



DEFEATING THE DOUBLE STANDARD IN DIABETES CARE

Exposing the exorbitant prices of diabetes medicines and injection devices

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INTRODUCTION

Diabetes currently affects over half a billion people worldwide, ranking among the top 10 causes of death globally.¹ Over 80% of those affected live in low- and middle-income countries (LMICs).^{1,2}

Diabetes is primarily of two types: type 1 (T1D) and type 2 (T2D). While T1D is an autoimmune condition characterised by the inability of the pancreas to produce insulin, T2D is characterised by resistance to insulin, which hinders the body from using insulin properly.

Insulin is a lifesaving medicine for all people with T1D, and an essential tool to achieve glucose control for people

with T2D whose glucose levels are not controlled with other oral or injectable medicines. An estimated 9 million people with T1D rely on life-long treatment with insulin for survival and among the 420 million people with T2D, an estimated 63 million people need insulin as part of their treatment. Globally, only about half of people who need insulin are treated with it or can access it.

Without access to insulin, people with T1D are placed at immediate risk of death, and people with T2D, who represent the vast majority (90%) of people with diabetes, are especially vulnerable to infections and other

complications of uncontrolled glucose levels.¹ People with diabetes are therefore particularly vulnerable in crises and humanitarian settings, given the risk of interrupted treatment and follow-up, impeded food supplies, and disrupted health services due to security issues and/or population movement.

Insulins are classified as either human or analogue. The differences between these types of insulin are outlined on Page 2. While all types of human insulin and long-acting insulin analogues are included in the WHO Model List of Essential Medicines (EML), rapid-acting analogues are not currently included.



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Sidra, 12, holds the insulin pen she received as part of her treatment for type 1 diabetes from MSF in Beirut, Lebanon. Despite their advantages over other insulin injection methods, insulin pens remain inaccessible for most people living with diabetes in low- and middle-income countries.

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TYPES OF INSULIN

- Insulin is classified as either human or analogue and by its onset and duration of action.
- Human insulins are synthetic insulins that are grown in the laboratory to mimic the body's insulin. Human insulin was developed through the 1960s and 1970s, replacing animal insulins, and was approved for pharmaceutical use in 1982.
- Insulin analogues, while similar to human insulins, have been modified to change their onset and duration of action after injection, enabling greater flexibility of use for people with diabetes and – for some people – facilitating a reduction in episodes of hypoglycaemia (low blood sugar levels).
- Insulin analogues are classified into rapid- and long-acting.
- Rapid-acting analogues (e.g., lispro, aspart, glulisine) take less time than regular human insulin to act. The first rapid-acting analogue was approved in 1996.
- Long-acting analogues (e.g., glargine, detemir, degludec), the first of which was approved in 2000, have a longer course of action than intermediate-acting human insulin, lasting up to 24 hours in the body and providing a consistent level of insulin for most of the day.
- Biosimilar insulin is a copy of an originator insulin.

MAKING INSULIN USE PATIENT CENTRED

Insulin can be delivered via an insulin syringe, pen or pump. Insulin vials are made of glass. An insulin pen is made of plastic and can be pre-filled or reusable, with the latter containing a replaceable glass insulin cartridge. Insulin pens are preferred by the majority of insulin users, and especially those with visual impairment, particularly if they lack adequate social support. Pens produce an audible click allowing visually impaired people to dose accurately and independently. Insulin in vials will continue to be needed for people with diabetes, especially those who use an insulin pump and for hospital management of acute diabetes complications.

In line with a patient-centred approach to care, people who use insulin should have a choice over their insulin delivery method. In high-income settings, people with diabetes are typically offered a choice between the various insulin injection options. Globally, 60% of people who use insulin use pens, with up to 94% in Europe using pens.³ However, the inequities in access to insulin injection devices mean this choice is often not available for people with diabetes in LMICs and humanitarian settings. Within the public sector in LMICs and in humanitarian settings – including those where Médecins Sans Frontières / Doctors Without Borders (MSF) works – insulin is only offered in vials to be injected with insulin syringes for the vast majority of people, primarily due to its lower price.

A survey of leading diabetes centres in LMICs carried out in 2019 by Life for a Child, an international programme for children and youth with diabetes in LMICs, showed that syringe use was the most common (83.1%) method of injecting insulin. In 48.6% of the 37 countries that responded, however, public health systems did not even provide the insulin syringes required to use the insulin.⁴

Similarly, use of insulin analogues is the norm for people with T1D in high-income countries, but they remain largely unaffordable or unavailable for most people in LMICs.

NEW AND MORE EFFECTIVE MEDICINES FOR T2D

In T2D, the majority of people manage their diabetes using oral medicines. However, over the last decade, there has been a transformational shift away from medicines that purely control

blood sugar to a “cardiometabolic” approach. Two new classes of medicines, sodium-glucose cotransporter-2 (SGLT-2) inhibitors and glucagon-like peptide-1 (GLP-1) receptor agonists, have been shown to have significant benefits in reducing cardiovascular and renal complications (including death) of diabetes. GLP-1s used in diabetes also often result in weight loss, which in itself can improve diabetes control, reducing complications and potentially delaying the need for insulin therapy.

SGLT-2s are oral tablets, while GLP-1s may be oral (semaglutide) or weekly injectables (e.g., semaglutide, dulaglutide). Injectable GLP-1s require a cold chain.⁵

Both of these new types of medicines are routinely included in treatment algorithms for T2D in high-income settings based on the evidence of their efficacy and safety from multiple randomised controlled trials. While SGLT-2s are included in the WHO EML, GLP-1s for diabetes, despite the evidence of their benefit, are not. Neither of these medicines is included in any international normative guidance (e.g., from WHO) and they are not routinely used in public sector programmes in LMICs or by humanitarian actors due to price and current global availability constraints. Hence, there is huge inequity in guidance, availability and access.

In this issue brief, co-authored by T1International, a non-profit that advocates for people with T1D, and MSF Access Campaign, we examine the preferences of people who use insulin for various injection devices, and the impact of different devices in diabetes management in humanitarian settings. We then present an analysis of the current market prices compared with the estimated cost-based prices for insulins (human and analogue) across all presentations (vial, cartridge and pre-filled pen), SGLT-2s and GLP-1s, and find that:

- 1) If market prices reflected cost-based prices, providing insulin analogues in pens would be more affordable than human insulin in vials with syringes; and
- 2) There are huge opportunities for price reductions for SGLT-2s and GLP-1s.

Based on the analysis of cost-based prices and preferences of people who use insulin, we call for decisive and urgent actions by manufacturers, WHO, national diabetes programmes and other treatment providers to ensure and expand access to these medicines for people with diabetes everywhere.

1. EXPERIENCE OF INSULIN USERS: WHAT DEVICE DO THEY PREFER?

To understand the experiences and preferences of people with diabetes related to injecting insulin, T1International and MSF carried out an online survey. The survey was shared through T1International’s global advocacy networks and with civil society organisations representing people living with diabetes. Anyone who has ever injected insulin for the treatment of T1D or T2D using vials with a syringe or a pen (reusable or pre-filled, with pen needles) was eligible to participate in the survey.

Questions included methods of insulin delivery used, experiences with vials and syringes, and experiences with pre-filled/reusable pens and cartridges. Additionally, open-ended questions were asked to understand likes and dislikes related to using different insulin delivery methods, as well as preference among them. The survey was made available online in English, French and Spanish.

The survey received 403 responses from 38 countries. The countries with highest representation were Panama (24%), USA (22%), Bolivia (17%), and India (14%). A third (34%) of respondents were children living with diabetes (< 18 years old) and/or their caregivers. Of adult users, 23% were in the 24–35-year-old age range. The vast majority of users (95%) were people living with T1D.

KEY FINDINGS

Users expressed a clear preference for insulin pens over vials and syringes. Out of all respondents, 355 (88%) had used both pens and vials and syringes. **82% of these preferred pens to vials and syringes. The most commonly cited reasons for this preference were because vials and syringes pose difficulty drawing up the correct dose, difficulty injecting insulin in public or due to lack of a clean space to inject, difficulty**

transporting insulin and equipment, and problems (e.g., scar tissue) at injection sites. Participants reported pain on injection at similar rates for insulin syringes and pens. However, we did not ask about syringe and/or pen needle diameter and length, and therefore lack sufficient information to draw a conclusion about extent of pain across delivery methods.

Qualitative responses highlighted themes of inconvenience on many levels related to using insulin vials and syringes, as well as extra work and pain associated with injecting, particularly in public spaces. Concern over vials breaking was also raised by respondents, highlighting the challenges of needing to use insulin when not in the home environment.

“Syringe would always get bubbles no matter what you did to avoid them. Carrying syringes around has a bigger stigma. Vials broke easily if dropped by accident...”

- Survey respondent, in response to what they disliked about vials

On the other hand, qualitative responses endorsed ease of use associated with insulin pens and a reduced likelihood of experiencing stigma.

“Very easy and great to carry in purse. Not too much stigma when injecting at the table.”

- Survey respondent, in response to what they liked about pens

These results highlight important considerations related to quality of life for people with diabetes, emphasising ease of management and medical safety. Simplifying the management of diabetes, through consistent use of insulin pens, may improve adherence, retention in care and thus outcomes in the longer term.

BENEFITS OF INSULIN PENS

- ACCURATE DOSING**
The dials on insulin pens make it easier for users to measure out accurate doses - especially for children and people with dexterity and visual difficulties
- ROBUST**
Unlike vials, insulin pens are made from material that is less likely to shatter - making them easy and safer to transport and carry around for everyday use
- LESS DISCOMFORT**
Using pens can reduce the discomfort of insulin injections
- COMPACT**
Insulin pens are compact and easy to carry, making them more convenient for people on the move and in humanitarian crises
- QUALITY OF LIFE**
The ease and accuracy of using insulin pens helps people stick to their treatment and avoid the dangerous complications of diabetes

2. INSULIN USE IN HUMANITARIAN SETTINGS

Ensuring continuity of care for people with diabetes in a humanitarian crisis, whether due to conflict or natural disaster, is critical. WHO has included human insulin in 10ml vials and insulin syringes in its NCD emergency kits since 2016, but insulin pens and long-acting insulin analogues (included in the WHO EML in 2021 and 2019 respectively) are not included. Often in acute emergencies people are forced to move either within or across national borders. People with diabetes must ideally move with their medicines, including insulin.

MSF has years of experience in implementing contingency plans for a range of chronic diseases in settings where people are at high risk of being affected by conflict or natural disasters.^{6,7,8} A key element of this is being able to provide a longer (e.g., three months') supply of medicines to patients routinely so that they can continue their treatment while on the move and while seeking care in a new setting.

When providing the bundle of diabetes tools (insulin, injecting device, glucometer and monitoring strips) to people with diabetes in such settings, feedback has been received that the compact, smaller physical volume of the package with pens, makes it more convenient to transport compared to the bigger, bulkier package with vials and syringes. There is also considerable concern expressed by people with diabetes in our care regarding the glass vials breaking during journeys that are often very precarious.

In addition, in many settings where MSF has responded to the emergency needs of people with diabetes (e.g., people displaced due to conflicts in Ukraine and Syria, and people in refugee camps in Greece), many present at clinics with insulin pens, often having used them since being diagnosed. Transitioning them to vials and syringes is extremely difficult in these acute settings for all the reasons cited in the survey. In a number of settings where MSF works, medical teams have reported this as a major barrier, leading to MSF procuring insulin pens, including analogues pens, to ensure continuity of care, reduce breakage and simplify treatment delivery.

Humanitarian actors can help improve access to insulin pens in order to facilitate continuity of care for people with diabetes in crisis settings who present using pens, and to provide a more convenient option for people with diabetes on the move. Through the operational experience of introducing insulin pens in diabetes programmes, MSF plans to use pre-filled insulin pens across its programmes.

Lebanon is one such country. MSF has been operating a chronic diseases programme in the country since 2012, treating refugees and local people with diabetes and other NCDs. The story of Moussa illustrates the advantages pens offer over syringes and vials, particularly for children with diabetes and their caretakers.⁹



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Dr Rasha Khamis examines a patient with diabetes at MSF's clinic in a camp for internally displaced persons in Debaga, northern Iraq. In humanitarian settings where MSF works, insulin pens are a more convenient option than vials and syringes for diabetes management.

INTRODUCING INSULIN PENS FOR CHILDREN WITH DIABETES IN LEBANON

Moussa is 10 years old and enjoys the same things other 10-year-old boys enjoy the world over. He spends his free time building Lego blocks with his siblings, colouring comics, and playing football with his schoolmates. Such activities, though seemingly ordinary, represent his way of triumphing over the challenges he faces daily. Moussa is living with diabetes while navigating the harsh conditions of the town he has been forced to call home.

In 2013, Moussa's family had to flee their home in Syria, and this journey led them to Arsal, a remote town located in northeastern Lebanon. According to local community leaders, nearly 77,000 refugees from Syria are now living in the town, and are desperately seeking basic necessities such as food, shelter, clean water, and medical care.

Moussa was diagnosed with type 1 diabetes at the age of three and takes insulin every day to control his blood sugar levels. For Moussa and his family, the precariousness of the living conditions in Arsal add to the challenges of treating this chronic, life-long condition.

The family—Moussa, his mother, father and four siblings—all live together in a single room. Early on in his treatment, Moussa's insulin was provided in a glass vial, and it was then injected with a syringe by his mother. Each time she drew up the insulin from the vial, she would worry about the accuracy of the dose that she was injecting into her son. Getting the dosage wrong could result in Moussa experiencing complications such as hypoglycaemia, a condition where blood sugar drops below healthy levels, which can sometimes be life-threatening.

The injections had to be given at home, as it made some of these challenges more manageable for Moussa's mother. But as a result, he would sometimes have to miss school in the afternoon to return home to get his injections. This curtailed his independence and affected his confidence in school.

Moussa gets his insulin from the MSF clinic in town. Since July 2022, all children and adolescents undergoing treatment at MSF's clinic for diabetes have been receiving insulin pens from MSF to help control their disease. In the past, many of them, like Moussa, used glass vials and syringes. Adults living with type 1 diabetes also started receiving insulin pens recently.

Moussa's mother explains how they are coping with Moussa's illness amid these challenges: "At first, we had to admit him into the hospital since I didn't know a lot about diabetes, insulin, and treatment. MSF teams helped me a lot and guided me to better deal with the situation, on how to give him the injection, what his lifestyle should be, what to feed him, and what should he do. We have got used to it now, but even after more than five years, it's still challenging."

Using the insulin vials and syringes was problematic for other reasons too for the family. For instance, Moussa found the injections with the syringe's needle very painful, and since he needed injections several times a day, this created stress for both mother and child, with Moussa often reluctant to take the injections.



Moussa, 10, with his mother in Arsal, Lebanon. Since switching to insulin pens, managing diabetes has become much less challenging for Moussa and his family.

Since switching to insulin pens last year, many of these challenges are much easier for Moussa and his family. Using pens has allowed Moussa to take control of his treatment. He is able to inject himself, and this has given him more mobility, autonomy and confidence when going to school. His mother, too, appreciates the simplicity of injections with the pens.

Dr Beverley Prater, who works in MSF's clinic in Arsal to support people with diabetes and other chronic non-communicable diseases, explains that children – all children – want to feel 'normal'. This is especially important in situations that many children and their families in Arsal find themselves as refugees. Rising anti-refugee rhetoric and restrictions on freedom of movement of refugees have added to the difficulties of life in Arsal for families like Moussa's.

"Life with diabetes is a challenge at baseline for any of us. But for people who lack a safe space or proper housing, food security, refrigeration or access to electricity, insulin pens ease their daily lives and facilitate long-term health," says Dr Prater. "In an unstable life situation, this also allows for hope, for long-term vision of growing up and growing old with diabetes."

For both Moussa and his family, the introduction of insulin pens has made a big difference to their lives, giving reassurance to his mother that he's less likely to experience hypoglycaemia, and giving Moussa the independence he craves to be out and about, playing with his friends, going to school, living something close to a 'normal' life in these challenging circumstances for himself and his family. With the pens, Moussa is also empowered to respond to his medical condition and cope without relying on someone else to help him carry on with his everyday activities.

Here's Moussa himself on how the pens have helped him to adapt to living with type 1 diabetes: "I have been using insulin pens for the last year. When I don't take it, my sugar level increases, and I get headaches. I take it at home or at school, and even when there's a party. I'm used to it now."

3. EXISTING BARRIERS TO NEW MEDICINES FOR DIABETES

LACK OF COMPETITION AND INTELLECTUAL PROPERTY (IP) BARRIERS

Three multinational corporations (Novo Nordisk, Sanofi and Eli Lilly) dominate the global market for insulin, with pricing practices and policies that make their insulin, especially analogues and pen devices, prohibitively expensive for most governments' budgets.¹⁰ While a number of other manufacturers make insulin, most of them operate as contract manufacturers for the three dominant corporations. At present, 'truly independent' insulin manufacturers do not represent enough global market share to have made the market competitive.

Insulin analogues

There are no patents on human insulin. With the recent expiry of patents on insulin analogues long-acting glargine and rapid-acting aspart, their biosimilar versions are starting to be produced in key manufacturing countries such as India, including in reusable and pre-filled pens.¹¹ However, the three multinational corporations continue to dominate the market even in LMICs for a variety of reasons, including biologics like insulin not yet being widely assessed or approved by medicines regulatory agencies and a generalised distrust of biosimilars in many countries.¹²

As new insulin analogues enter the market, they are covered by patent barriers. A new once weekly insulin, ICODEC, about to be approved for T2D, will be under monopoly market control by Novo Nordisk unless patent barriers are addressed.

GLP-1s

Novo Nordisk and Eli Lilly dominate the GLP-1 market, making extraordinarily huge profits. GLP-1s are indicated for T2D, but also marketed heavily for weight loss, which contributes to significant profiteering and shortages for health systems.^{13,14} Generic companies in India and China are already marketing generic liraglutide. Expiry of basic patents on dulaglutide and oral semaglutide in June 2024 and March 2026 is expected to open up alternative supply. However, secondary patent barriers may be faced by generic manufacturers in supplying semaglutide in injectable form, which is the preferred formulation based on its cardiovascular benefits. A "freedom to operate" analysis is necessary to understand the options for generic manufacturing (key manufacturing countries) and supply (LMICs) for the GLP-1 formulations and injection devices.

A number of pharmaceutical corporations have promising oral GLP-1-based products in development. If approved, they will be under monopoly until 2036, 2037 and 2038 respectively.^{15,16,17}

SGLT-2s

Basic patents on SGLT-2 inhibitor dapagliflozin (Bristol Myers Squibb in partnership with Astra Zeneca) expired in 2023, and will expire for empagliflozin (Boehringer Ingelheim/Eli Lilly) in 2025.¹⁸

Generics of dapagliflozin are already approved in Canada, India and South Korea after successful challenges to a secondary patent.^{19,20,21} Generic versions are also now available in South Africa, Tanzania, Ethiopia and Nigeria.²²

Some Indian manufacturers have already received approval for generic versions of empagliflozin, but their market entry is blocked until 2025 due to patent barriers. In the case of empagliflozin, generic versions were launched in India but the pharmaceutical corporation Boehringer Ingelheim managed to obtain injunctions from the Indian courts to prevent their supply. The US Food and Drug Administration, too, has approved generics from Indian manufacturers, but their market entry is blocked until 2025. However, secondary patents on new forms and formulations in some countries may extend the barrier to market entry.

How to address patent monopolies

Filing secondary patent applications covering routine changes in the form, formulation or delivery devices of existing pharmaceutical products, also known as evergreening, is a lucrative game for the pharmaceutical business. It can prevent generic competition – and ultimately, access – for these products and allow corporations to prolong their monopolies and thereby continue charging high prices. One way to shorten monopolies is to file pre-grant oppositions to secondary patent claims, wherever the mechanism is available in the national patent law.

Compulsory licenses are another avenue. Unlike communicable diseases such as HIV for which licenses have enabled generic supply, new NCD medicines, including those for diabetes that need to be delivered in cartridges and pens, rarely receive attention from policymakers in LMICs. No compulsory license has been issued on a diabetes medicine by any government.

One key challenge is that many newer classes of diabetes medicines such as insulin analogues, SGLT-2s and GLP-1s are not prequalified by WHO and not included in national EMLs and treatment guidelines; therefore, they are not targeted for procurement by the public health system. Inclusion of these new classes of medicines in national guidelines, EMLs and the WHO prequalification (PQ) programme will help bring attention to the need to reduce prices through generic competition, including by using health safeguards in patent laws such as compulsory licensing. (See "Lack of WHO guidance and few quality-assured sources" section below for more details.)

Compulsory licenses also strengthen efforts by entities like the Medicines Patent Pool (MPP) to seek voluntary licenses from otherwise reluctant pharmaceutical corporations.

Greater attention from civil society and governments in LMICs to the pricing and patenting practices of pharmaceutical corporations, and the resulting lack of competition, availability and affordability of diabetes medicines, is essential to increasing access for people.

HIGH PRICES

Prices of insulin, SGLT-2s and GLP-1s vary hugely across contexts. Data from countries where prices of insulin are publicly available demonstrates a difference of \$197 between the lowest market prices for human insulin in a 10ml vial (Table 2). Huge price differences also exist across countries for SGLT-2s and GLP-1s. For instance, the lowest price of the SGLT-2 dapagliflozin ranges from \$3.85 (in India) to \$526.80 (in the US), and the price of the GLP-1 semaglutide injectable ranges from \$38.21 (in Bangladesh) to \$353.74 (in the US).

Novo Nordisk offers its human insulin under an access-to-insulin commitment for LMICs.²³ However, this scheme offers human insulin only in a 10ml vial with a ceiling price of \$3 per vial. An Indian biosimilar manufacturer, Biocon, launched an access initiative for human insulin in vials in 2019 at \$0.10 per day.²⁴ However, neither Biocon's nor any other biosimilar human insulin has yet been prequalified by WHO.

In 2021, Sanofi introduced its Global Health Unit – as well as new Sanofi Impact branding in 2022 –for their glargine in vials and pens, but the programme's impact has not yet been evaluated, and they have not made public their pricing for LMICs.^{25,26,27}

Eli Lilly has primarily promoted its insulins through donations to organisations such as Life for a Child. In 2016 they also launched their own global access scheme, called Lilly 30x30.²⁸ Evaluation of the programme's impact is also awaited.

MSF procures human insulin in a 10ml vial for \$2/vial, but there is no publicly available access price for any human insulin specifically in pens, nor for any analogue insulin in any presentation; prices for these products are individually negotiated.^a No access pricing for LMICs exists for any SGLT-2s or GLP-1s from the originator companies listed above.

LACK OF WHO GUIDANCE AND FEW QUALITY-ASSURED SOURCES

Human insulin in vials has been on WHO's Model List of Essential Medicines (EML) since it was first published in 1977, and long-acting analogue insulins, including in pen devices, were added in 2021. In July 2023, the EML added human insulin in cartridges and pens.²⁹ This should encourage governments to include pens and cartridges in their national EMLs, thereby facilitating improved access. Rapid-acting analogues are still not listed.

TABLE 1: INCLUSION OF SELECTED DIABETES MEDICINES IN WHO EML

Diabetes medicine	Year of inclusion
Human insulin (vial)	1977
Long-acting analogues (vial, cartridge, pen)	2021
Human insulin (cartridge and pen)	2023
Rapid acting analogues	Not yet added
SGLT-2s	2019
GLP-1s	Not yet added

WHO PQ released its pilot expression of interest for human insulin in vials in 2019 with the goal of increasing the number of quality-assured biosimilar insulins and thus providing countries with greater choice and lower prices.³⁰ This goal has not yet been achieved, as no biosimilar insulins have been prequalified; indeed, the insulins that eventually were prequalified (in 2022 and 2023) are from two of the three major corporations already dominating the market.³¹ With the addition of pen devices and cartridges to the 2023 EML, WHO PQ has the opportunity to expand its expression of interest to include these devices to help increase access to insulin in all three presentations.

There is currently no WHO normative guidance for the clinical management of T1D, which leaves some countries who rely on this guidance without clarity on the circumstances in which and specific patient groups for whom the different insulin types and devices should be considered. In MSF programmes, pen devices were initially prioritised for children, elderly people with poor vision and for people on the move during emergencies where they were already on pens to facilitate continuity. WHO guidance for T2D exists, but similarly does not include specific guidance on what type of delivery device to consider.^{32,33}

SGLT-2s were included in the WHO EML in 2019 and mentioned in the 2020 WHO HEARTS-D guidance but only for use in patients for whom insulin is not suitable rather than earlier in the treatment algorithm as seen in high-income settings.³¹ GLP-1s for the indication of diabetes or obesity are neither included in the WHO EML nor any WHO clinical guidance.

^a Sanofi Impact offers insulin glargine 300IU/3ml pens in Tanzania but the price is not known.

4. ESTIMATED COST-BASED PRICES OF DIABETES MEDICINES AND REGIMENS

TABLE 2: MONTHLY COST-BASED PRICES (IN US\$) COMPARED WITH LOWEST MARKET PRICES AND MSF PROCUREMENT PRICES

INSULINS									
Medicine	Vial			Cartridge			Pre-filled pen		
	Estimated cost-based price range	Lowest market price range	MSF	Estimated cost-based price range	Lowest market price range	MSF	Estimated cost-based price range	Lowest market price range	MSF
Human insulins									
Regular insulin	\$2.37–\$5.94	\$1.93–\$198.90	\$3	\$3.00–\$9.13	\$10.62–\$53.27	\$12.4	\$4.69–\$29.44	\$9.37–\$31.73	\$18.5
Insulin NPH	\$2.40–\$5.98	\$1.93–\$198.15	\$3	\$3.02–\$9.17	\$10.71–\$30.70	\$12.4	\$4.71–\$29.48	\$9.37–\$251.40	\$18.5
Insulin NPH 30/70	2.39–5.97	\$1.93–\$198.90	\$3	\$3.02–\$9.15	\$10.71–\$214.65	\$12.4	\$4.71–\$29.47	\$9.98–\$453.45	\$18.5
Insulin analogues (rapid acting)									
Insulin aspart	\$4.86–\$10.59	\$19.42–\$208.35	NA	\$5.39–\$13.61	\$13.95–\$256.65	NA	\$7.08–\$33.92	\$25.48–\$268.20	\$24
Insulin lispro	\$4.87–\$10.62	\$25.18–\$118.65	NA	\$5.40–\$13.63	\$25.04–\$488.55	NA	\$7.09–\$33.94	\$26.71–\$152.70	NA
Insulin glulisine	\$4.79–\$10.47	\$21.47–\$407.70	NA	\$5.33–\$13.49	\$21.24–\$50.64	NA	\$7.02–\$33.81	\$23.51–\$526.95	NA
Insulin analogues (long acting)									
Insulin degludec	\$5.16–\$11.17	–	NA	\$5.69–\$14.16	\$51.19–\$98.55	NA	\$7.38–\$34.47	\$56.33–\$488.25	NA
Insulin detemir	\$16.97–\$33.31	\$443.25–\$443.25	NA	\$17.05–\$35.48	\$27.47–\$103.30	NA	\$18.74–\$55.79	\$48.98–\$443.70	NA
Insulin glargine	\$4.25–\$9.46	\$28.95–\$142.65	NA	\$4.81–\$12.52	\$27.47–\$65.25	NA	\$6.50–\$32.83	\$14.92–\$142.05	\$10
SGLT-2 INHIBITORS									
Medicine				Estimated cost-based price range			Lowest market price range		
canagliflozin (200mg daily)				\$25.00 - \$46.79			\$17.76 - \$364.69		
dapagliflozin (10mg daily)				\$1.30 - \$2.32			\$3.85 - \$526.84		
empagliflozin (17.5mg daily)				\$1.88 - \$3.45			\$6.08 - \$382.95		
GLP-1 AGONISTS									
Medicine				Estimated cost-based price range			Lowest market price range		
dulaglutide (1.12mg once weekly)				\$7.05 - \$17.40			\$22.20 - \$227.253		
exenatide (7.5mg twice daily)				\$0.75 - \$4.46			\$58.75 - \$577.66		
liraglutide (1.5mg daily)				\$21.56 - \$50.32			\$78.54 - \$851.40		
semaglutide (injectable, 0.77mg once weekly)				\$0.89 - \$4.73			\$38.21 - \$351.74		
semaglutide (oral, 10.5mg daily)				\$38.62 - \$72.49			\$71.15 - \$643.04		

WHAT COULD THE PRICE OF INSULIN PEN DEVICES, SGLT-2s AND GLP-1s BE?

An analysis by MSF Access Campaign published in the Journal of the American Medical Association (JAMA) Network Open in March 2024 compares the range of lowest monthly prices of insulins, SGLT-2s and GLP-1s in 12 countries with their estimated cost-based prices.³⁴ This includes four high-income countries (France, Latvia, the UK, and the US) and eight middle-income countries (Bangladesh, Brazil, China [data available only for insulins], El Salvador, India, Morocco, the Philippines, and South Africa).

Countries were chosen based on availability of data on prices and with an intention to provide geographic and economic diversity in the sample. We are not aware of a publicly available medicines price database for any low-income country.

The comparison is based on the use of 50U/day (0.5ml) of insulin – slightly higher than the WHO-estimated daily dose of 40U/day (0.4ml) – which was derived from a survey of MSF field programmes using insulin in a range of humanitarian settings – and commonly used doses for SGLT-2s and GLP-1s.

Cost-based prices of medicines have previously been estimated in a range of different therapeutic areas, including for insulin.^{35,36,37} However, the cost-based price of insulin pen devices has not previously been estimated and this is the first published estimation of cost-based prices for SGLT-2s and GLP-1s for the indication of diabetes. Estimated cost-based prices include the cost of active pharmaceutical ingredient (API), to which the costs of formulation and secondary packaging, logistical costs, profits, and an allowance for tax are added. Cost-based prices can be estimated with a ‘competitive’ formula that assumes economies of scale possible with large-scale production and a lower profit margin (10%), or a ‘conservative’ formula that assumes smaller production volumes and/or a higher profit margin (50%).

Table 2 compares selected lowest market price range of diabetes medicines with their estimated cost-based price range and—where available—MSF procurement prices.

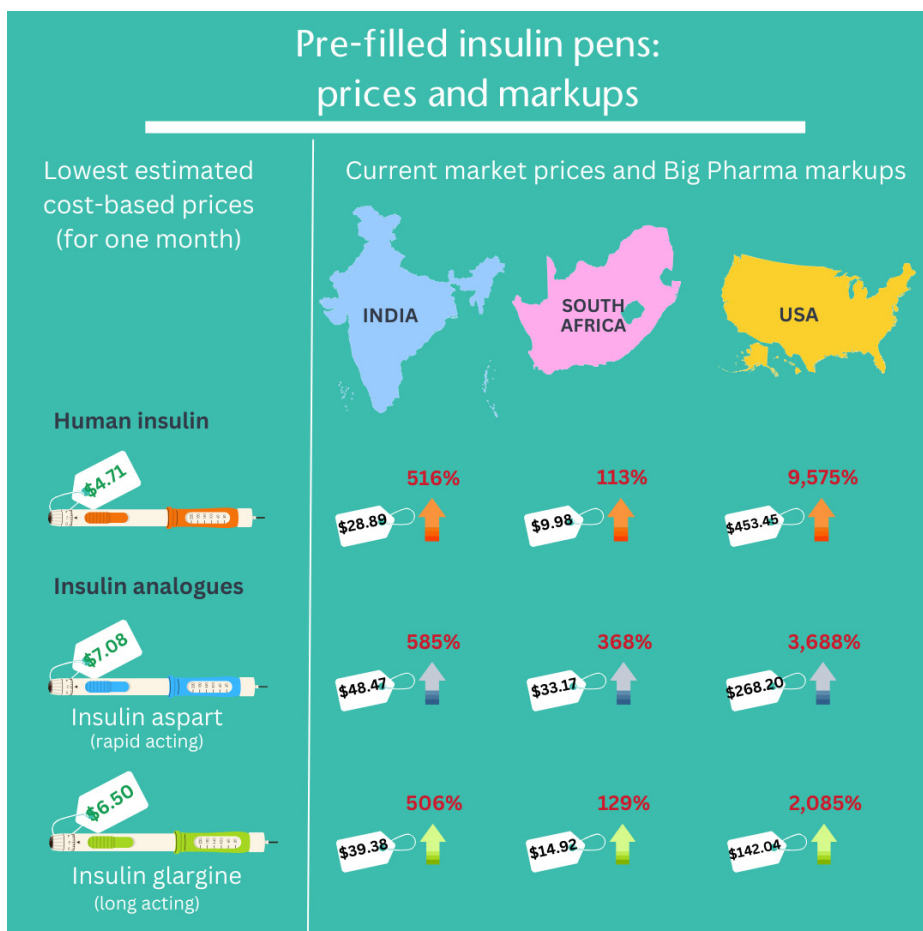


Figure 1: Prices and Big Pharma markups on pre-filled insulin pens

The prices are for a month's treatment with insulin [50U/day (0.5ml)]. Therefore, at the lowest cost-based prices a 10ml vial, 3ml cartridge and 3ml pre-filled pen of human insulin could be sold profitably for \$1.58, \$0.5 and \$0.93 respectively. A month of dapagliflozin could be sold profitably for \$1.3.

A month of once weekly injectable semaglutide could be sold at a profit for just \$0.89, compared to the price of \$95 per month charged in Brazil, \$115 per month charged in South Africa, \$230 charged in Latvia and \$353 charged in the US, which is a 39,562% markup over what the estimated price could be.

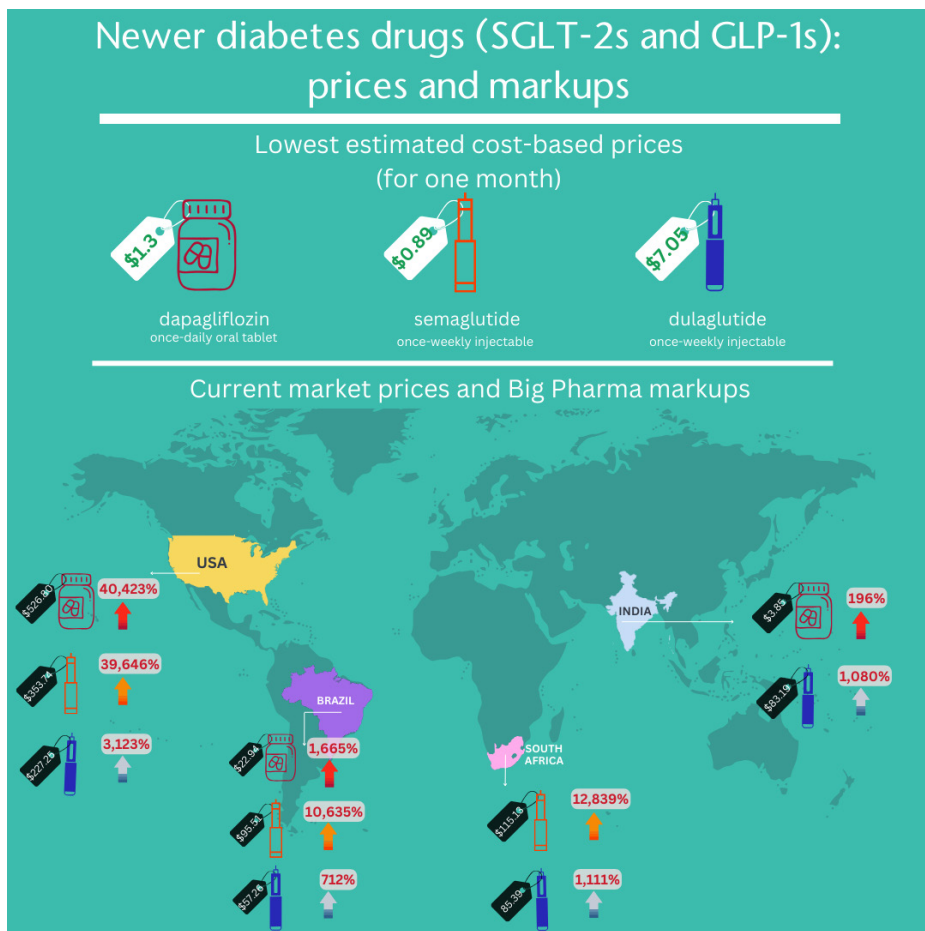


Figure 2: Prices and Big Pharma markups on newer diabetes drugs

TABLE 3: ANNUAL INSULIN REGIMEN PRICES (IN US\$)

	Syringe and vial		Reusable pen with cartridge		Pre-filled pen	
	Estimated cost-based price range	Lowest market price range	Estimated cost-based price range	Lowest market price range	Estimated cost-based price range	Lowest market price range
Basal-bolus regimens; price per person per year						
Insulin NPH twice daily + regular insulin three times a day	\$157-\$656	\$154-\$851	\$96-\$176	\$189-\$575	\$112-\$413	\$169-\$758
Insulin glargine once daily + insulin aspart three times a day	\$158-\$589	\$411-\$2,602	\$111-\$213	\$312-\$690	\$127-\$450	\$301-\$2,550
Mixed insulin regimens; price per person per year						
Insulin NPH 70/30 twice daily	\$80-\$306	\$75-\$579	\$61-\$138	\$154-\$897	\$79-\$380	\$144-\$1,861
Basal only (T2D); price per person per year						
Insulin NPH once daily	\$55-\$189	\$55-\$189	\$50-\$127	\$144-\$389	\$68-\$370	\$125-\$1,031
Insulin glargine once daily	\$77-\$232	\$407-\$1,852	\$72-\$168	\$347-\$810	\$90-\$410	\$192-\$1,739

WHAT COULD THE PRICE OF INSULIN-CONTAINING REGIMENS FOR T1D AND T2D BE?

T1D is ideally treated with a long-acting insulin analogue once a day and three rapid-acting doses prior to meals. This is known as a basal-bolus regimen. In some settings this regimen is difficult to implement and, although not ideal care, insulin is given just twice daily. For people living with T2D whose glucose levels are not controlled on oral medicines, insulin may be added once or, in a few cases, twice daily.

Currently, in the majority of LMICs and humanitarian settings, human insulin is the most affordable option. However, as described in previous sections, it is not the preferred option;

other types of insulin and better delivery devices can improve quality of life and safety for people who use insulin.

Table 3 compares the annual cost-based price range and the market price range for different, recommended insulin regimens, with the price of injection device (pen or syringe and single-use needles) included. The cost of a reusable pen is averaged over its lifespan. One reusable pen is used for each type of insulin, so two pens are used in regimens in which two types of insulin are used. Figures 3 and 4 show the lowest annual cost-based price estimates to deliver a basal bolus regimen for T1D and a once-daily regimen for T2D.

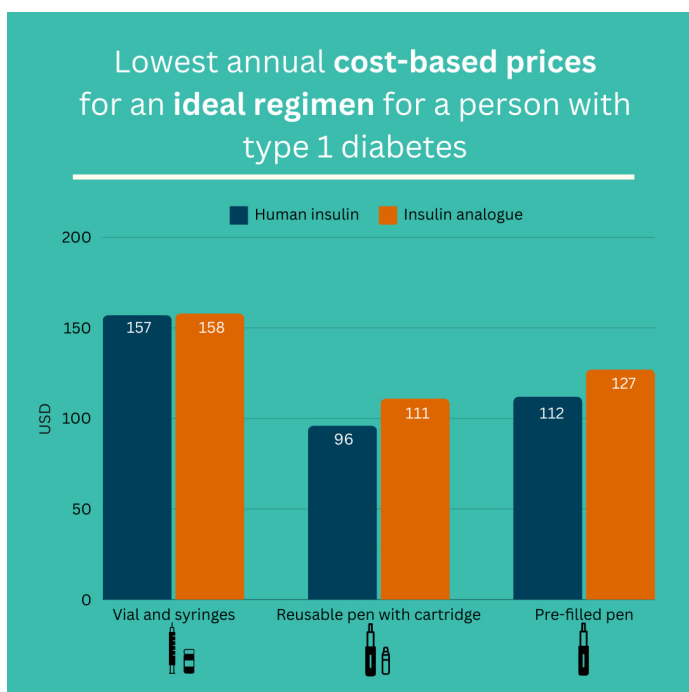


Figure 3: Lowest annual cost-based prices for basal-bolus regimen for T1D with different insulin injection devices

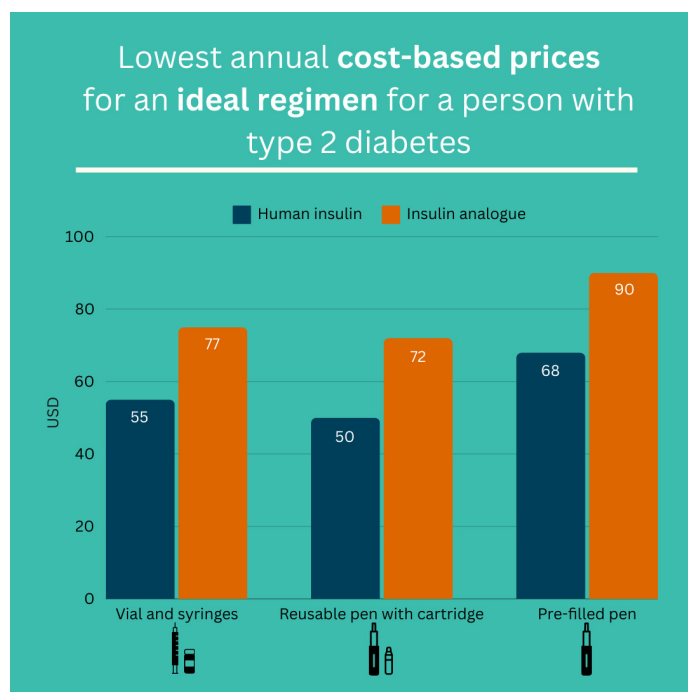


Figure 4: Lowest annual cost-based prices for once-daily regimen for T2D with different insulin injection devices

FINDINGS

Type 1 diabetes

At the lowest annual cost-based prices:

- Using human insulin in a vial is not the most affordable way of delivering a basal-bolus regimen;
- Using either a reusable or pre-filled pen with either human or analogue insulin is more affordable than human or analogue insulin from a vial when the price of needles and syringes is included; and
- When using a reusable pen, the price differential of moving from human to analogue insulin could be as low as \$15 per year.

Type 2 diabetes

- At the lowest annual cost-based prices, human insulin in a reusable pen is the most affordable way to deliver a once-daily regimen.

CONCLUSIONS AND RECOMMENDATIONS

The experience of people with diabetes demonstrates a clear preference for insulin pens over vials and syringes due to their ease of use, perceived reduced risk of dosing error and positive impact on quality of life. Feedback received by T1International and MSF's experience in humanitarian settings has also demonstrated the benefits of pens for people with diabetes, especially in acute humanitarian emergencies where they are a more practical and safer tool to transport and use.

Despite these advantages, insulin pens are not commonly used in LMICs due to their comparatively higher prices, lack of preferential pricing practices from corporations, and insufficient guidance from WHO. Newer medicines for T2D, SGLT-2s and GLP-1s, are mainly available only in HICs when part of public sector provision of diabetes care due to their high prices.

However, data on cost-based prices of diabetes medicines demonstrates that insulin pens and analogues could be a more affordable option than, and a viable alternative to, human insulin in a vial for LMICs and humanitarian settings. It also highlights the gulf between the current market prices and cost-based prices of SGLT-2s and GLP-1s, and the opportunities for price reduction for public and NGO treatment providers.

To address this inequality of access and in order to improve the affordability and availability of all diabetes medicines, we urge stakeholders to heed this evidence and take the following actions:

WHO:

- Include pre-filled insulin pens and insulin switching guides in its NCD emergency kits;
- Facilitate prequalification of all presentations of insulin (vials, cartridges, pre-filled pens);
- Develop updated clinical guidance, including considerations for choice of insulin type and injection device (T1D and T2D), and SGLT-2s and GLP-1s (T2D);
- Assess GLP-1s for the next WHO EML;
- Consider SGLT-2s and GLP-1s for WHO PQ; and
- Support pooled procurement mechanisms to facilitate access to insulin, including insulin pens.

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We would also like to acknowledge all the people living with diabetes who participated in the survey and who shared their experience of living with diabetes, and MSF technical and operational colleagues providing diabetes care in challenging and diverse settings.

GOVERNMENTS AND THEIR NATIONAL DIABETES PROGRAMMES:

- Include SGLT-2s, GLP-1s, human insulin, and insulin analogues – in vials, cartridges and disposable pens – in national EMLs and guidelines;
- Include analogues and pens in national diabetes guidelines;
- Budget for comprehensive public sector diabetes programmes, including inclusion of insulin pens as an option to consider for specific groups of people with diabetes;
- Publish insulin prices across all devices and health sectors to facilitate price transparency;
- Pool forecasts for associated volume-based pooled procurement mechanisms with willing collaborating countries/regions; and
- Identify opportunities for compulsory licensing of new diabetes medicines.

MANUFACTURERS:

- Include human and analogue insulin cartridges and pre-filled pens for all negotiations, including those with LMICs;
- Reduce prices of insulins, SGLT-2s and GLP-1s in all contexts to reflect their cost of production; and
- Allow licensing and technology transfers for SGLT-2s and GLP-1s to expedite expanded, generic production.

IMPLEMENTERS OF DIABETES CARE IN HUMANITARIAN SETTINGS:

- Ensure insulin switching guidance is available to clinicians working in humanitarian settings;
- Implement pens and analogues to simplify use and provide continuity of care for internally displaced persons and refugees who need insulin;
- Implement interagency pooled procurement negotiations to aid better prices of insulin, injection devices and other tools required for diabetes management; and
- Consider inclusion of SGLT-2s and GLP-1s within T2D guidance.

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Siwar, a young girl living with type 1 diabetes, holds up her insulin pen while lying down among her toys in her family's makeshift home in Arsal, Lebanon.