ISSUE BRIEF

MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN A

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.[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 uncontr
levels.[1] People with diabe
particularly vulnerable in c
humanitarian settings, give
interrupted treatment and f
impeded food supplies, and
health services due to securit
or population movement.

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

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 m

Defeating the Double Standard in Diabetes Care

Part 2: Access to GLP-1s and SGLT-2s for people living with diabetes

May 15th

Housekeeping

- Presentations first
  - Why do we need the new medicines for type 2 diabetes?
  - Who is making them and what could they cost?
  - Access barriers to SGLT-2 and GLP-1s
- Please write your questions in the chat
- During the discussion session you will be able to ask questions and unmute yourselves

537 million
adults are living with diabetes

3 in 4 adults with diabetes
live in low- and middle-income countries

6.7 million
deaths due to diabetes in 2021

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 - 1 in 10. This number is predicted to rise to **643 million** by 2030 and **783 million** by 2045.

Over 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..

Global, regional, and national burden of diabetes from 1990 to 2021, with projections of prevalence to 2050: a systematic analysis for the Global Burden of Disease Study 2021

1·31 billion people could be living with diabetes by 2050

Published:June 22, 2023DOI:https://doi.org/10.1016/S0140-6736(23)01301-6

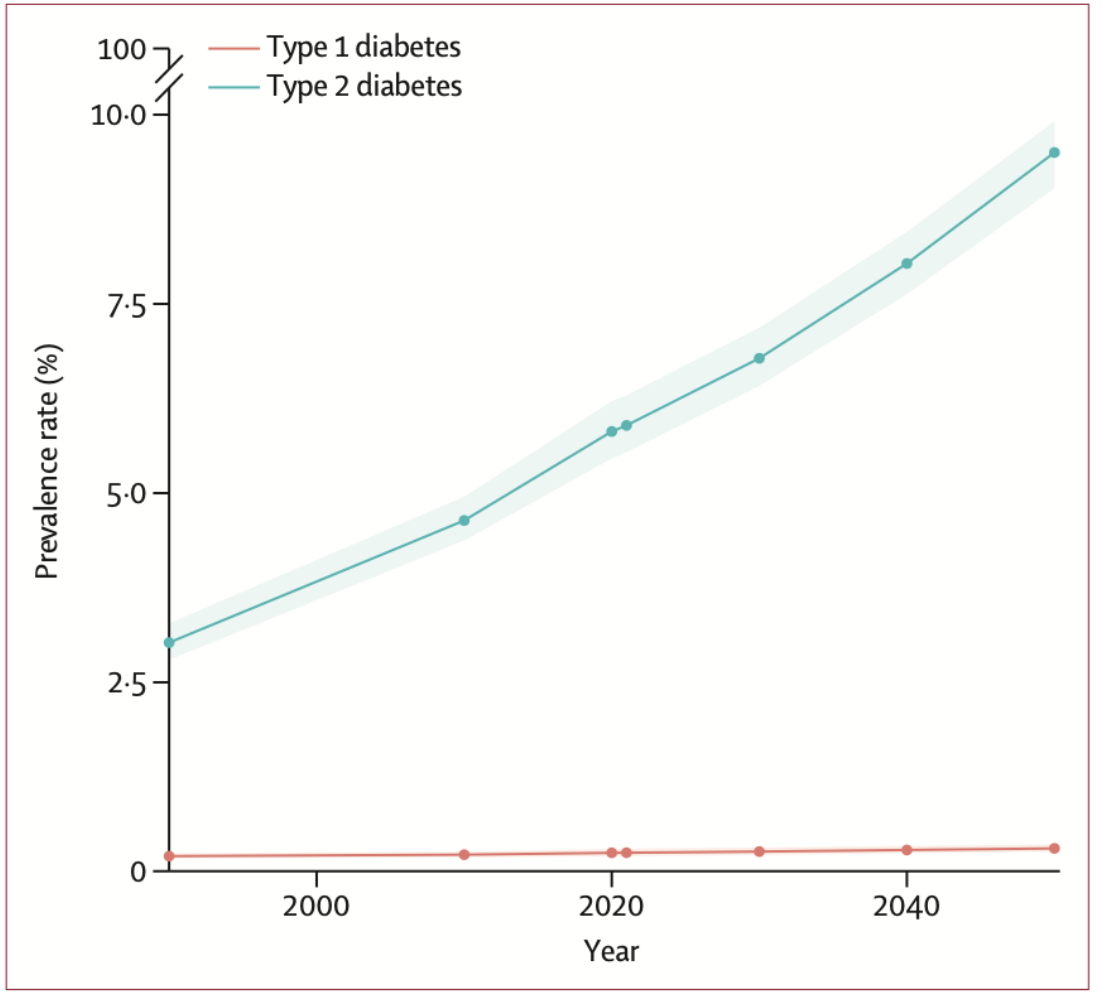
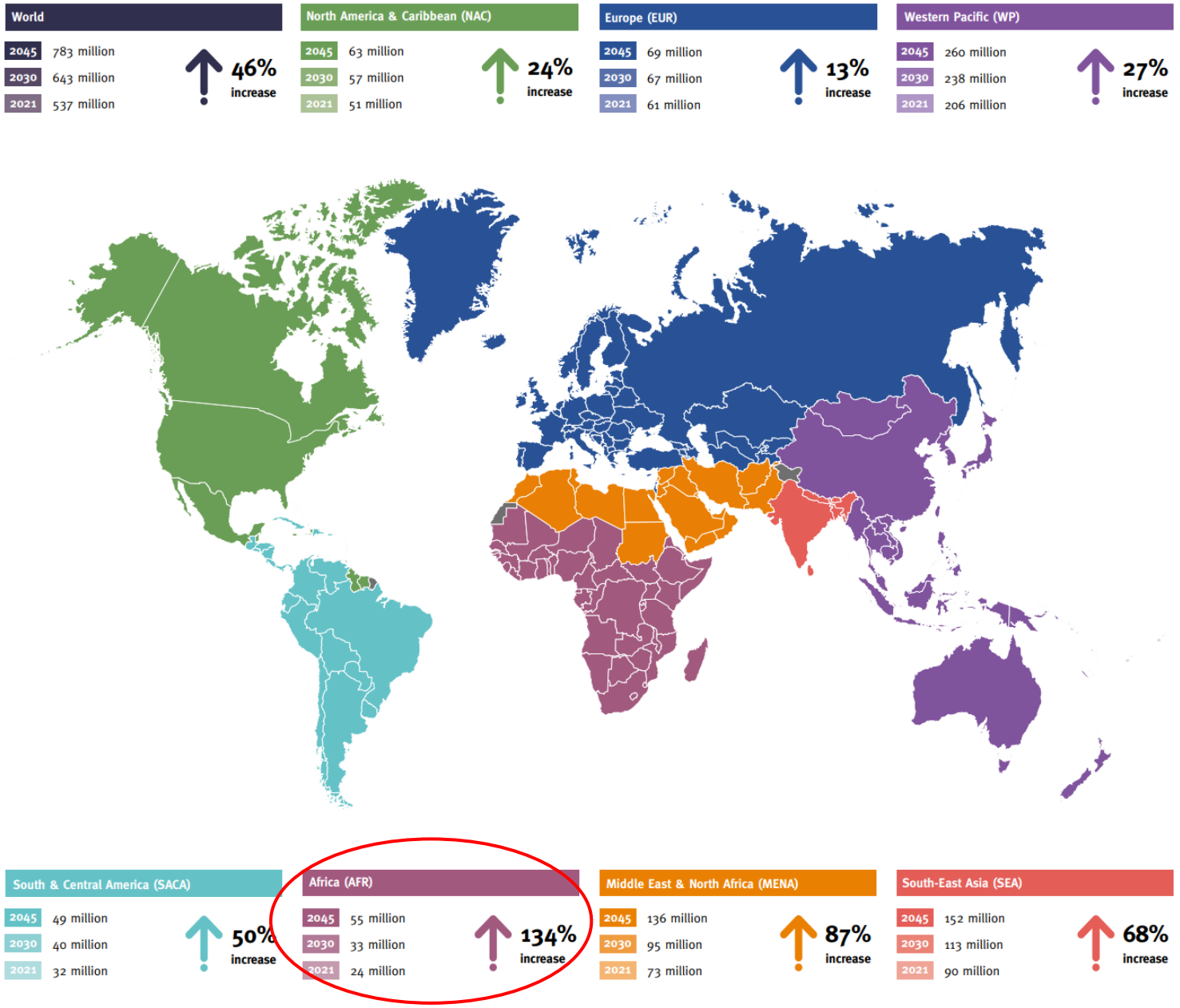


Figure 4: **Global age-standardised prevalence of type 1 and type 2 diabetes from 1990 through 2050 forecasts**

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

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



‘We need to act on the scale we did for HIV’: South Africa struggles to avert a diabetes ‘car crash’

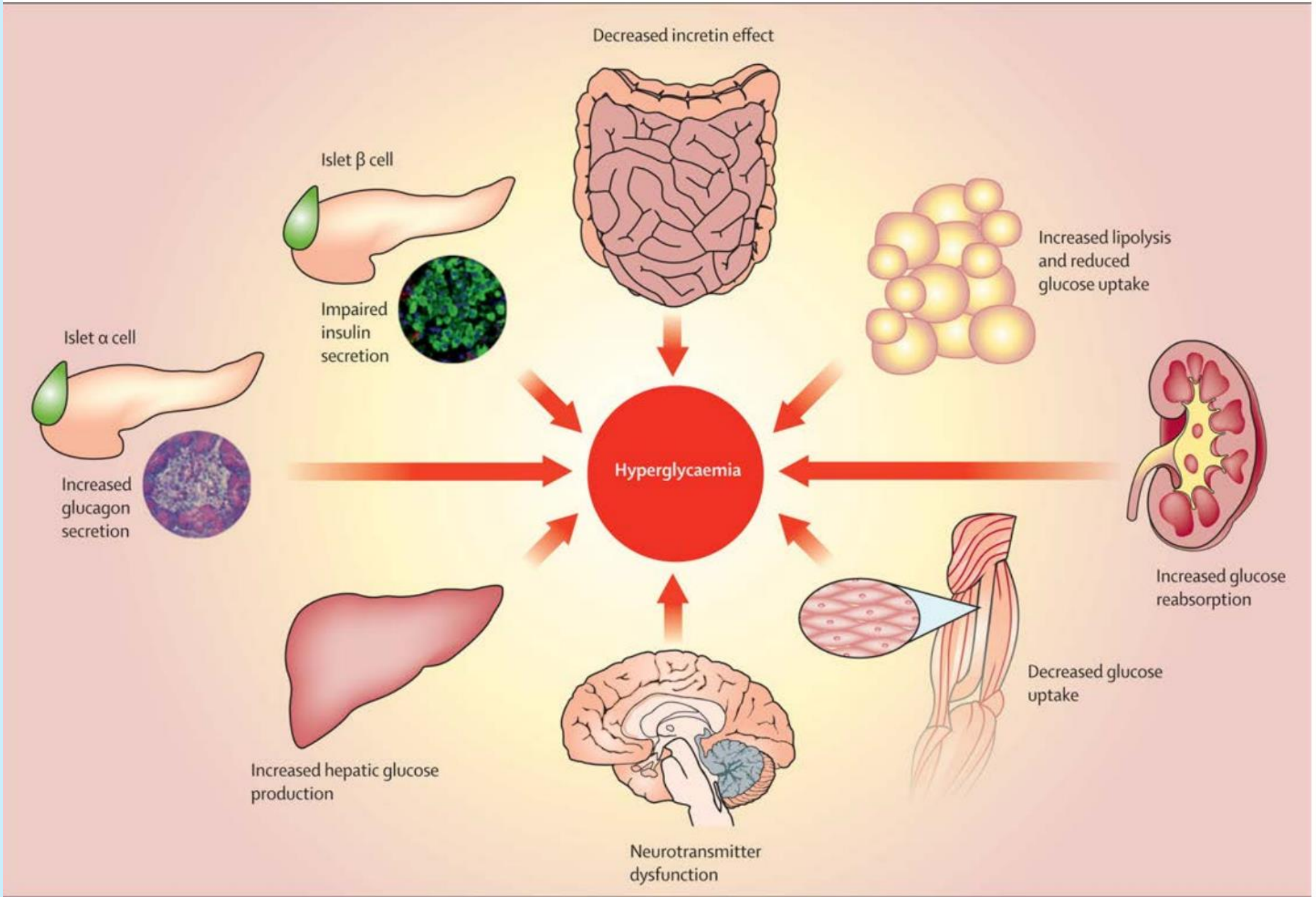
Members of the Ikaya diabetics support group wait to have their blood pressure and blood sugar levels tested at a restaurant in Kayamandi township

- Diabetes is the country’s leading underlying cause of death in women and second in the general population.
- Worryingly, nearly half of diabetics don’t know they have it.
- 4.2 million South Africans living with diabetes
- The prevalence has more than doubled between 2011 and 2021 by 2045, more than 7.4 million South Africans could be diabetic.

Introduction to Type 2 Diabetes

Thanks very much to Dr Sylvia Kehlenbrink

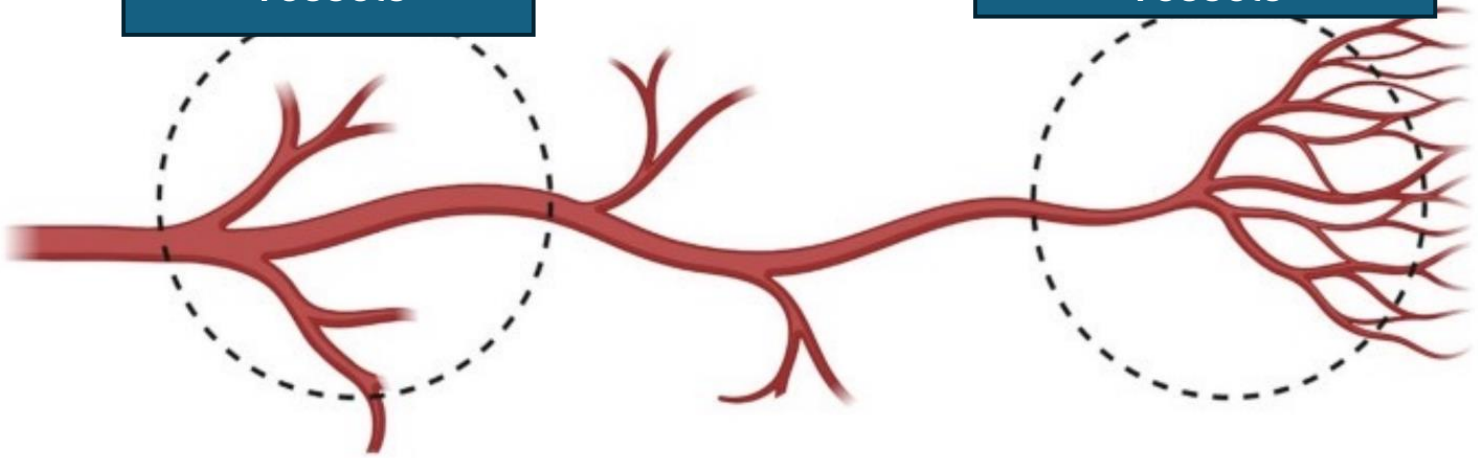
(Director, Global Endocrinology, Brigham and Women’s Hospital)


Decreased incretin effect
Islet β cell
Impaired insulin secretion
Islet α cell
Increased glucagon secretion
Increased lipolysis and reduced glucose uptake
Hyperglycaemia
Increased glucose reabsorption
Increased hepatic glucose production
Neurotransmitter dysfunction
Decreased glucose uptake

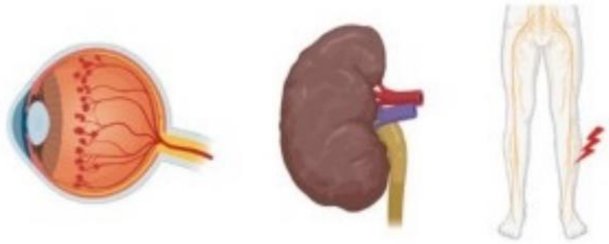
Persistent High Sugars Leads to Organ Damage Over Time

Large Blood Vessels

Smaller Blood Vessels



Heart Attacks; Stroke

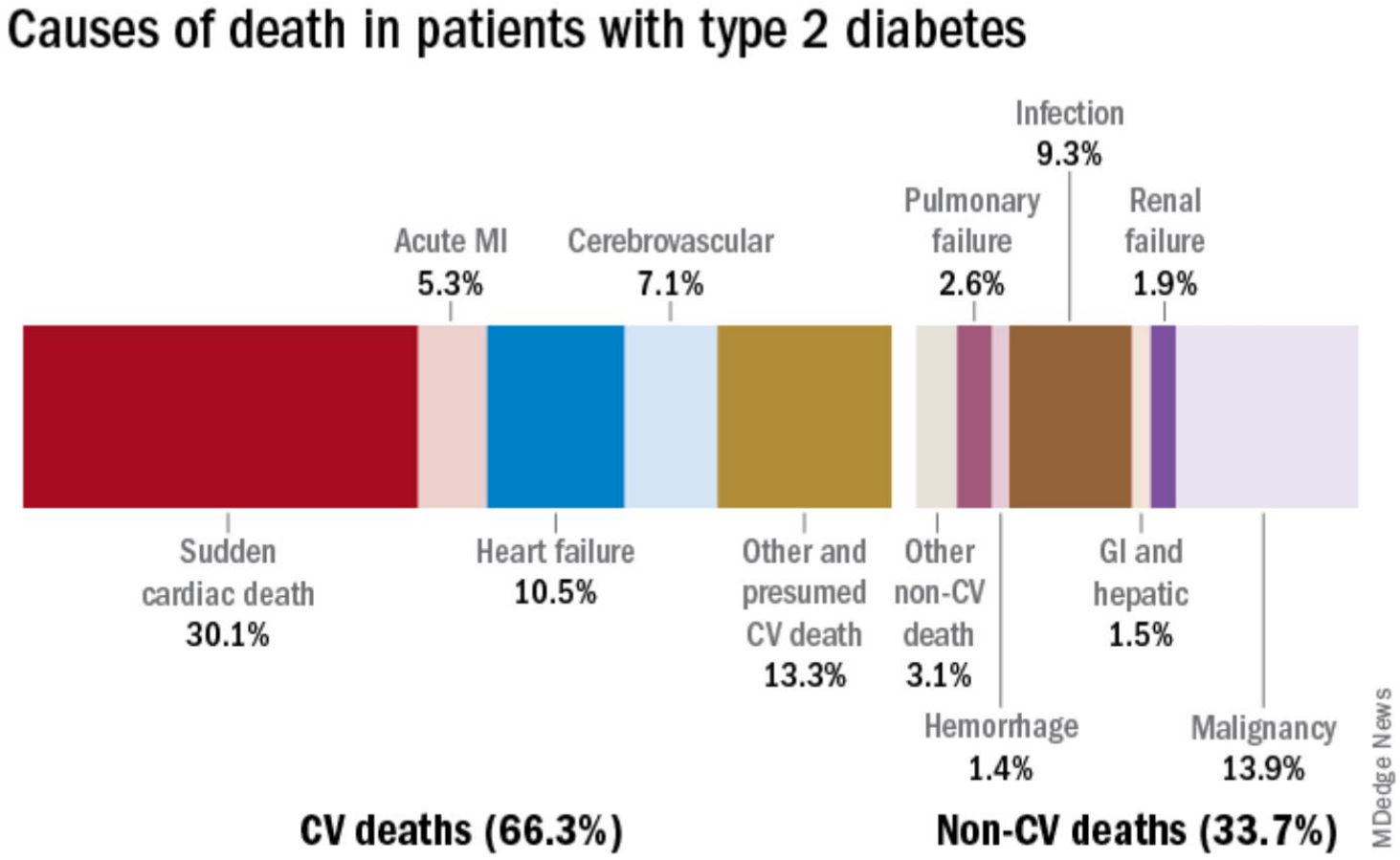


Blindness; Kidney failure; Nerve damage

➢ Death

➢ Misery

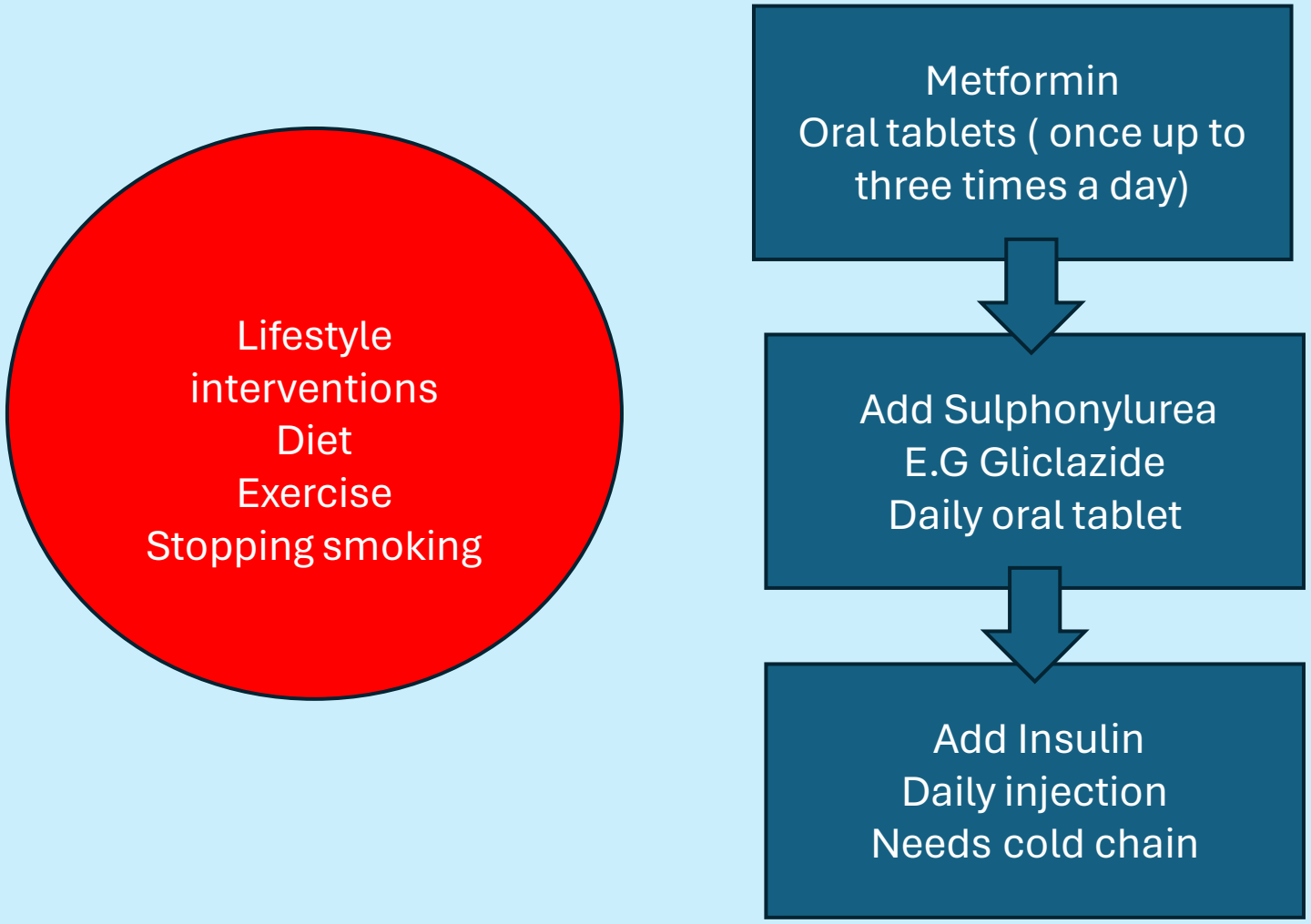
Type 2 Diabetes: Causes of Death



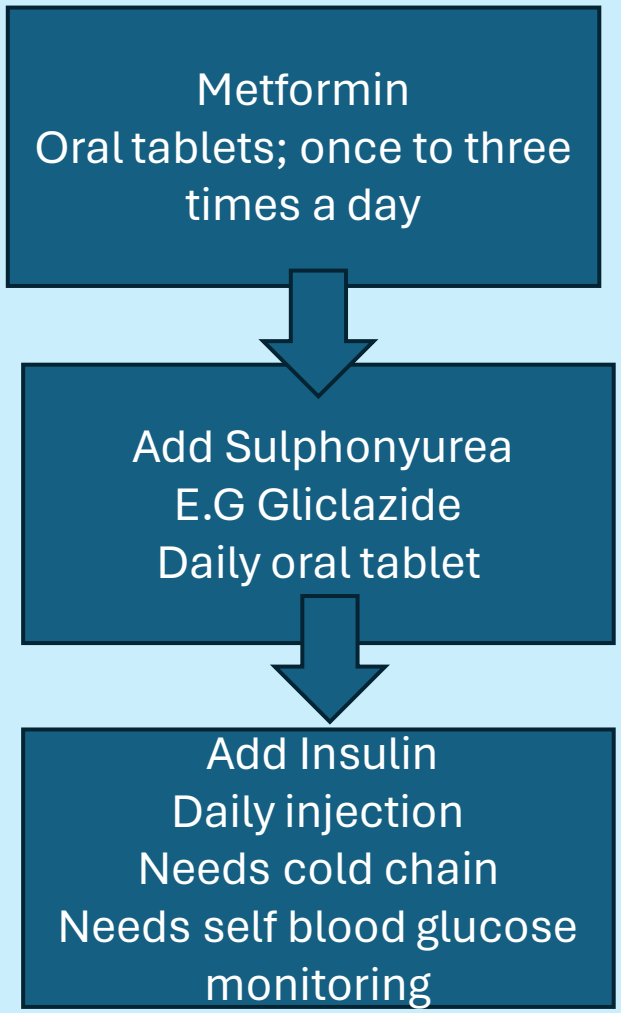
Note: There were 798 deaths in SAVOR-TIMI 53 after a median follow-up of 2.1 years.

Source: J Am Coll Cardiol. 2021 Apr 13;77[14]:1837-40

How are we currently managing type 2 diabetes ?



How are we currently managing diabetes ?

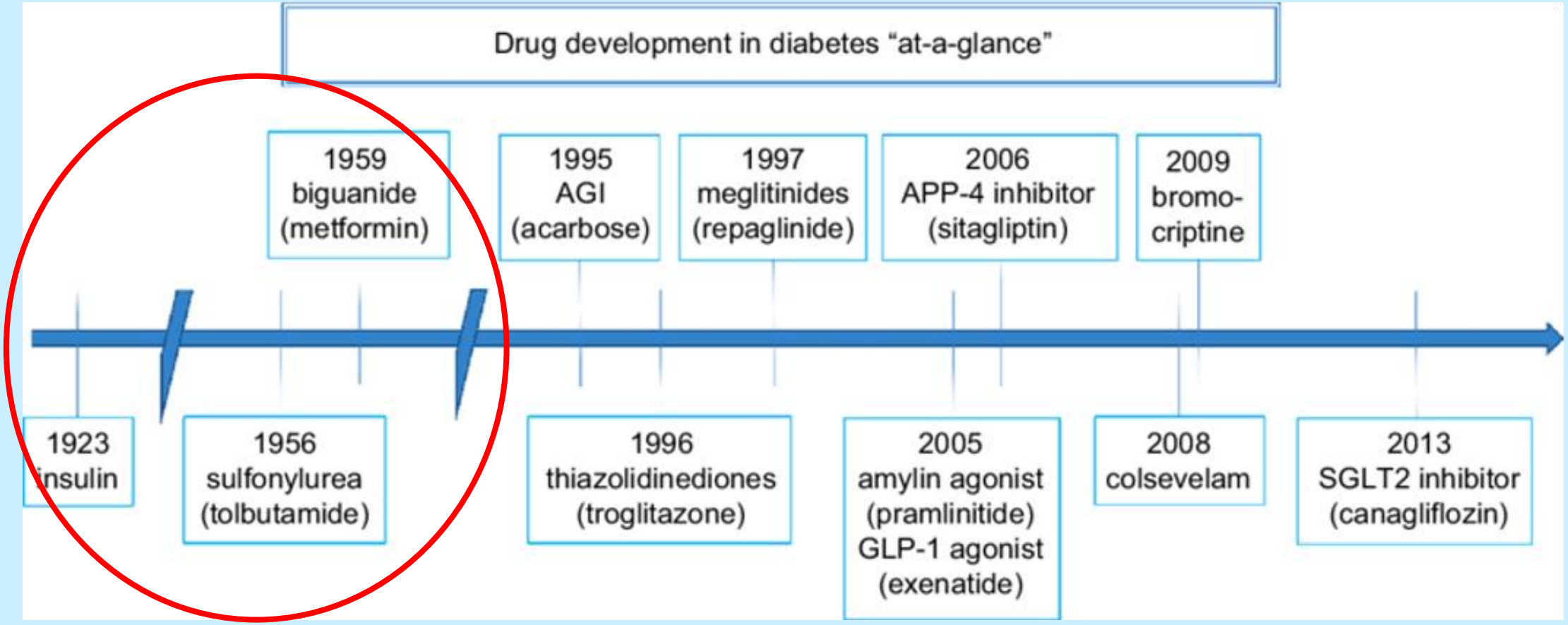


Diarrhea

Risk of low sugar
Weight gain

Risk of low sugar
Weight gain

High pill burden
No use of fixed dose combinations in guidelines or public sector to date
Need for simplified algorithms
(this has been considered in hypertension management)



- 2008: The US Food and Drug Administration (FDA) issues guidance
  - Recommended large cardiovascular outcome trials (CVOTs) for all new T2D therapies to demonstrate CV safety/ benefits
  - Based on concerns raised about the CV safety of T2D meds (e.g., rosiglitazone)

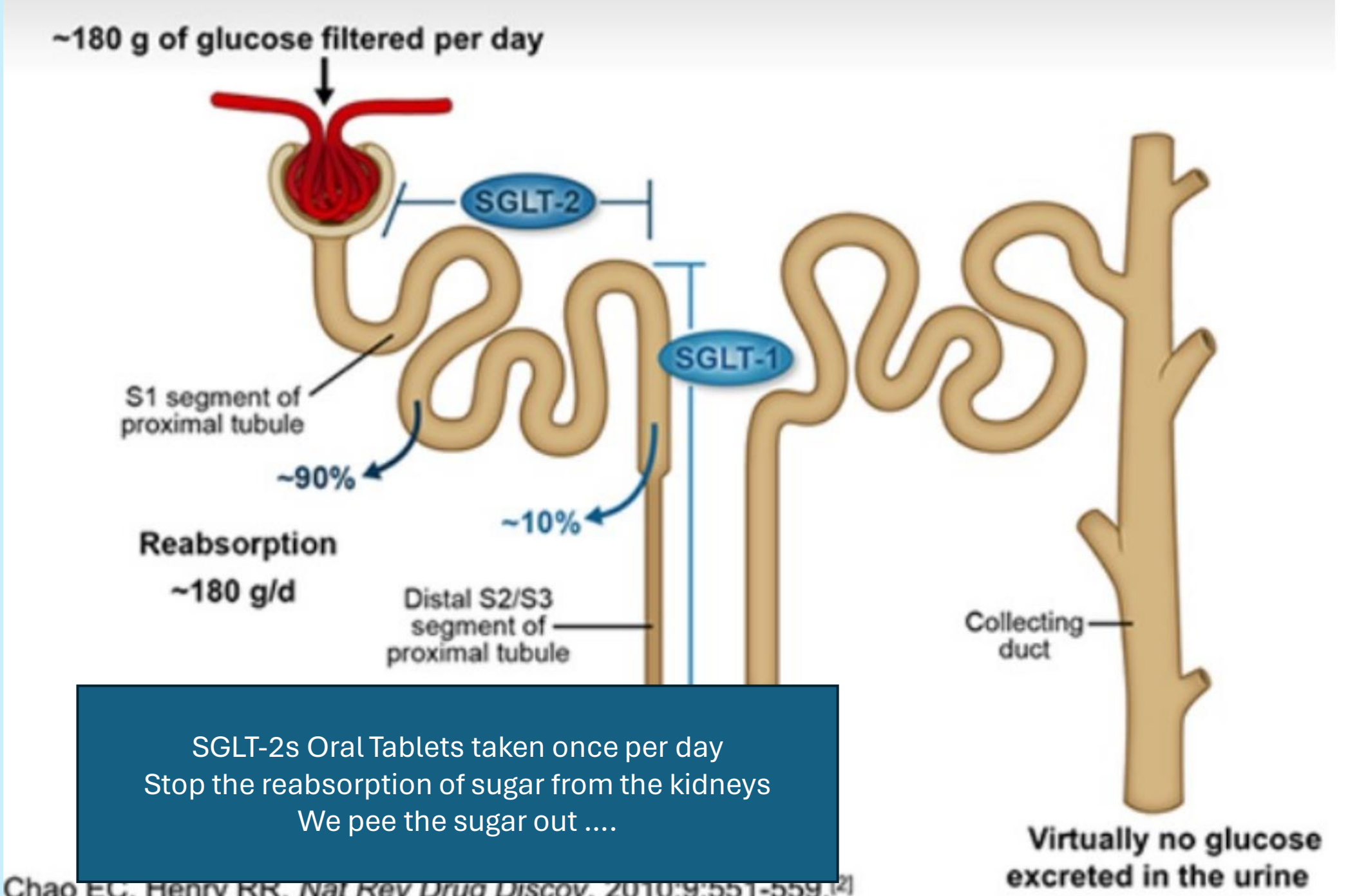
What are these new diabetes medicines for Type 2 diabetes

Sodium-glucose cotransporter-2 (SGLT-2) inhibitors

- Gliflozins
  - Empagliflozin
  - Dapagliflozin
  - Canagliflozin

Glucagon-like peptide-1 (GLP-1) receptor agonists

- For diabetes
  - Semaglutide = Ozempic (Novo – Nordisk)
  - Dulaglutide = Trulicity (Eli-Lilly)
  - Tirzapetide (GLP/GIP) =Mounjaro (Eli -Lilly
- For obesity (different doses)
  - Semaglutide= Wegovy (Novo Nordisk)
  - Tirzapetide (GLP-GIP)= Zepbound (Lilly)



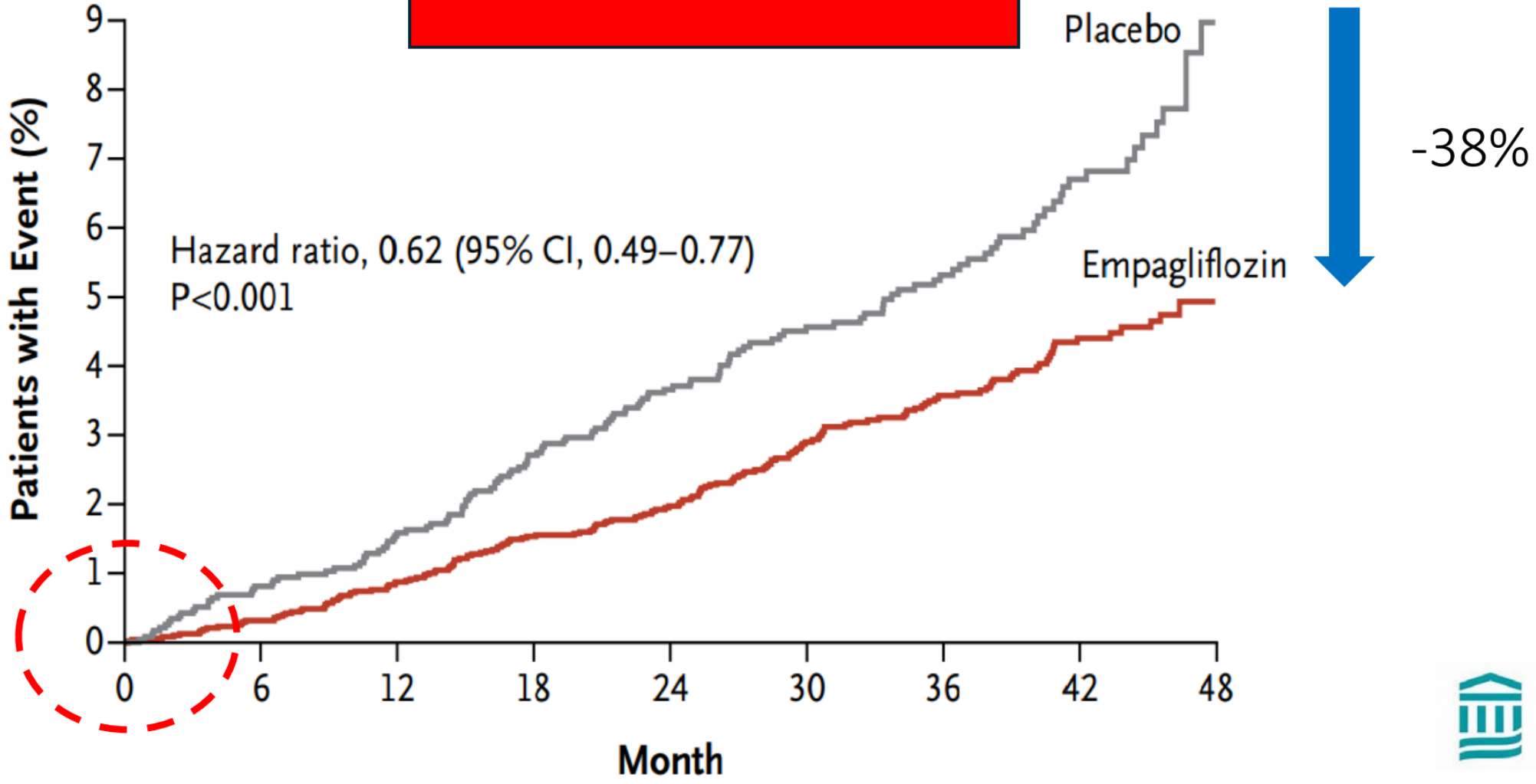
SGLT-2s Oral Tablets taken once per day
Stop the reabsorption of sugar from the kidneys
We pee the sugar out ....

Chao EC, Henry RR. *Nat Rev Drug Discov*. 2010;9:551-559.[2]

EMPA-REG

SGLT-2s reduce the risk of cardiac deaths

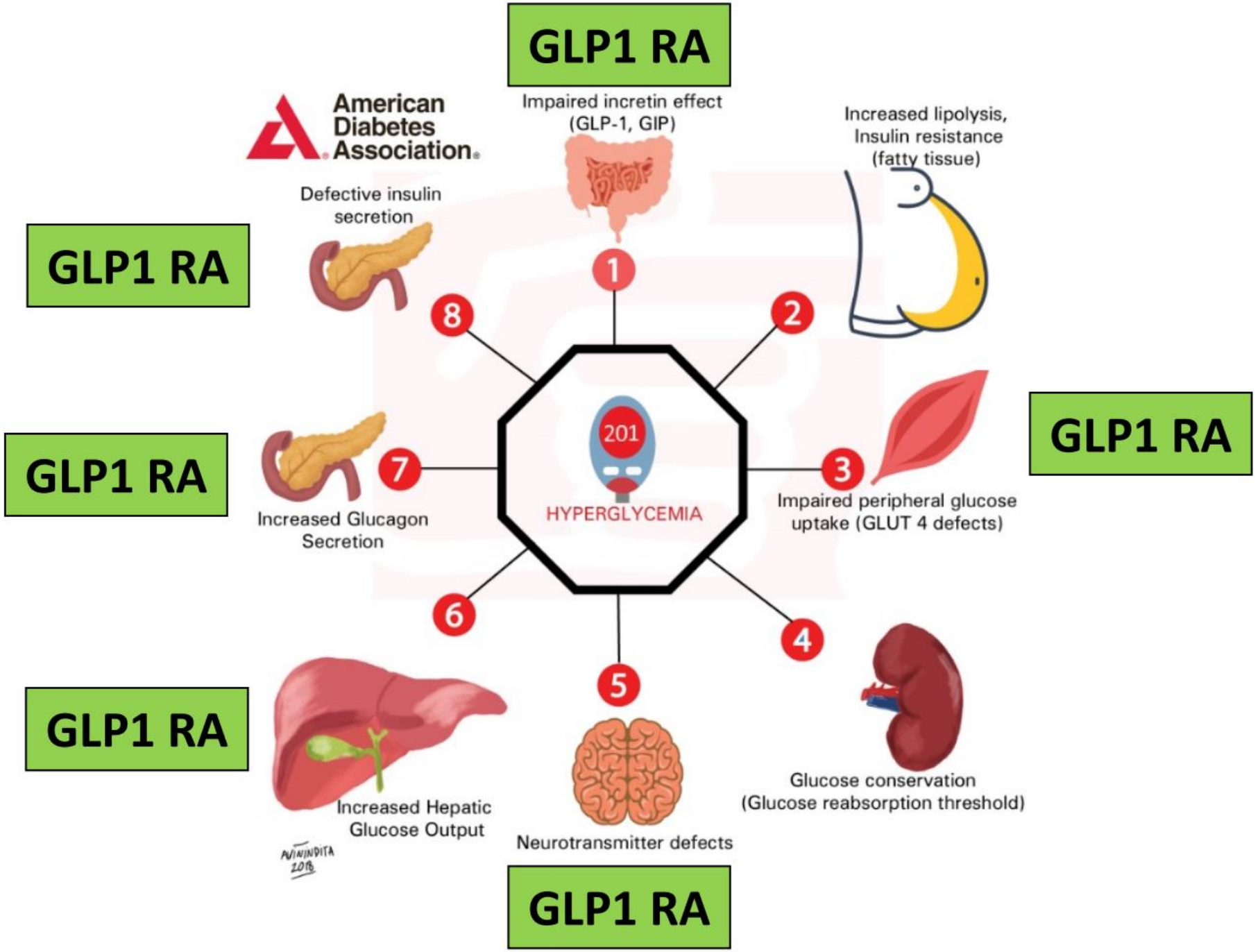
Death from CV causes



Zinman et al. N Engl J Med. 2015; 373:2117-2128

GLP-1s
Once weekly injections
Don’t need self- glucose monitoring
Does need cold chain prior to use
Better orals on the way

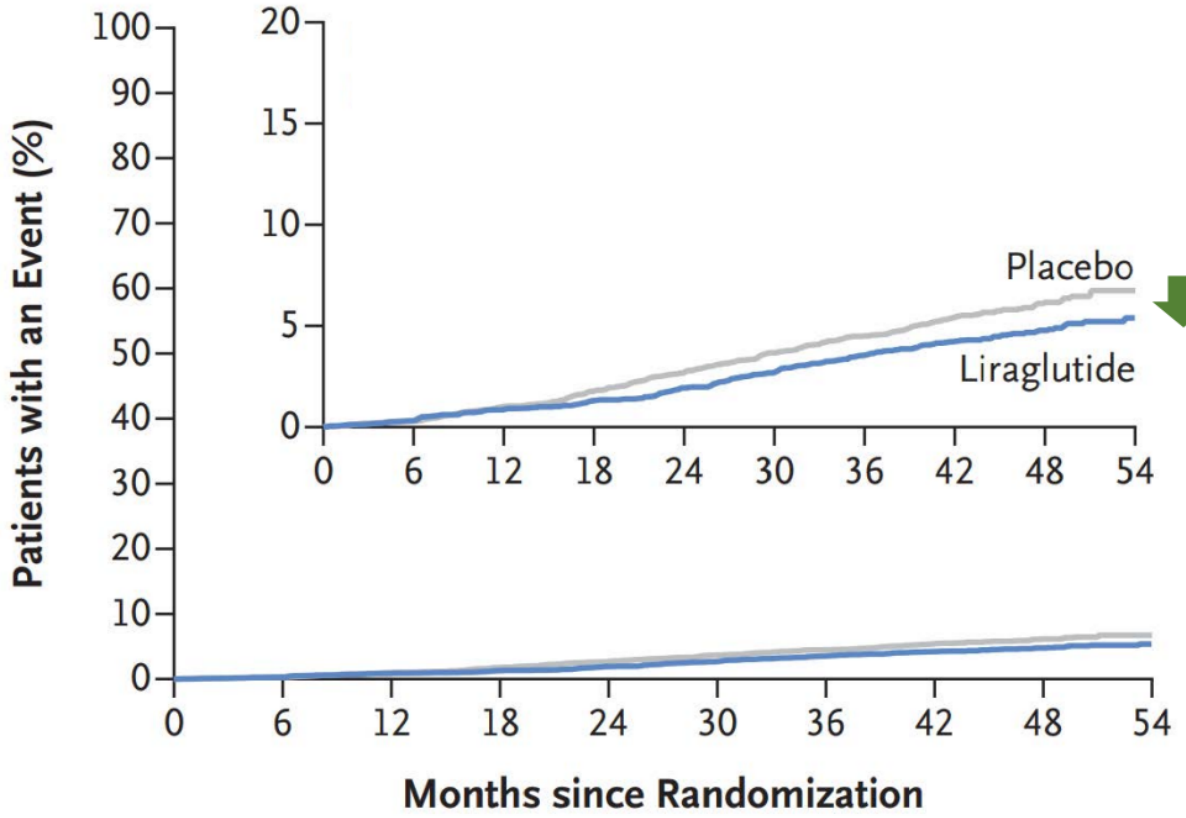
START	STEP	ESCALATE
0.25 mg once weekly for 4 weeks[a]	0.5 mg once weekly for at least 4 weeks[a]	1 mg once weekly if further glycemic control is needed
USE THE PEN THAT DELIVERS 0.25 MG OR 0.5 MG ONLY		USE THE PEN THAT DELIVERS 1 MG ONLY


GLP1 RA
American Diabetes Association.
Impaired incretin effect (GLP-1, GIP)
Increased lipolysis, Insulin resistance (fatty tissue)
Defective insulin secretion
GLP1 RA
GLP1 RA
GLP1 RA
1
2
3
4
5
6
7
8
201
HYPERGLYCEMIA
Impaired peripheral glucose uptake (GLUT 4 defects)
Increased Glucagon Secretion
Glucose conservation (Glucose reabsorption threshold)
Increased Hepatic Glucose Output
Neurotransmitter defects
GLP1 RA
GLP1 RA

LEADER Trial (liraglutide): CV death

GLP-1s reduce the risk of cardiac deaths

Death from CV causes



22%

HR 0.78 (95% CI, 0.66-0.93)
P=0.007

arso et al. *N Engl J Med* 2016; 375:311-322.

GLP1 RA – Weight loss

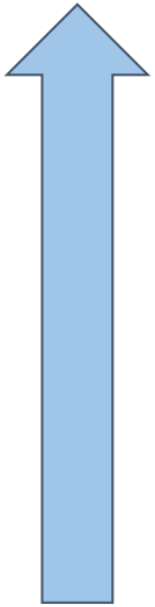
Semaglutide*

Liraglutide*

Dulaglutide

Exenatide

Lixisenatide



More effective for weight loss

* Approved for a specific indication for weight loss with or without T2D

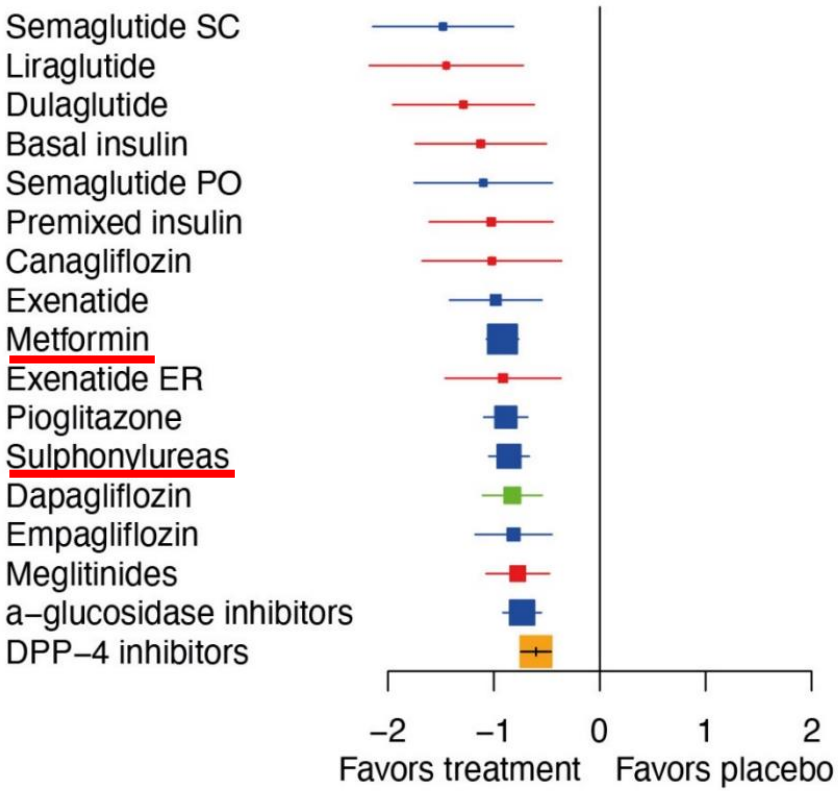
- **Semaglutide** at a dose of up to 2.4 mg SC weekly (Wegovy)
- **Liraglutide** at a dose of up to 3.0 mg SC daily (Saxenda)

In the pipeline (select)

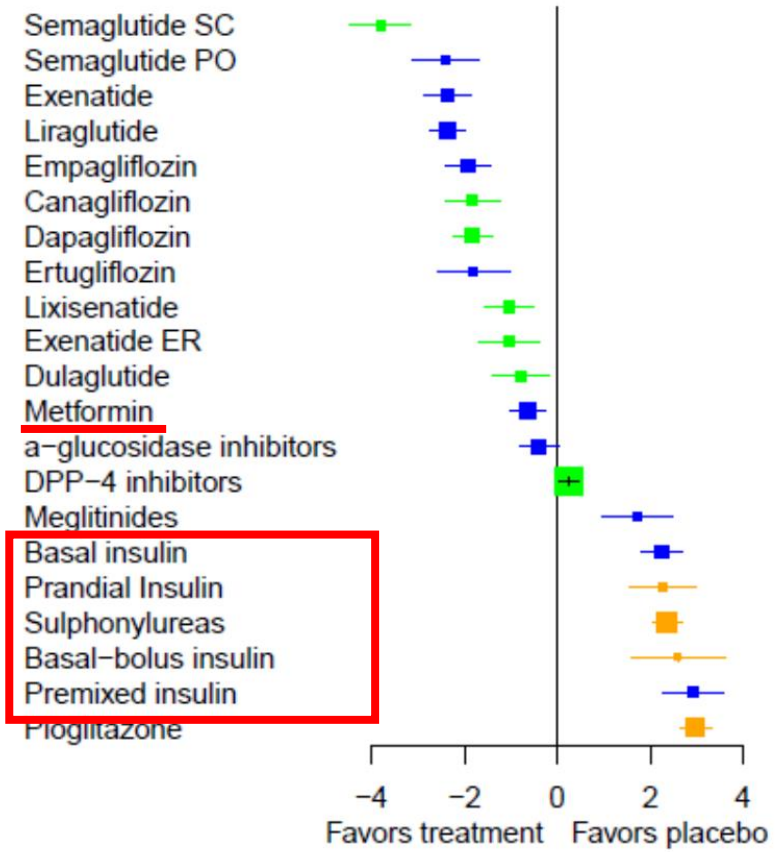
- **Small molecule oral GLP-1 RA:**
  - Orforglipron: in Phase III trials in both diabetes and obesity with readouts expected in 2025
  - Danuglipron**:** readouts expected in later 2024
  - Formulations of GLP-1/GIP co-agonists (like tirzepatide) in early stages
- **CagriSema**: combination of cagrilintide, a long-acting amylin analogue, and semaglutide
  - In phase III trials for type 2 diabetes and obesity
  - 2.2% reduction in A1c, 15.6% reduction in body weight in T2D
- **Triple receptor agonist (GLP-1/GIP/glucagon)**
  - Retratrutide:
    - T2DM: Change in A1c at 36 weeks: -2.02% A1c
    - 17% reduction in body weight vs. -2.02% with 1.5 mg dulaglutide
    - Obesity without DM: 24% reduction in body weight

Lancet 2023 402(10401):529-544.
N Engl J Med 2023; 389:514-526
Lancet 2023 402(10403):720-730
Lancet 2023 402(10400: 472-483

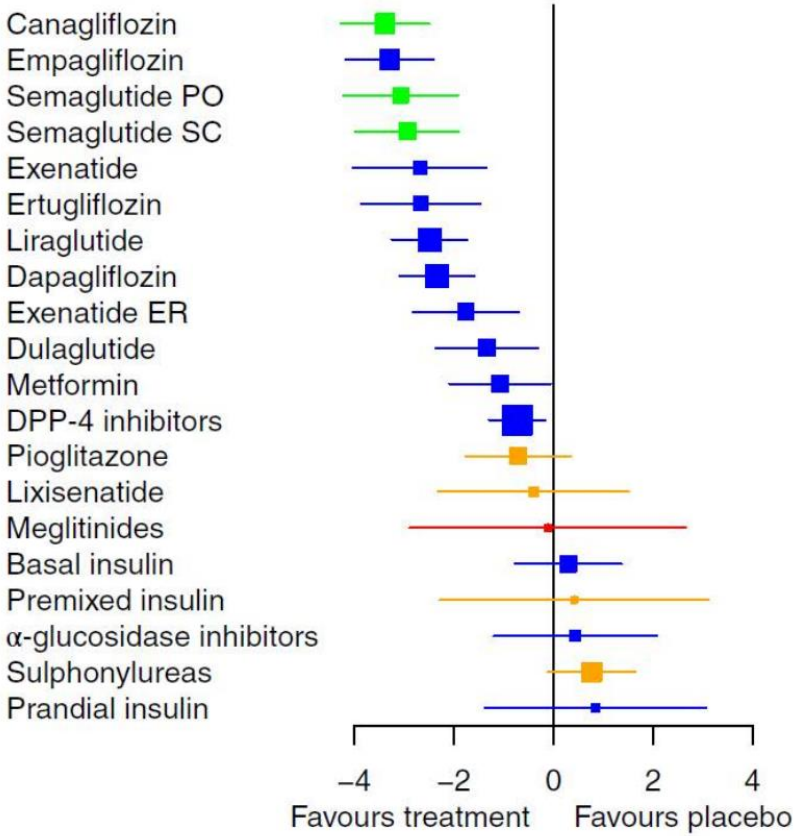
Change in HbA_{1C}



Change in body weight



Change in SBP



HbA_{1c}, glycated hemoglobin; SBP, systolic blood pressure
Tsapas A et al. Ann Intern Med 2020; 173: 278-286; Tsapas A et al. Diabetes Obes Metab 2021; 1-9.

	Glycemic efficacy	Hypoglycemia	Weight	Risk of MACE	Risk of HF	DKD progression
Metformin	↑↑	✖	→	? Potential benefit	→	→
SGLT-2i	↑↓	✖	↓	↓ (Canagliflozin) (Empagliflozin)	↓ (Canagliflozin) (Dapagliflozin) (Empagliflozin) (Ertugliflozin)	↓ (Canagliflozin) (Dapagliflozin) (Empagliflozin)
GLP-1 RAs	↑↑↓	✖	↓↓↓	↓ (Dulaglutide) (Liraglutide) (Semaglutide)	→	↓* (Dulaglutide) (Liraglutide) (Semaglutide)
SUs	↑↑	✓	↑	→	→	→
Insulin	↑↑↓	✓	↑	→	→	→

*Benefit for renal endpoints in CVOTs, driven by albuminuria outcomes
CVOT, cardiovascular outcomes trial; DDP-4i, dipeptidyl peptidase-4 inhibitor; DKD, diabetic kidney disease; GLP-1 RA, glucagon-like peptide-1 receptor agonist; GIP, glucose-dependent insulinotropic polypeptide; HF, heart failure; MACE, major adverse cardiovascular event; SGLT-2i, sodium–glucose cotransporter-2 inhibitor; SU, sulphonylurea; TZD, thiazolidinedione
Davies *et al. Diabetologia*. 2022;65:1925–1966

Summary

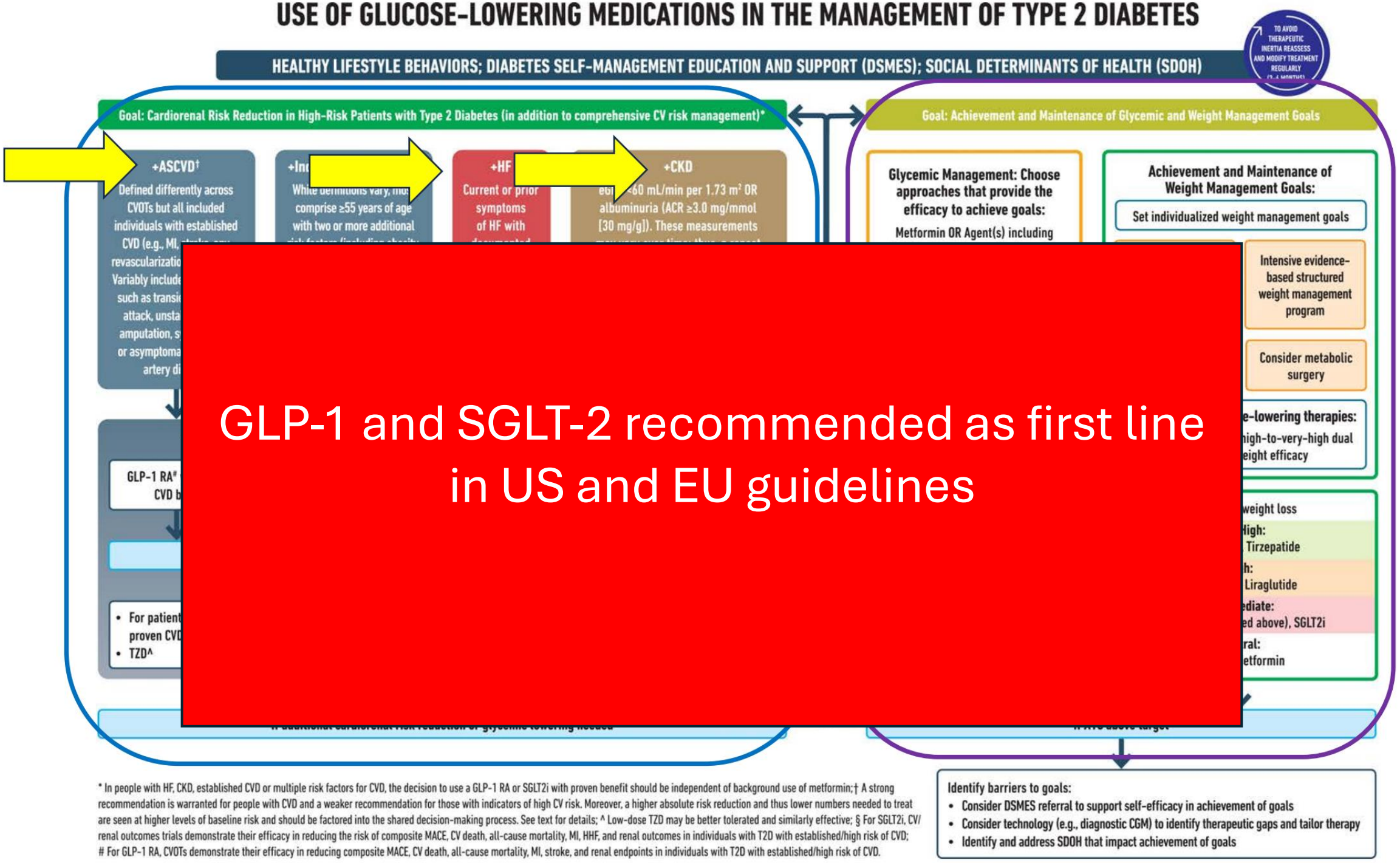
	SGLT-2	GLP-1
Formulation	Daily oral tablet	Weekly injectable
Cold chain needed	No	Yes
Needs SELF blood glucose monitoring	No	No
Generics available	Very soon	Definite Interest
On WHO EML	Yes	No
In WHO normative guidance	No	No

Shift from the traditional sugar-centric to a heart and kidney protection approach to T2D management

"I want to help to protect your organs from diabetes related problems"

"I want to help you to control your blood sugar and your weight"

Diabetes Care 2022; https://doi.org/10.2337/dci22-0034.
Diabetologia 2022; https://doi.org/10.1007/s00125-022-05787-


USE OF GLUCOSE-LOWERING MEDICATIONS IN THE MANAGEMENT OF TYPE 2 DIABETES
HEALTHY LIFESTYLE BEHAVIORS; DIABETES SELF-MANAGEMENT EDUCATION AND SUPPORT (DSMES); SOCIAL DETERMINANTS OF HEALTH (SDOH)
TO AVOID THERAPEUTIC INERTIA REASSESS AND MODIFY TREATMENT REGULARLY
Goal: Cardiorenal Risk Reduction in High-Risk Patients with Type 2 Diabetes (in addition to comprehensive CV risk management)*
+ASCVD†
Defined differently across CVOTs but all included individuals with established CVD (e.g., MI,
revascularizatio
Variably include
such as transi
attack, unsta
amputation, s
or asymptoma
artery di
+In
comprise ≥55 years of age with two or more additional
+HF
Current or prior symptoms of HF with
+CKD
albuminuria (ACR ≥3.0 mg/mmol [30 mg/g]). These measurements
GLP-1 RA#
CVD b
For patient
proven CVD
TZD^
Goal: Achievement and Maintenance of Glycemic and Weight Management Goals
Glycemic Management: Choose approaches that provide the efficacy to achieve goals:
Metformin OR Agent(s) including
Achievement and Maintenance of Weight Management Goals:
Set individualized weight management goals
Intensive evidence-based structured weight management program
Consider metabolic surgery
e-lowering therapies:
high-to-very-high dual
eight efficacy
weight loss
High:
Tirzepatide
h:
Liraglutide
diate:
ed above), SGLT2i
ral:
etformin
GLP-1 and SGLT-2 recommended as first line in US and EU guidelines
* In people with HF, CKD, established CVD or multiple risk factors for CVD, the decision to use a GLP-1 RA or SGLT2i with proven benefit should be independent of background use of metformin;† A strong recommendation is warranted for people with CVD and a weaker recommendation for those with indicators of high CV risk. Moreover, a higher absolute risk reduction and thus lower numbers needed to treat are seen at higher levels of baseline risk and should be factored into the shared decision-making process. See text for details; ^ Low-dose TZD may be better tolerated and similarly effective; § For SGLT2i, CV/renal outcomes trials demonstrate their efficacy in reducing the risk of composite MACE, CV death, all-cause mortality, MI, HHF, and renal outcomes in individuals with T2D with established/high risk of CVD; # For GLP-1 RA, CVOTs demonstrate their efficacy in reducing composite MACE, CV death, all-cause mortality, MI, stroke, and renal endpoints in individuals with T2D with established/high risk of CVD.
Identify barriers to goals:
Consider DSMES referral to support self-efficacy in achievement of goals
Consider technology (e.g., diagnostic CGM) to identify therapeutic gaps and tailor therapy
Identify and address SDOH that impact achievement of goals

GLP-1 agonists

1. Management of diabetes
Lower glucose
Reduce CVS risk
Support weight loss

2. Obesity

2022: 537 million people living with diabetes

2030 643 million

2020 2.6 billion people living with overweight and obesity

2035 4 billion

GLP-1 agonists

1. Management of diabetes
Lower glucose
Reduce CVS risk
Support weight loss

2. Obesity

2022: 537 million people living with diabetes

2030 643 million

Limited supply because no generics
How are these used using public health principles versus profit principles

PLUS responsibility for ongoing supply of insulin (and pens)

2020 2.6 billion people living with overweight and obesity

2035 4 billion

Have you been affected by a UK shortage of diabetes and weight loss drugs?

Amid a national shortage of liraglutide and semaglutide, we want to speak to people who rely on these medicines

There is a shortage of liraglutide and semaglutide, also licensed under the brand names Victoza and Ozempic respectively Photograph: Joel Saget/AFP/Getty Images

SGLT-2 and GLP-1s

- Who is making them
  - Blockbuster profits
  - Cost of production: what could their prices be?
  - MSF response and other global action (USA)

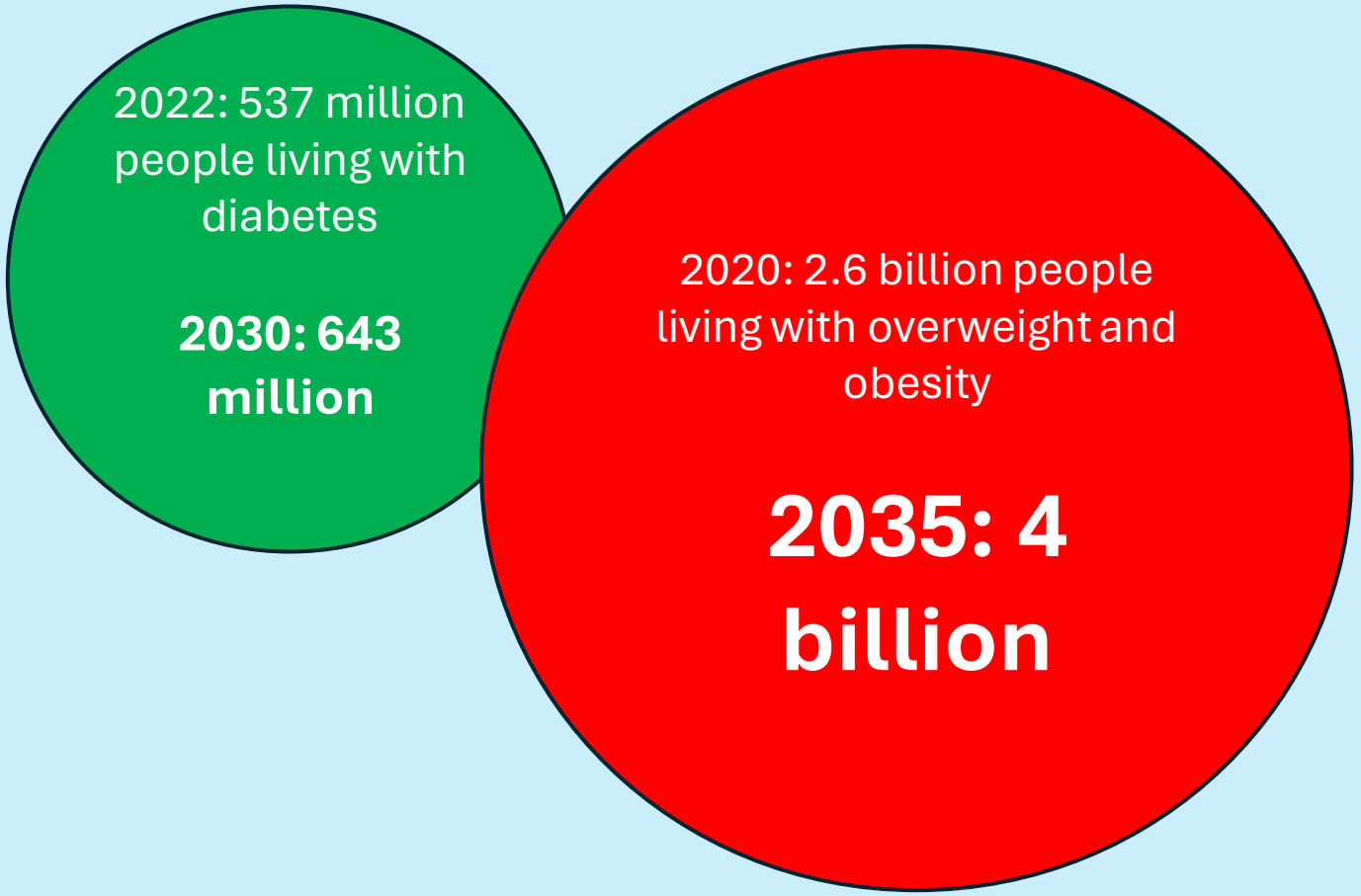
GLP-1 agonists for T2D and obesity

	Drug	Formulation	Diabetes	Obesity
Novo Nordisk	Semaglutide	Oral daily	Rybelsus	X
	Semaglutide	Injection weekly (cold chain)	Ozempic	Wegovy
	Liraglutide	Injection daily	Victoza	Saxenda
Eli Lilly	Dulaglatide	Injection weekly (cold chain)	Trulicity	X
	Tirzapitide (GIP/GLP-1)	weekly	Mounjaro	Zepbound
	Orforgliptin (Phase 3)	Oral		
	Retratrutide			

SGLT2s for T2D

Drug	Corporation
canagliflozin	A. Menarini Farmaceutica Internazionale SR
empagliflozin	Boehringer-Ingelheim & Eli-Lilly
dapagliflozin	AstraZeneca
ertugliflozin	MSD

who are the people in need

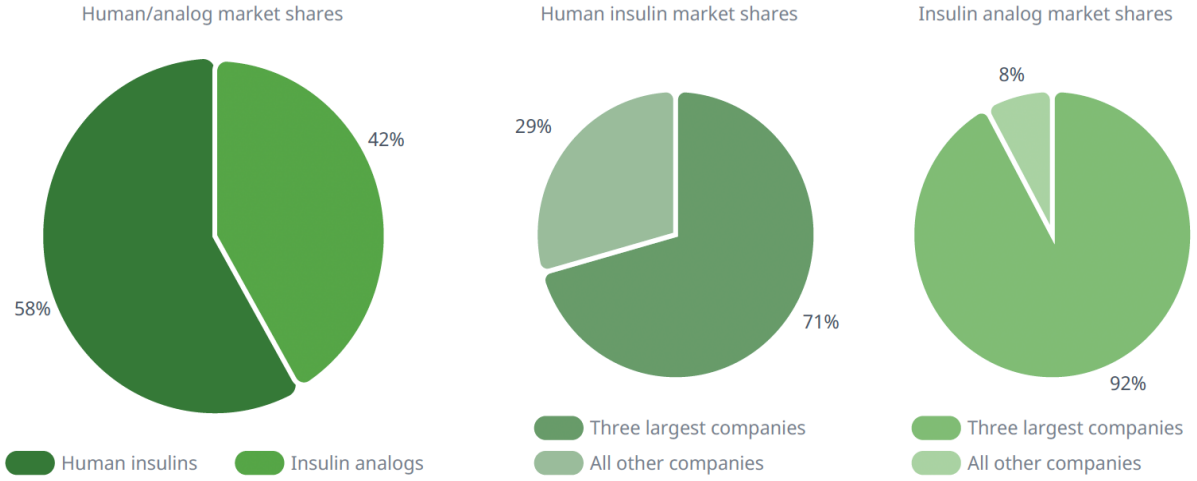


Insulin still dominated by three corporations



The three largest companies produce 71% of human insulins and 92% of insulin analogs

Exhibit 2: Insulin days of therapy (WHO-DDD) by type and by manufacturing company segment, 2019



Source: IQVIA MIDAS®, Sep 2020; IQVIA Institute, Dec 2020

In August, the government cited Novo when it lifted its economic growth forecast for this year, to 1.2% from 0.6%. The drugmaker last month overtook LVMH (LVMH.PA) as Europe's most valuable listed company, worth about 385 billion euros ($403 billion) - slightly more than Denmark's gross domestic product. Oct 5, 2023

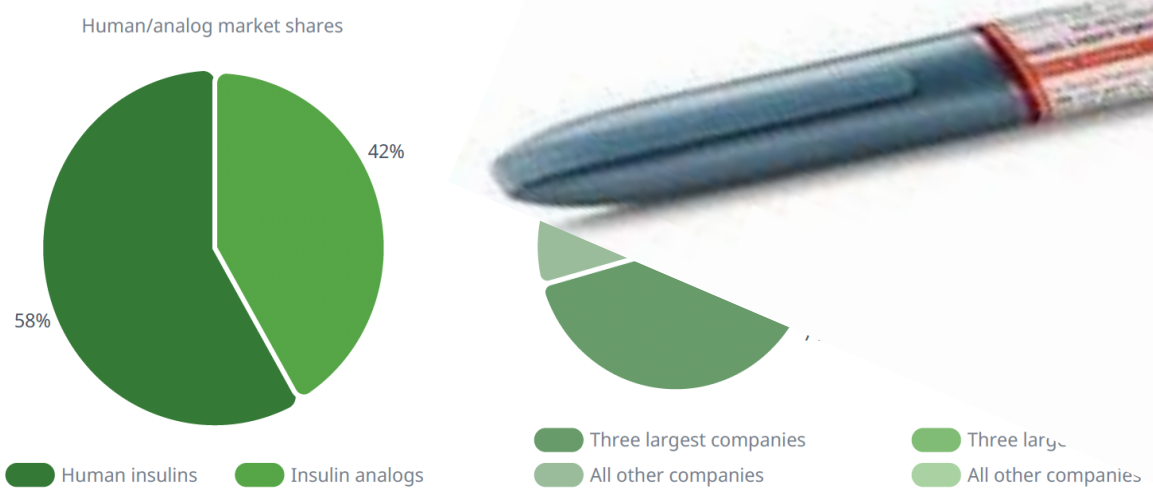
average profit margin / earning per share? **17% + 28% + 26%**

combined profit of Sanofi, NN and Eli Lilly for 2022 .... **10.3b + 28.5b + 21b**

Insulin still dominated by three corporatic

The three largest companies pro
and 92% of insulin analogs

Exhibit 2: Insulin days of therapy (WHO-DDD) by



Source: IQVIA MIDAS®, Sep 2020; IQVIA Institute, Dec 2020

In August, the government cited Novo when it lifted its economic growth forecast for this year, to 1.2% from 0.6%. The drugmaker last month overtook LVMH (LVMH.PA) as Europe's most valuable listed company, worth about 385 billion euros ($403 billion) - slightly more than Denmark's gross domestic product. Oct 5, 2023

average profit margin / earning per share? **17% + 28% + 26%**

combined profit of Sanofi, NN and Eli Lilly for 2022 .... **10.3b + 28.5b + 21b**

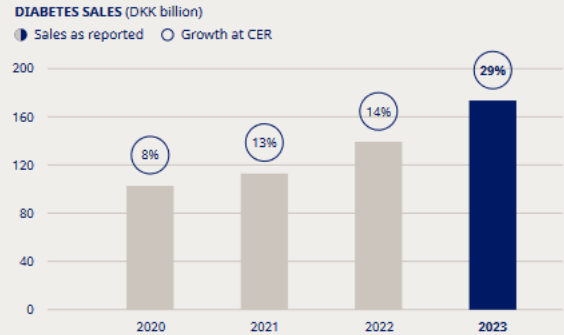
GLP1s dominated by two of the same

PERFORMANCE HIGHLIGHTS

Financial highlights

DKK million	2019	2020	2021			
Financial performance						
Net sales	122,021	126,946	140,800	17		
Sales growth as reported	9.1%	4.0%	10.9%			
Sales growth in constant exchange rates[1]	5.6%	6.7%	13.8%			
Operating profit	52,483	54,126	58,644	74,809	102,574	37%
Operating profit growth as reported	11.1%	3.1%	8.3%	27.6%	37.1%	
Operating profit growth in constant exchange rates[1]	5.6%	6.8%	12.7%	14.6%	43.7%	
Depreciation, amortisation and impairment losses	5,661	5,753	6,025	7,362	9,413	28%
EBITDA[1,2,3]	58,144	59,879	64,669	82,171	111,987	36%
Net financials	(3,930)	(996)	436	(5,747)	2,100	
Profit before income taxes	48,553	53,130	59,080	69,062	104,674	52%
Effective tax rate[3]	19.8%	20.7%	19.2%	19.6%	20.1%	
Net profit	38,951	42,138	47,757	55,525	83,683	51%
Purchase of property, plant and equipment[3]	8,932	5,825	6,335	12,146	25,806	112%
Purchase of intangible assets[3]	2,299	16,256	1,050	2,607	13,090	402%
Cash used for acquisition of businesses	—	—	18,283	7,075	—	
Free cash flow[1]	34,451	28,565	29,319	57,362	68,326	19%
Total assets	125,612	144,922	194,508	241,257	314,486	30%
Equity	57,593	63,325	70,746	83,486	106,561	28%

	2020	2021	2022	2023	2022-23 Change
	83.5%	83.2%	83.9%	84.6%	
	25.9%	26.3%	26.1%	24.4%	
	12.2%	12.6%	13.6%	14.0%	
Operating margin[3]	43.0%	42.6%	41.7%	42.3%	44.2%
Net profit margin[3]	31.9%	33.2%	33.9%	31.4%	36.0%
Cash to earnings[1]	88.4%	67.8%	61.4%	103.3%	81.6%
Return on invested capital[1]	98.0%	82.8%	69.0%	73.6%	88.5%
Share performance and capital allocation					
Basic earnings per share/ADR in DKK[3,5]	8.21	9.03	10.40	12.26	18.67	52%
Diluted earnings per share/ADR in DKK[3,5]	8.19	9.01	10.37	12.22	18.62	52%
Total number of shares (million), end of year[3,5]	4,800	4,700	4,620	4,560	4,510	(1%)
Dividend per share in DKK[3,4,5]	4.18	4.55	5.20	6.20	9.40	52%
Total dividend (DKK million)[4]	19,651	21,066	23,711	27,950	41,987	50%
Dividend payout ratio[3,5]	50.5%	50.0%	49.6%	50.3%	50.2%	
Share repurchases (DKK million)	15,334	16,855	19,447	24,086	29,924	24%
Closing share price (DKK)[3,5]	194	214	368	469	698	49%



In August, the government cited Novo when it lifted its economic growth forecast for this year, to 1.2% from 0.6%. The drugmaker last month overtook LVMH (LVMH.PA) as Europe's most valuable listed company, worth about 385 billion euros ($403 billion) - slightly more than Denmark's gross domestic product. Oct 5, 2023

average profit margin / earning per share? …. **28% + 26%**

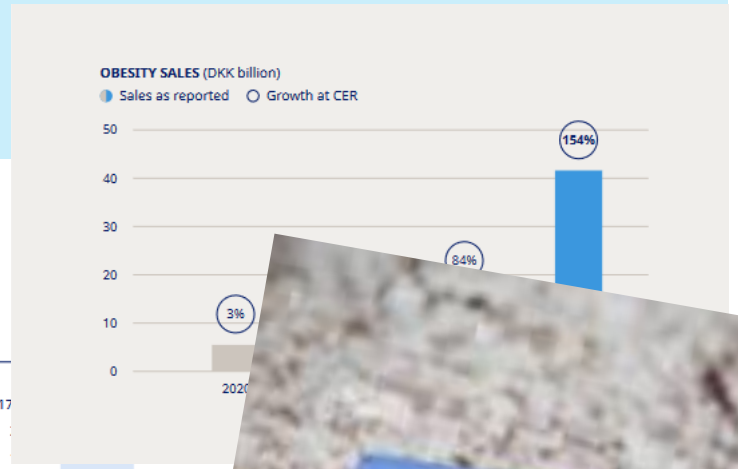
combined profit of NN and Eli Lilly for 2022 …. **28.5b + 21b**

GLP1s dominated by two of the same

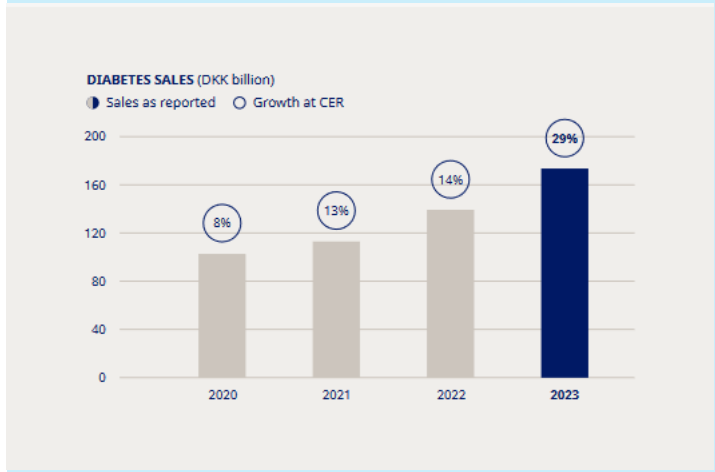
PERFORMANCE HIGHLIGHTS

Financial highlights

DKK million	2019	2020	2021			
Financial performance						
Net sales	122,021	126,946	140,800	17		
Sales growth as reported	9.1%	4.0%	10.9%			
Sales growth in constant exchange rates[1]	5.6%	6.7%	13.8%			
Operating profit	52,483	54,126	58,644	74,809	102,574	37%
Operating profit growth as reported	11.1%	3.1%	8.3%	27.6%	37.1%	
Operating profit growth in constant exchange rates[1]	5.6%	6.8%	12.7%	14.6%	43.7%	
Depreciation, amortisation and impairment losses	5,661	5,753	6,025	7,362	9,413	28%
EBITDA[1,2,3]	58,144	59,879	64,669	82,171	111,987	36%
Net financials	(3,930)	(996)	436	(5,747)	2,100	
Profit before income taxes	48,553	53,130	59,080	69,062	104,674	52%
Effective tax rate[3]	19.8%	20.7%	19.2%	19.6%	20.1%	
Net profit	38,951	42,138	47,757	55,525	83,683	51%
Purchase of property, plant and equipment[3]	8,932	5,825	6,335	12,146	25,806	112
Purchase of intangible assets[3]	2,299	16,256	1,050	2,607	13,090	40
Cash used for acquisition of businesses	—	—	18,283	7,075	—	
Free cash flow[1]	34,451	28,565	29,319	57,362	68,326	19%
Total assets	125,612	144,922	194,508	241,257	314,486	30%
Equity	57,593	63,325	70,746	83,486	106,561	28%



	2023	2022-23
		52%
		52%
		(1%)
		52%
		50%
		24%
Closing share price (DKK)		49%



In August, the government cited Novo when it lifted its economic growth forecast for this year, to 1.2% from 0.6%. The drugmaker last month overtook LVMH (LVMH.PA) as Europe's most valuable listed company, worth about 385 billion euros ($403 billion) - slightly more than Denmark's gross domestic product. Oct 5, 2023

average profit margin / earning per share? …. **28% + 26%**

combined profit of NN and Eli Lilly for 2022 …. **28.5b + 21b**

Pharma's Q3 growth rankings: GLP-1 drugs from Eli Lilly, Novo Nordisk were once again the big story

By **Kevin Dunleavy** · Nov 28, 2023 3:00am

Novo Nordisk | Eli Lilly | Quarterly Sales | obesity drugs

News

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.

Isaac Hanson | September 1, 2023

In a report released last week and titled "Will GLP-1s Eat the World?" Cowen projects the type 2 diabetes and obesity market to mushroom to

$102 billion by 2030.

It's a huge increase from the $30 billion market Cowen envisioned last year for 2030.

By then, Cowen **sees Lilly controlling 44% of the market, compared to 52% for Novo.**

JAMA Network Open

Original Investigation | Diabetes and Endocrinology

Estimated Sustainable Cost-Based Prices for Diabetes Medicines

Melissa J. Barber, PhD; Dzintars Gotham, MBBS; Helen Bygrave, MBBS; Christa Cepuch, MPH

Abstract

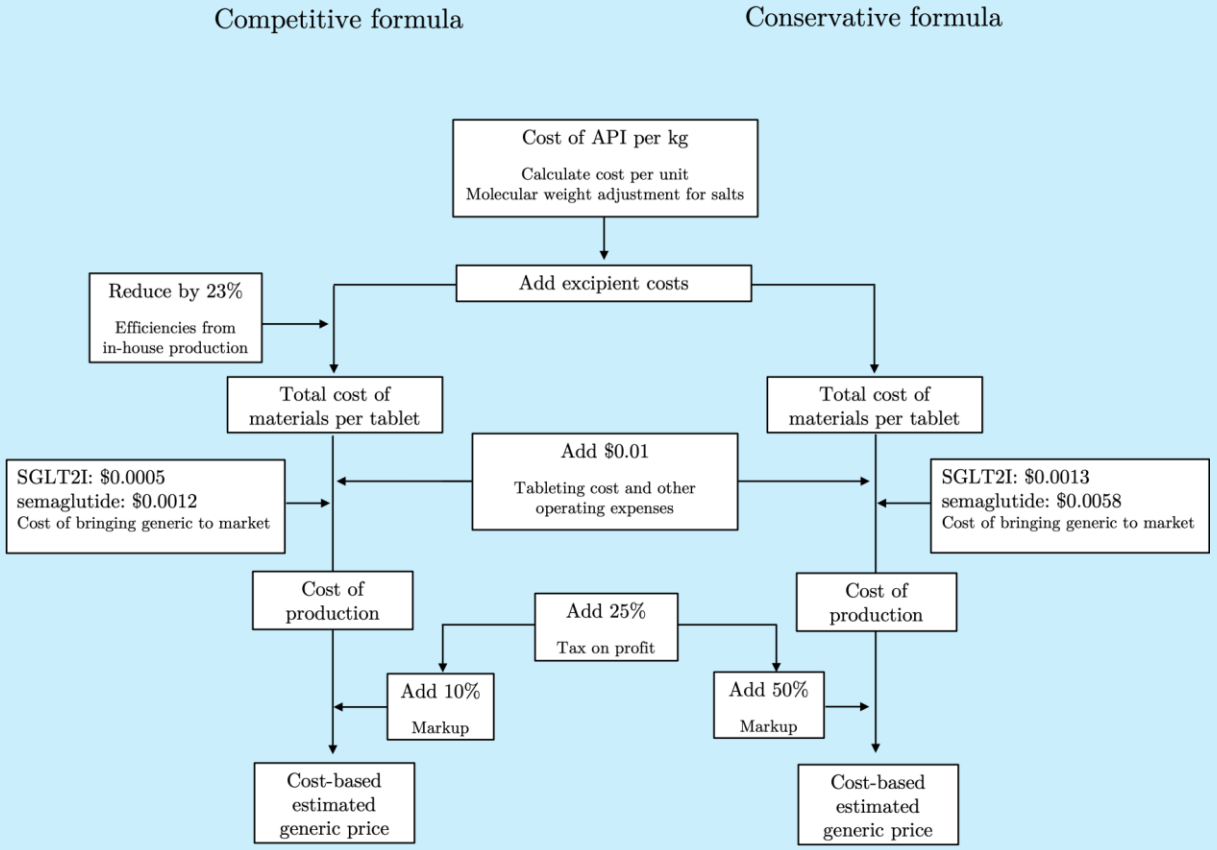
IMPORTANCE The burden of diabetes is growing worldwide. The costs associated with diabetes put substantial pressure on patients and health budgets, especially in low- and middle-income countries. The prices of diabetes medicines are a key determinant for access, yet little is known about the association between manufacturing costs and current market prices.

Key Points

Question What could prices of insulins, sodium-glucose cotransporter 2 inhibitors (SGLT2Is), and glucagonlike peptide 1 agonists (GLP1As) be if they were closer to the cost of production?

What could diabetes medicines cost to produce?

Algorithm for SGLT-2 and Oral Semaglutide

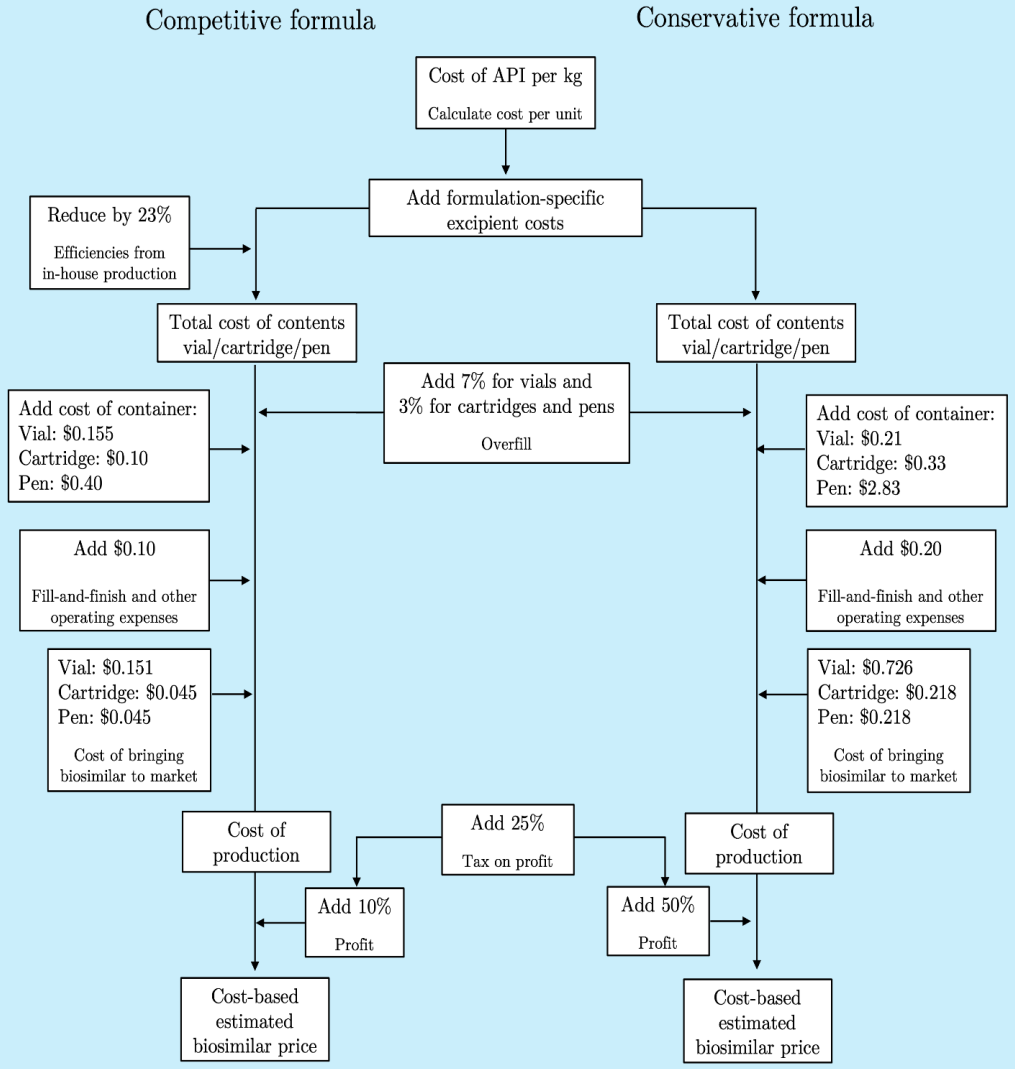


For Cost-based estimated sustainable price

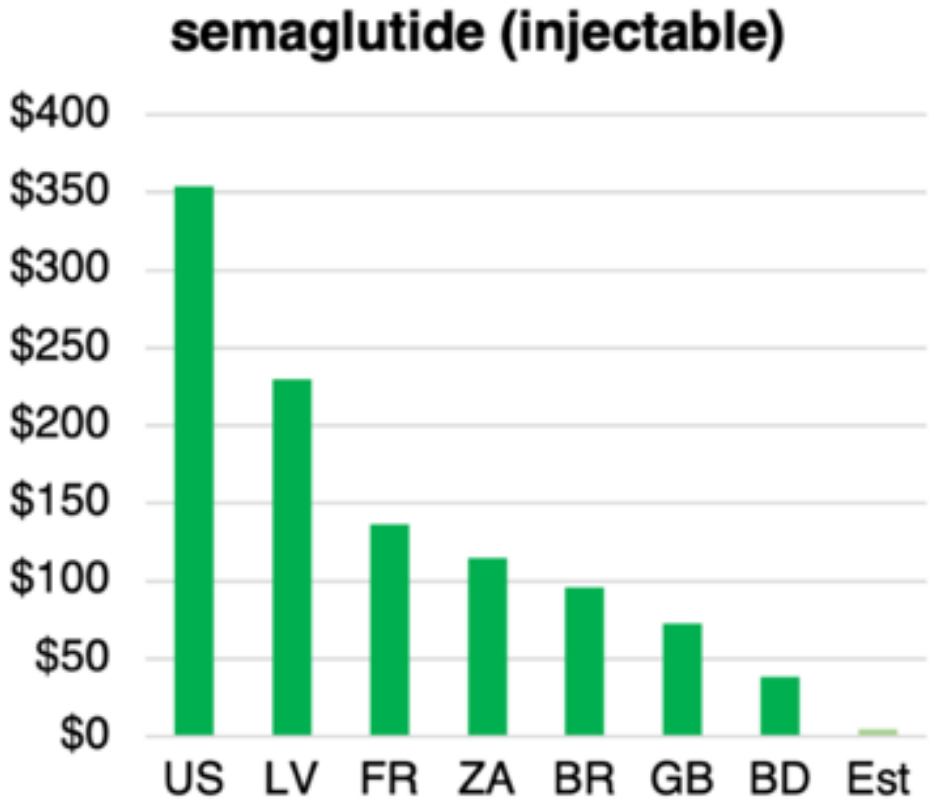
Competitive formula: Assuming scale of production

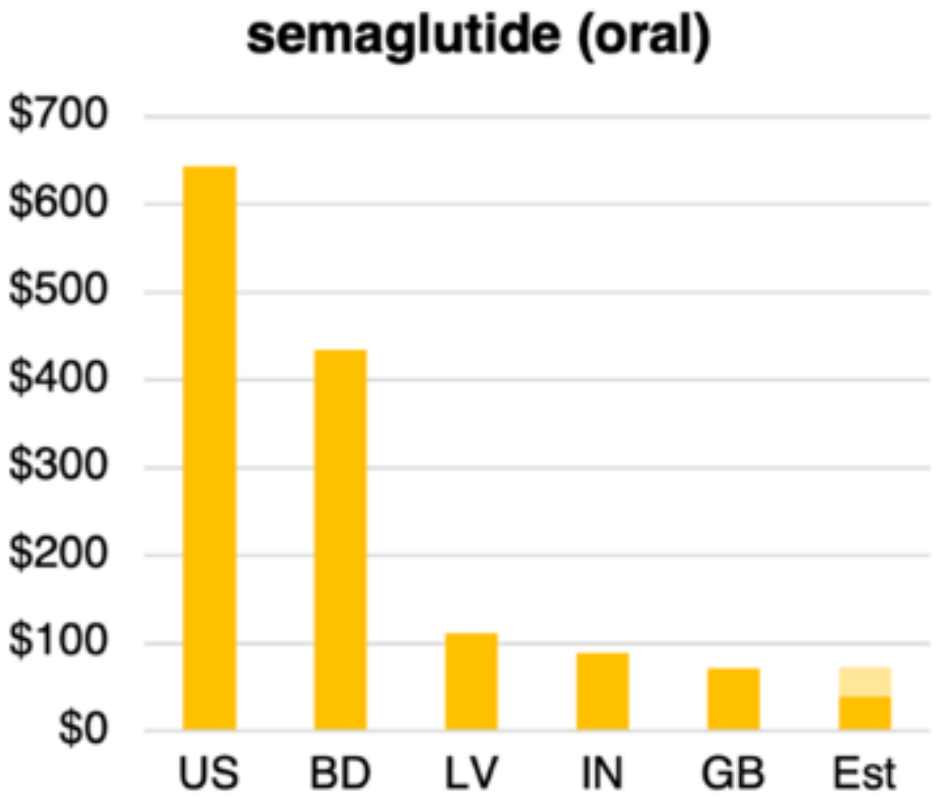
Profit included: 10% (competitive) v 50% (conservative)

Algorithm Injectable GLP-1 and Insulins



GLP1 agonists		
Medicine	Cost-based price per month ($)	Lowest market price per month ($)
dulaglutide (1.12mg once weekly)	7.05-17.40	22.20-227.253
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


semaglutide (injectable)
$400
$350
$300
$250
$200
$150
$100
$50
$0
US
LV
FR
ZA
BR
GB
BD
Est


semaglutide (oral)
$700
$600
$500
$400
$300
$200
$100
$0
US
BD
LV
IN
GB
Est

SGLT2s	Cost-based price per mth ($)	Market price per mth ($)
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

Costs and prices are per month and USD

Insulins						
Medicine	Vial		Cartridge		Pre-filled pen	
	Cost-based price	Lowest market price	Cost-based price	Lowest market price	Cost-based price	Lowest market price
Human insulins						
Regular human insulin	2.37–5.94	1.93–198.90	3.00–9.13	10.62–53.27	4.69–29.44	9.37–31.73
Insulin NPH	2.40–5.98	1.93–198.15	3.02–9.17	10.71–30.70	4.71–29.48	9.37–251.40
Insulin NPH 30/70	2.39–5.97	1.93–198.90	3.02–9.15	10.71–214.65	4.71–29.47	9.98–453.45
Insulin analogues (rapid-acting)						
Insulin aspart	4.86–10.59	19.42–208.35	5.39–13.61	13.95–256.65	7.08–33.92	25.48–268.20
Insulin lispro	4.87–10.62	25.18–118.65	5.40–13.63	25.04–488.55	7.09–33.94	26.71–152.70
Insulin glulisine	4.79–10.47	21.47–407.70	5.33–13.49	21.24–50.64	7.02–33.81	23.51–526.95
Insulin analogues (long-acting)						
Insulin degludec	5.16–11.17	–	5.69–14.16	51.19–98.55	7.38–34.47	56.33–488.25
Insulin detemir	16.97–33.31	443.25–443.25	17.05–35.48	27.47–103.30	18.74–55.79	48.98–443.70
Insulin glargine	4.25–9.46	28.95–142.65	4.81–12.52	27.47–65.25	6.50–32.83	14.92–142.05

SGLT2 inhibitors		
Medicine	Cost-based price	Lowest market price
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

GLP1 agonists		
Medicine	Cost-based price	Lowest market price
dulaglutide (1.12mg once weekly)	7.05-17.40	22.20-227.253
exenatide (7.5mcg 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

ISSUE BRIEF

MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN AND T1INTERNATIONAL

DEFEATING THE DOUBLE STANDARD IN DIABETES CARE

Exposing the exorbitant prices of diabetes medicines and injection devices

May 2024

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.

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.

Newer diabetes drugs (SGLT-2s and GLP-1s): prices and markups

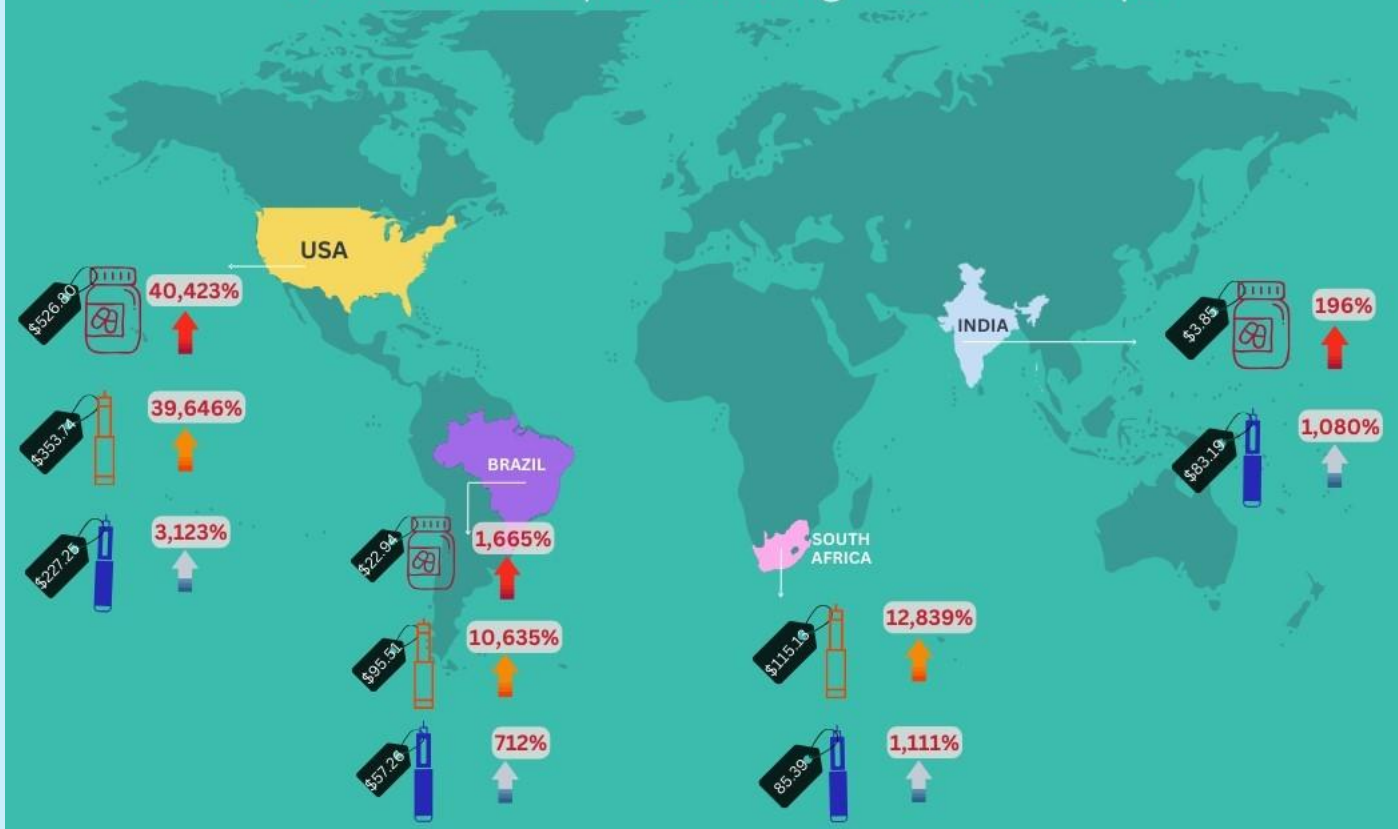
Lowest estimated cost-based prices (for one month)

dapagliflozin
once-daily oral tablet

semaglutide
once-weekly injectable

dulaglutide
once-weekly injectable

Current market prices and Big Pharma markups



Newer diabetes drugs (SGLT-2s and GLP-1s): prices and markups

cost-based prices
month)

$7.05

glutide
injectable

dulaglutide
once-weekly injectable

and Big Pharma markups

$57.2

85.39

1,111%

ISSUE BRIEF

INT

Diabete
a billion
among
globall
live in
countri

Diabet
1 (T1D
an aut
by the
produ
resista
body

Insuli
peopl
to achieve glucose control for people

ThePrint

POLITICS GOVERNANCE ECONOMY DEFENCE INDIA GROUND REPORTS OPINION EVENTS VIDEO MORE

Home › Health › Ozempic makers could be raking in 40,000% profit — study says diabetes...

Health

Ozempic makers could be raking in 40,000% profit — study says diabetes drug can be made for $1/month

Doctors Without Borders says new class of drugs & insulin devices could be leading to 'exorbitant corporate profiteering'. Study published in Journal of the American Medical Association.

SUMI SUKANYA DUTTA 28 March, 2024 02:57 pm IST

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.

Support the Guardian

Fund independent journalism with £10 per month

Support us

The Guardian

Newspaper of the year

News Opinion Sport Culture Lifestyle More

UK World Climate crisis Ukraine Football Newsletters Business Environment UK politics Education Society Science Tech Global development Obituaries

Headlines

Brent

Now 9°C

18:00	21:00	00:00	03:00
9°C	8°C	8°C	7°C

View full forecast

Labour

Starmer says he cannot 'turn the taps on' to fix council funding crisis

2h ago

Live Starmer defends 'difficult decisions' over dropped pledges

Angela Rayner Deputy leader denies wrongdoing over council house sale

Diabetes

'Gamechanger' drugs cost up to 400 times more than needed

2h ago

Bernie Sanders
@SenSanders

There is no rational reason, other than greed, for Novo Nordisk to charge Americans nearly $1,000 a month for Ozempic when it costs less than $5 to manufacture it and can be purchased in Germany for just $59. Novo must substantially reduce the price of Ozempic in the US now.

E COMMITTEE ON
, EDUCATION, LABOR & PENSIONS
ernie Sanders

**EWS: Sanders Statement
Outrageous Cost of Ozempi**

*N, March 27 – Sen. Bernie Sanders (I-Vt.), Chairman
ation, Labor, and Pensions (HELP) Committee, on Wed
disk to lower the list price of Ozempic and issued
r the release of a new study, which found that the
ug could be profitably produced for less than $5 a mont*

Today, a new Yale study found that Ozempic costs less than $5 a month to manufacture. And yet, Novo Nordisk charges Americans nearly $1,000 a month for this drug, while the same exact product can be purchased for just $155 a month in Canada and just $59 in Germany.

7:48 PM · Mar 27, 2024 · **3.4M** Views

Bernie Sanders tordner mod Novos priser: Hvorfor skriver jeg et debatindlæg til en dansk avis? Det er meget enkelt

Novo Nordisk lever ikke op til sine høje moralske idealer, når diabetesmedicinen Ozempic i USA koster 6.700 kr. om måneden, mens den i andre lande sælges for under 500 kr., skriver den amerikanske senator Bernie Sanders i dette indlæg.

▶ AUTOMATISK OPLÆSNING

Bloomberg the Company & Its Products | Bloomberg Terminal Demo Request | Bloomberg Anywhere Remote Login | Bloomberg Customer Support

Bloomberg

Sign In | Subsc

Live TV | Markets | Economics | Industries | Tech | Politics | Businessweek | Opinion | More | Europe

The Ozempic Effect: What You Need to Know | Shortages Explained | Obesity Drug Alternatives | Not Just Weight Loss | The Drug Race

Politics

Bernie Sanders Wants to Meet Novo CEO Next Week on Ozempic Price

- Sanders slams $1,000 monthly price for Ozempic as outrageous
- Ozempic can be made for under $5 a month, recent study found

Bernie Sanders *Photographer: Alex Wong/Getty Images*

By Madison Muller and Robert Langreth
March 28, 2024 at 5:50 PM GMT+1

Double standards in treatment

Two classes of medicines SGLT-2 & GLP-1s for patients diagnosed with type 2 diabetes are widely used in HICs

What can encourage their inclusion in natl guidelines and procurement lists of LMICs?

1. Inclusion in EML

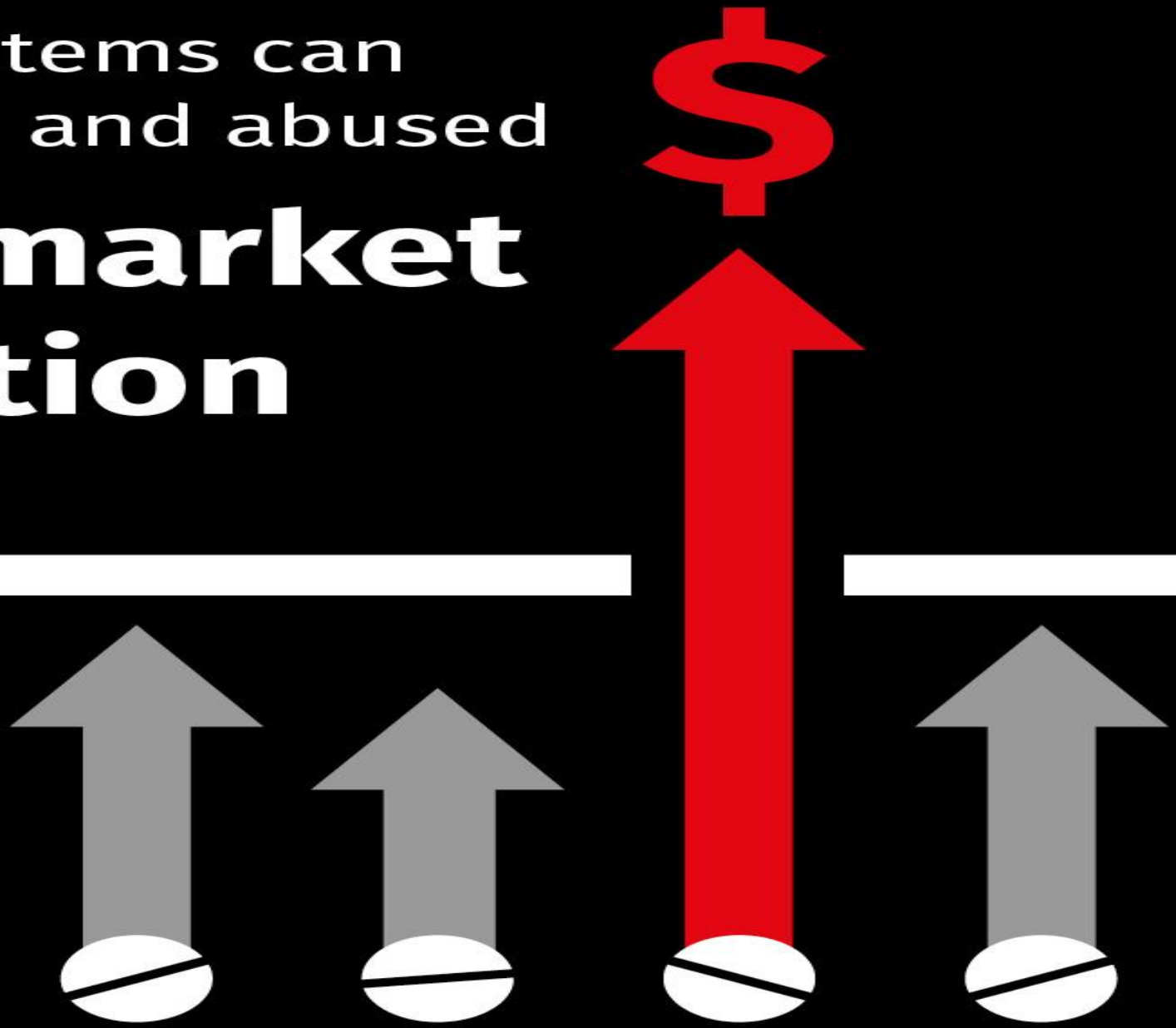
- ✓ *SGLT-2 in WHO EML*
- ✓ *GLP-1 is not included in the WHO EML*
- ✓ *Submission this year for the EML: Include GLP-1 agonists for the management of people living with diabetes (needs support from LMIC organisations and PLWD)*

2. Generic competition to lower prices

3. Targets for diabetes set by WHO member states at 2022 WHA for screening and interventions.

Drug patent systems can be manipulated and abused

limiting market competition



and blocking affordable alternatives

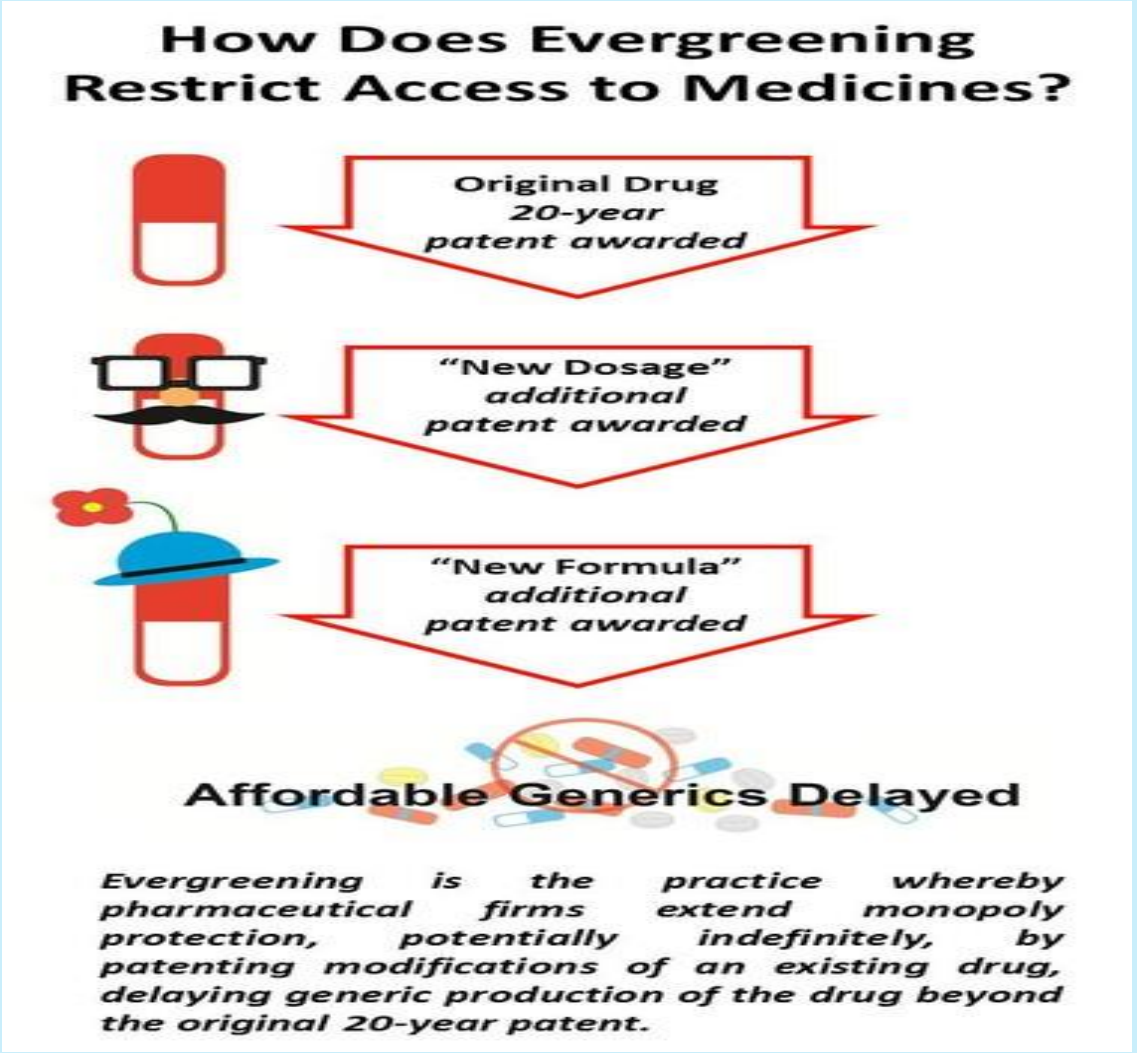
Pharma corporations will try and extend monopoly

Two classes of medicines for patients diagnosed with type 2 diabetes should be available to patients and in the health system:

- ✓ *sodium-glucose co-transporter inhibitors (SGLT-2)*
- ✓ *and glucagon-like peptide receptor agonists (GLP-1)*

Compound patents expiring in 2023, 2025 and 2026

Easy to produce as generics (oral and injectable). No tech transfer needed



Sodium glucose co-transporter inhibitors (SGLT-2)
Snapshot of IP battles – generics launched and on the horizon

SGLT-2 going off patent and generic competition will lead to lowering prices especially if governments tender

Dapaglifozin Indian generics launch generic after markush patent expires in 2020. Court battle follows but generics challenge the patent claims on the compound as invalid for lack of inventive step and being obvious to a person skilled in the art as it was previously disclosed in genus patent IN 205147.

2023: Dapagliflozin compound and salts expired in India and many other countries leading to launch of generics in many countries

The *empagliflozin* compound patent expires in 2025. Crystalline form in 2026

Ozempic

GLP-1 – Ozempic (semaglutide) basic patent expiring 2026.

Inclusion of GLP1 in EML for T2D imp step

However, secondary patent barriers may be faced by generic manufacturers in supplying semaglutide in injectable form (pen), which is the preferred formulation based on its cardiovascular benefits. Will device patents block access?

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.

Generic pipeline includes semaglutide pen

PIPELINE OF NICHE IN THE US

19 Para IVs in the pipeline [2]

Of which 7 are approved[2] (either tentative or fully)

SOLO FIRST TO FILE IN THE PIPELINE [1]

Key Brand	Molecule	Therapeutic Segment / Primary Indication
Tracleer	Bosentan (32mg)	Anti-hypertensive
Kyprolis	Carfilzomib (10mg)	Cancer/Multiple Myeloma
Imbruvica	Ibrutinib (tablet)	Cancer/Leukaemia
Zydelig	Idelalisib	Cancer
Lynparza	Olaparib	Ovarian/Breast Cancer
Ozempic	Semaglutide pen (8mg/3ml)	Diabetes

Promising oral GLP-1-based products

Pharmaceutical corporations have **promising oral GLP-1-based products** in development.

If approved, they will be under monopoly until 2036 (tirzepatide), 2037 (orforglipron) and 2038 (retatrutide)

Diabetes drugs and access to medicines movement

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

Medicines Patent Pool (MPP) will seek voluntary licenses

Leave no one behind - Major role of compulsory licenses

Background

Novo Nordisk Foundation – “We could become the world's largest donor”

Novo Holdings is the **investment arm of the Novo Nordisk** Foundation and has **77% of votes and 28% of shares in Novo Nordisk**, which produces blockbuster obesity drug Wegovy and diabetes treatment Ozempic

WHO Director-General's remarks at the Global Science Summit – 6 May 2024:

- *“I congratulate the Foundation on its 100th birthday, and for everything it has achieved in the past century.*
- *"We very much appreciate your support for WHO, and for global health more broadly.“*

US

- **Senate committee opens investigation into Ozempic, Wegovy prices**

Access Campaign plans in next 6 months

- Bilateral letters and negotiations with big three requesting pricing strategies reflecting cost of production SGLT-2 and GLP-1s
- Dependant on response- public letters and communications
- Briefings and engagement with diabetes and access to medicines civil society including lawyers
- Supporting Submission to EML for GLP-1s
- Deep dive dashboard in selected countries on registration, pricing and inclusion of diabetes medicines and monitoring tools in national health insurance schemes

Next actions

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