Freestyle Libre Flash Glucose Self-Monitoring System: A Single Technology Assessment

- Feedback from The Norwegian Diabetes Association

The Norwegian Diabetes Association is grateful for the opportunity to give our feedback to the assessment of Freestyle Libre Flash Glucose Self-Monitoring System.

We are an interest organization for people with diabetes, their families and health care professionals. We are in daily contact with patients and their families through diabetes “hot line” and social media. The organization also have an extended network of health professionals, and an advisory board consisting of leading diabetes expertise in Norway.

1. Diabetes and self management

Diabetes – both type 1 and type 2 – demands a very high level of self-management, probably more than any other disease. Diabetes affects the patient’s life continuously – and vice versa. Multiple factors has an influence, and the patient has to monitor the blood glucose level several times a day, to try and keep it stable enough to avoid hypo- or hyperglycemias and low enough to prevent a raised HbA1c-level. For most persons with diabetes this can be a very challenging task, regardless of the duration of the disease. According to the two diabetes registries in Norway, the majority of people with type 1 fail to reach their treatment targets.

1.2 Freestyle Libre (FGM)

People with diabetes are dependent on different medical devices and technological solutions for their self-management. Based on clinical and user experience we see that Flash Glucose Monitoring (FGM) has several fundamental advantages compared with SMBG:

- The FGM-sensor is more or less painlessly attached once every fortnight.
- The threshold for measuring the blood glucose during the day is much lower, when you do not have to get blood out of your already perforated fingertip. This reduces both the amount of pain and blood spill.
- Reducing pain also reduces the conflict level in families with children who have diabetes.
- Use of FGM makes cooperation with schools and kindergarten easier.
The FGM-reader gives various reports – i.e. giving the patient information about the crucially important movements and trends in the blood glucose level. This makes it a lot easier to find the correct insulin doses and/or amount of carbohydrates.

FGM provides easy access to both the glucose level, the last eight hours of regulation and the trend arrows indicating whether the level is rising, falling, rising fast, falling fast or is stable. For the user this enhances the important experience of coping with the blood glucose challenges, which is a major psychological aspect.

2. Comments on the HTA methodology

The HTA methodology used in this assessment excludes other sources of knowledge than RCTs. This weakens the foundation of decision making. We strongly recommend including elements from knowledge based practice, where decisions are based on systematically obtained research based knowledge, experience based knowledge and patient’s knowledge and needs. This approach will improve the decision-making basis and quality of the assessment.

The recently published guidelines for diabetes in Norway (2016) are founded on such knowledge based practice. Research, clinical experience and user experience are assessed collectively against desirable and undesirable consequences of suggested recommendations. In this process, decisions on topics where little or no research based knowledge was found, clinical knowledge and user experience were taken into account.

Technology such as FreeStyle Libre should be evaluated in a different way than pharmacotherapy, because of the fundamental differences, for instance the importance of user interface and satisfaction. Therefore, we will argue that single arm studies and real world data should be included in the evaluation to give a more complete picture. When a new pharmacotherapy is introduced, it may be used for 10–15 years, but a glucose monitoring device (CGM/FGM) is outdated approximately two years after introduction.

2.1 The French HTA (12 July 2016)

French National Committee for Evaluation of Medical Equipment and Health Technology concluded:

Freestyle Libre is considered to be adequate considering its diagnostic value and public health value, as well as reduction in severity in type 1 and type 2 complications. Due to the expected reduction of long-term complications in diabetes and cases of severe hypoglycaemia and the severity of the disease, the French committee assess that Freestyle Libre has a value for public health.

We must emphasize that the french HTA includes a wider range of studies and dialogue with both users and clinical experts.

3. Comments to the assessment of clinical effectiveness and safety

Randomized controlled studies have its strength in a homogenous group of people being randomized to either intervention or control. First of all the study population is different from the general

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1 Attachement 1. List of relevant published clinical trials, manuscripts and abstracts
population and is mostly uniform as well as compliant. The RCT may therefore provide data more on the efficacy of the intervention than the effectiveness itself.

The assessment is based on two RCTs, one regarding diabetes type 1 and the other regarding type 2. These are two different diseases, hence pooling the two study populations is like comparing apples and pears. This can explain the heterogeneities. Furthermore, the study population differ from the Norwegian diabetes population in regard to the average HbA1c, which in Norway is 8,0 % for both children and adults with type 2.

The QoL-assessment in the two studies do not cover important factors for the patient in using Freestyle Libre, like fundamental psychological aspects such as motivation and coping. For many families with children having diabetes, using FreeStyle Libre provides an increased sense of security. Furthermore, for many adolescents managing diabetes can be difficult in social settings, and the use of FGM can make measuring glucose easier and more discreet.

It could be anticipated that the provision of comprehensive glucose data for up to 14 days, from a system that is easy to use, with reduced pain and burden for the user where there is no requirement for finger prick calibration, could support enhanced diabetes management.

As mentioned, FGM and other methods of measuring glucose have a great impact on the patients’ self-management. Hence, the importance of user satisfaction and the views from the user must be given more weight.

4. Comments on the economic evaluation and budget impact analysis

It is unclear how the negative effects of hypoglycemia are incorporated into the cost-effectiveness analysis. Time spent in hypoglycemia is an important outcome, and in itself associated with micro- and macro cardiovascular endpoints.

The budget impact analysis is based on two scenarios; (1) cost related to adoption of FreeStyle Libre (2) cost without adoption of FreeStyle Libre, with the assumption of a 100 % adoption to Freestyle Libre in scenario (2). This is, in our opinion, a wrong assumption and does not take into account the use of continuous blood glucose monitors (CGM). Data from Sweden show that after adopting Freestyle Libre, 45 percent of children with type 1 diabetes use FGM while 45 percent use CGM. In adults with type 1 diabetes, the number was 30 percent CGM and 40 percent FGM. When considering the whole “tool box” in diabetes management, it is plausible that a number of patients will prefer FGM to CGM. In Sweden the cost of one CGM sensor is triple the cost of a FGM sensor.

5. Concluding remarks

The FreeStyle Libre system is user friendly, leads to a better and more precise self management for a lot of users – and is a natural part of the tool box available for persons with a disease where there is no phase response, but on the other hand individual considerations from person to person, from day to day.

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2 The Norwegian Childhood Diabetes Registry
The Norwegian Registry for Diabetes in Adults
Frier et al. *Hypoglycemia and Cardiovascular Risks*. Diabetes Care 2011;34:S131-7
For children with diabetes (and their parents) FGM is a much easier and less painful way of staying in control and live active lives like their friends do.

The Norwegian Diabetes Association is critical to the lack of relevant studies included in this assessment. Moreover, it is our strong opinion that this assessments methodological framework does not cover all necessary aspects of medical devices for measuring glucose.

The assessment is based on narrow and inadequate knowledge, lacking both the clinical and user perspective.

Basing the assessment on only two RCTs excludes other studies, which can give a broader view and a better decision foundation. These studies show a general view of Libre reducing HbA1c and where the self-estimated ability to achieve satisfactory glucose control is improved. The self-estimated treatment satisfaction is highly improved for both children and adults.

Commissioner Forum RHA (Bestillerforum) emphasized in their meeting June 13 2016 that there was a need for a HTA on Freestyle Libre to assess:

- Precision and accuracy
- Does the system need calibration
- The practical benefits for the patient in daily use
- What can this system can perform in the real world

In our opinion, these aspects are not addressed fully in this HTA.