TYPE 1 DIABETES TECHNOLOGY: A CONSENSUS GUIDELINE

What is the consensus guideline

This consensus guideline is designed for clinical teams to assist in decision-making to ensure the most appropriate use of technology to support improved glycaemic outcomes in adults and children with Type 1 diabetes. It brings together currently available technology into a simple unified pathway.

It is intended that this will also help guide local policymakers in making appropriate technology available and so realise the potential savings in the system by:

- improving management of blood glucose levels
- reducing HbA1c
- reducing hypoglycaemic events
- improving quality of life for people with Type 1 diabetes.

Why did we develop this position

Type 1 diabetes can be tough to manage. Achieving the level of glucose control required to minimise the risks of long-term complications requires a complex balance between insulin and carbohydrate delivery, frequent glucose monitoring, and often a fair deal of support. This relentless task also places a significant burden on people with Type 1 diabetes. There is international recognition that people using diabetes technology are more likely to achieve optimal glucose levels, so ensuring uptake and support for patients with Type 1 diabetes and professionals to access these technologies is key.

In 2017 Diabetes UK spoke to around 9,000 people about what would help them to live well in the future with diabetes. Access to technologies and treatments was one of the highest priorities – especially for people with Type 1 diabetes, who talked in particular about problems accessing pumps and CGM[1]. NICE guidance sets out clear guidelines for use of continuous glucose monitoring (CGM) and insulin pumps, but there is variation in access to these across the UK.

How did we develop this position

Diabetes UK and NHS England brought together a multi-disciplinary group of experts from across England, to develop a consensus document. The document was developed with the support and involvement of UK patient representative groups and expert patients and has the endorsement of Diabetes UK, Association of British Clinical Diabetologists (ABCD), Association of Children's Diabetes Consultants (ACDC), British Society for Paediatric Endocrinology and Diabetes (BSPED), Diabetes

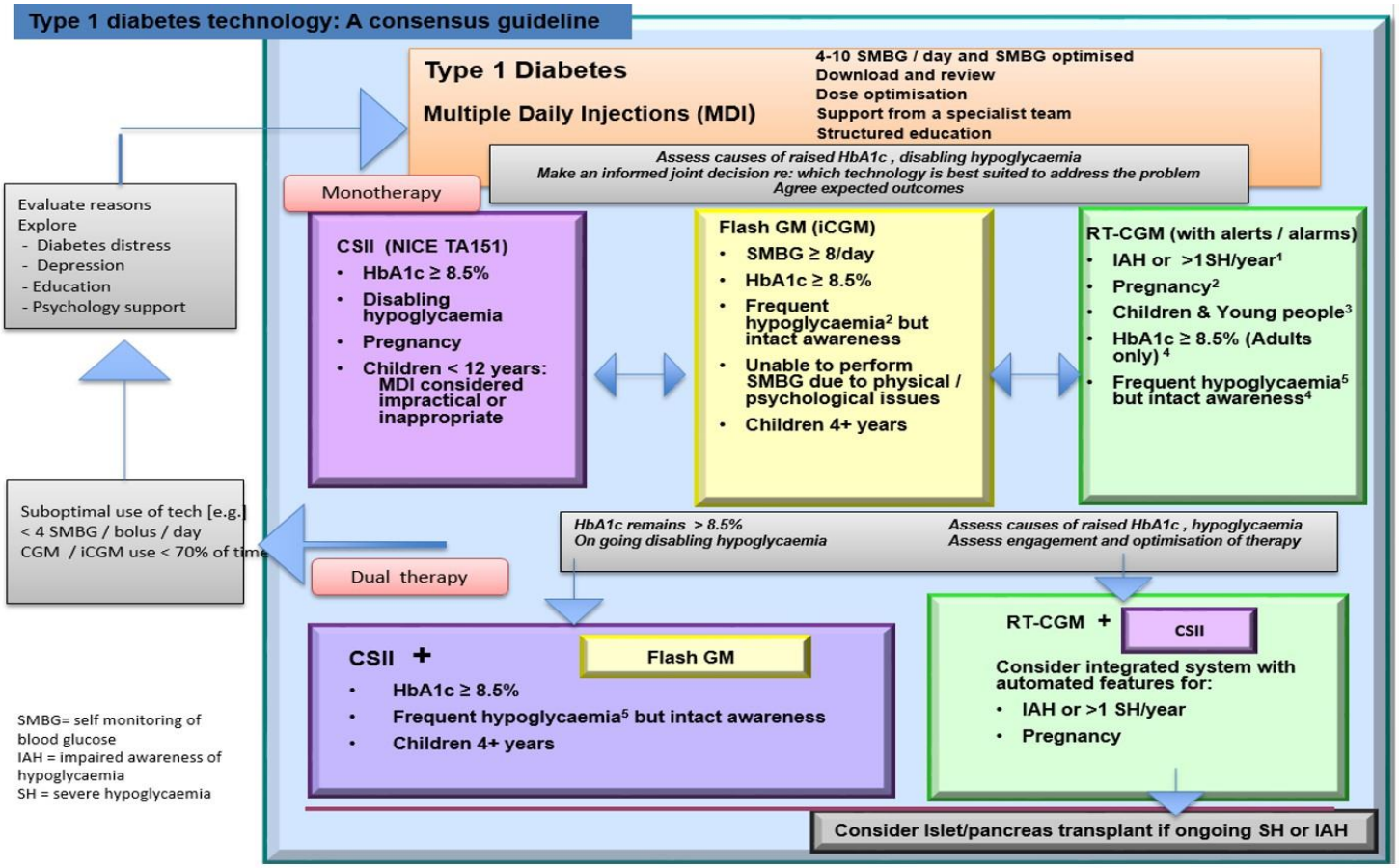
Technology Network UK (DTN-UK), INPUT, JDRF, DAFNE, National Children and Young Peoples Diabetes Network and Type 1 Diabetes Clinical Collaborative.

Diabetes UK recommendations

We recommend that clinicians and local decision makers use this pathway to guide clinical and commissioning decisions and policies on access to diabetes technology for people with Type 1 diabetes.

The consensus guideline pathway

The pathway supports people through progressive use of technology in the form of technology "monotherapy" or "dual-therapy" as required to achieve target HbA1c while minimising risk of hypoglycaemia. It underlies the importance of structured education, specialist support and access to psychology when appropriate as essential pillars on which use of diabetes technology can be optimised.



Explanatory notes for the pathway

Standard care (orange box)

All people living with Type 1 diabetes should be able to access a minimal standard of care which should include access to structured education, adequate SMBG and a specialist care team supporting dose optimisation and with whom they can download and review glucose information. We know that while access to this standard care can support a proportion of patients to achieve personalised glycaemic targets, many will be unable to do so. Teams should work with these patients to assess the causes of raised HbA1c or disabling hypoglycaemia.

First line technology – monotherapy

If it is felt that standard care has been optimised, and the patient is still not at their personalised target, then the addition of technological support as a "first line agent" after MDI should be agreed. This decision should be between the person with diabetes (PWD) and their health care professional (HCP) team based on individualised requirements. Suggestions from the guideline group are:

- **Note 1 on chart** - those who have impaired awareness of hypoglycaemia (IAH) and those with frequent severe hypoglycaemia should use rtCGM with automated features (such as alerts and alarms) as first line therapy[2].
- **Note 2 on chart -** for pregnancy, rtCGM with automated features (such as alerts and alarms) should be considered as first line therapy[3].
- **Note 3 on chart –** NICE guidance makes specific recommendations for children and young people[4].
- **Note 4 on chart -** in adults with HbA1c ≥ 8.5% it is important to assess the reasons – if they are related to problems with the delivery of insulin [need for frequent boluses / small boluses / insulin requirements total daily dose of < 20 units per day / lipohypertrophy] CSII maybe the preferred 1st option. In those with high variability, greater anxiety around hypoglycaemia, difficulty measuring glucose, Flash GM (iCGM) may be a better alternative. These are not exhaustive lists, but are suggestions to guide decision making
- **Note 5 on chart -** those with frequent biochemical hypoglycaemia but intact awareness may be expected to try Flash GM (iCGM) as first line therapy.

Movement between 1st line therapies: If people have tried Flash GM but this has not had the desired or expected benefit, it may be appropriate to move to another "1st line" treatment such as CSII or CGM before considering adding in another technology if the HCP and PWD feel this is appropriate.

Second line technology - dual therapy

If the person with diabetes has HbA1c > 8.5% or continues to have disabling hypoglycaemia despite addition of 1 technology, the group recommend evaluating causes of raised HbA1c and hypoglycaemia, and assessing engagement and appropriate use / optimisation of the technology.

If there is evidence of suboptimal use, such as inadequate bolusing on a pump, infrequent SMBG [< 4 / day] or < 70% use of Flash GM or CGM, then the causes for this should be assessed. Common causes for this are depression, diabetes distress, or lack of education which can then be addressed.

If the person with diabetes has suboptimal HbA1c [> 8.5%] or ongoing disabling hypoglycaemia, the group recommend adding in a second technology.

This can be the addition of pump to Flash GM or Flash GM to pump for those who are running high, or those who have frequent hypoglycaemia but intact awareness.

For those with impaired awareness of hypoglycaemia, or > 1 SH in the previous year, we recommend CSII + CGM, preferably as an integrated system with automated features such as predictive low glucose suspend systems.

In certain circumstances dual therapy may be considered as first line e.g. in pregnancy.

Islet/pancreas transplant

If there is ongoing severe hypoglycaemia, even with dual / third line therapy, an islet or pancreas transplant may be considered. This is not recommended for children and young people.

Definition of hypoglycaemia

Note 5 on chart: The International Hypoglycaemia Study Group has defined hypoglycaemia: http://ihsgonline.com/understanding-hypoglycaemia/definition/

Level 1 hypoglycaemia:

A glucose alert value of 3.9 mmol/L or less.

Level 2 hypoglycaemia:

A glucose level of 3.0 mmol/L is sufficiently low to indicate serious, clinically important hypoglycaemia.

Level 3 hypoglycaemia:

Severe hypoglycaemia: denotes severe cognitive impairment requiring external assistance for recovery.

Evidence

According to the last National Diabetes Audit, less than 15% of patients are able to achieve target glucose levels. International registries suggest that those achieving optimal glucose levels are more likely to be using diabetes technology to help insulin delivery, through insulin pumps, or provide more frequent glucose information through the use of continuous glucose monitoring (CGM).

In 2017 Diabetes UK spoke to around 9,000 people about what would help them to live well in the future with diabetes. Access to technologies and treatments was one of the highest priorities – especially for people with Type 1 diabetes, who talked in particular about problems accessing pumps and CGM[5]. As they said managing diabetes is relentless and time-consuming - no one needs the extra burden of having to battle to get what you need:

"For nearly 10 years I had tried for a pump. I changed hospitals and within months I was on a pump! The last three years have been the best in my 42 diabetic years, very few hypos and my HbA1c is perfect."

In addition to improved outcomes, people with Type 1 diabetes and parents have also described the way that technology can improve their ability to self-manage and engage in improved consultations with heath care professionals:

My son's consultant is happy to look at his Libre data profile to see how we can improve his levels. They interpret the graphs together and it's great to see them both so enthusiastic to improve my son's diabetes management. He's even arranged a Skype appointment to discuss the graphs in between clinic appointments to look at more ways to improve his glucose levels."

"*I have had diabetes for 30 years . . .Using the Libre has completely changed my relationship with monitoring my blood sugar. . . it meant I developed a new curiosity about what was happening with my blood sugars – it became an interest rather than a stress. I am more engaged with taking care of my diabetes therefore I am doing a better job"*[6].

The NICE TA 151 set out clear guidelines for the use of insulin pumps and has helped support a doubling of patients using insulin pumps across the country. However, despite the NICE guidance around insulin pumps, as well as CGM systems, access to CGM therapies have shown variation across the country[7]. The advent of flash (intermittent) glucose monitoring system allows patients to easily access frequent and detailed data on glucose levels but also the direction and rate of change. However, at the time of writing, local policies to guide the prescribing of Flash monitoring devices (Freestyle Libre) also vary and do not exist in a number of places[8] although good progress is being made.

References

[1] The Future of Diabetes, Diabetes UK, 2017 https://www.diabetes.org.uk/get_involved/campaigning/the-future-of-diabetes

[2] NICE Guidelines NG17 https://www.nice.org.uk/guidance/ng17/chapter/1-Recommendations#blood-glucose-management-2 and NG18 https://www.nice.org.uk/guidance/ng18/chapter/1-Recommendations#blood-glucose-and-plasma-glucose

[3] NICE NG3 https://www.nice.org.uk/guidance/ng3/chapter/1-Recommendations#antenatal-care-for-women-with-diabetes-2

[4] NG18 https://www.nice.org.uk/guidance/ng18/chapter/1-Recommendations#blood-glucose-and-plasma-glucose

[5] The Future of Diabetes, Diabetes UK, 2017 https://www.diabetes.org.uk/get_involved/campaigning/the-future-of-diabetes

[6] Diabetes UK Consensus Guideline for Flash Glucose Monitoring, November 2017 https://www.diabetes.org.uk/get_involved/campaigning/flash-glucose-monitoring

[7] Oliver, N et al, Diabetic Medicine, forthcoming; The National Diabetes Audit Insulin Pump Report 2015-16 https://digital.nhs.uk/data-and-information/publications/statistical/national-diabetes-audit/the-national-diabetes-audit-insulin-pump-report-2015-16

[8] https://www.diabetes.org.uk/Get_involved/Campaigning/Flash-glucose-monitoring

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