HTW GUIDANCE

Technoleg Iechyd Cymru
Health Technology Wales

FreeStyle Libre flash glucose monitoring for the management of type 1 or type 2 diabetes

Guidance Number:	FIELD: Diabetes
004 (November 2018)	TYPE: Diagnositc

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HEALTH TECHNOLOGY WALES (HTW) GUIDANCE 004 (November 2018)

FreeStyle Libre flash glucose monitoring for the management of type 1 or type 2 diabetes

Figure 1. Image of FreeStyle Libre sensor and reader (provided by Abbott Diabetes Care)

HTW guidance: Freestyle Libre shows promise for detecting and guiding the correction of hypoglycaemia in patients requiring multiple daily insulin dosing for Type 1 and Type 2 diabetes mellitus. The current evidence, however, does not support routine adoption. The use of Freestyle Libre may be considered as an alternative to finger-prick self-monitoring of blood glucose in clinical circumstances where multiple testing (eight or more times per day) is required.

The status of HTW guidance is that NHS Wales should adopt this guidance or justify why it has not been followed. HTW will evaluate the impact of its guidance.

Appraisal Panel considerations

- The panel concluded that the evidence shows that the use of Freestyle Libre is able to detect and guide the correction of biochemical hypoglycaemia in patients with Type 1 and Type 2 diabetes mellitus who require multiple daily dosing of subcutaneous insulin. There is uncertainty, however, about the extent to which this may or may not be translated into a reduction in clinically important hypoglycaemic events or improvements in diabetic control.
- Given the uncertainty about clinical benefits, the committee concluded that the cost-effectiveness of the routine adoption of Freestyle Libre would be difficult to determine with an acceptable level of confidence. Nonetheless, the panel were convinced that potential cost benefits of the use of Freestyle Libre are likely to be driven by the avoidance of multiple skin-prick testing of blood glucose as a means of self-monitoring in diabetes. In this regard, the panel noted that cost modelling indicates that if patients require skin-prick testing of blood glucose eight or more times per day, then the use of Freestyle Libre may be cost saving overall. A clinical expert explained that this circumstance is likely to be relevant to only the minority of patients (approximately 10%) with insulin-requiring Type 1 and Type 2 diabetes in Wales.
- The panel noted the potential benefits that the use of Freestyle Libre may offer patients in regard to the management and self-monitoring of their diabetes. The panel would encourage the prospective and methodical collection of local data that may provide useful additional information to inform future assessments of the cost-effectiveness of the routine adoption of Freestyle Libre in Wales.
- The panel noted a number of ongoing clinical trials, the results of which may provide important additional evidence on which to judge the clinical and cost effectiveness of the routine adoption of Freestyle Libre. The panel propose that the case for adoption of Freestyle Libre by NHS Wales should be reviewed by HTW if pivotal new evidence becomes available in the future. In the meantime, the panel would recommend that the use of Freestyle Libre in Wales be accompanied by the prospective accumulation of real-world clinical data that would allow the capture of possible clinical and cost benefits as well as any impact on patient experience.

SUMMARY OF EVIDENCE APPRAISAL REPORT[1]

Why did Health Technology Wales (HTW) appraise this topic?

HTW previously facilitated publication of an Interim Statement on the prescribing of FreeStyle Libre flash glucose monitoring system for people with diabetes (October 2017). HTW has now undertaken an appraisal of the clinical and cost effectiveness of FreeStyle Libre to provide guidance on its use to NHS Wales.

Context

People with diabetes who require insulin to control their blood glucose are advised to monitor their glucose levels to avoid the potentially serious consequences of hypo- or hyperglycaemia. The current standard option for monitoring is finger-prick testing (self-monitoring of blood glucose, SMBG), which is usually carried out several times per day.

The FreeStyle Libre (Abbott Diabetes Care) flash glucose monitoring system measures interstitial fluid glucose levels using a disposable sensor applied to the skin. The sensor is designed to be worn on the upper arm and lasts for up to 14 days, after which replacement is required. Glucose levels recorded by the sensor are accessed by scanning the sensor using either a dedicated reader or via a mobile phone app, and can show trends over time as well as a 'snapshot' of the current level. Flash glucose monitoring is intended as an alternative to SMBG, but some finger-prick testing is still required.

Evidence on clinical effectiveness, safety, economic analysis and patient issues

Evidence from two European multicentre randomised controlled trials suggests that FreeStyle Libre can reduce frequency and duration of biochemical hypoglycaemia and reduce the frequency of SMBG testing in patients with Type 1 and Type 2 diabetes. There was an absence in the reporting of these studies of convincing evidence about the incidence of clinically important hypoglycaemic events, the overall control of diabetes, and the prevention of long-term complications. The trials focused on adults with poorly-controlled type 2 diabetes (requiring multiple daily injections of insulin) or well-controlled type 1 diabetes. The most commonly-reported adverse events were related to sensor adhesion site symptoms.

Patients reported greater treatment satisfaction with the FreeStyle Libre system than those patients who were treated with SMBG. A patient organisation described the impact of this technology on daily life, commenting on the pain and inconvenience of finger-prick testing, and the freedom and confidence associated with flash glucose monitoring.

Reported cost effectiveness evidence suggests that FreeStyle Libre is likely to be more effective and more costly than SMBG, with incremental cost-effectiveness ratios within normally accepted thresholds. Budget impact modelling suggests that FreeStyle Libre would result in increased costs. Results are highly sensitive to the number of SMBG tests replaced by flash glucose monitoring. The evidence suggests that FreeStyle Libre is likely to be cost-saving compared to SMBG in patients who currently conduct a high frequency of finger-prick tests. Threshold analysis shows that FreeStyle Libre can be expected to be cost saving for patients who undertake eight or more SMBG tests a day.

[1]Summary of Evidence Appraisal Report intended for use by decision-makers in NHS Wales.

Organisational issues

FreeStyle Libre is intended as a replacement for SMBG, and would fit within current diabetes care pathways. Those new to this technology (both healthcare professionals and patients) need support when learning how to use FreeStyle Libre and how to interpret readings.

Further research

Generation of further randomised controlled trial evidence is recommended to assess the effectiveness of FreeStyle Libre in influencing the incidence of clinically important hypoglycaemic attacks and in improving overall glycaemic control in patients with diabetes. Further evidence is also needed to understand whether Freestyle Libre could be used as an alternative to SMBG in children or adolescents with diabetes, and in adults with diabetes who have poorly-controlled glucose levels. Of particular interest is the resource impact of hypoglycaemic and hyperglycaemic events in Wales, and the long-term consequences of poor glucose control.

Responsibilities for consideration of this Guidance

Health Technology Wales (HTW) was established by Ministerial recommendation[1,2] to support a strategic, national approach to the identification, appraisal and adoption of non-medicine health technologies into health and care settings. The HTW Appraisal Panel comprises senior representation from all Welsh boards with delegated authority to produce guidance 'from NHS Wales, for NHS Wales'. The status of HTW guidance is 'adopt or justify'. There is an expectation from Welsh Government that HTW guidance is implemented with adoption regularly audited by HTW.[3]

The guidance in this document is intended to assist Welsh care system decision makers to make evidence-informed decisions when determining the place of health technologies and thereby improve the quality of care services.

The content of this HTW guidance was based upon the evidence and factors available at the time of publication. An international evidence base was reviewed and external topic experts and HTW committee members consulted to contextualise available evidence to Wales. Readers are asked to consider the generalisability of the evidence reviewed to NHS Wales and that new trials and technologies may have emerged since first publication and the evidence presented may no longer be current. It is acknowledged that evidence constitutes only one of the sources needed for decision making and planning.

This guidance does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgment in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

No part of this guidance may be used without the whole of the guidance being quoted in full. This guidance represents the view of HTW at the date noted. HTW guidance is not routinely updated. It may, however, be considered for review if requested by stakeholders, based upon the availability of new published evidence which is likely to materially change the guidance given.

Standard operating procedures outlining HTWs evidence review methods and framework for producing its guidance are available from the HTW website.

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Declarations of interest were sought from all reviewers. All contributions from reviewers were considered by HTWs Assessment Group. However, reviewers had no role in authorship or editorial control and the views expressed are those of Health Technology Wales.

Chair, Health Technology Wales Appraisal Panel

1. National Assembly for Wales, Health and Social Care Committee. Access to medical technologies in Wales. December 2014.
2. Response to Recommendations from the Health & Social Care Committee: Inquiry into Access to Medical Technologies in Wales. February 2015.
3. Gethin, V. Letter to all Health Board Chairs re Funding for Sacral Nerve Stimulation in Wales. VG_01655_17. September 2017.