NICE advice

FreeStyle Libre for glucose monitoring

Medtech innovation briefing
Published: 3 July 2017
nice.org.uk/guidance/mib110

Summary

- **The technology** described in this briefing is the FreeStyle Libre flash glucose monitoring system, which measures interstitial fluid glucose levels in people with diabetes.
- The **innovative aspect** is that FreeStyle Libre measures glucose levels from a sensor applied to the skin as an alternative to routine finger-prick blood glucose testing, and can produce a near-continuous record of measurements which can be accessed on demand. It can also indicate glucose level trends over time.
- The **intended place in therapy** is as an alternative to routine blood glucose monitoring in people with type 1 and 2 diabetes who use insulin injections. Finger-prick blood glucose measurements are sometimes still needed, such as when a person is ill or to meet the requirements of the Driver and Vehicle Licensing Agency in assessing fitness to drive.
- The **main points from the evidence** summarised in this briefing are from 5 studies (6 papers) involving 700 people. These include 2 randomised controlled trials, 1 including people with type 1 diabetes (n=241; the IMPACT study) and the other including people with type 2 diabetes (n=224; the REPLACE study). Three of the studies reported device accuracy compared with self-monitored blood glucose, with results ranging from 84% to 88% accuracy and from 99% to 100% clinical acceptability, using an error grid. One study reported device accuracy and acceptability of 97% to 99% compared with venous blood sampling. The evidence suggests that using FreeStyle Libre for up to 12 months reduces time spent in hypoglycaemia compared with self-monitoring of blood glucose using finger-prick tests, and reduces the average number of finger-prick blood glucose tests needed.

- A **key uncertainty** around the evidence is that the randomised controlled trial of people with type 1 diabetes included only adults whose diabetes was well controlled.
- The current commercial list **price** of FreeStyle Libre is £57.95 for the reader, plus £57.95 for a disposable sensor (including VAT) that must be replaced every 2 weeks.
- The **resource impact** is uncertain, and depends upon the extent to which improved glucose control through the adoption of FreeStyle Libre translates into fewer complications, reduced emergency admissions and less use of glucose test strips.

The technology

The FreeStyle Libre flash glucose monitoring system (Abbott) measures interstitial fluid glucose levels. The system comprises a sensor and a reader. An optional companion app for Android mobile devices is also available.

The sensor is a few centimetres in diameter and is designed to stay in place for 14 days. It is applied to the skin, usually on the upper arm. A thin (0.4 mm), flexible and sterile fibre within the sensor is inserted in the skin to a depth of 5 mm; most people have described this as being painless. The fibre draws interstitial fluid from the muscle into the sensor, where glucose levels are automatically measured every minute and stored at 15-minute intervals for 8 hours. Glucose levels can be seen at any time by scanning the reader over the sensor.

To scan the sensor, the reader is held 1 cm to 4 cm above the sensor for 1 second. Readings can be taken through the wearer's clothes. At each scan, the reader displays current glucose levels, levels over the previous 8 hours, and whether glucose levels are trending upwards or downwards (and how fast). This is called the ambulatory glucose profile. For a full 24 hours of data, users must scan the sensor at least once every 8 hours.

The reader is reusable and has a rechargeable battery that must be charged every 7 days. It also has built-in blood glucose and blood ketone meters, which can be used with FreeStyle Optium blood glucose strips or Optium Beta ketone test strips to test finger-prick blood samples.

As an alternative to using the reader, the sensor can be scanned with a mobile device capable of near-field communication (NFC) and on which the LibreLink companion app has been installed. The LibreLink app can be used on Android mobile devices and has similar features to the reader. It can be used with the LibreLinkUp app to share glucose readings through the LibreView software. LibreView can be used to upload and store data to cloud storage and to view data on mobile devices and web browsers.

FreeStyle Libre does not provide real-time continuous glucose monitoring or a hypoglycaemia alarm.

Innovations

Unlike conventional finger-prick blood glucose testing, FreeStyle Libre uses 'flash' monitoring to measure interstitial fluid glucose levels at regular intervals. Once applied, the sensor allows readings to be taken non-invasively, potentially reducing the number of finger-prick blood glucose tests needed. This avoids the pain caused by finger-prick sampling, which can deter people with diabetes from taking regular measurements.

FreeStyle Libre allows people to see their glucose levels at times when readings are not usually taken, such as overnight. The ambulatory glucose profile allows day-to-day patterns in glucose levels to be seen, which can be used to plan treatment. Unlike continuous glucose monitoring, the factory-calibrated sensor does not need to be calibrated with the user's own blood samples.

Current NHS pathway

NICE has published several guidelines on the frequency of blood glucose and blood ketone level testing for different groups of people with diabetes (see table 1). Education and information on blood glucose monitoring are important parts of each guideline. People with diabetes should to be empowered to self-monitor their blood glucose, and be educated about how to measure it and interpret the results. They should also know what action to take. The guidelines recommend routine monitoring of blood glucose using a finger-prick capillary blood sample. Continuous monitoring of interstitial fluid glucose using a continuous glucose monitor is not recommended for routine use but can be considered for some people (see table 1). No NICE guidelines currently include recommendations for intermittent interstitial fluid glucose monitoring (such as that provided by FreeStyle Libre).

Table 1 Recommendations on frequency of blood glucose and ketone testing

NICE guidance	Blood glucose testing	Continuous glucose monitoring	Blood ketone testing

Type 1 diabetes in adults: diagnosis and management	Test at least 4 times a day, including before each meal and before bed. Test up to 10 times a day in certain circumstances, such as in illness, pregnancy or during sport. Enable testing more than 10 times a day if this is necessary because of the person's lifestyle (for example, driving for a long period of time, undertaking high-risk activity or occupation, travel).	Do not offer to adults with type 1 diabetes. Consider for adults with type 1 diabetes who are willing to commit to using continuous glucose monitoring at least 70% of the time and to calibrate as needed, and who have 1 of a number of criteria despite optimised use of insulin therapy and conventional blood glucose monitoring.	Consider ketone monitoring (blood or urine) during illness.

Diabetes (type 1 and type 2) in children and young people: diagnosis and management	Perform at least 5 capillary blood glucose tests per day. More frequent testing is often needed (for example with physical activity and during intercurrent illness).	Offer to children and young people with type 1 diabetes who have frequent severe hypoglycaemia, impaired awareness of hypoglycaemia associated with adverse consequences, or the inability to recognise, or communicate about, symptoms of hypoglycaemia. Consider for neonates, infants and pre-school children, children and young people who have high levels of physical activity, and children and young people who have comorbidities or who are having treatments that can make blood glucose control difficult. Consider its use to help improve blood glucose control in children and young people who continue to have hyperglycaemia despite insulin adjustment and additional support.	Offer children and young people with type 1 diabetes blood ketone testing strips and a meter, to use if they are ill or have hyperglycaemia.

Diabetes in pregnancy: management from preconception to the postnatal period	Pregnant women who are on a multiple daily insulin injection regimen for type 1, type 2 or gestational diabetes should be advised to test their fasting, pre-meal, 1-hour post-meal and bedtime blood glucose levels daily. Pregnant women who are on diet and exercise therapy, taking oral therapy (with or without diet and exercise therapy) or single dose intermediate acting or long acting insulin for type 2 diabetes or gestational diabetes should be advised to test their fasting and 1-hour post-meal blood glucose levels daily	Do not offer to pregnant women with diabetes. Consider for pregnant women on insulin therapy who have problematic severe hypoglycaemia (with or without impaired awareness of hypoglycaemia), who have unstable blood glucose levels (to minimise variability), or to gain information about variability in blood glucose levels.	Offer pregnant women with type 1 diabetes blood ketone testing strips and a meter, and advise them to use it and to seek urgent medical advice if they become hyperglycaemic or unwell.

Type 2 diabetes in adults: management	Do not routinely offer self-monitoring of blood glucose levels for adults with type 2 diabetes unless the person is on insulin, there is evidence of hypoglycaemic episodes, the person is on medication that may increase their risk of hypoglycaemia while driving or operating machinery or the person is pregnant, or is planning to become pregnant. Consider short-term self-monitoring of blood glucose levels in adults with type 2 diabetes when starting treatment with oral or intravenous corticosteroids or to confirm suspected hypoglycaemia.	No recommendations.	No recommendations.

NICE diagnostics guidance on integrated sensor-augmented pump therapy systems for type 1 diabetes recommends using the MiniMed Paradigm Veo continuous glucose monitoring system for people having episodes of disabling hypoglycaemia despite optimal management of their diabetes using insulin injections. People using this system should use the sensors at least 70% of the time, have a good understanding of the system, and have a structured education programme on diet and lifestyle. They should only continue to use it if they have fewer hypoglycaemic episodes.

NICE is aware of the following CE-marked devices that appear to fulfil a similar function to FreeStyle Libre:

- SugarBEAT (Nemaura Medical; not yet available to the NHS)
- Eversense (Senseonics).

Population, setting and intended user

FreeStyle Libre is intended to be used as an alternative to routine blood glucose monitoring for people aged 4 or over with type 1 or type 2 diabetes, who have multiple daily injections of insulin or who use insulin pumps and are self-managing their diabetes.

Finger-prick blood glucose testing would still be needed:

- during times of rapidly changing glucose levels when interstitial fluid glucose levels may not accurately reflect blood glucose levels
- if FreeStyle Libre shows hypoglycaemia or impending hypoglycaemia
- when symptoms do not match the system readings
- to fulfil Driving and Vehicle Licensing Authority requirements to assess fitness to drive.

The sensor is waterproof in up to 1 metre of water for 30 minutes and can be worn during all daily activities including bathing or showering.

Users would need support and training from diabetes specialist nurses in how to use FreeStyle Libre and interpret the readings. When used by a child aged 4 to 12 years, a caregiver at least 18 years old must supervise, manage and help the child in using the system and interpreting its readings.

The company offers e-learning for healthcare professionals, particularly nurses, in the range of Abbott glucose monitors. Online tutorials and videos are also available on the company website which are aimed at patients learning to use the system.

Technology costs

The commercial retail price (including VAT) of FreeStyle Libre is £57.95 for the reader, which has a 3-year lifespan, and £57.95 for each sensor, which must be replaced every 14 days (this equates to £1,526.02 per year). The company has an application pending for inclusion in the NHS Drug Tariff.

The current retail cost for FreeStyle Optium blood glucose test strips is £15.97 for 50 strips. FreeStyle Optium blood ketone test strips cost £21.36 for 10 strips. The FreeStyle lancets for taking finger-prick blood cost 3.5p each. The LibreLink app can be downloaded for free.

Costs of standard care

A number of different blood glucose meters and test strips are available in the NHS. Blood glucose meters are provided to the patient at no cost, whereas test strips are available on prescription. Meters are generally provided to the NHS at no cost from the company, but test strips and lancets may need to be bought.

Costs for blood glucose monitoring starter kits available through the NHS supply chain range from £14.93 for 1 meter and 10 glucose strips, lancets and a lancing device, to £107.85 for 1 meter and 900 glucose strips and lancets. Costs of blood glucose test strips to the NHS vary according to the meter used but are typically between £7 and £16 for a pack of 50, with bulk-buy savings available and total cost dependent on the meter chosen. Test strip prescribing is currently under review and specific types and quantities available (and therefore costs) may change in future.

Resource consequences

The resource impact of using FreeStyle Libre is uncertain. If adopted, additional costs would be incurred for the purchase of readers and sensors, but the number of blood glucose testing strips needed may be reduced. Additional clinician time may be needed to read and analyse the ambulatory glucose profile reports, although this may be equivalent to the time taken to read and analyse information from the patient's glucose log book. Costs may be saved if using FreeStyle Libre leads to better monitoring and control of glucose levels, and a subsequent reduction in hospital admissions to treat diabetic complications.

A cost-effectiveness analysis, which modelled randomised controlled trial evidence for type 1 diabetes across 6 European countries and Australia, estimated costs for each non-severe hypoglycaemic event averted of around £17 to £25 at 2015 prices, with incremental costs per quality-adjusted life year under published thresholds (Bilir et al. 2016).

Currently, FreeStyle Libre is mainly bought privately by the user, but it is also in use by selected NHS patients.

Regulatory information

The FreeStyle Libre flash glucose monitoring system reader kits, sensor kits and app were CE marked as class IIb devices in August 2014.

The company has stated that 2 Medicines and Healthcare products Regulatory Agency field safety notices have been issued in relation to FreeStyle Libre:

- 2014/010/002/081/016: A software feature designed to disable the sensor in the event of a possible loss of sensor power could malfunction, meaning that power loss could be missed. In these cases the sensor may provide previously collected glucose values as if they were current results. Advice was given to use the meter and test strips if this occurred and the company has since corrected this issue for all newly manufactured sensors.
- 2015/006/026/291/011: 22 individual sensors outside of the UK had a potential for erroneously high glucose results. Users were instructed to discontinue use and contact the company for replacements. The company implemented corrective actions.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

People with learning difficulties or certain mental health problems and pregnant women may particularly benefit from FreeStyle Libre. People with certain skin conditions or allergies may be unable to wear the sensor.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Five studies (reported in 6 publications) involving 700 people are summarised in this briefing. This includes 2 randomised controlled trials: the IMPACT study of adults with type 1 diabetes (n=241) and the REPLACE study of adults with type 2 diabetes (n=224). The other 3 are repeated measures,

within-patient studies (n=235), of which 1 involved adults, 1 involved children and young people and 1 involved pregnant women.

Overall assessment of the evidence

The current evidence base for FreeStyle Libre mainly comprises 2 good quality randomised controlled trials which assessed its use over 6 months (reported in Bolinder et al. 2016a, 2016b; and Haak et al. 2017). Neither the investigators nor patients were blinded to the intervention in these studies, but this would be very difficult to achieve practically for this kind of device.

Two fully published prospective studies using within-patient controls (Bailey et al. 2015; Edge et al. 2017) were also identified. These studies both investigated the use of FreeStyle Libre for 14 days, and so only short-term outcomes were reported. The Edge et al. study included people aged 4 to 17 years so the outcomes are relevant to children and young people with type 1 diabetes.

One study included pregnant women with type 1, type 2 or gestational diabetes. However, this is currently only available as a short conference abstract and the full details of this study, including its length, are not available (Scott and Kautzy-Willer 2017).

All of the included studies report a high level of user preference for FreeStyle Libre over finger-prick blood glucose monitoring, although some people had problems with inserting or wearing the sensor (despite allergies to medical adhesive being included in the exclusion criteria for several of these studies).

There are currently no high quality, peer-reviewed studies on the use of FreeStyle Libre by people with very unstable glucose levels. Studies in this patient group would be beneficial to understanding which people with diabetes would benefit most from using FreeStyle Libre.

Table 2. Summary of included studies

Bailey et al. (2015)	
Study size, design and location	72 adults (median age 48.5) were included in this prospective, within-subject study in 4 US clinical sites. Patients had type 1 or 2 diabetes needing insulin (by pump and/or injections) and stable for at least the past 6 months.

Intervention and comparator(s)	FreeStyle Libre results were compared with: • SMBG measured using built-in blood glucose meter ≥8 times daily • venous blood using YSI analyser for 8 hours on 3 separate days.
Key outcomes	Accuracy: Compared with SMBG, 85.5% of FreeStyle Libre readings were clinically accurate and 99.0% were clinically acceptable on a Clarke error grid, using linear mixed modelling. Compared with venous blood sampling, 96.5% of FreeStyle Libre readings were clinically accurate and 98.9% were clinically acceptable. There was 11.4% MARD between FreeStyle Libre and SMBG readings and 12% MARD between FreeStyle Libre and venous blood measurements. Accuracy was slightly improved when a consensus error grid method was used. Patient acceptability: 94% of patients reported favourable ratings on 9 out of 9 subjective statements such as sensor wear and pain compared with finger stick. Skin issues were seen in 202 site exams: moderate to severe itching (0.5% of the time) and moderate erythema (4% of the time). 1% of users reported unacceptable pain on insertion of sensor.
Strengths and limitations	3 variations of grid analysis were employed: Clarke error grid, consensus error grid and continuous glucose error grid without clear explanation why.
Bolinder et al. (2016a)	
Study size, design and location	This was an RCT of 241 adults self-managing stable and well-controlled insulin dependent type 1 diabetes from 23 diabetic centres in 5 European countries (Sweden, Austria, Germany, Spain, Holland). Patients known to be allergic to medical grade adhesives were excluded.
Intervention and comparator(s)	FreeStyle Libre compared with SMBG.

Key outcomes	Effectiveness: Patients using FreeStyle Libre experienced less time in hypoglycaemia than patients using SMBG, averaging 1.24 hours per day (SE 0.24) or 38% less time (p<0.0001) in hypoglycaemia and 1 hour more per day in euglycaemia (p=0.0006). The number of hypoglycaemic events per day reduced by mean of 0.45 (by over 25%; p<0.0001). There were no differences in HbA1c between the 2 groups and no differences in mean glucose levels but glucose variability decreased using a number of other measures (BGRI, CV glucose, LBGI, MAGE, CONGA). The mean number of SMBG tests per day reduced from 5.5 (SD 2.0) to 0.5 (SD 0.7) in the intervention group. Patient acceptability: Satisfaction with FreeStyle Libre was higher by 6.1 points on a scale of 0 to 18 compared with SMBG (p<0.0001). 8% of FreeStyle Libre sensor users had non-serious device-related adverse events (itchiness/rash allergy, erythema and oedema).
Strengths and limitations	The RCT included 6-month follow-up. Neither patients, staff nor investigators were blinded. The population was limited to self-managing stable and well-controlled adults.
Bolinder et al. (2016b)	
Study size, design and location	This study was a sub-analysis from the RCT reported by Bolinder et al. (2016a). Outcomes in 18 to 24 year olds (n=19) were compared to ≥25 year olds (n=222) over 6-month follow-up.
Intervention and comparator(s)	FreeStyle Libre compared with SMBG.

Key outcomes	After 6 months of device use there was no significant difference between age groups in the number of times the sensor was scanned daily. 18 to 24 year olds using FreeStyle Libre remained in euglycaemic range for nearly 3 hours longer than those using SMBG: TIR increased significantly by 2.9 (SE 0.89) hours per day (p=0.0055). Adults aged 25 or over significantly increased TIR by 0.9 (SE 0.31) hours per day (p=0.0073). There was no difference in length of time the sensor was worn (91.4% by 18 to 24 year olds and 92.9% by those aged ≥25 years), and no significant interaction of age with treatment group for the primary end point of time in hypoglycaemia at 6 months.
Strengths and limitations	There were only 10 people aged under 25 years in the intervention group. The study was only available as a conference abstract.
Edge et al. (2017)	
Study size, design and location	This was a single-arm prospective within-patient study of 89 4 to 17 year olds with type 1 diabetes treated with multiple daily injections of insulin or continuous insulin infusion, from 9 diabetic centres in the UK. Patients with a known or suspected allergy to medical grade adhesives were excluded.
Intervention and comparator(s)	FreeStyle Libre compared with SMBG.
Key outcomes	Accuracy: Compared with SMBG, 83.8% of FreeStyle Libre sensor results were clinically accurate and 99.4% were clinically acceptable on a consensus error grid. MARD was 13.9%. Patient acceptability: There was good user acceptability. There were 5 out of 89 mild or moderate sensor-related adverse events (allergy, blister, pink marks, mild bleeding, mild erythema, itching, oedema).
Strengths and limitations	The study ran for 14 days only. Sensor results were masked to patients.
Haak et al. (2017)	

Study size, design and location	12-month data from REPLACE RCT (n 224) with adult type 2 diabetes patients having intensive insulin therapy or continuous subcutaneous insulin infusion in 26 sites in Germany (n=10), UK (n=8) and France (n=8). Exclusions included patients with any severe hypo or hyperglycaemia in the preceding 6 months and patients with allergy to medical adhesives.
Intervention and comparator(s)	Randomised 2:1 to FreeStyle Libre or SMBG.
Key outcomes	Effectiveness: At 12 months the time in hypoglycaemia reduced by 50% compared with baseline, and the frequency of these events was reduced by 41%. There was no change in the time in hyperglycaemia. The number of SBMG tests reduced from 3.9 tests per day at baseline to 0.1 tests per day at 12 months. The median number of sensor scans per day was 5.7. 9 people reported 16 device-related adverse events, which were all related to the sensor adhesive or site reactions.
Strengths and limitations	Neither patients nor investigators were blinded to group allocation.
Scott and Kautzy-Willer (2017)	
Study size, design and location	This was a single-arm prospective within-patient study of 74 pregnant women, 24 with type 1 diabetes, 11 with type 2 and 39 with gestational diabetes from 9 sites in the UK and 4 in Austria. Average gestation was 26.6 weeks. Only 66.2% were taking insulin.
Intervention and comparator(s)	FreeStyle Libre compared with SMBG.

Key outcomes	Clinical accuracy: 88.1% of FreeStyle Libre readings were clinically accurate and 99.8% were clinically acceptable compared with SMBG by consensus error grid analysis. MARD was 11.8%. Clinically accurate results were reported to be obtained for each type of diabetes. Patient acceptability: User satisfaction questionnaires were reported to indicate high levels of acceptance for sensor wear and ease of use of the device. There were no unanticipated device-related adverse events.
Strengths and limitations	Published as a conference abstract with limited data. No information was given on how long the sensor was worn.
Abbreviations: BGRI, blood glucose risk index; CONGA, Continuous overall net glycaemic action; LBGI, low blood glucose index; MAGE, mean amplitude of glycaemic excursions; MARD, mean absolute relative difference (the lower the MARD, the more accurate a device is considered); SMBG, self-monitored blood glucose; TIR, time in range.	

Recent and ongoing studies

- Performance Check of the Abbott FreeStyle Libre Flash Glucose Monitoring System. ISRCTN identifier: ISRCTN87654534. Status: expected to run January 2015 to December 2026.
- An Evaluation of Self-Management of Diabetes Using FreeStyle Libre Flash Glucose Monitoring System in Young People (SELFY). ClinicalTrials.gov identifier: NCT02821117. Status: recruitment ceased December 2016. Results pending second half of 2017.
- Accuracy of Flash Glucose Monitoring FreeStyle Libre (Abbott) in Home Setting and In-patient Setting During Hypo-Hyperglycaemia. ClinicalTrials.gov identifier: NCT02734745. Status: recruiting.
- FreeStyle Libre Pro Use in Primary and secondary Care. ClinicalTrials.gov identifier: NCT02434315. Status: completed 2016.
- FreeStyle Libre: Effect on QOL in Type 2 Diabetes Patients. ClinicalTrials.gov identifier: NCT02809365. Status: not yet recruiting.
- An Evaluation of the FreeStyle Flash Glucose Monitoring System. ClinicalTrials.gov identifier: NCT02824549. Status: recruiting.

- Evaluation of a Flash Glucose Monitoring System in Ambulatory Patients with Type 1 Diabetes. ClinicalTrials.gov identifier: NCT02677454. Status: completed.
- Glucose Variability Pilot Study for the Abbott Sensor-Based Glucose Monitoring System-Professional. ClinicalTrials.gov identifier: NCT02336945. Status: completed.
- Standardized Evaluation of Subcutaneous Glucose Monitoring Systems Under Routine Environmental Conditions. ClinicalTrials.gov identifier: NCT02614768. Status: completed.
- Flash Glucose Monitoring Study for Diabetes. ClinicalTrials.gov identifier: NCT02898714. Status: recruiting.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

All 4 clinical experts stated that they regularly use FreeStyle Libre with patients and 1 is also a self-user.

Level of innovation

All 4 of the clinical experts agreed that FreeStyle Libre is an innovative technology, 1 of them describing it as a 'huge leap forward', another as a minor variation of continuous glucose monitoring. Although easy to use, the experts all felt that some basic training or information would need to be provided for patients and healthcare professionals using FreeStyle Libre.

Potential patient impact

All 4 experts felt that this technology could offer benefits to patients. One stated that the constant monitoring of glucose levels with FreeStyle Libre would improve patient outcomes because it allows for quicker interventions, would aid self-management and would improve insulin titration. Two experts reported that a number of their patients with type 1 diabetes showed improvements in Hb1A1c when using FreeStyle Libre. Three clinical experts felt it was particularly beneficial for people who are deterred from self-monitoring by finger pricks, and for pregnant women. One expert felt that people who need to test multiple times would also benefit. Another felt people with learning difficulties, people with mental health problems and people with hypoglycaemia unawareness would benefit most.

One clinical expert felt that FreeStyle Libre helped people who were disengaged from their treatment to monitor their glucose levels non-invasively, and that this could lead to fewer hospital admissions. In their clinical experience, people using this technology, with the right support, had improved HbA1c levels, indicating benefits in longer-term health outcomes. Another expert found it best suited for those who had already attended a structured education programme enabling them to self-manage intensive insulin therapy and under the care of a diabetes service experienced in intensive insulin therapy.

Patients with type 2 diabetes taking fixed doses of insulin may derive less benefit from the technology.

Potential system impact

Three clinical experts felt that using FreeStyle Libre would be cost effective because of improved diabetes management and reduced complications such as hospital admissions. One expert noted that managing complications accounts for 80% of diabetes spending, and so any reduction in the rate of complications would be meaningful. Another felt that it could be cost effective but only in a subset of patients, such as people who were testing their blood glucose excessively. In these people, FreeStyle Libre might be suitable for a fixed period of time and may not need to be used long term.

All 4 experts agreed that no significant changes in NHS infrastructure would be needed. Two noted that diabetes clinics need to have the appropriate software to download and analyse results installed on their computers. Another noted that diabetes education programmes would need to be updated to include the use of flash glucose monitoring.

General comments

One expert felt that FreeStyle Libre was a part of modernising care in diabetes and that it offered a less invasive form of monitoring. They noted that it is supported by healthcare professionals in the type 1 diabetes community and by diabetes charities. Another stated that in their experience, FreeStyle Libre had been a powerful tool but a number of their patients had not used it as much as they thought they would, had been allergic to the adhesive, or found that it made them 'paranoid' about their glucose values leading to them over-testing. The expert felt that suitable people could be offered FreeStyle Libre for a trial period before reviewing its use and only providing it in the longer term to people who showed a benefit.

Patient organisation comments

Diabetes UK gave the following comments on FreeStyle Libre.

FreeStyle Libre is unique and novel, fitting in between finger-prick monitors and continuous glucose monitors. It provides more information to the user than finger-prick testing, allowing them to better manage their insulin dosing, food intake and activity. It is convenient because it can provide predicted HbA1c measurements between clinic appointments, and can be used with home computers and smartphones. Because it is factory-calibrated and can be used as a finger-prick glucose and ketone monitor, it avoids the need to use several pieces of technology.

In its experience, Diabetes UK stated that it has found that education and training would be needed for both healthcare professionals and users of FreeStyle Libre to ensure that the full benefits are delivered. Users should be made aware of the device's limitations, for example that finger-prick tests are still needed before driving or at times of rapid changes in blood glucose levels, and that adverse and severe skin reactions to the sensor have been a common problem. Some users need to use a skin covering in order to be able to use the sensor. The charity recommended that longer-term studies should investigate this.

Diabetes UK noted that FreeStyle Libre might be particularly useful for certain groups of people. Continuous glucose monitors are sometimes recommended for pregnant women, but because these are fixed to the abdomen FreeStyle Libre may be a suitable alternative. Other people who may benefit include people with highly variable blood glucose, people with poor peripheral circulation, older people, and hospital inpatients who need regular monitoring. FreeStyle Libre should not be used for people with no awareness of the symptoms of hypoglycaemia.

Using FreeStyle Libre may benefit people in certain jobs where finger-prick testing is not always practical. It could also provide education by allowing people to link certain foods or behaviours to changes in their glucose levels.

FreeStyle Libre could have a positive impact on NHS services because of improved management of HbA1c levels leading to potentially fewer emergency admissions, less inpatient care and better outcomes for patients. It would help people to meet the frequency of glucose testing recommended in NICE guidance. It could also save costs associated with glucose test strips.

Clinical experts

The following clinicians contributed to this briefing:

- Dr Partha Kar, diabetes consultant, Portsmouth Hospitals NHS Trust, and associate national clinical director for diabetes, NHS England. Dr Kar has done consultancy work for pharmaceutical companies such as Novo Nordisk, Eli Lilly and Sanofi.
- Dr Parth Narendran, reader in diabetes medicine, University of Birmingham, and consultant diabetologist, The Queen Elizabeth Hospital, Birmingham: No conflict of interest declared.
- Mrs Debbie Hicks, nurse consultant in diabetes, Enfield Health, Barnet, Enfield and Haringey Mental Health Trust. Mrs Hicks has received honoraria from Abbott for giving presentations at educational events plus attendance on advisory boards.
- Dr Karen Anthony, consultant in diabetes and endocrinology, The Whittington Hospital NHS Trust: No conflicts of interest declared.

Additional reviewer:

- Mrs Victoria Gibson, formulary support/contracts and commissioning senior pharmacist, Medicines Optimisation Team, Cambridgeshire and Peterborough CCG.

Representatives from the following patient organisations contributed to this briefing:

- Diabetes UK.

Development of this briefing

This briefing was developed for NICE by Birmingham and Brunel Consortium. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

ISBN: 978-1-4731-2580-3