Health value assessment of *Dexcom* Continuous Glucose Monitoring devices for patients with type 1 diabetes

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Abstract

The goal of this paper is to analyze the impact of the Dexcom G6 continuous glucose monitoring device in diabetes patients. This analysis will be conducted across several dimensions, beginning with an overview of the conventional measuring methods, their limitations and the physiopathology of the disease, and the clinical benefits of this intervention.

The current state and limitations of health value measurement methodologies will be explored in their capability to assess value of devices such as the Dexcom, and the bureaucratic and governmental/economic aspects will be explored too.

The Dexcom proves to be not only beneficial to individual patients but to the overall healthcare systems, reducing complications and costs. As this disease grows rampant in our society, new methods such as QALY-based cost effectiveness analyses and multi-criteria decision making, despite being useful, have observable limitations. Novel approaches based on broader, more humane, criteria such equity, hope and insurance value will be explored.

Assessing new technologies' impact on diabetes management is crucial for sustainable healthcare systems resource allocations, and by addressing the current limitations and improving our metrics we can improve patient outcomes and efficiency of care.

Keywords: CGM, Diabetes, Dexcom, Health Value Assessment, Monitoring Devices.

1. Introduction

Diabetes Mellitus (DM) is a chronic disease, defined by elevated levels of glucose in the blood (hyperglycemia). It is increasingly prevalent in our society, with its prevalence escalating significantly with age, affecting both sexes and all age groups.

Individuals with diabetes may develop a range of complications. However, the damage can be mitigated through rigorous control of hyperglycemia. Controlled diabetes requires maintaining blood sugar levels within certain limits, which depend on various factors (age, lifestyle, activity level, presence of other diseases) which determine the target blood glucose values for fasting and postprandial periods in individuals. The most common method to ascertain whether a person with diabetes has the disease under control is through daily and multiple times a day capillary blood glucose testing before and after meals.

In 2021, the estimated prevalence of diabetes in the Portuguese population aged 20 to 79 was 14.1%. There is also a notable increase in diabetes prevalence with age, with over a quarter of individuals aged

60-79 having diabetes. This condition continues to play a significant role in mortality, accounting for 3.3% of deaths in 2020. [1]

Broadening to the world prevalence, it is estimated that 1 in 10 adults suffer from diabetes, this number duplicates for individuals over 65. By 2030, this number is projected to increase to 1 in 9 adults. This high incidence was responsible for 11.5% of healthcare expenditures in 2021 and caused 6.7 million deaths in the same year.[2]

With diabetes being so prevalent and a great source of expenditure, it is crucial to employ metrics to evaluate the impact of new technologies. In a 2017 OECD report there was an estimated range of 10% to 34% of wasteful spending in health.[3] This underscores the necessity for cost-effective approaches in healthcare policy-making particularly due to resources (both economical and human), are limited.

2. State of the art

Self-monitoring of blood glucose (SMBG), involving the periodic measurement of blood sugar levels, has been a conventional method employed for managing diabetes. However, it requires invasive blood samples from fingertips, which lowers patient satisfaction and prevents them from providing frequent measurements.

The continuous glucose monitoring (CGM) devices appeared as a solution to this problem and, in the past twenty years, they proved its ability to introduce a revolutionary solution for diabetes management. In addition, the devices are significantly improved for accuracy, biocompatibility, length of usage time, data collection, metrics, alarms and features sharing, allowing an individualized and improved treatment of diabetes.

SSpecifically, the Dexcom G6 sensor is classified as a medical device of class IIb[4] (medium risk) in Portugal and it's the first real-time CGM that does not require calibration, marketed for 10-day use and approved for children > 2 years. It is the only iCGM device that can detect and predict dangerous hypoglycemic episodes 20 minutes before occurrence, warning the patients. Besides that, Dexcom G6 data is compatible with multiple mobile applications, making it easy for both patients and providers to monitor glucose levels.

Dexcom G6 has three main components:

- **Sensor (2)** inserted under skin via an auto applicator (1) and monitors glucose levels in the interstitial fluid;
- **Transmitter (2)** attached to the sensor in order to wirelessly send data to the display device to be viewed;
- **Display device (3)** which shows the glucose readings as frequently as every five minutes.

Figure 1: Components of Dexcom G6

Besides this, patients can use the receiver or a compatible smart device to view the data. They can share up to 90 days of glucose data with providers and can also receive insights on glycemic patterns. Patients also have the option to receive push notifications from the device.

3. Methods

For the purpose of our study, an early on PICO framework was established: Type 1 diabetes patients (Population); the use of Dexcom CGM system (Intervention); traditional methods of glucose monitoring, such as

fingerstick blood glucose monitoring (Comparison); glycemic control (Primary outcome) and CGM metric time above range and patients satisfaction (Secondary outcomes). This will directly impact the type of evidence that will be searched for in our literature review.

4. Results

4.1 Benefits of the Technology

4.1.1 Clinical Benefits

There are two types of diabetes – one and two. The first one is caused by a lack of insulin production while the other is related to increased insulin resistance and unresponsiveness. Insulin is an essential hormone in metabolism since it allows the intracellular transport of glucose, lowering glucose levels in the blood. [5] Hyperglycemia (excess levels of blood glucose), which in diabetic patients presents as greater than 125 mg/dL, can lead to tissue damage in the eyes, kidney, nerves, heart and vascular system. [6].

Traditionally, Diabetic patients detect postprandial (after meals) spikes in glucose using SMBG methods. This process involves individuals pricking their finger to obtain a small sample of blood for immediate testing using enzyme-enriched strips. This measuring process is rarely done more than 4 times a day [7], which results in an insufficient temporal resolution and therefore insufficient knowledge for determining glucose fluctuation patterns for daily activities. This makes it impossible to directly relate glucose variations with physical activity, rest time, medication dosing, etc [8]

The DEXCOM device is a new way of CGM using a sensor that is put on the skin that measures glucose levels in interstitial fluid (IF). Glucose is transported from the capillaries to the IF, and is then measured by the sensors which have been previously calibrated against traditional blood glucose strips. This way, there's a direct correlation between IFG levels and BG levels. [9] This device allows the user to observe real time numbers, log daily activities, shows trend arrows and graphs, gives customizable alerts and allows sharing your data with your caretakers. For example, it can warn you 20 minutes in advance that your glucose will drop under 55 md/dL so that you take preventive measures. [10]

Obtaining this information is relevant for future adjustment of treatment, or even immediate injection of insulin. Using CGM devices, users had 240x the median number of glucose measurements during a 6 months period. Studies show that glycemic excursion events became less frequent.

A meta-analysis showed that CGM devices result in a decrease of HbA1C (an indicator which shows how much glucose there has been in the sampled blood over the past few months) in patients, as well as a lowered BMI (Body-Mass Index). Patients with Dexcom devices visit the emergency department less frequently, due to increased self awareness and pattern recognition alarms that go off prior to the emergent state. [8]

4.1.2 Enhancing health literacy and education

The real-time collection of data helps patients and healthcare providers recognize and understand the patterns and fluctuations in their glucose levels, which helps them understand the impact of their lifestyle choices on their diabetes in real-time and lead to better self-management and adherence to treatment plans, potentially leading to improved glycemic control and reduced risk of complications. [11] The system has an alert function that notifies users when glucose levels fall outside of a healthy range, keeping them informed about their status and helping to manage both hyperglycemia and hypoglycemia.

The data can be shared with healthcare providers and family, facilitating better-informed clinical decisions and personalized care plans, and enabling them to educate patients more effectively on managing their diabetes and to tailor their advice based on the patient's unique glucose trends. This followup is critical for parents with children with diabetes and for elderly patients who are not capable of managing their diabetes.

[12] Additional, Dexcom provides free access to online training videos, documents and a telephone support service for users, training and educating both the users and the healthcare providers. [13]

The easing of this burden and simplification of the glucose monitoring aspect of proper diabetes management contributes to improved outcomes in this population, minimizing the guesswork derived from making diabetes treatment decisions based on a single blood glucose meter reading.

4.1.3 Broader implications for the healthcare system

So far we have focused on the advantages of Dexcom G6 for personal use when compared with standard fingerstick glucose monitoring. However, the impact of this medical device extends to a broader scale when considering its potential role in the healthcare system.

In Portugal, the Dexcom G6 it's not yet integrated into hospital settings. However, in the US, numerous studies integrated this medical device into intensive care units where CGM is essential for patients on intravenous insulin infusion, thereby potentially reducing hospital complications and length of stay. Besides that, research has also shown that CGM users tend to have fewer emergency department visits compared to those using standard monitoring, addressing a prominent issue within the current national Portuguese healthcare system. Based on this, despite the initial higher cost of the device, the Dexcom G6 has demonstrated a reduction in overall long-term healthcare costs in the US, attributed to the reduction in intensive treatments and hospital admissions due to severe hypoglycemic events.

However, the adoption of Dexcom G6 in healthcare settings may require additional training for clinicians to effectively manage the technology and support patients, therefore more studies have to be made to evaluate if these investments in training and support are justified.

Overall, the implementation of Dexcom G6 could bring significant implications for the healthcare system. Firstly, it would improve patient outcomes and therefore contribute to patient-centered feedback from the clinicals. Secondly, it would lead to reduced healthcare utilization and long-term costs. Lastly, an integration into hospital settings allied with potential future advancements would lead to better diabetes management.

4.1.4 Health Technology Assessment in the population

The European Commission defines Health Technology Assessment (HTA) as the summarization of information about medical, economic, social and ethical issues related to the use of a health technology. [14] The HTA involves multiple steps aimed at bridging research with decision-making. However, we will direct our attention to the assessing social, legal and ethical implications stage.

In Portugal, there's a regime for state reimbursement of medical devices used in diabetes management, but access to CGMs is limited to individuals with Type 1 Diabetes Mellitus (T1DM).

Also, underserved communities, including those in remote or socio-economically disadvantaged areas, face challenges in accessing advanced diabetes technologies like the Dexcom G6 so it's vital to decrease the bureaucracy for the reimbursement. This justifies the fact that low socioeconomic status is linked with higher morbidity and mortality rates among adults with T1DM.

Lastly, psychological support as part of diabetes care is available but may be challenging to access in Portugal. With this in mind, HTA processes must evolve to encompass not only clinical effectiveness but also patient-reported outcomes and mental health considerations, highlighting both progress and persistent challenges in CGM access.

4.2 Current methodologies and tools for the technology's value assessment

Several methodologies are currently used to assess the value of Dexcom's CGM device. One of these is the IQVIA CORE Diabetes Model, a simulation model that projects long-term outcomes in type 1 or 2 diabetes. [15] This model uses various parameters such as patient demographics, baseline risk factors, treatment

effects, treatment costs, mortality risk, costs of complications, costs of other medication and lab tests to estimate the direct and indirect costs of diabetes management, and adjusts for quality of life.

The Hypoglycemia Fear Survey (HFS), a diabetes-specific Quality of Life (QoL) Patient-Reported Outcome Measures (PROMs), and its adjusted version, the HFS-II, measures behaviors and worries related to the fear of hypoglycemia (FoH) in people with type 1 diabetes. The responses are made on a 5-point Likert scale, from 0 (never) to 4 (always). [16] The values obtained by this survey are then converted to a utility value in the EQ-5D [15], a generic and standardized measure of health-related quality of life that assesses health status in terms of five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, according to a Time-Trade off. Each domain has a single question which has 5 severity levels. [**proms**]

The utility scores derived from the EQ-5D are used to calculate Quality Adjusted Life Years (QALYs), a measure that takes into account both the quantity and quality of life generated by healthcare interventions and is therefore a useful measure of the value for money that a health technology can provide. [17]

4.3 Decision Making and Economic evaluation of the technology

4.3.1 QALY-based cost-effectiveness analysis (CEA)

A common approach is to convert health gains into duration of life, modified by its quality, or quality-adjusted life-years (QALYs), and then calculate the ratio between the difference of two intervention costs and their QALY's. To summarize the cost-effectiveness of a healthcare intervention we can use the ICER (Incremental Cost-Effectiveness Ratio) were the effectiveness is measured in QALYS. The equation is [18]:

$$\text{ICER} = \frac{\text{CostA} - \text{CostB}}{\text{QALY A} - \text{QALY B}}$$

If for a given intervention the ICER is above a certain threshold it will be deemed too expensive and thus should not be funded, whereas if the ICER lies below the threshold the intervention can be judged cost-effective and it might be funded.[19]

4.3.2 Threshold

The CE threshold is defined as the maximum cost per health outcome that a health system is willing to pay. That threshold vary from countries and how to set a threshold has been a source of considerable debate. Three general approaches to set CE thresholds are commonly used, including per capita income based thresholds, benchmarking interventions, and league tables, it can also be used GDP. In America a common threshold is 50000$ and in the UK is 20000-30000£.[20]

4.3.3 Long-term Cost-Effectiveness of Dexcom G6 Versus Self Monitoring of Blood Glucose in Patients With Type 1 Diabetes in the U.K [15]

A long-term health economic analysis, using IQVIA CORE Diabetes Model was performed to assess the cost-effectiveness of Dexcom G6 (RT-CGM) in comparison of self-monitoring of blood glucose (SMBG) on U.K. patients with type-1 diabetes.

It was measured an utility benefit of 0.05536 (0.02536 + 0.03) for patients using RT-CGM. This value is the sum of 0.02536 gains from decreased FoH in Dexcom users (assed by HFS-II) and the benefit of 0.03 by avoiding finger stick SMBG testing (valued published by by Matza et al). So, in the base case analysis the use of RT-CGM relative to SMBG was associated with an incremental gain in quality-adjusted life expectancy of 1.49 quality-adjusted life years (QALYs).

Regarding the costs, the total annual treatment costs of the RT-CGM (36 sensors, 4 transmitters and occasional fingerstick testing) was 1,850£ and SMBG was 486£ (usage of 4.6 tests per day and pharmacy

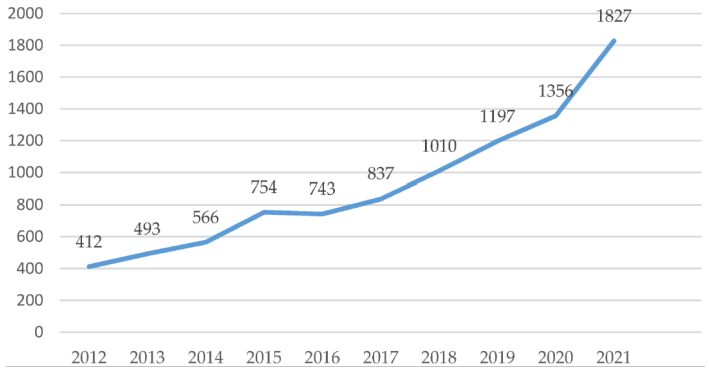

Figure 2: Studies on MCDM—Number of Articles from 2012 to 2021[21]

costs associated with insulin were not accounted). Overall, costs were 14,234 higher with RT-CGM driven primarily by the higher costs associated with the system itself.

Using this data, the incremental cost-effectiveness ratio (ICER) of £9,558 per QALY gained was calculated for Dexcom compared to Self-Monitoring of Blood Glucose. Keeping in mind that the willingness-to-pay (WTP) threshold in U.K is 20,000£ per QALY gained, this analysis suggests that RT-CGM significantly enhances clinical outcomes and represents a cost-effective alternative to SMBG.

4.3.4 The multiple criteria decision analysis (MCDA)

MCDA or MCDM (Multi-criteria decision-making) allows to incorporate different value attributes into decision-making. Assuming all relevant attributes have been identified and measured appropriately, participants then can allocate different weights to each attribute to generate an aggregated value. This decision analysis can be applied in various settings such as business, government, and medicine.

Over the past few decades, numerous MCDM methods have been developed by different authors. These methods differ in their algorithmic complexity, criteria weighting approaches, weighting methods for criteria, uncertain data possibility, and data aggregation type.[21]

It's worth to highlight that MCDM strategies are particularly effective in healthcare crisis scenarios. Per example, given the multidimensional nature of healthcare crises like the COVID-19 pandemic and the complex interplay between socio-economic and health systems, MCDM approaches were increasingly favored for simulating and addressing COVID-19 concerns. This emphasises the significance of MCDM techniques and their rapid growth through last years, as can be seen in Figure 2. [21]

5. Discussion

5.1 Challenges in the assessment of Dexcom's technology value

While taking into account various costs associated with diabetes management, the IQVIA CORE Diabetes Model does not include indirect costs, such as lost productivity due to diabetes-related complications might not be fully captured. Not only that but the results may not be generalizable to all populations as factors like age, duration of diabetes, and other comorbidities can influence the outcomes. [22]

The PROMs used also face some limitations due to their nature, typically assuming that all questions or domains are equally important and that the difference in severity across all response options is equal. While PROMs focus on health-related quality of life, they do not consider the quantity of life, and both morbidity and mortality are still crucial health outcomes. The EQ-5D, as a generic PROM it may not capture all aspects of quality of life that are specially relevant to people with diabetes. Generic PROMs cover broad areas of health which may not be sensitive to specific symptoms. This may be because they are missing specific domains of

health. These often lack the sensitivity to detect differences that arise as a consequence of treatment policies which are compared in clinical trials. [23]

On the other hand, the Hypoglycemia Fear Survey (HFS), as a more specific PROM, does not capture all aspects of health or quality of life, making it difficult to compare results across different measures and potentially leading to an incomplete evaluation of a technology's impact. Potentially it also increases the fear of hypoglycemia in some patients by making them more aware of their fears, affecting the accurate assessment of the health technology's value. [24]

Lastly, the QALYs as a measurement fails to consider all health benefits such as wellbeing and to weight on the importance of equity implications on health. [17]

In a last consideration, there's still a lack of standardization of outcome measures for glycemic control and glucose variability, making it challenging measuring the technologies value. [25]

5.2 Limitations of economical evaluation of health technologies

If the goal is to maximize overall health outcomes, then using cost-effectiveness based on QALY gained against a specified threshold, appears attractive. However, an alternative perspective argues that fairness matters and that assuming a QALY is a QALY regardless of who receives it is not entirely fair because of relevant aspects like severity of illness. Advances in technology have led to the development of expensive technology for rare and severe disorders and traditional health economic evaluation methods might result in the exclusion of this services from funding due to their failure to meet the thresholds. Evidence suggests that this exclusion does not align with prevailing societal values.[26] There is, therefore, a need for further research into social preferences and the means for translating them into workable funding formulae. If societal healthcare objectives expand beyond health gain, any number of other aspects might be considered we explore this aspects in the next section of this paper

Setting the threshold for the maximum amount society is willing to pay for a given technology has limitations regarding the approach used to define it. For example The World Health Organization' Choosing Interventions that are Cost-Effective (WHO-CHOICE) project recommends a cost-effectiveness threshold of less than three times the national annual gross domestic product (GDP) per capita, considering interventions costing less than once the national annual GDP per capita highly cost-effective. Approaches like this prioritize the value of health from a consumption perspective rather than being solely based on the healthcare resources needed to improve health outcomes. [27]

5.3 Novel approaches for health value measurement

The need for new methods to asses value is clear, methods that aim to go beyond the traditional measures of cost-effectiveness (such as cost-per-QALY)[28]. Decision-makers must embrace new tools such as multi-criteria analysis, patient preference measures and other less objective indicators such as equity, hope, insurance value, affordability, etc. [29]

This comes with the challenge of recognizing and appreciating the diversity among the pool of patients. A treatment may be considered beneficial, on average, but that doesn't mean it benefits everyone. It's crucial to keep in mind patient diversity and preferences when assessing value.[29]

A new metric, Value of Hope, takes into account that some patients may care about the variability of benefits and risks, and not just the average value. Considering two treatments with the same average survival rate but differing variability: Risk-tolerant individuals may favor the treatment with higher variability, hoping for better benefits even thought the risks are more severe. On the other hand, risk-averse individuals choose the procedure with lower variability at the cost of "exceptional" benefits.

Another metric, Insurance Value, is a combination of both physical risk protection and financial risk protection. The first focuses on the fact that a new intervention doesn't only affect patients directly by improving their health. Instead it offers a reduced fear of the risk associated with the disease, for those who don't have

it. The existence of a treatment makes it feel safer for those who might develope that condition. The other aspect, financial risk,is related to the fact that once an effective treatment exists, the risk of becoming sick (which was insurable) can now be insured, with a concrete value, and therefore managed through insurance mechanisms that support the patient.

Finally, conventional CEA (Cost Effective Analysis) does not measure inequality. Traditional CEA measures averages in populations, but an intervention isn't well suited for an individual simply because it is, on average, beneficial for a population. Distributional CEA brings this new piece of information, how an intervention impacts different sub populations, analysing all equity-relevant subgroups.

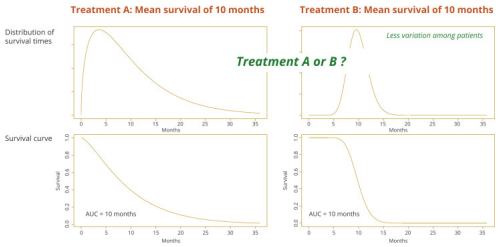

Figure 3: Value of Hope

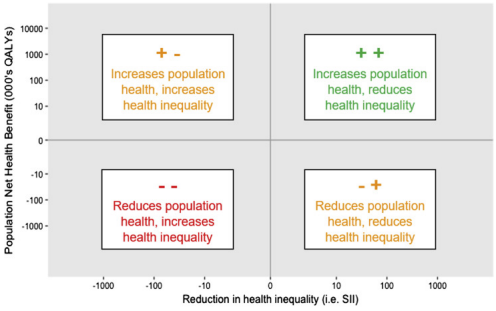

Figure 4: Plane of Health Equity

Using measures such as the ones presented strengthens the evaluation process, allowing for more informed decision-making and equitable healthcare systems.

6. Future areas of research

Insulin pumps and continuous glucose monitoring systems are now minimally invasive and more accurate than ever. There is now a new focus in integrating these two technologies, creating Closed Loop Insulin Delivery systems, or artificial pancreas as they're sometimes called. Initial attempts required the patient to be connected intravenously for blood withdrawal and analysis in one arm, and intravenous injection line of insulin in the other.

Fully automated Insulin closed loops face the challenge of not taking any kind of user input, including information about mealtime and food consumption that has been used to allow the system to respond in time to post-prandial hyperglycemia. Researchers have focused on discovering new algorithms that recognize announced meals and estimate the intake of carbohydrates. A research group developed a smartphone app that uses user-submitted images of meals to predict carbohydrate content using machine learning algorithms. In general, postprandial hyperglycemia still remains the biggest challenge in these technologies, and its usefulness may vary between individuals and their ability to predict/calculate mealtime boluses.

Exercise and physical activity also presents a challenge to closed loop systems. Ideally they adapt their output to the intensity of the exercise. This could be done using biometric data meaning that a fully functioning monitoring system must gather information regarding all different kinds of physiological activity. Recent attempts at doing this integrations have not shown, yet, a reduction in hyperglycemic events. (Breton et al.).

Looking at current studies done with systems such as MM780G and Control-IQ that have implemented closed loop systems (Control-IQ for example, is used in tandem with Dexcom devices), we can see these have shown decreased results in HFS (Hypoglycemia Fear Survey), DDS (Diabetes Distress Scale) and decreased levels of reported poor sleep quality in the PSQI scale (Pittsburgh Sleep Quality Index). On the other hand, they have showed higher cores in GME (Glucose Monitoring Experience Questionnaire) and INSPIRE measures (related to patients expectations regarding the intervention). [30]

Even though these technologies are still under development, we're still far away from Fully Closes Loop Systems being an accessible therapy for everyone (let alone, multi-hormone ones), investing in this are is an investment on increasing quality of life for millions of patients worldwide.

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