



# GLOBAL ACCESS TO AFFORDABLE INSULIN UNDERSTANDING THE BARRIERS

Molly Lepascka and Marg Ewen  
ACCISS Study, Health Action International

# Health Action International (HAI)

- Established 1981 in Amsterdam, The Netherlands
- Research and evidence-based advocacy
- Advance policies that enable access to medicines & improved use
- Currently four programmes of work: ACCISS Study, EU projects, Snakebite Envenoming, Health Systems Advocacy (sexual and reproductive health commodities)

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

- Collaboration between HAI (Marg Ewen & Molly Lepaska), 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
- Goal: Improve the life-expectancy and quality of life for people with diabetes requiring insulin by addressing inequities and inefficiencies in the global insulin market
- Phase I of the study focused on identifying the barriers to access to insulin and creating interventions. Phase II focuses on piloting these tools and interventions at a country level while continuing to work globally.
- Started in 2015, funded by The Leona M. and Harry B. Helmsley Charitable Trust and Stichting ICF

# ACCISS Expert Advisory Group

- Guido Alarcon, Ecuador
- Mark Atkinson, University of Florida
- Merith Basey, Director, Universities Allied for Essential Medicines
- Carine de Beaufort, ISPAD
- Oumar Diallo, Guinea and USA
- Edwin Gale, International Insulin Foundation
- Hans Hogerzeil, Former head Medicines Dept. at WHO
- Cécile Macé, UNDP
- Christophe Perrin, Independent
- Kaushik Ramaiya, Endocrinologist, Tanzania
- Carla Silva-Matos, Ministry of Health, Mozambique
- Hanne Bak Pederson
- John S. Yudkin, International Insulin Foundation
- Aigerim Zhaparova, Kyrgyzstan

# About Insulin

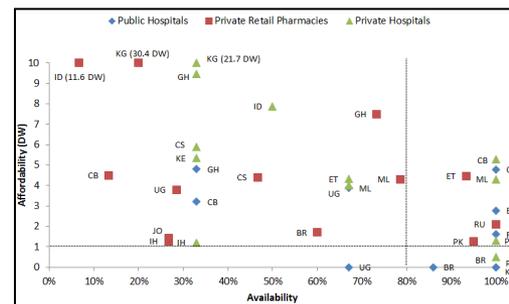
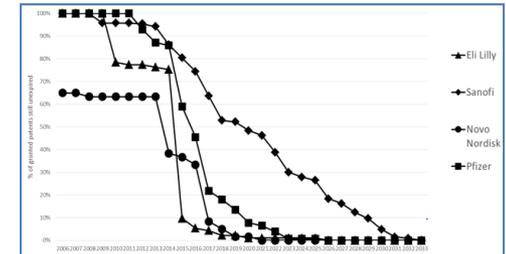
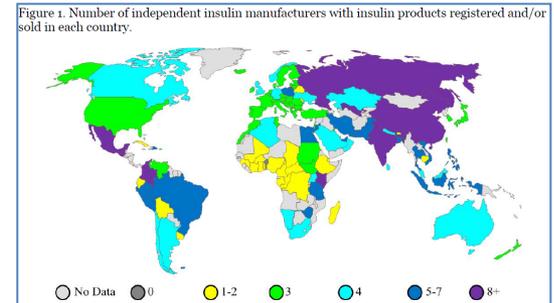
- Biological, first discovered in 1921
- Essential for type 1 diabetes; increasingly being used to manage type 2 diabetes (estimated 63 million people)
- Initially pork and beef extracts; 1982 recombinant DNA (human) insulin (short-acting, intermediate-acting, mixed); mid-1990's analogue insulins (rapid-acting, long-acting, mixed)



# ACCISS Research

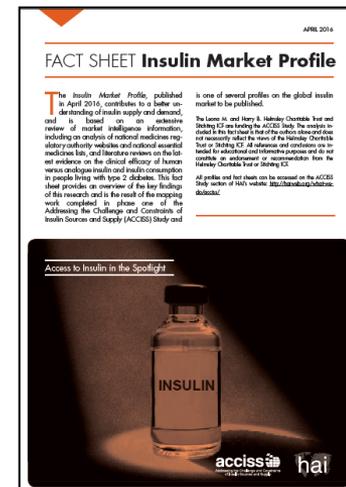
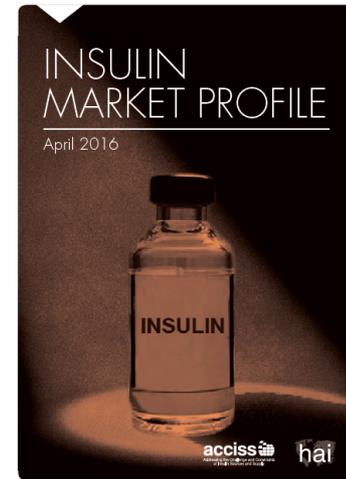
## 'Angles' looked at by ACCISS starting 2015:

- Market
- Intellectual property
- Trade
- Regulatory
- Perspective of diabetologists, insulin users and manufacturers
- Initiatives
- Need for insulin
- Cost of production
- Availability, prices, affordability, price components



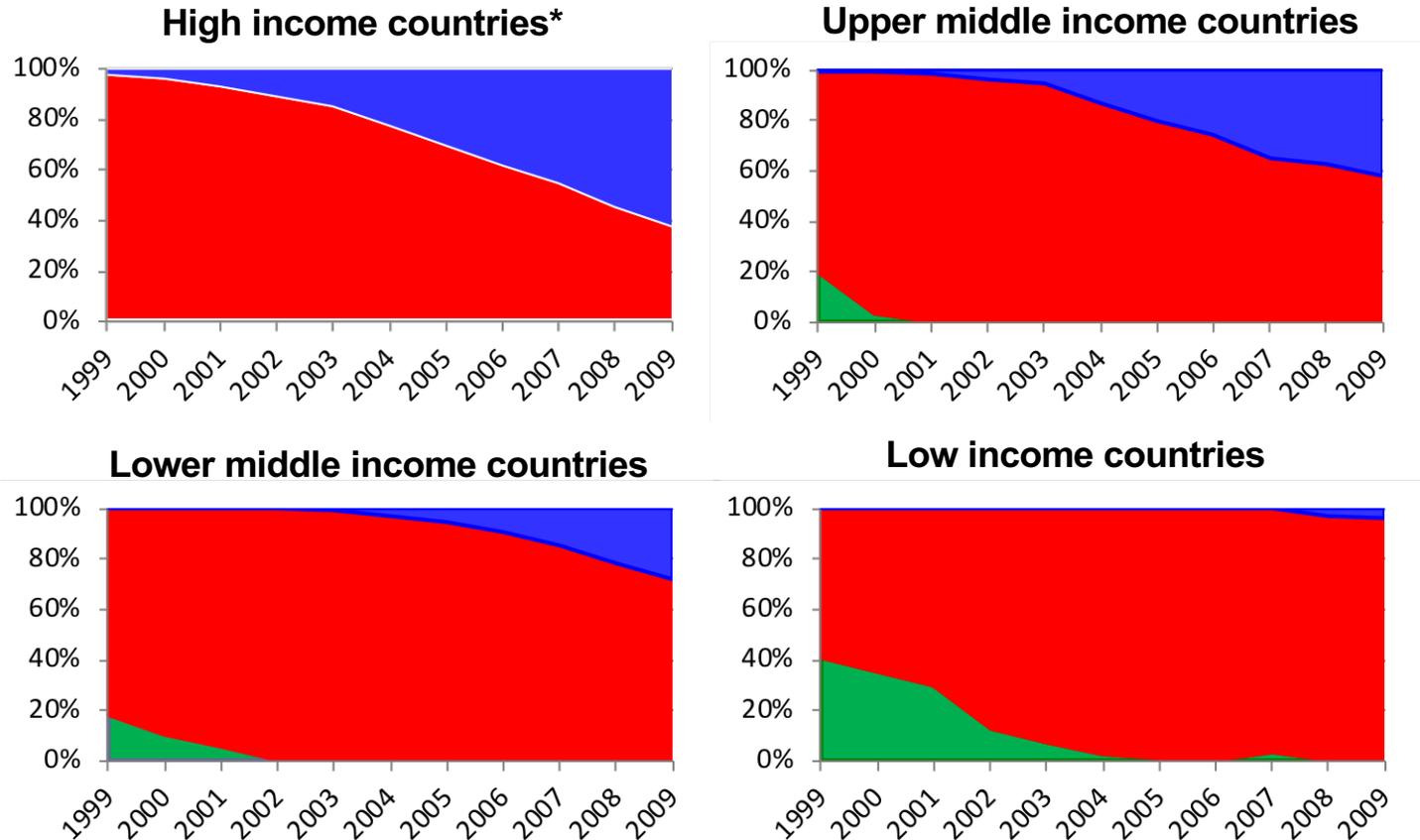
# Insulin Market

- Analysis of 100 NEMLs: nearly all countries list both intermediate-acting and short-acting human insulin
- Global insulin market valued at US\$20.8 billion (2012)
- Three major insulin suppliers have >90% global insulin market by value and volume - Eli Lilly, Novo Nordisk and Sanofi
- Of 121 countries, Novo Nordisk products registered in 111 countries, Sanofi -101 countries, Eli Lilly - 94 countries. Sole suppliers of insulin in 55% countries
- 39 smaller insulin manufacturers were identified
  - 23 only sell insulin in one country
  - From discussions, probably only 10 or so are truly independent



# Changes in Insulin Use

(red: human; blue: analogue; green: animal)



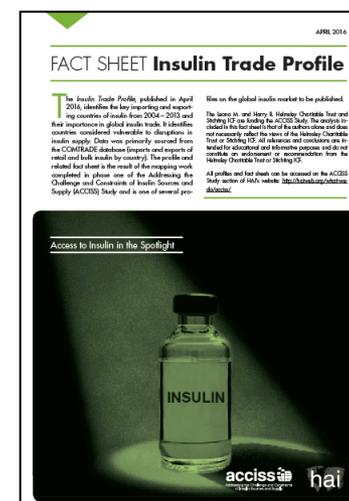
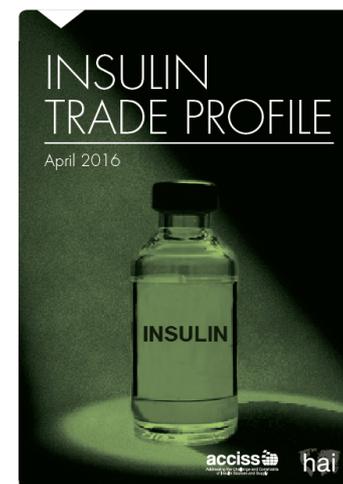
Beran et al. 2016

\*USA: According to a 2019 Health Cost Institute, 90% of people with type 1 diabetes now use analogue insulin for their treatment in the US



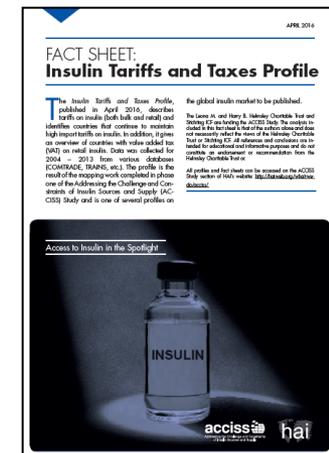
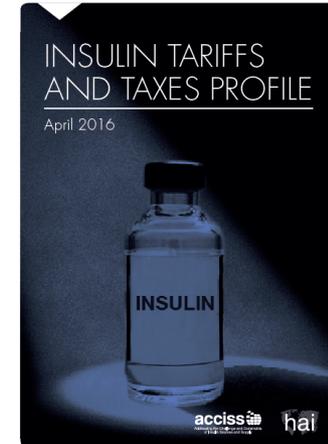
# Trade in Insulin

- 10 countries made up 98-99% of the global value of retail insulin exports (2004-2013)
  - Germany, Denmark, and France collectively exported between 85-96%
- Approximately 50% of global imports of retail insulin were to the US, UK, Germany and Japan (2004-2013)
- Around 60 countries imported insulin from only one country for at least one year (2004-2013)
  - Vulnerable to any disruption in supply



# Tariffs and Taxes on Insulin

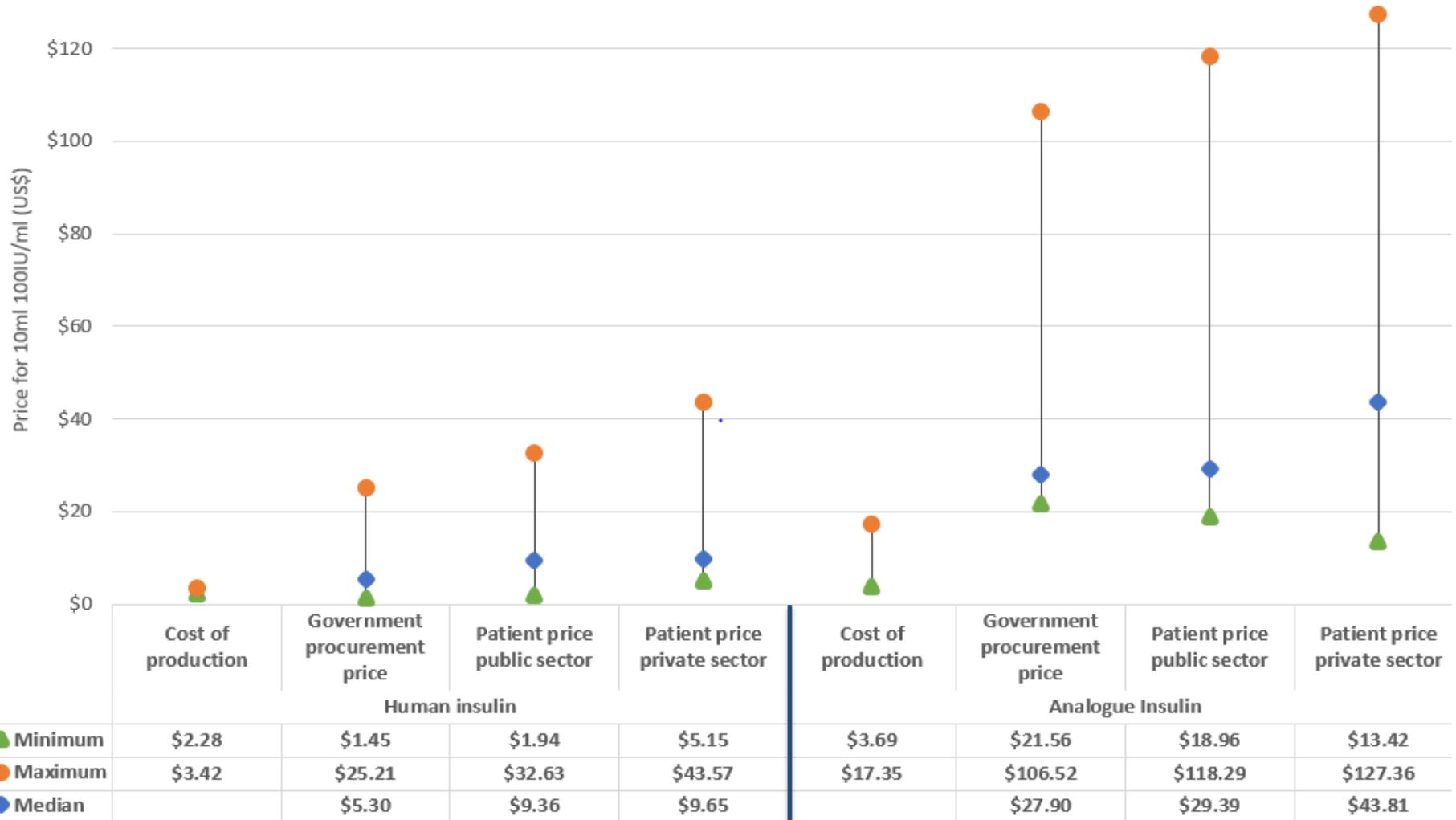
- Majority of countries have no import tariffs on retail insulin
  - Proportion of countries without tariffs has increased since 2004 (52 to 77%)
- Global weighted average import tariff has decreased from slightly less than 3.5% (2004) to about 1.9% (2013)
  - In 2012 and 2013, most of countries with the highest import tariffs were from Latin America
- VAT on insulin ranged from 0-24%
  - Average VAT levels:
    - 8.3% in OECD countries
    - 4.6% in non-OECD high-income
    - 7.0% in all other income groups



# The Biosimilar Insulin Market

|   |  |
|---|--|
| <b>Income</b>   | <ul style="list-style-type: none"> <li>• Size of local market, most seeking new markets</li> </ul>   |
| <b>Manufacturing</b>  | <ul style="list-style-type: none"> <li>• High cost of investment, underutilised capacity</li> </ul>  |
| <b>Challenges expressed by companies &amp; current situation on approvals</b> | <ul style="list-style-type: none"> <li>• Competing with the three large MNCs on price</li> <li>• Marketing</li> <li>• Awareness of biosimilars</li> <li>• Human versus analogue biosimilars. Priority is getting EMA &amp;/or USFDA approval for analogues</li> <li>• Analogues: Abasaglar (Lilly), Semglee (Biocon/Mylan), Admelog (Sanofi) approved. Lusduna (MSD) approved but then withdrew</li> <li>• Currently no biosimilar human insulins have marketing authorisation from a stringent regulatory authority. Told Novartis/Gan&amp;Lee will apply; Julphar?</li> </ul>  |
| <b>Biosimilar regulations</b>   | <ul style="list-style-type: none"> <li>• Not all countries have regulatory procedures for approving biosimilars</li> <li>• Inconsistent regulatory requirements across national medicines regulatory authorities. Tend to adopted the European Medicines Agency (EMA) regulatory process</li> <li>• The stronger the evidence about structural, biological and formulation similarity between the biosimilar and reference, the less non-clinical and clinical data is needed for approval</li> <li>• EMA stated that clinical data will not be required for biosimilars but it doesn't appear to have been put in practice</li> </ul> |

# Estimated Cost of Production and Insulin Prices in 13 LMICs



## HUMAN INSULIN

## ANALOGUE INSULIN

# Median Prices of Originators vs Biosimilars

## Govt. Procurement Prices – biosimilars (vials)

Pakistan: 16% ↓ (regular, isophane, 30/70)

Russia, Kazan: 10% ↑ (regular)

China, Shaanxi: 11% ↓ (30/70)

China, Hubei: 14% ↓ (regular, isophane)

## Patient Prices – biosimilars (vials)

| Country       | Insulin Type | Public sector | Private Pharmacies |
|---------------|--------------|---------------|--------------------|
| Ethiopia      | Isophane     |               | 26% ↓              |
| Russia, Kazan | Isophane     | 19% ↓         | 26% ↑              |
| Brazil        | Isophane     |               | 3% ↓               |
| Pakistan      | Isophane     |               | 20% ↓              |
| Pakistan      | Glargine     |               | 28% ↓              |
| Uganda        | Glargine     |               | 17% ↓              |

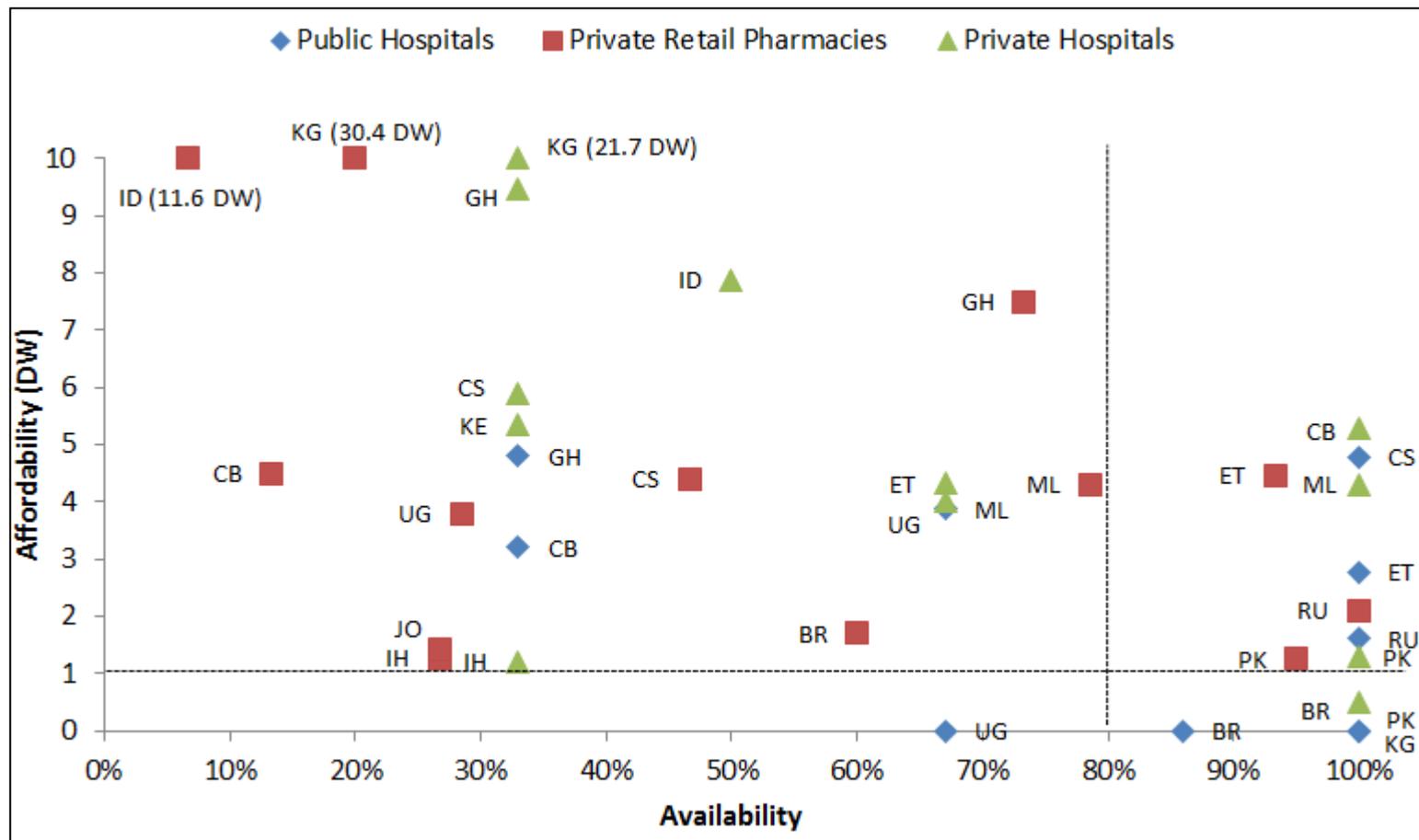
# Insulin Affordability in 13 LMICs

Number of days' wages needed for the lowest-paid unskilled government worker to purchase 10ml 100IU/ml insulin

| Sector               | HUMAN INSULIN                        |  | ANALOGUE INSULIN                     |  |
|----------------------|--------------------------------------|--|--------------------------------------|--|
|                      | Median days' wages depending on type | Range across insulin types and countries | Median days' wages depending on type | Range across insulin types and countries |
| Public               | 3.5 – 3.9                            | 0.3 - 6.8                                | 6.1 – 7.9                            | 2.8 - 17.3                               |
| Private pharmacies   | 2.2 – 4.3                            | 1.2 – 30.4                               | 6.6 – 15.6                           | 2.7 – 94.2                               |
| Private hosp/clinics | 3.7 – 5.0                            | 0.5 – 22.1                               | 6.7 – 14.3                           | 3.1 – 43.1                               |

# Affordability and Availability in LMICs: Isophane

Affordability: number of days wages needed by the lowest paid unskilled government worker to purchase 10ml isophane



← Target

# Insulin Prices in the US

The Washington Post Magazine

## Life, Death and Insulin

THE WALL STREET JOURNAL

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HEALTH

### 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 IU<sup>1</sup>
- Price rapid-acting analogue Humalog® (Eli Lilly) reduced to \$187 for uninsured in March 2019; Sanofi reduced prices for uninsured to \$99 a month
- 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

# Perceptions of People Using Insulin

**Questionnaire/interviews with 18 people with type 1, and 16 people with type 2 diabetes, in 11 countries:**

- Satisfaction with the insulin they were using
- Respondents (except the UK) struggled to pay for their insulin and/or insulin related supplies and other costs
- Issues with supply reliability and availability
- Members of diabetes associations seem to have more knowledge of types of insulin and manufactures
- Knowledge of brand name versus manufacturer
- Brand loyalty versus company loyalty in changing insulin
- Doctors have a big influence in terms of insulin selection

**“I would [have] reservations [about changing insulins] because I’m used to what I use and because I trust it. Anything else would be a risk. The origin doesn’t interest me, it’s what I’m using that’s keeping me healthy.”** Canada analogue insulin user, type 1 diabetes

**“No preference (on type of insulin). I trust what my doctors say. What they say I should do, I will do.”** Mexico analogue insulin user, type 2 diabetes

# Perceptions of Healthcare Providers

## Questionnaire/interviews with 9 key opinion leaders

- Price of insulin and barriers to access persist
- Human insulin was the main insulin prescribed in LMICs
- Prescribers did not see difference between human and analogue insulin in practice
- Majority of respondents were in favor of pens
- Price of insulin and supplies was a key factor influencing prescribing practices
- Overall issues with health systems and comprehensive diabetes care

# Summary

- \$20 billion market (and growing) yet limited competition
- Availability in outlets in LMICs is poor. Where found and not free, insulin is largely unaffordable.
- Biosimilars: inconsistent regulatory requirements, low use (limited understanding & quality perceptions), manufacturing under capacity
- Increasing use of higher-priced analogue insulins over human insulin

# Multiple issues require a range of interventions, and pilot their use in different settings

## 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

- Database: govt. procurement
- price
- Estimation of cost of production of insulin
- Addressing mark-ups in the supply chain

# In-Country Work



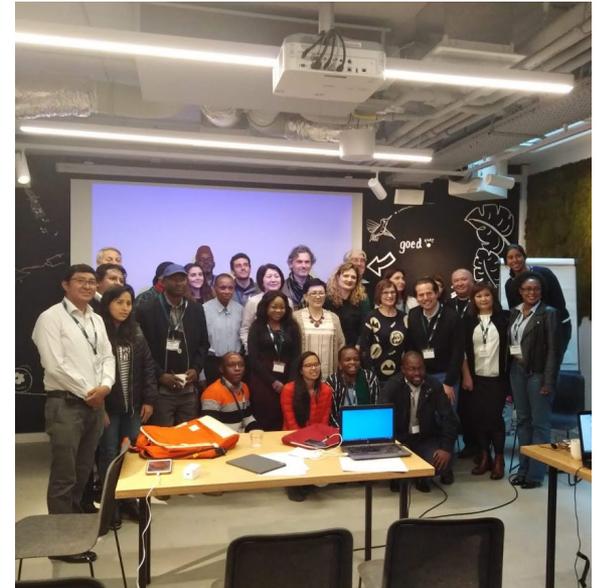
Partnering with Health Policy Analysis Center (HPAC)



Partnering with Santé Diabète



Partnering with CRONICAS



Partnering with Tanzania NCD Alliance

# Improving Access to Affordable, Quality-assured Insulin

Discussions with WHO include:

- Inclusion of biosimilar human insulin in their Prequalification Programme
- Expand WHO guidance on the evaluation of biosimilar insulins
- Support regular monitoring of insulin availability and affordability in countries
- Work with countries to regulate mark-ups in the insulin supply chain
- Support the ACCISS Study's insulin price database
- Activities around insulin centenary in 2021

Work with partners on current 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



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Addressing the Challenge and Constraints  
of Insulin Sources and Supply

# ACCISS STUDY

Learn more about ACCISS

<http://haiweb.org/what-we-do/acciss>

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