# Review of glycaemic control, nutritional status and lung function after initiation of flash glucose monitoring for patients with cystic fibrosis related diabetes

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**Background** ~200 patients with cystic fibrosis (CF) are under the care of St Bartholomew's Hospital (SBH). Of these, 69 are on treatment for cystic fibrosis related diabetes (CFRD). CFRD occurs in people with CF due to inflammation and scarring of the pancreas preventing the effective production of insulin. National arrangements for funding for Flash Glucose Monitoring devices (the freestyle libre) changed from the 1st of April 2019 for patients with CFRD. As a result of this change in funding, devices were offered to all patients with CFRD at SBH when they attended clinic or as an inpatient. The availability of flash monitoring to patients with CFRD marks a significant change in the management of their diabetes and the purpose of this service evaluation was to explore the impact of this on health outcomes and patient experience.

Null hypothesis: There is no significant difference in HbA1c, BMI, FEV1 and quality of life 6 months post initiation of flash glucose monitoring in patients with CFRD.

Exclusion criteria: - Patient not consented to use of device - inconsistent use of device - use of device for <6 months - pregnancy/transplant/steroid adjustment/change from insulin pens to pump therapy during the 6 month study period.

## Methods

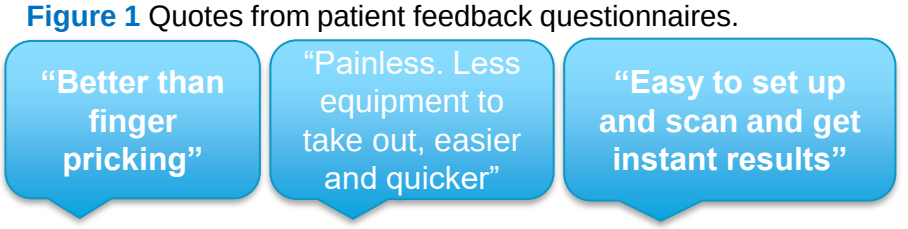
All patients with CFRD at SBH were offered flash glucose monitoring devices from 1st April. Data was collected pre and 6 months post commencement of freestyle libre use; including BMI, HbA1c, FEV1 (lung function) and insulin doses, as part of routine care. Data was analysed using a paired T-test and a p value of <0.05 taken to indicate statistical significance.

Qualitative feedback questionnaires were sent out to the patients included in the data analysis. A pre-paid envelope was enclosed and patients were requested to send responses back with a 2 week deadline. This feedback was used to support the quantitative findings.

**Table 1:** Data (with associated P value) pre and post use of libre.

| | Pre freestyle libre | 6 months post freestyle libre use | P value |
|---|---|---|---|
| HbA1c (mmol/mol) | 62 | 54 | 0.03 |
| BMI (kg/m2) | 21.5 | 21.75 | 0.45 |
| FEV1 (ml) | 1733 | 1784 | 0.55 |
| Bolus insulin (units/day) | 16 | 24 | 0.09 |
| Background insulin (units/day) | 12 | 14 | 0.22 |

**Figure 1** Quotes from patient feedback questionnaires.




## Results

Of ~35 patients who trialled the freestyle libre in the time frame, only 18 met the inclusion criteria and had a complete data set for analysis. Results showed there was a significant reduction in HbA1c. However there was no significant difference in BMI, lung function and total insulin doses (bolus or background) (see Table 1). Due to the significant difference in HbA1c, the null hypothesis cannot be fully rejected. Feedback questionnaires were returned with a 50% response rate. Overall, very positive feedback was received (see Figure 1).

## Discussion

The significant improvement in HbA1c may be explained by ease of scanning giving patients more confidence to increase their insulin doses. However, the increase in insulin doses was not found to be significant. Mixed responses were received from patients around this. It is evident that patients felt they tested their blood glucose levels more frequently with the libre, but how this leads to an improvement in HbA1c in the absence of increasing insulin doses is not clear. The data from this service evaluation demonstrate an association between freestyle libre use and improvement in HbA1c, but it does not prove a causal relationship. The time of the service evaluation coincided with the user of Symkevi and this is a confounding factor.

## Conclusion

Limited conclusions can be drawn mainly due to the limited sample size and time frame. Despite this, it is clear that use of flash glucose monitoring does improve HbA1c (and likely overall glycaemic control). This is in line with anecdotal observations. The mechanism of this improvement in HbA1c is unclear. Use of the device did not seem to have statistically significant benefits on the other parameters measured. Weight and lung function did increase when comparing pre and post data, but these increases were not significant. Despite the lack of statistically significant improvements in clinical outcomes, very positive feedback on the device was received and the vast majority of patients felt that the device improved their diabetes management, through more frequent testing, and would recommend the device to someone else. It would be useful to repeat the service evaluation, increasing the time frame of data collection, and recruiting a larger number of participants. Statistically significant improvements in HbA1c and the perceived benefits on diabetes management for patients support the continued use of the freestyle libre for those patients that consent.