

Amsterdam Session on Diabetes Care

access to medicine

9 APRIL 2024

MEETING REPORT

Securing worldwide access to diabetes care by 2030: Spotlight on strategies and solutions to close the equity gap

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On 9 April 2024, the Access to Medicine Foundation hosted a full-day roundtable to discuss the equity gap for insulin-dependent people living with diabetes (PLWD) in low- and middle-income countries (LMICs). This event marked the third installment of the Foundation's Diabetes Care series, known as the Amsterdam Sessions, which aim to provide experts in diabetes treatment, diagnostics and strategy with a forum for collaboratively discussing action-oriented solutions. The event was hosted at Deloitte's offices in Amsterdam and attendees included representatives from leading insulin and glucose self-monitoring device manufacturers, experts from global health organisations, procurement agencies, and government bodies, as well as PLWD. Claudia Martínez, the Foundation's Head of Research, served as the event chair.

Despite progress in expanding access to diabetes care in LMICs, too many PLWD still lack access to insulin and essential commodities that are needed to lead healthy lives. Many parents in LMICs face the difficult choice between buying medicine for their children and meeting other needs. PLWD continue to die from preventable causes due to the lack of access or affordability of essential medicines like insulin.

Three years have passed since the World Health Organization's (WHO's) Global Diabetes Compact launched in 2021, and with less than six years left to meet the WHO's 2030 global targets on diabetes care, urgent action is needed - not only to achieve objectives, but to save lives. To this end, it is vital that private sector actors, governments and organisations continue to collaborate and work to address the gaping inequalities in access in LMICs.

"Hearing concrete examples of progress and challenges being overcome helps us [industry stakeholders] with identifying what we need to do to move from where we are to where we need to be, and be a catalyst for change."

ABOUT THE EVENT

Following the Chatham House Rule, participants' opinions and contributions to discussions during the Amsterdam Session are kept anonymous. The event's programme featured introductory presentations, two moderated dialogues and a roundtable discussion focused on distinct themes.



Joining us as moderators and guest speakers were:

- Andreas Altemark, Global Head of Access, Roche Diabetes Care, Roche
- Carissa Vados, Head of Diabetes Health Equity, Novo Nordisk
- Klara Tisocki, Team Lead, Affordability, Access, Pricing of Medicines, World Health Organization
- Jean Claude Mbanya, Professor of Medicine and Endocrinology, University of Yaoundé I, Cameroon
- Joon Hyuk Chun, Managing Director, i-SENS GmbH
- Katerina Zakrzewska, Senior Director Market Access & Government Affairs International, Embecta
- Nine Steensma, NCD Programme Lead, Clinton Health Access Initiative
- Richard Neci Cizungu, Executive Director, Ecumenical Pharmaceutical Network
- Sylvia Brachet, Cardio-metabolic Therapeutic Area Lead, Global Health Unit, Sanofi

KEY TAKEAWAYS

Practical steps to widen the scope and scale of access to the diabetes continuum of care are captured in the report, alongside good practices and learnings that were identified during the event. Three key themes emerged throughout the Amsterdam Session.

- 1. Centre access efforts around the needs of PLWD
- 2. Create tailored access solutions with sustainability in mind
- 3. Build more efficient and collaborative supply chains

1. Centre access efforts around the needs of PLWD

The importance of including PLWD in designing solutions for access issues, which was a prominent sentiment at last year's session, was echoed in the 2024 Amsterdam Session by attendees. This is crucial to delivering care that addresses PLWDs' comprehensive needs throughout their life, and to ensure the long-term success of access programmes.

- Involve PLWD of all ages in all diabetes care-related activities and decisions. This was repeatedly raised as an urgent necessity, including by PLWD who called for their involvement in more partnerships. Participants agreed that this must start early in the development process for medicines, medical devices, and other diabetes-related products and services.
 - PLWD need to be engaged, including in informing treatment preferences during procurement; supporting the development of relevant training and educational resources; and assessing the effectiveness of programmes and policies.
 - Companies must leverage PLWDs' experiences to develop strategies that cater to their diverse needs, with company representatives highlighting they are already involving PLWD in access programmes- and promising to expand further.
- Ensure patient choice and access to the full spectrum of insulin products, including analogue insulins. This is critical to ensuring PLWD in LMICs receive the same 21st century standards of care as those in high-income countries. However, in LMICs, the cost of analogue insulin can be more than six times higher than that of human insulin, and LMIC governments typically pay a higher median price for analogue insulin, rendering it out of reach for many PLWDs.
 - One company already integrates analogues into its LMIC access programmes, aiming to expand access to analogues to 300,000 insulin-dependent patients by 2030.
 - Continued generation and dissemination of quantitative evidence in LMICs regarding the benefits of analogues for PLWD - as demonstrated by studies such as those by <u>Médecins</u> <u>Sans Frontières</u>, and the Helmsley Charitable Trust, including in <u>Bangladesh and Tanzania</u>-



is needed to inform companies' strategies for analogues and facilitate their future integration into LMIC access initiatives.

Future plans should consider making innovations, such as GLP-1 agonists, available in LMICs. Insulin pens are also important, providing multiple benefits for patients compared to syringes, and their expansion must also be prioritised in LMICs.

"Human insulin in a vial is 80 years old. It should not be the standard of care anywhere in the world."

- Measure access programme outcomes beyond product delivery. Companies and their partners were urged to move beyond outcomes focused solely on product availability and a singular timepoint. Specifically, LMIC clinicians and PLWDs suggested measuring longer-term outcomes that capture the multifaceted nature of diabetes as a chronic condition, as well as assessing care quality.
 - Several insulin and glucose monitoring device manufacturers provided examples of outcome measures from their access programmes, including numbers of patients reached, healthcare professionals trained, and healthcare facilities supported. Many of these companies also presented new targets for 2030, including numbers of PLWD or children reached with the products. One device company aims to reach 10 million PLWD, which will translate into serving 700,000 PLWD continuously with glucose monitoring devices within three years.
 - Suggested long-term and quality-focused outcome measures included tracking the number of times a PLWD has been supported; the percentage of PLWDs who have achieved glycaemic control; and how many PLWD develop complications, such as diabetic nephropathy.
- Consistently report and communicate progress on access efforts and outcomes in LMICs. This can help pinpoint successful initiatives and areas requiring additional action. The <u>WHO's Global Diabetes</u> <u>Compact's</u> reporting mechanism for the private sector will become publicly available at the end of 2024. The Access to Medicine Foundation's reports and Amsterdam Sessions also provide a platform to support the communication of progress made by insulin manufacturers.

"With most of these programmes, there is no long-term outcome. What about complications, even if products were supplied? All that is happening is prolonging the time of death and not actually solving the problem."

- Ensuring greater affordability of diabetes care treatment and commodities in LMICs. High prices of both glucose monitoring devices (BGMs) and insulin persist in LMICs. In some lower-income countries, prices of BGMs are even higher than middle-income and high-income countries, leading to major out-of-pocket (OOP) costs for many families. Attendees also highlighted that PLWD who graduate out of company programmes need support to continue receiving the products they need.
 - Even with existing price ceiling commitments from some insulin manufacturers, PLWD in LMICs still face high prices due to mark-ups along the supply chain. An NGO participant from an LMIC highlighted their struggle to access the insulin at these ceiling prices due to these mark-ups, calling on companies to evaluate what is happening on the ground.
 - Utilising access brands offered at lower price points or on a not-for-profit basis is one strategy companies can adopt to enhance affordable access to insulin in LMICs. However, close collaboration with governments, healthcare professionals (HCPs), and regulatory authorities is essential to raise awareness and facilitate the introduction of such brands into countries.

- The cost of test strips varies greatly across LMICs and can pose a major barrier to access. A model that was highlighted was that of FIND, who collaborated with glucose test strip manufacturers to improve affordability of BGMs in LMICs, allowing governments and procurers to access their device test strips at affordable free-on-board prices.
- As noted by a device manufacturer, pricing of BGMs and strips must also consider what payers are able to pay, especially in countries where patients rely on the private sector and are faced with high OOP payments.
- Improve education on diabetes care for HCPs, PLWD and their families. This requires increased collaboration among all stakeholders, including companies. However, companies need to act responsibly and ethically in their approach to avoid any potential conflicts of interest.
 - One participant highlighted the need for training HCPs on data management to support national-level tracking of diabetes, which remains a challenge.
 - A company representative called for increased education on appropriate injection techniques to ensure correct dosage and reduce insulin waste.
 - Participants agreed training for community health workers (CHWs) on non-communicable disease (NCD) care and management must be expanded and standardised as many currently lack the knowledge and skills to effectively deliver NCD services.

"Bringing the product to a country is not enough if there is no training on how to use the product."

2. Create tailored access solutions with sustainability in mind

Discussions throughout the day emphasised the need for sustainable access programmes which will last beyond company commitments. Several solutions were proposed to achieve these goals.

- Strive for more multi-stakeholder, intersectoral and meaningful partnerships. Calls for partnerships came from all parties and were highlighted as a precondition to achieving sustainable impact at scale. Intersectoral partnerships allow stakeholders to benefit from each other's strengths, reduce duplication, pool resources, and ensure comprehensive solutions that are appropriate to local contexts. This is particularly important amid sparse funding for NCDs globally and locally. Partnerships also need to be meaningful and focused on co-creation, with clearly defined and common expectations, and genuine and transparent communication. Company representatives also urged for these partnerships to be long-term commitments.
 - Several manufacturers highlighted how the success of their integrated access business models and initiatives have been closely tied to their co-creation with LMIC governments, local implementers, distributors and other partners.
 - ➤ A new cross-sectoral partnership between an insulin manufacturer and a glucose monitoring device company was announced that will enable the expansion of affordable glucose meters, alongside insulin, in many LMICs. More of these partnerships are needed.
 - An insulin manufacturer reflected on an example of a meaningful partnership with an LMIC ministry of health (MoH) in which open and honest communication lines, including on programme challenges, enabled a collaborative approach. The government's early involvement and shared ownership of the programme were crucial, with the programme being part of the government's Key Performance Indicators.
 - MoH representatives also emphasised the importance of co-creation in access programmes and noted an improvement in government involvement from companies. They called for further improvements from companies, including continuous feedback, discussions on implementing partners, and a greater emphasis on sustainability.

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"Unless we work in partnership and combine our resources, it will be difficult to reach the people we need to."

- Align access initiatives with local needs. A 'cookie-cutter' approach cannot be applied across countries. Assessing local needs, the maturity level and availability of local healthcare system solutions such as reimbursement policies and pre-existing in-country programmes is key when establishing access programmes. These must also be integrated into existing health systems. Empowering governments to take ownership of programmes, beyond company commitments is also key for sustainability.
 - An insulin manufacturer partners with local providers and co-creates solutions tailored to LMIC country needs. This includes using existing training modules and aligning its regions of focus to the local government's priorities.
 - Progress is being made in developing products adapted to settings lacking cold chain storage capacity by pursuing longer insulin stability conditions to make insulins more thermostable.
 - Device manufacturer representatives also reiterated the importance of MoH support within their initiatives, although they also highlighted the long timeframes required for signing Memoranda of Understanding.

"[...] importing models from the west will not work."

- Develop and implement sustainable business models for LMICs that go beyond philanthropy. This is essential to ensure PLWDs in LMICs have steady access to all essential diabetes products. Product donation initiatives, for example, are not sustainable.
 - Insulin manufacturers are advancing sustainability through innovative business models that are integrated into their corporate strategies, with the aim to supply many LMICs through multi-pronged, financially stable approaches. These models include a focus on affordability and strengthening health system delivery. Additionally, some companies are also ensuring continued access to their products by supporting local manufacturing, reinvesting margins product sales from these models into in-country programmes and engaging in partnerships across the supply chain and with local stakeholders.
 - A device company highlighted the need to strike a balance between achieving a reasonable level of commercial profit and ensuring the long-term sustainability of business models in LMICs. Establishing a sustainable access programme can take years because there is a need to move beyond one-time donations and develop the right partnerships to incorporate elements such as education, support, screening and supply into their initiatives. This plays into its decision-making process.

3. Build more efficient and collaborative supply chains

Inefficient procurement processes and fragmented supply chains have a critical impact on product costs, and consequently on affordability for PLWD, particularly in rural areas. Several strategies and models were identified to overcome these challenges.

• Strive for coordinated procurement. Attendees emphasised the potential benefits of improved coordination in procurement efforts, both across countries and types of products/commodities (e.g. jointly procuring insulins and glucometers). Company representatives expressed their willingness to participate in tender processes in more LMICs. This can help leverage economies of scale, offer



manufacturers greater certainty of demand and volumes, and ultimately enhance access to these products. Particularly in the absence of a donor-funded market, the role of coordinated procurement and robust information sharing among procurement bodies was seen as crucial.

- Procurers and companies were urged to shift their mindset regarding tendering by prioritising factors like quality, reliability and manufacturers meeting specific requirements over seeking the lowest price.
- The ARV Procurement Working Group (APWG) is a successful example of an initiative that supports the antiretroviral (ARV) market in LMICs which, through coordinated procurement, enabled partners to overcome low and fragmented demand. A key component of the APWG's approach was the creation of an information sharing platform for forecasting and demand quantification which facilitated data exchange between procurers, governments, NGOs, industry, and other stakeholders.
- NCD Connect is a digital platform offering an integrated solution for both suppliers and buyers, including NGOs and MoHs, to procure or sell NCD treatments and devices, including for diabetes. It provides buyers with access to quality-assured products and competitive pricing, and suppliers with simplified negotiations and aggregated demand.
- Diabetes CarePak is an example of a co-packaging solution that includes glucose monitoring devices, test strips, needles/syringes, lancets, educational materials etc., which could be procured in bulk and included in healthcare packages. It is a means of increasing access to the whole continuum of diabetes care for PLWD, while also improving awareness and education regarding insulin administration.
- Another innovative example from a high-income country was cited where pen needles, digital health tools, monitoring devices, pumps and other commodities were procured together.
- Jointly tackle mark-ups along diabetes care supply chains. Pharmaceutical supply chains are intricate with multiple stages before medicines reach patients from manufacturing to distribution to retailing. Mark-ups accumulate at these various points, driving up the overall price of medicines. Attendees identified successful models in managing mark-up costs along the supply chain and highlighted the complementary roles of the public and private sectors in achieving this.
 - MEDS (Mission for Essential Drugs and Supplies) and their partnership with Novo Nordisk in Kenya enables direct procurement from the manufacturer instead of through wholesalers, reducing prices by 20-30% and preventing mark-up cost transfers to PLWD.
 - Faith-based organisations and networks, such as the <u>Ecumenical Pharmaceutical Network</u>, were highlighted as reliable conduits for ensuring access to affordable diabetes products.
 - One insulin manufacturer is trialing a model where it partners with European distributors who are willing to commit to access prices and reduce their mark-ups. The company then empowers these distributors to choose local LMIC distributors who are also committed to reducing their margins. If these commitments are not maintained, the partnerships are dissolved by the manufacturer. Mixed results have been observed to date, with increased prices in one Latin American country and distributor mark-ups cut by two thirds in one African country.
 - Advocacy efforts by civil society and PLWD have helped to achieve government subsidies for diabetes care in some LMICs.
 - Some LMIC MoHs have established regulations and policies regarding supply chain markups to reduce product prices. One country even has pricing transparency regulations implemented in its national law.

"The problem is not always about not having access to insulin; sometimes it is available but the supply chain for all products is lacking."

- **Build the capacity of local distributors.** Although the need for distributors to reduce their mark-ups was consistently raised, attendees also recognised that distributors face operational costs and that capacity building for distributors and wholesalers based on their maturity levels is needed to ensure they meet access-related mark-up targets.
- Engage in local manufacturing to ensure sustainable supply. By investing in manufacturing facilities in LMICs or producing in neighbouring regions, companies can help ensure greater security of supply. Some insulin manufacturers currently engaged in such initiatives highlighted progress in this area. They emphasised the need for partners who are committed to the access agenda and cited challenges including technology transfers and regulatory barriers. However, some companies choose not to invest in local manufacturing in LMICs due to the ability to produce cost-effectively elsewhere.
 - A government representative mentioned that local manufacturing is an important priority for Africa. They highlighted initiatives to transfer technology and improve insulin production, including in South Africa. Advancements in discussions surrounding local manufacturing of BGMs were also noted.
 - One insulin manufacturer reflected on their collaboration with an LMIC-based manufacturer to increase access to human insulin in vials. They aim to produce 16 million vials in the first year, quadrupling that output in the second. A critical next step is to work with regulatory authorities to ensure the uptake of these insulins by countries.
 - Similar technology transfers are being discussed in other LMICs by other manufacturers.
- Ensure access to the last mile. Attendees discussed the challenge of ensuring access and affordability of insulin and devices at the last mile, including in rural areas. Due to this lack of availability, PLWD located in hard-to-reach areas may need to travel long distances and take multiple modes of transport to reach health facilities providing these products.
 - The PEN-Plus initiative, a regional strategy endorsed by the 47 Member States of the WHO African Region, which seeks to build capacity of first-level facilities, including district hospitals in rural and peri-urban areas, was mentioned as a good example of decentralising access to different care levels.
 - The <u>Ecumenical Pharmaceutical Network</u>, operating in over 30 countries, also demonstrates an effective approach to last-mile delivery by partnering with member church health institutions in local communities, particularly in underserved and remote areas with limited government health services.
- Use existing country models to streamline supply chains. MoH representatives outlined other effective models that they have implemented in their respective countries:
 - Contracting at the national level.
 - Directly linking poor supplier performance to clear repercussions, including contract termination or lack of contract renewal.
 - > Having quarterly meetings with suppliers to discuss and address issues transparently.
 - Creating national committees overseeing quality procedures and medicine/device distribution.
 - The use of a single institute, such as a centralised supply pharmacy, to manage procurement and distribution.
 - The Africa Resource Center for Excellence in Supply Chain Management was highlighted as a successful public-private partnership between manufacturers, wholesalers and the

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Nigerian government, which enables these partners to better coordinate their efforts to streamline supply chains in the country.

- Establishing a common denominator for quantifying the population in need of insulin access. Attendees highlighted the urgent need to define the total 'denominator' of PLWD, differentiating between type 1 and 2 diabetes, to quantify and more accurately forecast product demand. This can inform procurement, effective resource utilisation, opportunities for resource sharing across the care continuum and strengthen health information systems. This is particularly critical considering recent company announcements of insulin supply and availability constraints. Companies, advocacy groups, local implementing organisations and HCPs at the community level can collaborate with governments to provide more granular, real-world data to refine insulin demand forecasts.
 - The NCD Medicines and Health Technologies Demand Forecasting Tool, which is being developed by WHO, is a platform aimed at helping countries improve their capacity for demand forecasting and improved data quality.

NEXT STEPS

The Foundation's event provided an important platform for stakeholders to not only take stock of ongoing efforts and accomplishments, but also identify new avenues for collaboration and joint action. The clear and numerous calls for action from PLWDs, companies, ministry of health representatives and global health partners undoubtedly testified to overwhelming interest and willingness from the public, private and not-for-profit sectors to work collaboratively towards a joint commitment to improving the lives of people living with diabetes – a goal that can only be accomplished through united and concerted effort.

To support these intentions, key actions for all partners are outlined below. Attendees agreed that the progress of many of the initiatives discussed, as well as on the actions set out below, needs to be evaluated at future Amsterdam Sessions and through publications from the Foundation.

"We can do more, and we will."

Next steps for companies

- 1. Design sustainable access programmes, tailoring initiatives to local needs and contexts and available resources in collaboration with governments and other stakeholders.
- 2. Collaborate closely with national governments and other implementation partners to ensure affordable access and patient choice for both existing and innovative insulin products and administration methods. Simultaneously, invest in the development of adapted and novel products to cater to the needs of people in LMICs.
- 3. Pursue partnerships with organisations operating within countries (i.e. insulin manufacturers, manufacturers of monitoring and diagnostic tools and other partners) to coordinate efforts and increase impact.
- 4. Systematically measure and publicly report on access programme outcomes, including long-term measures and patient complications.
- 5. Negotiate maximum margins with distributors, foster constructive competition among local distributors, and establish distributor selection criteria to manage supply chain costs including by prioritising distributors who share a commitment to access.
- 6. Communicate maximum recommended retail to guide distributors' prices and enable price awareness with PLWD.



- 7. Increase open communication with procurers about supply chain issues to facilitate timely mitigations, while sharing data and intelligence on potential threats and disruptions.
- 8. Proactively communicate with procurement officers before tenders are released to gain insights into the buying organisation's needs and requirements.
- 9. Where ethical and appropriate, engage in capacity building for education and training to support better product use and strengthen local systems.
- 10. Submit products for WHO prequalification and collaborative procedures, as well as filing for registration with Stringent Regulatory Authorities.

Next steps for governments and procurers

- 1. Continue to prioritise diabetes as part of Universal Health Coverage (UHC) and implement policies to improve access to care.
- 2. Engage and ensure involvement of manufacturers ahead of tendering processes to help define procurement specifications and standards.
- 3. Involve PLWD in pre-tender stages to gather input on suitable requirements and treatment preferences.
- 4. Define clear, transparent tender processes timeframes, specifications, and tender scopes, and minimum quality specifications to the risk of low-quality products being procured.
- 5. Establish longer tendering time horizons (e.g., several years) and plan for multiple suppliers to reflect the life-long nature of diabetes, ensure continuity for suppliers and avoid redundancy.
- 6. Procure integrated solutions covering the whole care continuum (e.g., insulins, glucose monitoring devices and delivery devices) and include these in local healthcare packages.
- 7. Implement legislative, policy and regulatory frameworks, including guidelines to promote generic prescriptions, and utilise performance-based supplier engagement to control mark-ups along the supply chain and promote price transparency.
- 8. Improve coordination and support for National Regulatory Authorities to better leverage collaborative registration procedures and other mechanisms to enable faster registration of essential diabetes products in LMICs.
- 9. Increase awareness and education about testing and diagnosis to boost demand for glucose monitoring devices and other commodities, promoting better use and efficiency.

Next steps for all partners, including global health organisations and PLWD

- 1. Meaningfully involve PLWD in all activities and decisions across the diabetes care continuum.
- 2. Improve current partnerships and form new multisectoral, meaningful partnerships focused on:
 - The expansion of access to treatments, including all types of insulins, but also glucose monitoring devices and other commodities, such as needles and syringes.
 - Jointly work to build the capacity of local HCPs, local distributors and manufacturers, enhance PLWD education and reduce costs across manufacturing, supply and distribution networks.
 - Strengthen data collection, sharing and reporting on the total number of PLWD in LMICs and their diabetes care needs. Companies can also contribute to this via systematically and publicly reporting their access programme outcomes.
- 3. Identify and pursue opportunities for coordinated procurement, especially in markets with smaller returns on investment, including by utilising available digital tools.

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