



ACCESSING INSULIN: PRICE AND OTHER CHALLENGES

Margaret Ewen, ACCISS Study - Health Action International

Addressing the Challenge and Constraints of Insulin Sources and Supply (ACCISS) Study

- Addressing inequities and inefficiencies in the insulin market to improve access
- Collaboration between HAI (Marg Ewen & Molly Lepeska), David Beran (University of Geneva), Richard Laing (Boston University School of Public Health) and a large group of international experts in diabetes and access to medicines
- Started in 2015, funded by The Leona M. and Harry B. Helmsley Charitable Trust & Stichting ICF



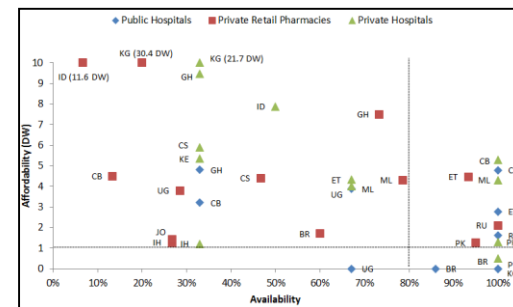
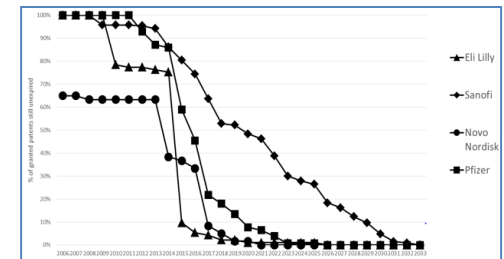
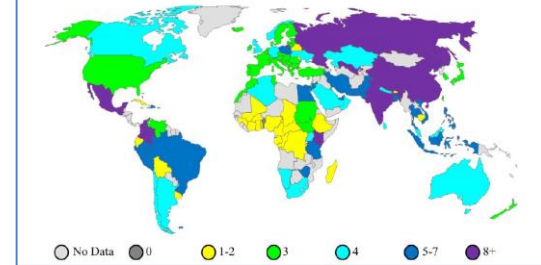
- **Biological, first discovered in 1921**
- **Essential for type 1 diabetes, used by 63 million people with type 2 diabetes**
- **Initially pork and beef extracts**
1982 recombinant DNA (human) insulin (short- and intermediate-acting & premixed)
mid-1990's analogue insulins (rapid- and long-acting & premixed)

Research on the Global Insulin Market

Angles looked at by ACCISS

- Market
- Regulatory
- Trade
- Intellectual property
- Availability, prices, affordability, price components
- Perspective of diabetologists, insulin users and manufacturers
- Initiatives to improve insulin access
- Need for insulin in type 1 & type 2 diabetes
- Cost of production

Figure 1. Number of independent insulin manufacturers with insulin products registered and/or sold in each country.



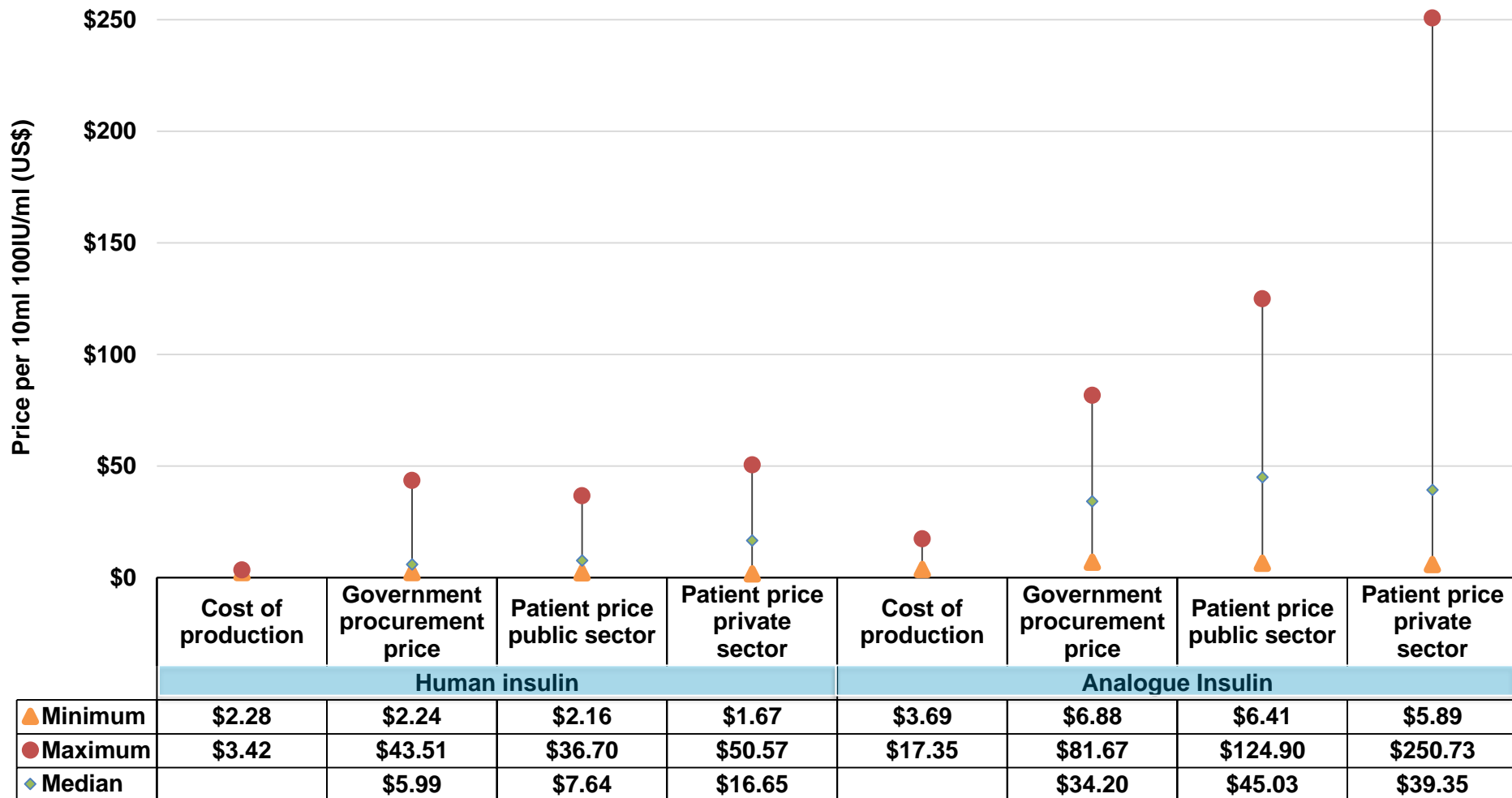
The Global Insulin Market: What We Know

- \$20 billion market, dominated by 3 large multi-national companies – Novo Nordisk, Eli Lilly and Sanofi
 - 99% by value
 - 96% by volume
 - 88% by product registrations
- Identified 39 smaller insulin manufacturers
 - 23 only sell insulin in one country
 - Probably only 10 insulin manufacturers globally truly independent
- Increasing use of high-priced analogue insulins despite limited evidence of benefit over human insulin
 - Only one independent study - showed long-acting analogues were not cost-effective (Canada)

The Biosimilar Insulin Market

Income	<ul style="list-style-type: none"> • Size of local market, most seeking new markets
Manufacturing	<ul style="list-style-type: none"> • High cost of investment, underutilised capacity
Challenges expressed by companies	<ul style="list-style-type: none"> • Competing with the three large MNCs on price • Marketing • Awareness of biosimilars • Human versus analogue biosimilars. Priority is getting EMA &/or USFDA approval for analogues – Abasaglar (Lilly), Semglee (Biocon/Mylan), Admelog (Sanofi). Lusduna (MSD) approved but then withdrew • Currently no biosimilar human insulins have marketing authorisation from a stringent regulatory authority. Told Novartis/Gan&Lee will apply; Julphar?
Biosimilar regulations	<ul style="list-style-type: none"> • Not all countries have regulatory procedures for approving biosimilars • Inconsistent regulatory requirements across national medicines regulatory authorities

Estimated Cost of Production vs. Prices

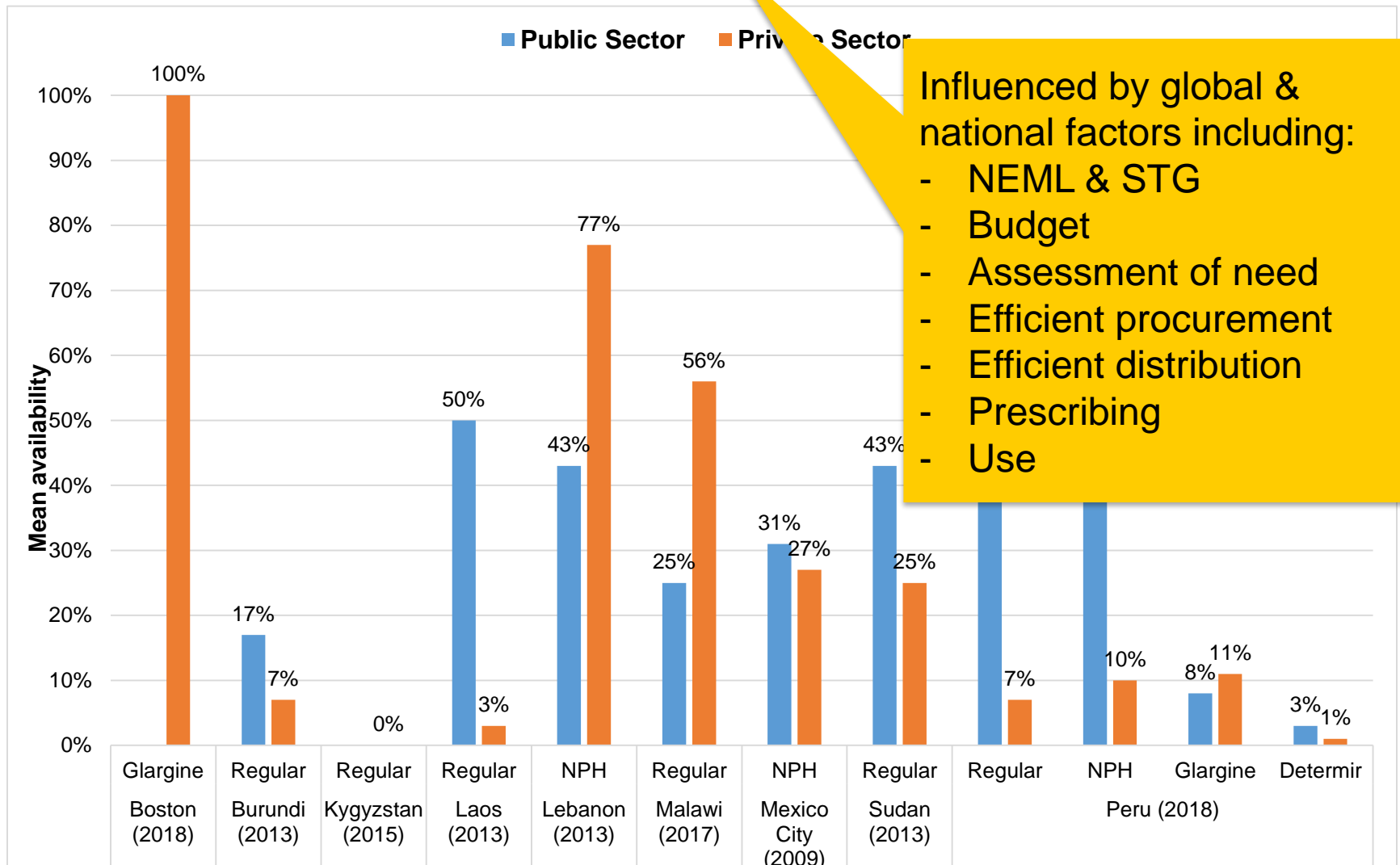


Insulin Affordability

Number of days' wages needed by the lowest-paid unskilled government worker to purchase 10ml 100IU/ml insulin (approx. 30 days' supply)

Sector	HUMAN INSULIN		ANALOGUE INSULIN	
	Mean days' wages	Range day's wages	Mean days' wages	Range day's wages
Public	2.5	0.5 - 6.2	7.5	1.0 - 19.1
Private	3.5	0.2 - 48.9	9.5	0.3 - 77.9

Insulin Availability



Influenced by global & national factors including:

- NEML & STG
- Budget
- Assessment of need
- Efficient procurement
- Efficient distribution
- Prescribing
- Use

Insulin Prices in the US

The Washington Post Magazine

Life, Death and Insulin

THE WALL STREET JOURNAL

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Insulin Quest: When Lifesaving Drugs Are Out of Reach

1,963 views | Mar 22, 2019, 11:29am

Rising Out-Of-Pocket Costs For Insulin Indicates Market Failure

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The human cost of insulin in America

By Ritu Prasad
BBC News

- From 2012 to 2016, US average price increased from 13 cents per IU to 25 cents per IU¹
- Price rapid-acting analogue Humalog® (Eli Lilly) reduced to \$187 for uninsured in March 2019
- Much advocacy in US/ Congressional hearings
- Impact on global market yet to be seen

(1) Health Care Cost Institute. Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices January 2019

Improving Access to Affordable, Quality-assured Insulin

WHO establishes an independent working group on the issue of access to insulin, including relevant WHO clusters and key partners including people using insulin

- Activities leading up to the 2021 insulin centenary including WHA resolution
- Global compact between WHO and insulin manufacturers to keep human insulin on the market for the foreseeable future
- Support regular monitoring of insulin availability, prices and affordability in countries
- Work with partners on health system challenges regarding access to insulin and delivery of diabetes care:
 - Strengthening supply systems
 - Evidence-based standard treatment guidelines
 - Improving delivery of care
 - Diabetes in UHC
 - Management of diabetes in humanitarian settings

Improving Access to Affordable, Quality-assured Insulin *continued*

Addressing regulatory and related barriers for biosimilar insulins

- Inclusion of biosimilar human insulin in WHO's Prequalification Programme
- Further identify regulatory barriers for biosimilar insulins through discussions with NMRAs and insulin manufacturers
- Expand WHO guidance on the evaluation of biosimilar insulins
- Train regional regulatory harmonization initiatives and promote recognition by NMRAs
- Pilot a pooled procurement mechanism for insulin, linked to prequalification

Develop a more comprehensive approach on insulin price issues

- Direct negotiation with insulin manufacturers on prices of insulin for low-income populations
- Support the ACCISS Study's insulin price database to increase transparency
- Work with countries to regulate mark-ups in the insulin supply chain

Improving Access to Affordable, Quality-Assured Insulin *continued*

Increase the evidence base and disseminate findings widely

- Cochrane Collaboration review of the use of long-acting insulin analogues in Type 1 diabetes
- Independent assessment of the price at which analogue insulins would be seen as value for money for health systems and individuals
- More actively disseminate current WHO Guidelines on second- and third-line medicines and type of insulin for the control of blood glucose levels in non-pregnant adults with diabetes
- Identify other areas where evidence based and independent guidelines are needed



ACCESS TO INSULIN TOOLKIT

- Estimation of need for insulin in type 1 and type 2

ABOUT

NEED FOR INSULIN



- Country need estimates
- Price data (where available)

- Transition guidelines
- Case studies of countries providing insulin for free
- Cost of care model
- Managing diabetes
- Alternative funding mechanisms for insulin

HEALTH SYSTEMS

PRICE OF INSULIN

INSULIN SELECTION

- Review on the value of insulin
- Guideline on different issues surrounding the use of insulin
- Biosimilar insulin FAQs
- Interchangeability

- Advocacy communications guide
- Insulin FAQs
- Infographics and more

COMMUNICATIONS

- Clearing house: govt. procurement, patient prices, reimbursement, patient prices
- Estimation of cost of production of insulin
- Addressing mark-ups in the supply chain