National Institute for Health and Clinical Excellence

Diabetes in children (update)
Scope Consultation Table
4 July - 29 August 2012

Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
A. Menarini Diagnostics Ltd	1	3.1.1	The draft scope recognises that 'children and young people with type 1 diabetes have the worst rates of very high risk glucose control and of the acute metabolic complication diabetic ketoacidosis (DKA). Nine per cent of children and young people with diabetes experienced at least one episode of DKA in 2009–2010.' The current guidelines recognise in section number 5.2, that 'Diabetic ketoacidosis is the most common cause of diabetes-related deaths in children and young people.' This review is an opportunity to reverse that trend by ensuring that all children and young people with type 1 diabetes are given education and encouraged to monitor blood ketone levels at appropriate times, i.e. illness and periods of persistently elevated blood glucose, for the short term prevention of DKA.	Thank you for your comment. Blood ketone monitoring for the prevention of diabetic ketoacidosis has now been included in the scope
A. Menarini Diagnostics Ltd	3	3.1.1 4.3.2	With regard to patient education and blood ketone monitoring, the guidelines should be consistent with the following publication: Joint British Diabetes Societies Inpatient Care Group The Management of Diabetic Ketoacidosis in Adults - March 2010 **i.e.** 1. Improved patient education with increased blood glucose and ketone monitoring has led to partial treatment of DKA prior to admission with consequent lower blood glucose levels at presentation. 2. Patients with diabetes who are admitted with DKA should be counselled about the precipitating cause and early warning symptoms of DKA. Failure to do so is a missed educational opportunity. Things to consider	Thank you for your comment. Blood ketone monitoring for the prevention of diabetic ketoacidosis has now been included in the scope. We will consider this publication if it meets our inclusion criteria

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			are: • Identification of precipitating factor(s) e.g. infection or omission of insulin injections • Prevention of recurrence e.g. provision of written sick day rules • Insulin ineffective e.g. the patient's own insulin may be expired or denatured. This should be checked prior to reuse • **Provision of handheld ketone meters and education on management of ketonaemia** 3. The resolution of DKA depends upon the suppression of ketonaemia and measurement of blood ketones now represents best practice in monitoring the response to treatment.	
A. Menarini Diagnostics Ltd	2	4.3.2	f) monitoring of blood ketones The draft scope indicates that the original guideline will not be updated. The original guideline, at section number 5.2 states that 'It has been recommended that children and children with diabetes measure hydroxybutyrate when symptoms such as nausea or vomiting occur (to differentiate ketoacidosis from gastroenteritis), during infections, during periods with high blood glucose (> 15 mmol/l), and when they are aware of ketonuria.' There is an opportunity to make it clear that the measurement of hydroxybutyrate necessitates **blood ketone monitoring**, rather than urine ketone monitoring (ref. 1). And replacing urine ketone testing with blood ketone testing alone has been shown to reduce DKA hospitalisations by 50% (ref. 1). [1]Sick day management using blood 3-hydroxybutyrate (3-OHB) compared with urine ketone monitoring reduces hospital visits in young people with T1DM : a randomised clinical trial : Laffel LM et al. Diabet Med 2005;23(3):278-284	Thank you for your comment. Blood ketone monitoring for the prevention of diabetic ketoacidosis has been included in the scope

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Abbott Diabetes Care	1	4.3.1 (b)	We propose that within the section on structured education and behavioural interventions, consideration be given to new emerging tools that support patients in managing their diabetes, especially patients with special challenges such as low numeracy or low literacy skills. These supportive tools include insulin bolus advisors, calculators, insulin logbooks, and structured education programmes. Evidence suggests that use of these tools may improve self-management of diabetes and metabolic control among adolescents. • Glaser NS, et al. Benefits of an Insulin Dosage Calculation Device for Adolescents with Type 1 Diabetes Mellitus. Journal of Pediatric Endocrinology and Metabolism. 2004; 17:1641-51. • Sussman A, et al. Performance of a Glucose Meter with a Built-In Automated Bolus Calculator versus Manual Bolus Calculation in Insulin Using Subjects. Journal of Diabetes Science and Technology. 2012;6:339-44.	Thank you for your comment. We will include evidence for these groups and tools if available and have amended the equalities form accordingly
Abbott Diabetes Care	2	4.3.1 (d)	We recommend that the latest guidance from IDF/ISPAD (International Diabetes Federation/International Society for Paediatric and Adolescent Diabetes) be considered in the scope of blood glucose targets; HbA1C < 7.5% for all age groups Preprandial capillary plasma gucose 90-145 mg/dL (6-8mmol/L) Peak postprandial capillary plasma glucose 90-180 mg/dL (5-10mmol/L) • Global IDF/ISPAD guideline for diabetes in children and adolescence 2011 (http://www.idf.org/sites/default/files/Diabetes%20in%20Childhood%20and%20Adolescence%20Guidelines_0.pdf)	Thank you for your comment. We will consider this evidence if it meets our inclusion criteria
Abbott Diabetes Care	3	4.3.1 (d)	We propose that the scope consider advancements in technology for real-time monitoring of glucose. Real-time CGM has demonstrated clinical benefits, which include reductions in HbA1c, more time in euglycemia, prevention/detection of hypoglycaemia and reduction of time spent in	Thank you for your comment. We will include real-time continuous glucose monitoring within

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			hypoglycaemia. • Battelino T, et al. Effect of continuous glucose monitoring on hypoglycemia in type 1 diabetes. Diabetes Care. 2011 34: 795–800 • Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group; Tamborlane WV, et al. Continuous glucose monitoring and intensive treatment of type 1 diabetes. N Engl J Med. 2008; 359:1464-76.	the glucose monitoring topic
Abbott Diabetes Care	4	4.3.1 (d)	We recommend that a clear distinction be made between the use of retrospective CGM (diagnostic and risk evaluation) and real-time CGM (therapeutic) in order to differentiate the role of each indication towards behavioural modification, reduction in A1c, detection and prevention of hypoglycaemia, and improving diabetes outcomes.	Thank you for your comment. We will include real-time continuous glucose monitoring within the glucose monitoring topic. Details of monitoring methods will be recorded as reported in the literature
Abbott Diabetes Care	5	4.3.1 (d)	We recommend that CGM be considered as a glucose monitoring strategy in children and young people with type 1 diabetes as CGM has demonstrated improvements in HbA1c and glucose stability, compared to conventional SMBG, among poorly controlled and well controlled type 1 diabetes patients. • Riveline J et al. Assessment of Patient-Led or Physician-Driven Continuous Glucose Monitoring in Patients with Poorly Controlled Type 1 Diabetes Using Basal-Bolus Insulin Regimens. Diabetes Care, Volume 35, May 2012. • Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group The effect of continuous glucose monitoring in well-controlled type 1 diabetes. Diabetes Care. 2009 Aug;32(8):1378-83. Epub 2009 May 8.	Thank you for your comment. Continuous glucose monitoring is included within the glucose monitoring topic
Abbott Diabetes	6	4.3.2 (f)	We recommend that the section "Monitoring of blood ketones" include specific guidance on blood ketone monitoring for the prevention and detection of DKA	Thank you for your comment. Blood ketone

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Care			in children and adolescents.	monitoring for the prevention of diabetic ketoacidosis has been included in the scope
Abbott Diabetes Care	7	4.4	People with Diabetes experience significant clinical, psychological, emotional, and social challenges to managing and caring for their disease. We propose that the main outcomes be broadened to include all outcomes relevant to diabetes patients including: a). Patient reported outcome measures - Quality of life - Diabetes-related stress - Treatment satisfaction - Fear of hypoglycemia - Confidence in self-managing diabetes - Patient engagement / motivation b). Glycaemic control - HbA1c - Time in target / euglycemia - Glycaemic variability - Hypoglycaemia (nocturnal hypoglycaemia, hypoglycaemia unawareness) c). Adverse effects d). Complications from diabetes e). Mortality f). Resource utilisation • Standards of Medical Care in Diabetes – 2012. Diabetes Care 2012;35:S11-63. • Perlmuter LC, et al. Glycemic Control and Hypoglycemia. Is the Loser the Winner? Diabetes Care. 2008; 31:2072-6. • Garg S, et al. Improvement in Glycemic Excursions With a Transcutaneous, Real-Time Continuous Glucose Sensor. Diabetes Care. 2006; 29:44-50.	We have outlined broad categories of outcomes but expect that the specific outcomes used in each evidence review will vary. The guideline development group will decide on a question by question basis which 7 outcomes would best influence the clinical and patient decision-making process

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Association of British Clinical Diabetologists (ABCD)/Royal College of Physicians	1	4.1.1.a and b	The Best Practice Tariff for Paediatric Diabetes, standards and payment, extends to those up to the age of 19 years. The age cut point for this guideline should be amended to under19 years to keep uniformity with this.	Thank you for your comment. Birth to 18 years is the accepted age range for children and young people in the 2004 Type 1 diabetes guideline, and it has been agreed by NICE and the four teams updating the Type 1 diabetes in adults, Type 2 diabetes in adults, Diabetes in children and young people, and Diabetes in pregnancy guidelines that it is appropriate to maintain this age cut-off for the guideline updates. We are aware that other cut-offs are used in some areas of clinical practice such as the Best Practice Tariff for Paediatric Diabetes
Association of children's diabetes clinicians	1		Currently the scope includes antibody testing at diagnosis but excludes blood ketone testing. We do not think this is the right priority order and that spending a lot of time on which antibodies should be measured was a low priority and that the use of blood ketone monitoring would be much more useful as many PCTs still do not allow this to be used. There is evidence that this prevents DKA an admissions if used in sick days.	The role of antibody testing in the diagnosis of type 1 and type 2 diabetes is included in the scope. It is expected that the evidence review on this topic (including young people) will be undertaken by the type 1 diabetes in adults

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				guideline and that the same recommendations will apply in both guidelines. We agree that it is important to investigate the effectiveness of blood ketone monitoring to prevent diabetic ketoacidosis and we have added this to the scope
British Psychological Society	1.	4.3.1 b) & g)	It is important that 'structured education programmes' (for CYP with type 1 or type 2 diabetes) stress the importance of considering their impact on black and minority ethnic families – respecting cultural difference, while providing education grounded in evidence and explained in a way which is understood.	Thank you for your comment. We agree and we will pay particular attention to culture-specific education programmes where evidence exists
British Psychological Society	2.	4.3.1 b) & g)	Psychologists have identified methods of assessment specifying taxonomies of behaviour change techniques (BCTs) (Abraham & Michie, 2008) and competency frameworks (Dixon & Johnston, 2010). The BPS recommends that evaluations of BCTs for CYP with diabetes use these frameworks to evaluate: (a) which techniques are effective; (b) what levels of competence are required; and (c) who should deliver them (see also point 9 below). *References:* Abraham, C. & Michie, S. (2008). A Taxonomy of Behavior Change Techniques Used in Interventions. *Health Psychology*, *27(3)*, 379-387. Dixon, D. & Johnston, M. 2010. *Health Behaviour Change Competency Framework: Competences to deliver interventions to change lifestyle behaviours that affect health.* http://www.healthscotland.com/uploads/documents/14543-HBCC_framework1.pdf	Thank you for your comment. The guideline development group will consider the documents cited in the comment if they meet inclusion criteria for the group's review questions. The developers will seek to appoint a clinical psychologist with expertise in diabetes in children and young people as an expert advisor for relevant topics, for example, those pertaining to behavioural

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			Accessed August 2012.	interventions
British Psychological Society	3.	4.4 (f)	The BPS recommends that several psychological outcomes be considered in CYP, including emotional (stress, anxiety, depression), cognitive (concentration, intellectual functioning) and behavioural (eating disorders, behavioural problems). Often, studies may also include positive outcomes such as well-being, self-efficacy and adjustment, so we suggest that NICE consider including these (they may or may not be assessed in relation to 'quality of life' depending on the method of assessment used). For example, Rubin *et al.,* 1993; Skinner *et al.,* 2000). *References:* Rubin, R.R., Peyrot, M. & Saudek, C.D. (1993). The Effect of a Diabetes Education Program Incorporating Coping Skills Training on Emotional Well-Being and Diabetes Self-Efficacy. *The Diabetes Educator*, *19(3)*, 210-214. Skinner, T. C., John, M. & Hampson, S. (2000). Social Support and Personal Models of Diabetes as Predictors of Self-Care and Well-Being: A Longitudinal Study of Adolescents With Diabetes. *Journal of Paediatric Psychology, 25(4)*, 257-267.	Thank you for your suggestion. The guideline development group once assembled will decide on the primary 7 outcomes for each review question
British Psychological Society	4.	4.4 (f)	The BPS believes that wider outcomes, such as family functioning and parental distress should also be assessed.	Thank you for your suggestion. The guideline development group once assembled will decide on the primary 7 outcomes for each review question
British Psychological Society	5.	4.5.1 (Type 1 diabetes) and 4.5.2 (Type 2 diabetes)	*"What is the effectiveness of behavioural interventions to improve adherence in children and young people with type 1 diabetes? (and engagement with clinical services for children and young people with type 2 diabetes)."* As noted in point 6 above, the BPS recommends that this question is enhanced to assess: (a) which techniques are effective; (b) what levels of competence	Thank you for your suggestion. This will be borne in mind when assessing the effectiveness of behavioural interventions

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		Review Questions	are required; and (c) who should deliver them.	
British Psychological Society	6.	General	Children and young people (CYP) with diabetes are more vulnerable than their peers to emotional, behavioural and cognitive difficulties (Grey *et al.*, 2002; Dantzer *et al.*, 2003). Previous NICE guidance identified key priorities for those in this age group with type 1 diabetes, including provision of ongoing psychosocial support for children, young people and their families, and ensuring that multidisciplinary diabetes teams working with children were trained to facilitate maintenance of healthy 'lifestyle' and promotion of 'mental health'. These issues have equal relevance for those with type 2 diabetes, and we therefore recommend that such key priorities are included within the scope of this guidance. *References:* Grey, M., Whittemore, R. & Tamborlane W. (2002). Depression in Type 1 Diabetes in Children: Natural history and correlates. *Journal of Psychosomatic Research* 2002; 53(4):907-911. Dantzer, C., Swendson J., Maurice-Tyson, S. & Salamon, R. (2003). Anxiety and Depression in Juvenile Diabetes: A critical review. *Clinical Psychology Review*, *23*, 787-800.	Thank you for your suggestion. Psychological support for children and young people with type 2 diabetes has not been prioritised for inclusion in this update. However, we will be examining the evidence surrounding behavioural interventions to improve adherence and promote engagement in children and young people with type 2 diabetes
British Psychological Society	7.	General	It is increasingly recognised that effective self-management of diabetes should focus on the two broad areas of mental health/well-being and lifestyle/behaviour change skills. Evidence suggests that including regular assessment and theoretically-based psychological interventions in diabetes care leads to improvements in diabetes control (behaviour change), and greater well-being (mental health) in CYP with diabetes (Winkley *et al.,* 2006). Interventions with evidence of benefit in this age group include motivational interviewing, goal setting skills and cognitive behaviour therapy, including family therapy (summarised in Scottish Intercollegiate Guidelines Network 116,	Thank you for your comment and citations. We expect that this will be covered in the review of behavioural interventions

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			2010). Effective lifestyle interventions are also very important for CYP with type 2 diabetes and their families. *Reference:* Scottish Intercollegiate Guidelines Network 116, 2010. *Management of Diabetes.* http://www.sign.ac.uk/guidelines/fulltext/116/index.html Accessed August 2012. Winkley, K., Landau, S., Eisler, I. & Ismail, K. (2006). Psychological Interventions to Improve Glycaemic Control in Patients with Type 1 Diabetes: Systematic review and meta-analysis of randomised controlled trials. *British Medical Journal*, *333*, 65-68. http://www.bmj.com/cgi/content/abstract/bmj.38874.652569.55v1?rss=1 Accessed August 2012.	
British Psychological Society	8.	General	The BPS recommends that applied psychologists with specialist knowledge of diabetes are involved in delivery of care for CYP with diabetes as they have expert skills in delivering both mental health and behaviour change interventions. Further, we believe that psychologists should be involved in training members of the diabetes team to deliver these interventions at appropriate levels of competence, as exemplified in the Health Behaviour Change Competency Framework (Dixon & Johnston, 2010) *Reference:* Dixon, D. & Johnston, M. 2010. Health Behaviour Change Competency Framework: Competences to deliver interventions to change lifestyle behaviours that affect health. http://www.healthscotland.com/uploads/documents/14543-HBCC_framework1.pdf Accessed August 2012.	We agree and we expect that this will be considered in the developers' deliberation on the evidence for behavioural interventions
British	9.	General	In order to contribute relevant expertise on diabetes specific mental health and	Thank you for your

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Psychological Society			behaviour change issues to the guideline review, the BPS recommends the inclusion of at least one applied psychologist with specialist knowledge of diabetes on the Guideline Development Group and ideally both a clinical psychologist and a health psychologist.	suggestion. We will seek to recruit a clinical psychologist with specialist expertise in paediatric diabetes as an expert advisor to the guideline development group
British Society for Paediatric Endocrinology and Diabetes	1	4.3.1 (d)	If the guidelines can give clear criteria for when CGMS would be recommended, this would be very helpful. Presumably, this would be covered under this section.	Thank you for your comment. We will examine the evidence for retrospective versus real-time continuous glucose monitoring and also the evidence of intermittent versus continuous real-time monitoring. The guideline development group will make recommendations on the use of continuous glucose monitoring taking account of that evidence
British Society for Paediatric Endocrinology and Diabetes	2	4.3.1(f) and section 4.3.2 (t)	NICE Coeliac guidelines were revised in 2009 and the previous recommendation in the 2004 NICE diabetes guideline to screen for coeliac disease 3 yearly was changed to only recommending screening at diagnosis. This was on the grounds that there was no evidence to screen other than at diagnosis. The BSPED was not invited as a stakeholder to comment on the coeliac guidelines during their revision and we wrote to the NICE review committee after they were published, disagreeing with their findings. We presented a large body of evidence to show that coeliac disease can present many years after diagnosis of diabetes, the process is often indolent and only detected with	Thank you for your comment. The developers have been informed by NICE that the Coeliac disease guideline is being updated and this topic will be considered again in that guideline. The current recommendations on screening for coeliac

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			screening. We feel that recommendations for screening for coeliac disease MUST be reviewed with this guidance (evidence included as appendix below). There is also no mention of thyroid disease as a co-morbidity in the draft scope. Is this because it is taken as read, since it is in the current guidance? To be certain of inclusion, should this not be specifically included along with the references to nephropathy and retinopathy? See below for comment about dyslipidaemia	disease in children and young people with diabetes will remain in place until then and the topic will remain excluded from the Diabetes in children and young people update scope. Recommendations on monitoring for thyroid disease in children and young people with type 1 diabetes exist in the current guidance and there is no indication that this topic requires updating. This topic will therefore remain excluded from the Diabetes in children and young people update scope
British Society for Paediatric Endocrinology and Diabetes	3	4.3.2 (f) & 4.5.1	Would be very helpful to have clear recommendations (or otherwise) about monitoring blood ketones as PCTs increasingly refusing to fund this. Children on insulin pumps in particular need to be able to test for blood ketones because of the risk of rapid metabolic decompensation and DKA if pump fails. Also, this is now recommended in the DKA guidelines; anecdotally, children can be kept out of hospital by parents monitoring blood ketones at home, saving the cost of an admission (and potentially life-threatening DKA) but would be useful if there was evidence to back this up. This is probably more important than focussing on antibody tests to	The role of antibody testing in the diagnosis of type 1 and type 2 diabetes has been included in the scope. It is expected that the evidence review on this topic (including young people) will be undertaken by the type 1 diabetes in adults guideline and that

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			differentiate between T1DM & T2DM, based on numbers of CYP with both in the UK.	the same recommendations will apply in both guidelines We agree that it is important to investigate the effectiveness of blood ketone monitoring to prevent diabetic ketoacidosis and we have added this to the scope
British Society for Paediatric Endocrinology and Diabetes	4	4.5.2	Dyslipidaemia is specifically mentioned with respect to T2DM – what about dyslipidaemia in T1DM?	Thank you for your comment. The topic of monitoring for dyslipidaemia in children and young people with type 2 diabetes has been prioritised for inclusion; however, the existing recommendations on monitoring for dyslipidaemia in children and young people with type 1 diabetes were felt to be sufficient as dyslipidaemia is usually related to glucose control in these children and young people
British Society for Paediatric Endocrinol	5	General	The current recommendations around transition from paediatric to adult diabetes services are actually quite comprehensive and detailed. The main issue is around encouraging services to follow them! We feel they remain valid and excluding them from the review is reasonable.	Thank you for your comment. The guideline developers note that NICE will be commissioning a

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ogy and Diabetes				clinical guideline on the topic of transition from child to adult services which might be of interest to the stakeholder
Coeliac UK	1	4.3.2 (t)	The NICE clinical guideline on recognition and assessment of coeliac disease C86 (2009) recommends that children and adults with Type 1 diabetes are offered serological testing to screen for coeliac disease at diagnosis. This guideline also noted that there was no evidence to support a specific recommendation on the regularity of repeat testing for coeliac disease. Since this time, NICE has updated its clinical guideline on diagnosis and management of Type 1 diabetes in children, young people and adults to remove the recommendation to re-test for coeliac disease at least every three years after diagnosis. These changes have led to some debate about the frequency of repeat testing for coeliac disease in people with Type 1 diabetes. There have been recent reports suggesting that there is often a delay between Type 1 diabetes and coeliac disease diagnoses, and that coeliac disease cases would be missed if testing for coeliac disease occurred in children with Type 1 diabetes only at diagnosis. To support the case for a recommendation on repeat testing please see the following references: Jones H and Warner J (2010) NICE clinical guideline 86. Coeliac disease: recognition and assessment of coeliac disease. Archives of Disease in Childhood. 94: 312-313; Babiker A, Morris MA and Datta V (2010) Coeliac disease and type 1 diabetes: 7 years of experience versus NICE guidance 2009. Archives of Disease in Childhood. 95: 1068-1069. We therefore propose that the scope of the 'Diabetes in children and young people' guideline is amended to include monitoring for complications and co-morbidities of Type 1 diabetes <u>including coeliac disease</u>. This would allow any developments in the evidence on this issue to be taken into account and reflected in the updated guidance.	Thank you for your comment. The developers have been informed by NICE that the Coeliac disease guideline is being updated and this topic will be considered again in that guideline. The current recommendations on screening for coeliac disease in children and young people with diabetes will remain in place until then and the topic will remain excluded from the Diabetes in children and young people update scope

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Deaf Diabetes UK	1		- to remove access + communication barriers for Deaf BSL users who have diabetes, Deaf Parents with a Deaf or hearing Child or children who have diabetes + pregnant Deaf mothers who have diabetes / need to be aware of diabetes health condition during pregnancy to NHS Diabetes Care + Services + NHS Information relating to diabetes. Need to know what treatment/services they should be receiving to deal with the diabetes health condition. - unable to access to current NHS Diabetes Support Group in their local NHS area - making an appointment with their GP difficult due to phone system appointment only - some Doctors /Diabetes Nurse/Health Professionals display reluctant attitude to have a RSLI (Registered Sign Language Interpreter) with their Deaf Patient placing Deaf Patient in an uncomfortable environment - NHS's letter offering a hospital appointment omitting information if a RSLI has been booked as requested often leaving Deaf Patient with no choice but to cancel appointment via third party involvement to phone them on their Telephone voice number given in the letter to rearrange an appointment with a RSLI or bring a family member including a child to "interprete" to avoid cancelling the appointment. - some Doctors Surgeries have a Textphone but Deaf Patients making a direct text phone call unanswered + had to use Typetalk Service which Receptionist Staff always answered quickly. Some Surgeries have Textphone Service facility but often unused / out of sight or unplugged. - NHS Information in written English + no BSL Format on information relating to	Thank you for this comment which raises many important issues relating to provision of, and access to, services and information. As part of the NICE clinical guideline development process, the guideline development group will be required to consider the need to advance equality and prevent unlawful discrimination for each and every recommendation proposed. This means that the specific needs and preferences of individuals, including those protected by law, will be considered. This includes those who are deaf or hard of hearing. These considerations are documented in an equalities form which will be published on NICE's website. The issues raised affect diabetes care, as illustrated by the examples provided, but relate to

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			diabetes but available in other written community spoken language. - Deaf people who have diabetes experience lack of communication support / lack of Deaf awareness amongst Doctors/Diabetes Nurse + Reception Staff leaving them feeling not receiving an inadequate consultation / not really clear or knowing much more about their diabetes condition /what are they supposed to do next or even know how to take the medicine prescribed to them / unsure about their ongoing healthcare plans / lack of aftercare support / lots of concern/confusion over altered diet advice advisable / insulin treatment / misunderstandings information relating to diabetes issues. The need for clearer writing from the Doctors on the use of medication in writing in plain English before Deaf Patients leave the surgery NHS Staff who learnt BSL commendable but are not trained to "Interprete" should not be used as "Interpreter" replacing RSLI. NHS BSL users helpful for informal situation like welcoming Deaf Patient on arrival, signposting them to correct department / Refreshment + Toilet facilities, checking if RSL booked arrived yet as good examples. - Deaf Patients struggled + missed their appts with a Tannoy Public Announcement system calling Patients's name at GP's Surgery / NHS Diabetes Care + Services + A&E department despite informing/reminding the Receptionist to alert them when their name called out but Receptionist often forget if busy. Feedback offered solutions that - all GP surgeries/NHS Diabetes Care + Services a) should ask/check Deaf person their communication preference b) should know how to get / book a RSLI (= Registered Sign Language Interpreter) who are registered with the NRCPD = The National Register of	quality of care more generally. Specific changes to the guideline scope have not been made in response to these comments, because the population and particular sub-groups to be covered would include people with diabetes who are deaf or hard of hearing. The guideline developers will therefore continue to adhere to the principles outlined above throughout the development of the guideline. The Patient and Public Involvement Programme (PPIP) and the Implementation team at NICE have also been informed of these issues. PPIP will help all the teams at NICE to ensure that these issues are considered during their work. When the diabetes guidelines are published, the Implementation team will help to raise these issues to staff working in the wider National Health

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			Communication Professionals working with Deaf + Deafblind People. NRCPD is supported by Signature. How to find/Book a RSLI? Visit www.signature.org.uk E: enquiries@nrcpd.org.uk / Tel 0191 383 1155 / Text 0191 383 7915 / Fax 0191 383 7914 c) should have a list of RSLI available on hand to save time with good planning ahead with booking a RSLI d) should comply with The Equality Act 2010 to provide RSLI provision for Deaf BSL users who need one. - all surgeries should have a way for Deaf BSl users to contact them directly to make an appointment with technology aid available (SMS/Email) - all surgeries / NHS Diabetes care + Services plus A&E departments should consider installing a visual patient system. Note more Surgeries are adopting this but should be a national standard practice including NHS Hospitals + A&E departments. - all NHS Staff particularly medical Staff who work directly with Deaf Patients should receive basic Deaf Awareness training including how to get / book a RSLI + how to work with RSLI / be familiar with their role to ensure effective communication with Deaf BSL user. Note Not appropriate to use a Child family member to take on "Interpreter" role. Not acceptable + must be discouraged. Sometimes Deaf BSL user may use an Adult family member / friend or husband/wife/partner not advisable + not to be encouraged as they only give a summary / confidentially an issue / controlling + often Health Professionals engaged with them instead of Deaf Patient. Deaf Patients need to be explained on the importance of using a RSLI to access full information + make an informed choice on their diabetes health	Service (NHS).

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			condition. RSLI will always relay full account / full access of whats being said by NHS Professionals to Deaf Patient. RSLI to follow the NRCDP's Code of Conduct including confidentially + impartially. - need support for Deaf people with Type 1/2 diabetes / Deaf parents with their child/children with diabetes + pregnant Deaf mothers who have diabetes or need to understand their pregnancy related to diabetes to access information on all aspects of diabetes health condition in Deaf friendly format leaflets / DVD on specific diabetes related issues + via RSLI provision when needed + suitable BSL format for Deaf children too. Currently none available. - DDUK advocate positive working partnerships with NHS Diabetes Care + Services via education, training, research, services accessible, ensuring that the NHServices comply with the Equality Act 2010, understanding of / to improve awareness of Deaf BSL users who have diabetes needs to take control of / to manage their diabetes health condition better, raise confidence + make informed choice. NOTE Access + Communication issues are the main issues that the NHS needs to address if Deaf people with diabetes are to be provided with a service that truly to meet their needs / what NHS Diabetes Care + Services they should be receiving. Including knowing how to make complaints + understanding how the NHS work. NOTE NHS Services should offer RSLI provision for any Deaf Patient who needs one on ALL health matters affecting them.	
Departme	2	3.1 (DPT)	The onset is often in childhood but more adults have the condition.	Thank you for your

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nt of Health				comment. The remit for this guideline is for children and young people but we will be liaising closely with the type 1 diabetes in adults and type 2 diabetes in adults guideline development teams
Department of Health	3	3.1.2g (DPT)	Comparison with historical data Most likely to occur in children from ethnic minority communities.	Thank you for pointing this out. We have updated the scope and equalities form accordingly
Department of Health	4	4.1.2a (DPT)	Management of planned and actual pregnancy is included in the pregnancy guidance. However guidance for children and young people (CYP) must include education about avoidance of unplanned pregnancy, and the risks of unplanned pregnancy. 15 year olds with diabetes get pregnant!	Thank you for your comment. The issue of education on the diabetes-specific risks of unplanned pregnancy and contraception will be covered in the Diabetes in Pregnancy guideline update. The Diabetes in children and young people guideline will cross-refer to this where appropriate
Department of Health	5	4.1.2b	Other forms of diabetes should be included. There are estimated to be about 20,000 with monogenic diabetes, and another 20,000 with maternally inherited diabetes and deafness, in addition to those with secondary diabetes, e.g. cystic fibrosis	Thank you for your comment. Recognition of other types of diabetes is already referred to in existing recommendations. Management of other types of diabetes is outside the remit for this guideline

Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
Department of Health	6	4.3.1 (General) (DPT)	Insulin pumps and sensor augmented pumps.	Thank you for your comment. The topic of insulin pumps is covered in "Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus", NICE Technology Appraisal 151 (2008) which is considered up-to-date and therefore has not been prioritised for inclusion in this update
Department of Health	7	4.3.1d (DPT)	Include glucose monitoring for CYP with T2 diabetes. Also include continuous glucose monitoring (including real-time)	Thank you for your comment. Monitoring for glycaemic control in type 2 diabetes in children and young people relies mainly on HbA_{1c} measurement, and so this will be the focus of the review Real-time continuous glucose monitoring is included within the topic on glucose monitoring for type 1 diabetes. However, glucose monitoring for type 2 diabetes in children or young people was considered a lower priority clinically and is therefore

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				not included in this update
Department of Health	8	4.3.1e (DPT)	Include bariatric surgery for obese children with T2 diabetes	Thank you for your comment. Children and young people with type 2 diabetes are included in the existing Obesity guideline (CG43), which makes recommendations on the use of bariatric surgery in these groups. The Diabetes in children and young people guideline may cross-refer to this guidance where necessary but the topic will not be included in the scope
Department of Health	9	4.3.1f (DPT)	Include foot care	Thank you for your comment. As foot care problems are rare in children and young people with diabetes, and there are recommendations on this topic in the current guideline and in the Type 2 diabetes: prevention and management of foot problems guideline (CG10), this topic has not been prioritised for inclusion in the update scope

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Department of Health	10	4.3.1h (DPT)	Include other treatments for T2 diabetes	Thank you for your comment. We have included metformin monotherapy for children and young people with type 2 diabetes. Recommendations on lifestyle interventions for children and young people with type 2 diabetes exist in the Obesity clinical guideline (CG43) and the Promoting physical activity for children and young people public health guidance (PH17). The Diabetes in children and young people guideline may cross-refer to these guidelines but the topic will not be included in the scope
Department of Health	11	4.3.1j (DPT)	Include treatment of complications/co-morbidities e.g. nephropathy, hypertension	Thank you for your comment. The treatment of complications and co-morbidities is outside of the scope of the original guideline and other topics are of higher priority for the update. These topics will therefore remain excluded from the update scope

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Department of Health	13	4.3.2.f g (DPT)	Blood ketones are standard use nowadays. They measure beta hydroxybutyrate which is the main ketone in Diabetic Ketoacidosis, rather than acetone which is the main urinary ketone. This should be included and updated.	Thank you for your comment. Blood ketone monitoring for the prevention of diabetic ketoacidosis has been included in the scope
Department of Health	20	4.3.2cc (DPT)	Include guidance on the management of microalbuminuria, and hypertension in CYP with diabetes	Thank you for your comment. The treatment of complications and co-morbidities is outside of the scope of the original guideline and other topics are of higher priority for the update. These topics will therefore remain excluded from the update scope. The recognition of some complications has been included in the update scope
Department of Health	12	4.3.2d (DPT)	This should be included – insulin pump guidance is old	Thank you for your comment. The topic of insulin pumps is covered in "Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus", NICE Technology Appraisal 151 (2008) which includes the use of pumps for children under the age of 12 years. This guidance is considered up-to-date

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				and therefore this topic has not been prioritised for inclusion in this update
Department of Health	14	4.3.2u (DPT)	Include glucose monitoring in T2	Thank you for your comment. Monitoring for glycaemic control in type 2 diabetes in children and young people relies mainly on HbA_{1c} measurement, and so this will be the focus of the review Real-time continuous glucose monitoring is included within the continuous glucose monitoring for type 1 diabetes topic. However glucose monitoring for type 2 diabetes in children and young people was considered a lower priority clinically and is therefore not included in this update
Department of Health	15	4.3.2v (DPT)	It is essential to include contraceptive advice and conception advice, see above. Also, as T2 diabetes becomes commoner, guidance is required on drugs other than metformin. And sulfonylureas are needed in monogenic diabetes which should be included	The issue of education on the diabetes-specific risks of unplanned pregnancy and contraception will be covered in the Diabetes in pregnancy guideline update. The Diabetes in

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				children and young people guideline will cross-refer to this where appropriate The scoping group felt there was a lack of evidence on antidiabetic drugs for children and young people with type 2 diabetes for whom metformin is not sufficient, and that this was a very small group. As a result this has not been prioritised for inclusion in the update scope Other forms of diabetes in children and young people, including monogenic diabetes, are not included in this guideline and therefore drugs used in the management of these conditions are not included in the scope
Department of Health	16	4.3.2w (DPT)	You mean statins and these should be included as failure to manage hypercholesterolaemia in YP misses opportunities to prevent later cardiovascular disease	Thank you for bringing this typographical error to our attention. We have amended the scope accordingly

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				The treatment of complications and co-morbidities is outside of the scope of the original guideline and other topics are of higher priority for the update. This topic will therefore remain excluded from the update scope
Department of Health	17	4.3.2x (DPT)	Hypoglycaemic unawareness can kill at any age. Of course it should be included	We agree that this is an important topic. The original guideline on type 1 diabetes in children and young people makes a recommendation on the use of continuous glucose monitoring in these children and young people, and it was considered that this did not require updating
Department of Health	18	4.3.2y, aa (DPT),	Include T2 dietary/exercise advice, bariatric surgery – there is increasing obesity among CYP with diabetes	Thank you for your comment. Children and young people with type 2 diabetes are included in the existing Obesity guideline (CG43), which makes recommendations on, for example, the use of bariatric surgery in these groups. The Diabetes in children and young people

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				guideline may cross-refer to this guidance where necessary but the topic will not be included in the scope
Department of Health	19	4.3.2z (DPT)	Include reference to foot care. Foot problems start in childhood e.g. deformities, poor footcare	Thank you for your comment. As foot care problems are rare in children and young people with diabetes, and there are recommendations on this topic in the current guideline and in the Type 2 diabetes: prevention and management of foot problems guideline (CG10), this topic has not been prioritised for inclusion in the update scope
Department of Health	21	4.4 (DPT)	Outcomes important to children, their families and carers e.g missed school days.	Thank you for your suggestion. The guideline development group once assembled will decide on the primary 7 outcomes for each review question
Department of Health	22	4.5.1 (DPT)	Screening, detecting and managing psychological problems.	Thank you for your suggestion. However, we consider that the existing guidance is sufficient
Department of	23	4.5.1 (DPT)	Consider use of C peptide in differentiation between T1 and T2	Thank you for your comment. We consider

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Health				that the use of c-peptide was of lower priority than other topics and so is not included in this scope
Department of Health	24	4.5.1 (DPT)	Include hypertension	Thank you for your suggestions. However, we believe that the existing guidance does not require updating at this time
Department of Health	25	4.5.1 (DPT)	Include street drug use	Thank you for your suggestions. However, we believe that the existing guidance is sufficient
Department of Health	26	4.5.1 (DPT)	Consider idenfication of CYP at high risk of diabetic ketoacidosis or severe hypoglycaemia	Thank you for your suggestions. The existing guidance on the management of diabetic ketoacidosis and hypoglycaemia was considered to be sufficient. The update scope has now been expanded to include role of ketone monitoring as a strategy for preventing diabetic ketoacidosis
Department of Health	27	4.5.1 (DPT)	Include more guidance on infection and diabetes – a common cause of decompensation	Thank you for your suggestions. However, we believe that the existing guidance is sufficient
Department of Health	28	4.5.1 (DPT)	Immunisation in addition to usual	Thank you for your suggestions. However, we believe that the existing

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				guidance on influenza and pneumococcal infection in children and young people with type 1 diabetes does not need to be updated. There is existing Department of Health guidance on the issue of immunisation for children and young people with type 2 diabetes and the developers will seek to reflect this in the Diabetes in children and young people guideline. We will not review evidence in relation to immunisation schedules in diabetes and so it has not been included in the scope
Department of Health	29	4.5.2 (DPT)	Screening, detecting and managing psychological problems.	Thank you for your comment. However, we believe that the existing guidance on psychological problems is sufficient
Department of Health	30	General (CHB)	I cannot identify the clinical issue of initial diagnosis. There is concern that the diagnosis of diabetes (certainly type 1) can be delayed, resulting in diagnosis and intervention not occuring until the child is extremely sick. The Secretary of State recently commissioned an independent forum to consider children's and young people's health outcomes and, although this has yet to be published, delay in diagnosis of serious long-term conditions such as	Thank you for your comment. The original type 1 diabetes guideline gave specific advice on the diagnosis of type 1 diabetes. We do not consider that the existing

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			diabetes is likely to feature. I think that it is important that there is appropriate guidance to NHS professionals in primary care, in timely recognition of symptoms and signs of diabetes in children.	guidance requires updating at this time. However, the issue of antibody testing is included in the scope
Department of Health	1	General (DPT)	This guidance cannot be considered in isolation from the guidance for Type 1, Type 2 and pregnancy. There are common issues and these should be linked to ensure consistency of approach and inappropriate duplication	We agree. We are working closely with the teams developing these guidelines to ensure that there is consistency of approach and minimum duplication
Department of Health - National Clinical Director for Diabetes (Additional comments)	1		For the first time, all four major NICE clinical guidelines for diabetes care are being updated around the same time. Different guideline committees are responsible for each, sometimes even different organisations. This is an excellent opportunity to update diabetes care. It also presents a high risk for duplication and confusion. Diabetes care is a continuum. The girl with Type 1 diabetes becomes an adult. She may become pregnant, as may a woman with Type 2 diabetes. Most diabetes care is the same whatever the age or type of diabetes. It is essential that these four guidelines are consistent in the advice they provide so that confusion does not arise as the patient moves from one situation to another. It is also essential that duplication and confusion are avoided from the point of view of healthcare professionals, providers and commissioners. It also seems a great waste of time for four committees to duplicate effort over issues communal to all four guidelines. It is therefore absolutely essential that arrangements are made, so that each of	Thank you for your comments. We agree. NICE has set up a steering committee to oversee the production of these pieces of guidance. The group, which includes guideline development group chairs, staff from all three guidance-producing centres and staff from NICE, will identify and act on any gaps or overlaps across the different guidance topics in order to ensure that the final guidance produced is complementary and consistent.

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			the guideline committees is linked to the others to ensure consistency in guidance, and save resource. It is also strongly advisable to agree, before work starts, what areas are communal to all guidelines, and how such work is to be tackled. These areas will include: • Prompt accurate diagnosis; • Emotional and psychological support for patients, family and carers; • Diabetes education; • Care planning; • Initial management – lifestyle and medication; • Nutrition, including weight normalisation; • Exercise; • Patient self monitoring; • Routine clinical monitoring – annual and interim review: identification of risk factors for complications so as to prevent them; detection of complications; detection of common co-morbidities (e.g. depression, thyroid etc) risk stratification; • Risk factor management e.g. glucose control, blood pressure and cholesterol control; • Prevention and management of acute complications (e.g. high and low glucose) (this includes diabetes care in hospital); • Prevention and management of longer term complications; • Integrated multi-disciplinary care; • Audit and outcome measurement. The main drugs used are largely the same: • Glucose-lowering;	

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			• Insulins; • Oral, non-insulin injectable; • Blood pressure lowering; • Cholesterol lowering; • Renoprotective.	
Diabetes Management and Education Group (DMEG)	3	Page 10 glucose monitoring strategies	• Targets for children are 4-7mmol in day and 8-10 at bedtime	Thank you for your comment. We will be considering if these targets are appropriate
Diabetes Management and Education Group (DMEG)	4	Page 10/11 Dietetic advice	• Carbohydrate counting is paramount in maintaining BG control in children. Even if on fixed doses and mixes, patients and cares control BG better if they are carb aware and know which foods have carbs and how much in a portion. Carb counting and MDI go hand in hand, neither working without the other • Glycaemic index (GI) is very useful when controlling BG in patients using continuous subcutaneous insulin infusion (CSII) therapy. It is useful to explain it if patients are struggling to control their BG with particular meals such as Pizza but generally GI is not explained or used widely with this group. I think GI is a very useful tool but sometimes there is enough for patients to remember and this will only be explained to the most motivated and interested families	Thank you for your advice and we agree that there will be some crossover between the questions. The recommendations will be made after consideration of all the evidence from the differing questions
Diabetes Management and Education Group (DMEG)	2	Page 10- MDI vs mixed insulin	• Mixed insulin is useful for children who can't/wont inject themselves at lunchtime or the family/school can't organise someone to do it for a very young child • It is not as effective as MDI because you can't correct high blood glucoses (BGs), you have to eat snacks to keep BG up which could be high fat and sugar and salt, you have to eat breakfast even if you don't	Thank you for your comment. The update scope includes a topic reviewing mixed insulins and multiple daily injections

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			feel like it. It is very inflexible compared to MDI but can be useful in some cases for some time frames. We don't start anyone on mixes now; they all start on MDI from diagnosis.	
Diabetes Management and Education Group (DMEG)	1	Page 10-structured education and behavioural interventions	• Structured education can be done both in a clinical setting, school setting or home visit • Structured education only woks if the patients and carers attend. Attendance is a big issue in our area as parents are low income and can't get the time off work to attend day time sessions. Evening sessions are a problem as families with younger siblings have no child care. • In my experience behavioural interventions are very effective. Using motivational interviewing techniques makes the patients and carers feel listened to and you can work toward solving joint problems together.	Thank you for your comment. We will review the use of educational programmes in different settings and attendance may be an important outcome
Diabetes Management and Education Group (DMEG)	5	Page 11-structured education and behavioural interventions	• Structured education can be done both in a clinical setting, school setting or home visit • Structured education only works if the patients and carers attend. Attendance is a big issue in our area as parents are low income and can't get the time off work to attend day time sessions. Evening sessions are a problem as families with younger siblings have no child care. • In my experience behavioural interventions are very effective. Using motivational interviewing techniques makes the patients and carers feel listened to and you can work toward solving joint problems together.	Thank you for your comment. We will review the use of educational programmes in different settings and attendance may be an important outcome
Diabetes UK	1	3.1.2.(i)	NICE Public Health Guidance *Preventing Type 2 Diabetes: Risk identification and interventions for individuals at high risk* includes people of Chinese family origin as a group in which type 2 diabetes is more prevalent (p.44): "In the UK, type 2 diabetes is more prevalent among people of South Asian, Chinese, African–Caribbean and black African descent than among the white population. People in these groups tend to develop it at a younger age (DH	Thank you for pointing this out. We have updated the scope accordingly

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			2006). They also tend to progress from impaired glucose tolerance to diabetes much more quickly (more than twice the rate of white populations) (Webb et al. 2011)."	
Diabetes UK	2	4.3.2.(s)	On the proposed exclusion of transition from paediatric to adult care, the recommendations should be updated. For example, assessment of cognitive maturity and diabetes knowledge prior to transfer to adult services are well recognised as factors that inform readiness for transfer but do not form part of the current recommendations.	Thank you for your comment. The existing recommendations on planning transition from paediatric to adult services are felt to be sufficient and the topic has therefore not been prioritised for inclusion in the update. The guideline developers note, however, that NICE will be commissioning a clinical guideline on the topic of transition from child to adult services which might be of interest to the stakeholder
Faculty of Dental Surgery	1	general	The Dental team including Oral medicine specialists play a major role in screening for oral care in adult and paediatric patients with diabetes. Through oral screening, adult and paediatric patients with undiagnosed diabetes presenting with oral signs and symptoms suggestive of diabetes can be referred to the physician for further evaluation.	Thank you for your comment. The guideline developers recognise the importance of good dental hygiene, but the potential role of dental services in recognising diabetes and providing clinical management will not be covered in the scope of this guideline
Faculty of	2	general	Through educating patients on improving oral health and preventing	Thank you for your

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Dental Surgery			development of oral complications associated with diabetes, they can improve the metabolic control of diabetes.	comment. The guideline developers recognise the importance of good dental hygiene, but the potential role of dental services in recognising diabetes and providing clinical management will not be covered in the scope of this guideline
Faculty of Dental Surgery	3	general	Through working with both the physician and the nutritionist, they play an important role in ensuring that the patient's glycaemic control is optimised in order to prevent systemic complications of diabetes.	Thank you for your comment. The guideline developers recognise the importance of good dental hygiene, but the potential role of dental services in recognising diabetes and providing clinical management will not be covered in the scope of this guideline
Faculty of Dental Surgery	4	general	They can discuss indications and contraindications of medications for treatment of oral complications in patients with systemic complications associated with diabetes.	Thank you for your comment. The guideline developers recognise the importance of good dental hygiene, but the potential role of dental services in recognising diabetes and providing clinical management will not be covered in the scope of this guideline

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Faculty of Dental Surgery	5	general	They can also reduce co-morbidity factors resulting from diabetes by supporting patient's in tobacco-use cessation programs.	Thank you for your comment. The guideline developers recognise the importance of good dental hygiene, but the potential role of dental services in recognising diabetes and providing clinical management will not be covered in the scope of this guideline
Hindu Council UK	1	4.1.1	Our comments are as follows: From a Hindu Council UK perspective we feel that religion could also be a protected characteristic that may be helpful to collect the population statistics on. However, we do understand that collecting this type of data may be difficult but you could use schools data to help.	Thank you for your suggestion. We will extract this data if it is available
Hindu Council UK	2	4.5.2	The use of temples or indeed the Hindu Council UK in part of your Educational programmes (structured or otherwise) would be beneficial to the Hindu community that mainly derive from South Asia.	Thank you for this comment. As part of the NICE clinical guideline development process, the guideline development group will be required to consider such issues in the context of each and every recommendation proposed for inclusion in the guideline update. This will take the form of a systematic consideration of the needs and preferences of groups that are

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				protected by law to promote equalities and prevent unlawful discrimination
Juvenile Diabetes Research Foundation	1	**3.1.1 – a**	JDRF feels that there is a variation in the description of type 1 diabetes. Rather than *It predominantly affects children and young people,* JDRF believes this should become *It is diagnosed in young people.*	Thank you for pointing this out. We have updated the scope accordingly
Juvenile Diabetes Research Foundation	2	**4.3.2 - d**	JDRF believes that methods of delivering insulin should be included in the final scope as there have been significant developments in insulin pump therapy, notably the use of patch pumps.	Thank you for your comment. The topic of insulin pumps is covered in "Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus", NICE Technology Appraisal 151 (2008) which is considered up-to-date and therefore has not been prioritised for inclusion in this update
Juvenile Diabetes Research Foundation	3	**4.4 – g**	JDRF also believes that parent/carer satisfaction should also be included in the final scope, as type 1 in young children affects more than just the child themselves, typically involving the whole family.	Thank you for your suggestion. The guideline development group once assembled will decide on the primary 7 outcomes for each review question
LifeScan and Animas	1	4.3.1 Clinical management Areas	We would like to put forward the following paper for inclusion in the guideline review Ziegler R et al. Frequency of SMBG correlates with HbA1c and acute complications in children and adolescents with type 1 diabetes. Pediatric	Thank you for your suggestion. We will include this study if it meets our inclusion criteria

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		from the original guideline that will be updated d) Glucose monitoring strategies in children and young people	Diabetes 2011;12: 11–17.	
Lilly UK	1	4.4	Hypoglycemia and frequency and severity of hypoglycemic episodes have been included as main outcomes in the scope of Type 1 and Type 2 diabetes in adults respectively. Lilly recommends that hypoglycaemia is considered as a main outcome in the scope of diabetes in children and young people as well.	Thank you for your suggestion. The guideline development group once assembled will decide on the primary 7 outcomes for each review question
Lilly UK	2	4.4	Lilly would like to suggest adding changes in lipid levels as a main outcome in children and young people with Type 2 diabetes. (References: Rosenbloom AL,et al. ISPAD Clinical Practice Consensus Guidelines 2009 Compendium Type 2 diabetes in children and adolescents. Pediatric Diabetes 2009: 10(Suppl. 12): 17–32. American Diabetes Association, Management of Dyslipidemia in Children and Adolescents With Diabetes, Consensus Statement, Diabetes Care, Volume 26, Number 7, July 2003.)	Thank you for your suggestion. The guideline development group once assembled will decide on the primary 7 outcomes for each review question
NHS Direct	1	General	NHS Direct welcome the update of this guideline and have no comments on the scope	Thank you for your comment

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Novo Nordisk Ltd	2	4.3	Insulin degludec may also have a licence for use in paediatrics in the future. There is a fully recruited trial on-going in children with type 1 diabetes down to 1 years of age using insulin degludec in a basal-bolus setting. This trial will expectedly give the licence for use in children down to 1 years of age by end of Q3 2014. Reference: A Trial Investigating the Efficacy and Safety of Insulin Degludec in Children and Adolescents With Type 1 Diabetes Mellitus (BEGIN™) http://clinicaltrials.gov/ct2/show/NCT01513473?term=insulin+degludec&rank=4 (Last accessed 20th Aug 2012).	Thank you for your comment. A review of the evidence around specific types of insulin and their time-action profiles has not been prioritised for this update. However, the guideline development group will consider all types of insulin used in trials identified in the review of multiple daily injection regimens
Novo Nordisk Ltd	1	4.3.2 (c)	We note that this section outlines areas from the original clinical guidelines that will not be updated. We would like to point out that since the original guidelines were published, insulin detemir has obtained a licence for use in paediatrics. For this reason we would recommend that its use is given further consideration within the clinical guideline update.	Thank you for your comment. A review of the evidence around specific types of insulin and their time-action profiles has not been prioritised for this update. However, the guideline development group will consider all types of insulin used in trials identified in the review of multiple daily injection regimens
Novo Nordisk Ltd	3	4.4 (b)	NovoNordisk would like to recommend that hypoglycaemia is explicitly stated as an outcome. Hypoglycaemia is a common side effect of treatment with insulin which can have a serious impact on children and young people.	Thank you for your suggestion. The guideline development group once assembled will decide on the primary 7 outcomes for each review question

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Roche Diagnostics Limited	1	4.3.1, point D	The General Medical Council advises that children and young people should be involved as much as possible in decisions about their care, even when they are not able to make decisions on their own. '*0 – 18 years: guidance for all doctors'* states, 'Children and young people are individuals with rights that should be respected. This means listening to them and taking into account what they have to say about things that affect them.' Children should have freedom to access blood glucose test strips and test cassettes as well as systems which suit their requirements. In several areas within England PCTs have made a decision to move to one type of meter for their whole diabetes population regardless of age, type of diabetes or treatment regimes. For children and young adults it is imperative that they are engaged in their therapy and treatment and with that the type of system that will help and best support them manage their diabetes on a daily basis.	Thank you for your comment. The guideline development group will consider evidence for children and young people and if appropriate will formulate recommendations specific to this age group on the topic of glucose monitoring
Roche Diagnostics Limited	2	4.3.1, point E	The use of bolus advisors in pump therapy is well established and recent advances in technology have made it available to patients on MDI. Bolus advisors support patients on MDI, using a long acting basal insulin analogue. The system is individually programmed to help patients achieve optimal diabetes control. Once programmed you can just test your blood glucose levels with the system, enter the carbs. you're about to eat and receive bolus advise. An online user survey showed that the majority of respondents felt that using the bolus advisor was easier than manual bolus calculation, improved confidence in the accuracy of the mealtime bolus insulin dose and reduced their fear of hypos. Patients found the system easy and motivating to use with 72% respondents reporting overall wellbeing/life with diabetes had improved or significantly improved since using their bolus advisor, with greater confidence and control in their diabetes management. *Barnard K, Parkin C et al. Use of an automated bolus calculator reduces fear of hypoglycaemia and improves confidence in dosage accuracy in T1DM patients treated with multiple daily insulin injections., J Diabetes Sci Technol 2012;6:145–149*	Thank you for your comment. Although not included specifically in the scope, when considering their recommendations regarding insulin therapy the guideline development group may wish to consider the value of bolus advisors

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			The BolusCal Study is the first randomized, controlled study investigating the effect of a new ABC in poorly controlled patients with Type 1 diabetes. Furthermore it is also the first report on successful communication of the principles of F11T during a structured group teaching only 3 hours in length. The main findings of this study were a clinically relevant and statistically significant change in HbA1c in the two intervention arms and statistically significant improvement in treatment satisfaction, most pronounced in the CarbCount ABC arm. *Use of an Automated Bolus Calculator in MDI-Treated Type 1 Diabetes – Clinical Care/Education/Nutrition/Psychosocial Research – Schmidt et al. Diabetes Care 2012. DOI:10.2337/dc11-2044*	
Roche Products Ltd	1	3.1.2	Could the reference for the prevalence rate figure for children with Type 2 diabetes (quoted as 300) be provided? A Diabetes UK (2010) report quoted the following: 'Prevalence figures for children are limited but as many as 1,400 children may have Type 2 diabetes in the UK'. The reference document is attached to our response (see pg.7).	Thank you for pointing this out. This sentence has been revised for clarity. The number quoted is for confirmed type 2 diagnoses in children and young people. It is taken from Barrett T, Gray Z, Ilsley E, Cotter C, Ford A, Turner K, Heywood J, Barnett A, Dunger D, Hamilton-Shield J, Wales J.White UK children are older, more obese and more insulin resistant than non-White UK children at diagnosis of type 2 diabetes: baseline results of the UK national type 2 diabetes cohort. Endocrine Abstracts 2011; 27: OC4.2.

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				(the citation has not been included in the scope in accordance with the NICE scope template)
Roche Products Ltd	2	4.3.1a	This bullet indicates that the diagnosis of 'Type 1 diabetes' will be included in the update. This guideline is being extended to cover type 2 diabetes as well as type 1. Therefore we would recommend that this bullet should read: 'Diagnosis of type 1 and type 2 diabetes'.	Thank you for your comment. The existing recommendations of differentiation between type 1 and type 2 are sufficient and these will remain. However, the use of antibody testing in the differentiation is included in the scope and we have rephrased as requested
Roche Products Ltd	3	4.3.2c	We recommend that there should be a cost effectiveness analysis performed of 'Insulin preparations including new short-and long-acting insulins'. These are currently listed as items that will not be updated from the original guideline. New formulations may have a different drug acquisition cost than that of existing formulations. This in combination with potential differences in efficacy, side effects, or resource use all have the potential to affect the cost effectiveness estimates.	Thank you for your comment. A review of the evidence around specific types of insulin and their time-action profiles has not been prioritised for this update. However, the guideline development group will consider all types of insulin used in trials identified in the review of multiple daily injection regimens
Roche Products Ltd	4	4.3.2v	We recommend that this current bullet is split into two bullets. 1) 'Contraceptive, pre-pregnancy and contraception advice' and 2) 'Treatment for children and young people with type 2 diabetes in whom glycaemic control is not maintained with metformin'	Thank you for bringing this to our attention. We have amended the scope accordingly

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Roche Products Ltd	5	4.3.2w	There is a typographical error in this bullet ('statins' should replace 'stains')	Thank you for bringing this to our attention. We have amended the scope accordingly
Roche Products Ltd	7	4.4	We would recommend that a 'measure of adherence to treatment' be added to the main outcomes. Diabetes is a long term condition and adherence to treatment with multiple drugs, especially injections in children, is paramount to effective diabetes control and management.	Thank you for your suggestion. The guideline development group once assembled will decide on the primary 7 outcomes for each review question
Roche Products Ltd	6	4.4d	We recommend the outcome currently defined as 'Complications of diabetes' is re-worded to 'The development of microvascular and macrovascular complications' for consistency with the language used in the adult Type 2 Diabetes guideline update. This wording also provides clarity around the type of outcomes being sought (clinical complications) in preference to other complications that may arise from the disease (such as lifestyle restrictions).	Thank you for your suggestion. We have included broad categories of outcomes in the scope but expect that the specific outcomes used in each evidence review will vary. The guideline development group will decide on a question by question basis which 7 outcomes would best influence the clinical and patient decision-making process
Roche Products Ltd	8	4.5.1/4.5.2 subsection 'recognition of complications and	We would recommend that screening and monitoring for retinopathy / dyslipidaemia / nephropathy should occur for all patients and not be dependent on a specific prevalence rate. These are significant complications that should be screened for and monitored in all patients.	Thank you for your comments. We have re-worded these questions for clarity. Consideration of the optimal monitoring strategy may be influenced by evidence regarding prevalence rates at

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		co-morbidities'		presentation and during follow up
Roche Products Ltd	9	5.1.2	It would be helpful if the title of the NICE Technology Appraisal Guidance for TA248 and TA203 (both referred to here) are mentioned in this section.	Thank you for bringing this to our attention. We have updated the scope and added these titles
Roche Products Ltd	10	5.1.2	We recommend inclusion of the 'Medicines Adherence' (CG76) as guidance which is related to this clinical guideline for the reasons outlined in our comment (7) above.	Thank you for your suggestion. We have added this guideline into section 5.1.2 as requested
Roche Products Ltd	11	5.2	It would be helpful if the title of the guidance 'Type 1 diabetes (update)' and 'Type 2 diabetes (update)' is referred to as 'Type 1 diabetes in adults' and 'Type 2 diabetes in adults' to make it clear these guidelines cover different patient populations.	Thank you for your suggestion. We have cited these guidelines as per NICE advice. We have passed on your comments to NICE editors
Roche Products Ltd	12	General	 Diabetes in the UK 2010	Thank you for submitting this document. We have drawn on it for review topics
Royal College of Nursing	4	3.2 'F'	Suggest expansion to lifestyle to incorporate child's time spent at school, therefore all structured educational packages and training needs to incorporate schools, colleges and early years establishments. Says 'cyp with diabetes receive' – more accurate to say 'should' or 'must'? receive.	Thank you for your comment. We agree and will be including studies carried out in education settings Thank you for pointing this out. We have updated the scope accordingly
Royal	3	3.2 'G'	Age of children monitored for retinopathy 12 years and above ? based old	Thank you for your

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College of Nursing		3.2 h	evidence, when children are now being diagnosed much younger. See IDF/ISPAD recommendations over 11 years and annually 2yrs after diagnosis. Mention HbA1C – glycaemic control? Annual podiatry checks from 12 years.	comment. We will be reviewing data on retinopathy before the age of 12 years This section has been expanded to include glycaemic control and HbA_{1C} Thank you for pointing this out. We have updated the scope accordingly
Royal College of Nursing	6	4.1 'C'	Evidence of reporting by socioeconomic group is not requested on the NPDA data set - ? further consideration required - NPDA will be able to link to deprivation through postcode:	Thank you for your suggestion, which we will follow up if we attempt to use primary data
Royal College of Nursing	5	4.1.2 a)	There is a need to clarify in this guidance who should care for young women under the age of 18 years old who become pregnant as paediatric teams do not have the expertise and adult teams who limit themselves to only looking after those greater than 18 years old are very reluctant to care for them due to safeguarding issues etc. The RCN should ensure that this very vulnerable group do not fall between two stools and are not catered for in this guidance and equally are not cared for in the pregnancy guidance which is being updated. There should be reference in this guideline on how Paediatric teams should proceed.	Young women with diabetes (those under 18 years) are included in the scope of the diabetes in pregnancy guideline which is also being updated
Royal College of Nursing	7	4.3.1 'A-J' General	Involvement in working group or focus groups needs to include members of the RCN CYPDC	The guideline development group includes two paediatric nurses with expertise in diabetes in children and young people

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Royal College of Nursing	9	4.3.1 d)	Welcome the review of blood glucose targets in view of the continuing poor control	Thank you for your comment
Royal College of Nursing	10	4.3.1 e	Evidence for grams or portions depending on MDI or Pumps. Importance of understanding Glycaemic index on BG monitoring. Different bolus types depending on glycaemic index of food. Lipids and screening.	Thank you for your suggestions. The guideline development group will consider evidence for varying carbohydrate count depending on insulin regimen if available. The interconnectedness of glucose monitoring, glycaemic index and insulin dose has been noted and the guideline developers will not consider these topics in isolation. The topic of monitoring for dyslipidaemia in children and young people with type 2 diabetes is included
Royal College of Nursing	11	4.3.1 f)	There is a need for clearer guidance on recognition of complications in type 1 including dislipidemia and autonomic symptoms. Suggested screening frequency should be clarified. e.g in case of dislipidemia at what age to start screening, frequency of screening and wether random or fasting specimins.	Thank you for your comment. The topic of monitoring for dyslipidaemia in children and young people with type 2 diabetes has been prioritised for inclusion; however, the existing recommendations on

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				monitoring for dyslipidaemia in children and young people with type 1 diabetes were felt to be sufficient as dyslipidaemia is usually related to glucose control in these children and young people With regard to autonomic symptoms, this topic was not thought to be a high priority relative to other topics included in the scope
Royal College of Nursing	12	4.3.1 i)	Clarification of HbA1c target for type 2 diabetes is extremely important	Thank you for your comment
Royal College of Nursing	8	4.3.2 'U-cc General	Area not covered by original or update when will these areas be reviewed.	NICE clinical guidelines are currently reviewed every three years. Topics not currently prioritised for inclusion in the update may be considered again at the next review
Royal College of Nursing	13	4.3.2 a	Home management from diagnosis is at odds with intensive diabetes management – we would strongly recommend this is reviewed.	Thank you for your comment. Home management from diagnosis is not felt to be a high priority topic in comparison to other areas

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				and has therefore not been included in the update scope
Royal College of Nursing	15	4.3.2 e)	The use of metformin in addition to insulin should be covered in this guideline not excluded as it is becoming clinical practice with no clear guidance on when it should be used, what age group and complications to look out for. It was suggested the the last guideline that this would be looked at next time.	Thank you for your comment. The use of metformin in addition to insulin for children and young people with type 1 diabetes was addressed in the existing guideline and it was felt that it did not require updating at this time
Royal College of Nursing	18	4.3.2 l)	Care during surgery should be covered in this guidance as the greater use of insulin pump therapy causes different practice in different areas and patient safety is paramount as there could be risks associated with the use of this equipment in the operating theatre.	Thank you for your comment. The existing guideline includes recommendations on the development of local protocols for the care of children and young people with diabetes during surgery. The development of more detailed guidance was felt to be of lower priority and has not been included in the update scope
Royal College of Nursing	21	4.3.2 v)	Contraceptive and pre pregnancy advice should be provided by Paediatric teams from a young age to help with reducing unplanned pregnancies. This extremely important issue should be covered in this guidance not excluded	Thank you for your comment. The issue of education on the diabetes-specific risks of unplanned pregnancy and

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				contraception will be covered in the Diabetes in pregnancy guideline update. The Diabetes in children and young people guideline will cross-refer to this where appropriate
Royal College of Nursing	23	4.3.2 z)	The update should clarify what constitutes foot care and who should screen.	Thank you for your comment. As foot care problems are rare in children and young people with diabetes, and there are recommendations on this topic in the current guideline and in the Type 2 diabetes: prevention and management of foot problems guideline (CG10), this topic has not been prioritised for inclusion in the update scope
Royal College of Nursing	17	4.3.2.9	BSPED 2009	This is not a comment and so no response can be provided. The developers note, however, a separate comment on section 4.3.2.f is specific about the context for mentioning BSPED 2009 and the developers have been able to provide a response in

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				that case
Royal College of Nursing	16	4.3.2.f	BSPED 2009 guideline gives blood ketone monitoring a central role	Thank you for your comment. Blood ketone monitoring for the prevention of diabetic ketoacidosis has been included in the scope
Royal College of Nursing	19	4.3.2.m	Systematic review by Winkley et al (2006) reports which psycho-educational interventions are effective in CYP. IDF/ISPAD (2009) recommends screening for depression. Additional training for team in counselling techniques etc. Regular consistent uninterrupted care by diabetes team. Monitor school performance if diagnosed under 5yrs and significant history of hypos. Transition should be carefully planned and discussed and not just a transfer of care. Screening tools for eating disorders etc	Thank you for your comments. The current guideline includes recommendations on screening for and management of depression, eating disorders and 'brittle diabetes' in children and young people with diabetes and also on planning the transition from child to adult services. These are felt to be sufficient and therefore these topics have not been prioritised for inclusion in the update scope. The guideline developers note, however, that NICE will be commissioning a clinical guideline on the topic of transition from child to adult services which might be of interest to the

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				stakeholder
Royal College of Nursing	22	4.3.2.x	Hypo unawareness See IDF/ ISPAD (2011) guideline. Can be reversed if scrupulously avoided for 2 weeks but adjusting BG targets for 2 weeks – guidance on this very important. Links with role of Pumps and CGM also. Change in recommendations for hypo treatment has also changed since IDF/ ISPAD (2009, 2011).	The current guideline includes recommendations on the use of continuous glucose monitoring in hypoglycaemia unawareness in children and young people with type 1 diabetes. There are also recommendations on concerns surrounding alcohol and the associated risks of hypoglycaemia. These recommendations are felt to be sufficient and therefore the topic of hypoglycaemia unawareness has not been prioritised for further review in the update
Royal College of Nursing	14	4.3.2d	Insulin pump therapy is effective from diagnosis in NICE CS!! Guidance bit in NICE CYP D is rec over 12yrs. We would recommend review	Thank you for your comment. The topic of insulin pumps is covered in "Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus", NICE Technology Appraisal 151 (2008) which includes the use of pumps for children under the age of 12 years. This guidance is considered up-to-date

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				and therefore this topic has not been prioritised for inclusion in this update
Royal College of Nursing	20	4.3.2q and s	Transition should be carefully planned and discussed and not just a transfer of care. Continued support through adolescence = better outcomes	Thank you for your comment. The existing recommendations on planning transition from child to adult services are felt to be sufficient and the topic has therefore not been prioritised for inclusion in the update. The guideline developers note, however, that NICE will be commissioning a clinical guideline on the topic of transition from child to adult services which might be of interest to the stakeholder
Royal College of Nursing	24	4.5 review questions	All the review questions are valid but I would like to see the addition of some of the points above.	Thank you for your comment. The scope includes draft review questions to cover the included topics, and the guideline development group once assembled will finalise the review questions
Royal College of Nursing	1	General	Welcome that the guidance has been extended to include Type 2 diabetes in children & young people	Thank you for your comment

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Royal College of Nursing	25	Glucose monitoring strategies	Philip, Dannet et al 2012 Use of CGM in children and adolescents Pediatric diabetes 13, 215-228 BG targets see IDF ISPAD 2009 and IDF/ ISPAD 2011 Recommend as close to normal as possible whilst avoiding severe hypos. Germany aim for 3.5 – is the slogan "4s the floor" too high?	Thank you for this reference. We are considering the effectiveness of various strategies of glucose monitoring including continuous glucose monitoring, and the topic of glucose target ranges for children and young people will also be addressed. We will include this study if it meets our inclusion criteria
Royal College of Nursing	2	I 3.2.j	Transition should include the transfer into a young person adult clinic in line with recommendations from Best Practice Tariff	Thank you for your comment. The guideline developers note that NICE will be commissioning a clinical guideline on the topic of transition from child to adult services which might be of interest to the stakeholder
Royal College of Nursing	26	Type 2 diabetes	See IDF/ ISPAD 2011 HbA1c <7%	Thank you for your comment. We will be reviewing HbA_{1c} target ranges for children and young people with type 2 diabetes in this update
Royal College of Ophthalm	1	4.1.1	We welcome the inclusion of Type 2 DM	Thank you for your comment

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ologists				
Royal College of Ophthalmologists	2	4.3.1	We welcome the inclusion of complications relating to Type 2 DM	Thank you for your comment
Royal College of Ophthalmologists	3	4.3.2	Although transition is not within the scope, this is unlikely to affect the screening of retinopathy as children currently attend the same service as adults therefore continuity is already accounted for.	Thank you for your comment. The guideline developers note that NICE will be commissioning a clinical guideline on the topic of transition from child to adult services which might be of interest to the stakeholder
Royal College of Ophthalmologists	4	4.4	Within outcomes, a specific field relating to CVI (certificate of visual impairment – blind registration) might be a useful marker	Thank you for your suggestion. The guideline development group once assembled will decide on the primary 7 outcomes for each review question
Royal College of Ophthalmologists	5	4.5.1	We welcome the targeted questions relating to age at onset of screening and prevalence of retinopathy.	Thank you for your comment. The scope includes draft review questions to cover the included topics, and the guideline development group once assembled will finalise the review questions
Royal	6	4.5.2	We welcome the targeted questions relating to age at onset of screening and	Thank you for your

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College of Ophthalmologists			prevalence of retinopathy	comment. The scope includes draft review questions to cover the included topics, and the guideline development group once assembled will finalise the review questions
Royal College of Paediatrics and Child Health	9		Appendix 1- Rationale for screening for coeliac disease regularly in type 1 diabetes The 2009 NICE guidelines on the management of coeliac disease recommend screening in 'high risk' populations, which includes people with type 1 diabetes. However, deep within the text is buried the recommendation that this should only be done at diagnosis as: 'The GDG noted the lack of evidence regarding the possibility of repeat serological testing for coeliac disease, specifically in people with coexisting conditions for whom serological testing has been recommended (including type 1 diabetes and autoimmune thyroid disease). It was felt, with the lack of evidence and without expert consensus, that a recommendation on repeat testing could not be made'. This has led to an amendment of the 2004 NICE guidelines on the management of type 1 diabetes in children and young people stating that screening for coeliac disease should only be performed at diagnosis, whereas the original document recommended repeat screening every 3 years. It is interesting to note that in the list of stakeholders involved in the consultation process of the Coeliac Disease Guideline, patient groups such as Diabetes UK were involved but the British Society of Paediatric Endocrinology and Diabetes was not. Anecdotally, we can all think of patients in our clinics who had negative coeliac screens at diagnosis but who have subsequently gone on to develop positive	Thank you for your comment. The developers have been informed by NICE that the Coeliac disease guideline is being updated and this specific diabetes-related issue will be considered again in that guideline. The current recommendations on screening for coeliac disease in children and young people with diabetes will remain in place until then and the topic will remain excluded from the Diabetes in children and young people update scope

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			antibodies on repeat screening and who have had confirmed coeliac disease on biopsy. However, this does not constitute evidence (the complaint of the Coeliac Disease guideline development group) and so a brief literature search was undertaken to see if any studies could indeed be found. PubMed and Ovid were searched using the terms 'coeliac/celiac disease', 'type 1 diabetes' and 'child'. The abstracts were then scanned, (or full text where easily available) to assess their relevance to the question 'is there evidence for coeliac disease presenting later in children and young people with type 1 diabetes who have had negative coeliac screens at diagnosis?' Going through the first 40 references, 12 papers were found that were potentially relevant. Also included is a draft copy of a paper from Birmingham Children's Hospital which has now been published in Pediatrics (currently only on-line), also looking at this issue. The relevant references have been attached at the end (in no particular order), including abstracts where available. Deja et al found that of 450 patients newly diagnosed with diabetes during the period 2001-2006, 27 were found to have positive coeliac screening. Children were screened at diagnosis of diabetes with tissue transglutaminase (tTG) antibodies and annually thereafter. Only one was positive at diagnosis, the rest going on to develop positive tTG antibodies 2-4 years after diagnosis. Poulain's group in France analysed the data on 950 children with diabetes from 1994-2001. Children had coeliac screens were performed between 1-7 times in each patient and 15 were found to have histologically confirmed coeliac disease. Of those 15, 2 had positive coeliac screens at diagnosis, 1 developed coeliac disease before developing diabetes but the remainder did not develop positive antibodies until an average of 4 years after diagnosis (range 4 months-13 years after diagnosis). The group from Birmingham Children's Hospital (Narula et al) present data on 22 children with coeliac disease and diabetes, the majority again who were diagnosed some time after being found to have diabetes. Barera et al prospectively evaluated 273 diabetic children for coeliac disease. 3.3% were found to have coeliac disease at diagnosis, with a further 2.9% being diagnosed thereafter, up to 4 years after diabetes onset.	

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			Therefore, there does appear to be a reasonable body of evidence to support screening for coeliac disease at the time of diagnosis of type1 diabetes but also at regular intervals thereafter as it can take many years to develop. References. 1. Kordonouri O. Dieterich W. Schuppan D. Webert G. Muller C. Sarioglu N. Becker M. Danne T. Autoantibodies to tissue transglutaminase are sensitive serological parameters for detecting silent coeliac disease in patients with Type 1 diabetes mellitus. Diabetic Medicine. 17(6):441-4, 2000 Jun. Abstract AIMS: To investigate the clinical significance of the determination of IgA antibodies to tissue transglutaminase (tTG) for the detection of silent coeliac disease in patients with Type 1 diabetes mellitus. METHODS: A total of 520 patients with diabetes (median age 14.2 years, range 1-27) were tested for IgA antibodies to tTG (IgA anti-tTG, ELISA), endomysium (EmA, indirect immunofluoresence) and gliadin (IgA-AGA, enzyme immunometric assay) after ruling out IgA deficiency. RESULTS: The prevalence of IgA anti-tTG among patients with diabetes was 4.4% (23 of 520), and that of EmA and IgA-AGA 3.5% (18 of 520, respectively). The coefficient of agreement between IgA anti-tTG and EmA was high (Cohen's kappa = 0.87, P < 0.001). Thirteen of the 23 IgA anti-tTG-positive patients underwent duodenal biopsy. Coeliac disease was confirmed in nine of 13 patients. One of them was negative for EmA and AGA, but positive for IgA anti-tTG. Retrospective annual determinations up to 8 years in six IgA anti-tTG-positive patients showed both permanent and transient elevations of the serological markers. CONCLUSIONS: These data show that a positive IgA antibody test to tTG is a more sensitive parameter than EmA for silent coeliac disease in patients with diabetes. Confirmatory small bowel biopsy, however, remains necessary for diagnosis as some patients with positive antibodies may be without histological changes.	

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			2. Deja G. Myrda A. Jarosz-Chobot P. Siekiera U. The assessment of autoimmunological status and prevalence of different forms of celiac disease among children with type 1 diabetes mellitus and celiac disease. Mediators of Inflammation. 2008:285989, 2008. Abstract This study aims to assess the autoimmunological status and forms of celiac disease (CD) among children with type 1 diabetes mellitus (T1DM). The study group comprises 27 patients at the mean age of 12.30 years (+/-SD 3.12). The measurement of the level of diabetes-specific antibodies and organ-specific antibodies was gained at the T1DM-onset and repeated annually. The following risk factors influencing time of CD diagnosis were analyzed: age, sex, T1DM duration, autoantibodies, and HLA-haplotype. The prevalence of antibodies was GADA-74%, IAA-63%, IA2A-67%, ATA-11%, and ATG-4%. The intestinal biopsy revealed in 19% no changes and in 77% stage 3 (Marsh scale). In most cases, no clinical manifestation of CD was observed. The diagnosis of Hashimoto's disease was made twice. The negative correlation between the age at T1DM-onset and the interval between onset of T1DM and CD ($r = -0.35$, $p < .05$) was noted. The high-comorbidity ratio of CD and thyroiditis with T1DM demands regular screening tests especially in the first years after T1DM-onset. 3. Karaguzel G. Simsek S. Deger O. Okten A. Screening of diabetes, thyroid, and celiac diseases-related autoantibodies in a sample of Turkish children with type 1 diabetes and their siblings. Diabetes Research & Clinical Practice. 80(2):238-43, 2008 May. Abstract OBJECTIVE: The purpose of this study was to investigate the presence of diabetes, thyroid, and celiac diseases (CD)-related autoantibodies in children with type 1 diabetes (DM1) and their siblings. MATERIALS AND METHODS: The study population included 57 children with DM1, aged 11.7+/-4.5 years and their 89 healthy siblings, aged 11.0+/-5.4 years. Autoantibodies to glutamic	

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			acid decarboxylase (GAD65), islet cell (ICAs), insulin (IAAs), antiendomisial antibody (EMA), thyroid peroxidase, thyroglobulin, and thyrotropin receptor antibodies were studied both in diabetic patients and their siblings. RESULTS: The frequencies of GAD65, ICAs and IAAs positivity were found to be 63.2, 56.1 and 84.2% in patients with DM1 and 53.9, 24.4 and 3.4% in their siblings, respectively. The frequencies of autoimmune thyroid diseases (ATD) as determined by positive thyroid-related autoantibodies were 38.6 and 21.4% (p=0.024) among patients with DM1 and siblings, respectively. Subclinical hypothyroidism or hyperthyroidism was detected in 5.3% of patients with DM1 but in none of their siblings. EMA was positive in 3.5% of diabetic patients and 1.1% of their siblings. CONCLUSIONS: Our findings supported the view that children with DM1 should be screened annually for ATD. Relatively lower frequency of CD in the present study indicated that screening for CD-related autoantibodies might be postponed to older ages in asymptomatic patients. The present findings also suggested that the screening for diabetes-(especially GAD65) and thyroid diseases-related autoantibodies in siblings may ensure some useful information about the clinical course. 4. Mankai A. Ben Hamouda H. Amri F. Ghedira-Besbes L. Harbi A. Tahar Sfar M. Sahloul Essoussi A. Jeddi M. Ghedira I. Screening by anti-endomysium antibodies for celiac disease in Tunisian children with type 1 diabetes mellitus. Gastroenterologie Clinique et Biologique. 31(5):462-6, 2007 May. AIM: Celiac disease (CD) and type 1 diabetes mellitus (DM1) can frequently coexist, presumably due to a common genetic predisposition. The present study was designed to evaluate the frequency of CD among Tunisian children with DM1.PATIENTS AND METHODS: A total of 205 diabetic children (92 girls, 113 boys, age range 6 months-15 years, median 11 years) were screened for CD by determination of IgA anti-endomysium antibodies (EMA).RESULTS: EMA were positive in 17 out of 205 (8.3%) children with DM1. The median age of DM1 at onset was significantly lower in patients with EMA than those without EMA (P<10(-7)). In 13 of 17 EMA-positive patients, duodenal biopsy could be	

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			performed and a destructive type of CD was confirmed in 11 of them: 8 patients showed total villous atrophy, 3 patients showed a partial villous atrophy. The other two patients showed a normal histological picture with normal number of intraepithelial lymphocytes. Parents of the remaining EMA-positive children refused endoscopy. Thus the prevalence of biopsy-proven CD was 5.3% (11/205). It was 7.6% (7/92) in girls and 3.5% (4/113) in boys but the difference was not statistically significant. Seventy three percent of patients with CD were asymptomatic. CONCLUSIONS: The prevalence of clinically unrecognized CD, found by EMA screening, is high in Tunisian children with DM1. We suggest that children with diabetes should be screened for CD. 5. Spiekerkoetter U. Seissler J. Wendel U. General screening for celiac disease is advisable in children with type 1 diabetes. Hormone & Metabolic Research. 34(4):192-5, 2002 Apr. Abstract The association between celiac disease (CD) and diabetes mellitus type 1 is well known. Only about one-third of all patients with CD are diagnosed in childhood as a result of typical gastrointestinal symptoms or growth retardation. To evaluate the feasibility of CD screening in diabetic children, we tested autoantibodies to tissue transglutaminase (tTGA) in all children with type 1 diabetes from our pediatric department during a 12-month period. In antibody-positive cases, we analyzed the clinical presentation and offered a duodenal biopsy to confirm the diagnosis and grade the severity of the inflammatory process. Of 205 children, 13 (6.3 %) were tTGA-positive. In seven of eight children who agreed to perform a biopsy, CD typical histological signs were detected (Marsh 1: n = 1, Marsh 3: n = 6). In three patients with confirmed disease, symptoms (iron deficiency, recurrent abdominal pain) remained undiscovered up to time of screening (latent form); in four, the disease was asymptomatic (silent form). Since clinical symptoms are mostly mild or absent in spite of severe signs of duodenal inflammation, we recommend tTGA screening in all diabetic children. This strategy may allow the identification of	

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			patients in an early stage in respect of prevention of long-term complications. 6. Fraser-Reynolds KA. Butzner JD. Stephure DK. Trussell RA. Scott RB. Use of immunoglobulin A-antiendomysial antibody to screen for celiac disease in North American children with type 1 diabetes. Diabetes Care. 21(11):1985-9, 1998 Nov. Abstract OBJECTIVE: Our objective was to determine if a serological marker, the immunoglobulin A antiendomysial antibody (IgA-EMA), can be used to screen for celiac disease in North American children with type 1 diabetes. RESEARCH DESIGN AND METHODS: Subjects included 236 diabetes clinic patients and 56 gastrointestinal clinic patients who underwent intestinal biopsy for suspected malabsorption. Total IgA and IgA-EMA assays were performed. Diabetic patients who were positive for IgA-EMA were asked to undergo biopsy. RESULTS: Of 236 diabetic patients tested, none were IgA deficient and 19 were positive for IgA-EMA (8%). Of 17 patients biopsied, 12 had celiac disease and 3 were symptomatic. The estimated prevalence of celiac disease was 5.1%, consistent with data from European diabetic clinics. Of the 56 gastrointestinal clinic patients, the 3 who were IgA-EMA positive had biopsies diagnostic of celiac disease. Three were found to be IgA deficient, one of whom had celiac disease. Of the 50 IgA-sufficient and IgA-EMA-negative patients, 1 had celiac disease and 49 did not. The IgA-EMA test had a sensitivity of 94% and a specificity of 91% for IgA-sufficient biopsied patients. CONCLUSIONS: IgA-EMA is an appropriate tool for demonstrating an increased prevalence of celiac disease in a North American pediatric diabetic population. Positive testing should be confirmed by intestinal biopsy, and false-positive results require serial follow-up. Symptomatic children require biopsy regardless of their IgA-EMA status. 7. Calero P. Ribes-Koninckx C. Albiach V. Carles C. Ferrer J.	

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			IgA antigliadin antibodies as a screening method for nonovert celiac disease in children with insulin-dependent diabetes mellitus.[see comment]. [Comments: Comment in: J Pediatr Gastroenterol Nutr. 1997 Sep;25(3):367-8]; Journal of Pediatric Gastroenterology & Nutrition. 23(1):29-33, 1996 Jul. Abstract One hundred forty-one children with insulin-dependent diabetes mellitus were screened for serum immunoglobulin A (IgA) antigliadin antibodies by means of an enzyme-linked immunosorbent assay (ELISA) method. None of them had gastrointestinal symptoms, and no major nutritional disturbances were detected except for a girl with moderate growth delay. Twelve patients with positive IgA antigliadin antibodies on two or more consecutive measurements underwent a small intestinal biopsy; four of them had a subtotal villous atrophy, and celiac disease was diagnosed; in another patient, a partial villous atrophy was observed. Children suffering from both diabetes and celiac disease showed an onset of diabetes at a younger age than did nonceliac patients. Prevalence of celiac disease in the screened population is 2.85%, which is higher than in the general population of the Comunidad Valenciana (one in 2,500 live births). 8. Rami B. Sumnik Z. Schober E. Waldhor T. Battelino T. Bratanic N. Kurti K. Lebl J. Limbert C. Madacsy L. Odink RJ. Paskova M. Soltesz G. Screening detected celiac disease in children with type 1 diabetes mellitus: effect on the clinical course (a case control study). Journal of Pediatric Gastroenterology & Nutrition. 41(3):317-21, 2005 Sep. Abstract OBJECTIVE: To investigate clinical and metabolic characteristics of diabetic children with screening detected celiac disease in a multicenter case-control study. METHODS: Cases: 98 diabetic patients were diagnosed as having silent celiac disease by screening with endomysial antibodies and subsequent biopsy. Controls: two controls in the same center were chosen, (stratified by age and age-at-diabetes onset) who were negative for endomysial antibodies (n = 195). Height, weight, HbA1c, insulin dosage and acute complications were	

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			documented for at least 1 year of follow up. RESULTS: Mean age of diabetes manifestation was 6.5 +/- 4.1 years and diagnosis of celiac disease was made at 10.0 +/- 5.4 years. Biopsy showed total or subtotal mucosal atrophy in 74 patients. The mean observation period after the diagnosis of celiac disease was 3.3 +/- 1.9 years. Mean HbA1c levels were similar between cases and controls (8.63% +/- 1.45% versus 8.50% +/- 1.39%; P = 0.35). There was also no difference in the frequency of severe hypoglycemia, ketoacidosis and the applied insulin dosage (P = 0.45). Body mass index-standard deviation score at celiac disease diagnosis (0.57 +/- 1.24 versus 0.52 +/- 1.07) and height-standard deviation score (0.14 +/- 1.13 versus 0.30 +/- 0.95) did not differ between cases and controls. After diagnosis of celiac disease, weight gain was diminished in boys with celiac disease compared with their controls (P < 0.05). Female cases also had a lower body mass index than female controls (P = 0.067). CONCLUSION: In a cohort of diabetic children, silent celiac disease had no obvious effect on metabolic control but negatively influenced weight gain. 9. Gadd S. Kamath KR. Silink M. Skerritt JH. Co-existence of coeliac disease and insulin-dependent diabetes mellitus in children: screening sera using an ELISA test for gliadin antibody. Australian & New Zealand Journal of Medicine. 22(3):256-60, 1992 Jun. Abstract The prevalence of coeliac disease in children with insulin-dependent diabetes mellitus was investigated using a screening test of serum for antigliadin antibody by ELISA. One hundred and eighty (180) unselected diabetic children were screened for IgA and IgG class antigliadin antibodies (AGA); children with either grossly elevated or slightly elevated AGA had small bowel biopsies. The four children with the highest IgA AGA had total villous atrophy. These four children were considered to have unsuspected coeliac disease. The prevalence of coeliac disease in this group of children was one in 45. Anti-gliadin IgA and IgG tests are suitable for screening children at high risk of having coeliac disease.	

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			10. Schober E. Rami B. Granditsch G. Crone J. Coeliac disease in children and adolescents with type 1 diabetes mellitus: to screen or not, to treat or not?. Hormone Research. 57 Suppl 1:97-100, 2002. Abstract Coeliac disease is more prevalent in individuals with type 1 diabetes mellitus than in the normal population. It often presents in an atypical or silent form. Specific autoantibodies are found in almost all cases. Untreated coeliac disease may be associated with long-term health risks, so screening and early treatment with a gluten-free diet seem to be justified. However, extended follow-up is needed to document the clinical benefits of screening and treatment in diabetic patients. 11. Freemark M. Levitsky LL. Screening for celiac disease in children with type 1 diabetes: two views of the controversy. Diabetes Care. 26(6):1932-9, 2003 Jun. 12. Barera G, Bonfanti R, Viscardi M, Bazzigaluppi E, Calori G, Meschi F, Bianchi C, Chiumello G Occurrence of celiac disease after onset of type 1 diabetes: a 6 year prospective longitudinal study. Pediatrics 109:833-838, 2002 13. Poulain C, Johanet C, Delcroix C, Levy-Marchal C, Tubiana-Rufi N. Prevalence and clinical features of celiac disease in 950 children with type 1 diabetes in France Diabetes and Metabolism 33:453-458, 2007 13. Priya Narula, Lesley Porter, Josephine Langton, Veena Rao, Paul Davies, Carole Cummins, Jeremy Kirk, Timothy Barrett, and Susan Protheroe	

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			Gastrointestinal Symptoms in Children With Type 1 Diabetes Screened for Celiac Disease Pediatrics published online August 10, 2009 (10.1542/peds.2008-2434)	
Royal College of Paediatrics and Child Health	5	4.3.1 (d)	If the guidelines can give clear criteria for when CGMS would be recommended, this would be very helpful. Presumably, this would be covered under this section.	Thank you for your comment. We will examine the evidence for retrospective versus real-time continuous glucose monitoring and also the evidence of intermittent versus continuous real-time monitoring. The guideline development group will make recommendations on the use of continuous glucose monitoring taking account of that evidence
Royal College of Paediatrics and Child Health	6	4.3.1(f) and section 4.3.2 (t)	NICE Coeliac guidelines were revised in 2009 and the previous recommendation in the 2004 NICE diabetes guideline to screen for coeliac disease 3 yearly was changed to only recommending screening at diagnosis. This was on the grounds that there was no evidence to screen other than at diagnosis. The BSPED was not invited as a stakeholder to comment on the coeliac guidelines during their revision and we wrote to the NICE review committee after they were published, disagreeing with their findings. We presented a large body of evidence to show that coeliac disease can present many years after diagnosis of diabetes, the process is often indolent and only detected with screening. We feel that recommendations for screening for coeliac disease MUST be reviewed with this guidance (evidence included as appendix 1 below).	Thank you for your comment. The developers have been informed by NICE that the Coeliac disease guideline is being updated and this topic will be considered again in that guideline. The current recommendations on screening for coeliac disease in children and young people with diabetes will remain in place until

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			There is also no mention of thyroid disease as a co-morbidity in the draft scope. Is this because it is taken as read, since it is in the current guidance? To be certain of inclusion, should this not be specifically included along with the references to nephropathy and retinopathy? See below for comment about dyslipidaemia.	then and the topic will remain excluded from the Diabetes in children and young people update scope. Recommendations on monitoring for thyroid disease in children and young people with type 1 diabetes exist in the current guidance as stated in the comment and there is no indication that this topic requires updating. This topic will therefore remain excluded from the Diabetes in children and young people update scope but existing recommendations will remain
Royal College of Paediatrics and Child Health	4	4.3.1(f) and section 4.5.1	Recognition of complications and co-morbidities in CYP with type 2 diabetes (retinopathy and nephropathy). This doesn't appear to cover the co-morbidities of celiac disease and thyroid disease. Under the review questions in section 4.5 for type 1 diabetes there is no mention of co-morbidities. Currently the NICE guidance about screening for celiac disease states that screening is not required after diagnosis. This is not the clinical impression where much of the celiac disease occurs after diagnosis of type 1. Is this going to be reviewed? What about thyroid disease?	Thank you for your comment. With regard to the update of type 1 diabetes in children and young people, recognition of nephropathy and retinopathy are included. In the new guidance for type 2 diabetes in children and young people we will

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				consider recognition of dyslipidaemia, nephropathy and retinopathy Regarding coeliac disease in type 1 diabetes, the developers have been informed by NICE that the Coeliac disease guideline is being updated and this topic will be considered again in that guideline. The current recommendations on screening for coeliac disease in children and young people with diabetes will remain in place until then and the topic will remain excluded from the Diabetes in children and young people update scope. Coeliac disease is not associated with type 2 diabetes and therefore will not be considered Recommendations on monitoring for thyroid disease in children and young people with type 1 diabetes exist in the

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				current guidance and there is no indication that this topic requires updating. This topic will therefore remain excluded from the Diabetes in children and young people update scope. Thyroid disease is not associated with type 2 diabetes and therefore will not be considered
Royal College of Paediatrics and Child Health	7	4.3.2 (f) & 4.5.1	It would be very helpful to have clear recommendations (or otherwise) about monitoring blood ketones as PCTs are increasingly refusing to fund this. Children on insulin pumps in particular need to be able to test for blood ketones because of the risk of rapid metabolic decompensation and DKA if pump fails. This is now also recommended in the DKA guidelines; anecdotally, children can be kept out of hospital by parents monitoring blood ketones at home, saving the cost of an admission (and potentially life-threatening DKA) but it would be useful if there was evidence to back this up. This is probably more important than focussing on antibody tests to differentiate between T1DM & T2DM, based on numbers of CYP with both in the UK.	The role of antibody testing in the diagnosis of type 1 and type 2 diabetes is included in the scope. It is expected that the evidence review on this topic (including young people) will be undertaken by the type 1 diabetes in adults guideline and that the same recommendations will apply in both guidelines. We agree that it is important to investigate the effectives of blood ketone monitoring to prevent diabetic ketoacidosis and we have added this to the scope
Royal College of	8	4.5.2	Dyslipidaemia is specifically mentioned with respect to T2DM – what about dyslipidaemia in T1DM?	Thank you for your comment. The topic of

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Paediatrics and Child Health				monitoring for dyslipidaemia in children and young people with type 2 diabetes has been prioritised for inclusion; however, the existing recommendations on monitoring for dyslipidaemia in children and young people with type 1 diabetes were felt to be sufficient as dyslipidaemia is usually related to glucose control in these children and young people
Royal College of Paediatrics and Child Health	1	General	Appropriate contents for the scope	Thank you for your comment
Royal College of Paediatrics and Child Health	2	General	Economic Aspects - Should there be a link to the best practice tariff for Diabetes in Children which came into effect in 2012?	The health economic analysis for this guideline will influence the guideline development group in the deliberations on the cost effectiveness of different interventions and management strategies. We anticipate that these recommendations will

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				influence the Best Practice Tariff in the future
Royal College of Paediatrics and Child Health	3	Section 4.3.1 b, e and g; 4.3.2 y	We would like to know why specific diet, exercise and lifestyle advice for children and young people with type 2 diabetes are excluded, but not for type 1 when the education programmes are included for both 1 and 2. Can it be separated so easily?	Thank you for your comment. Children and young people with type 2 diabetes are included in the existing Obesity guideline (CG43), which makes recommendations on the use of bariatric surgery in these groups. The Diabetes in children and young people guideline may cross-refer to this guidance where necessary but the topic will not be included in the scope
Royal College of Pathologists	1	4.3.1	As well as type 1 and type 2 diabetes, suggest that the identification of patients with monogenic diabetes should also be covered.	Thank you for your comment. Recognition of other types of diabetes is referred to in the original guideline. Management of other types of diabetes is outside the remit for this guideline
Royal College of Pathologists	2	4.5.1	Suggest review the value of urine c-peptide in the context of differentiation between type 1, type 2 and monogenic diabetes.	Thank you for your suggestion. The existing guidance gives clinical advice on recognition of other type of diabetes. The use of c-peptide was

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				considered to be low priority and consequently is not included in the scope
Royal College of Pathologists	3	4.5.1	In addition to antibody testing, suggest review the indications for looking for evidence of monogenic diabetes, including genetic testing	The diagnosis of other types of diabetes other than type 1 and type 2 was considered to be of lower priority relative to other topics and consequently is not included in the scope for this guideline
Sanofi	1	4.3.1 – c	With a wide choice of BGM devices on the market, considerations for choice of meter should include ISO accreditation and the cost of support given to diabetes teams to ensure patients have a fully functioning device.	Thank you for your comment. We agree and the guideline development group will consider optimal choices of device when considering the evidence
Sanofi	4	4.5.1	In addition to considering the relative merits of multiple daily injections vs mixed insulin injections, the guideline should include continuous subcutaneous insulin infusions (CSII). Access to CSII can be life changing for some children and should be incorporated into this guideline.	Thank you for your comment. The topic of insulin pumps is covered in "Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus", NICE Technology Appraisal 151 (2008) which is considered up-to-date and therefore has not been prioritised for inclusion in this update
Wockhardt UK Ltd	2	4.3.1	**As comment 1, above, the section on Management of Diabetic Ketoacidosis should therefore be moved from under 4.3.2 to under 4.3.1 "Areas from the original guideline that will be updated"**	Thank you for your comment. Management of diabetic ketoacidosis has

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				not been prioritised for this update and will therefore remain in section 4.3.2, however, the scope has been expanded to include the role of ketone monitoring (as a strategy for preventing diabetic ketoacidosis).
Wockhardt UK Ltd	4	4.3.1	**As comment 3, above, the point regarding Insulin preparations should be moved from 4.3.2 to under 4.3.1 ""Areas from the original guideline that will be updated".**	Thank you for your comment. A review of the evidence around specific types of insulin and their time-action profiles has not been prioritised for this update. However, the guideline development group will consider all types of insulin used in trials identified in the review of multiple daily injection regimens. The topic of insulin preparations will therefore remain in section 4.3.2
Wockhardt UK Ltd	3	4.3.2 (c)	**Insulin preparations** is another section not identified for updating. In the previous version of CG15 (children). Under **1.2.3 Insulin preparations** in the original version**,** long-acting insulin analogues were included but long-acting non-analogue insulins were not listed. This is an omission. **Under "Insulin preparations" in the revised CG15, another paragraph**	Thank you for your comment. A review of the evidence around specific types of insulin and their time-action profiles has not been prioritised for this update and therefore

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			should be inserted between the paragraphs on intermediate acting insulins and long-acting insulin analogues, as follows: **"Long-acting (non-analogue) insulins. These have an onset of action of approximately 2-6 hours, maximal effects between 8 and 20 hours and a duration of action of 30-36 hours"**	recommendations in this section cannot be altered. The guideline development group will consider all types of insulin used in trials identified in the review of multiple daily injection regimens
Wockhardt UK Ltd	1	4.3.2 (g)	**Management of diabetic ketoacidosis** has not been identified for updating. In the previous version of CG15 (children), under **Management of diabetic ketoacidosis 3. Insulin**, was stated: "Once rehydration fluids and potassium are running, blood glucose will already be falling. However, insulin is essential to switch off ketogenesis and reverse the acidosis...Make up a solution of 1 unit per ml. of **human** soluble insulin (e.g. **Actrapid**) by adding 50 units (0.5 ml) insulin to 50 ml 0.9% saline in a syringe pump." **The formulation and Trade Name of soluble insulin to be used should not be specified in this section of the guideline. Any soluble insulin (including porcine or bovine) would be appropriate.** **This paragraph should be revised to state simply "Make up a solution of 1 unit per ml. of soluble insulin by adding 50 units (0.5 ml) insulin to 50 ml 0.9% saline in a syringe pump."**	Thank you for your comment. The current recommendations on the management of diabetic ketoacidosis are considered sufficient and this topic has not been prioritised for inclusion in the update
Wockhardt UK Ltd	5	4.5.1	Under **Review Questions, 4.5.1 Type 1 diabetes,** the following item should be included: **Evidence for the long-term safety (or otherwise) of genetically-modified (GM) insulins and relevance for use of GM insulins in children with Type 1 diabetes for whom insulin therapy will be life-long - therefore safety is of paramount importance.**	Thank you for your comment. Different types of insulin was not considered a high priority for this guideline so consequently is not included in this scope

These organisations were approached but did not respond:

Abertawe Bro Morgannwg University NHS Trust
Advisory Committee for Community Dentistry
African HIV Policy Network
Alder Hey Children's NHS Foundation Trust
Alere
Allocate Software PLC
AMORE Studies Group
Anglian Community Enterprise
Association for Dance Movement Psychotherapy UK
Association for Family Therapy and Systemic Practice in the UK
Association for the Study of Obesity
Association of Anaesthetists of Great Britain and Ireland
Association of Breastfeeding Mothers
Association of British Healthcare Industries
Association of British Insurers
Association of Child Psychotherapists, the
Association of Clinical Pathologists
Association of Renal Industries
Astrazeneca UK Ltd
B. Braun Medical Ltd
Bailey Instruments Ltd
Bard Limited
Barnsley Hospital NHS Foundation Trust
Barnsley Primary Care Trust
Baxter Healthcare
Bayer HealthCare
Bayer plc
BEAT
Birmingham Women's Health Care NHS Trust
Black and Ethnic Minority Diabetes Association
Black Country Partnership Foundation Trust
Boehringer Ingelheim
Bolton Primary Care Trust
Bradford District Care Trust

Breakspear Medical Group Ltd
Brighton and Sussex University Hospital NHS Trust
Bristol-Myers Squibb Pharmaceuticals Ltd
British Association for Counselling and Psychotherapy
British Association of Behavioural and Cognitive Psychotherapies
British Association of Prosthetists & Orthotists
British Association of Psychodrama and Sociodrama
British Association of Social Workers
British Dietetic Association
British Geriatrics Society
British Heart Foundation
British Hypertension Society
British Infection Association
British Liver Trust
British Medical Association
British Medical Journal
British National Formulary
British Obesity Surgery Society
British Paediatric Mental Health Group
British Pain Society
British Renal Society
British Society for Human Genetics
British Society for Immunology
British Society of Interventional Radiology
BUPA Foundation
Cambridge University Hospitals NHS Foundation Trust
Camden Link
Camden Provider Services
Capsulation PPS
Cardiff Research Consortium
Cardiff University
Care Quality Commission (CQC)
Central & North West London NHS Foundation Trust
Central Lancashire Primary Care Trust
Central London Community Healthcare
Children, Young People and Families NHS Network

Children's Commissioner for Wales
CIS' ters
College of Emergency Medicine
College of Optometrists
Cook Medical Inc.
Countess of Chester Hospital NHS Foundation Trust
County Durham Primary Care Trust
Coventry and Warwickshire Cardiac Network
Covidien Ltd.
Croydon Primary Care Trust
Cytori Therapeutics Inc
Daiichi Sankyo UK
Department for Communities and Local Government
Department of Health, Social Services and Public Safety - Northern Ireland
Derbyshire County Primary Care Trust
Diabetes Power
Diet Plate Ltd, The
Diving Diseases Research Centre, The
DJO UK Ltd
Dorset Primary Care Trust
Dudley Primary Care Trust
East and North Hertfordshire NHS Trust
East Midland Ambulance Services NHS
East Midlands Ambulance Service NHS
Education for Health
Elective Cesarean
Equalities National Council
ESyDoc
Expert Patients Programme CIC
Experts in Severe and Complex Obesity
Faculty of General Dental Practice
Faculty of Pharmaceutical Medicine
Faculty of Public Health
Fair Play for Children
Ferring Pharmaceuticals
George Eliot Hospital NHS Trust

GlaxoSmithKline
Gloucestershire Hospitals NHS Foundation Trust
Gloucestershire LINk
GP Care
Great Western Hospitals NHS Foundation Trust
Greater Manchester West Mental Health NHS Foundation Trust
Group B Strep Support
Guy's and St Thomas' NHS Foundation Trust
Haag-Streit UK
Halton & St. Helens Primary Care Trust
Hammersmith and Fulham Primary Care Trust
Healing Honey International Ltd
Health Protection Agency
Health Quality Improvement Partnership
Healthcare Improvement Scotland
HEART UK
Humber NHS Foundation Trust
Independent Children's Homes Association
Independent Healthcare Advisory Services
Information Centre for Health and Social Care
INPUT Patient Advocacy
Institute of Biomedical Science
Insulin Dependent Diabetes Trust
Insulin Pump Awareness Group - Scotland
Johnson & Johnson Medical Ltd
L.IN.C.Medical
Lancashire Care NHS Foundation Trust
Leeds Community Healthcare NHS Trust
Luton and Dunstable Hospital NHS Trust
Medicines and Healthcare products Regulatory Agency
Medicines for Children Research Network
Medtronic
Mental Health Group- Nutrition & Dietetics
Merck Sharp & Dohme UK Ltd
Ministry of Defence
National Clinical Guideline Centre

National Collaborating Centre for Cancer
National Collaborating Centre for Mental Health
National Collaborating Centre for Women's and Children's Health
National Institute for Health Research Health Technology Assessment Programme
National Patient Safety Agency
National Treatment Agency for Substance Misuse
NDR UK
Neonatal & Paediatric Pharmacists Group
NHS Confederation
NHS Connecting for Health
NHS Medway
NHS Plus
NHS Sheffield
NHS Trafford
North Cheshire Hospitals NHS Trust
NORTH EAST LONDON FOUNDATION TRUST
North Essex Mental Health Partnership Trust
North Tees and Hartlepool NHS Foundation Trust
North West London Hospitals NHS Trust
North West London Perinatal Network
North Yorkshire & York Primary Care Trust
Northumberland Hills Hospital, Ontario
Northumbria Healthcare NHS Foundation Trust
Nottingham City Hospital
Nottinghamshire Healthcare NHS Trust
Nova Biomedical UK
Novartis Pharmaceuticals
Nutricia Clinical Care
Optical Confederation, The
Owen Mumford Ltd
Oxford Centre for Diabetes, Endocrinology and Metabolism
Parkwood Healthcare
Patient Assembly
Peterborough City Hospital
Pharmametrics GmbH
Primary Care Cardiovascular Society

Primary Care Diabetes Society
Public Health Agency
Public Health Wales NHS Trust
Randox Laboratories Limited
Renal Nutrition Group, British Dietetic Association
Rethink Mental Illness
RioMed Ltd.
Royal Berkshire NHS Foundation Trust
Royal Brompton Hospital & Harefield NHS Trust
Royal College of Anaesthetists
Royal College of General Practitioners
Royal College of General Practitioners in Wales
Royal College of Midwives
Royal College of Obstetricians and Gynaecologists
Royal College of Paediatrics and Child Health , Gastroenetrology, Hepatology and Nutrition
Royal College of Psychiatrists
Royal College of Psychiatrists in Wales
Royal College of Radiologists
Royal College of Surgeons of England
Royal National Institute of Blind People
Royal Pharmaceutical Society
Royal Society of Medicine
Royal United Hospital Bath NHS Trust
Salford Primary Care Trust
Sanctuary Care
Sandwell Primary Care Trust
Scarborough and North Yorkshire Healthcare NHS Trust
SCHOOL AND PUBLIC HEALTH NURSES ASSOCIATION
Scottish Intercollegiate Guidelines Network
Sebia
Sheffield Childrens Hospital
Sheffield Teaching Hospitals NHS Foundation Trust
Shrewsbury and Telford Hospital NHS Trust
Slimming World
SNDRi

Social Care Institute for Excellence
Society for Cardiological Science and Technology
Society of Chiropodists & Podiatrists
Solihull NHS Primary Care Trust
Solvay
South Asian Health Foundation
South East Coast Ambulance Service
South London & Maudsley NHS Trust
South West Yorkshire Partnership NHS Foundation Trust
South Western Ambulance Service NHS Foundation Trust
Southend Hospitals NHS Foundation Trust
Southern Health & Social Care Trust
Spectranetics Corporation
St Mary's Hospital
Stockport Clinical Commissioning Pathfinder
Swansea NHS Trust
Takeda UK Ltd
Teva UK
Thames Reach
The Association for Clinical Biochemistry
The Brecon Group c/o Heather OConnel
The British In Vitro Diagnostics Association
The National LGB&T Partnership
The Rotherham NHS Foundation Trust
The University of Glamorgan
Tunstall Healthcare UK Ltd
UK Clinical Pharmacy Association
UK Ophthalmic Pharmacy Group
UK Thalassaemia Society
University College London
University College London Hospital NHS Foundation Trust
University Hospital Aintree
University Hospital Birmingham NHS Foundation Trust
University Hospitals of Leicester NHS Trust
University of Huddersfield
University of Nottingham

Walsall Local Involvement Network
Walsall Teaching Primary Care Trust
Welsh Endocrine and Diabetes Society
Welsh Government
Welsh Scientific Advisory Committee
West Hertfordshire Primary Care Trust
West Herts Hospitals NHS Trust
West Midlands Ambulance Service NHS Trust
Western Cheshire Primary Care Trust
Wirral University Teaching Hospital NHS Foundation Trust
Worcestershire Acute Hospitals Trust
Wrightington, Wigan and Leigh NHS Foundation Trust
Wye Valley NHS Trust
York Hospitals NHS Foundation Trust
Young Diabetlolgists Forum