance.	Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (metformin combined with insulin for the management of type 1 diabetes in this case). The guideline development group have, however, retained the 2004 research recommendation related to this topic
Alder Hay Children's NHS Foundation Trust	NICE	21	1.2.34	Diabetes Team Dieticians - Should this read glycaemic control and long term health rather than diabetes	Thank you for this comment. This recommendation is specific to dietary management for children and young people with type 1 diabetes and so the suggested changes have not been made
Diabetes UK	NICE	21	1.2.37	We welcome introduction of carbohydrate counting from diagnosis as allows greater flexibility in food choices, timing and amounts. We would like to see an explanation of "level 3 carbohydrate counting".	Thank you for this comment in support of the recommendation to offer carbohydrate counting from diagnosis. Level 3 carbohydrate counting is the use of carbohydrate counting with the adjustment of insulin dosage according to carbohydrate content of meals and blood glucose levels, using an insulin:carbohydrate ratio. This has been clarified in a footnote to the recommendation
National Children and Young	NICE	22	1.2.37	Repeat the offer. This is vague is this the original offer for level 3 CHO counting training or regular updates if so what frequency	Thank you for this comment. Repeating the offer of level 3 carbohydrate counting is a pragmatic recommendation to ensure

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People's Diabetes Network				Not everyone automatically knows what level 3 education is.	that a child or young person who does not take up the approach at diagnosis has opportunities to consider doing so later. The guideline development group did not identify any evidence to specify the timing and frequency of repeating the offer and so this is not specified in the recommendation Level 3 carbohydrate counting is the use of carbohydrate counting with the adjustment of insulin dosage according to carbohydrate content of meals and blood glucose levels, using an insulin:carbohydrate ratio. This has been clarified in a footnote to the recommendation
Alder Hay Children's NHS Foundation Trust	NICE	22	1.2.41	Diabetes Team Dieticians - Fruit or vegetables? Is this correct? This should be fruit and vegetables as 5 portions of fruit may not be appropriate.	Thank you for this comment. This recommendation has been amended to read fruit and vegetables
Royal College of Nursing	NICE	22	1.2.41	As all CYP with diabetes are recommended 5 fruits and vegetables a day should this sentence be amended to include the wordings: 'as part of healthy diet'?	Thank you for this comment. The guideline development group have not amended the recommendation as they believe this is addressed by other recommendations in this section
Diabetes UK	NICE	22	1.2.42	We are concerned that the recommendation around low GI diets is misleading as some low GI foods are high in fat, which could lead to weight gain. We recommend that what constitutes a healthy balanced diet is made clearer.	Thank you for this comment. The concern about low glycaemic index diets that are high in fat is discussed in Section 6.4.4.6.2

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					of the full guideline
National Children and Young People's Diabetes Network	NICE	22	1.2.42 1.2.43	There is not sufficient evidence to consider using the Glycaemic index in children and young people	The guideline development group refer to Sections 6.4.4.2 and 6.4.4.3 of the full guideline which present moderate- and high-quality evidence from two studies that assess the use of low glycaemic index diets in children and young people. A discussion of the balance of benefits and harms is presented in Section 6.4.4.6.2 of the full guideline
National Children and Young People's Diabetes Network	NICE	22	1.2.42	Concerned that the recommendation around low GI diets is misleading as some low GI foods are high in fat, which could lead to weight gain. We recommend that what constitutes a healthy balanced diet is made clearer. We also note that a low GI diet is not recommended for blood glucose management in the adult Type 1 guideline.	Thank you for this comment. The concern about low glycaemic index diets that are high in fat is discussed in Section 6.4.4.6.2 of the full guideline The difference between the evidence base for children and young people and that for adults has been clarified in the evidence to recommendations section of the full guideline
Royal College of Paediatrics and Child Health	NICE	22	1.2.42 1.2.43	There is not sufficient evidence to consider using the Glycaemic index in children and young people	The guideline development group refer to Sections 6.4.4.2 and 6.4.4.3 of the full guideline which present moderate- and high-quality evidence from two studies that assess the use of low glycaemic index diets in children and young people. A discussion of the balance of benefits and harms is presented in Section 6.4.4.6.2 of the full guideline

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British Psychological Society	NICE	23	1.2.50	The Society recommends highlighting how hormonal factors can impact on HbA1c targets (a lack of understanding may be interpreted by individuals or healthcare professional as poor self-management).Again, this issue is covered in the language position statement, under the issue of referring to 'controlling' blood glucose which is often an unrealistic expectation precisely because of hormonal changes, stress, illness, and other unpredictable factors beyond the person's direct control Similarly, adolescence can be hugely challenging from a psychosocial perspective. Simply stating that this "may in part be due to non-adherence to therapy" does not acknowledge this. Non-adherence is often used in this document and really does not give adequate acknowledgement of the everyday burden of managing type 1 diabetes Stress can also lead to hyperglycaemia and, less often and more idiosyncratically, hypoglycaemia despite best efforts to manage the diabetes. (I don't know of evidence for such stress effects in children but there is a substantial literature in adults to which one of my former PhD students has contributed and every reason to anticipate that such reactions will also occur in children with diabetes) How to anticipate and deal with stress effects may not even be taught and always requires experience and judgement. Use of the term 'non-adherence' here would be particularly inappropriate. References: Riazi A,Pickup J and Bradley C (2004) Daily stress and glycaemic control in Type	This comment refers to a recommendation about exercise but the text of the comment refers to adolescence and non-adherence. Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (exercise, adolescence and non-adherence in this case)

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				1 diabetes: individual differences in magnitude, direction and timing of stress-reactivity. Diabetes Research and Clinical Practice 66 (3) 237-244. http://www.ncbi.nlm.nih.gov/pubmed/15536020 Riazi A and Bradley C (2007) Diabetes, Type 1. In G Fink (Ed) Encyclopedia of Stress, 2nd Edition Oxford: Academic Press, 792-796. http://digirep.rhul.ac.uk/items/1546572b-642f-676c-50a8-728f86e4b825/1/	
Diabetes UK	NICE	23	1.2.50	We would recommend adding the possibility of needing to monitor blood glucose levels during exercise as well as before and after, depending on length of time spent exercising.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (exercise in this case)
Alder Hay Children's NHS Foundation Trust	NICE	24	1.2.54	Diabetes Team Dieticians - The responsibility for ongoing prescription of blood ketone strips is not clear. This is an excellent recommendation and ongoing supplies of ketone testing strips must be provided in the community.	Thank you for this comment. The fact that blood ketone monitoring is recommended means that testing strips should be prescribed
National Children and Young People's Diabetes Network	NICE	24	1.2.54	Use of rapid acting analog insulin mentioned in 1.2.30 but not mentioned here.	Thank you for this comment. This is covered by the bullet about adjusting the insulin regimen in the recommendation that summarises the content to be included in sick-day rules
Royal College of Nursing	NICE	24	1.2.54	The use of rapid acting analogue insulin is mentioned in 1.2.30 but not mentioned here.	Thank you for this comment. This is covered by the bullet about adjusting the

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					insulin regimen in the recommendation that summarises the content to be included in sick-day rules
Royal College of Paediatrics and Child Health	NICE	25 1.2.55 57	General	The GDG state in full version that the Relative Risk of severe hypoglycaemia was almost 3 times greater with intensive control in the DCCT and more common in the younger cohort . There is also comment in the paper regarding altered hypoglycaemic awareness in some CYP . The new 2015 recommendations for BG and HbA1c targets if applied generally almost appear to invite the outcome of 'problematic hypoglycaemia' that 1.2.57 states care providers should avoid. Although 1.2.70 page 27 states the most sensible pragmatic approach this contrast with so much stated earlier. The statement in 1.2.9 that the health care professional should advise that any reduction if above 48 mmol/l will reduce the risk of long term complications' may not be justified . The reality of reduction in complications in DCCT was when Hba1c eman of 58 mmol/mol was attained . Is there clear outcome evidence that those who attained an HbA1c of 48 had less complications than 58?	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the

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					ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in

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					the revised evidence to recommendations section in the full guideline The reference in the comment to hypoglycaemia is covered by the individualised targets (with safely achievable for the individual being a key consideration) and recommendations elsewhere in the guideline. The guideline development group was also of the view that modern insulin regimens reduce the risk of hypoglycaemia compared to those in place when, for example, the Diabetes Control and Complications Trial was undertaken. This is also documented in the evidence to recommendations section in the full guideline
Abertawe Bro Morgannwg University NHS Trust (HQ)	NICE	25	1.2.55	Guidance says "the optimal target ranges for short-term blood glucose control are: □□fasting blood glucose level of 4–7 mmol/litre (or 5–7 mmol/litre for young people intending to drive the following morning)" does the following morning mean "that day" or "the day after". This language could be clarified	There was a typographical error in the draft guideline for consultation. This has now been corrected to clarify that for fasting blood glucose a target range of 5–7 mmol/litre is advised when the young person intends to drive that morning
Diabetes UK	NICE	25	1.2.55	We find the use of the terms "fasting BGL" and "before meals" confusing as this target seems to relate to the same thing. If this is the case we recommend clarification eg. to say "on waking and before meals…"	Thank you for this comment. Fasting in this recommendation refers to overnight fasting, and the phrasing has been revised to clarify that this means a fasting target on waking whereas the bullet that refers to before meals means meals at other times of the day. This mirrors the phrasing in the

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					guideline for type 1 diabetes in adults
				If "fasting" refers to on waking, should "5-7 for young people intending to drive the following morning" read "5-7 for young people intending to drive that morning"?	There was a typographical error in the draft guideline for consultation. This has now been corrected to clarify that for fasting blood glucose a target range of 5–7 mmol/litre is advised when the young person intends to drive that morning
				The guideline must state how long after meals the targets should be reached, eg 1 hour/2 hours.	The guideline development group do not support this statement. The timing after meals by which the target should be met will depend on what the child or young person has eaten and how old they are. Usually it will be 2 hours, but in some children and young people it might be sooner, and one rule will not suit all children and young people
				The guideline must suggest a bedtime target for blood glucose level and strategies to avoid night time hypoglycaemia as this is a major concern for parents.	The guideline development group discussed this issue in detail and concluded that in young children a blood glucose test around 2 hours after the last meal will coincide with bedtime. Older children and young people should go to bed with a blood glucose level of 4-7 mmol/litre and that does not require a separate recommendation as the guideline emphasises the need for blood glucose targets to be individualised

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National Children and Young People's Diabetes Network	NICE	25	1.2.55	Explain to children and young people with type 1 diabetes and their family members or carers (as appropriate) that the optimal target ranges for short-term blood glucose control are: •fasting blood glucose level of 4–7 mmol/litre (or 5–7 mmol/litre for young people intending to drive the following morning) •a blood glucose level of 4–7 mmol/litre before meals •a blood glucose level of 5–9 mmol/litre after meals. [new 2015] Similar comment to the lower HbA1c target.	There was a typographical error in the draft guideline for consultation. This has now been corrected to clarify that for fasting blood glucose a target range of 5–7 mmol/litre is advised when the young person intends to drive that morning
National Children and Young People's Diabetes Network	NICE	25	1.2.55	Re guide for post prandial BG levels – should it not state when to test after the meal – 1 hour or 2 hours?	Thank you for this comment. The guideline development group discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that should be recommended, but also the timing at which the tests should be performed. The evidence reviewed for the guideline demonstrated that glycaemic control improves with the number of capillary tests performed up to 5 five tests per day. The guideline development group concluded, therefore, that at least 5 tests should be performed routinely, and emphasised in the revised recommendations that it is often necessary to conduct more than 5 tests. They did not, however, wish to specify an upper limit for the number of tests, nor the exact timing for the minimum number of tests because to do so would remove some flexibility that

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					is otherwise available to the child or young person and their family members or carers (as appropriate)
National Children and Young People's Diabetes Network	NICE	25	1.2.55	Find the use of the terms "fasting BGL" and "before meals" confusing as this target seems to relate to the same thing. If this is the case we recommend clarification eg. to say "on waking and before meals…"	Thank you for this comment. Fasting in this recommendation refers to overnight fasting, and the phrasing has been revised to clarify that this means a fasting target on waking whereas the bullet that refers to before meals means meals at other times of the day. This mirrors the phrasing in the guideline for type 1 diabetes in adults
				If "fasting" refers to on waking, should "5-7 for young people intending to drive the following morning" read "5-7 for young people intending to drive that morning"?	There was a typographical error in the draft guideline for consultation. This has now been corrected to clarify that for fasting blood glucose a target range of 5–7 mmol/litre is advised when the young person intends to drive that morning
				The guideline must suggest a bedtime target for blood glucose level and strategies to avoid night time hypoglycaemia as this is a major concern for parents.	The guideline development group discussed this issue in detail and concluded that in young children a blood glucose test around 2 hours after the last meal will coincide with bedtime. Older children and young people should go to bed with a blood glucose level of 4-7 mmol/litre and that does not require a separate recommendation as the guideline emphasises the need for blood glucose targets to be individualised

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National Children and Young People's Diabetes Network	NICE	25	1.2.55 1.2.57	The GDG state in full version that the Relative Risk of severe hypoglycaemia was almost 3 times greater with intensive control in the DCCT and more common in the younger cohort . There is also comment in the paper regarding altered hypoglycaemic awareness in some CYP . The new 2015 recommendations for BG and HbA1c targets if applied generally almost appear to invite the outcome of 'problematic hypoglycaemia' that 1.2.57 states care providers should avoid. Although 1.2.70 page 27 states the most sensible pragmatic approach this contrast with so much stated earlier . The statement in 1.2.9 that the health care professional should advise that any reduction if above 48 mmol/l will reduce the risk of long term complications' may not be justified . The reality of reduction in complications in DCCT was when Hba1c eman of 58 mmol/mol was attained . Is there clear outcome evidence that those who attained an HbA1c of 48 had less complications than 58 ?	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The

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					phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline

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					The reference in the comment to hypoglycaemia is covered by the individualised targets (with safely achievable for the individual being a key consideration) and recommendations elsewhere in the guideline. The guideline development group was also of the view that modern insulin regimens reduce the risk of hypoglycaemia compared to those in place when, for example, the Diabetes Control and Complications Trial was undertaken. This is also documented in the evidence to recommendations section in the full guideline
British Psychological Society	NICE	25 31	1.2.57 1.2.86 1.2.87	The Society believes that this would benefit from being broken into two points. The second point... (Ensure that children…do not experience undue emotional distress when achieving, or attempting to achieve blood glucose and HbA1c) needs more elaboration. There needs to be an emphasis on screening for emotional distress. There also needs an emphasis on ensuring that all targets are collaboratively agreed with young person, family and health professional, and that they need to take into account the wider psychosocial factors and lifestyle choices of the young person to ensure that they are achievable and owned. Needs relating to point 1.2.70	Thank you for this comment. While screening for emotional distress is not prevented by this recommendation, the clinical and cost effectiveness of a formal screening programme was not evaluated as part of the updated guidance. The guideline development group agree that in order to agree an individualised target, psychosocial factors and lifestyle choices should be taken into consideration. They believe the current wording of the recommendation reflects this and the linking evidence to recommendations section in the full guideline has been amended to more

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					clearly state this
Diabetes UK	NICE	25	1.2.57	We welcome the recommendation to ensure that children and young people do not experience problematic hypoglycaemia or undue emotional distress when attempting to achieve blood glucose and HbA1c targets, but would like to see strategies that can be employed to manage this.	Thank you for this comment. The guideline development group's view is that other recommendations in the guideline cover the issues raised in the comment. For example, there are recommendations about agreeing individualised HbA1c targets, considering the 'whole child' when interpreting blood glucose levels, explaining the benefits of safely achieving and maintaining the lowest attainable HbA1c level, and supporting the child or young person to safely achieve and maintain their individual HbA1c level. Taken together these will allow healthcare professionals to identify and communicate strategies tailored to the individual child or young person
Diabetes UK	NICE	25	1.2.58	We welcome the awareness of potential conflict between children and young people and parents and the need to agree a compromise	Thank you for this comment in support of the guideline
Diabetes UK	NICE	25	1.2.59	We are concerned about the recommendation of 5 or more tests a day and question how children and young people will be able to achieve the new lower HbA1c targets on 5 tests a day. We appreciate that "at least" is stated but feel the figure 5 will be the one that is remembered. We note that in the adult Type 1 guidance, 10 or more tests a day may be appropriate in certain circumstances. We appreciate that some of the circumstances applicable to adults will not be the same for children, but the recommendation must take into account the effect of growth and development on blood glucose level, the risks associated with hypos in children and potential of driving in older teenagers, and recognise that a higher number of tests per day	Thank you for this comment. The guideline guideline development group 's discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that should be recommended, but also the timing at which the tests should be performed. The evidence reviewed for the guideline demonstrated that glycaemic control improves with the number of capillary tests performed up to 5 five tests

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				may need to be the norm. We are concerned that the recommendation of "at least 5 tests a day" may result in a restriction of test strips as GPs may only prescribe enough for 5 tests a day, which will not be sufficient for many children and young people. We therefore think the recommendation should state that testing up to 10 or more times a day may be necessary for some children and young people.	per day. They concluded, therefore, that at least 5 tests should be performed routinely, and emphasised in the revised recommendations that it is often necessary to conduct more than 5 tests. They did not, however, wish to specify an upper limit for the number of tests, nor the exact timing for the minimum number of tests because to do so would remove some flexibility that is otherwise available to the child or young person and their family members or carers (as appropriate), which supports the possibility of more frequent testing highlighted in the comment, and will promote continuity of approach during transition to adult services The recommendations have been revised to emphasise the need to have enough test strips available to meet the child or young person's needs in terms of testing at least 5 times per day and often even more frequently than this
National Children and Young People's Diabetes Network	NICE	25	1.2.59	Guidance of the timings of these 5 tests would be helpful	Thank you for this comment. The guideline guideline development group 's discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that should be recommended, but also the timing at which the tests should be performed. The evidence reviewed for

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					the guideline demonstrated that glycaemic control improves with the number of capillary tests performed up to 5 five tests per day. They concluded, therefore, that at least 5 tests should be performed routinely, and emphasised in the revised recommendations that it is often necessary to conduct more than 5 tests. They did not, however, wish to specify an upper limit for the number of tests, nor the exact timing for the minimum number of tests because to do so would remove some flexibility that is otherwise available to the child or young person and their family members or carers (as appropriate)
National Children and Young People's Diabetes Network	NICE	25	1.2.59	Concerned about the recommendation of 5 or more tests a day and question how children and young people will be able to achieve the new lower HbA1c targets on 5 tests a day. We appreciate that "at least" is stated but feel the figure 5 will be the one that is remembered. We note that in the adult Type 1 guidance, 10 or more tests a day may be appropriate in certain circumstances. We appreciate that some of the circumstances applicable to adults will not be the same for children, but the recommendation must take into account the effect of growth and development on blood glucose level, the risks associated with hypos in children and potential of driving in older teenagers, and recognise that a higher number of tests per day may need to be the norm.	Thank you for this comment. The guideline guideline development group 's discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that should be recommended, but also the timing at which the tests should be performed. The evidence reviewed for the guideline demonstrated that glycaemic control improves with the number of capillary tests performed up to 5 five tests per day. They concluded, therefore, that at least 5 tests should be performed routinely, and emphasised in the revised recommendations that it is often necessary to conduct more than 5 tests. They did not,

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					however, wish to specify an upper limit for the number of tests, nor the exact timing for the minimum number of tests because to do so would remove some flexibility that is otherwise available to the child or young person and their family members or carers (as appropriate), which supports the possibility of more frequent testing highlighted in the comment, and will promote continuity of approach during transition to adult services The recommendations have been revised to emphasise the need to have enough test strips available to meet the child or young person's needs in terms of testing at least 5 times per day and often even more frequently than this
Royal College of Nursing	NICE	25	1.2.59	We feel that guidance around the timings of these 5 capillary glucose tests would be helpful.	Thank you for this comment. The guideline guideline development group 's discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that should be recommended, but also the timing at which the tests should be performed. The evidence reviewed for the guideline demonstrated that glycaemic control improves with the number of capillary tests performed up to 5 five tests per day. They concluded, therefore, that at least 5 tests should be performed

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					routinely, and emphasised in the revised recommendations that it is often necessary to conduct more than 5 tests. They did not, however, wish to specify an upper limit for the number of tests, nor the exact timing for the minimum number of tests because to do so would remove some flexibility that is otherwise available to the child or young person and their family members or carers (as appropriate)
Royal College of Paediatrics and Child Health	NICE	25	1.2.59	Guidance of the timings of these 5 tests would be helpful	Thank you for this comment. The guideline development group 's discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that should be recommended, but also the timing at which the tests should be performed. The evidence reviewed for the guideline demonstrated that glycaemic control improves with the number of capillary tests performed up to 5 five tests per day. They concluded, therefore, that at least 5 tests should be performed routinely, and emphasised in the revised recommendations that it is often necessary to conduct more than 5 tests. They did not, however, wish to specify an upper limit for the number of tests, nor the exact timing for the minimum number of tests because to do so would remove some flexibility that is otherwise available to the child or young

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					person and their family members or carers (as appropriate)
Royal College of Paediatrics and Child Health	NICE	25	1.2.59	Guidance of the timings of these 5 tests would be helpful	Thank you for this comment. The guideline development group 's discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that should be recommended, but also the timing at which the tests should be performed. The evidence reviewed for the guideline demonstrated that glycaemic control improves with the number of capillary tests performed up to 5 five tests per day. They concluded, therefore, that at least 5 tests should be performed routinely, and emphasised in the revised recommendations that it is often necessary to conduct more than 5 tests. They did not, however, wish to specify an upper limit for the number of tests, nor the exact timing for the minimum number of tests because to do so would remove some flexibility that is otherwise available to the child or young person and their family members or carers (as appropriate)
Royal College of Nursing	NICE	25	1.2.60	We agree that it is helpful to have a suggested number of blood glucose tests (1.2.59) – however, it is very likely that more frequent testing will be required during illness. Experience from clinical practice suggests that it is very likely that more frequent testing will be required during illness.	Thank you for this comment. The guideline development group discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that should be recommended, but also the timing at which the tests should be

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				We are also aware of some parents' complain of the difficulty they experience in getting sufficient testing strips from GPs during this time period. It would be helpful to discuss night time blood glucose testing at this point. We would suggest that the recommendation should be in alignment with International Society for Pedriatric and Adolescent Diabetes (ISPAD) Consensus 2014 guidelines which recommend that blood glucose should be monitored at least every 3–4 hours including through the night and sometimes every 1–2 hours during illness.	performed. They concluded that at least 5 tests should be performed routinely, and emphasised in the revised recommendations that it is often necessary to conduct more than 5 tests. They did not, however, wish to specify an upper limit for the number of tests, nor the exact timing for the minimum number of tests because to do so would remove some flexibility that is otherwise available to the child or young person and their family members or carers (as appropriate) The recommendations have also been revised to emphasise the need to have enough test strips available to meet the child or young person's needs. This will support more frequent testing during intercurrent illness as is also recommended
The Royal College of Pathologists	NICE	25	5	The phrase 'the following morning' is ambiguous. It is not clear whether it means same day or 24 hours later. The full guideline states '5-7 mmol/litre for young people who drive' is much clearer (although it has a slightly different meaning).	There was a typographical error in the draft guideline for consultation. This has now been corrected to clarify that for fasting blood glucose a target range of 5–7 mmol/litre is advised when the young person intends to drive that morning
Dexcom	NICE	26	1.2.63	Suggest adding CGM use for patients with nocturnal hypoglycaemia. It is a very viable option for children and families as it is unrealistic for patients to wake in the night to monitor SMBG multiple times in patients nocturnal hypoglycaemia	The guideline development group identified very little evidence on which to base recommendations about continuous glucose monitoring in children and young

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					people with type 1 diabetes. Their consensus view was that 'real-time' continuous glucose monitoring should be offered because it allows immediate recognition of changes in blood glucose concentrations in relation to treatments and activities and this in allows for more effective treatment choices to be made. The group felt that the previous strong recommendation to offer continuous glucose monitoring to children and young people with recurrent hypo- or hyperglycaemia remained justified. The group also felt there was sufficient reason to justify the consideration of continuous glucose monitoring for some children and young people in whom tight glycaemic control might be of particular concern. However, the group did not identify nocturnal hypoglycaemia as a specific indication for offering or considering continuous glucose monitoring, although the reference to devices with alarms would cover their use in such circumstances
Juvenile Diabetes Research Foundation	NICE FULL	26 195	1.2.63 7.6 63 18-22	We very much welcome the recommendation to offer ongoing unblinded continuous glucose monitoring with alarms to children and young people who have frequent severe hypoglycaemia or impaired awareness of hypoglycaemia. Hypoglycaemia is a significant risk posed by intensive insulin therapy and is also known to be a primary barrier to glycaemic control.	Thank you for this comment in support of the guideline. The guideline development group identified very little evidence on which to base recommendations about continuous glucose monitoring in children and young people with type 1 diabetes.

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				As set out earlier, we would also recommend that the GDG consider the benefits of low glucose suspend systems to reduce the risk of nocturnal hypoglycaemia and diabetic coma, particularly in light of the forthcoming NICE Diagnostic Assessment Programme for the Medtronic MiniMed Paradigm Veo (due October 2015).	Their consensus view was that 'real-time' continuous glucose monitoring should be offered because it allows immediate recognition of changes in blood glucose concentrations in relation to treatments and activities and this in allows for more effective treatment choices to be made. The group felt that the previous strong recommendation to offer continuous glucose monitoring to children and young people with recurrent hypo- or hyperglycaemia remained justified. The group also felt there was sufficient reason to justify the consideration of continuous glucose monitoring for some children and young people in whom tight glycaemic control might be of particular concern. However, the group did not identify any evidence to support a specific recommendation to offer devices incorporating glucose suspend systems
National Children and Young People's Diabetes Network	NICE	26	1.2.63	This is ideal but funding is variable stronger requirements for this is needed to support teams applying for funding which often has to be via IFR	NICE guidelines do not have the same funding directive (mandatory implementation) that applies to NICE Technology Appraisal guidance, but it is expected that services will be commissioned to implement the guideline recommendations. By including a recommendation about offering real-time continuous glucose monitoring as a key

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					priority for implementation (key recommendation) the guideline development group have emphasised the importance of this recommendation for clinical practice
Royal College of Nursing	NICE	26	1.2.63 1.2.64	Funding is variable for continuous glucose monitors, stronger requirements for this is needed to support teams applying for funding which often has to be via individual funding requests.	NICE guidelines do not have the same funding directive (mandatory implementation) that applies to NICE Technology Appraisal guidance, but it is expected that services will be commissioned to implement the guideline recommendations. By including a recommendation about offering real-time continuous glucose monitoring as a key priority for implementation (key recommendation) the guideline development group have emphasised the importance of this recommendation for clinical practice
Abbott Diabetes Care	NICE	26	1.2.64	We support this recommendation and also propose that real time unblinded CGM is also considered for those who have unstable glucose levels or above target A1C levels to improve glycaemic variability. We also propose that this recommendation includes the use of real time CGM to gain information about variability in blood glucose levels. This would also align with the recently published NG3 guidelines on diabetes in pregnancy.	Thank you for this comment in support of the guideline. The guideline development group identified very little evidence on which to base recommendations about continuous glucose monitoring in children and young people with type 1 diabetes. Their consensus view was that 'real-time' continuous glucose monitoring should be offered because it allows immediate recognition of changes in blood glucose concentrations in relation to treatments

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					and activities and this in allows for more effective treatment choices to be made. The group felt that the previous strong recommendation to offer continuous glucose monitoring to children and young people with recurrent hypo- or hyperglycaemia remained justified. The group also felt there was sufficient reason to justify the consideration of continuous glucose monitoring for some children and young people in whom tight glycaemic control might be of particular concern. However, the group did not identify the factors mentioned in the comment as specific indications for offering or considering continuous glucose monitoring in children and young people with type 1 diabetes
Juvenile Diabetes Research Foundation	NICE FULL	26 195	1.2.64 7.6 64 23 29	We support the recommendation to consider ongoing unblinded continuous glucose monitoring for the children and young people as identified at 1.2.64 (NICE version) and would urge healthcare professionals to clearly discuss the pros and cons of the technology with children and their families during consultation.	Thank you for this comment. The guideline development group did not identify any evidence to support a specific recommendation as suggested in the comment. However, other recommendations in the guideline emphasise providing opportunities for the child or young person and their family or carers (as appropriate) to discuss any concerns and raise questions. There are also recommendations both to offer continuous glucose monitoring

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					(emphasising management of hypoglycaemia as a priority) and to consider continuous glucose monitoring for specific groups. Recommendations phrased as consider are more likely to depend of patients' values and preferences and so healthcare professionals should spend more time considering and discussing the options with the relevant groups of patients. This is reflected in the standard text included at the beginning of the NICE guideline (short version) under the heading of patient-centred care
Royal College of Nursing	NICE	26	1.2.64	It is really helpful to see the inclusion of continuous glucose monitoring in this document and we support the recommendation that consideration should be given for those with severe hypoglycaemia and/or the younger age group.	Thank you for this comment in support of the guideline
Royal College of Paediatrics and Child Health	NICE	26	1.2.64	This is ideal but funding is variable stronger requirements for this is needed to support teams applying for funding which often has to be via IFR	NICE guidelines do not have the same funding directive (mandatory implementation) that applies to NICE Technology Appraisal guidance, but it is expected that services will be commissioned to implement the guideline recommendations. By including a recommendation about offering real-time continuous glucose monitoring as a key priority for implementation (key recommendation) the guideline development group have emphasised the importance of this recommendation for

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					clinical practice
Juvenile Diabetes Research Foundation	NICE FULL	26 195	1.2.65 7.6 65	JDRF requests revision of draft recommendation 65 to reflect better the evidence supporting the efficacy of CGM in reducing HbA1c in children and young people with type 1 diabetes. This recommendation is based on evidence from individual randomised controlled clinical trials and systematic reviews and Endocrine Society/European Society of Endocrinology co-sponsored Clinical Practice Guidelines for Continuous Glucose Monitoring (http://www.ese-hormones.org/guidelines/docs/ESEJointEndocrineSocietyGuidelines.pdf and http://press.endocrine.org/doi/pdf/10.1210/jc.2010-2756). Below we highlight our recommendations for revising recommendation 65. 65. ~~Consider~~ Offer ~~intermittent (~~unblinded ('real-time') ~~or blinded ('retrospective'))~~ continuous glucose monitoring to help improve blood glucose control in children and young people who are willing to commit to using it at least 70% of the time and to calibrate it as needed and who continue to have hyperglycaemia despite insulin adjustment and additional support. [new 2015] In addition to the evidence already presented in the Institute's draft guidelines, JDRF offers additional evidence. Battelino T, Conget I, Olsen B, et al. The use and efficacy of continuous glucose monitoring in type 1 diabetes treated with insulin pump therapy: a randomised controlled trial. Diabetologia 2012: 3155-3162. The randomised controlled trial reported on by Battelino et al. was a multicentre, randomised, controlled crossover study to determine the efficacy of adding continuous glucose monitoring (CGM) to insulin pump therapy in type 1 diabetes. The primary endpoint of the trial was change in HbA1c level between sensor on	Thank you for this comment. The conclusions of the systematic reviews related to continuous glucose monitoring and self-monitoring of blood glucose were led by evidence meeting the inclusion criteria set out in relevant review protocols (Appendix E of the full guideline). Recommendations for continuous glucose monitoring were mainly informed by evidence from two systematic reviews conducted as part of the guideline development process. One review assessed the effectiveness of 'real-time' continuous glucose monitoring in comparison with intermittent monitoring, while the other compared the effectiveness of continuous glucose monitoring against self-monitoring of blood glucose. The guideline development group have checked the evidence mentioned in the comment, however none of the articles met the inclusion criteria in our review protocols, specifically: • Battelino 2012: the study assessed the efficacy of adding continuous glucose monitoring to insulin pump therapy in comparison with not adding

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				and sensor off arms after 6 months of follow-up. The trial enrolled both children and adults who were randomised to one of two continuous glucose monitoring arms – sensor on/sensor off sequence or sensor off/sensor on sequence. In the sensor on/sensor off sequence arm, participants wore unblinded real-time CGM for 6 months, followed by a 4 month washout period, and then 6 months of blinded CGM. In the sensor off/sensor on sequence arm, participants work blinded CGM for 6 months, followed by a 4 month washout period, and then 6 months of real-time CGM. Results were reported separately for children. The mean difference in HbA1c between sensor on and sensor off arms was -0.46% (-5.0 mmol/mol) (95% CI -0.26%, -0.66% [-2.8, -7.2 mmol/mol]; p<0.001) in paediatric participants. From study results, the study authors conclude that in paediatric participants with type 1 diabetes using insulin pump therapy alone, the addition of CGM results in an improvement in HbA1c and the removal of CGM resulted in a loss of benefit. Bergenstal RM, Tamborlane WV, Ahmann A, et al. Effectiveness of sensor-augmented insulin-pump therapy in type 1 diabetes. N Engl J Med 2010: 311-320. (Note: Data from this study was included in the systematic review identified for inclusion in the guideline review (Langendam 2012), but was not considered by the Institute.) The 1 year, multicentre, randomised, controlled trial reported on by Bergenstal et al. compared the efficacy of sensor-augmented pump therapy (pump + CGM) to the efficacy of multiple daily injections (MDI + SMBG) in adults and children with inadequately controlled type 1 diabetes. The primary endpoint was the change from baseline HbA1c. At 1 year, among children, the baseline mean HbA1c had decreased -0.5 percentage points (95% CI, -0.8 to -0.2; p<0.001). Poolsup N, Suksomboon N, Kya AM. Systematic review and meta-analysis of the effectiveness of continuous glucose monitoring (CGM) on glucose control in	continuous glucose monitoring to the insulin pump therapy; thus the comparison was between having continuous monitoring and not having continuous monitoring. This comparison was not relevant to either of the guideline review protocols. The lists of excluded studies (Appendix H) have been revised to clarify that the main reason for exclusion of this study was irrelevant comparison of interventions rather than results for children and young people and those for adults not being reported separately. • Bergenstal 2010: the study was excluded because participants were randomly assigned to insulin pump therapy or insulin injection therapy and then given a form of continuous glucose monitoring. The care delivered in the two groups was not comparable, therefore the study was unable to tell whether any differences between the groups was due to the form of continuous glucose monitoring or the

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				diabetes. Diabetology & Metabolic Syndrome 2013. 5:39. This systematic review and meta-analysis looks specifically at the evidence related to the effectiveness of CGM in children and young people with type 1 diabetes. The meta-analysis related to real-time CGM included five studies (Battelino 2012, Bergenstal 2010, JDRF 2008, Kordonouri 2010, and Mauras 2012). The results of the meta-analysis indicate that glycaemic control (HbA1c) is better with real-time CGM compared with self-monitoring of blood glucose (SMBG) [mean difference -0.18% (95% CI, -0.35% to -0.02%, p=0.02). Moreover, although the studies included in the meta-analysis have clinical and methodological differences, the heterogeneity of the model specific to real-time CGM vs SMBG as assessed by the I^2 statistic was only 48% - indicating only some heterogeneity. Pickup JC, Freeman SC, Sutton AJ. Glycaemic control in type 1 diabetes during real time continuous glucose monitoring compared with self-monitoring of blood glucose: meta-analysis of randomised controlled trials using individual patient data. BMJ 2011;343:d3805. Although not specific to children and young people, this IPD meta-analysis does include data for this population and is a unique examination of the impact of real time continuous glucose monitoring compared with self-monitoring of blood glucose. IPD meta-analyses are considered the gold standard of systematic reviews. Results from IPD meta-analyses are regarded as more reliable and interpretable than results from other types of systematic reviews. Because reviewers have access to raw data, IPD meta analyses allow for more detailed analyses such as subgroup analyses. For example, Pickup et al. were able to test the effect of baseline HbA1c, sensor usage, age, and other covariates on CGM outcomes	different insulin regimens (i.e. insulin pump therapy versus insulin injection therapy). • As commented, this study was included in the Langendam 2012 systematic review that was included in the guideline review. However, Langendam 2012 was included under a review that focused on the comparison between continuous blood glucose monitoring and capillary (finger-prick) testing. The evidence table in the full guideline (Appendix I) states that not all studies included in Langendam 2012 met the review protocol inclusion criteria. Therefore findings from Bergenstal 2010 were not considered there either. • Poolsup 2013: this systematic review examined the effectiveness of continuous blood glucose monitoring on HbA1c in comparison with self-monitoring of blood glucose. All relevant studies included in this review were included in the guideline

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				because they utilised individual patient data. These types of analyses are not possible using aggregate or summary data from published trials – the type of approach utilised in the 2012 Cochrane Review or the 2013 systematic review described by Poolsup, Suksomboon, and Kyaw. The results of this IPD indicate that CGM reduces HbA1c and that reductions are greatest in those with higher baseline HbA1c and those who use CGM consistently. Moreover, the analysis indicates that age has only a small effect on the efficacy of CGM compared with self-monitoring of blood glucose. The specific effect is 0.002%. The authors provide a concrete example to describe the effect – "…continuous glucose monitoring would be expected to reduce the HbA1c level by only an extra 0.05% in a 40 year old with diabetes compared with a 15 year old with diabetes." Endocrine Society/European Society of Endocrinology co-sponsored Clinical Practice Guidelines for Continuous Glucose Monitoring 2.0 RT-CGM in children and adolescent outpatients 2.1 We recommend that RT-CGM with currently approved devices be used by children and adolescents with type 1 diabetes mellitus (T1DM) who have achieved glycosylated hemoglobin (HbA1c) levels below 7.0% because it will assist in maintaining target HbA1c levels while limiting the risk of hypoglycemia. 2.2 We recommend RT-CGM devices be used with children and adolescents with T1DM who have HbA1c levels $\geq$ 7.0% who are able to use these devices on a nearly daily basis. 2.3 We make no recommendations for or against the use of RT-CGM by children withT1DMwho are less than 8 yr of age.	review except for Battelino 2012, which did not meet the review protocol inclusion criteria as stated above. • Pickup 2011: this systematic review examined the effectiveness of continuous blood glucose monitoring in comparison with self-monitoring of blood glucose, but the mean age of the participants exceeded 18 years in all of the included studies and no separate results were reported for children and young people (< 18 years), therefore this review was not included in the guideline review, nor were any of the individual studies in the published review. The lists of excluded studies (Appendix H) have been revised to clarify the exclusions summarised above

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				2.4 We suggest that treatment guidelines be provided to patients to allow them to safely and effectively take advantage of the information provided to them by RT-CGM.	
Medtronic	NICE	26	10	We feel that the use of the word 'unblinded' is not necessary in the description of CGM and may be confusing. Use of the word 'unblinded' in relation to CGM is also inconsistent with the Type 1 Diabetes in Adults Guideline, where it is solely referred to as 'real-time'. We suggest that this is removed and replaced throughout with: • 'real-time continuous glucose monitoring' Regarding the specific patient groups mentioned in this statement, we believe that children and young people with poor control of HbA1c should also be included as a subgroup for consideration of CGM. Cochrane reviewers (Langendam et al., 2012) found that children using CGM were more successful at improving their HbA1c by at least 0.5% compared with children using self-monitored blood glucose at 3 months (46% vs. 28%, 95% CI 1.02 to 2.78) and at six months after baseline (54% versus 31%, 95% CI 1.10 to 2.72), as based on the JDRF trial (JDRF, 2008). Early optimisation of HbA1c and good blood glucose control in the initial months following diagnosis may result in better HbA1c control in later years (Samuelsson et al., 2014). This Swedish review also demonstrated that children with poor HbA1c control during the 3-15 months after diagnosis were also at a higher risk of microvascular complications in early adulthood. Given the evidence from RCTs and real-life registries, we feel it is therefore important to consider poor control of HbA1c as a criterion for offering CGM in children and young people. In keeping with these findings, Sweden has recently published updated clinical guidelines on	Thank you for this comment. The terminology with regard to continuous glucose monitoring has been harmonised across the NICE diabetes guidelines that are being updated concurrently. As part of this process the term unblinded has been deleted The guideline development group identified very little evidence on which to base recommendations about continuous glucose monitoring in children and young people with type 1 diabetes. Their consensus view was that 'real-time' continuous glucose monitoring should be offered because it allows immediate recognition of changes in blood glucose concentrations in relation to treatments and activities and this in allows for more effective treatment choices to be made. The group felt that the previous strong recommendation to offer continuous glucose monitoring to children and young people with recurrent hypo- or hyperglycaemia remained justified. The group also felt there was sufficient reason

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				the use of long-term CGM in children, noted below. Current Swedish Guidelines (2015) - Indications for long-term use of CGM: • CGM should preferably be initiated before the child´s glycaemic control deteriorates, given the long-term risks associated with a high HbA1c. • CGM shall be offered to children if treating physicians judges it necessary to measure blood glucose levels> 10 times per day to achieve good glycaemic control, i.e. HbA1c <50-57 mmol/ mol with good variability (glucose variability where SD <3.5 mmol/l) and minimal number of hypoglycaemic events. • Children younger than seven years with T1DM should be offered CGM considering the sensitivity the very young brain has to abnormal glucose levels and very young children's difficulty in identifying hypoglycaemia. • Children / young people in puberty (Tanner stage II-IV) should be offered CGM, considering the growth-related difficulties encountered with insulin therapy during this period and puberty as an accelerator for the development of complications. • Children with additional disabilities of cognitive or neuropsychiatric nature beyond T1DM should be offered CGM, given the particular difficulties this involves. • Families with two or more children with T1DM should be offered CGM considering the parents high workload of treating the children. • If a child with T1DM have extremely high HbA1c (> 70 mmol / mol), CGM should be offered as part of a multidisciplinary team collaboration to help the child to	to justify the consideration of continuous glucose monitoring for some children and young people in whom tight glycaemic control might be of particular concern. However, the group did not identify any evidence to support a specific recommendation to offer continuous glucose monitoring to other groups of children and young people with type 1 diabetes other than those who are unable to recognise, or communicate about, symptoms of hypoglycaemia (for example, due to cognitive or neurological disabilities). The recommendation has been expanded to include the latter group

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				lower their HbA1c to a level that has a significantly lower complication risk. References Langendam et al., 2012. Continuous glucose monitoring systems for type 1 diabetes mellitus (Review). The Cochrane Collaboration. The Cochrane Library 2012, Issue 2. JDRF, 2008. Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes. N Engl J Med, 394(14). Samuelsson et al., 2014. A high mean-HbA1c value 3–15 months after diagnosis of type 1 diabetes in childhood is related to metabolic control, macroalbuminuria, and retinopathy in early adulthood – a pilot study using two nation-wide population based quality registries. Pediatric Diabetes: 15: 229–235 Swedish Clinical Guidance Document: Issued by the Pediatric Society of Endocrinology and Diabetes, 2015. http://www.dagensdiabetes.se/home/diabetologNytt/1794-riktlinjer-2015-foer-kontinuerlig-glukosmaetning--continuous-glucose-monitoring-cgm-foer-barn-och-ungdomar-med-t1dm.html	
Diabetes UK	NICE	27	1.2.68	Whilst we appreciate this target may be ideal in helping to avoid long term complications, we are concerned that the lower Hba1c target is potentially unachievable, especially give the recommendation for 5 tests a day. We feel that this lower target will also potentially increase the risk of hypoglycaemia, which parents and children and young people tell us is of great concern to them. It could also dis-incentivise children and young people who are already struggling to meet the current target of 53 mmols/mol.	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1

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				The guideline must also put greater emphasis on the need to set individual targets through discussion with the child and family.	diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should

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					be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline The reference in the comment to the minimum number of times per day that blood glucose monitoring should be performed has been considered carefully. The revised recommendations emphasise that more frequent testing is often needed, and examples of situations where this

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					would apply are provided in the recommendations. The minimum number of 5 tests per day is, however, based on the available evidence; there is no evidence to support an added clinical benefit of setting the minimum number at a higher level for all children and young people with type 1 diabetes
National Children and Young People's Diabetes Network	NICE	27	1.2.68	I particularly have concerns about this target for the following reasons It is a target we will be measured on Without funding of CGMS it will be hard to achieve Families major concerns are nocturnal hypoglycaemia and dead in bed we need to get the best control possible and a target of 53 mol/ mol (7%) would be more realistic/ achievable The risks of low HBA1c in children has not been established in the past adult target was tighter & was released after some studies This is the evidence I am basing comments on http://m.diabetes.diabetesjournals.org/content/63/5/1457.full	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully, including this comment and the reference to evidence within it, and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances.

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					The avoidance of hypoglycaemia was a key aim of the review (see the review protocol in Appendix E) and this was carefully taken into consideration when agreeing the target based on the evidence identified for inclusion.The guideline development groupstrongly believe that lowering the target compared to the previous (2004) guideline is an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline
National Children and Young People's Diabetes Network	NICE	27	1.2.68	Appreciate this target may be ideal in helping to avoid long term complications, we are concerned that the lower Hba1c target is potentially unachievable, especially give the recommendation for 5 teats a day. Will also potentially increase the risk of hypoglycaemia, which parents and CYP tell us is of great concern to them. Also could dis-incentivise CYP who are already struggling to meet the current target of 53 mmols/mol. The guideline must also put greater emphasis on the need to set individual targets through discussion with the child and family	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is

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					achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that

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					the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline The reference in the comment to the minimum number of times per day that blood glucose monitoring should be performed has been considered carefully. The revised recommendations emphasise that more frequent testing is often needed, and examples of situations where this would apply are provided in the recommendations. The minimum number of 5 tests per day is, however, based on the available evidence; there is no evidence to support an added clinical benefit of setting the minimum number at a higher level for all children and young people with type 1 diabetes

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Royal College of Nursing	NICE	27	1.2.68	Whilst we agree with the importance of optimising glycaemic control, the ISPAD 2014 consensus guidelines highlighted concerns re hypoglycaemia in the developing brain. We also have further concerns about this target for the following reasons: It is a target will be measured on and without funding of continuous glucose monitors it will be hard to achieve. Families' major concerns are nocturnal hypoglycaemia and 'dead-in–bed' syndrome and healthcare professionals need to get the best control possible. We consider that a target of 53 mol/ mol (7%) would be more realistic/ achievable and more appropriate given the restrictions to those available to benefit from real time continuous glucose monitors. The risks of low HBA1c in children has not been established in the past. Adult target was tighter was released after some studies (Clark et al 2014) Reference: Clark A.L, Best C. J & Fisher S.J (2014) Even Silent Hypoglycemia Induces Cardiac Arrhythmias, Diabetes May 2014 vol. 63 no. 5 1457-1459 http://m.diabetes.diabetesjournals.org/content/63/5/1457.full	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The

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					phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline

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					The guideline development group did not consider it necessary to make a specific recommendation about night-time testing, but the recommendations do not prevent this, since the timing of the minimum number of 5 tests that should be performed each day is not prescribed in the recommendations. Night-time testing to avoid or detect nocturnal hypoglycaemia is, therefore, not an issue that requires more specific discussion in the recommendations
Royal College of Nursing	NICE	27	1.2.68	Following from our comments above; the wording '48 mmol/mol (6.5%) or lower' should be clarified to give some guidance as to how low an HbA1c is safe in children.	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people

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					and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1

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					diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline
Royal College of Paediatrics and Child Health	NICE	27	1.2.68	I particularly have concerns about this target for the following reasons It is a target we will be measured on Without funding of CGMS it will be hard to achieve Families major concerns are nocturnal hypoglycaemia and dead in bed we need to get the best control possible and a target of 53 mol/ mol (7%) would be more realistic/ achievable The risks of low HBA1c in children has not been established in the past adult target was tighter & was released after some studies This is the evidence I am basing comments on http://m.diabetes.diabetesjournals.org/content/63/5/1457.full	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully, including this comment and the reference to evidence within it, and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children

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					and young people and their families or carers that targets should be individualised to take account of personal circumstances. The avoidance of hypoglycaemia was a key aim of the review (see the review protocol in Appendix E) and this was carefully taken into consideration when agreeing the target based on the evidence identified for inclusion. The guideline development group strongly believed that lowering the target compared to the previous (2004) guideline is an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline
Royal College of Paediatrics and Child Health	NICE	27	1.2.68	Appreciate this target may be ideal in helping to avoid long term complications, we are concerned that the lower Hba1c target is potentially unachievable, especially give the recommendation for 5 teats a day. Will also potentially increase the risk of hypoglycaemia, which parents and CYP tell us is of great concern to them. Also could dis-incentivise CYP who are already struggling to meet the current target of 53 mmols/mol. The guideline must also put greater emphasis on the need to set individual targets through discussion with the child and family	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very

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					carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based

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					on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline The reference in the comment to the minimum number of times per day that blood glucose monitoring should be performed has been considered carefully. The revised recommendations emphasise that more frequent testing is often needed, and examples of situations where this would apply are provided in the recommendations. The minimum number of 5 tests per day is, however, based on the available evidence; there is no evidence to support an added clinical

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					benefit of setting the minimum number at a higher level for all children and young people with type 1 diabetes
National Children and Young People's Diabetes Network	NICE	27	1.2.69 1.2.70	These 2 statements are potentially contradictory for the team, which one would they prioritise?	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the

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					ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. In this sense, the individualisation of targets would take precedence over aiming for or achieving a lower target that did not take account of the individual's circumstances. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an

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					important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline
Dexcom	NICE	27	1.2.7	Consideration to the value of HbA1c: the A1c does not reflect glycaemic variability (frequency of hypos or hyperglycaemia) as it only reflects the past 3 month average. As patients strive for a normal A1c, the most common downside is frequent hypoglycaemia. Therefor CGM may be a useful tool for these patients as a way to measure "time in target" which is a good estimate of A1c while also identifying hypo or hyperglycaemic excursions.	Thank you for this comment. The recommendations with regard to HbA1c targets have been rephrased and strengthened in the light of stakeholder comments on the draft guideline, and the explanations for the recommendations in the evidence to recommendations section of the full guideline have been expanded and clarified. With regard to using continuous glucose monitoring, the recommendations in the guideline take account of the available evidence and the indications for offering or considering continuous glucose monitoring have been clarified in the revised recommendations
National Children and Young People's Diabetes Network	NICE	27	1.2.70	This will not happen if teams are measured via NPDA BPT & DQUINS on %patients with specific HbA1cs	Thank you for this comment. While the recommended target for HbA1c has been retained in the revised guideline, a further recommendation has been added stating that diabetes services should document the proportion of children and young people with type 2 diabetes in a service who achieve an HbA1c level of 53 mmol/mol (7%) or lower. The targets for

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					HbA1c and the documentation of service-level achievement were agreed collaboratively through discussions involving the various guideline development groups updating diabetes guidelines for NICE, and this process was coordinated by NICE
Royal College of Nursing	NICE	27	1.2.70	We consider that there might be barriers to the implementation of this guideline if teams are measured via the National Paediatric Diabetes Audit Best Practice Tariff and Diabetes Quality Improvement Network Systems on % of patients with specific HbA1c.	Thank you for this comment. While the recommended target for HbA1c has been retained in the revised guideline, a further recommendation has been added stating that diabetes services should document the proportion of children and young people with type 2 diabetes in a service who achieve an HbA1c level of 53 mmol/mol (7%) or lower. The targets for HbA1c and the documentation of service-level achievement were agreed collaboratively through discussions involving the various guideline development groups updating diabetes guidelines for NICE, and this process was coordinated by NICE
Royal College of Nursing	NICE	27	1.2.72	Rather than the word "poor control" would HbA1c > be more appropriate.	This recommendation has been revised to state that children and young people with type 1 diabetes should be offered measurement of their HbA1c level more than 4 times a year if there is concern about suboptimal blood glucose control. This phrasing allows for clinical judgement

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					to be used, taking account of individualised targets and personal circumstances. This recommendation is, however, in part of the guideline that is not covered by the 2015 update scope and so the evidence to specify what constitutes suboptimal control in this context has not been reviewed and the recommendation cannot be made more specific
The Royal College of Pathologists	NICE	27	2	Should strictly say 'Calibrate HbA1c assays' rather than 'results', or perhaps 'Use only HbA1c assay that are calibrated according to …..'	Thank you for this comment. The phrasing has been revised as requested and now refers to using methods to measure HbA1c results that have been calibrated according to International Federation of Clinical Chemistry (IFCC) standardisation. This change has been made in both the type 1 and type 2 diabetes sections of the guideline
National Children and Young People's Diabetes Network	NICE	27 207	32 7	Omit "give" and change to "Oral complex long-acting carbohydrate may be required to maintain blood glucose levels if: Mixed insulin is being used Prolonged exercise has been taken Alcohol has been ingested Blood glucose was initially lower"	This change has not been made because it would involve inserting a new recommendation in part of the guideline that is excluded from the 2015 update (management of hypoglycaemia)
Association of British Clinical Diabetologists	NICE	28	General	There is no comment here on modified hypoglycaemia awareness detection and management . The impact of tight targets and hypoglycaemic episodes as a predictor of recurrent and potential severe hypoglycaemia has and the ongoing need to relax control to regain symptoms (assuming carb counting aware) deserves comment .	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been

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					reviewed since the original (2004) guideline (detection and management of hypoglycaemia in this case)
Diabetes UK	NICE	28	1.2.73	The guidance should also add that children, young people and their family members should be educated in how to interpret blood ketone results and action to be taken if blood ketones test positive.	Thank you for this comment. The recommendations have been revised to state that children and young people with type 1 diabetes should be offered blood ketone testing strips and a meter and advised to test for ketonaemia if they become hyperglycaemic or unwell. It was already implicit in the recommendation about providing sick-day rules that children and young people with type 1 diabetes and their family members or carers (as appropriate) should be advised how to interpret blood ketone results, but this has been made explicit in the revised recommendations. The recommendations about intercurrent illness (sick-day rules) and testing blood ketones have been brought together in the revised guideline so that the links between the recommendations are emphasised
National Children and Young People's Diabetes Network	NICE	28	1.2.73	Also need to state provide family with meter that will measure beta ketones, advise the family to carry with them and provide written guidance on the interpretation of beta ketone result with actions to be taken	Thank you for this comment. The recommendations have been revised to state that children and young people with type 1 diabetes should be offered blood ketone testing strips and a meter and advised to test for ketonaemia if they become hyperglycaemic or unwell. It was

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					already implicit in the recommendation about providing sick-day rules that children and young people with type 1 diabetes and their family members or carers (as appropriate) should be advised how to interpret blood ketone results, but this has been made explicit in the revised recommendations. The recommendations about intercurrent illness (sick-day rules) and testing blood ketones have been brought together in the revised guideline so that the links between the recommendations are emphasised
Royal College of Nursing	NICE	28	1.2.73	We also feel that recommendations need to state that the families need to be provided with meters that will measure beta ketones, advice the family to carry the meter with them. They should also be provided with written guidance on the interpretation of beta ketone results with advice on actions to be taken.	Thank you for this comment. The recommendations have been revised to state that children and young people with type 1 diabetes should be offered blood ketone testing strips and a meter and advised to test for ketonaemia if they become hyperglycaemic or unwell. It was already implicit in the recommendation about providing sick-day rules that children and young people with type 1 diabetes and their family members or carers (as appropriate) should be advised how to interpret blood ketone results, but this has been made explicit in the revised recommendations. The recommendations about intercurrent illness (sick-day rules) and testing blood ketones have been

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					brought together in the revised guideline so that the links between the recommendations are emphasised
Royal College of Paediatrics and Child Health	NICE	28	1.2.73	Also need to state provide family with meter that will measure beta ketones, advise the family to carry with them and provide written guidance on the interpretation of beta ketone result with actions to be taken	Thank you for this comment. The recommendations have been revised to state that children and young people with type 1 diabetes should be offered blood ketone testing strips and a meter and advised to test for ketonaemia if they become hyperglycaemic or unwell. It was already implicit in the recommendation about providing sick-day rules that children and young people with type 1 diabetes and their family members or carers (as appropriate) should be advised how to interpret blood ketone results, but this has been made explicit in the revised recommendations. The recommendations about intercurrent illness (sick-day rules) and testing blood ketones have been brought together in the revised guideline so that the links between the recommendations are emphasised
Diabetes UK	NICE	29	1.2.79	This point of the guidance is not fully in line with current ISPAD recommendations https://www.ispad.org/sites/default/files/resources/files/12-assessment_and_management_of_hypoglycemia_in_children_and_adolescents_with_diabetes.pdf and should be clarified to reflect these. Oral complex carbohydrate may not be required for all children and young people following immediate treatment of hypoglycaemia especially for those on pumps and some on MDI. The guideline must be changed to reflect this.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004)

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					guideline (management of hypoglycaemia in this case)
National Children and Young People's Diabetes Network	NICE	29	1.2.79	Smaller amounts of fast acting glucose may be required for young Children	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case)
National Children and Young People's Diabetes Network	NICE	29	1.2.79	ISPAD guidance suggests restoring blood glucose to 5.6 mol / l should a suggested level be provided here.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case)
National Children and Young People's Diabetes Network	NICE	29	1.2.79	Oral complex carbohydrate may not be required for all children and young people following immediate treatment of hypoglycaemia especially for those on pumps and some on MDI. The guideline must be changed to reflect this.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case)
Royal College	NICE	29	1.2.79	Bullet: fast acting glucose: Smaller amounts of fast acting glucose may be	Thank you for submitting comments in

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of Nursing				required for young children.	response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case)
Royal College of Nursing	NICE	29	1.2.79	ISPAD guidance suggests restoring blood glucose to 5.6 mol. Should a suggested level be provided here?	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case)
Royal College of Nursing	NICE	29	1.2.79	ISPAD 0.3g/kg – helps for those pre puberty: If restoring to 5.5 for 45minutes is recommended for those adults driving would it be useful to consider this for CYP who are more reliant on others especially at school and during exams etc?	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case)
Royal College of Paediatrics and Child Health	NICE	29	1.2.79	Smaller amounts of fast acting glucose may be required for young Children	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the

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					guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case)
Royal College of Paediatrics and Child Health	NICE	29	1.2.79	ISPAD guidance suggests restoring blood glucose to 5.6 mol / l should a suggested level be provided here.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case)
Royal College of Paediatrics and Child Health	NICE	29	1.2.79	Smaller amounts of fast acting glucose may be required for young Children	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case)
Royal College of Paediatrics and Child Health	NICE	29	1.2.79	Oral complex carbohydrate may not be required for all children and young people following immediate treatment of hypoglycaemia especially for those on pumps and some on MDI. The guideline must be changed to reflect this.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004)

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					guideline (management of hypoglycaemia in this case)
Royal College of Paediatrics and Child Health	NICE	29	1.2.79	ISPAD guidance suggests restoring blood glucose to 5.6 mol / l should a suggested level be provided here.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case)
Diabetes UK	NICE	30	1.2.85	The word "consider" should be removed - diabetes teams must refer children and young people who have frequent hypos and/or recurrent seizures.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case)
National Children and Young People's Diabetes Network	NICE	30	1.2.85	Remove the word "consider" - diabetes teams must refer CYP who have frequent hypos and/or recurrent seizures	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case)
Royal College	NICE	30	1.2.85	Diabetes teams should consider referring children and young people with type 1	The recommendations about HbA1c

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of Paediatrics and Child Health	FULL			diabetes who have frequent hypoglycaemia and/or recurrent seizures for assessment of cognitive function, particularly if these occur at a young age. [2004] May be referring a lot of CYP if we aim for new targets! Were do we refer to?	targets emphasise the need to take individual circumstances into account and that safely achievable targets should be set. This should reduce the risk of hypoglycaemia, especially given the clinical benefits of modern insulin regimens. The recommendation referred to in the comment is, in any case, in part of the guideline that is not covered by the 2015 update scope and so it cannot be made more specific in terms of to whom the referral should be made. Other recommendations ensure that mental health professionals are included in the multidisciplinary diabetes team and so appropriate referrals may be made through them
Royal College of Ophthalmologists	NICE	30 31	48 4	'Offer children and young people with type 1 diabetes monitoring for: • diabetic retinopathy annually from the age of 12 years' Comment: The guideline only addresses one part of the question (starting age) and has not commented on any evidence for the frequency of the screening. The guideline later stated that 'The aim of this review was to determine when screening for retinopathy should start and how frequently it should be repeated in children and young people with type 1 diabetes (section 11.4.1.1, page 251 lines 9-12). We assume that given that the low quality of the evidence the group decided to maintain this feature of the screening strategy, but the rationale behind this decision would have been a useful addition to the guideline.	Thank you for this comment. The recommendations state that monitoring should be conducted annually in children and young people with type 1 diabetes and those with type 2 diabetes. The 2004 guideline recommended screening annually for children and young people with type 1 diabetes, and the guideline development group found no evidence to direct a change in that aspect of the 2004 recommendation. In the clinical experience of the guideline

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				11.4.1.6.1 Relative value placed on the outcomes considered (page 259) 'The GDG considered the main aim of retinal screening in children and young people with diabetes to be the identification of retinopathy that requires treatment (that is, more advanced stages of retinopathy than background retinopathy). Nevertheless the group felt that there may be some benefit from the identification of minor (background) retinopathy, because in their experience, awareness of this can encourage children and young people to improve their blood glucose control' Comment: A key definition in any screening is the relevant/valuable outcome considered as the main aim of the programme. The relevant outcome defines the screening strategy and pathways for positive results. The GDG appear to consider that treatment is not necessary for background retinopathy. This could either be because • by 'treatment', they mean ophthalmic intervention (which is an unsuitable main aim as laser / intravitreal treatments are associated with a risk of visual morbidity) rather than conservative / systemic treatment to improve disease control and reduce the morbidity associated with microvascular complications • or that background retinopathy does not require systemic treatment (ie improvement of blood sugar control). This reading of their intended meaning is supported by their statements that: 'the incidence of microaneurysms in children and young people is unknown and it is unclear if background retinopathy is specifically associated with DM (section 11.4.1.6.1, page 259, lines 9-11)' 'background retinopathy may fluctuate (section 11.4.1.6.2, lines 35)' although they also later state that 'background retinopathy is often found through monitoring, and improving blood glucose control will reduce the risk of this progressing to serious forms of diabetic retinopathy (section 1.5.116, page 3, lines 20-28)'	development group, although background retinopathy can fluctuate, it remains an important indicator of progression to further damage. This view was neither confirmed nor disproved by the data. As patient outcomes are largely driven by improvements in blood glucose control, the recommendations do not intend to suggest that background retinopathy does not require systemic treatment. The guideline development group believe this is clearly stated in the recommendation for children and young people with type 1 diabetes which advises that 'background retinopathy is often found through monitoring and improving blood glucose control will reduce the risk of this progressing to significant diabetic retinopathy. In this case, the term significant retinopathy is referring to any degree of retinopathy that requires treatment. The same message is conveyed to children and young people with type 2 diabetes: 'background retinopathy is often found through monitoring and improving blood glucose control will reduce the risk of this progressing to significant diabetic retinopathy'

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				We would suggest that whilst there is no evidence on the prevalence of retinal microaneurysms in non-diabetic children, the evidence from adult studies show the whilst microaneurysms are not specifically associated with DM in the elderly population (because they are also present in vasculopathies, eg hypertension), presence of retinal microaneurysms in working age non-diabetic adults predicts a future diagnosis of diabetes (Klein et al. 2006. The relationship of retinopathy in persons without diabetes to the 15-year incidence of diabetes and hypertension: Beaver Dam Eye Study. Trans Am Ophthalmol Soc.104:98-107). This supports the importance of the finding of background retinopathy in children diagnosed with DM, and the importance of intervention at this early stage. Whilst background retinopathy (BDR) may fluctuate in severity there is no evidence that it fluctuates in the absence of medical intervention, whether that be due to conservative measures following a diagnosis of BDR. The proportion of children who show signs of regression is unknown and more studies are needed to examine the natural history of background retinopathy and more advanced stages of the disease. Without evidence about the natural history of background retinopathy, the relationship between benefits and harms is difficult to calculate. As a related issue, we also feel it is important for the GDG to define what they mean by 'significant retinopathy', as used in the following statements: ' annual screening from the age of 12 years is important because, if significant diabetic retinopathy is found, early treatment will improve the outcome. (section 1.5.116, page 31, line 29-31, and section 11.4.1.6.6, page 260 lines 37-38') We suggest that any degree of retinopathy including BDR is significant retinopathy (for the reasons outlined above), and that the main aim of eye examination in	

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				children with type 1 and 2 DM is to identify those at risk of both visual impairment due to retinopathy and further systemic morbidity due to microvascular complications. This would fall under screening rather than monitoring, although once BDR is detected, further examinations would constitute monitoring in order to detect worsening of retinopathy which would justify referral to hospital eye services. We support the recommendation that in children with type 2 DM 'the identification of any grade of retinopathy (even that which is not immediately sight threatening) may be of importance" (section 17.3.6.1, page 316, lines 16-17).	
Diabetes UK	NICE	32	1.2.95 1.2.97	We feel that the guideline should be consistent with the Paediatric Diabetes Best Practice Tariff which states: "Each patient must have an annual assessment by their MDT as to whether input to their care by a clinical psychologist is needed, and access to psychological support, which should be integral to the team, as appropriate". The guideline should be altered to reflect this.	The guideline development group consider that the recommendations are complementary to the Best Practice Tariff and do not preclude an annual assessment to determine the need for psychological support. The linking evidence to recommendations section of the review has been amended to clearly state this
British Psychological Society	NICE	32 33 43	1.2.98 1.2.99 1.3.36	The language here is potentially misleading, and also the evidence is poor to support offering behavioural family systems therapy. Clinically, however, addressing the role of the parents and family is crucial, but the intervention needs to be individualised (based on a formulation), and effective. Anecdotally, most of my clinical interventions are working to decrease anxiety/PTSD and depression in the main carer, and booster their approach-based coping strategies, by using a range of therapeutic models and interventions based on a Formulation. The Full guideline (pg. 214) acknowledges the impact on parents, but this in not translated in the NICE document.	Thank you for this comment. The guideline development group acknowledge that the evidence base for psychological interventions was weak and has reflected this in the strength of the recommendation, i.e. 'consider' (please refer to the section in the NICE guideline on strength of recommendations). The guideline development group believe that the recommendations are sufficiently broad to

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				Consider a re-word as follows: 'Offer a formulation based approach to assess the role of parent and family factors. Offer specific family/parent based interventions, if there are difficulties with diabetes related-family conflict, parent anxiety or mental health difficulties including parental PTSD'.	include the psychological support of parents as well as children and young people
Royal College of Ophthalmologists	NICE	32	11 17 38 44	<u>121 & 124. Recommendation about eye examination (page 32, lines 11-17 & lines 38-44)</u> 'Explain to children and young people with type 1/2 diabetes and their family members or carers (as appropriate) that like others they are advised to have: • an eye examination by an optician every 2 years. [2004 amended 2015]' Comment; In version 2004 "Children and young people with type 1 diabetes and their families should be informed that, as for other children, regular dental examinations [2] and eye examinations (every 2 years) are recommended. (1.3.5.4)". Reason for the change: An explanation has been added to the bullet on eye examination to make it clear this refers to standard eye tests rather than retinopathy monitoring. In addition, 'recommended' has been changed to 'advised to have' as part of the editorial changes to make this sentence active. The aim of this eye examination or pathways for abnormal results are not explained in the guideline. No evidence for this recommendation is presented in the guideline. Additionally, this does not fit with any current RCOphth guidance on community optometric care for children. We advise that this should be changed to 'Parents should be advised that their child is entitled to a free NHS eye examination with an optometrist up to the age of 16 (19 if in full time education)' (RCOphth guidance on Ophthalmic Services for Children)	Thank you for this comment. The pathway of care beyond the identification of an abnormal retinopathy screening result was outside the scope of the guideline. The evidence supporting the screening recommendations is presented in Sections 11.4.1 and 17.3 of the full guideline. The recommendations are in line with the National Screening Programme for Diabetic Retinopathy
British Psychological	NICE	33	1.2.100	Here the current evidence base is of insufficient quality to be prescriptive (FULL guidance: pages 235-238). In addition, the approaches used in these RCT's are	Thank you for this comment. The terminology used to reflect the strength of

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Society				often a combination of different therapeutic approaches, without defining the active components (for example BFST includes CBT). The evidence is also low. This section needs a 'lighter touch' until further research in completed to disentangle the components of therapy that bring about change in any domain. Consider a re-word as follow: Offer Psychological Therapy for young people with type 1 diabetes in whom there are concerns about psychological wellbeing, adherence, glycaemic control and quality of life. The approach needs to be based on a Psychological Formulation of the individual child and family. A range of approaches could be considered including, first, modification to the diabetes treatment regimen, and secondly if needed, Cognitive Behavioural Therapy (and third wave CBT approaches), therapeutic approaches based on motivational interviewing or solution-focused therapy, and family-based interventions.	a recommendation is presented in the NICE guideline. The guideline development group do not believe these recommendations are prescriptive and that they appropriately reflect the evidence base. A number of recommendations for further research are presented at the end of the chapter. Please note that Table 37 in the full guideline describes the components of each of the therapeutic interventions used in the studies
National Children and Young People's Diabetes Network	NICE	33	1.2.100 1.2.101	Who are these guidelines aimed at? The Team as a whole or the Psychologist? Perhaps better to refer to existing mental health NICE guide lines for children e.g. for depression the first line of intervention is not necessarily motivational interviewing.	Thank you for this comment. The recommendation has been amended so that it cross-refers to the existing NICE guidance on the treatment of depression in children and young people. The previous version of the recommendation reflected the association between improved depression and motivational interviewing that was found in the evidence specific to those with type 1 diabetes
National Children and Young People's	NICE	33	1.2.100	Family therapy is usually offered via CAMHS rather than Clinical Psychologist therefore this statement should advise referral on to CAMHS after assessment by Clinical Psychologist on team	Thank you for this comment. The guideline development group have not specified the referral details as these might differ depending on the local service

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Diabetes Network					configuration
British Psychological Society	NICE	33	1.2.101	The psychological treatment of childhood anxiety/depression needs to be in-line with recommendations made by the relevant NICE guidelines. We believe that it would be worth signposting to these guidelines and also a statement taken from those guidelines for therapy recommendations for mild/moderate levels, as many children will now be treated for mild/moderate mental health problems by the mental health professional in the MDT, not reaching criteria for CAMHS support.	Thank you for this comment. The existing recommendation has been amended and no longer includes a reference to treatment for depression. A new recommendation has been added that cross-refers to existing NICE guidance on depression and anxiety in children and young people.
Royal College of Nursing	NICE	33	1.2.101	Consider including solution focused strategies	Thank you for this comment. The recommendation is based on the evidence that was identified in the systematic review of psychological interventions
Royal College of Nursing	NICE	33	1.2.102	Define "poor blood glucose control"?	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (anxiety and depression in this case). However the guideline development group have changed the term poor in this recommendation to suboptimal because it is more patient-friendly and yet it does not change the intended meaning of the recommendation
Alder Hay Children's	NICE	34	1.2.108	Diabetes Team Dieticians - CYP with Type 1 Diabetes present with Coeliac Disease post diagnosis and the recommendation of screening only at diagnosis	Thank you for submitting comments in response to the stakeholder consultation.

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NHS Foundation Trust				means CYP may have undetected and untreated CD which can be detrimental to diabetes control and long term control. Dr Ghatak – If we only screen at diagnosis we will miss cases – will this be addressed in the Coeliac NICE Guidance in development?	Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (coeliac disease in this case). However the guideline development group recognise that NICE has produced separate guidance and so the recommendations in this guideline have been amended to cross-refer to the NICE coeliac disease guideline for guidance on monitoring for coeliac disease in children and young people with type 1 diabetes
Diabetes UK	NICE	34	1.2.108	We feel that monitoring programmes work best when they are kept simple, and so are concerned that the differing times for monitoring for complications and associated conditions are confusing to parents and there is a risk that they will be forgotten. Long term complications are a real concern to parents, particularly for parents who have a child diagnosed very young. We would therefore suggest that the monitoring programme is simplified, perhaps to monitoring for all complications and associated conditions every year from one year post diagnosis.	Thank you for this comment. The recommendations related to monitoring for complications are led by the evidence in each systematic review. The majority of recommendations for monitoring specify annual assessment
National Children and Young People's Diabetes Network	NICE	34	1.2.108	Coeliac screening at diagnosis only This contravenes the most recent guidance from Europe which suggests that high risk individuals should be retested. ESPGHAN guidelines 2012 on coeliac disease management and screening. It states: ' In individuals with DQ2 or DQ8 positivity or without HLA testing, IgA anti-TG2 and serum total IgA determination should be performed. If IgA anti-TG2 is negative and IgA deficiency is	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (coeliac disease in this case). However the guideline development group

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				excluded, then CD is unlikely; however, the disease may still develop later in life. Therefore, serological testing should be repeated at regular intervals. No data support any firm recommendations, but it was the opinion of the working group members that a child should be investigated by serology every 2 to 3 years to avoid the detrimental effects of unrecognised CD on growth and bone health. If EMA is positive, then the likelihood for CD increases because of the high specificity of EMA. In this situation, the patient should be referred for endoscopy in spite of low anti-TG2 titres. If EMA are negative, then the patient should be followed up on a normal diet and anti-TG2 testing should be repeated every 3 to 6 months until the antibody levels either turn negative or the levels increase to levels at which endoscopy is indicated' Taken from ESPGHAN guidelines 2012 http://www.espghan.med.up.pt/position_papers/Guidelines_on_coeliac_disease.pdf The evidence used was 2009 guidance therefore this should be looked at before changing the advice on retesting.	recognise that NICE has produced separate guidance and so the recommendations in this guideline have been amended to cross-refer to the NICE coeliac disease guideline for guidance on monitoring for coeliac disease in children and young people with type 1 diabetes
Royal College of Paediatrics and Child Health	NICE	34	1.2.108	Coeliac screening at diagnosis only This contravenes the most recent guidance from Europe which suggests that high risk individuals should be retested. ESPGHAN guidelines 2012 on coeliac disease management and screening. It states: ' In individuals with DQ2 or DQ8 positivity or without HLA testing, IgA anti-TG2 and serum total IgA determination should be performed. If IgA anti-TG2 is negative and IgA deficiency is excluded, then CD is unlikely;	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (coeliac disease in this case). However the guideline development group

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				however, the disease may still develop later in life. Therefore, serological testing should be repeated at regular intervals. No data support any firm recommendations, but it was the opinion of the working group members that a child should be investigated by serology every 2 to 3 years to avoid the detrimental effects of unrecognised CD on growth and bone health. If EMA is positive, then the likelihood for CD increases because of the high specificity of EMA. In this situation, the patient should be referred for endoscopy in spite of low anti-TG2 titres. If EMA are negative, then the patient should be followed up on a normal diet and anti-TG2 testing should be repeated every 3 to 6 months until the antibody levels either turn negative or the levels increase to levels at which endoscopy is indicated' Taken from ESPGHAN guidelines 2012 http://www.espghan.med.up.pt/position_papers/Guidelines_on_coeliac_disease.pdf The evidence used was 2009 guidance therefore this should be looked at before changing the advice on retesting.	recognise that NICE has produced separate guidance and so the recommendations in this guideline have been amended to cross-refer to the NICE coeliac disease guideline for guidance on monitoring for coeliac disease in children and young people with type 1 diabetes
National Children and Young People's Diabetes Network	NICE	35 36	General	There is no indication for lipid screening here It is currently part o NPDA data set to be evaluated from 12 years of age. Dyslipidemia (cholesterol, LDL, HDL, triglyceride) is common in both type 1 and 2 diabetes and is a marker of future cardiovascular disease. Levels rise during puberty but may be abnormal during pre-puberty, and in ethnic minority groups. If abnormal, more intensive insulin therapy and focussed dietetic management is required during pre-puberty and possible intervention with a statin may be required during puberty. The type of dyslipidaemia may vary according to diabetes subtype and ethnic group. For example, South Asians have increased levels of	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (monitoring for dyslipidaemia in children and young people with type 1 diabetes in

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				triglycerides and lower HDL levels. Treatment and advice may vary according to the exact abnormality and for this a full lipid screen is required.	this case)
Diabetes UK	NICE	35	1.2.111	While we are aware of the rarity of retinopathy in children under that age of 12, see comment 16	Thank you for this comment. There is evidence of steadily increasing prevalence of retinopathy after 12 years and no evidence of significant retinopathy before 12 years
Diabetes UK	NICE	36 46	1.3	We feel that the recommendations for Type 2 diabetes in children and young people need to far more detailed, in particular in terms of treatment both for the Type 2 diabetes itself (as there is no mention of treatment strategies if metformin is ineffective) and for the treatment of any complications and associated conditions. We recommend that this part of the guideline is reviewed, and reflect the ISPAD/ADA guidelines https://www.ispad.org/sites/default/files/resources/files/3-type_2_diabetes_in_the_child_and_adolescent.pdf /http://care.diabetesjournals.org/content/38/Supplement_1	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that the part of the guideline that considers type 2 diabetes in children and young people is constrained by the scope for the 2015 update to cover metformin but no other pharmacological treatments, and to cover monitoring for long-term complications but not their subsequent management
Royal College of Nursing	NICE	36	1.3	This section on care for Type 2 diabetes is very repetitive of the Type 1 diabetes guidance – is there an alternative way of setting out this information?	Thank you for this comment. The guideline development group felt there was a strong rationale for keeping the recommendations for type 1 diabetes and type 2 diabetes separate: in practice the two sets of recommendations will be read as stand-alone documents; the separation makes the guidance more patient-focused; and the link to the separate guidelines on diagnosis and management of type 1 and type 2 diabetes in adults further emphasises the relevance of having separate sets of recommendations for the

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					different conditions
Diabetes UK	NICE	36	1.2.112	While we are aware of the rarity of nephropathy in children under that age of 12, see comment 16	Thank you for this comment. The guideline development group has reviewed the evidence and have not found any evidence to support monitoring before 12 years
National Children and Young People's Diabetes Network	NICE	36	1.2.112	While aware of the rarity of nephropathy in children under that age of 12, see comment 16	Thank you for this comment. The guideline development group has reviewed the evidence and have not found any evidence to support monitoring before 12 years
National Children and Young People's Diabetes Network	NICE	36	1.2.114	Individual labs have individual reference ranges. There is a different cut off for males & females locally our reference is NORMAL = ACR < 2.5 mg/mmol in men NORMAL = ACR < 3.5 mg/mmol in women MICROALBUMINURIA = 2 x ACRs 2.5 – 30 in men or MICROALBUMINURIA = 2 x ACRs 3.5 – 30 in women NEPHROPATHY = 2 x ACR > 30 ie macroalbiminuria	Thank you for this comment. The guideline development group has considered the NICE chronic kidney disease guideline and harmonised with definitions and thresholds used there
Royal College of Nursing	NICE	36	1.2.114	This is welcomed, however, it should be noted that individual laboratories have individual reference ranges. There is also a different cut off for male and female patients and references may vary across trusts. For example one trust's reference is: NORMAL = ACR < 2.5 mg/mmol in men NORMAL = ACR < 3.5 mg/mmol in women MICROALBUMINURIA = 2 x ACRs 2.5 – 30 in men or MICROALBUMINURIA = 2 x ACRs 3.5 – 30 in women	Thank you for this comment. The guideline development group has considered the NICE chronic kidney disease guideline and harmonised with definitions and thresholds used there

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				NEPHROPATHY = 2 x ACR > 30 i.e. macroalbiminuria	
The Royal College of Pathologists	NICE	36	1.2.114	This is a useful statement but presumably it intends to stipulate that 2 out of 3 tests positive constitutes microalbuminuria. The present wording if anything implies that all 3 should be positive.	Thank you for this comment. The guideline development group has considered the NICE chronic kidney disease guideline and harmonised with definitions and thresholds used there
Royal College of Ophthalmologists	NICE	36	31 33	170. Specific recommendation about type 2 diabetes (page 36 lines 31-33) "Consider referring children and young people with type 2 diabetes who are younger than 12 years to an ophthalmologist for retinal examination if blood glucose control is suboptimal. [new 2015]" We suggest that referring these children to the local diabetic eye screening programme could be a better option than referring direct to an ophthalmologist because (1) this maintains a central register of screened diabetic children, (2) pathways for normal/abnormal results are already established and (3) it is likely to be more cost-effective. This recommendation is only for type 2 (in type 1 they suggested a similar conduct, but it is not a formal recommendation, section 11.4.1.6.2, lines 39-42).	Thank you for this comment. The recommendation does not specify local referral but the guideline development group felt that it was necessary to consider a retinal examination in this selected group of younger children and young people with type 2 diabetes via an ophthalmologist as the national screening programme covers children aged 12 years and older
Association of British Clinical Diabetologists	NICE	39	General	Lack of comment of the challenges of insulin treatment when insulin resistance and no comment on the role (or lack of) of incretin modulators in those aged over 16 with type 2 DM	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that the part of the guideline that considers type 2 diabetes in children and young people is constrained by the scope for the 2015 update to cover metformin but no other pharmacological treatments (this also excludes consideration of incretin modulators)

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National Children and Young People's Diabetes Network	NICE	39	1.3.14	Young people & their families should receive advice on best time to take Metformin to minimise side effects & non compliance. Consideration should be given to use of modified released tablets in those who have gastrointestinal side effects.	Thank you for this comment. As there is no current evidence to support a recommendation about the best time to take metformin, this has not been added to the guideline. It is standard practice in NICE guidelines to assume that prescribers will use a medicine's summary of product characteristics (SPC) to inform decisions made with individual patients. There is text at the beginning of the NICE guideline that explains this. There was no evidence identified for the effectiveness of extended release metformin and so the guideline development group included a research recommendation on this topic
Royal College of Nursing	NICE	39	1.3.14	We feel that young people and their families should receive advice on best time to take Metformin to minimise side effects and non-compliance. Consideration should also be given to use of modified released tablets in those	Thank you for this comment. As there is no current evidence to support a recommendation about the best time to take metformin, this has not been added to the guideline. It is standard practice in NICE guidelines to assume that prescribers will use a medicine's summary of product characteristics (SPC) to inform decisions made with individual patients. There is text at the beginning of the NICE guideline that explains this. There was no evidence identified for the

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				who have gastrointestinal side effects.	effectiveness of extended release metformin and so the guideline development group included a research recommendation on this topic
Alder Hay Children's NHS Foundation Trust	NICE	39	1.3.15	Diabetes Team Dieticians - Benefits of physical activity and physical fitness rather than simply physical activity?	Thank you for this comment. The guideline development group refer to the existing NICE guidance Obesity: identification, assessment and management of overweight and obesity in children, young people and adults which reviews the evidence on physical activity and is included in this recommendation. The effectiveness of physical fitness is outside the scope of this guideline
National Children and Young People's Diabetes Network	NICE	41	1.3.30	Theses protocols should include assessment of cardiovascular function with B/P assessment & ECG prior to planned surgery and stopping of Metformin. Individuals should also be assessed for venous thromboembolism prevention	This recommendation was inserted in the section about type 2 diabetes to mirror the corresponding recommendation for type 1 diabetes. The other aspects of these recommendations are excluded from the 2015 update and so no further changes have been made. Safe surgery implies that the other risks specific to type 2 diabetes alluded to in the comment are taken into account
National Children and Young People's Diabetes Network	NICE	43	1.3.36	Diabetes teams should have appropriate access to mental health professionals to support them in psychological assessment and the delivery of psychosocial support. [2004, amended 2015] and have robust protocols in place for onward referral to specialist mental health teams as appropriate and offer joint working with specialist teams.	Thank you for this comment. The guideline development group agree that access to mental health professionals is important. The configuration of the service model was not considered as part of this update

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National Children and Young People's Diabetes Network	NICE	44	1.3.44	This recommendation should also apply to Type 1 diabetes	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline. This applies to monitoring for hypertension in children and young people with type 1 diabetes. Monitoring for hypertension in children and young people with type 2 diabetes is, however, included in the scope for the 2015 update
Royal College of Nursing	NICE	44	1.3.44	This recommendation should also apply to Type 1 diabetes patients.	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline. This applies to monitoring for hypertension in children and young people with type 1 diabetes. Monitoring for hypertension in children and young people with type 2 diabetes is, however, included in the scope for the 2015 update
The Royal College of Pathologists	NICE	44	1.3.47	It is regrettable that there is no guidance in the NICE guideline regarding exactly what constituted significant dyslipidaemia even though these are mentioned in 17.2 65 in Full guideline. It is appreciated however that this is a difficult area with little or no evidence base.	Thank you for this comment. As stated in the full guideline, there are no validated measures of cardiovascular risk associated with dyslipidaemia in children

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					and young people and therefore it is challenging to define a threshold for diagnosis. The values found in the evidence are stated in the full guideline
National Children and Young People's Diabetes Network	NICE	45	1.3.49	Why is this recommendation not for Type 1 diabetes as well especially if duration of diabetes greater than 5 years	Thank you for this comment. The evidence for the recommendation in type 2 diabetes suggested, but did not confirm, that retinopathy might occur earlier in this group of patients. The same pattern of effect was not found in the type 1 population. However, as noted in the full guideline in Section 11.4.1.6.2, healthcare professionals should exercise discretion and refer any child or young person whom they feel may be at higher risk of retinopathy (for example, due to suboptimal glycaemic control or long duration of disease) in addition to the screening offered by the national programme
Royal College of Nursing	NICE	45	1.3.49	We consider that this recommendation should also apply Type 1 diabetes patients especially if duration of the diabetes is greater than five years?	Thank you for this comment. The evidence for the recommendation in type 2 diabetes suggested, but did not confirm, that retinopathy might occur earlier in this group of patients. The same pattern of effect was not found in the type 1 population. However, as noted in the full guideline in Section 11.4.1.6.2, healthcare professionals should exercise discretion and refer any child or young person whom

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					they feel may be at higher risk of retinopathy (for example, due to suboptimal glycaemic control or long duration of disease) in addition to the screening offered by the national programme
Royal College of Paediatrics and Child Health	NICE FULL	46 56	General	Should not include urinary ketone measurement as should use blood ketone measurement. Is the current DKA guideline going to be reviewed to ensure it is in line with NICE? DKA - new the fact that can be treated with oral fluids/s/c insulin if patient alert, nou nauseous/vomiting or clinically dehydrated. - calculations allow 10% dehydration if pH,7.1and only subtract boluses at more then 20 mls/kg from total fluid calculations. - Mainatenance fluids more restricted. Probably these changes in fluid management will lead to a total less fluids in total. Noted Insulin starting at 0.05-0.1 Units/kg/hour, reflcting the idea that insulin can be started at lower dose.	Measurement of blood ketones (ketonaemia) or urine ketones (ketonuria) are both allowed for in the recommendations about diagnosis of diabetic ketoacidosis, although blood ketones are to be preferred if near-patient testing is available. Whether or not existing (non-NICE) guidance is updated to reflect the guideline recommendations will be at the discretion of the organisations that publish such guidance The guideline development group agree that this is likely to be the case The guideline development group acknowledge the recognition of the potential for a lower starting dose of intravenous insulin as indicated in the comment
Diabetes UK	NICE	46	1.4.1	We would like to see this statement changed to: "Measure capillary blood glucose at presentation in children and young people without known diabetes who have increased thirst, polyuria, recent unexplained weight loss or excessive tiredness and any of the following:"	The stem of the recommendation referred to in the comment has been revised to include recent unexplained weight loss or excessive tiredness as suggested

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Royal College of Nursing	NICE	46	1.3.52	As per our earlier comments, individual laboratories have individual reference ranges. There is also a different cut off points for male and female patients and local references may vary across trust.	Thank you for this comment. The guideline development group has considered the NICE chronic kidney disease guideline and harmonised with definitions and thresholds used there
Royal College of Paediatrics and Child Health	NICE	46	1.3.52	Individual labs have individual reference ranges. There is a different cut off for males & females locally our reference is NORMAL = ACR < 2.5 mg/mmol in men NORMAL = ACR < 3.5 mg/mmol in women MICROALBUMINURIA = 2 x ACRs 2.5 – 30 in men or MICROALBUMINURIA = 2 x ACRs 3.5 – 30 in women NEPHROPATHY = 2 x ACR > 30 ie macroalbiminuria	Thank you for this comment. The guideline development group has considered the NICE chronic kidney disease guideline and harmonised with definitions and thresholds used there
The Royal College of Pathologists	NICE	46	1.3.52	This is a useful statement but presumably it intends to stipulate that 2 out of 3 tests positive constitutes microalbuminuria. The present wording if anything implies that all 3 should be positive.	Thank you for this comment. The guideline development group has considered the NICE chronic kidney disease guideline and harmonised with definitions and thresholds used there
The Royal College of Pathologists	NICE	47	1.4.5	It would be useful to state what constitutes a significantly elevated blood beta-hydroxybutyrate concentration e.g. ? >0.6 mmol/L (upper reference limit), >1.5 mmol/L or >3.0 mmol/L (probably too high for initial triage decisions).	The guideline development group's view is that a specific level for ketones should not be specified in the recommendation that triggers sending a child or young person with possible diabetic ketoacidosis to hospital. This is because the evidence reviewed for the guideline does not support ketone testing as being a specific test for diabetic ketoacidosis, and the recommendation should not risk preventing the child or young person being sent to hospital by including an arbitrary

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					threshold that may not quite be met in individual circumstances. This recommendation is not for diagnosing diabetic ketoacidosis (this will be done in the hospital) and a child or young person with known diabetes should already have ketone testing equipment and advice about seeking help plus an individualised sick-day management plan so they will be able to detect elevated ketones
The Royal College of Pathologists	NICE	48	1.4.15	The word 'Consider …blood ketone testing' seems rather soft given the due prominence given to ketone testing elsewhere in the document. During ongoing treatment (see 1.4.53) blood ketone testing is mandated alongside other acute tests. It would make more sense to use the same wording in 1.4.15	The difference between the 'consider' recommendation here (ketone monitoring during management of diabetic ketoacidosis) and the stronger 'offer' or 'use' recommendation elsewhere (ketone self-monitoring during management of intercurrent illness) is that there is a lack of specific evidence of cost effectiveness of near-patient testing of ketones in the hospital setting
Diabetes UK	NICE	49	1.4.17	We suggest this statement specifies a paediatric high dependency unit.	Thank you for this comment. The recommendation referred to in the comment has been changed to state that children and young people with diabetic ketoacidosis should be cared for with one-to-one nursing either on a high-dependency unit (preferably a paediatric unit), or on a general paediatric ward with one-to-one nursing. This change clarifies and emphasises that 1:1 care is most

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					important and the revised recommendation allows for care in an adult high dependency unit if there is no other option
Diabetes UK	NICE	50	1.4.27	We suggest that perhaps there is no place for a bolus unless there is severe haemodynamic collapse. We would also question whether 3% saline might be considered if hyponataemia is present.	The guideline development group agree that an intravenous fluid bolus should not be given routinely even in the case of severe diabetic ketoacidosis. Another recommendation has been added to the guideline to clarify this as follows: do not routinely give an intravenous fluid bolus to a child or young person with severe DKA. 3% saline should not be considered at this stage because normal saline (0.9% sodium chloride) is an appropriate treatment for hyponatraemia at this stage
National Children and Young People's Diabetes Network	NICE	51	1.4.34	Why is the new guidance to NOT subtract boluses from the total fluid calculations as this is the current standard practice?	The reason that resuscitation boluses are not subtracted from the 48-hour fluid calculation is that the fluid quantities recommended in the guideline are already less than in previous guidance and only rarely will a child or young person with diabetic ketoacidosis be given more than 20 ml/kg of intravenous fluid
National Children and Young People's Diabetes Network	NICE	52	1.4.38	Should it state" after 1 hour and before 2 hours"?	This wording means any time from 1 hour to 2 hours. The timing was considered very carefully by the guideline development group taking into account the available evidence

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Royal College of Nursing	NICE	52	1.4.42	We feel there needs to be more clarification around this recommendation.	This recommendation has been clarified and now states the following: in discussion with a diabetes specialist, think about continuing subcutaneous basal insulin in a child or young person with diabetic ketoacidosis who is was already using a basal insulin before the onset of diabetic ketoacidosis
Diabetes UK	NICE	52	1.4.43	We suggest that plasma osmolality is considered as a factor in the decision to change fluids.	This recommendation is about ensuring that the child or young person does not become hypoglycaemic and so the only change to management recommended at this stage is the addition of glucose to the fluid. There is no change in the recommended sodium chloride concentration and so osmolality has not been included in the recommendation. Another major difference in this guideline compared to previous guidance is that nowhere is hypotonic sodium chloride solution recommended
Royal College of Paediatrics and Child Health	NICE	52	1.4.43	Suggest that plasma osmolality is considered as a factor in the decision to change fluids.	This recommendation is about ensuring that the child or young person does not become hypoglycaemic and so the only change to management recommended at this stage is the addition of glucose to the fluid. There is no change in the recommended sodium chloride concentration and so osmolality has not been included in the recommendation.

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					Another major difference in this guideline compared to previous guidance is that nowhere is hypotonic sodium chloride solution recommended
Royal College of Nursing	NICE	53	1.4.46	It is very helpful to have advice regarding when to restart subcutaneous insulin after commencing IV insulin.	Thank you for this comment in support of the guideline
National Children and Young People's Diabetes Network	NICE	53	1.4.48	This needs clarification if giving basal via pump only then will need 90-120 mins start beforehand if bolus start up as eating then 30 mins beforehand. IV half life is only 2 minutes stopping IV insulin without adequate wetting in of pump / basal insulin can cause hyperglycaemia	Thank you for this comment. The recommendation has been changed to state that for a child or young person with diabetic ketoacidosis who is using insulin pump therapy, the pump should be restarted at least 60 minutes (rather than 30 minutes as in the consultation draft) before stopping intravenous insulin. This change is supported by the clinical experience of the guideline development group in that it takes 1 hour for the insulin infusion to reach steady state. More than 1 hour (as suggested in the comment) is not necessary
Royal College of Nursing	NICE	53	1.4.48	This needs clarification; giving basal via pump only will need 90-120 minutes to start beforehand and if bolus start up as eating then 30 will need minutes beforehand. Intravenous half life requires only two minutes. Stopping IV insulin without adequate wetting in of pump / basal insulin can cause hyperglycaemia.	Thank you for this comment. The recommendation has been changed to state that for a child or young person with diabetic ketoacidosis who is using insulin pump therapy, the pump should be restarted at least 60 minutes (rather than 30 minutes as in the consultation draft) before stopping intravenous insulin. This change is supported by the clinical experience of the guideline development

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					group in that it takes 1 hour for the insulin infusion to reach steady state. More than 1 hour (as suggested in the comment) is not necessary
National Children and Young People's Diabetes Network	NICE	54	1.4.51	Should this not just be for severe DKA – ward nurses may not know what to look for on the ECG monitor!	There may be a training issue for interpretation of ECG, but the recommendation states the signs to look out for on the ECG
Diabetes UK	NICE	54	1.4.55	We suggest that assessment of the ECG trace should specify to review for evidence of hypo/hyperkalaemia.	The recommendation about ECG monitoring already covers this
National Children and Young People's Diabetes Network	NICE	54	1.4.55	Suggest that review of the ECG trace specify to review for evidence of hypo/hyperkalaemia	The recommendation about ECG monitoring already covers this
Royal College of Nursing	NICE	54	1.4.55	"At each face to face review…" Suggest include 'assessment of injection sites for lipohypertrophy'	This face-to-face review is specific to management of diabetic ketoacidosis, whereas examination of injection sites is covered elsewhere in the guideline (and changes to those recommendations would be outside the scope of the 2015 update)
Royal College of Paediatrics and Child Health	NICE	54	1.4.55	Suggest that review of the ECG trace specify to review for evidence of hypo/hyperkalaemia	The recommendation about ECG monitoring already covers this
Neonatal and Paediatric	NICE	55	15	The term "saline" is not an approved synonym. The correct term is sodium chloride. The following information is taken from Martindale:	The phrase hypertonic saline has been changed to hypertonic sodium chloride as

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Pharmacists Group			19 27	An aqueous solution of sodium chloride 0.9% is often known as physiological saline. SALINE is a code approved by the BP 2014 for use on single unit doses of eye drops containing sodium chloride 0.9% where the individual container may be too small to bear all the appropriate labelling information. Ref- Martindale: The Complete Drug Reference. London: The Royal Pharmaceutical Society of Great Britain. Electronic version. Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com/ (cited: 03/03/2015).	suggested
National Children and Young People's Diabetes Network	NICE	57	1.5.2	Offer children and young people with diabetes and their family members or carers (as appropriate) 24-hour access to advice from their diabetes team. [2004, amended 2015] better to say: their diabetes team or an identified diabetes out-of-hours service.	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (24-hour access to the diabetes team in this case). The recommendation referred to in the comment has been inserted in the guideline to mirror the corresponding recommendation for type 1 diabetes, but the other aspects of the recommendation have not been changed because the topic is excluded from the update scope
Royal College of Nursing	NICE	57	1.5.5	This guideline has already discussed offering continuous subcutaneous insulin infusion where multiple daily injections is not practical and also discussed training requirements (1.2.22). This is likely to be most applicable to the preschool children – can this group be safely initiated onto insulin pump therapy, at diagnosis, within the home environment?	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been

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					reviewed since the original (2004) guideline (care setting at diagnosis in this case). However, in this case the guideline development group 's view is that the recommendations to offer multiple daily injection regimens from diagnosis, and the alternative insulin regimens (such as insulin pump therapy) that may be considered, are compatible with home-based care at diagnosis
Association of British Clinical Diabetologists	NICE FULL	58 375 378	General	Remarkably little mention of the importance of this phase of care . The evidence base from literature review is limited given the fundamental challenge of comparing different models . However there is an abundance of evidence as to what NOT to do in trying to engage young people at the critical time of transfer and over a period when 16-19 when adult and paediatric services need to jointly support the care in MDT services. The lack of mention of joint working between adult and paediatric services is a serious omission, particularly as previous quality standard documents have made clear the need for such coordinated care. The term transition is also used loosely .There are a range of attached references from NHS England-NHS Diabetes on appropriate standards for effective transition and transfer . The core principle is to consider transition a phased period and not a single event . The impression in the document is that transition = transfer and this is a single episode of care. It would seem logical that there is alignment between this diabetes document and the ongoing' NICE Transition from children's to adult services guideline development group'	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (transition from paediatric to adult services in this case) The guideline development group recognise the importance of the separate NICE guidance on transition that is being developed but note that it is not completed at present

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				Invited expert testimony and references have been attached :	This material was provided to the developers in separate rows of the stakeholder comments table and is addressed there
British Psychological Society	NICE	58	2	Recommendation 1.2.89 of old guideline which said alcohol education should be given but the replacement makes no mention at all of alcohol and its effects on blood glucose levels. They could include information about how the adverse effects of alcohol on blood glucose can be managed. Clearly it is not appropriate to provide the detailed education to children who don't currently drink but they need to know from an early age that alcohol can be managed safely with care. This information is needed before they need the detail not after they have experimented, in ignorance, with alcohol for the first time with unfortunate results.	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia and the effects of alcohol in this case). The guideline development group were not aware of any specific alcohol education programmes and that is why the specific recommendation about these has been deleted in the 2015 update. There are, however, other recommendations in the guideline that cover provision of information about alcohol and its effects on hypoglycaemia. This has been clarified in the tables about changes to 2004 recommendations in the revised guideline
Diabetes UK	NICE	58	1.5.9 1.5.13	This section must be expanded to include all aspects of transition such as preparation, education, appropriate timing for transition, the need for joint paediatric and adult clinics/joint clinics/young person's clinics/transition clinics, liaison between paediatric and adult teams etc.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015

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					update, where the evidence has not been reviewed since the original (2004) guideline (transition from paediatric to adult services in this case)
Neonatal and Paediatric Pharmacists Group	NICE	60	1	We agree with Research recommendation number 2.3	Thank you for this comment in support of the guideline
National Children and Young People's Diabetes Network	NICE	95	General	In the table in column under consideration should be given to the possibility of other types of diabetes after Maturity-onset diabetes of the young add neonatal diabetes. To the list of features add 1. Diagnosis less than 6 months as this is neonatal diabetes and not type 1 diabetes. (Edgehill et Diabetes 55:1895–1898, 2006). This is very important as 50% of these patients will have a potassium channel mutation and despite being insulin dependent 90% can get improved control on a sulphonylurea (Pearson ER et al N Engl J Med 2006;355:467-77.). the international guidelines ISPAD are that all these patients should have an immediate molecular genetic diagnosis a decision which is supported bythechange in treatment and also health economics Greeley SA, et al he cost-effectiveness of personalized genetic medicine: the case of genetic testing in neonatal diabetes. Diabetes Care. 2011 Mar;34(3):622-7. PMID: 21273495; 2. Incidental hyperglycaemia that is mild (the commonest cause >50% is glucokinase MODY) in at least 3 national surveys Lorini R et al Maturity-onset diabetes of the young in children with incidental hyperglycemia: a multicenter Italian study of 172 families. Diabetes Care. 2009 Oct;32(10):1864-6.PMID: 19564454: Codner E, et al Pediatr Diabetes. 2009 Sep;10(6):382-8. PMID: 19309449; Feigerlová E, Et al . Aetiological heterogeneity of asymptomatic hyperglycaemia in children and adolescents. Eur J Pediatr. 2006 PMID: 16602010	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The revised recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first

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					year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The bullet about having diabetes in the first year of life has been included in the revised recommendations specifically to cover neonatal diabetes which is not otherwise captured by the characteristics listed. Moreover, the term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY
National Children and Young People's Diabetes Network	NICE	96	General	In the central column in line with comments above remove the clinical feature if" rarely or never produce ketone bodies" as this is not correct Neonatal diabetes presents in ketoacidosis (Gloyn et al NEJM 2004), ketones do occur in MODY and although very rare ketoacidosis can occur (like in Type 2 diabetes) As above important clinical features that should be included in this section are: 1. Diagnosis less than 6 months as this is neonatal diabetes and not type 1 diabetes. (Edgehill et Diabetes 55:1895–1898, 2006). This is very important as 50% of these patients will have a potassium channel mutation and despite being insulin dependent 90% can get improved control on a sulphonylurea (Pearson ER et al N Engl J Med 2006;355:467-77.) 2. Parental diabetes (especially when an extended family and the absence of obesity) as this suggests MODY rather than Type 1 or Type 2 diabetes.	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are

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				3. Incidental hyperglycaemia that is mild (the commonest cause >50% is glucokinase MODY) in at least 3 national surveys Lorini R et al Maturity-onset diabetes of the young in children with incidental hyperglycemia: a multicenter Italian study of 172 families. Diabetes Care. 2009 Oct;32(10):1864-6.PMID: 19564454: Codner E, et al Pediatr Diabetes. 2009 Sep;10(6):382-8. PMID: 19309449; Feigerlová E, Et al . Aetiological heterogeneity of asymptomatic hyperglycaemia in children and adolescents. Eur J Pediatr. 2006 PMID: 16602010. 4. Absence of autoantibodies (discussed below McDonald T et al Islet autoantibodies can discriminate maturity-onset diabetes of the young (MODY) from Type 1 diabetes. Diabet Med. 2011Sep;28(9):1028-33. PMID: 21395678 This approach has been proven to be successful in identifying MODY in the paediatric population (Pihoker C, et al Prevalence, characteristics and clinical diagnosis of maturity onset diabetes of the young due to mutations in HNF1A, HNF4A, and glucokinase: results from the SEARCH for Diabetes in Youth. J Clin Endocrinol Metab. 2013 Oct;98(10):4055-62. PubMed PMID: 23771925) 5. Acanthosis nigricans in a slim child (suggests a genetic disorder of insulin resistance)	strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The revised recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The bullet about having diabetes in the first year of life has been included in the revised recommendations specifically to cover neonatal diabetes which is not otherwise captured by the characteristics listed. Moreover, the term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY. Additionally the recommendations have been revised to include family history of

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					diabetes. However, the limitations of the scope for the 2015 update prevent the guideline development group from providing more detail about the diagnosis or management of forms of diabetes other than type 1 or type 2
National Children and Young People's Diabetes Network	NICE	171	6	No mention of harms of large fluctuations in blood glucose or of severe hypoglycaemia	The guideline development group note that the section referred to in the comment is from the full guideline where the studies included in the 2004 guideline are discussed. It is noted that the guideline development group did not include a specific recommendation about glycaemic targets related to age. The linking evidence to recommendations section for this review stresses the importance of maintating 'tight control' in order to reduce the risk of developing long-term complications, while severe hypoglycaemia was considered a priority outcome for the review as outlined in the review protocol in Appendix E
National Children and Young People's Diabetes Network	NICE	195	7	Include blood glucose meters with bolus advisor function	There was no evidence identified for inclusion in the guideline systematic review that would allow the guideline development group to recommend use of blood glucose meters with a bolus adviser function. This aspect was not a specific criterion identified for consideration in the systematic review and so no

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					recommendation has been made to address this
National Children and Young People's Diabetes Network	FULL	General	General	Terminology around 'therapy' and 'intervention' is inaccurate throughout the document and particularly in this section. - Behavioural intervention therapy – This is not a therapy. - Cognitive Behavioural therapy – this is not a behavioural intervention. Behaviour is a component of the model of therapy. It also does not focus on quality of life per se – CBT has been evidenced to be effective in multiple RCTs and reported in NICE guidance as the core intervention for anxiety disorders (including panic attack and post-traumatic stress), bipolar disorder, depression, OCD, chronic fatigue, chronic pain, eating disorders. - Multi-systemic therapy – This is not an evidence based intervention in diabetes. Evidence has only been growing in juvenile offenders and looked after children. - Mentoring – This is not a therapy or an intervention. - Motivational interviewing – this is not a behavioural intervention.	Thank you for this comment which highlights the inconsistent use of many of these terms within the field of study, not just the guideline. In the absence of clear definitions, the content of the interventions has been described in Table 37 in the full guideline. The guideline development group have amended the terminology in this section where required for clarity. Please note that the inclusion of interventions in the systematic review has been led by the evidence, regardless of whether it the interventions are currently available in the UK, e.g. multi-systemic therapy
National Children and Young People's Diabetes Network	FULL	General	General	The HbA1c target of 48 mmol/mol will be very difficult to achieve and the risks of low HbA1c in children have not been investigated. A target of 53 mmol/mol without severe hypoglycaemia would be more achievable and still an improvement on the current one, leading to a reduction in risk of long term complications. If the target is too tight, children, young people and their families may feel a sense of frustration and learned helplessness, and may not feel able to do anything about the higher HbA1c. Also, the guidelines highlight the importance of the entire team sharing the same targets consistently, yet proposes the principle of agreeing individual targets for HbA1c, which will lead to inconsistency.	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance

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					by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in

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					the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline The reference in the comment to providing consistency in agreement and communication of individualised targets is important. The target will be individualised to the child or young person with type 1 diabetes, rather than depending on who is providing care at a given time or through a particular clinical contact. This should ensure that the necessary consistency is achieved
National Children and Young	FULL	General	General	No clinical psychologist was invited to be a GDG panel member for the 2015 guideline development. Katherine Bernard, on the expert panel, is a chartered health psychologist., with research expertise in diabetes.	Thank you for this comment. Feedback on the proposed constitution of the guideline development group is sought at the

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People's Diabetes Network				Clinical psychology is a doctorate profession, with clinicians being both producers and consumers of research. Clinical experience is a central feature of evidence based medicine and is required in addition to a health psychology research perspective. The lack of a practicing clinical psychologist in a diabetes team, on the GDG is apparent throughout the guidelines in terms of the clinical psychology scope, language, research questions posed, interpretation of the literature and recommendations both for clinical practice and future research. To this effect, therefore: 1. Give due consideration to the BPS stakeholder comments, particularly as there was no clinical psychology representation on the GDG 2. Consider making recommendations for secondary research, in addition to primary research i.e. systematic reviews of the psychology literature in diabetes in order to capture the emerging literature. 3. Notify the Chair of the Paediatric Psychology Network about future NICE Guideline developments on children with diabetes and children with other chronic health problems at an early stage, when future GDGs are being established.	stakeholder workshop before positions are advertised on the NICE website and other places such as NICE Twitter, social media and websites of stakeholders, medical Royal Colleges and professional organisations. Registered stakeholders are notified of the advertisements and the composition of the group for all NICE guidelines. Recruitment is conducted in accordance with NICE's policy and procedure for recruitment and selection to advisory bodies and topic expert groups. In this case, expert advice on the mental health literature was sought from an external adviser on an as-required basis, in line with the process outlined in the NICE guidelines manual Stakeholder consultation comments are treated equally and responded to in line with the NICE guidelines manual. Please note that only key research recommendations are presented in the NICE short version of the guideline. A full set of research recommendations can be found in the full guideline. The Chair of the Paediatric Psychology Network could contact NICE with a view to

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					registering as a stakeholder to keep abreast of future guidance developments
Royal College of Paediatrics and Child Health	FULL	General	General	No clinical psychologist was invited to be a GDG panel member for the 2015 guideline development. Katherine Bernard, on the expert panel, is a chartered health psychologist. with research expertise in diabetes. Clinical psychology is a doctorate profession, with clinicians being both producers and consumers of research. Clinical experience is a central feature of evidence based medicine and is required in addition to a health psychology research perspective. The lack of a practicing clinical psychologist in a diabetes team, on the GDG is apparent throughout the guidelines in terms of the clinical psychology scope, language, research questions posed, interpretation of the literature and recommendations both for clinical practice and future research. To this effect, therefore: 1. Give due consideration to the BPS stakeholder comments, particularly as there was no clinical psychology representation on the GDG 2. Consider making recommendations for secondary research, in addition to primary research i.e. systematic reviews of the psychology literature in diabetes in order to capture the emerging literature. 3. Notify the Chair of the Paediatric Psychology Network about future NICE Guideline developments on children with diabetes and children with other chronic health problems at an early stage, when future GDGs are being established.	Thank you for this comment. Feedback on the proposed constitution of the guideline development group is sought at the stakeholder workshop before positions are advertised on the NICE website and other places such as NICE Twitter, social media and websites of stakeholders, medical Royal Colleges and professional organisations. Registered stakeholders are notified of the advertisements and the composition of the group for all NICE guidelines. Recruitment is conducted in accordance with NICE's policy and procedure for recruitment and selection to advisory bodies and topic expert groups. In this case, expert advice on the mental health literature was sought from an external adviser on an as-required basis, in line with the process outlined in the NICE guidelines manual Stakeholder consultation comments are treated equally and responded to in line with the NICE guidelines manual. Please note that only key research recommendations are presented in the NICE short version of the guideline. A full

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					set of research recommendations can be found in the full guideline. The Chair of the Paediatric Psychology Network could contact NICE with a view to registering as a stakeholder to keep abreast of future guidance developments
Royal College of Paediatrics and Child Health	FULL	General	General	Glycaemic Index: our dietitians agree with the principles of a low Glycaemic Index diet so that seems reasonable, but we would not usually write it down as such for patients, but consider it within our general healthy eating advice. i.e. not using the GI figures with patients for calculations to avoid confusion. Would it need to consider glycaemic load?	Thank you for this comment. The guideline development group considered this suggestion, but did not change the recommendations. Some children and young people with type 1 diabetes are familiar with the concept of glycaemic index. The recommendations are to advise taking account of glycaemic index. How that is explained to the child or young person should be based on their individual circumstances
Royal College of Paediatrics and Child Health	FULL	General	General	Terminology around 'therapy' and 'intervention' is inaccurate throughout the document and particularly in this section. - Behavioural intervention therapy – This is not a therapy. - Cognitive Behavioural therapy – this is not a behavioural intervention. Behaviour is a component of the model of therapy. It also does not focus on quality of life per se – CBT has been evidenced to be effective in multiple RCTs and reported in NICE guidance as the core intervention for anxiety disorders (including panic attack and post-traumatic stress), bipolar disorder, depression, OCD, chronic fatigue, chronic pain, eating disorders. - Multi-systemic therapy – This is not an evidence based intervention in diabetes. Evidence has only been growing in juvenile offenders and looked after children.	Thank you for this comment which highlights the inconsistent use of many of these terms within the field of study, not just the guideline. In the absence of clear definitions, the content of the interventions has been described in Table 37 in the full guideline. The guideline development group have amended the terminology in this section where required for clarity. Please note that the inclusion of interventions in the systematic review has been led by the evidence, regardless of

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				- Mentoring – This is not a therapy or an intervention. - Motivational interviewing – this is not a behavioural intervention.	whether it the interventions are currently available in the UK, e.g. multi-systemic therapy
Royal College of Paediatrics and Child Health	FULL	General	General	The HbA1c target of 48 mmol/mol will be very difficult to achieve and the risks of low HbA1c in children have not been investigated. A target of 53 mmol/mol without severe hypoglycaemia would be more achievable and still an improvement on the current one, leading to a reduction in risk of long term complications. If the target is too tight, children, young people and their families may feel a sense of frustration and learned helplessness, and may not feel able to do anything about the higher HbA1c. Also, the guidelines highlight the importance of the entire team sharing the same targets consistently, yet proposes the principle of agreeing individual targets for HbA1c, which will lead to inconsistency.	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the

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					ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in

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					the revised evidence to recommendations section in the full guideline The reference in the comment to providing consistency in agreement and communication of individualised targets is important. The target will be individualised to the child or young person with type 1 diabetes, rather than depending on who is providing care at a given time or through a particular clinical contact. This should ensure that the necessary consistency is achieved
Royal College of Paediatrics and Child Health	FULL	19	23 27	This statement is inaccurate and stating that children and young people should be offered access to 'mental health professionals' does not follow from the Best Practice Criteria stated in the Department of Health, (2012) guidance that psychology should be "integral to the multi-disciplinary team" and that each patient should have an annual assessment by their MDT as to whether input to their care by a psychologist is needed. The Global ISPAD Consensus Guidelines (2000) stated that "psychosocial factors are the most important influences affecting the care and management of diabetes" and made the following three recommendations: (i) Psychologists should be part of the interdisciplinary health care team (ii) Overt psychological problems should receive support from the diabetes care team and expert attention from psychology (iii) The diabetes care team should receive training in the recognition, identification, and provision of information on psychosocial problems related to diabetes	The guideline development group consider that the recommendations are complementary to the Best Practice Tariff and do not prevent an annual assessment to determine the need for psychological support or inclusion of psychologists as a part of the multidisciplinary team. The linking evidence to recommendations section of the review has been amended to clearly state this. Please note that the 2004 review on behavioural interventions, which included the ISPAD guideline as a source of evidence, has been updated in 2015. The ISPAD guideline did not meet the inclusion criteria for the review and therefore is not

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					used to inform the 2015 recommendations
Royal College of Paediatrics and Child Health	FULL	20	34	Please see comments from Andrew Hattersley about other types of diabetes, and note that Neonatal Diabetes has been missed from these guidelines.	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis (specifically evidence for distinguishing between type 1 and type 2 diabetes) and concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility

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					of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY
Royal College of Paediatrics and Child Health	FULL	20	42	Pancreatic antibodies have been shown to differentiate between type 1 diabetes and MODY (maturity onset diabetes of the young) at diagnosis and can indicate type 2, see comments from Andrew Hattersley for reference. They should therefore be removed from this recommendation.	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes (including maturity onset diabetes in the young (MODY)) was excluded from the 2015 update. The recommendations have been revised to clarify that C-peptide and diabetes-specific autoantibody titres should not be measured at initial presentation to distinguish type 1 diabetes from type 2 diabetes (this recommendation previously referred to distinguishing type 1 diabetes from other forms of diabetes, which as the comment indicates is incorrect as C-peptide can be used to distinguish between type 1 diabetes and MODY)
Royal College of Paediatrics	FULL	21	1.2.37	Offer level 3 carbohydrate-counting education – we have no idea what this means. Needs to be more specific, i.e. teach insulin adjustment for carb content of meals	Thank you for this comment. Level 3 carbohydrate counting is the use of

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and Child Health		112		(or whatever level 3 means)	carbohydrate counting with the adjustment of insulin dosage according to carbohydrate content of meals and blood glucose levels, using an insulin:carbohydrate ratio. This has been clarified in a footnote to the recommendation
Royal College of Paediatrics and Child Health	FULL	22	48	See FIT guidelines for latest evidence re needle length.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (needle choice in this case)
Royal College of Paediatrics and Child Health	FULL	23	45	What are level 3 carbohydrates counting? Is clarification needed?	Thank you for this comment. Level 3 carbohydrate counting is the use of carbohydrate counting with the adjustment of insulin dosage according to carbohydrate content of meals and blood glucose levels, using an insulin:carbohydrate ratio. This has been clarified in a footnote to the recommendation
Royal College of Paediatrics and Child Health	FULL	25	1.2.59	Rather than just saying 5 tests, should it recommend timings of tests, I.e. before meals and bedtime, pre and 2-3 hrs post meals?	Thank you for this comment. The guideline development group discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that should be recommended, but also the timing at which the tests should be

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					performed. They concluded that at least 5 tests should be performed routinely, and emphasised in the revised recommendations that it is often necessary to conduct more than 5 tests. They did not, however, wish to specify an upper limit for the number of tests, nor the exact timing for the minimum number of tests because to do so would remove some flexibility that is otherwise available to the child or young person and their family members or carers (as appropriate)
Royal College of Paediatrics and Child Health	FULL	25	6	Fast acting carbohydrate should be available during exercise and intermediate/long acting carbohydrate post exercise.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (exercise in this case)
Royal College of Paediatrics and Child Health	FULL	27	1.2.68	As so few of our children nationally achieve the current target of 58mmols/mol, is it realistic to now say should be achieving 48mmols/mol. This just makes even more parents and children feel that they have failed.	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to

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					fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c

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					level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline
Royal College of Paediatrics and Child Health	FULL	27	7	Add "discuss actual (low) risk of severe hypo in order to minimise fear of hypoglycaemia.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case)
National Children and	FULL	29	24	Assessment of emotional and psychological well-being should not be focused on children who present with diabetes ketoacidosis only.	The guideline development group consider that the recommendations are

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Young People's Diabetes Network				The BPT criteria (Department of Health, 2012) stipulate that psychology should be "integral to the multi-disciplinary team" and that each patient should have an annual assessment by their MDT as to whether input to their care by a clinical psychologist is needed, and access to psychological support.	complementary to the Best Practice Tariff and do not preclude an annual assessment to determine the need for psychological support. The linking evidence to recommendations section of the review has been amended to clearly state this
Royal College of Paediatrics and Child Health	FULL	29	24	Assessment of emotional and psychological well-being should not be focused on children who present with diabetes ketoacidosis only. The BPT criteria (Department of Health, 2012) stipulate that psychology should be "integral to the multi-disciplinary team" and that each patient should have an annual assessment by their MDT as to whether input to their care by a clinical psychologist is needed, and access to psychological support.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (assessment of emotional and psychological wellbeing of young people with type 1 diabetes who present with frequent episodes of diabetic ketoacidosis in this case)
Royal College of Paediatrics and Child Health	FULL	29	27	This point is inaccurate and lacks evidence base. Children with type 1 diabetes are at higher risk for adjustment problems during the initial period of adaptation after diagnosis. When adjustment problems exist children are at higher risk for continuing difficulties (Kovacs, Ho & Pollock, 1995). There is growing evidence that young people with diabetes have a greater incidence of psychosocial problems including depression, eating disorders, and anxiety disorders, all of which are associated with poor glycaemic control and long term complications (Northam et al., 2004).	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (adjustment and adaptation following diagnosis in this case)
National Children and	FULL	29	31	The use of 'mental health professionals' is misleading. The department of health guidelines (2012) clearly stipulated the need for psychology as a core member of	The guideline development group use the term 'mental health professional' so that

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Young People's Diabetes Network				the MDT. There is good evidence on the psychological impact of diabetes both on individuals and family unit (see below) there is no evidence that diabetes leads to 'conduct disorder' – this term is inaccurate and inappropriate. Rates of depression have been reported to double in people with diabetes compared to controls (Anderson et al., 2001). The 'costs' of (untreated) depression in diabetes are high. It is associated with poor adherence to treatment and hyperglycaemia; an increased risk of microvascular complications, cardiovascular disease, hospitalizations and medical costs; loss of productivity (work days/days in bed) and increased mortality. (Egede et al, 2003 and Katon et al, 2005) Type 1 Diabetes is also regarded as a risk factor for disordered eating in adolescents. Research strongly suggests there is an increased prevalence of eating disorders, particularly Bulimia Nervosa and Eating Disorder Not Otherwise Specified (EDNOS), in girls with Type 1 diabetes (Colton et al., 2004). The prevalence of General Anxiety Disorder (GAD) in people with diabetes is higher than in the general population. Anxiety can have a negative impact on glycaemic control (HbA1c) both through the disruptive effects of high levels of stress hormones and the avoidance behaviours and dysfunctional coping strategies that people may use to cope with anxiety. In addition, young people with type 1 diabetes are at risk of diabetes specific anxieties, including: • Needle phobia and fear of self-injecting and or self-testing, which is associated with poor glycaemic control (High HBA1c) and is often accompanied by serious psychological co-morbidity such as depression and/or other phobias (Mollema et al., 2001) • Fear of hypoglycaemia (low blood glucose levels), which has an increased risk with elevated trait anxiety and hypoglycaemia 'unawareness'(Snoek et al, 2000) • Fear of hyperglycaemia (high blood glucose levels) and future complications	the recommendation covers access to a wide range of professional services including psychologists, family therapists, psychiatrists, etc. A sentence has been added to the linking evidence to recommendations section of the full guideline to explain this more clearly. The guideline development group consider that the recommendations are complementary to the Best Practice Tariff and do not prevent an annual assessment to determine the need for psychological support. The linking evidence to recommendations section of the review has been amended to clearly state this. NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (conduct disorders, anxiety and depression, eating disorders and cognitive function in this case)

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				(Neumark-Sztainer et al., 2002), which is associated with abnormal frequent self-testing, adjustment of insulin, and extreme low HbA1c's Studies of neuro-cognitive functioning indicate that diabetes can impact on academic achievement particularly in children with poor metabolic control (Naguib et al., 2009)	
Royal College of Paediatrics and Child Health	FULL	29	31	The use of 'mental health professionals' is misleading. The department of health guidelines (2012) clearly stipulated the need for psychology as a core member of the MDT. There is good evidence on the psychological impact of diabetes both on individuals and family unit (see below) there is no evidence that diabetes leads to 'conduct disorder' – this term is inaccurate and inappropriate. Rates of depression have been reported to double in people with diabetes compared to controls (Anderson et al., 2001). The 'costs' of (untreated) depression in diabetes are high. It is associated with poor adherence to treatment and hyperglycaemia; an increased risk of microvascular complications, cardiovascular disease, hospitalizations and medical costs; loss of productivity (work days/days in bed) and increased mortality. (Egede et al, 2003 and Katon et al, 2005) Type 1 Diabetes is also regarded as a risk factor for disordered eating in adolescents. Research strongly suggests there is an increased prevalence of eating disorders, particularly Bulimia Nervosa and Eating Disorder Not Otherwise Specified (EDNOS), in girls with Type 1 diabetes (Colton et al., 2004). The prevalence of General Anxiety Disorder (GAD) in people with diabetes is higher than in the general population. Anxiety can have a negative impact on glycaemic control (HbA1c) both through the disruptive effects of high levels of stress hormones and the avoidance behaviours and dysfunctional coping strategies that people may use to cope with anxiety. In addition, young people with type 1 diabetes are at risk of diabetes specific anxieties, including:	The guideline development group use the term 'mental health professional' so that the recommendation covers access to a wide range of professional services including psychologists, family therapists, psychiatrists, etc. A sentence has been added to the linking evidence to recommendations section of the full guideline to explain this more clearly. The guideline development group consider that the recommendations are complementary to the Best Practice Tariff and do not prevent an annual assessment to determine the need for psychological support. The linking evidence to recommendations section of the review has been amended to clearly state this. NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (conduct disorders, anxiety and depression, eating disorders and cognitive function in this case)

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				• Needle phobia and fear of self-injecting and or self-testing, which is associated with poor glycaemic control (High HBA1c) and is often accompanied by serious psychological co-morbidity such as depression and/or other phobias (Mollema et al., 2001) • Fear of hypoglycaemia (low blood glucose levels), which has an increased risk with elevated trait anxiety and hypoglycaemia 'unawareness'(Snoek et al, 2000) • Fear of hyperglycaemia (high blood glucose levels) and future complications (Neumark-Sztainer et al., 2002), which is associated with abnormal frequent self-testing, adjustment of insulin, and extreme low HbA1c's Studies of neuro-cognitive functioning indicate that diabetes can impact on academic achievement particularly in children with poor metabolic control (Naguib et al., 2009)	
Royal College of Paediatrics and Child Health	FULL	29	40	The Best Practice Tariff criteria (Department of Health, 2012) stipulate that psychology should be "integral to the multi-disciplinary team". Having 'access' to mental health care is not sufficient or adequate.	The guideline development group consider that the recommendations are complementary to the Best Practice Tariff and do not preclude an annual assessment to determine the need for psychological support, nor the inclusion of psychologists as part of the multidisciplinary team. The linking evidence to recommendations section of the review has been amended to clearly state this
Royal College of Paediatrics and Child Health	FULL	29	43	The BPT criteria (Department of Health, 2012) clearly state that all children and young people with a diagnosis of diabetes should have an annual assessment by their MDT as to whether input to their care by a clinical psychologist is needed, and access to psychological support.	The guideline development group consider that the recommendations are complementary to the Best Practice Tariff and do not preclude an annual assessment to determine the need for psychological support. The linking evidence to recommendations section of

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				The use of the term 'conduct disorder' is inappropriate. The use of the term 'mental health professional' is inaccurate. The DoH have clearly recommended psychology professionals in their 2012 guidance.	the review has been amended to clearly state this. Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (conduct disorders in this case) The guideline development group use the term 'mental health professional' so that the recommendation covers access to a wide range of professional services including psychologists, family therapists, psychiatrists, etc. A sentence has been added to the linking evidence to recommendations section of the full guideline to explain this more clearly
Royal College of Paediatrics and Child Health	FULL	29	46	Screening only children who have poor glucose control is inappropriate and has not been recommended. This statement is unclear. It is not stated 'who' should carry out the screening. The DOH 2012 guidance and Best Practice Tariff guidance have clearly stated that ALL children should have an annual assessment by their MDT as to whether input to their care by a psychologist is needed, and access to psychological support.	The guideline development group consider that the recommendations are complementary to the Best Practice Tariff and do not preclude an annual assessment to determine the need for psychological support. The linking evidence to recommendations section of the review has been amended to clearly state this. This recommendation highlights the need for screening in a population at high risk of anxiety and depression. As

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					with all of these recommendations, the intervention should be performed by an appropriately skilled professional
Royal College of Paediatrics and Child Health	FULL	30	1	As above. This point is misleading and does not reflect the DoH 2012 guidance. The risk of 'anxiety/or depression' is inaccurate and not in line with current evidence base (see order number 5 above) Children and young people with diabetes are at risk of anxiety, depression, eating disorders, and neuro-cognitive difficulties. All children should have access to a yearly assessment by their MDT as to whether clinical psychology input is needed.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (anxiety and depression, eating disorders, cognitive function and general aspects of care delivered by mental health professionals in this case)
Royal College of Paediatrics and Child Health	FULL	30	5	The use of 'child mental health professionals' is misleading and inaccurate. Current DoH guidance has clearly requested the presence of psychology as core member of the diabetes MDT and all children and young people with type 1 diabetes should have access to psychological intervention via a clinical psychologist.	Thank you for this comment. The term 'child mental health professionals' is terminology that was used in the 2004 guideline. The guideline development group consider that the recommendations are complementary to the Best Practice Tariff and do not preclude an annual assessment to determine the need for psychological support. The linking evidence to recommendations section of the review has been amended to clearly state this
National Children and Young People's	FULL	30	17	The use of 'child mental health professionals' is misleading and inaccurate. Current DoH guidance has clearly requested the presence of psychology as core member of the diabetes MDT and all children and young people with type 1	Thank you for this comment. The term 'child mental health professionals' is terminology that was used in the 2004 guideline. The guideline development

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Diabetes Network				diabetes should have access to psychological intervention via a clinical psychologist. Evidence base on eating disorders also states the need for a psychologist to lead on interventions.	group consider that the recommendations are complementary to the Best Practice Tariff and do not preclude an annual assessment to determine the need for psychological support. The linking evidence to recommendations section of the review has been amended to clearly state this
Royal College of Paediatrics and Child Health	FULL	30	17	The use of 'child mental health professionals' is misleading and inaccurate. Current DoH guidance has clearly requested the presence of psychology as core member of the diabetes MDT and all children and young people with type 1 diabetes should have access to psychological intervention via a clinical psychologist. Evidence base on eating disorders also states the need for a psychologist to lead on interventions.	Thank you for this comment. The term 'child mental health professionals' is terminology that was used in the 2004 guideline. The guideline development group consider that the recommendations are complementary to the Best Practice Tariff and do not preclude an annual assessment to determine the need for psychological support. The linking evidence to recommendations section of the review has been amended to clearly state this
National Children and Young People's Diabetes Network	FULL	30	20	To my knowledge 'specific family-based behavioural interventions' do not exist. I have never heard of 'behavioural family systems therapy' - this is not an evidence based therapy. There is a growing evidence base for Family Therapy using systemic models and theory (Delamater et al., 2001; Wysocki et al., 2007). There is evidence base for behavioural interventions with individuals (e.g. using functional analysis of behavior). There is evidence base for the use of Motivational Interviewing to improve long-term glycaemic control and psychosocial outcomes (ISPAD, 2009).	Thank you for your suggestions. The terminology used within the review of psychological interventions reflects the descriptions contained in the studies that meet the inclusion criteria set out in the systematic review protocol (Appendix E). More generally, the terminology has been broadened so that the review refers to psychological, and not just behavioural, interventions

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Royal College of Paediatrics and Child Health	FULL	30	20	To my knowledge 'specific family-based behavioural interventions' do not exist. I have never heard of 'behavioural family systems therapy' - this is not an evidence based therapy. There is a growing evidence base for Family Therapy using systemic models and theory (Delamater et al., 2001; Wysocki et al., 2007). There is evidence base for behavioural interventions with individuals (e.g. using functional analysis of behavior). There is evidence base for the use of Motivational Interviewing to improve long-term glycaemic control and psychosocial outcomes (ISPAD, 2009).	Thank you for your suggestions. The review of psychological interventions reflects the descriptions contained in the studies that meets the inclusion criteria set out in the systematic review protocol (Appendix E) More generally, the terminology has been broadened so that the review refers to psychological, and not just behavioural, interventions
Royal College of Paediatrics and Child Health	FULL	30	23	See order number 9. 'Behavioural intervention therapy' is inaccurate terminology. CBT does not focus on quality of life. This is inaccurate. Multi-systemic therapy is not a behavioural intervention. There is no evidence of its effectiveness in diabetes. Mentoring is not a behavioural intervention and is not a therapy. There is no adequate evidence base for the use of mentoring in diabetes. NICE guidance has clearly stated that CBT is the recommended intervention for depression based on RCTs and current evidence base. Recommending motivational interviewing is inaccurate and goes against current gold standards of care. The evidence base for motivational interviewing is in adherence and shown to improve long-term glycaemic control and psychosocial outcomes (ISPAD, 2009).	Please note the following responses to each point raised in the comment. • The terminology referring to 'behavioural interventions' has been amended throughout the guideline to 'psychological interventions' as required. • In this instance, 'CBT focussing on quality of life' is how the paper described the intervention, which is further explained in Table 37 of the full guideline and in the evidence tables in Appendix I (de Wit 2008). • Six studies were included in the review which considered the effectiveness of multi-systemic therapy interventions for children and young people with type 1 diabetes. The evidence was found to be in favour of treatment with this therapy

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					when compared with standard care. • The terminology referring to 'behavioural interventions' has been amended to 'psychological interventions' and evidence for mentoring is presented in the systematic review. • The recommendation has been amended so that it cross-refers to the existing NICE guidance on the treatment of depression in children and young people. The previous version of the recommendation reflected the association between improved depression and motivational interviewing that was found in the evidence specific to those with type 1 diabetes. • The evidence for motivational interviewing referred to here is from Channon 2007 in the ISPAD 2009 guidance which is included in the systematic review of psychological interventions. As only p values were presented in the article they could not be used in the evidence review. The results that were included were not adjusted for baseline and did not demonstrate the same pattern of efficacy.

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Royal College of Paediatrics and Child Health	FULL	31	27	Need to specify what is blood glucose should be raised up to i.e. Consistent with ISPAD Guidance to treat Hypoglycaemia up to 5.6mmol. Relevant for consistent standardised management across England including in school plans and to prevent over treatment of hypoglycaemia which is also important for improving HbA1C's and long term outcomes.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case)
Royal College of Paediatrics and Child Health	FULL	32	18	The NSF (2001) has stated that the provision of information, education and psychological support that facilitates self-management is the cornerstone of diabetes care. Psychological wellbeing should be part of the programme of education from diagnosis.	The guideline development group agree that the psychological well-being and quality of life of all children and young people with diabetes is a very important consideration and have therefore included a recommendation that children, young people and their family members or carers receive access to mental health professionals with an understanding of diabetes. The evidence review did not consider the effectiveness of systematic monitoring of psychological well-being and quality of life
Royal College of Paediatrics and Child Health	FULL	34	46	This point is identical to the one on page 29 – In view of the differences in aetiology and medical management between type 1 and type 2 diabetes, it is unlikely the will have the same identical psychological needs. This is therefore misleading.	Thank you for this comment. The guideline development group recognise that the aetiology and medical management of type 1 and type 2 diabetes are different and that the psychological needs of the children and young people in each of these groups will therefore be different. The recommendation is not prescriptive

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					about what these needs might be
Royal College of Paediatrics and Child Health	FULL	35	1.2.111	Never been certain what is magic about the age 12. Should there be some advice re length of diagnosis as well? A child diagnosed at 11 months will have had diabetes for almost 12 years before being screened, yet a child diagnosed at 12 will be screened within a year.	Thank you for this comment. The guideline development group noted that studies commonly reported only the presence or absence of retinopathy, with little emphasis on severity. Therefore, it was difficult for them to determine the prevalence of retinopathy requiring treatment at any given age. Of the studies which commented on severity of retinopathy at different ages, 5 reported no incidence of proliferative retinopathy in children and young people under the age of 13 years (Cerutti 1989; Frank 1982; Goldstein 1993; Johansen 1994; Klein 1989). This was consistent with the clinical experience of the guideline development group, which was that retinopathy requiring treatment is extremely rare in children and young people under the age of 12 years. They therefore recommended that screening for significant diabetic retinopathy should begin at the age of 12 years. This threshold is consistent with the National Screening Programme
Royal College of Paediatrics and Child Health	FULL	40	4	This will be quite difficult for non-diabetes specialists to follow and may lead to errors. Is it not better to subtract all resuscitation bolus from 48 hour requirement?	The difference between the 'consider' recommendation here (ketone monitoring during management of diabetic ketoacidosis) and the stronger 'offer' or

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					'use' recommendation elsewhere (ketone self-monitoring during management of intercurrent illness) is that there is a lack of specific evidence of cost effectiveness of near-patient testing of ketones in the hospital setting.The reason that resuscitation boluses are not subtracted from the 48-hour fluid calculation is that the fluid quantities recommended in the guideline are already less than in previous guidance and only rarely will a child or young person with diabetic ketoacidosis be given more than 20 ml/kg of intravenous fluid
Royal College of Paediatrics and Child Health	FULL	44	General	There are no recommendations for research on the effectiveness and/or impact of psychological interventions. This is in spite of DoH stating that psychology is a core member of the MDT and The Global ISPAD Consensus Guidelines (2000) stating that "psychosocial factors are the most important influences affecting the care and management of diabetes"	The broad research recommendation highlighting the need for further studies to evaluate the effectiveness of behavioural and social interventions on anxiety and depression, eating disorders, behavioural and conduct disorders, and adherence to therapy in children and young people with type 1 diabetes, especially in adolescence, from diagnosis and in established diabetes which was included in the original (2004) guideline has been retained in the 2015 update. As several specific topics related to psychological and psychosocial issues affecting children and young people with type 1 diabetes are excluded from the 2015 update (for example, anxiety and

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					depression, eating disorders and behavioural and conduct disorders) it has not been possible to be more specific about the form this research should take. The guideline development group agree, however, that systematic reviews to complement those already undertaken for topics included in the update could form part of these further research studies
Royal College of Paediatrics and Child Health	FULL	46	37	Clinical psychologists are stated as one of the professionals for whom this guidance may be relevant. To make this statement accurate all prior mentions of 'child mental health workers' should be corrected to 'clinical psychologists'.	The guideline development group use the term 'mental health professional' so that the recommendations cover access to a wide range of professional services including psychologists, family therapists, psychiatrists, etc. A sentence has been added to the linking evidence to recommendations section of the full guideline to explain this more clearly. The statement about the professionals for whom the guideline may be relevant has been revised accordingly
National Children and Young People's Diabetes Network	FULL	51	9	Specific outcome measures for psychological factors have omitted to include the following: - Adherence (Evidence of adherence to treatment and higher levels of attendance at clinic appointments has already been evidenced (Lemanek et al., 2001)). - Adjustment - Depression (Rates of depression have been reported to double in people with diabetes compared to controls (Anderson et al., 2001)) - Anxiety (including diabetes specific anxieties such as needle phobia, fear of hypoglycaemia, fear of hyperglycaemia)	The selected outcome measures are specified in each individual review protocol in Appendix E. The guideline development group believe the text referred to in the comment is from methods of the 2004 guidance. In the 2015 update, psychological outcomes including adherence, depression and anxiety were considered important outcomes for

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				Most research studies would have included outcomes on one or more of the above (rather than 'quality of life' as the only outcome).	inclusion. These outcomes were considered in addition to quality of life, which is a requirement by NICE as it is used to inform health economic evaluation. Please refer to individual review protocols for details relevant to each systematic review. Unfortunately, the outcomes prioritised for inclusion were not often reported in the literature
Royal College of Paediatrics and Child Health	FULL	51	9	Specific outcome measures for psychological factors have omitted to include the following: - Adherence (Evidence of adherence to treatment and higher levels of attendance at clinic appointments has already been evidenced (Lemanek et al., 2001)). - Adjustment - Depression (Rates of depression have been reported to double in people with diabetes compared to controls (Anderson et al., 2001)) - Anxiety (including diabetes specific anxieties such as needle phobia, fear of hypoglycaemia, fear of hyperglycaemia) Most research studies would have included outcomes on one or more of the above (rather than 'quality of life' as the only outcome).	The selected outcome measures are specified in each individual review protocol in Appendix E. The guideline development group believe the text referred to in the comment is from methods of the 2004 guidance. In the 2015 update, psychological outcomes including adherence, depression and anxiety were considered important outcomes for inclusion. These outcomes were considered in addition to quality of life, which is a requirement by NICE as it is used to inform health economic evaluation. Please refer to individual review protocols for details relevant to each systematic review. Unfortunately, the outcomes prioritised for inclusion were not often reported in the literature
Royal College of Paediatrics and Child	FULL	76	29	Fears and anxieties should be identified by someone with expertise in this area, preferably the clinical psychologist embedded within the MDT (as prescribed in the DoH 2012 guidance).	Thank you for this comment. The guideline development group recognise the importance of identifying depression early

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Health				Depression is often undetected in diabetes clinics by health professionals and the diagnosis of depression is missed in 30 - 50% of the cases in primary and secondary care (Egede et al, 2003)	in this patient group, but did not consider the effectiveness of monitoring psychological well-being in the clinical setting. Making a recommendation about regular screening in this population is therefore outside the remit of the guidance
Royal College of Paediatrics and Child Health	FULL	78	5.2.4	Focusing on evidence base of interventions specific to type 1 diabetes is flawed. There is a wealth of research and evidence base of psychological interventions across chronic health conditions. Flawed outcome criteria in the search for evidence base has led to lack of evidence (see point made in order number 20 above) Furthermore, there is evidence base of the impact of type 1 diabetes on parents (e.g. Streisand et al., 2008) and therefore the need to focus on anxiety and depression in parents and families, not just children and young people with the diagnosis of type 1 diabetes.	Thank you for this comment. The guideline development group acknowledge the points made in relation to the extrapolation of evidence from other long-term conditions and adult populations. At the time of protocol development the option of including studies that enrolled participants with other conditions was considered, but the guideline development group concluded that there were issues specific to children and young people with diabetes that were not present in other conditions. Also, due to concerns around the interpretation of such data and their reliability for informing national recommendations, indirect evidence is typically sought only if there is no evidence available in the population of interest. The need for more data directly relevant to this population is captured in a research recommendation. In addition, the guideline development group carefully considered, and decided to focus on, the impact of type 1 diabetes on the child or young

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					person only, given the available resources
Royal College of Paediatrics and Child Health	FULL	80	5	A lot of weight has been placed on what and how parents feel education should be delivered to the dismissal of the evidence base and what has been found to have the greatest clinical impact. There is strong evidence base to suggest that specialist diabetes nurses need communication skills training and training in the assessment and recognition of the emotional impact of diabetes from appropriately trained psychologists with expertise in child development and family dynamics (e.g. Lowes et al., 2015). Evidence for psychological group interventions with children and young people have been shown to improve adherence and adjustment (e.g. Greco et al., 2001)	There was no evidence identified to support structured education from diagnosis (structured here meaning a formal training or education package with a recognised curriculum and approaches to delivery). The guideline recommendations do, however, list core topics that should be covered as part of (unstructured) education An individualised approach to education is already covered in the recommendations and the guideline development group's remit did not include consideration of who delivers care and training to deliver education Thank you for this comment. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (non-adherence and adjustment to diagnosis in this case).
Royal College of Paediatrics and Child Health	FULL	81	General	There is no mention of education for the emotional impact on parents of a diagnosis of type 1 diabetes on their child.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on topics that

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					are outside the scope of the guideline, which applies in the case of this comment
Royal College of Paediatrics and Child Health	FULL	81	General	Educational aims for infants and preschool children should also include education on changes in their child's mood and behaviour (e.g. anxiety, depression, and anger) and how to manage these.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (education according to age group in this case).
Royal College of Paediatrics and Child Health	FULL	81	General	Educational aims for primary school children should also include education on changes in their child's mood and behaviour (e.g. anxiety, depression, and anger) and the possible impact on peer relationships and activities, and how to manage these.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (education according to age group in this case). Moreover there was no evidence identified to support structured education from diagnosis (structured here meaning a formal training or education package with a recognised curriculum and approaches to delivery). The guideline recommendations do, however, list core topics that should be covered as part of (unstructured) education. The guideline development group 's view is that the core topics and the recommendations to tailor

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					education to the individual and add other topics as needed cover much of the stakeholder's comment. The majority of children and young people with diabetes will not have anxiety or depression anyway, despite being at increased risk, and so these do not need to be listed as core topics
Royal College of Paediatrics and Child Health	FULL	81	8	Change to or add "hyperglycaemia"	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (education according to age group in this case)
Royal College of Paediatrics and Child Health	FULL	81	43 46	The wording on this statement is inappropriate and pathologises and belittles young people's experiences of the transition into adolescence. Adolescence is a period of high risk for all young people (regardless of whether or not they live with a chronic illness) due to physiological and psychosocial changes, including cognitive neuro-developments. Living with Type 1 diabetes places adolescents at higher risk for problems with anxiety, depression, disordered eating, and deterioration of adherence to their diabetes regimen.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (adolescence in this case)
Royal College of Paediatrics and Child Health	FULL	82	6 8	There is no evidence base for conflict resolution and bargaining techniques as 'coping skills training'. 'Coping skills training' is not a standardised intervention.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the

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				'Coping skills training' is a phrase used to denote a range of skills which are chosen by the researcher/therapist (e.g. coping skills in a standardised CBT intervention, in group interventions ranging from coping with pain, coping with diagnosis of personality disorder, treating substance abuse, etc…) The use of the term 'coping skills training' is misleading and inaccurate and is not supported by evidence base.	guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (education according to age group in this case)
Royal College of Paediatrics and Child Health	FULL	100	General	Recommendations should include education on psychological wellbeing in children and young people as well as parents and family members. This is in line with The Global ISPAD Consensus Guidelines (2000), which state that "psychosocial factors are the most important influences affecting the care and management of diabetes"	There was no evidence identified to support structured education from diagnosis (structured here meaning a formal training or education package with a recognised curriculum and approaches to delivery). The guideline recommendations do, however, list core topics that should be covered as part of (unstructured) education. The guideline development group's view is that the core topics and the recommendations to tailor education to the individual and add other topics as needed cover much of the stakeholder's comment. The majority of children and young people with diabetes will not experience psychological or psychosocial issues, despite being at increased risk, and so these do not need to be listed as core topics
Royal College of Paediatrics and Child Health	FULL	100	40 43	"Take particular care" does not specify what resources need to be used to communicate with children and/or families with physical and sensory and/or where English isn't the first language. This section should be removed if not amended appropriately.	Thank you for this comment. The guideline development group deliberately left these recommendations broad as they did not look at evidence as part of the 2015

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				Accessible communication options should be listed (e.g. written information or audiotaped material and professional interpreters should be sought for those whose preferred language is not English).	update to allow specific individual circumstances to be considered (because this part of the guideline was excluded from the 2015 update) and so no specific resources are recommended. Although the guideline development group were unable to amend the phrasing or content of these recommendations they selected them as key priorities for implementation (key recommendations) because of the importance of the content
Royal College of Paediatrics and Child Health	FULL	101	General	Research recommendations do not highlight the need to explore the benefits of education in wellbeing and/or what aspects of the education have the greatest benefits.	Thank you for this comment. The evidence for components and topics of an education package is presented in Section 5.2 and includes a Health Technology Appraisal which examined the effects on psychosocial outcomes. This evidence review was not updated in the 2015 guideline as it was not included in the scope of the update
Royal College of Paediatrics and Child Health	FULL	117	17	Change "dietary" to "insulin" regimen	Thank you. This typographical error in the full guideline has been corrected
Novo Nordisk Ltd	FULL	121	6	The guideline states 'Another type of long-acting insulin analogue (insulin detemir) is in the process of being licensed.' This is factually inaccurate. Insulin detemir (Levemir®) is indicated for treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above. We would request that this statement is corrected.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been

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				Also on 30 Jan 2015 the European Commission approved the license for insulin degludec for treatment of diabetes mellitus in adults, adolescents and children from the age of 1 year. Insulin degludec is a basal insulin with a -long duration of action and stable action profile that results in a glucose lowering effect beyond 42 hours and a lower day-to-day variability in glucose-lowering effect compared with insulin glargine (Tresiba® SPC).	reviewed since the original (2004) guideline (insulin preparations in this case)
Royal College of Paediatrics and Child Health	FULL	149	23 46	Carbohydrate counting: We understand that 'level 3 carbohydrate counting' derives from an American system in 1998, where Level 1 is basic looking at meal volume, Level 2 is advanced learning – identifying carbohydrate- and Level 3 is what we would usually consider as carbohydrate counting. We don't believe there is any robust evidence that this is required from diagnosis. We wonder if it may be unrealistic as families have so much to take on board when adjusting to the diagnosis. Level 1 certainly seems important with a view to working towards Level 3. We wonder what the psychology view on this would be as recent presentations suggest that there is too much to learn at diagnosis.	Thank you for this comment. Level 3 carbohydrate counting is the use of carbohydrate counting with the adjustment of insulin dosage according to carbohydrate content of meals and blood glucose levels, using an insulin:carbohydrate ratio. This has been clarified in a footnote to the recommendation. There is evidence of the effectiveness of using level 3 carbohydrate counting and its use is in keeping with common practice in the UK, which the guideline development group felt was justification for recommending it from diagnosis
Royal College of Paediatrics and Child Health	FULL	179	50 51	Blood sugar tests: 5 blood tests a day – where is the evidence for this and why a change from four per day? When would the 5th one be? – if NICE stick to this, they should specify when the tests should be taken. We think that one extra during the night may be ok initially but sets a precedent and anxiety that families may not be able to break. Guidance should state a minimum of 4 blood sugar tests per day. The pre-prandial targets set seem reasonable, not sure where the post-	Thank you for this comment. The guideline development group discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that should be recommended, but also the timing at which the tests should be

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				prandial targets come from, but again seem reasonable. The guidance should state a target for before bed.	performed. The evidence reviewed for the guideline demonstrated that glycaemic control improves with the number of capillary tests performed up to 5 five tests per day. The guideline development group concluded, therefore, that at least 5 tests should be performed routinely, and emphasised in the revised recommendations that it is often necessary to conduct more than 5 tests. They did not, however, wish to specify an upper limit for the number of tests, nor the exact timing for the minimum number of tests because to do so would remove some flexibility that is otherwise available to the child or young person and their family members or carers (as appropriate)
Royal College of Paediatrics and Child Health	FULL	213	General	Behavioural interventions are rarely used in isolation (e.g. cognitive behavioural therapy, CBT uses behavioural interventions as one component of the therapy but rarely on its own). A review of behavioural interventions is a very narrow view of the evidence base and outcomes research in psychological interventions in paediatric diabetes.	Thank you for this comment. The literature search for the guideline was sufficiently broad that it would have captured the literature covering interventions that were assessed in combination with each other. The guideline development group recognise that these interventions often comprise multiple parts, but this was not reflected in the literature.. A systematic review of behavioural interventions was specified as part of the scope of the guideline update

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Royal College of Paediatrics and Child Health	FULL	213	10	Cognitive disorders is a term used inaccurately.	Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (cognitive disorders in this case)
Royal College of Paediatrics and Child Health	FULL	213	10.2	This whole section is badly written and psychological terminology is used incorrectly throughout. The section needs re-writing for it to be accurate and have meaning. In its current status, it is meaningless.	Thank you for this comment. The guideline development group have reviewed the terminology and amended it where appropriate
National Children and Young People's Diabetes Network	FULL	213	29 31	The Global ISPAD Consensus Guidelines (2000) stated that "psychosocial factors are the most important influences affecting the care and management of diabetes".	Thank you for this comment recognising the importance of psychosocial factors in children and young people with diabetes
Royal College of Paediatrics and Child Health	FULL	213	33	'Conditions such as depression, and eating..' – This sentence is grammatically and conceptually incorrect. Eating is not a condition!	This is a matter of punctuation in a section of the guideline that is excluded from the 2015 update (emotional and behavioural problems). The phrase continues as follows: 'Conditions such as depression, and eating, cognitive and behavioural disorders …' and the sense is that eating appears in in conjunction with disorders (i.e. the reference is to eating disorders). No change has been made in response to this comment
Royal College	FULL	213	36	'Severe conduct or attachment difficulties' – Conduct difficulties is a meaningless	Please note that NICE is not able to

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of Paediatrics and Child Health				term. Behaviour difficulties and conduct disorder are appropriate terms (for different concepts) and are not the same as attachment difficulties. This sentence in its current form is meaningless.	accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (emotional and behavioural problems in this case)
Royal College of Paediatrics and Child Health	FULL	213	39	This sentence is unclear: 'in a partnership between paediatric and child mental health services' Does this refer to paediatric psychologists working in partnership with Child and Adolescent Mental Health services? Or Does this refer to paediatric health professionals working in partnership with clinical psychologists to address mental health issues?	Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (emotional and behavioural problems in this case)
Royal College of Paediatrics and Child Health	FULL	213	40 42	The sentence: 'Diagnosis of a chronic condition such as type 1 diabetes may be accompanied by a period of denial followed by gradual acceptance during which feelings of grief, stress and difficulty in coping may be experienced'. This is a poor description of the process of adjustment to a chronic illness. There are multiple and varying models of adjustment to chronic illness, none of which are well represented by the sentence above. The word 'denial' is a pathologising term.	Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (emotional and behavioural problems in this case)
Royal College of Paediatrics and Child Health	FULL	215	3	'In the medically ill' is a pathologising term and should be removed.	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is generally not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (anxiety and depression in this

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					case). In this case, it has, however, been possible to amend the terminology of the introductory sentence to replace 'in the medically ill' with 'when associated with other medical conditions'
Royal College of Paediatrics and Child Health	FULL	215	8 11	These statistics are not relevant to the NICE guidance for children and young people with type 1 diabetes.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (anxiety and depression in this case)
Royal College of Paediatrics and Child Health	FULL	215	14	Does the term 'sex' denote 'gender'? If so, this should be amended appropriately.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (anxiety and depression in this case)
National Children and Young People's Diabetes Network	FULL	216	General	This section is inaccurate and poorly written. There is no gold standard method of diagnosing or detecting 'depressive symptoms'. What exists are tools that aid in the detection of depressive symptoms (e.g. the CDI and the BDI) with cut off scores that identify those more or less at risk. Clinical depression can be diagnosed using DSM-IV criteria by psychiatrists and/or psychologists. The impact of depressive symptoms on daily functioning is the most important	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004)

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				factor.	guideline (anxiety and depression in this case)
Royal College of Paediatrics and Child Health	FULL	216	General	The NICE guidance 'Depression in children and young people: Identification and management in primary, community and secondary care' is comprehensive and highlights the importance of psychological intervention, using CBT. Focusing on evidence of CBT for depression in children with type 1 diabetes is not appropriate. The existing evidence base for interventions targeting depression has been done with children and young people who have symptoms of depression, regardless of their chronic health condition. Managing depression with antidepressants is not the first line of treatment for children and young people. Research done with adult populations cannot be extrapolated or generalized to children and young people, especially if this is with regards to medication. This section has omitted to report on managing children and young people with suicidal ideation and/or intention despite discussing research that highlights the risk of self-harm and suicide in this population.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (anxiety and depression in this case)
Royal College of Paediatrics and Child Health	FULL	216	23 27	Poorly written section with gross inaccuracies. It also offers an interpretation for the risk of depression. This is a rudimentary way of conceptualising depressive symptoms and does not highlight that a diagnosis of type 1 diabetes places children, young people and their families at greater risk of depressive symptoms.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (anxiety and depression in this case)
Royal College	FULL	217	Gener	Section 10.4 on Eating Disorders confuses evidence on the prevalence of eating	Thank you for submitting comments in

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of Paediatrics and Child Health		218	al	disorders in type 1 diabetes with research on interventions for the management of eating disorders in this population. Research strongly suggests there is an increased prevalence of eating disorders, particularly Bulimia Nervosa and Eating Disorder Not Otherwise Specified (EDNOS), in girls with Type 1 diabetes (Colton et al., 2004). Insulin omission ('purging') is most frequently reported (10% skip injections; 7.5% under dose insulin). 'NICE guidance: Eating disorders: Core interventions in the treatment and management of anorexia nervosa, bulimia nervosa and related eating disorders' specifies that all children and young people with Type 1 diabetes and poor adherence should be screened and assessed for the presence of an eating disorder. Evidence base interventions recommended by the NICE guidance above include cognitive analytic therapy (CAT), cognitive behaviour therapy (CBT), interpersonal psychotherapy (IPT), focal psychodynamic therapy and family interventions focused explicitly on eating disorders all of which need to be carried out by an appropriately trained professional in psychological therapies.	response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (eating disorders in this case)
British Psychological Society	FULL	217	12 20	Section 10.4 on Eating Disorders confuses evidence on the prevalence of eating disorders in type 1 diabetes with research on interventions for the management of eating disorders in this population. The literature suggests that there is an increased prevalence of eating disorders, particularly Bulimia Nervosa and Eating Disorder Not Otherwise Specified (EDNOS), in girls with Type 1 diabetes (Colton, P et al, 2004) Insulin omission ('purging') is most frequently reported (10% skip injections; 7.5% under dose insulin).	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (eating disorders in this case)

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				'NICE guidance: Eating disorders: Core interventions in the treatment and management of anorexia nervosa, bulimia nervosa and related eating disorders' specifies that all children and young people with Type 1 diabetes and poor adherence should be screened and assessed for the presence of an eating disorder. Evidence-based interventions recommended by the NICE guidance above include; cognitive analytic therapy (CAT), cognitive behaviour therapy (CBT), interpersonal psychotherapy (IPT), focal psychodynamic therapy and family interventions focused explicitly on eating disorders all of which need to be carried out by an appropriately trained professional in psychological therapies. References: Colton, P. Olmsted, M., Daneman, D., Rydall, A. and Rodin, G. (2004) Disturbed Eating Behavior and Eating Disorders in Preteen and Early Teenage Girls With Type 1 Diabetes: A case-controlled study. Diabetes Care, 27(7), 1654-1659.	
Royal College of Paediatrics and Child Health	FULL	217	12 20	'Studies' do not tend to advise on what health professionals give treatment or intervention on depression (e.g. I equally do not know of any studies that specify who should lead the medical healthcare of children with type 1 diabetes) There are numerous professionals who can advise children and young people on depression, including: - GP - Clinical psychologists in CAMHS - Paediatric clinical psychologists embedded within the MDT - Child psychiatrists - Child and adolescent mental health care professionals Furthermore:	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (methods of managing depression in this case)

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				The Global ISPAD Consensus Guidelines (2000) made the following three recommendations: (i) Psychologists should be part of the interdisciplinary health care team (ii) Overt psychological problems should receive support from the diabetes care team and expert attention from psychology (iii) The diabetes care team should receive training in the recognition, identification, and provision of information on psychosocial problems related to diabetes	
Royal College of Paediatrics and Child Health	FULL	219	10.5	The term 'cognitive disorders' is inaccurate and misleading. Cognitive disorders is a term used in DSM-IV diagnostic manual to specifically denote mental health disorders that affect memory, learning, perception and problem solving (including amnesia, dementia and delirium). Studies of neuro-cognitive functioning indicate that young people with diabetes are at increased risk for information processing weaknesses and learning problems, especially with early diabetes onset and history of sever hypoglycaemia or chronic hyperglycaemia. There is also evidence to suggest that diabetes can impact on academic achievement particularly in children with poor metabolic control (Naguib et al., 2009)	The phrase in this title (behavioural and conduct disorders) is what was used in the original (2004) guideline. Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (the section titled behavioural and conduct disorders in this case)
National Children and Young People's Diabetes Network	FULL	221	General	The title ' Behavioural and Conduct Disorders' is inaccurate and misleading. 'Behavioural disorders' is a term that encompasses diagnosis such as Oppositional Defiant Disorder, Conduct Disorder, and Attention Deficit Hyperactivity Disorder. Behavioural problems and conduct disorders are very different things. Discussing both in parallel is inappropriate and misrepresents the evidence base. Conduct disorder is a diagnostic term from DSM-IV that is characterised by	The phrase in this title (behavioural and conduct disorders) is what was used in the original (2004) guideline. Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (the section titled behavioural and conduct disorders in this case)

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				fighting and physical cruelty, destructiveness, lying and stealing, truancy and running away from home. Psychiatrists and clinical psychologists can help to diagnose conduct disorder. Behavioural problems can occur in children of all ages and include temper tantrums and occasional outbursts of aggressive behavior. These do not meet criteria for a diagnosis of conduct disorder.	
British Psychological Society	FULL	221	10.6	The term 'cognitive disorders' is potentially misleading. Cognitive disorders is a term used in DSM-IV diagnostic manual to specifically denote mental health disorders that affect memory, learning, perception and problem solving (including amnesia, dementia and delirium). Studies of neuro-cognitive functioning indicate that young people with diabetes are at increased risk for information processing weaknesses and learning problems, especially with early diabetes onset and history of sever hypoglycaemia or chronic hyperglycaemia. There is also evidence to suggest that diabetes can impact on academic achievement particularly in children with poor metabolic control (Naguib et al., 2009). References: Naguib, J.M., Kulinskaya, E., Lomax, C.L. & Garralda, M.E. (2009). Neuro-cognitive performance in children with type-1 diabetes – a meta-analysis. Journal of Pediatric Psychology, 34(3): 271-282.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (cognitive disorders in this case)
Royal College of Paediatrics and Child Health	FULL	221	10.6	The title ' Behavioural and Conduct Disorders' is inaccurate and misleading. 'Behavioural disorders' is a term that encompasses diagnosis such as Oppositional Defiant Disorder, Conduct Disorder, and Attention Deficit Hyperactivity Disorder. Behavioural problems and conduct disorders are very different things. Discussing	The phrase in this title (behavioural and conduct disorders) is what was used in the original (2004) guideline. Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original

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				both in parallel is inappropriate and misrepresents the evidence base. Conduct disorder is a diagnostic term from DSM-IV that is characterised by fighting and physical cruelty, destructiveness, lying and stealing, truancy and running away from home. Psychiatrists and clinical psychologists can help to diagnose conduct disorder. Behavioural problems can occur in children of all ages and include temper tantrums and occasional outbursts of aggressive behavior. These do not meet criteria for a diagnosis of conduct disorder.	(2004) guideline (the section titled behavioural and conduct disorders in this case)
National Children and Young People's Diabetes Network	FULL	223	General	Behavioural interventions are a specific type of intervention that is based on behavioural theory and behavioural models (e.g. operant conditioning, classical conditioning, reinforcement, extinction and reward). The research evidence summarised in this section is overall not in line with behavioural interventions. This heading and review question is therefore invalid.	Thank you for this comment. The guideline development group have amended the terminology where appropriate
Royal College of Paediatrics and Child Health	FULL	223	General	Behavioural interventions are a specific type of intervention that is based on behavioural theory and behavioural models (e.g. operant conditioning, classical conditioning, reinforcement, extinction and reward). The research evidence summarised in this section is overall not in line with behavioural interventions. This heading and review question is therefore invalid.	Thank you for this comment. The guideline development group have amended the terminology where appropriate
Royal College of Paediatrics and Child Health	FULL	223	24 27	Motivational Interviewing is not a behavioural intervention. It is a conversational tool that leads to behaviour change. Motivational interviewing is a collaborative, goal-oriented style of communication with particular attention to the language of change. It is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person's own reasons for change within an atmosphere of acceptance and compassion (Miller & Rollnick).	Thank you for this comment. The guideline development group have amended the terminology where appropriate

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Royal College of Paediatrics and Child Health	FULL	223	35	Family-based teamwork is not a model of therapy or an evidence based intervention.	Thank you for this comment. The terminology has been amended throughout to more accurately reflect the content of the interventions. The review is led by the evidence identified in the systematic review
Royal College of Paediatrics and Child Health	FULL	223	41	Behavioural family systems therapy is a variation on the family therapy model used at the Maudsley Hospital for eating disorders, where most of the evidence base lies. BFST is not widely used in paediatric settings, outside of eating disorders. Only one RCT has been carried out in diabetes with this model (Wysocki et al., 2007). It is inadequate to base evidence in this guidance based on one paper only.	Thank you for this comment. The purpose of the review is to determine the effectiveness of behavioural family systems therapy in children and young people with type 1 diabetes. The extent of this therapy's application in other settings and disease areas is not relevant to the review. The recommendation states that the healthcare professional should consider its application in this setting and is accompanied by a recommendation for further research
Royal College of Paediatrics and Child Health	FULL	223	45	Multisystemic Therapy (MST) is not a behavioural intervention. MST is an intensive family and community based intervention that has good evidence base for young people at risk in either care or custody due to their offending or having severe behaviour problems. The training for MST comes from the USA and is expensive. To my knowledge it has not been used in paediatric diabetes settings in the UK and there is no evidence base for its effectiveness in this population.	Thank you for this comment. The terminology has been amended throughout to more accurately reflect the content of the interventions
Royal College of Paediatrics and Child Health	FULL	224	General	Description of included studies – this section is not coherent. It is not valid to campare the interventions listed as they all derive from different therapeutic models.	Thank you for this comment. The guideline development group have amended the terminology throughout this section so that it reflects the content of the interventions.

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				It is also misleading to focus on 'behavioural outcomes' and HBA1c for these interventions as none of the interventions included in this section can be defined as purely behavioural interventions. There is a large evidence base on the effectiveness of CBT on depression, anxiety, and eating disorders. Focusing on 'quality of life' as the only outcome is not an adequate report of the evidence base. There is a large evidence base on the effectiveness of Motivational Interviewing on adherence to treatment. Focusing on HBA1C as the main outcome is under reporting of the evidence base.	The systematic review sought all available evidence in this population and did not directly compare the interventions via any quantitative analysis. The guideline development group discussed the heterogeneity of the evidence in the linking evidence to recommendations section of the review. Please note that the outcomes prioritised for inclusion in this systematic review (Appendix E) included depression, anxiety and adherence in addition to health-related quality of life. These outcomes were included in the evidence base when they were reported in the included studies
Royal College of Paediatrics and Child Health	FULL	224	1 3	Mentoring is not a behavioural intervention. It is a supportive relationship where young people are able to share and participate in activities with their mentor and get help to reach their goals (e.g. write a CV). "Mentoring is to support and encourage people to manage their own learning in order that they may maximise their potential, develop their skills, improve their performance and become the person they want to be." Eric Parsloe, The Oxford School of Coaching & Mentoring	Thank you for this comment. The terminology has been amended as required
Royal College of Paediatrics and Child Health	FULL	224	4 5	Peer support is not a behavioural intervention. Peer support can be defined as people supporting each other on an equal basis, to offer something based on shared experiences. This is usually provided informally via groups.	Thank you for this comment. The terminology has been amended throughout to more accurately reflect the content of the interventions

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Royal College of Paediatrics and Child Health	FULL	235	General	An overall summary of the evidence base on these interventions is not satisfactory as they cannot be compared to each other.	Thank you for this comment. The interventions have not been compared to each other, but rather considered in the context of their clinical and cost effectiveness
Royal College of Paediatrics and Child Health	FULL	239	General	The Global ISPAD Consensus Guidelines (2000) stated that "psychosocial factors are the most important influences affecting the care and management of diabetes" HBA1c is a medical measure and is not a fit outcome for psychological interventions that focus on exploring and working on relationships, overall mood and quality of life. Thus, placing HBA1C as the highest priority outcome of psychological interventions dismisses a large part of the evidence base.	Thank you for this comment. The guideline development group recognise the importance to children, young people and their family members or carers the need for improving psychological outcomes which is why the protocol for this review question included a set of six psychological outcomes (health-related quality of life; children and young people's and families' satisfaction with intervention; depression; anxiety; school performance or attendance; and risk-taking behaviours). In addition to this, HbA1c provides a valid and reliable measure of clinical benefit
Royal College of Paediatrics and Child Health	FULL	240	34 37	The BPT criteria (Department of Health, 2012) stipulate that psychology should be "integral to the multi-disciplinary team" and that each patient should have an annual assessment by their MDT as to whether input to their care by a clinical psychologist is needed, and access to psychological support as appropriate. The GDG considering whether or not to offer psychological interventions to families based on whether they consider it to be 'burdensome' is inappropriate. This implies a subjective opinion on whether children and families should have access to psychology and is discriminatory (i.e. only the children and families who shout loudest will have access to psychological support). Furthermore, attending 4x clinic appointments to meet Best Practice Tariff criteria (and ensure the trust in question gets the financial reward) also impacts on school attendance and family	The guideline development group consider that the recommendations are complementary to the Best Practice Tariff and do not preclude an annual assessment to determine the need for psychological support. The linking evidence to recommendations section of the review has been amended to clearly state this. The statement that behavioural

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				functioning, particularly for those children and young people who have good adherence and well controlled blood glucose levels. All children and young people with type 1 diabetes should have equal access to psychological assessment and support as stipulated by the DoH guidelines and the ISPAD guidelines. Some children and their families may decline or chose not to engage with psychology services and this will be at the choice and discretion of the families, while their needs should continue to be monitored by the wider MDT.	interventions could be inconvenient or even burdensome for some reflects the diversity of attitude toward the uptake of psychological interventions by children, young people and their families which may affect decision-making. It should not influence the offering of, or availability of access to services. The statement has been revised to clearly reflect this intention
Royal College of Paediatrics and Child Health	FULL	240	38 45	The GDGs reflections on who is best placed to deliver psychological interventions is moot. Most of the interventions listed in the guidance can only be carried out by trained professionals who would only have access to training if they are professionally qualified to do so (with the exception of counselling, mentoring, peer support and family-based teamwork).	Thank you for this comment. Not all of the interventions require delivery by an appropriately skilled professional and therefore the guideline development group have not amended the text
Royal College of Paediatrics and Child Health	Full	241	General	The quality of the evidence is impacted by the choice of outcomes in the review process and the lack of understanding about psychological concepts such as: behavioural interventions, conduct disorder, behaviour disorder, quality of life, counselling etc… (see numerous points above) Key conclusions are flawed and lack evidence base in view of the above. There is extensive evidence base on the impact of motivational interviewing for adherence in children and young people The key recommendation for depression is CBT as per NICE gold standard guidance. There are no conclusions or recommendations for self-harm and suicidal risk despite this being highlighted in previous sections of the guidance.	The guideline development group acknowledge the concerns highlighted in this comment and have responded to each point individually in the previous comments and made amendments to the guideline where appropriate. No data on self-harm were identified in the evidence reviewed for psychological interventions. The discussion about suicidal risk was in the 2004 guidance which was not updated in 2015
British Psychological Society	FULL	241	5 7	The quality of the evidence is impacted by the choice of outcomes in the review process and the lack of understanding about psychological concepts such as: behavioural interventions, conduct disorder, behaviour disorder, quality of life, counselling etc… (See previous comments above). This has had an impact on the	The guideline development group acknowledge the concerns highlighted in this comment and have responded to each point individually in the previous comments

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				key conclusions. There is extensive evidence for the effectiveness of motivational interviewing for adherence in children and young people. The key recommendation for depression is CBT as per NICE guidance. There are no conclusions or recommendations for self-harm and suicidal risk despite this being highlighted in previous sections of the guidance.	and made amendments to the guideline where appropriate. No data on self-harm were identified in the evidence reviewed for psychological interventions. The discussion about suicidal risk was in the 2004 guidance which was not updated in 2015
Royal College of Paediatrics and Child Health	FULL	241	5 7	Psychological intervention has proved to significantly reduce number of readmissions into hospital (Martin et al., 2013). High levels of parental anxiety have been shown to increase use of health care resources and therefore increase the cost of treatment (Goldman and Owen, 1994). In addition, children with Type 1 diabetes who have associated low mood have higher utilisation of health services (Cote et al., 2003). Integrated psychology into paediatric diabetes is likely to offset medical costs, including: • Better adherence to treatment and higher levels of attendance at clinic appointments (Lemanek et al., 2001). This will reduce medical costs through the prevention of long-term complications and reduced number of DNA's at clinic appointments. • Psychological interventions for procedural fear or anxiety can reduce the number of cancelled blood tests and medical procedures and maximise resources. • Indirect cost benefits of improved staff retention and reduction of staff sick days as a result of staff feeling well supported by having a clear referral route for complex psychological cases. The Department of Health has stipulated that transition from paediatric to adult services should be a purposeful, planned process that addresses the medical, psychosocial and educational and vocational needs of adolescents and young adults with diabetes (DOH, 2012). Holmes, Walker, Llewellyn and Farrell (2007)	Thank you for this comment. The systematic review conducted in the 2015 guideline update demonstrates a positive association between psychological intervention and patient benefit, including a reduction in diabetic ketoacidosis (DKA)-related admissions to hospital (Ellis 2007). None of the studies cited in this comment met the inclusion criteria for the review as set out in the review protocol (Appendix E). The guideline development group discuss the benefits of psychological interventions in the evidence to recommendations section of the full guideline following the evidence review and, while they agree with many of the points raised in the comment, the evidence was limited with regard to some key outcomes The transition from paediatric to adult

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				showed that the cost of providing a transition care programme was covered by the cost savings made through fewer admissions to hospital	services is the focus of a NICE guideline currently in development: http://www.nice.org.uk/guidance/indevelopment/gid-scwave0714
Royal College of Paediatrics and Child Health	FULL	295	12 16	HbA1c target: Where is the evidence for this target? We don't doubt the principle of aiming for the best HbA1c possible for the individual, but think this target is too much of a jump and will be demotivating for individual patients and their teams. A change to less than or equal to 53mmol/mol (7%) seems reachable. If NICE persist with the target of <48mmol/mol (6.5%), they should state what is safe in terms of frequency and severity of hypoglycaemia.	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c

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					preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These

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					considerations have been documented in the revised evidence to recommendations section in the full guideline
Royal College of Paediatrics and Child Health	General	31 273	1 3	Add "and if any symptoms, e.g. poor growth, gastrointestinal symptoms, anaemia or post-prandial hypoglycaemia".	Thank you for this comment. The symptoms referred to in the comment are quoted from the 2000 ISPAD consensus guideline recommendations on the diagnosis of coeliac disease in children and young people with diabetes. The recommendations have been amended to cross-refer to the NICE coeliac disease guideline on monitoring for coeliac disease in children and young people with type 1 diabetes
Royal College of Paediatrics and Child Health	General	40	1.3.17	1.3.17 Talking about healthy eating at EACH contact. 'Regularly' would suffice	This recommendation relates to children and young people with type 2 diabetes and the guideline development group felt it was important to discuss healthy eating at every visit, whereas regularly would be ambiguous and potentially much less frequent
Royal College of Paediatrics and Child Health	General	43 377	38 32	Preparation for Transition should start around 12 years of age. Ensure that the young person has the knowledge and skills to self-manage their diabetes prior to transfer to young adult or adult services (unless physical or learning disabilities prevent this). This should be documented on an individual Transition Plan.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (transition from paediatric to adult services in this case)

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Royal College of Paediatrics and Child Health	General	47 50	General	Management of Diabetic Ketoacidosis: We are disappointed to see changes to this with no evidence to support it. Adapting to the previous guidance took a lot of effort of education and some of the changes seem to go back. The principle of restricting fluids is appropriate, but why change to not taking the fluid boluses into account having previously taken them off the 48 hour total? It will cause further confusion. Should there be a restriction on number of boluses given? The restriction of maintenance fluids to 40mls/hour for bigger children seems random and will cause increased hypoglycaemia on 0.1 units/kg/hour insulin infusion (we already see more than previously). We note the change to 0.05-0.1 units/kg/hour – if there is a need to change back, it should specify when to use which rate. Also 1.4.44 gives a range for infusion rate but surely should either recommend starting at highest or lowest and then titrate up or down depending on rate of fall of blood sugar. No oral fluid at all unless ketones <1 – again, where is the evidence? Should patients follow this principle at home? It seems extreme.	The guideline development group sought evidence for each of their review questions related to the scope of the 2015 update, including the section on diabetic ketoacidosis. Where evidence is lacking they have used their clinical expertise and experience to formulate recommendations and this is discussed in the linking evidence to recommendations section of the full guideline. The reason that resuscitation boluses are not subtracted from the 48-hour fluid calculation is that the fluid quantities recommended in the guideline are already less than in previous guidance and only rarely will a child or young person with diabetic ketoacidosis be given more than 20 ml/kg of intravenous fluid The restriction of fluids to 40 ml/hour does not tend to increase the risk of hypoglycaemia (this is based on the expertise and experience of the guideline development group) and the guideline recommends relatively low doses of insulin (as low as 0.05 units/kg/hour) It is not possible to choose between 0.05 units/kg/hour and 0.1 units/kg/hour based

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					on the available evidence and so the recommendation allows for any dosage in that range The recommendation about restricting oral fluids has been changed to avoid specifying a value for ketones and now states that oral fluids should not be given to a child or young person who is receiving intravenous fluids for diabetic ketoacidosis unless ketosis is resolving, the chid or young person is alert, and there is no nausea or vomiting
Royal College of Paediatrics and Child Health	General	58	General	Consideration of transition to adult services: there should be care that the guidance links to adult guidance. I understand that the adult guideline is likely to say that metformin should be used in combination with insulin for those with insulin resistance due to obesity. It has been beneficial in some young people, so our guidance should be more flexible. In Type 2 diabetes, should we always use metformin from diagnosis or might there be some who benefit from lifestyle changes?	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (transition from paediatric to adult services in this case). This guideline emphasises that some aspects of diabetes care will change at transition. Moreover, the scope for the 2015 update did not include pharmacological treatments other than metformin for children and young people with type 2 diabetes, and this is why insulin is not considered for type 2 diabetes in this guideline. The guideline

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					development group's view is that metformin should be offered to children and young people with type 2 diabetes from diagnosis, but there are also recommendations about lifestyle advice (diet, physical activity and weight loss)
Royal College of Paediatrics and Child Health	General	91		Sick day rules: reviewing these annually with patients seems a reasonable standard. Previously, there had been suggestions e.g. how much extra insulin to give and we think these basic principles should still be included.	Thank you for this comment in support of the guideline. The recommendations which mention sick-day rules include adjustments to insulin regimens, which is broad enough to cover the issues highlighted in the comment
Royal College of Paediatrics and Child Health	General	99		Calculating Body Mass Index at each clinic visit? We do that when recording on our database, but unsure that is helpful information for every patient – we already see some insulin mismanagement as a form of eating disorder. Measuring and plotting height and weight at each clinic visit should be enough	We agree that it is not necessary to measure BMI at every clinic visit for children and young people with type 1 diabetes and so the bullet about BMI measurement has been deleted from the corresponding recommendation. However, BMI is the most important measure of response to treatment in children and young people with type 2 diabetes and so the bullet about BMI measurement has been retained in the recommendation for that group
Royal College of Paediatrics and Child Health	NICE	General	General	This guidance document should include information on neonatal diabetes. It is a new subtype to be recognized since the 2004 guidelines. At present there is no information on neonatal diabetes. This subtype is important as 1) there are over 200 cases diagnosed in the UK (information from Prof Ellard, Exeter with 90 having potassium channel mutations) 2) these patients can be recognized clinically and the correct diagnosis can great alter treatment leading to a massive	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes,

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				change in outcome and quality of life 3) they present with DKA so can be easily misdiagnosed as Type 1 if the significance of the age of diagnosis is not appreciated. The key thing is that a diagnosis less than 6 months is neonatal diabetes and not type 1 diabetes. (Edgehill et Diabetes 55:1895–1898, 2006). This is very important as 50% of these patients will have a potassium channel mutation and despite being insulin dependent 90% can get greatly improved control without hypoglycaemia on a sulphonylurea (Pearson ER et al N Engl J Med 2006;355:467-77.). A recent review is in the ISPAD guidelines of monogenic diabetes.	type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY. However, the limitations of the scope for the 2015 update prevent the

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					guideline development group from providing more detail about the diagnosis or management of forms of diabetes other than type 1 or type 2
Royal College of Paediatrics and Child Health	NICE	3	3	The clear intention in this summarised intro of achieving near normoglycaemia and an HbA1c in the normal range sets an unrealistic starting point that will be alien to the vast majority managing the care of children and young people up till the age of 19. The extended document of course makes the vital need (as in all diabetes care) for individualisation of care and in turn HbA1c targets and in the interests of best care and credibility for the rest of the document it would be sensible to add this important statement at this stage of the document	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c

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					preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These

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					considerations have been documented in the revised evidence to recommendations section in the full guideline
National Children and Young People's Diabetes Network	NICE	10	General	'routinely perform at least 5 times a day' – this and the HbA1c are a counsel of perfection , based on a research study of a self selected highly motivated cohort with considerable sustained specialist support . Apart from the gulf between the research protocol and best clinical care , the recommendation is impractical at best and if the intention is to generalise this there would be serious concern this would demotivate this challenging group of young people . Individualised frequency of testing is deliverable.	Thank you for this comment. The guideline development group discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that should be recommended, but also the timing at which the tests should be performed. The evidence reviewed for the guideline demonstrated that glycaemic control improves with the number of capillary tests performed up to 5 five tests per day. The guideline development group concluded, therefore, that at least 5 tests should be performed routinely, and emphasised in the revised recommendations that it is often necessary to conduct more than 5 tests. They did not, however, wish to specify an upper limit for the number of tests, nor the exact timing for the minimum number of tests because to do so would remove some flexibility that is otherwise available to the child or young person and their family members or carers (as appropriate), and this is supported by the individualised testing suggested in the comment
Royal College of Paediatrics	NICE	10	General	Mentioned in more detail in full version and later in the NICE document but implication here is MDI or CSII as the only options from diagnosis . Premixed bd-	Thank you for this comment. The guideline development group did not feel that use of

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and Child Health				tds insulin or split pm insulin (premix , quick acting and bed time basal) should also be stated options not least as the principle of intensification of control and complexity of regime may naturally follow loss of honeymoon phase , more independent self-management or the impact of puberty.	insulin regimens other than multiple daily injections (or insulin pump therapy if a multiple daily insulin injection regimen is not appropriate) was appropriate at diagnosis hence the strong recommendation to offer multiple daily injection regimens from diagnosis. The later recommendation referring to mixed insulin is included to cover those children and young people who might be using such a regimen although these are not recommended strongly
Royal College of Paediatrics and Child Health	NICE	10	General	'routinely perform at least 5 times a day' – this and the HbA1c are a counsel of perfection , based on a research study of a self selected highly motivated cohort with considerable sustained specialist support . Apart from the gulf between the research protocol and best clinical care , the recommendation is impractical at best and if the intention is to generalise this there would be serious concern this would demotivate this challenging group of young people . Individualised frequency of testing is deliverable.	Thank you for this comment. The guideline development group discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that should be recommended, but also the timing at which the tests should be performed. The evidence reviewed for the guideline demonstrated that glycaemic control improves with the number of capillary tests performed up to 5 five tests per day. The guideline development group concluded, therefore, that at least 5 tests should be performed routinely, and emphasised in the revised recommendations that it is often necessary to conduct more than 5 tests. They did not, however, wish to specify an upper limit for the number of tests, nor the exact timing

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					for the minimum number of tests because to do so would remove some flexibility that is otherwise available to the child or young person and their family members or carers (as appropriate), and this is supported by the individualised testing suggested in the comment
Royal College of Paediatrics and Child Health	NICE	10	10	Consider including alternative insulin regimes e.g. Twice daily fixed, mixed insulin if indicated by patient need.	Thank you for this comment. The guideline development group did not feel that use of insulin regimens other than multiple daily injections (or insulin pump therapy if a multiple daily insulin injection regimen is not appropriate) was appropriate at diagnosis hence the strong recommendation to offer multiple daily injection regimens from diagnosis. The later recommendation referring to mixed insulin is included to cover those children and young people who might be using such a regimen although these are not recommended strongly
Royal College of Paediatrics and Child Health	NICE	10	27	Team would recommend 'At least 4 tests' but wonder why the number 5 had been arrived at- when would the 5th be placed in the day?	Thank you for this comment. The guideline development group discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that should be recommended, but also the timing at which the tests should be performed. The evidence reviewed for the guideline demonstrated that glycaemic control improves with the number of

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					capillary tests performed up to 5 five tests per day. The guideline development group concluded, therefore, that at least 5 tests should be performed routinely, and emphasised in the revised recommendations that it is often necessary to conduct more than 5 tests. They did not, however, wish to specify an upper limit for the number of tests, nor the exact timing for the minimum number of tests because to do so would remove some flexibility that is otherwise available to the child or young person and their family members or carers (as appropriate)
Royal College of Paediatrics and Child Health	NICE	11	General	'48 mmol/mol or lower' – similarly to the BG monitoring frequency and BG targets are derived from DCCT – not replicable in NHS clinical practice . Individualised Hba1c targets stated in all other NICE DM guidance should be applicable to children and young people with 58 mmol/mol as in last CYP guidance still retained as legitimate target , not least as this was the mean achieved in DCCT so by definition even in that trial setting 50% could not attain that level of control .	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence),

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					while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been

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					chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline
Royal College of Paediatrics and Child Health	NICE	11	1	Unsure as to how the number '48' has been arrived at. Is this based on particular evidence, is this in the hope that setting a strict guideline will 'shift' patient behaviour towards better control? Wonder if it might be better to refer to 'as close to normal/non-diabetic' range rather than suggest 1 particular number.	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing

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					reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the

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					guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline
National Children and Young People's Diabetes Network	NICE	12	General	No explicit recommendations re treatment but stated that 'early treatment will improve outcome' – presumably ACE inhibitor therapy. I am not aware there is such outcome data yet in children and young people but there is clearly evidence of reversability of microalbuminuria in type 1 diabetes in the younger age cohort which is not mentioned in the document .	Thank you for submitting comments in response to the stakeholder consultation. Please note that the scope of this guideline covers only the detection of long-term complications of diabetes and not their subsequent management. The guideline development group 's view is, however, that appropriate management of such complications will be beneficial Evidence for the natural history, including potential reversibility of microalbuminuria, was not evaluated by the guideline development group
Royal College of Paediatrics and Child Health	NICE	12	General	No explicit recommendations re treatment but stated that 'early treatment will improve outcome' – presumably ACE inhibitor therapy. I am not aware there is such outcome data yet in children and young people but there is clearly evidence of reversability of microalbuminuria in type 1 diabetes in the younger age cohort	Thank you for submitting comments in response to the stakeholder consultation. Please note that the scope of this guideline covers only the detection of long-

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				which is not mentioned in the document .	term complications of diabetes and not their subsequent management. The guideline development group 's view is, however, that appropriate management of such complications will be beneficial Evidence for the natural history, including potential reversibility of microalbuminuria, was not evaluated by the guideline development group
National Children and Young People's Diabetes Network	NICE	13	1.1.1	Recommend the addition of excessive tiredness	Thank you for this comment. The recommendation is not strictly included in the scope of the 2015 update, but excessive tiredness is well recognised as being associated with diabetes, and as the corresponding change has been made in the section about recognition of diabetic ketoacidosis (which is covered by the 2015 update) the requested change has been made
Royal College of Paediatrics and Child Health	NICE	13	1.1.1	Recommend the addition of excessive tiredness	Thank you for this comment. The recommendation is not strictly included in the scope of the 2015 update, but excessive tiredness is well recognised as being associated with diabetes, and as the corresponding change has been made in the section about recognition of diabetic ketoacidosis (which is covered by the 2015 update) the requested change has been made

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Royal College of Paediatrics and Child Health	NICE FULL	13	1.1.2	Refer children and young people with suspected type 1 diabetes immediately (on the same day) to a multidisciplinary paediatric diabetes team with the competencies needed to confirm diagnosis and to provide immediate care. [2004, amended 2015] This confuses the need for same day referral by GP to acute paediatric services with the BPT measure of ensuring discussion with a senior member of the paed diabetes team within 24hrs of presentation & being seen by a senior member of the specialist paed diabetes team on the next working day.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (referral to the diabetes team at diagnosis in this case)
National Children and Young People's Diabetes Network	NICE	14	General	MODY – remarkable no mention here of family history of DM in young adulthood as necessary basis to consider this possible diagnosis	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The revised recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected

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					diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY. Additionally the recommendations have been revised to include family history of diabetes. However, the limitations of the scope for the 2015 update prevent the guideline development group from providing more detail about the diagnosis or management of forms of diabetes other than type 1 or type 2
Royal College of Paediatrics and Child Health	NICE	14	General	MODY – remarkable no mention here of family history of DM in young adulthood as necessary basis to consider this possible diagnosis	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was

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					excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The revised recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY. Additionally the recommendations have been revised to include family history of diabetes. However, the limitations of the scope for

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					the 2015 update prevent the guideline development group from providing more detail about the diagnosis or management of forms of diabetes other than type 1 or type 2
Royal College of Nursing	NICE	14	1.17	We would strongly recommend that the measurement of antibodies is removed from this recommendation. There is very clear evidence that autoantibodies can differentiate at diagnosis from MODY with a difference in prevalence of 80% v 1%. McDonald T et al (2011) Islet autoantibodies can discriminate maturity-onset diabetes of the young (MODY) from Type 1 diabetes. Diabet Med. 2011Sep; 28(9):1028-33. PMID: 21395678. In addition, in the USA, screening patients who were antibody negative at diagnosis identified MODY Pihoker C, et al (2013) Prevalence, characteristics and clinical diagnosis of maturity onset diabetes of the young due to mutations in HNF1A, HNF4A, and glucokinase: results from the SEARCH for Diabetes in Youth. J Clin Endocrinol Metab. 2013 Oct; 98(10):4055-62. PubMed PMID: 23771925). The data reviewed to support this statement has not included IA2 antibodies which greatly increase the detection rate in Type 1 diabetes and do not contribute false positive results. In addition at present Professor Barrett uses the absence of antibodies in the definition of Type 2 diabetes in children for the UK MRC cohort study see https://www.bsped.org.uk/research/docs/jump/JUMPProtocol.pdf	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis (specifically evidence for distinguishing between type 1 and type 2 diabetes) and concluded that C-peptide and diabetes-specific autoantibody titres should not be measured at initial presentation to distinguish type 1 diabetes from type 2 diabetes. However, the revised recommendations emphasise that measuring C-peptide after initial presentation should be considered if there is difficulty distinguishing type 1 diabetes from other types of diabetes and that genetic testing should be performed if atypical disease behaviour, clinical characteristics or family history suggest monogenic diabetes. The 'do not use' form of recommendation reflects the evidence base
Royal College of Paediatrics and Child Health	NICE	14	1.17	We would strongly recommend that the measurement of antibodies is removed from this recommendation, There is very clear evidence that autoantibodies can differentiate at diagnosis from MODY with a difference in prevalence of 80% v 1% McDonald T et al Islet autoantibodies can discriminate maturity-onset diabetes of the young (MODY) from Type 1 diabetes. Diabet Med. 2011Sep;28(9):1028-33.	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis (specifically evidence for distinguishing between type 1 and type 2 diabetes) and concluded that C-peptide

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				PMID: 21395678 In addition in the USA screening patients who were antibody negative at diagnosis identified MODY Pihoker C, et al Prevalence, characteristics and clinical diagnosis of maturity onset diabetes of the young due to mutations in HNF1A, HNF4A, and glucokinase: results from the SEARCH for Diabetes in Youth. J Clin Endocrinol Metab. 2013 Oct;98(10):4055-62. PubMed PMID: 23771925). The data reviewed to support this statement has not included IA2 antibodies which greatly increase the detection rate in Type 1 diabetes and do not contribute false positive results. In addition at present Prof Barrett uses the absence of antibodies in his definition of Type 2 diabetes in children.	and diabetes-specific autoantibody titres should not be measured at initial presentation to distinguish type 1 diabetes from type 2 diabetes. However, the revised recommendations emphasise that measuring C-peptide after initial presentation should be considered if there is difficulty distinguishing type 1 diabetes from other types of diabetes and that genetic testing should be performed if atypical disease behaviour, clinical characteristics or family history suggest monogenic diabetes. The 'do not use' form of recommendation reflects the evidence base
Royal College of Paediatrics and Child Health	NICE	14	1.1.6	The important clinical features that should be included in this section are: 1. Diagnosis less than 6 months as this is neonatal diabetes and not type 1 diabetes. (Edgehill et Diabetes 55:1895–1898, 2006). This is very important as 50% of these patients will have a potassium channel mutation and despite being insulin dependent 90% can get improved control on a sulphonylurea (Pearson ER et al N Engl J Med 2006;355:467-77.) 2. Parental diabetes (especially when an extended family and the absence of obesity) as this suggests MODY rather than Type 1 or Type 2 diabetes. 3. Incidental hyperglycaemia that is mild (the commonest cause >50% is glucokinase MODY) in at least 3 national surveys Lorini R et al Maturity-onset diabetes of the young in children with incidental hyperglycemia: a multicenter Italian study of 172 families. Diabetes Care. 2009 Oct;32(10):1864-6.PMID: 19564454: Codner E, et al Pediatr Diabetes. 2009 Sep;10(6):382-8. PMID: 19309449; Feigerlová E, Et al . Aetiological heterogeneity of asymptomatic hyperglycaemia in children and adolescents. Eur J Pediatr. 2006 PMID:	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The revised recommendations

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				16602010. 4. Absence of autoantibodies (discussed below McDonald T et al Islet autoantibodies can discriminate maturity-onset diabetes of the young (MODY) from Type 1 diabetes. Diabet Med. 2011Sep;28(9):1028-33. PMID: 21395678 This approach has been proven to be successful in identifying MODY in the paediatric population (Pihoker C, et al Prevalence, characteristics and clinical diagnosis of maturity onset diabetes of the young due to mutations in HNF1A, HNF4A, and glucokinase: results from the SEARCH for Diabetes in Youth. J Clin Endocrinol Metab. 2013 Oct;98(10):4055-62. PubMed PMID: 23771925) 5. Acanthosis nigricans in a slim child (suggests a genetic disorder of insulin resistance)	emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY. Additionally the recommendations have been revised to include family history of diabetes. However, the limitations of the scope for the 2015 update prevent the guideline development group from providing more detail about the diagnosis or management of forms of diabetes other than type 1 or type 2
National Children and	NICE	15	1.2.1	Welcome the detail on content of continuing education programme and that this should be tailored to the individual.	Thank you for this comment in support of the guideline

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Young People's Diabetes Network			1.2.2		
Royal College of Paediatrics and Child Health	NICE	15	1.2.1 1.2.2	Welcome the detail on content of continuing education programme and that this should be tailored to the individual.	Thank you for this comment in support of the guideline
Association of British Clinical Diabetologists	NICE	16	1.2.4	Unclear why role for optician if 12+ enrolled in retinal screening separately – this may lead to confusion as evidence base to have separate optician checks is not apparent to me	Thank you for this comment. The rationale for the recommendation on screening for retinopathy is discussed in Section 11.4.1 of the full guideline. The consensus recommendation from 2004 about the frequency of routine eye tests reflects good clinical practice and that section of the guideline was not updated in 2015
National Children and Young People's Diabetes Network	NICE	16	1.2.4	Unclear why role for optician if 12+ enrolled in retinal screening separately – this may lead to confusion as evidence base to have separate optician checks is not apparent to me	Thank you for this comment. The rationale for the recommendation on screening for retinopathy is discussed in Section 11.4.1 of the full guideline. The consensus recommendation from 2004 about the frequency of routine eye tests reflects good clinical practice and that section of the guideline was not updated in 2015
National Children and Young People's Diabetes Network	NICE	19	1.2.19	Welcome the recommendation to consider family circumstances and personal preference when choosing an insulin regimen.	Thank you for this comment in support of the guideline

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Royal College of Paediatrics and Child Health	NICE	19	1.2.19	Welcome the recommendation to consider family circumstances and personal preference when choosing an insulin regimen.	Thank you for this comment in support of the guideline
Royal College of Paediatrics and Child Health	NICE	19	1.2.20	Those going straight onto CSII should also be taught the skill of injecting insulin with a pen device in the event of pump failure. This skill should regularly be reviewed.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (insulin pump therapy in this case). Moreover, the indications for and other aspects of the use of insulin pump therapy are determined by the NICE Technology Appraisal (TA) guidance mentioned in the comment and the guideline development group are unable to change the TA guidance
Royal College of Paediatrics and Child Health	NICE	19	1.2.20	Those going straight onto CSII should also be taught the skill of injecting insulin with a pen device in the event of pump failure. This skill should regularly be reviewed.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (insulin pump therapy in this case). Moreover, the indications for and other aspects of the use of insulin pump therapy are determined by the NICE

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					Technology Appraisal (TA) guidance mentioned in the comment and the guideline development group are unable to change the TA guidance
National Children and Young People's Diabetes Network	NICE	19	1.2.22	Recommend that what constitutes a specialist team in terms of CGMS should be specified	The guideline development group did not prioritise a review question on whether or not continuous glucose monitoring should be supported by a specialist team. The recommendation in the guideline that refers to a specialist team is that for continuous subcutaneous insulin infusion (CSII or insulin pump) therapy and the reason that is included is because it comes from the related NICE Technology Appraisal guidance to which the guideline refers
Royal College of Paediatrics and Child Health	NICE	19	1.2.22	Recommend that what constitutes a specialist team in terms of CGMS should be specified	The guideline development group did not prioritise a review question on whether or not continuous glucose monitoring should be supported by a specialist team. The recommendation in the guideline that refers to a specialist team is that for continuous subcutaneous insulin infusion (CSII or insulin pump) therapy and the reason that is included is because it comes from the related NICE Technology Appraisal guidance to which the guideline refers
Royal College of Paediatrics	NICE	20	1.2.25	…..48 mmol/mol (6.5%).	Thank you for this comment. The views expressed by stakeholders with regard to

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and Child Health	FULL			General feeling is that this will be very hard to attain for families (currently those that do achieve it manage diabetes with all available technical & canine support & still suffer hypos/hypo unawareness). Are we being unrealistic and ensuring our patients will rarely achieve this goal so feel that it is not worth trying? Longitudinal studies post DCCT suggest that current targets are appropriate to reduce complications. ISPAD (2009) suggests: HbA1c targets. A target range for all age-groups of <7.5% is recommended These targets are intended as guidelines. Each child should have their targets individually determined with the goal of achieving a value as close to normal as possible while avoiding severe hypoglycemia as well as frequent mild to moderate hypoglycemia.	targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to

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					avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline
Royal College of Nursing	NICE	20	1.2.30	Please add wording "and detailed instructions in its use" to this statement.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not

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					able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (insulin injection techniques and needle choice in this case)
Royal College of Paediatrics and Child Health	NICE	20	1.2.30	Please add wording "and detailed instructions in its use".	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (insulin injection techniques and needle choice in this case)
Royal College of Paediatrics and Child Health	NICE FULL	21	1.2.32	Metformin in combination with insulin is suitable for use only within research studies because the effectiveness of this combined treatment in improving blood glucose control is uncertain. [2004] This is effective treatment in those CYP with type 1 diabetes & insulin resistance.	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (metformin combined with insulin for the management of type 1 diabetes in this case). The guideline development group have, however, retained the 2004 research recommendation related to this topic
National Children and	NICE	21	1.2.37	Welcome introduction of carbohydrate counting from diagnosis as allows greater flexibility in food choices, timing and amounts	Thank you for your feedback in support of the recommendation to offer carbohydrate

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Young People's Diabetes Network					counting from diagnosis
Royal College of Paediatrics and Child Health	NICE	21	1.2.37	Welcome introduction of carbohydrate counting from diagnosis as allows greater flexibility in food choices, timing and amounts	Thank you for your feedback in support of the recommendation to offer carbohydrate counting from diagnosis
Royal College of Paediatrics and Child Health	NICE	22	1.2.37	Repeat the offer. This is vague is this the original offer for level 3 CHO counting training or regular updates if so what frequency Not everyone automatically knows what level 3 education is.	Thank you for this comment. Repeating the offer of level 3 carbohydrate counting is a pragmatic recommendation to ensure that a child or young person who does not take up the approach at diagnosis has opportunities to consider doing so later. The guideline development group did not identify any evidence to specify the timing and frequency of repeating the offer and so this is not specified in the recommendation Level 3 carbohydrate counting is the use of carbohydrate counting with the adjustment of insulin dosage according to carbohydrate content of meals and blood glucose levels, using an insulin:carbohydrate ratio. This has been clarified in a footnote to the recommendation
Royal College of Paediatrics	NICE	22	1.2.37	Repeat the offer. This is vague is this the original offer for level 3 CHO counting training or regular updates if so what frequency	Thank you for this comment. Repeating the offer of level 3 carbohydrate counting

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and Child Health				Not everyone automatically knows what level 3 education is.	is a pragmatic recommendation to ensure that a child or young person who does not take up the approach at diagnosis has opportunities to consider doing so later. The guideline development group did not identify any evidence to specify the timing and frequency of repeating the offer and so this is not specified in the recommendation Level 3 carbohydrate counting is the use of carbohydrate counting with the adjustment of insulin dosage according to carbohydrate content of meals and blood glucose levels, using an insulin:carbohydrate ratio. This has been clarified in a footnote to the recommendation
Royal College of Paediatrics and Child Health	NICE	22	1.2.42	Concerned that the recommendation around low GI diets is misleading as some low GI foods are high in fat, which could lead to weight gain. We recommend that what constitutes a healthy balanced diet is made clearer. We also note that a low GI diet is not recommended for blood glucose management in the adult Type 1 guideline.	Thank you for this comment. The concern about low glycaemic index diets that are high in fat is discussed in Section 6.4.4.6.2 of the full guideline The difference between the evidence base for children and young people and that for adults has been clarified in the evidence to recommendations section of the full guideline
National Children and	NICE	23	1.2.50	Would recommend adding the possibility of needing to monitor blood glucose levels during exercise as well as before and after depending on length of time	Thank you for submitting comments in response to the stakeholder consultation.

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Young People's Diabetes Network				spent exercising	Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (exercise in this case)
Royal College of Paediatrics and Child Health	NICE	23	1.2.50	Would recommend adding the possibility of needing to monitor blood glucose levels during exercise as well as before and after depending on length of time spent exercising	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (exercise in this case)
Royal College of Paediatrics and Child Health	NICE	24	1.2.54	Use of rapid acting analogue insulin mentioned in 1.2.30 but not mentioned here.	Thank you for this comment. This is covered by the bullet about adjusting the insulin regimen in the recommendation that summarises the content to be included in sick-day rules
Royal College of Paediatrics and Child Health	NICE	24	1.2.54	Use of rapid acting analog insulin mentioned in 1.2.30 but not mentioned here.	Thank you for this comment. This is covered by the bullet about adjusting the insulin regimen in the recommendation that summarises the content to be included in sick-day rules
Association of British Clinical Diabetologists	NICE	25	1.2.55 1.2.57	The GDG state in full version that the Relative Risk of severe hypoglycaemia was almost 3 times greater with intensive control in the DCCT and more common in the younger cohort . There is also comment in the paper regarding altered hypoglycaemic awareness in some CYP . The new 2015 recommendations for BG and HbA1c targets if applied generally almost appear to invite the outcome of 'problematic hypoglycaemia' that 1.2.57 states care providers should avoid.	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing

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				Although 1.2.70 page 27 states the most sensible pragmatic approach this is in contrast with so much stated earlier . The statement in 1.2.9 that the health care professional should advise that any reduction if above 48 mmol/l will reduce the risk of long term complications' may not be justified . The reality of reduction in complications in DCCT was when Hba1c eman of 58 mmol/mol was attained . Is there clear outcome evidence that those who attained an HbA1c of 48 had less complications than 58 ?	children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some

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					stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group of this guideline strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline The reference in the comment to hypoglycaemia is covered by the individualised targets (with safely achievable for the individual being a key consideration) and recommendations

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					elsewhere in the guideline. The guideline development group was also of the view that modern insulin regimens reduce the risk of hypoglycaemia compared to those in place when, for example, the Diabetes Control and Complications Trial was undertaken. This is also documented in the evidence to recommendations section in the full guideline
Royal College of Paediatrics and Child Health	NICE	25	1.2.55	Re guide for post prandial BG levels – should it not state when to test after the meal – 1 hour or 2 hours?	Thank you for this comment. The guideline development group discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that should be recommended, but also the timing at which the tests should be performed. The evidence reviewed for the guideline demonstrated that glycaemic control improves with the number of capillary tests performed up to 5 five tests per day. The guideline development group concluded, therefore, that at least 5 tests should be performed routinely, and emphasised in the revised recommendations that it is often necessary to conduct more than 5 tests. They did not, however, wish to specify an upper limit for the number of tests, nor the exact timing for the minimum number of tests because to do so would remove some flexibility that is otherwise available to the child or young

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					person and their family members or carers (as appropriate)
Royal College of Paediatrics and Child Health	NICE	25	1.2.55	Find the use of the terms "fasting BGL" and "before meals" confusing as this target seems to relate to the same thing. If this is the case we recommend clarification eg. to say "on waking and before meals…"	Thank you for this comment. Fasting in this recommendation refers to overnight fasting, and the phrasing has been revised to clarify that this means a fasting target on waking whereas the bullet that refers to before meals means meals at other times of the day. This mirrors the phrasing in the guideline for type 1 diabetes in adults
				If "fasting" refers to on waking, should "5-7 for young people intending to drive the following morning" read "5-7 for young people intending to drive that morning"?	There was a typographical error in the draft guideline for consultation. This has now been corrected to clarify that for fasting blood glucose a target range of 5–7 mmol/litre is advised when the young person intends to drive that morning
				The guideline must suggest a bedtime target for blood glucose level and strategies to avoid night time hypoglycaemia as this is a major concern for parents.	The guideline development group discussed this issue in detail and concluded that in young children a blood glucose test around 2 hours after the last meal will coincide with bedtime. Older children and young people should go to bed with a blood glucose level of 4-7 mmol/litre and that does not require a separate recommendation as the guideline emphasises the need for blood glucose targets to be individualised
Royal College	NICE	25	1.2.55	Explain to children and young people with type 1 diabetes and their family	There was a typographical error in the

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of Paediatrics and Child Health	FULL			members or carers (as appropriate) that the optimal target ranges for short-term blood glucose control are: •fasting blood glucose level of 4–7 mmol/litre (or 5–7 mmol/litre for young people intending to drive the following morning) •a blood glucose level of 4–7 mmol/litre before meals •a blood glucose level of 5–9 mmol/litre after meals. [new 2015] Similar comment to the lower HbA1c target.	draft guideline for consultation. This has now been corrected to clarify that for fasting blood glucose a target range of 5–7 mmol/litre is advised when the young person intends to drive that morning
National Children and Young People's Diabetes Network	NICE	25	1.2.57	Welcome the recommendation to ensure that children and young people do not experience problematic hypoglycaemia or undue emotional distress when attempting to achieve blood glucose and HbA1c targets, but would like to see strategies that can be employed to manage this	Thank you for this comment. The guideline development group's view is that other recommendations in the guideline cover the issues raised in the comment. For example, there are recommendations about agreeing individualised HbA1c targets, considering the 'whole child' when interpreting blood glucose levels, explaining the benefits of safely achieving and maintaining the lowest attainable HbA1c level, and supporting the child or young person to safely achieve and maintain their individual HbA1c level. Taken together these will allow healthcare professionals to identify and communicate strategies tailored to the individual child or young person
Royal College of Paediatrics and Child Health	NICE	25	1.2.57	Welcome the recommendation to ensure that children and young people do not experience problematic hypoglycaemia or undue emotional distress when attempting to achieve blood glucose and HbA1c targets, but would like to see strategies that can be employed to manage this	Thank you for this comment. The guideline development group's view is that other recommendations in the guideline cover the issues raised in the comment. For

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					example, there are recommendations about agreeing individualised HbA1c targets, considering the 'whole child' when interpreting blood glucose levels, explaining the benefits of safely achieving and maintaining the lowest attainable HbA1c level, and supporting the child or young person to safely achieve and maintain their individual HbA1c level. Taken together these will allow healthcare professionals to identify and communicate strategies tailored to the individual child or young person
National Children and Young People's Diabetes Network	NICE	25	1.2.58	Welcome the awareness of potential conflict between children and young people and parents and the need to agree a compromise	Thank you for this comment in support of the guideline
Royal College of Paediatrics and Child Health	NICE	25	1.2.58	Welcome the awareness of potential conflict between children and young people and parents and the need to agree a compromise	Thank you for this comment in support of the guideline
Royal College of Paediatrics and Child Health	NICE	25	1.2.59	Concerned about the recommendation of 5 or more tests a day and question how children and young people will be able to achieve the new lower HbA1c targets on 5 tests a day. We appreciate that "at least" is stated but feel the figure 5 will be the one that is remembered. We note that in the adult Type 1 guidance, 10 or more tests a day may be appropriate in certain circumstances. We appreciate that some of the circumstances applicable to adults will not be the same for children, but the	Thank you for this comment. The guideline development group discussed at length not only the frequency of self-monitoring of blood glucose via capillary testing that should be recommended, but also the timing at which the tests should be performed. The evidence reviewed for the

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				recommendation must take into account the effect of growth and development on blood glucose level, the risks associated with hypos in children and potential of driving in older teenagers, and recognise that a higher number of tests per day may need to be the norm.	guideline demonstrated that glycaemic control improves with the number of capillary tests performed up to 5 five tests per day. They concluded, therefore, that at least 5 tests should be performed routinely, and emphasised in the revised recommendations that it is often necessary to conduct more than 5 tests. They did not, however, wish to specify an upper limit for the number of tests, nor the exact timing for the minimum number of tests because to do so would remove some flexibility that is otherwise available to the child or young person and their family members or carers (as appropriate), which supports the possibility of more frequent testing highlighted in the comment, and will promote continuity of approach during transition to adult services The recommendations have been revised to emphasise the need to have enough test strips available to meet the child or young person's needs in terms of testing at least 5 times per day and often even more frequently than this
Royal College of Paediatrics and Child Health	NICE	26	1.2.63	This is ideal but funding is variable stronger requirements for this is needed to support teams applying for funding which often has to be via IFR	NICE guidelines do not have the same funding directive (mandatory implementation) that applies to NICE Technology Appraisal guidance, but it is

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					expected that services will be commissioned to implement the guideline recommendations. By including a recommendation about offering real-time continuous glucose monitoring as a key priority for implementation (key recommendation) the guideline development group have emphasised the importance of this recommendation for clinical practice
Royal College of Paediatrics and Child Health	NICE	26	1.2.63	This is ideal but funding is variable stronger requirements for this is needed to support teams applying for funding which often has to be via IFR	NICE guidelines do not have the same funding directive (mandatory implementation) that applies to NICE Technology Appraisal guidance, but it is expected that services will be commissioned to implement the guideline recommendations. By including a recommendation about offering real-time continuous glucose monitoring as a key priority for implementation (key recommendation) the guideline development group have emphasised the importance of this recommendation for clinical practice
National Children and Young People's Diabetes Network	NICE	26	1.2.64	This is ideal but funding is variable stronger requirements for this is needed to support teams applying for funding which often has to be via IFR	NICE guidelines do not have the same funding directive (mandatory implementation) that applies to NICE Technology Appraisal guidance, but it is expected that services will be commissioned to implement the guideline

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					recommendations. By including a recommendation about offering real-time continuous glucose monitoring as a key priority for implementation (key recommendation) the guideline development group have emphasised the importance of this recommendation for clinical practice
Royal College of Paediatrics and Child Health	NICE	26	1.2.64	This is ideal but funding is variable stronger requirements for this is needed to support teams applying for funding which often has to be via IFR	NICE guidelines do not have the same funding directive (mandatory implementation) that applies to NICE Technology Appraisal guidance, but it is expected that services will be commissioned to implement the guideline recommendations. By including a recommendation about offering real-time continuous glucose monitoring as a key priority for implementation (key recommendation) the guideline development group have emphasised the importance of this recommendation for clinical practice
Royal College of Paediatrics and Child Health	NICE	27	1.2.68	I particularly have concerns about this target for the following reasons It is a target we will be measured on Without funding of CGMS it will be hard to achieve Families major concerns are nocturnal hypoglycaemia and dead in bed we need to get the best control possible and a target of 53 mol/ mol (7%) would be more realistic/ achievable The risks of low HBA1c in children has not been established in the past adult target was tighter & was released after some studies	Thank you for this comment. The views expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or

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				This is the evidence I am basing comments on http://m.diabetes.diabetesjournals.org/content/63/5/1457.full	carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully, including this comment and the reference to evidence within it, and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. The avoidance of hypoglycaemia was a key aim of the review (see the review protocol in Appendix E) and this was carefully taken into consideration when agreeing the target based on the evidence identified for inclusion. The guideline development group strongly believed that lowering the target compared to the previous (2004) guideline is an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in the revised evidence to recommendations section in the full guideline
Royal College	NICE	27	1.2.69	These 2 statements are potentially contradictory for the team, which one would	Thank you for this comment. The views

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of Paediatrics and Child Health			1.2.70	they prioritise?	expressed by stakeholders with regard to targets for HbA1c were divergent, with healthcare professionals tending to favour the tighter targets proposed in the draft guideline and stakeholders representing children and young people with type 1 diabetes and their family members or carers (as appropriate) tending to consider the tighter targets as setting them up to fail. The guideline development group considered all of the comments very carefully and sought to achieve a balance by retaining the overall target of 48 mmol/mol (6.5%) for those in whom it is achievable (as this is based on evidence), while at the same time providing reassurance for children and young people and their families or carers that targets should be individualised to take account of personal circumstances. This is reflected by the order in which the recommendations appear in the revised guideline, with the explanation of the benefits of safely achieving and maintaining the lowest attainable HbA1c preceding the recommendation about the ideal HbA1c target level being 48 mmol/mol (6.5%) or lower to minimise the risk of long-term complications. In this sense, the individualisation of targets

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					would take precedence over aiming for or achieving a lower target that did not take account of the individual's circumstances. The phrasing of the recommendations has been revised throughout the guideline to avoid judgemental terms such as good and poor blood glucose control (in these specific cases the terms optimal and suboptimal are now used instead). Some stakeholders commented that there should be a minimum level specified for HbA1c targets, but the guideline development group's view was that there is no HbA1c level below which the risk of long-term complications is eliminated (again, based on evidence) and this is also reflected in the wording of the recommendations. Some stakeholders also suggested that the target of 48 mmol/mol (6.5%) had been chosen simply because that is what the guideline development group for type 1 diabetes in adults wished to recommend. This was not the case, the guideline development group strongly believed that lowering the target compared to the previous (2004) guideline was an important change to make. Ultimately the groups decided the target of 48 mmol/mol (6.5%) or lower was ideal. These considerations have been documented in

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					the revised evidence to recommendations section in the full guideline
Royal College of Paediatrics and Child Health	NICE	27	1.2.70	This will not happen if teams are measured via NPDA BPT & DQUINS on %patients with specific HbA1cs	Thank you for this comment. While the recommended target for HbA1c has been retained in the revised guideline, a further recommendation has been added stating that diabetes services should document the proportion of children and young people with type 2 diabetes in a service who achieve an HbA1c level of 53 mmol/mol (7%) or lower. The targets for HbA1c and the documentation of service-level achievement were agreed collaboratively through discussions involving the various guideline development groups updating diabetes guidelines for NICE, and this process was coordinated by NICE
Royal College of Paediatrics and Child Health	NICE	27	1.2.70	This will not happen if teams are measured via NPDA BPT & DQUINS on %patients with specific HbA1cs	Thank you for this comment. While the recommended target for HbA1c has been retained in the revised guideline, a further recommendation has been added stating that diabetes services should document the proportion of children and young people with type 2 diabetes in a service who achieve an HbA1c level of 53 mmol/mol (7%) or lower. The targets for HbA1c and the documentation of service-level achievement were agreed collaboratively through discussions

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					involving the various guideline development groups updating diabetes guidelines for NICE, and this process was coordinated by NICE
National Children and Young People's Diabetes Network	NICE	28	General	There is no comment here on modified hypoglycaemia awareness detection and management . The impact of tight targets and hypoglycaemic episodes as a predictor of recurrent and potential severe hypoglycaemia has and the ongoing need to relax control to regain symptoms (assuming carb counting aware) deserves comment .	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (detection and management of hypoglycaemia in this case)
Royal College of Paediatrics and Child Health	NICE	28	General	There is no comment here on modified hypoglycaemia awareness detection and management. The impact of tight targets and hypoglycaemic episodes as a predictor of recurrent and potential severe hypoglycaemia has and the ongoing need to relax control to regain symptoms (assuming carb counting aware) deserves comment .	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (detection and management of hypoglycaemia in this case)
Royal College of Paediatrics and Child Health	NICE	28	1.2.73	Also need to state provide family with meter that will measure beta ketones, advise the family to carry with them and provide written guidance on the interpretation of beta ketone result with actions to be taken	Thank you for this comment. The recommendations have been revised to state that children and young people with type 1 diabetes should be offered blood ketone testing strips and a meter and advised to test for ketonaemia if they become hyperglycaemic or unwell. It was already implicit in the recommendation

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					about providing sick-day rules that children and young people with type 1 diabetes and their family members or carers (as appropriate) should be advised how to interpret blood ketone results, but this has been made explicit in the revised recommendations. The recommendations about intercurrent illness (sick-day rules) and testing blood ketones have been brought together in the revised guideline so that the links between the recommendations are emphasised
Royal College of Paediatrics and Child Health	NICE	30	1.2.85	Remove the word "consider" - diabetes teams must refer CYP who have frequent hypos and/or recurrent seizures	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (management of hypoglycaemia in this case)
Royal College of Nursing	NICE	33	1.2.100	Family therapy is usually offered via Child and Adolescent Mental Health Services (CAMHS) rather than clinical psychologist therefore we feel that this statement should advise referral on to CAMHS after assessment by clinical psychologist on the team.	Thank you for this comment. The guideline development group have not specified the referral details as these might differ depending on the local service configuration
Royal College of Paediatrics and Child Health	NICE	33	1.2.100 1.2.10	Who are these guidelines aimed at? The Team as a whole or the Psychologist? Perhaps better to refer to existing mental health NICE guide lines for children e.g. for depression the first line of intervention is not necessarily motivational interviewing.	Thank you for this comment. The recommendation has been amended so that it cross-refers to the existing NICE guidance on the treatment of depression in

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			1		children and young people. The previous version of the recommendation reflected the association between improved depression and motivational interviewing that was found in the evidence specific to those with type 1 diabetes
Royal College of Paediatrics and Child Health	NICE	33	1.2.100	Family therapy is usually offered via CAMHS rather than Clinical Psychologist therefore this statement should advise referral on to CAMHS after assessment by Clinical Psychologist on team	Thank you for this comment. The guideline development group have not specified the referral details as these might differ depending on the local service configuration
Royal College of Paediatrics and Child Health	NICE	33	1.2.100	Family therapy is usually offered via CAMHS rather than Clinical Psychologist therefore this statement should advise referral on to CAMHS after assessment by Clinical Psychologist on team	Thank you for this comment. The guideline development group have not specified the referral details as these might differ depending on the local service configuration
National Children and Young People's Diabetes Network	NICE	34	1.2.108	Feel that monitoring programmes work best when they are kept simple, and so are concerned that the differing times for monitoring for complications and associated conditions are confusing to parents and there is a risk that they will be forgotten. Long term complications are a real concern to parents, particularly for parents who have a child diagnosed very young. We would therefore suggest that the monitoring programme is simplified, perhaps to monitoring for all complications and associated conditions every year from one year post diagnosis	Thank you for this comment. The recommendations related to monitoring for complications are led by the evidence in each systematic review. The majority of recommendations for monitoring specify annual assessment
Royal College of Paediatrics and Child Health	NICE	34	1.2.108	Feel that monitoring programmes work best when they are kept simple, and so are concerned that the differing times for monitoring for complications and associated conditions are confusing to parents and there is a risk that they will be forgotten. Long term complications are a real concern to parents, particularly for parents who have a child diagnosed very young. We would therefore suggest that the monitoring programme is simplified, perhaps to monitoring for all complications and associated conditions every year from one year post diagnosis	Thank you for this comment. The recommendations related to monitoring for complications are led by the evidence in each systematic review. The majority of recommendations for monitoring specify annual assessment

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Royal College of Paediatrics and Child Health	NICE	34	1.2.108	Coeliac screening at diagnosis only This contravenes the most recent guidance from Europe which suggests that high risk individuals should be retested. ESPGHAN guidelines 2012 on coeliac disease management and screening. It states: 'In individuals with DQ2 or DQ8 positivity or without HLA testing, IgA anti-TG2 and serum total IgA determination should be performed. If IgA anti-TG2 is negative and IgA deficiency is excluded, then CD is unlikely; however, the disease may still develop later in life. Therefore, serological testing should be repeated at regular intervals. No data support any firm recommendations, but it was the opinion of the working group members that a child should be investigated by serology every 2 to 3 years to avoid the detrimental effects of unrecognised CD on growth and bone health. If EMA is positive, then the likelihood for CD increases because of the high specificity of EMA. In this situation, the patient should be referred for endoscopy in spite of low anti-TG2 titres. If EMA are negative, then the patient should be followed up on a normal diet and anti-TG2 testing should be repeated every 3 to 6 months until the antibody levels either turn negative or the levels increase to levels at which endoscopy is indicated' Taken from ESPGHAN guidelines 2012 http://www.espghan.med.up.pt/position_papers/Guidelines_on_coeliac_disease.pdf The evidence used was 2009 guidance therefore this should be looked at before	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (coeliac disease in this case). However the guideline development group recognise that NICE has produced separate guidance and so the recommendations in this guideline have been amended to cross-refer to the NICE coeliac disease guideline for guidance on monitoring for coeliac disease in children and young people with type 1 diabetes

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				changing the advice on retesting.	
Royal College of Nursing	NICE	35 36	General	There is no indication for lipid screening here It is currently part of NPDA data set to be evaluated from 12 years of age. Dyslipidemia (cholesterol, LDL, HDL, triglyceride) is common in both type 1 and 2 diabetes and is a marker of future cardiovascular disease. Levels rise during puberty but may be abnormal during pre-puberty, and in ethnic minority groups. If abnormal, more intensive insulin therapy and focussed dietetic management is required during pre-puberty and possible intervention with a statin may be required during puberty. The type of dyslipidaemia may vary according to diabetes subtype and ethnic group. For example, South Asians have increased levels of triglycerides and lower HDL levels. Treatment and advice may vary according to the exact abnormality and for this a full lipid screen is required.	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (monitoring for dyslipidaemia in children and young people with type 1 diabetes in this case)
Royal College of Paediatrics and Child Health	NICE	35 36	General	There is no indication for lipid screening here It is currently part of NPDA data set to be evaluated from 12 years of age. Dyslipidemia (cholesterol, LDL, HDL, triglyceride) is common in both type 1 and 2 diabetes and is a marker of future cardiovascular disease. Levels rise during puberty but may be abnormal during pre-puberty, and in ethnic minority groups. If abnormal, more intensive insulin therapy and focussed dietetic management is required during pre-puberty and possible intervention with a statin may be required during puberty. The type of dyslipidaemia may vary according to diabetes subtype and ethnic group. For example, South Asians have increased levels of triglycerides and lower HDL levels. Treatment and advice may vary according to the exact abnormality and for this a full lipid screen is required.	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (monitoring for dyslipidaemia in children and young people with type 1 diabetes in this case)
Royal College of Paediatrics and Child Health	NICE	35 36	General	There is no indication for lipid screening here It is currently part o NPDA data set to be evaluated from 12 years of age. Dyslipidemia (cholesterol, LDL, HDL, triglyceride) is common in both type 1 and 2 diabetes and is a marker of future cardiovascular disease. Levels rise during	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not able to accept comments on parts of the guideline

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				puberty but may be abnormal during pre-puberty, and in ethnic minority groups. If abnormal, more intensive insulin therapy and focussed dietetic management is required during pre-puberty and possible intervention with a statin may be required during puberty. The type of dyslipidaemia may vary according to diabetes subtype and ethnic group. For example, South Asians have increased levels of triglycerides and lower HDL levels. Treatment and advice may vary according to the exact abnormality and for this a full lipid screen is required.	that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (monitoring for dyslipidaemia in children and young people with type 1 diabetes in this case)
National Children and Young People's Diabetes Network	NICE	35	1.2.111	While aware of the rarity of retinopathy in children under that age of 12, see comment 16	Thank you for this comment. There is evidence of steadily increasing prevalence of retinopathy after 12 years and no evidence of significant retinopathy before 12 years
Royal College of Paediatrics and Child Health	NICE	35	1.2.111	While aware of the rarity of retinopathy in children under that age of 12, see comment 16	Thank you for this comment. There is evidence of steadily increasing prevalence of retinopathy after 12 years and no evidence of significant retinopathy before 12 years
National Children and Young People's Diabetes Network	NICE	36 46	1.3	Feel that the recommendations for Type 2 diabetes in children and young people need to far more detailed, in particular in terms of treatment both for the Type 2 diabetes itself (as there is no mention of treatment strategies if metformin is ineffective) and for the treatment of any complications and associated conditions. We recommend that this part of the guideline is reviewed, and reflect the ISPAD guidelines https://www.ispad.org/sites/default/files/resources/files/3-type_2_diabetes_in_the_child_and_adolescent.pdf (?ADA http://care.diabetesjournals.org/content/38/Supplement_1	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that the part of the guideline that considers type 2 diabetes in children and young people is constrained by the scope for the 2015 update to cover metformin but no other pharmacological treatments, and to cover monitoring for long-term complications but not their subsequent management
Royal College of Paediatrics	NICE	36	1.3	Feel that the recommendations for Type 2 diabetes in children and young people need to far more detailed, in particular in terms of treatment both for the Type 2	Thank you for submitting comments in response to the stakeholder consultation.

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and Child Health		46		diabetes itself (as there is no mention of treatment strategies if metformin is ineffective) and for the treatment of any complications and associated conditions. We recommend that this part of the guideline is reviewed, and reflect the ISPAD guidelines https://www.ispad.org/sites/default/files/resources/files/3-type_2_diabetes_in_the_child_and_adolescent.pdf (?ADA http://care.diabetesjournals.org/content/38/Supplement_1	Please note, however, that the part of the guideline that considers type 2 diabetes in children and young people is constrained by the scope for the 2015 update to cover metformin but no other pharmacological treatments, and to cover monitoring for long-term complications but not their subsequent management
Royal College of Paediatrics and Child Health	NICE	36	1.2.112	While aware of the rarity of nephropathy in children under that age of 12, see comment 16	Thank you for this comment. The guideline development group has reviewed the evidence and have not found any evidence to support monitoring before 12 years
Royal College of Paediatrics and Child Health	NICE	36	1.2.114	Individual labs have individual reference ranges. There is a different cut off for males & females locally our reference is NORMAL = ACR < 2.5 mg/mmol in men NORMAL = ACR < 3.5 mg/mmol in women MICROALBUMINURIA = 2 x ACRs 2.5 – 30 in men or MICROALBUMINURIA = 2 x ACRs 3.5 – 30 in women NEPHROPATHY = 2 x ACR > 30 ie macroalbiminuria	Thank you for this comment. The guideline development group has considered the NICE chronic kidney disease guideline and harmonised with definitions and thresholds used there
Royal College of Paediatrics and Child Health	NICE	36	1.2.114	Individual labs have individual reference ranges. There is a different cut off for males & females locally our reference is NORMAL = ACR < 2.5 mg/mmol in men NORMAL = ACR < 3.5 mg/mmol in women MICROALBUMINURIA = 2 x ACRs 2.5 – 30 in men or MICROALBUMINURIA = 2 x ACRs 3.5 – 30 in women NEPHROPATHY = 2 x ACR > 30 ie macroalbiminuria	Thank you for this comment. The guideline development group has considered the NICE chronic kidney disease guideline and harmonised with definitions and thresholds used there
National Children and	NICE	39	General	Lack of comment of the challenges of insulin treatment when insulin resistance and no comment on the role (or lack of) of incretin modulators in those aged over	Thank you for submitting comments in response to the stakeholder consultation.

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Young People's Diabetes Network				16 with type 2 DM	Please note, however, that the part of the guideline that considers type 2 diabetes in children and young people is constrained by the scope for the 2015 update to cover metformin but no other pharmacological treatments (this also excludes consideration of incretin modulators)
Royal College of Paediatrics and Child Health	NICE	39	General	Lack of comment of the challenges of insulin treatment when insulin resistance and no comment on the role (or lack of) of incretin modulators in those aged over 16 with type 2 DM	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that the part of the guideline that considers type 2 diabetes in children and young people is constrained by the scope for the 2015 update to cover metformin but no other pharmacological treatments (this also excludes consideration of incretin modulators)
Royal College of Paediatrics and Child Health	NICE	39	1.3.14	Young people & their families should receive advice on best time to take Metformin to minimise side effects & non-compliance. Consideration should be given to use of modified released tablets in those who have gastrointestinal side effects.	Thank you for this comment. As there is no current evidence to support a recommendation about the best time to take metformin, this has not been added to the guideline. It is standard practice in NICE guidelines to assume that prescribers will use a medicine's summary of product characteristics (SPC) to inform decisions made with individual patients. There is text at the beginning of the NICE guideline that explains this. There was no evidence identified for the effectiveness of extended release

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					metformin and so the guideline development group included a research recommendation on this topic
Royal College of Paediatrics and Child Health	NICE	39	1.3.14	Young people & their families should receive advice on best time to take Metformin to minimise side effects & non compliance. Consideration should be given to use of modified released tablets in those who have gastrointestinal side effects.	Thank you for this comment. As there is no current evidence to support a recommendation about the best time to take metformin, this has not been added to the guideline. It is standard practice in NICE guidelines to assume that prescribers will use a medicine's summary of product characteristics (SPC) to inform decisions made with individual patients. There is text at the beginning of the NICE guideline that explains this. There was no evidence identified for the effectiveness of extended release metformin and so the guideline development group included a research recommendation on this topic
Royal College of Nursing	NICE	41	1.3.30	These protocols should also include assessment of cardiovascular function with blood pressure assessment and electrocardiogram (ECG) prior to planned surgery and stopping of Metformin. Individuals should also be assessed for venous thromboembolism prevention.	This recommendation was inserted in the section about type 2 diabetes to mirror the corresponding recommendation for type 1 diabetes. The other aspects of these recommendations are excluded from the 2015 update and so no further changes have been made. Safe surgery implies that the other risks specific to type 2 diabetes alluded to in the comment are taken into account

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Royal College of Paediatrics and Child Health	NICE	41	1.3.30	Theses protocols should include assessment of cardiovascular function with B/P assessment & ECG prior to planned surgery and stopping of Metformin. Individuals should also be assessed for venous thromboembolism prevention	This recommendation was inserted in the section about type 2 diabetes to mirror the corresponding recommendation for type 1 diabetes. The other aspects of these recommendations are excluded from the 2015 update and so no further changes have been made. Safe surgery implies that the other risks specific to type 2 diabetes alluded to in the comment are taken into account
Royal College of Paediatrics and Child Health	NICE	41	1.3.30	Theses protocols should include assessment of cardiovascular function with B/P assessment & ECG prior to planned surgery and stopping of Metformin. Individuals should also be assessed for venous thromboembolism prevention	This recommendation was inserted in the section about type 2 diabetes to mirror the corresponding recommendation for type 1 diabetes. The other aspects of these recommendations are excluded from the 2015 update and so no further changes have been made. Safe surgery implies that the other risks specific to type 2 diabetes alluded to in the comment are taken into account
Royal College of Paediatrics and Child Health	NICE FULL	43	1.3.36	Diabetes teams should have appropriate access to mental health professionals to support them in psychological assessment and the delivery of psychosocial support. [2004, amended 2015] and have robust protocols in place for onward referral to specialist mental health teams as appropriate and offer joint working with specialist teams.	This recommendation was inserted in the section about type 2 diabetes to mirror the corresponding recommendation for type 1 diabetes. The other aspects of these recommendations are excluded from the 2015 update and so no further changes have been made. Safe surgery implies that the other risks specific to type 2 diabetes alluded to in the comment are taken into account

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Royal College of Paediatrics and Child Health	NICE	44	1.3.44	This recommendation should also apply to Type 1 diabetes	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline. This applies to monitoring for hypertension in children and young people with type 1 diabetes. Monitoring for hypertension in children and young people with type 2 diabetes is, however, included in the scope for the 2015 update
Royal College of Paediatrics and Child Health	NICE	44	1.3.44	This recommendation should also apply to Type 1 diabetes	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline. This applies to monitoring for hypertension in children and young people with type 1 diabetes. Monitoring for hypertension in children and young people with type 2 diabetes is, however, included in the scope for the 2015 update
Royal College of Paediatrics and Child Health	NICE	45	1.3.49	Why is this recommendation not for Type 1 diabetes as well especially if duration of diabetes greater than 5 years	Thank you for this comment. The evidence for the recommendation in type 2 diabetes suggested, but did not confirm, that retinopathy might occur earlier in this

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					group of patients. The same pattern of effect was not found in the type 1 population. However, as noted in the full guideline in Section 11.4.1.6.2, healthcare professionals should exercise discretion and refer any child or young person whom they feel may be at higher risk of retinopathy (for example, due to suboptimal glycaemic control or long duration of disease) in addition to the screening offered by the national programme
Royal College of Paediatrics and Child Health	NICE	45	1.3.49	Why is this recommendation not for Type 1 diabetes as well especially if duration of diabetes greater than 5 years	Thank you for this comment. The evidence for the recommendation in type 2 diabetes suggested, but did not confirm, that retinopathy might occur earlier in this group of patients. The same pattern of effect was not found in the type 1 population. However, as noted in the full guideline in Section 11.4.1.6.2, healthcare professionals should exercise discretion and refer any child or young person whom they feel may be at higher risk of retinopathy (for example, due to suboptimal glycaemic control or long duration of disease) in addition to the screening offered by the national programme
National Children and	NICE	46	1.4.1	Would like to see this statement changed to: "Measure capillary blood glucose at presentation in children and young people without known diabetes who have	The stem of the recommendation referred to in the comment has been revised to

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Young People's Diabetes Network				increased thirst, polyuria, recent unexplained weight loss or excessive tiredness and any of the following"	include recent unexplained weight loss or excessive tiredness as suggested
Royal College of Paediatrics and Child Health	NICE	46	1.4.1	Would like to see this statement changed to: "Measure capillary blood glucose at presentation in children and young people without known diabetes who have increased thirst, polyuria, recent unexplained weight loss or excessive tiredness and any of the following"	The stem of the recommendation referred to in the comment has been revised to include recent unexplained weight loss or excessive tiredness as suggested
National Children and Young People's Diabetes Network	NICE	46	1.3.52	Individual labs have individual reference ranges. There is a different cut off for males & females locally our reference is NORMAL = ACR < 2.5 mg/mmol in men NORMAL = ACR < 3.5 mg/mmol in women MICROALBUMINURIA = 2 x ACRs 2.5 – 30 in men or MICROALBUMINURIA = 2 x ACRs 3.5 – 30 in women NEPHROPATHY = 2 x ACR > 30 ie macroalbiminuria	Thank you for this comment. The guideline development group has considered the NICE chronic kidney disease guideline and harmonised with definitions and thresholds used there
Royal College of Paediatrics and Child Health	NICE	46	1.3.52	Individual labs have individual reference ranges. There is a different cut off for males & females locally our reference is NORMAL = ACR < 2.5 mg/mmol in men NORMAL = ACR < 3.5 mg/mmol in women MICROALBUMINURIA = 2 x ACRs 2.5 – 30 in men or MICROALBUMINURIA = 2 x ACRs 3.5 – 30 in women NEPHROPATHY = 2 x ACR > 30 ie macroalbiminuria	Thank you for this comment. The guideline development group has considered the NICE chronic kidney disease guideline and harmonised with definitions and thresholds used there
National Children and Young People's Diabetes Network	NICE	49	1.4.17	Suggest this statement specifies a paediatric high dependency unit.	Thank you for this comment. The recommendation referred to in the comment has been changed to state that children and young people with diabetic ketoacidosis should be cared for with one-to-one nursing either on a high-

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					dependency unit (preferably a paediatric unit), or on a general paediatric ward with one-to-one nursing. This change clarifies and emphasises that 1:1 care is most important and the revised recommendation allows for care in an adult high dependency unit if there is no other option
Royal College of Paediatrics and Child Health	NICE	49	1.4.17	Suggest this statement specifies a paediatric high dependency unit.	Thank you for this comment. The recommendation referred to in the comment has been changed to state that children and young people with diabetic ketoacidosis should be cared for with one-to-one nursing either on a high-dependency unit (preferably a paediatric unit), or on a general paediatric ward with one-to-one nursing. This change clarifies and emphasises that 1:1 care is most important and the revised recommendation allows for care in an adult high dependency unit if there is no other option
National Children and Young People's Diabetes Network	NICE	50	1.4.27	Suggest that perhaps there is no place for a bolus unless there is severe haemodynamic collapse. We would also question whether 3% saline might be considered if hyponataemia	The guideline development group agree that an intravenous fluid bolus should not be given routinely even in the case of severe diabetic ketoacidosis. Another recommendation has been added to the guideline to clarify this as follows: do not routinely give an intravenous fluid bolus to a child or young person with severe DKA. 3% saline should not be considered at this

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				is present.	stage because normal saline (0.9% sodium chloride) is an appropriate treatment for hyponatraemia at this stage
Royal College of Paediatrics and Child Health	NICE	50	1.4.27	Suggest that perhaps there is no place for a bolus unless there is severe haemodynamic collapse. We would also question whether 3% saline might be considered if hyponataemia is present.	The guideline development group agree that an intravenous fluid bolus should not be given routinely even in the case of severe diabetic ketoacidosis. Another recommendation has been added to the guideline to clarify this as follows: do not routinely give an intravenous fluid bolus to a child or young person with severe DKA. 3% saline should not be considered at this stage because normal saline (0.9% sodium chloride) is an appropriate treatment for hyponatraemia at this stage
Royal College of Paediatrics and Child Health	NICE	51	1.4.34	Why is the new guidance to NOT subtract boluses from the total fluid calculations as this is the current standard practice?	The reason that resuscitation boluses are not subtracted from the 48-hour fluid calculation is that the fluid quantities recommended in the guideline are already less than in previous guidance and only rarely will a child or young person with diabetic ketoacidosis be given more than 20 ml/kg of intravenous fluid
Royal College of Paediatrics and Child Health	NICE	52	1.4.38	Should it state" after 1 hour and before 2 hours"?	This wording means any time from 1 hour to 2 hours. The timing was considered very carefully by the guideline development group taking into account the available evidence
National	NICE	52	1.4.43	Suggest that plasma osmolality is considered as a factor in the decision to change	This recommendation is about ensuring

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Children and Young People's Diabetes Network				fluids.	that the child or young person does not become hypoglycaemic and so the only change to management recommended at this stage is the addition of glucose to the fluid. There is no change in the recommended sodium chloride concentration and so osmolality has not been included in the recommendation. Another major difference in this guideline compared to previous guidance is that nowhere is hypotonic sodium chloride solution recommended
Royal College of Paediatrics and Child Health	NICE	53	1.4.48	This needs clarification if giving basal via pump only then will need 90-120 mins start beforehand if bolus start up as eating then 30 mins beforehand. IV half life is only 2 minutes stopping IV insulin without adequate wetting in of pump / basal insulin can cause hyperglycaemia	Thank you for this comment. The recommendation has been changed to state that for a child or young person with diabetic ketoacidosis who is using insulin pump therapy, the pump should be restarted at least 60 minutes (rather than 30 minutes as in the consultation draft) before stopping intravenous insulin. This change is supported by the clinical experience of the guideline development group in that it takes 1 hour for the insulin infusion to reach steady state. More than 1 hour (as suggested in the comment) is not necessary
Royal College of Paediatrics and Child Health	NICE	53	1.4.48	This needs clarification if giving basal via pump only then will need 90-120 mins start beforehand if bolus start up as eating then 30 mins beforehand. IV half life is only 2 minutes stopping IV insulin without adequate wetting in of pump / basal insulin can cause hyperglycaemia	Thank you for this comment. The recommendation has been changed to state that for a child or young person with diabetic ketoacidosis who is using insulin

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					pump therapy, the pump should be restarted at least 60 minutes (rather than 30 minutes as in the consultation draft) before stopping intravenous insulin. This change is supported by the clinical experience of the guideline development group in that it takes 1 hour for the insulin infusion to reach steady state. More than 1 hour (as suggested in the comment) is not necessary
Royal College of Paediatrics and Child Health	NICE	54	1.4.51	Should this not just be for severe DKA – ward nurses may not know what to look for on the ECG monitor!	There may be a training issue for interpretation of ECG, but the recommendation states the signs to look out for on the ECG
Royal College of Paediatrics and Child Health	NICE FULL	57	1.5.2	Offer children and young people with diabetes and their family members or carers (as appropriate) 24-hour access to advice from their diabetes team. [2004, amended 2015] better to say: their diabetes team or an identified diabetes out-of-hours service.	Thank you for submitting comments in response to the stakeholder consultation. Please note that NICE is not generally able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (24-hour access to the diabetes team in this case). The recommendation referred to in the comment has been inserted in the guideline to mirror the corresponding recommendation for type 1 diabetes, but the other aspects of the recommendation have not been changed because the topic is excluded from the update scope

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National Children and Young People's Diabetes Network	NICE FULL	58 375-8	General	Remarkably little mention of the importance of this phase of care . The evidence base from literature review is limited given the fundamental challenge of comparing different models . However there is an abundance of evidence as to what NOT to do in trying to engage young people at the critical time of transfer and over a period when 16-19 when adult and paediatric services need to jointly support the care in MDT services. The lack of mention of joint working between adult and paediatric services is a serious omission, particularly as previous quality standard documents have made clear the need for such coordinated care. The term transition is also used loosely .There are a range of attached references from NHS England-NHS Diabetes on appropriate standards for effective transition and transfer . The core principle is to consider transition a phased period and not a single event . The impression in the document is that transition = transfer and this is a single episode of care. It would seem logical that there is alignment between this diabetes document and the ongoing' NICE Transition from children's to adult services guideline development group' Invited expert testimony and references have been attached :	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (transition from paediatric to adult services in this case) The guideline development group recognise the importance of the separate NICE guidance on transition that is being developed but note that it is not completed at present This material was provided to the guideline development group in separate rows of the stakeholder comments table and is addressed there
Royal College of Paediatrics and Child Health	NICE FULL	58 375	General	Remarkably little mention of the importance of this phase of care . The evidence base from literature review is limited given the fundamental challenge of comparing different models . However there is an abundance of evidence as to what NOT to do in trying to engage young people at the critical time of transfer and over a period when 16-19 when adult and paediatric services need to jointly	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015

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		378		support the care in MDT services. The lack of mention of joint working between adult and paediatric services is a serious omission, particularly as previous quality standard documents have made clear the need for such coordinated care. The term transition is also used loosely .There are a range of attached references from NHS England-NHS Diabetes on appropriate standards for effective transition and transfer. The core principle is to consider transition a phased period and not a single event . The impression in the document is that transition = transfer and this is a single episode of care. It would seem logical that there is alignment between this diabetes document and the ongoing' NICE Transition from children's to adult services guideline development group' Invited expert testimony and references have been attached :	update, where the evidence has not been reviewed since the original (2004) guideline (transition from paediatric to adult services in this case) The guideline development group recognise the importance of the separate NICE guidance on transition that is being developed but note that it is not completed at present This material was provided to the guideline development group in separate rows of the stakeholder comments table and is addressed there
National Children and Young People's Diabetes Network	NICE	58	1.5.9 1.5.13	Section must be expanded to include all aspects of transition such as preparation, education, appropriate timing for transition, the need for joint paediatric and adult clinics/joint clinics/young person's clinics/transition clinics, liaison between paediatric and adult teams etc	Thank you for submitting comments in response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (transition from paediatric to adult services in this case)
Royal College	NICE	58	1.5.9	Section must be expanded to include all aspects of transition such as preparation,	Thank you for submitting comments in

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of Paediatrics and Child Health			1.5.13	education, appropriate timing for transition, the need for joint paediatric and adult clinics/joint clinics/young person's clinics/transition clinics, liaison between paediatric and adult teams etc.	response to the stakeholder consultation. Please note, however, that NICE is not able to accept comments on parts of the guideline that are excluded from the 2015 update, where the evidence has not been reviewed since the original (2004) guideline (transition from paediatric to adult services in this case)
Royal College of Paediatrics and Child Health	NICE	95	General	In the table in column under consideration should be given to the possibility of other types of diabetes after Maturity-onset diabetes of the young add neonatal diabetes. To the list of features add 1. Diagnosis less than 6 months as this is neonatal diabetes and not type 1 diabetes. (Edgehill et Diabetes 55:1895–1898, 2006). This is very important as 50% of these patients will have a potassium channel mutation and despite being insulin dependent 90% can get improved control on a sulphonylurea (Pearson ER et al N Engl J Med 2006;355:467-77.). the international guidelines ISPAD are that all these patients should have an immediate molecular genetic diagnosis a decision which is supported by the change in treatment and also health economics Greeley SA, et al he cost-effectiveness of personalized genetic medicine: the case of genetic testing in neonatal diabetes. Diabetes Care. 2011 Mar;34(3):622-7. PMID: 21273495; 2. Incidental hyperglycaemia that is mild (the commonest cause >50% is glucokinase MODY) in at least 3 national surveys Lorini R et al Maturity-onset diabetes of the young in children with incidental hyperglycemia: a multicenter Italian study of 172 families. Diabetes Care. 2009 Oct;32(10):1864-6.PMID: 19564454: Codner E, et al Pediatr Diabetes. 2009 Sep;10(6):382-8. PMID: 19309449; Feigerlová E, Et al . Aetiological heterogeneity of asymptomatic hyperglycaemia in children and adolescents. Eur J Pediatr. 2006 PMID: 16602010	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The revised recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first

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					year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The bullet about having diabetes in the first year of life has been included in the revised recommendations specifically to cover neonatal diabetes which is not otherwise captured by the characteristics listed. Moreover, the term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY
Royal College of Nursing	NICE	95	General	In the table in the column under "consideration should be given to the possibility of other types of diabetes after Maturity-onset diabetes of the young add neonatal diabetes…" To the list of features suggest add: 1. Diagnosis less than 6 months as this is neonatal diabetes and not type 1 diabetes. (Edgehill et Diabetes 55:1895–1898, 2006). This is very important as 50% of these patients will have a potassium channel mutation and despite being insulin dependent 90% can get improved control on a sulphonylurea (Pearson ER et al N Engl J Med 2006; 355:467-77.). The international guidelines ISPAD are that all these patients should have an immediate molecular genetic diagnosis a decision which is supported by the change in treatment and also health economics Greeley SA, et al (2011) the cost-effectiveness of	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are

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				personalized genetic medicine: the case of genetic testing in neonatal diabetes. Diabetes Care. 2011 Mar; 34(3):622-7. PMID: 21273495. 2. Incidental hyperglycaemia that is mild (the commonest cause >50% is glucokinase MODY) in at least 3 national surveys Lorini R et al (2009) Maturity-onset diabetes of the young in children with incidental hyperglycemia: a multicenter Italian study of 172 families. Diabetes Care. 2009 Oct; 32(10):1864-6.PMID: 19564454: Codner E, et al Pediatr Diabetes. 2009 Sep; 10(6):382-8. PMID: 19309449; Feigerlová E, et al. Aetiological heterogeneity of asymptomatic hyperglycaemia in children and adolescents. Eur J Pediatr. 2006 PMID: 16602010	strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The revised recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The bullet about having diabetes in the first year of life has been included in the revised recommendations specifically to cover neonatal diabetes which is not otherwise captured by the characteristics listed. Moreover, the term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY
Royal College of Nursing	NICE	96	General	In the central column in line with comments above, suggest remove the clinical feature of "rarely or never produce ketone bodies" as this is not correct Neonatal	Thank you for this comment. The guideline development group reviewed the evidence

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				diabetes presents in ketoacidosis (Gloyn et al NEJM 2004), ketones do occur in MODY and although very rare ketoacidosis can occur (like in Type 2 diabetes). As above important clinical features that should be included in this section are: 1. Diagnosis less than 6 months as this is neonatal diabetes and not type 1 diabetes. (Edgehill et al (2006) Diabetes 55:1895–1898, 2006). This is very important as 50% of these patients will have a potassium channel mutation and despite being insulin dependent 90% can get improved control on a sulphonylurea (Pearson ER et al N Engl J Med 2006; 355:467-77.) 2. Parental diabetes (especially when an extended family and the absence of obesity) as this suggests MODY rather than Type 1 or Type 2 diabetes. 3. Incidental hyperglycaemia that is mild (the commonest cause >50% is glucokinase MODY) in at least 3 national surveys Lorini R et al (2009) Maturity-onset diabetes of the young in children with incidental hyperglycemia: a multicenter Italian study of 172 families. Diabetes Care. 2009 Oct; 32(10):1864-6.PMID: 19564454: Codner E, et al Pediatr Diabetes. 2009 Sep; 10(6):382-8. PMID: 19309449; Feigerlová E, et al. Aetiological heterogeneity of asymptomatic hyperglycaemia in children and adolescents. Eur J Pediatr. 2006 PMID: 16602010. 4. Absence of autoantibodies (discussed below McDonald T et al (2011) Islet autoantibodies can discriminate maturity-onset diabetes of the young (MODY) from Type 1 diabetes. Diabet Med. 2011Sep; 28(9):1028-33. PMID: 21395678. This approach has been proven to be successful in identifying MODY in the paediatric population (Pihoker C, et al (2013)	related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial diabetes. The revised recommendations emphasise that healthcare professionals should think about the possibility of types of diabetes other than types 1 or 2 (such as other insulin resistance syndromes, monogenic or mitochondrial diabetes) in children and young people with suspected diabetes who: have diabetes in the first year of life; rarely or never develop ketone bodies in the blood (ketonaemia) during episodes of hyperglycaemia; or have associated features, such as optic atrophy, retinitis pigmentosa, deafness, or another systemic illness or syndrome. Together these characteristics cover the possibility of both maturity onset diabetes in the young (MODY) and neonatal diabetes. The bullet about having diabetes in the

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				Prevalence, characteristics and clinical diagnosis of maturity onset diabetes of the young due to mutations in HNF1A, HNF4A, and glucokinase: results from the SEARCH for Diabetes in Youth. J Clin Endocrinol Metab. 2013 Oct; 98(10):4055-62. PubMed PMID: 23771925) 5. Acanthosis nigricans in a slim child (suggests a genetic disorder of insulin resistance).	first year of life has been included in the revised recommendations specifically to cover neonatal diabetes which is not otherwise captured by the characteristics listed. Moreover, the term monogenic diabetes has been used in the revised recommendations so that neonatal diabetes is covered as well as MODY. Additionally the recommendations have been revised to include family history of diabetes. However, the limitations of the scope for the 2015 update prevent the guideline development group from providing more detail about the diagnosis or management of forms of diabetes other than type 1 or type 2
Royal College of Paediatrics and Child Health	NICE	96	General	In the central column in line with comments above remove the clinical feature if" rarely or never produce ketone bodies" as this is not correct Neonatal diabetes presents in ketoacidosis (Gloyn et al NEJM 2004), ketones do occur in MODY and although very rare ketoacidosis can occur (like in Type 2 diabetes) As above important clinical features that should be included in this section are: 1. Diagnosis less than 6 months as this is neonatal diabetes and not type 1 diabetes. (Edgehill et Diabetes 55:1895–1898, 2006). This is very important as 50% of these patients will have a potassium channel mutation and despite being insulin dependent 90% can get improved control on a sulphonylurea (Pearson ER et al N Engl J Med 2006;355:467-77.) 2. Parental diabetes (especially when an extended family and the absence of obesity) as this suggests MODY rather than Type 1 or Type 2 diabetes. 3. Incidental hyperglycaemia that is mild (the commonest cause >50% is glucokinase MODY) in at least 3 national surveys Lorini R et al Maturity-onset	Thank you for this comment. The guideline development group reviewed the evidence related to diagnosis, and specifically evidence for distinguishing between type 1 and type 2 diabetes, whereas distinguishing between type 1 diabetes, type 2 diabetes and other forms of diabetes such as monogenic diabetes was excluded from the 2015 update. It was concluded that when diagnosing diabetes in a child or young person, type 1 diabetes should be assumed unless there are strong indications of type 2 diabetes, monogenic diabetes or mitochondrial

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