National Institute for Health and Clinical Excellence

Type 1 Diabetes

Scope Consultation Table

04.07.2012 – 29.08.2012

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	RCGP	2	A o	Dietary protein estimation and coverage should be assessed as well as carbohydrate estimation and coverage for optimal blood sugar control.	The scope of this guideline is already large and protein estimation is not considered a priority.
SH	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 this information. The team agrees that Dentists can play an important role in the management of diabetic patients. Most of the points you make would be better placed in guidance specifically aimed dentists rather than general guidance for diabetes management. We will make the GDG aware of your comments with regard to making clinicians aware of the role of Dentists in Diabetes management.
SH	FACULTY OF DENTAL SURGERY	2	General	Through educating patients on improving oral health and preventing development of oral complications associated with diabetes, they can improve the metabolic control of diabetes.	Thank you for this information, see above.
SH	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 this information, see above.
SH	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 this information, see above.
SH	FACULTY OF DENTAL	5	General	They can also reduce co-morbidity factors resulting from diabetes by supporting patient's in tobacco-use cessation programs.	Thank you for this information, see above.

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	SURGERY				
SH	Birmingham And Solihull Cluster	1	General	No mention of Insulin in combination with GLP1 inhibitors	The Guideline will consider the addition of other glucose-lowering agents to Insulin, but only metformin has been prioritised at this stage.
SH	Birmingham And Solihull Cluster	2	General	Self blood glucose monitoring and frequency of testing	These will be covered in the scope see Section 4.3.1 c
SH	Birmingham And Solihull Cluster	3	General	Combination of insulin with Gliptins, Glitazones, other oral agents	The Guideline will consider the addition of other glucose-lowering agents to Insulin, but only metformin has been prioritised at this stage.
SH	Birmingham And Solihull Cluster	4	General	Guidance on use of high dose insulin. Position in therapy	Insulin regimens will be considered (section 4.3.1.d) but consideration of dosage within those regimens has not been suggested by any other Stakeholder.
SH	Birmingham And Solihull Cluster	5	General	Use of NPH insulin first line before the newer insulin. A treatment flowchart	Recommendations will be made on treatments and there will be a flowchart.
SH	WOCKHARDT UK	7	General	'Human' insulins should always be shown with inverted commas, to convey the fact that they are not actually of human origin (but actually of animal origin, genetically-modified to resemble human insulin).	Thank you for this, we will make a note of this.
SH	British Pain Society	1	General	As diabetes is associated with neuropathic pain the guideline is quite correctly cross referenced to the NICE neuropathic pain guideline we feel it should also be cross referenced to the NICE TAG 159 on spinal cord stimulation for neuropathic and ischaemic pain	Thank you this has been added to the scope.
SH	National Diabetes Inpatient Specialist	1	General	Scope for the guideline is fine	Thank you for your comment.

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	Nurse Group				
SH	NHS Direct	1	General	NHS Direct welcome this guideline and have no comments on the scope.	Thank you for your comment.
SH	The British Psychological Society	3	General	In order to contribute relevant expertise on diabetes specific mental health and behaviour change issues to the guideline review for Type 1 Diabetes, 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	The GDG is a small working group and therefore the numbers are limited. As this guideline will not address psychological issues specifically but will cross refer to the several relevant guidelines, a psychologist is not a priority..
SH	Hindu Council UK	1	General	Our comments are as follows: Dietary and culture will not be updated, from the Hindu Council UK perspective this would be fine as long due regard is given to the equality of opportunity for religions and religious bodies that can help. From the Hindu perspective it is always of interest what the treatment and medication consists of or what it is derived from, the use of vegetable based treatment is preferred as opposed to animal based medication specifically if it is Bovine derived. Muslim and Jewish colleagues would equally be concerned with any porcine derived medication. However in the absence of this information the Hindu perspective would allow any treatment to preserve the sanctity of Human life.	Thank you for this information. This will be considered by the Guideline Development Group at all stages as part of delivering personal care rather than as part of the evidence base.
SH	ELCENA JEFFERS FOUNDATION	1	General	EJF agree with the whole document and wish to be part of this research to ensure that persons who lives with diabetes are in the leading pack to find real solutions.	Thank you for your comment.
SH	Kidney Alliance	3	General	Will this update refer to or look at any pancreatic transplantation guidelines?	We have included a cross reference to the NICE

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					guidance on this.
SH	Association of British Clinical Diabetologists (ABCD)/Royal College of Physicians (RCP)	1	General	The Best Practice Tariff for Diabetes in Children extends to an age group of 19 years. It would therefore be worth changing the age band to under 19 years to ensure uniformity.	This was discussed amongst the four diabetes guidelines teams and it was agreed to set the age at 18 as this was more consistent with the research literature. We recognise the difficulty, however.
SH	Faculty of Pharmaceutical Medicine	3	General	Secondary and other causes of diabetes such as cystic fibrosis and MODY/pancreatic disease should be recognised.	We have revised the wording to say the guideline will address distinguishing Type 1 from other forms of diabetes.
SH	Department of Health	1	General	This guidance cannot be considered in isolation from the guidance for Children and young people, Type 2 and pregnancy. There are common issues and these should be linked to ensure consistency of approach and inappropriate duplication	The guidelines will be considered together and cross-ref made where appropriate. The diabetes suite of GLs are all being updated at the same time in order to ensure that common issues that are relevant to all these pt groups with diabetes will be covered / considered.
SH	Department of Health	21	General	- Type I adult add: People who have type 1 diabetes are at increased risk of developing autoimmune related conditions than background population e.g. thyroid disease, addisons disease, pernicious anaemia, coeliac disease and vitiligo.	Thank you for this information. The guideline will address screening for thyroid disease and cross refer to the relevant NICE guidelines.
SH	The British Psychological Society	4	General and 4.3.1	The BPS believes it is important that the guideline considers not only specific psychiatric disorders which people with diabetes may experience, such as depression, anxiety and eating disorders (which have received much attention in the literature), but also other psychological difficulties. There is a danger that exclusive focus on psychiatric disorders and treatment thereof could obscure the increasing evidence that psychological difficulties which do not meet the criteria for the diagnosis of a	The guideline will cross refer to the several relevant NICE guidelines in the field, in particular the guideline relating to depression in chronic conditions. We acknowledge that people with diabetes may have other psychological difficulties, although this statement also applies to many other chronic conditions. We cannot prioritise all of these which may be better

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				specific psychiatric disorder, can also contribute significantly to poor physiological outcomes by undermining positive self-care behaviours. As people with diabetes learn how to adapt their lives and adjust to life with the condition, they face a number of psychological challenges, such as: • acceptance; • treatment concordance; • needle distress; • behavioural change following long held habits; • treatment regime changes; • impacts on romantic relationships (including pregnancy, fertility, erectile dysfunction in men, reduced desire in women and negative body image perception); • deterioration in health; and • specific complications. These challenges and associated psychological distress have an adverse effect on outcomes, both medical and psychological.	served in generic guidance.
SH	ELCENA JEFFERS FOUNDATION	1	Not stated	We are commenting on the whole document, with a view to implement changes where and when evidence call for changes. Looking forward to working with you.	Thank you for your comment.
SH	Diabetes Management and Education Group (DMEG)	1	Not stated	Somewhere there needs to be something about the correct diagnosis ie not labelling later onset T1D as T2D. This should be explicitly covered in both T1 and T2 guidelines and cross referenced	We have revised the wording to say the guideline will address distinguishing Type 1 from other forms of diabetes.
SH	Diabetes Management and Education	2	Not stated	It was not planned to update the physical activity section, however in the 'Evidence based nutrition guidelines' 2011 there is a clearer statement on how to manage than in the present NICE guideline.	Thank you for this information. NICE guidelines can only cross refer to other NICE guidance.

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	Group (DMEG)				
SH	Diabetes Management and Education Group (DMEG)	3	Not stated	Worthwhile to update diet section as well – i.e. plant sterols and stanols, MUFA's, and Omega 3 fish.	These issues are addressed in the Lipids Modification guideline which is currently being updated.
SH	Diabetes Management and Education Group (DMEG)	4	Not stated	What to do if HbA1c unreliable eg anaemia/role of fructosamine/other tests	We have revised the scope and will not delete the fructosamine recommendation
SH	Diabetes Management and Education Group (DMEG)	5	Not stated	HPC competencies required for type 1 diabetes management	This is beyond the scope of this guideline which is not about service provision. This could be taken up at implementation.
SH	Diabetes Management and Education Group (DMEG)	6	Not stated	Management of diabetes specific psychological issues such as needle phobia, psychological insulin resistance, denial	It has been agreed that the guideline on diabetes in children will address needle phobia and behavioural therapies. The GDG of this guideline will be made aware of any relevant evidence.
SH	Deaf Diabetes UK - DDUK	1	Not stated	Hello This is my first time feedback as a registered Stakeholder + hope this is okay? Not sure if I understand about comments proforma?	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

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				At short notice I have highlighted similar access+communication issues affecting all 4 consultation areas on behalf of DDUK. First Feedback for NICE's consultations on Diabetes clinical guidelines From Deaf Diabetes UK - DDUK DDUK is Deaf-led + works specifically with Deaf sign language users mainly BSL - British Sign Language First Feedback / comments in Key points format from Deaf BSL users attendees at - 2010 DDUK Conference - 2011 NHS Education Session for Deaf BSL users + Hard of Hearing people (HOH), Carers - and those who contacted DDUK SupportLine relating to * Type 1 Diabetes in Adults * Type 2 Diabetes in Adults * Diabetes in Children * Diabetes in Pregnancy - 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	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 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 Service (NHS).

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				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 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	

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				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 Communication Professionals working with Deaf + Deafblind People. NRCPD is supported by Signature. How to find/Book a	

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				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 condition.	

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				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. DDUK - Registered Stakeholder	

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				Catherine Forry / Deaf BSL user / Type 2 Diabetes DDUK Founder	
SH	Cambridge University Hospitals NHS Foundation Trust (CUHFT)	1		Somewhere there needs to be something about the correct diagnosis ie not labelling later onset T1D as T2D. This should be explicitly covered in both T1 and T2 guidelines and cross referenced	We agree, and indeed this was always our intention. We have revised the wording to make this clearer.
SH	Cambridge University Hospitals NHS Foundation Trust (CUHFT)	2		It was not planned to update the physical activity section, however in the 'Evidence based nutrition guidelines' 2011 there is a clearer statement on how to manage than in the present NICE guideline.	Thank you for this information. NICE guidelines can only cross refer to other NICE guidance.
SH	Cambridge University Hospitals NHS Foundation Trust (CUHFT)	3		Worthwhile to update diet section as well – i.e. plant sterols and stanols, MUFA's, and Omega 3 fish.	Our review of new evidence, and the opinion of other Stakeholders, did not suggest that the dietary section needs updating. We note that advice on Lipid Modification in diabetes will be part of the NICE guideline on Lipid modification which is currently being updated.
SH	Cambridge University Hospitals NHS Foundation Trust (CUHFT)	4		What to do if HbA1c unreliable eg anaemia/role of fructosamine/other tests	We have revised the scope and will not delete the fructosamine recommendation
SH	Cambridge University	5		HPC competencies required for type 1 diabetes management	This is beyond the scope of this guideline

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	Hospitals NHS Foundation Trust (CUHFT)				
SH	Cambridge University Hospitals NHS Foundation Trust (CUHFT)	6		Management of diabetes specific psychological issues such as needle phobia, psychological insulin resistance, denial	It has been agreed that the guideline on diabetes in children will address needle phobia and behavioural therapies. The GDG of this guideline will be made aware of any relevant evidence.
SH	Cambridge University Hospitals NHS Foundation Trust (CUHFT)	7		New drugs like pramlintide	This drug is not licensed for this condition in the UK and therefore will not be reviewed.
SH	Cambridge University Hospitals NHS Foundation Trust (CUHFT)	8		Include more on physical activity recommendations	We will cross refer to relevant NICE guideline that cover physical activity.
SH	Department of Health	2	3.1 (a)	Autoimmune condition, failure of pancreatic beta cells to produce insulin resulting in elevated blood glucose levels, no cure at present.	Introduction adjusted, paragraph 1.1a to include reference to these features
SH	Department of Health	3	3.1 (b)	Mainly talking about type 2 diabetes, state estimated total number of individuals in England and the split between adults and children and mean age at onset.	We have adjusted the wording to refer specifically and exclusively to Type 1 diabetes, using data from the National Diabetes Audit..
SH	Department of Health	4	3.1 ©	What is current life expectancy for a child diagnosed with type 1 diabetes?	These data are not all readily available. We have commented on the fact that most mortality is from chronic

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				What is the mean age at death? What are people dying from is it acute or chronic complications?	complications in the final scope
SH	Menarini Diagnostics	1	3.2	The draft scope recognises that, 'e) Rates of diabetic ketoacidosis appear to be increasing in the UK.' The National Diabetes Audit 09/10 recognises that 'over one in ten people with diabetes have had DKA in the past 5 years. In many cases this could have been prevented.' (3.9% of the type 1 population suffered hospitalisation due to DKA in the audit year) Also the report highlights the variation in DKA rates across PCTs, explaining that 'this is likely to reflect diabetes related self-care and supported care factors alone'. This NICE review is an opportunity to reverse that trend by ensuring that all 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 – please see 4.3.1	Thank you. The review will include examination of the evidence for the use of blood ketone monitoring in both prevention and treatment of DKA.
SH	Kidney Alliance	1	3.2 (e)	We think there may be an error in this sentence	Thank you, there were some words missing and the sentence has been adjusted
SH	Medtronic UK & Ireland	1	3.2 (e)	Error in the wording of the sentence requires clarification by the authors, it seems likely that the sentence finishes prematurely in the draft.	Thank you, there were some words missing and the sentence has been adjusted
SH	Medtronic UK & Ireland	2	3.2 (g)	There seem to be different percentages quoted throught the guideline for the same areas, is 15 – 20% the agreed figure?	We are unsure where these different percentages are, is it in the original guideline? 15-20% is the current figure which we will confirm during the development of the guideline
SH	Sanofi	1	3.2 (b)	Should the sentence "only 31.9% of people with type 1 diabetes in England and Wales receive all 9 of the care processes recommended by NICE" read 'only 31.9% of people with type 1 diabetes in England and Wales have a record of having received all 9 of the care processes recommended by NICE'	This is a fair comment and we have adjusted the text

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SH	Department of Health	5	3.2 (c)	Could compare this with German data.	I was unable to find current population data from Germany giving HbA1c for its type 1 diabetes population. The only data available are from selected populations such as graduates of quality assured structured education programmes but I was unable to find data for the type 1 population as a whole.
SH	RCGP	1	3.2 (e)	Kidney disease left in limbo –needs corrected about what you wanted to say.	Thank you, we have corrected the text
SH	WOCKHARDT UK	1	3.2 (e)	Under 3.2 Current Practice (e) There appears to be some text missing from the second sentence of this paragraph relating to diabetic ketoacidosis and end-stage kidney disease.	Thank you, we have corrected the text
SH	Department of Health	6	3.2 (e)	Part of the sentence is missing.	Thank you, we have corrected the text
SH	INPUT Patient Advocacy	1	4.3.1 (d)	Cross referencing – NICE TA 151 should be cross-referenced in 4.3.1 d (insulin regimens) and 4.3.1 f (insulin delivery)	We have amended the scope; this TA will be referred to where appropriate.
SH	Faculty of Pharmaceutical Medicine	1	4.1.1	Our comment is as follows: Should there be a sub-paragraph (b) and treatment of very old people with Type 1 DM. This paragraph could be extended to discuss other groups for whom hypoglycaemia is a high risk or for whom the consequences of hypoglycaemia could be more significant, rather than the general adult population.	In reference to section 4.1.1,, if a particular group is mentioned e.g. the very old, it could be assumed that that are not mentioned are not included. Therefore it is better to be inclusive. However the point about the elderly is noted.
SH	Diabetes UK	1	4.1.2	Monogenic diabetes should be included in the groups that will not be covered.	This has been added.
SH	Community Diabetes Consultants	1	4.3	Under clinical management CDC would like to see that all people with Type 1 diabetes have easy and ready access to a specialist MDT and that this team has recognised designated skills and competencies to provide care to people with Type 1 diabetes. People with type 1 diabetes should always be known to the specialist team	The remit of this guideline did not include service delivery, but this is a point that can be taken up at the time of implementation of the guideline.
SH	WOCKHARDT UK	5	4.3.1	The question "What are the long-term safety issues associated with the use of GM insulins?" should be listed under 4.3.1 Key clinical issues that will be covered under "Areas not in the original guideline that will be included in the update".	The evidence risks and harms of all treatments is routinely searched for and reviewed.

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SH	The University of Glamorgan	1	4.3.1	Our comments regarding areas for inclusion are as follows: we agree that accurate diagnosis is essential for appropriate treatment and should be included within the guidelines	Thank you for your comment.
SH	The University of Glamorgan	2	4.3.1	Another possible area for inclusion is guidance on the management of inter-current illness i.e. 'sick day rules' as inappropriate advice can increase hospital admissions and costs to the NHS and person with diabetes	These will be addressed within educational packages, should there be evidence.
SH	The University of Glamorgan	3	4.3.1	Equality of opportunity might be enhanced by considering diabetes care at the end of life i.e. diabetes and palliative care	Thank-you. This topic has not been suggested by any other Stakeholder and given the considerable size of the current Scope, we do not feel it should be included.
SH	Menarini Diagnostics	2	4.3.1	All people with type 1 diabetes (adults, children and young people) should receive education and be 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. This is due to: 1. potentially life threatening nature of DKA 2. cost burden to NHS due to preventable hospitalisations 3. comparable cost of appropriately used blood ketone sensors is preferential to the cost of hospitalisations 4. increasing prevalence of DKA in type 1 group year on year 5. lack of efficacy of urine ketone testing	This topic will be covered by the guideline. We have revised the scope to make it clear what is going to be covered.
SH	Menarini Diagnostics	3	4.3.1	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	Thank you for this information. This guidance will be reviewed but our recommendations will not necessarily be the same; they will be based on all available evidence. .

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				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 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.	
SH	Department of Health	7	4.3.1	No mention of pumps, psychology, islet cell or pancreatic transplantation, what about new and evolving technology e.g. sensor augmented pumps.	With regard to pumps the guideline will refer to the NICE TA. New and evolving technologies in this field should then be updated by the TA. The scope now cross refers to the IP guidance on transplantation.
SH	Association of British Clinical Diabetologists (ABCD)/Royal College	4	4.3.1 (a)	Distinguishing type 1 from type 2 diabetes : it may be worth looking at the literature on urinary C-peptide/creatinine ratios which has been published by Prof A Hattersley. This is a promising avenue although the literature may not yet be sufficiently robust.	Thank you for this information which will be incorporated into the review questions and evidence reviews if appropriate.

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	of Physicians (RCP)				
SH	Juvenile Diabetes Research Foundation	1	4.3.1 (b)	JDRF believes that alcohol consumption should be covered under Education programmes and self-care.	If these topics are included in the research evidence on education programmes they will be evaluated.
SH	The British Psychological Society	1	4.3.1 (b) & 4.4	Structured education programmes which are based on learning theories are linked with improved psychological well-being and increased self-efficacy for people with Type 1 diabetes (e.g. Ellis *et al* 2004; George *et al* 2008). The BPS believes that these aspects of positive psychological health (such as well-being and self-efficacy) should therefore be considered as outcomes, in addition to quality of life and bio-markers such as HbA1c. References: Ellis, S. E., Speroff T., Dittus, R. S., Brown, A., Pichert J. W. & Elasy T. A. (2004). Diabetes patient education: a meta-analysis and meta-regression. *Patient Education and Counselling,* 52, 1, 97-105. George, J. T., Valdovinos, A.P., Russell, I., Dromgoole, P., Lomax, S., Togerson, D. J. *et al.* (2008). Clinical effectiveness of a brief educational intervention in Type 1 diabetes: Results from the BITES, Brief Intervention in Type 1 Diabetes Education for Self-efficacy. *Diabetic Medicine,* 25, 12, 1447-53.	Thank you for this information. We will be looking for evidence for structured education programmes. We will make the GDG aware of your suggestions for outcomes.
SH	Sanofi	2	4.3.1 (b)	Selection of meter should be informed by patient choice. Patient choice will reduce wastage and drive compliance.	This would be part of the discussion the GDG will have on the topic
SH	Kidney Alliance	2	4.3.1 (b)	We suggest consideration of self-management or peer educator programmes which are aimed specifically at the BME community.	Thank you for this information and we will search for programmes aimed at the BME communities.
SH	Abbott	1	3.1	We propose that within the scope section on education programmes and self-care,	Thank you for this information and references. We will be searching for education programmes and will

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	Diabetes Care			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 give patients more confidence in caring for their disease, reduces insulin dosing errors, and assists patients to better self-manage their disease. □ 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. □ Cavanaugh K, et al. Association of numeracy and diabetes control. Annals of Internal Medicine. 2008; 148:737-46. □ Kerr D. Poor Numeracy: The Elephant in the Diabetes Technology Room. Journal of Diabetes Science and Technology. 2010; 4:1284-7.	consider the issues of low literacy and numeracy skills.
SH	Community Diabetes Consultants	2	4.3.1 (c)	People with type 1 diabetes should be able to have their HbA1c measured every 2 months either in a specialist setting or at the GP practice to facilitate self management	The GDG will consider the evidence for frequency of HbA1c measurement. This is now clearer in the scope.
SH	Sanofi	3	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.	. Blood glucose monitoring will be considered in some detail (section 4.3.1.c) but we will not be comparing different meters unless our review of the evidence suggests that there are important differences between them. If a de novo cost-effectiveness model is built it would include staff costs.
SH	Abbott	2	4.3.1 (c)		We have made it clearer in the scope what will and will

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	Diabetes Care			We recommend that there is clear distinction in the scope 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 hypoglycaemia, and improving diabetes outcomes.	not be covered with regard to CGM and will compare the different approaches.
SH	Abbott Diabetes Ca	3	4.3.1 (c)	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 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.	Thank you for the references which will be considered if appropriate.
SH	Abbott Diabetes Care	4	4.3.1 (c)	In the clinical monitoring of glucose section we suggest that recommendations be made for healthcare professionals and patients to use data management software programmes for both continuous glucose monitoring and self-monitoring of blood glucose to better identify patterns and trends of hyper or hypoglycaemia and to adjust treatment based on these patterns and trends to improve outcomes.	If the evidence is available which assesses data management software programmes these will be reviewed as part of section 4.3.1.c.II.
SH	Abbott Diabetes Ca	5	4.3.1 (c)	We propose that the recommended target for blood glucose control in adults be consistent with targets recommended by EASD and ADA: HbA1C 7.0% Preprandial capillary plasma glucose 70–130 mg/dL(3.9–7.2	Thank you for this information. Targets will be reviewed.

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				mmol/L) Peak postprandial capillary plasma glucose < 180 mg/dL(< 10.0 mmol/L) Standards of Medical Care in Diabetes - 2012, Diabetes Care. 2012;35: S11-63.	
SH	Department of Health	8	4.3.1 (c)	Type I diabetes adults – section1.8.2 on 'Self monitoring of glucose' change to 'Self monitoring of capillary blood glucose'. CG15 Update 1.8.28 ' monitoring using sites other than the fingertips (often forearm, using meters that require small volumes of blood and devices to obtain those small volumes) cannot be used as a routine alternative to conventional self-blood glucose monitoring' Also, include real time continuous glucose monitoring (which may include linkage to insulin pumps)	Thank you for this information. This section of the scope has been expanded and gives more detail on what will be reviewed. This will include a comparison of the different approaches.
SH	WOCKHARDT UK	2	4.3.1 (d)	Under 4.3.1 Areas from the original guideline that will be updated, the point (d) should not be focussed on rapid-acting insulins and new background insulins. This paragraph should state "All available insulin regimens, including animal, 'human' and analogue insulins, rapid-acting, intermediate and long-acting."	Since this is an update it is appropriate to specifically mention newer insulins which were not covered in the previous guideline. However, use of these newer agents will be compared to loder regimens (section 4.3.1.d)
SH	Department of Health	9	4.3.1 (d)	Need link to insulin pumps In the UK insulin strength is U100 (100 UNITS insulin in 1ml). Some patients (including those from abroad) use U500 (500 UNITS insulin in 1ml). This should be mentioned as a safety issue Insulin absorption, lipohypertrophy/site problems	The guideline will refer to the NICE TA on insulin pumps.
SH	Sanofi	4	4.3.1 (e)	The Type 2 guideline update scope specifically excludes SGLT-2 inhibitors as they are to be addressed in NICE STAs. Therefore they do not need to be addressed in the T1 guideline update.	The guideline will not look at SGLT-2.
SH	Eli Lilly and	1	4.3.1 (e)	Lilly considers that SGLT-2 inhibitors in combination with insulin	The guideline will not look at SGLT-2.

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	Company Limited			should not be evaluated, as this is not a licensed combination and is unlikely to be a licensed combination in the near future for patients with type 1 diabetes. (www.clinicaltrials.gov).	
SH	Juvenile Diabetes Research Foundation	2	4.3.1 (f)	Insulin Pumps are regarded as an effective mechanism of treatment for type 1 diabetes. JDRF would like to see the inclusion of insulin pumps in this section for the delivery of Insulin.	The guideline will cross refer to the NICE Technology Appraisal on insulin pumps.
SH	Abbott Diabetes Ca	6	4.3.1 (h)	We propose that the scope be extended from prevention and management of DKA to prevention, detection and management of DKA. The evidence suggests that use of blood ketone testing to detect potential DKA can reduce the incidence of acute DKA events, reduce DKA-related hospitalisations, and improve patient confidence in self-managing potential diabetic emergencies. □ Laffel LMB, et al. Sick day management using blood 3-hydroxybutyrate (3-OHB) compared with urine ketone monitoring reduces hospital visits in young people with T1DM; a randomized clinical trial. Diabetic Medicine. 2005; 23:278-84.	This section has been revised and clarifies what will be addressed. The reference given is noted.
SH	Abbott Diabetes Ca	7	4.3.1 (h)	We propose when the scope reviews Diabetic Ketoacidosis that it considers the value blood ketone monitoring has when integral to the patient pathway. In a study of type 1 patients conducted in Cornwall the number of DKA hospital admissions was reduced by 23% one year after implementing blood ketone testing as part of a formalised protocol. □ Dunstan C, Blood ketone monitoring in type 1 diabetes; A proactive approach to reducing DKA admissions. Supplement to Journal of Diabetes Nursing, Volume 14, No 7, 2010.	This section has been revised and clarifies what will be addressed. The reference given is noted.
SH	Medtronic UK & Ireland	3	4.3.1 (h)	No reference is made to treatment or monitoring techniques, clarification at the earliest stage with stakeholders is advised to ensure comprehensive inclusion of options.	Thank-you. Our intention was to look at the role of ketone monitoring, and this is now specified in 4.3.1m.
SH	Bayer plc	2	4.3.1 (i)	Areas from the original guideline that will be updated	Thank you for this information and for the references. It has been agreed that the Type 2 Diabetes guideline

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				i) Treatment of specific late-stage complications, namely insulin-induced neuritis, gastroparesis and erectile dysfunction. When updating this section it should be bourne in mind that hypogonadism is associated with erectile dysfunction (ED),[1] and may make men less responsive, or even nonresponsive, to phosphodiesterase type 5 (PDE5) inhibitors.[2] Several studies (both RCTs[3,4] and non-RCTs[5-10]) have shown that administration of testosterone therapy can improve response in PDE5i non-responders. The British Society for Sexual Medicine (BSSM) guidelines on the management of ED, recommend that all men with ED should have their serum testosterone measured. Also that men with a total serum testosterone that is consistently <12nmol/l might benefit from up to a 6 months trial of testosterone replacement therapy for ED. [2] (1) NHS Diabetes. Factsheet No. 36. Hypogonadism and diabetes - under diagnosed and under treated. March 2012. Available from: http://www.diabetes.nhs.uk/document.php?o=3381. (Last accessed: 20/8/2012). (2) British Society for Sexual Medicine. Guidelines on the management of erectile dysfunction. July 2009. Available from: http://www.bssm.org.uk/downloads/BSSM_ED_Management_Guidelines_2009.pdf. (Last accessed: 15/8/2012). (3) Buvat J et al. Hypogonadal men nonresponders to the PDE5 inhibitor tadalafil benefit from normalization of testosterone levels with a 1% hydroalcoholic testosterone gel in the treatment of erectile dysfunction (TADTEST study). *J Sex Med* 2011; 8(1):284-293. (4) Shabsigh R et al. Randomized study of testosterone gel as adjunctive therapy to sildenafil in hypogonadal men with	will address Erectile Dysfunction and there will be a cross reference in this guideline.

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				erectile dysfunction who do not respond to sildenafil alone. *J Urol* 2004; 172(2):658-663. (5) Aversa A et al. Androgens improve cavernous vasodilation and response to sildenafil in patients with erectile dysfunction. *Clin Endocrinol (Oxf)* 2003; 58(5):632-638. (6) Yassin AA et al. Testosterone and erectile function in hypogonadal men unresponsive to tadalafil: results from an open-label uncontrolled study. *Andrologia* 2006; 38(2):61-68. (7) Rosenthal BD et al. Adjunctive use of AndroGel (testosterone gel) with sildenafil to treat erectile dysfunction in men with acquired androgen deficiency syndrome after failure using sildenafil alone. *Urology* 2006; 67(3):571-574. (8) Kalinchenko SY et al. Oral testosterone undecanoate reverses erectile dysfunction associated with diabetes mellitus in patients failing on sildenafil citrate therapy alone. *Aging Male* 2003; 6(2):94-99. (9) Shamloul R et al. Testosterone therapy can enhance erectile function response to sildenafil in patients with PADAM: a pilot study. *J Sex Med* 2005; 2(4):559-564. (10) Hwang TI et al. Combined use of androgen and sildenafil for hypogonadal patients unresponsive to sildenafil alone. *Int J Impot Res* 2006; 18(4):400-404.	
SH	Medtronic UK & Ireland	4	4.3.1 (i)	Additional guidance is in existence to be included / referenced regarding gastroparesiss such as the current IPG 103 for the condition which touches on type 1 diabetes	This IPG has been added to the scope.
SH	Department of Health	10	4.3.1 (i)	Insulin neuritis can be an acute complication.	While it can occur at any stage when insulin is replaced rapidly after prolonged deficiency but probably requires a degree of organic neuropathy and so is rare at onset of type 1 diabetes.
SH	Juvenile Diabetes	3	4.3.1 (j)	JDRF believes Coeliac disease should also be monitored and included in this section.	Thank you for this information. The guideline will cross refer to the Coeliac disease guideline.

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	Research Foundation				
SH	Department of Health	11	4.3.1 (k)	Include more on diabetes management in inpatients with Type 1 diabetes – avoidance drug errors, hypoglycaemia, etc. See National Diabetes Inpatient Audit reports	We have clarified this section of the scope and will look at these issues..
SH	WOCKHARDT UK	3	4.3.1 (l)	Animal insulins were only mentioned once in the original version of CG15, Section 7.3 Insulin Regimens, as follows: *"Insulin and insulin analogues* Insulin with the molecular structure of human and animal insulins is currently available. Evidence from the majority of studies[126–8] reports no significant differences in hypoglycaemic episodes and glycaemic control between the insulin of human and animal chemical structures." Under "4.3.1 Areas not in the original guideline that will be included in the update", besides (l) there should be an additional point stating "Animal insulins (porcine and bovine), which were not adequately covered in the original version of CG15".	Thank-you. Our Review for update work, and the views of other Stakeholders, do not support this as a priority area for the updated Guideline.
SH	WOCKHARDT UK	4	4.3.1 (l)	The three studies cited under Section 7.3 Insulin Regimens in the original version of CG15 (references 126-8) by no means represent "the majority of studies" on animal versus 'human' insulins. Moreover, Richter 2002 has been superseded by Richter 2004 (Cochrane review), George 1997 was a small study (n=20) and Karlson 1994 does not appear to relate to animal insulins at all! The published literature on animal insulins should be thoroughly reviewed before production of the revised CG15 so that the use of animal insulins can be accurately and comprehensively addressed under Insulin Regimens.	Thank-you. Our Review for update work, and the views of other Stakeholders, do not support this as a priority area for the updated Guideline.
SH	Novo Nordisk Ltd	1	4.3.1 (l)	Novo Nordisk welcomes the inclusion of insulin degludec, insulin degludec/aspart and insulin detemir in the update to the type 1 clinical guidelines.	**Thank you for your comment.**

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SH	Novo Nordisk Ltd	2	4.3.1 (m)	Novo Nordisk strongly supports the inclusion of hypoglycaemia within the guidelines, however we would suggest that in addition to 'identification of hypoglycaemia' that the 'appropriate management of hypoglycaemia' is also considered. This is particularly important following the recent changes to the DVLA guidelines for people with diabetes.	Thank-you. Our Review for update work, and the views of other Stakeholders, do not suggest that there is a sufficient new evidence on the management of hypoglycaemia to support this as a priority area for the updated Guideline. However, we will consider the evidence on hypoglycaemia unawareness.
SH	Medtronic UK & Ireland	5	4.3.1 (m)	Identification of hypoglycaemia – could more detail be provided on the setting and type of hypoglycaemia being identified such as acute or sub acute, using what measures and methods etc?	We will consider hypoglycaemia as a general topic, not confining this to any particular setting.
SH	Department of Health	12	4.3.1 (m)	Hypoglycaemic unawareness needs expanding	It has been clarified that this will be addressed in the guideline.
SH	Abbott Diabetes Ca	8	4.3.1 (n)	We encourage a review of blood ketone monitoring as there is evidence to support blood ketone testing as a better clinical measure than urine ketone testing; Mackay L, Lyall MJ, Delaney S, McKnight JA, Strachan MWJ. Are blood ketones a better predictor than urine ketones of acid base balance in diabetic ketoacidosis?. Pract Diab Int. 2010;27(9):396-399. Laffel LMB, et al. Sick day management using blood 3-hydroxybutyrate (3-OHB) compared with urine ketone monitoring reduces hospital visits in young people with T1DM; a randomized clinical trial. Diabetic Medicine. 2005; 23:278-84.	This will be addressed in the guideline. Thank you for the references.
SH	Medtronic UK & Ireland	6	4.3.1 (n)	Blood ketone monitoring, can we assume this topic will look at outcomes such as AUC, time spent in hypo. Will this section also considers different settings such as primary care studies?	Outcomes for specific questions will be considered by the GDG.
SH	Department of Health	13	4.3.1 (n)	In addition to noting now standard use of blood ketone monitoring, the diabetic ketoacidosis section needs updating (see JBDS guidance)	This has been clarified in the scope.
SH	Juvenile Diabetes Research Foundation	4	4.3.1 (o)	JDRF welcomes the inclusion of carbohydrate counting in the update, however we believe this should be grouped together under section *4.3.1 – b*, Education programmes and self-care.	Thank you for this suggestion. It is here in the scope to make clear it is an addition. The structure of the scope does not necessarily reflect the structure of the final guideline.

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SH	Abbott Diabetes Ca	9	4.3.1 (o)	We propose that consideration be given to tools and technology that support the practice of carbohydrate counting and matching carbohydrate with appropriate insulin doses to prevent postprandial hyper or hypoglycaemia.	We will consider the role of carbohydrate counting, but do not propose to look at different methods of realising this unless our review of the overall evidence suggests that there are important differences..
SH	Medtronic UK & Ireland	7	4.3.1 (o)	Carbohydrate counting, it is unclear in the draft form which perspective Carb counting will be looked at – ie: is it best practice to be followed or is the intention to revisit cost effectiveness? Some clarification would help to focus the expectations.	The evidence for its effectiveness will be reviewed. If there is any evidence of cost effectiveness this will also be reviewed.
SH	Eli Lilly and Company Limited	2	4.3.1 (o)	Glycaemic index has been included in the draft scope for diabetes in children and young people with Type 1 diabetes. Lilly suggests incorporating glycaemic index to the scope of Type 1 diabetes in adults along with carbohydrate counting.	GI will now be addressed jointly by both guidelines.
SH	Roche Diagnostics Limited	1	4.3.1 (o)	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 the information and references. Bolus calculators will be reviewed as part of Clinical monitoring of glucose control(section 4.3.1.c)

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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*	
SH	Faculty of Pharmaceutical Medicine	2	4.3.2	Although HbA1c is now the standard assessment for DM control, should not the issue of how DM is assessed in patients with haemoglobinopathies be addressed (that will also apply to Type 2 DM as well)?	This topic is beyond the scope of this guideline. We acknowledge this problem and will consider it when debating the evidence on HbA1c, but detailed review of the different haemoglobinopathies will not be carried out.
SH	Department of Health	14	4.3.2	Fructosamine still in use if HbA1c appears wrong	This is agreed and will not be deleted from the guideline
SH	Department of Health	17	4.3.2	Would not one comprehensive document be useful to cover all aspects of the care of the individual with type 1 diabetes?	There will be comprehensive document – we are just updating specific sections where new evidence has emerged, or practice has or needs to change. These updated areas will appear in one comprehensive document which will still include the areas in the original guideline that have not been updated and remain unchanged. T1D in children / young people guideline will be more relevant to paediatricians and it was thought to be

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					important to keep separately as there are some specific issues arising for that patient group.
SH	Royal College of Pathologists	1	4.3.2 (a)	Whilst it may be appropriate to cross reference to NICE CG 67 (Lipid modification) and TA 94 (statins), these documents currently say very little about treatment in type 1 (as opposed to type 2) diabetes. Cardiovascular risk assessment in type 1 diabetes is also not well covered in these documents. Unless the current update of CG 67 covers type 1 diabetes in greater detail, this issue should be covered in the present update. This is an area of considerable current uncertainty.	The Lipids Modification guideline currently being updated and will address lipids modification for patients with diabetes.
SH	Association of British Clinical Diabetologists (ABCD)/Royal College of Physicians (RCP)	2	4.3.2 (a)	Cross reference will be made to generic NICE guidance on lipid modification. There are some specific areas where guidance in type 1 diabetes would be useful. Mention should be made of the value of the risk assessment tools to be used in diabetes. Mention might also be made on HDL cholesterol levels in people with type 1 diabetes	The Lipids Modification guideline currently being updated and will address lipids modification for patients with diabetes.
SH	Department of Health	15	4.3.2 (a) b	Contraception and preconception care must be noted as failure to consider these leads to unplanned high risk pregnancy with poor outcomes (see point 1)	These topics will be addressed in the Diabetes in Pregnancy guideline and cross referred to in this guideline.
SH	Department of Health	16	4.3.2 (b)	As well as CHO counting include protein and fat counting	The scope of this guideline is already very large and protein and fat counting were not seen as a priority.
SH	The British Psychological Society	2	4.3.2 (e) Cross-reference	Although the scoping document suggests links to other NICE guidance on Depression with a Chronic Physical Illness (NICE 91), Depression in Adults (NICE 90) and Eating Disorders (NICE 9), it does not focus on stress and anxiety disorders. NICE guidance on Anxiety Disorders (CG113, p13) notes that a diagnosis of anxiety should be considered for people with a chronic health problem.	We will ensure that the relevant NICE guidelines are cross referenced.

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			of guidelines	People with Type 1 diabetes have higher levels of clinical anxiety than population norms (Grigsby *et al* 2002). Anxiety is an important threat to well-being in Type 1 diabetes. Anxiety disorders and phobias, particularly needle phobia are linked with poorer self-management (National Collaborating Centre for Chronic Conditions, 2004). On this basis it would be helpful in this review to consider the evidence for a) screening for anxiety in people with Type 1 diabetes to assist health professionals in their delivery of care, and b) evidence for interventions to reduce anxiety. References: CG 113 (2011). *Generalised anxiety disorder and panic disorder (with or without agoraphobia) in adults.* NICE. http://guidance.nice.org.uk/CG113/NICEGuidance/pdf/English Accessed August 2012. Grigsby, A. B., Anderson, R. J., Freedland, K. E., Clouse, R. E. & Lustman, P. J. (2002). Prevalence of anxiety in adults with diabetes: a systematic review. *Journal of Psychosomatic Research.* 53(6):1053-60. National Collaborating Centre for Chronic Conditions (2004). *Type 1 diabetes in adults.* London, Royal College of Physicians.	
SH	Association of British Clinical Diabetologists (ABCD)/Royal College of Physicians (RCP)	3	4.3.2 (e)	Cross reference will be made to existing guidance on psychological issues in people with type 1 diabetes. It would be of value to have a specific statement in the guidance on the value of psychological support in services managing people with type 1 diabetes	This will be the decision of the GDG.

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SH	Department of Health	18	4.3.2 (e)	Diagnosis and recognition of eating disorders and psychological problems.	The guideline will cross refer to the NICE guidelines on psychological problems as appropriate, including the eating disorders guideline.
SH	Bayer plc	1	4.3.2 e	Areas from the original guideline that will not be updated e) Monitoring for retinopathy. It would be useful if this section were updated to make reference to the NHS Diabetic Eye Screening Programme.[1] (1) NHS Diabetic Eye Screening Programme. 2012. Available from: http://diabeticeye.screening.nhs.uk/. (Last accessed: 21/8/2012). (2)	We have made a note of this and it will be addressed by NICE across all of the diabetes guidelines.
SH	Medtronic UK & Ireland	8	4.3.2 (f)	We wonder if with the recent peripheral vascular disease guidelines and the creation of best practice tariffs for treatment of diabetic peripheral vascular disease if there is not an opportunity to update this section rather than leave it unchanged?	We can cross refer to the guideline if appropriate.
SH	Diabetes UK	2	4.3.2.(f)	On the management of diabetic eye disease, can the guideline look at the pathways of treatment for diabetic macular oedema to provide clear recommendations on the use of all of the available treatments for this condition (including licensed and unlicensed treatments)?	Management of retinopathies is covered in the T2D Guideline and by TA's. We will cross-refer.
SH	Juvenile Diabetes Research Foundation	5	4.4	Under point *4.3.1 – h* diabetic ketoacidosis is mentioned in relation to prevention and management, JDRF feel that Ketoacidosis should have its own outcome point in section *4.4*	Each clinical question will have relevant individual outcomes, agreed by the GDG.
SH	Sanofi	5	4.4	'Resource use and cost' should be included as an additional outcome.	Cost effectiveness evidence is searched for every topic.
SH	Abbott Diabetes Ca	10	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 for patients with type 1 be broadened to include all outcomes	Evidence of effectiveness is searched for and reviewed for everyone clinical questions. Each clinical question will also have relevant individual outcomes, agreed by the GDG.

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				relevant to diabetes patients including: a). Patient reported outcome measures - Quality of life - Diabetes-related stress - Treatment satisfaction - Fear of hypoglycaemia - 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.	
SH	Novo Nordisk Ltd	3	4.4	Novo Nordisk recognises the importance of HbA_{1c} as a diabetes outcome measure. We would also like to highlight the requirements of Treat-to-target (TTT) design for clinical trials as recommended in the FDA and EMA guidance[1]. TTT studies are considered best practice and the most ethical way to assess insulin therapies. In these studies the insulin dose is adjusted for each individual subject with the aim of achieving identical glycaemic targets. In such studies any between-treatment	Thank you this is noted.

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				differences are therefore detected via other parameters, for example, the rate of hypoglycaemia. A result of the TTT design is that HbA_{1c} differences between treatment groups will most likely not be significantly different, as the primary aim of the study is to bring all patients to the same glycaemic target. The main difference between insulin therapies subject to this design will be seen in terms of safety parameters, for instance, rates of hypoglycaemia. The rationale behind this trial design is that the benefits of glycaemic control should be balanced with associated side effects of a therapy (e.g. risk of hypoglycaemia), that is, a risk-benefit assessment can be made. The TTT design should result in more balanced outcomes than a trial-design that focuses solely on reducing HbA_{1c}. In summary the Treat-to-target design means limited difference and therefore hypoglycaemia becomes the most important outcome. [1] Food and Drug Administration. Guidance for Industry. Diabetes mellitus: Developing drugs and therapeutic biologics for treatment and prevention - Draft Guidance. Feb 2008. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm071624.pdf. Last accessed 20th Aug 2012.	
SH	Eli Lilly and Company Limited	3	4.4	We suggest that the main outcomes section be expanded to include: ▪ Resource use and cost ▪ Development of microvascular and macrovascular complications ▪ Changes in lipid levels and systolic blood pressure (SBP) ▪ Changes in weight or body mass index (BMI) ▪ Patient satisfaction ▪ Treatment-specific aspects that impact QoL, e.g, treatment satisfaction, ease of device use and fear of	Thank you. Cost effectiveness evidence is reviewed for every question. Also, each clinical question will have relevant individual outcomes, agreed by the GDG.

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				hypoglycaemia	
SH	Department of Health	19	4.4	Outcomes that matter to patients e.g. work days missed.	Thank you, these will be considered.
SH	Medtronic UK & Ireland	9	4.4 (a)	It is important to include disease specific measurements for QoL outcomes where good mapping algorithm exist particularly when considering the fear of Hypoglycaemic events. Could ythere be some clarity of which rating scales are acceptable and included – EQ5D, SF36, Fear Of Hypo etc etc	This will be in the final guideline.
SH	Medtronic UK & Ireland	10	4.4 (b)	Adverse events have not been defined – could there be a list of AE that will be considered that could be commented upon?	These will be considered by the Guideline Development Group. Another consultation is not in the NICE process.
SH	Department of Health	20	4.4 (b)	Could be divided into acute and chronic adverse events and complications.	
SH	Medtronic UK & Ireland	11	4.4 (d)	Glycaemic control not defined in the scope. Will this include measurements such as A1c status, Area Under Curve, Time spent in hypo etc etc. There are many parameters that could be used to measure glycaemic control and the draft could benefit form clarification and debate around which ones will be considered.	Each clinical question will have relevant individual outcomes, agreed by the GDG who will have this debate.
SH	Medtronic UK & Ireland	12	4.4 (e)	Suggest that hyperglycaemia is also included as a negative outcome that must be measured in addition to hypoglycaemeia. Could we have more clarity around what is to be included when considering hypoglycaemia – for example what will be measured to constitute an episode of hypoglycaemia,will fear of hypo be included, are variables such as carer utilization when dealing with hypoglycaemia to be included, what about patients with hypo unawareness will they be considered	Each clinical question will have relevant individual outcomes, agreed by the GDG. The components of hypoglycaemia to which you refer will not be considered in most analyses because they are unlikely to be reported in the available evidence.
SH	Sanofi	6	4.5 [relating to 4.3.1 d & l]	To be consistent with other recent appraisals of insulin we would suggest that the Core Diabetes Model (IMS) is used as the basis for cost effectiveness analyses of the new agents	Thank you very much for your comment. We are aware of the potential usefulness of the CORE diabetes model and the need for consistency with the health economic literature that uses the CORE model. With the commencement of GDG meetings we will decide whether this is an effective and efficient use of resources on a model by model basis.
SH	Sanofi	7	4.5	In principle, given equal efficacy/a cost minimisation framework,	Thank you very much for your comment. When the clinical

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				the drug treatment of choice should be the lowest cost in class.	evidence is reviewed, a difference in efficacy may or may not be found. This will be analysed along side cost in order to establish its cost effectiveness. It is not possible to say at this point whether one drug or class of drug may be cost effective in any given population but consideration of both costs and efficacy will be given to all clinical questions including those on drugs.
SH	Medtronic UK & Ireland	13	4.5	Using the NICE reference case it can be assumed that costs will be broader than the reference case of the NHS & PSS, particularly when considering that the parent/carer and the long term chronic nature of the disease and the costs borne by other Government agencies. NICE Methods does allow for the inclusion of cost outside the NHS & PSS where it has a significant impact on other part of the economy with prior approval from DoH. We believe It is important to formally confirm whether this is such a case prior to the economic evaluation being undertaken	Thank you very much for your comment. When conducting novel economic analyses as part of the guideline we try to conform to the standards set by the NICE reference case. In some situations variations from the NICE reference case are acceptable. The models that are constructed are subject to prioritisation by the GDG depending on the importance of any given topic. The perspective of the analysis will depend on the scope of clinical question that the analysis seeks to answer. Discussions will be held with the GDG and with NICE about the possibility of extending the perspective if the situation is deemed appropriate.
SH	Medtronic UK & Ireland	14	5.2	Additional guidance to be included regarding gastroparesis IPG 103	Thank you this has been included.
SH	WOCKHARDT UK	6	Appendix A	Under Appendix A: Clinical questions and search strategies, the issue of long-term safety of genetically-modified (GM) insulins should be addressed.	The risks and adverse events of all clinical question is reviewed.
SH	RCGP	3	religion	Advice on insulin management during periods of fasting should be considered.	This is considered in the original guideline and won't be updated
SH	RCGP	5	Visual impairment	Advice on management ofpatients with visual impairment should be done. This is a particularly difficult group of people to manage because so much of diabetic control is visual eg pens, meters, daily foot examination.	We agree that this is an important issue. The GDG will consider the implications of visual impairment when formulating their recommendations.
SH	RCGP	4	women	Advice on pre-conceptual blood sugar management should be	This will be addressed in the Diabetes in Pregnancy

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				considered (unless this will explicitly be done in the pregnancy guideline.) The problem is that many type one pregnancies are still unplanned.	guideline and cross referred as appropriate in this guideline.

These organisations were approached but did not respond:

Abertawe Bro Morgannwg University NHS Trust
African HIV Policy Network
Alder Hey Children's NHS Foundation Trust
Alere
Allocate Software PLC
AMORE health Ltd
Anglian Community Enterprise
Association for Family Therapy and Systemic Practice in the UK
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 Children's Diabetes Clinicians
Association of Clinical Pathologists
Association of Renal Industries
B. Braun Medical Ltd
Bailey Instruments Ltd

Bard Limited
Barnsley Hospital NHS Foundation Trust
Baxter Healthcare
BEAT
Bedfordshire and Hertfordshire Tissue Viability Nurses Forum
Birmingham Women's Health Care NHS Trust
Black and Ethnic Minority Diabetes Association
Boehringer Ingelheim
Bolton Primary Care Trust
Bradford District Care Trust
Brahms UK Limited-Thermo Fisher Scientific
Breakspear Medical Group Ltd
Brighton and Sussex University Hospital NHS Trust
Bristol-Myers Squibb Pharmaceuticals Ltd
British and Irish Orthoptic Society
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 Cardiovascular Society
British Dietetic Association
British Hypertension Society
British Infection Association
British Liver Trust
British Medical Association
British Medical Journal

British National Formulary
British Nuclear Cardiology Society
British Paediatric Mental Health Group
British Society for Disability and Oral Health
British Society for Immunology
British Society for Paediatric Endocrinology and Diabetes
British Society for Sexual Medicine
British Society of Interventional Radiology
BUPA Foundation
Calderstones Partnerships NHS Foundation Trust
Camden Link
Camden Provider Services
Capsulation PPS
Capsulation PPS
Care Quality Commission (CQC)
Central & North West London NHS Foundation Trust
Central Lancashire Primary Care Trust
Central London Community Healthcare
Chartered Society of Physiotherapy
CIS' ters
Coeliac UK
College of Emergency Medicine
College of Optometrists
Commission for Social Care Inspection
Countess of Chester Hospital NHS Foundation Trust
County Durham Primary Care Trust
Covidien Ltd.

Croydon Primary Care Trust
Cygnet Hospital Harrow
Cytori Therapeutics Inc
Department for Communities and Local Government
Department of Health, Social Services and Public Safety - Northern Ireland
Diet Plate Ltd, The
Diving Diseases Research Centre, The
DJO UK Ltd
Dorset Primary Care Trust
Dudley Group Of Hospitals NHS Foundation Trust
East and North Hertfordshire NHS Trust
Education for Health
Expert Patients Programme CIC
Faculty of General Dental Practice
Federation of Ophthalmic and Dispensing Opticians
George Eliot Hospital NHS Trust
GlaxoSmithKline
Gloucestershire Hospitals NHS Foundation Trust
Gloucestershire LINk
GP Care
Great Western Hospitals NHS Foundation Trust
Haag-Streit UK
Hammersmith and Fulham Primary Care Trust
Health Angels UK Ltd
Health Protection Agency
Health Quality Improvement Partnership
Healthcare Improvement Scotland

HEART UK
Humber NHS Foundation Trust
Independent Healthcare Advisory Services
Institute of Biomedical Science
Insulin Dependent Diabetes Trust
Insulin Pump Awareness Group - Scotland
Integrity Care Services Ltd.
Intensive Care Society
JBOL Ltd
Johnson & Johnson
Johnson & Johnson Medical Ltd
karimahs cuisina
KCI Medical Ltd
King's College Hospital NHS Foundation Trust
L.IN.C.Medical
Lancashire Care NHS Foundation Trust
Launch Diagnostics
Leeds Community Healthcare NHS Trust
Leeds Primary Care Trust (aka NHS Leeds)
LifeScan
Liverpool PCT Provider Services
Liverpool Primary Care Trust
Luton and Dunstable Hospital NHS Trust
McCallan Group, The
Medicines and Healthcare products Regulatory Agency
Medicines for Children Research Network
Medway Community Centre

Merck Sharp & Dohme UK Ltd
Mid Yorkshire Hospitals NHS Trust
Ministry of Defence
MSD Ltd
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 Concern for Healthcare Infection
National Diabetes Nurse Consultant Group
National Institute for Health Research Health Technology Assessment Programme
National Obesity Forum
National Patient Safety Agency
National Pharmacy Association
National Public Health Service for Wales
National Treatment Agency for Substance Misuse
NDR UK
Neonatal & Paediatric Pharmacists Group
Nester Healthcare Group Plc
Neurocare Europe Ltd
NHS Blood and Transplant
NHS Bournemouth and Poole
NHS Clinical Knowledge Summaries
NHS Confederation
NHS Connecting for Health
NHS London
NHS Manchester

NHS Medway
NHS Nottingham City
NHS Plus
NHS Sheffield
NHS Warwickshire Primary Care Trust
NHS Yorkshire and the Humber Strategic Health Authority

North East London Community Services
NORTH EAST LONDON FOUNDATION TRUST
North East Yorkshire and Northern Lincolnshire Cardiac & Stroke Network
North Essex Mental Health Partnership Trust
North Tees and Hartlepool NHS Foundation Trust
North Yorkshire & York Primary Care Trust
Northumberland Hills Hospital, Ontario
Northumbria Healthcare NHS Foundation Trust
Northumbria Healthcare NHS FT
Nottingham City Hospital
Nova Biomedical UK
Novartis Pharmaceuticals
Nutricia Clinical Care
Nutrition and Diet Resources UK
Obesity Management Association
Office of the Children's Commissioner
OPED UK Ltd
Optical Confederation, The
Overeaters Anonymous
Owen Mumford Ltd
Oxford Centre for Diabetes, Endocrinology and Metabolism

Oxford Nutrition Ltd
Pancreatic Cancer UK
Parkwood Healthcare
Patients Watchdog
PERIGON Healthcare Ltd
Pfizer
Pharmametrics GmbH
Powys Local Health Board
Public Health Agency
Public Health Wales NHS Trust
Randox Laboratories Limited
Renal Association
Renal Nutrition Group, British Dietetic Association
RioMed Ltd.
Robert Jones & Agnes Hunt Orthopaedic & District Hospital NHS Trust
Royal Berkshire NHS Foundation Trust
Royal Brompton Hospital & Harefield NHS Trust
Royal College of Anaesthetists
Royal College of General Practitioners in Wales
Royal College of Midwives
Royal College of Nursing
Royal College of Ophthalmologists
Royal College of Paediatrics and Child Health
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 Surrey County Hospital NHS Trust
Royal United Hospital Bath NHS Trust
Salford Primary Care Trust
Sanctuary Care
Sandwell Primary Care Trust
SCHOOL AND PUBLIC HEALTH NURSES ASSOCIATION
Scottish Intercollegiate Guidelines Network
Sebia
Sexual Advice Association
Sheffield Childrens Hospital
Sheffield Teaching Hospitals NHS Foundation Trust
Slimming World
SNDRi
Social Care Institute for Excellence
Social Exclusion Task Force
Society for Cardiological Science and Technology
Society of Chiropodists & Podiatrists
Solvay
South Asian Health Foundation
South East Coast Ambulance Service
South Staffordshire Primary Care Trust
South Warwickshire NHS Foundation Trust
South West Yorkshire Partnership NHS Foundation Trust

South Western Ambulance Service NHS Foundation Trust
Southern Health & Social Care Trust
St Mary's Hospital
Thames Ambulance Service Ltd
Thames Reach
The Association for Clinical Biochemistry
The British In Vitro Diagnostics Association
The Rotherham NHS Foundation Trust
Torbay and Southern Devon Health and Care NHS Trus
Tunstall Healthcare UK Ltd

UK Clinical Pharmacy Association
UK Ophthalmic Pharmacy Group
UK Thalassaemia Society
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
Welsh Endocrine and Diabetes Society
Welsh Endocrinology and Diabetes Society
Welsh Government
Welsh Scientific Advisory Committee
West Midlands Ambulance Service NHS Trust
Western Cheshire Primary Care Trust
Western Health and Social Care Trust
Westminster Local Involvement Network

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