NICE guideline for the management of diabetes in children and young people – comments from the Guideline Development Group

Jo Dalton, Julie Edge, Jeremy Wales, Jacqui Double, Sarah Eaton, Zosia Beckles, Yelan Guo, Bill Lamb, Carol Metcalfe, Claire Pesterfield, Francesca Annan, Kath Barnard

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Article points

1. New national guidelines from NICE cover all aspects of care for children and young people with diabetes.
2. Routine management should be delivered from diagnosis by a multidisciplinary team to ensure adequate education and support, and individualisation of targets.
3. Intensive management should be employed from the outset in order to improve long-term glycaemic control.

Key words

- Children and young people
- NICE guidelines
- Type 1 diabetes
- Type 2 diabetes

Authors

For author details, see end of article.

NICE has published new national guidance covering all aspects of treatment and care for children and young people with diabetes: *Diabetes (type 1 and type 2) in children and young people: diagnosis and management* (NG18). The specific management requirements and complications of type 2 diabetes mean that guidance on this condition is incorporated for the first time. Also included is a recommendation that children and young people with type 1 diabetes attempt to maintain normal blood glucose levels. From their different perspectives, this article presents the thoughts of the Guideline Development Group on the development, evidence base and impact on practice of the new guidance.

Type 1 diabetes is a chronic condition affecting over 24 000 children and young people (CYP) in the UK. Managing type 1 diabetes has a huge impact on the life of the child or young person as well as their carers, and requires specialist advice and support. The newly published NICE guideline, *Diabetes (type 1 and type 2) in children and young people: diagnosis and management* (NICE, 2015a), covers all aspects of care, with the aim of making services equitable and evidence-based. This is an update of the 2004 guidance (NICE, 2004) and it is the first time that type 2 diabetes has been included in a guideline for CYP. There are a variety of monogenic disorders, including neonatal diabetes, cystic fibrosis-related diabetes and other syndromic conditions, with a large combined incidence (greater than that of type 2 diabetes). Although these all require expert care, the diverse management of these conditions was beyond the scope of this guideline.

The Guideline Development Group (GDG) included three consultant paediatricians, three paediatric diabetes nurses, a paediatric dietitian, a young adult with diabetes, a GP and a parent of two children with type 1 diabetes. The GDG was supported by representatives from NICE, including researchers, information scientists and health economists, as well as a psychologist and a consultant in paediatric intensive care for specific sections of the guidance. The guideline development was coordinated by experienced developers from the National Collaborating Centre for Women's and Children's Health. In this article the GDG share their thoughts on the new guideline, its development, the evidence base and its impact on practice from their different perspectives.

Technical aspects of guideline development

The guideline was developed in accordance with NICE's 2012 edition of *The Guidelines Manual* (NICE, 2012), which sets out processes and methods for producing evidence-based guidelines. This includes methods for scoping the guideline, developing review questions, identifying, reviewing and synthesising evidence, and transparently linking evidence to recommendations.

At an early stage, the scope was developed to identify the population and key issues to be covered by the guideline. Following consultation

with stakeholders, the agreed key issues were then translated into 47 review questions, each of which had to be addressed by a systematic review of the evidence. To ensure that this could be achieved within the 2-year development time, protocols were developed for each review question by the technical team in collaboration with the GDG. The specific structure of the protocol varied with the type of question, but usually included details of the population of interest, specific intervention, prognostic factor or test, comparators (if appropriate), and relevant patient-important outcomes. By clearly defining those factors relevant to the topic, the protocol set up criteria for the identification and selection of evidence. Studies that did not meet the criteria stated in the protocol were not searched for or included in reviews.

On occasions where evidence was not available, consensus recommendations were developed, based on the GDG's clinical experience and expert opinion. To ensure transparency, these instances have been clearly documented in the full guideline. For example, no evidence was found to inform the review on HbA_{1c} targets. The decision to recommend an ideal HbA_{1c} target level of 48 mmol/mol (6.5%) or lower in order to minimise the risk of long-term complications was made after thorough discussion among the GDG, including careful consideration of the psychological impact of the tighter target.

GDG members also had long discussions about the impact of a lower HbA_{1c} target and the fear of hypoglycaemic episodes, particularly in CYP who received their diagnosis some years ago when targets were higher. With multiple daily insulin injections and carbohydrate counting with dose adjustment now being recommended from diagnosis, it is anticipated that this fear will reduce, as mild, treatable episodes are not uncommon when living with diabetes. Having an individualised target for every patient allows teams and families to take into account any particular patient's fears.

Parent representative view

My son was diagnosed with type 1 diabetes in 2000 when he was 1 year old. The expectations for his care then were very different to those that I and his specialist team have now. It was suggested then that we would only need to take one blood glucose reading a day – even dropping this, we were told with a reassuring smile, to one per week as his levels became balanced. We were advised that he could eat whatever he wanted, no mention being made of carbohydrate counting or dose adjustment, and we were sent home. Diabetes might have nearly killed him before he was diagnosed, but our then clinical team made it sound like the care-at-home part would be no big deal.

Five years later and my second son was diagnosed. My expectations of care for type 1 had changed drastically by this point, but those of the clinical team had not changed much at all. Having lived with a baby, toddler and infant-school child with type 1, the eyes of our whole family and school staff were well and truly open to the care it really took. The team were always very happy that our first son's HbA_{1c} was about 69 mmol/mol (8.5%), being below their typical average for the whole clinic. But I could see with our second son that his control seemed far easier and his HbA_{1c} was always lower; so perhaps this was about treating each case individually and making use of all the tools available for each child.

Therefore, the particular change to the NICE guidance that excites me most is the one which should at last dispel a myth still in evidence when both my children were diagnosed: that being diagnosed pre-puberty affords you protection from complications, a thought that always seemed to be reflected in the higher HbA_{1c} target of 58 mmol/mol (7.5%) for CYP compared to the adult target of 48 mmol/mol (6.5%). A clear statement that all people with type 1 diabetes should attempt to safely achieve an HbA_{1c} of 48 mmol/mol (6.5%) is factually correct and, when matched with the tools and support our families need, should help to drive clinical expectation into line with that of experienced carers.

I know that HbA_{1c}, that "magic" measurement announced every 3 months, can feel like a judgement from on high to parents and CYP – one where you are tested and found wanting by your team, who may just demand you do better without seeming to offer choices to make this happen. But our guideline also hopes to change this by making it very clear that targets should be set on an individual basis and should reflect all the present circumstances of the family and young person.

Page points

1. The new guideline was developed based on a systematic review of the evidence, the clinical experience of the Guideline Development Group and expert opinion.
2. The guideline recommends an ideal HbA_{1c} target for children and young people with type 1 diabetes of 48 mmol/mol (6.5%) or lower in order to minimise the long-term risk of complications.
3. Nevertheless, targets should be set on an individual basis and match the present circumstances of the family.

Page points

1. Optimal management of type 1 diabetes should be delivered by a multidisciplinary team working to ensure adequate patient education and support, and individualising targets.
2. Intensive insulin therapy, including insulin dose adjustment according to blood glucose levels and activity plans, should be initiated from diagnosis.
3. Education should be planned and continuous from diagnosis. Educators should ensure that it is appropriate for the child or young person, their family and carers.

Actually stating that the target HbA_{1c} should be the same for both adults and children is a huge but equitable step that acknowledges both the damage this condition can do to our children's bodies (given that their diagnosis at an early age means living longer with it) and the expectations of care we need to have if we hope to keep our children well into adulthood. You do not help those who care for children with type 1 by trying to introduce this disease as gently as possible. You help us by clearly acknowledging the demands of it and equipping us with the knowledge and tools to do the 24-hour, 7-days-a-week care that diabetes in CYP makes necessary. This target makes that Herculean task more apparent, whilst also stating plainly that this will only be achieved by an effort from a team that includes a proactive, educated family, a clinical team and, most importantly, a child or young person who is educated, equipped and expected to be well.

Summary of type 1 diabetes recommendations

Type 1 diabetes is becoming slowly more common and seems to be affecting children at a younger age. Since the previous NICE guidance in 2004, there have been major changes in the routine management of type 1 diabetes in an effort to reduce further the long-term risks of the condition by achieving stricter targets for glycaemic control. Optimal management should be delivered from the outset by a multidisciplinary team working to ensure adequate patient education and support, and individualising targets as described above. There is now a requirement to ensure access to sufficient blood-checking strips, as well as blood ketone measurements during illness. Easy access to psychological services, and a carefully planned and coordinated transition to adult services at an appropriate psychosocial time (not on a specific birthday) are also requirements. Screening for complications was reviewed, but the evidence agreed with the 2004 recommendations.

Intensive insulin management from diagnosis

The initial management at diagnosis should be with intensive therapy as a multiple daily injection (basal–bolus) regimen, together with carbohydrate counting that includes the use of an insulin-to-carbohydrate ratio. Intensive management includes insulin dose adjustment according to blood glucose levels and activity plans. Carbohydrate counting (see more below) should be taught from diagnosis to all CYP with type 1 diabetes and their parents and carers by a paediatric diabetes dietitian. Diabetes healthcare teams should explain that rapid-acting insulin analogues should be injected before rather than after eating, to optimise blood glucose control and reduce post-prandial blood glucose levels. Where multiple daily injections are deemed inappropriate, then insulin pump therapy can be used as an alternative, as recommended in NICE technology appraisal guidance 151 (NICE, 2008).

Paediatric diabetes specialist nurses (PDSNs) will be required to update ward staff competencies and ensure training is in place for intensive insulin therapy. Newly diagnosed care pathways and school healthcare plans will also require updating to accommodate this. In practice, many centres already offer this education and support within the first 2 weeks of diagnosis, and many examples of good practice can be found throughout the Paediatric Networks in England and Wales.

Education

Education and support for CYP with diabetes and their families is vital to independence and empowerment (Lange et al, 2014). The updated guideline recommends that the education is planned and continuous from diagnosis, and includes for the first time CYP with type 2 diabetes. Direction is given for certain areas of diabetes management to be included within education programmes, and educators should ensure that all planned education is appropriate for age and maturity, and that learning is evaluated. Special consideration should be given to ensuring that provision is made for families and carers if English is not their first language, or if sensory or physical difficulties are present. One of the difficulties in coming to firm conclusions is the lack of good evidence for specific education programmes. One of the key research areas suggested by the GDG was to look at the effectiveness of education programmes in which young people with type 1 diabetes provide training for their peers.

HbA_{1c} and blood glucose targets

The 2015 NICE guideline is the first outside pregnancy to recommend attempting to achieve a glycated haemoglobin value near the normal range and near normoglycaemia. The recommendation most likely to cause controversy within diabetes teams and with some families is the recommendation to aim for an HbA_{1c} level below 48 mmol/mol (6.5%). This may cause some anxiety because one of the main concerns of families is hypoglycaemia (Barnard et al, 2010). However, as described earlier by the parent involved in the GDG, it is important that teams are aware of the evidence for improved control so that they can discuss this with individual families and recognise which families will need more support and, possibly, reassurance to achieve this target. This guideline states that if families are not achieving optimal glucose levels, steps must be taken to offer further support. PDSNs must ensure that clear pathways are in place and documentation of the process is recorded.

The recommendations state that families should be informed that the ideal target for blood glucose levels is 4–7 mmol/L before meals and 5–9 mmol/L following meals. The aim with intensive management from diagnosis is to achieve these target levels early with the intention of improving long-term control. These targets were attempted in the Diabetes Control and Complications Trial (White et al, 2001), but were not achieved in the majority of cases. We believe, however, that they are achievable using intensive insulin management (multiple daily injections or pump therapy) accompanied by carbohydrate counting from diagnosis and a strong team message. It is clear that there will be ongoing discussions around the new targets, but we hope that by ambitiously attempting to implement such strict control from diagnosis, improved glycaemic control may reduce the impact of the condition on the future health of CYP in England and Wales.

Blood glucose monitoring

There is evidence that HbA_{1c} levels are improved with up to five blood glucose checks per day (Ziegler et al, 2011), and so a recommendation was made for at least five checks per day to be routine. This number will need to increase in times of illness, exercise or other circumstances, so liaison with primary care will be needed to ensure that adequate blood glucose testing strips are provided.

The use of continuous glucose monitoring (CGM) every day for CYP with diabetes remains controversial, with limited evidence of its long-term benefit on diabetes control. Using the latest research available and the opinions of the GDG, it was felt that there are some situations where the use of CGM would benefit CYP with diabetes. Real-time CGM with alarms could be offered to CYP who either have had frequent episodes of severe hypoglycaemia or have impaired awareness of hypoglycaemia with additional adverse consequences, such as episodes of seizures or significantly increased anxiety. CGM could also be considered for neonates, infants and pre-school children with type 1 diabetes; CYP who undertake a high level of physical activity, such as participating at regional, national or international standards; and CYP who have comorbidities, such as an eating disorder, or who are receiving treatments (such as corticosteroids) that complicate blood glucose control.

Intermittent CGM (either real-time or retrospective) should be considered in CYP who continue to have hyperglycaemia despite additional support, education and insulin adjustment, in order to identify problem areas of glucose control that cannot be identified by conventional blood glucose monitoring. It is likely that newer "loop" technology may require reappraisal of this evidence.

Nutrition in type 1 and type 2 diabetes

The 2015 update is not a comprehensive review of the nutritional management of diabetes in children. The 2004 guidance includes information on composition of the diet as well as education and teaching strategies for nutritional management in type 1 diabetes, and much of this was not updated.

The key areas of review in 2015 are carbohydrate counting and glycaemic index. In addition, the updated guidance covers the management of type 2 diabetes. Carbohydrate counting, as described by Gillespie et al (1998) and explained in the International Society for Pediatric and Adolescent Diabetes (ISPAD) consensus guidelines (Smart et al, 2014), should be taught in a timely fashion from diagnosis to all CYP with type 1 diabetes.

Page points

1. Teams need to be aware of the evidence in support of improved glycaemic control so that they can discuss it with families.
2. At least five blood glucose checks per day are recommended. This number should increase during times of illness, exercise or other circumstances.
3. This guideline does not comprehensively review the nutritional management of diabetes in children, but does look at the key areas of carbohydrate counting, glycaemic index and the management of type 2 diabetes.

Page points

1. Children and young people with type 1 diabetes and their family members or carers should be offered timely and ongoing access to psychological support.
2. Teachers, friends and extended family can provide social support to help diabetes management and reduce barriers to treatment.
3. Specific interventions, such as behavioural family systems therapy, can be effective in improving glycaemic control, relationships and adherence to therapy.

This should include how to quantify carbohydrate and the use of an insulin-to-carbohydrate ratio to decide on insulin doses based on amount of carbohydrate consumed, blood glucose levels, insulin on board and activity. In addition, education about glycaemic index should be given to help guide carbohydrate food choices and support the development of understanding of the post-prandial effects of carbohydrate consumption. Glycaemic index education has been shown in the paediatric population to decrease post-prandial hyperglycaemia (Gilbertson et al, 2001). The impact of mixed meal composition was not included in the scope of the review; however, emerging evidence about effective ways to manage meals with adjustment to insulin delivery should be taken into account, particularly for those CYP using insulin pump therapy with CGM.

Guidance on the composition of the diet is as published in 2004; however, clinicians should consider the latest guidance about carbohydrates and health from the Scientific Advisory Committee on Nutrition (SACN; 2015) and the ISPAD guidance on composition of the diet when determining macronutrient distribution (Smart et al, 2014).

Management of type 2 diabetes requires nutrition support to achieve an appropriate energy balance to promote weight loss where achievable. This has been described as a shared responsibility across the team, with all multidisciplinary team members taking opportunities to promote an overall healthy lifestyle. The management of weight and lifestyle to promote healthier outcomes is covered in NICE guidelines on maintaining a healthy weight (NICE, 2015b) and managing obesity (NICE, 2014).

Psychological and social issues in type 1 and type 2 diabetes

Although psychological support was highlighted as a key area in the 2004 diabetes guidance (NICE, 2004), recommendations from that guideline have still not been fully implemented and this remains a key area for implementation in the new guideline. Psychological disorders such as distress, depression and anxiety disorders are highly prevalent in CYP with diabetes. CYP with type 1 diabetes and their family members or carers, as appropriate, should be offered timely and ongoing access to support, as recognised in the *Best Practice Tariff for Paediatric Diabetes*, which provides for annual psychological assessment (Monitor and NHS England, 2013: pp. 56–9). Fear of hypoglycaemia is a particular concern and associated with maladaptive coping strategies that can lead to sub-optimal glycaemic control (Barnard et al, 2010) and chronic sleep disturbance (Barnard et al, 2015).

It is important to reduce psychological morbidity as early as possible to reduce the burden of recurrence throughout adulthood (Cox et al, 2012). Depression is experienced by 15–25% of adolescents with type 1 diabetes (Grey et al, 2002; Hood et al, 2006), which is 2–3 times the rate found in the general population, and recent reports suggest that youths with type 2 diabetes are at equal, if not greater, risk than youths with type 1 (Hood et al, 2014). Furthermore, depression often presents in childhood but persists chronically into adulthood and later life (Cox et al, 2012).

Living with diabetes can feel overwhelming for CYP and their parents alike. Social support is an important factor in optimal adjustment to living with diabetes. Teachers, friends and extended family can support diabetes management and reduce barriers, such as insulin administration in public. Increasing communication in families is associated with greater perceived emotional support and empathy from parents, leading to more positive interactions (Northam et al, 1996).

Individual and family-based therapeutic options are effective in improving health-related quality of life and treatment adherence, and in reducing diabetes-related psychological morbidity and diabetes-related family conflict. Recommendations have been provided for the first time about specific interventions. Behavioural family systems therapy, for example, is effective in improving glycaemic control, family–adolescent relationships and adherence to therapy (Wysocki et al, 2007). However, the lack of literature was very marked in this area, and large studies of psychological and behavioural interventions still need to be done.

Specific type 2 diabetes recommendations

Type 2 diabetes in childhood is a serious condition that has been clearly acknowledged by NICE with its inclusion in this guideline. Since the previous

guidance, type 2 diabetes is being recognised with increasing frequency, affecting around 450 CYP in the UK, mostly in their teenage years. While much of the guidance is similar to that for type 1 diabetes, there are some clear distinctions. There is evidence to suggest that metformin should be prescribed early, even in the pre-diabetic phase if insulin resistance is recognised, along with advice on levels of activity and weight management as given in the NICE guidelines on maintaining a healthy weight (NICE, 2015b) and managing obesity (NICE, 2014).

However, because there is no evidence for the use of other oral agents or injectable treatments in type 2 diabetes in this age group, the committee were not able to include treatment options other than metformin in the guidance. Although insulin is often used, the lack of evidence in CYP was clear and meant that, for now, the adult type 2 diabetes guidance would need to be consulted. However, the GDG felt strongly that more research is required in this area, coordinated through experienced centres and a national registry able to conduct randomised controlled trials to improve the evidence base, such that any young person with type 2 diabetes should be entered into a study.

Another major difference is the recommendation of annual screening for complications from diagnosis with type 2 diabetes. Specific guidance on the form of screening and the need for prompt treatment is given, particularly with regard to diabetic kidney disease, which is common and occurs early in the disease process. Hypertension and dyslipidaemia associated with the accompanying overweight and obesity required separate guidance from type 1 diabetes, and was included for the first time.

Diabetic ketoacidosis

This guideline is the first to recommend that all CYP use blood ketone checking at home as the norm, rather than urine ketone testing, for episodes of elevated blood glucose or in times of intercurrent illness, as it was shown to reduce hospitalisation and to be cost-effective (Laffel et al, 2006). Liaison with primary care staff will be required to ensure repeat prescriptions are updated to reflect this.

The management of diabetic ketoacidosis (DKA) has evolved over the last 20 years with the aim of improving safety and, in particular, preventing cerebral oedema, which is the main cause of death and disability. The guidance has taken this further and has included advice from an expert paediatric intensivist with a particular interest in the fluid management of DKA.

There are several notable changes in the guidance compared to previous British Society of Paediatric Endocrinology and Diabetes (BSPED) recommendations (BSPED, 2009), and also compared to the recent international guidance from ISPAD (Wolfsdorf et al, 2014). The recognition of DKA has been covered in a lot more detail, and includes reminding GPs to refer direct to a hospital with appropriate facilities any child with possible diabetes and symptoms of DKA. The measurement of blood (rather than urine) ketone levels is emphasised throughout the NICE guideline, and is also recommended during the investigation and management of DKA in hospital. There is more emphasis on safe nursing care and on ensuring that anaesthetists and paediatric intensivists are involved in discussion of very sick patients.

Recommended fluid and insulin management has changed. Maintenance and rehydration fluid volumes have been made easier to calculate. Maintenance rates are based on a volume per hour, and rehydration rates should be calculated at 5% in mild to moderate DKA, or 10% in severe DKA (pH <7.1). The total fluid calculated by these regimens is similar to those used in some centres, and is adequate to promote rehydration and recovery, but is significantly lower than in the BSPED or ISPAD guidance (Hsia et al, 2015; *Figure 1*), and so should help to reduce the risk of cerebral oedema.

Evidence was reviewed suggesting that a lower dose of insulin than has previously been recommended can be used safely to treat DKA (Puttha et al, 2010), and so doses of 0.05 units/kg/hour to 0.1 units/kg/hour are recommended in the new guidance. However, as there is still insufficient evidence of efficacy and duration of treatment with lower doses, a research recommendation to compare these two doses in a large controlled study has again been made. There are recommendations around ongoing monitoring and ensuring that insulin rates are adequate to resolve ketosis. Recommendations have been made

Page points

1. Type 2 diabetes is being recognised with increasing frequency in children and young people (CYP).
2. While evidence suggests that metformin should be prescribed early for type 2 diabetes in this age group, there was not enough evidence to include other treatment options in the guidance.
3. The guideline recommends that CYP use blood ketone checking at home during episodes of elevated blood glucose or in times of intercurrent illness.
4. GPs must refer direct to a hospital with appropriate facilities any child with possible diabetes and symptom of diabetic ketoacidosis.

"The early identification and initiation of treatment is essential and a key role for the primary care team."

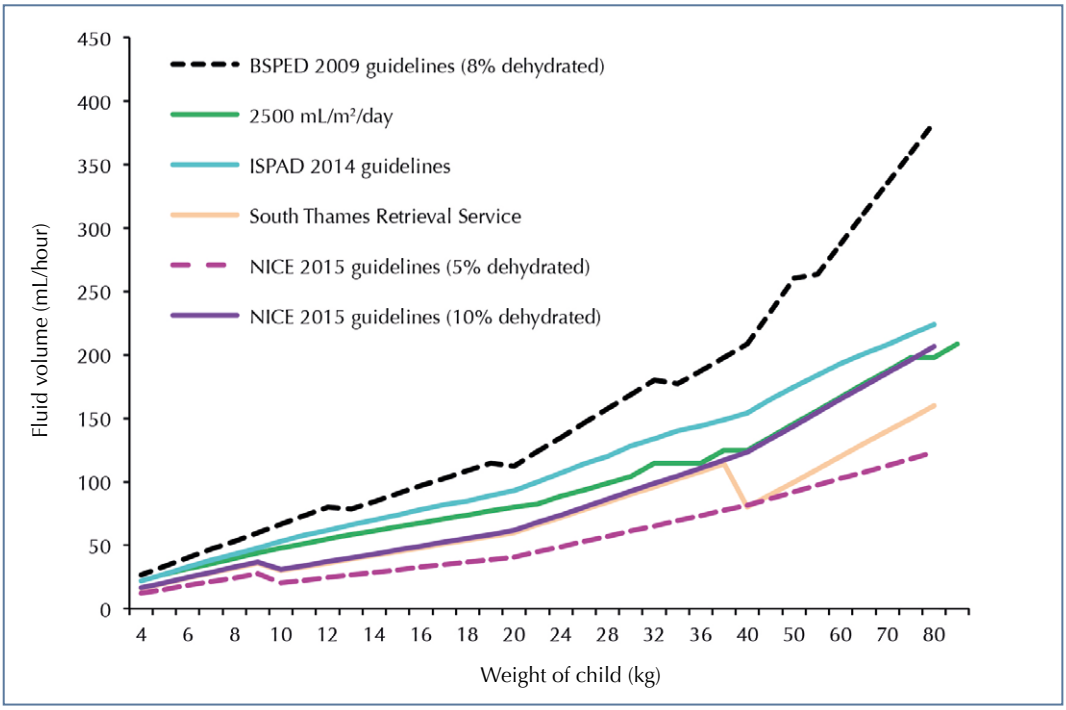

Figure 1. Fluid volumes per hour for the first 24 hours following diagnosis of diabetic ketoacidosis, calculated for various weights of child or young person from several guidelines.
BSPED=British Society for Paediatric Endocrinology and Diabetes; ISPAD=International Society for Pediatric and Adolescent Diabetes.

about the clinical monitoring that should occur to detect early signs of possible or definite cerebral oedema, and the first-line treatment if signs are present. However, the ongoing investigation and management of cerebral oedema is outside the scope of this guidance.

Many of these recommendations make the management much clearer and they are based on the most up-to-date evidence, which has been examined in a systematic way for the first time. The BSPED guideline has been updated in the light of this NICE guideline (BSPED, 2015).

Importance for primary care

A large number of the recommendations from this updated guideline will be implemented in secondary care and so the guideline may feel less relevant to primary care, but this is not true. Like all NICE guidelines, it has implications for primary care as primary care forms a major part of the healthcare service provided to patients. Primary care is often the first port of call for patients when unwell, and the primary care team needs to remain vigilant to the symptoms of undiagnosed diabetes and also DKA, and then start the patient on the care pathway in an appropriate timeframe.

The primary care team also offers ongoing support to patients and their families and carers throughout their lives with diabetes. Two specific changes that have been made will impact on primary care. Supplies of equipment on prescription will need to reflect the increased number of daily recommended blood glucose checks. Also, the recommendation to offer CYP with type 1 diabetes blood ketone checking strips will mean that primary care will need to review and adjust prescriptions accordingly. These are two practical changes that will have to occur, but the early identification and initiation of treatment for these patients is also essential and a key role for the primary care team. ■

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Author details

Jo Dalton is a Diabetes Nurse Specialist – Transition, Poole Diabetes Centre, Poole Hospital NHS Trust; Julie Edge is a Consultant in Paediatric Diabetes, Oxford Children's Hospital and Chair of the Diabetic Ketoacidosis Guideline Development Group; Jeremy Wales is Director of Endocrinology, Lady Cilento Children's Hospital, Brisbane, Professor, University of Queensland, and Chair of the Guideline Development Group; Jacqui Double is a parent of two children with type 1 diabetes; Sarah Eaton is a GP, York; Zosia Beckles is an Information Scientist, National Collaborating Centre for Women's and Children's Health; Yelan Guo is a Research Fellow, National Collaborating Centre for Women's and Children's Health; Bill Lamb is a Consultant in Paediatric Diabetes, The Great North Children's Hospital, Newcastle upon Tyne; Carol Metcalfe is a Lead Paediatric Diabetes Nurse, East Cheshire NHS Trust; Claire Pesterfield is a Lead Paediatric Diabetes Specialist Nurse, Cambridge University Hospitals NHS Foundation Trust; Francesca Annan is a Paediatric Diabetes Dietitian, Alder Hey Children's NHS Foundation Trust; Kath Barnard is a Health Psychologist, Human Development and Health Faculty of Medicine, University of Southampton.