MARKET ANALYSIS AND CLINICAL EFFECTIVENESS OF CONTINUOUS GLUCOSE MONITORING

Dissertation Submitted to

The IIHMR University, Jaipur

for the partial fulfillment for the award of the degree of

Master of Business Administration (MBA)

in

Healthcare Analytics

by

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Under the Supervision and Guidance of

Dr. Ram Krishan Chahar

2026

IIHMR UNIVERSITY

CERTIFICATE

This is to certify that Mr. Nikhil Garg, in partial fulfillment of the requirements for the award of the degree of MBA (Healthcare Analytics) from IIHMR University, Jaipur, has successfully completed his dissertation titled "Market Analysis and Clinical Effectiveness of Continuous Glucose Monitoring (CGM)" during February 25 – June 09, 2026.

Place: Jaipur

Date: June 26, 2026

Faculty Guide

DR. Ram Krishan Chahar
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CERTIFICATE

This is to certify that dissertation titled "Market Analysis and Clinical Effectiveness of Continuous Glucose Monitoring" is a record of the research work undertaken by Nikhil Garg in partial fulfillment of the requirements for the award of the degree of MBA (Healthcare Analytics) from the IIHMR University, Jaipur under my guidance and supervision and his approach to the research study has been sincere, scientific, and analytical.

Dr. Ram Krishan Chahar

Assistant Professor

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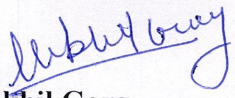
Date: 23/06/2026

DECLARATION BY STUDENT

I, **Nikhil Garg** (Roll No. **[0018**-Batch **2024–26**), hereby declare that this dissertation titled **"[market analysis and clinical effectiveness of continuous glucose monitoring]"** is my own original work, carried out during my internship under the supervision of [DR. Ritu Vasistha] and guidance of **[ram krinshnachahar], IIHMR University, Jaipur**. This work has not been submitted elsewhere for any degree or diploma. All sources referred to in this dissertation have been duly acknowledged, and a complete list of references has been provided at the end of the dissertation.



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Abstract

This research report presents a comprehensive secondary data analysis of Continuous Glucose Monitoring (CGM) systems, examining both their clinical effectiveness in diabetes management and the global market landscape. Diabetes Mellitus remains one of the most prevalent chronic metabolic disorders worldwide, affecting approximately 589 million adults as of 2024. CGM technology has emerged as a transformative approach to glucose management, offering real-time data on glucose fluctuations that enable timely clinical interventions.

Evidence synthesized from published clinical studies demonstrates measurable improvements in glycemic control among CGM users, including reductions in HbA1c levels from a pre-CGM mean of 11.21% to 7.04%, an increase in Time in Range (TIR) from 18% to 74%, and meaningful reductions in both mild and severe hypoglycemic episodes. The global CGM market was valued at approximately USD 13.38 billion in 2025 and is projected to reach USD 41.41 billion by 2033, reflecting a compound annual growth rate (CAGR) of 15.10%.

The competitive landscape is dominated by Abbott Laboratories, Dexcom, Medtronic, and Senseonics, each occupying distinct strategic positions based on product performance, pricing, and target markets. Strategic analysis using SWOT, PESTLE, and Porter's Five Forces frameworks highlights both the opportunities and challenges shaping this rapidly growing industry. This report supports a conclusion in favor of the alternative hypothesis that CGM systems significantly improve glycemic control relative to conventional self-monitoring methods.

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1. Introduction

1.1 Background

Diabetes Mellitus is a chronic metabolic disease characterised by a continuous high glycemic state and a long-term course of potentially serious complications such as cardiovascular disease, nephropathy, neuropathy, and retinopathy. Good glucose control is key to preventing these complications and keeping patients healthy.

Self-monitoring of blood glucose (SMBG) with glucometer has been the mainstay of diabetes self-care for many years. These approaches, however, provide only snapshots in time, and are not very sensitive to trends, nightly fluctuations, or quick changes in glucose levels. With these built-in restrictions, there has been a need for a more continuous and informative system.

To fill these gaps, the Continuous Glucose Monitoring (CGM) technology was developed. CGM systems use small, needle-like sensors that are placed under the skin to measure the level of glucose between meals and throughout the day and night, usually every 1 to 5 minutes. The resulting data stream offers a rich picture of glucose levels over time, day and night, for the patient and the clinician, and allows for proactive treatment rather than reactive treatment.

1.2 Significance of CGM Technology

There are a number of clinically relevant benefits to CGM over conventional monitoring. They can provide upto 288 glucose readings in a single day, provide trend and pattern analysis over time, provide alerts for upcoming hypoglycemia or hyperglycemia events and can connect to insulin delivery devices. These features have brought great value to people who rely on intensive insulin management for their Type 1 diabetes and are now increasingly important for Type 2 diabetes patients and even people who don't have diabetes but are interested in wellness.

From the market point of view, the increasing prevalence of diabetes around the world and the introduction of new technology and expanding insurance coverage have driven CGM into one of the fastest-growing categories in the medical device market. The clinical need and the business opportunity at the intersection of the two make CGM a fascinating topic for research and business analysis.

1.3 Scope of the Report

This report summarizes secondary data published in the public domain to assess clinical effectiveness of CGM systems in improving glycemic control, market structure and dynamics of the global CGM market, competitive

positioning of major CGM manufacturers and the market's strategic landscape. The analysis is based on peer-reviewed clinical literature, open market research reports and company product information.

2. Research Objectives and Hypothesis

2.1 Primary Objective

To assess the effectiveness of Continuous Glucose Monitoring systems to enhance glycemic control in diabetes patients, using secondary data from published studies.

2.2 Secondary Objectives

- To identify and characterize major companies operating in the global CGM market.
- To analyze market share distribution and global market size estimates across regions.
- To compare product offerings, features, and performance metrics among leading CGM manufacturers.
- To conduct a competitive analysis of CGM companies based on product performance, innovation strategy, and market presence.
- To examine historical growth trends and project future market potential.

2.3 Research Hypothesis

Null Hypothesis (H_0)

CGM does not offer a statistically significant improvement in glycemic control over the standard approach to blood glucose monitoring.

Alternative Hypothesis (H_1)

CGM systems are shown to have a statistically significant improvement in glycemic control over traditional blood glucose monitoring.

3. Methodology

3.1 Study Design

The research design used in this study is secondary data research design which combines findings from existing clinical studies, systematic reviews, and market intelligence reports. When the goal is to integrate existing primary sources to gain a deeper understanding, secondary research is suitable. This strategy can also be used for market analysis, where proprietary data and industry reports are used as sources.

3.2 Data Sources

The following types of published material were used as data for this report:

- Peer-reviewed clinical journals accessed through PubMed, Google Scholar and Scopus such as Diabetes Technology & Therapeutics, Cureus, Diabetes, Obesity & Metabolism, International Journal of Environmental Research and Public Health.
- Market intelligence and market reports from various sources such as Grand View Research, Mordor Intelligence, MarketsandMarkets, Technavio, Global Market Insights and others.
- Official publications of the International Diabetes Federation (IDF), the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC).
- Abbott Laboratories, Dexcom, Medtronic and Senseonics' manufacturer product documents and corporate disclosures.

3.3 Study Variables

Clinical Variables

- HbA1c: main outcome for long term glycemic control, which indicates the average glucose level for the last 2-3 months.
- Time in Range (TIR): Percentage of time spent within the target glucose range of 70-180 mg/dL.
- Hypoglycemia incidence: Number of mild (55-70) and severe (<54) hypoglycemic episodes.
- Average blood glucose: Glucose average over the glucose monitoring period.
- Glycemic variability: which is expressed in terms of coefficient of variation (CoV) and other related measures.

Market Variables

- Global and regional CGM market size (USD millions/billions) 2012-2017.
- The CAGR for market growth.
- Share of markets of the top manufacturers.
- The type of sensor, wear time, and connectivity are just some product portfolio characteristics.

Competitive Variables

- Innovation course and product development process.
- The technology features and sensor accuracy (MARD).
- The pricing strategy and positioning of the market.
- Distribution channels and reimbursement environments.

3.4 Analytical Framework

The analysis integrates three complementary methodological approaches:

Descriptive analysis is the process of organizing and summarizing quantitative data on market size, market growth and clinical outcome studies across studies. Comparative analysis involves detailed and organized evaluation of both CGM devices and manufacturers, based on the same set of criteria, including accuracy, durability, cost, and user-friendliness. Strategic environmental analysis is based on a set of business methodologies used to assess the competitive and macro environment of the CGM industry, such as SWOT analysis, PESTLE analysis, and Porter's Five Forces analysis.

3.5 Ethical Considerations of Methodology

No primary data collection occurred and this study did not pose a risk to human subjects. All cited information is accessible or can be found in academic databases. Citations have been created to guarantee complete and proper citations, and to uphold academic honesty. Data have not been quoted but interpreted and paraphrased, and independent scholarly synthesis of the data is reflected in the analysis.

3.6 Limitations

Findings are limited as a secondary data study in that they depend upon the quality and quantity of published evidence available for the study. The number of patients and length of follow-up reported in the clinical studies vary, so direct comparisons are not possible. The estimates are subject to interpretation as they vary among sources, depending on the methodology and the assumptions made. The limitations of these are recognized during the analysis.

4. Market Analysis: Global and Regional CGM Market

4.1 Global Market Overview

The CGM devices market across the globe has seen tremendous growth in recent decade and is expected to grow at a robust pace during the forecast period. On the other hand, the market value was estimated to be around USD 13.38 billion in 2025 and is anticipated to hit USD 41.41 billion by 2033 with a CAGR of 15.10% during the forecasting period. This rate of growth is significantly higher than the overall medical devices industry, reflecting the exceptional momentum in the CGM market globally.

This growth has several underlying structural factors. The global burden of diabetes is likely the biggest driver. In 2024, the International Diabetes Federation estimated there were 589 million adults with diabetes, with the Western Pacific, Southeast Asia and Europe having the highest prevalence. This expanding patient population creates a steady demand for sophisticated monitoring solutions, with CGM systems increasingly becoming an expected component of patient care.

4.2 Market Size Summary

Metric	Value
Global Market Size (2025)	USD 13.38 Billion
Global Market Size (2033, Projected)	USD 41.41 Billion
CAGR (2026–2033)	15.10%
Largest Regional Market (2025)	North America (63.3% share)
Fastest Growing Region	Asia-Pacific
Dominant Product Segment	Sensors (62.8% share)
Leading Indication Segment	Type 1 Diabetes (64.9% share)

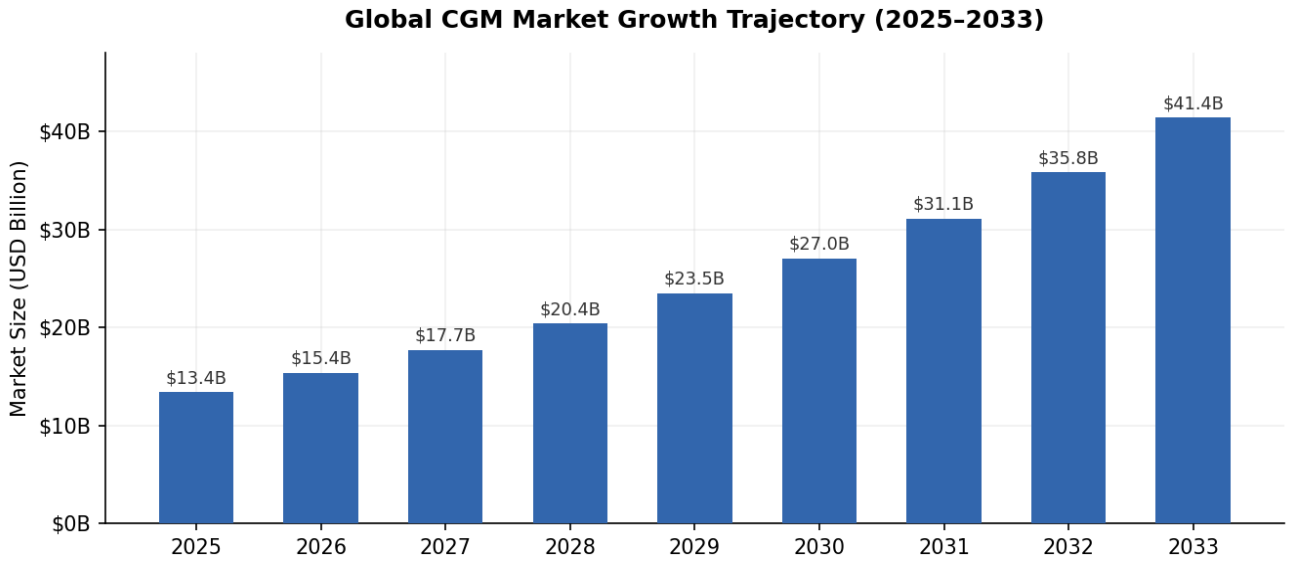

Figure 1: Global CGM Market Growth Trajectory (2025–2033)

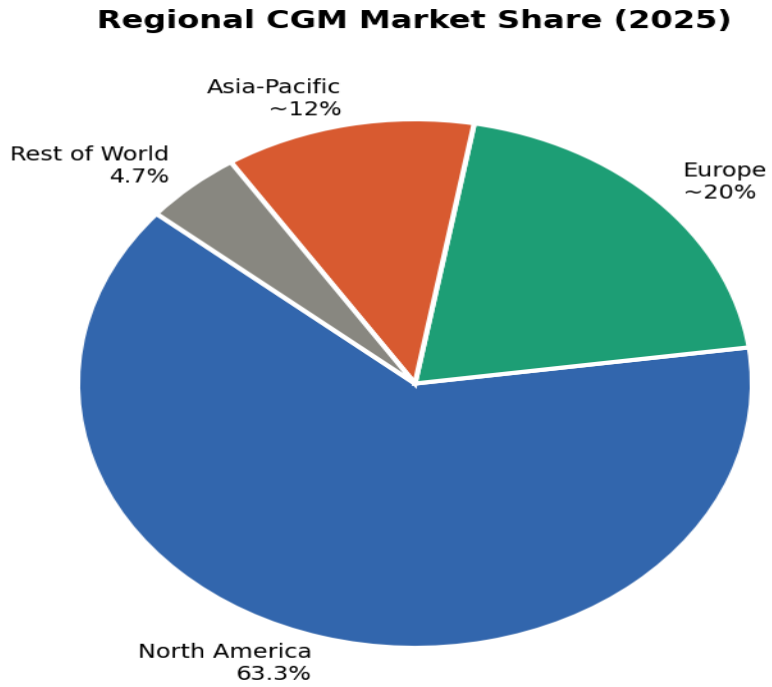

Figure 2a: Regional Market Share (2025)

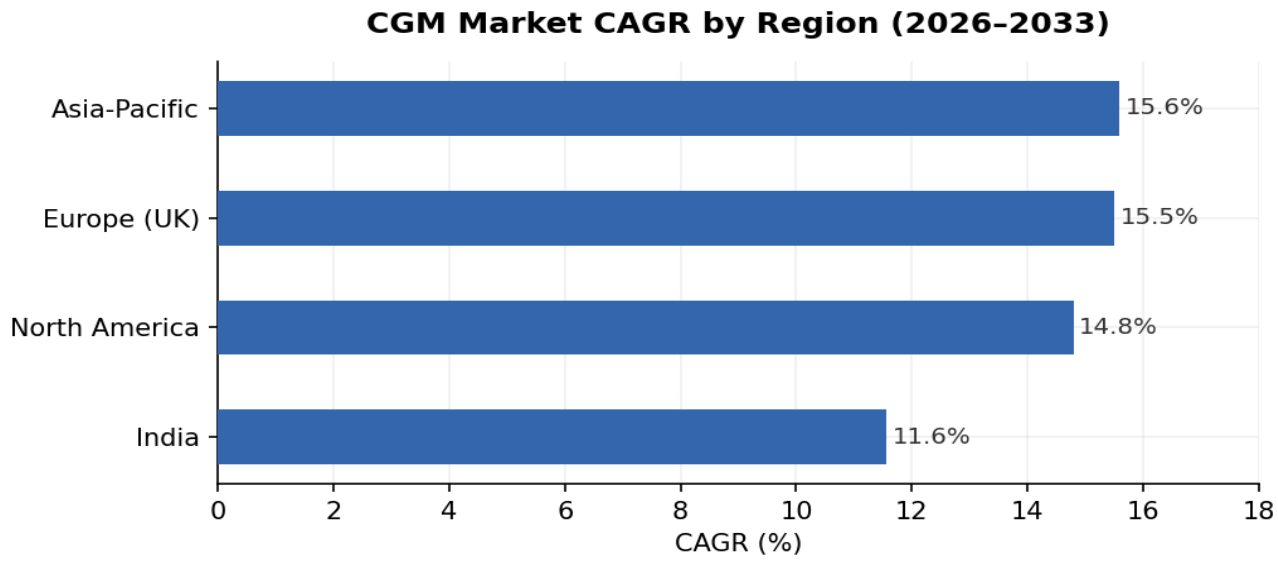

Figure 2b: CGM Market CAGR by Region (2026–2033)

4.3 Regional Market Analysis

North America

In 2025, North America is expected to be the largest regional CGM market, making up of about 63.3% of the total global revenue. This dominance is the result of the established health care infrastructure, effective reimbursement systems and a high level of awareness on the part of both patients and health care providers. This has been especially exciting news for the United States market, as the introduction of regulatory changes, like the inclusion of Type 2 diabetes (T2D) patients not receiving insulin under Medicare CGM coverage has expanded the patient population significantly. With the launch of over-the-counter CGMs like Dexcom's Stelo, the adoption of these devices by consumers is further driven by the elimination of prescription requirements.

Europe

Growth in the European market is steady and policyled. CGM devices have increasingly been integrated into the routine care of diabetes in the United Kingdom, Germany, France and other countries across Europe. The UK CGM market, for instance, was worth USD 532.2 million in 2024 and will increase to USD 1,952.8 million by 2033 at 15.5% CAGR. CGM support in the NHS, especially in insulin-treated Type 1 and Type 2 patients, has played a vital role in allowing the use of CGM. Regulatory bodies like the MHRA are still supporting innovation, with the approval of next generation products and approval of clinical trial authorisations.

Asia-Pacific

Asia-Pacific is anticipated to see the most rapid growth during the forecast period, fueled by the huge and growing diabetic population in India and China. India, in particular, has a population of about 89.8 million adults with diabetes, and 10.5% of the adult population suffer from diabetes. Nevertheless, the use of CGM is still relatively low and there is a big addressable market for affordable and available solutions. The India CGM market size was USD 45.92 million in 2025 and is expected to reach USD 105.67 million by 2033 at a 11.56% CAGR.

4.4 Market Segmentation

By Indication

The main user group of CGMs has historically been individuals with type 1 diabetes because they have a lifetime need for insulin and have a high level of need for monitoring. The segment accounted for 64.9% of the market share in 2025 and is expected to grow at 14.83% CAGR for the forecast period. Type 2 diabetes is the fastest growing indication with the CAGR of 15.60%. There is growing clinical evidence to support CGM use in patients with Type 2 diabetes, even those not taking insulin, with evidence of improvement in HbA1c, cardiovascular risk factors and patient engagement.

By Distribution Channel

The top channel is Pharmacies, which will generate around 59.4% of market revenue in 2025. This channel is now so entrenched because of the partnership between manufacturers and big pharmacy groups. The eCommerce segment is expected to experience the highest CAGR, at 15.31%, as it mirrors the shift towards a direct-to-consumer approach, subscription model delivery and provision of remote healthcare services.

5. Major Companies and Competitive Landscape

5.1 Market Concentration

The CGM market is moderately concentrated, with the top three manufacturers claiming the lion's share of global revenue. Abbott Laboratories, Dexcom, and Medtronic are the dominant players based on their high levels of brand awareness, distribution reach and R&D resources. This concentration poses high barriers to entry for new challengers, as well as adding competitive dynamics to the existing incumbents.

Company	Estimated Market Share	Strategic Positioning
Abbott Laboratories	~38–56%	Volume leader; cost and accessibility
Dexcom	~32–35%	Premium accuracy and digital health
Medtronic	~6–12%	Integrated insulin management systems
Senseonics	<2%	Niche implantable CGM innovation

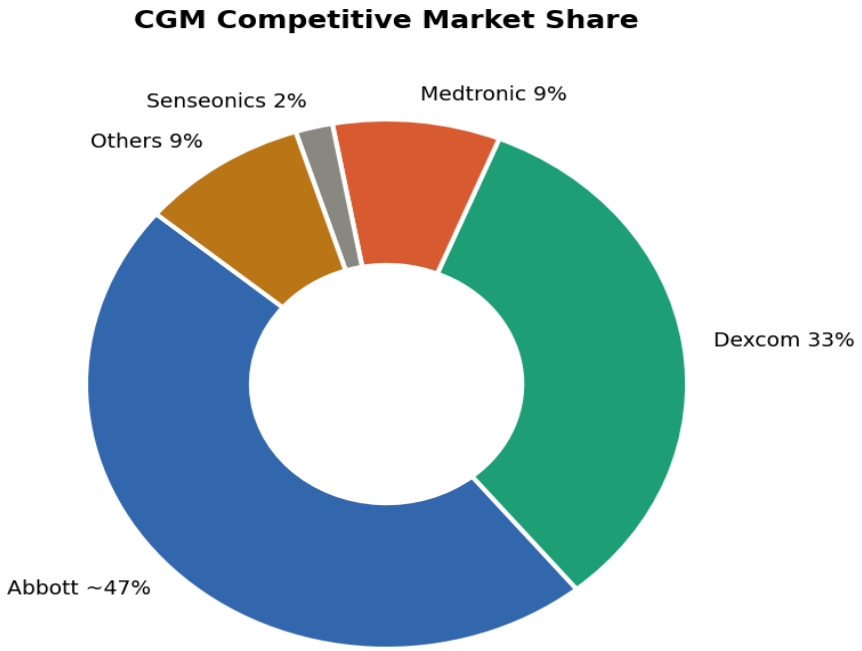

Figure 3: Competitive Market Share Distribution

5.2 Company Profiles

Abbott Laboratories

Abbott is the global volume leader for CGM with its FreeStyle Libre series. The product line is characterized by factory-calibrated sensors, the absence of regular fingerstick calibration, and being competitively priced and available in both developed and emerging markets. The newest version, FreeStyle Libre 3, provides live continuous glucose monitoring data to a smartphone and has a 14-day duration of wear. The strategy of Abbott is based on cost leadership and mass market penetration, which has worked well in price sensitive markets like India and the emerging economies. The recently announced collaboration with Medtronic, where the company plans to combine FreeStyle Libre technology with automated insulin delivery systems, is a strategic expansion of its ecosystem capabilities (August 2024).

Dexcom

Dexcom has established itself as a competitors' top performer in the CGM market. Its flagship offerings include the Dexcom G6 and G7 sensors, which are known for their accuracy, immediate data transmission, and advanced alarm system to alert for hypoglycemia and hyperglycemia. The G7 device is about 60% smaller than the previous model, features a simplified one-handed insertion mechanism and offers a 12 hour grace period at the end of each sensor session. Its commitment to integration with digital health and automated insulin delivery systems is a key factor in its position as a leader in patients who need intensive diabetes management, particularly Type 1 diabetes. Its newer Stelo product is geared toward the over-the-counter wellness marketplace.

Medtronic

Medtronic's area of unique expertise is the combination of glucose monitoring and insulin delivery. The company's primary products are the Guardian Connect system and the MiniMed series, the Guardian 4 sensor being a central part of the automated insulin delivery system. Medtronic, in January 2024, was granted CE Mark approval for its MiniMed 780G system with the next-generation Simplera Sync CGM sensor. This combination generates substantial switching costs and enhances retention of patients, especially in hospital and specialty clinics.

Senseonics

Senseonics distinguishes itself from other transcutaneous CGM products with its 180-day implantable sensor, which lasts much longer than the other products. This helps to ensure that sensors are not changed frequently and provides a steady long-term monitoring solution. The need for a minor clinical procedure to implant the sensor, however, and the high price of the device have prevented widespread use, with only a small number of patients for whom long-duration monitoring is important using it.

5.3 UK Market: Detailed Competitive Overview

One of the most illustrative examples of country-level competition is the United Kingdom market. Abbott and Dexcom are the leaders, with a host of other companies trying to carve out a niche.

Company	Device	Type 1	Type 2	Key Feature
Dexcom	G6 / G7	Yes	Yes	Real-time CGM; NHS supported; no calibration
Abbott	FreeStyle Libre 2 / 3	Yes	Yes	Flash CGM; cost-effective; NHS wide use
Medtronic	Guardian Connect	Yes	Limited	SmartGuard with predictive alerts; pump integrated
Senseonics / Ascensia	Eversense E3	Yes	No	Implantable; 180-day sensor life
GlucoRx	AiDEX CGM	Yes	No	Affordable; targets cost-sensitive Type 2 segment
Nemaura Medical	SugarBEAT	No	Yes	Non-invasive daily-wear patch
Medtrum	Nano CGM	Yes	Yes	Tubeless; smartphone compatible; emerging option

5.4 India Market: Competitive Overview

The CGM market in India is in the nascent phase but has seen a rapid growth. Abbott's FreeStyle Libre is the market leader in prescription-based CGM, and there are emerging locally adapted solutions being developed to tackle affordability.

Company	Device	Category	Target Segment
Abbott Laboratories	FreeStyle Libre	Prescription	Type 1 & 2; clinically monitored
Medtronic PLC	Guardian Connect	Prescription	Advanced diabetic care
DrStore Healthcare	Tracky CGM	OTC	Mass market; cost-sensitive users
Ultrahuman	Ultrahuman M1	OTC	Health-conscious; fitness-focused
Roche Diagnostics	Accu-Chek CGM	Prescription	General diabetes management
Nemaura Medical	SugarBEAT	OTC (Global)	Preventive care; Type 2 diabetes

6. Clinical Effectiveness of CGM Systems

6.1 Overview

There are a number of well-established and peer-reviewed studies that demonstrate clinical effectiveness of CGM systems in a wide range of care settings and patient backgrounds. The results obtained from the studies conducted on adults with uncontrolled diabetes, pregnant women with Type 1 diabetes, patients at cardiovascular risk with Type 2 diabetes and physically active people are summarized in the next section.

6.2 Glycemic Control in Uncontrolled Diabetes

Twenty-five patients with uncontrolled diabetes at the internal medicine resident clinic at MountainView Hospital, Las Vegas, who were preparing to switch from SMBG to Dexcom G6 CGM were included in this retrospective study. All primary glycemic parameters showed significant improvements.

Parameter	Before CGM (SMBG)	After CGM	Change
Mean HbA1c	11.21%	7.04%	↓ 4.17 percentage points
Average Blood Glucose	286 mg/dL	158 mg/dL	↓ 128 mg/dL
Time in Range (TIR)	18%	74%	↑ 56 percentage points
Coefficient of Variation (CoV)	39%	29%	↓ 10 percentage points
Mild Hypoglycemia Rate	4.75%	0.78%	↓ 3.97 percentage points
Severe Hypoglycemia Rate	3.01%	0.20%	↓ 2.81 percentage points

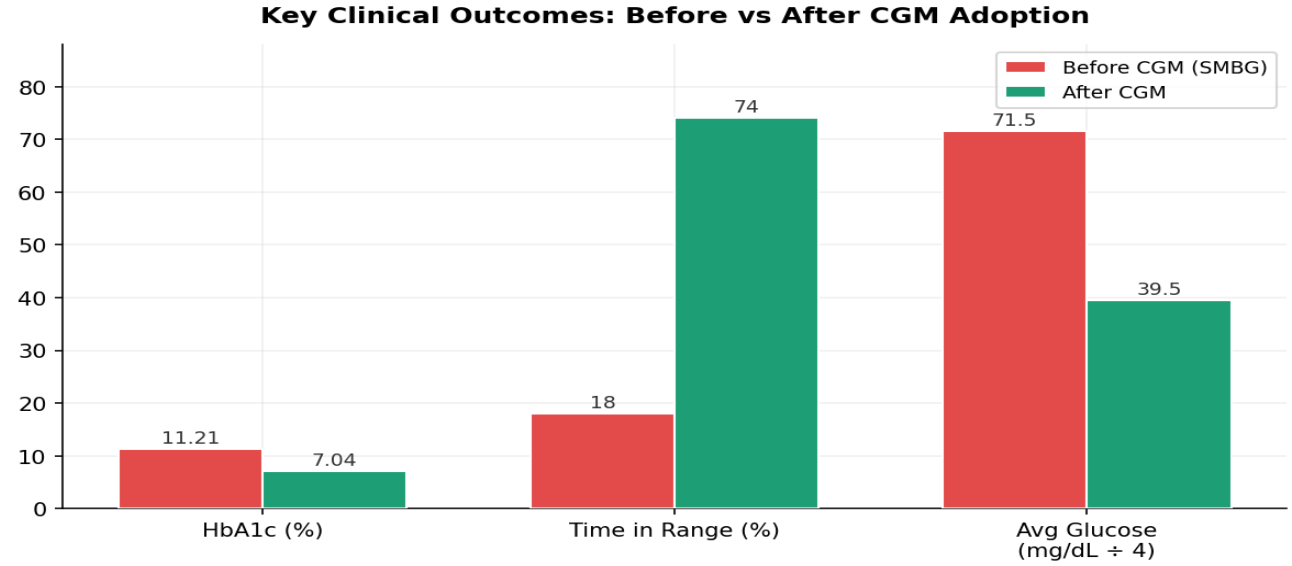

Figure 4: Key Clinical Outcomes Before vs After CGM

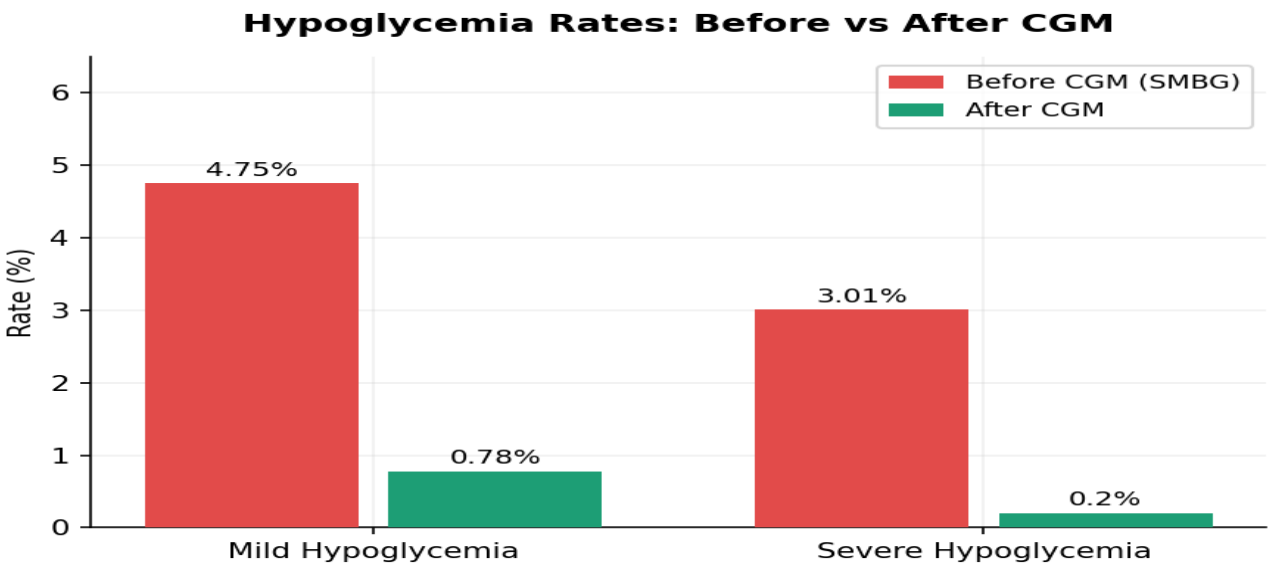

Figure 5: Hypoglycemia Rates Before vs After CGM

These findings are of clinical importance. The reduction in HbA1c of 4.17 percentage points is significant, going beyond the level of improvement that can be expected by simply pharmacologically intensifying treatment. The improvement in TIR from 18% to 74% exceeded the American Diabetes Association's suggested goal of 70%. In addition, a small subset of Type 2 patients (around 16%) made it possible to switch to oral anti-diabetic drugs or weekly GLP-1 receptor agonists and become completely insulin-free, highlighting the potential for CGM to lower insulin use in some patients.

6.3 CGM in Pregnancy with Type 1 Diabetes

In a real-world study at the Barbara Davis Center for Diabetes, researchers compared outcomes of 160 pregnancies with Type 1 diabetes treated with CGM and those treated with SMBG. Women in the CGM group achieved significantly higher HbA1c goals during pregnancy and postpartum. The only neonatal outcomes significantly different between the CGM and SMBG groups were macrosomia, which was less common in the CGM group (12.8%) than in the SMBG group (29.4%). CGM users' infants did not need to be admitted to the neonatal intensive care unit (NICU) as often, although this was not statistically significant. These results indicate that CGM is beneficial for maternal glycemic management in a clinically relevant, diverse patient population.

This pilot study focused on CGM with remote monitoring by family members or friends (CGM Share) to determine its added value to CGM alone in pregnant women with Type 1 diabetes. HbA1C decreased in all groups during pregnancy but the greatest decrease in HbA1C was seen in the CGM Share group compared to the CGM only and no CGM groups ($p = 0.0042$). Lower levels of sensor glucose and percent time above 180 mg/dL were also seen in the CGM Share group, suggesting that social support through the sharing of monitoring might enhance the glycemic benefits of the CGM technology.

6.4 CGM in Type 2 Diabetes: Glycemic and Cardiovascular Outcomes

A cross-over clinical trial recruited 47 adults with Type 2 diabetes, a mean HbA1c of 8.4%, obesity (mean BMI of 37 kg/m²) with elevated atherosclerotic cardiovascular disease risk (mean 10 year predicted ASCVD risk of 24%). Patients had fewer average glucose readings after 90 days of unblinded CGM use with the Dexcom G6 device, and their TIR increased significantly from 57.8% to 82.8%, while their HbA1c levels also dropped significantly. Importantly, statistically significant improvement was also seen in BMI, triglycerides, blood pressure, total cholesterol and diabetes distress scores. Of the patients taking CGM, the proportion using sodium-glucose cotransporter-2 (SGLT2) inhibitors rose from 36.2% to 83.0%, while the proportion of GLP-1 receptor agonists prescribed in these patients increased from 42.5% to 87.2%, indicating that CGM-derived data facilitated more evidence-based prescribing. The present study shows that in patients not in need of insulin therapy, CGM use can lead to a reduction in cardiometabolic risk.

6.5 CGM and Physical Activity

There is also evidence that CGM can be helpful in controlling glucose responses to exercise, especially in patients with Type 2 Diabetes. CGM allows for immediate monitoring of glucose changes associated with exercise, so that interventions can be made to avoid both exercise-induced hypoglycemia and night-time hypoglycemia after exercise. The continuous glucose data stream enables personalized exercise plans and can help determine the best time to exercise in relation to food and medication intake. These features make CGM a valuable device to help manage metabolism and also aid in safe and effective involvement in physical activity programs.

6.6 Sensor Accuracy: Dexcom G7

An important multicenter study of 316 adult subjects in 12 investigational sites in the United States measured the accuracy and safety of the Dexcom G7 CGM. Fully 10.5 days the sensors were worn at the same time, as well as on the abdomen, and glucose levels were compared to lab reference glucose readings from the YSI 2300 Stat Plus analyzer.

Metric	Arm Placement	Abdomen Placement
Mean Absolute Relative Difference (MARD)	8.2%	9.1%
%20/20 Agreement Rate	95.3%	93.2%
%30/30 Agreement Rate	98.8%	98.1%
Mean Time Lag	3.6 minutes	3.4 minutes
Serious Adverse Events	None reported	None reported

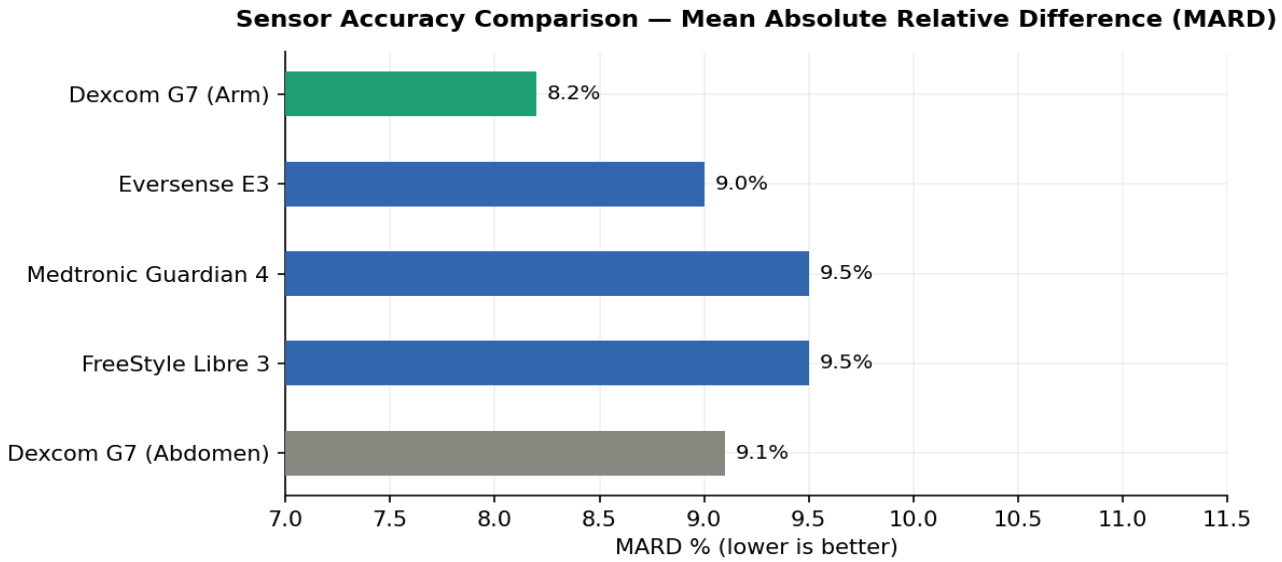

Figure 6: Sensor Accuracy Comparison (MARD — Lower is Better)

The accuracy of arm placed sensors is high with the mean absolute relative difference of 8.2%, which is comparable or better than many commercially available CGM systems. The G7 also improved on warm-up times (27 minutes versus 2 hours on G6), extended end-of-life for sensors by 12 hours, and reduced device footprint by 60% compared to the previous G6. The device has a safety profile that was confirmed by the absence of any serious adverse events reported.

6.7 Comparative Accuracy: Dexcom G7 vs. FreeStyle Libre 3

A head-to-head accuracy comparison of the Dexcom G7 and FreeStyle Libre 3 involving 55 adults with Type 1 or Type 2 diabetes found that the FreeStyle Libre 3 achieved a lower overall MARD (8.9%) compared to the Dexcom G7 (13.6%), along with a higher proportion of glucose values within 20 mg/dL or 20% of reference values (91.4% vs. 78.6%). The FreeStyle Libre 3 continued to give it the edge in terms of accuracy after 12 hours of sensor wear. Notable is the fact that these results are the first head-to-head comparison of the two largest CGM brands, yet the absolute MARD values reported in this study are different from those reported in the pivotal accuracy trial, which illustrates the variability in real-world comparisons.

6.8 Three-Device Accuracy Comparison

The Dexcom G5 was tested for accuracy in a home use study performed in 6 weeks compared to Abbott's FreeStyle Libre Pro and Senseonics Eversense in 23 adults with Type 1 who were using all three devices at the same time.

When comparing these three, Eversense had the smallest nominal MARD of 14.8%, with Dexcom G5 at 16.3% and FreeStyle Libre Pro at 18.0%. It is important to point out that the actual MARD in the real world is generally greater than that recorded in controlled clinical situations due to the complexity of the home environment, diversity of wear conditions and lack of glucose manipulation.

6.9 Exploratory Data Analysis: CGM vs SMBG Dataset Comparison

To supplement the clinical study evidence presented in preceding sub-sections, an exploratory data analysis was conducted comparing a real-world CGM dataset sourced from the Stanford CGM Database with SMBG-equivalent readings derived from the same data. SMBG-equivalent values were extracted at four fixed daily time points corresponding to standard clinical practice: 07:00 (fasting), 11:00 (pre-lunch), 15:00 (pre-dinner), and 19:00 (evening). This approach mirrors how a patient relying solely on SMBG would monitor their glucose throughout the day, enabling a direct empirical comparison between continuous and intermittent monitoring approaches within the same dataset.

6.9.1 Descriptive Statistics: CGM vs SMBG

The descriptive statistics derived from the two monitoring approaches are summarised in the table below. On the surface, the mean glucose values appear nearly equivalent, with the CGM dataset recording a mean of 112.6 mg/dL and the SMBG-equivalent subset recording 111.2 mg/dL. This convergence is an expected methodological artefact: since SMBG values were extracted from the CGM time series at fixed intervals, the central tendency of both samples naturally aligns. However, examining the distributional extremes and variability metrics reveals clinically meaningful differences that the mean alone conceals.

Metric	CGM Dataset	SMBG Dataset	Clinical Significance
Mean glucose (mg/dL)	112.6	111.2	Comparable — expected sampling artefact
SD — variability (mg/dL)	32.7	26.9	CGM 22% higher — captures true glucose biology
Minimum glucose (mg/dL)	43 mg/dL	66 mg/dL	SMBG missed severe hypoglycaemia (43 mg/dL)
Maximum glucose (mg/dL)	309 mg/dL	195 mg/dL	SMBG missed severe hyperglycaemic spike
Reading frequency	~288 per day	4 per day	CGM provides 72× more data points per day

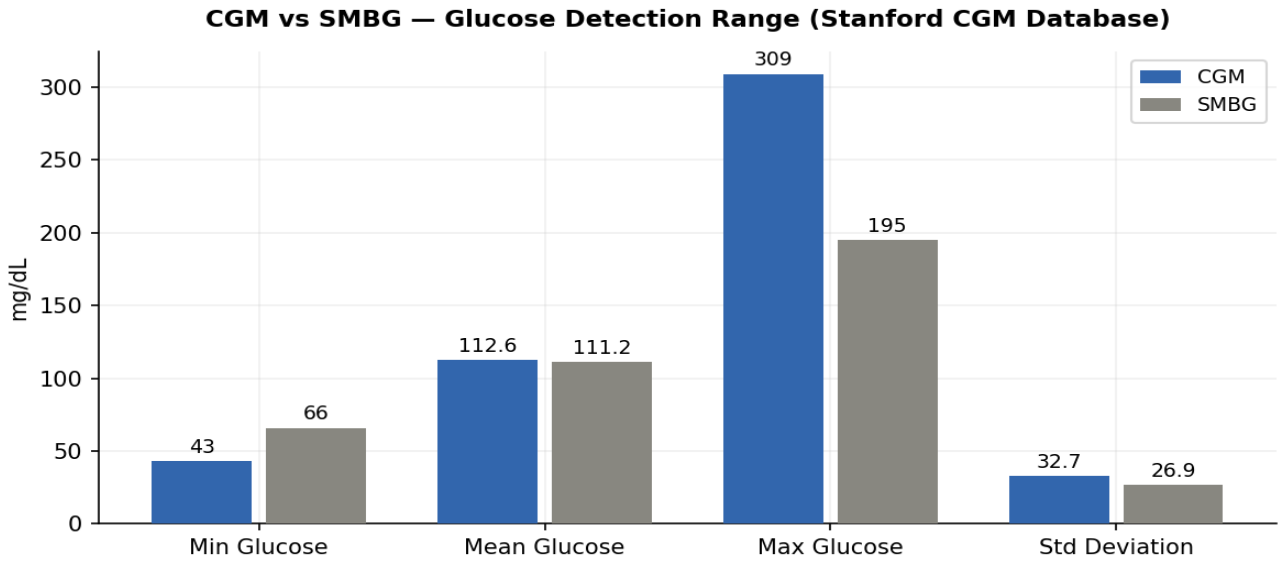

Figure 7: Glucose Detection Range — CGM vs SMBG (Stanford Database)

6.9.2 Interpretation of EDA Findings

From the EDA comparison, four clinically relevant observations are made:

- **Hypoglycaemia detection failure:** The glucose level recorded in the CGM data was at a minimum of 43 mg/dL, which is consistent with severe neurological impairment and loss of consciousness. The SMBG-equivalent subset only had a single value of 66 mg/dL as the lowest, completely failing to capture the critical hypoglycaemic event. This patient has a blood glucose reading of 43 mg/dL, which is an immediate risk of seizure and requires immediate intervention, but would not have been recognized or raised an alarm had the patient only had SMBG monitoring.
- **Hyperglycaemia underestimation:** This is the peak glucose recorded by the CGM system, probably due to an acute increase from eating or as a result of stress. The SMBG approach had the highest of 195 mg/dL, which is 114 mg/dL less. This difference would lead to underestimation of the hyperglycaemic burden for the patient on SMBG results, possibly leading to insufficient insulin dose optimisation and continuing exposure to high glucose levels for the patient's end organs.
- **True glycaemic variability:** The standard deviation was 32.7 mg/dL for CGM and 26.9 mg/dL for SMBG, a difference of 22%. In diabetes, it is known that glycaemic variability, apart from the average glucose, is a marker of oxidative stress and endothelial dysfunction, as well as cardiovascular risk. SMBG has been found to systematically underestimate variance as it measures glucose at relatively stable and predictable time points and can't measure inter-meal variation or nocturnal excursions at all.
- **Why mean glucose being similar does not validate SMBG:** If the near-identical means (112.6 vs 111.2 mg/dL) are directly related to the method used for sampling (taking SMBG values from the same CGM time series at fixed points, which is a method artefact) then the similarity does not validate SMBG. This convergence is predicted and does not suggest clinical equivalence. The important differences are in the extremes and the variability measures – showing that there is a significant percentage of clinically hazardous events that occurs outside the four SMBG sampling windows.

6.9.3 Triple C Study: Real-World CGM Effectiveness in Pregnancy

Gao et al. (2024) conducted a rigorous real world evaluation of the effectiveness of CGM at the Barbara Davis Center for Diabetes in the USA, in a clinically high-stakes population: women with Type 1 diabetes during pregnancy. The study identified 160 pregnancies over a 6.5-year period (2014-2020) and compared those who had CGM therapy (109) with those who had SMBG therapy (51). CGM use was considered to be at least 60% of the second and third trimesters of CGM use. Student's t-test and chi-square tests were used for statistical analysis of continuous and categorical variables, respectively.

The data showed that the number of CGM users who met HbA1c targets for each trimester was significantly higher, as well as in the postpartum period ($p < 0.01$ for each trimester). There were more participants in the SMBG group who did not achieve HbA1C goals in each trimester than in the CGM group ($p < 0.001$). Neonatal outcomes were significantly better for infants of CGM users (12.8%) than for infants of SMBG users (29.4%), with macrosomia being significantly less common ($p = 0.01$). This is a relative risk reduction of about 57%, and has direct implications for birth complications, caesarean section and neonatal metabolic sequelae.

The infants of CGM users were less likely to be admitted to the neonatal intensive care unit (NICU) (52.9% vs 68.3%), but this was not a statistically significant difference ($p = 0.099$), perhaps because of the small sample size of infants in this study. Most other neonatal outcomes were similar in both groups without any statistically significant differences. These observations are in line with the mechanistic reasoning that sustained glucose monitoring allows better control of glucose levels within the intrapartum period, minimizing the chronic foetal hyperinsulinaemia underlying macrosomia and foetal metabolic problems at birth.

Outcome	CGM group (n=109)	SMBG group (n=51)	p-value	Significance
HbA1c trimester-specific target achievement	Higher throughout	Lower throughout	<0.01	Significant
Never met HbA1c target (any trimester)	Fewer	More	<0.001	Significant
Macrosomia rate	12.8%	29.4%	0.01	Significant
NICU admission rate	52.9%	68.3%	0.099	Trend only

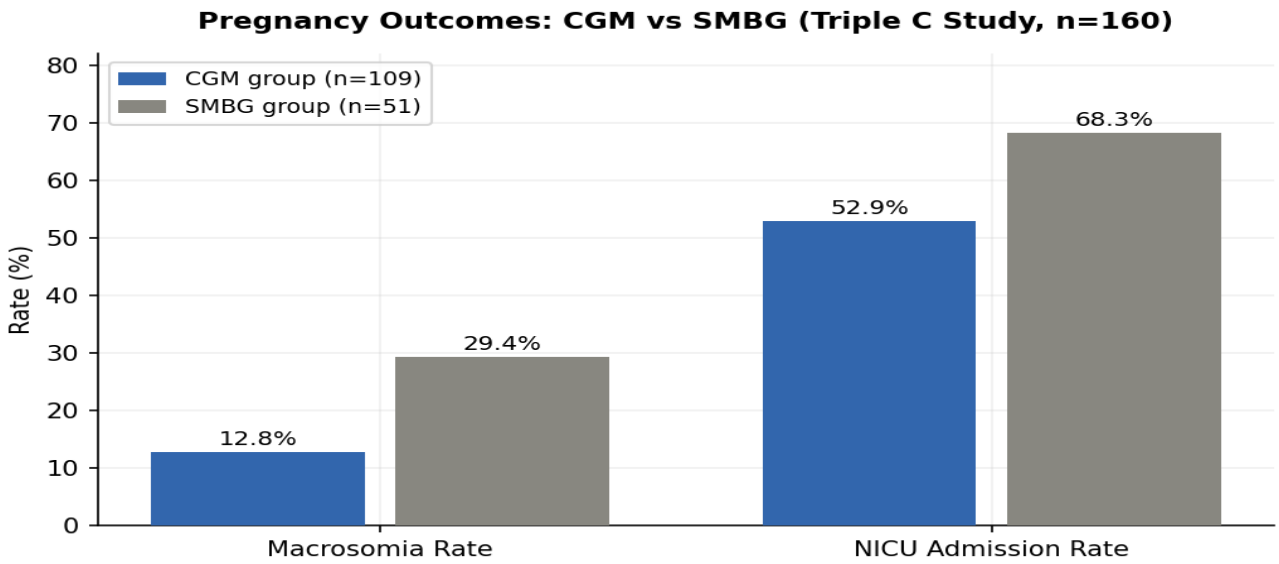

Figure 8: Pregnancy Outcomes — CGM vs SMBG (Triple C Study, n=160)

The EDA findings and the Triple C Study, when analyzed together, offer convergent evidence from different analytical methods, one based on data, the other on prospective planning and clinical validation, to confirm that CGM is significantly superior to SMBG in detecting and managing clinically significant glucose events. CGM does not make the mean glucose lower, it is the 24/7 monitoring of CGM that makes it an advantage over the SMBG monitoring of glucose during just a few narrow windows.

7. Comparative Product Analysis

7.1 Product Feature Comparison

Parameter	Dexcom G6/G7	Abbott Libre 2/3	Medtronic Guardian	Eversense
Sensor Type	Wearable (transcutaneous)	Wearable (transcutaneous)	Wearable (transcutaneous)	Implantable
Wear Duration	10 days	14 days	7 days	90–180 days
Real-Time Monitoring	Yes	Yes (Libre 2/3)	Yes	Yes
Calibration Required	No	No	Yes	Minimal
Alerts / Notifications	Yes	Yes	Yes	Yes
Connectivity	App + Receiver	App-based	App + Pump	App + Transmitter
Integration with Insulin Pump	Yes (selected systems)	Yes (Abbott partnership)	Yes (MiniMed)	No

7.2 Accuracy Comparison

Company	Device	Approximate MARD	Accuracy Level
Dexcom	G7	~8.2–9.1%	Very high (single-digit MARD)
Abbott	FreeStyle Libre 3	~8.9–11%	High
Medtronic	Guardian 4	~9–10%	High
Senseonics	Eversense E3	~8.5–9.5%	High (in-clinic)

7.3 Cost and Market Accessibility

Company	Relative Cost Level	Primary Market Focus
Abbott Laboratories	Low to moderate	Mass market; emerging economies; NHS-covered
Dexcom	Moderate to high	Premium users; Type 1 intensive management
Medtronic	Moderate to high	Hospital-based; integrated pump users
Senseonics	High (procedure required)	Niche; long-term monitoring preference

8. Strategic Framework Analysis

8.1 SWOT Analysis

Strengths and Opportunities (SO Strategy)

CGM technology is a technology with both high intrinsic quality and a good external environment. CGM systems provide continuous, high-frequency glucose data – which provides better clinical decision making compared to intermittent monitoring methods – from a strength perspective. The clinical efficacy for meaningful HbA1C reductions and better TIR, as well as fewer hypoglycemic events, provides strong evidence for adoption. On a technical level, the market is enjoying continuous innovation in sensor miniaturization, prolonging sensor life and digitalizing the sensor.

These strengths have strategic value connected to important market opportunities. The diabetes epidemic is growing worldwide, and the numbers of patients addressed are increasing. Expansion to Type 2 diabetes and, in recent years, the general wellness market greatly increases the customer base for CGM. The integration of smartphone, cloud and AI systems creates new opportunities for value added services. In the Asia and Africa region, emerging markets are large untapped growth markets where diabetes is becoming more prevalent, but need to catch up with CGM adoption.

Weaknesses and Threats (WT Strategy)

There are also inherent vulnerabilities to the market. In low and middle resource areas, the cost of the device is still a major limitation and may not be accessible to the patient who could benefit the most from intensive monitoring. Digital connectivity alone ignores people who do not have a smartphone and/or digital literacy. With some CGM systems, the monthly requirement of sensor replacement puts an additional financial burden on patients and operational strain on providers.

External threats encompass fast developments in technology that can yield obsolete products and shorten product life cycles. Different jurisdictions impose different regulations, leading to compliance costs and delays in market entry. The risks to data privacy from the continuous collection of health data also include reputational and legal risks. New technologies, such as non-invasive and minimally invasive ones, could challenge the current sensor paradigm.

8.2 PESTLE Analysis

Factor	Key Considerations
Political	Government reimbursement policies, NHS and Medicare coverage expansions, public health diabetes programs, regulatory frameworks (FDA, CE Mark, MHRA, CDSCO) governing device approvals.
Economic	Healthcare expenditure capacity, device affordability across income levels, insurance penetration, cost-effectiveness analyses supporting reimbursement decisions.
Social	Rising diabetes prevalence and awareness, demand for non-invasive and convenient monitoring, shifting patient expectations toward real-time health data, aging populations.
Technological	Advances in sensor accuracy and longevity, Bluetooth and smartphone integration, AI-driven glucose prediction, closed-loop insulin delivery systems, research into non-invasive CGM.
Legal	Medical device regulations, clinical trial requirements, data protection legislation (GDPR, HIPAA), intellectual property protections and patent landscapes.
Environmental	Medical waste reduction imperatives, sustainable product design, eco-friendly manufacturing practices, device recyclability considerations.

8.3 Porter's Five Forces Analysis

Force	Intensity	Key Drivers
Threat of New Entrants	Moderate	High R&D costs and regulatory barriers limit entry; however, digital health innovations and venture capital activity attract new participants.
Bargaining Power of Suppliers	Low to Moderate	Specialized component requirements exist, but established firms maintain strong supply chain control and multi-supplier strategies.
Bargaining Power of Buyers	Moderate to High	Multiple competing products, price sensitivity among patients and payers, and growing NHS/Medicare influence on procurement decisions increase buyer leverage.
Threat of Substitutes	Moderate	SMBG remains available and lower-cost; however, clinical evidence of CGM superiority and expanding reimbursement reduce long-term substitution risk.
Industry Rivalry	High	Intense competition among Abbott, Dexcom, and Medtronic on accuracy, features, pricing, and ecosystem integration; frequent product launches accelerate competitive cycles.

9. Data Analysis and Key Findings

9.1 Hypothesis Evaluation

The evidence compiled in this report constitutes substantial backing of the alternative hypothesis. Studies have consistently shown statistically and clinically significant improvements in glycemic control after CGM adoption in a variety of patient populations across a spectrum of care settings.

The most compelling evidence is from a retrospective study at MountainView Hospital, which showed that when SMBG was replaced by CGM, mean HbA1c was reduced by 4.17 percentage points, TIR was improved by 56 percentage points and there were significant decreases in both mild and severe hypoglycemia. The changes in these magnitudes are well beyond chance or regression to the mean, especially when no other treatment changes were found that could be seen as confounding.

The findings across all of these different patient groups and studies (pregnant women, Type 2 diabetes with cardiovascular risk, and the systematic reviews of Type 1 and Type 2 diabetes) all corroborate that CGM is more effective than SMBG in improving glycemic outcomes. So, the available evidence supports the alternative hypothesis (H_1).

9.2 Key Clinical Findings Summary

Clinical Outcome	Pre-CGM	Post-CGM	Direction
Mean HbA1c	11.21%	7.04%	Significant reduction
Time in Range (TIR)	18%	74%	Significant improvement
Mean Blood Glucose	286 mg/dL	158 mg/dL	Significant reduction
Glucose Variability (CoV)	39%	29%	Reduction (target <36% achieved)
Mild Hypoglycemia	4.75%	0.78%	Significant reduction
Severe Hypoglycemia	3.01%	0.20%	Significant reduction

9.3 Market Growth Findings

Glance at the market statistics and the trend of growth is clear and is accelerating over time, worldwide. The projected increase in market value from 2025 through 2033 has been nearly tripled due to clinical demand, new technology, and positive reimbursement environments. Looking at the market by region, Asia-Pacific is identified as the highest growth opportunity, as it has the biggest diabetic population, which is under-served, whereas North America leads the market volume.

9.4 Competitive Intelligence Findings

The competitive analysis shows a well-defined hierarchy in the market. Abbott has a dominant position through its cost leadership and extensive coverage of reimbursements in the NHS and internationally. Dexcom continues to hold a premium position with the best sensor accuracy and an extensive app system with market leading clinical performance. The switching costs and specialist adoption that come from integrated care systems provide Medtronic with a competitive advantage. Senseonics is playing in a protected market segment with its implantable technology, but with low commercial volumes.

As an ecosystem competition emerges, the competitive edge is no longer just in the sensor itself but in the ecosystem of data management, app integration, clinical decision support tools and much more that surrounds it. The merger of high accuracy, long sensor life, low cost and AI capabilities will define the future competitive landscape with a seamless patient experience.

10. Ethical Considerations

All data used in this research came from secondary sources, such as published peer-reviewed research studies, market intelligence reports, and publicly available corporate disclosures. No attempts to recruit patients, to intervene in their clinical care, or to collect personal health information was made during the research process. Thus, this study falls outside the criteria as per the standard guidelines of secondary research and does not need the ethics committee approval.

In this report, all data interpreted and presented have been properly cited to its source. The analysis is not a 'copy and paste' job but a synthesis and independent interpretation that is academically sound and respectful of intellectual property. The sources chosen have been identified based on their credibility, transparency in methodology and relevance to the research goals. This study's results are presented in an objective and unbiased manner. If the evidence is 'mixed' or 'contested' the two sides are recognised. Due to the limitations of the studies that formed the basis for this document, such as small sample sizes, single center designs, and short follow-up periods in some clinical studies, there has been a balanced and honest representation of the evidence base noted.

11. Implications of Research

11.1 Clinical Implications

Clinical evidence presented in this report strongly suggests the increased use of CGM systems in the broader diabetes care arena. Healthcare providers can expect significant reductions in hypoglycemia rates, HbA1c, and improvements in TIR when moving patients from SMBG to CGM, especially when a patient has suboptimal glycemic control. This evidence needs to be used to develop clinical guidelines and to help guide prescribing choices, especially with the increasing availability and affordability of CGM.

The cardiac effects that have been shown in Type 2 patients who have used CGM, such as lowering blood pressure, lipids, and predicted 10-year cardiovascular risk, extend beyond the management of glucose, with the potential to be beneficial for other risk factors. The implications for these findings are for cardiovascular prevention strategies in high-risk diabetic groups.

11.2 Market and Business Implications

The study emphasizes the need to strike a balance between performance and accessibility for industry stakeholders. Abbott's volume leadership is proof that low cost innovation can be a more effective growth strategy than premium positioning in the global markets. On the other hand, Dexcom's triumph in the high-end markets is a testament to the fact that there are loyal and high-value customers willing to pay more for improved accuracy and digital integration.

Companies with the capability to create cost-effective, easy-to-use devices that will appeal to OTC consumers have a structural opportunity with the growth of the Type 2 diabetes and wellness CGM market. Access to the drug from prescription-only to over-the-counter status, such as Dexcom's Stelo, may be a major competitive landscape in the next ten years, if not a more determinant one in the next ten years.

11.3 Policy Implications

Evidence indicates that health systems and policy makers should invest in CGM access programs, especially for insulin-treated patients. Medicare's new reimbursement policy, which covered CGM for T2D patients who are not insulin users, is a positive policy shift forward that is consistent with the clinical evidence. Targeted subsidies or public procurement programmes in emerging markets like India may help to speed up the uptake of these products in a large, underdiagnosed and undertreated diabetic population.

12. Conclusion

This report has conducted a thorough secondary data analysis of the Continuous Glucose Monitoring (CGM) systems, reviewing their clinical utility and market landscape. The results show that CGM offers significant glycemic control benefits in a wide variety of patient populations, with decreases in HbA1C, increases in Time in Range, and decreases in hypoglycemic events. Based on the weight of the evidence, the null hypothesis is rejected and the conclusion is accepted that CGM is significantly better at improving glycemic outcomes than conventional SMBG.

On a market level, the CGM market is progressing through a period of strong and steady growth, fuelled by the rising incidence of diabetes, more positive reimbursement policies and ongoing technology advancement. The market is projected to expand at 15.10% CAGR from USD 13.38 billion in 2025 to USD 41.41 billion in 2033. Abbott Laboratories and Dexcom dominate the market with complementary strategies, while Medtronic and Senseonics hold strong secondary market shares.

The CGM market is taking shape as a medical device specialty product line now becoming a larger part of the digital health landscape. The technology must be more widely accessible in a cost-effective manner, integrate high accuracy sensors with an AI data platform and expand its use to Type 2 diabetes and prediabetes and wellness applications to ensure its future competitive success. The message for healthcare stakeholders of this research is clear: CGM is not a new technology, but a proven diabetes care standard that has the potential to transform the diabetes care landscape on a global scale.

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