

How Have Health Technology Assessment Bodies Interpreted the Early Evidence on FreeStyle Libre™ in Type 1 and Type 2 Diabetes?

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1. Background

Health Technology Assessment (HTA) processes vary between countries. Differing objectives, methods and assessment timings mean different types of evidence (RCT, RWE, HCP/patient feedback) are considered to varying degrees. This heterogeneity coupled with additional challenges faced by medical devices (e.g. difficulty in conducting blinded studies) leads to different conclusions and recommendations between HTAs for the FreeStyle Libre™ system.¹

The FreeStyle Libre system is an interesting case to study when considering medical device HTA processes. The continuous glucose monitoring system provides an alternative to self-monitoring blood glucose (SMBG) for adults, children, and pregnant women with type 1/2 diabetes (T1DM/T2DM) requiring multiple times per day insulin injection (MDI). The clinical benefit of the FreeStyle Libre system has been demonstrated in 2 RCTs: IMPACT² (T1DM MDI) and REPLACE³ (T2DM MDI).

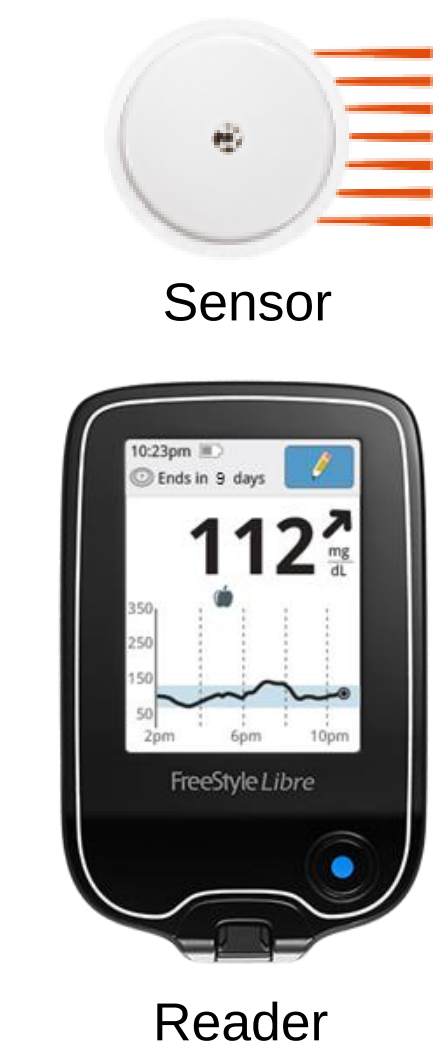
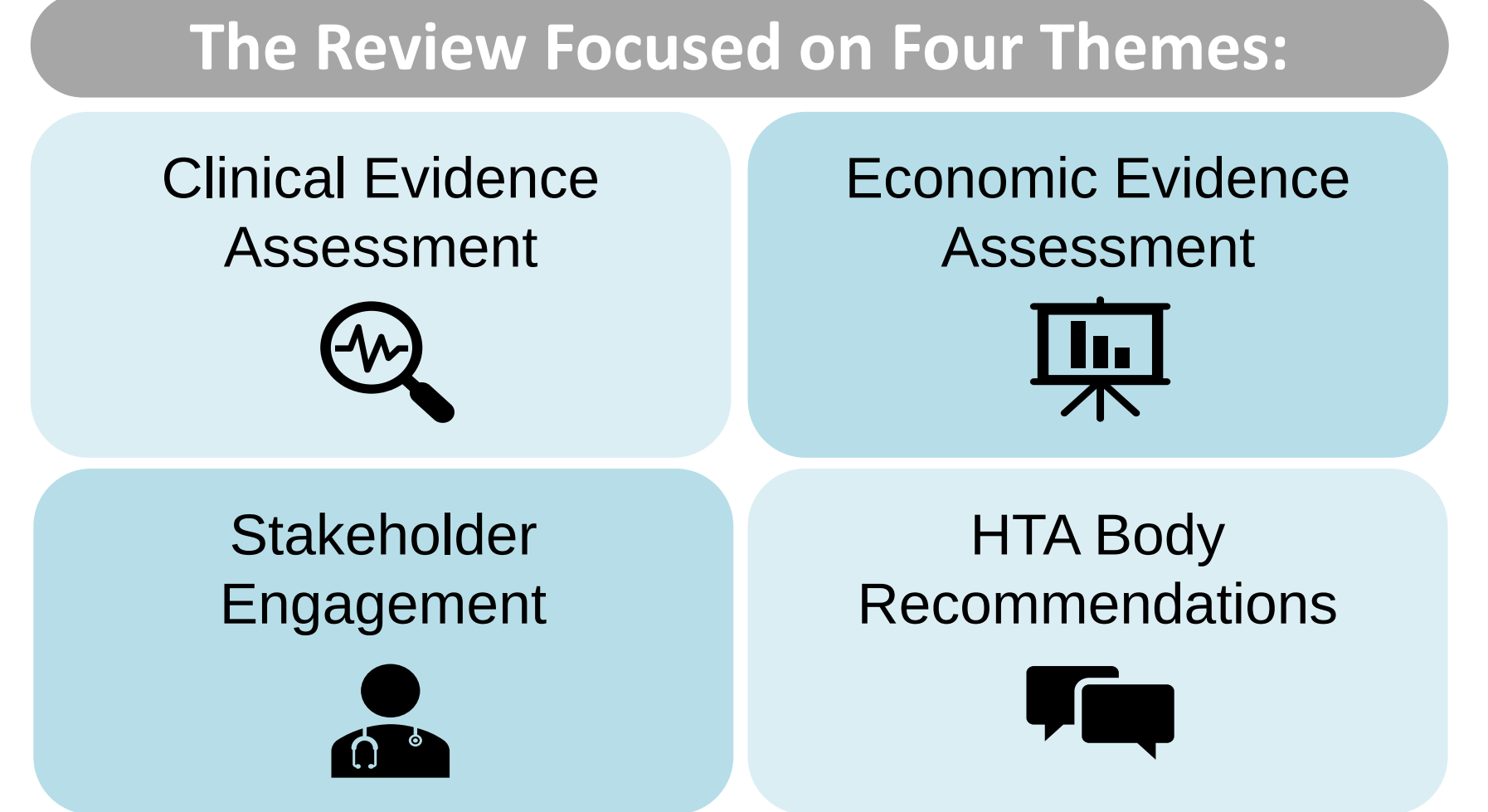


Figure 1: The FreeStyle Libre System

2. Objectives

- The primary objective of this study was to compare the methodologies and conclusions in published HTA appraisals of the FreeStyle Libre system, from market launch in September 2014 to October 2018
- A secondary objective was to further understand how medical device HTA methodologies contribute to variation in decision-making
- The study is intended to help decision-makers understand how the evidence for the FreeStyle Libre system has been assessed by different HTA bodies at different stages of evidence generation

3. Methods



- A literature search was conducted in October 2018 with the aim to identify all HTA reports on the FreeStyle Libre system published by HTA bodies since CE approval in 2014
- A manual search of 158 HTA body websites in 45 countries, where the FreeStyle Libre system held market authorization, was undertaken in addition to searches in the Centre for Reviews and Dissemination
- Where appropriate, the results obtained were supplemented with local knowledge e.g. in the absence of methodology details in the final HTA report

5. Discussion and Conclusions

This study has demonstrated the presence of heterogeneity in the assessment methodologies of different HTA bodies. Regardless of this, most HTA bodies concluded that compared to SMBG, the FreeStyle Libre system offers clinical and economic benefits including better self-monitoring, reduced time in hypoglycemia, and improved QoL.⁴

Similarities

- Reporting of RCT results
- Expression of uncertainties

Differences

- Quality assessment methods, early evidence consideration & stakeholder feedback
- Such differences may relate to delays in availability of innovation for patients and clinicians

4. Results

A total of 17 HTA reports were included in this analysis from European (n = 14) and North American (n = 3) HTA bodies. Figure 2 demonstrates the publication timelines of the HTA reports with key details from each report shown below in Table 1.

Figure 2: Health Technology Assessment Reports, Conclusions and Pivotal Manuscripts of the FreeStyle Libre System

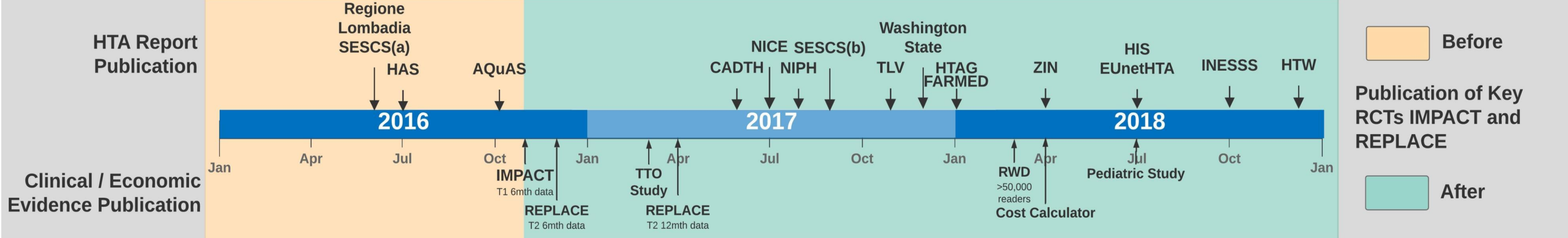


Table 1: Overview of Included Health Technology Assessment Reports

Agency	Country / Region	The FreeStyle Libre System Only	Population	Clinical Evidence	Economic Evidence	HCP/Patient Involvement	Reimbursement Recommendation
AQUAS	Spain / Regional	✓	T1/T2 Adult & Child	✓	✓	NR / Yes	No – out of scope
HAS	France / National	✓	T1/T2 Adult & Child	✓	✗	Yes / Yes	Yes
SESCS(a)	Spain / Regional	✓	T1/T2 Adult & Child	✓	✓	Yes / Yes	Yes
SESCS(b)	Spain / Regional	✓	T1/T2 Adult & Child	✓	✓	Yes / Yes	Yes
CADTH	Canada / National	✓	T1/T2 Adult & Child	✓	✓	NR / NR	No – out of scope
HTAG	Ireland / National	✓	T1/T2 Adult & Child	✓	✓	Yes / NR	Yes
NICE	England / National	✓	T1/T2 Adult & Child	✓	✗	Yes / Yes	No – out of scope
NIPH	Norway / National	✓	T1/T2 Adult & Child	✓	✓	Yes / Yes	No – out of scope
Regione Lombardia	Italy / Regional	✓	T1/T2	✓	✗	Yes / Yes	Yes
TLV	Sweden / National	✓	T1/T2 Adult & Child	✓	✓	NR / NR	No – out of scope
Washington State	USA / Regional	✗	T1/T2 Adult & Child	✓	✓	NR / NR	No – out of scope
EUnetHTA	NA / Pan-European	✗	T1/T2 Adult & Child	✓	✗	Yes / Yes	No – out of scope
HIS	Scotland / National	✓	T1/T2 Adult & Child	✓	✓	Yes / Yes	Yes
INESSS	Canada / Regional	✓	T1/T2 Adult	✓	✓	Yes / Yes	Yes
INFARMED	Portugal / National	✗	T1/T2 Adult & Child	✓	✓	NR / NR	Yes
HTW	Wales / National	✗	T1/T2 Adult & Child	✓	✓	Yes / Yes	Yes
ZIN	Netherlands/National	✓	T1/T2 Adult & Child	✓	✗	Yes / Yes	Yes

Abbreviations = AQUAS: Agència del Qualitat i Avaluació Sanitàries de Catalunya; CADTH: Canadian Agency for Drug and Technologies in Health; EUnetHTA: European Network of Health Technology Appraisal; HAS: Haute Autorité de Santé; HIS: Health Improvement Scotland; HTAG: Health Technology Assessment Group; HTW: Health Technology Wales; INESSS: Institut National d'Excellence en Santé et en Services; INFARMED: Autoridade Nacional do Medicamento e Produtos de Saúde; NICE: National Institute for Health and Care Excellence; NIPH: Norwegian Institute of Public Health; SESCO: Servicio de Evaluación y Planificación, Canarias; T1/T2: Type 1/2; TLV: Tandvårds-och Läkemedelsförhållanden; Washington State: Washington State Health Care Authority; ZIN: Zorginstituut Nederland.

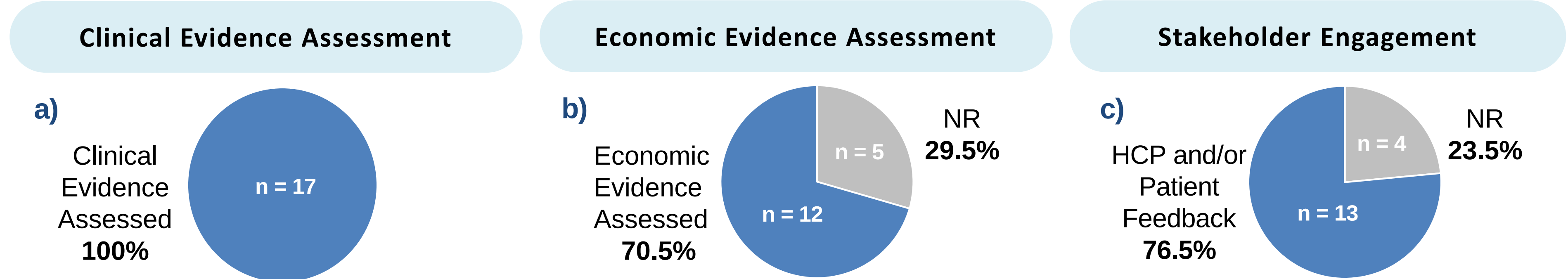
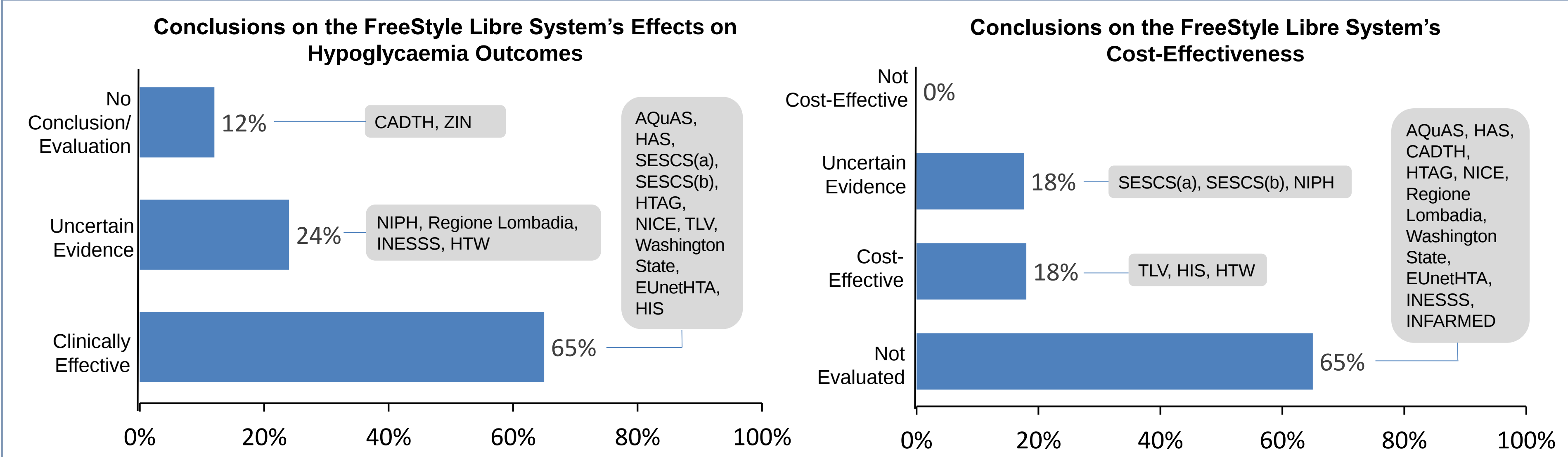


Figure 3: Percentage of HTA Reports Evaluating a) Clinical Evidence b) Economic Evidence c) Stakeholder Engagement

- The majority of reports concluded the FreeStyle Libre system is more effective at reducing time in hypoglycemia (Figure 4) and improving patient satisfaction versus SMBG
- Economic analyses returned mixed results with some HTA bodies concluding it cost-effective and/or cost-saving, whilst others suggested populations in which the FreeStyle Libre system would be cost saving/effective (e.g. patients with high test frequencies)
- Feedback was consistently positive across all HTAs, consultation approaches varied (focus groups, comment invitation, letter submission)
- Benefits reported include convenience, greater flexibility in managing diabetes, and being a 'life-changing device'

Figure 4: Health Technology Assessment Reports Conclusions and Recommendations



6. References

- Rothery C, Claxton K, Palmer S, Epstein D, Tarricone R, et al. (2017) Characterising uncertainty in the assessment of medical devices and determining future research needs. J Health Econ 26: 109-123.
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Abbreviations = DM: Diabetes Mellitus; HCP: Healthcare Professional; HTA: Health Technology Assessment; MDI: Multi Daily Insulin Therapy; Mth: Month; NR: Not Reported; RCT: Randomised Controlled Trial; QoL: Quality of Life; RWE: Real World Evidence; SMBG: Self-Monitoring Blood Glucose; T1/T2: Type 1/2

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