Essential Medicines for Universal Health Coverage

Highlights of the report

“Without essential medicines, no health system can ensure that the population it serves progressively realises its right to health. Yet essential medicines policies have received insufficient attention...”

A Commission by The Lancet
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)**
  • 1\textsuperscript{st} 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>Patient</th>
<th>Condition</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Priti, 41 yrs</td>
<td>Asthma</td>
<td>Hospitalized because of <strong>inadequate financing</strong> of medicines</td>
</tr>
<tr>
<td>Jomkwan, 65 yrs</td>
<td>Diabetes</td>
<td>Suffering from side-effects due to an incorrect prescription</td>
</tr>
<tr>
<td>Adia, domestic</td>
<td>Diabetes</td>
<td>Not able to take insulin because the medicine is <strong>unaffordable</strong></td>
</tr>
<tr>
<td>Bina, single mother with 3 children, diagnosed with drug resistant TB</td>
<td>Fails to initiate treatment as there is no adequate dosage forms developed</td>
<td></td>
</tr>
<tr>
<td>Adwoa, a girl aged 2 yrs suffering from malaria</td>
<td>Permanent harm due to substandard medication</td>
<td></td>
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</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

• **3 key cross-cutting themes** – increasing equity, strengthening institutions and promoting accountability, especially through greater transparency and independent review

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

Low income countries

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

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;
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
  • Help guide future data collection efforts and more detailed modeling in the future
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.
2010 to present – UHC demands essential medicines

Essential Medicines for Universal Health Coverage
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 on Medicines, Promoting innovation, technologies, was widely reported. These tensions are not new. The debate over how intellectual property (IP) systems serve the needs of patients and the public is well where public health and access to medicines are often at odds with commercial interests. It is not a new issue. But the report’s recommendations and block its release widely.

Essential Medicines in the United States—Why Access

The challenge of costly drugs

Essential Medicines for Universal Health Coverage

VITAL DIRECTIONS FROM THE NATIONAL ACADEMY OF MEDICINE

VIEWPOINT

IMPROVING BENEFIT DESIGN TO PROMOTE EFFECTIVE, EFFICIENT, AND AFFORDABLE CARE

Essential Medicines in the United States—Why Access

The Lancet
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 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.
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.
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.”
A 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
<table>
<thead>
<tr>
<th>Indicator (ID)</th>
<th>Description</th>
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<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>
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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
# Five dimensions of access to medicines

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<thead>
<tr>
<th>Dimension</th>
<th>Description</th>
<th>Measures (Examples)</th>
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<tbody>
<tr>
<td>Availability</td>
<td>Relationship between type/quality of medicine required and type/quality of medicine delivered</td>
<td>Ratio of type of medicines in stock at the time of the inspection and type of medicines that should be available (often expressed as percent)</td>
</tr>
<tr>
<td>Affordability</td>
<td>Ability of the user to pay for the product</td>
<td>Ratio of price and income, Percentage of household income or assets spent on medicines.</td>
</tr>
<tr>
<td>Accessibility</td>
<td>Ability of an individual to access care when needed</td>
<td>Travel time to nearest facility, Proportion of patients not being able to access a facility when needed in the last month</td>
</tr>
<tr>
<td>Acceptability (adoption)</td>
<td>The use of medicines, including appropriate prescription by providers and adherence by patients</td>
<td>Proportions of prescriptions according to local guidelines, Proportion of patients adherent to treatment over the last year</td>
</tr>
<tr>
<td>Quality of medicines</td>
<td>Medicines produced by manufacturers and authorized by the national medicines regulatory authority that meet quality specifications set by national standards (correct dose of active ingredient, dissolution time)</td>
<td>Proportion of medicines failing the quality test, Total number of medicines tested</td>
</tr>
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</table>
Proportion of countries with secondary prevention medication class on the national essential medicine list by income status

ACEI = indicates angiotensin-converting enzyme inhibitor; LIC = low-income country; MIC = middle-income country.

High-income countries were excluded.
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