

FLASH GLUCOSE MONITORING

Position statement (October 2021)

Key points

- We welcome progress made in recent years to increase access to Flash glucose monitoring (Flash). However, many more people living with diabetes can and should be given access to it through the health service
- Flash should be made available to the following groups:
 - all people living with type 1 diabetes
 - people with any type of diabetes using insulin intensive therapy
 - all people with any type of diabetes who are undergoing any form of dialysis
- Consider offering Flash to people living with any type of diabetes who are treated with insulin and/or:
 - experience problematic hypoglycaemia [>2 episodes of hypoglycaemia per week] or hyperglycaemia [HbA1c $>8.5\%$]
 - live with a learning disability
 - are pregnant (including gestational diabetes)
 - their insulin administration or glucose monitoring must be undertaken by a third party
 - physical, psychosocial or occupational reasons preclude finger prick glucose monitoring
- People with diabetes using Flash should have education and support from healthcare professionals to optimise their use of the technology
- Healthcare professionals should recognise the benefits of using Flash for people with diabetes
- Healthcare professionals should have the knowledge and skills to support people with diabetes using Flash
- Health service decision makers should recognise the short and long-term benefits of funding Flash for people with diabetes
- Attention should be paid to ensure Flash is offered to people with diabetes on an equitable basis and where evidence suggests it is not, health service decision makers and diabetes care teams should seek to address this urgently

Why have we produced this position?

Flash glucose monitoring (Flash) is a wearable medical device which continuously measures blood glucose levels, via interstitial fluid. The person wearing the device can scan it with either the associated sensor or their smart phone to see their blood glucose level, its direction of travel and what it has been for the previous eight hours. A newer version of the technology (Flash 2) also provides predictive alarms for high and low blood glucose levels.

The benefits of Flash are well documented, both for clinical outcomes and for quality of life, and since 2017 good progress has been made towards more people living with diabetes accessing the technology through the health service in the United Kingdom (UK).

In Scotland, for example, at least 45% of the type 1 population now has access to the technologyⁱ. In England, around 50% of the type 1 population now has access to the technology through the NHS, compared to an estimated 3-5% before April 2019. In Northern Ireland, an estimated 80% of the type 1 population has access. In 2019 we estimated that 33% of the type 1 population in Wales was using Flash. While more up-to-date data from Wales is not currently available, we expect this number to have risen.

There is growing consensus that Flash can benefit many more people living with all types of diabetes. Indeed, Health Technology Wales appraised the technology and in August 2021 published recommendations stating that its use should be considered for people with any type of diabetes requiring insulin treatmentⁱⁱ.

Despite the strong evidence base supporting wider use of Flash, access to it is still restricted, with significant variation and inequity in access across the UK. This includes regional variations within the four UK nations. In England, for example, we estimate that the percentage of people being prescribed Flash as of January 2021 varied between 16% in some areas and 65% in othersⁱⁱⁱ.

Available data also suggests that people from ethnic minority communities and those living in areas of high deprivation are least likely to have access to Flash. This inequity must be urgently addressed, not least given those least likely to be accessing Flash are also those most likely to have a higher HbA1c.

We have therefore developed these recommendations for the use of Flash GM in the NHS, jointly with other diabetes organisations representing people with diabetes and clinicians. These recommendations are based on the best currently available clinical and scientific evidence as well as experiences from people living with diabetes.

How did we develop this position?

Diabetes UK spoke to a wide range of people living with and affected by diabetes to develop this position statement, through focus groups, surveys and our Council of People with Diabetes.

We also consulted with healthcare professionals working in diabetes to develop this position. This has included our Council of Healthcare Professionals. We note the close alignment this position statement has with the recently published Diabetes Technology Network position statement regarding Flash glucose monitoring^{iv}.

Recommendations

Flash glucose monitoring has been a major advance over routine finger prick glucose monitoring. It is easier, quicker and less painful to use. The density of data and the ability to follow trends in blood glucose levels, which are not available from sporadic blood glucose testing, has been shown to help patients improve glucose control and reduce hypoglycaemia. We therefore recommend that more people living with diabetes should be given access to the technology through the NHS.

Who should have access to Flash?

- All people living with type 1 diabetes
- People living with any type of diabetes using insulin intensive therapy (basal/bolus MDI or insulin pump therapy)
- Consider offering Flash to people living with any type of diabetes who are treated with insulin and/or:
 - experience problematic hypoglycaemia [>2 episodes of hypoglycaemia per week] or hyperglycaemia [HbA1c $>8.5\%$]
 - live with a learning disability
 - are undergoing any form of dialysis
 - are pregnant (including gestational diabetes)
 - their insulin administration or glucose monitoring must be undertaken by a third party
 - physical, psychosocial or occupational reasons preclude finger prick glucose monitoring

How should healthcare professionals support patients to get optimum use of this technology?

- People who use Flash should have a good understanding of intensive insulin therapy and how to self-manage their diabetes. The completion of a structured diabetes education programme, as recommended by NICE^v, is crucial and should be offered between 6-12 months after diabetes diagnosis

- It is essential that people using Flash have education to make sure they can best use the information the device provides to improve management of their glucose levels
 - This training can be face-to-face or online, and this decision should be jointly made between patient and clinician
- Healthcare professionals will also need training on how to interpret the information on glucose trends in relation to patients' daily living and in insulin dose adjustment
 - A number of education modules on Flash exist for healthcare professionals, including via the Diabetes Technology Network's Academy Programme^{vi}
- Where possible, healthcare professionals should encourage patients to share the data from Flash with them, for example, via the LibreLink app^{vii}
- Flash should not be considered as an alternative to continuous glucose monitoring and people living with diabetes who meet the access criteria NICE recommends should be supported to use CGM (see Appendix 1)

Considerations for health service funders and providers when making decisions on funding for specific patients and patient groups

- Local health decision makers should recognise the long-term benefits of Flash GM use and the potential for use of the technology to reduce the risk of devastating and costly long-term complications
- People using Flash will still need access to test strips on prescription, although the number of test strips required would normally be lower
- People who use Flash will still need access to test strips and meters. For example, people are still required to use finger-prick blood glucose tests in certain circumstances when they drive
- Health service providers should ensure diabetes healthcare professionals are encouraged and given the time to undertake training on the use of Flash
- Commissioners should not introduce additional barriers to access Flash - asking people with diabetes to sign a contract about how they will use it, for example
- Local health commissioners should use data to understand whether Flash is being offered to people with diabetes equitably and, where it is not, seek to work with healthcare professionals to address this problem
- GPs should be supported to initiate patients on to Flash, particularly for patients whose diabetes management is not supported in a secondary care setting

Discussion and analysis of evidence

What is the clinical evidence for flash glucose monitoring?

Flash GM has been shown to safely improve time in target glucose range, reduce hypoglycaemia and hyperglycaemia, and improve HbA1c^{viii, ix, x, xi} for people using insulin intensive therapy, regardless of diabetes type.

The ABCD Flash Glucose Monitoring Audit^{xii}, with follow up data from 3182 users, has demonstrated a mean reduction of 5.2 mmol/mol in all users of Flash Glucose Monitoring following 7.5 months of follow-up, with a greater reduction of 12.4 mmol/mol in those with initial HbA1c over 69 mmol/mol.

Impaired awareness of hypoglycaemia was resolved in 53% of those where it was present at baseline. There were also significant reductions in paramedic callouts and hospital admissions due to hypoglycaemia and hyperglycaemia/diabetic ketoacidosis.

The ABCD Flash Audit has also showed a significant reduction in diabetes distress scores, demonstrating a clear improvement in quality of life for people with diabetes using Flash Glucose Monitoring. This reflects what people living with diabetes have told us – that Flash use has improved their emotional and psychological wellbeing and their confidence managing their condition.

There is also a growing evidence that Flash use is associated with a reduction in risk of developing diabetes-related complications, like cardiovascular disease.

While the availability of real-world data from the UK on Flash use in people with type 2 diabetes who use insulin intensive therapy is limited, there is a growing international evidence base showing similar clinical benefit of Flash use in this group as those outlined above^{xiii, xiv}.

What people with diabetes have told us about using Flash

Flash has a number of benefits that can improve people's diabetes clinical outcomes over and above glucose testing. The technology can also improve someone's engagement with the management of their condition and their quality of life. It can:

- Reduce the need for painful, stressful and inconvenient finger prick glucose monitoring
- Help people to better manage their diabetes and support them to confidently engage in self-management of their condition
- Improve quality of life for people living with diabetes and their parents and carers
- Improve the emotional and psychological wellbeing of people living with diabetes

Reduce the need for painful, stressful and inconvenient finger prick glucose monitoring

Unlike finger-prick monitoring, Flash is discreet to use, significantly reduces the need for finger prick tests, and is very often accepted when finger pricking is rejected (7). It is beneficial to people with diabetes who have learning difficulties or have a fear of needles. It can also be particularly useful for people who find finger prick testing challenging during the working day (teachers or shop workers, for example).

Some people with diabetes can be unwilling to perform finger prick blood glucose checks due to pain, inconvenience, and unwillingness to be open about their diabetes. This is especially so in children and young people which can be immensely difficult for their families.

'It is difficult to stress the horror we went through at the beginning of diagnosis when my daughter had to finger prick all the time. She thoroughly hated it. It was the worst time. She would scream, cry, run away from us and hide. It was just beyond awful. There are no words to describe the incredible positive difference the flash monitoring can make.' Mother of a child with Type 1 diabetes

Helps people to better manage their diabetes and confidently engage in self-management of their condition

In addition to enabling people to check their glucose levels more frequently, Flash also provides more detailed information on glucose levels compared with finger-prick glucose monitoring.

It allows people to better adjust insulin, food intake and activity related to the current test result, what has happened immediately before (as shown on the glucose profile), and what is predicted to happen. This information is considerably more valuable than a one-off blood glucose result.

The flash reader presents the user with data; glucose levels, trends and an overview of the data, displayed as an ambulatory glucose profile (AGP). The AGP data can be downloaded onto the user's computer and shared with healthcare professionals or shared directly via the LibreLink app.

The Flash GM reader tells someone what percentage of the time their glucose levels are in their target range across the day. Increasing time in target range leads to lower HbA1c (8).

"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." Fiona, mother of teenager living with Type 1 diabetes for three years

We also know that where people use Flash they report significant improvements in their confidence managing their condition. A survey we ran in early 2020 found that 67% of respondents reported improved confidence managing their condition when using technologies like Flash.

"Without having a clear picture of what my glucose levels are doing, I'm essentially poking around in the dark. Even with a finger prick test, it's a moment in time rather than a direction. Flash gives an interactive way of managing my diabetes. I can watch things unfolding and

react accordingly. I am now trying to avoid the events rather than avoiding recording the events. It takes away the stress and guesswork around testing and management of the condition” Mike, who’s living with Type 1 diabetes.

Improved quality of life and emotional wellbeing

Our survey about diabetes technology access and a number of research papers all show that using technologies like Flash can improve both quality of life and emotional wellbeing^{xv, xvi, xvii}. This is not just the case for people living with diabetes but their parents and carers too.

However, we also know that being refused access to Flash can negatively impact a person’s psychological wellbeing too. For many people with type 1 diabetes and most people with type 2 diabetes it can be very difficult to access Flash on the NHS.

“When Flash came out, my husband was entitled to one on the NHS. But I’ve had to buy mine, even though we do the same thing – we both test before every meal and inject at meal times” Person living with type 2 diabetes.

Discussion

The evidence is clear – Flash can offer significant benefit to many people living with diabetes, particularly those managing their condition with insulin intensive therapy. There is also a growing evidence base showing that use of the technology is associated with a reduced risk of developing long-term diabetes-related complications – a large contributing factor in the NHS’s annual £10 billion spend on diabetes.

It is crucial that the benefits of this technology are recognised and investment is made to widen access. Flash offers the ability to deliver diabetes care in a more individualised way, with the additional benefit of allowing clinicians to review data from the device remotely.

Significant progress has been made in recent years towards more people having access to Flash. However, available data highlights inequities in this access with people from areas of high deprivation, those from ethnic minority backgrounds and older people having lowest access to the technology^{xviii}.

This position statement outlines who should be given access to Flash and the support they will require to use the technology. It is crucial that progress made to increase access in recent years is not lost. This position should be used by clinicians and decision makers to guide the work they do to improve access to Flash and, in turn, the lives of many people living with diabetes and their families and carers.

Appendices

Appendix 1: Flash GM vs Continuous Glucose Monitoring (CGM)

Flash GM should not be considered as an alternative to continuous glucose monitoring. There are differences between the two systems that make one more appropriate than the other, depending on the needs of the person. The main differences are summarised in the table below.

Flash GM	Continuous Glucose Monitoring (CGM)
Flash GM is continuous monitor however it does not continuously send data to the reader- only when scanned. The flash sensor continuously measures interstitial glucose, updating the reading every minute and stores a reading every 15 minutes for the last eight hours. It only displays readings from interstitial fluid when the user scans the sensor.	CGM glucose sensors record interstitial glucose every five minutes not continuously and continuously sends that data to a reader.
The reader needs to scan the sensor to gather readings, it does not transmit the readings to a reader.	CGM sensors automatically transmits glucose readings to a reader or insulin pump every five minutes and transmits that data to a reader.
Flash GM does not alert the user or carer that their glucose levels are too low or too high, unless set and at the time of scanning.	CGM alarms can be set to alert the user that their glucose levels are too low or too high.
Flash GM is not licenced for children under the age of four.	CGM is licensed for children over the age of two years old.
Flash GM does not require finger prick calibration.	CGM requires twice daily calibration with a finger prick reading.

Appendix 2. Driving

Users of Flash must carry finger prick capillary glucose testing equipment for driving purposes as there are times when a confirmatory finger prick blood glucose level is required. If using Flash (or CGM), the blood glucose level must be confirmed with a finger prick blood glucose reading in the following circumstances:

- when the glucose level is 4.0 mmol/L or below
- when symptoms of hypoglycaemia are being experienced
- when the glucose monitoring system gives a reading that is not consistent with the symptoms being experienced (eg symptoms of hypoglycaemia and the system reading does not indicate this)

For Group 2 licences Flash is not currently permitted for blood glucose testing, meaning a finger-prick test is always required before driving.

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- ⁱ Jeyam, A., Gibb, F.W., McKnight, J.A. *et al.* Flash monitor initiation is associated with improvements in HbA_{1c} levels and DKA rates among people with type 1 diabetes in Scotland: a retrospective nationwide observational study. *Diabetologia* (2021).
- ⁱⁱ <https://www.healthtechnology.wales/wp-content/uploads/2021/09/GUI004-FlashGM-FINAL.pdf>
- ⁱⁱⁱ <https://openprescribing.net/analyse/#org=CCG&numIds=21480000100&denom=nothing&selectedTab=summary>
- ^{iv} <https://abcd.care/resource/dtn-uk-position-statement-regarding-flash-glucose-monitoring>
- ^v <https://www.nice.org.uk/guidance/ng17/chapter/Recommendations#education-and-information-2>
- ^{vi} <https://abcd.care/dtn/academy>
- ^{vii} <https://www.freestyle.abbott/ie/en/librelink/index.html>
- ^{viii} McKnight JA and Gibb FW (2017) Flash Glucose Monitoring is associated with improved glycaemic control but use is largely limited to more affluent people in a UK diabetes centre *Diabet Med.* 2017 May; 34(5):732.
- ^{ix} Campbell F, et al (2017) FreeStyle Libre Use for Self-Management of Diabetes in Children and Adolescents Poster based on SELFY study (An Evaluation of Self-Management of Diabetes Using FreeStyle Libre Flash Glucose Monitoring System in Young People.) American Diabetes Association
- ^x Bolinder J, et al. (2016) Novel glucose-sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial. *The Lancet.* Nov 11;388 (10057):2254-63.
- ^{xi} Haak, T. et al. (2017) Flash glucose-sensing technology as a replacement for blood glucose monitoring for the management of insulin-treated type 2 diabetes: a multicenter, open-label randomized controlled trial. *Diabetes Therapy*, 8(1), pp.55-73.
- ^{xii} Harshal Deshmukh, Emma G. Wilmot, Robert Gregory, Dennis Barnes, Parth Narendran, Simon Saunders, Niall Furlong, Shafie Kamaruddin, Rumaisa Banatwalla, Roselle Herring, Anne Kilvert, Jane Patmore, Chris Walton, Robert E.J. Ryder, Thozhukat Sathyapalan on behalf of the ABCD nationwide FreeStyle Libre Audit. Effect of Flash Glucose Monitoring on Glycemic Control, Hypoglycemia, Diabetes-Related Distress, and Resource Utilization in the Association of British Clinical Diabetologists (ABCD) Nationwide Audit. *Diabetes Care* 2020 Sep; 43(9): 2153-2160.
- ^{xiii} Rose L, Klausmann G, Seibold A. Improving HbA_{1c} Control in Type 1 or Type 2 Diabetes Using Flash Glucose Monitoring: A Retrospective Observational Analysis in Two German Centres. *Diabetes Ther.* 2021 Jan;12(1):363-372.
- ^{xiv} KATARINA EEG-OLOFSSON, ANN MARIE SVENSSON, STEFAN FRANZÉN, HODAN ISMAIL, FLEUR LEVRAT-GUILLEN; Sustainable HbA_{1c} Decrease at 12 Months for Adults with Type 1 and Type 2 Diabetes Using the FreeStyle Libre System: A Study within the National Diabetes Register in Sweden; *Diabetes* Jun 2020, 69 (Supplement 1)
- ^{xv} Al Hayek, A.A., Al Dawish, M.A. The Potential Impact of the FreeStyle Libre Flash Glucose Monitoring System on Mental Well-Being and Treatment Satisfaction in Patients with Type 1 Diabetes: A Prospective Study. *Diabetes Ther* 10, 1239–1248 (2019).
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- ^{xvii} Charleer S, De Block C, Nobels F, Radermecker RP, Lowyck I, Mullens A, Scarnière D, Spincemaille K, Strivay M, Weber E, Taes Y, Vercammen C, Keymeulen B, Mathieu C, Gillard P; RESCUE Trial Investigators. Sustained Impact of Real-time Continuous Glucose Monitoring in Adults With Type 1 Diabetes on Insulin Pump Therapy: Results After the 24-Month RESCUE Study. *Diabetes Care.* 2020 Dec;43(12):3016-3023.