

The Lancet Commission on Essential Medicines for Universal Health Coverage



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

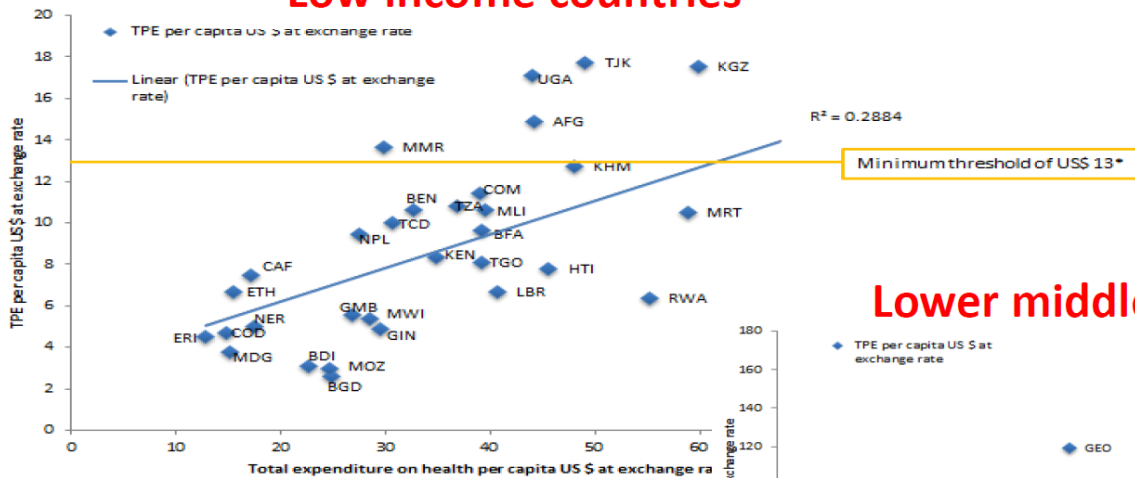


1. Paying for a basket of essential medicines

Per capita in low- and middle-income countries \$13 - \$25 per capita*

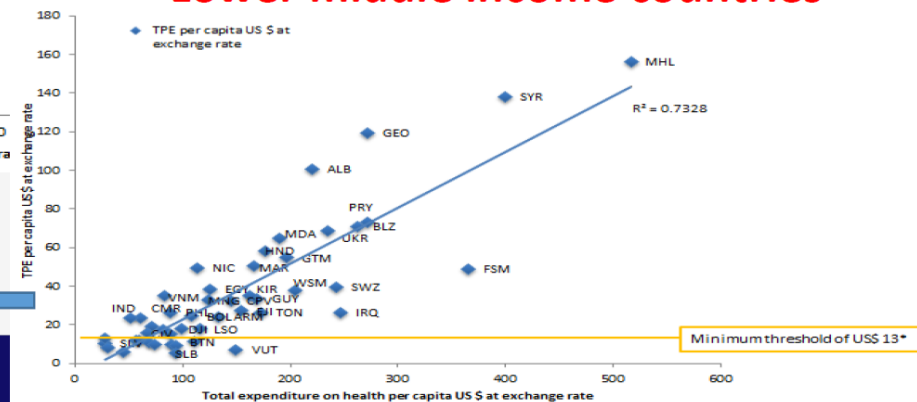
Current pharmaceutical expenditure

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;

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2. Making essential medicines affordable

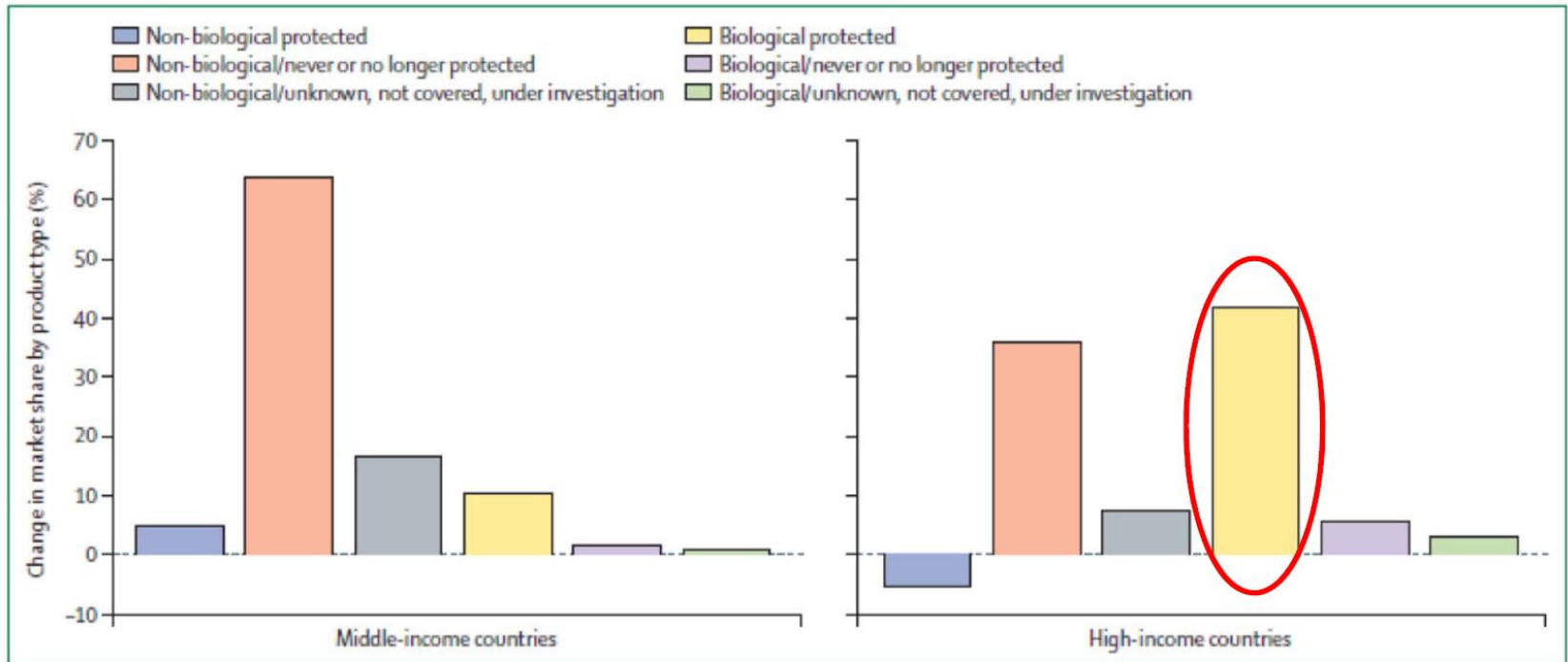


Figure 5: Percentage contribution to change in market share by type of product in middle-income and high-income countries in 2005-15



2. Making essential medicines affordable

Novartis wins approval for world's most expensive drug

US FDA gives green light for \$2.1m treatment of spinal muscular atrophy



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Hannah Kuchler in New York MAY 25, 2019



The US Food and Drug Administration on Friday approved what will be the most expensive drug in the world, a gene therapy from Novartis that treats

THE NUMBER ONE Prescription drug

The 10 most expensive prescription drugs in the U.S.



DRUG	CONDITION TREATED	PRICE PER MONTH
1. Sovaldi	Hepatitis C	\$81,000
2. Harvoni	Hepatitis C	\$79,200
3. Cinryze	Hereditary Angioedema	\$72,100
4. Daklinza	Hepatitis C	\$54,300
5. HP Acthar	Multiple Sclerosis	\$51,600
6. Olysio	Hepatitis C	\$44,800
7. Orkambi	Cystic fibrosis	\$44,200
8. Cuprimine	Wilson's disease	\$39,800
9. Firazyr	Hereditary Angioedema	\$35,800
10. Viekira Pak	Hepatitis C	\$34,600

Source: GoodRx

Top drugs by category in the U.S.

MOST EXPENSIVE OVERALL DRUG	MOST-FILLED DRUG	BEST-SELLING DRUG	MOST-PRESCRIBED DRUG
Sovaldi Treats Hepatitis C	Vicodin Painkiller	Humira Reduces inflammation	Synthroid Treats hypothyroidism
			

Source: Medscape



2. Making essential medicines affordable

- Procurement interventions
- Pro-generic policies
- Pricing interventions
- Quality use of medicines interventions
- Trade-Related Aspects of Intellectual Property Rights (TRIPs) flexibilities

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.

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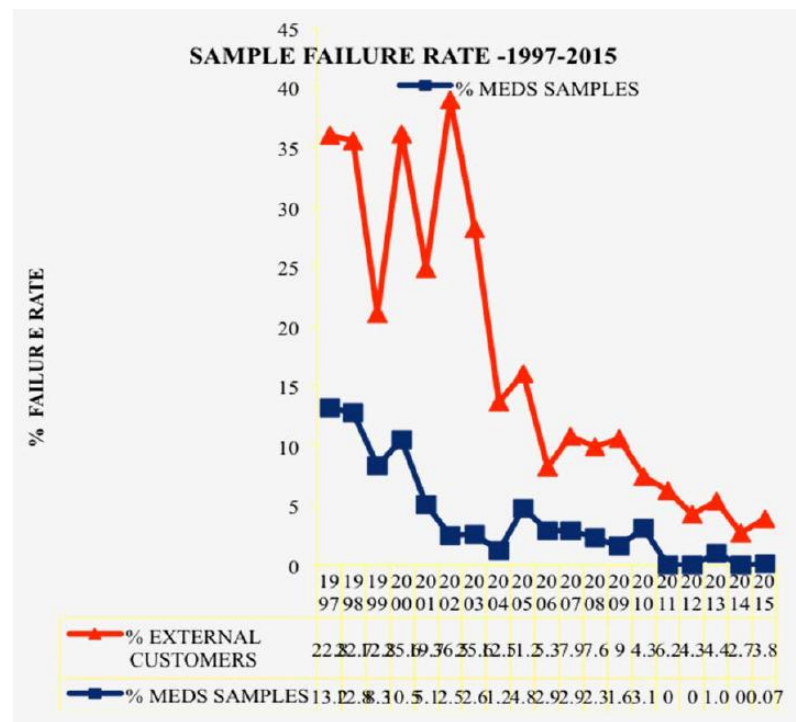
Essential Medicines for Universal Health Coverage



3. Assuring quality and safety of essential medicines

“Prescribers and patients cannot verify the quality, safety and efficacy of a product themselves; that is an essential public function”

- Emphasis on international harmonization, regional collaboration and WHO Prequalification Programme
- Better quality assurance in procurement agencies
- Redirect activities of FDA to those that add value
 - Less emphasis on national sovereignty*
 - Focus on targeted enforcement (social media)*
- Involve other stakeholders and the general public in quality assurance, through new technologies
- Promote transparency of information
- Promote accountability, by independent assessment of the performance of FDAs



4. Promoting quality use of medicines

Insulin analogue

VS

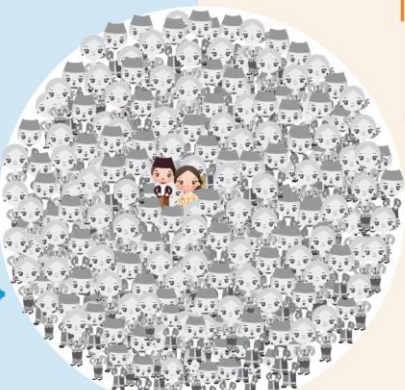
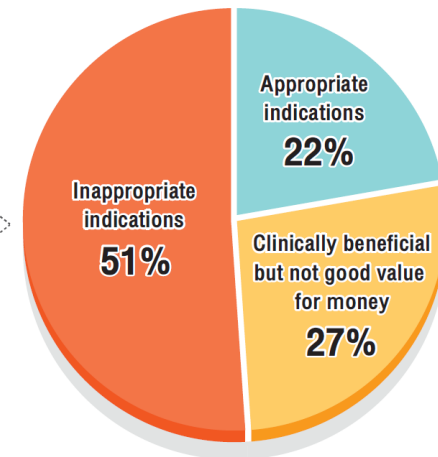
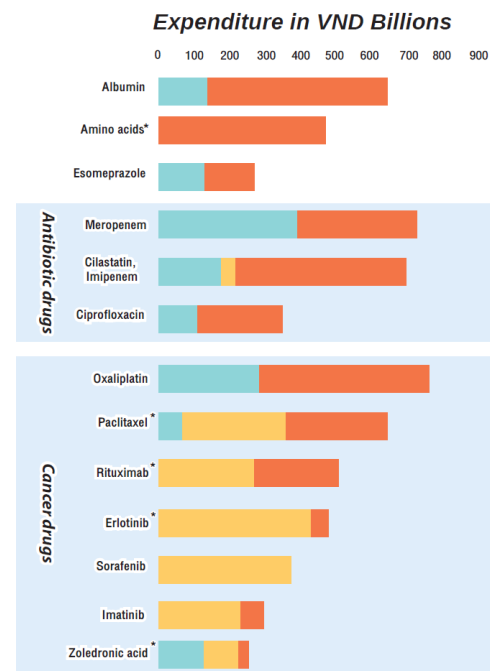
Human insulin

99.5% of diabetics in Indonesia that require insulin treated with insulin analogue

Offers few clinical advantages over human insulin

Almost no use of human insulin in Indonesian patients although many guidelines recommend it as first line treatment

Average price of human insulin is 2-4 times more expensive than neighboring Thailand

*Include indications that were found to be inappropriate or could not be verified as being appropriate.



4. Promoting quality use of medicines

- Recent global discourse focused on access.

“Undertreatment improves but overtreatment does not”

- 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.



4. Promoting quality use of medicines

- 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**.



5. Developing missing essential medicines

The current problems

- **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



5. Developing missing essential medicines

The current effort

- **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



“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”

The Lancet Commissions

Essential medicines for universal health coverage

Deviakaj Wertz*, Nans Vongpradit†, Anshul Garg†, Maywendyefi Lemelir‡, R. Jayachandran, Margaret A. Eaton, Martha A. Gyau, Githinji Karanja, Virendra Kumar, Rogan M. Mhambiro, Arlene Moller, Corinna Muenchmann, Elm and Poojai, Lomita Rago, Anish Roshanika, Devraj Sankaraguru, Pooja Singhgupta, Rick Swartzman, Yoon-Jin Yoo, Anand Wilson, Prakash Sharma, Michael K. S. Subissi

Executive summary

Essential medicines satisfy the priority health-care needs of the population. Essential medicines policies are crucial to promoting health and achieving sustainable development. Sustainable Development Goal 3.8 specifically emphasises the importance of “access to safe, effective, quality and affordable essential medicines and vaccines for all” as a central component of Universal Health Coverage (UHC) and Sustainable Development Goal 3.6 emphasises the need to “strengthen medicines to address persistent resistance”.

The recognition of the importance of essential medicines is not new. At the 1985 Nairobi Conference on the Rational Use of Drugs, government representatives and other stakeholders proposed a comprehensive set of essential medicines policies. 30 years later, The Lancet’s Commission on Essential Medicines Policies convened to explore these questions: what progress has been achieved? What challenges remain to be addressed? Which lessons have been learned to inform future approaches? And how can essential medicines policies be harmonised to promote UHC and contribute to the global sustainable development agenda? This report addresses these questions, with the intent to reposition essential medicines policies as the global development agenda.

The Commission identified five areas that are crucial to essential medicines policies: paying for a basket of essential medicines, making essential medicines affordable, ensuring the quality and safety of medicines, promoting quality use of medicines, and developing robust essential medicines. The Commission located essential medicines policies within the context of current global debates about balancing trade and intellectual property policies with human rights, ensuring health security, strengthening people-centred health systems, and advancing access to essential technologies, in all policy areas, particular attention was paid to furthering equity in access, strengthening relevant institutions, and creating accountability for each policy area. The Commission made actionable recommendations, thereby reaffirming essential medicines policies as a central pillar of the global health and development agenda.

Paying for a basket of essential medicines to promote sustainable access for all

Globally, a quarter of all health expenditure is on medicines. In many countries, the main source of financing for medicines is direct payment by the individual and households—the source is both highly

inequitable and inefficient, and its reduction is a key target for UHC. Furthermore, the Commission found that the available data on pharmaceutical expenditure in many countries lack sufficient detail on the types of medicines procured or sold, public and private sector spending, and the degree of access by key population subgroups.

For this report, the Commission developed a new model-based global estimate of the total financing that would be needed to achieve universal access to a basic package of essential medicines in low-income and middle-income countries (LMICs). A costing model was developed on the basis of disease prevalence, current or projected consumption of medicines, and international reference prices. Using two consumption scenarios, the Commission estimated that between US\$77.4 and US\$1.9 billion (or \$13 to \$15 per capita) is required to finance a basic package of 201 essential medicines (978 dosage forms) in all LMICs. Yet in 2010, the majority of low-income countries (LICs) and 13 out of 47 middle-income countries, spent less than \$1 per capita on pharmaceuticals. Thus, the Commission confirmed that many people worldwide do not have access to even a limited basket of essential medicines. Countries should adapt the Commission’s model to their national contexts to create a locally relevant estimate as a benchmark for measuring performance on essential medicines. The Commission’s recommendations on financing of essential medicines are:

- Governments and national health systems must provide adequate financing to ensure inclusion of essential medicines in the benefit packages provided to the public sector and all health insurance schemes.
- Governments and national health systems must implement policies that reduce the amount of out-of-pocket spending on medicines.
- The international community must fulfil its human rights obligations to support governments of LICs in financing a basic package of essential medicines for all, if they are unable to do so domestically.
- Governments and national health systems must invest in the capacity to accurately track expenditure on medicines, especially essential medicines, in both the public and private sectors, disaggregated between prepaid and non-prepaid expenditures, and among important key populations.

Making essential medicines affordable is necessary to achieve equity in access
The affordability of essential medicines is a core challenge for any health system working to achieve UHC.

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