FACT SHEET

OCTOBER 2021

MARKET REPORT ON **DIABETES SELF-MONITORING DEVICES**

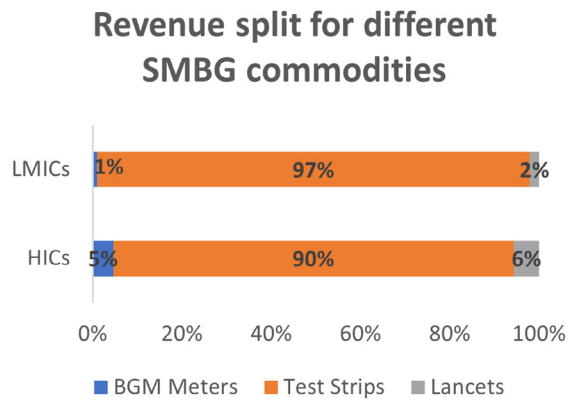
INTRODUTCTION

Self-monitoring of blood glucose is an essential aspect to diabetes care for people with type 1 diabetes, and for many with type 2 diabetes, particularly those who use insulin. The glucose monitoring device market is made up on two main types of systems (referred to here as devices): self-monitoring blood glucose (SMBG) devices (which prick the skin, with blood then applied to a test strip that is inserted and read by a portable meter), and continuous glucose monitoring devices (CGM) (a sensor under skin takes readings that are transmitted to a reader or smartphone that shows levels every 1-5 minutes and displays trends). The market is fast-growing and worth over $US10 billion. Despite this growth, access to these devices, particularly in low- and middle-income countries (LMICs), is still a challenge. To better understand the barriers to access to monitoring devices, the ACCISS Study, together with FIND, the global alliance for diagnostics, commissioned a report by the Clinton Health Access Initiative (CHAI) that outlined the current issues with access to self-monitoring devices. Below are the key findings from the report.

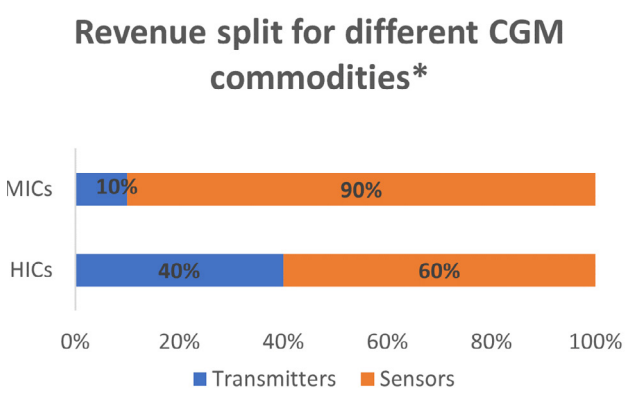
THE SELF-MONITORING SYSTEMS MARKET

- In 2018, the SMBG devices market was worth $US6.4 billion (across 71 countries). While there are over 100 manufacturers, the report found only four make up 80% of the market.
- The CGM device market is fast growing, with suppliers' revenue estimated at $US4.5 billion in 2020. Currently there are only three main companies in this market.
- Both device markets generate most of their revenue from the frequently used consumables (i.e., test strips or sensors). For the SMBG market, test strip sales account for over 90% of total revenue.

Revenue (by value) split from annual consumption of SMBG commodities by insulin-requiring individuals



Revenue split from annual consumption of CGM commodities by insulin-requiring individuals

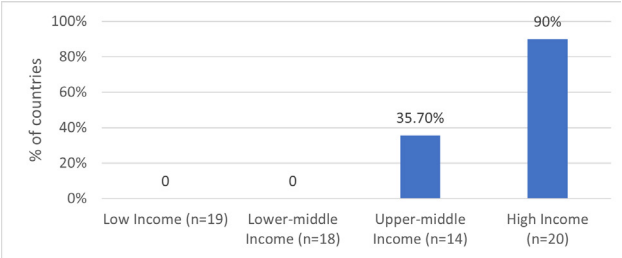


BARRIERS TO ACCESS TO SELF-MONITORING DEVICES IN LMICS

High Prices

- *Lack of funding for glucose monitoring devices in the public sector*: While diabetes is considered a priority non-communicable disease in many LMICs, funding for commodities, such as SMBG devices, is typically low priority.

Full provision by governments of 2+ blood glucose test strips per day for children <15 years



- *High prices in the private sector*: With limited provision of these devices in the public sector in LMICs, most sales occur in the private sector, where prices are typically higher, and often seen as a primary barrier to access. Although data is lacking, the report estimated that test strips alone can cost between US$87.6-1,285/year assuming an individual uses four test strips per day.

- *Private sector prices result of suppliers' selling prices, mark-ups and other add-ons in the supply chain:* According to sources in the report, mark-ups (importers/distributors and retailers) may be 50-200% of the supplier's selling price. Price component studies are needed for these products.

- *Out-of-pocket costs greatly increase diabetes costs overall*: The largest contributor to the cost of diabetes care can be the glucose monitoring devices. For example, 2020 data from Mali indicated that a monthly supply of insulin (2 vials of 10ml 100IU/ml human insulin) costs individuals $US18-20, compared to $US36 for a modest monthly supply of test strips (2 test strips per day)

Product Incompatibility and Other Issues

- *Lack of universality to SMBG devices and supplies*: Suppliers generally make test strips that only work with their brand of meter or even a specific model under the same brand. This is problematic when the specific test strips are not available for an individual's device, or prices increase. As well, suppliers regularly make product upgrades resulting in new test strips that are incompatible with the individual's meter.

- *Products not suited to country settings*: There is no international guidance on target product specifications for self-monitoring glucose devices for LMIC markets, for example, taking into consideration extreme heat or humidity, or lack of literacy.

- *Shortage of health care workers trained in diabetes management*: In LMICs there is generally limited support to individuals on testing and using the results to adjust the amount of insulin needed.

- *Lack of education:* Proper diabetes education on how to use glucose monitoring systems and why they are important is often lacking in LMICs, which is a barrier to use.

Regulatory Barriers

- Lack of adequate or consistent regulatory oversight in many LMICs due to capacity and technical constraints.
- Due to limited oversight, the process for seeking national registration can vary significantly as systems develop or change.
- Even in the high-income contexts, the enforcement of regulations on self-monitoring glucose devices was found to be lacking. The report noted a publication that found that of the top 18 SMBG systems in the US, all of which met the International Organization for Standardization (ISO) standards and were approved by the US FDA, 12 did not consistently meet the quality standards they once demonstrated.

For more on regulatory challenges to glucose monitoring tools, please see the ACCISS *Study* *Regulatory Profile: Glucose Self-Monitoring Tools.*

To generate market conditions that would enable widespread and equitable access to glucose self-monitoring devices in LMICs, the report proposes a mix of interventions, including:

- Advocating for bilateral donor support for glucose self-monitoring.
- Developing a target product profile for devices appropriate for LMIC settings.
- Improving market transparency, both on the demand and supply side.
- Establishing access price agreements with suppliers.
- Exploring alternative procurement channels, such as pooled procurement across multiple countries.
- Including glucose self-monitoring devices in national health insurance programmes.
- Strengthening overall diabetes care.
- Conducting additional research to fill key evidence gaps.

Click here to read the full report 'Diabetes Self-Monitoring Devices in Low- and Middle-Income Countries' or go to https://haiweb.org/wp-content/uploads/2021/09/Market-Report_Self-monitoring-Devices-in-LMICs.pdf

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