Flash glucose monitoring: the story so far and the journey ahead

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ABSTRACT
Just a few years ago FreeStyle Libre (FSL) was a rarely encountered device, used only by a select few people with type 1 diabetes who could afford to self-fund it. This small disc has a small cannula under the skin which allows for interstitial glucose measurements and remains in situ for 14 days. Over the last 4 years the number of people with access to this life-changing technology on the National Health Service (NHS) has increased rapidly. Although there were barriers to implementing access and encouraging uptake of this technology, including systems, healthcare professionals and the users themselves, innovative interventions from NHS England and diabetes organisations ensured those who stood to gain the most benefit were not impeded in their access, with a particular emphasis on enabling FSL use in those who are often the hardest to reach. This article reviews the impact of FSL on type 1 diabetes care in England, the key events to date and the lessons learnt that can be applied in the future for newer diabetes technologies.

INTRODUCTION
Just a few years ago FreeStyle Libre (FSL) was a rarely encountered device, used only by a select few people with type 1 diabetes who could afford to self-fund it. Now FSL is standard of care in type 1 diabetes clinics and is increasingly encountered in other situations, from additional medical uses to its use in elite sports for fuel management. The story of this device, its roll-out nationally and the lessons learnt since are important to reflect on as we continue to move forward with diabetes technology.

The FSL technology is most correctly called intermittently scanned continuous glucose monitoring or flash glucose monitoring (FGM). Launched in 2014 as a potential way of replacing capillary blood glucose monitoring, the device became available on the NHS Drug Tariff in 2017. FSL entered the market as a less costly alternative to real-time continuous glucose monitoring (rtCGM) devices which include predictive alarms. The original FSL device monitored interstitial glucose levels and the sensor had to be scanned with a mobile phone or reader in order for the user to view their glucose levels. Additionally, the device stored the data, allowing an ambulatory glucose profile (a 24-hour curve of glucose levels) to be produced. More recently the FSL2 device has added alarms activated via Bluetooth to alert users to glucose levels which have crossed individually defined high or low glucose thresholds.

In the IMPACT randomised controlled trial, FSL reduced the amount of time spent in hypoglycaemia, but haemoglobin A1c (HbA1c) levels remained static over 6-month follow-up.1 Similar results were also noted in the REPLACE trial for people with type 2 diabetes.2

What is already known?
► FreeStyle Libre was launched in 2017, as the next generation of glucose monitoring without finger-prick testing.
► Initially, access across England was variable, with barriers including the existing systems, healthcare professionals and users.

What are the new findings?
► Barriers to the roll-out of any new technology exist but can be overcome.
► Actions taken by diabetes organisations and NHS England mitigated these barriers and ensured access to this new technology, especially for hard-to-reach groups such as those with mental health difficulties or learning disabilities.
► Lessons can be learnt from the methods employed in the roll-out of FreeStyle Libre for future diabetes technologies.
Some observational studies demonstrated reductions in HbA1c in people with type 1 and type 2 diabetes, reductions in diabetes distress and improved treatment satisfaction, alongside the previously reported reduction in hypoglycaemia.1–3 Adverse events associated with FSL were rare and limited to cutaneous reactions to wearing the sensor.1

CHALLENGES IN IMPLEMENTATION
The barriers experienced in the implementation of FSL can broadly be broken down into system barriers, specialist barriers and patient barriers.

As with any new technology, the systems were concerned about the additional cost of this technology, with limited evidence of long-term benefits. In 2017 FSL became available on the NHS Drug Tariff and the Regional Medicines Optimisation Committee (RMOC) published recommendations that listed some key criteria for access to FSL. Despite this, there were increasing reports of varied local interpretations of the RMOC recommendations, leading to patchy national uptake and a real ‘postcode lottery’.6

As specialist teams we often formed some barriers ourselves. Many of us required upskilling and education to provide support for the roll-out of FSL and support people with diabetes in using this new technology (although many found it intuitive). Furthermore, many were uncertain of the benefits of FSL beyond providing additional glucose data, but many have now recognised the impact on the quality of life of people living with diabetes. A few strove for perfection and felt that FSL was a less effective alternative to rtCGM and therefore put efforts into funding these systems over funding FSL.

On occasion, people with diabetes formed barriers, with many finding the variable access frustrating and, in a similar vein to some centres, recognising the product as a less effective rtCGM. Others were simply unaware of the technology which was talked about by few and accessed by fewer. Divides in access were noted among those who struggle to access care, including those from the most deprived backgrounds, those with mental health problems or learning disabilities, and those from minority ethnic backgrounds. Furthermore, as with all technologies, some users were reluctant to wear a visible device or found there were problems with adhesives or the sensor dislodging.

OVERCOMING THE BARRIERS
Barriers can be overcome and those discussed have been broken down by a multipronged approach. These are summarised in table 1.

In recognition of the inequitable access to the technology, NHS England criteria with ring-fenced funding to provide FSL to 20% of people with type 1 diabetes in each region were launched following the efforts of Professor Partha Kar, National Specialty Advisor for Diabetes, and the team at the NHS Diabetes Programme. These criteria included access for those with occupational or psychosocial circumstances to improve access in hard-to-reach groups. This approach was quickly successful in achieving access in 20% of people living with type 1 diabetes across all regions in England within a year.

In addition, increasing awareness of FSL via Facebook, Twitter (#GBdoc), Diabetes UK Fight for Flash campaign and the then-Prime Minister Theresa May wearing one in public probably prompted people with diabetes to start discussions with their healthcare professionals about whether they too could benefit.

It was then important to address the barriers around education of healthcare professionals as well as people

### Table 1 Barriers to implementation of FreeStyle Libre and the approaches taken to overcome these

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Category</th>
<th>Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSL lacked some of the function of an rtCGM.</td>
<td>Specialists/users</td>
<td>Despite NICE guidance from 2015, rtCGM access remains challenging. FSL2 now has alarms.</td>
</tr>
<tr>
<td>Education needed to fully implement FSL and optimise management.</td>
<td>Specialists/users</td>
<td>Education provided to services from national organisations, for example, DTN-UK. Educational opportunities provided to users via organisations, trickle down of knowledge from specialist teams. FSL relatively intuitive for users.</td>
</tr>
<tr>
<td>FSL uptake lower in harder-to-reach groups.</td>
<td>Systems/users</td>
<td>Criteria expanded to include access for all people with learning disabilities and psychosocial indications.</td>
</tr>
<tr>
<td>Awareness of technology and fear of stigma.</td>
<td>Users</td>
<td>FSL seen in use in public by increasing numbers, including UK prime minister. Campaigns from Diabetes UK.</td>
</tr>
<tr>
<td>Limited data on outcomes in the long term.</td>
<td>Systems</td>
<td>ABCD audit programme, access to quality of data and real-world outcomes showing reductions in DKA and hospitalisation and improved HbA1c.5</td>
</tr>
<tr>
<td>Varied access nationally and inconsistent application of RMOC criteria.</td>
<td>Systems/specialists</td>
<td>Introduction of ring-fenced funding and a standard platform of criteria by NHS England for 20% of those with type 1 diabetes.</td>
</tr>
</tbody>
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ABCD, Association of British Clinical Diabetologists; DKA, Diabetic Ketoacidosis; DTN, Diabetes Technology Network; FSL, FreeStyle Libre; HbA1c, haemoglobin A1c; NHS, National Health Service; NICE, National Institute for Health and Care Excellence; RMOC, Regional Medicines Optimisation Committee; rtCGM, real-time continuous glucose monitoring.
with diabetes. Initially many healthcare professionals found it difficult to review and understand the huge amount of data generated, and there were concerns about how people with diabetes would deal with the data as well. Given the amount to learn, the Diabetes Technology Network UK launched a series of modules to upskill both healthcare professionals and people with diabetes in how to get the most from the device and interpreting the ambulatory glucose profile graphs that it generates. These modules have been updated and expanded into wider technology education programme called the Glooko Academy, which provides approved education for continuing professional development (CPD) on FGM but also a variety of other diabetes technologies. This model of online education is novel within the National Health Service (NHS), with many clinics simply accepting confirmation that patients have watched the education modules as confirmation of education. The online videos have had over 10,000 views. The Glooko Academy programme has had almost 600 clinicians log in and complete the modules, with over 10,000 hours of educational content consumed in the year since launch.

It is recognised that certain groups experience inequitable access to technology, including those from the most deprived backgrounds. NHS England, acutely aware of this concern, enabled access to FSL for those with a ‘psychosocial indication’. This allowed clinicians to facilitate access for some of the most vulnerable in their services. In addition, the later addition of learning difficulties, independent of diabetes type as an indication, was also a welcome inclusion.

The UK roll-out of FSL was captured in a real-world audit by the Association of British Clinical Diabetologists (ABCD). With follow-up data from over 3000 FSL users, it demonstrated significant reductions in HbA1c (greatest in those with very elevated levels at baseline), a reduction in diabetes-related distress, improvements in hypoglycaemia awareness, and a reduction in paramedic callouts and hospital admissions due to hypoglycaemia/hyperglycaemia emergencies. Further real-world data from beyond the UK, France and the USA also report a reduction in hospitalisations, while a meta-analysis of published studies describes a clinically significant -0.55% reduction in HbA1c. This real-world evidence builds on the randomised controlled trial data and many diabetes teams are considering the need for funding beyond national criteria, recognising the potential benefits and potential cost savings.

The events to date are summarised in the timeline in figure 1.

FSL AND THE COVID-19 PANDEMIC

It would be remiss not to discuss the impact of COVID-19 on diabetes services. In March 2020 diabetes services rapidly switched to remote/virtual consultations. In a specialty where data are often key to providing the best support possible, access to FSL data in the cloud facilitated effective remote consultations. It also allowed us to identify the most at-risk individuals in our services to provide targeted support to those with the highest glucose levels or most frequent hypoglycaemia to minimise the risk of a hospital admission.

Education and start-up sessions for FSL moved online where appropriate and organisations such as the Diabetes Technology Network UK and ABCD supported this virtual approach by providing targeted education on remote management of technologies. Additionally, and despite the new barrier of the virtual world, it became clear that FSL use and interpretation of the data generated were often intuitive. People

Figure 1  Timeline showing the key events and uptake of FreeStyle Libre since 2017. NHS, National Health Service; RMOC, Regional Medicines Optimisation Committee.
with diabetes would recognise and respond to recurrent glucose levels above target after eating or newly detected overnight hypoglycaemia and using knowledge of their own condition to better self-manage than they could have with capillary glucose testing. This was often achieved without the need for healthcare professional intervention, which may have been less available due to redeployment, sickness or shielding, and allowed those of us who remained within the diabetes team to focus on those with the greatest need.

Data in the cloud, in the new virtual world, continue to support the virtual working of our services. The proprietary platform provided by Abbott for use with FSL was invaluable in accessing data remotely. It remains clear to us that any shift to predominantly virtual working by diabetes teams must be supported by access to technology in order for people with diabetes to not get left behind. Further targeted support to facilitate access to technology and virtual consultations may need to be considered for people in some groups to avoid a widening digital divide—this might include support for people to access the internet at home or supplementary education to provide a basic level of computer literacy.

THE FUTURE

Recent data from France have demonstrated the important benefits of FSL in insulin-treated type 2 diabetes with significant reductions in acute diabetes emergencies. Recent guidance from the Diabetes Technology Network (DTN) as well as a healthcare technology assessment from Wales support the cost effectiveness of FSL use in all insulin-treated people.13 14 To date, FSL use is mostly limited to secondary care or intermediate care services, but it seems inevitable that access to FSL will continue to increase as new groups who may benefit are identified. Given the building evidence it would be reasonable to assume access may become available for those with other types of diabetes in the future. This would include people with type 2 diabetes requiring insulin therapy, alongside those with types of diabetes particularly prone to hypoglycaemia, such as type 3c (pancreatogenic) diabetes. We would do well to remember how to overcome the barriers of the first wave of FSL roll-out to people with type 1 diabetes for future expansions of FSL or for any other future technologies when they arrive. What our current experience has shown, and what the success of the roll-out in England compared with other European countries has shown, is that this glucose monitor can be prescribed, that demand is there in the diabetes population and that most can adapt to using this technology easily and quickly.

Many people will have seen FSL advertised on social media by influencers or elite sports people who are increasingly using a version of the system (called the Libre Sense) to manage fuel intake while competing or training. Others are using FSL as a weight loss aid—noting which foods create spikes in glucose and avoiding them or using it to trigger exercise to lower glucose levels. This can also be useful to aid behaviour modification in early type 2 diabetes. At present, there is only limited evidence to support this approach,15 although there does appear to be a market for it, demonstrating an unexpected application of this technology.

Beyond the sensor, the FSL online platform ‘LibreView’ is fairly intuitive and allows for data sharing in almost real time between people with diabetes and their healthcare professional teams if they are using a smart phone. However, with many people with diabetes using insulin pump therapy, or increasingly smart pens, access to these data in one place will be needed. Integration of data for convenience of both healthcare professionals and users needs to be a priority. Furthermore, consideration needs to be given for how to support people who cannot afford or do not know how to use a smart phone so similar data sharing can take place and in order to prevent the digital divide widening further.

Future iterations of the FSL device are on the horizon. FSL2 recently arrived with the addition of alarms, allowing further improved recognition of glucose levels above target or in the hypoglycaemic range. Many of us have already seen people with diabetes in our clinics benefit from these alarms, and we look forward to seeing randomised control trial data from the FLASH-UK study, which is currently underway and will hopefully further support the use of the updated system.16

For the time being, however, there remain some distinctions between FSL and rtCGM. The CORRIDA study found rtCGM to be superior to FSL in terms of time in glucose ranges, with the notable caveat that this study used the FSL1 system without alarms.17 Several other studies demonstrate reduced time spent in hypoglycaemia and reductions in hypoglycaemia fear scores.18 19 Therefore, it continues to be important to remember that it is not an answer to every problem we encounter in diabetes clinic. Those with recurrent severe hypoglycaemia and impaired awareness should continue to receive appropriate treatment with pump therapy, rtCGM, closed-loop automated insulin delivery or even islet cell transplantation where appropriate. This should be in accordance with guidelines and as highlighted by the Diabetes UK technology in type 1 diabetes pathway.20 21 It is not a less costly alternative to more appropriate treatments the person with diabetes may require.

FSL3 is foreseen to be a fully fledged rtCGM but with an anticipated lower price point. With the competition this would introduce into that market, the prices of all rtCGM devices may reduce. This may enable access to even better technological options, including closed-loop automated insulin delivery systems in the future. FSL is the new standard of care for glucose monitoring in type 1 diabetes. Years from now we will look back at asking people with diabetes to prick their fingers for capillary blood glucose as outdated and impractical, the same way
we would consider dipping urine an ineffective measure of glucose levels today. One thing clear, FSL has changed the face of diabetes management for the long haul and there is certainly more to come.

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