Essential Medicines for Universal Health Coverage

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#LancetEMC
#essentialmeds
Scope and process

- Prompted by the 30th anniversary of the 1985 Nairobi Conference on the Rational Use of Drugs, to ask:
  1. What progress has been achieved?
  2. What challenges remain to be addressed?
  3. Which lessons have been learned to inform future approaches?
  4. How can essential medicines policies be harnessed to promote UHC and contribute to the global sustainable development agenda?

- 3 co-chairs (Veronika Wirtz, Hans Hogerzeil, Andy Gray)
- 18 other invited Commissioners, chosen for their international expertise, in their individual capacity
Three eras of the essential medicines concept

- **First era (1970s-1990s)**
  - 1st WHO Model List of Essential Medicines (1977)
  - Alma Ata Conference (1978),
  - uptake of national EMLs and NMPs

- **Second era (1990s-2010s)**
  - growing complexity,
  - new global financing mechanisms,
  - medicines as part of health systems
  - new focus on essential medicines for children
Third era - 2010 to present – UHC demands essential medicines

**Goal 3.8** “[…] access to safe, effective, quality and affordable essential medicines and vaccines for all”

**Goal 3.b** “Support research and development of vaccines and medicines for communicable and non-communicable diseases primarily affecting developing countries….”
Five key challenges the report addresses

1. Paying for a basket of essential medicines
2. Making essential medicines affordable
3. Assuring quality and safety of essential medicines
4. Promoting quality use of medicines
5. Developing missing essential medicines

Cross-cutting -> measuring progress
Five patient examples to show how access to essential medicines affect all people

<table>
<thead>
<tr>
<th>Name</th>
<th>Age</th>
<th>Condition</th>
<th>Issue</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Priti, 41 years old,</td>
<td>41 years</td>
<td>with asthma</td>
<td>=&gt; hospitalized because of inadequate financing of medicines</td>
<td></td>
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<tr>
<td></td>
<td>old,</td>
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<td>with</td>
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<tr>
<td></td>
<td>asthma</td>
<td></td>
<td></td>
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<tr>
<td>Jomkwan, 65 years</td>
<td>65 years</td>
<td>with diabetes</td>
<td>=&gt; suffering from side-effects due to an incorrect prescription</td>
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<tr>
<td></td>
<td>old,</td>
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<td></td>
<td>with</td>
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<tr>
<td></td>
<td>diabetes</td>
<td></td>
<td></td>
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<tr>
<td>Adia, domestic helper,</td>
<td></td>
<td>with diabetes</td>
<td>=&gt; not able take insulin because the medicine being unaffordable</td>
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<td></td>
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<tr>
<td>Bina, single mother</td>
<td></td>
<td>with 3 children</td>
<td>=&gt; fails to initiate treatment as there is no adequate dosage forms</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>diagnosed with</td>
<td>developed</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>drug resistant</td>
<td></td>
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<td></td>
<td></td>
<td>TB</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adwoa, a girl aged 2</td>
<td></td>
<td>suffering from</td>
<td>=&gt; permanent harm due to substandard medication</td>
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</tr>
<tr>
<td></td>
<td>years</td>
<td>malaria</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>suffering</td>
<td></td>
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<td></td>
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<td></td>
<td>from</td>
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<td></td>
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</tr>
<tr>
<td></td>
<td>malaria</td>
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</tbody>
</table>
Key outputs of the report

• In each policy area, a series of **22 actionable recommendations**, directed to governments, national health systems, the international community, multilateral bodies, medicines regulatory authorities, the pharmaceutical industry

• A set of **24 core indicators** to measure progress in the implementation of comprehensive essential medicines policies

• **3 key cross-cutting themes** – increasing equity, strengthening institutions and promoting accountability, especially through greater transparency and independent review
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Essential Medicines for Universal Health Coverage

Section 1:
Paying for a Basket of Essential Medicines

Section Authors: Corrina Moucheraud, Veronika Wirtz, Andrew Gray, Peter Stephens, Prashant Yadav
Estimated global costs of providing a basic package of essential medicines in low- and middle-income countries

- Offers guidance in setting preliminary targets for resource mobilization,
- Helps in the development of financing strategies and overall policy dialogue,
- Illuminates the core uncertainties around costing a package of essential medicines,
- Guides future data collection, and
- Highlights preliminary opportunities for efficiency.
Important caveats and limitations

• “Lower bound” on the plausible range of overall financing required
  • excludes program, personnel, other administrative function costs
  • assumes adherence to standard treatment guidelines
  • ignores some of the current constraints in the cascade of care
• Not suitable for projecting or estimating country-level essential medicine budgets
• Not dynamic (does not account for changing epidemiology or market forces)
• Basket of medicines should be updated as new treatment options emerge
# Main results

<table>
<thead>
<tr>
<th>Total annual cost (in USD)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Full package of medicines</strong></td>
<td>$77.4 - $151.9 billion*</td>
</tr>
<tr>
<td><strong>Per capita in low- and middle-income countries</strong></td>
<td>$12.90 - $25.40 per capita*</td>
</tr>
<tr>
<td>Antiretroviral medicines for HIV/AIDS</td>
<td>$4.9 billion</td>
</tr>
<tr>
<td>Medicines for tuberculosis</td>
<td>$0.44 billion (first-line) + $0.32 billion (for MDR-TB)</td>
</tr>
<tr>
<td>Medicines for malaria</td>
<td>$1.2 billion</td>
</tr>
<tr>
<td>Medicines for diabetes</td>
<td>$12.5 billion</td>
</tr>
<tr>
<td>Medicines for cardiovascular conditions</td>
<td>$9.2 - $44.0 billion*</td>
</tr>
<tr>
<td>Medicines for respiratory conditions</td>
<td>$4.9 - $11.7 billion*</td>
</tr>
<tr>
<td>Antimicrobials</td>
<td>$15.5 - $15.6 billion*</td>
</tr>
</tbody>
</table>

* Varies by analysis scenario (i.e., data inputs to estimate quantity needed)
Current pharmaceutical expenditure

Low income countries

1 in 5 countries spent less than the minimum threshold of US $13

Lower middle income countries

Countries below the threshold:
BTN=Bhutan; LAO=Laos; GHA=Ghana; SLV=El Salvador; PNG=Papua New Guinea; STP=Sao Tome and Principe; SEN=Senegal; SLB=Solomon Islands; SDN=Sudan;

Minimum threshold of US $13
Summary

• A preliminary estimate of the global costs of providing a basic package of essential medicines in all low- and middle-income countries

• Results help initiate a policy dialogue around financing strategies and resource mobilization for essential medicines

• NOT a substitute for detailed national level costing, which is imperative for national budgeting and planning for essential medicines

• Highlights key gaps in data required for creating precise estimates for medicine costs
Recommendations

• Governments and national health systems:
  • Must provide **adequate financing** to ensure the inclusion of essential medicines in benefit packages provided by the public sector and all health insurance schemes.
  • Must implement policies that **reduce the amount of out-of-pocket spending** on medicines.
  • Must invest in the **capacity to accurately track expenditure on medicines**, especially essential medicines, in both the public and private sectors. Data should be disaggregated between prepaid and OOP expenditure, and among important key populations.

• The international community must fulfil its **human rights obligations** to support governments of low-income countries in financing a basic package of essential medicines for all, if they are unable to do so domestically.
Making Essential Medicines affordable

Andy Gray, Yot Teerawattananon, Martha Gyansa-Lutterodt, Marg Ewen, Ellen ‘t Hoen, Veronika Wirtz
Making Essential Medicines affordable

A patient’s experience
Adia has worked all her life as a domestic helper in a large city. Ten years ago she was diagnosed with type 2 diabetes, for which she has recently been prescribed insulin. A month’s supply of insulin costs the equivalent of 7 days’ salary. Additionally, for each visit she must pay for transport to the clinic while losing a day’s wages. Adia feels trapped in a vicious cycle of losing more and more of her salary to pay for her treatments.
Questions

• Why insulin?
• Which insulin?
• At what price?
• And, what makes up the final price Adia pays?
Viewing affordability through the 3 eras of the essential medicines concept

• 1970s-1990s – essential medicines as part of selective PHC; old medicines for the poorest, largely focused on infectious diseases

• 1990s-2010s – new money to tackle AIDS, TB and malaria – making the donor dollar stretch

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Essential Medicines for Universal Health Coverage
2010 to present – UHC demands essential medicines
Affordability questions everywhere, for everyone

Access to medicines—the status quo is no longer an option

Last week, the much anticipated report of the UN Secretary-General’s High-Level Panel To Medicines, Promoting innovation technologies, was sought. Its recommendations and block its release widely reported. These tensions are not new. The intellectual property (IP) system serves well where public health and rights are often on access to medicines. It is on

Essential Medicines in the United States — Why Access

Is Diminishing

Jonathan D. Alpern, M.D., John Song, M.D., M.P.H., and William M. Stauffer, M.D., M.S.P.H.

The challenge of costly drugs

Essential Medicines for Universal Health Coverage
Impact of new, often biological medicines in high-income countries

Figure 5: Percentage contribution to change in market share by type of product in middle-income and high-income countries in 2005–15
The options – rationing or *ad hoc* solutions

**Hepatitis C - rationing**

- 184 million people living with hepatitis C virus infection.
- New direct acting antivirals (DAAs) dramatically improved efficacy and safety.
- List prices high (e.g. $84 000 for a course of sofosbuvir).
- Budget impact substantial – to treat all eligible patients in the USA with DAAs would require an additional US$65 billion over the course of 5 years.

**Cancer – ad hoc**

- Failure to obtained approval from NICE for reimbursement (e.g. trastuzumab; then trastuzumab emtansine)
- UK Cancer Drug Fund – dedicated additional funding – avoiding the usual HTA process
- Financially unsustainable – replaced with the Managed Access Fund.
A lack of data on medicines affordability

- MDG Gap Task Force Report 2015 - “[a]ccess to essential medicines at affordable prices remains highly problematic, with many households squeezed out of the market due to high prices and limited availability.”

- 2015 World Health Statistics
  - only 38 (19.6%) of 194 countries had survey results generated between 2007 and 2013.
  - All were based on cross-sectional survey data.

=> SUBSTANTIAL GAP in information on TRUE consumer prices of medicines as well as availability
A comprehensive and interlinked suite of policies – well-described but poorly implemented

- Procurement interventions
- Pro-generic policies
- **Pricing interventions**
- Quality use of medicines interventions
- Trade-Related Aspects of Intellectual Property Rights (TRIPs) flexibilities
Assessing value: 
Role of HTA in making medicines more affordable

• **IMPORTANT:** Health Technology Assessment (HTA) alone cannot make essential medicines affordable.

• **Role of HTA:**
  - contribute to the evidence base for selection and reimbursement decisions related to medicines.
  - input in price negotiations over new essential medicines.

• **Preconditions for effective HTA:**
  - capacity to assess clinical evidence, consider local costs of services and inputs, and project potential budget impacts of competing options.
  - transparency and effective stakeholder engagement.
Assessing value in middle-income countries: lessons from Thailand

Assessments by the Health Intervention and Technology Assessment Program (HITAP) of Thailand have resulted in:

- **Price negotiation**: resulting in a 70% reduction in the price paid for oxaliplatin for metastatic colorectal cancer (FOLFOX regimen).
- **Off-label use**: using intravitreal bevacizumab rather than ranibizumab for the treatment of age-related macular degeneration.
- **Cost-sharing arrangement**: imiglucerase for the treatment of type 1 Gaucher disease 50% reduction for the first 5 patients per year, 100% for subsequent patients identified in the same year.
Recommendations

• Governments and health systems must create and maintain information systems for routine monitoring of data on the affordability of essential medicines, as well as price and availability, in the public and private sectors.
• Governments must implement a comprehensive set of policies to achieve affordable prices for essential medicines.
• Governments and health systems must develop national capacity to create medicines benefit packages that guide procurement and reimbursement for affordable essential medicines.
• Governments, national health systems, and the pharmaceutical industry must promote transparency by sharing health and medicines information.
Assuring the quality and safety of essential medicines
Lembit Rägo and Hans V. Hogerzeil

Health professionals like to think about patients, not about pills
Richard Horton, 2014
Prescribers and patients cannot verify the quality, safety and efficacy of a product themselves; that is an essential public function

**Risk for the patient:** Poor-quality medicines can cause serious, even fatal, harm to patients. Money spent on poor-quality medicines is wasted; additional costs are incurred to counteract harm

**Risk for society:** Poor-quality medicines reduce health outcomes, endanger public health (e.g. antimicrobial resistance) and reduce public trust in the health system
Examples of substandard quality medicines in LMICs

• 76/267 (28%) antimalarial medicines in Cameroon, Ethiopia, Ghana, Kenya, Nigeria, and Tanzania were substandard (large variations)

• 33/291 (11%) anti-tuberculosis medicines from Armenia, Azerbaijan, Belarus, Kazakhstan, Ukraine, and Uzbekistan failed; (rifampicin 28%)

• 122 350 deaths in children <5 in 39 sub-Saharan African countries by poor-quality antimalarials

• Dramatic incidents: 100 children in Panama, 230 adults in Pakistan died from wrong ingredients

• 57/66 (86%) studies on substandard and falsified medicines focus on infectious diseases
Example:
Active ingredient in misoprostol tablets in 15 LMICs

Hall PE, Tagontong N. *WHO Drug Inf* 2016; 30: 35–39
Strategic direction of the Commission’s recommendations

- Emphasis on international harmonization, regional collaboration and WHO Prequalification Programme
- Redirect activities of NMRAs to those that add value
  - Less emphasis on national sovereignty
  - Focus on targeted enforcement
- Involve other stakeholders and the general public in quality assurance, through new technologies
- Promote transparency of information, e.g. outcome of assessments and inspections
- Promote accountability, by independent assessment of the performance of NMRA’s
Five areas of opportunity:

2) **Evolve the WHO / UN Prequalification programme**

• WHO should evolve the WHO/UN Prequalification Programme, to maintain a moving focus on new essential medicines and on those with regulatory challenges, such as human insulin, biosimilars

• PQ standards, WHO Public Assessment Reports and WHO Public Inspection Reports should form the basis for regulatory convergence and mutual recognition, leading to rapid regulatory approval

• A sustainable financial base must be created to maintain its full independence from donors and manufacturers.
Five areas of opportunity:

3) Better quality assurance in procurement agencies

- Payers and procurement agencies must adopt good procurement practices with transparent quality assurance
- Quality assurance mechanisms must exist at all points in the supply chain; this requires investment
- Sharing test results and findings of inspections can avoid duplication and increase efficiency.
Five areas of opportunity:

4) Redirect NMRA activities to those that add value: enforcement

In 2015 an Instagram posting featuring Kim Kardashian promoted a morning sickness medicine to her 42 million social media followers. The US FDA ordered the manufacturer to remove the posting, as it was “false or misleading”.

By the time the decision was reached the post had received nearly half a million “likes” and 11,000 comments.
Proposed performance indicators for regulatory authorities

• Public regulatory website with regulations and approved products
• Product applications and dossiers published
• Inspections performed and reports published
• Risk-based surveys, samples tested/failed
• Pharmacovigilance reports submitted to global database (Uppsala Monitoring Centre)
• Regulation of products for export
• Absence of legal obligation of TRIPS-PLUS, e.g. patent linkage and data exclusivity
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Essential Medicines for Universal Health Coverage

Section 4: Promoting Quality Use of Medicines

Section Authors:
Vera Luiza, Dennis Ross-Degnan, Peter Stephens, Jing Sun, Anita Wagner
Overview

- Appropriate use of medicines
- Inappropriate use: Types, examples, magnitude
- A system perspective on medicines use
  - Targeted interventions to improve use
    - Prescribers and consumers
  - System-wide interventions to improve use
    - Lessons from Australia, Brazil, China
- Opportunities and recommendations
Appropriate Medicines Use = RIGHT:
Overuse

Ampigrin Infantil c/3 ampolletas
Solucion inyectable 250mg
Ampicilina/Metamizol/Guaifenesina/
Lidocaina/Clorfeniramina

Misuse

Prescribing of injections

<table>
<thead>
<tr>
<th>Year</th>
<th>% of prescriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1992</td>
<td>34</td>
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<tr>
<td>1992-94</td>
<td>60</td>
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<tr>
<td>1995-97</td>
<td>68</td>
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<td>1998-00</td>
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<td>2001-03</td>
<td>65</td>
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<tr>
<td>2004-06</td>
<td>29</td>
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<tr>
<td>2007-09</td>
<td>17</td>
</tr>
</tbody>
</table>

Underuse

Yusuf et al, Lancet, 2011

Inefficient Use

Holloway et al, TM&IH, 2013

Beran et al, Lancet Diabetes & Endocrin, 2016
Good Evidence about Effective Prescriber-Targeted Interventions

- Educational materials
- Educational meetings
- Educational outreach visits
- Opinion leaders
- Audit and feedback
- Local consensus processes
- Reminders - computer drug dosing
- Reminders - order entry
- Reminders – general
- Financial incentives
- Mass media
- Patient-mediated interventions
- Tailored interventions
- Multifaceted interventions

Based on data from CADTH, Rx for Change

Number of relevant high quality systematic reviews

- Generally effective
- Mixed or limited effects
- Generally ineffective

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Essential Medicines for Universal Health Coverage
Consumer-Targeted Interventions More Challenging

Based on data from CADTH, Rx for Change

**Information or education**
- Generally effective
- Mixed or small effects
- Generally ineffective

**Supporting behavior change**

**Communication, decision making**

**Improving care coordination**

**Reviews to prevent adverse events**

**Building skills and competencies**

**Support in care management**

**Involving consumers in systems**

Number of relevant high quality systematic reviews

Essential Medicines for Universal Health Coverage
Examples of System-Wide Interventions

• **NPS MedicineWise, Australia**
  - National, independent organization
  - Multiple interventions targeting prescribers & consumers
  - Demonstrated improved use and return on investment

• **Farmácia Popular, Brazil**
  - Government provides selected NCD medications for free
  - Both public & private pharmacies to increase access
  - Improved use and adherence

• **Improving antibiotic use, China**
  - Multiple interventions over time in hospitals
  - Performance monitoring and penalties
  - Decrease high rates of antibiotic use
<table>
<thead>
<tr>
<th>Performance measures</th>
<th>2015</th>
<th></th>
<th>2014</th>
<th></th>
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<tbody>
<tr>
<td></td>
<td>Target</td>
<td>Actual</td>
<td>Target</td>
<td>Actual</td>
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<tr>
<td>Reported PBS Savings (AU$ M)*</td>
<td>69.28</td>
<td>69.24</td>
<td>69.26</td>
<td>70.44</td>
</tr>
<tr>
<td>Reported MBS Savings (AU$ M)†</td>
<td>4.5</td>
<td>33.05</td>
<td>5.0</td>
<td>N/A</td>
</tr>
<tr>
<td>Number unique GP participants</td>
<td>14,000</td>
<td>14,447</td>
<td>14,000</td>
<td>13,129</td>
</tr>
<tr>
<td>Number consumer interactions</td>
<td>200,000</td>
<td>1,732,635</td>
<td>200,000</td>
<td>942,436</td>
</tr>
</tbody>
</table>

* The PBS savings reported for a particular year are based on the evaluation report completed during the year, based on prior year data.
† The MBS savings reported in 2015 covers savings for both 2014 and 2015.

Estimated savings to PBS of ~$AU 69.2 million in 2015
Total PBS spending on NPS of ~AU$ 9 billion in 2013-14
Total revenue in 2014-15 ~AU$ 45 million
Lessons from System-Wide Interventions

- Political will and resources
- Focus specifically on medicines use
- Engage public & private stakeholders
- Focus on factors driving behaviors
- IT systems and metrics
- Routine evidence on medicines use
But Limited Progress in Improving Use - Why?

- Recent global discourse focused on access.
- No single actor owns responsibility.
- Multiple actions needed at many levels.
- Concerted, system-focused interventions are challenging to implement.
- Success requires sustained engagement and investment.
Recommendations: System-Wide, Evidence-Based National Strategy to Improve Medicines Use

• Governments and payers should establish independent pharmaceutical analytics units to generate information to promote quality medicines use, along with other objectives.

• Pharmaceutical analytics units must collaborate with multiple stakeholders to increase engagement and accountability, and to intervene jointly on medicines use problems.

• Engaged stakeholders, informed by data, should identify and prioritize medicines use problems and contributing factors across the system, and develop and implement sustainable, long-term, multi-faceted interventions.
Section 5: Developing Missing Essential Medicines

E ‘t Hoen, B Pecoul and H Hogerzeil
Outline

• Key problems

• Lessons learned

• Towards a global R&D framework

• Conclusion

• Recommendations
Key Problems: the current innovation system

- **R&D focus on modifying existing medicines**
  Adds little therapeutic value

- **Essential medicines and diagnostics with insufficient profit potential are not developed**
  E.g. antibiotics, neglected diseases (e.g. Ebola), paediatric formulations (e.g. HIV)

- **Essential medicines abandoned for lack of commercial potential**
  E.g. Benzyl penicillin, anti-venoms for snake bites

- **New medicines are highly priced and widely patented**
  E.g. oncology, hepatitis C, MDRTB, orphan drugs

Lack of access and innovation is now a global problem - no longer a developing country
Lessons learned: R&D initiatives

Vaccine

Microbicides & preventatives

Therapeutic product

Diagnostics

HIV/AIDS  TB  Malaria  NTD  Diarrhea  Respiratory

Source: BIL & MELINDA GATES FOUNDATION  BCG
<table>
<thead>
<tr>
<th>PDPs* and partners</th>
<th>Disease</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>DNDi with Sanofi</td>
<td>Malaria</td>
<td>Artesunate-amodiaquine</td>
</tr>
<tr>
<td>DNDi with Farmanguinhos/Cipla</td>
<td>Malaria</td>
<td>Artesunate-mefloquine</td>
</tr>
<tr>
<td>DNDi with Laboratório Farmacêutico do Estado de Pernambuco (LAFEPE) Institute for OneWorld Health (iOWH)</td>
<td>American trypanosomiasis (Chagas Disease)</td>
<td>Paediatric benznidazole</td>
</tr>
<tr>
<td></td>
<td>Leishmaniasis</td>
<td>Paromomycin</td>
</tr>
<tr>
<td>MMV with Novartis</td>
<td>Malaria</td>
<td>Artemether-lumefantrine dispersible tablets</td>
</tr>
<tr>
<td>MMV with Guilin</td>
<td>Malaria</td>
<td>Injectable artesunate</td>
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<tr>
<td>MMV with Sigma-Tau</td>
<td>Malaria</td>
<td>Dihydroartemisinin-piperaquine</td>
</tr>
<tr>
<td>MMV with Shin Poong</td>
<td>Malaria</td>
<td>Pyronaridine-artesunate</td>
</tr>
<tr>
<td>MMV with Guilin</td>
<td>Paediatric malaria</td>
<td>Sulfadoxine-pyrimethamine and amodiaquine</td>
</tr>
<tr>
<td>DNDi</td>
<td>African trypanosomiasis (sleeping sickness)</td>
<td>Nifurtimox and eflornithine combination therapy</td>
</tr>
<tr>
<td>DNDi</td>
<td>Visceral leishmaniasis (East Africa)</td>
<td>Sodium stibogluconate and paromomycin combination therapy</td>
</tr>
<tr>
<td>DNDi</td>
<td>Visceral leishmaniasis (Asia)</td>
<td>Liposomal amphotericin B, miltefosine, and paromomycin combination therapy</td>
</tr>
</tbody>
</table>

*PDP: Product development partnership; DNDi: Drugs for Neglected Diseases Initiative; MMV: Medicines for Malaria Venture
Source: European Union Product Development Partnership (PDP) Coalition. 7 May 2015
Lessons learned

• New alternative incentives: push and pull
  E.g. UNITAID, GHIT Fund, Longitude Prize

• Regulatory incentives: mixed results
  PRVs, paediatric formulations

• Public funding
  Often initial R&D publically funded but final steps by for-profit companies who gain IP rights

• Patent pooling
  MPP (HIV, Hep C, TB)

• TRIPS flexibilities
  Compulsory licensing, government use, LDC waiver on patents
Costs of developing a new medicine

<table>
<thead>
<tr>
<th>Publication Year</th>
<th>R&amp;D Cost Estimate</th>
<th>Source</th>
</tr>
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<tr>
<td>1991</td>
<td>US$ 231 million <em>(expressed in 1987 dollars)</em></td>
<td>DiMasi</td>
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<tr>
<td>1993</td>
<td>US$ 140-194 million <em>(expressed in 1990 dollars)</em></td>
<td>OTA</td>
</tr>
<tr>
<td>2003</td>
<td>US$ 802 million</td>
<td>DiMasi</td>
</tr>
<tr>
<td>2012</td>
<td>US$ 1.5 billion</td>
<td>OHE</td>
</tr>
<tr>
<td>2014</td>
<td>US$ 2.5 billion</td>
<td>DiMasi</td>
</tr>
</tbody>
</table>

- 2001 TB Alliance R&D cost estimate for a new chemical entity for TB *(including costs of failure)*: US$ 76-115 million
- 2013 DNDi R&D cost estimate for a new chemical entity for a neglected tropical disease *(including costs of failure)*: US$ 100-150 million
Towards a global R&D framework

Market failure or public policy failure?

“We have to recognize that the free market, as good a servant as it is, is a bad master. We cannot take important global decisions on the basis of the free market alone.”

Nobel laureate Sir John Sulston
Towards a global R&D framework

- **Public spending – public policy**
  Permanent solution needed for essential R&D and finance new models of innovation
- **Delinking R&D costs and medicine pricing**
- **Missing Essential Medicines List**
- **Public policy in a global R&D framework**
  Objectives: innovation and access
- **TRIPS flexibilities**
- **Pooling patents**
  Essential Medicines Patent Pool
- **Pharma Industry’s special responsibilities**
  Human rights responsibilities, ATM Index
Conclusion

Some progress but:

- Current approaches are piecemeal, lack prioritization, coordination, sustainable financing and the equitable input of and access for all stakeholders
- Some under threat (e.g. TRIPS+ trade agreements)
- Some have mixed results (e.g. regulatory incentives)
- Private sector should do more to meet its responsibilities
- Missing essential medicines are a public policy failure
- Greater public leadership and new global approaches needed to ensure essential innovation and affordability
Recommendations

- Governments and WHO: international leadership to set essential R&D priorities
- Governments: lead process for a global R&D policy framework
- Creation of Essential Medicines Patent Pool
- Governments and national stakeholders: implement national action plans guaranteeing equitable access to new essential medicines
- Pharmaceutical industry: better align their R&D priorities with global health needs and develop access strategies
THE LANCET

Essential Medicines for Universal Health Coverage

Section 6:
Measuring progress to hold all stakeholders accountable

Lead authors: Veronika Wirtz, Andrew L. Gray, Hans Hogerzeil
With input from all commissioners
No common framework for accountability

- No comprehensive framework
  - Existing measuring tools not routinely used
  - Data systems fragmented
- No continuous routine update on specific indicators
- Lack of transparency
- Lack of incentives to improve measurement and reporting

“If we do not know where we are going, every road is the right one.”
An new accountability framework requires…

- Commitment from all stakeholders
- Transparency
- Independent review by multiple institutions
- Incentivise improvement and implement corrective action if needed
- National and global leadership

The Commission proposes to track progress via

24 core and 12 complementary indicators
### Indicators to measure progress on paying for a basket of essential medicines

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Total pharmaceutical expenditure (TPE) as a % of total health expenditure</td>
</tr>
<tr>
<td>2</td>
<td>Per capita TPE</td>
</tr>
<tr>
<td>3</td>
<td>Public sector expenditure on pharmaceuticals as a % of TPE</td>
</tr>
<tr>
<td>4</td>
<td><strong>Household expenditure on pharmaceuticals as a % of total household expenditure</strong></td>
</tr>
<tr>
<td>5</td>
<td>Out-of-pocket expenditure on pharmaceuticals as a percentage of TPE</td>
</tr>
</tbody>
</table>

Data should be stratified by: gender, ethnicity, education, place of residence, and wealth quintile

**Indicators with specific focus on equity**
## Indicators to measure progress on making essential medicines affordable

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>Median availability of a basket of essential medicines in the public and private sectors (%)</td>
</tr>
<tr>
<td>7</td>
<td><strong>Median consumer price ratio of a basket of essential medicines in the public and private sectors</strong></td>
</tr>
<tr>
<td>8</td>
<td>Median public sector procurement price of essential medicines as % of international reference price</td>
</tr>
<tr>
<td>9</td>
<td>Market share of multi-source medicines by volume and value in public and private sector</td>
</tr>
</tbody>
</table>

**Well established indicators but gap in routinely measuring and reporting**
**Indicators measuring progress on ensuring quality and safety of essential medicines**

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td># of national approvals of new chemical entities and generic products based on a Common Technical Document without any additional national requirements for quality, efficacy, and safety, as a percentage of total new chemical entities ad generic approvals</td>
</tr>
<tr>
<td>11</td>
<td>Current and accumulated total # of medicines included in the WHO/UN Prequalification Programme (disaggregated by unique strength and dosage and pharmaceutical classes)</td>
</tr>
<tr>
<td>12</td>
<td># of failed quality control samples of essential medicines procured as a % of total # of samples of procured products tested per year (per procurement agency)</td>
</tr>
</tbody>
</table>

New indicators which require validation
### Indicators measuring progress on ensuring quality and safety of essential medicines

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td># of pharmacovigilance reports for medicines submitted to the Uppsala Monitoring Centre per million population per year</td>
</tr>
<tr>
<td>14</td>
<td>Results of quality testing are publicly available</td>
</tr>
<tr>
<td>15</td>
<td># of core National Medicine Regulatory Agency performance indicators that are independently assessed and publicly reported</td>
</tr>
</tbody>
</table>

*Established indicators in green*  
*New indicators in blue*  

New indicators which require validation
<table>
<thead>
<tr>
<th>Indicator</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>16</strong></td>
<td>Existence of an independent national programme or institute promoting scientifically sound and cost-effective use of medicines (yes/no)</td>
</tr>
<tr>
<td><strong>17</strong></td>
<td>Stakeholder representation including civil society and patient representatives in the independent programme or institute is specifically provided for (yes/no)</td>
</tr>
<tr>
<td><strong>18</strong></td>
<td>Quality of prescribing in public and private sector</td>
</tr>
<tr>
<td><strong>19</strong></td>
<td>Adherence to national standard treatment guidelines for common conditions in public and private sectors*</td>
</tr>
<tr>
<td><strong>20</strong></td>
<td>A legally enforceable code of marketing practice is in place and implemented (yes/no)</td>
</tr>
</tbody>
</table>

**New indicators which require validation**

**Composite indicator of five individual indicators**

*Data should be stratified*
### Indicators measuring progress on developing new essential medicines

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>21</td>
<td># of licence agreements concerning essential medicines concluded through patent pooling, stratified by in-licence and out-licence</td>
</tr>
<tr>
<td>22</td>
<td># of products produced under an Essential Medicines Patent Pool licence that are authorised by at least one of the following: International Council for Harmonisation or PIC/S or WHO/UN Prequalification Programme</td>
</tr>
<tr>
<td>23</td>
<td>National laws, including patent and medicines regulation laws, contain effective provisions for the application of all Trade-Related Aspects of Intellectual Property Rights -compatible flexibilities (yes/no)</td>
</tr>
<tr>
<td>24</td>
<td>Share of the research pipeline reflecting new molecules for diseases within the scope of the ATM Index* per company</td>
</tr>
</tbody>
</table>

*ATM Index: [Access to Medicine Index](https://atmindex.org/)

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**New indicators which require validation**

**Adopted indicators**
Call for action

- to increase transparency in the pharmaceutical sector
- to create baseline measurements for assessing essential medicines policy development and implementation.
- to set appropriate targets for indicators at national level
- to share learning between countries and institutions on measuring progress to refine indicators
- to promote global leadership to set up independent accountability mechanisms
“The Commission presents this report in the strong belief that the world can get essential medicines right, promoting improved performance and equity in health systems, while supporting UHC and enabling sustainable development”
Essential Medicines for Universal Health Coverage