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

About Insulin

• 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 & pemixed)
  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
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

<table>
<thead>
<tr>
<th>Income</th>
<th>• Size of local market, most seeking new markets</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manufacturing</strong></td>
<td>• High cost of investment, underutilised capacity</td>
</tr>
</tbody>
</table>
| **Challenges expressed by companies** | • 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** | • Not all countries have regulatory procedures for approving biosimilars  
• Inconsistent regulatory requirements across national medicines regulatory authorities |
### Estimated Cost of Production vs. Prices

**Gotham et al. 2018; ACCISS Study 2016**

<table>
<thead>
<tr>
<th></th>
<th>Human insulin</th>
<th>Analogue Insulin</th>
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</thead>
<tbody>
<tr>
<td><strong>Cost of production</strong></td>
<td>$2.28</td>
<td>$3.69</td>
</tr>
<tr>
<td><strong>Government procurement price</strong></td>
<td>$2.24</td>
<td>$6.88</td>
</tr>
<tr>
<td><strong>Patient price public sector</strong></td>
<td>$2.16</td>
<td>$6.41</td>
</tr>
<tr>
<td><strong>Patient price private sector</strong></td>
<td>$1.67</td>
<td>$5.89</td>
</tr>
<tr>
<td><strong>Minimum</strong></td>
<td>$1.67</td>
<td>$5.89</td>
</tr>
<tr>
<td><strong>Maximum</strong></td>
<td>$50.57</td>
<td>$124.90</td>
</tr>
<tr>
<td><strong>Median</strong></td>
<td>$5.99</td>
<td>$45.03</td>
</tr>
</tbody>
</table>

**Prices per 10ml 100IU/ml (US$)**
Insulin Affordability

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

<table>
<thead>
<tr>
<th>Sector</th>
<th>HUMAN INSULIN</th>
<th>ANALOGUE INSULIN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean days’ wages</td>
<td>Mean days’ wages</td>
</tr>
<tr>
<td></td>
<td>Range day’s wages</td>
<td>Range day’s wages</td>
</tr>
<tr>
<td>Public</td>
<td>2.5</td>
<td>0.5 - 6.2</td>
</tr>
<tr>
<td></td>
<td>0.5 - 6.2</td>
<td>1.0 - 19.1</td>
</tr>
<tr>
<td>Private</td>
<td>3.5</td>
<td>0.2 - 48.9</td>
</tr>
<tr>
<td></td>
<td>0.2 - 48.9</td>
<td>0.3 - 77.9</td>
</tr>
</tbody>
</table>

ACCISS Study 2016
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

- From 2012 to 2016, US average price increased from 13 cents per IU to 25 cents per IU\(^1\)
- Price rapid-acting analogue Humalog\(^\circledast\) (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:
  o Strengthening supply systems
  o Evidence-based standard treatment guidelines
  o Improving delivery of care
  o Diabetes in UHC
  o 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  

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
- Country need estimates
- Price data (where available)
- Review on the value of insulin
- Guideline on different issues surrounding the use of insulin
- Biosimilar insulin FAQs
- Interchangeability

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

- Advocacy communications guide
- Insulin FAQs
- Infographics and more

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

http://accisstoolkit.haiweb.org