Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Association of British Clinical Diabetologists (ABCD)	Guideline	General	General	1.3.21 with metformin, suggest a "low and slow" dose titration with empowerment of the pt / carer to decrease dose if intolerable side effects. Mention risk of B 12 deficiency after several years of use.	*Thank you for your comment. This is out of scope for this update.*
Association of British Clinical Diabetologists (ABCD)	Guideline	General	General	Somewhere there needs to be the mention that young people with diabetes are potentially as fertile as their non-diabetic peers, this then should lead to discussion around contraception and risk of passing on diabetes to their off spring (often an un voiced concern of both YP and parents). NICE should explicitly say the 16-18 year olds admitted under paeds should eb treated using the BSPED guideline, and if admitted under the adult team, use the JBDS guideline KD mention the possibility of SGLT-2 use – in type 1 and type 2, in CYP, and the risk of euglycaemic DKA in both (even though this will be unlicensed, they cannot say it does not happen) KD	*Thank you for your comment. This is out of scope for this update.*
Association of British Clinical Diabetologists (ABCD)	Guideline	004	018	1.1.2 Suggest rewording – same day referral is not the same as "same day seen" – need to mention a 7 day accessible service.	*Thank you for your comment. Recommendations on diagnosis are out of scope for this update.*
Association of British Clinical Diabetologists (ABCD)	Guideline	005	005	1.1.4 ? replace "unless there are stong indications…" with – assume type 1 until proven otherwise and manage pt + carers expectations that there may be some diagnostic uncertainty, initially.	*Thank you for your comment. Recommendations on diagnosis are out of scope for this update.*
Association of British Clinical Diabetologists (ABCD)	Guideline	005	027	1.1.7 I don't understand this recommendation – in an obese 18 yr old for eg. we would be checking c peptide and diabetes specific antibodies	*Thank you for your comment. Recommendations on diagnosis are out of scope for this update.*
Association of British Clinical Diabetologists (ABCD)	Guideline	007	005	1.2.3 do they need to attend physically? Possibility of having a meaningful virtual consultation in addition to face to face	*Thank you for your comment. Recommendations on education and information are out of scope for this update.*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Association of British Clinical Diabetologists (ABCD)	Guideline	007	019	1.2.6 sounds as though NICE are pushing towards specific diabetes organizations - ? re phrase stressing benefits of peer support and good governance with regards to information	*Thank you for your comment. Recommendations on education and information are out of scope for this update.*
Association of British Clinical Diabetologists (ABCD)	Guideline	007	024	1.2.7 ? emphasise that it's better to "wear" than carry – we learnt from the Manchester bomb, people get separated from their phones / wallets etc	*Thank you for your comment. Recommendations on education and information are out of scope for this update.*
Association of British Clinical Diabetologists (ABCD)	Guideline	007	027	1.2.8 fully agree with signposting to appropriate state support but is the language right ???disability	*Thank you for your comment. Recommendations on education and information are out of scope for this update.*
Association of British Clinical Diabetologists (ABCD)	Guideline	008	001	1.2.9 why not mental as well	*Thank you for your comment. Recommendations on education and information are out of scope for this update.*
Association of British Clinical Diabetologists (ABCD)	Guideline	008	005	1.2.10 should we be saying teams should actively promote the benefits of sport and offer advice and guidance on how to do this safely	*Thank you for your comment. Recommendations on education and information are out of scope for this update.*
Association of British Clinical Diabetologists (ABCD)	Guideline	009	013	1.2.17 add a caveat around managing expectation – insulin regimes may change over time due to growth, personal circumstances and scientific developments	*Thank you for your comment. Recommendations on insulin therapy are out of scope for this update.*
Association of British Clinical Diabetologists (ABCD)	Guideline	009	020	1.2.18 co prescribe glucagon kit at initiation of insulin therapy	*Thank you for your comment. Recommendations on insulin therapy are out of scope for this update.*
Association of British Clinical Diabetologists (ABCD)	Guideline	010	017	1.2.25 stress the benefits of prolonging the honeymoon phase for as long as possible	*Thank you for your comment. Recommendations on insulin therapy are out of scope for this update.*
Association of British Clinical	Guideline	012	026	1.2.40 suggest practical considerations as opposed to "difficulties"	*Thank you for your comment. Recommendations on dietary management are out of scope for this update.*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Diabetologists (ABCD)					
Association of British Clinical Diabetologists (ABCD)	Guideline	013	016	1.2.46 be mindful of sensitivities around being weighed, and use the opportunity to discuss persons (carers) attitude to their body habitus	*Thank you for your comment. Recommendations on oral medicines are out of scope for this update.*
Association of British Clinical Diabetologists (ABCD)	Guideline	017	005	1.2.65 ? only hyperglycaemia – surely labile glycaemic control too	*Thank you for your comment. This is out of scope for this update.*
Association of British Clinical Diabetologists (ABCD)	Guideline	018	009	1.2.74 mention that other drugs may need to be "paused", if on ace inhibitor for eg	*Thank you for your comment. This is out of scope for this update.*
Association of British Clinical Diabetologists (ABCD)	Guideline	021	001	1.2.84 the whole discussion around alcohol needs to be more wide ranging – alteration in perception of hypoglycaemia (pt and those with them), ability to be able to react to it	*Thank you for your comment. This is out of scope for this update.*
Association of British Clinical Diabetologists (ABCD)	Guideline	021	020	1.2.88 include that the MDT should have an understanding of adolescent brain development and decision making	*Thank you for your comment. This is out of scope for this update.*
Association of British Clinical Diabetologists (ABCD)	Guideline	027	014	1.3 stress that it may be possible to put into remission and in adulthood other treatment options may be offered	*Thank you for your comment. This is out of scope for this update.*
Association of British Clinical Diabetologists (ABCD)	Guideline	028	022	1.3.6 see previous comment around language	*Thank you for your comment. This is out of scope for this update.*
Association of children's diabetes	Evidence review	036	028 - 029	There is no strong evidence for leaving it at 5 and 10% dehydration as stated in point above - For a 40 kg child, it will make a difference(deficit of 5% vs 7%) of 400 mls/24 hours of fluid which might be significant.	*Thank you for your comment. In the PECARN FLUID trial two different protocols were followed in which 10% deficit and 5% deficit were assumed. This study highlighted that these protocols were safe to use as the study did not identify a*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
clinicians (ACDC)					*significant difference in mortality or clinically apparent brain injury. Based on this evidence, the committee retained the 2015 recommendations and stated that in children and young people with mild to moderate DKA, 5% dehydration should be assumed and 10% dehydration should be assumed in children and young people with severe DKA. The committee's discussion and interpretation of evidence is highlighted in section 1.1.11 in the evidence review.*
Association of children's diabetes clinicians (ACDC)	Guideline	General	General	Cleary we can see that the interim DKA guidelines issued by the BSPED was rushed through without adequate consultation and already changes have been made within a few months. This poses a significant issue with having to repeatedly re-educate juniors and general paediatricians who manage vast majority of DKA, about an already detailed guideline/protocol which they struggle to begin with	*Thank you for your comment and for highlighting this issue. We will liaise with our implementation team to see how we can address this*
Association of children's diabetes clinicians (ACDC)	Guideline	040	023	The signs and symptoms of shock have been clearly described, but how does the doctor recognise hypovolaemia	*Thank you for your comment. The committee have removed the term 'hypovolaemia' from recommendation 1.4.23 and amended it to include the term 'clinically dehydrated'.* *The committee have also amended the signs of shock specified in recommendation 1.4.24. The new recommendation includes the following symptoms: weak thready pulse (low volume pulse) and hypotension.* *The committee's discussion and interpretation of evidence section (section 1.1.11) in the evidence review has also been updated based on these amendments.*
Association of children's diabetes clinicians (ACDC)	Guideline	041	004	Does this mean we exclude boluses given for hypokalaemia as well as shock	*Thank you for your comment. Recommendation 1.4.24 has been amended to state that fluid bolus should not be subtracted from the total fluid deficit in children who are in shock. The committee's discussion and interpretation of evidence section (section 1.1.11) in the evidence review has also been updated based on this amendment.*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Association of children's diabetes clinicians (ACDC)	Guideline	041	008 - 009	Children and young people in shock should receive 20mls/kg of normal saline bolus. I assume this is not to be subtracted from maintenance fluid. This should be made clear as there is already a lot of confusion around what needs subtracting in light of new BSPED guideline.	*Thank you for your comment. Recommendation 1.4.24 has been amended to state that fluid bolus should not be subtract from the total fluid deficit in children who are in shock.* *The committee's discussion and interpretation of evidence section (section 1.1.11) in the evidence review has also been updated based on this amendment.*
Association of children's diabetes clinicians (ACDC)	Guideline	041	014	The guideline has categorised the severity of DKA into mild moderate and severe which is in line with new BSPD guidance, however the fluid deficit to be calculated is limited at 5% or 10% as oppose to another addition of 7% in BSPEd guidance. This difference in guidance has potential to confuse clinicians managing the children and young people with DKA. What is the significance in making 3 categories? Why not leave it at mild and moderate if there is no difference in management	*Thank you for your comment. In the PECARN FLUID trial two different protocols were followed in which 10% deficit and 5% deficit were assumed. This study highlighted that these protocols were safe to use as the study did not identify a significant difference in mortality or clinically apparent brain injury. Based on this evidence, the committee retained the 2015 recommendations and stated that in children and young people with mild to moderate DKA, 5% dehydration should be assumed and 10% dehydration should be assumed in children and young people with severe DKA. The committee's discussion and interpretation of evidence is highlighted in section 1.1.11 in the evidence review.*
Association of children's diabetes clinicians (ACDC)	Guideline	042	005	The recommendation is to give 40mmol/l of potassium in fluids unless they have AKI- (stage 1-defined as s. Creatinine> 1.5x normal). Our concern is that this recommendation implies starting on fluid without potassium for those with AKI and normal potassium levels, they will end up with hypokalemia unless there are specific instructions when to review this, We also have reservations about this recommendation as just AKI in absence of anuria doesn't warrant fluid without potassium. There is no evidence for this recommendation	*Thank you for your comment. The committee have amended the recommendation to state that 40 mmol/litre (20 mmol/500ml) potassium chloride should be included in all fluids (except the initial intravenous boluses) given to children and young people with DKA, unless they have anuria or their potassium level is above the normal range. The committee further noted adding potassium should not be delayed because hypokalaemia can occur once the insulin infusion begins. The committee's discussion and interpretation of evidence section (section 1.1.11) in the evidence review has also been updated based on this amendment.*
BNF				We notice that the British Society for Paediatric Endocrinology (BSPED) published some interim guidance in April this year on the Management of Children and Young People under the age of 18 years with Diabetic Ketoacidosis, which differs from some of the updates on diabetic ketoacidosis (DKA)	*Thank you for your comment.* • *Recommendation 1.4.26 has been amended to state that when calculating the total fluid requirement,*

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				mentioned in the draft guideline. We were wondering whether these differences were being taken into account with the NICE guideline update? Particularly since the BSPED DKA Special Interest Group finished revising the 2015 guideline and in view of new evidence felt it should be published as an interim recommendation pending the publication of the future NICE review in 2020/2021. The differences we noticed are as follows: • For children with DKA who require IV fluids but are not in shock, o BSPED recommend a bolus of 10ml/kg 0.9% sodium chloride over 60 minutes, no repeat bolus mentioned, and Plasmalyte 148 is mentioned as a suitable alternative; NICE 1.4.23 recommends the same bolus of 10ml/kg 0.9% sodium chloride but over 30 minutes with repeat ones if needed. o BSPED recommend that the initial 10ml/kg bolus given to all non-shocked patients requiring IV fluids should be subtracted from total calculated fluid deficit; NICE 1.4.23 recommends that when calculating the total fluid requirement, the initial bolus volumes should be excluded from the total • For children with DKA who require IV fluids and are in shock, o BSPED recommend the initial IV bolus of 20ml/kg 0.9% sodium chloride to be given over 15 minutes; NICE 1.4.24 gives the same dose but a time frame of 'as soon as possible'. o BSPED recommend that further boluses of 10ml/kg of 0.9% sodium chloride may be given if required to restore adequate circulation up to a total of 40ml/kg at which stage inotropes should be considered; NICE do not mention further bolus doses for children with DKA who are in shock. • For calculating the fluid deficit, there is a difference in assumptions for mild, moderate and severe DKA,	*subtract any initial bolus volume given from the total fluid deficit (except in children who are in shock).* • *The committee noted that the International Society for Paediatric and Adolescent Diabetes (ISPAD) guideline states that the resuscitation fluids should be administered over 30 to 60 minutes, however, if tissue perfusion is poor the initial fluid bolus is given more rapidly (e.g. over 15-30 minutes). Based on this information the committee highlighted that resuscitation should not be delayed and therefore opted to state initial intravenous bolus of 10 ml/kg 0.9% sodium chloride should be given over 30 minutes.* • *Only one small study (Williams 2020) was identified which compared PlasmaLyte with 0.9% normal saline. This study (which referred to the fluid as PlasmaLyte -A) could not differentiate between the two fluids in outcomes such as incidence of acute kidney injury, mortality, and cerebral oedema. Based on these findings, the committee were unable to form a recommendation. However, the committee are aware that PlasmaLyte-148 is being used in some paediatric units. Based on this, the committee highlighted that further research is needed to explore the effectiveness of PlasmaLyte 148 as a resuscitation fluid in the management of DKA in children and young people with diabetes. Therefore, the committee drafted a research recommendation.* • *In recommendation 1.4.24, the committee specifically stated 'as soon as possible' because they did not want treatment to be delayed.* • *In the PECARN FLUID trial two different protocols were followed in which 10% deficit and 5% deficit were assumed. This study highlighted that these protocols were safe to use as the study did not*

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				o BSPED assume a 5% fluid deficit in children and young people in mild DKA (indicated by a blood pH 7.2-7.29 &/or bicarbonate <15), a 7% fluid deficit in children and young people in moderate DKA (indicated by a blood pH of 7.1- 7.19 &/or bicarbonate <10), and a 10% fluid deficit in children and young people in severe DKA (indicated by a blood pH <7.1 &/or bicarbonate <5); whereas NICE 1.4.25 assumes a 5%deficit in mild to moderate DKA (blood pH 7.1 or above), and a 10% deficit in severe DKA (blood pH below 7.1). • For calculating the fluid management requirement using the Holliday-Segar formula, o BSPED state to give 100ml/kg/day for the first 10kg of body weight, then 50 ml/kg/day for the next 10 to 20 kg and then 20 ml/kg/day for each additional kilogram above 20 kg; whereas NICE 1.4.25 states to give 100 ml/kg for the first 10 kg of weight, then 50 ml/kg for the second 10 kg of weight, then 20 ml/kg for every kg after this. o BSPED recommend that consideration be given to using a maximum weight of 80kg or 97th centile weight for age (whichever is lower) when calculating both deficit and maintenance requirements; whereas NICE 1.4.25 state to use a maximum weight of 75 kg in the calculation. • For oral fluids, o BSPED do not recommend oral fluids for a child who is receiving IV fluids for DKA until ketosis is resolving and there is no nausea or vomiting; whereas NICE 1.4.22 mentions the child should also be alert. • For stopping IV fluids, o BSPED recommend thinking about stopping when ketosis is resolving and oral fluids are tolerated without nausea or vomiting; whereas NICE 1.4.37 recommend thinking about stopping ketosis is resolving, their pH has reached 7.3, the child is alert, and they can take oral fluids without nausea or vomiting.	*identify a significant difference in mortality or clinically apparent brain injury. Based on this evidence, the committee retained the 2015 recommendations and stated that in children and young people with mild to moderate DKA, 5% dehydration should be assumed and 10% dehydration should be assumed in children and young people with severe DKA.* • *The committee noted that the formula has shown to be safe with no adverse events and is commonly used in practice. The formula was also used in the PECARN FLUID trial and has been recommended in the ISPAD guideline.* • *The committee used 75kg for the maximum weight for the calculations because this weight corresponds closest to an 18-year-old in the 75th centile on the UK WHO growth chart.* • *The committee retained the 2015 recommendation that states that oral fluids should not be given to a child or young person who is receiving IV fluids for DKA unless ketosis is resolving, they are alert and they are not nauseated or vomiting.* • *Thank you for your comment. The committee noted that resolution of DKA is defined as pH greater than 7.3. The committee retained the pH threshold but amended the recommendation to state that clinicians should think about stopping intravenous fluid therapy for DKA in a child or young person if ketosis is resolving and blood pH has reached 7.3, they are alert, and they can take oral fluids without nausea or vomiting. In children and young people who still have mild acidosis or ketosis, discuss with the responsible senior paediatrician before stopping intravenous fluid therapy and changing to oral fluids.*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					Committee's full discussion is highlighted in section 1.1.11 in the evidence review.
British Dietetic Association – Obesity group	Guideline	General	General	Thank you for the opportunity to comment on this document. After consideration, we do not have any comments to make given the limited scope of the update.	*Thank you for your comment.*
Central and North West London NHS Foundation Trust	Guideline	General	General	Cross referencing the diabetic standards for schools	*Thank you for your comment. This is out of scope for this update.*
Central and North West London NHS Foundation Trust	Guideline	General	General	Cross referencing with Diabetes UK starter pack for newly diagnosed children and young people.	*Thank you for your comment. This is out of scope for this update.*
Central and North West London NHS Foundation Trust	Guideline	General	General	Disability Act- It should be made clearer that it is the child's right to attend mainstream school with diabetes as a disability as long as there is support in the school for it to be safely managed. This is an expectation of schools for equal opportunities but it is dependent upon partnership working between the health professionals and the school.	*Thank you for your comment. This is out of scope for this update.*
Central and North West London NHS Foundation Trust	Guideline	General	General	Consideration for literature on diabetes to be written in other languages, not only English.	*Thank you for your comment. This is out of scope for this update.*
Central and North West London NHS Foundation Trust	Guideline	General	General	Health care professionals should be considering the impact of school examinations and diabetes- medical letters for extensions and ensuring that breaks to check blood sugars in exams should be provided.	*Thank you for your comment. This is out of scope for this update.*
Central and North West London NHS	Guideline	General	General	Cross reference with the Eatwell plate and the use of encouraging accurate reading of food labels: Sorbitol in foods can cause diarrhoea and abdominal pain in diabetic children	*Thank you for your comment. This is out of scope for this update.*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Foundation Trust					
Central and North West London NHS Foundation Trust	Guideline	General	General	If seen in SN clinic – discuss any concerns, discuss diet/weight if applicable, ensure they're attending their appointments and feel supported by Diabetic Team	*Thank you for your comment. This is out of scope for this update.*
Central and North West London NHS Foundation Trust	Guideline	General	General	Inform of any organisations/groups for Diabetics where they can meet others with condition	*Thank you for your comment. This is out of scope for this update.*
Central and North West London NHS Foundation Trust	Guideline	General	General	Emotional/Mental Health support as chronic illnesses were proven to affect children and young people's mental health – assessment and appropriate support needs to be in place	*Thank you for your comment. This is out of scope for this update.*
Central and North West London NHS Foundation Trust	Guideline	006	011	The Guidelines mention educating parents and carers but not Schools. It is essential that information is shared with the School and training of education staff is provided in school to manage the child's condition. Delivery of education for teachers tailored to children that they have at school for any specific training to ensure safety of the pupil.	*Thank you for your comment. Recommendations on diagnosis are out of scope for this update.*
Central and North West London NHS Foundation Trust	Guideline	007	014	We consider that annually and not two-yearly optician screening is necessary for diabetic children. Children without a medical condition are encouraged to have annual screening routinely and it is even more imperative for a diabetic child.	*Thank you for your comment. Retinopathy recommendations were updated as part of a refresh of the guideline. Recommendation 1.2.4 is a standard recommendation on eye examination. Diabetic screening is covered by recommendation1.2.117.* *Recommendation 1.2.4 has been amended to state that children and young people with type 1 diabetes should have an eye examination by an optician at least every 2 years.*
Central and North West London NHS	Guideline	007 028	027 022	Have awareness of Disability Benefits that family may be able to claim	*Thank you for your comment. Recommendations on education and information are out of scope for this update.*

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Foundation Trust					
Central and North West London NHS Foundation Trust	Guideline	008 028	01 025	Be aware of any potential communication barriers (language, disability etc) – avoid medical jargon (health literacy of adults can be that of a 11 year old so ensure that they understand and are encouraged to ask questions – never rush so that they feel comfortable to ask for clarification)	*Thank you for your comment. Recommendations on education and information are out of scope for this update.*
Central and North West London NHS Foundation Trust	Guideline	009 029	004 019	Ensuring immunisations are up to date	*Thank you for your comment. Recommendations on immunisation are out of scope for this update.*
Central and North West London NHS Foundation Trust	Guideline	015	014	It is not advisable to drive with high blood sugar as well as with low blood sugar.	*Thank you for your comment. Recommendations on blood glucose targets are out of scope for this update.*
Central and North West London NHS Foundation Trust	Guideline	018	018	A 24 hour help line service should be available from the Specialist Diabetic clinic/ Nurses for urgent specialist advice and help	*Thank you for your comment. This is out of scope for this update.*
Central and North West London NHS Foundation Trust	Guideline	025 034	004 001	Monitoring of condition – changes to frequency of usage, A&E attendances increase, any reported concerns from teachers to be followed up with diabetes team. If unsure of current treatment plan or any changes then liaise with specialist team/GP	*Thank you for your comment. This is out of scope for this update.*
Coeliac UK	Guideline	025	017	We are pleased to see a reference to coeliac disease within the draft guideline. However we would like to request that the recommendation for testing people with type 1 diabetes for coeliac disease is clearly stated within recommendation 1.2.111 rather than cross-referencing the NICE guideline for coeliac disease (NG20).	*Thank you for your comment. This is out of scope for this update.*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				We are concerned that the recommendation from NICE NG20 that everyone with type 1 diabetes should be offered serological testing for coeliac disease at diagnosis will be missed with the guideline in its current format. Between 4 - 9% of people with Type 1 diabetes will have coeliac disease [1] and so it is important to raise awareness of the recommendation for testing for coeliac disease to ensure that the diagnosis is not missed. The NICE guideline for coeliac disease (NG20) also recommends that people with type 1 diabetes who have a negative test for coeliac disease should be advised that coeliac disease may present with a wide range of symptoms and that they should consult their healthcare professional if any symptoms suggestive of coeliac disease arise. [1] As coeliac disease can develop at any age, this patient education is important as people with type 1 diabetes experiencing gastrointestinal symptoms may not consider these symptoms relevant to their diabetes and therefore may not report such symptoms to their healthcare team during their annual review. [1] National Institute for Health and Clinical Excellence (2015) Coeliac disease: recognition, assessment and management	
Dexcom International	Guideline	016	018	Recommend that real-time continues glucose motoring is recommended for insulin using adolescent diabetics with HbA1c over 7.5%. In individuals with type 1 diabetes, the opportunity to have optimal glycaemic control as early as possible is critical to establishing good long-term HbA1c. It has been shown that people with Type 1 diabetes HbA1c is heavily influenced in	*Thank you for your comment. Review of CGM has been deferred while a review is being carried out on integrated sensor- augmented pump therapy systems for managing blood glucose levels in type 1 diabetes (https://www.nice.org.uk/guidance/dg21/evidence/review-decision-january-2020-pdf-8830079533).*

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				the first five years of treatment[1]. In addition to this it has been demonstrated that people with Type 1 diabetes with poorly controlled HbA1c attending school have suboptimal educational outcomes in comparison to people without diabetes[2]. Recently, Mulinacci et al (2019)[3] performed a retrospective analysis of 396 patients with newly-diagnosed T1D, clearly demonstrated that initiating patients on rt-CGM within a year of diagnosis, with or without insulin pump therapy, provided superior and sustained HbA1c benefit compared to insulin pump or MDI therapy alone. At baseline, mean HbA1c did not vary significantly between groups and was ~ 102 mmol/mol [~11.5%]. For 2.5 years of follow-up, the MDI+CGM group had 16.4 mmol/mol [1.5%] lower HbA1c than the MDI-only group (61 vs 77 mmol/mol [7.7% vs. 9.2%,] [P < 0.0001]). The number of diabetes-related emergency department visits was also significantly lower among early rt-CGM users compared with non-CGM users (P = 0.003). As previously mentioned, glycaemic control may settle into long-term patterns within the first 5 years after diagnosis, this study supports the notion that early initiation of rt-CGM within 1 year of diagnosis may help to improve long-term control and reduce long-term complications.	

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				Thabit et al (2020)[4] conducted a randomized crossover trial in young people with type 1 diabetes (16–24 years old) comparing the Dexcom G6 rt-CGM system and self-monitoring of blood glucose (SMBG). This analysis demonstrated that even in this hard to treat population the introduction of rt-CMG resulted in significant improvements in glycaemic control. HbA1c level reduced by 0.53 ± 0.74% (5.9 ± 8.0 mmol/mol) during the rt-CGM period and increased by 0.24 ± 0.69% (2.6 ± 7.5 mmol/L) during the control (SMBG) period (mean difference CGM v s. control; -0.76% [95% CI -1.1 to -0.4] [-8.5 mmol/mol (95% CI -12.4 to -4.6); P,0.001]). HbA1c was lower in participants on rt-CGM during the first and second treatment periods. It is noteworthy that 58% of the participants lived in areas of relatively high deprivation and 30% lived in the most deprived areas of England. References 1. Nirantharakumar K, et al. Clinically meaningful and lasting HbA1c improvement rarely occurs after 5 years of type 1 diabetes: an argument for early, targeted and aggressive intervention following diagnosis. Diabetologia 2018;61:1064–1070.	

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				2. Fleming M et al, Educational and Health Outcomes of Children Treated for Type 1 Diabetes: Scotland-Wide Record Linkage Study of 766,047 Children, Diabetes Care, 2019 3. Mulinacci et al., Glycemic Outcomes with Early Initiation of Continuous Glucose Monitoring System in Recently Diagnosed Patients with Type 1 Diabetes. Diabetes Technol Ther. 2019;21(1):6-10. 4. Thabit et al, Comparison of Dexcom G6 CGM with Self-Monitoring Blood Glucose in Young Adults with Type 1 Diabetes: The Millennial Study, 2020, American Diabetic Association	
Diabetes UK	Guideline	General	General	Diabetes UK welcomes the update to this guideline, but we are disappointed with the limited remit of the scope and proposed updates included within the draft guideline. There are several areas we would urge the Committee to consider updating, despite not having been considered in the scope or draft guideline. For example, we know that growing numbers of children are using a hybrid closed-loop system for integrated blood glucose monitoring and insulin delivery, and we believe that the decision not to provide recommendations to healthcare professionals on the care of children using closed-loop systems risks affecting clinicians' confidence in using the guidance more broadly. We also argue that decisions not to update guidance on the frequency of finger-	*Thank you for your comment. The review of CGM has been deferred while a review is being carried out on integrated sensor- augmented pump therapy systems for managing blood glucose levels in type 1 diabetes (https://www.nice.org.uk/guidance/dg21/evidence/review-decision-january-2020-pdf-8830079533).* *Recommendations on emotional and psychological support and frequency of finger-prick blood glucose monitoring were out of scope for this review question.* *We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				prick blood glucose monitoring will mean that the guidance does not reflect international consensus. Additionally, we believe the existing recommendations do not reflect clinical practice in the care of children and young people with type 2 diabetes, and the draft guideline should provide more comprehensive guidance on treatment options. We also note that elements of the scope appear not to have been taken forward for update – specifically covering blood glucose monitoring for type 1 diabetes, and monitoring for complications and associated conditions of both type 1 and type 2 diabetes. We consider mental ill-health and diabetes-related eating disorders to be clearly associated conditions of diabetes, and the decision not to update recommendations on emotional and psychological support and on insulin omission for weight loss, known as diabulimia, are missed opportunities. These are issues people living with diabetes and healthcare professionals have told us are important, and the lack of detailed recommendations is impacting on the level of tailored support available to those affected. We urge that the final guidance, when published, reflects current good clinical practices, and focuses on achieving the outcomes important for people living with diabetes. In its current format, this draft guideline risks not being fit-for-purpose and therefore having a significant impact on how healthcare professionals engage with it and children and young people living with type 1 and type 2 diabetes benefit from it.	
Diabetes UK	Guideline	General	General	We know that continuous glucose monitors can sometimes be integrated with insulin pumps to form hybrid closed-loop artificial pancreas systems. We consider it a clear missed opportunity for this draft guideline not to make	*Thank you for your comment. Review of CGM has been deferred while a review is being carried out on integrated sensor- augmented pump therapy systems for managing blood glucose levels in type 1 diabetes*

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				recommendations about the benefit of insulin pumps with predicted low glucose suspend and hybrid closed-loop systems. These systems are widely accepted as the future of type 1 diabetes treatment. Diabetes UK is aware that growing numbers of children and young people with type 1 diabetes are using closed-loop systems to manage their condition, and guidance around their use and appropriateness for some groups would be beneficial for diabetes healthcare professionals as well as closed-loop users, their families, and their carers. As noted in the ISPAD Consensus Guidelines, low glucose suspend systems reduce the severity and duration of hypoglycaemia while not leading to the deterioration of glycaemic control, and predictive low glucose suspend systems can prevent episodes of hypoglycaemia and have been shown to reduce hypoglycaemia exposure. Closed-loop systems improve time in range of target blood glucose levels, including minimizing hypoglycaemia and hyperglycaemia. Closed-loop systems have also proven beneficial in reaching targeted control in the overnight period. Further research has shown that whilst CGM technology is useful, hybrid closed-loop systems are the best option in maintaining optimal glycaemic control for preventing the occurrence of severe hypoglycaemia in young people with type 1. A 2016 RCT assessing the effectiveness of closed-loop systems in adolescents with no remote monitoring found that the use of closed-loop systems was more effective than sensor-augmented pump therapy as young people spent a greater percentage of time with their glucose level in their target range. Children are found to have experienced similar benefits from using closed-loop systems. Another recent study showed that children using a closed-loop system over	*(https://www.nice.org.uk/guidance/dg21/evidence/review-decision-january-2020-pdf-8830079533).*

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				16 weeks spent an average of 11% more time in range, compared to sensor segmented pump delivery.	
Diabetes UK	Guideline	General	General	**Immunotherapy trials for children – treating type 1 diabetes** Insulin remains the only treatment for type 1 diabetes recommended by the draft guideline. Immunotherapy treatments present a potential alternative form of treatment for children diagnosed with type 1 diabetes, and we recommend the draft guideline encourage further participation and support research into clinical trials. At the time of diagnosis, people with type 1 diabetes have up to 20% of their beta-cells remaining, which make blood glucose control easier. Data from the National Paediatric Diabetes Audit (2018/19) shows that the average HbA1c in children and young people in the first year after their diagnosis is 59.0 mmol/mol. Over the subsequent five years, it's estimated that over 90% of people lose the majority of their residual beta-cell function and average HbA1c rises to 68.1 mmol/mol. Immunotherapy treatments could prevent or delay autoimmune attacks when given at the point of diagnosis, allowing patients to retain insulin. Evidence shows that even a small amount of insulin production is associated with improved blood glucose control, a reduction in severe hypoglycaemia and fewer diabetes complications. Despite immunotherapy drugs for type 1 diabetes being tested in clinical trials, with several therapies showing evidence that they're able to slow the rate of beta-cell reduction, there are still no licensed treatments. Immunotherapy drugs need to be given when people still have some beta-cell function, and as such, most trials have a 100-	*Thank you for your comment. This is out of scope for this update.*

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				day window after diagnosis when someone can take part. This significantly narrows the pool of people with type 1 diabetes who could be eligible for trials. This lack of participation is a barrier to progress, and we believe that the draft guideline should reflect that more people should be referred to clinical trials.	
Diabetes UK	Guideline	025 - 027	017 - 019	1.2.11 - 1.2.121: **Monitoring for complications and associated conditions of type 1 diabetes** Despite the consultation scope including monitoring for complications and associated conditions of type 1 diabetes, we are disappointed to note that this area has not been updated within the draft guidance. The draft guidance currently recommends an annual review of potential complications of type 1 diabetes from the age of 12. This should be reviewed in light of the ISPAD Consensus Guidelines and American Diabetic Association Standards of Medical Care which both make evidence-based recommendations for earlier screening. Specifically, these guidelines recommend screening for albuminuria, retinopathy, neuropathy, and dyslipidaemia from the age of 11. Early screening of complications is important as childhood and young adulthood is a period during which education and early treatment interventions may prevent or delay the onset and progression of complications. This section should also include recommendations on the treatment of complications. This is often highlighted by paediatric diabetes teams as an area they need guidance on. Recommendations for the treatment of dyslipidaemia, hypertension, albuminuria, and retinopathy should be developed and included in this draft guideline.	*Thank you for your comment. This is out of scope for this update.*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				1.2.113: The draft guidance refers to NG20: Coeliac Disease for guidance on monitoring for coeliac disease in children and young people with type 1 diabetes. The evidence for this is not up-to-date and NG18 should be reviewed and amended to be in line with ISPAD Consensus Guidelines and ADA Standards of Medical Care, which are widely recognised and accepted internationally. NG20 correctly acknowledges that people with conditions such as type 1 diabetes are at a higher risk than the general population of having coeliac disease, however, there are limited specific recommendations for treating coeliac disease alongside type 1 diabetes, and the guideline particularly lacks specific recommendations for children and young people. The draft guideline should include a recommendation to consider screening for coeliac disease. The ISPAD and ADA recommend that screening for coeliac disease should be performed at 2 and 5 years after diabetes diagnosis, with more frequent assessments if the clinical situation suggests the possibility of coeliac disease. The final guideline should include recommendations to refer children and young people with type 1 diabetes detected to have positive celiac antibodies to a paediatric gastroenterologist. Upon diagnosis of coeliac disease, children and young people and their families or carers should receive educational support from a paediatric dietitian experienced in managing both diabetes and coeliac disease, along with educational materials.	
Diabetes UK	Guideline	016	002 - 029	1.2.59: **Blood Glucose Monitoring** We note that while the published scope of this consultation included blood glucose monitoring as an area for update, the draft guideline does not include any new or amended recommendations.	*Thank you for your comment. Review of CGM has been deferred while a review is being carried out on integrated sensor- augmented pump therapy systems for managing blood glucose levels in type 1 diabetes*

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				We are concerned that the recommendation of "at least 5 capillary blood glucose tests per day" may result in a restriction of test strips being prescribed to children and young people, as GPs may only prescribe enough for 5 tests a day, which will not be sufficient for children and young people. We, therefore, suggest that the guidance surrounding the frequency of finger-prick blood glucose checking should be reviewed in light of the ISPAD Clinical Practice Consensus Guidelines 2018 and ADA Type 1 Diabetes in Children and Adolescents: A Position Statement recommendations of at least 6 – 10 times a day with regular and frequent reviews of results to optimize glycaemic control. This should include pre-meal and pre-bedtime checks and checks as needed for safety in specific situations such as exercise, driving, illness, or the presence of symptoms of hypoglycaemia. There is also a missed opportunity to make clear recommendations in this draft guideline around the use of Flash glucose monitoring in children and young people – despite evidence showing that it can improve short- and long-term clinical outcomes. It is short-sighted for NICE not to revisit recommendations about methods of glucose monitoring in children and young people. There is a clear risk that, as growing numbers of children and young people are given access to Flash glucose monitoring, this guideline will no longer feel relevant to the community it is designed to serve. Further, we suggest that given international consensus states that children and young people should test blood glucose levels 6-10 times a day, Flash is likely to be a cost-effective alternative to finger-prick testing. There are also real-world data showing the benefit of Flash use in clinical practice. We hope NICE will consider this type of evidence, as per the statement of intent NICE recently published on this topic.	*(https://www.nice.org.uk/guidance/dg21/evidence/review-decision-january-2020-pdf-8830079533).*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				1.2.64: **Real-time Continuous Glucose Monitoring** (CGM) We suggest that this recommendation should be reviewed and amended to address the qualification "for example national-level sport" in particular. This qualification presents a barrier to the provision of CGM, as commissioning bodies often refuse CGM for children who undertake high levels of exercise but are not yet competing at this high level. Lack of CGM could risk impairing their diabetes management meaning that they are never able to achieve such level of a sport. See also Diabetes UK's Position Statement on Type 1 Technology.	
Diabetes UK	Guideline	021	015 - 018	1.2.87: **Assessment of cognitive function** This recommendation should be updated considering clear evidence showing that hypoglycaemia, as well as hyperglycaemia, can cause cognitive impairment during childhood and young adulthood. The ADA's Standards of Medical Care have developed recommendations in this area that we suggest could be used to update the draft guideline. A constant supply of glucose to the brain is critical for normal cerebral metabolism, however, the dysglycaemia of type 1 diabetes can affect activity, survival, and function of neural cells. Clinical studies in type 1 diabetes have shown impairments in brain morphology and function. To prevent adverse effects of type 1 diabetes on cognition during childhood and young adulthood, the ADA recommends that meticulous use of new therapies (such as rapid- and long-acting insulin), technological advances (e.g., continuous glucose monitors, low-glucose suspend insulin pumps, and	*Thank you for your response. This is out of scope for this update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.*

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				closed-loop systems), and intensive self-management education now make it more feasible to achieve glycaemic control while reducing the incidence of severe hypoglycaemia. They also note the strong relationship between the frequency of blood glucose monitoring and glycaemic control. We recommend that the draft guideline recognises the potential for cognitive impairment to occur due to hypoglycaemia and hyperglycaemia and make specific recommendations around the proper use of therapies and technologies to help children and young people to avoid these adverse outcomes.	
Diabetes UK	Guideline	022 032	General	1.2.95 - 1.2.110 and 1.3.32 - 1.3.41: **Psychological and social issues** We note that the published scope for this draft guideline included the complications and associated conditions in type 1 and type 2 diabetes – we consider mental ill health a clear associated condition of both types of diabetes. There is evidence to support further detail and recommendations being added to the draft guidance around mental health. Recommendations around screening for emotional distress and mental health problems in children and young people should be reviewed and the draft guideline updated accordingly, with reflection on the recommendations from the ADA Standards of Medical Care (2020). The ADA recommends assessing psychosocial issues and family stresses that could impact diabetes management and providing referrals to trained health professionals, preferably experienced in childhood diabetes. Additionally, mental health professionals should be considered integral members of the paediatric diabetes team. From the age of 7 to 8 years old, assess youth with diabetes for psychosocial and diabetes-	*Thank you for your response. This is out of scope for this update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date*

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				related distress, generally starting at 7 to 8 years old. Early detection of depression, anxiety, eating disorders, and learning disabilities can facilitate effective treatment options and help minimize adverse effects on diabetes management and adverse outcomes.	
Diabetes UK	Guideline	024 025	019 - 028 001 - 003	1.2.108 - 1.2.110: **Eating disorders** We note that the published scope for this draft guideline included the complications and associated conditions of type 1 diabetes – we consider diabulimia (insulin omission for weight loss) a clear associated condition of type 1 diabetes. We appreciate that the draft guideline notes that children and young people with type 1 diabetes (in particular young women) have an increased risk of eating disorders, there is, however, currently no specific mention of insulin omission for weight loss, also known as diabulimia, in the draft guideline. Diabulimia is a term used to describe a 'disordered eating behaviour' in the practice of reducing or omitting insulin in order to lose weight. Omitting insulin can lead to hyperglycaemia and puts individuals at risk of long-term complications from high blood glucose levels. Risk factors and signs that may indicate diabulimia should be reviewed and the draft guideline should include clear recommendations on this condition. The draft guideline currently refers to NG69: Eating Disorders, which recognises diabulimia and provides a treatment plan for people with diabetes who are misusing insulin and recommends joint management of patients involving their diabetes team and child mental health professionals. We appreciate that this guideline notes that providing treatment which fully addresses eating disorders and diabetes requires both the input of eating disorder and diabetes specialist teams working together, however, this along with the referral to	*Thank you for your response. This is out of scope for this update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				NG69 is not sufficient as neither include specific information or recommendations for children and young people with diabetes and eating disorders, including diabulimia. The lack of detailed recommendations is impacting on the level of tailored support available to those affected. We recommend that the draft guideline should reflect that better access is needed to diabetes specialist psychological services that can provide the integrated support that children and young people with diabulimia need. See also Diabetes UK's Position Statement on Diabulimia (2018).	
Diabetes UK	Guideline	032	007 - 015	1.3.30 – 1.3.31**: Metabolic surgery** NG18 currently only recommends Metformin as a treatment option for children and young people living with type 2 diabetes, which many healthcare professionals view as inadequate. Diabetes UK is very disappointed to see no update to this section of the guidance and would suggest this decision renders this draft guideline inadequate for the needs of children and young people living with type 2 diabetes. Metabolic surgery has emerged as a potential treatment for obesity as research has shown it to result in substantial and durable weight reduction. Increasing interest in the application of metabolic surgery for adolescents with type 2 diabetes has emerged in part because of the evidence demonstrating improvement or remission in many adults with diabetes after surgery. Despite this, NG18 provides very limited recommendations on metabolic surgery for adolescents with type 2 diabetes. The evidence in this area should be reviewed in light of research showing the benefit of metabolic surgery for adolescents with type 2 diabetes.	*Thank you for your response. This is out of scope for this update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				Mirroring results seen in adults, metabolic surgery improved glycaemic control in adolescent patients with type 2 diabetes, with remission being observed in as many as 95 – 100% of adolescents with type 2 diabetes. Recent studies also suggest that type 2 diabetes-related comorbidities may also improve after surgery. Guidance on criteria for metabolic surgery and signposting to existing NICE guidelines should be included in NG18, specifically NICE Clinical Guideline 189: Obesity: identification, assessment and management (2014). CG189 states that metabolic surgery may be considered for children and young people only in exceptional circumstances, and if they have achieved or nearly achieved physiological maturity. This recommendation was last updated in 2006. The metabolic surgery section doesn't provide guidance for young people with type 2 diabetes, nor does it include assessment criteria to be used in considering young people with type 2 diabetes for surgery. The ADA recommends that metabolic surgery may be considered for the treatment of young people with type 2 diabetes who are markedly obese (BMI >35 kg/m^2) and who have uncontrolled glycemia and/or serious comorbidities despite lifestyle and medication. The draft guideline should be updated to reflect the ADA recommendations, and provide recommendations for metabolic surgery specifically for young people with diabetes, including advice around paediatric and diabetes specialist expertise requirements and recommended follow-up care specific to young people with type 2 diabetes.	
Diabetes UK	Guideline	034	005 - 007	1.3.21: **Metformin** NG18 currently recommends only metformin as a treatment option for type 2 diabetes. However, there is strong evidence to support the fact that children and young people with type 2	*Thank you for your response. This is out of scope for this update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.*

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				diabetes fail to meet glycaemic targets within an average of 11 months on metformin alone. Children and young people with type 2 diabetes are often then prescribed insulin, which is not covered by the guidance. As such, existing recommendations do not reflect clinical practice in the care of children and young people with type 2 diabetes. We recommend that the draft guideline includes guidance on treating children and young people who develop type 2 diabetes with insulin, in line with internationally recognised and accepted ISPAD Consensus Guidelines and ADA Standards of Medical Care guidelines. The ADA recommends that when the HbA1C target is no longer met on metformin alone, or if contraindications or intolerable side effects of metformin develop, insulin therapy should be initiated, either alone or in combination with metformin. Children and young people with type 2 diabetes and their families or carers should be educated about the avoidance, recognition, and treatment of hypoglycaemia, although the incidence of hypoglycaemia in young people with type 2 diabetes is low. The draft guideline should also recommend that a dietitian is involved in patient care when insulin treatment is initiated, as treatment may result in weight gain. Given the poor outcomes of children and young people with type 2 diabetes, it is vital that the available evidence on medication is thoroughly reviewed, and recommendations are made accordingly. New evidence suggests that liraglutide improves glycaemic management in adolescents. In children and adolescents with type 2 diabetes, liraglutide, at a dose of up to 1.8 mg per day (added to metformin, with or without basal insulin), was efficacious in improving glycaemic control over 52 weeks.	

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Diabetes UK	Guideline	034 – 036	General	1.3.42 - 1.3.57: **Monitoring for complications and associated conditions of type 2 diabetes** Despite the consultation scope including monitoring for complications and associated conditions of type 2 diabetes, we are disappointed to note that this area has not been updated within the draft guidance. The draft guideline currently provides little in recommendations for screening for complications when compared to the guidelines from IPSAD Consensus Guidelines and the ADA Standards of Medical Care guidelines. Given the poor outcomes of children and young people with type 2 diabetes, the incidence of comorbidities and the faster progression to complications, it is essential that NICE provides robust recommendations in this area. The draft guideline should also include recommendations on treating complications and comorbidities in children and young people with type 2 diabetes. Recommendations for the treatment of dyslipidaemia, hypertension, albuminuria, and retinopathy, specifically, should be included.	*Thank you for your comment. This is out of scope for this update.*
Diabetes UK	Guideline	040 – 044	General	1.4.21 - 1.4.40: **Fluid and insulin therapy** We welcome the addition of new and updated recommendations on fluid and insulin therapy for diabetic ketoacidosis. Diabetes UK has supported the creation of a National Inpatient Diabetes Covid-19 Response Team chaired by Professor Gerry Rayman. The group have published a series of new guidance to support inpatient diabetes care during the Covid-19 pandemic. Please see the guidance specific to	*Thank you for your response.*

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				managing DKA using subcutaneous insulin, and the guidance for managing inpatient hyperglycaemia. COncise adVice on Inpatient Diabetes (COVID:Diabetes): Guideline for managing DKA using subcutaneous insulin. COncise adVice on Inpatient Diabetes (COVID:Diabetes): Guidance for managing inpatient hyperglycemia.	
Imperial College Healthcare NHS Trust, St Mary's Hospital	Guideline	General	General	**Two important issues that could be helpful to include in the guidelines** **1- Hyperchloremic Acidosis** • It would be helpful like to see a section in the guidelines that addresses hyperchloremic acidosis as it is quite commonly encountered following the treatment of DKA particularly after the use of boluses and/or prolonged infusion of normal saline. Not only it takes a while of this acidosis to resolve, prolonging the unnecessary stay in the hospital, but the high sodium associated with hyperchloremia may be interpreted as dehydration and dangerously more fluid may be given increasing the risk of cerebral oedoema. **2- Insulin sensitivity** We find establishing accurate insulin sensitivity for each individual diabetic extremely helpful in managing hyperglycemia and helping to clear ketones safely and quickly. I feel there should be some guidance within the guidelines about establishing insulin sensitivity factor.	*Thank you for your comment. The committee have added a further recommendation (Rec 1.4.28) to state that some children and young people may develop hyperchloremic acidosis (defined as a persisting base deficit or low bicarbonate concentration despite evidence of resolving ketosis and clinical improvement) but this resolves spontaneously over time and does not require any specific management. The committee's discussion and interpretation of evidence section (1.1.11) in the evidence review has been amended to highlight their discussion.* *Insulin insensitivity is out of scope of this update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.*
Imperial College Healthcare NHS Trust, St	Guideline	General	General	**I would like to make suggestions for additional guidance managing type 1 diabetes**	*Thank you for your comment. This is out of scope for this update. We will pass your comment to the NICE surveillance team which monitors guidelines to ensure that they are up to date.*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Mary's Hospital				Modern management of type 1 diabetes depends on establishing 3 important factors: **- Insulin Sensitivity ISF,** **- Glucose Sensitivity GSF and** **- Insulin Carb Ratio ICR.** ISF and ICR are very important to manage type 1 diabetes whether on the pump or on the basal bolus with carb counting and have to be accurate to provide the best results. GSF which is the number of grams of carb that raises the blood glucose by 1 mmol/L is equally important and has two important roles: 1- Very usefully quantify the treatment of hypo. it is based on the weight of the child. 2- It create a very helpful link between ICR and ISF **(ISF X GSF = ICR**) This is really important in adjusting the dose of insulin whether on the pump or on the basal bolus because whenever ICR changes ISF has to follow and ease in the same direction Our team at St Mary's always try to establish these 3 factors with tremendous help in the management of type 1 diabetes	
Imperial College Healthcare NHS Trust, St Mary's Hospital	Guideline	019	016 - 022	**The guidelines recommend** "Immediately treat mild to moderate hypoglycaemia in children and young people with type 1 diabetes as follows. • Give oral fast-acting glucose (for example, 10 to 20 g) (liquid carbohydrate may be easier to swallow than solid) **Comment:** This is one size fit all for all treatment which is too much for a 10kg child and too little for 50 or 60 kgs young person **Suggestion**	*Thank you for your comment. This is out of scope for this update.*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				Use the 500 mg/kg recommended by this guidelines on the next page(page20) lines 3-7 for treating any hypo including oral correction at home. It is size dependant and we use it (orally or IV) successfully to raise the blood glucose by about 4 mmo/L which is quite enough to safely correct the big majority of hypos.	
Imperial College Healthcare NHS Trust, St Mary's Hospital	Guideline	040	017 - 019	**The NICE guidelines recommend:** "Treat DKA with intravenous fluids and intravenous insulin if the child or young person is not alert, is nauseated or vomiting, or is clinically dehydrated". [2020] **The BSPED guidelines recommend:** "Children who are alert, not clinically dehydrated, not nauseated or vomiting, do not always require IV fluids, even if their ketone levels are high. They usually tolerate oral rehydration and subcutaneous insulin but do require monitoring regularly to ensure that they are improving and their ketone levels are falling." **Suggestion:** The BSPED statement is preferable and encourages flexibility in the use of oral fluids and SC insulin.	*Thank you for your comment. The committee noted a stronger and more direct steer was required for when intravenous fluids and intravenous insulin should be used as appropriate treatment should not be delayed, therefore no changes were made to recommendation 1.4.21.*
Imperial College Healthcare NHS Trust, St Mary's Hospital	Guideline	040	023 - 026	**The NICE guidelines recommend:** "For children and young people who are hypovolaemic but not in shock: • give an initial intravenous bolus of 10 ml/kg 0.9% sodium chloride over 30 minutes" **The BSPED guidelines recommend:** "All children and young people with mild, moderate or severe DKA who are not shocked and are felt to require IV fluids should receive a 10 ml/kg 0.9% sodium chloride bolus over 60 minutes. (PlasmaLyte 148 is used by some teams in the UK for initial resuscitation in place of 0.9% sodium chloride and either are suitable)"	*Thank you for your comment. Only one small study (Williams 2020) was identified which compared PlasmaLyte with 0.9% normal saline. This study (which referred to the fluid as PlasmaLyte -A) could not differentiate between the two fluids in outcomes such as incidence of acute kidney injury, mortality, and cerebral oedema. Based on these findings, the committee were unable to form a recommendation.* *However, the committee are aware that PlasmaLyte-148 is being used in some paediatric units. Based on this, the committee highlighted that further research is needed to explore the effectiveness of PlasmaLyte 148 as a resuscitation fluid in the management of DKA in children and*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				Suggestion: • PlasmaLyte 148 should be included as an option for use as resuscitation fluid. Consistency in bolus duration would also be preferable (30 v 60 mins).	*young people with diabetes. Therefore, the committee drafted a research recommendation.* *The committee's discussion and interpretation of evidence section has been updated to highlight the committee views. Appendix M has also been updated with a proposed PICO for the research recommendation.* *The committee noted that the International Society for Paediatric and Adolescent Diabetes (ISPAD) guideline states that the resuscitation fluids should be administered over 30 to 60 minutes, however, if tissue perfusion is poor the initial fluid bolus is given more rapidly (e.g. over 15-30 minutes). Based on this information the committee highlighted that resuscitation should not be delayed and therefore opted to state initial intravenous bolus of 10 ml/kg 0.9% sodium chloride should be given over 30 minutes.*
Imperial College Healthcare NHS Trust, St Mary's Hospital	Guideline	041	011 - 019	**The NICE guidelines recommend:** "Calculate the total fluid requirement for the first 48 hours in children and young people with DKA by adding the estimated fluid deficit to the fluid maintenance requirement: • For the fluid deficit: − in mild to moderate DKA (blood pH 7.1 or above), assume 5% dehydration (so a 10 kg child needs 500 ml) − in severe DKA (blood pH below 7.1), assume 10% dehydration" **The BSPED guidelines recommend:** "Assume a 5% fluid deficit in children and young people in mild DKA (indicated by a blood pH 7.2-7.29 &/or bicarbonate <15) Assume a 7% fluid deficit in children and young people in moderate DKA (indicated by a blood pH of 7.1- 7.19 &/or bicarbonate <10) Assume a 10% fluid deficit in children and young people in severe DKA (indicated by a blood pH <7.1)"	*Thank you for your comment. In the PECARN FLUID trial two different protocols were followed in which 10% deficit and 5% deficit were assumed. This study highlighted that these protocols were safe to use as the study did not identify a significant difference in mortality or clinically apparent brain injury. Based on this evidence, the committee retained the 2015 recommendations and stated that in children and young people with mild to moderate DKA, 5% dehydration should be assumed and 10% dehydration should be assumed in children and young people with severe DKA.* *The committee used 75kg for the maximum weight for the calculations because this weight corresponds closest to an 18-year-old in the 75th centile on the UK WHO growth chart.* *The committee have also made a recommendation to think about stopping intravenous fluid therapy for DKA in a child or young person if, ketosis is resolving and their blood pH has*

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				Suggestion: • Consistency between the guidelines in relation to % dehydration estimation would be preferable to avoid confusion • There is also discrepancy in max weight for calculations (75 v 80kg) **Further Comment:** If we are to depend on pH to estimate dehydration then we should accept that when pH is corrected dehydration is corrected. The acidosis of the great big majority of uncomplicated DKA usually resolve within 12-18 hours when IV fluid is usually stopped. In such cases we would have delivered only half of a daily requirement of fluid and 1/4 of the calculated dehydration over 48 hours and yet the patient has fully recovered. In my view, and very much in line of being very careful with fluid, maintenance fluid, whenever indicated for all non-shocked alert DKA patient with pH above 7.1, would be perfectly adequate.	*reached 7.3 and they are alert and they can take oral fluids with nausea or vomiting.* *The committee's full discussion and interpretation of evidence is highlighted in section 1.1.11 in the evidence review.*
Imperial College Healthcare NHS Trust, St Mary's Hospital	Guideline	042	027 - 028	**The NICE guidelines recommend:** "When calculating the total fluid requirement, exclude any initial bolus volumes given. [2020]" **The BSPED guidelines recommend:** "Resuscitation fluid – The volume of any fluid boluses given for resuscitation in children with shock should NOT be subtracted from the estimated fluid deficit. The initial 10ml/kg bolus given to all non-shocked patients requiring IV fluids SHOULD be subtracted from total calculated fluid deficit." **Suggestion:**	*Thank you for your comment. Recommendation 1.4.26 has been amended to state that when calculating the total fluid requirement, subtract any initial bolus volume given from the total fluid deficit (except in children who are in shock). The committee's discussion and interpretation of evidence section (section 1.1.11) in the evidence review has also been updated based on this amendment.*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				In the most recent BSPED guidance, there is an increased emphasis on ensuring adequate restoration of the circulation and treatment of shock (partly as cerebral perfusion is dependent on both perfusion pressure and intracranial pressure and hypotension may exacerbate the risk of brain injury). As in BSPED guidance, it would be preferable not to subtract boluses used to treat shock from fluid calculations.	
Imperial College Healthcare NHS Trust, St Mary's Hospital	Guideline	043	017 - 020	**The NICE guidelines recommend:** "Think about stopping intravenous fluid therapy for DKA in a child or young person if ketosis is resolving, their pH has reached 7.3, they are alert, and they can take oral fluids without nausea or vomiting. [2020]" **The BSPED guidelines recommend:** "Children who are alert, not clinically dehydrated, not nauseated or vomiting, do not always require IV fluids, even if their ketone levels are high. They usually tolerate oral rehydration and subcutaneous insulin but do require monitoring regularly to ensure that they are improving and their ketone levels are falling." **Suggestion:** Removal of the pH threshold of 7.3 would be preferable.	*Thank you for your comment. The committee noted that resolution of DKA is defined as pH greater than 7.3. The committee retained the pH threshold but amended the recommendation to state that clinicians should think about stopping intravenous fluid therapy for DKA in a child or young person if ketosis is resolving and blood pH has reached 7.3, they are alert, and they can take oral fluids without nausea or vomiting. In children and young people who still have mild acidosis or ketosis, discuss with the responsible senior paediatrician before stopping intravenous fluid therapy and changing to oral fluids. The committee's discussion and interpretation of evidence is highlighted in section 1.1.11 in the evidence review.*
Imperial College Healthcare NHS Trust, St Mary's Hospital	Guideline	045	006 - 012	**The NICE guidelines recommend** "At 2 hours after starting treatment, and then at least every 4 hours, carry out and record the results of the following blood tests in children and young people with DKA: • glucose (laboratory measurement) • blood pH and pCO2 • plasma sodium, potassium and urea • beta-hydroxybutyrate." **Comment** in my experience with Non-PICU managed patients, if blood glucose is responding to treatment, blood gases should not be	*Thank you for your comment. This is out of scope for this update.*

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				repeated 2 hours after starting the treatment. It will almost certainly show worsening pH, BE, and BIC because of the dilutional effect of the fluid on the serum bicarbonate which is directly responsible for the level of pH. I find repeating blood gases at least 4 or more hours after starting insulin more helpful.	
Juvenile Diabetes Research Foundation	Guideline	General	General	JDRF is concerned that there is no mention of flash glucose monitoring anywhere in the draft guideline. The final surveillance decision in June 2019 from the scoping for this guideline update stated that the following would be considered for update: "Currently the NICE guideline does not contain any recommendations on flash glucose monitoring, however a number of topic experts and stakeholders highlighted UK guidance on its use, which indicate that children aged 4 years and older may receive a monitor (if other conditions are met): NHS England guidance on Flash Glucose Monitors for Type 1 diabetes patients, the Regional Medicines Optimisation Committee FreeStyle Libre Position Statement and Diabetes UK Type 1 diabetes technology: A consensus guideline. Stakeholders also reported that it is currently being prescribed to some children and young people on the NHS." Further, the final scope, published in July 2020 states that NICE plans to review evidence for blood glucose monitoring and that "In children and young people with type 1 diabetes, what is the most effective method of blood glucose monitoring to improve diabetic control: − continuous glucose monitoring − flash glucose monitoring − intermittent capillary blood glucose monitoring?" was identified as a key issue/question to be considered.	*Thank you for your comment. Review of CGM has been deferred while a review is being carried out on integrated sensor- augmented pump therapy systems for managing blood glucose levels in type 1 diabetes (https://www.nice.org.uk/guidance/dg21/evidence/review-decision-january-2020-pdf-8830079533).*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				Due to the above, and its already wide use on the NHS, JDRF believes that guidance around the use of flash glucose monitoring should be included in NG18.	
Manchester University NHS Foundation Trust	Guideline	General	General	From the comments received, there was unanimous agreement that the changes to the guideline for DKA were fully supported. In particular we agreed with the allowance of additional fluid for resuscitation and the increase in iv fluid maintenance. Since January 2020 we have been using the new BSPED guideline in the trust. There are differences between the new NICE draft and the BSPED guideline in relation to subtracting bolus fluid amounts from the overall total. We would support the approach if NICE. We hope that agreement can be reached such that there is one agreed guideline in use in the in the future. When we were using the 2015 NICE DKA Guideline, we did encounter problems in the management of children with hypokalaemia such that we developed a guideline for this. Whilst we are less likely to see such problems in future because there has been an increase in iv fluid maintenance which allows more potassium to be given, we have seen a few cases of hypokalaemia using the BSPED guideline. I have attached our guideline for management of hypokalaemia in case you wish to consider incorporating any of this. With regard to the 2 sections on retinopathy screening, these looked fine although we failed to see where the changes had been made.	*Thank you for your comment. Recommendation 1.4.26 has been updated to state that when calculating the total fluid requirement, subtract any initial bolus volumes given from the total fluid deficit (except in children who are in shock). The committee's discussion and interpretation of evidence section (Section 1.1.11) in the evidence review has also been amended.* *Recommendations on retinopathy screening (1.2.4 and 1.2.117) were refreshed to provide further clarity about the eye examinations and to avoid overlap with the NHS Diabetic Eye Screening Programme.*
NEL CSU Health Policy Support Unit (HPSU)	Guideline	016	018	NICE have not updated guidelines on continuous glucose monitoring (CGM). The evidence review for the updated draft guidance concerns fluid therapy for DKA. We understand that when NICE met in December 2019 there was a presentation about the review protocols for CGM and digital technologies.	*Thank you for your comment. Review of CGM has been deferred while a review is being carried out on integrated sensor- augmented pump therapy systems for managing blood glucose levels in type 1 diabetes*

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				Has NICE undertaken an evidence review or conducted a scoping exercise on the extent and quality of the most recent evidence for CGM? We are aware of two trials on CGM for children, published in 2018 and 2019 respectively, that recruited children and young people aged up to 17 years. There are also studies of young people aged 16 to 24, that may be excluded by a review protocol for under-18s. Does NICE judge that more recent evidence on CGM is not sufficiently persuasive to revisit guidelines on CGM for children? Does NICE plan to review the evidence base concerning closed loop devices?	*(https://www.nice.org.uk/guidance/dg21/evidence/review-decision-january-2020-pdf-8830079533).*
NHS Blood and Transplant	Guideline	General	General	Thank you for inviting NHSBT to review this guideline. We have no comments	*Thank you for your comment.*
NHS England and NHS Improvement	Guideline	General	General	Should returning data to the National Paediatric Diabetes audit be mentioned? (SK)	*Thank you for your comment. The committee highlighted that the National Paediatric Diabetes audit does not currently collect data on DKA.*
NHS England and NHS Improvement	Guideline	008	014	It would be good to see clear advice about the risks of drinking alcohol here as well as in the section about hypoglycaemia (SK)	*Thank you for your comment. This is out of scope for this update.*
NHS England and NHS Improvement	Guideline	009	022	Could criteria for insulin pumps be clarified ? (SK)	*Thank you for your comment. Recommendations on insulin therapy are out of scope for this update.*
NHS England and NHS Improvement	Guideline	010	011	Is there a standard core advice document available to link to? (SK)	*Thank you for your comment. Recommendations on insulin therapy are out of scope for this update.*
NHS England and NHS Improvement	Guideline	010	024	Should this be higher up in the document sequence? Links to comment #6(SK)	*Thank you for your comment. Recommendations on insulin therapy are out of scope for this update.*
NHS England and NHS Improvement	Guideline	011	021	This should be rephrased as language is cumbersome eg For children with Type 1 diabetes Metformin should only be used in research studies because there is no current evidence of efficacy in improving blood glucose management. Similar comment for acarbose / sulfonylureas (SK)	*Thank you for your comment. Recommendations on oral medicines are out of scope for this update.*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
NHS England and NHS Improvement	Guideline	014	027	Worth discussing wider investigation of morbidly obese children – eg liver disease / sleep apnoea ? referral to specialist obesity clinic (SK)	*Thank you for your comment. This is out of scope for this update.*
NHS England and NHS Improvement	Guideline	040	025	The BPSED guidance is to give 10mls/kg over 60 mins. Is there a clear evidence base for the discrepancy which may cause confusion (SK)	*The committee noted that the International Society for Paediatric and Adolescent Diabetes (ISPAD) guideline states that the resuscitation fluids should be administered over 30 to 60 minutes, however, if tissue perfusion is poor the initial fluid bolus is given more rapidly (e.g. over 15-30 minutes). Based on this information the committee highlighted that resuscitation should not be delayed and therefore opted to state initial intravenous bolus of 10 ml/kg 0.9% sodium chloride should be given over 30 minutes. The committee's discussion and interpretation of evidence is highlighted in section 1.1.11 in the evidence review.*
NHS England and NHS Improvement	Guideline	040	017	Consideration as to how the revised guidance will be communicated within Ambulance Trusts if appropriate, where dissemination of guidance can be more difficult	*Thank you for your comment and for highlighting this issue. We will liaise with our implementation team to explore raising awareness with ambulance trusts.*
NHS England and NHS Improvement	Guideline	042	003	Are you confident that iv fluid with 40 mmol/litre potassium chloride is widely available? BPSED recommends 20mls/litre potassium which is commonly stocked on paediatric wards (SK)	*Thank you for your comment. The committee noted that 40 mmol/l potassium chloride is available, but recommendations have been updated to include 20 mmol/500ml. The committee's discussion and interpretation of evidence section (section 1.1.11) in the evidence review has also been updated based on this amendment.*
NHS England and NHS Improvement	Guideline	046	019	It might be helpful to state multiple doses of hypertonic saline can be given if signs of raised ICP persist. (SK)	*Thank you for your comment. This is out of scope for this update.*
NHS London Clinical Networks - London Type 1 Diabetes Network	Guideline	General	General	The PECARN FLUID study (the data from which was used to help create these new guidelines NICE 2020 and BSPED 2020 DKA guidelines) didn't include patients with the most severe DKA pH <7.1 who are felt to be most at risk of cerebral oedema	*Thank you for your comment. The committee amended 2015 DKA recommendations due to the risk of under resuscitation associated with the recommendations. Additionally, since the 2015 recommendations were published, the evidence base has developed further, which prompted an update of these recommendations.* *As highlighted in the summary of studies table in section 1.1.5 of the evidence review, the PECARN FLUID trial (Kupperman*

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					2018) included participants with all severities of DKA. The study also presented data for the outcome confirmed decline in Glasgow Coma Scale for the whole population as well as for participants with severe DKA (forest plot and GRADE table in appendix F and H). *The committee highlighted that while the trial did not identify a significant difference in important outcomes, the study is a large, high quality RCT and did demonstrate that both fast and slow fluid protocols are safe to use in children and young people with all severities of DKA. However, the committee did agree that critically ill children and young people were not captured in the PECARN Fluid trial.* *Based on this, the committee drafted recommendations that covered all severities of DKA but did amend the recommendations further to state that the aim should be to replace the fluid deficit evenly over 48 hours but in critically ill children and young people, the fluid regimen should be discussed early with the senior paediatrician or paediatric intensivists (or both), because the risk of cerebral oedema is higher. The committee further noted that it is crucial that treatment is not delayed due to the risk of cerebral oedema. The committee's discussion and interpretation of evidence section (1.1.11) in the evidence review has been amended to highlight this discussion.*
NHS London Clinical Networks - London Type 1 Diabetes Network	Guideline	General	General	Since this guideline was published, BSPED has published updated national guidance for the management of DKA (2020). ELCH guidance has always advocated the use of national guidance for mild/moderate cases, and the STRS DKA management for severe cases, and this continues to be our approach. The new BSPED guidelines advocate the classification of patients based on biochemical criteria below. Pending formal	*Thank you for your comment. In the PECARN FLUID trial two different protocols were followed in which 10% deficit and 5% deficit were assumed. This study highlighted that these protocols were safe to use as the study did not identify a significant difference in mortality or clinically apparent brain injury. Based on this evidence, the committee retained the 2015 recommendations and stated that in children and young people with mild to moderate DKA, 5% dehydration should be*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				update of the ELCH guideline, please stratify management as follows: • Mild (pH <7.3, bicarb <15) – please refer to the updated BSPED guideline (2020) • Mod (pH <7.2, bicarc <10)– please refer to the BSPED guideline (2020) • Severe (pH <7.1, bicarb <5) – please refer to the STRS guidance in full, whether the child is admitted to PICU or the ward. Important notes: • Any initiation or change in treatment protocol should be discussed with the responsible consultant in the department (including A&E or ward) • The rate of fluid bolus administration should remain cautious and limited to 10ml/kg aliquots with frequent review. No more than 20ml/kg total fluid resuscitation without consultant review • Overall clinical status of the patient overrides the biochemical criteria of severity above. Any clinical concerns (in particular relating to altered consciousness or fluctuating GCS) should immediately trigger senior review and discussion with STRS, regardless of the patient's pH or bicarbonate levels."	*assumed and 10% dehydration should be assumed in children and young people with severe DKA.* *Rec 14.23 does state discussions should take place with the responsible senior paediatrician that before giving more than one intravenous bolus of 10ml/kg 0.9% sodium chloride to a child or young people with DKA.* *Committee's full discussion is highlighted in section 1.1.11 in the evidence review.*
Novo Nordisk	Guideline	040 - 043	General	We agree with the importance of the area identified for updated recommendations. We are not commenting on the detail as we do not have expertise in this area.	*Thank you for your comment.*
Paediatric Critical Care Society	Guideline	General	General	Section 1.4 of this guidance summarises recommendations relating to the management of DKA. NICE should recognise that severe DKA is managed, in the main, by paediatric critical care specialists. This either occurs through advice given to local DGHs via national paediatric intensive care transport	*Thank you for your comment. The committee amended 2015 DKA recommendations due to the risk of under resuscitation associated with the recommendations. Additionally, since the 2015 recommendations were published, the evidence base has developed further, particularly with the publication of the*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				networks or directly in regional PICUs. Many in the paediatric critical care community feel extremely uncomfortable with the updated BPSED guidance which they believe dramatically changes historical management without sufficient justification. The main premise underpinning BPSED is the FLUID trial which notably included vary few children at the most severe end of DKA. Specifically, PCCS are concerned that excess fluid administration in the sickest cohort of this population of patients may result in harm. It follows therefore that, since this updated NICE consultation is closely aligned with the BPSED guidance, that PCCS also feels that significant revision to this draft guideline is necessary Individual comments from members below highlight 3 important factors; shock is rare in DKA, cerebral oedema is rare in DKA, and overzealous fluid administration without evidence for this change may result in harm. As mentioned above information from the PECARN FLUID DKA FLUID trial may not be relevant to the sickest of children presenting in DKA. Whilst individual clinical judgement is of paramount importance, we hope the considerable clinical experience of the UK's paediatric retrieval services and PCC community as a whole is taken into account when updating these NICE guidelines to create safe, evidence based guideline that can be used by all relevant practitioners.	*PECARN trial which prompted an update of these recommendations.* *As highlighted in the summary of studies table in section 1.1.5 of the evidence review, the PECARN FLUID trial (Kupperman 2018) included participants with all severities of DKA. The study also presented data for the outcome confirmed decline in Glasgow Coma Scale for the whole population as well as for participants with severe DKA (forest plot and GRADE table in appendix F and H).* *The committee highlighted that while the trial did not identify a significant difference in important outcomes, the study is a large, high quality RCT and did demonstrate that both fast and slow fluid protocols are safe to use in children and young people with all severities of DKA. However, the committee did agree that critically ill children and young people were not captured in the PECARN Fluid trial.* *Based on this, the committee drafted recommendations that covered all severities of DKA but did amend the recommendations further to state that the aim should be to replace the fluid deficit evenly over 48 hours but in critically ill children and young people, the fluid regimen should be discussed early with the senior paediatrician or paediatric intensivists (or both), because the risk of cerebral oedema is higher. The committee further noted that it is crucial that treatment is not delayed due to the risk of cerebral oedema. The committee's discussion and interpretation of evidence section (1.1.11) in the evidence review has been amended to highlight this discussion.*
Paediatric Critical Care Society	Guideline	039	016 - 026	The description of the location of where children with severe DKA should be managed seems confused. It is suggested that guidance should simply state that they be cared for in a	*Thank you for your comment. Recommendations do not provide description of where children with severe DKA should be managed however recommendations 1.4.23 and 1.4.34 do*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				paediatric HDU and that there should be liaison with a paediatric critical care specialist.	*state that paediatric intensivists should be involved in the decision making*
Paediatric Critical Care Society	Guideline	040	023 - 028	Hypovolaemic is not defined and very poorly understood. We are concerned that this is vague and therefore unhelpful. There is no evidence that treating perfusion (which is confounded by acidosis and hypocapnia) is the correct trigger for bolus fluid administration. This is a VERY low risk condition and the risk from shock is tiny – the potential risks and benefits of volume resuscitation are unknown but are likely to trend towards harm. (Please see attached position piece for ADC EP which includes relevant references). We would strongly suggest removing "only consider giving a second intravenous bolus if needed to improve tissue perfusion" because we cannot know this is beneficial. The only perfusion-based shock RCT with patient related outcome (ICU mortality) is 1) in adults 2) with septic shock 3) has a control group mortality of 43.4% 4) employs a standardised approach to detecting perfusion abnormalities and 5) was probably underpowered / negative for primary outcome measure. These data are not at all comparable to childhood DKA. JAMA. 2019;321(7):654-664. doi:10.1001/jama.2019.0071	*Thank you for your comment. The committee have removed the term 'hypovolaemia' from recommendation 1.4.23 and amended it to include the term 'clinically dehydrated'.* *In the PECARN FLUID trial, protocols were followed which included the use of a second fluid bolus This study highlighted that these protocols were safe to use as the study did not identify a significant difference in mortality or clinically apparent brain injury. The committee have also amended recommendation 1.4.23 to state that a second intravenous bolus should only be considered if needed to improve tissue perfusion after careful reassessment of clinical status.* *The committee's discussion and interpretation of evidence section (section 1.1.11) in the evidence review has also been updated based on this amendment.*
Paediatric Critical Care Society	Guideline	041	006 - 010	"For children and young people who have signs of shock (weak thread pulse, tachycardia, prolonged capillary refill, tachypnoea or hypotension), give an initial intravenous bolus of 20 ml/kg 0.9% sodium chloride as soon as possible." We are concerned that weak pulse or thready pulse are non-specific terms and suggest 'low volume pulse' would be more definite and therefore should be used in this context.	*Thank you for your comment. Signs of shock outlined in rec 1.4.24 have been updated to state, weak thready pulse (or low volume pulse) and hypotension. The committee have also added a new recommendation (Rec 1.4.25) to state that prolonged capillary refill, tachycardia and tachypnoea are common in children and young people with moderate to severe DKA, but this does not mean the child or young person is in shock (these are signs of vasoconstriction caused by metabolic acidosis and hypocapnia).*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				The use of prolonged capillary refill to define shock in DKA should be omitted. Within the PCC experience all children with severe DKA have a prolonged capillary refill time due to hypocapnoea and this sign should therefore not be used to guide additional fluid boluses. Tachypnoea is also common in DKA due to compensation for metabolic acidosis and should not be used to define shock. We would suggest that the only signs listed that are specific to shock in DKA would be low volume pulse or hypotension. We would also suggest adding lactic acidosis as a biochemical sign of shock. The 2015 NICE guidance recommended 60% maintenance as the Holliday-Segar formula has been shown to overestimate fluid requirements in critically ill children. Since this guidance was published there has been no new evidence published showing harm from this fluid regime. The FLUID trial (Kuppermann, NEJM 2018) did not show any benefit to the faster rehydration arm of the study. We are concerned that NICE is changing its fluid regime significantly without evidence of benefit. The guidance for DKA, recommending volumes of fluid similar to 2015 NICE guidance, from one of the busiest PCC retrieval services, has been in place since 2008 from which time there have no deaths. We advocate fluid boluses received by children who are not shocked should be subtracted from the total volume of rehydration received over 48 hours as per the protocol in The FLUID trial (Kuppermann, NEJM 2018).	*While the committee noted that the PERCARN trial did not identify a significant difference between fast and slow administration, the study did demonstrate that the two protocols are safe to use. The study also utilised the Holliday-Segar formula for the calculation of the fluid maintenance. The committee were also concerned with the risk of under resuscitation associated with the current recommendations.* *Based on the study and their clinical expertise, the committee recommended (Rec 1.4.26) that total fluid requirement should be calculated for the first 48 hours, maintenance requirement to be calculated using the Holliday-Segar formula and any initial bolus volume should be subtracted from the total fluid requirements (except in children who are in shock).* *The committee's discussion and interpretation of evidence section (section 1.1.11) in the evidence review has also been updated based on this amendment.*
Paediatric Critical Care Society	Guideline	046	003 - 009	This list should include 'reduced GCS'	*Thank you for your comment. This is out of scope for this update.*
Paediatric Critical Care Society	Guideline	054	General	"This evidence showed no significant difference between the 2 protocols, and it showed that the restrictions on the rate of fluid administration were not needed." We believe this is	*Thank you for your comment. The committee amended 2015 DKA recommendations due to the risk of under resuscitation associated with the recommendations. Additionally, since the*

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				incorrect because the sickest patients with DKA have not been appropriately evaluated. The FLUID trial (Kuppermann, NEJM 2018[1]) shows there is no benefit to either regime with regards to time to resolution of DKA and many other outcomes. It therefore shows there is no benefit to change the NICE guidance so significantly. Moreover, there is not yet evidence available on whether giving more fluid is harmful in **severe** DKA. The FLUID trial is the largest high quality RCT in paediatric DKA however the mean pH of 7.16 in the population studied is not representative of the critically ill children we care for in paediatric critical care who have a mean pH of 6.9 or those who we advise on their care but remain in their local hospital with a pH of 6.96 (Lillie, Archives 2020)[2]. We would argue NICE guidance on severe DKA should not be changed without better evidence in this group. In the FLUID trial there were 282 children included with a pH< 7.1 However there was selection bias for this group as the sickest patients had already been excluded: 1377 children who had received >10ml/kg fluid bolus, 289 were withdrawn by the physician and 42 children had osmolar therapy prescribed. These 1,708 children excluded from the trial are likely to represent the huge majority of the sickest patients with DKA who have a pH of <7.1, therefore limited conclusions can be drawn about the best management for children in this category. We do not think that it can be justified to increase the fluids advised by NICE in the group most at risk of cerebral oedema (pH <7.1) without evidence of benefit and reassurance that there is no harm. We note the only child who died in the FLUID trial was in the fast rehydration arm of the study.	*2015 recommendations were published, the evidence base has developed further, which prompted an update of these recommendations.* *As highlighted in the summary of studies table in section 1.1.5 of the evidence review, the PECARN FLUID trial (Kupperman 2018) included participants with all severities of DKA. The study also presented data for the outcome confirmed decline in Glasgow Coma Scale for the whole population as well as for participants with severe DKA (forest plot and GRADE table in appendix F and H).* *The committee highlighted that while the trial did not identify a significant difference in important outcomes, the study is a large, high quality RCT and did demonstrate that both fast and slow fluid protocols are safe to use in children and young people with all severities of DKA. However, the committee did agree that critically ill children and young people were not captured in the PECARN Fluid trial.* *Based on this, the committee drafted recommendations that covered all severities of DKA but did amend the recommendations further to state that the aim should be to replace the fluid deficit evenly over 48 hours but in critically ill children and young people, the fluid regimen should be discussed early with the senior paediatrician or paediatric intensivists (or both), because the risk of cerebral oedema is higher. The committee further noted that it is crucial that treatment is not delayed due to the risk of cerebral oedema. The committee's discussion and interpretation of evidence section (1.1.11) in the evidence review has been amended to highlight this discussion.* *The committee also highlighted in their discussions that no prospective audit was established after the 2015 DKA*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				Looking at the case summary in the supplement, this child had a GCS of 14 and then developed cerebral oedema and coned with falling corrected sodium. A large PCC retrieval service recognised cases like this in the 2000s but since they restricted their DKA fluid regime in 2008, they have had no further similar deaths. PCCS is concerned the UK will have iatrogenic deaths in patients with severe DKA if this change is instituted[2]. We would recommend that 2015 fluid guidance is not changed however if the 2020 fluid regime is published the recommendations should only apply to mild and moderate DKA and not extrapolated to severe DKA. Reference: 1: Kuppermann N, Ghetti S, Schunk JE, et al. Clinical trial of fluid infusion rates for pediatric diabetic ketoacidosis.	*recommendations were produced. The committee agreed that it was important to assess the implementation of these updated recommendations. As there is no existing audit, the committee could not make any research recommendations but agreed that an audit of practice would be valuable.*
Paediatric Critical Care Society	Guideline	054	General	"Practice has changed since the 2015 recommendations were made, and there was concern that these 2015 recommendations could result in children and young people receiving less fluid than they need over the first 48-hour period." Within the PCC retrieval teams of the UK, practice has been to follow the 2015 guidance. BSPED's publication of new guidance in January 2020 has caused widespread confusion and most regions have advised the more liberal fluid regime be used for mild or moderate DKA only. In cases of severe DKA, they have advocated continuing to follow the 2015 NICE guidance.	*Thank you for your comment. The committee amended 2015 DKA recommendations due to the risk of under resuscitation associated with the recommendations. Additionally, since the 2015 recommendations were published, the evidence base has developed further, which prompted an update of these recommendations.* *As highlighted in the summary of studies table in section 1.1.5 of the evidence review, the PECARN FLUID trial (Kupperman 2018) included participants with all severities of DKA. The study also presented data for the outcome confirmed decline in Glasgow Coma Scale for the whole population as well as for participants with severe DKA (forest plot and GRADE table in appendix F and H).* *The committee highlighted that while the trial did not identify a significant difference in important outcomes, the study is a large, high quality RCT and did demonstrate that both fast*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
					and slow fluid protocols are safe to use in children and young people with all severities of DKA. However, the committee did agree that critically ill children and young people were not captured in the PECARN Fluid trial. *Based on this, the committee drafted recommendations that covered all severities of DKA, but did amend the recommendations further to state that the aim should be to replace the fluid deficit evenly over 48 hours but in critically ill children and young people, the fluid regimen should be discussed early with the senior paediatrician or paediatric intensivists (or both), because the risk of cerebral oedema is higher. The committee further noted that it is crucial that treatment is not delayed due to the risk of cerebral oedema. The committee's discussion and interpretation of evidence section (1.1.11) in the evidence review has been amended to highlight this discussion.*
Paediatric Critical Care Society	Guideline	055	General	"The new recommendations are in line with current practice". It is not true to say that the 2020 recommendations are in line with current practice. Most cases of severe DKA, although managed appropriately by general paediatricians outwith PICU, are discussed with specialist paediatric critical care expertise – this is usually the local paediatric intensive care retrieval service. Our practice has not changed. Until very recently, practice across all hospitals was to follow the 2015 NICE guidance advising a more restrictive fluid regime than is now being proposed. In some cases the new guidance proposed would almost double the amount of fluid received by a child in the first 24 hours of their care. Thus the new recommendations are almost doubling the volume of fluid received for the sickest patients with DKA who are less than 20kg (1.7-2 fold increase).	*Thank you for your comment. The rationale impact to state that there is variation in practice and new recommendations are in line with other clinical guidelines such as the ISPAD and BSED guideline.* *The committee amended 2015 DKA recommendations due to the risk of under resuscitation associated with the recommendations. Additionally, since the 2015 recommendations were published, the evidence base has developed further, which prompted an update of these recommendations.* *As highlighted in the summary of studies table in section 1.1.5 of the evidence review, the PECARN FLUID trial (Kupperman 2018) included participants with all severities of DKA. The study also presented data for the outcome confirmed decline in Glasgow Coma Scale for the whole population as well as*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				It was only in 2020 after BSPED published their guidance that there has been confusion as to what practice should be. Many hospitals continued to follow NICE guidance until BSPED performed an audit instructing diabetologists to follow their guidance. Over the last few months there has been variability as to which practice has been adopted. As NICE provides evidence-based guidance, we believe the 2015 fluid regime should not be changed for severe DKA without evidence showing its benefit. Example of huge increase in fluid for child with pH of < 7.1, assuming not shocked. 2 year old, 12 kg child: NICE 2015 receiving 10ml/kg fluid bolus,10 % deficit, reduced maintenance: 1.0 L in first 24 hours NICE 2020 receiving 20ml/kg/fluid bolus,10 % deficit, Holliday-Segar maintenance: 1.9 L in first 24 hours	*for participants with severe DKA (forest plot and GRADE table in appendix F and H).* *The committee highlighted that while the trial did not identify a significant difference in important outcomes, the study is a large, high quality RCT and did demonstrate that both fast and slow fluid protocols are safe to use in children and young people with all severities of DKA. However, the committee did agree that critically ill children and young people were not captured in the PECARN Fluid trial.* *Based on this, the committee drafted recommendations that covered all severities of DKA but did amend the recommendations further to state that the aim should be to replace the fluid deficit evenly over 48 hours but in critically ill children and young people, the fluid regimen should be discussed early with the senior paediatrician or paediatric intensivists (or both), because the risk of cerebral oedema is higher. The committee further noted that it is crucial that treatment is not delayed due to the risk of cerebral oedema. The committee's discussion and interpretation of evidence section (1.1.11) in the evidence review has been amended to highlight this discussion.*
Pennine Acute Trust	Guideline	040 047	023 - 028 001 - 008	It is recognised that signs of hypovolemia and dehydration are often misinterpreted in DKA especially in mild cases. We recommend amending section 1.4.23 and giving 10ml/kg bolus to all children if treated with IV fluids over 30 minutes (same as recommended by BSPED). On management of hypokalaemia, we recommend to emphasise that after discussion with regional paediatric critical care specialist if the child or young person requires more than 40mmol/litre of potassium, these should be only administered in PICU.	*Thank you for your comment. The committee noted that the International Society for Paediatric and Adolescent Diabetes (ISPAD) guideline states that the resuscitation fluids should be administered over 30 to 60 minutes, however, if tissue perfusion is poor the initial fluid bolus is given more rapidly (e.g. over 15-30 minutes). Based on this information the committee highlighted that resuscitation should not be delayed and therefore opted to state initial intravenous bolus of 10 ml/kg 0.9% sodium chloride should be given over 30 minutes. The committee's discussion and interpretation of evidence is highlighted in section 1.1.11 in the evidence review.*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				This will help DGH hospitals to have a clear guide to discuss with regional PICU in rare cases where DKA need to be manged in critical care. Although true persistent hypernatraemia is rare in DKA but its management should be covered in national guidelines.	*The committee have drafted new recommendations to state that sodium levels should be monitored throughout the course of therapy and calculate the corrected sodium initially to identify if the patient hyponatraemic. The committee further recommended that when monitoring serum sodium, be aware that serum sodium should rise as DKA is treated as blood glucose falls, falling serum sodium is a sign of possible cerebral oedema and a rapid and ongoing rise in serum sodium concentration may also suggest cerebral oedema, caused by the loss of free water in the urine.* *The committee's discussion and interpretation of evidence section (section 1.1.11) in the evidence review has also been updated based on this amendment.*
Royal College of Nursing	General	General	General	Dear colleague, Thank you for the opportunity to contribute to this guideline but we do not have any comments to add on this occasion.	*Thank you for your comment.*
Royal College of Paediatrics and Child Health	General	General	General	The reviewers are happy with the draft guideline.	*Thank you for your comment.*
Royal College of Paediatrics and Child Health	Guideline	025	014	1.2.112 and 1.2.117 - The annual retinopathy screening for children from 12 years onwards is causing confusion. NICE states annual screening and refers to the PHE recommendation that was due an update in 2017. However most screening programmes in England are now only offering biannual screening for children deeming them as low risk. Therefore, the guidance and reality do not match up. There is no reference to the eye screening programme in Wales despite NICE guidance being for Wales as well. However, the only evidence supporting annual screening for	*Thank you for your comment. Recommendation 1.2.117 is in line with the diabetic eye screening programme. The committee have acknowledged the eye screening programme in Wales, but we are unable to add a reference to this screening programme. NICE guidelines are evidence-based recommendations for health and care in England.*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				Type 1 diabetes comes from Wales (Thomas et al The European Journal of Health Economics (2020) 21:993–1002).	
Royal College of Paediatrics and Child Health	Guideline	049	General	Section 8 - Insulin pumps should be discussed in detail.	*Thank you for your comment. Further details about insulin pumps are provided in recommendations 1.2.17 to 1.2.31.*
Royal College of Physicians (RCP)	General	General	General	The RCP is grateful for the opportunity to respond to the above consultation. In doing so we would like to endorse the response submitted by the Association of British Clinical Diabetologists (ABCD). We also have liaised with our Young Adult and Adolescents Steering Group and would like to comment as below.	*Thank you for your comment.*
Royal College of Physicians (RCP)	General	General	General	NICE should explicitly say the 16-18 year olds admitted under paediatric service with DKA should be treated using the BSPED guideline, and if admitted under the adult team, use the JBDS guideline Our experts believe that they should mention the possibility of SGLT-2 use – in type 1 and type 2, in CYP, and the risk of euglycaemic DKA in both (even though this will be unlicensed, they cannot say it does not happen).	*Thank you for your comment. The committee have not reviewed the evidence of management of DKA in adults and therefore cannot refer to adult guidelines. SGLT-2 is out of scope for this update.*
South Thames Paediatric Network	Guideline	040	027	**Advice for children who are hypovolaemic but not in shock:** **Section 1.4.23 Advice for children who are hypovolaemic but not in shock:** There is a lack of clinical or laboratory features to identify children who are hypovolaemic but not in shock. This may lead to inappropriate treatment as clinical signs alone are often unreliable in this cohort of patients. Unfortunately "tissue perfusion" is a poor indictor of fluid status in DKA patients. Children with severe DKA are hypocapnic which causes vasoconstriction and prolongs	*Thank you for your comment. The committee have removed the term 'hypovolaemia' from recommendation 1.4.23 and amended it to include the term 'clinically dehydrated'* *The committee have also added anew recommendation (1.4.25) to state that prolonged capillary refill, tachycardia and tachypnoea. The committee's discussion and interpretation of evidence section (section 1.1.11) in the evidence review has also been updated based on this amendment. In the PECARN FLUID trial, protocols were followed which included the use of a second fluid bolus. This study highlighted that these protocols were safe to use as the study did not identify a significant difference in mortality or clinically apparent brain injury. The committee have also amended recommendation 1.4.23 to state that a second intravenous bolus should only be*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				capillary refill time[1]. Therefore reduced tissue perfusion and prolonged capillary refill (CRT) cannot be directly extrapolated to the need for extra fluid therapy. For this reason the latest UK Advanced Paediatric Life Support Guidance has specifically de-emphasised the reliance on CRT in paediatric patients[2]. Moreover, there is no evidence that giving rapid fluid boluses to children in this situation is beneficial. The FLUID trial (Kuppermann, NEJM 2018[3]) did not show any benefit to giving a second fluid bolus. Therefore STRS and STPN would suggest that this NICE guidance does not recommend an additional 10ml/kg bolus. Giving a 2nd 10ml/kg fluid bolus to children with DKA who by definition are not shocked is illogical; patients with DKA have developed dehydration over days and generally require rehydration not resuscitation. Rapid correction of dehydration risks fluid shifts that may be detrimental in the sickest patients as physiologic compensatory mechanisms will be in place. Reference: 1: Fleishman M, Scott J, Haddy FJ. Effect of pH change upon systemic large and small vessel resistance. Circ Res 1957;5:602–6. 2: Advanced Paediatric Life Support: A Practical Approach to Emergencies, Sixth Edition. Advanced Life Support Group. Wiley 2016. DOI:10.1002/9781119241225 3: Kuppermann N, Ghetti S, Schunk JE, et al. Clinical trial of fluid infusion rates for pediatric diabetic ketoacidosis. N Engl J Med 2018;378:2275–87.	*considered if needed to improve tissue perfusion and only after reassessing clinical status.* *Additionally, from the provided reference list:* • *Kuppermann (2018) trial was included in this review* • *Fleisheman (1957) did not meet the PICO for this review (highlighted in the evidence review section 1.1.2)* • *APLS: practical approach to emergencies did not meet the inclusion criteria for this review as only systematic reviews, RCTs and comparative prospective observational studies were included in this review (review protocol can be found in appendix A of the evidence review).*
South Thames Paediatric Network	Guideline	041	004	The 10ml/kg fluid bolus received by children who are not shocked should be subtracted from the total volume of rehydration received over 48 hours. The FLUID trial (Kuppermann, NEJM 2018[1]), which is the article that has led	*Thank you for your comment. Recommendation 1.4.24 states that when calculating the total fluid requirement, initial bolus*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				to NICE guidance being changed, subtracted the "initial fluid bolus volumes from the fluid deficit". As the new NICE fluid regime is being changed based on this trial then advice on fluid boluses should follow this study's protocol. Reference: 1: Kuppermann N, Ghetti S, Schunk JE, et al. Clinical trial of fluid infusion rates for pediatric diabetic ketoacidosis. N Engl J Med 2018;378:2275–87.	*volumes should be subtracted from the total fluid deficit. Recommendation 1.4.26 further reinforces this statement.* *The committee's discussion and interpretation of evidence has been highlighted in section 1.1.11 in the evidence review.*
South Thames Paediatric Network	Guideline	041	006	The use of prolonged capillary refill to define shock in DKA should be omitted. In our experience as a paediatric critical care retrieval service all children with severe DKA have a prolonged capillary refill time due to hypocapnoea and this sign should not be used to guide additional fluid boluses. Similarly, tachypnoea is also common in DKA due to compensation for metabolic acidosis and should not be used to define shock. We would suggest that the only signs listed that are specific to shock in DKA would be weak pulses or hypotension. We would also suggest adding lactic acidosis as a biochemical correlate of shock.	*Thank you for your comment. Signs of shock outlined in rec 1.4.24 have been updated to state, weak thready pulse (low volume pulse) and hypotension. The committee have also added a new recommendation (Rec 1.4.25) to state that prolonged capillary refill, tachycardia and tachypnoea are common in children and young people with moderate to severe DKA, but this does not mean the child or young person is in shock (these are signs of vasoconstriction caused by metabolic acidosis and hypocapnia). The committee's discussion and interpretation of evidence section (section 1.1.11) in the evidence review has also been updated based on this amendment.*
South Thames Paediatric Network	Guideline	041	020	The 2015 NICE guidance recommended 60% maintenance as the Holliday-Segar formula has been shown to overestimate fluid requirements in critically ill children. Since this guidance was published there has been no new evidence published showing harm to this fluid regime. The FLUID trial (Kuppermann, NEJM 2018) did not show any benefit to the faster rehydration arm of the study. STRS and South Thames Paediatric Network do not understand why NICE is changing its fluid regime so significantly without evidence of benefit to the new guidance or harm in the previous one. Our own guidance for DKA, recommending volumes of fluid similar to 2015 NICE guidance, has been in place since 2008 from	*Thank you for your comment. The Kupperman 2018 (PECARN FLUID Trial) trial was included in this review. The PECARN FLUID trial used the Holliday-Segar to fluid maintenance requirement. While the study did not identify any significant results, it did highlight that these protocols were safe to use. The committee also noted that the Holliday-Segar formula is commonly used in practice and is recommended in the ISPAD and BSEPD guideline.* *Recommendation 1.4.26 has been amended to state that when calculating the total fluid requirement, subtract any initial bolus volume given from the total fluid deficit (except in children who are in shock). The committee's discussion and*

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				which time there have been no deaths nor morbidity in children following this guidance. Fluid boluses received by children who are not shocked should be subtracted from the total volume of rehydration received over 48 hours as per the protocol in The FLUID trial (Kuppermann, NEJM 2018). The children have received this volume and there is no evidence base or theoretical argument to exclude this from the total fluid requirement calculation. Reference: 1: Kuppermann N, Ghetti S, Schunk JE, et al. Clinical trial of fluid infusion rates for pediatric diabetic ketoacidosis. N Engl J Med 2018;378:2275–87.	*interpretation of evidence section (section 1.1.11) in the evidence review has also been updated based on this amendment.*
South Thames Paediatric Network	Guideline (Rational and impact)	054	009	"This evidence showed no significant difference between the 2 protocols, and it showed that the restrictions on the rate of fluid administration were not needed." **This is incorrect as the sickest patients with DKA were not adequately evaluated.** The FLUID trial (Kuppermann, NEJM 2018[1]) shows there is no benefit to either regime with regards to time to resolution of DKA and many other outcomes. It therefore shows there is **no benefit** to change the NICE guidance so significantly. Moreover, there is not yet evidence available on whether giving more fluid is harmful in **severe** DKA. The FLUID trial is the largest high quality RCT in paediatric DKA however the mean pH of 7.16 in the population studied is not representative of the critically ill children we care for: -in paediatric critical care who have a mean pH of 6.9 or -the majority of patients who remain in their local hospital with a pH of 6.96 (Lillie, Archives 2020)[2].	*Thank you for your comment. The committee amended 2015 DKA recommendations due to the risk of under resuscitation associated with the recommendations. Additionally, since the 2015 recommendations were published, the evidence base has developed further, which prompted an update of these recommendations.* *As highlighted in the summary of studies table in section 1.1.5 of the evidence review, the PECARN FLUID trial (Kupperman 2018) included participants with all severities of DKA. The study also presented data for the outcome confirmed decline in Glasgow Coma Scale for the whole population as well as for participants with severe DKA (forest plot and GRADE table in appendix F and H).* *The committee highlighted that while the trial did not identify a significant difference in important outcomes, the study is a large, high quality RCT and did demonstrate that both fast and slow fluid protocols are safe to use in children and young people with all severities of DKA. However, the committee did*

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				We would argue NICE guidance on severe DKA should not be changed without better evidence in this group. There were 282 children included in this trial with a pH< 7.1 however there was enormous selection bias for this group as the sickest patients had already been excluded from the trial: 1377 children who had received >10ml/kg fluid bolus, 289 were withdrawn by the physician and 42 children had osmolar therapy prescribed. These 1,708 children excluded from the trial are likely to represent the majority of the sickest patients with DKA who have a pH of <7.1 which means limited conclusions can be drawn about the best management for children in this category. We do not think that it can be justified to increase the fluids advised by NICE in the group most at risk of cerebral oedema (pH <7.1) without evidence of benefit and reassurance that there is no harm. The only child who died in the FLUID trial was in the fast rehydration arm of the study; the summary of this case in the supplement is extremely worrying as this child had a GCS of 14 and then developed fatal cerebral oedema as the corrected sodium fell significantly. This suggests that the mechanism for the only death in this trial was due to a fall in osmolality which would have been exacerbated by receiving more fluid[3]. We reported deaths similar to this in the 2000s but since STRS restricted our own DKA fluid regime in 2008, we have had no deaths due to cerebral oedema and fear that the UK will have iatrogenic deaths in patients with severe DKA if this change is instituted[2]. Our paediatric intensive care team would not support the recommendations in our critically ill population however the STPN recognise we should ideally have one national DKA guideline that applies across all regions. We would advocate that 2015 fluid guidance is not changed however if the 2020	*agree that critically ill children and young people were not captured in the PECARN Fluid trial.* *Based on this, the committee drafted recommendations that covered all severities of DKA, but did amend the recommendations further to state that the aim should be to replace the fluid deficit evenly over 48 hours but in critically ill children and young people, the fluid regimen should be discussed early with the senior paediatrician or paediatric intensivists (or both), because the risk of cerebral oedema is higher. The committee further noted that it is crucial that treatment is not delayed due to the risk of cerebral oedema. The committee's discussion and interpretation of evidence section (1.1.11) in the evidence review has been amended to highlight this discussion.* *The committee also highlighted in their discussions that no prospective audit was established after the 2015 DKA recommendations were produced. The committee agreed that it was important to assess the implementation of these updated recommendations. As there is no existing audit, the committee could not make any research recommendations but agreed that an audit of practice would be valuable.* - *Kupperman 2018 – included in the review* - *Lillie 2020 – not included in review as this is a letter and we only included RCTs, systematic reviews and comparative observational studies* - *Durward 2011- study did not include interventions listed in the PICO.* *The PICO of this review question is in section 1.1.2 of the evidence review.*

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				fluid regime is published the recommendations should only apply to mild and moderate DKA and not extrapolated to severe DKA. **There is no published benefit to the liberal fluid regime and the potential for harm in patients at highest risk of cerebral oedema: pH<7.1, younger age, reduced GCS means that they should continue to follow the 2015 pathway. Rigorous audit should be undertaken to assess the impact of these changes.** Reference: 1: Kuppermann N, Ghetti S, Schunk JE, et al. Clinical trial of fluid infusion rates for pediatric diabetic ketoacidosis. N Engl J Med 2018;378:2275–87. 2: Lillie J, Boot E, Tibby SM, et al. Management of fluids in paediatric diabetic ketoacidosis: concerns over new guidance. Arch Dis Child. 2020 Oct;105(10):1019-1020. 3: Durward A, Ferguson LP, Taylor D, Murdoch IA, Tibby SM. The temporal relationship between glucose-corrected serum sodium and neurological status in severe diabetic ketoacidosis. Arch Dis Child. 2011 Jan;96(1):50-7. doi: 10.1136/adc.2009.170530.	
South Thames Paediatric Network	Guideline	054	012	"In response to this evidence and applying their clinical experience, the committee updated the recommendations to use more rapid fluid administration (including fluid boluses)." We recognise, acknowledge and respect the NICE committee's experience and expertise in managing diabetes in children. However, our concerns relate to a specific high-risk subset of critically unwell children with severe diabetic ketoacidosis, typically managed by paediatric transport teams and paediatric critical care units.	*Thank you for your comment. The committee amended 2015 DKA recommendations due to the risk of under resuscitation associated with the recommendations. Additionally, since the 2015 recommendations were published, the evidence base has developed further, which prompted an update of these recommendations.* *As highlighted in the summary of studies table in section 1.1.5 of the evidence review, the PECARN FLUID trial (Kupperman 2018) included participants with all severities of DKA. The study also presented data for the outcome confirmed decline in Glasgow Coma Scale for the whole population as well as*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				Of the 33 members of the committee, there are only two paediatric endocrinologists, two paediatric diabetes specialist nurses and one paediatric intensivist. STRS manages approximately 30 children per year with DKA with a mean pH of <6.95[1] who are at particular risk of cerebral oedema. We request from NICE more extensive consultation with greater input from paediatric intensivists, general paediatricians and paediatric emergency physicians to make recommendations relating to this critically ill subgroup. 1: Lillie J, Boot E, Tibby SM, et al. Management of fluids in paediatric diabetic ketoacidosis: concerns over new guidance. Arch Dis Child. 2020 Oct;105(10):1019-1020.	*for participants with severe DKA (forest plot and GRADE table in appendix F and H).* *The committee highlighted that while the trial did not identify a significant difference in important outcomes, the study is a large, high quality RCT and did demonstrate that both fast and slow fluid protocols are safe to use in children and young people with all severities of DKA. However, the committee did agree that critically ill children and young people were not captured in the PECARN Fluid trial.* *Based on this, the committee drafted recommendations that covered all severities of DKA, but did amend the recommendations further to state that the aim should be to replace the fluid deficit evenly over 48 hours but in critically ill children and young people, the fluid regimen should be discussed early with the senior paediatrician or paediatric intensivists (or both), because the risk of cerebral oedema is higher. The committee further noted that it is crucial that treatment is not delayed due to the risk of cerebral oedema. The committee's discussion and interpretation of evidence section (1.1.11) in the evidence review has been amended to highlight this discussion.*
South Thames Paediatric Network	Guideline	054	019	"Practice has changed since the 2015 recommendations were made, and there was concern that these 2015 recommendations could result in children and young people receiving less fluid than they need over the first 48-hour period." Within the South Thames region of 2.4 million children, our practice has been to follow the 2015 guidance. BSPED's publication of new guidance in January 2020 has caused great confusion within our region and a South Thames Paediatric Network group with clinical representatives from the majority of hospitals within the network have advised that	*Thank you for your comment. The committee were aware that there are no prospective audits that monitored the change after 2015 DKA recommendations were produced. As highlighted in the committee's discussion and interpretation of evidence section, the committee noted that it was important to assess the implementation of these updated recommendations in practice. As there are no existing audits, the committee were not able to make any research recommendations but agreed that an audit of practice would be valuable.*

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				although a more liberal fluid regime can be used for mild or moderate DKA, we should continue to follow the 2015 NICE guidance. Within this group of paediatricians from approximately 20 hospitals no one had seen a patient suffer harm from the restricted regime, introduced five years ago[1]. Before making these significant changes, it would be necessary to evaluate the impact the 2015 guidance has had. Within our own region the 2015 guidance was welcomed. It would be useful to see what affect the 2015 recommendations has had on cerebral oedema and deaths from DKA in the UK. 1: South Thames Paediatric Network DKA working group to discuss NICE guidance. October 19th, 2020.	- *Lillie 2020 – not included in review as this is a letter and we only included RCTs, systematic reviews and comparative observational studies.* *The PICO of this review question is in section 1.1.2 of the evidence review.*
South Thames Paediatric Network	Guideline	055	006	"The new recommendations are in line with current practice". It is not true to say that the 2020 recommendations are in line with current practice. The South Thames region is the most populated ODN in the country, containing 2.4 million children. Until very recently, practice across all hospitals was to follow the 2015 NICE guidance advising much more restrictive fluid than what is proposed. In some cases the new guidance proposed would almost double the amount of fluid received by a child in the first 24 hours of their care. Thus the new recommendations are almost doubling the volume of fluid received for the sickest patients with DKA who are less than 20kg (1.7-2 fold increase). It was only in 2020 after BSPED published their guidance that there has been confusion as to what practice should be. Over the last few months there has been variability in what practice has been adopted. Currently, 17 out of 20 of the STPN hospitals surveyed are following the BSPED guidance for	*Thank you for your comment. The committee amended 2015 DKA recommendations due to the risk of under resuscitation associated with the recommendations. Additionally, since the 2015 recommendations were published, the evidence base has developed further, which prompted an update of these recommendations.* *As highlighted in the summary of studies table in section 1.1.5 of the evidence review, the PECARN FLUID trial (Kupperman 2018) included participants with all severities of DKA. The study also presented data for the outcome confirmed decline in Glasgow Coma Scale for the whole population as well as for participants with severe DKA (forest plot and GRADE table in appendix F and H).* *The committee highlighted that while the trial did not identify a significant difference in important outcomes, the study is a large, high quality RCT and did demonstrate that both fast and slow fluid protocols are safe to use in children and young people with all severities of DKA. However, the committee did*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				mild/moderate DKA but continue to follow STRS guidance for those with severe DKA or signs of cerebral oedema. STRS guidance is aligned to the NICE 2015 fluid regime. As NICE provides evidence-based guidance, the 2015 fluid regime should not be changed for severe DKA without evidence showing its benefit. Example of huge increase in fluid for child with pH of < 7.1, assuming not shocked. 2 year old, 12 kg child: NICE 2015 receiving 10ml/kg fluid bolus,10 % deficit, reduced maintenance: 1.0 L in first 24 hours NICE 2020 receiving 20ml/kg/fluid bolus,10 % deficit, Holliday-Segar maintenance: 1.9 L in first 24 hours	*agree that critically ill children and young people were not captured in the PECARN Fluid trial* *Based on this, the committee drafted recommendations that covered all severities of DKA but did amend the recommendations further to state that the aim should be to replace the fluid deficit evenly over 48 hours but in critically ill children and young people, the fluid regimen should be discussed early with the senior paediatrician or paediatric intensivists (or both), because the risk of cerebral oedema is higher. The committee further noted that it is crucial that treatment is not delayed due to the risk of cerebral oedema. The committee's discussion and interpretation of evidence section (1.1.11) in the evidence review has been amended to highlight this discussion.*
Sussex Community Foundation NHS Trust	Guideline	015	013	Guideline doesn't specify duration after meals for proposed glucose range	*Thank you for your comment. Recommendations on blood glucose targets are out of scope for this update.*
Sussex Community Foundation NHS Trust	Guideline	019	027	Our young adult team felt the term long acting carbohydrate to be outdated and would prefer low glycaemic index carbohydrate and possibly an amount in g	*Thank you for your comment. This is out of scope for this update.*
Sussex Community Foundation NHS Trust	Guideline	049	013	There doesn't appear to be any mention of Type 2 Diabetes in transitioning to adult services	*Thank you for your comment. This is out of scope for this update.*
Sussex Community Foundation NHS Trust	Guideline	049	02	Our young adult team would like further guidance on the definition of enough time to aid commissioners	*Thank you for your comment. This is out of scope for this update.*
Sussex Community Foundation NHS Trust	Guideline	050	008	We wondered whether links to contraceptive advice should be included in the guideline	*Thank you for your comment. This is out of scope for this update.*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Sussex Community Foundation NHS Trust	Guideline	052	011	As to the management of type 2 Diabetes mellitus in CYP) what's NICE position /stand with the SGLT-2i ,GLP_1 RA , low calorie diet in children and young people with high BMI and type 2 Diabetes mellitus – should there be research recommendations ?	*Thank you for your comment. This is out of scope for this update.*
The Royal College of Ophthalmologists	Guideline	025	014	The Royal College of Ophthalmologists requests clarification on whether the guidance will include commentary about: 1. Evidence of uptake of DR screening by children and young people, especially during transition to adult health care services 2. What could be done to make the National Diabetic Eye Screening Programme (NDESP) more child-centred- for example changing the existing communication using standard letters designed for adults is also being used for children and young persons. The NDESP was created as a programme for adults and was not modified to cater for the needs for children and young people. 3. Review the co-ordination and communication between the three provider elements where children and young persons with diabetes are cared for i.e. primary care, secondary/tertiary care with the local DESP 4. Reviewing the role of the annual diabetic eye screening exam to encompass other interventional elements of general care and wellbeing of children and young people, such as patient education, nutrition, exercise etc in order to reduce the long term risks of complications of diabetes such as retinopathy.	*Thank you for your comment. The scope of the guideline was limited to fluid therapy in DKA and recommendations on the diabetic eye screening programme were updated as part of an editorial refresh of the recommendations. While these points cannot be incorporated in the current update, these can be considered when planning future updates.*
University Hospitals Bristol & Weston NHS	Guideline	041	004, 006 + 027	The recommendation to exclude the 10ml/kg fluid bolus given to all children from the subsequent calculation of IV fluid replacement is clear however it is unclear in these recommendations whether or not the 20ml/kg bolus given to	*Thank you for your comment. Recommendation 1.4.24 has been amended to state that fluid bolus should not be*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
Foundation Trust				children who are clinically shocked should similarly be subtracted from subsequent fluid calculations. This should be explicitly stated if intended. I would however argue that in shocked patients this larger bolus is required to restore circulating intravascular volume and is additional to fluid required to correct dehydration. To include this in subsequent fluid replacement is counter to established clinical practice when treating dehydration in other clinical situations e.g. gastroenteritis.	*subtracted from the total fluid deficit in children who are in shock.* *The committee's discussion and interpretation of evidence section (section 1.1.11) in the evidence review has also been updated based on this amendment.*
University Hospitals of Leicester NHS Trust	Guideline	040	023	We are concerned about differentiating hypovolemia from shock. What criteria will be used to differentiate this? Signs of shock is defined in page 41, line 6	*Thank you for your comment. The committee have removed the term 'hypovolaemia' from recommendation 1.4.23 and amended it to include the term 'clinically dehydrated'.* *The committee have also amended the signs of shock specified in recommendation 1.4.24. The new recommendation includes the following symptoms: weak thready pulse (low volume pulse) and hypotension.* *The committee's discussion and interpretation of evidence section (section 1.1.11) in the evidence review has also been updated based on these amendments.*
University Hospitals of Leicester NHS Trust	Guideline	040	025	BSPED guidelines advise to give 10ml/kg bolus of 0.9% sodium chloride over 60 minutes instead of 30 minutes in non-shocked patients.	*The committee noted that the International Society for Paediatric and Adolescent Diabetes (ISPAD) guideline states that the resuscitation fluids should be administered over 30 to 60 minutes, however, if tissue perfusion is poor the initial fluid bolus is given more rapidly (e.g. over 15-30 minutes). Based on this information the committee highlighted that resuscitation should not be delayed and therefore opted to state initial intravenous bolus of 10 ml/kg 0.9% sodium chloride should be given over 30 minutes. The committee's discussion and interpretation of evidence is highlighted in section 1.1.11 in the evidence review.*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
University Hospitals of Leicester NHS Trust	Guideline	040	027	Only consider giving a second intravenous bolus if needed to improve tissue perfusion – this sentence is confusing as we did not give first bolus for treating shock.	*Thank you for your comment. Recommendation for children and young people who show signs of shock state that an initial bolus of 20 ml/kg 0.9% sodium chloride should be given as soon as possible. Recommendation on second intravenous bolus are for children and young people who are hypovolaemic but not in shock.*
University Hospitals of Leicester NHS Trust	Guideline	041	014	Regarding calculation of fluid deficit BSPED guidelines have recommended 3 levels of fluid deficit- mild 5%, moderate 7%, Severe 10%. Even though we have defined DKA as mild, moderate and severe we have using fluid calculation for only 2 levels of severity – Mild/moderate and Severe	*Thank you for your comment. In the PECARN FLUID trial two different protocols were followed in which 10% deficit and 5% deficit were assumed. This study highlighted that these protocols were safe to use as the study did not identify a significant difference in mortality or clinically apparent brain injury. Based on this evidence, the committee retained the 2015 recommendations and stated that in children and young people with mild to moderate DKA, 5% dehydration should be assumed and 10% dehydration should be assumed in children and young people with severe DKA. The committee's discussion and interpretation of evidence is highlighted in section 1.1.11 in the evidence review.*
University Hospitals of Leicester NHS Trust	Guideline	041	027	It is not clear whether we have to subtract bolus given for treatment of shock from the fluid calculation. BSPED guidelines advises not to subtract bolus given for resuscitation in children presenting with shock.	*Thank you for your comment. Recommendation 1.4.26 has been amended to state that when calculating the total fluid requirement, subtract any initial bolus volume given from the total fluid deficit (except in children who are in shock). The committee's discussion and interpretation of evidence section (section 1.1.11) in the evidence review has also been updated based on this amendment.*
University of Brighton	Guideline	General	General	I am concerned that education in the widest sense for young people with T1 diabetes remains underspecified. While frequent references are made to education and while I would be happy to allow for variation/adjustment in line with localities, population needs etc, I find the lack of detail regarding what education means disconcerting. The lack of detail concerns all aspects of fully structured and opportunistic education, around objectives, duration, format including issues of remote delivery as we are likely to live with COVID for some time. No reference is made to what might be called	*Thank you for your comment. This is out of scope for this update.*

Diabetes (type 1 and type 2) in children and young people: diagnosis and management (update)

Consultation on draft guideline - Stakeholder comments table
23/09/2020 – 21/10/2020

Stakeholder	Document	Page No	Line No	Comments	Developer's response
				the philosophy behind educational intervention: this can range from more didactic, instructional to more supportive, encouraging problem solving etc approaches; as reflected by different structured education programmes available in the UK and elsewhere.	

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