

access to medicine FOUNDATION

Amsterdam Session on Diabetes Care

15 JUNE 2023

MEETING REPORT

From insulin to glucose selfmonitoring devices: ramping up access along the diabetes continuum of care

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On 15 June 2023, the Access to Medicine Foundation convened an all-day roundtable to discuss practices and solutions for improving access to essential treatment and health commodities for insulin-dependent people living with diabetes (PLWD) in low- and middle-income countries (LMICs). The latest in the Foundation's series of Amsterdam Sessions, this was one of the first opportunities to bring together people involved in diabetes treatment, diagnostics and strategy. In addition to representatives of some of the leading manufacturers of insulins and glucose self-monitoring devices for diabetes, participants included experts from global health organisations, procurement agencies and government bodies. The event was chaired by the Foundation's Chief Executive Officer Jayasree K. Iyer.

For many years, the discussion around access to diabetes care has focused on insulin. But insulin can only be effective when administered correctly – i.e., at the right dosage, and with an appropriate delivery device. This requires access to monitoring devices (e.g. blood glucose monitoring devices or continuous glucose monitoring devices) and delivery devices (e.g. needles). In order to ensure equitable access to diabetes care, it is necessary to look beyond treatment and also consider all diabetes-related health products across the continuum of care for PLWD. While there has been promising progress, huge numbers of PLWD in LMICs still lack access to the full range of products they need to stay healthy and keep their diabetes under control, and many more do not have access to a choice of products, which is something that all patients deserve.

Taking a holistic approach means not only ensuring access to the treatments and devices needed, but also systemic support through stronger supply chains, sustainable business models and local capacity building. While acknowledging difficulties such as a lack of sound infrastructure and immature markets for some products, companies can take steps to ensure every PLWD, no matter where they are, can access the diabetes care they need.

Practical solutions for improving access across the continuum of care

The event aimed to generate practical next steps and commitments from manufacturers and other stakeholders, to foster solutions, models and partnerships to scale-up access to both insulins and glucose self-monitoring devices for PLWD in LMICs. The programme started with an introductory presentation, followed by two moderated discussions and two breakout groups on different themes.

Joining us as moderators and guest speakers during the event were:

- Andreas Altemark, Global of Market Access, Roche Diabetes Care Solutions, Roche Diagnostics
- Dr Malick Anne, Head of Non-Communicable Disease Control Division, Ministry of Health, Senegal (virtual participation)
- Loren Becker, Senior Director, Global Health Policy, Eli Lilly
- Bashier Enoos, Technical Officer, Integrated Service Delivery at World Health Organization (Access to NCD Medicines and Health Products)
- Adrian Gut, Senior Director International Access and Government Affairs, Dexcom
- Nicolai Haugaard, Vice President and Global Head of Health Equity, Novo Nordisk
- Jenna Mezhrahid, Senior Manager, Global Markets Team, Clinton Health Access Initiative
- Edith Mukantwari, Executive director, Africa Diabetes Alliance & person living with diabetes, Uganda
- Richard Neci Cizungu, Executive Director of the Ecumenical Pharmaceutical Network (virtual participation)
- Prof Eva Njenga, Consultant Physician/Endocrinologist, Chairman of the Kenya Diabetes Management & Information Centre
- Fiona Olivier, Global Head / Vice President, Corporate Affairs, General Medicines, Sanofi
- Sylvia Brachet, Cardio-metabolic Therapeutic Area Lead Global Health Unit, Sanofi
- Charles Toomey, Co-Founder, Action4Diabetes
- Beatrice Vetter, Deputy Director, Non-communicable Diseases Programme, FIND

The event was held under the Chatham House Rule, and this meeting report summarises the outcomes of the discussion. The report captures different points of view and shares practical solutions different stakeholders could take forward, develop and implement.

About this report

The outcomes of the Amsterdam Session are summarised in the following sections:

- 1. Engage and involve people living with diabetes
- 2. Develop business models and products specifically for LMICs
- 3. Increase the involvement of and partnership with device manufacturers
- 4. Shape a collaborative supply chain to the last mile
- 5. Scale up healthcare capacity locally to support Universal Healthcare (UHC)

1. Engage and involve people living with diabetes

There was a clear call to action for all parties to involve people living with diabetes in discussions around access to insulin and glucose self-monitoring devices, in government-led or company-led initiatives, and in the development of new business models. PLWD need to be integrated in the ecosystem and empowered in their own care. Participants reflected on what needs to change to make this more of a reality.

- Look at care more holistically. Participants talked about the importance of taking holistic approaches, including addressing comorbidities that PWLD might face, and the impact these can have on their lives and ability to access care. Companies, implementation partners and national healthcare delivery agencies could consider different distribution channels that make it easier for people to access integral care, such as direct home delivery, community spaces and healthcare facilities.
- Keep the patient perspective at the centre. To truly understand indirect costs to PLWD beyond the direct costs of medicines and devices, such as the time and financial burden of traveling to seek care, companies can actively engage and listen to the experiences of people living in LMICs who have diabetes, and integrate them into their strategies and initiatives.
 - → Because of the social context and the legacy of social stigma, limited awareness, and limited treatment options, the status quo is that PLWD in LMICs are often discouraged from seeking care and can feel isolated. Companies can address this by being intentional about ensuring the voices of PLWD are incorporated into their strategies, and prioritising people's needs when implementing initiatives.
 - → Companies can also be more proactive about responding to issues reported by patients in LMICs; for example, many PLWD in Africa have found that insulin dosage calculations developed in the West are not directly transferable, leading to issues with managing their condition.
- Support patient education, where ethical and appropriate. There is an overall need for patient education in LMICs, so PLWD can be empowered in their own care. However, companies must act responsibly and avoid conflicts of interest (COI) when participating in patient education initiatives.

"Patients need to be at the centre of these things, we need them to be able to be empowered. This needs to be an intentional effort."

• Support efforts to improve diagnosis and create clarity about demand. Companies can support initiatives to improve screening capacity and ensure timely diagnosis for PLWD in LMICs. Companies can rise to the challenge of meeting the increased demand for their products that comes from those who have now been accurately diagnosed.

2. Develop business models and products specifically for LMICs

To ensure PLWD in LMICs have continuous, long-term access to essential diabetes products, such as insulin and glucose self-monitoring devices, companies need to develop and implement sustainable business models. Participants from industry shared insights about the different approaches their companies are taking, while participants from LMICs reflected on the impact of those approaches and the opportunities for change.

- Move beyond philanthropy. Philanthropic approaches can be relatively short-term and often limited in scale. While these programmes increase access to quality-assured medicines in many cases, access often disappears as people graduate out of these programmes (e.g. as participants age out of paediatric programmes). There is also a huge impact on participants if companies withdraw from a country, without having first transitioned to a sustainable model.
- → One participant highlighted that donation-based programmes for insulin in one African country have led to the growth of a healthier, more competitive market for other products involved in the diabetes continuum of care, e.g. glucometers. This could be an indication that donation-based models can lay groundwork for facilitating the availability of a broader range of essential health products.
- Develop financially sustainable business models. Speakers from industry emphasised that, while there does need to be some level of profit for a company when doing business in an LMIC (outside of donation-based models), this business does not necessarily need to generate as much profit as in a higher-income country.
 - → Some companies are rolling out innovative business models in LMICs in which existing products are offered at more affordable prices.
 - → Internal buy-in is more likely if a company's access-focused initiatives are financially netpositive. Securing executive and CEO-level buy-in is vital when exploring new sustainable business models and access-to-medicine approaches.

"Sustainability means it works from mid-term and long-term perspective, not just focusing on one element but really providing a comprehensive solution. Donations can be part of it for some time, but there needs to be some level of revenue."

- Monitor and evaluate new approaches. Some participants urged companies to design monitoring and evaluation of any new business activities into the process. Companies can develop plans to assess the impact and communicate transparently about the progress and outcomes, preferably in partnership with an independent third party.
 - → When exploring business models that could potentially be more sustainable, participants mentioned the benefit of starting small, tangible and specific before scaling up. This can make it possible to measure progress and show change clearly, providing evidence for expansion.

"We need testing, evidence and to discuss things openly."

- **Consider facilitating factors for LMIC-specific business models.** Some of the factors participants discussed include working with partners in LMICs (e.g. including distributors and ministries of health), improving screening, capacity building, and tailoring efforts to the local setting to ensure a strong supply chain to the last mile.
- **Develop quality-assured products specifically for LMICs.** Developing products that are tailored to the needs of people living in LMICs, and/or the financial capability of LMIC markets, can help increase affordability.
 - → For example, if simpler and cheaper-to-produce designs for glucose self-monitoring devices can be introduced, this would increase affordability in LMICs.
 - → The development of access brands is an option companies can pursue. One insulin manufacturer stated that it can take a long time to launch an access brand, especially in multiple countries, due to regulatory bottlenecks.

- → Participants identified coordinated registration as a facilitating factor, which could be supported by World Health Organization (WHO) prequalification programme for insulins, and its future expansion to include glucose monitoring devices.
- Engage in local manufacturing to ensure sustainable supply. It was argued that, when companies invest in manufacturing their products in LMICs or nearby regions, this can be a positive way of developing long-term sustainability by building capacity and security of supply (see section 4).
- Collaborate to increase impact. There are many promising initiatives underway individually, and the topic of partnership came up throughout the discussions. It is important to ensure initiatives take different perspectives into account: patient groups, healthcare providers, ministries of health (and other governmental departments such as finance), NGOs, WHO and companies including both insulin and device manufacturers. Collaboration can help break down silos that can exist when each organisation is following its own agenda.
 - → There was a clear call to begin by looking at existing mechanisms and partnerships such as the Coalition for Access to NCD Medicines & Products and build on those by communicating and encouraging others to join.
 - → One participant suggested creating a consortium of companies to enable knowledge sharing and avoid duplication of efforts. While collaboration was widely welcomed, there was concern about anti-trust and not cutting out competition.
 - → Participants highlighted the role of the WHO Global Diabetes Compact, particularly its
 "Access to essential diabetes medicines and associated health technologies" workstream.
 The Compact sets distinct targets and provides a platform for engagement with the
 private sector, including representatives from international business associations,
 pharmaceutical companies, and the health technology industry.
- Collect more accurate data in LMICs. It is a common approach to make decisions based on extrapolating from small quantities of data about diabetes in LMICs. However, participants called for greater effort to gather accurate data, pointing out that this approach would not be considered acceptable in high-income countries (e.g. in Europe). There is an opportunity to work with patient organisations to get better data.
 - → Companies can proactively engage in collaborative efforts with national governments and local implementing organisations, sharing data on demand forecasts, even in situations where exact volumes cannot be guaranteed.
- Explore digital solutions that work for people in LMICs. Most people have a mobile phone and participants noted the importance of using available technology rather than designing new approaches. For example, digital solutions could facilitate glucose monitoring in rural areas by community health workers and help track outcomes.

3. Increase the involvement of, and pursue partnership with, device manufacturers

Much of the access conversation to date has been around insulin, with the spotlight on how to expand affordable and reliable access to insulin in LMICs. But taking a holistic approach to ensuring PLWD can keep their insulin levels under control means also ensuring the affordability and accessibility of glucose monitoring devices. The discussion covered both traditional blood glucose monitoring (BGM) devices and continuous glucose monitoring (CGM) devices, acknowledging that the situation differs due to various factors, including the maturity of the market and cost of production.

- Increase access to devices across all levels of care. Glucose monitoring devices should be available at health care facilities. However, it is also vital to ensure that devices are made available at lower levels of care and in the community, e.g. for home-based and self-testing, and that this is understood as a priority for PLWD. Demand for a greater quantity of devices would also improve volume predictability for suppliers, and may lead to more availability and affordability in the market.
- Ensure devices supplied in LMICs are quality-assured. There was discussion around the quality of some BGM devices and strips available on the market in some LMICs and a lack of compatibility between strips and devices from different brands.
 - → There is a need for more clarity about who is, and who should be, regulating the quality of diagnostics and devices, e.g. BGMs.
 - → WHO is urging companies to participate in prequalification of glucose monitoring devices, once this option is made available. There is an opportunity for companies to provide feedback on experiences of the prequalification process.

"Who is checking the quality of the glucometers [in LMICs]? Which devices should patients be using?"

- Address affordability. Test strips vary greatly in price, both between and within countries; in one country, an organisation observed prices ranging from USD 0.06 0.88 per strip. And at around USD 50 in many LMICs, CGM sensors are unaffordable for many people. Companies could:
 - → Lead by example and lower their prices to a more affordable level. This requires insight not just into the cost of manufacturing, but also into what payers are able to pay including governments procuring for the public sector, and individuals purchasing in the private market.
 - → Optimise the supply chain, including by partnering with distributors to secure volumeindependent prices. Examples were shared of successful partnerships between companies and delivery organisations with distributors, and such approaches should be examined and replicated where possible.
- Ensure CGMs are part of the discussion about access in LMICs. CGMs are so far mainly available to PLWD in high-income countries, and even in these countries there are still significant access issues. In LMICs, access to CGMs is currently very limited, and there is very low availability. Manufacturers of CGMs are new to these markets, and most do not yet have a strong presence in LMICs to draw upon.
 - → One aspect consider is the need for CGM users to have continuous access to support platforms, and to engage in a long-term relationship with the device manufacturer. This means that there is additional cost and commitment needed from the device manufacturer when launching the product in a new market. There is also the concern about whether local healthcare capacity is strong enough to support users of this product.
 - → However, participants were optimistic about progress and pointed out that as technology continues to develop, CGMs will become simpler and less costly to manufacture, easier to distribute, and easier to use.

"Many years ago, the [CGM] devices were complex and hard to use. Now the technology is easier for end users. We are moving towards devices that are less costly, easier to use and to distribute."

• Bring insulin and devices together. Speakers and participants recognised the potential benefit of pharmaceutical companies partnering with device companies. For example, this could involve a "co-packaging" solution including, insulins, glucose monitoring devices and

associated health commodities, and other essential health products needed by people living with diabetes.

"As a pharmaceutical company it's difficult for us to say we can provide devices, because we don't make them. Our aim is to call on devices companies to join us and give patients access to affordable devices. If they are open to same approach, that's great!"

4. Shape a collaborative supply chain to the last mile

Supply and distribution are essential elements in securing the availability of, and access to, insulin and devices. Even if a product is available on the market in a given country, PLWD may need to travel long distances to collect insulin or access a monitoring device, and when they arrive they might find the product is no longer available. They may also find that prices are marked up, for example at a local pharmacy. Discussions centred around how to ensure products reach the people who need them, at prices they can afford.

- Understand the current state of the supply chain through research and data collection. All those involved need to take accountability for their role in the supply chain to ensure it is robust enough to serve the people who need care.
 - → There were calls to make use of existing initiatives and structures, which requires mapping, monitoring, documenting and reporting. Some supply chain mapping efforts are underway, looking at governance, supply and price mark-ups.
 - → Long-term understanding of the changing supply chain requires visibility. Logistics information systems and systems to track products through the supply chain could be helpful here.
 - → With more (and earlier) diagnosis, there will be a need for scale-up in manufacturing to meet increased demand. Forecasting would be helpful; and to be reliable, it should be based on high-quality, interoperable data. There are many sources of data currently available, and participants suggested looking at this first.

"Until we understand the current situation, we won't necessarily know how to tackle it."

- Learn from supply chain management and distribution in other areas. Although there are specific challenges in optimising the supply chain for diabetes products, those involved in supplying and distributing diabetes products such as insulin and monitoring devices can learn from success stories for other types of products.
 - → For example, there has been progress on ensuring a steady supply of products to diagnose and treat HIV and tuberculosis (TB) in LMICs. This is due, in part, to coordinated procurement and global funding mechanisms. While the global funding may not be available for diabetes, participants mentioned that the improvements in the supply chains for HIV and TB products could provide learnings for the supply of products for non-communicable diseases (NCDs), including diabetes. Aggregating demand via coordinated procurement and data sharing could also be explored.
 - → Other industries, such as fast-moving consumer goods (FMCG), have tested different models for last-mile distribution. It may be possible to overlay the mapping behind those approaches with health data to find solutions.
 - → Similarly, different countries' approaches could provide insights applicable elsewhere, such as systems for managing stock across the supply network in Saudi Arabia.
- Partner with local manufacturers and distributors to minimise mark-ups. The mark-up of prices is a major issue for insulin and devices. Participants noted mark-ups of as much as

800% on insulin, depending on location and whether buyers are public or private institutions. While it is difficult for companies and governments to control mark-ups, participants recognised that to reach affordability, companies can work together with partners in the supply chain with a shared goal. This includes bringing companies along the entire supply chain on board with new business models.

- → One company reported that it has been able to reduce mark-ups from 40% to 20% by working with distributors to secure them higher volume. A country survey supported this with evidence of some pharmacies reducing shelf prices by 40%, but not all are buying into the mission.
- → One company put logistics cost into cost of distribution to the end user through an agreement between the manufacturer and distributor e.g. a product is USD 1, and 7 cents of that is for logistics.
- → One other dimension to tackling mark-ups is the integral role of PLWD themselves. For example, individuals or patient groups can campaign on issues related to price capping and retail prices, or they can use online marketplaces and forums to increase transparency and highlight pharmacies where pricing is lower or higher.
- Engage in local manufacturing. Local manufacturing in LMICs can make supply chains more sustainable and empower the countries involved. In Africa, the Pharmaceutical Manufacturing Plan for Africa aims to strengthen local pharmaceutical production and improve public health outcomes by enhancing sustainability in the supply chain and empowering participating countries. Capacity building is a critical element, and working with organisations like WHO and, in the future, the African Medicines Agency (AMA), will be an important step.
 - → A participant from one company shared their approach to manufacturing in a lowermiddle income country in Africa, highlighting that local investment needs local commitment; setup can make products more costly initially. Long-term sustainability requires a commitment to support that with financing so that the project can succeed, and the cost does not get passed on to patients.
 - → Participants discussed how, when collaborating with local manufacturing partners, companies can share skills and technology. Companies can also provide support to their local manufacturing partners in attaining WHO prequalification. These approaches can foster growth, boost manufacturing capacity, and improve access to quality-assured products in LMICs.
- Use digital tools to increase supply chain traceability and accountability. Mobile phone use is more widespread than ever in LMICs, and participants identified an opportunity to use the technology for multiple supply-related purposes.
 - → Offer an alternative way to buy products directly or through resellers, via apps or mobile finance. For example, there is an online market for glucometers and strips in Indonesia. Generic product portfolios in online markets could give people direct access to those products at set prices.

5. Scale up healthcare capacity locally to support Universal Healthcare (UHC)

There is a continued call for governments to prioritise diabetes, make policies to improve access to care, and invest. With those facilitating factors in place, governments could partner with industry more effectively. Several speakers shared their companies' integration of capacity building efforts and other healthcare system strengthening work.

"We have to voice our collective thoughts that insulin, delivery devices and blood glucose monitoring devices need to be part of UHC in order to be affordable, and people need to know their entitlements."

- Show the value of diabetes care. Participants suggested to carry out more impact analyses of clinical outcomes to show governments the added value of diabetes care. There is a potential role for industry to provide that evidence, which could in turn establish demand, increase volume and decrease unit cost.
 - → For example, research in Tanzania showed how much money the government could save by avoiding complications through proper diabetes monitoring and treatment.
- Support training of healthcare professionals to improve sustainability. As governments set up diabetes centres with monitoring and treatment capabilities in more rural areas to improve access, healthcare professionals (HCPs) or community health workers need to be trained so that there is long-term sustainable access.
 - → A co-financing role was suggested for industry partners, with the acknowledgement that companies want to do more than provide money. Participants discussed rethinking models to bring initiatives into a broader context for example by coordinating community-level screening.
 - → Participants discussed the need for training incentives for HCPs, such as payment or accreditation. They also discussed professionalisation among volunteers and the benefit of recognising them as community health workers to boost esteem for the role and stimulate professional development.
 - → However, there is a potential conflict of interest: training is the responsibility of governments. This makes government buy-in critical, and participants highlighted that training should be prioritised, nationalised and certified centrally. If the impetus and input for training comes from companies, it will be important that these companies incorporate transition plans from the beginning, so that others for example governments can take on the role in the long term.

"We are doing projects [for health system strengthening], but the question is, who is going to continue financing these projects in the future?"

- Communicate needs in terms of procurement processes in LMICs. Participants highlighted the need for governments to provide more clarity on specifications for public tenders and procurement practices, and for companies to proactively communicate their needs. This can help streamline procurement processes, enhance transparency and increase efficiency. Some participants from global health organisations and local implementing organisations shared how they are already assisting LMIC governments in restructuring tenders and optimising their investments.
- **Coordinate to help governments navigate initiatives.** A first step for industry partners could be to identify synergies many companies are already working on the ground, and alignment of objectives and coordination of efforts could be helpful for governments as well as being more effective.
 - → There is a risk of such conversations being halted due to companies' differing interests. To overcome this, a programme with concrete objectives looking for funding could be effective.
 - → One participant suggested bringing together key stakeholders from governments and key leaders from industry to solve issues where activities overlap.

"Governments have multiple partners knocking on their doors. If they [companies and organisations] pool resources to come together to governments, it can be less confusing."

Next steps

The Access to Medicine Foundation will continue to facilitate these conversations with an emphasis on action and progress, to make sure people living with diabetes get the care they need. Towards the end of the event there was a strong call to action for companies to "be brave", to sometimes take a leap of faith and embrace collaboration. Throughout the day, there were instances of organisations identifying opportunities to work together, and it is hoped that these conversations will develop into partnerships and solutions. The insights in this report will also inform the Foundation's ongoing research and analyses.

For more information or to discuss the contents of this report, please contact Claudia Martínez at <u>cmartinez@accesstomedicinefoundation.org</u>.