Qualitative analysis of patient responses to the ABCD FreeStyle Libre® audit questionnaire

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Introduction

The Abbott FreeStyle Libre® flash glucose monitoring system (FGMS) is a novel sensor-based, factory–calibrated device that allows individuals with diabetes to monitor their interstitial glucose levels, capture up to 8 hours of interstitial glucose data, and predict future changes in interstitial glucose by scanning a temporary implantable glucose sensor with a reader device or compatible mobile phone.[1]

Introduction of the device was controversial initially because of concerns regarding lack of evidence of clinical effectiveness. Presently there are no randomised controlled trials confirming the improvement in HbA1c (as a surrogate marker for risk of complications) seen in observational studies, although there is RCT evidence of significant reduction in hypoglycaemia for individuals with both Type 1 and Type 2 diabetes.[2] The device is not licensed for use in pregnancy despite increasing evidence that use of continuous glucose monitoring systems (CGMS) is associated with a reduction in adverse outcomes.[3] The Driver and Vehicle Licensing Agency have recently updated their advice that flash and continuous glucose

monitoring systems may be used by drivers, with a requirement that capillary blood gluocose monitoring is required if interstitial glucose is 4mmol/l or less.[4] However, at the time of this study, the DVLA required a capillary blood glucose level to be measured prior to driving. [5]

NHS funding for the device became available in November 2017 in North Cumbria and individuals with Type 1 diabetes could be prescribed the device according to criteria agreed by the Regional Medicines Optimisation Committee (see Box 1).[6] The Association of British Clinical Diabetologists (ABCD) are supporting nationwide data collection regarding use and impact of FGMS, and have produced data collection forms for central submission and analysis of quantitative data.[7] However, the data collection forms also offer opportunity to collect qualitative data from individuals using the device in addition to health care professional comments regarding progress. This data provides some interesting insights into FreeStyle Libre® use and supports the view that FGMS has an important impact on quality of life in addition to (and sometimes irrespective of) quantitative clinical improvement measures which have been reported elsewhere for this cohort.[8]

Methods

Individuals with Type 1 diabetes who were identified as meeting RMOC criteria for FGMS use during the course of routine clinical care gave verbal consent to collection of audit data according to the recommendations of the ABCD Nationwide FreeStyle Libre audit, including submission to the central audit platform and dissemination of anonymised data locally and nationally.

Data collection was undertaken as part of routine clinical care. The intention was to collect data using the ABCD audit form prior to FGMS initiation and again at 6 months. Where this was not possible, including for those users who had self-funded a FGMS for 6 months, the audit form for use prior to FGMS initiation was completed retrospectively at the same time as the follow up audit form, as recommended by ABCD.

At 6 months' follow up, additional patient comments were sought regarding their experience of using the FreeStyle Libre® FGMS and these were recorded in the relevant section on the follow up audit form. After completion of follow up audit forms for 40 consecutive patients, data was collated and analysed for local dissemination of early quantitative findings including overall trends towards improvement in HbA1c, hypoglycaemia experience and diabetes distress screening scores.[8] Sixteen of the seventeen individuals in the cohort who had a contemporaneous DDS-2 (Diabetes Distress Scale-2) score available prior to use of the FreeStyle Libre® device and at 6 months' follow up showed an improvement, with only 12% reaching a DDS-2 score >6 at follow up compared to 65% prior to initiation.[8] A DDS-2 score of greater than 6 indicates high levels of "diabetes-related distress" defined as patient concerns about disease management, support, emotional burden and access to care, and identifies those who may benefit from a more detailed assessment of causes of distress to tailor intervention.[9] Early analysis of qualitative data appeared to provide evidence which supported the trend toward improvement in quality of life scores, and this was deemed worthy of further analysis.

Study aim and questions

The study aim was to determine whether use of a Flash Glucose Monitoring System had an impact on quality of life and to explore patients' narratives as to why this was the case.

Data Collection and Analysis

Raw data was collected as part of a brief semi-structured interview supported by the ABCD FreeStyle Libre® Follow-Up Visit Data Collection form.[7]

Data was collected pragmatically at outpatient clinic follow up visits, and the first forty patients to complete 6 months of continuous use were included in the study. Participants were asked "What was positive?" and "What was negative?" about their experience of the device, and answers were transcribed by the reviewing clinician and read back to the participant to ensure appropriate data capture. Data were subsequently collated and anonymised, and because data collection had been undertaken by a single clinician (Consultant Diabetologist, LO), an additional researcher (Diabetes Specialist Dietician, ES) was recruited for data analysis to improve robustness and help reduce observer bias. Thematic analysis using a grounded theory approach was then undertaken independently by both researchers ensuring that each response was considered and accounted for in the final analysis.[10]

Feedback on use of the device was overwhelmingly (although not unanimously) positive. A number of basic themes were identified independently by the investigators, which were then grouped into four organising themes: Contrast with Capillary Blood Glucose Monitoring

(CBGM); Impact on Hypoglycaemia Experience; Glycaemic control and complications; and Improved Wellbeing and Quality of Life. Participant responses, as documented on the ABCD audit form, have been quoted to represent and illustrate the commonalities and variations within these themes.

Findings

Forty patients were surveyed during the course of routine review of their use of the device. Patients were reviewed in a number of different outpatient clinic settings including a general Diabetes MDT (Multidisciplinary team) clinic, Young Adults Clinic and Insulin Pump clinic. The age range of participants was 20-79 years, 46% were male, and duration of Type 1 diabetes ranged from 4 to 56 years. Two participants were recognised to have cognitive impairment or learning disability and were dependent on additional care, and 12 participants used insulin pumps to deliver insulin whilst the remainder used multiple daily injections. Seventeen of the cohort had initially self-funded the device. Use of the device was in accordance with locally agreed criteria (Box 1).

Theme 1: Contrast with Capillary Blood Glucose Monitoring (CBGM)

a) **Reduction in pain and scarring associated with conventional CBGM**

A majority of respondents stated that no longer having to undertake conventional capillary blood glucose monitoring (using a lancet device to

pierce the skin of the fingertips to measure blood glucose) was a significant benefit of the FGMS. The predominant complaint regarding conventional blood glucose monitoring was that of pain from use of the lancet device for conventional blood glucose monitoring. Responses included *"My fingers are sore from blood glucose monitoring"*, *"I no longer have sore fingers",* and from the carer of an individual with cognitive impairment *"His fingers were so sore previously"*. For some users, the pain of conventional blood glucose monitoring was sufficient for the individual to avoid monitoring at detriment to their glycaemic control, for example, *"when it hurts you don't monitor, do you?"* and *"before the Libre I wouldn't prick my fingers because it hurt"*. A large number of respondents identified the absence of "fingerpicks" as a major benefit of the FGMS, with responses including *"taking away fingerpricks makes a big difference", "I was sick to death of blood glucose monitoring",* and *"fingerpricking is a chore"*.

A number of respondents identified significant scarring to their fingertips as a consequence of frequent testing, for example, *"My fingertips were so sore and scarred and now they're healing", "I have obliterated my fingertips with frequent monitoring"* and in one extreme case of an individual who had physical disability and sufficiently scarred fingertips that he could no longer obtain blood for conventional monitoring *"I no longer have to pick at scabs to obtain blood for glucose testing"*.

For some individuals, conventional blood glucose monitoring had negatively affected their ability to work or pursue hobbies, and use of a FGMS had a positive impact: *"It's nice to be able to feel my fingertips - I couldn't pick anything up in work", "You need your fingers to work when*

you're blowing up stuff for a living", "It's great at work when I'm doing cleaning jobs – more hygienic".

b) Alternative sites testing

Prior to introduction of the FreeStyle Libre® FGMS device, individuals who had difficulty with conventional blood glucose monitoring were offered an alternative sites tester device to allow sampling of blood from the palm, forearm or even thighs if not obtainable from the fingertips. Respondents were generally negative about alternate sites blood glucose testing with responses including "*alternate sites testing didn't work", "alternate sites tester was unworkable" and "alternative sites tester useless".* It is recognised that individuals successfully using alternate sites testers will not be included in this sample, but the experience of the local multi-disciplinary team suggests that few individuals are successfully using this alternative device.

c) Use of blood testing strips and equipment

Related to the theme of conventional blood testing is that of use of blood testing equipment. A number of respondents identified concerns about excessive consumption of blood glucose testing equipment, likely influenced by ongoing campaigns to reduce costs associated with capillary blood glucose monitoring (predominantly aimed at individuals with Type 2 diabetes). Responses included *"can scan as frequently as I like without worrying about fingerpricking or test strips", "It has stopped me worrying about running out of test strips and equipment"* and "*I'm testing more*

frequently because I can" as well as numerous references to testing *"more frequently", "whenever I need"* and *"when unwell".*

In addition, conventional blood testing equipment can be difficult for some users with physical disability *"I can't monitor my fingerprick glucose because of neuropathic pain and dexterity problems"* and *"I can only do blood glucose testing on one hand",* and these users rated the FGMS highly.

d) Convenience and ease of use

As predicted from the decreased reliance on painful capillary blood glucose monitoring, a strong theme amongst respondents was that the FGMS was convenient and easy to use, supporting frequent testing: *"easiest thing in the world to check glucose regularly and frequently"* and additional testing in situations where conventional CBGM can be more difficult, for example *"it's easier in work when my hands are dirty", "I can have a quick look whenever I want to",* "*especially good for sport", "I can check when exercising, frequently".* One respondent who had used a continuous glucose monitoring system (CGMS) stated *"It's easier than continuous glucose monitoring sensors or blood glucose".*

For individuals with learning disability, FGMS was deemed "*useful for patients and carers*", with one individual with learning disability stating *"I can use it on my own".* A carer for her partner with acquired cognitive impairment stated *"I don't have to do battle with him now to monitor his glucose levels".*

Many respondents felt that the speed of using FGMs was a key improvement from CBGM: *"The immediacy of it is brilliant", "I can get a faster result or others can do it for me", "It's so easy and quick", "I can check instantly".*

e) Accuracy and reliability of Flash Glucose Monitoring

The area in which most negative responses were received concerned the accuracy and reliability of FGM. While most users felt that the FreeStyle Libre® device was accurate when compared to CBGM, advising *"seems to be as accurate as blood glucose", "it's really close to blood glucose readings", "the sensor is pretty much the same as a blood glucose 9 times out of 10"*, others pointed out discrepancies: such as "*the time lag and need to measure blood glucose",* and that the *"discrepancy between blood and sensor glucose can be confusing*". For one respondent, this was noted but insufficient to prevent ongoing use of the device, given the other benefits it provided.

Other users noted problems with adhesiveness of the product, including "*difficulty getting sensors to stick. I have to wear a bandage*" and "*it can be easy to knock off*". One user noted "*longest any sensor lasted was 9 days*". Users who noted a significant discrepancy between FGMS and CBGM values, or who had problems with adhesiveness of the product, were advised to discontinue use.

Two users felt that it would be useful if the sensor could transmit directly to their insulin pump, with one user stating that *"I still do blood tests to enter into the pump".*

Theme 2: Impact on Hypoglycaemia Experience

f) Improved awareness of hypoglycaemia

Hypoglycaemia was an important theme for many respondents. A number of respondents with reduced awareness of hypoglycaemia, reported benefits from using FGMS, including subjective improvement in hypoglycaemia awareness, stating *"my hypo awareness is better", "pre-use I couldn't detect nocturnal hypoglycaemia".* Use of the device also offered greater opportunity for carers to identify and intervene earlier during hypoglycaemia episodes: *"sometimes when I'm low I rely on my wife to notice. Now she prompts me to check with my sensor and I treat my hypos more quickly"* and *"it allows me as a carer to help manage his diabetes and reduce hypos".* Ease of use by a caregiver was seen as a positive attribute in this context by some *"If I was hypo, someone else can use it".*

Most users with a history of severe or frequent, disabling hypoglycaemia reported a reduction in frequency and severity of hypoglycaemia episodes and severe hypoglycaemia episodes (defined as requiring assistance of a third party[11]: *"Hypos have reduced a lot – I was having several a day", "fewer hypos- I've had none since using it", "No severe hypos since using", "I have had far fewer paramedic call outs – once 3 times in a day - and none since using"*.

For most respondents, reduction in hypoglycaemia was because of evasive action taken by the user in response to an indication from the device that interstitial glucose levels were declining: *"able to prevent hypos by reacting to rapid falls", "I'm more aware of falling glucose and able to avert*

hypoglycaemia", "able to detect night-time hypos and change pump settings to avoid".

g) Impact of hypoglycaemia on quality of life

A significant recurring theme was how the FGM had directly addressed the negative impact of frequent or disabling hypoglycaemia on quality of life for individuals. For example: *"I no longer have the embarrassment of hypos in public", "I'm no longer frightened of hypos. I used to worry because I live on my own and it might be four days before anyone would find me", "I used to have to monitor my blood glucose through the night".* In some cases, fear of hypoglycaemia was present even if the individual did not have frequent or severe hypoglycaemia episodes, and FGMS provided additional reassurance: *"I no longer worry whenever I feel under the weather that it is due to a hypo- the sensor acts like a safeguard", "it is a great assurance to family knowing that the chances of my slipping into a hypo unknowingly are greatly reduced", "helps me to work out if hypo or just unwell".*

Theme 3: Glycaemic control and complications of diabetes

h) Improved glycaemic control

Reported improvement in glycaemic control was less predominant amongst respondents than reduction in hypoglycaemia, but a number of users reported tangible improvements: *"I rarely have a blood glucose more than 15", "I'm pleased with the direction of my HbA1c", "pleased with fall in HbA1c", "my average glucose is much improved", "lowest HbA1c in 8 years".* Interestingly for healthcare professionals used to reviewing CBGM

data, one respondent stated *"I can't cheat- before you could check your blood glucose levels when you knew it would be OK".*

i) Reduction in complications

For most respondents, data collection was undertaken approximately six months after initiating use of a FGMS, which is not likely to be sufficiently long enough to detect a reduction in long term complications. Nevertheless, some users reported a reduction in symptoms: *"neuropathy and diarrhoea symptoms have improved", "my neuropathy is better", "better quality of life and fewer symptoms"* and there was a perception that *"long term it's going to stop complications".* A particularly poignant comment from an individual with a previous pregnancy loss was *"it's the difference between a normal birth…it could have prevented my previous pregnancy loss at 36 weeks".*

j) Trend arrows

The FreeStyle Libre® reader device or compatible mobile phone displays "trend arrows" in addition to interstitial glucose levels, by using an internal algorithm to analyse preceding data and predict future changes in glucose levels. This additional feature was cited as being invaluable to patients in helping them to improve their diabetes control, with a large number of patients reporting their usefulness. The feature was referred to as *"almost better than the values", "a Godsend"* and additional to the information provided by CBGM: *"blood glucose is just a snapshot – the trends are really useful"*, *"the arrows help me predict and plan".*

However, some users reported that the trend arrows could influence decision making more than the actual glucose values, stating *"the trend arrows can make me overreact", "sometimes hypo avoidance strategies because of downwards arrows can lead to hypers".*

Theme 4: Improved wellbeing and quality of life

k) Improved self-care

A key aspect of the FGM was its role in improving patient self-care. For most users this reflected increased engagement with self-management, for example *"For long term monitoring and understanding it makes it so much better and easier, and you pay more attention to your diabetes", I can engage more with my diabetes control", "it gives me the opportunity to control my blood glucose better"*. This suggested a change in behaviours regarding blood glucose control, such as one user who reported that prior to the FGM *"I was really aggressively managing my diabetes and causing hypos".*

The combination of ease of use, reduced time taken to measure and improved awareness was also reported to be of benefit to carers and partners of users as well: *"It was great when I was unwell with migraine – my partner scanned me", "my wife scans me whilst I'm driving – it's reassuring".* This suggests that, in these cases, the FGM has facilitated a culture of self-care in the user's lives.

l) Confidence and empowerment

"It's given me reassurance and my confidence back" and *"I'm in control"* were common themes amongst users, especially those with disabling hypoglycaemia. Poignantly, one user reported *"I can sleep at night"*. For some users, this confidence was significant in reducing social isolation: *"I never used to go out without my husband and recently I went to town on the bus on my own", "I didn't want to go out anymore but it's made a lot of difference".* For users with leaning or physical disability, use of the device represented independence: *"I can manage my diabetes without the support of my partner".* A service user who had psychological difficulties in adjusting to life with diabetes since diagnosis stated *"the visibility of the device has stopped me from hiding my diagnosis. Now the more people I tell, it helps me deal with it".*

For others, the removal of the need for finger-tip testing allowed more lifestyle activities to be explored: *"It's nice to be able to feel my fingertips. I am thinking about trying to learn guitar again".*

m) Psychological well-being and self-esteem

Some respondents acknowledged the negative psychological impact of their diabetes diagnosis prior to FGMS use*: "managing my diabetes used to get me down", "before I had the FSL I was in a bad place, I was low, I had low self-esteem".* Strikingly, many users reported that using FGMS had a positive impact on their psychological wellbeing and self-esteem, using statements such as *"I can't express how much better I feel", "Improved mental wellbeing", "I feel normal. You have made me 100% better", "I'm a lot happier".* Many users referred to the device as *"fantastic"*, *"life-*

changing" or a "game-changer". Other recurring themes were *"diabetes is less of a problem", "makes you feel less diabetic".*

DISCUSSION

The themes identified in the qualitative data suggest that Flash Glucose Monitoring Systems can have a positive impact on most users' quality of life. Four of the cohort discontinued use of the Flash Glucose Monitoring System, for a number of reasons including progression to insulin pump therapy, lack of clinical effectiveness, or problems with adhesiveness and unacceptable discrepancy between blood and interstital glucose levels in two of these users.[8] Users reported improved awareness of hypoglycaemia, and a perception that glycaemic control had improved. Improvements in self-care and broader self-esteem were also linked to the use of FGMS. It is to be noted that users who found the device to be non-adhesive requiring frequent replacement of sensors, or inaccurate when compared to conventional capillary blood glucose monitoring, were less likely to rate the device as useful or report an improvement in quality of life, and were more likely to discontinue use. Further research is required to establish the disparity between readings, and the other variables which may be involved in this outcome.

Alongside the strong evidence of positive impact were other significant findings. One such finding was in relation to hypoglycaemia, where participants reported a number of significant negative psychological sequelae associated with recurrent hypoglycaemia or fear of hypoglycaemia which had not previously been elicited in depth during routine clinical care.

This indicates a potential relationship between FGM and user's ability to articulate their concerns around diabetes management. Further research would enable the role of monitoring equipment in routine clinical care to be explored further. Likewise, reduction in hypoglycaemia, or reassurance that hypoglycaemia could be averted, appeared to have a key positive effect on wellbeing. This has implications for future eligibility criteria and funding of flash glucose systems, especially as regards those patients with reduced hypoglycaemia awareness. Currently, NICE recommends consideration of a continuous glucose monitoring system (CGMS) with hypoglycaemia alarms for individuals with reduced hypoglycaemia awareness.[12] These systems have a much higher acquisition cost and are often less intuitive for users. However, a number of individuals reported previously unrecognised reduction in hypoglycaemia awareness but declined use of a CGMS system with alarms because of confidence in the FGMS trend arrows and convenience of frequent use, enabling evasive action to be taken by the user or their carers. Use of the device could therefore, lead to important clinical outcomes even for those with reduced hypoglycaemia awareness including a reduction in severe hypoglycaemia episodes requiring third party assistance, paramedic intervention and hospital admissions.

Early local analysis of data obtained using the ABCD Nationwide FreeStyle Libre® Audit tools indicated that there was an improvement in quality of life scores for a number of patients in whom the Diabetes Distress Screening Scale had been recorded contemporaneously at initiation of the FreeStyle Libre® system. Despite the limited number of participants for whom this score was completed contemporaneously, this study confirms that there is a

quality of life improvement in users of this Flash Glucose Monitoring system, which relates to improved awareness of glucose levels and the opportunity to improve glycaemic control, in terms of reducing both hypoglycaemic and hyperglycaemic excursions. Reducing the pain and other difficulties associated with conventional capillary blood glucose monitoring, including the stress of consuming excessive healthcare resources in the form of test strips and other consumables, was important to many users.

CONCLUSION

Use of a Flash Glucose Monitoring System (FGMS) by individuals with Type 1 diabetes selected according to agreed criteria results in an improved sense of wellbeing and quality of life for most users. This relates to perceived improvement in glycaemic control, reduction in hypoglycaemia and fear of hypoglycaemia, convenience of use and enhanced feelings of empowerment and independence. This paper has highlighted some key thematic areas regarding the nature of and reasons for this impact.

LIMITATIONS OF THE STUDY

Due to the pragmatic nature of data collection by the Specialist Diabetes team, there are limitations to this study. Data collection was based on the ABCD audit form, and this placed some limitations on the flexibility and depth of data collection. Further work involving semi-structured interviews would enable some of the themes raised to be explored in more detail, allow correlation with diabetes-specific quality of life instruments, and explore the reasons for the themes identified in this paper in greater depth.

It is possible that the participants are not representative of the whole population of individuals with Type 1 diabetes. Specifically, findings cannot be generalised to young people under the age of 18 years, and it is possible that those who did not attend for follow up had discontinued use of the device or found it of no benefit, leading to a positive bias amongst those sampled.

BOX 1: RMOC Criteria for FreeStyle Libre® use in North Cumbria

Eligible patients may be identified in Primary or Secondary Care and must have the following characteristics:

- Type 1 diabetes
- Aged 4 years and older
- Attending Specialist Type 1 diabetes care or agreeable to referral
- Using multiple daily injections (MDI) or CSII (insulin pump)
- Individual or carer is willing to undertake training in use of the device
- Agreeable to ongoing regular follow up and monitoring as deemed appropriate by the Diabetes Specialist team

Individuals with these characteristics are eligible for FGMS funding if they meet one of the following additional criteria:

- Undertaking intensive blood glucose monitoring 8 or more times daily
- Those who meet the current NICE TA151 criteria for insulin pump therapy (HbA1c >64mmol/mol or disabling hypoglycaemia) where a successful trial of FreeStyle Libre® may avoid the need for pump therapy
- Those who have recently developed impaired awareness of hypoglycaemia. (Please note: CGMS with an alarm function is recommended for persistent hypoglycaemia unawareness (NICE NG17)
- Frequent admissions (>2 per year) with DKA or hypoglycaemia
- Those who require third parties to carry out monitoring, and where conventional blood testing is not possible.

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