INSULIN: BE PREPARED...
EXPECT THE UNEXPECTED

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WELCOME FROM THE MODERATOR

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INSULIN:
BE PREPARED... EXPECT THE UNEXPECTED

OPENING STATEMENT

PROF ANDREW BOULTON
IDF President
UK
TOGETHER
TOWARDS
TOMORROW
INSULIN: BE PREPARED... EXPECT THE UNEXPECTED

TOGETHER TOWARDS TOMORROW

DR LORENZO MOJA
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PAST PRESIDENT, CHINESE DIABETES SOCIETY
CHINA

MS CYRINE FARHAT
IDF BLUE CIRCLE VOICE
LEBANON
STAY INFORMED: KNOW WHAT IS AVAILABLE TO YOU
(THE WHO ESSENTIAL MEDICINES LIST)

DR LORENZO MOJA
Secretariat of the WHO Model List of Essential Medicines
Italy
Conflict of interests

Global access to essential medicines

I declare I have no conflict of interests

I have been supporting the EML Committee during the last 4 editions (2015, 2017, 2019, 2021)
Insulin prices, availability and affordability in 13 low-income and middle-income countries

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Handling editor Seye Aimbola

ABSTRACT

Introduction. Globally, one in two people needing insulin lack access. High prices and poor availability are thought to be key contributors to poor insulin access. However, few studies have assessed the availability, price and affordability of different insulin types in low-income and middle-income countries in a systematic way.

Methods. In 2016, 15 insulin price and availability surveys were undertaken (using an adaptation of the WHO/Health Action International medicine price and availability measurement methodology) in Brazil, China (Hubei and Shaanxi Provinces), Ethiopia, Ghana, India (Haryana and Madhya Pradesh States), Indonesia, Jordan, Kenya, Kyrgyzstan, Mali, Pakistan, Russia (Kazan Province) and Uganda. Data were collected in three sectors (public, private pharmacies and private hospitals/clinics) in three regions per survey. Insulin prices were standardised to 10 mL 100IU/mL in US dollars ($) and were also collected for four comparator medicines.

What is already known?

► Despite being discovered nearly 100 years ago, one in every two people globally needing insulin lack access to this life-saving medicine.

► The global insulin market is dominated by only three companies, but it is estimated that increased competition with biosimilar insulin could lead to large price reductions.

What are the new findings?

► In low-income and middle-income countries, insulin availability in outlets is poor, and treatment is unaffordable for those on low wages having to pay out of pocket.

► Biosimilar insulins are mostly (but not always) cheaper than originator brands, and analogue insulins, in particular, are far higher priced than estimated costs of production including profit.

What do the new findings imply?

► High insulin prices and poor availability need to be addressed through national and global actions.
WHO EML and its role

• In 1977, the World Health Organization (WHO) published the first Model List of Essential Medicines (Essential Medicines List, EML).

• It introduced the idea that some medicines are more important than others.

• Many later considered the first EML ‘a revolution in public health’.

EML since 1977: an early evidence-based adopter

Since 1977:
- Insulin
- Antibiotics
- Neglected diseases
- Pain
- Mental health
- Chronic diseases
- Cancer

In EML no medicines for:
- Memory loss and dementia
- “Hepatoprotectants” and “Immunostimulants”
- Medicines for dubious conditions (disease mongering / medicalisation of life conditions)
- No medicines listed subsequently withdrawn for unexpected risks (e.g., cox-2 inhibitors)

EML is listing:
- New HepC pan-genotypic combinations
- Dolutegravir and PreP for HIV
- All new TB drugs
- Checkpoint inhibitors for cancer … and … all highly effective treatments
EML since 1977: one standard for all

- Since 1977 and up to now insulin has been in the WHO EML
- The approach on insulin(s) has been for a (too?) long time similar to the one we had on morphine for cancer pain – need to stay basic and insist on that

- Recent revisions of insulin analogues and second line agents led to rejections

- At the same time increasing perception of our very limited impact (failure?) on access to essential medicines for diabetes
IDF and the Medicines Patent Pool welcome the inclusion of SGLT2 inhibitors to the WHO Essential Medicines List

01 October 2021

The two organisations commit to working together to improve affordable access to SGLT2 inhibitors in low- and middle-income countries (LMICs).

The International Diabetes Federation (IDF) and the Medicines Patent Pool (MPP) welcome the inclusion of SGLT2 inhibitors – oral medications used to lower blood glucose levels – to the 2021 World Health Organization (WHO) Essential Medicines List (EML), namely empagliflozin with canagliflozin and dapagliflozin as therapeutic alternatives. The WHO Expert Committee called on originators to license their medicines to MPP to scale up access in LMICs.
WHO EML- 22nd list, 2021 - Diabetes

New additions 2021

Long-acting insulin analogues

• For patients at high risk of experiencing hypoglycaemia with human insulin
• Aim: facilitate access to insulins (prequalification) while also expanding access to human insulin

SGLT2 inhibitors

• Add on treatment for adults with type 2 diabetes with or at high risk of cardiovascular disease and/or diabetic nephropathy (reduction in mortality)

Section 18.5 – medicines for diabetes

https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.02
• Magnitude of clinical benefit of long-acting insulin analogues over human insulin for most clinical outcomes was small, making the large price differential between insulin analogues and human insulin difficult to justify

• Observed benefits of analogues over human insulin (i.e. lower incidence of symptomatic and nocturnal hypoglycaemia) were consistent and clinically important justifying the decision to recommend inclusion

• Therapeutic clinical equivalence to increase competition and favor best price tenders

• Prices offered to patients and procurers differ considerably among countries, with analogues often much more expensive than human insulin

• Overall use of analogues seems to be expanding and prices are decreasing for those no longer under patent protection

• Dedicated policy actions (cost containments and efficient negotiations) on insulin prices seem to increase affordability and access

• Affordable access to human insulin remains a critical priority, globally
EML 2021
Possible actions for more affordable insulins

• Two main questions:
  • Shouldn’t all insulins be costing less?
  • AND, shouldn’t we providing one standard for all?

• Prequalification process - increase in the number of insulin manufacturers, including biosimilars

• Strong preference for pen devices

• Comprehensive approach to address insulin prices, including:
  • mechanisms for pooled procurement at global level (Unicef, UNDP, other agencies) and at national (or more local level)
  • Price control policies
  • potential for global index price
  • Prefernce for pens

• Identification of evidence and research gaps regarding insulin use and supply, including setting-specific differences (e.g, food insecurity, displaced populations, emergencies)
«Among novel agents, SGLT2 inhibitors hold particular promise for reducing complications of diabetes and meeting common price targets, particularly when used among people with established cardiovascular or kidney disease. These findings are consistent with the choice to include SGLT2 inhibitors in the WHO Essential Medicines List»

Cost-effectiveness or cost-savings can be achievable with modest price reductions for SGLT2 inhibitors, but would require large price reductions for glargine insulin, and other newer agents (e.g. GPL-1)

NPH insulin was priced $10 per 10 mL vial of 100 IU/mL ($9–17; $13), and of glargine insulin was $29 per 10 mL vial of 100 IU/mL ($17–54; $37)
It should be acknowledged that these evaluations are important contributions on UHC and well-designed research.

Mixed effects on medicine adherence, access and prices. Limited effects (so far) on clinical outcomes.
Conclusions

• Access to insulins is a complex issue
• WHO might have more prominent role in price settings despite prices and reimbursement/coverage are countries’ responsibilities
• Prioritize insulin/SGLT2 access in UHC agenda for full coverage for all (universal)
• WHO can/should coordinate all different/many stakeholders in a health system perspective on UHC
• UHC is a commitment of multiple organizations and requires political will
THE IDF WESTERN PACIFIC DISASTER PLAN: ARE WE PREPARED TO MAKE A DIFFERENCE?

PROF ALICIA J ENKINS
Sydney Medical School
Australia

Existent guidelines at: www.ajenkinsdiabetes.org and www.idf-wpr
IDF- WPR Guidelines 2nd Ed. For release in 2022
INCREASING DISASTERS, DECLINING DEATH RATES, BUT LOWER INCOME REGIONS REMAIN HIGH RISK
DISASTERS: NOT IF, BUT WHEN?

• Increasing numbers of major disasters globally
• High prevalence of diabetes: 8 – 35% population
• Many with diabetes will be impacted:
  o particularly vulnerable: T1D, complications, pregnant, frail, isolated

DISASTER RESPONSE FRAMEWORK
• Prevention, Preparation, Response, Recovery (PPRR)

WHO TO INVOLVE
• Person with diabetes, family, carers, disaster-experienced people
• Community, including volunteers
• Clinicians, Healthcare system, Diabetes Associations (professional and lay)
• Other organisations:
  o Local: medical groups, hospitals, local govt., NGOs, industry, utilities
  o National: govt., general disaster responders, diabetes associations, pharma, NGOs; media, VIPs, philanthropists
  o International industry, other govts, NGOs e.g. IDF, Red Cross, MSF,, UN, WHO, IFL, LFAC
WHAT TO PREPARE FOR

• **Loss of:**
  o shelter, power: Leaks of gas, water, downed power-lines
  o communication – *avoid dependence on internet + phones*: paper
  o clean water and healthy food supply
  o medicines and related devices e.g. syringes, glucose monitoring
  o diagnostic + treatment facilities (e.g. dialysis, hospitals) + staff
  o access to medical records (hospital and personally held)

• **Diversion / fragmentation of healthcare system**

• **For people with diabetes** worsening of glycaemia, BP, cardiac status,
  o kidney dysfunction, medication errors, injuries, infection e.g. foot, eyes

• **Psycho-social distress**

• **Evacuation**

1st responders and available clinicians may not know diabetes well, nor have resources
DIABETES AND DISASTERS - NEW IN 2ND EDITION

PANDEMICS

- Risk Factors and Care Strategies
- Low-cost home-made sanitisers, water decontamination, rehydration solutions

SPECIFIC DIABETES CARE GUIDELINES

- Conversion charts: glucose (mg/dl - mmol/l), eAG and TIR to HbA1c
- Insulin swapping charts
- Alternate refrigeration
- Safe use of non-refrigerated insulin during emergencies
- Sharps reuse and safe disposal
- DKA treatment by sc or im insulin injection in a low resource setting
- Hypoglycaemia, ketone testing, sick day care
- Diabetes care for first responders + shelter staff

SPECIAL CIRCUMSTANCES

- Birth, Palliative Care
- Human Rights
- Who to ask for help

MORE LISTS, RESOURCES, TEMPLATES, SLIDE-SET
STRATEGIES AGAINST THE DUAL CHALLENGES OF DIABETES CARE AND COVID-19

PROF WEIPING JIA

Member of the Chinese Academy of Engineering
Member of the Chinese Academy of Medical Sciences
Immediate Past President, Chinese Diabetes Society

China
PREVALENCE OF DIABETES AND INSULIN USE IN CHINA

425 million patients with diabetes estimated globally

125 million in China, top of the world

Prevalence in China: 11.2%, Awareness rate: 38%

An estimated total of 20 million patients use insulin in China in 2019

Prevalence of diabetes in China(%)

- Adults
- Young people
  - 1994: 25-44 years old
  - 2013: 18-39 years old

1979: 1.14%
1994: 1.7%
2013: 10.4%
2017: 11.2%

IDF Atlas (9th edition); Report of chronic diseases and nutritional surveillance in China (2013, 2020); Report of insulin clinical demand and supply capacity in China (2021)
NATURAL DISASTERS AND INSULIN PREPAREDNESS FOR PATIENTS

China is one of the countries severely affected by natural disasters, including floods, earthquakes, typhoons and rainstorms:

• Tangshan Earthquake, happening in 1976, had the 2\textsuperscript{nd} largest death toll from the earthquake history in the 20\textsuperscript{th} century

• Sichuan Earthquake, in 2008, an 8.0 magnitude earthquake with the biggest intensity of 11 degree, caused 69,227 dead, and 17,923 missing
NATURAL DISASTERS AND INSULIN PREPAREDNESS FOR PATIENTS

Insulin preparedness strategies for patients suffering from earthquake:

- For those in early stage of diabetes, not fully relying on insulin, change to oral medication temporarily is suggested.
- For those with T1DM or T2DM of poor pancreatic islet function, insulin must be delivered to disaster areas by rescue helicopter or ambulance through emergency channel.
- For those with physical trauma, seriously injured patients with diabetes should be transferred to a medical institution as soon as possible by rescue helicopter or ambulance if possible to prevent acute complications. Otherwise, insulin should be injected subcutaneously or through intravenous infusion on the spot, with blood glucose monitored by experienced medical personnel.
DUAL CHALLENGES OF DIABETES CARE AND COVID-19 IN CHINA

China’s shift response to the public health emergency

• Pooling premium resources to treat severe cases
• Early intervention for patients with mild symptoms
• Mobilized all its medical resources to support the efforts in Wuhan and other locations in Hubei
  o Health staff from the S6PH supported Leishenshan hospital in Wuhan during the emergency
Research shows virus disproportionately affects diabetics

Covid-19 patients with high blood sugar had a significantly higher risk of poor outcomes, such as requiring intensive care, respiratory machines and falling into critical condition...

Use CGM to strengthen individualized diabetes care in Leishenshan hospital in Wuhan

A feasible and effective way of CGM under quarantine:

• Improve the outcomes of patients with diabetes complicated with COVID-19
• Compared with traditional monitoring, isCGM provide comprehensive information on glycemic fluctuations, and exposures to hyperglycemia and hypoglycemia
• Reduce the risks of biological exposures during hospitalization
IMPROVE INSULIN ACCESS DURING THE PANDEMIC OF COVID-19

Internet hospital for those quarantined:
• With negative PCR test results within 48 hours, patients could go to hospitals as usual
• Otherwise, patients could also get online services through internet hospitals, get prescriptions from endocrinologists online and, then medication like insulin will be delivered home through cold chain

To solve the inconvenience in medication access in communities:
• Patients can check the Diabetes Pharmacy Map online for insulin access on nearby drugstores in communities
• Wechat is also a useful platform for improving patients’ access to insulin from nearby drugstores
THANK YOU!
ACCESSING INSULIN DURING EMERGENCIES AND DISASTERS

MS CYRINE FARHAT
IDF Blue Circle Voices
Lebanon
CLOSING REMARKS AND THANKS

DR HELEN BYGRAVE
Access Campaign, Medecins Sans Frontières
South Africa
CLOSING REMARKS AND THANKS

- Thanks to Gan & Lee for their support to this webinar

- The link to the webinar recording will be sent via email

- Please respond to the feedback questionnaire to help improve future IDF online events

- Send any questions to advocacy@idf.org