

#### médecins sans frontières access campaigna DEFEATING THE DOUBL STANDARD IN DIABETES

Exposing the exorbitant prices of diabetes medicines and injection devices

#### **INTRODUCTION**

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

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

their treatment. Globally, only about hal 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

e not complications of uncontritable levels.<sup>1</sup> People with diabepeople particularly vulnerable in c. t with humanitarian settings, given e 420 interrupted treatment and fc impeded food supplies, and health services due to security ut half or population movement.

Insulins are classified as either or analogue. The differences but le with these types of insulin are outlin sk of Page 2. While all types of humai ho and long-acting insulin analogue %) of included in the WHO Model List cially Essential Medicines (EML), rapidper analogues are not currently inclu

## Defeating the Double Standard in Diabetes Care

## Part 1: Lowering the price of insulin everywhere: Let's make it a reality

May 14th





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

## Housekeeping

- Presentations first
  - Introduction
  - Insulin device user preference survey
  - Insulin access initiatives from the manufacturers
  - How much could insulin cost
- Please write your questions in the chat or Q and A box
- During the discussion session you will also have a chance to ask questions- raise your zoom hand and we will unmute you

million adults are living with adults with diabetes middle-income 6.7 million deaths due to

#### Key global findings 2021

The **IDF Diabetes Atlas 10th edition** reports a continued global increase in diabetes prevalence, confirming diabetes as a significant global challenge to the health and well-being of individuals, families and societies.

Download the IDF Diabetes Atlas 10th Edition and other resources.

View all the latest national and regional data in our data portal

#### **Diabetes around the world in 2021:** 537 million adults (20-79 years) are living with diabetes 10. This number is predicted to rise to **642 million** by 202

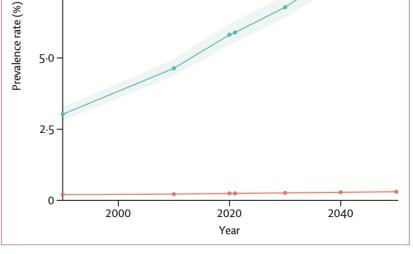
**537 million** adults (20-79 years) are living with diabetes - 1 in 10. This number is predicted to rise to **643 million** by 2030 and **783 million** by 2045.

Image: Second systemOver 3 in 4 adults with diabetes live in low- and middle-income countries.

Diabetes is responsible for **6.7 million** deaths in 2021 - 1 every 5 seconds.

Diabetes caused at least **USD 966 billion** dollars in health expenditure – a 316% increase over the last 15 years.

**541** million adults have Impaired Glucose Tolerance (IGT), which places them at high risk of type 2 diabetes..



Type 1 diabetes

Type 2 diabetes

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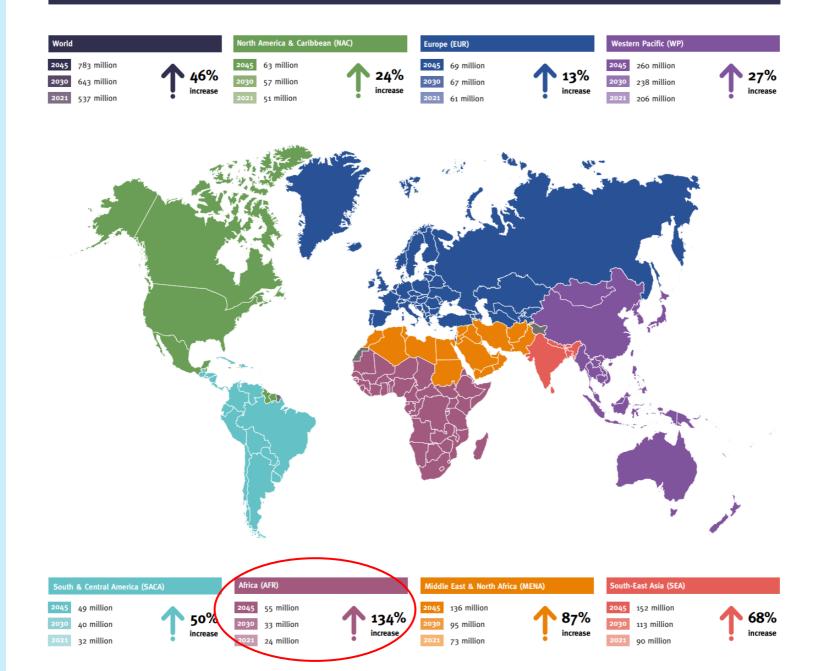
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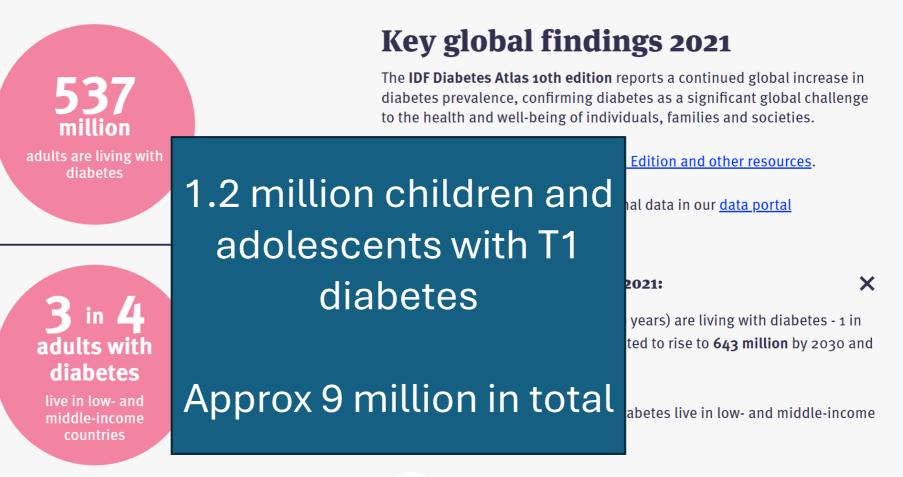
*Figure 4*: Global age-standardised prevalence of type 1 and type 2 diabetes from 1990 through 2050 forecasts

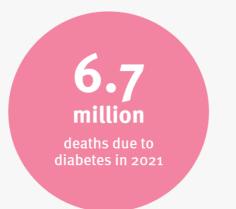
The shaded area represents 95% uncertainty intervals. Total diabetes is the sum of type 1 and type 2 diabetes.

#### 1.3 billion by 2050

#### Map 1 Number of people with diabetes worldwide and per IDF Region in 2021–2045 (20–79 years)







 $\overline{\mathbb{A}}$ 

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**541** million adults have Impaired Glucose Tolerance (IGT), which places them at high risk of type 2 diabetes..

## Who needs insulin?

People living with T1 Diabetes

- Unable to produce insulin
- Everyone with T1 needs insulin to survive
- Immediate lifesaving medicine

People living with Type 2 diabetes

- Able to produce insulin but body is resistant to it
- Approx 10-15 % of people living with T2DM will need insulin after use of other glucose lowering medicines
- This may be changing with introduction of new diabetes medicines

## What is the global need for insulin

- Everyone with T1Diabetes approx. 9 million (at least 1.2 M children/adolescents)
  - Unable to produce insulin
  - without they will die within days
- Approx 60 million with T2D approx 11% of people living with with T2D
  - Insulin resistance
  - Could some of the newer drugs for diabetes (SGLT-2 and GLP-1)
    - reduce the need for insulin
    - Make delivery simpler (once a week, no need for self blood glucose monitoring)

Keeping the 100-year-old promise: making insulin access universal (who.int)

**Key publications** 

## Towards insulin for all: operationalising the WHA74 resolution on diabetes

## 2021 First WHA resolution on diabetes



(6) to ensure that national strategies for the prevention and control of noncommunicable diseases contain the necessary provisions to cover persons living with diabetes with quality essential health services and promote access to diagnostics and quality, safe, effective, affordable and essential medicines, including insulin, oral hypoglycemic agents and other diabetes-related medicines and health technologies for all people living with diabetes, in accordance with national context and priorities;

- 80% of people with diabetes are diagnosed (this includes all types of diabetes)
- 80% of people with diagnosed diabetes have good control of glycaemia
- 80% of people with diagnosed diabetes have good control of blood pressure
- 60% of people with diabetes of 40 years or older receive statins
- 100% of people with type 1 diabetes have access to affordable insulin treatment (including devices for insulin delivery, such as syringes and needles) and blood glucose self-monitoring *(the bundle)*

# 2022: **First ever** global targets set

ACCESS TO MEDICINE

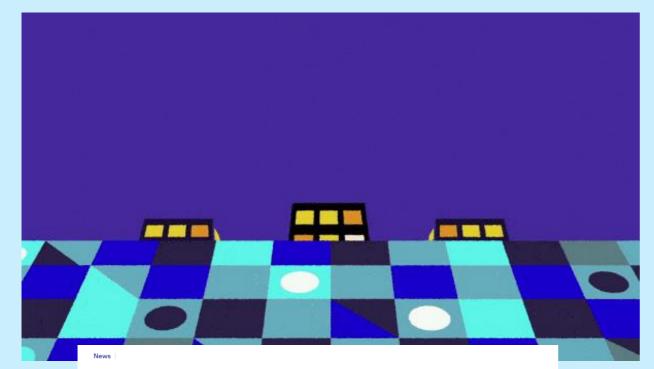
AND HEALTH PRODUCT

Keeping the 100-year-old promise: making insulin access universal





### **The Insulin Market**

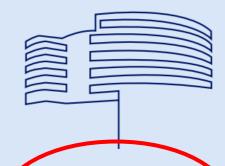


#### Signal: Novo Nordisk market cap higher than Danish GDP due to obesity drugs

Novo Nordisk's obesity drugs are driving Danish growth as well as record profits as the company becomes second-most valuable in Europe.

- The big 3 : Novo Nordisk (Denmark); Eli Lilly (US) ; Sanofi (France)
- Control over 90% of global insulin market by value
- Produce 83% of the insulin sold in LMICS- where they have 95% of market share
- Novo Nordisk and Eli Lilly also make GLP-1s
- Novo Nordisk the largest company in Europe
- Lilly heading towards being a \$trillion company

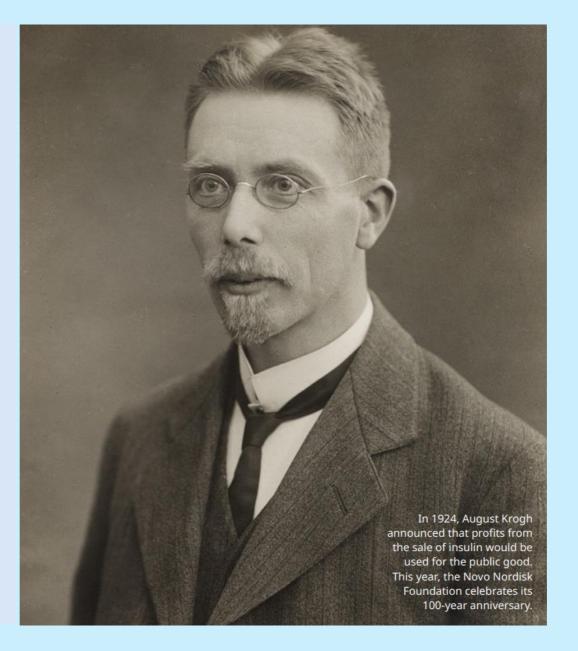
#### **Creating long-term value**



The Novo Nordisk Foundation holds 77.1% of votes and 28.1% of shares in Novo Nordisk A/S through Novo Holdings A/S

The Novo Nordisk Foundation awards grants in three strategic areas: Health, Sustainability and Life Science Ecosystem. In 2023, more than DKK 9 billion were awarded in grants.

1.3 billion in grants in 2023



VIAL	CARTRIDGE	PRE-FILLED PEN
		A
Analogue: Rapid or long acting		

TIMELINE : Innovations and developments in the century after the discovery of insulin<sup>7-12</sup>

1921

Discovery of insulin

**1949** Production of first standardised insulin syringes

#### 1978

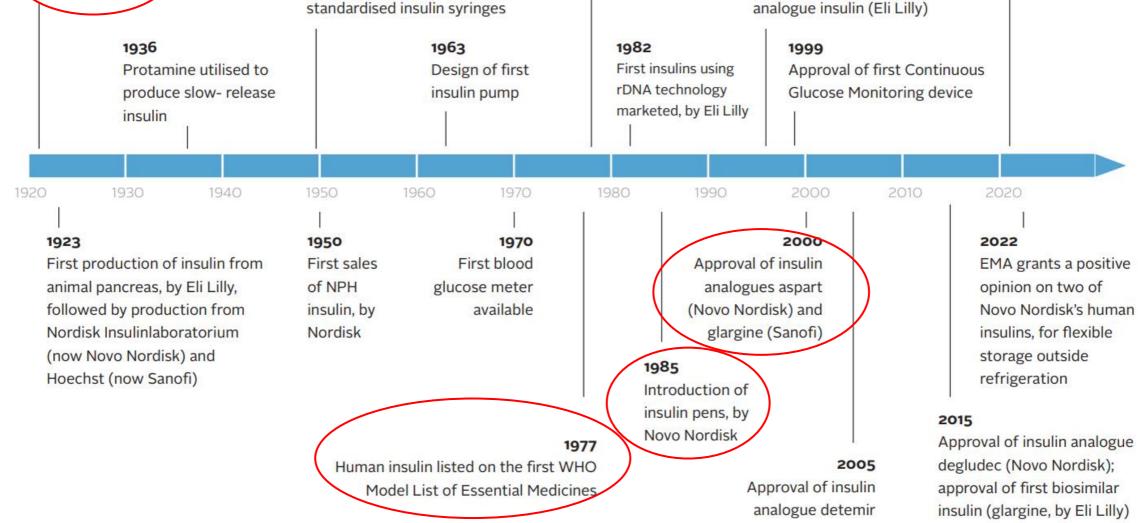
First recombinant DNA synthetic human insulin prepared. First portable insulin pumps developed.

1996

Approval of lispro, first

2021

Long-acting insulin analogues listed on the WHO Model Lists of Essential Medicines





#insulin4all
#insulin4all
#insulin4all
#insulin4all
#insulin4all
#insulin4all
#insulin4all



### Vision

We believe in a world where everyone with type 1 diabetes – no matter where they live – has everything they need to survive and achieve their dreams.

### Mission

We support local communities by giving them the tools they need to stand up for their rights so that access to insulin and diabetes supplies becomes a reality for all.

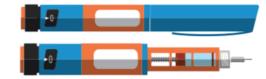


### We are Patient-led and Pharma-free

**Patient-led:** We amplify patient voices, and we give people living with diabetes a direct role in organisational decision-making to ensure T1International and the #insulin4all movement keep patient voices front and center. Our messaging, focus, and mindset are patient-led.

**Independent:** We do not accept funding from the pharmaceutical industry or any entity that we believe would compromise our independence, integrity or ability to speak out freely.

## **Diabetes Management**



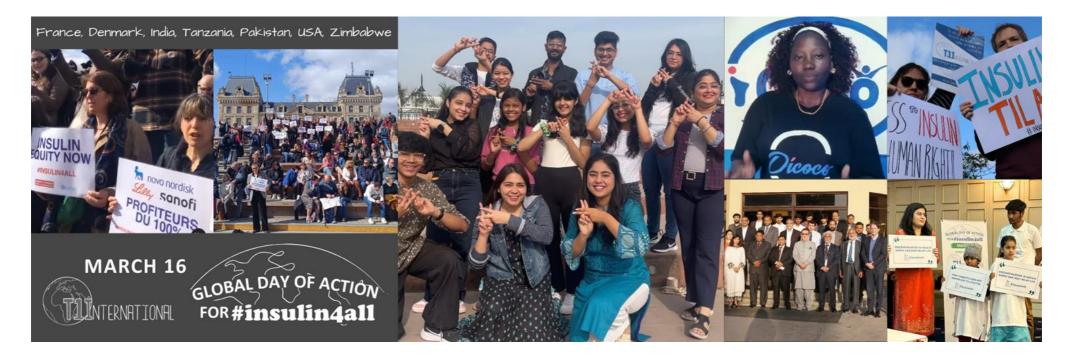


- Insulin is just the tip of the iceberg in the hierarchy of needs for people with diabetes.
- There are so many other essential pieces to diabetes management to ensure a healthy life with diabetes.
- Quality of life is a vital indicator that also must be taken into account.



## **Fight for Five:** the cost of insulin and glucose testing supplies represents less than 5% of a person's income in any given country

We're calling on all insulin manufacturers to: Make all of their insulins that are on the WHO's Essential Medicines List available for government contract for \$2 or less per vial or \$5 or less for a box of pens in low and middle income countries.





## **User Device Preference Survey**



Photo: Daniela Rojas, person with type 1 diabetes in Costa Rica

- 403 responses from 38 countries
- 88% used both pens and vials and syringes

82% preferred pens to vials and syringes, because of ease of pens in:

- Drawing up the correct dose
- Injecting insulin in public
- Transporting equipment





SULIN

The dials on insulin pens

make it easier for users to

especially for children and people with dexterity and

visual difficulties

measure out accurate doses -

### **BENEFITS OF** INSULIN PENS

#### ROBUST

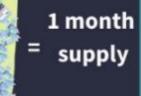
Unlike vials, insulin pens are made from material that is less likely to shatter making them easy and safer to transport and carry around for everyday use





Using pens can reduce the discomfort of insulin injections

## COMPACT 1 month =



supply

Insulin pens are compact and easy to carry, making them more convenient for people on the move and in humanitarian crises



The ease and accuracy of using insulin pens helps people stick to their treatment and avoid the dangerous complications of diabetes

## **User Device Preference Survey**



A HUMAN RIGHT Xinsulin4all KUPATA INSULIN NI HAKI YA BINADAMU

finsulinkwawote



Photo Credit: DiCoCo (Partner in Tanzania)

"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, on what they disliked about vials

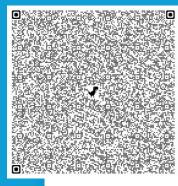
"Very easy and great to carry in purse. Not too much stigma when injecting at the table."

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



## Christa slides

## What Could Insulin Cost?



# Estimated sustainable cost-based prices for diabetes medicines

What should we be paying for diabetes medicines ? Melissa Barber, Dzintars Gotham, Helen Bygrave, Christa Cepuch

## What's in this paper?

What are production costs and estimated cost-based generic prices for diabetes medicines?

- Production costs: cost of manufacturing a unit
- Cost-based generic prices: manufacturing costs + profit margin

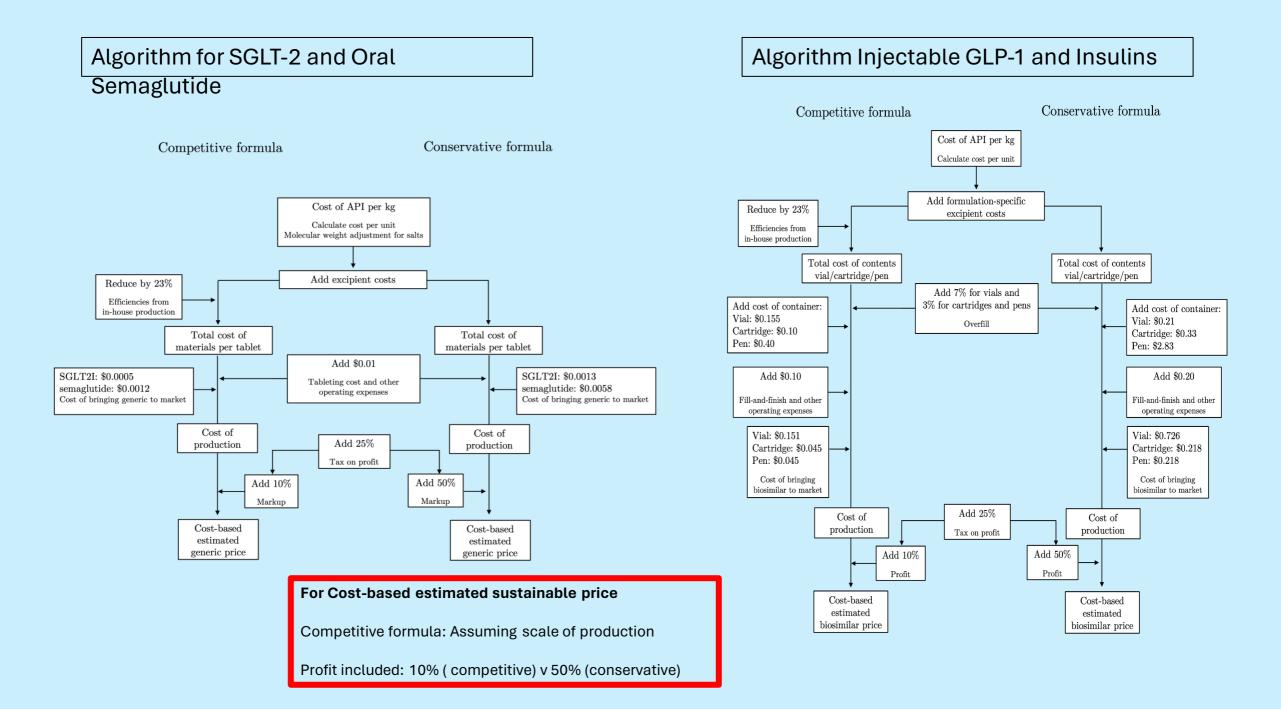
How do these costs compare to currently observed prices?

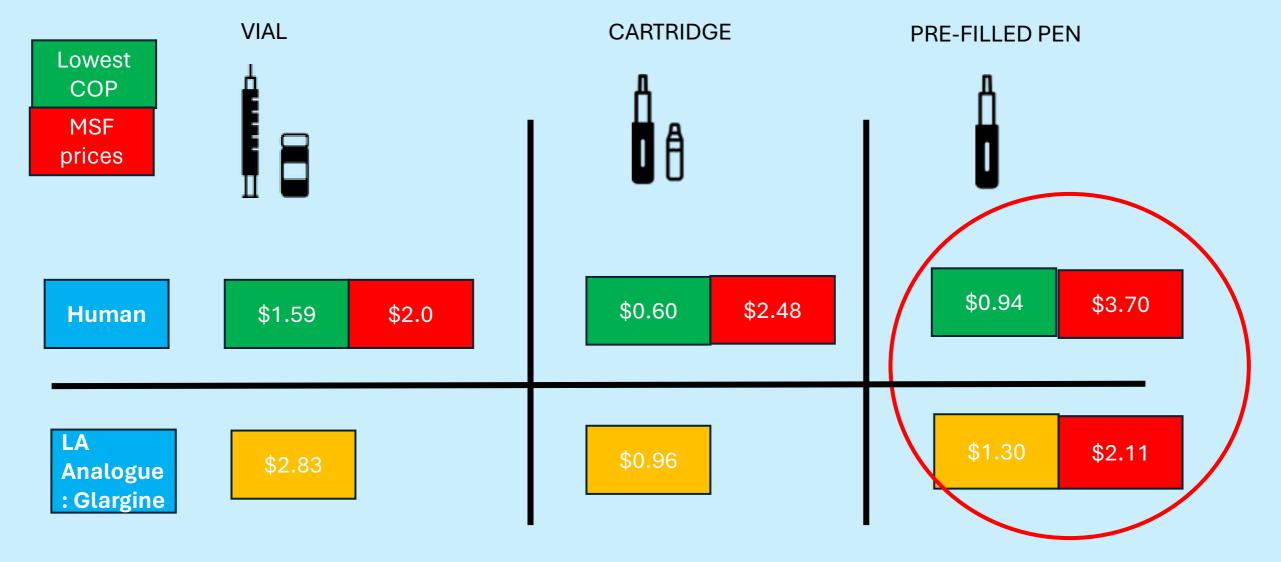
- Insulin (for T1 and T2 diabetes) and injection devices
  - all human and analogue insulins
  - all presentations: vials, cartridges, pre-filled pens using "cost per month"
  - calculation of "annual cost" of delivering a regimen (T1 and T2) including the injection device
- Glucagon-like peptide 1 agonists (GLP1RAs)
- Sodium glucose co-transporter 2 inhibitors (SGLT2s)

## Methods

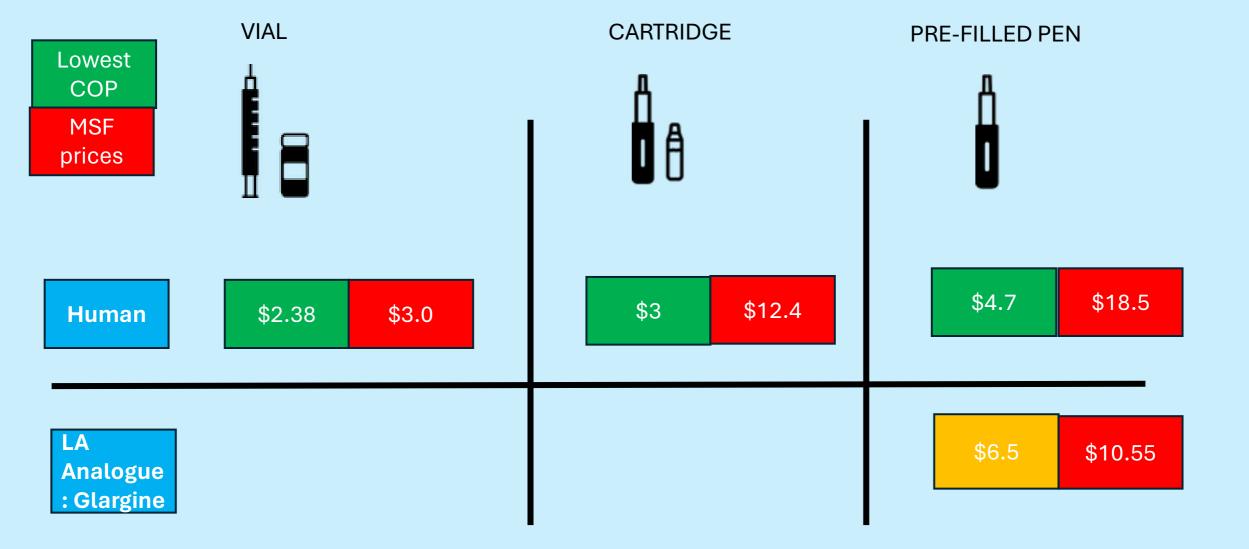
### **Market Prices**

- Four high-income countries (France, Latvia, UK, US)
- Eight middle-income (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



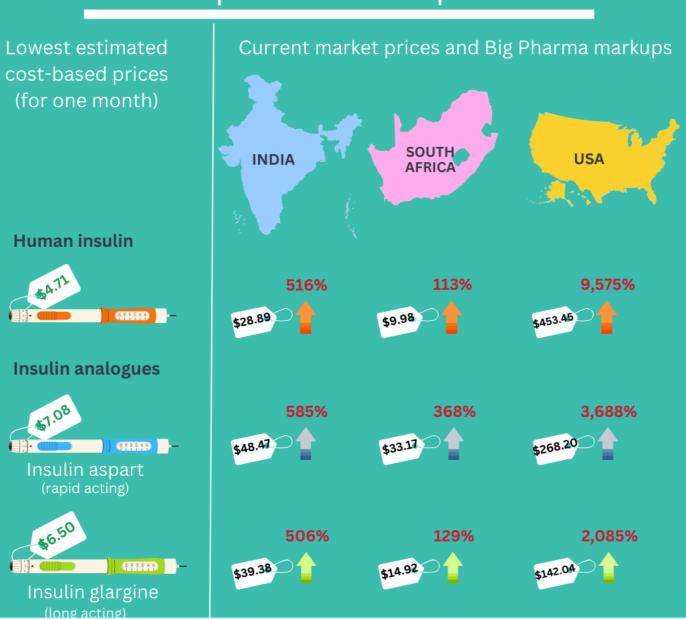


Lowest estimated sustainable cost based prices for each unit compared to MSF procurement



### Lowest estimated sustainable cost based prices for per month compared to MSF procurement

### Pre-filled insulin pens: prices and markups



Annual regimen costs including syringes, disposable pens , pen needles: T1DM

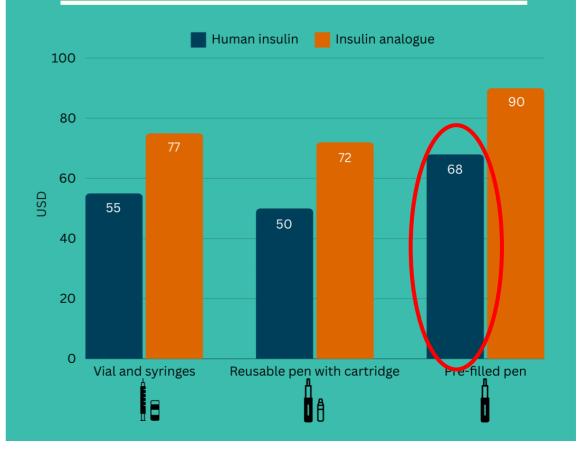
At the lowest cost based price, a basal bolus regimen with analogues in pens **could** cost less than human insulin in vials Lowest annual **cost-based prices** for an **ideal regimen** for a person with type 1 diabetes



Annual regimen costs including syringes, disposable pens , pen needles. T2DM

Less of argument for analogues

Shift to human insulin pens could cost just \$13 per patient per year more Lowest annual **cost-based prices** for an **ideal regimen** for a person with type 2 diabetes



### What are our asks in the briefer?

- WHO
- Governments
- Manufacturers
- Implementers

#### **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.

#### 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:**

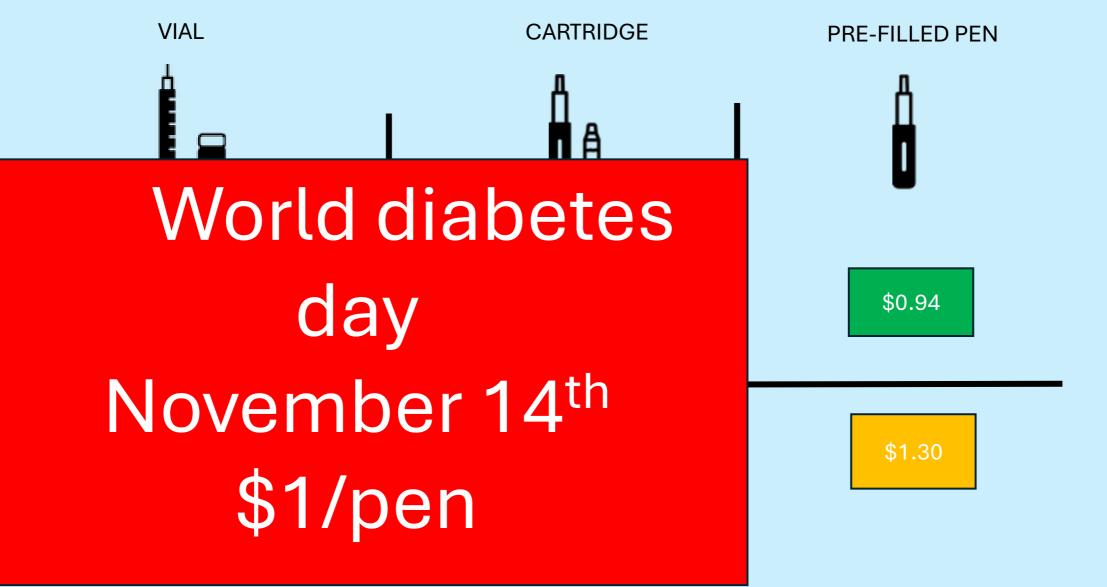
- Include human and analogue insulin cartridges and prefilled pens for all negotiations, including those with LMICs;
- Reduce prices of insulins, SGLT-2s and GLP-1s in all contexts to reflect their cost of production; and
- Allow licensing and technology transfers for SGLT-2s and GLP-1s to expedite expanded,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

## Access Campaign plans in next 6 months

- Bilateral letters and negotiations with big three requesting pricing strategies reflecting cost of production – for insulins ( human and analogue) in all presentations
- Dependant on response- public letters and communications
- Briefings and engagement with diabetes and access to medicines civil society including lawyers
- Planning Submission to EML for short acting analogues
- Deep dive dashboard in selected countries on registration, pricing and inclusion of diabetes medicines and monitoring tools in national health insurance schemes



## Q&A

- The use of insulin pens and analogues is the norm for people for insulin-dependent diabetes patients in high-income countries, but they remain largely unaffordable or unavailable for most people in LMICs.
- Patients want to be offered them because vials and syringes pose difficulty drawing up the correct dose, difficulty in injecting insulin in public or due to lack of a clean space to inject, difficulty transporting insulin and equipment.
- Patent barriers have expired for human insulin, glargine and aspart but lack of competition persists
- Countries and patients struggle to procure insulin pens as a choice for people living with diabetes (availability and affordability)- double standard

Can we monitor the situation of insulin pen availability in our countries in the health system?

What are your country's prices for human insulin pens and insulin analogue (rapid and longacting) in the different presentation (vials and pens)?

What types of insulin and devices are on the national EML?

## Next actions

- Action listserve
- Are region specific calls helpful?
- Support a report similar to Out of Step / UTW reports done for TB and HIV