Our Brave New World

reat news for some individuals with type 1 diabetes: since April 2019, all Clinical Commissioning Groups (CCGs) have been compelled by NHS England to allow patients access to flash glucose monitoring technology. Indeed, if this dictate is fully implemented, approximately 20–25% of individuals with type 1 diabetes will have assess to flash technology (NHS England, 2019). While many will be celebrating with champagne, other parties may well be reaching for a glass of water and the paracetamol!

Strings

Naturally, there are strings attached regarding access to flash technology. NHS England (2017) sets out who should be allowed access to the technology (*Box 1*). However, as in all NHS guidance, there is the ever-elusive phrase which CCGs love: "**should** be prescribed", as opposed to the no-quibble "**must** be prescribed".

Then there is the contentious statement that if there has been no improvement in glycaemic control after 6 months of use, then flash technology should be discontinued. Echoes of the insulin pump debate come to mind. Theoretically, the statement is eminently sensible but in the real world it is difficult to implement. How do you define improvement or success for the individual? The person with diabetes may have a rather different interpretation of benefit than the healthcare professional or indeed the CCG. Going from zero blood tests a day to one or two, or even just testing before driving, as a result of access to flash technology could be considered progress. Then there are the ethics to consider; after all, it is very contentious and extremely difficult to discontinue a therapy that a patient feels is of benefit to them, even if the "numbers" say otherwise.

Type 2 diabetes

Let's not forget the thorny issue of those people with type 2 diabetes who use insulin. According to

the experts involved in the NICE (2017) Medtech Innovation Briefing (MIB110), the intended place for flash technology was as an alternative to routine blood glucose monitoring, both in people with type 1 diabetes and in those with type 2 diabetes who use insulin injections. However, any potential benefits of flash technology for those with the latter condition have been brushed aside, given that they are denied access to the technology in the NHS England guidance. However, don't people with type 2 diabetes get pregnant and need to monitor their blood glucose levels intensively? For that matter, is there not a case to use flash technology in women who have gestational diabetes? And let's not forget about those with type 2 diabetes who use intensive insulin regimens.

It has been suggested that people who use fixed doses of insulin may not fully benefit from use of flash technology (NICE, 2017). But surely a case could be made for those who use fixed doses of insulin but need third-party assistant to check their blood glucose levels?

Evidence

Common sense states that flash technology, which allows intensive glycaemic observation and analysis,

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Box 1. Eligibility criteria to access flash glucose monitoring technology (NHS England, 2017).

It is recommended that patients aged 4 years and above with type 1 diabetes who meet one or more of the following criteria should be prescribed flash technology:

- 1. Those who undertake intensive monitoring >8 times daily.
- 2. Those who meet the current NICE criteria for insulin pump therapy (HbA_{1c} >69.4 mmol/mol [8.5%]) or disabling hypoglycaemia as described in NICE TA151), where a successful trial of the FreeStyle Libre may avoid the need for pump therapy.
- 3. Those who have recently developed impaired awareness of hypoglycaemia.
- 4. Frequent admissions (>2 per year) with diabetic ketoacidosis or hypoglycaemia.
- 5. Those who require third parties to carry out monitoring and in whom conventional blood testing is not possible.

"Since April 2019, all Clinical Commissioning Groups have been compelled by NHS England to allow patients access to flash glucose monitoring technology." is a positive thing. After all, let's be honest, who really wants to effectively "self-mutilate" every time a blood glucose check is required?! But, as the saying goes, "Houston, we have a problem!" The evidence base for flash technology is lacking (NICE, 2017). However, looking forward, all is not lost if individual diabetes centres collate their information and collaborate with national research and audit projects. Indeed, in this section of the Journal, we have two articles presenting data from two areas, <u>Southampton</u> and <u>Eastern Cheshire</u>, in which the FreeStyle Libre has been offered for over a year. The results, in a combined 181 people, show that the device can be extremely helpful in lowering HbA_{1c} and is very popular with users.

Although local data are useful, it is multicentre data that will provide the real "punch" of indisputable evidence that flash technology is value for money, and then the eligibility criteria for this therapy may be relaxed. As this Journal has recently reported, the first results from the Association of British Clinical Diabetologists' national audit on the Libre were just presented at the American Diabetes Association 79th Scientific Sessions. Data from 4709 users at 114 centres in the UK showed a reduction in mean HbA, from 66 to 60 mmol/mol (8.2% to 7.6%) after 6 months' follow-up. In addition, the rate of hospital admissions due to hypoglycaemia or diabetic ketoacidosis fell from 7.3% to 1.9%. This is the sort of evidence that CCGs cannot ignore, and I would encourage all centres to contribute to the audit (for more information, go to: https://bit.ly/2Gk9yRL).

Cost implications

Both studies in this section of the Journal have shown substantial reductions in HbA_{1c} in users of flash technology, and these, if sustained, could lead to savings over the long term due to significant reductions in diabetes complication rates. CCGs are always looking at ways to save money in the short term. However, the golden nugget for them is that the number of blood glucose test strips used by patients will be reduced with flash technology. So it is unfortunate that there is still a need for traditional finger-prick tests in certain situations, such as periods of rapid blood glucose changes.

Intensive blood glucose monitoring

Intensive blood glucose monitoring is certainly not

for everyone. As an expert involved in the NICE (2017) MIB acknowledged, access to these intensive blood glucose monitoring systems can "make them [patients] 'paranoid' about their blood glucose values, leading them to over-testing" and potentially so stressed that they effectively give up on managing their diabetes. And let's face it, some people just cannot cope with the "know-hows" associated with modern technologies and are unable to manage the equipment, let alone interpret the data.

The NHS Long Term Plan

According to the new 10-year plan for the NHS, innovation and technology must be embraced as it is envisaged that it will transform services (NHS, 2019). If the politicians are to be believed, use of technology will provide cost-effective, patientcentred healthcare that frees up time and resources, so theoretically flash technology fits the bill. It is true that many people with diabetes love that blood glucose diaries are a thing of the past and find the concept of emailing information directly to a clinician for analysis appealing, as does an electronic response or discussion via the phone. However, from the healthcare professionals' perspective, will flash technology save time? I think the jury is out on this one, and our current tech-savvy Minister for Health may need to wake up and smell the coffee!

Technology systems seem designed to provide copious amounts of information, often making it difficult to see the wood for the trees. Downloading in clinic takes time, and analysis of electronic information and completing an electronic response can take just as long as a face-to-face consultation. Indeed, even without the issue of information overload from the technology, the healthcare professional often still needs to speak to the patient to confirm and clarify certain pertinent points, before suggesting a change in treatment. Then there are situations such as examining injection sites that still need to be done in the flesh, so to speak, and I'm sure I am not alone finding people with poor injection technique or even using the wrong insulin.

One could argue that the evils of flash technology, such as sensor management, dealing with information overload and analysing data, can be overcome by education. However, developing and implementing education programmes for flash technology, even if delivered in a group, will also have a detrimental impact on professional time. There are, at least, some helpful educational resources for users available online, such as the Edinburgh Centre for Diabetes and Endocrinology guide, available here.

Security

Many NHS computer systems are old and need replacing – remember we are talking of the service that still uses faxes and bleeps! Quite rightly, IT security and patient confidentially are serious themes within the NHS; however, these factors can be a barrier for those who want to use flash technology and expect an electronic response from their clinician. In addition, fear of computer viruses means many authorities do not allow direct input of external data onto their systems.

Conclusion

There is no doubt that access to flash technology is a huge step forward for some individuals with type 1 diabetes, but there are so many more people with diabetes who will benefit from this tool. The NHS England Chief Executive, Simon Stevens, has stated that "Supporting people with modern tools to manage conditions such as type 1 diabetes is about to become much more widespread". Nice words, but I'm not sure I'd hold my breath – wait for the debates on continuous glucose monitoring sensors, or indeed those of other expensive technologies that are undoubtedly in the pipeline.

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The Edinburgh Centre for Diabetes and Endocrinology has provided a helpful guide for users of the FreeStyle Libre. Available here.