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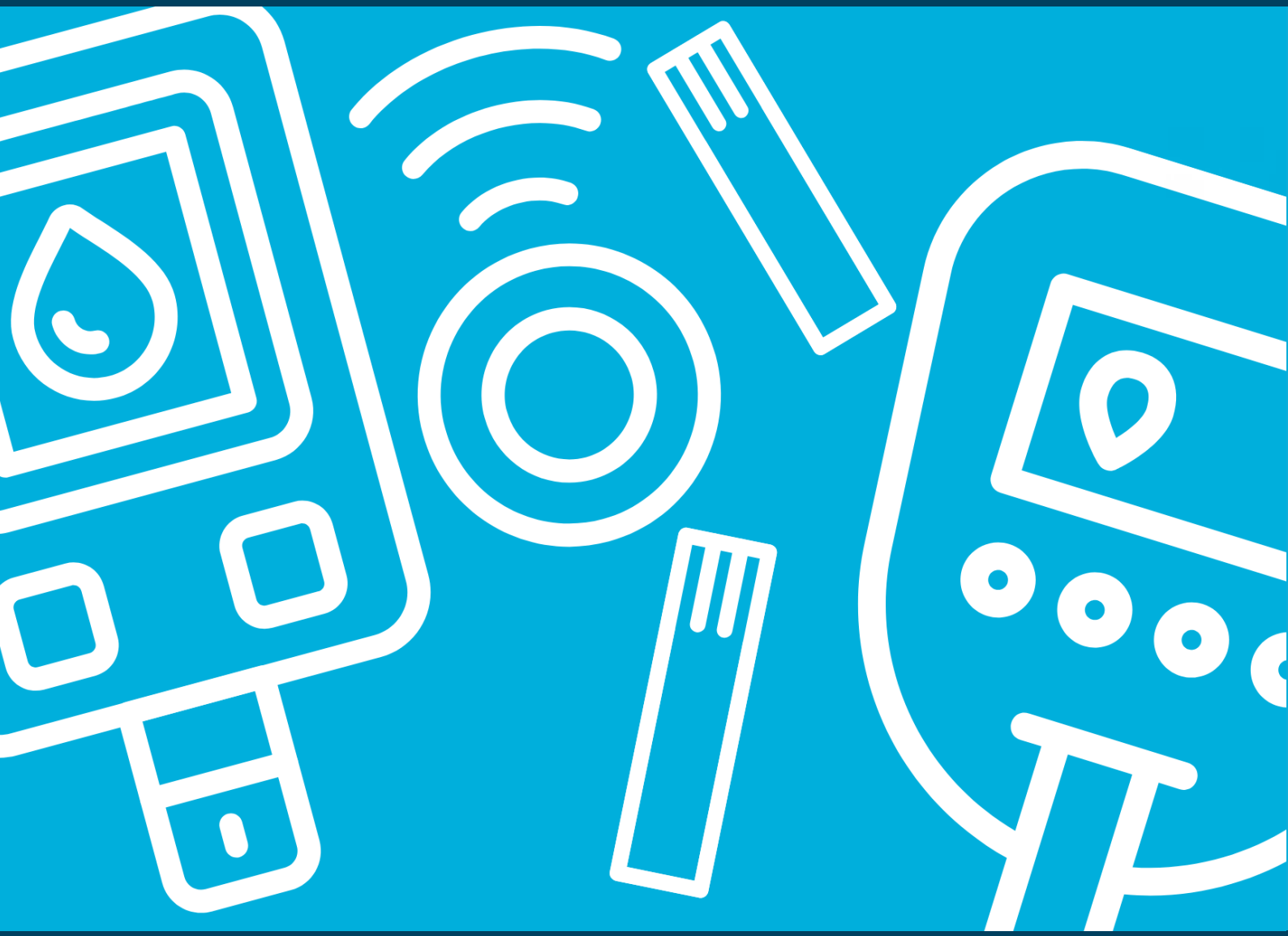
Addressing the Challenge and Constraints of Insulin Sources and Supply

HAI HEALTH ACTION INTERNATIONAL

Moving Forward on **Access** to **Glucose Self-Monitoring** Technologies for the Management of **Diabetes**



MOVING FORWARD ON **ACCESS** TO **GLUCOSE SELF-MONITORING** TECHNOLOGIES FOR THE MANAGEMENT OF **DIABETES**

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CONTENTS

1. Context

Diabetes is a global challenge, affecting an estimated 589 million people worldwide - 81% of whom live in low-and middle-income countries (LMICs).[1]

Regular monitoring of glucose is an integral part of diabetes management and ever since technology made it possible to measure glucose levels at home, self-monitoring of glucose has become standard practice in diabetes management.[2] People living with diabetes who use insulin require daily self-monitoring, which includes everybody living with type 1 diabetes and a proportion of people living with type 2 diabetes.[3,4] This requires reliable access to affordable self-monitoring technologies, such as blood glucose meter and test strips or continuous glucose monitoring devices.

However, to date, it is estimated that only a fraction of people in LMICs are able to practice regular self-monitoring.[5] Reasons for this are multifactorial and span across all areas of a country's health system and the life cycle of self-monitoring technologies in this system.

In 2022, the World Health Organization (WHO) published five global diabetes coverage targets, two of which cannot be achieved without reliable access to glucose testing: "80% of people with diagnosed diabetes have good control of glycaemia" and "100% of people with type 1 diabetes have access to affordable insulin and blood glucose self-monitoring".[6] These targets, together with the 2021 World Health Assembly (WHA) resolution 74.4 to strengthen prevention and control of diabetes , brought momentum and strong commitment by the global health community to move forward on better access to glucose self-monitoring technologies.[7]

1.1. Objective and approach

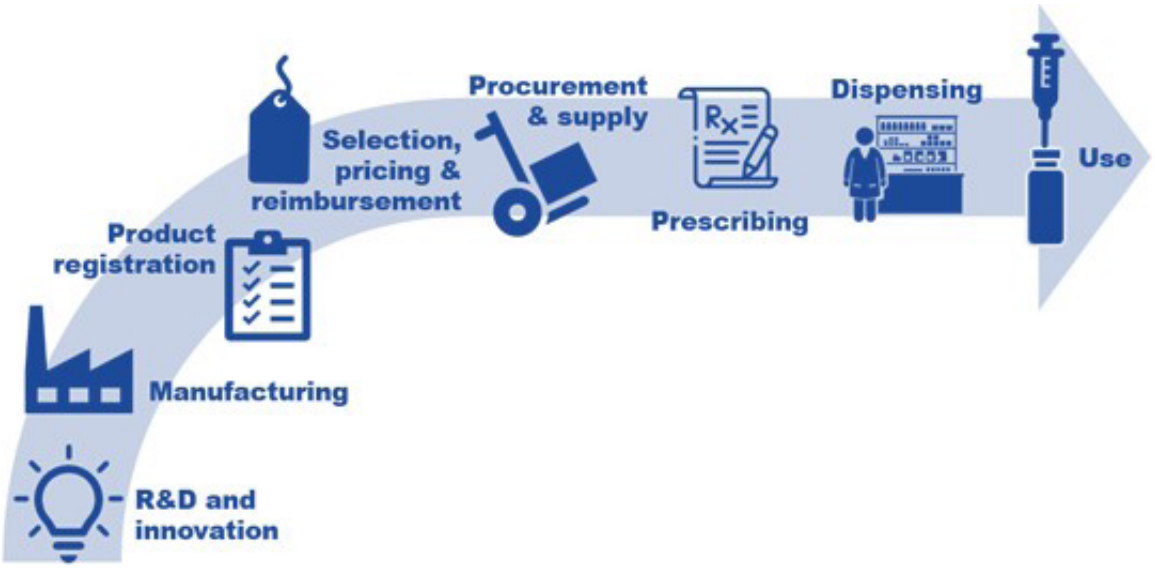
The product life cycle framework used in this report is based on WHO's framework for the life cycle of medicines, and adapted based on a paper employing the framework for insulin.[8,9] It provides a useful model for mapping barriers and facilitators of access to self-monitoring technologies and laying out within each where current stakeholders are engaging in activities and research. A number of international organisations have undertaken activities in recent years across various areas of the life cycle of self-monitoring technologies, aimed at addressing barriers to accessing these technologies in LMICs. The aim of this report is to map their activities and categorise them within a structured life cycle framework in order to identify gaps and opportunities for future work.

Section 1.2 provides the definitions of the life cycle stages of the framework and the scope per stage. The technologies in scope of this report are the two major device types currently used for glucose self-monitoring: 1) blood glucose meters (BGMs) and test strip to measure glucose levels in blood obtained via a finger-prick and 2) continuous glucose monitoring devices (CGMs) to measure glucose in the interstitial fluid every few minutes via a sensor that is attached to the body for several days.

1.2. Definitions and scope – life cycle stages

The product life cycle framework used in this report covers eight stages: 1) R&D and innovation, 2) manufacturing, 3) product registration, 4) selection, pricing, reimbursement, 5) procurement and supply, 6) prescribing, 7) dispensing and 8) use (see Figure 1).
Table 1 lists the scope for each life cycle stage of the framework, in order to categorise activities conducted on self-monitoring technologies for this report.

Figure 1. Framework of product life cycle stages



Source: ACCISS toolkit , adapted from Beran et al.[9]

Table 1. Scope of Life cycle stages of assessment framework

Life cycle stage	Scope
R&D and Innovation	• Technology evolution and innovation • Patents
Manufacturing	• Manufacturing process and technical complexity • Cost of production • Manufacturer and/or product landscape; market presence
Product registration	• Registration and regulatory requirements (SRA, WHO-PQ, NRA) • Technical capacity of regulators • Pre-market scientific evaluations to test accuracy, usability, safety
Selection, pricing, reimbursement	• WHO EDL, WHO and other technical specification documents • Post-market scientific evaluations to test accuracy, usability, safety • Mechanisms of prices setting (HTA, policies, market dynamics, WTP) • Government provision, health insurance schemes
Procurement and supply	• Procurement practices (public and private sector) • Donation programmes • Relationship pricing & procurement (affordability) • Supply chain practices and costs (tariffs, taxes, transport, mark ups)

Life cycle stage	Scope
Prescribing[a]	• Prescription and recommendation practices for self-monitoring by HCPs and pharmacy professionals (public and private sector) • Selection of products that are prescribed, recommended or purchased (by HCPs, pharmacy professionals or users)
Dispensing	• Availability of BGMs, strips and/or CGMs in pharmacies (public and private) and other retail channels • Product prices (public and private sector)
Use	• Socioeconomic factors • Diabetes knowledge • Human factors of testing (psychosocial barriers; product usability) • Impact on diabetes care and quality of life

SRA – Stringent regulatory authorities; WHO-PQ – WHO prequalification; NRA – National regulatory authorities; EDL – Essential diagnostics list; HTA – Health technology assessment; WTP – Willingness to pay; HCP – Healthcare professionals
[a]BGMs can usually be obtained without prescription, hence this category includes practices of healthcare providers and pharmacy professionals to recommend glucose self-monitoring, as well as guidelines including such recommendations (the descriptor "Prescribing" was maintained for consistency with the original framework)

2. Situational analysis – life cycle stages

The following section reflects on the current situation of self-monitoring technologies per life cycle stage and barriers to access as well as recommendations for each stage. The reflections include references to key activities conducted by the international organisations whose activities on self-monitoring have been included in the mapping exercise of this report (all activities listed in this section are summarised by organisation in the Appendix).

2.1. R&D and Innovation

Technology evolution and innovation | Patents

Barriers

The research & development (R&D) and innovation space for glucose self-monitoring tools is quite active, particularly for technologies that are minimally- or non-invasive. Some of these new tools lend themselves to intermittent on-demand testing (e.g., saliva-based test strips or non-invasive devices that can be applied to the body only for taking a measurement). However, the majority focus on continuous measurement with devices that need to be attached to the body semi-permanently for a longer period of time (i.e., continuous glucose monitoring devices, CGMs). This does not allow the user to balance testing frequency and cost, which is a significant barrier to use as currently available CGMs are very highly priced.

While new devices are welcome, they also need to be accurate, which is a challenge that many developers of new self-monitoring tools struggle to master, particularly for non-invasive devices and those using externally accessible body fluids (e.g., saliva and sweat), but also for early versions of new CGMs. This poses a significant risk and barrier to uptake as inaccurate readings can lead to suboptimal decision making by the user and result in harm or limit confidence in the device.

For BGMs and test strips based on finger-prick blood, the R&D and innovation scope is more limited, though opportunities exist. Particularly applicable to LMICs are innovations to enable meter-free glucose determination via a colorimetric strip and glucose quantification through the use of a mobile phone App. Some progress has been made in recent years, however, limitations persist as the current solution is only approved for use in type 2 diabetes and only provides semi-quantitative glucose ranges, not enabling the user to make insulin dose decisions.[10]

A further barrier in better access to self-monitoring is the lack of interchangeability of test strips between different meter brands. This does not allow the user to choose test strips based on availability and affordability, but rather binds them to the particular meter in which they have invested. Interchangeable BGMs and test strips present a challenge due to the variety of chemistries and detection technologies used, as well as the intellectual property and proprietary technologies of different manufacturers. Resistance from manufacturers is also likely to be encountered to allow interchangeability of their products with competing companies.

Organisations & activities addressing barriers

Table 2. R&D and innovation

Organisation(s)	Activity	Explanation	How it addresses barriers	Links
FIND and HAI/ ACCISS	Target Product Profile: Together with a group of experts, FIND and HAI/ACCISS led the development of a target product profile (TPP) for new glucose self-monitoring technologies for use in LMICs[11]; Scope: CGMs and other minimally and non-invasive technologies.	Users, healthcare providers and carers from four LMICs (Kyrgyzstan, Mali, Peru and Tanzania) provided critical input to the optimal and minimal requirements of the product characteristic through a qualitative study.[12]	The TPP is intended to support product design and development decisions in order to address barriers to use particularly relevant in LMICs.	Safary et al. TPP development for new glucose self-monitoring technologies for use in LMICs; PLoS One 2024 Safary et al. User requirements for glucose self-monitoring devices in LMICs; BMJ Open 2024
FIND	Technology landscape of "Products for Monitoring Glucose Levels in the Human Body With Non-invasive Optical, Non-invasive Fluid Sampling, or Minimally Invasive Technologies".[13]	Provides an overview of technologies that do not use finger-prick blood as sample to test for glucose.	Complements the TPP work, allowing purchase decision makers to match user requirements to products on the market or in late-stage development.	Shang et al. Landscape of new technologies for self-monitoring of glucose; JDST 2021

Organisation(s)	Activity	Explanation	How it addresses barriers	Links
UNICEF	A "Target Product Profile: Glucometer – Point-of-Care Diagnostics"[14], outlining optimal and minimal requirements for BGMs when used by healthcare professionals for diagnosing and managing neonates in LMICs.	All characteristics in this TPP can be applied to glucose meters used for self-testing by people with diabetes (except potentially the linear range requirements).	The document serves as guide for developers as well as purchase decision makers in LMICs (in conjunction with technical specifications for BGMs developed by WHO, see section 2.4)	UNICEF Glucose meter TPP 2020
University of Geneva	A publication of "An Empirical Review of Key Glucose Monitoring Devices: Product Iterations and Patent Protection".[15]	Assessing the landscape of BGM and test strip product and patent evolution of five manufacturers.	This brings valuable insights on the complexity of patent protection and opportunities to leverage off-patent devices.	Darrow et al. Glucose Monitoring Devices; JDST 2023

Recommendations

Given the self-monitoring needs globally—and particularly in LMICs, where self-monitoring is often influenced by cost amongst other factors—more R&D and innovation is needed in the area that brings the greatest possible flexibility in use. Furthermore, any new technology needs to provide fully quantitative, quality-assured results to ensure best results for people living with diabetes. R&D and innovation efforts should make use of TPPs developed for glucose self-monitoring technologies, as these outline the breadth of user needs and environmental conditions. Manufacturers may be unaware of the distinct user needs in LMICs, which are influenced by socioeconomic, environmental and cultural aspects, meaning that product requirements and preferences can markedly differ from users in high income countries. Ideally, partnerships should be formed between manufacturers and technology development organisations focusing on LMIC needs to jointly develop optimal products.

An opportunity for BGM innovation is the development of interchangeable BGMs and test strips to enable the user to "mix-and-match" products from different manufacturers. While meeting accuracy and regulatory standards may prove difficult, as each meter/strip combination would need to meet these standards, attempts have been made to overcome at least the technical hurdles through development of prototype "open" BGMs to be used with different test strips.[16,17] Further creative ideas how to overcome the exclusivity of meter and strip match would be welcome.

Overall new products should be developed with the lowest cost of manufacturing in mind already at low-volume production, and marketing strategies should include LMICs from the outset. Targeting a product development and launch strategy exclusively to LMICs may be an innovative approach to capture the potential that lays in these markets.

2.2. Manufacturing

Manufacturing process and technical complexity | Cost of production | Manufacturer and/or product landscape; market presence

Barriers

Test strips can be manufactured at large scale in sheets that are subsequently cut to produce thousands of strips. The manufacturing process requires high precision and spacious, specialised equipment, as well as facilities for accurate layering of the sheets, application of chemical components and subsequent drying and cutting. The entire production process either takes place in a single location from where the finished product (strips in vials) is shipped for sale, or the production process is divided into separate steps. Here, for example, uncut sheets of strips are produced in one location and subsequently sold and shipped to a supplier in another location (i.e., semi-finished) who cuts the sheets and fills the strips into the vial for sale. This gives the supplier the opportunity to market the finished strips under their own brand and access the glucose test strip market without needing to invest in the full production process. While this fosters local business opportunities and stimulates brand competition, it also leads to a fragmentation of the market, which is particularly challenging for consumers in LMICs, where continued availability of specific test strip brands is not always ensured.

Local production of test strips in LMICs has been discussed as possible opportunity to reduce test strip prices. However, this may only be the case if the production process is fully automated, meaning production volumes need to be sufficiently large to make the capital investment and process cost-effective. Given the large number of BGM manufacturers, marketing their products particularly in LMICs (as demand is declining in high-income countries due to the growing use of CGMs[1]), it can be challenging for local manufacturers to achieve the necessary volumes.

For CGMs the market has long been dominated by very few large manufacturers. However, in recent years, several new manufactures have entered the market, bringing much needed competition and user choice. CGM manufacturing is also a highly complex process, requiring specific, high precision equipment for production of the sensor/transmitter and needle with its chemical compounds. Furthermore, the application device needed for each CGM requires precision moulding equipment. Given the highly individualised design of each CGM, the production process is not easily transferred or replicated outside of the original manufacturer's facilities. Like all complex manufacturing processes, the cost of production reduces dramatically as volumes increase, which has been a barrier for new manufacturers to enter markets at competitive price points, particularly in LMICs.
Cost of Goods Sold (CoGS)—for both glucose test strips and CGMs when produced at scale—have been estimated and are well below prices paid for these products by LMIC buyers. Cost remains one of the main barriers to better access to self-monitoring technologies in LMICs.

Organisations & activities addressing barriers

Table 3. Manufacturing

Organisation(s)	Activity	Explanation	How it addresses barriers	Links
FIND	Analysis of current practices, barriers and opportunities to "Local manufacturing of blood glucose test strips in LMICs".[18]	Includes an analysis of the viability and cost-effectiveness of LMIC production of glucose test strips, as well as market data.	This analysis can serve as data source to inform policy and investment strategies in diagnostics manufacturing.	FIND Report on Local manufacturing of blood glucose test strips in LMICs 2025
HAI/ACCISS, FIND, CHAI	Together, the organisations published a "Market Report: Diabetes Self-monitoring Devices in Low- and Middle-Income Countries".[19]	It provides a general overview of the global market landscape for SMBG and CGM devices, aspects on product manufacturing, quality standards, product characteristic and costs	The market reports serve to bring knowledge and transparency to decision makers and provide recommendations to address barriers to access, enabling governments, payers, and partners to design policies, adjust financing, and shape procurement strategies.	HAI, ACCISS, CHAI, FIND Glucose self-monitoring LMIC market report 2021
LFAC	A peer reviewed publication of a market report and mapping entitled "Blood glucose meters and test strips: global market and challenges to access in low-resource settings".[20]	In addition to general market considerations, the publication provides pricing and country data for glucose test strips.		Klatman et al. BGMs and test strip global market and low-resource settings; Lancet D&E 2019
FIND	Test directories for BGMs and CGMs have been compiled.[21,22]	The BGM test directory includes all products from 19 large and medium-sized BGM manufacturers; the CGM test directory lists all market-approved devices at the time of publication, including key technical characteristics.	The test directories help to navigate the complex landscape of technologies and their key technical features to aid product selection.	FIND BGM test directory 2024 FIND CGM test directory 2024
FIND, HAI/ACCISS	CoGS for glucose test strips[18] and CGMs.[41]	CoGS estimates are based on technical evaluations of the products and manufacturing processes	Understanding CoGS supports decision making in price negotiations and product procurement.	FIND Report on Local manufacturing of blood glucose test strips in LMICs 2025 Ewen et al. Availability, prices & affordability of SMBG/CGM devices in 6 LMICs; BMJ Public Health 2025

Recommendations

To leverage the possibility of greater affordability of glucose tests strip through local manufacturing, efforts should be made in LMICs to increase demand for test strips, in conjunction with government commitment to purchase higher volumes and tenders to guarantee volumes high enough for fully locally produced, lower-cost products. Furthermore, pooling demand regionally is a mechanism to increase production volumes. To this end, local manufacturers should aim to obtain stringent regulatory approval and WHO pre-qualification for their products to potentially lower the complexity of product registration in neighbouring countries.

A commitment by global donors to include glucose test strips from LMIC manufacturers on their procurement list may drive demand and as such de-risk the investment in a cost-effective manufacturing process.

For CGMs, greater demand and thus higher volumes are also a lever to stimulate availability and affordability. New CGM manufacturers in particular will benefit from the impact of higher-volume production on their CoGS and thus allow them to enter new markets at a competitive price point. Currently, no LMIC government purchases CGMs (with the exception of Brasilia in Brazil, where CGMs are provided for people living with type 1 diabetes) and initial public sector volumes in any LMIC are unlikely to meet volumes required to reduce CoGS considerably. A pooling of demand across countries and collaborative purchasing or a joint volume guarantee could be a mechanism to overcome the barrier of low volumes to better pricing. Dedicated efforts are needed to investigate the feasibility of such mechanisms. More market competition may also put pressure on established manufacturers with high volumes and significantly lower CoGS compared to market rates to lower their prices to buyers.

2.3. Product registration

Registration and regulatory requirements (SRA, WHO-PQ, NRA) **|** Technical capacity of regulators **|** Pre-market scientific evaluations to test accuracy, usability, safety

Barriers

Registration of BGMs by stringent regulatory authorities usually requires that the products either meet the ISO 15197 standard or the FDA BGM Guidance, in addition to further locally defined technical requirements.[23,24] The availability of these standards and their adoption by regulatory authorities enables comparability of product quality and performance at the time of registration. However, unlike other in-vitro diagnostics (IVDs), test strips for BGMs are not subject to lot-release checking by external authorities (as is the case for e.g., HIV IVDs), neither is it necessary to refresh certification of a product after a period of time to ensure consistent product quality. This can lead to a drift in accuracy over time due to variability in the production process or use of raw materials. Several independent studies have assessed on-market products against the ISO standards and FDA guidance finding that not all met the required criteria.[25,26] This results in inconsistent glucose readings in the hands of the user, critically impacting decision-making and confidence in the readings. While accuracy is of utmost importance to any user globally, the impact on LMIC users may be augmented by limited access to healthcare professionals and diabetes education to support the user during times of uncertainty.

Regulatory requirements for CGMs are currently standardised to a lower degree compared to BGMs, particularly with respect to data requirements for determination of system accuracy. This gives manufacturers more flexibility in trial design (e.g., number of participants with type 1 diabetes vs type 2 diabetes or number of data points per glucose range), which may subsequently lead to over-optimistic

performance data for a product. A recent independent performance evaluation of two on-market CGMs showed one product performing well below the manufacturer claim, resulting in potentially dangerous readings for the user. Nevertheless, the product is registered in several countries, including at least one LMIC. While it is priced below current market rate, its suboptimal performance does not contribute to improved access to CGMs.

Regulatory capacity to assess technical data of CGMs can be a weakness in LMICs, as the experience of regulators is limited because not many manufacturers are entering LMIC markets. The lack of regulatory capacity and clear, harmonised requirements across LMICs for CGMs can also cause reluctance of manufacturers to attempt to register their product, as this can make the process lengthy and cumbersome, requiring individual approaches per country.

In general, most self-monitoring products entering LMIC markets have not been evaluated for accuracy under local environmental conditions (e.g., heat and humidity), nor have they been tested in the hands of the local users. This poses a barrier to uptake, particularly of new products, as no data or experience exists among users, potentially causing a reluctance to adopt potentially good products with a competitive price point.

Organisations & activities addressing barriers

Table 4. Product registration

Organisation(s)	Activity	Explanation	How it addresses barriers	Links
HAI/ACCISS, FIND	A "Regulatory Profile: Glucose Self-monitoring Tools".[27]	Brings together the range of international regulatory frameworks and examples of local regulations for BGM and CGM devices.	As the global and national regulatory landscape is complex, the report serves to inform and highlight regulatory strengths and weaknesses.	HAI, ACCISS, FIND Regulatory Profile Glucose Self-monitoring 2021
WHO	"Technical Specification Series 19: In-vitro diagnostic medical devices for monitoring of blood glucose and capillary blood" - Prequalification Programme (PQ).[28]	Outlining data required for submission to WHO by diagnostic manufacturers to apply for WHO-PQ.	The PQ programme provides reassurance to LMIC procurers on product quality and serves to strengthen regulatory standards.	WHO PQ TSS 19

Other technical organisations that do not specifically focus on global health needs have critically contributed to better standardisation of regulatory requirements—such as the Institute for Diabetes Technology and the International Federation of Clinical Chemistry and Laboratory Medicine Working Group—through thought leadership and evidence generation for better standardisation of CGM regulatory requirements.[29]

Recommendations

In order to address test strip quality issues, lot-testing should be considered in LMICs (e.g., prior to release of a product lot into the national market). In 2017, WHO and FIND developed lot release testing capacity for Malaria rapid diagnostic tests and a similar model could be tested for glucose test strips. Other factors in the supply chain may also impact quality (e.g., temperature and humidity exposure), and thorough data are critically needed on the consistency of product quality along the full supply chain in order to determine the most effective intervention to ensure consistency of quality products in the market.

Post-market surveillance and investigation of technical complaints also plays a critical role in identified sub-standard products. This is the role of national regulatory authorities, however, many national bodies in LMICs lack the capacity to set up a standardised system for complaint investigations or thorough post-market surveillance. Experience sharing from institution in countries with established systems would be valuable to strengthen post-market surveillance in LMICs and build the required capacity.

For CGMs, efforts are under way by experts to define minimum expectations for market authorisation of CGMs more consistently, which will lead to more reliable products on the market if regulatory authorities adopt the requirements.[29,31] A clear set of standards will be very valuable to facilitate regulatory review, approval and market authorisation and efforts need to be made at regulatory authority level to adopt these standards. Furthermore, harmonisation or collaborative registration across countries is a possibility to overcome reluctance of manufacturers to register their products in new markets. These approaches should be tested at a regional level with concrete initiatives.

Ideally, all products used in LMICs should have local pre-market scientific evaluations to confirm accuracy under different local environmental conditions (e.g., heat and humidity), as well as in the hands of the local users. With the launch of the WHO PQ process, this gap is partly filled for BGMs as manufacturers are required to submit performance and usability data from at least two LMIC geographies. This provides LMIC regulatory authorities with a degree of certainty of product performance in their context for BGMs. To this end, awareness building among LMIC regulators and procurers is needed now to ensure WHO PQ is considered a requirement.

Given the diversity of LMIC geographies, country-specific performance and usability data remain highly valuable as they can be critical in building trust in the product locally and encourage adoption among users.

2.4. Selection, pricing, reimbursement

Selection: WHO EDL, WHO and other technical specification documents | Post-market scientific evaluations to test accuracy, usability, safety

Barriers: Selection

The WHO model list of essential diagnostics (EDL) serves as a global guidance document for governments to develop national EDLs and procurement plans. While BGMs have always been included in the EDL's section for use in healthcare facilities without laboratories (i.e., use by healthcare providers), the 4th edition of the EDL now also includes specific mention of BGM availability for self-monitoring at home. While this is a welcome addition to the EDL, so far no LMIC has adopted the use-case of glucose self-monitoring explicitly in their EDL, potentially overlooking the critical need of additional BGM and test strip supplies for self-monitoring.

Product selection by purchase decision makers (e.g., government procurers, distributors, private individuals) depends on a multitude of factors, including technical features (such as accuracy, measuring range and user features), the use case (for self-testing or facility-based testing) and cost-benefit considerations (i.e., investment for an anticipated health impact). Currently, unless BGMs and test strips are provided by the government under universal health coverage (UHC) schemes or through private health insurance providers (including for CGMs, which are covered by private insurers in some LMICs), selection of products for self-testing is made by the users. While users highly value accuracy of a product, it can be difficult to interpret technical specifications from a package insert. Furthermore, performance may differ from what is claimed in the package insert, unintentionally leading to suboptimal choices of self-monitoring devices. Furthermore, product selection can also be highly influenced by marketing, conflicting with a user's wish to select the product with the best features for their needs and a company's desire to sell their product.

Post-market scientific evaluations are critical to tests accuracy, usability and safety. For BGMs there is a small but continuous stream of study data being published on post-market device performance. However, such data is far less available for CGMs, particularly for the many new CGMs now entering the market. Moreover, not many product evaluations cover performance in LMIC geographies, leaving a critical data gap to guide selection.

Guidance documents for the selection of products for different use cases are also critical on the road to better access to self-monitoring devices, as these are used by governments to make procurement decisions.

Organisations & activities addressing barriers: Selection

Table 5. Selection

Organisation(s)	Activity	Explanation	How it addresses barriers	Links
HAI/ACCISS, FIND, UNICEF	Target Product Profiles for BGMs and CGMs (see also Table 2).	Outlining minimal and optimal specifications within which a product should fall.	To guide product R&D and selection	Safary et al. TPP development for new glucose self-monitoring technologies for use in LMICs; PLoS One 2024 UNICEF Glucose meter TPP 2020
WHO	Technical specification requirements for BGMs.[32]	Describing exact requirements of products.	To guide product R&D and selection	WHO Technical Specifications BGMs 2023

Organisation(s)	Activity	Explanation	How it addresses barriers	Links
FIND, University of Geneva, CRONICAS	Technical landscapes and reviews of BGMs and CGMs (see also Table 2 and Table 3).	Listing technical characteristic and specifications of marketed products; includes assessments against the REASSURED criteria.[33,34]	Landscapes of available products to match actual and desired specifications more easily.	FIND BGM test directory 2024 FIND CGM test directory 2024 Shang et al. Landscape of new technologies for self-monitoring of glucose; JDST 2021 Zafra-Tanaka Technologies for Diabetes Self-Monitoring: A Scoping Review; JDST 2021
FIND	Field study of "Analytical and user performance of four blood glucose monitoring devices in low- and middle-income countries" (Cambodia, Nigeria, Colombia).[35]	An independent post-market performance accuracy and usability study of BGMs in the hands of trained and lay users.	Bringing valuable information for product selection in different geographical regions and environmental conditions	Singh et al. Analytical and user performance of four blood glucose monitoring devices in low- and middle-income countries; manuscript in preparation 2025
FIND	Field study of "Performance Assessment of Three Continuous Glucose Monitoring Systems in Adults With Type 1 Diabetes".[36]	An independent post-market performance evaluation of CGMs.	Showed that CGM accuracy can markedly differ in field evaluations, compared to a manufacturer's claim, thereby supporting informed product selection.	Kölle et al. Performance assessment of three CGMs in adults with type 1 diabetes; JDST 2024
FIND	A "CGM performance evaluation fact sheet".[37]	A fact sheet for users and healthcare providers to make understanding of CGM analytical performance data simpler and judge quality of the evidence.	This can aid in product selection and avoid using CGMs with low quality evidence when tested for accuracy in studies.	CGM performance evaluation fact sheet
WHO, LFAC, FIND	4th edition of WHO's "Model List of Essential Diagnostics List" (EDL).[38]	Following an application by LFAC and FIND, the 4th EDL now includes the listing of glucose meters specifically for self-monitoring for diabetes.	This inclusion highlights the critical importance of BGMs for self-monitoring and paves the way for inclusion in national essential diagnostics lists.	WHO announcement Essential Diagnostics List 2023

Recommendations: Selection

The technical guidance documents for BGMs and CGMs published to help buyers make informed choices are critical for in-depth information but can be complex to navigate. Easy-to-use factsheets or digital quick guides on how to select a self-testing technology based on desired specifications can be valuable, particularly for new technologies. For CGMs, FIND has developed a factsheet on how to interpret data from package inserts or scientific publications on key data aspects to help the user gauge the reliability of performance data. Development of such factsheets or quick guides should be considered alongside any new technical documentation that is intended to aid in product selection.

Independent post-market scientific evaluations in LMICs should complement technical documentation and data generated by manufactures. There is strong interest from LMIC clinics and academic institutions to conduct such performance evaluations, and more funding needs to be made available from manufacturer-independent sources to conduct such studies for BGMs and CGMs.

At policy level, efforts must be made to ensure adaptation of national EDLs with respect to the addition of a self-monitoring use case for BGMs, as per the 4th edition of the global EDL.

Barriers: Pricing, reimbursement

Pricing, reimbursement: Mechanisms of prices setting (HTA, policies, market dynamics, WTP) | Government provision, health insurance schemes

Several analyses have shown that the cost of self-monitoring tools can outweigh the cost of insulin, posing a significant barrier to access for people with diabetes, as well as governments and their constrained health budgets.

Pricing for test strips in the private sector is significantly driven by product branding and margin-setting by sellers, keeping them at an unaffordable level for many people living with diabetes. While there are a range of factors influencing self-monitoring behaviour, a US study on lowering cost share for home self-monitoring suggests that this may improve rates of self-testing.[39] Currently, solid data are lacking on the effect of lower-priced test strips on pharmacy shelfs in LMICs and the impact on consumer purchasing behaviour.

CGMs are out of reach for most in LMICs due to the significant cost per CGM sensor and the absence of government provision in (almost) any LMIC. Private sector market dynamics, which are strongly driven by manufacturer price-setting, allowed a certain price and margin expectation to gain foothold in the CGM market. Limited data are available to predict market dynamics at different CGM price-points based on willingness to pay (WTP) surveys. There is likely a sizeable untapped market potential for CGMs, if market prices are adjusted to consumer purchasing power, as well as governments and private health insurer's willingness and ability to invest in CGMs.

Organisations & activities addressing barriers: Pricing, reimbursement

Table 6. Pricing, reimbursement

Organisation(s)	Activity	Explanation	How it addresses barriers	Links
LFAC	A market report entitled "Blood glucose meters and test strips: global market and challenges to access in low-resource settings".[20] (see also Table 3)	Contains glucose test strip pricing information from 46 countries and the west African and central American region, as provided by a market research company. The study also puts test strip prices in the context of insulin pricing for a number of countries.	Brings transparency to pricing and aids procurement decisions.	Klatman et al. BGMs and test strip global market and low-resource settings; Lancet D&E 2019
HAI/ACCISS	A study on "Availability, prices and affordability of self- monitoring blood glucose devices: surveys in six low- income and middle- income countries".[40]	Providing data on the cost for BGMs and test strips in the public and private sector in six LMICs (Fiji, Indonesia, Kyrgyzstan, Mali, Peru and Vietnam) The study also includes insulin pricing and puts data in context of affordability (see Table 7).	Brings transparency to pricing and aids procurement and resource allocation decisions.	Ewen et al. Availability, prices & affordability of SMBG/CGM devices in 6 LMICs; BMJ Public Health 2025
WHO	A report on "Availability, price and affordability of health technologies for the management of diabetes".[41]	Providing data on the cost of BGMs and test strips as provided in the published literature and obtained through price collection from third parties and an online survey The study also puts prices in the context of affordability (see Table 7).	Brings transparency to pricing and aids procurement and resource allocation decisions.	WHO Availability, price and affordability of health technologies for the management of diabetes
FIND	Two "Willingness to Pay" surverys: 1)"Willingness to pay survey for continuous glucose monitoring devices in South Africa and Kenya"[42], 2) Willingness to pay for continuous glucose monitoring in the public sector in South Africa".[43]	First survey assessed acceptable price ranges for the product in relation to current market rates; the second survey focused exclusively on people accessing public health services.	This puts market prices in relation to willingness to pay by users and serves to highlight the differences, potentially encouraging manufactures to adjust their prices strategies to increase their market reach.	Kamau et al. Willingness to Pay for CGMs in SA and KE; 2024 Girdwood et al. Willingness to pay for CGMs in SA public sector 2025

Recommendations: Pricing, reimbursement

As private sector retail channels are still the most frequent source of glucose self-monitoring technologies for people living with diabetes in many LMICs, it is critical to achieve lower prices in this sector, in line with willingness to pay. Market models should be developed to quantify the accessible market based on different product prices in relation to population income levels. This should be complemented by interventions testing the impact of different price points on consumer purchasing behaviour in the market.

Willingness to pay is also critical with respect to government purchasing, as well as private health insurance providers. Structured assessments of scenarios under which these two types of payers may be willing to reimburse self-monitoring technologies may pave the way for negotiations with manufacturers, particularly with respect to CGMs, considering these are largely absent from their reimbursement portfolio to date.

2.5. Procurement and supply

Procurement practices (public and private sector) **|** Donation programmes **|** Relationship pricing & procurement (affordability) **|** Supply chain practices and costs (tariffs, taxes, transport, mark ups)

Barriers

A fragmented and highly competitive market makes effective procurement practices for glucose test strips challenging. While tenders can achieve fairly competitive test strip prices due to high volumes and government bargaining power, many countries do not prioritise glucose test strips for consolidated procurement at national level to achieve large volumes. This results in higher price offering for bids and a fragmentation in the market due to sub-national purchasing.

Manufacturers often supply free glucose meters in public tenders in the hope that this triggers product loyalty. Procurement and tender practices, however, often do not take this into account, making it less attractive for manufacturers to offer lower strip prices, as the costs of the glucose meters may not be recovered. Furthermore, procurement of self-testing supplies is also often not aligned (or deprioritised) with insulin procurement, resulting in a need and availability mismatch of these commodities and lack of self-testing supplies. Co-procurement and co-packaging solutions have been given consideration to optimise supply availability (see below).

In general, the lack of large volumes, gaps in market knowledge and suboptimal need and demand forecasting can put buyers in a disadvantaged position when it comes to price negotiations with suppliers. Pre-negotiated product prices available through NGOs or social business enterprises can be a mechanism to achieve better prices for buyers without over-burdening the procurement process with volume consolidations and negotiations. As pre-negotiated prices usually exclude shipping and other supply chain costs, it is critical that they withstand the pressure of margins in the supply chain. However, none of these mechanisms have yet achieved prices that make glucose test strips significantly more affordable for people with diabetes who do not benefit from public sector provision of BGMs under UHC schemes. Several recent analyses have shown that test strips remain unaffordable to many in LMICs. Thus, donation programmes are frequently the only option to enable access to self-monitoring tools (and insulin).

CGM procurement in LMICs is limited to the private sector and largely happens through online retail channels, either through distributors within a country where the product is registered, or through cross-border shipments. The latter practice frequently results in very high shipping costs and potentially in the purchase of a product that is "geo-fenced" by the manufacturer and thus unusable in the country of the consumer unless they have a dedicated reader. Triggering this behaviour is the dire absence of registered CGMs and official sales channels in many LMICs due to manufacturer's perception of absence of demand high enough to justify the cost and effort of local registration.

Organisations & activities addressing barriers

Table 7. Procurement & supply

Organisation(s)	Activity	Explanation	How it addresses barriers	Links
Procurement practices & supply chain				
HAI/ACCISS	Two guideline documents on "Procurement of Insulin and Associated Supplies" and "Pooled Procurement of Insulin and Associated Supplies".[44,45]	Assessing mechanisms for efficient procurement of insulin and glucose test strips.	Provides information how to optimise procurement practices and thus potentially achieve more affordable product prices	HAI, ACCISS Guidelines for procurement of insulin and associated supplies, 2021 HAI, ACCISS Pooled procurement of insulin and associated supplies, 2022
University of Geneva	A fact sheet listing "Sources of insulin, oral medicines, and medical devices for diabetes in low- and middle-income countries" (NCD Policy Lab).[46]	Including (where available) prices and contacts to agencies through which supplies can be procured.		NCD Policy Lab - Medicines and devices sources and supply 2024
FIND	Pre-negotiated access pricing agreements with two BGM manufacturers for meters and test strips.[47]	Prices are available to public and private buyers in LMICs and those with operations in LMICs. Products and prices are accessible through FIND's DxConnect Marketplace.[48]	Enables eligible buyers to access lower BGM and test strip prices without needing to negotiate with manufacturers and regardless of volumes.	FIND Glucose meter and test strip access pricing agreements 2021 FIND DxConnect Marketplace
IDA Foundation	NCD Connect.[49]	Online procurement platform for NCD products. FIND and the IDA Foundation entered into a partnership[50] making available the FIND negotiated products (BGMs, test strips) through NCD Connect.	The procurement platform leverages IDA's ability to optimise supply chain costs under their social-business enterprise model and thus makes products potentially more affordable.	IDA Foundation NCD Connect NCD Connect IDA and FIND partnership 2024

Organisation(s)	Activity	Explanation	How it addresses barriers	Links
HAI/ACCISS	A case study on "Price components of Blood Glucose Meters and Test Strips (China, Peru, Uganda)".[51]	The study analyses mark ups per country and specific product along the supply chain.	Brings transparency to prices along the supply chain.	HAI/ACCISS Country case studies on price components of BGMs and test strips, 2024
Supply bundles				
Santé Diabète, MSF	A technical brief on diabetes supplies.[52]	Explores the total cost of a "product bundle" of insulin and associated supplies, using different available access pricing.	Brings visibility to procurement costs when the need for insulin and self-monitoring tools is matched	MSF-SD NCD TechBrief 2022
PATH	The "Diabetes CarePak" project.[53]	The project explores a human-centred co-packaging solution of diabetes supplies needed for safe administration of insulin and self-care.	Improve access to safe administration of insulin in a practical way by increasing the affordability and availability of diabetes management supplies.	PATH Diabetes CarePak 2025
Prices and affordability				
HAI/ACCISS	A study on: "Availability, prices and affordability of self- monitoring blood glucose devices: surveys in six low- income and middle- income countries" (see also Table 3 and Table 6).[41]	Providing data on the cost for BGMs and test strips and insulin in the public and private sector in six LMICs (Fiji, Indonesia, Kyrgyzstan, Mali, Peru and Vietnam) and puts data in the context of affordability.	Affordability data are critically needed to put prices for self-testing equipment into context and demonstrate the gaps in affordability for diabetes supplies.	Ewen et al. Availability, prices & affordability of SMBG/CGM devices in 6 LMICs; BMJ Public Health 2025
HAI/ACCISS	A study on "Availability, prices and affordability of insulin, delivery devices and SMBG devices in Indonesia".[54]	Providing data on the cost of testing supplies and insulin and puts them into context of affordability.		Ramadaniati et al. SMBG devices in Indonesia, 2024
WHO	A report on "Availability, price and affordability of health technologies for the management of diabetes" (see also Table 6).	Providing data on the cost of BGMs and test strips as provided in the published literature and obtained through price collection from third parties and an online survey The study also puts prices in the context of affordability.		WHO Availability, price and affordability of health technologies for the management of diabetes

Organisation(s)	Activity	Explanation	How it addresses barriers	Links
Global donation programmes				
LFAC	Donation programme in 53 LMICs.[56]	In partnership with Eli Lilly, Roche, Trividia Health, and i-SENS supporting children and young adults with insulin and testing supplies.	For people who cannot afford diabetes supplies and in the absence of UHC, donation programmes are the only option to ensure continued access to insulin and testing supplies.	LFAC Annual impact reports
Roche, Novo Nordisk	Donation programme in 30 LMICs.[57]	Supporting children and young adults with insulin and testing supplies.		Roche - CDiC

Recommendations

Pooling procurement at national level or across countries within a region is an option to achieve lower price offerings through large volumes and better bargaining power. For glucose test strips, this has been successful, for example, in South Africa with the first national tender for glucose tests strip in 2020 and learnings should be shared broadly on the process of moving away from sub-national tender procurement practices for this product. For CGMs, a pooling of demand across countries and collaborative purchasing could be a mechanism to overcome the barrier of low volumes to better pricing, as mentioned in section 2.2. Dedicated efforts are needed to investigate the feasibility of such mechanisms.

Moreover, continued efforts need to be made to engage with national governments on the implementation of procurement practices as outlined in published guidance documents.[45] FIND's available access price agreement for glucose test strips provides a good opportunity for procurers to overcome some of the mentioned procurement barriers. Yet its uptake has been limited, particularly by large procurers often bound by institutional product selection processes and thus less able to leverage prices on pre-selected products. Under these circumstances, procurement entities should use the existing access price agreements as guidance to negotiate their respective deals with glucose test strip manufacturers, as most large procurers have test strip and BGM deals far less favourable.

HAI/ACCISS have long conducted work to put diabetes supply prices in relation to affordability. These data are highly valuable as they demonstrate the massive gap between market prices and ability to pay for supplies. It is now critical that national organisations leverage these data to advocate for inclusions of diabetes testing supplies in UHC schemes. Furthermore, the data should be used for incorporation into models quantifying the accessible market under lower price points (see also 2.4).

2.6. Prescribing

Prescription and recommendation practices for self-monitoring by HCPs and pharmacy professionals (public and private sector) | Selection of products that are prescribed, recommended or purchased (by HCPs, pharmacy professionals or users)

Barriers

All guidelines on diabetes management adapted to a LMIC context include recommendations to practice self-monitoring (see Table 8). However, these can differ across internationally recognised diabetes guidelines from the American Diabetes Association (ADA), the International Society for Pediatric and Adolescent Diabetes (ISPAD) or the European Association for the Study of Diabetes (EASD).[57,58,59]

Unfortunately, it is not uncommon that HCPs do not discuss the topic of self-monitoring in depth as they lack knowledge of self-monitoring practice. This knowledge gap needs to be addressed in order to increase awareness and practice of self-monitoring.

When possible and given the choice, the selection or recommendation of specific products by HCPs, pharmacy professionals or users is highly driven by consumer preference of product features. While these can be generic, such as size and shape of the meter and strip, type of power source (batteries or rechargeable) or the presence of a strip ejector, it is important to be aware of a few technical specifications that can facilitate interpretation of the results, such as colour-coded range indicators or symbols for low/high readings, large displays or audio-reading of the result. Guidance is needed on product selection when recommending or purchasing BGMs, as a suboptimal choice of equipment may be a barrier to continued use.

Recommendations of CGMs by HCPs is uncommon in LMICs outside of private sector health facilities. Only in instances where manufacturers have donated supplies to public sector clinics or where people with diabetes obtain products themselves, are they used in public clinics. While cost plays a major role in the absence of CGM recommendation in public sector clinics, the lack of thorough training for HCPs how to integrate CGM data into diabetes care, as well as the lack of diabetes educators to support transition to self-monitoring with CGMs, are also major barriers to their recommendation. In case HCPs do discuss CGM use with their patients, selection of the right product is also important for this technology, as technical aspects such as location on the body, type of reader to obtain data and alarm settings can pose barriers to use of CGMs.

Organisations & activities addressing barriers

Table 8. Prescribing

Organisation(s)	Activity	Explanation	How it addresses barriers	Links
Guidelines and technical briefings adapted to LMICs				
WHO	The "Package for Essential Noncommunicable Disease Intervention (PEN-package)".[60]	Includes recommendations for self-monitoring of blood glucose for people with type 1 and type 2 diabetes on insulin in the document's section on Self-Care.	Guidelines and technical briefings with recommendations to practice self-monitoring, adapted to LMICs.	WHO PEN Package 2020
WHO	The "HEARTS-D guideline on Diagnosis and Management of Type 2 Diabetes".[61]	Mentions the relevance of measuring glucose profiles with several pre- and postprandial measurements throughout the day, suggesting encouragement of home self-monitoring		WHO HEARTS-D 2020
WHO	The "WHO recommendations on care for women with diabetes during pregnancy".[62]	Provides recommendations when to practice glucose self-monitoring with glucose meters and strips or CGMs for women with different types of diabetes.		WHO Diabetes in pregnancy 2025
WHO	A "Technical Briefing for Appendix 3" of the "Global Action Plan for Non-Communicable Diseases".[64]	Includes a recommendation of home glucose monitoring for people treated with insulin and the supply of a glucose monitoring device and three test strips per day for self-monitoring.		WHO GAP Appendix 3 Technical Briefing Diabetes 2022 WHO Global Action Plan for NCDs 2013-20230
WHO	The "Best Buys and other recommended interventions for the prevention and control of noncommunicable diseases".[65]	List Home glucose monitoring as an effective intervention for managing diabetes.		WHO Best Buys for NCDs 2024
Humanitarian organisations	An Operational Guide on "Integrating Non-communicable Diseases Care in Humanitarian Settings".[66]	Including guidance to plan for home monitoring of blood glucose levels and support access to glucose meters and tests strips.		Operational Guide - Integration of NCD Care in humanitarian settings 2020

Organisation(s)	Activity	Explanation	How it addresses barriers	Links
IDF	The "Good Clinical Practice Recommendations for Type 2 Diabetes Management".[67]	Including recommendations on self-monitoring of blood glucose using BGMs and continuous glucose monitoring using CGMs.		IDF Global Clinical Practice Recommendations T2D 2025
Training and education				
IDF, FIND	Several courses hosted under the "IDF School of Diabetes".	Trainings including or specifically addressing glucose self-monitoring 1) Type 1 diabetes: overview, treatments and targets.[68] 2) Continuous Glucose Monitoring for Healthcare professionals.[69] 3) Continuous Glucose Monitoring for People living with diabetes.[70]	Upskilling HCPs and people living with diabetes on self-monitoring.	IDF course - Type 1 diabetes: Overview, treatments and targets FIND-IDF CGM online training for healthcare professionals FIND-IDF CGM online training for people with diabetes
LFAC	A range of "Education & Training" resources.[71]	Trainings include self-monitoring of blood glucose.		LFAC Education & training materials
NCD Poverty Network, Breakthrough T1D, CHAI	Examples of global organisations who have developed training materials for their country initiatives.[72,73,74]	Training materials include aspects of glucose self-monitoring.		NCD Poverty Network - PEN Plus Breakthrough T1D Global Health Initiatives CHAI's approach Diabetes and Hypertension
FIND	Digital education for pharmacy professionals.[75]	Training on self-monitoring for pharmacy professionals to provide education to people with diabetes in pharmacies.	Leveraging channels outside healthcare facilities as education opportunities for self-monitoring.	Haldane et al. Diabetes and glucose monitoring knowledge and practice among pharmacists in KH and VN; BMC Medical Education 2023
Product selection guidelines				
HAI/ACCISS, FIND, WHO, UNICEF, University of Geneva, CRONICAS	TPPs, technical specifications, technical landscapes and test directories as listed in Table 2, Table 3 and Table 5.	Documents describing and listing the technical differences, minimal and optimal product requirements and available products.	Understanding the technical differences and requirements of the various types and brands of self-monitoring tools is critical in order to recommend a high quality, accurate and appropriate tool for self-monitoring.	Listed in Table 2, Table 3 and Table 5.

Recommendations

Educational materials to support prescription and recommendation practices for self-monitoring, as well as product selection documents have been developed and some recommendations, particularly with respect to product selection documents, have been made in a previous section.
Many national and local organisations have developed context-specific education material for diabetes, which is critical to enable most effective learning. Their focus is largely on self-monitoring with BGMs and tests strips and their use should be continuously encouraged to address the persistent knowledge gap on the value of self-monitoring.

The free online CGM training course for HCPs and people living with diabetes, developed by IDF and FIND, has seen considerable uptake in LMICs, indicating a need for more training resources, ideally adapted to the local healthcare system and context. Medical training councils should be encouraged to include CGM use in their curriculum.

No global diabetes guideline adapted to LMICs include considerations around use of CGMs in diabetes management. While this is understandable, given the dire lack of access, it may be valuable to consider a degree of information or guidance for CGMs in order to build capacity among HCPs.

2.7. Dispensing

Availability of BGMs, strips and/or CGMs in pharmacies (public and private) and other retail channels | Product prices (public and private sector)

Barriers

Even if countries have committed to provision of glucose test strips under UHC and public sector procurement takes place, products may not be consistently available in pharmacies and healthcare facilities. Likewise, private sector pharmacies and healthcare facilities may have inconsistencies in their product availability. Thus, supply issues in both sectors are likely to impact availability of self-monitoring equipment at the household level.

Moreover, a challenge is not only lack of general availability but also the variability of types of products, meaning that users may need to obtain different meters to adapt purchase of strips based on pharmacy or facility availability. This requires further financial resources in addition to the already high cost of tests strip, not to mention the impact on adequate glucose management through the use of different BGMs.

Manufacturers are often unaware of the supply challenges that users face due to the multitude of players in the product supply chain (e.g., distributors, re-sellers, pharmacies).
CGMs are not usually sold in pharmacies in LMICs but available through online retail channels, impacting cost and accessibility. Also, costs of CGMs are beyond reach for most people with diabetes in LMICs (see section 2.4) and retail prices do not mirror the lower purchasing power of LMIC consumers.

Organisations & activities addressing barriers

Table 9. Dispensing

Organisation(s)	Activity	Explanation	How it addresses barriers	Links
Availability				
HAI/ACCISS	A study on: "Availability, prices and affordability of self- monitoring blood glucose devices: surveys in six low-income and middle-income countries" (see also Table 3 and Table 6).[41]	Providing data on the availability of BGMs, test strips and CGMs (and insulin) in the public and private sector in six LMICs (Fiji, Indonesia, Kyrgyzstan, Mali, Peru and Vietnam).	Brings transparency on availability and lack of supplies, which is frequently unknown at the level of country procurement.	Ewen et al. Availability, prices & affordability of SMBG/CGM devices in 6 LMICs; BMJ Public Health 2025
LFAC	A study "Documenting and visualising progress towards Universal Health Coverage of insulin and blood glucose test strips for people with diabetes".[76]	Provides data on availability of test strips in less-resourced health systems.		Klatman et al. Coverage of insulin and blood glucose test strips; Diabetes Res&Clin Practice 2019
LFAC	Modelling on "Costs and outcomes of "intermediate" vs "minimal" care for youth-onset type 1 diabetes in six countries".[77]	Includes aspects of different numbers of test strips used per day for self-monitoring and the impact on cost and outcomes.	Demonstrates the impact on outcomes in case of lower availability of test strips.	Gregory et al. Costs and outcomes of intermediate v minimal care for T1D in 6 countries; Pediatric Diabetes 2020
IADA	The UNITED Study: "An inter-humanitarian agency study of diabetes care and surveillance in humanitarian settings".[78]	Includes the assessment of availability of home glucose monitoring in 65 humanitarian sites.	Brings visibility to the availably and lack of supplies for self-monitoring in humanitarian settings.	Kehlenbrink et al. Humanitarian Agency study of Diabetes Care; The Lances D&E 2022
HAI/ACCISS	The "Monitoring Access to Insulin (MAIn) tool".[79]	An app-based survey tool for phone or in-person regular monitoring (or one-off surveys) of facilities and households who use insulin and blood glucose self-monitoring devices within countries.	An online dashboard provides real-time data and transparency on access to self-monitoring devices, which can be used to track availability over time.	ACCISS MAIn Tool

Organisation(s)	Activity	Explanation	How it addresses barriers	Links
Product prices				
HAI/ACCISS, FIND, CHAI, LFAC	Market reports and Willingness to Pay analysis.	Reports and publications provide information and examples of product prices in different countries and in the public and private sector.	Price transparency is key to advocate for adjustments in order to improve affordability; publicly available pricing information also helps in negotiations with manufacturers.	See Table 3, Table 6 and Table 7
WHO	Conducted "Engagements with private sector".[80]	Structured engagement sessions with manufacturers to encourage them to commit to a set of "Asks", including greater affordability of self-monitoring tools.	Aimed at improving availability and affordability of diabetes medicines and technologies.	WHO Diabetes Private Sector Dialogue information 2021
Access to Medicine Foundation	Annual "Amsterdam Sessions"[81,82,83]	Meetings to bring together manufacturers, public sector partners, global health organisations and experts who operate in LMICs to discuss practices and solutions for closing the gaps in access to diabetes care.	The sessions intend to share knowledge, highlight critical gaps and find solutions among sector participants to overcome access barriers.	Access to Medicine Foundation Amsterdam session 2022 Access to Medicine Foundation Amsterdam session 2023 Access to Medicine Foundation Amsterdam session 2024
Access to Medicine Foundation	Three reports entitled "What are pharma companies doing to expand access to insulin – and how can efforts be scaled up (2022)"[84], "Access to diabetes care for children and young people: Pharma companies' current actions and opportunities ahead (2025)"[85], and "Bridging the gaps: Making insulin and diabetes drugs more accessible in the Pacific (2025)".[86]	Three reports on manufacturer-supported strategies to improve access to diabetes care products for people living with Type 1 diabetes, with one of the three focused on children and young people, and another focused on access in Pacific Island countries.	Documenting activities enables to track progress and identify opportunities to address access barriers.	Access to Medicine Foundation Report – What are pharma companies doing; 2022 Access to Medicine Foundation Report - Access for Children and Young People; 2025 Access to Medicine Foundation Report – Access in the Pacific; 2025

Recommendations

Manufacturers, their distributors and country procurers should work together closely as much as possible to ensure consistent supply. It is critical that original manufacturers maintain a sense of ownership and responsibly for their product to ensure consistent local supply, rather than handing over supply responsibility to the first buyer in the supply chain, which is usually a distributor. As original manufacturers may have limited awareness of LMIC supply challenges for the user as identified through assessments by the global health community, it is critical to involve them as much as possible in conversations on better access to glucose self-monitoring. This will also help to increase awareness on the impact of product prices and the relationship to affordability.

Progress monitoring and a set of outcome measures of WHO's initiative of engagement with the private sector are key levers to strengthen manufacturers' awareness, commitment and activities in better access to glucose self-monitoring technologies. Access to Medicine Foundation monitors activities of manufacturers to improve access to their products, though to date the focus is largely on insulin manufacturers, some of which have started initiatives on access pricing for their products.[87,88] More pressure needs to be put on manufacturers of glucose self-monitoring technologies to start access pricing initiatives, moving beyond donation programmes. The only access price for glucose test strips available to LMIC buyers is through an agreement FIND has with two medium-sized manufacturers.[48] While a step in the right direction, their impact is limited due to market dynamics. The market dominating large manufacturers also need to offer access pricing in order to move the needle on affordability for their products.

In the CGM market, some manufacturers are starting to drive a dual-product strategy, selling their regular CGMs as premium product and a version with fewer features at lower cost (both limited to the private sector).[90] While this is a welcome development to see manufacturers adapt product strategies and prices somewhat, it raises concern of equity, given that the lower cost products are technically identical but certain features have been disabled by the manufacturer.

2.8. Use

Socioeconomic factors □ Diabetes knowledge | Human factors of testing (psychosocial barriers; product usability) | Impact on diabetes care and quality of life

Barriers

A paper published in 2014 developed a comprehensive visual representation of factors influencing a person's self-monitoring behaviour[90], including human factors of testing (psychosocial ones such as attitude, social support and health status, as well as equipment factors (such as reliability and ease of use), socioeconomic factors (such as lifestyle and cost) and diabetes knowledge (awareness, skills and education by HCPs). The paper discusses barriers and facilitators of self-monitoring around these aspects and many other articles in the published literature also aim to understand what factors influence self-monitoring behaviour. Given that most studies were conducted in countries where access to self-monitoring technologies is available, it demonstrates that barriers to "Use" continue to persist, even if other stages of the product lifecycle are largely addressed. Hence it is imperative to put a strong focus on work to address this final stage of the product life cycle in LMICs.

Addressing impact on diabetes care and quality of life is also critically important for self-monitoring tools to address the misconception that self-monitoring is a nice-to-have.

Organisations & activities addressing barriers

Table 10. Use

Organisation(s)	Activity	Explanation	How it addresses barriers	Links
Activities mentioned previously that address equipment factors, usability and training				
FIND, HAI/ ACCISS, UNICEF, WHO	TPPs and technical specifications.	Documents addressing equipment factors.	Comprehensive information of all factors influencing self-monitoring behaviour supports care delivery and adherence to self-management plans.	See Table 2 and Table 5
HAI/ACCISS, FIND, WHO	Studies and regulatory requirements.	Performance and usability assessments, as well as documents addressing regulatory requirements with respect to Use.		See Table 2, Table 4 and Table 5
IDF, LFAC, FIND	Training materials.	Training materials addressing human factors of testing.		See Table 8
Activities on CGMs				
MSF	Study on "Implementation of continuous glucose monitoring in a humanitarian setting, CGM use in humanitarian settings".[91]	A retrospective study on CGM use in a refugee camp in Lebanon.	The activities identify and address potential barriers related to the use of CGMs in LMICs. CGMs bring a different set of aspects to self-monitoring with respect to human, equipment and socioeconomic factors, as well as diabetes management knowledge and it is key to understand these well in a range of contexts to address access barriers holistically.	Masri et al. Implementation of CGMs in a humanitarian setting; 2020
NCDI Poverty network	A study on "Appropriateness and acceptability of continuous glucose monitoring in people with type 1 diabetes at rural first-level hospitals in Malawi: a qualitative study".[92]	A feasibility study on the use of CGMs in Malawi.		Appropriateness and acceptability of CGMs in T1D in Malawi; BMJ Open 2024
FIND	A study on "Benefits of Usability Evaluation in the Development Process of Diabetes Technologies Using the Example of a Continuous Glucose Monitoring System Prototype".[93]	A prospective study showing the value of assessing usability in the CGM product development process.		Beltzer et al. Benefits of usability evaluation in the development process of a CGM; JDST 2024
FIND, Cronicas	A publication on "Use of continuous glucose monitoring in low- and middle-income countries".[94]	A scoping review analysing the available evidence of CGM use on impact on diabetes management for people living with diabetes in LMICs.		Bernabe-Ortiz et al. Use of CGMs in LMICs: A scoping review; Diabetic Medicine 2023
FIND	A study on CGM use in people with type 1 diabetes.[95]	An operational research study to address the evidence gap on the impact of CGM use on clinical outcomes and quality of life in South Africa and Kenya.		Marban-Castro Implementation research protocol, CGM use in SA and KE; Trials 2024

Organisation(s)	Activity	Explanation	How it addresses barriers	Links
Impact on diabetes care				
Breakthrough T1D	T1D Index.[96]	A data simulation tool that maps how many people live with type 1 diabetes (T1D) in every country, the healthy years of life the condition takes from people and the number of people who would still be alive today had they not died prematurely from complications.	Specifically for self-monitoring, the T1D Index contains estimations how many hours of health life are restored for each glucose test strip or CGM sensor used for self-monitoring per person, which allows estimations of cost-effectiveness in removing access barriers.	The T1D Index

Recommendations

While these efforts support the understanding and removal of barriers to self-testing from the "Use" perspective, more efforts are needed to generate strong evidence based on the inter-connectedness of all self-testing barriers in LMICs. Test strip prices and lack of diabetes education are often cited as the key factors for limited self-testing. However, as seen in high-income settings, even once these are no longer a key concern, many barriers remain and these need to be fully understood for different geographies and population segments in LMICs to advocate for the right resources going forward. Demonstrating that self-monitoring has a quantifiable impact on diabetes care and quality of life through modelling and studies continues to be important for any self-monitoring technology in order to cement the notion that self-monitoring is critical for people living with diabetes.

Table 11. Barriers, Activities and Opportunities per lifecycle stage

Life cycle stage	Barriers	Activities	Recommendations
R&D and innovation	• Most R&D is in CGMs, but devices do not allow the user to balance testing frequency & cost • Accuracy of new devices is often sub-optimal • Innovation activity for BGMs is limited • Strong patent protection impedes innovation	• R&D guidance for BGMs, CGMs and other new self-monitoring technologies developed (TPPs) • Landscape with in-development devices available • Review of product iterations and patent protection conducted	• R&D and innovation for new technologies should focus on highly flexible devices, adaptable to user needs • TPPs need to be taken into consideration, more awareness raising among developers is needed • Partnerships needed between manufacturers and technology development organisations focusing on LMIC needs, to jointly develop optimal products • Innovative ideas are required to overcome meter/strip exclusivity • Assess degree of opportunities that may lay in off-patent aspects of self-monitoring technologies
Manufacturing	• Local manufacturing of test strips can be cost-effective, but only if process is fully automated • LMIC market volumes for test strips are frequently too low for investment in full automation • New CGM manufacturers struggle to drive down CoGS due to initial low volumes	• Global and country-level analysis of test strip manufacturing landscape, prices and approaches conducted • Market reports and landscapes for BGMs and CGMs available • CoGS estimations for test strips and a CGM available	• Explore market mechanisms on viability to secure test strip volumes for fully locally manufactured test strips in combination with government / payer commitments at national or regional level • Explore pooling of CGM demand at regional level to enable new CGM manufacturers to drive down CoGS and launch products at competitive prices • Pressure on established CGM manufacturers should be increased to adjust selling prices in relation to CoGS; more CoGS examples are needed, particularly for CGMs
Product registration	• BGMs/CGMs can often obtain registration in LMICs without local pre-market scientific evaluations • Test strip product quality can decline, once the product is registered • Capacity of local regulators to detect and investigate products of sub-standard quality is limited • Lack of CGM registration in LMIC markets	• Standards are available for BGM evaluation requirements for market authorisation, including WHO PQ • Overview of regulatory requirements and strengths and weaknesses has been published • Harmonisation efforts of CGM regulatory requirements are under way	• Raise awareness among LMIC regulators and procurers of added value of WHO PQ • Conduct technical research on supply chain impact of test strip product quality; consider lot-testing • Strengthen capacity of national regulators for post-market surveillance and investigation of technical complaints • Work with CGM manufacturers and regional regulatory fora to harmonise registration requirements; test approach of collaborative registration

Life cycle stage	Barriers	Activities	Recommendations
Selection, pricing, reimbursement	• Technical documents to aid in product selection are complex and likely underused by LMIC buyers/ procurers • Not enough independent post-market scientific evaluations of BGMs sold in LMICs and new CGMs are conducted • National EDLs may not prioritise inclusion of BGMs for self-testing • BGM (test strip)/CGM price setting does not consider WTP, data are lacking of price impact and market potential	• Technical documents with product specifications developed (TPPs, tech specs), quick guide for CGMs in development • Limited BGM post-market scientific evaluation of products sold in LMICs conducted • CGM post-market scientific evaluation done in HICs • WHO EDL now includes use of BGMs for self-monitoring • Examples of current market prices for BGMs/test strips and CGMs available • WTP for CGMs assessed	• Develop easy-to-use fact sheets or digital quick guides to support product selection for all self-testing technologies • Conduct more independent scientific evaluations for BGMs and CGMs in LMICs to close the local data gap • Work with relevant authorities to ensure BGM use for self-monitoring is included in national EDLs • Explore market dynamics and purchasing behaviour for self-testing products based on WTP data
Procurement and supply	• Procurement practices for test strips are not optimised, leading to higher prices • Procurement of test strips for self-testing is not prioritised • Supply chain costs can be considerable • CGM procurement is limited to the private sector • Self-testing technologies remain unaffordable to the majority	• Test strip procurement guidelines developed • Procurement channels for access to lower cost test strips setup • Commodity bundling explored • BGM supply chain cost data analysed • Affordability for BGMs and CGMs evaluated	• Raise awareness at country level of test strip procurement guidelines and opportunities (pooling, procurement channels); identify concrete opportunities to test these • Explore mechanisms for links to insulin procurement • Use available data on affordability to advocate at country level for inclusion of self-testing tools into UHC • Use affordability data to quantify accessible market at lower price points
Prescribing	• HCPs often do not discuss self-monitoring with patients in depth due to knowledge gap • Recommendation of BGMs may not prioritise technical features that aid management • Large knowledge gap exists in LMICs around CGM integration into diabetes management	• LMIC-adapted diabetes management guidelines include recommendation for self-monitoring • Training resources for self-monitoring are available, largely focusing on BGMs • Technical product selection documents developed	• Continue to encourage use of available training resources for self-monitoring to address knowledge gap • Develop locally-adapted CGM training courses and encourage medical training councils to include CGM use in curriculum • Integrate CGM considerations into LMIC-adapted global guidelines • Develop quick guides for product selection (see above)

Life cycle stage	Barriers	Activities	Recommendations
Dispensing	• BGM/test strip product availability can be inconsistent • Complex supply chains augment the problem of reliable supply • CGM retail prices do not mirror lower purchasing power in LMICs	• Pricing and availability data for BGMs published at facility and household level • Global engagement with BGM/CGM manufacturers on product prices and availability ongoing	• Bring together manufacturers, distributors and country procurers to jointly work on consistent supply and maintain product ownership • Identify levers to mandate manufacturers to develop and implement access strategies for BGMs/CGMs in LMICs and monitor progress
Use	• Barriers to “Use” are better researched and documented in HICs • Relationship between the different barriers to “Use” not well quantified	• Use aspects are given consideration in TPPs and tech specs • Data on BGM/CGM feasibility and quality of life impact being gathered • Modelling data of BGM/CGM use on heathy years of life made available	• Generate data on the interconnectedness of all self-testing barriers in LMICs in different geographies and population segments • Continue modelling and studies to quantify impact of self-monitoring on diabetes care and quality of life

3. Conclusion and opportunities for a way forward

The situational analysis of the product life cycle in relation to activities conducted by international organisations, shows that a considerable amount of work has been done in recent years to address access barriers to glucose self-monitoring tools: Technical documents have been developed to optimise product development and selection; quantitative data on costs, availability and affordability have been gathered and serve as a strong baseline to monitor progress over time; insights on product performance and quality have been gained through studies; diabetes guidelines and training materials addressing self-monitoring have been developed to build capacity among healthcare providers and people living with diabetes. While more work in these areas is needed (see summary of Recommendations in Table 11), the output of these activities is a valuable beginning.

Practical solutions to some key challenges have also been proposed, such as optimisation of technologies, cost-lowering approaches via market shaping, optimised procurement and local manufacturing, or regulatory capacity strengthening for reliable product quality.

Now it is time to put knowledge and ideas into practice: concrete partnership initiatives in several areas are needed to implement the proposed solutions. These require investments, courage and patience. For example, a partnership between a device manufacturer and a technology development organisation for LMICs will take several years to bring a product to fruition but could be truly disruptive as the first self-monitoring device developed with LMIC users and markets in mind from the outset. Likewise, gathering a group of countries to explore pooled procurement and/or regulatory harmonisation demands long-term commitment from donors, countries, international organisations and the private sector to produce results, with the potential to put in place lasting processes and mechanisms that will truly make a difference for people at country level.

The stakeholder landscape of international organisations in this report demonstrates that a substantial number of organisations integrate self-monitoring activities in their diabetes work. Their activities either focus on self-monitoring alone or in conjunction with other diabetes activities (e.g., access to insulin). Going forward, it is critical to strengthen the conduct of activities focusing explicitly on self-monitoring, while, of course, being considerate of all needs of people with diabetes in the management of the condition. This will not only serve to close crucial data, knowledge and solution gaps but also to elevate the importance of self-monitoring among decision makers at global and national level. For example, activities such as WHO's and Access to Medicine Foundation's engagement at international level with the private sector has finally brought awareness of the need for access discussions to manufacturers of BGMs and CGMs—in stark contrast to insulin manufacturers, who have been involved in such discussions for many years. To translate international activities to country-level action, more dedicated national partnerships, initiatives and activities for self-monitoring are now needed.

Any effort for better access to glucose self-monitoring technologies must result in self-sustained lasting change at country-level. On the road to such change, donor funding will remain critical to allow practical solutions to be tested. This applies to both, BGMs and CGMs. While CGM adoption in high-income countries is high, their use in LMICs is still extremely limited. As such, BGMs and test strips will remain critical self-monitoring tools for LMIC users for many years to come and this must be acknowledged with appropriate donor support.

Together, this can result in innovative self-testing technologies fit-for-purpose for LMIC users, greater availability and affordability of products, more countries with quality products, and increased capacity of HCPs and users to implement self-testing.

4. Disclaimer

International organisations listed in this report or other international organisations not mentioned in this report may have conducted additional activities to improve access to self-monitoring technologies for which information is not publicly available or the authors of this report were unaware of at the time of publication. We apologise for any unintentional omissions.

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5. Appendix

International organisations and their activities to improves access

International organisations listed in this section are organisations, institutions and entities that have undertaken activities that address access to glucose self-monitoring technologies at international level or across several LMICs. Organisations are categorised into UN-agencies, international NGOs, humanitarian organisations, academic institutions, social business enterprises, international alliances and corporates.

In total, the report lists 72 activities (or groups of activities), conducted by 26 organisations, either in collaboration or individually at organisational level. The large majority of activities addressed multiple stages of the product life cycle (for detailed categorisation per activity, see below) and were either focused only on BGMs or CGMs or addressed both technologies (see Figure 2). The timeframe of listed activities approximately spans the years 2020 – mid-2025.

Figure 2. Activities per life cycle, type of technology and focus

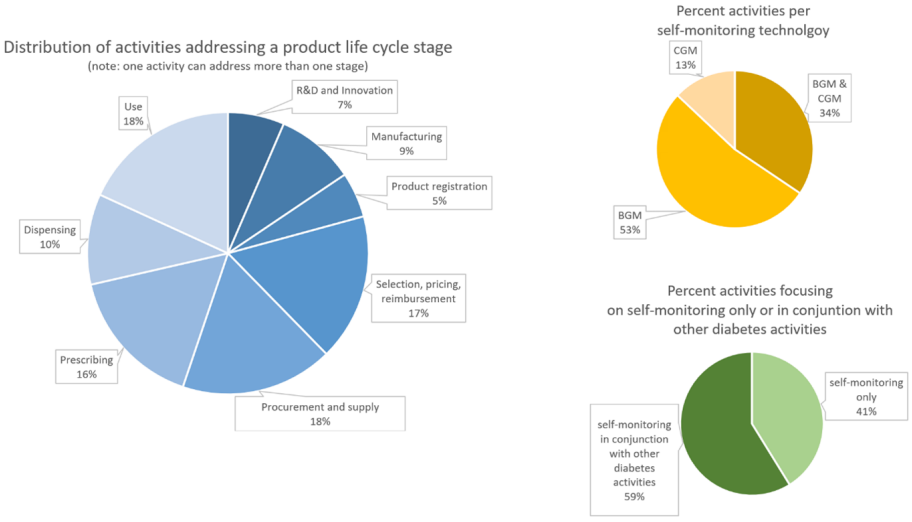

Table 12 provides an overview of all stakeholders. A brief description of their activities, as well as links to their work, are listed in sections 5.1 to 5.7.

Table 12. Stakeholders addressing access to devices for glucose self-monitoring

UN agencies*	International NGOs	Humanitarian organisations	Academic institutions	Social business enterprises	International alliances and federations	Corporates
WHO UNICEF	• HAI • FIND • LFAC • CHAI • PATH • Access to Medicine Foundation • Breakthrough T1D • NCDI PN • Santé Diabète	• MSF • ICRC • UNHCR • IRC • Elrha	• University of Geneva • Cronicas • Lancet Commissions	IDA Foundation	NCD Alliance IDF IADA	Roche Eli Lilly Sanofi

*Humanitarian UN agencies are listed in the section of "Humanitarian organisations"

5.1. UN agencies

5.1.1. World Health Organization (WHO)

The WHO has undertaken a number of activities across different departments to address access to glucose self-monitoring specifically

Global Diabetes Compact

The Global Diabetes Compact (GDC) was launched in 2021 as a global WHO initiative to reduce the risk of diabetes and ensuring access to "equitable, comprehensive, affordable and quality treatment and care" . The GDC operates through six workstreams, addressing access to essential diabetes medicines and health technologies; technical products; prevention, health promotion, and health literacy; country support; research and innovation; and governance.

Outputs of the GDC addressing glucose self-monitoring specifically are:

a. The Global Diabetes Coverage Targets (2022)6 with target two addressing the achievement of "good control of glycemia" and target five aiming for "access to affordable insulin and glucose self-monitoring" for all people with type 1 diabetes.
b. Engagement with private sector, including companies producing blood glucose test strips[80] to encourage manufacturers to commit to a set of "Asks" aimed at improving availability and affordability of diabetes medicines and technologies.
c. The publication of Guidance on global monitoring for diabetes prevention and control (2024)[98], which includes aspects on financing of self-monitoring devices.
d. A report on Availability, price and affordability of health technologies for the management of diabetes (2025)[42], covering BGM and test strip prices as provided in the published literature and obtained through price collection from third parties and an online survey.

Technical documents for product specification

A number of technical documents addressing product requirements have been published by WHO:

a. Under its Prequalification Programme (PQ) the Department of Essential Medicines and Health Products has published the Technical Specification Series 19: In-vitro diagnostic medical devices for monitoring of blood glucose and capillary blood, outlining data required for submission to WHO by diagnostic manufacturers to apply for WHO-PQ[28]
b. 4th edition of the Model List of Essential Diagnostics (EDL), overseen by the Health Product and Policy Standards Department, now includes the listing of glucose meters specifically for self-monitoring for diabetes.[39]
c. Technical specifications for blood glucose meters were published by the Health Product and Policy Standards Department, providing guidance on critical technical requirements for these devices.[32]

Guidance on interventions

WHO has published clinical guidance and intervention recommendations for diabetes, and these include specific mentioning of self-monitoring of blood glucose:

a. The Package for Essential Noncommunicable Disease Intervention (PEN-package) includes recommendations for self-monitoring of blood glucose for people with type 1 and type 2 diabetes on insulin in the document's section on Self-care.[61]
b. The HEARTs-D guideline on Diagnosis and Management of Type 2 Diabetes mentions the relevance of measuring glucose profiles with several pre- and postprandial measurements throughout the day, suggesting encouragement of home self-monitoring.[62]
c. The WHO recommendations on care for women with diabetes in pregnancy providing recommendations when to practice glucose self-monitoring with glucose meters and strips or CGMs for women with different types of diabetes.[63]
d. The Technical Briefing for Appendix 3 of the Global Action Plan for Non-Communicable Diseases includes a recommendation of home glucose monitoring for people treated with insulin and the supply of a glucose monitoring device and three test strips per day for self-monitoring.[63,64]
e. The document Best Buys and other recommended interventions for the prevention and control of noncommunicable diseases include a recommendation for home glucose monitoring as an effective intervention for managing diabetes.[65]

5.1.2. United Nations International Children's Emergency Fund (UNICEF)

In the context of its work to promote and protect the rights of children worldwide, UNICEF has a number of past and present activities addressing health and diabetes. Some most recent ones have a specific relation to self-monitoring:

a. Target Product Profile: Glucometer – Point-of-Care Diagnostics14, outlining optimal and minimal requirements for these devices when used by healthcare professionals for diagnosing and managing neonates in LMICs. All characteristics in this TPP can be applied to glucose meters used for self-testing by people with diabetes (except potentially the linear range requirements).
b. Partnerships with Eli Lilly to address NCDs in children. Considering that most children with diabetes are living with insulin-dependent type 1 diabetes, this partnership is likely to include aspects of strengthening self-monitoring.

5.1.3. United Nations High Commissioner for Refugees (UNHCR)

See below under Humanitarian Actors (section 5.3.3).

5.2. International NGOs

5.2.1. Health Action International (HAI)

HAI, together with the University of Geneva, started work on access to insulin in 2015 through the ACCISS study (Challenge and Constraints of Insulin Sources and Supply). Since 2020, the ACCISS study has expanded its scope to include access to testing devices for diabetes, including for glucose self-monitoring. In partnership with a range of other NGOs, the ACCISS study has since produced a number of outputs specifically to self-monitoring. Outputs addressing BGM and CGM devices:

a. A Market Report: Diabetes Self-monitoring Devices in Low- and Middle-Income Countries (2021) including a global market landscape for SMBG and CGM devices, aspects on product manufacturing, quality standards, product characteristic and costs. The report was a joint effort between HAI/ACCISS, FIND and CHAI.[19]
b. A Regulatory Profile: Glucose Self-monitoring Tools (2021), outlining international and examples of local regulations and frameworks for SMBG and CGM devices. The regulatory profile was a joint effort between HAI/ACCISS and FIND.[27]
c. A study assessing Availability, prices and affordability of self- monitoring blood glucose devices: surveys in six low- income and middle- income countries (Fiji, Indonesia, Kyrgyzstan, Mali, Peru and Vietnam), providing valuable data on the high cost and variable availability for BGMs and demonstrating the stark absence of CGMs in the public and private sector in these countries.[41]

Outputs addressing BGM devices only:

a. Guidelines for Procurement of Insulin and Associated Supplies and Pooled Procurement of Insulin and Associated Supplies, both providing mechanisms for efficient procurement of blood glucose meters and test strips.[45,46]
b. The Monitoring Access to Insulin (MAIn) tool, which is an app-based survey tool for phone or in-person regular monitoring (or one-off surveys) of facilities and households who use insulin and blood glucose self-monitoring devices within countries. The results are uploaded into an online dashboard, which can be viewed on the HAI ACCISS toolkit website and providing real-time data and transparency on access to self-monitoring devices.[79]
c. Case studies on Price components of Blood Glucose Meters and Test Strips (72, Peru, Uganda), analysing mark ups per country and specific product along the supply chain.[100]
d. A country-specific report on Availability, prices and affordability of insulin, delivery devices and SMBG devices in Indonesia.[55]

Outputs addressing CGM devices only:

a. Together with FIND and a group of experts, HAI/ACCISS co-developed a Target Product Profile (TPP) for new self-monitoring technologies, including CGMs, defining optimal and minimal requirements of a range of characteristic, with critical input from users, healthcare providers and carers in four LMICs (Mali, Peru, Tanzania and Kyrgyzstan) – see more in section 5.2.2.

5.2.2. FIND

FIND started to address access to diabetes diagnostic and monitoring devices in 2020 across three workstreams: Improving affordability of existing tools; Advancing technology through evaluation and R&D guidance; Strengthening the care cascade by implementing optimised testing strategies . For glucose self-monitoring, FIND has conducted work on BGMs and CGMs, as well as new technologies for self-monitoring in development.
Outputs addressing BGM devices only:

a. Pre-negotiated access pricing agreements with two BGM manufacturers for meters and test strips, available to public and private buyers in LMICs and those with operations in LMICs. Products and prices are accessible through FIND's DxConnect Marketplace, where FIND channels requests for quotes from prospective buyers to the manufacturers.[48,49]
b. A test directory for BGMs, listing all currently available BGMs and test strips with technical details from 19 large and medium-sized BGM manufacturers to facilitate product selection.[21]
c. A field performance evaluation study of four BGMs in Cambodia, Nigeria and Colombia, assessing accuracy of the products in the hands of trained and lay users, in line with requirements of TSS-19 for WHO PQ.[34628]
d. A study assessing *Diabetes and blood glucose monitoring knowledge and practices among pharmacy professionals in Cambodia and Vietnam*: digital survey and education, showing that digital education can strengthen pharmacy professional capacity.[75]
e. A report analysing current practices, barriers and opportunities to Local manufacturing of blood glucose test strips in LMICs.[18]

Outputs addressing CGMs and other new or in-development devices:

a. A technology landscape of Products for Monitoring Glucose Levels in the Human Body With Noninvasive Optical, Noninvasive Fluid Sampling, or Minimally Invasive Technologies, providing an overview of technologies that do not use finger-prick blood as sample to test for glucose.[13]
b. FIND and the ACCISS study group, together with a group of experts, led the Development of a target product profile for new glucose self-monitoring technologies for use in low- and middle-income countries.[11] The scope of the TPP includes CGMs and other minimally and non-invasive technologies. Users, healthcare providers and carers from four LMICs provided critical input to the optimal and minimal requirements of the product characteristic through a qualitative study.[12]
c. A Test directory for CGMs, listing all market-approved CGMs for self-monitoring at the time of publication, including key technical characteristics per product.[22]
d. Conduct of a Performance Assessment of Three Continuous Glucose Monitoring Systems in Adults With Type 1 Diabetes, demonstrating the value of independent performance assessments for on-market and in-development CGMs.[37]
e. An assessment of the Benefits of Usability Evaluation in the Development Process of Diabetes Technologies Using the Example of a Continuous Glucose Monitoring System Prototype, showing the value this approach in the product development process.[93]
f. An analysis of Cost of Goods Sold (GoGS) for CGMs to estimate the direct costs associated with producing a particular CGM (see Discussion section of Ewen et al.[41])
g. Results of two "Willingness to Pay" surveys: Willingness to pay survey for continuous glucose monitoring devices in South Africa and Kenya, and Willingness to pay for continuous glucose monitoring in the public sector in South Africa, showing that acceptable price ranges for CGMs is well below current CGM market rates in both countries, indicating that manufacturers need to adjust their pricing structures to enable wider access to CGMs.[43,44]

In 2023, FIND started the ACCEDE project (Access to CGMS for Equity in Diabetes management)[102] which seeks to make CGMs more accessible and affordable in Kenya and South Africa, as well as generating valuable resource and data for the global community. To date, the project had the following outputs:

a. Two free CGM online trainings, co-developed with the International Diabetes Federation (IDF): one for healthcare professionals66 and one for people living with diabetes, hosted under the IDF School for Diabetes.[69,70]
b. An operational research study to address the evidence gap on the impact of CGM use on clinical outcomes in LMICs, assessing different use-cases.[103] The research protocol of the study has been published and results are expected in early 2026.[95]
c. A CGM performance evaluation fact sheet, for users and healthcare providers to aid in the understanding of CGM analytical performance data and judge the quality of the evidence.[38]

Joint work with other international NGO partners (listed in other sections):

a. HAI/ACCISS, FIND and CHAI co-published the Market Report (see also 5.2.1): Diabetes Self-monitoring Devices in Low- and Middle-Income Countries (2021)19 the Regulatory Profile: Glucose Self-monitoring Tools (2021) and Availability, prices and affordability of self- monitoring blood glucose devices: surveys in six low- income and middle- income countries.[19,27,41]
b. Life for a Child and FIND co-submitted the aforementioned application to WHO for inclusion of glucose meters specifically for self-monitoring for diabetes into the version 3 of the EDL (see also 5.1.1).[39]
c. The University of Geneva, CRONICAS and FIND co-published an article and a commentary assessing self-monitoring tools against the REASSURED criteria: *Technologies for Diabetes Self-Monitoring: A Scoping review and Assessment Using the REASSURED Criteria* and "Diagnostics and monitoring tools for noncommunicable diseases: a missing component in the global response", assessing existing glucose monitoring tools (BGMs and CGMs) and those in development against the criteria used to evaluate their suitability for limited-resource settings.[34,35]

5.2.3. Life for a Child (LFAC)

Life for a Child's mission is the provision of the best possible healthcare, given local circumstance, to all children and youth with diabetes in less-resourced countries. They address this through a donation programme providing insulin, insulin pens and needles, and blood-glucose monitoring equipment, as well as implementation of educational activities, conduct of research and advocacy. Several of LFAC's activities relate specifically to self-monitoring:

a. The Donation programme in 53 countries includes blood glucose test strips for self-monitoring of glucose by beneficiaries.[56] LFAC is able to access discounted BGMs and strips from Roche, Trividia Health, and i-SENS.
b. A market analysis and mapping of Blood glucose meters and test strips: global market and challenges to access in low-resource settings.[20]
c. Impact modelling on diabetes Costs and outcomes of "intermediate" vs "minimal" care for youth-onset type 1 diabetes in six countries (Mali, Tanzania, Pakistan, Bolivia, Sri Lanka, and Azerbaijan), including assumptions of different numbers of test strips used per day for self-monitoring.[77]
d. A study Documenting and visualising progress towards Universal Health Coverage of insulin and blood glucose test strips for people with diabetes, providing data on availability of test strips in less-resourced health systems.[76]

e. Co-submitted with FIND the previously mentioned application to WHO for inclusion of glucose meters specifically for self-monitoring for diabetes into the version 3 of the EDL (see also 5.1.1) and published a correspondence Milestone achievement for global access to blood glucose meters and test strips.[39,104]
f. Publication of Education & training resources68 including on self-monitoring of blood glucose, and implementation in partner centres.[71]

5.2.4. Clinton Health Access Initiative (CHAI)

CHAI's work on diabetes aims to expand access to diagnosis, treatment and continued care for NCDs through laying the foundation to scale up quality delivery of services, generating demand at primary healthcare level and ensuring access to essential commodities.[74] In this context, the following activities relate to self-monitoring of blood glucose specifically:

a. HAI/ACCISS, FIND and CHAI co-published the Market Report (see also 5.2.1): *Diabetes Self-monitoring Devices in Low- and Middle-Income Countries* (2021).[19]
b. *Demand generation activities through forecast modelling* with LMIC governments for glucose monitoring tools and healthcare worker training to generate demand for self-monitoring tools.[74]
c. Planned program to evaluate the implementation and effectiveness of interventions at the primary healthcare and community levels in enhancing the timely diagnosis of Type 1 diabetes in children and adolescents, including education on self-testing (Ethiopia, Ghana, and Nigeria).

5.2.5. PATH

PATH evaluates new methods to advance promising interventions and increase access to diagnosis and treatment of NCDs, including diabetes.[98] A key diabetes activity including a focus on self-testing is the following:

a. The Diabetes CarePak explores a human-centred co-packaging solution of diabetes supplies needed for safe administration of insulin and self-care. The CarePak includes items such as glucose meters, test strips, lancets, needles and syringes and educational materials for people living with diabetes.[54]

5.2.6. Access to Medicine Foundation

The Access to Medicine Foundation launched a dedicated workstream on diabetes in 2022 including activities and discussions on access to glucose self-monitoring tools[106]:

a. Amsterdam sessions: these are annual sessions bringing together industry leaders, public sector partners, global health organisations and experts who operate on the ground in LMICs to discuss practices and solutions for closing the gaps in access to diabetes care. Three sessions have taken place to date and included discussion on access to blood glucose meters, test strips and CGMs.[81,82]
b. Two reports entitled *What are pharma companies doing to expand access to insulin – and how can efforts be scaled up* (2022) and Access to diabetes care for children and young people: Pharma companies' current actions and opportunities ahead (2025) detailing efforts of major insulin manufacturer to address access to diabetes care in LMICs, including their activities to provide access to self-monitoring tools.[88,87]

5.2.7. Breakthrough T1D

Breakthrough T1D's mission is to accelerate life-changing breakthroughs to cure, prevent and treat type 1 diabetes and its complications.[107] The organisation's scope includes high and low- and middle-income countries. Activities to address better access to self-monitoring in LMICs include the following:

a. The T1D Index is a data simulation tool that maps how many people live with type 1 diabetes (T1D) in every country, the healthy years of life the condition takes from people and the number of people who would still be alive today had they not died prematurely from complications.[96] Specifically for self-monitoring, The T1D Index contains estimations how many hours of health life are restored for each glucose test strip or CGM sensor used for self-monitoring per person.
b. Under their Global Health Initiatives, they collaborate with key stakeholders in Africa and India to increase access to type 1 diabetes care, including devices and test strip for self-monitoring.[73]
c. Breakthrough T1D, together with Helmsley Charitable Trust, has convened a working group bringing together industry, philanthropy, civil society, and people living with type 1 diabetes to expand equitable access to timely diagnosis, insulin, self-monitoring of blood glucose and diabetes education. Entitled ALIGN-T1D, its mission is to close survival and quality-of-life gaps faced by people with T1D living in LMICs.[108]

5.2.8. NCDI Poverty Network

The NCDI Poverty Network works to bring lifesaving care to children and young adults, burdened with severer, chronic NCDs and extreme poverty. Work on type 1 diabetes, including self-monitoring is included in their activities:

a. The PEN-Plus initiative focuses on delivering integrated chronic care for people living with severe NCDs in impoverished rural areas, including type 1 diabetes. Better access to glucose self-monitoring is addressed through training of healthcare workers and people living with diabetes on the importance and integration of self-testing into diabetes management.[72]
b. A feasibility study on the use of CGMs in Malawi was conducted to evaluated the Appropriateness and acceptability of continuous glucose monitoring in people with type 1 diabetes at rural first-level hospitals in Malawi: a qualitative study.[92]

5.2.9. Santé Diabète

Santé Diabète is an international NGO working in Africa to address the lack of access to healthcare for people living with diabetes through sustainable health system strengthening across all aspects of the health system.[109] Better access to self-monitoring tools is embedded in all their workstreams, to highlight here is the following:

a. Co-published a paper with MSF to show bundle prices using different available access pricing.[53]
b. Works on Universal Health Coverage (UHC) with different countries in Africa (Mali, Burkina Faso, Comoros) to include drugs and supplies (including meters and strips) under national UHC.
c. Key partner of the International Alliance for Diabetes Action (IADA) – see section 5.6.3.
d. Key partner organisation to collect country input from users, healthcare providers and carers in four LMICs to develop the Target Product Profile (TPP) for new self-monitoring technologies (led by FIND & HAI/ACCISS), including CGMs, defining optimal and minimal requirements of a range of characteristic.[11,12]

e. Participant in the HAI-led study assessing Availability, prices and affordability of self- monitoring blood glucose devices: surveys in six low- income and middle- income countries (Fiji, Indonesia, Kyrgyzstan, Mali, Peru and Vietnam).[41]

5.3. Humanitarian organisations

5.3.1. Médicines Sans Frontières (MSF)

Under its Access Campaign (now MSF Access), MSF has been working to improve availability of good medical tools to people and doctors in humanitarian settings for over two decades, including work on better access to insulin and self-monitoring devices.[110] Specific activities on self-monitoring for diabetes are:

a. Pilot Programs: MSF teams are pilot-testing home blood sugar monitoring in areas like Cox's Bazar, Bangladesh, and Northwest Syria, providing patients with insulin-dependent diabetes with glucometers, test strips, and lancets.[111]
b. A retrospective study analysing the *Implementation of continuous glucose monitoring in a humanitarian setting, CGM use in humanitarian settings* in a refugee camp in Lebanon.[91]
c. Key partner of the International Alliance for Diabetes Action (IADA) – see section 5.6.3.
d. Participation in the expert group that developed the *Target Product Profile (TPP) for new self-monitoring technologies* (led by FIND & HAI/ACCISS), including CGMs, defining optimal and minimal requirements of a range of characteristic, with critical input from users, healthcare providers and carers in four LMICs (Mali, Peru, Tanzania and Kyrgyzstan).[11]

5.3.2. International Committee of the Red Cross (ICRC)

The ICRC has long worked on improving access to diabetes care in humanitarian settings, including through partnership activities on affordable pricing of insulin and glucose test strips. Specific activities relating to glucose self-monitoring devices are:

a. A partnership with FIND to address the high prices of glucose test strips through preferential prices agreements, resulting in FIND's *Pre-negotiated access pricing agreements with two BGM manufacturers for meters and test strips*.[48]
b. Participation in the expert group that developed the *Target Product Profile (TPP) for new self-monitoring technologies* (led by FIND & HAI/ACCISS), including CGMs, defining optimal and minimal requirements of a range of characteristic, with critical input from users, healthcare providers and carers in four LMICs (Mali, Peru, Tanzania and Kyrgyzstan).[11]
c. Key partner of the International Alliance for Diabetes Action (IADA) – see section 5.6.3

5.3.3. United Nations High Commissioner for Refugees (UNHCR)

UNHCR's primary purpose is to safeguard the rights and well-being of refugees. They also play a key role across the humanitarian sector, including in collaboration with others to improve access to diabetes care:

a. Convening of the *Informal Inter-Agency Group on NCDs in Humanitarian Settings*, which brings together UN agencies, NGOs and academia to exchange information on activities and initiatives and to identify collaboration opportunities to meet NCD care needs in humanitarian settings, including better access to glucose self-monitoring.[112]

b. Co-development of the *Operational Guide on Integrating Non-communicable Diseases Care in Humanitarian Settings* (2020), including guidance to plan for home monitoring of blood glucose levels and support access to glucose meters and tests strips (co-developed with the IRC and the *Informal Inter-Agency Group on NCDs in Humanitarian Settings*).[66]

5.3.4. International Rescue Committee (IRC)

The ICR helps people affected by conflict and disaster by providing emergency relief.[113]

a. Implementation of the development of a research agenda for NCDs in humanitarian settings, including research questions addressing self-care (commissioned by Elrha, see section 5.3.5)
b. Co-development of the *Operational Guide on Integrating Non-communicable Diseases Care in Humanitarian Settings* (2020), including guidance to plan for home monitoring of blood glucose levels and support access to glucose meters and tests strips (co-developed with UNHCR and the Informal Inter-Agency Group on NCDs in Humanitarian Settings).[66]

5.3.5. Elrha

While Elrha is not a humanitarian organisation, they are a global organisation that focuses their work on solutions to complex humanitarian problems through research and innovation. Through their work on NCDs they also include considerations on self-monitoring of glucose:

a. In 2022 they commissioned the development of a *consensus-based ten-year research agenda for NCDs in humanitarian settings*, focusing on Cardiometabolic Syndrome.[114] This includes research questions to be addressed for self-care, which has the potential to expand knowledge and demand for self-monitoring devices in the future.

5.4. Academic Institutions

5.4.1. University of Geneva

The Division of Tropical and Humanitarian Medicine of the University Hospital Geneva conducts research on access to insulin, health systems and the needs of people living with type 1 diabetes. Activities relating specifically to glucose self-monitoring are as follows:

a. Implementation of the ACCISS study, together with HAI, and its outputs relating to self-monitoring tools (see section 5.2.1).
b. Publication of *An Empirical Review of Key Glucose Monitoring Devices: Product Iterations and Patent Protection* assessing the landscape of blood glucose meter and test strip product and patent evolution of five manufacturers.[15]
c. Co-publication (with CRONICAS and FIND) of an article and a commentary assessing self-monitoring tools against the REASSURED criteria: *Technologies for Diabetes Self-Monitoring: A Scoping review and Assessment Using the REASSURED Criteria*, and "Diagnostics and monitoring tools for noncommunicable diseases: a missing component in the global response" assessing existing glucose monitoring tools (BGMs and CGMs) and those in development against the criteria used to evaluate their suitability for limited-resource settings.[35,34]
d. Co-publication (with NCDA) of a *Time-to-lead action call: Access to essential medicines, diagnostics and medical devices for NCDs: Priorities for the 4th UN High Level Meeting on NCDs*, including advocacy for better access to self-testing devices (see section 5.6.1).

e. Under the NCD Policy initiative, a fact sheet was published listing sources of insulin, oral medicines, and medical devices for diabetes in low- and middle-income countries, including (where available) prices.[47,44]

5.4.2. CRONICAS Centre for Excellence in Chronic Diseases

CRONICAS is part of the Universidad Peruana Cayetano Heredia (UPCH) and has long standing relationships with international partners, resulting in the following outputs specifically related to self-monitoring tools[115]:

a. A scoping review on the Use of continuous glucose monitoring in low- and middle-income countries, co-published with FIND, analysing the available evidence of CGM use on impact on diabetes management for people living with diabetes in LMICs.[87]
b. Co-publication (with University of Geneva and FIND) of an article and a commentary assessing self-monitoring tools against the REASSURED criteria *Technologies for Diabetes Self-Monitoring: A Scoping review and Assessment Using the REASSURED Criteria*, and *Diagnostics and monitoring tools for noncommunicable diseases: a missing component in the global response*[34] assessing existing glucose monitoring tools (BGMs and CGMs) and those in development against the criteria used to evaluate their suitability for limited-resource settings.[35,34]
c. Key partner organization to collect country input from users, healthcare providers and carers in four LMICs to develop the Target Product Profile (TPP) for new self-monitoring technologies (led by FIND & HAI/ACCISS), including CGMs, defining optimal and minimal requirements of a range of characteristic.[11,12]
d. Participant in the HAI-led study assessing *Availability, prices and affordability of self- monitoring blood glucose devices: surveys in six low- income and middle- income countries* (Fiji, Indonesia, Kyrgyzstan, Mali, Peru and Vietnam).[41]

5.4.3 Lancet Commissions

Two Commissions have been established to address diabetes: The Lancet Commission on Diabetes in 2020 and The Lancet Diabetes & Endocrinology Commission on Type 1 Diabetes in 2024.[116,117] The commissions are groups of international experts from universities, medical, and health institutions and NGOs.

a. Lancet Commission on Diabetes: Their goal was to evaluate the global burden of diabetes and recommend actions to improve prevention, early detection, diagnosis and care. Key messages included ensuring access to tools for monitoring blood glucose and the commission recommends that all individuals with type 1 diabetes should have access to equipment for self-monitoring blood glucose to close the gap in diabetes care.[118]
b. Lancet Diabetes & Endocrinology Commission: Their goal is to develop a comprehensive and pragmatic global plan to improve the quality of life and care of people with type 1 diabetes. The Commission will emphasise the critical importance of acquiring comprehensive data, education, and training as well as access to insulin and other related supplies.

5.5. Social business enterprises

5.5.1. IDA Foundation

The IDA Foundation is an independent social enterprise providing medicine and medical goods to healthcare organisations worldwide, at the best price possible.[119] Under the health topic of NCDs they also address access to self-testing devices:

a. The NCD Connect procurement platform was launched in 2023 and includes access pricing for BGMs and test strips, based on FIND's pre-negotiated price agreements to these products.[50,47]

5.6. International alliances

5.6.1. NCD Alliance

The NCD Alliance is the umbrella organisation of a global network of national and regional NCD alliances to unite civil society and drive action on NCD prevention and care.[120] At the global level, the NCDA has contributed to better access to glucose self-monitoring in with the following activities:

a. General advocacy for better access to self-care and self-testing, with inclusion of the topic in the Policy Research Report on Integrating noncommunicable diseases prevention and care into global health initiatives and under universal health coverage.[121]
b. Co-publication (with the University of Geneva) of a Time-to-lead action call: Access to essential medicines, diagnostics and medical devices for NCDs: Priorities for the 4th UN High Level Meeting on NCDs, including advocacy for better access to self-testing devices. Continued advocacy around this issue within various versions of the political delcaration.[122]

5.6.2. International Diabetes Federation (IDF)

IDF is an umbrella organisation of over 250 national diabetes associations in more than 160 countries and territories, working to achieve its mission of access to affordable, quality diabetes care and education worldwide.[123] Key to IDF's work is provision of training and guideline development, including for self-testing:

a. Development of several courses hosted under the IDF School of Diabetes, including, or specifically addressing glucose self-monitoring: 1) Type 1 diabetes: overview, treatments and targets; 2) Continuous Glucose Monitoring for Healthcare professionals; 3) Continuous Glucose Monitoring for People living with diabetes (CGM courses co-developed with FIND, see section 5.2.2).[68,69,70]
b. Development of *Good Clinical Practice Recommendations for Type 2 Diabetes Management* (2025), including recommendations on self-monitoring of blood glucose using BGMs and continuous glucose monitoring using CGMs.[67]

5.6.3. International Alliance for Diabetes Action (IADA)

IADA was formed in 2019 and is a partnership of organisations from different sectors ranging from humanitarian organisations, intergovernmental and UN agencies to academic institutions, civil society, philanthropic organisations and the private sector. IADA is dedicated to ensuring vulnerable people in humanitarian crises have access to quality diabetes care.[124] Glucose self-monitoring is addresses

specifically:

a. In the workstream on Access to Medicines and Diagnostics through collaboration with FIND and CHAI.[125]
b. In the workstream on Data and Surveillance through the UNITED Study: *An inter-humanitarian agency study of diabetes care and surveillance in humanitarian settings*, including the assessment of availability of home glucose monitoring in 65 humanitarian sites.[78]

5.7. Corporates

5.7.1. Roche and Novo Nordisk

Roche and Novo Nordisk launched the programme Changing Diabetes in Children in 2009 as public-private-partnership that consolidates efforts to address barrier to healthcare.[57] The programme is active in 30 countries, where:

a. Roche donates blood glucose meters and test strips to beneficiaries, as well as provides training and education to people with diabetes and healthcare professionals.
b. Novo Nordisk provides insulin.

5.7.2. Eli Lily

Eli Lilly conducts healthcare access efforts through its foundation, as well as the company's corporate partnership approach with NGOs:

a. Partnership with Unicef (see section 5.1.2) to address NCDs in children. Considering that most children with diabetes are living with insulin-dependent type 1 diabetes, these partnerships are likely to include aspects of self-monitoring.[99]
b. Provision of insulin for the LFAC Donation programme in 53 countries.[56]

5.7.3. Sanofi

In 2022, Sanofi's Global Health Unit announced the launch of the Impact Brand for 30 medicines, including insulin, in low-income countries.[126]

a. The market access work Sanofi undertakes for the Impact-branded Insulin includes efforts to make available affordable glucose test strips, including a partnership with a device company based in Taiwan willing to provide BGMs and strips at affordable prices for Sanofi's Global Health Unit countries. Through this partnership Sanofi has started to leverage its commercial network and its programmatic investments to make BGMs and strips more affordable and accessible.

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