MARKET REPORT

DIABETES SELF-MONITORING DEVICES IN LOW- AND MIDDLE-INCOME COUNTRIES

OCTOBER 2021

CLINTON HEALTH ACCESS INITIATIVE
FIND Diagnosis for all
acciss Addressing the Challenge and Constraints of Insulin Sources and Supply
HAI HEALTH ACTION INTERNATIONAL

Market Report of Diabetes Self-Monitoring Devices in LMICs

Developed by the Clinton Health Access Initiative (CHAI)

October 2021

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Acronyms

ACCISS	Addressing the Challenge and Constraints of Insulin Sources and Supply
ADA	American Diabetes Association
APAC	Asia Pacific
CAGR	Compound Annual Growth Rate
CGM	Continuous Glucose Monitoring
CHAI	Clinton Health Access Initiative
COGS	Cost of Goods Sold
DM	Diabetes Mellitus
EMEA	Europe, Middle East, and Africa
FDA	Food and Drug Administration
FGM	Flash Glucose Monitoring
FIND	Foundation for Innovative New Diagnostics
HAI	Health Action International
HCW	Health Care Worker
HIC	High-Income Country
IDF	International Diabetes Federation
ISO	International Organization for Standardization
LADA	Latin American Diabetes Association
LATAM	Latin America
LIC	Low-Income Country
LMIC	Low- and Middle-Income Country
MCH	Maternal and Child Health
MIC	Middle-Income Country
MoH	Ministry of Health
NCD	Non-Communicable Disease
NHI	National Health Insurance
OEM	Original Equipment Manufacturer
OOP	Out-of-Pocket
PQ	Pre-Qualification
RoW	Rest of the World
SEA	South-East Asia
SMBG	Self-Monitoring Blood Glucose
SSA	Sub-Saharan Africa
type 1 diabetes	Type 1 Diabetes Mellitus
type 2 diabetes	Type 2 Diabetes Mellitus
TPP	Target Product Profile
UHC	Universal Health Coverage
UMIC	Upper Middle-Income Countries
WB	World Bank
WHO	World Health Organization

EXECUTIVE SUMMARY

The burden of diabetes mellitus (DM) is large and growing worldwide. Low- and middle-income countries (LMICs) are disproportionately affected and account for over three-quarters of the global diabetes burden. A chronic non-communicable disease (NCD), diabetes can have severe and life-threatening outcomes if not properly managed. Glucose self-monitoring, or the use of home-based diagnostic devices to routinely monitor glucose levels, is recommended for people living with diabetes to adjust treatment dosages and prevent dangerous fluctuations in glucose levels. Glucose self-monitoring is, therefore, an integral component of diabetes management. There are two broad product classes of glucose self-monitoring devices: (1) self-monitoring blood glucose (SMBG) systems whose basic technology has been the standard of care for decades; and (2) continuous glucose monitoring (CGM) systems, which are a newer, more expensive, and technologically advanced product class.

Despite the significant and growing need, multiple key market barriers exist that limit access to glucose self-monitoring devices for people living with diabetes in LMICs:

1. **High annual cost of devices and consumables** is a primary barrier to access. High cost is driven by product life cycle, since products are designed to be frequently updated, and by the need for a continuous supply of ancillary product components (i.e., SMBG test strips and lancets, and CGM sensors). High markups along the supply chain further contribute to the products' high prices. Total annual cost of SMBG systems in LMICs is cost-prohibitive for many, especially given the need to use the devices alongside lifelong diabetes treatment.
2. **Minimal public financing** for product procurement and provision results in glucose self-monitoring devices being accessed primarily in private pharmacies. In turn, access is dependent on individuals' ability to pay out-of-pocket (OOP) for the devices, leading to inequitable access and health disparities.
3. **Lack of optimal product profile for LMICs** leaves buyers to select products based on factors such as price or brand preference, as opposed to clinical or regulatory guidance. As such, glucose self-monitoring devices are increasingly marketed and purchased as health accessories, including products with potentially sub-optimal quality or contextual relevance.
4. **Inadequate diabetes health services and programs** lead to inadequate education and support for individuals managing their diabetes. As a result, people living with diabetes are left without adequate knowledge of how to self-monitor their glucose levels, including lack of training on how to use glucose self-monitoring devices properly.

Given the complex interplay of these barriers, no one intervention is sufficient as a standalone solution. We, therefore, propose several recommendations at the international and national levels to address these challenges, including: (1) Advocating for bilateral donor support for glucose self-monitoring; (2) Developing a Target Product Profile for devices appropriate for LMIC settings; (3) Improving market transparency, both on the demand and supply side; (4) Establishing access price agreements with suppliers; (5) Exploring alternative procurement channels such as coordinated procurement across multiple LMICs; (6) Including glucose self-monitoring devices in National Health Insurance (NHI) plans; (7) Strengthening overall diabetes care in LMICs; and (8) Conducting additional research to fill key evidence gaps.

We posit that these actions are an essential step to meaningfully shape the glucose self-monitoring device market and significantly improve health outcomes for people living with diabetes in LMICs.

1. SCOPE AND METHODOLOGY

1.1. Report Scope

This report explores the current state of access to blood glucose self-monitoring devices in LMICs. While SMBG and CGM systems are also used in clinical settings, the focus of the report is on the technology's use in home settings. In some cases, however, the data presented may also include the use of the technology in hospital settings given challenges in disaggregating the data by use case. Although paramount to improving health outcomes of people living with diabetes, insulin and other diabetes medicines and their access challenges in LMICs are beyond the scope of this report.

1.2. Data Collection and Analysis

This report intends to promote transparency in the glucose self-monitoring market by addressing the lack of LMIC-relevant market intelligence. The insights presented are drawn from various sources:

- **Desktop research** including a review of published data, policy documents, supplier websites, and data internal to Health Action International (HAI), the Foundation for Innovative New Diagnostics (FIND) and the Clinton Health Access Initiative (CHAI) covered the following topics: the burden of diabetes in LMICs, the purpose of glucose self-monitoring, the population requiring self-monitoring, corresponding clinical guidelines, regulatory requirements, and supplier profiles.
- **Primary and secondary quantitative market intelligence data** collected by Mordor Intelligence and IQVIA provided high-level trends in glucose self-monitoring device sales and pricing across regions and income levels.[i] To mitigate data gaps, the data were cross-checked and validated using other public market reports, desktop research, and expert consultations.
    - IQVIA provided 2018 market-size data for 71 countries (see Appendix A) and SMBG pricing insights for select countries (USA, Brazil, Mexico, and Argentina).
    - Mordor Intelligence provided 2019-2025 market-share data and pricing insights for 19 countries for both SMBG and CGM systems.[ii]
- **Surveys administered to country-level diabetes stakeholders** across eight countries. The surveys asked about trends in glucose self-monitoring guidelines, procurement, accessibility, and affordability in the public and private sectors to understand barriers to access that people living with diabetes face.
- **Interviews with individuals from glucose self-monitoring device suppliers** were conducted with 13 current or former employees across five companies'[iii] relevant business units.[iv] The interviews explored companies' commercialisation strategies in LMICs across the value chain, as well as their approaches to addressing barriers to access.

[i] Given price variability, individual country prices are not quoted in the report.
[ii] The report did not look deeply into pricing trends and specific in-country dynamics to avoid compounding assumptions (those that Mordor used to arrive at certain data plus assumptions based on our understanding of the market).
[iii] Individuals from SMBG manufacturers interviewed: Lifescan, Roche, SD Biosensor. Individuals from CGM manufacturers interviewed: Dexcom, Medtronic
iv Interviewees were representative of various business units, including: Research & Development, Manufacturing & Operations, Access Program, Emerging Markets, Marketing & Commercialization. Information provided from the experts are solely their opinion and do not represent the views of the authors or of the suppliers.

Throughout the report, assumptions on the frequency of self-monitoring, product use, and replacement were used to contextualise market data. Assumptions were based on: (a) international guidelines; (b) expert opinion; and (c) operational experience in LMICs. Details of the assumptions can be found in Appendix B.

2. INTRODUCTION

2.1. Diabetes Mellitus Overview

Diabetes Mellitus is a chronic metabolic condition, characterised by insufficient production or utilisation of insulin which regulates glucose, or blood sugar.[1] The number of people living with diabetes worldwide is increasing rapidly and is projected to grow from 463 million in 2019 to 700 million in 2045.[v, 2] LMICs shoulder a disproportionate and growing burden of disease, accounting for 79% of people living with diabetes (368 million) in 2019 and expecting to reach 83% (588 million) by 2045.[3]

There are two[vi] main types of diabetes:

- **Type 1 Diabetes Mellitus (type 1 diabetes)**: Characterised by an absence or insufficient amount of beta cells in the pancreas leading to the body's lack of insulin production. type 1 diabetes develops more frequently in children and adolescents and accounts foran estimated nine million cases globally.[vii, 4]
- **Type 2 Diabetes Mellitus (type 2 diabetes)**: Characterised by the body's inability to use the insulin produced. type 2 diabetes is most commonly diagnosed in adults and accounts for most cases of diabetes diagnoses worldwide.[viii, 5]

Without functioning insulin, the body cannot convert glucose into energy, leading to raised glucose levels in the blood (known as 'hyperglycemia').[6] Over time, hyperglycemia can cause debilitating damage, including cardiovascular disease, nerve damage (neuropathy), kidney damage (nephropathy), and vision loss/blindness (retinopathy).[7] Given the body's inability to regulate glucose, people living with diabetes who take insulin and/or some oral medicines, are also at risk of very low blood glucose levels (known as 'hypoglycemia')[ix] — which in severe cases can cause seizure, loss of consciousness, and even death.[8] These complications can be delayed or even prevented by carefully managing glucose levels, including via glucose self-monitoring products.

2.2. Glucose Self-Monitoring Products

Glucose self-monitoring refers to the practice of individuals self-testing their glucose levels outside of health facilities. Glucose self-monitoring guides individuals' decisions on treatment, nutrition, and physical activity,[9] and is specifically used to (a) adjust insulin dosages; (b) ensure oral medication is adequately controlling glucose levels; and (c) monitor potential hypoglycemic or hyperglycemic incidents.[10]

Glucose self-monitoring devices fall under two main product classes:

1. **Self-monitoring of blood glucose (SMBG) systems,** which have been in use since the 1980s,[11] operate by pricking the skin with a disposable lancet and applying the blood sample to a disposable test strip, which is inserted into a portable reader (alternatively, called a meter) to produce a point-of-care reading on an individual's blood glucose level.[12]

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[v] Diabetes prevalence growth is primarily driven by a rise in type 2 diabetes.
[vi] Gestational Diabetes (GDM) is characterized by high blood glucose during the pregnancy and is not considered here as it usually disappears after pregnancy.
[vii] type 1 diabetes causes are still unknown but at present cannot be prevented.
[viii] type 2 diabetes principal causes are consumption of unhealthy foods and inactive/sedentary lifestyles.
[ix] Hypoglycemia can be caused by taking too much insulin or other diabetes medicine, not eating enough, or exercising too much.

2. **Continuous glucose monitoring (CGM) systems** first emerged as a standalone alternative to SMBG in 2016,[13] and operate by burrowing a semi-permanent microneedle sensor under the skin which conducts readings that a transmitter sends wirelessly to a portable meter (or a smartphone) that displays average glucose readings every 1-5 minutes as well as glucose trend data.[14] There are two types of CGM: *real-time* and *intermittently scanned* (also known as flash glucose monitoring (FGM) devices). While both products provide glucose levels over a range of time, FGM devices require users to purposefully scan the sensor to receive glucose readings (including readings performed by the device during the scans), while real-time CGM systems automatically and continuously provide glucose readings.

Table 1 below outlines key differentiating characteristics for SMBG and CGM systems.

Table 1. Key differentiating characteristics for SMBG and CGM systems

Component	Description
SMBG Meter *(Durable)*	Meter technology is relatively standardised, including basic to premium products. Key differences among them include meter size/weight, battery requirements, data memory size, test time (typically 5-30 seconds), display type (i.e., touch screen vs. e-ink screen), wireless connectivity, and test strip compatibility.[15, 16] Whereas meters are marketed and designed to be long-lasting durables (if cared for, meters can generally work for ten years), consumers are not guaranteed use of meters for their full lifetime given that technical and/or operational upgrades to the meters every several years often result in new test strips that are incompatible with the old meter. [17]
SMBG Test Strip *(Consumable)*	Test strips are single-use products that, despite being operationally standardised, are designed for specific meter model(s), such that test strips do not fit or work when used across different company brands, or even across different models under the same brand. The key differences between test trips include the enzyme used (glucose oxidase or glucose dehydrogenase)[18].
SMBG Lancet *(Consumable)*	The most basic of the SMBG components, lancets are intended to be single-use devices used to prick the skin for blood samples. Although lancets can be used independently, reusable lancing devices can help the lancets prick the skin more effectively and less painfully.[19]
CGM Receiver[20] *(Durable)*	Increasingly, CGM receivers can be replaced by compatible smartphones. The key differences among CGM receivers/operating systems include: - **Ability to provide glucose level alerts:** Known as alerts if glucose levels are too high or low. Real-time alerts available in Dexcom and Medtronic's products but not in Abbott's product; - **Automatic versus purposeful scanning to begin data collection**[21,22:] Only Abbott's product requires the individuals to purposively scan the sensor using their reader to initiate data collection.
CGM Sensor *(Consumable)*	Key differences between the sensors include[23]:

	- **Accuracy:** Dexcom is known to have the most accurate sensors, followed by Abbott; - **Warm-up period**: Known as the time after sensor insertion until the sensor can be accurately used. Ranges from 1 hour (Abbott), to 2 hours (Dexcom and Medtronic); - **Replacement rate**: Sensor lifespan ranges from 7 days (Medtronic), 10 days (Dexcom), and 14 days (Abbott). An alternative is Eversense, which is a surgically implanted sensor that can be used for 3-6 months; - **Application mode:** While most of the suppliers' sensors are applied with a single push sensor insert, Senseonics' sensor is surgically implanted in the arm. - **Calibration requirements**[24]: Whereas Abbott and Dexcom's products do not require calibration, Medtronic's must be calibrated twice daily with a finger-stick glucose reading to ensure accuracy.
CGM Transmitter *(Durable)*	The key difference among transmitters is their **charging requirement**[25]: Some transmitters require daily/bi-daily charging (Senseonics), others need charging once weekly (Medtronic), whereas some must be replaced every 90 days (Dexcom). Abbott's product does not have a separate transmitter which is instead combined with the sensor.

In high-income countries (HICs), CGMs are emerging as the preferred product for many individuals, particularly those on insulin-intensive regimens. In LMICs, SMBG systems still dominate the market given that CGMs are a newer technology with higher costs.

2.3. Clinical Guidelines for Glucose Self-Monitoring

Glucose self-monitoring clinical guidelines depend on whether the individual requires insulin treatment:

- **Insulin-requiring individuals** include all people living with type 1 diabetes and insulin-requiring type 2 diabetes[x][26] individuals. Both the World Health Organization (WHO) and the American Diabetes Association (ADA)[xi] recommend glucose self-monitoring for these groups.[27,28,29] Although the frequency of self-monitoring varies on a case-by-case basis, the ADA recommends that individuals on insulin-intensive regimens (multi-dose or insulin pump therapy) check their glucose levels anywhere from six to 10 or more times per day if using SMBG systems, at least every eight hours if using an intermittently scanned CGM (to obtain stored data), or daily use of a real-time CGM.[xii,30] Alternatively, the ADA recommends that CGM be "considered from the outset of the diagnosis of diabetes that requires insulin management,"[31] (including intensive and non-intensive treatment).
- **Non-insulin-requiring individuals** are people living with type 2 diabetes that are not on insulin treatment. There are no World Health Organization (WHO) or American Diabetes

[x] An estimated 63M people living with Type 2 diabetes require insulin, projected to increase to 79M people by 2030.

[xi] Every year, the ADA releases updated guidelines on diabetes clinical practice which are widely recognised as the gold standard.

[xii] The ADA encourages checking glucose levels prior to meals and snacks, at bedtime, occasionally postprandially, prior to exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to and while performing critical tasks such as driving.

Association (ADA) recommendations on the use of glucose self-monitoring devices for non-insulin-treated individuals living with type 2 diabetes.[xiii] The ADA's cited data, however, suggests that more frequent monitoring is correlated with an increased likelihood of achieving healthy glucose levels or glycemic targets.[xiv, 32, 33]

Adhering to ADA guidelines can be challenging. With regards to SMBG, the burden of continuous manual testing can be taxing, especially for people who need to test multiple times a day. CGM systems can streamline glucose monitoring as testing is automated and can be integrated with automated treatment delivery systems. However, CGM systems are also associated with drawbacks, including (1) perceived or actual discomfort of having a device attached to the body;[34] (2) skin irritation including allergic reactions[35-36]; and (3) excessive data and monitoring particularly for individuals on non-intensive therapies. As a result, even where ADA guidelines are widely implemented and CGM systems are accessible, they may not be fully adopted by people with diabetes due to the adherence challenges they present.

[xiii] Although glucose self-monitoring has not been proven to improve clinical outcomes among noninsulin-requiring people living with type 2 diabetes patients, the ADA suggests that it may be helpful when altering diet, physical activity, and/or medications (particularly medications that can cause hypoglycemia) in conjunction with a treatment adjustment program.

[xiv] Glycosylated Hemoglobin (or A1c) is a measure of your average blood glucose control over the previous three months. The ADA's goal A1c for most people living with diabetes is <7% (53 mmol/mol)— people without diabetes have A1c levels between 4-6%.

3. GLOBAL MARKET LANDSCAPE

3.1. Market for Glucose-Self-Monitoring Devices

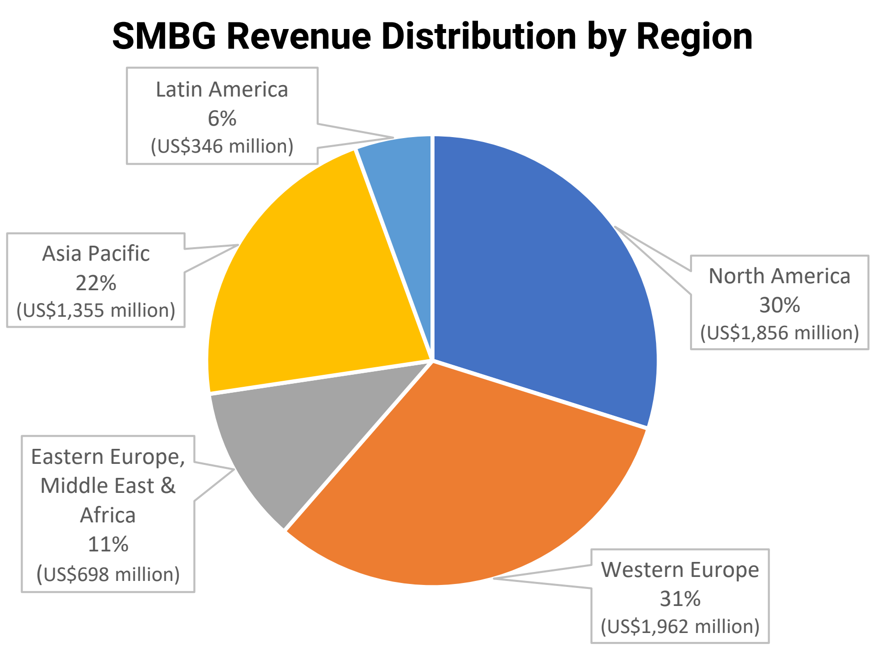
3.1.1. SMBG Market

3.1.1.1.1. Global revenue distribution

According to 2018 IQVIA data, the annual market value for SMBG systems (including meters, test strips, and lancets) is estimated to be US$6.4 billion for the 71 countries listed in Appendix A.[xv] While the overall market for SMBG systems is expanding due to increasing awareness of diabetes and favourable reimbursement policies (Mordor Intelligence data suggest an estimated Compound Annual Growth Rate (CAGR) of 8%), its total share of the self-glucose monitoring market is expected to contract due to a comparatively faster-growing CGM market in HICs.[37]

The majority of SMBG revenue continues to be driven by HICs in North America and Western Europe, as highlighted in Graph 1.

Graph 1. SMBG revenue (from meters and test strips) distribution by region, 2018 figures [38]



3.1.1.2. Suppliers

Globally, there are over 100 suppliers of glucose self-monitoring devices,[39] predominantly SMBG suppliers with undifferentiated products. However, a handful of suppliers dominate approximately 80% of the market (according to 2018 IQVIA data). Table 1 below presents the SMBG suppliers with the largest footprint in HICs and LMICs.

[xv] This section uses value data since volume data is not reported by manufacturers and market intelligence agencies often estimate volume data based on average selling prices. Therefore, accuracy of volume data is questionable.

Table 2. Profiles of major SMBG suppliers[40]

Company	HQ	Product Portfolio	Ownership	HIC Market Share[xvi] (2018)	Rest of World Market Share[xvii] (2018)	SMBG Revenue (in USD Millions), 2018 figures
Abbott*	US	SMBG & CGM	Public	9%	13%	$737[xviii]
Ascencia	Switzerland	SMBG	Private	21%	18%	$1,040
Lifescan	US	SMBG	Private	24%	21%	$1,341[xix]
Roche*	Switzerland	SMBG	Public	24%	39%	$1,793
Other Suppliers	N/A	SMBG	N/A	23%	28%	$1,478

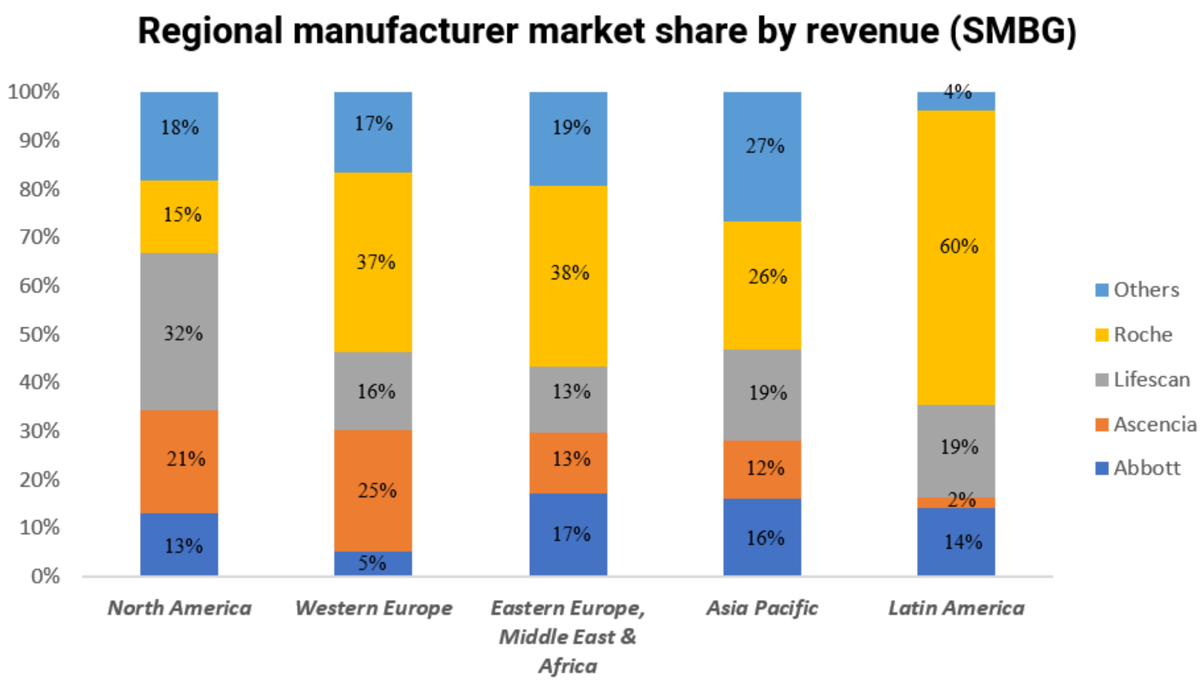
*Companies whose portfolios range a number of disease areas and products in addition to diabetes and SMBG systems.

Expert interviews suggest that SMBG market leaders are seeing declining revenues in HICs, sparking expansion into LMICs for two reasons:

1. **Growing CGM market share** is contracting the SMBG market in HICs where there are already high levels of met need for glucose self-monitoring devices.[41] For example, in 2020, Roche's diabetes care sales decreased by 5% due to users switching to CGM (and partly due to COVID-19) with the main decline (~11%) coming from the Europe, Middle East and Africa (EMEA) region (notably, Germany, UK, and Italy).[42]
2. **Stiff SMBG supplier competition** from smaller manufacturers from India and China has slowed market growth, particularly in the Asia Pacific region where these smaller manufacturers are headquartered.[43] This can be seen in Graph 2 where multiple 'Other Suppliers' collectively control approximately 34% of the total market in the Asia Pacific region. However, smaller suppliers have struggled to become market leaders in LMICs since most sales are in retail pharmacies and are driven by brand-conscious consumers.[44]

[xvi] HIC countries constitute the US, Canada, Japan, and Western Europe. The analysis does not include all HICs and may include some non-HICs in the Western European region.
[xvii] Rest of the World (RoW) includes Eastern Europe, Middle East, and Africa (EEMEA), Latin America and APAC (excluding Japan).
[xviii] Includes the SMBG products only and excludes FreeStyle Navigator CGM and FreeStyle Libre FGM product revenues.
[xix] Lifescan was a former subsidiary of Johnson & Johnson, and was sold to Platinum Equity, LLC in 2018. According to a 2018 press release by Lifescan, their net revenue in 2017 was approximately US$1.5 billion

Graph 2. Global SMBG revenue (from meters and test strips) split by region, 2018 figures[45]



3.1.1.3. Product Differentiation

Compared to models offered in HICs, the glucose self-monitoring devices available in LMICs are often limited to suppliers' basic or stripped-down models to align with consumers' purchasing power. This is also reflected in the availability of test pack sizes for strips: conversations with suppliers reveal that[46] they may offer packs of 25 test strips or smaller, as compared to the standard packs of 50 or even 100 test strips for HIC markets.

That said, strong supplier competition has led market leaders to try to differentiate their products from the cheaper, basic, smaller suppliers' models by focusing their marketing on minor differences in product features (e.g., colour-coded glucose level readings) and emphasising the accuracy of their products even if they meet the same quality standards as other suppliers (see Section 4.2). This market strategy enables market leaders to sell higher-priced products, regardless of if the product offers meaningful advantages to consumers. As a result, products purchased in LMICs may not be the most cost-effective.

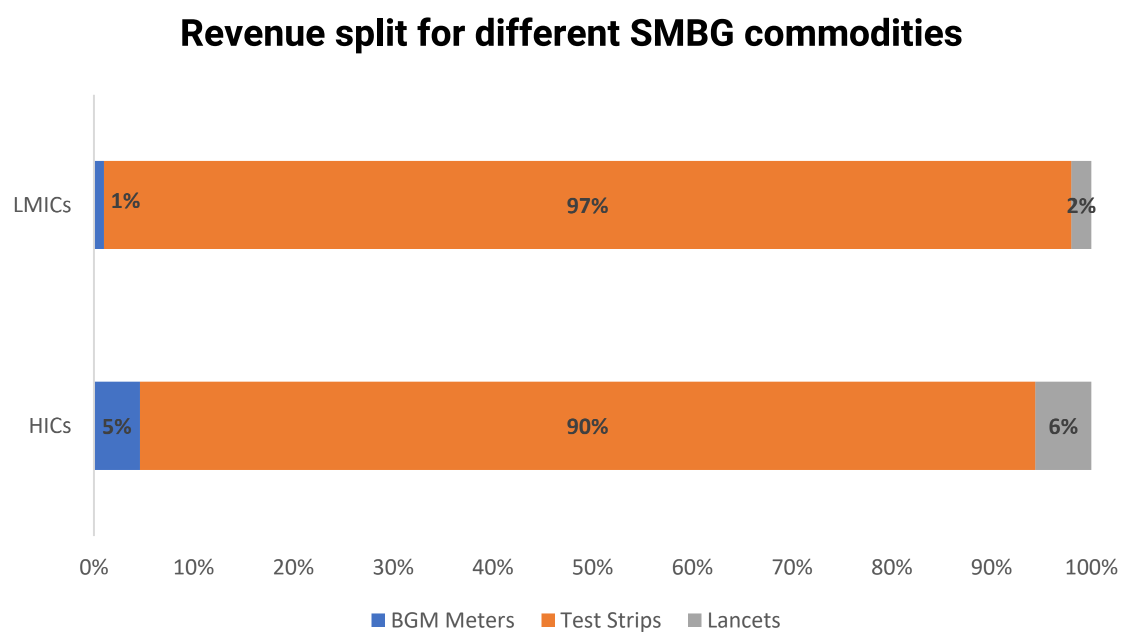
Further detail on SBGM system components and differentiating characteristics is provided in Appendix D.

3.1.1.4. Revenue Drivers for SMBG Suppliers

As illustrated in Graph 3, the revenue for SMBG suppliers is driven primarily by test strips, regardless of country income level. The main reason for this is because people living with diabetes require several strips per day, leading to high volumes of consumption (see Appendix B for replacement frequencies). To guarantee test strip sales, suppliers limit the compatibility of proprietary test strips with particular meter models, such that test strips do not work with other meter brands, or often even with other models within the same brand (a similar strategy to that used in retail/consumer industries, such as razors and blades[47,48] or printers and cartridges). Many suppliers also provide meters for free to encourage consumers to switch over to their platform, thereby driving test strip sales and reducing revenue generation from meters. Although meters are more costly to manufacture than test strips, suppliers are willing to absorb the cost of providing free meters given the potential for increased test strip sales, which are their revenue driver.

Although lancets are theoretically used as frequently as test strips, they are not a revenue driver given that the product is not specialised, are often reused, and can be easily replaced with alternate sharps or low-cost brands.

Graph 3. Revenue (by value) split from annual consumption of SMBG commodities by insulin-requiring individuals[xx]



3.1.2. CGM Market

3.1.2.1. Global revenue distribution

Based on suppliers' revenue (see Table 2), it is estimated that the market for CGM systems was upwards of $4.5 billion in 2020. Mordor Intelligence data suggest the CGM market is growing rapidly at an estimated global CAGR of 13%.[49] Although CGM was initially created for people living with type 1 diabetes and insulin-treated type 2 diabetes, they are becoming increasingly popular with the larger cohort of people living with type 2 diabetes and "pre-diabetes" in HICs. This could be due to the growing market for devices enabling continuous monitoring of health data in daily life (for example, Fitbit or Apple Watch) which encourage healthier lifestyles. In line with this trend, CGM suppliers are now marketing the devices in HICs as tools used to improve lifestyle habits in addition to managing diabetes treatment.

[xx] This is a conversative estimate based on lower thresholds for each commodity as listed in Appendix B.

3.1.2.2. Suppliers

Unlike the SMBG market, the CGM market only has a few suppliers, each with differentiated products. Medtronic was the product class originator and market leader until Dexcom's 2012 G-series release established a new standard for CGM accuracy.[50] Since then, Medtronic has focused on developing a niche market of CGM systems that are integrated with insulin pump therapy, while Dexcom has established broader CGM market leadership.[51] Abbott also emerged as a strong CGM competitor with the release of the FreeStyle Libre platform in 2014 in Europe and the US in 2017[52], being the lowest priced CGM and the first CGM system to eliminate the need for finger-pricking calibration, Abbott's FreeStyle Libre is now the world's most used CGM system.[xxi, 53, 54]

Further detail on CGM system components and differentiating characteristics is provided in Appendix D.

Table 3. Profiles of Major CGM Suppliers

Company	HQ	Product Portfolio	Ownership	CGM Global Diabetes Revenue (in USD Millions), 2020 figures[xxii]
Abbott*	US	SMBG & CGM	Public	$2,635[55, xxiii]
Dexcom	US	CGM	Public	$1,927[56]
Medtronic*	US	CGM	Public	$2,368[xxiv, 57]

*Companies whose portfolios range a number of disease areas and products in addition to diabetes and CGM devices.

3.1.2.3. Revenue Drivers for CGM Systems

Within the CGM market, the revenue for suppliers is driven primarily by sensors. Like test strips, sensors are consumed frequently (every 10-14 days on average) and account for 60-90% of the total sales revenue in the CGM market.[58] By contrast, transmitters can last for 90 days or be recharged, depending on the model, and therefore are not sold in high volumes. Similarly, although receivers can last for years, they are increasingly being replaced by smartphones and are therefore not a major source of revenue for suppliers.

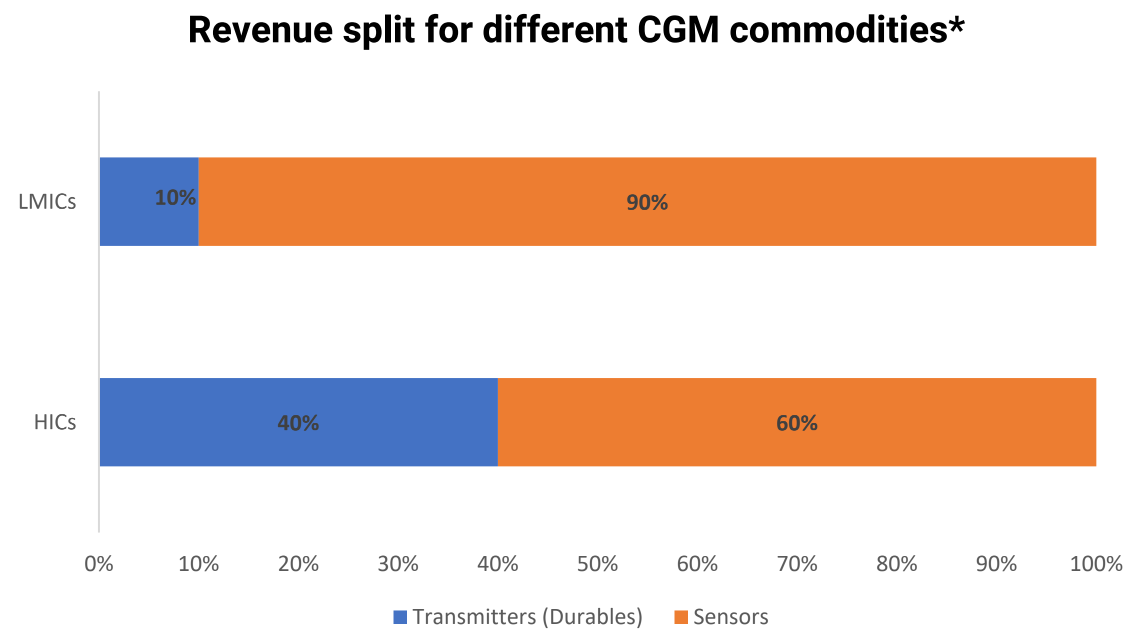
[xxi] Growth in Abbott's diabetes care revenue is primarily attributed to Abbott's CGM series, FreeStyle Libre, whose sales grew 43% from 2019 to 2020 and ~70% from 2018 to 2020.

[xxii] CGM penetration is expectedly concentrated to HICs and thus, it is expected that most of this revenue is in HICs.

[xxiii] Abbott's total diabetes revenue in 2020 was US$3.2 billion of which US$2.6 billion is estimated to be from their FreeStyle Libre (FGM device) (based on Abbott's 2020 Annual Report).

[xxiv] This includes revenues from Medtronic's Insulin Pump sales. Split between their insulin pump and glucose monitoring devices is not available.

Graph 4. Revenue split from annual consumption of CGM commodities by insulin-requiring individuals [xxv, xxvi]



*The difference between transmitter-driven revenue in HICs versus in LMICs may be explained by the predominance of Abbott's CGM in LMICs whose transmitter is combined with its sensor. Therefore, sales of Abbott's CGM are only reflected as sensor sales.

3.2. Product Manufacturing

Manufacturing processes are important drivers of product accuracy, affordability and availability, and therefore an important determinant of market dynamics. The various product components and their differing frequencies of use and replacement are unique to glucose self-monitoring devices and pose several key manufacturing considerations.

3.2.1. Complexity of Manufacturing Process

Unlike the relatively simple manufacturing process for SMBG systems, CGM systems have more complex requirements. Sensors, specifically, are the most complex product component to manufacture, driven by the nature of the product part being (i) semi-implantable and the precise chemistry ensuring their (ii) accurate reading and transmission of glucose levels over time. Furthermore, because sensors are the most frequently replaced part of a CGM, reaching high levels of sensor production is key to ensuring a sustainable business. Given the complexities of sensor manufacturing, however, only the few CGM suppliers on the market have managed to manufacture highly accurate sensors at high volumes.

3.2.2. Quality Control Measures

The need for accuracy in glucose self-monitoring products has led market leaders to engage in voluntary quality control processes—ranging from destructive testing during the manufacturing process to routine accuracy trials for products sold to consumers. Because such quality control processes add additional steps, scrap, and production costs, some suppliers may not be as rigorous,

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[xxv] This is a conversative estimate based on lower thresholds for each commodity as listed in. Appendix B.
[xxvi] Most CGM models have independent transmitters while Abbot's FreeStyle Libre, only has a sensor (with an in-built transmitter) and receiver.

especially smaller suppliers without expendable capital. Lack of strict quality control methods can result in sub-quality or non-reliable products—an identified problem, including for products that originally met international regulatory standards (see Section 4.2).

3.2.3. Production Capacity and Planning

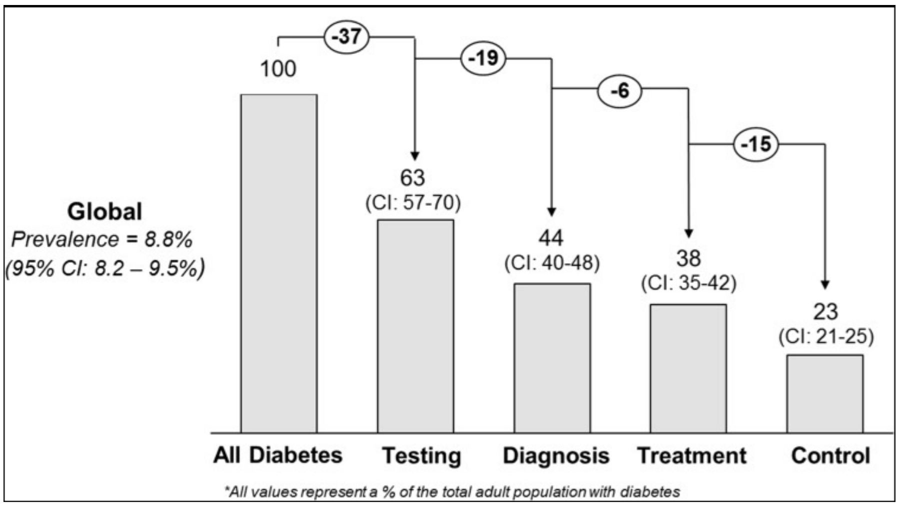
The need for a continuous supply of consumables (SMBG test strips and lancets, and CGM sensors) requires that suppliers have adequate production capacity and robust capacity planning processes. With the SMBG manufacturing process largely standardised, most large manufacturers have adequate production processes to meet current demand. However, visibility into future demand is a challenge, particularly in LMICs where there is limited historical consumption and epidemiological data. To plan for production capacity changes given demand uncertainties, suppliers may invest in a reserve of additional production capacity, known as buffer capacity, to use in case of demand surges, or suppliers may simply avoid expanding into new markets to ensure they can meet demand in existing markets. In the longer term, suppliers may establish new manufacturing sites or partnerships to increase overall production capacity and expedite entry or competition in new markets.

These production capacity challenges are felt acutely by smaller suppliers without high levels of capital to invest in high-volume production facilities and which as a result are operating at maximum, or near-maximum capacity. Consequently, these smaller companies may struggle to meet fluctuations in demand, potentially causing supply shortages or stockouts, particularly affecting consumers who opt for products from these smaller companies due to price.

4. BARRIERS TO ACCESS IN LMICS

The diabetes cascade of care is a major problem. Notably, the the gap between diabetes treatment and glycemic control indicates that even individuals receiving diabetes treatment are not guaranteed good health outcomes. A 2019 study across 28 LMICs suggests that there is a 15% drop between people living with diabetes who receive treatment and who have glycemic control (Figure 1).[59] Although influenced by numerous factors, this discrepancy is driven by irregular access to insulin and oral anti-diabetic drugs, as well as poor access to and use of glucose self-monitoring devices, which are essential to managing glucose levels.

Figure 1. The global diabetes cascade of care in population-based surveys conducted in 28 LMICs between 2008 and 2016.[60]



This section outlines factors that hamper access to glucose self-monitoring for people living with diabetes in LMICs, including barriers that manifest at the global, supplier, country, and individual levels. Given the limited footprint of CGM systems in LMICs, this section focuses predominantly on access challenges for SMBG systems.

4.1. Product Characteristics

Access to glucose self-monitoring is dependent upon the availability of the right products that fit the needs of individuals in LMIC settings. Although there are numerous glucose self-monitoring devices on the market, there remain technology-specific challenges preventing widespread usage of these products.

4.1.1. Target Product Profile

Although several WHO publications recommend glucose meters and test strip use in health facilities,[xxvii] the WHO does not provide any technical guidance on desired product characteristics for glucose self-monitoring devices.[61-62]

Lack of WHO guidance on minimal and optimal product characteristics and the variety of commercialised glucose self-monitoring products available lead to several issues. Firstly, it results in low confidence among buyers (both public and private procurement agents as well as individual

[xxvii] Glucose meters and test strips are included in the WHO Package of Essential Non-communicable (PEN) Diseases Interventions for Primary Health Care's Essential NCD Technologies and Tools List and the WHO Model List of Essential In Vitro Diagnostics.

consumers) on which products to purchase. In response, buyers often rely on high-priced, branded commodities that are trusted over smaller, unknown suppliers. In other cases, buyers can feel paralysed by the number of options available and not purchase anything at all. For public-sector procurers, this paralysis also stems from severe resource constraints and the need for cost-effective purchases. Lastly, uncertainty over the right product can lead to purchasing low volumes across several product types, resulting in higher unit prices, especially if the devices are purchased from different manufacturers/suppliers.

4.1.2. Product Incompatibility and Phase-outs

As discussed in Section 3.1.1.3, suppliers customise SMBG test strips for specific meter brands and models, such that test strips do not fit or produce a result when used across meters form different companies, or even across different models under the same brand. This product design strategy limits consumers' flexibility in using combinations of products that are readily available or affordable.

Moreover, SMBG systems often undergo technical and/or operational upgrades every several years that can result in new test strips that are incompatible with the old meter. In turn, the old meters and their associated test strips become obsolete as they are discontinued or withdrawn from the market over time. In LMICs, this constant product evolution exacerbates challenges related to the supply security of strips and requires unnecessary purchases/acquisition of new meters. In fact, the unavailability of compatible test strips for old meters in pharmacies was reported by a quarter of people living with diabetes in Kyrgyzstan who had glucose self-monitoring access challenges.[63]

4.2. Quality Standards and Regulation

Access to quality-assured glucose monitoring devices is critical. However, regulatory challenges at both global and country-levels compromise the quality of products on the market in LMICs.

4.2.1. Global Level

The major body that set standards for the accuracy of glucose monitoring devices is the International Organization for Standardization (ISO).[64] Once cleared, however, peer reviewed publications have shown that the devices do not always perform up to the standards for which they were cleared.[65, 66, 67] Recent US-based evidence indicates that 12 of the top 18 SMBG systems which claimed to meet ISO standards and are cleared by the US FDA are not consistently meeting the quality standards they once demonstrated.[68] A similar study recently found that four of 18 current generation, CE-labeled SMBG systems also did not meet ISO standards in independent post-market assessments.[69] Relatedly, the ADA and US FDA warn about expired or preowned test strips available in the black market which may compromise product accuracy.[70-71] Products with compromised quality, or without regulatory oversight can pose significant safety and health risks to individuals. A 2014 assessment of SMBG accuracy in Germany revealed that a reduction in SMBG error from 20% to 15% was associated with reductions of 1% in severe hypoglycemia, 0.14% in A1c, and 0.18% in myocardial infarctions.[72, 73]

4.2.2. Country Level

Given the evidence of substandard glucose self-monitoring devices on the market and their health implications, tight regulatory control at the national level is paramount. However, adequate regulatory oversight and enforcement in many LMICs is a challenge due to capacity and technical constraints. This is of particular concern as LMICs are seeing an influx of low-priced products from Asia without ISO certification, as well as experience of counterfeit SMBG meters sold in the black market.[74]

Another consequence of limited device regulation in LMICs is that the processes for seeking national registration may vary significantly and change frequently as the systems develop, causing confusion and substantial resources from suppliers to keep registrations up to date. Given these challenges, product entry into LMIC markets can be delayed and inhibit the registration of products from smaller or emerging companies with resource constraints, both of which impact competition. Furthermore, while large countries or markets with known demand may offer a commercial incentive to suppliers to pursue national regulatory approval, smaller countries or markets with poor visibility into demand may not be prioritised—resulting in inequitable access.

Notably, there is limited research on the real-world accuracy of self-monitoring devices in LMICs because international standards are largely based on HIC settings and norms. According to a 2018 analysis, the upper operating temperatures of three commonly used systems ranged from 45-47°C, with manufacturers recommending storing test strips in under 30°C, non-humid environments.[75] These temperatures are rarely met consistently in the hot and humid climates of many LMICs, casting doubt on their accuracy.[76]

Additional details on the quality and regulatory challenges in the glucose self-monitoring device market are provided in the paper *Regulatory Profile for Glucose Self-Monitoring Tools, 2021,* compiled by NSF Health Science, ACCISS and FIND.

4.3. Costs and Pricing

Given that glucose self-monitoring devices are needed throughout an individual's lifetime, their aggregated price is a key determinant of access. Unsurprisingly, high prices are overwhelmingly cited as the leading barrier to access in LMICs and are driven by several key factors.

4.3.1. Supplier Pricing Considerations

Although visibility into the Cost of Goods Sold for SMBG and CGM systems is limited, the following statements generally apply across suppliers:

- **Research and Development (R&D) Costs:** The R&D budgets for SMBG systems have been largely amortised given that the technology has been available and relatively unchanged for decades. The R&D budgets for CGM systems, however, are potentially still significant given innovation taking place within the product class.
- **Production Costs:** Raw materials are a small percentage of the overall costs for SMBG and CGM systems per unit. When fully automated, assembly is a minor production cost, however some CGM systems still require costly manual assembly. Moreover, the high volumes of SMBG test strips and CGM sensors require significant investments in production capacity and can be a cost driver if economies of scale are not met.

To recoup R&D and production costs and to generate profits, the medical device industry generally enjoys healthy gross margins (50-80%).[77] Although the glucose self-monitoring market is likely to follow a similar trend, SMBG system suppliers compete on price to maintain or expand market share given the multiple SMBG suppliers. That said, suppliers' price setting is wide-ranging as it is determined by two key factors:

1. **Supplier Competition**: In LMICs, smaller suppliers, including those without ISO approval, often offer lower prices to be competitive with the larger, brand-name suppliers. Smaller suppliers' low prices are putting pricing pressure on the larger, brand-name suppliers in many LMIC markets. Relatedly, suppliers may give away their meters for free to encourage consumers to switch over to their products and encourage future sales of test strips, which is their main revenue driver. Although it may yield high gains, this approach is risky for suppliers as there is no guarantee that customers who are provided free meters will, in turn,

continue to purchase test strips.

2. **Reimbursement Policies:** Suppliers may offer lower prices in markets in which individuals must pay for products entirely OOP, versus markets with reimbursement policies in place (i.e., government or insurance coverage of product cost). In reimbursement markets, reimbursement rates set by national authorities or private insurance companies can be influenced by suppliers, in turn influencing suppliers' pricing. Ultimately, this pricing strategy is designed to maximise sales/profits by ensuring that price-sensitive consumers can still access their products, either OOP or through a reimbursement channel.

4.3.2. Product Mark-Ups

In addition to the price which companies charge for their products, glucose self-monitoring products are known to experience wide-ranging markups along the supply chain, though the exact range of markups varies by country and facility and is difficult to generalise. However, according to different experts interviewed, markups may be between 50-200%[78] of the supplier's selling price, due to markups from distributors, importers, and retailers:

- **Distributor Markups:** Most LMICs are distributor-dominated markets known to have significantly higher markups than markets that operate via wholesalers or direct sales, as suppliers have limited to no control over the markups that distributors set. One way in which suppliers may try to limit distributor markups is by providing distributors with a high ratio of free meters along with test strip boxes to guarantee distributors' high margins on meter sales while ensuring competitive pricing of their product for end-users. Additionally, selling in bulk orders and reducing nodes or shipping stops in the supply chain process can further reduce distributor markups.
- **Import Tariffs and Sales Tax:** According to a 2019 analysis,[79] import duties[xxviii, 80] for LMICs range from 0-20%. The study also reports that in low-income countries (LIC) with no import duties, sales and administrative taxes were still levied. In Tanzania, for example, the government had an 18% sales tax whereas Uganda had an 18% sales tax and 6% withholding taxes. These import duties and other taxes can significantly add to the cost of the product for the end buyer.
- **Retail Markups:** Retail markups further contribute to the unaffordability of devices in the private sector, which is the main market for glucose self-monitoring devices in LMICs. Although not a perfect comparison due to different volume orders and use cases for test strips[xxix], comparing available LMIC public and private sector pricing data can serve as a proxy for understanding price hikes in the private sector. For example, while test strip prices procured by the public sector through high volume multi-year tender processes ranged from US$0.06-0.12/strip in South Africa, Tanzania, Ethiopia, and Brazil[81], their price in private sector pharmacies can range from US$0.23-0.88. Such drastic price differences point to the value of public sector procurement, with procurement prices passed onto people forced to pay out-of-pocket in the public sector, in achieving the cost-effective provision of devices.

4.3.3. Cost to Consumers

[xxviii] Normal non-discriminatory tariff charged on imports (excludes preferential tariffs under free trade agreements and other schemes or tariffs charged inside quotas).
[xxix] Public sector procurement is largely for hospital-based testing (instead of self-testing) and is often for large-volume orders which can lower unit prices.

The final cost to consumers is a result of suppliers' selling prices and markups and other add-on charges along the supply chain. Where available, data indicate that the cost to consumers and the resulting price per patient per year (PPPY) of glucose self-monitoring devices (including durables and consumables) is prohibitively expensive for individuals in LMICs and a primary barrier to access.

The majority of sales in LMICs take place in the private sector through retail pharmacy channels where prices are typically higher than in public sector channels.[82] Using the price examples in Appendix C, test strips alone can cost between US$87.6-1,285/year assuming an individual uses four test strips/day. For many, this is simply unaffordable.

The high price and recurring need for glucose self-monitoring commodities frequently result in glucose self-monitoring being more expensive than insulin,[83] and often the largest diabetes-related cost to lower-income households with people on insulin. For example, 2020 data from Mali indicate that a monthly supply of insulin (2 vials of 10ml 100IU/ml human insulin) costs individuals $18-20, compared to $36 for a modest monthly supply of test strips (2 test strips/day).[84] A survey in Tanzania in 2019 also found test strips were less affordable than insulin. In the public sector, two vials of insulin and 60 test strips cost $12 and $19 respectively, while private sector prices were $16 and $21 respectively.[85]

An overview of product price estimates and PPPY estimates can be found in Appendix C.

4.4. Financing for Product Procurement and Purchase

Given the high price of devices, financing is a critical driver of access. Glucose self-monitoring devices can either be purchased through private/public health insurance, given freely to users, or paid by individuals through OOP expenditure. However, a lack of adequate and consistent financing for glucose self-monitoring devices at global, national, and individual levels poses a major barrier to access in LMICs.

4.4.1. Donor Funding

There are no bilateral donors prioritising diabetes at a scale seen for infectious diseases. Most donor funding, therefore, comes from independent non-governmental organisations (NGOs) and major suppliers' Corporate Social Responsibility (CSR) initiatives. Life for a Child, for example, receives in-kind support from suppliers and some donor funds to procure meters and test strips for LMICs for children and young adults with type 1 diabetes.[86] The lack of centralised donor funding has left LMIC governments to finance procurement on their own—resulting in low-volume orders without substantial price discounts or no procurement at all.

4.4.2. Public Sector Financing

Although many LMIC governments consider diabetes a priority NCD due to its disease burden, public sector financing for NCDs is generally low. Even within diabetes, glucose self-monitoring is usually a low priority when compared to diabetes management products, such as insulin and oral therapies.

4.4.2.1. Public Sector Procurement of Devices

Centralised and effective procurement of diabetes commodities and devices comes with an opportunity to achieve low product prices, based on volume efficiencies—enabling access to these commodities through the public sector. New Zealand, for example, has lowered test strip prices through a nation-wide tender ($0.17/strip in 2016) due to the government's high volume public procurement[xxx] and corresponding test strip subsidies.[87] In LMICs, public procurement is often limited for SMBG systems and virtually non-existent for CGM systems. Where examples of public procurement in LMICs do exist, procurement has typically occurred at the sub-national level where it is fragmented and sporadic, limiting the possibility of volume efficiencies. In Indonesia, for example, each hospital, including those at primary and referral levels, has its own procurement body and cycle for glucose monitoring tests[xxxi]—all of which are highly varied. However, some countries, such as Brazil, have achieved good prices in high-volume tenders ($0.10/strip in 2020 for 17.5M test strips)[88] showing that lower prices can be achieved with centralised and/or large-scale procurement.

Fragmented procurement constrains access to glucose self-monitoring products in the public sector and leaves individuals to seek access in the private sector where costs are higher.

4.4.2.2. National Health Insurance (NHI)

Countries in which NHI programs partially or fully reimburse glucose self-monitoring products enable individuals to access self-monitoring products at little or no cost. Although common in HICs,[89] public reimbursement in LMICs is uncommon and limited in scope for SMBG systems, and nonexistent for CGM systems. For example, in Kyrgyzstan, 50% of the cost of test strips purchased in private pharmacies[xxxii] is reimbursed for insured individuals via the public sector's mandatory health insurance,[xxxiii] which covers 75% of the total population.[90] However, the standard test strip allocation is 200 strips per patient per year—or about 7% of the ADA's recommended testing frequency for insulin-requiring individuals.[91, 92] Furthermore, many people living with diabetes do not know about these entitlements, leading to low coverage levels.[93]

Even when LMIC governments do prioritise diabetes in their NHI schemes, they may prioritise other diabetes commodities. For example, Vietnam and Kyrgyzstan cover the cost of diabetes medications in NHI, but not, or at limited level, glucose self-monitoring devices.

4.4.2.3. State-Provided Care

A few LMICs use public healthcare budgets to purchase and distribute glucose self-monitoring devices (namely test strips) to individuals for free or at a reduced cost as illustrated in Figure 2. South Africa, which provides free healthcare to over 84% of the population, is one of the few countries where SMBG commodities are purchased by the state. Even with this commitment, however, people living with diabetes only receive ~25 test strips/month[xxxiv] and are not guaranteed the provision of a meter.[94] Such low levels of glucose self-monitoring provision are inadequate for proper diabetes management.

[xxx] According to Klatman et. al., IQVIA recorded 60 million test strips purchased by New Zealand in 2016.

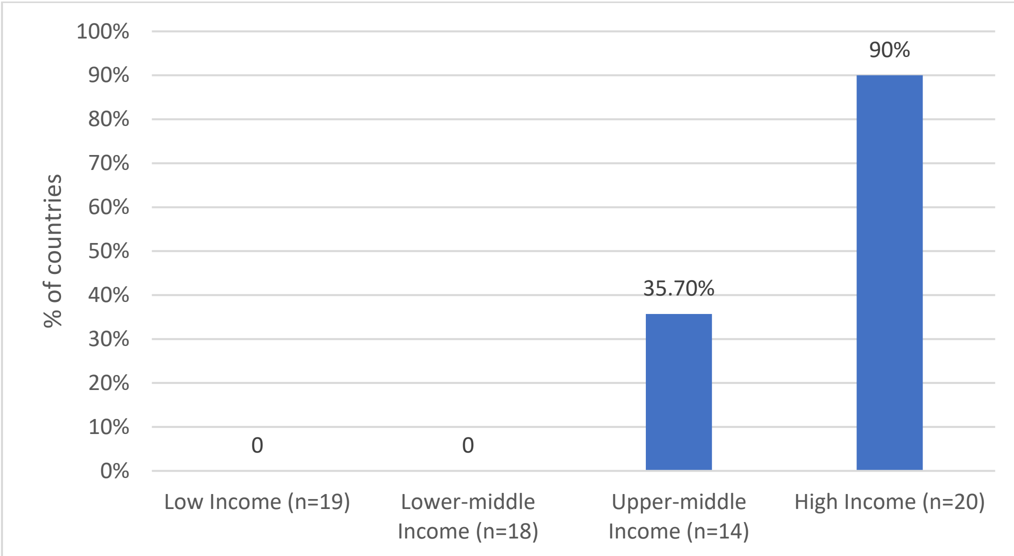
[xxxi] Glucose self-monitoring tests procured publicly in Indonesia are for primary health facility screening, not take-home use for people living with diabetes.

[xxxii] Nearly all the pharmacies in Kyrgyzstan are private.

[xxxiii] Although Kyrgyzstan's NHI does cover individuals' diagnosis and treatment costs (including insulin and syringes), meters are not covered.

[xxxiv] The ADA recommends 180-300 strips/month (6-10 strips/day) for people living with type 1 diabetes.

Figure 2. Full provision by governments of 2+ blood glucose test strips per day for children <15 years[95]



To expand market presence in LMICs without public financing options, suppliers often advocate for governments to finance the provision of glucose self-monitoring devices by demonstrating the clinical efficacy of their products and conducting health economic modeling and cost-benefit analyses to demonstrate value. However, the impact of such advocacy is limited as governments are often unwilling to make budgetary considerations based on the advice of an interested party.

4.4.3. Private Sector Reimbursement

Because of limited public insurance reimbursement in LMICs, sufficient access to self-monitoring devices and consumables is limited to populations that have greater purchasing power and can afford private sector insurance. For example, in 2021, a private insurance company in South Africa, Discovery, began offering CGM reimbursement for people living with type 1 diabetes.[96] However, this reimbursement was only possible due to the low number of people with diabetes qualifying for CGM and the high premiums afforded by privately insured patients in South Africa.

4.4.4. Out-of-Pocket Expenditure

Most LMICs are markets in which individuals pay entirely OOP because coverage is not guaranteed by the public sector or private insurance. In Vietnam, for example, while oral antidiabetic medicines and insulin are covered in the NHI scheme, glucose self-monitoring products are not covered. Using local pricing information[97] and expected usage frequency (see Appendix B), glucose self-monitoring can cost between $700-800/year,[xxxv] which is unaffordable to many, requiring individuals to choose between life-saving care and financial stability.[98] At times, individuals get their glucose levels tested at retail pharmacies where service charges can be high.[xxxvi] While this mitigates the upfront investment in a meter, the approach is cost-prohibitive and inconvenient if one was to test at the recommended frequency.[99]

Ultimately, limited public reimbursement and variable private sector reimbursement in LMICs lead to severe access inequities and health disparities among countries and individuals depending on their purchasing power.

[xxxv] Meters in Vietnam cost $26-74; test strips are $0.4-0.6 USD each. Assuming 4 tests per day, this sums to US$700-800/year.
[xxxvi] Anecdotal evidence suggests that prices can be as high as US$1 per test conducted using test strips.

4.5. Distribution & Supply Chain

A robust supply chain is critical for suppliers to reliably meet recurring demand of glucose self-monitoring products, especially the frequently replaced consumables. Because most sales for self-monitoring devices in LMICs are through private pharmacies, as opposed to the smaller-numbered public health facilities, suppliers either establish their own distribution network or seek out partnerships to distribute their products to consumers. Typically, suppliers pursue distribution partners in LMICs as they enable suppliers to (i) respond to demand in existing and new markets without assuming substantial legal or financial risk, and (ii) in some cases, meet government requirements of either utilising a local distributor or setting up a local subsidiary. However, in smaller or emerging markets, suppliers often struggle to identify distributors that meet company standards.[xxxvii] This factor is a frequently cited challenge to establishing SMBG markets in LMICs. While larger suppliers can afford to establish their own distribution affiliates, smaller suppliers without as many resources are left to pursue distribution partnerships with potentially sub-optimal partners. This challenge is acutely felt in smaller LMIC markets with limited glucose self-monitoring device presence, inhibiting consumers' secure and sustainable access to glucose self-monitoring devices.

4.6. Provision of Care

Even if glucose self-monitoring devices are on the market and affordable, there are several barriers associated with the ability to receive diabetes care and use devices properly.

4.6.1. Clinical Guidelines

Clinical guidelines in some LMICs fail to optimally enable access to glucose self-monitoring, in two ways. First, due to resource constraints or other reasons, treatment guidelines do not always recommend glucose self-monitoring, or they recommend lower-frequency testing than the ADA guidelines. For example, in Vietnam, the National Diabetes Diagnosis and Treatment Guidelines do not recommend glucose self-monitoring for people living with type 2 diabetes, who are instead recommended to visit health facilities every four weeks for a check-up, blood sugar testing, and take-home treatment. Additionally, regional guidelines from the Latin American Diabetes Association (ALAD)[100] recommend testing three times per day for people on insulin-intensive regimens[xxxviii]—far below the ADA's recommended six to 10 times perday.

Second, even if glucose self-monitoring is recommended in national guidelines, it may not be fully implemented. For example, despite South Africa's recommendations on relatively frequent self-monitoring for insulin-requiring individuals,[xxxix] a 2019 study found that national diabetes guidelines were not known or available in all primary care centers in one district.[101]

The lack of guideline harmonisation and effective communication/implementation, therefore, compromise access to glucose self-monitoring for people living with diabetes in LMICs.

4.6.2. Service Delivery

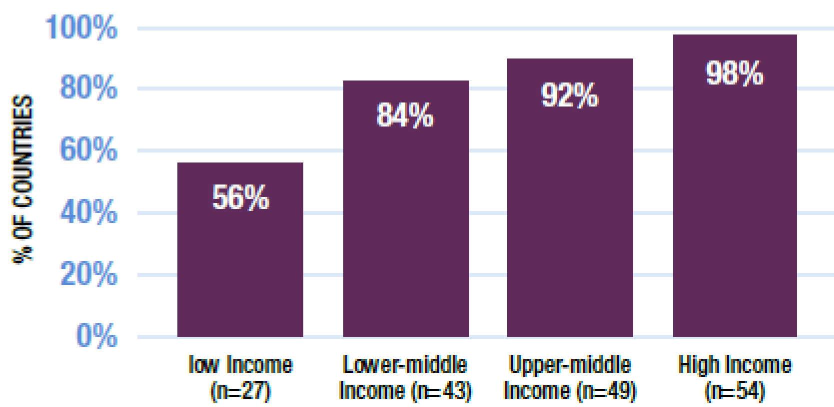
Diabetes management is lifelong and requires intentional actions to be properly managed, not to mention a continuous supply of insulin, oral anti-diabetes medicines, and glucose self-monitoring

[xxxvii] Many large suppliers often have strict policies on distributor compliance. Some examples of distributor compliance include: invoice generation process, tracking adverse events and bad batches, anti-corruption and anti-bribery policies.
[xxxviii] The ALAD also recommends testing 2-3 times/week for patients on non-intensive insulin regimens, which the ADA does not provide clear guidance on apart from suggesting frequent testing.
[xxxix] South Africa's guidelines recommend that most individuals test 3-5 times/week, while people on insulin-intensive regimens should test >3 times/day, and people on non-intensive insulin regimens should test 2 times/day.

devices. In most LMICs, there are three main barriers to diabetes-related health care service delivery generally, and glucose self-monitoring provision and support specifically:

1. **Shortage of health care workers (HCWs) trained in diabetes management:** This results in inadequate screening and support to diagnosed individuals on properly managing their condition.[102] Specifically, training HCWs in precise titration of insulin is a major challenge to ensuring people receive effective diabetes management.[103]
2. **Limited patient education and support on glucose monitoring:** In addition to the overall low levels of diabetes awareness, care-seeking, and treatment adherence,[104] limited education on the value and proper use of glucose self-monitoring devices poses further challenges.[105] For example, the fear of finger pricking[106] and high rates of illiteracy that inhibit individuals from accurately interpreting glucose readings[107] have often been cited as key barriers for SMBG system use. For CGMs, the lack of awareness of the product class and the perceived difficulty in using this system have been cited as barriers to adoption.[108]
3. **Poor availability of glucose testing in health facilities:** As Figure 3 illustrates, the availability of glucose testing is poor even at health facilities in LICs. This means people living with diabetes are not guaranteed access to glucose testing at home or even in health facilities.

Figure 3. Availability of glucose testing at public primary healthcare facilities[109]



To improve the provision of glucose self-monitoring devices in LMICs, suppliers may create parallel service delivery channels. For example, suppliers often work with NGOs and/or collaborate with CSR initiatives of the three largest[xl] insulin providers to donate test strips and meters for free to either patients or physicians in countries where there is limited public procurement. While they alleviate short-term access concerns, donation campaigns are not sustainable solutions to access challenges as individuals do not have replacement test strips in case donation programs are discontinued. Suppliers may also work with governments to provide HCW training to strengthen diabetes healthcare services, including glucose self-monitoring sensitisation. Alternatively, suppliers may establish their service delivery channels through in-country customer service networks and direct-to-consumer campaigns, sometimes in partnership with national diabetes associations.

[xl] The large insulin providers are Novo Nordisk, Eli Lilly, and Sanofi.

5. FUTURE MARKET TRENDS IN LMICS

5.1. Market Growth

Expected to account for 83% of people living with diabetes worldwide (588 million people) by 2045, LMICs are increasingly important markets for glucose self-monitoring devices.[110] Furthermore, the largest increase in diabetes prevalence will take place in economies that are moving from low-income to middle-income status.[xli, 111] As such, middle-income countries (MIC), particularly those with large populations, are likely to be become key drivers of market growth. LMICs' market size will, however, be dependent on health systems' ability to diagnose people living with diabetes and link them to life-long care. Currently, under-diagnosis is common in many LMICs, particularly in the Sub-Saharan Africa (SSA) region, where about 60% of diabetes cases are undiagnosed.[112]

5.2. Financing Diabetes Programs

Because of the growing burden of diabetes described above, LMICs are increasingly seeking ways to include diabetes within their NHI or general NCD benefit packages. However, in order to do so, they will need to identify new financing options to ensure that diabetes programs do not put significant burden on government health budgets or undermine the sustainability of their Universal Health Coverage (UHC) goals.[113]

5.3. Technological Trends

Although LMIC markets often benefit from technological advancements later than HICs, suppliers anticipate that LMIC markets for insulin-requiring people living with diabetes will switch to CGM products in the near term (five to 10 years)—especially in reimbursement markets.[114] This anticipated shift is due to the emerging evidence of clinical advantages of CGM over SMBG, and the ability to assess "time in range," the anticipated price reductions in CGM, and the burden alleviation for individuals who require frequent glucose testing.[115] CGM systems that are integrated with automated treatment delivery systems (i.e., insulin pumps) can offer additional benefits as individuals do not have to manually adjust insulin dosages based on CGM readings and are therefore may likely gradually penetrate LMIC markets. However, widespread and equitable access to these devices will be contingent upon LMICs' health financing and UHC implementation, as discussed above.

[xli] International Diabetes Federation estimates that approximately 84% of all people living with diabetes (total: 700 million) will reside in LMICs in 2045. This is an increase from 79% in 2019.

6. PROPOSED INTERVENTIONS

This report highlighted various key barriers to access to glucose self-monitoring devices in LMICs, which manifest at multiple levels:[116]

- **International Level:** Lack of donor funding, lack of optimal/target product profile for LMICs, and high-priced products (especially consumables).
- **National Level:** Limited public health budgets for glucose self-monitoring device procurement and provision, weak diabetes services and programs, limited visibility into demand, inadequate regulatory oversight, and high product markups (distributor, customs/import, and retail) and other charges (sales taxes).
- **Individual Level.** High OOP expenditure, and limited education and support for diabetes management.

Given these complexities, there is no silver bullet to address all access issues in LMICs. However, collaborative efforts from LMIC governments, donors, manufacturers/suppliers, and implementing partners can significantly improve access to glucose self-monitoring through the following interventions:

1. **Bilateral Donor Support:** Bilateral donor support is crucial to catalyse financing and action for the recommendations listed, particularly in the context of the COVID-19 pandemic, which has required dramatic shifts in resources from NCDs to infectious disease programs in already financially constrained LMICs.
2. **Target Product Profile Development:** Alignment on the ideal product profile is needed to ensure the availability and affordability of the optimal product for people living with diabetes, including potentially developing new technologies to better serve LMIC needs. In the shorter-term, the planned SMBG WHO Pre-Qualification (PQ) process will be an important step in identifying existing product(s) that meet quality standards[117] for LMIC settings, particularly those with constrained national regulatory oversight. WHO PQ can facilitate market consolidation to select product(s) that meet key quality and regulatory standards, enabling higher volume manufacturing/procurement orders and unlocking lower prices.
3. **Market Transparency Improvement**: Further efforts to mitigate the general lack of transparency in this market can improve competitive pricing, procurement, and quality control. Examples of activities to improve market transparency include, but are not limited to: (a) establishing a virtual marketplace; (b) quoting prices in public catalogs, such as those of UNICEF Supply Division; (c) publishing public procurement outcomes; (d) conducting and publishing findings from routine quality and accuracy testing of devices in LMICs; (e) routine national monitoring of availability in facilities, prices to individuals and affordability. Lastly, creating better visibility on potential demand volumes from LMICs may constitute an incentive for suppliers to enter LMICs and improve their product proposition for these markets.
4. **Access Price Agreements:** Price agreements like those seen in established disease programs of HIV, TB, Malaria, or Vaccines can drive the glucose self-monitoring market to one that is low-margin, high-volume while still ensuring profitability and sustainability for manufacturers and distributors. Relatedly, governments can waive import taxes and set price ceilings in retail pharmacies to limit markups and ensure affordability for end-users.

5. **Alternative Procurement Channels:** Coordinated procurement across multiple LMICs can pool volumes and increase buying power, unlocking lower prices from suppliers. Additionally, levering existing international procurement platforms (e.g., UNICEF, Global Fund) can streamline procurement and yield cost savings along the supply chain.
6. **Glucose Self-Monitoring Device Inclusion in NHI**: Given LICs' severe resource constraints, this intervention is likely to be most feasible for MICs with more substantial health budgets. The inclusion of glucose self-monitoring in NHI can address one of the major roadblocks of poor reimbursement by governments and subsequently, high OOP for people living with diabetes.
7. **Diabetes Service Delivery Strengthening:** Greater diabetes prioritisation and resource allocation from LMIC governments and donors is needed to improve broader diabetes care systems—including screening and diagnosis, treatment, health care workforce, and individual awareness and education. Such efforts not only improve health outcomes but also increase the demand for glucose self-monitoring devices and can support volume efficiencies.
8. **Additional Research:** There remain notable evidence gaps that are key to achieving these recommendations and broader market transparency and improvement. Key research gaps include price sensitivity of LMIC buyers (including governments and individuals); country-specific cost-effectiveness analyses of SMBG and CGM products; need and demand forecasting in LMICs; and context-specific SMBG and CGM system efficacy and uptake/adherence challenges.

7. APPENDIX

7.1. Appendix A: Countries Covered by IQVIA

Countries included in the IQVIA regional data[118]

Asia Pacific (APAC)	Africa	North America (NA)
1. Taiwan 2. China 3. South Korea 4. Australia 5. Philippines 6. Singapore 7. Hong Kong 8. Malaysia 9. Indonesia 10. Thailand 11. Vietnam 12. India 13. Pakistan 14. Bangladesh 15. Kazakhstan 16. Japan	33. Egypt 34. South Africa 35. Algeria 36. Morocco 37. Angola 38. Sudan 39. Ethiopia 40. Kenya 41. Tanzania 42. Tunisia 43. Ghana 44. Nigeria 45. Uganda	70. United States of America 71. Canada
Eastern Europe	**Western Europe (WE)**	
17. Turkey 18. Poland 19. Czechia 20. Slovakia 21. Hungary 22. Romania 23. Russia 24. Ukraine 25. Belarus	46. Germany 47. France 48. Italy 49. Spain 50. Belgium 51. Austria 52. Netherlands 53. Portugal 54. Finland 55. Greece 56. Sweden 57. Denmark 58. Norway 59. United Kingdom 60. Switzerland	
Middle East	**Latin America (LATAM)**	
26. Israel 27. Saudi Arabia 28. United Arab Emirates 29. Iran 30. Iraq 31. Qatar 32. Kuwait	61. Brazil 62. Argentina 63. Mexico 64. Peru 65. Colombia 66. Chile 67. Venezuela 68. Ecuador 69. Dominican Republic	

7.2. APPENDIX B: ASSUMPTIONS

In HICs, we assume that product usage follows the guidelines set forth by the American Diabetes Association (Table 4). In LMICs, however, limited availability and affordability of glucose self-monitoring commodities result in less frequent testing and product replacement. The frequencies listed in Table 4 are not target testing frequencies for people living with diabetes in LMICs, but rather approximations of current product usage in LMICs based on expert opinion and operational experience.

Table 4. Replacement Frequency for Glucose Self-Monitoring Commodities in HICs and LMICs

Product Type	HICs		LMICs	
	Insulin Requiring Individuals	Non-Insulin-Requiring Individuals	Insulin Requiring Individuals	Non-Insulin-Requiring Individuals
Standard Glucose Meter	Every 5 years	Every 5 years	Every 2 years*	Every 2 years*
Test Strips	6-10 times/day (average: 8)	0.5 times/day	4 times/day	0.5 times/day
Lancets	4-5 times/day	0.5 times/day	2 times/day	0.5 times/day
Transmitter (CGM) [xlii]	Every 3 months	Not Required	Every 3-6 months	Not Required
Sensor (CGM)	Every 10-14 days	Not Required	Every 10-14 days	Not Required

*SMBG meter replacement frequency in LMICs is more often than that in HICs given that meters in LMICs are often replaced once their batteries die, unlike in HICs where it is more common to simply replace the batteries.

[xlii] Most CGM models have independent transmitters while Abbot's FreeStyle Libre, only has a sensor (with an in-built transmitter) and receiver.

7.3. Appendix C: Pricing Estimates of SMBG and CGM commodities in LMICs and HICs

Table 5 shows the retail price ranges for different SMBG and CGM commodities in HICs and LMICs over the past five years (2016-2020). Data sources include a combination of information found via desktop research, market intelligence agencies (IQVIA and Mordor Intelligence), and price estimates from in-country stakeholders. These prices can include private and public sector prices and are brand agnostic.

Table 5. Price estimates for SMBG and CGM commodities, all values in US$

WB Income Group	SBGM Meters	SMBG Test Strips	SMBG Lancets	CGM Durables [xliii]	CGM Sensors
LMIC (n=21)	$9 – $25	$0.06 – $0.88	$0.01 – $0.03	$67 – $136	$45 – $57
HIC (n=8)	$10 – $45	$0.17 – $0.87	$0.06 – $0.14	$305 – $533	$70 – $83

Table 6 presents the estimated PPPY for insulin-requiring individuals, using the price estimates from Table 5 and the assumptions on product replacement in Table 4. These are prices for the main suppliers only (those listed in Tables 2 and 3) and do not represent lower prices that LMICs may get from smaller suppliers.

Table 6. Estimated PPPY for insulin-requiring people with diabetes, all values in US$

WB Income Group	SMBG	CGM
LMIC	$98 – $1,300	$1,300 – $2,600
HIC	$470 – $3,400	$3,000 – $5,200

Calculations make the following assumptions:

1. Frequencies are listed in Appendix B.
2. Prices used in LMICs and HICs are listed in Table 5 above.
3. The lowest and highest price in each income group/product category is matched with the corresponding lowest and highest frequency to yield results.

[xliii] Most CGM models have independent transmitters while Abbot's FreeStyle Libre, only has a sensor (with an in-built transmitter) and receiver.

8. ENDNOTES

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