A Budget Impact Model Assessing Continuous Glucose Monitoring Devices in Type 2 Diabetes Mellitus in Sweden

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INTRODUCTION

- Type 2 diabetes mellitus (T2DM) is a chronic disease that occurs when the body can no longer use insulin properly due to insulin resistance and deficiency.[1] T2DM accounts for more than 90% of diabetes cases.[2]
- Timely glucose monitoring is essential for patients on insulin-treated T2DM to prevent hypoglycaemic events, hyperglycaemic events, and severe complications like diabetic ketoacidosis.[3]
- Real-time continuous glucose monitoring (rtCGM) devices provide real-time glucose values, while the intermittent-scanning glucose monitoring (isCGM) devices require users to manually check their current glucose level with a smart phone or connected device. Both rtCGM and isCGM serve as alternatives to traditional self-monitoring of blood glucose (SMBG) due to their additional features like glucose alarms and information sharing with relatives or healthcare providers.

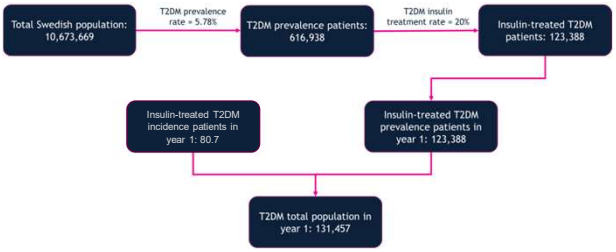
OBJECTIVES

- The objective of this study is to assess the budget impact of replacing SMBG and isCGM devices with rtCGM devices in T2DM, from a Swedish healthcare perspective.

METHODS

- A budget impact model (BIM) with a 5-year time horizon was developed to compare the costs associated with rtCGM devices versus isCGM devices and traditional SMBG.
- The model population was determined using data on the prevalence, annual incidence, and treatment rate for insulin-treated T2DM in Sweden.[4-6] A total of 131,457 insulin-treated T2DM patients entered the model in year one (Figure 1).
- Cost categories included device acquisition, drug acquisition, resource use, adverse events (AEs) and diabetes complications. Cost inputs were based on Swedish sources.[7-10] All costs used are in 2024 price in SEK. Costs were converted from original sources after applying the Krona inflation rate and exchange rate, if needed.
- The incidence of AEs was derived from the devices' pivotal trials.[3,6] The incidence of complications was based on risk equations identified from Base et. al., 2018[11], where patient characteristics were assumed equal for rtCGM devices, isCGM devices, and SMBG, except for glycosylated haemoglobin (HbA1c) levels, which were informed by an indirect treatment comparison (ITC).
  - The clinical efficacy of rtCGMs devices versus isCGM devices was evaluated via ITC by assessing the HbA1c level, measured as a percentage. The ITC utilized two RCTs: the DIAMOND trial[3], which compared the rtCGM device against SMBG, and the REPLACE trial[6], which compared the isCGM device against SMBG. Both trials reported HbA1c outcomes at 24 weeks. It was assumed that the rtCGM suite of devices exhibit equivalent clinical efficacy, while the isCGM suite of devices demonstrate equivalent clinical efficacy. In addition, it was assumed that the HbA1c levels of patients who use rtCGM devices and isCGM devices start at the same baseline, with outcomes at the end of the study (24 weeks) differing by the amount observed by the ITC.
  - Based on the ITC, the adjusted difference in HbA1c level is -0.43% (95% CI: -0.80,-0.06), favouring rtCGM devices compared to isCGM devices at the end of the study.

Figure 1. Patient funnel



Abbreviations: T2DM, Type 2 Diabetes Mellitus

RESULTS

- The total budget impact by device for insulin-treated T2DM population in Sweden is presented in Figure 2.
- In a market with rtCGM devices, the total expenditure for insulin-treated T2DM over five years is projected to be around 18.49 billion SEK while in the market without rtCGM devices, the total expenditure is expected to be approximately 18.34 billion SEK.
- The introduction of rtCGM devices will lead to a cost saving of 149.836.443 SEK over five years for the insulin-treated T2DM population.

LIMITATIONS

- The epidemiological inputs and market shares are speculative which introduce uncertainties into the outcomes of the budget impact analysis.
- The current BIM is based on a time horizon and sustained HbA1c treatment effect of up to five years. It is unclear whether the relative HbA1c treatment effect associated with rtCGM devices will persist for the entirety of this period, or even beyond. If this is not the case, the cost related to complications could be overestimated.

CONCLUSIONS

- Despite the higher acquisition costs, the introduction of rtCGM devices for insulin-treated T2DM is expected to result in overall cost savings over a five-year time horizon, from a Swedish payer perspective.
- The increased device acquisition costs, due to rtCGM's higher unit price and higher replacement frequency, are offset by the reductions in resource use costs, complication costs, and AE costs.
- It is expected that per-patient cost offsets will increase over time. To fully assess the potential impact of the HbA1c difference, a comprehensive cost-utility analysis over patients' lifetime is needed.

Figure 2. Total Yearly Budget Impact by Device

	2024	2025	2026	2027	2028
Budget impact	-SEK 21.995.643	-SEK 31.516.910	-SEK 34.134.545	-SEK 32.862.765	-SEK 29.326.579
DEXCOM	SEK 815.502.876	SEK 1.276.593.404	SEK 1.642.529.068	SEK 1.936.953.355	SEK 2.196.310.703
FSL2	-SEK 101.098.389	-SEK 196.779.392	-SEK 304.513.004	-SEK 418.187.250	-SEK 537.616.103
SMBG	-SEK 736.400.130	-SEK 1.111.330.921	-SEK 1.372.150.609	-SEK 1.551.628.869	-SEK 1.688.021.179

Note - negative Budget impact values indicate savings
Abbreviations: isCGM, Intermittent-Scanning Glucose Monitoring; rtCGM, Real-time Continuous Glucose Monitoring; SMBG, Self-monitoring of Blood Glucose

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