

A qualitative evaluation of patients' perspectives of the FreeStyle Libre flash glucose monitor

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Abstract

Background and aims: This qualitative project sought to evaluate the FreeStyle Libre flash glucose monitor (FSLFGM) from the perspective of patients of an outpatient diabetes clinic. The aim was to evaluate patients' experience of the device, and based thereon to create a brief assessment pro-forma for routine clinic use to justify continued prescription.

Method: A purposive sample was recruited. Telephone interviews were conducted until saturation was achieved. A total of 10 patients were interviewed using a flexible topic guide created in collaboration with the multidisciplinary diabetes team and a consultative panel of people with diabetes. Thematic analysis was used to analyse the interviews.

Results and conclusions: Four superordinate themes, along with subordinate themes, were identified and triangulated by members of the multidisciplinary diabetes team: (1) checking bloods; (2) freedom; (3) impact on others; and (4) perceived disadvantages. Overall, patients reported a strongly positive experience of using the FSLGM, with all expressing a desire to continue use. Using these themes, a brief pro-forma was created for use in review clinics to facilitate discussion and to support decision-making about continued prescription.

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Introduction

The FreeStyle Libre flash glucose monitor (FSLFGM) was made available on the NHS drug tariff in November 2017.¹ Specialist diabetes teams are required to audit and evaluate its use among patients.² The Association of British Clinical Diabetologists (ABCD) created a national audit tool for clinical review of patients who have recently commenced using the FSLFGM.³

Several studies have indicated high levels of patient satisfaction with this device.³ Olafsdottir *et al*⁴ found that patients reported the FSLFGM to be pain-free, easy to use and simple to interpret. Although improvement in HbA_{1c} through using the FSLFGM has yet to be demonstrated empirically, at least one research study has shown that using the FSLFGM frequently increases glucose monitoring.⁵ The same study reported that FSLFGM has a measurable benefit to the patient's health-related quality of life (HRQOL), levels of worry and fear of hypoglycaemia.

The specialist multidisciplinary diabetes team in Belfast City Hospital were keen to develop a brief easy-to-use assessment tool to review patients in a busy outpatient clinic. The multidisciplinary team felt that, whilst the ABCD audit tool³ is a comprehensive method for gathering clinically valuable information, it was found to be difficult to fully complete with patients due to clinic time pressures. With this in mind, the team wished to develop a pro-forma to evaluate patients' experience of the device. The key characteristics of the pro-forma were that it would be quick to administer and it would be based on patients' perceptions of the benefits, or otherwise, of the FSLFGM.

This study therefore had two aims: (1) to evaluate patients' perceptions of the FSLFGM and (2) to use the resulting data to create a brief pro-forma to review existing users of the device in clinic.

Methods

Design

This project employed a qualitative methodology. Thematic analysis was considered the most appropriate method of analysing patients' narratives and to provide a rich, detailed and complex account of data.⁶

A semi-structured topic guide (see Appendix 1 online at www.bjd-abcd.com), designed collaboratively with the multidisciplinary diabetes team based on conversations with patients in the clinic, was used to guide conversations during telephone interviews.

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The methodology was agreed and the topic guide was designed in collaboration with a consultative panel of people with diabetes convened by Diabetes UK Northern Ireland in advance of data collection. The panel reviewed the topic guide and commented on whether it was impartial and provided the opportunity to capture all relevant information.

Sample and recruitment

A purposive sample was recruited to ensure a range of genders and ages were included. A list of all 48 patients using the FSLFGM at the time the study began (April 2018), ordered by the date FSLFGM training was provided, was reviewed systematically (top down) by members of the multidisciplinary team. In total, 27 patients were selected as potential participants. The remaining 21 were excluded if their demographic characteristics were already included or if they were known to be experiencing high levels of stress or to have complex mental health issue such as a personality disorder. It should be noted that all patients who had been provided with a FSLFGM were advised they would be reviewed after approximately 3–6 months' use of the device, and that this may be done via telephone interview.

Selected patients received a letter by post between April and June 2018, detailing the project, how they would be contacted and the option to opt out by a given date. Once this date had passed, participants were called by telephone to organise a longer telephone interview. One opted out and 14 did not respond to initial telephone calls. Two more, who initially agreed to participate, were unable to complete interviews at arranged times due to unforeseen circumstances.

In total, 10 participants (3 men and 7 women aged 27–73 years) were interviewed. All participants were born and raised in Northern Ireland and were of white ethnicity. All met local eligibility criteria and all but two commenced use of the device in November 2017; two self-funded the device prior to this date. Duration of participants' use of the FSLFGM at the time of interview ranged from 5 months to 24 months. After these interviews were completed, the opportunity arose to recruit further participants who had started to use the FSLFGM since April 2018, but as it was felt that saturation had been reached it was decided to stop data collection.

Participants were interviewed by one of the authors (AG) using a telephone with loudspeaker function. Verbal consent was received from each patient to allow conversations to be recorded using a dictaphone. Interviews varied in length from 11 to 42 minutes, with the mode time being 15 minutes. Each interview was transcribed and analysed using thematic analysis,⁶ with the decision to continue data collection made after each analysis was complete depending on the emergence of new themes. Seven of the interviews were randomly selected and were analysed by a member of the multidisciplinary team to validate superordinate and subordinate themes.

Results

Four superordinate themes, along with subordinate themes, were derived from the data. These are detailed below, with the

Table 1 Overview of superordinate and subordinate themes

Superordinate themes	Subordinate themes
Checking bloods	Increase in checking Improved health-related decision-making Increased motivation Reduced avoidance of hypoglycaemia Increased awareness
Freedom	Less interference from diabetes Autonomy Psychological well-being
Impact on others	Peace of mind Improved interpersonal relationships Normalisation
Perceived disadvantages	Getting the sensor to remain attached Visibility Accuracy

superordinate themes represented in ***bold italics*** and the subordinate themes represented in *underlined italics*. Pseudonyms have been used to protect confidentiality. "Bloods" will be used to refer to interstitial glucose, as this was the narrative used by patients. This did not reflect a lack of understanding. Overall, patients were strongly positive in describing their experience with the FSLFGM with one commenting "*It's been life changing*". An overview of the themes is provided in Table 1.

Checking bloods

This theme encapsulates one of the facets of self-monitoring made easier by the less invasive FSLFGM compared with traditional finger-prick testing:

"It's just so much easier to use; you just scan it and you know what your bloods are doing."

Some participants noted that this led to *an increase in checking*, providing more blood glucose-related information upon which to make decisions about insulin requirements. Amy described the impact on her mood that an increase in blood glucose checking has had:

"This now means I do test. That makes me much happier."

Increased checking led to *better health-related decision-making*, as the provision of more information and the ease of scanning meant *increased awareness* for some. Amy mentioned the benefit to her confidence when sleeping:

"I've more of an idea of what my blood sugar is ... I can now look at this and see oh, I dipped during the night and came back up again."

Increased checking resulted in increased motivation to self-manage for many. Catherine had begun to exercise since using the FSL, as seeing how her bloods responded to the activity was motivating:

"All the extra information has given me a push to exercise."

Jane attributed *reduced avoidance of hypoglycaemia* to increased awareness. Due to the demanding nature of her job, she was maintaining a higher than recommended blood glucose. However, this was no longer necessary as the glucose trends indicated on the FSL provided peace of mind.

"I would have taken less insulin before going out because of fear of going low; now at least I can check if I'm going low, or if I'm just tired."

Freedom

This theme emphasises the degree to which participants indicated the FSLFGM allowed them to have more choice in their lives. Amy had begun to consider starting a family, which before using the FSLFMG she felt was not an option for her:

"I've even begun to consider having children, something I had completely ruled out before."

John indicated that the FSLFGM provided the opportunity to exercise with *less interference* from his diabetes:

"When I run, I used to have to stop and prick my finger; now I can just put the wee reader to my arm, and it's confidence it gives you."

Elizabeth noted now having the freedom to exercise, having not had the confidence to do so before:

"I've now started exercising ... previously I would never have done that ... but now in the middle of a spin class, I can scan my arm."

Mary mentioned feeling able to go outside unaccompanied, and being fearful of doing so prior to commencing use of the FSLFGM:

"It's given me independence in my own life now... I do things I never in a million years would have done unless there was someone with me."

An increase in freedom and *autonomy* positively impacted the mood, confidence and *psychological well-being* of some. Amy described this:

"It's made me generally a happier person, as a diabetic, you have to stab yourself so much with needles ... to not have to do that as much is amazing."

Impact on others

Participants frequently narrated the indirect impact of the FSLFGM on others. Many felt the FSLFGM gave their family *"peace-of-mind"*. Two discussed their partner's ability to scan their arm during the night without waking them up, facilitating an *improvement in relationships*. Mary mentioned her husband's ability to scan her arm to check her blood glucose, rather than seeking reassurance from her:

"It's a massive difference in my relationship with my husband ... he's happier, so I'm happier. He says it's taken a huge weight off his shoulders."

Jane spoke about the impact that diabetes has had on her family, believing this has improved since using the FSLFGM:

"We always talk about the impact it's had on me, but my mum ... they (parents) don't sleep at night because of me."

Normalisation was also referred to, with more than one participant alluding to greater integration of their diabetes into their family. Jane discussed how her children had become more involved in her self-management:

"My children now love scanning me."

Perceived disadvantages

The perceived disadvantages of the FSLFGM were, for the most part, raised by participants only in response to a direct question about whether there was anything they did not like about the device. Many participants were keen to say that any perceived disadvantages were far outweighed by the advantages. Amy expressed this sentiment by saying: *"Now we would be getting into pernickities here"*.

The main disadvantage cited was problems getting the *sensors to remain attached*. Mary recounted an incident abroad when the sensor fell off her arm on holiday:

"The only thing I don't like is that it doesn't last."

Another slight negative of the device from some was its *visibility*. Amy noted that, aesthetically, the device was very obvious:

"Last weekend I had a lovely fake tan done and then there's a big white thing stuck to my arm."

Mary felt that the visibility of the sensor attracted unanticipated attention, which encouraged her to wear clothing with sleeves. Issues like these led to many querying whether the sensor could be placed elsewhere on the body.

Almost all participants raised the *accuracy* of the device. Three noted that the sensor tended to lack accuracy when blood glucose was particularly high or low. However, all those who raised this issue acknowledged they had received advice about

it and some acknowledged that it may be related to the lag between interstitial and blood glucose. Nevertheless, two participants noted that discrepancies between the FSLFGM and a finger-prick test caused them to “not trust it 100%”.

All but one of the participants were wholly positive about the device. Jane did not feel that the device had impacted her in any way other than it reduced her avoidance of hypoglycaemia.

“I haven’t done anything differently that I wouldn’t have done before, no.”

However, she also described taking more insulin, having previously reduced her recommended dose to avoid hypoglycaemia. She also noted that, despite this, she would continue to use it:

“What’s the alternative? It’s still the best we’ve got.”

Creating the assessment pro-forma

The themes that emerged during interview were used to create a pro-forma (see Appendix 2 online at www.bjd-abcd.com). The pro-forma contains 10 questions, nine of which require a Yes/No response and one involving a Likert-scaled response included to measure preference, as it was felt this would provide the clinician with insight into the value of continued use of the FSLFGM to the patient. It was piloted at an initial recall clinic and was reported by one of the medical staff to be “*a quick and efficient way to capture patients’ experience*” of the device. One consultant endocrinologist noted, however, that the information captured by the pro-forma would be most useful when combined with clinical and medical indicators such as HbA_{1c} and frequency of hypoglycaemia.

Discussion

This study evaluated the FSLFGM from a patient perspective and used the findings to generate an assessment pro-forma for use in the diabetes clinic when reviewing those who have recently commenced use. Four superordinate themes, confirmed by cross-validation, emerged: (1) checking bloods; (2) freedom; (3) impact on others; and (4) perceived disadvantages. Overall, patients were highly satisfied with the device, with all communicating a desire to continue use.

Consistent with previous studies,⁵ participants reported checking their bloods more frequently since using the FSLFGM resulting in increased motivation and better health-related decision-making. Participants also reported an increased awareness of blood glucose levels. This was in line with the findings of McPhater *et al* who reported improved awareness of blood glucose and self-management behaviours as a result of using the FSLFGM.⁷

All participants reported a greater sense of freedom, with the FSLFGM providing important new opportunities for some including, for example, having children. Others described feeling safer about doing things they were once anxious about which enhanced their confidence, self-efficacy and mood. Importantly,

previous research has consistently demonstrated that self-efficacy beliefs are a key factor in how an individual copes with diabetes self-management.⁸

The positive effect FSLFGM has on family members was acknowledged, and others becoming more helpfully involved in self-management was felt to improve interpersonal relationships. This issue should be considered in the light of previous research findings⁹ which have demonstrated that the impact of an individual’s diabetes on others, and the level of partner involvement, was a significant interpersonal challenge for people with diabetes.

All participants wished to continue to use the device despite noting a number of relatively minor disadvantages, such as the sensors not always lasting 14 days. Concerns about accuracy also arose, with some participants noting a discrepancy between the FSLFGM and finger-prick testing, particularly when blood glucose was very high or very low. However, unlike previous studies such as that by McPhater *et al*,⁷ there was no reported wish to discontinue because of these issues.

To the authors’ knowledge, this is the first qualitative evaluation of patients’ experience of the FSLFGM. Patient involvement in the study design strengthened the methodology and the face validity of the findings. Despite attempts to make the sample as heterogeneous as possible, only three men were recruited and it is recognised that a sample recruited in Northern Ireland is likely to have less ethnic diversity than others areas of the UK. Sample size was determined by saturation. As with all qualitative research, the findings of this study do not claim to be generalisable to a wider population. Cross-validation reduced bias in data interpretation but was undertaken only on seven of the 10 completed interviews. Although the telephone interviews varied in how long they took to complete, this did not seem to cause variability in the data.

This study was designed to complement the work already undertaken by the ABCD in developing a national audit tool for clinical review of patients who have recently commenced use of the FSLFGM. Medical staff will inevitably be primarily interested in assessing medical outcomes, and will use these to judge whether or not an individual is benefiting from devices such as the FSLFGM and to justify whether or not access should be continued. However, the impact on quality of life should also be considered, particularly as the use of technology is likely to become more widespread in the coming years. Clinicians are likely to be asked increasingly to make judgements about whether or not patients should be ‘allowed’ to continue to use devices and, if there are differences of opinion on such matters, disrupted patient-doctor rapport may occur. Moreover, undertaking assessments from a patient point of view underlines the importance of involving patients in their treatment and care to effectively manage their condition and maximise well-being.¹⁰ In this way, the authors suggest that the pro-forma can be used in routine clinics to facilitate discussion about using the device and to support decision-making about continued prescription.

With these issues in mind, along with the time constraints inherent in routine clinical practice, a pro-forma was designed



Key messages

- Participants felt very positively towards the Libre FGM and reported it was beneficial to their quality of life and their self-management behaviours
- Participants reported an indirect benefit to carers and loved ones
- When considering whether someone should be continued to be prescribed a Libre FGM, it is important that patient reported outcomes are considered along with clinical outcomes

to capture information that can be used to justify continued prescription as currently no NICE guidelines exist for this purpose. While one consultant endocrinologist noted its usefulness alongside medical markers such as HbA_{1c} and frequency of hypoglycaemia, it provides diabetes professionals with a quick and efficient means to gather patient-reported outcome.

Conflict of interest None.

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Appendix 1. Topic Guide

Topic guide: Telephone interview to evaluate the Freestyle Libre

Brief introduction

Reminder about the purpose of the telephone call – to evaluate the FreeStyle Libre Flash Monitor.

Introduce self, training and position on the specialist diabetes team. Two-fold purpose of the interview explained: Evaluating the device for the hospital team, but also be written-up for submission to Queen's University Belfast.

The interviews and their transcription will be stored in the patient's medical file, in the diabetes clinic. Your name or any other identifiable information will not appear in the write-up of the feedback. Information will only be accessible to the diabetes team and the trainee clinical psychologist. Introduce interview: eg, please provide as much detail as possible in response to the questions, the interview will take approximately **15 minutes**. The interview will be recorded, and if you are still happy to proceed, I will begin recording.

If Yes: Begin recording.

General information

- Name
- DoB
- Gender
- How long have you had diabetes?
- How long have you been using the Libre device? (Self-fund?)

Expectations

- How did you first hear about Libre and what was it that attracted you to the idea of using it?
- What did you hope Libre would help you with?

Using Libre

- In what ways have you found the Libre device to be helpful?
- Are there any things you don't like about using Libre?
- Has Libre met your expectations?
- How have you been doing things differently since using the Libre (re diabetes self-management and daily life)?
- What impact has it had on your HbA_{1c}? If so, how? If none, why not?
- What do your family (or partner) think about Libre?
- If you were to advise a friend/family member on starting Libre, what would your advice be?
- Do you plan to continue using it?
- Any other concerns or comments?

End of interview: Ensure patient has author's contact information. Reiterate ability to contact should they have any more questions or should they decide they no longer want to participate.

Appendix 2. Assessment Pro-forma



Pro-forma for reviewing adults using the FreeStyle Libre Flash Glucose Monitor (FSL)

Patient Name: _____

Date of Birth: _____

H&C Number: _____

- | | | |
|-----|---|--------|
| 1. | Since using Libre, have you been checking your glucose more frequently? | YES/NO |
| 2. | Has Libre helped you to be more aware of when your glucose is high or low? | YES/NO |
| 3. | Have you felt more motivated to self-manage your diabetes? | YES/NO |
| 4. | Have you felt more confident about adjusting insulin doses? | YES/NO |
| 5. | Have you noticed improved physical wellbeing? | YES/NO |
| 6. | Have you noticed improved psychological wellbeing? | YES/NO |
| 7. | Have you felt more able to do things you were once anxious about? | YES/NO |
| 8. | Has the FSL benefitted your relationships with others? | YES/NO |
| 9. | Has it reduced worry of close family/significant others? | YES/NO |
| 10. | Please indicate on the scale below to what degree you prefer either the FSL or finger-prick testing, or whether you have no preference. | |

-5 -4 -3 -2 -1 0 1 2 3 4 5
Prefer finger-prick No preference Prefer FSL