

## Diabetes UK Position Statements

# A Type 1 diabetes technology pathway: consensus statement for the use of technology in Type 1 diabetes

P. Choudhary<sup>1</sup> , F. Campbell<sup>2</sup>, N. Joule<sup>3</sup> , P. Kar<sup>4</sup> and on behalf of Diabetes UK

<sup>1</sup>Diabetes Research Group, London, <sup>2</sup>St James's University Hospital, Leeds Teaching Hospitals NHS Trust, Leeds, <sup>3</sup>Diabetes UK and <sup>4</sup>Diabetes, NHS England, London, UK

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### Abstract

In both adults and children with diabetes, technologies such as continuous subcutaneous insulin infusion using insulin pumps and continuous glucose monitoring can help improve diabetes control, reduce hypoglycaemia and improve quality of life. Access to these technologies in the UK is very variable. Some technologies are recommended by the National Institute for Health and Care Excellence, while others have not been appraised, and new technologies are emerging all the time. Additionally, different guidelines for adults and children further complicate access to diabetes technology in the transition from paediatric to adult care. Against this background, Diabetes UK and NHS England have brought together a multidisciplinary group of experts, including clinicians and people with diabetes, to develop this consensus guideline, combining the different technologies into a common pathway to aid clinical and policy decision-making. We created a pathway that supports the incremental addition of technology as monotherapy and then dual therapy in the same way that we incrementally add in therapeutic agents to support people with Type 2 diabetes to achieve their personalized glycaemic targets. The pathway emphasizes the importance of structured education, specialist support and appropriate access to psychological therapies, as essential pillars for optimized use of diabetes-related technology, and recommends the re-evaluation of its use when the individual is unable either to use the technology appropriately or to achieve the intended outcomes. This pathway is endorsed by UK-wide clinical and patient associations and we recommend that providers and commissioners use it to ensure the right individual with diabetes has access to the right technology in a timely way to help achieve better outcomes.

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### Introduction

Achieving the level of glucose control required to minimize the risks of long-term complications in Type 1 diabetes requires a complex balance between insulin delivery, carbohydrate intake and physical activity. This relentless task places a significant burden on people living with this condition and is one of reasons why, according to the latest national diabetes audits, fewer than 15% of adults and 28.9% of children are able to achieve target glucose levels [1,2].

Mean HbA<sub>1c</sub> levels are much higher in the UK compared to data from large registries from the USA, Sweden and Germany [3–6]. Data from these registries offer real-world insights into factors associated with greater achievement of glucose targets. One of these is the fact that those achieving target HbA<sub>1c</sub> values are far more likely to be using technology such as continuous glucose monitoring (CGM) or continuous subcutaneous insulin infusion (CSII) with an insulin pump [3,8,9].

Indeed, both CSII and CGM have a large body of randomized controlled trial (RCT) as well as real-world observational evidence demonstrating benefits to people with Type 1 diabetes in terms of improved HbA<sub>1c</sub>, reduced hypoglycaemia and improved quality of life [8,10–15].

The latest National Institute for Health and Care Excellence (NICE) guidance for Type 1 diabetes in adults and in children (NG17 and NG18 [2]) state that the key priority for implementation was to 'support adults (and children and young adults) to aim for a target HbA<sub>1c</sub> level of 48 mmol/mol [6.5%] or lower' [16]. If we are indeed serious about supporting people with diabetes to achieve their personal glucose targets, then we need to recognize that for many people this will not be possible without some form of technological support.

The NICE technology appraisal TA 151 [17] set out clear guidelines for the use of insulin pumps and has helped support a doubling of patients using insulin pumps across the country [18]. There is, however, no similar NICE technology appraisal for access to CGM, although the NICE guidance for Type 1

Correspondence to: Pratik Choudhary. E-mail: pratik.choudhary@kcl.ac.uk

**What's new?**

- This consensus statement makes recommendations for a number of diabetes technologies that are available to patients today.
- It describes a pathway that moves through 'monotherapy' to 'dual therapy', in a similar way as we do for Type 2 diabetes, with the aim of supporting patients to reach National Institute for Health and Care Excellence-approved targets for glucose control.
- The guideline covers adults, children, young people and pregnant women with Type 1 diabetes.

diabetes does recommend the use of real-time glucose monitoring in certain circumstances, such as recurrent severe hypoglycaemia, complete loss of hypoglycaemia awareness, extreme fear of hypoglycaemia or hyperglycaemia  $>75$  mmol/mol (9%) despite  $>10$  self-monitored glucose measurements per day when the use of CGM results in a sustained fall in HbA<sub>1c</sub> of at least 27 mmol/mol (2.5%) or a sustained HbA<sub>1c</sub> below 53 mmol/mol (7.5%). A recent freedom-of-information request showed that many Clinical Commissioning Groups in the UK still do not have a policy for CGM, or have a blanket policy to refuse funding for CGM [19].

In the last couple of years, the advent of flash glucose monitoring (GM) has provided another alternative to conventional CGM. It allows patients to easily access frequent and detailed data on their glucose levels as well as on the direction and rate of change [20]. This has some advantages over conventional CGM, such as lower price and ease of use, as well as some important differences from CGM, such as the lack of alarms and intermittent nature of the data. There has been huge media and patient interest in the use of this technology, especially with some high-profile users in the news [21]. The Regional Medicines Optimization Committee published a position statement in October 2017 that set out five indications in which flash GM was recommended [22]; however, these recommendations and guidelines are being reviewed and re-assessed at multiple local and regional levels, with huge duplication of work, leading to delays and regional variation in patient access.

To clinicians and commissioners working in this area, one of the challenges concerning equitable access to medical technology was the fact that recommendations for CSII, CGM and flash GM were all sitting independently of each other and there was therefore a need for an integrated pathway that helped clinicians, patients and policy-makers to make consistent and informed decisions.

## Process for the development of the pathway

With the task of developing an integrated pathway in mind, Diabetes UK and NHS England convened a group of experts

to develop a technologies pathway that could be implemented across the country. Stakeholder organizations and healthcare providers came together with people living with diabetes to place currently available technologies within a common and unified framework. The group considered current available literature, clinical experience and opinion, as well as relative costs, along with testimonies and comments from the people living with diabetes. The group reviewed current UK guidance on the management of Type 1 diabetes and the use of different technologies and aimed to bring them together into a cohesive integrated pathway. The purpose was not to comprehensively review existing guidelines, but to integrate currently available guidelines in a way that patients, clinicians and policy-makers would find helpful.

The outline of the 'pathway' was based on the model of the American Diabetes Association/ European Association for the Study of Diabetes guidelines for Type 2 diabetes that set out a roadmap for incremental escalation of treatment to try and support patients to achieve their individualized glycaemic goal [23]. In the setting of Type 2 diabetes, we are used to a clear stepwise progression, advancing to dual- and triple-combination therapy [23]. Using the same principle, we recommend a baseline minimum standard of care that all people with Type 1 diabetes should be able to access. If that alone is not able to help them achieve their targets, we suggest adding in first one, and then potentially two complementary technologies to stay true to the NICE guidance (NG17) and support adults with Type 1 diabetes to aim for a target HbA<sub>1c</sub> level of 48 mmol/l (6.5%) in a safe manner.

The pathway was then endorsed by stakeholders in this field, including the Association of British Clinical Diabetologists, the Association of Children's Diabetes Consultants, the British Society for Paediatric Endocrinology and Diabetes, the Diabetes Technology Network-UK, Diabetes UK, the Juvenile Diabetes Research Foundation (JDRF), INPUT, Dose Adjustment for Normal Eating (DAFNE), the National Children and Young Peoples Diabetes Network and the Type 1 Clinical Collaborative, and was published on the Diabetes UK website in June 2018 [24].

## Consensus guideline pathway

### Initial treatment

All people living with diabetes should be able to access a minimum standard of care that should include access to a structured education programme of proven benefit, adequate capillary glucose monitoring (a minimum of four and up to 10 measurements, if required) [16] and a specialist diabetes multidisciplinary team that supports the person to download and analyse glucose information and optimize treatment decisions. The group felt that these were the minimal 'ingredients' required to achieve glycaemic targets, and

provide the skills and support required to maximize the benefits of any added therapy. As per NICE guidance, we agreed that structured education should be offered within 6–12 months of diagnosis, or at any time that is clinically appropriate and suitable for the person, regardless of duration of diabetes. Structured education programmes, such as DAFNE, are recommended by NICE [16] and have been shown in RCTs as well as national audits to help improve glucose control, reduce hypoglycaemia and improve quality of life [25–27]. They teach people with diabetes key skills such as carbohydrate-counting, dose adjustment and managing illness and hypoglycaemia. Structured education such as DAFNE has also been shown to be cost-effective within a few years of being used [28]. There are also a number of alternative structured education programmes available across the UK, some of which have published outcomes [29]. The NICE guidance for children with diabetes also emphasizes the importance of structured education in this group [2]. It is important to realize that, even though these programmes provide real benefit in terms of improved HbA<sub>1c</sub> and quality of life and lead to significant reductions in acute complications of diabetes such as severe hypoglycaemia and ketoacidosis, data from audits and the clinical trials of these programmes show that only a proportion of patients using these principles achieve target HbA<sub>1c</sub> levels using multiple daily injections (MDI) and capillary blood glucose monitoring. It therefore stands to reason that many people with Type 1 diabetes will require extra tools to use their knowledge and skills more effectively to achieve greater benefit.

### Technology monotherapy

If standard care with MDI has been optimized, and the person with diabetes is using carbohydrate-counting skills, performing adequate capillary glucose monitoring and making appropriate adjustments, but is still not at their personalized glucose target, then the addition of one of the available technologies as a ‘monotherapy’ should be considered and discussed. This decision should be taken between the person with diabetes, their family/carer and their healthcare professional, and should be discussed at a multidisciplinary team meeting.

### Insulin pump therapy

The use of insulin pump therapy (CSII) is clearly set out in the NICE technology appraisal TA151 [17] and we have endorsed and aligned with this. The guideline recommends the use of CSII for adults and children aged  $\geq 12$  years with Type 1 diabetes, provided that attempts to achieve target HbA<sub>1c</sub> levels with MDI result in disabling hypoglycaemia or HbA<sub>1c</sub> levels have remained high despite a high level of care. This guidance defines disabling hypoglycaemia as the ‘repeated and unpredictable occurrence of hypoglycaemia that results in

persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life’. It also recommends use of CSII in children aged  $< 12$  years where MDI treatment was considered impractical or inappropriate. The NICE guidance and cost-benefit analysis was based on the CORE model, and assumed a baseline HbA<sub>1c</sub> level of 72.7 mmol/mol (8.8%) and a reduction of 9.8 mmol/mol (0.9%). Interestingly, data from large UK-based audits of CSII demonstrate similar reductions in these scenarios [11,12,30].

### Flash glucose monitoring

The Regional Medicines Optimization Committee (RMOC) guidance recommends the use of flash GM for five specific indications. These include those who are undertaking intensive capillary glucose monitoring  $\geq 8$  times/day, or those for whom conventional glucose monitoring is not possible. This guidance also recommends flash GM as a cheaper alternative in those who meet the NICE TA151 guidance, i.e. those with HbA<sub>1c</sub>  $> 69.4$  mmol/mol (8.5%) or disabling hypoglycaemia as described in NICE TA 151. It also suggests flash GM can be used by those who have recently developed impaired awareness of hypoglycaemia, but notes that, for those with persistent hypoglycaemia unawareness, NICE recommends CGM with alarms. There are also recommendations for use of flash GM in those with frequent admissions for diabetic ketoacidosis or hypoglycaemia and in those who require third parties to carry out monitoring and where conventional blood glucose testing is not possible.

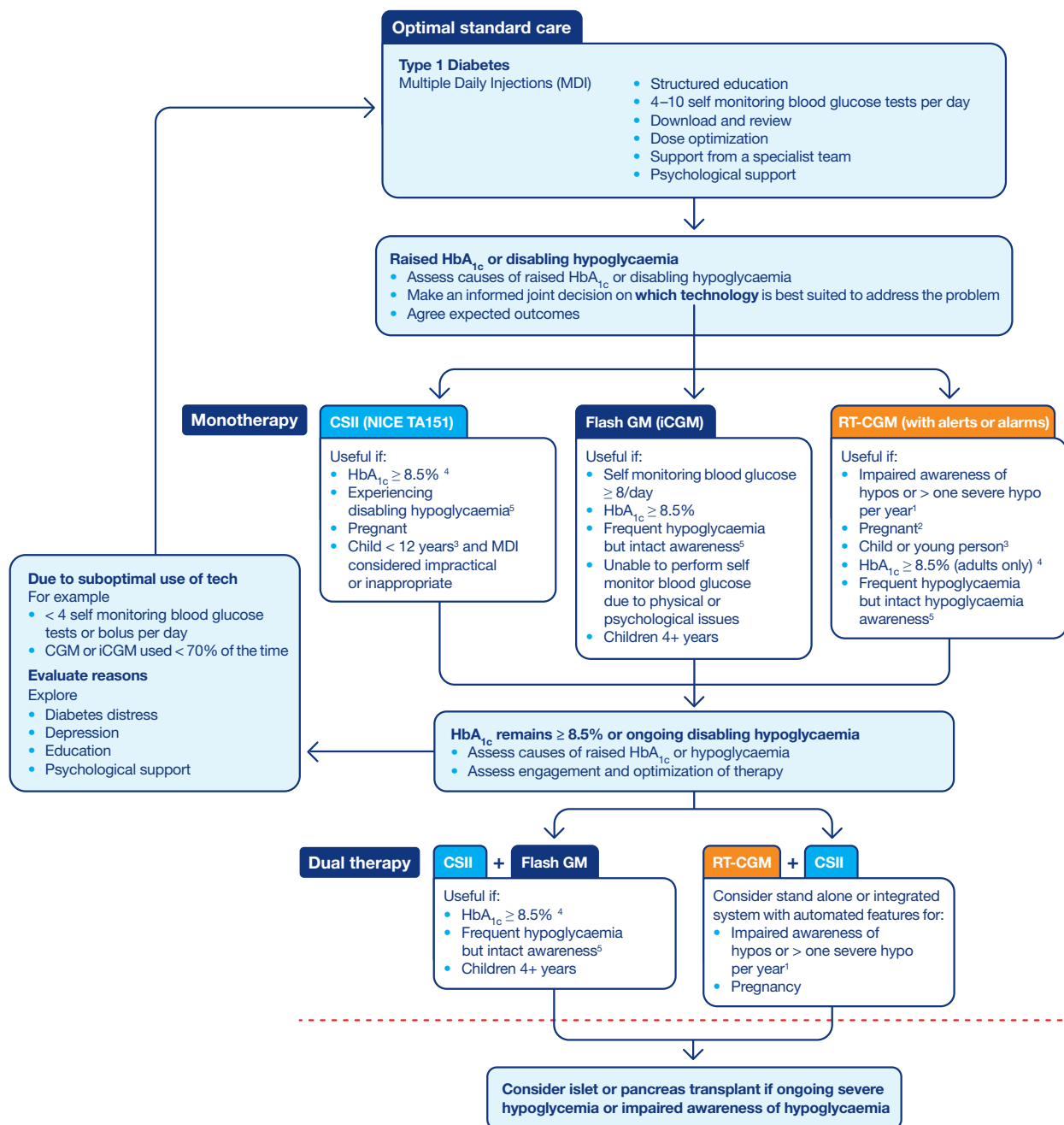
Although there are limited RCT data demonstrating the benefit of this technology in terms of HbA<sub>1c</sub> [31], there are observational data in children and adults demonstrating safety and clinical benefit in the groups for whom flash GM is recommended under the RMOC guidance [32,33].

### Real-time continuous glucose monitoring

Since NICE TA151 was published, there have been a number of studies demonstrating improvements in HbA<sub>1c</sub> and reductions in hypoglycaemia when CGM is used as an adjunct to MDI, rather than in combination with CSII. These improvements are of a similar magnitude to those seen in studies of CSII alone [34,35]. Two recent RCTs have also demonstrated the safety and efficacy of CGM in those with impaired awareness of hypoglycaemia [13,36] and, in this group, CGM may be an effective alternative to CSII in order to reduce the risk of severe hypoglycaemia. Notably, in a head-to-head study conducted in people with impaired awareness of hypoglycaemia, CGM with alarms had a greater impact on hypoglycaemia risk than flash GM [37]. A recent multicentre RCT demonstrated the safety and efficacy of CGM in pregnancy, showing improved glucose control, reduced birth weight and, crucially, reduced maternal and neonatal morbidity [14]. Over a 4-year cost cycle, CGM and CSII have a similar cost and,

given their comparable efficacy, it seems reasonable to offer people with diabetes a choice between CGM and CSII.

The pathway (Fig. 1) recommends that either of these three diabetes technologies can be used as first line in those who meet the relevant criteria. The decision about which



**FIGURE 1** Pathway for use of technology in Type 1 diabetes. <sup>1</sup>For those with impaired awareness of hypoglycaemia and/or recurrent severe hypoglycaemia, the pathway recommends opting for real-time continuous glucose monitoring (CGM) with alarms as first-line therapy. <sup>2</sup>For pregnancy, real-time CGM with alarms should be considered as first-line therapy. <sup>3</sup>The National Institute for Health and Care Excellence (NICE) guidance makes specific recommendation about the use of insulin pumps in children below 12 years of age and the use of CGM in very young children who are unable to report hypoglycaemia. <sup>4</sup>In adults with HbA<sub>1c</sub> > 8.5%, it is important to assess the reason for the high HbA<sub>1c</sub> and use the appropriate technology. <sup>5</sup>In those with disabling or frequent hypoglycaemia with intact awareness, either of the technologies could be used. This meets NICE guidance for continuous subcutaneous insulin infusion (CSII), and in those with intact awareness flash glucose monitoring may be a suitable alternative. FGM, flash glucose monitoring; GM, glucose monitoring; IAH, impaired awareness of hypoglycaemia; RT, real-time; SH, severe hypoglycaemia; SMBG, self-monitoring of blood glucose.

technology should be used should be a joint decision with the person with diabetes and their family/carer, and should include documentation of current problems and anticipated outcomes. This should include the use of validated tools such as the Gold score, Diabetes Distress Scale or Hypoglycaemia Fear Score, and performance against these expected outcomes should be reviewed regularly.

Suggestions from the guideline group were that, given the current evidence base, it may be appropriate to recommend CGM as the first-line technology in those with impaired awareness of hypoglycaemia or disabling hypoglycaemia, or in pregnancy. They did however recognize that there are observational data demonstrating benefits of CSII alone in both of these situations, highlighting the importance of patient preference. In those with HbA<sub>1c</sub> levels  $\geq 69.4$  mmol/mol (8.5%), it is important to assess the reasons for the raised glucose levels. If they are related to problems with insulin delivery, such as very low (< 20 units/day) or very high (> 100 units/day) doses, or problems with absorption from injection sites, lipohypertrophy, or the need for frequent or small boluses, then insulin pump therapy may be a better choice. Similarly, in those with high glucose variability, anxiety, difficulty measuring glucose or a fear of hypoglycaemia flash GM may be a more appropriate choice. Although real-time CGM with alarms has been shown to reduce HbA<sub>1c</sub> significantly, given the lower cost it is reasonable to suggest a trial of flash GM in the first instance.

### Re-evaluation

Simply providing someone with expensive and complex technology does not guarantee clinical benefit. In this regard, technology is different from the use of a pharmacological intervention. For benefit with a pump, patients need to be able to perform frequent monitoring of their glucose levels, bolus pre-meal [38] and change their infusion sets and cannula sites at regular intervals [39]. If they do not measure their glucose levels adequately, they are also at greater risk of diabetic ketoacidosis. Similarly, for flash GM or CGM, users need to wear the sensors at least 70% of the time, look at the data frequently, have clear education and plans for how to use the extra information provided and for how to use the data to reflect on and optimize treatment.

At each clinic visit (a minimum of four times a year for children and at least annually for adults), the clinician and the patient/family should re-evaluate the benefit being achieved and the adequacy of use. If there is a lack of measurable benefit, or a concern about safe use of the technology, this may be related to sub-optimal use of the technology (<70% use of flash GM or CGM; or <4 capillary glucose measurements/day or <4 bolus administrations/day with CSII) and the reasons for this need to be explored. Potential reasons could be high diabetes distress, depression or a lack of education and skills in the use of the technology. At this point, a decision about ongoing use of the technology

and the benefit it is providing must be made. Where diabetes distress or depression are key factors, access to psychological support is key to addressing these factors and supporting the patient. A clear plan should be made to support the patient to re-engage with the technology, but if the patient is not in a position to do this at that time, it may be appropriate to temporarily suspend the use of the technology, or consider changing to a more suitable technology at this point [40].

### Movement between monotherapies

If people have tried flash GM but have not been able to achieve the desired or expected benefits, it may be appropriate to move to another first-line treatment, such as CSII or real-time CGM before considering adding in another technology if both the healthcare professional and the person with diabetes feel this is appropriate.

### Technology dual-therapy

If the person with diabetes is using their first-line diabetes technology appropriately, and has had the expected improvement in diabetes control from their baseline but has still not achieved their personalized target, it may be appropriate to consider adding another complementary technology as 'dual therapy'.

For those using flash GM as a first-line technology, we recommend adding in insulin pump therapy if the HbA<sub>1c</sub> level remains >69.4 mmol/mol (8.5%) despite this. Similarly, we recommend the addition of flash GM to CSII if the HbA<sub>1c</sub> remains above >69.4 mmol/mol (8.5%) despite appropriate engagement with insulin pump therapy.

For those with ongoing problematic hypoglycaemia despite either CSII or CGM, adding the two technologies together, especially using systems with automated insulin suspension in response to actual or predicted hypoglycaemia can significantly reduce the frequency and duration of hypoglycaemia [10,41,42] and is in line with NICE guidance.

The use of CGM and CSII together is of particular relevance as they potentially open up the possibility of 'hybrid closed-loop' systems that can automatically adjust basal insulin delivery and, in real-world data from the USA, these have shown the ability to support patients in achieving tight glucose control [43]. Of course, as with existing technologies, access to these technologies will have to reflect funding constraints and undergo appropriate cost-effectiveness analyses.

### Islet or pancreas transplantation

The UK is one of only a few countries in the world with a centrally funded programme for islet and pancreas transplantation [44]. Transplantation is indicated for adult patients who continue to have recurrent, severe hypoglycaemia despite optimized medical therapy. In most cases

this will include insulin pump therapy and/or CGM. Ideally, this will be done using a system with automated insulin suspension features. If deemed suitable, access to psychological support may also be recommended [45]; however, despite these interventions, some people will continue to experience recurrent severe hypoglycaemia, and islet (or pancreas) transplantation should be considered as an option for these patients [46]. Islet and pancreas transplantation are nationally commissioned and patients who meet the criteria [recurrent severe hypoglycaemia despite optimized medical therapy, or suboptimal glucose control ( $HbA_{1c} > 53$  mmol/mol or 7%) in those with a functioning renal transplant] should be referred to one of the transplant centres.

## Impact

The aim of this integrated pathway for technology in Type 1 diabetes is to assist clinicians in choosing the most appropriate technology to support people with diabetes in achieving glucose levels that minimize their risk of complications and improve their quality of life. By using current guidelines, we hope to have kept the scope of this pathway within the remit of what should already be commissioned in the UK, and this pathway can support local commissioning and improve the quality of care for Type 1 diabetes in the UK

## Summary

The optimal treatment for Type 1 diabetes must take into account the individual needs and desires of the patient, as well as an understanding of where they are on their individual diabetes journey. Our current management pathways are failing our patients, leading to reductions in both quality of life and longevity. While putting together this guideline, the authors were aware of the financial pressures on the NHS, but each of these treatments is cost-effective if they produce the desired and expected results. The key aim of this guide was to provide a pathway for people with diabetes to achieve the best diabetes outcomes they can, and create a document that both commissioners and providers can use to guide local decision-making.

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PC has received fees from Medtronic, Dexcom, Insulet, Abbott, and Roche. NJ is employed by Diabetes UK. PK is associated National Clinical Director for Diabetes at NHS England, FC has received personal fees from Medtronic, Abbott, Novo Nordisk and Lilly.

## Competing interests

None declared.

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