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Essential Medicines for Universal Health Coverage

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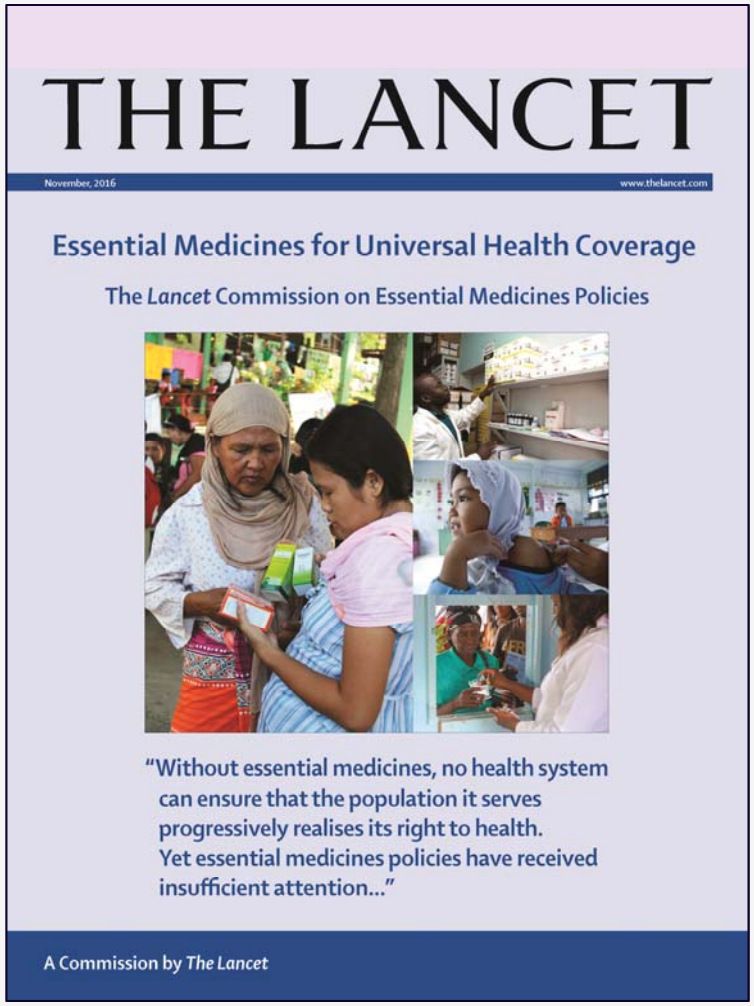


Scope and process

- 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

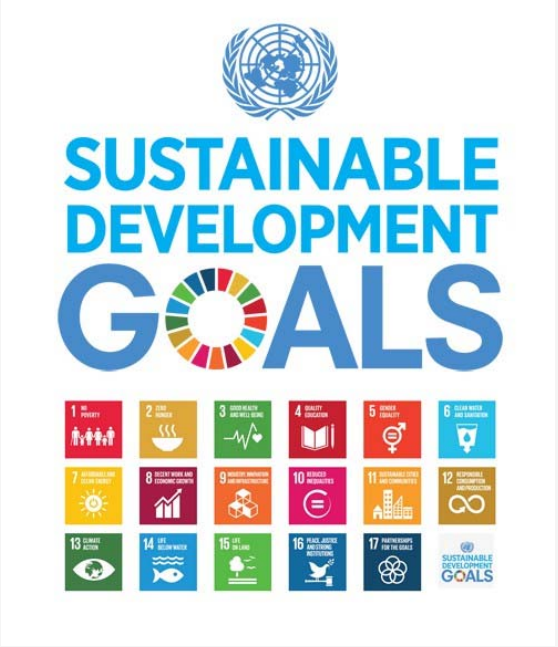
- **First era (1970s-1990s)**
  - 1st WHO Model List of Essential Medicines (1977)
  - Alma Ata Conference (1978),
  - uptake of national EMLs and NMPs

- **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

Priti, 41 years old, with asthma => hospitalized because of ***inadequate financing*** of medicines		**Jomkwan, 65 years old, with diabetes** => suffering from side-effects due to an ***incorrect prescription***
Adia, domestic helper, with diabetes => not able take insulin because the medicine being ***unaffordable***	**Bina, single mother with 3 children, diagnosed with drug resistant TB** => fails to initiate treatment as there is ***no adequate dosage forms developed***	**Adwoa, a girl aged 2 years suffering from malaria** => permanent harm due to ***substandard medication***

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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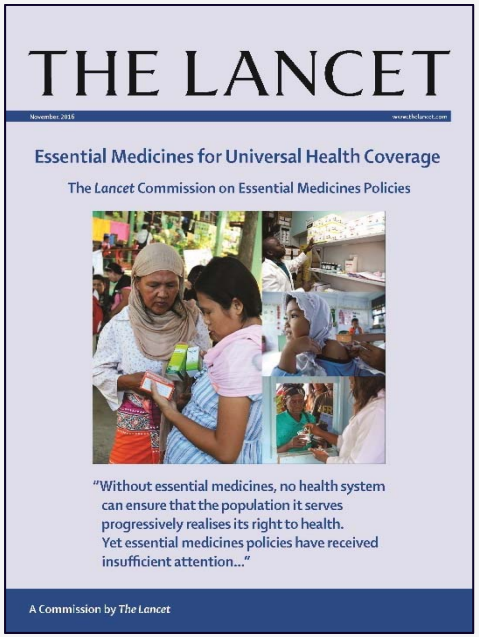
Essential Medicines for Universal Health Coverage

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

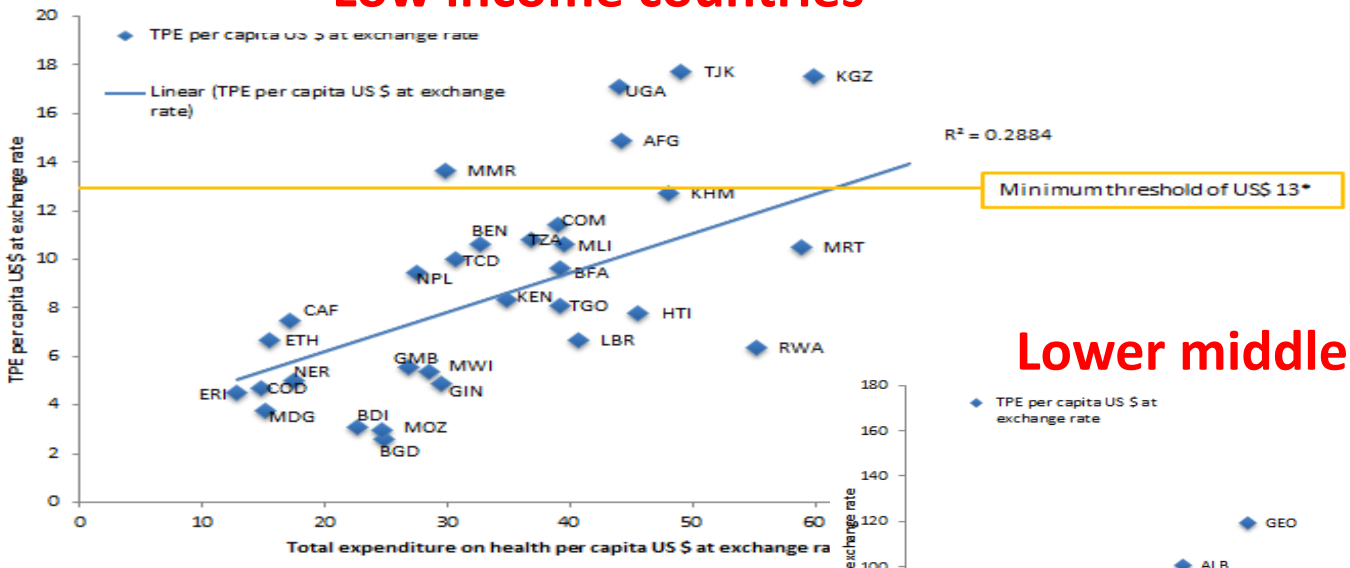
Main results

	Total annual cost (in USD)
Full package of medicines	$77.4 - $151.9 billion*
Per capita in low- and middle-income countries	$12.90 - $25.40 per capita*
Antiretroviral medicines for HIV/AIDS	$4.9 billion
Medicines for tuberculosis	$0.44 billion (first-line) + $0.32 billion (for MDR-TB)
Medicines for malaria	$1.2 billion
Medicines for diabetes	$12.5 billion
Medicines for cardiovascular conditions	$9.2 - $44.0 billion*
Medicines for respiratory conditions	$4.9 - $11. 7 billion*
Antimicrobials	$15.5 - $15.6 billion*

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

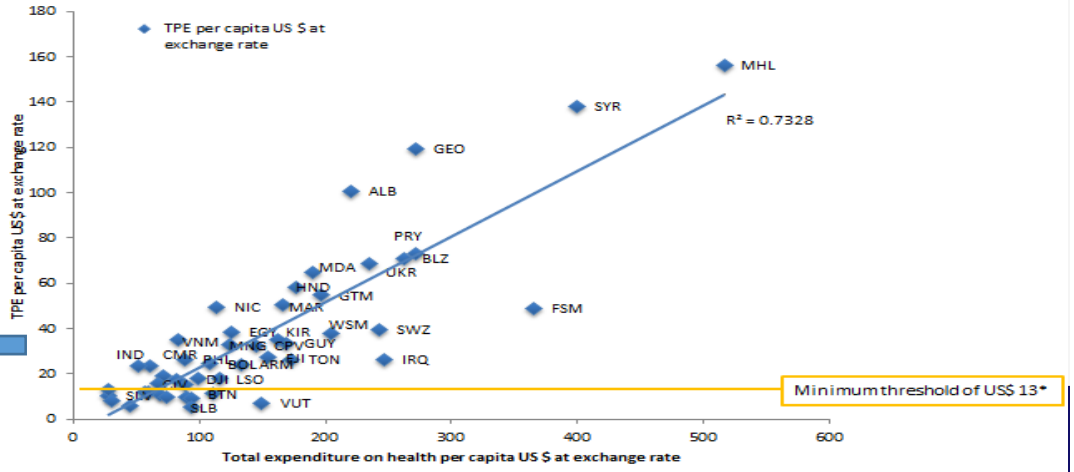
Current pharmaceutical expenditure

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;

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.

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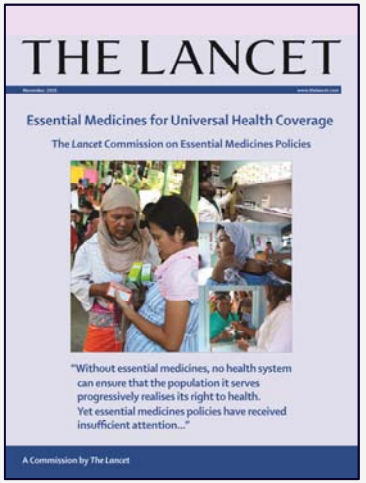


Making Essential Medicines affordable

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

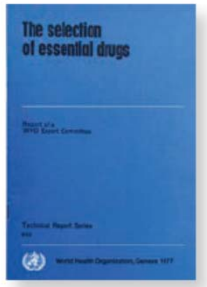
- Why insulin?
- Which insulin?
- At what price?
- And, what makes up the final price Adia pays?

Viewing affordability through the 3 eras of the essential medicines concept

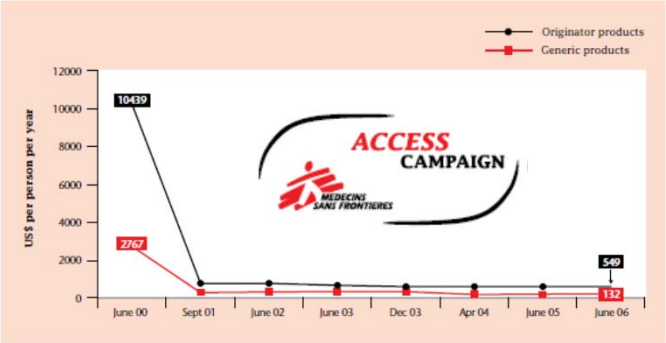
- 1970s-1990s – essential medicines as part of selective PHC; old medicines for the poorest, largely focused on infectious diseases
- 1990s-2010s – new money to tackle AIDS, TB and malaria – making the donor dollar stretch

1977

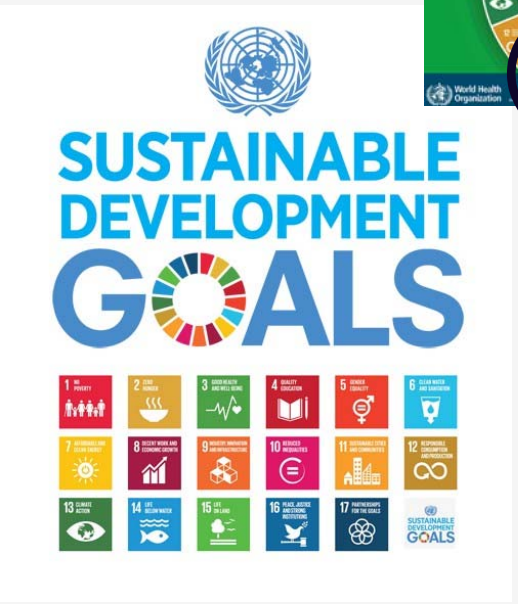
The first Essential Medicines List is published. This core list outlines the medicines that a basic health system needs. Each medicine is selected based on evidence for its safety, effectiveness and value for money.



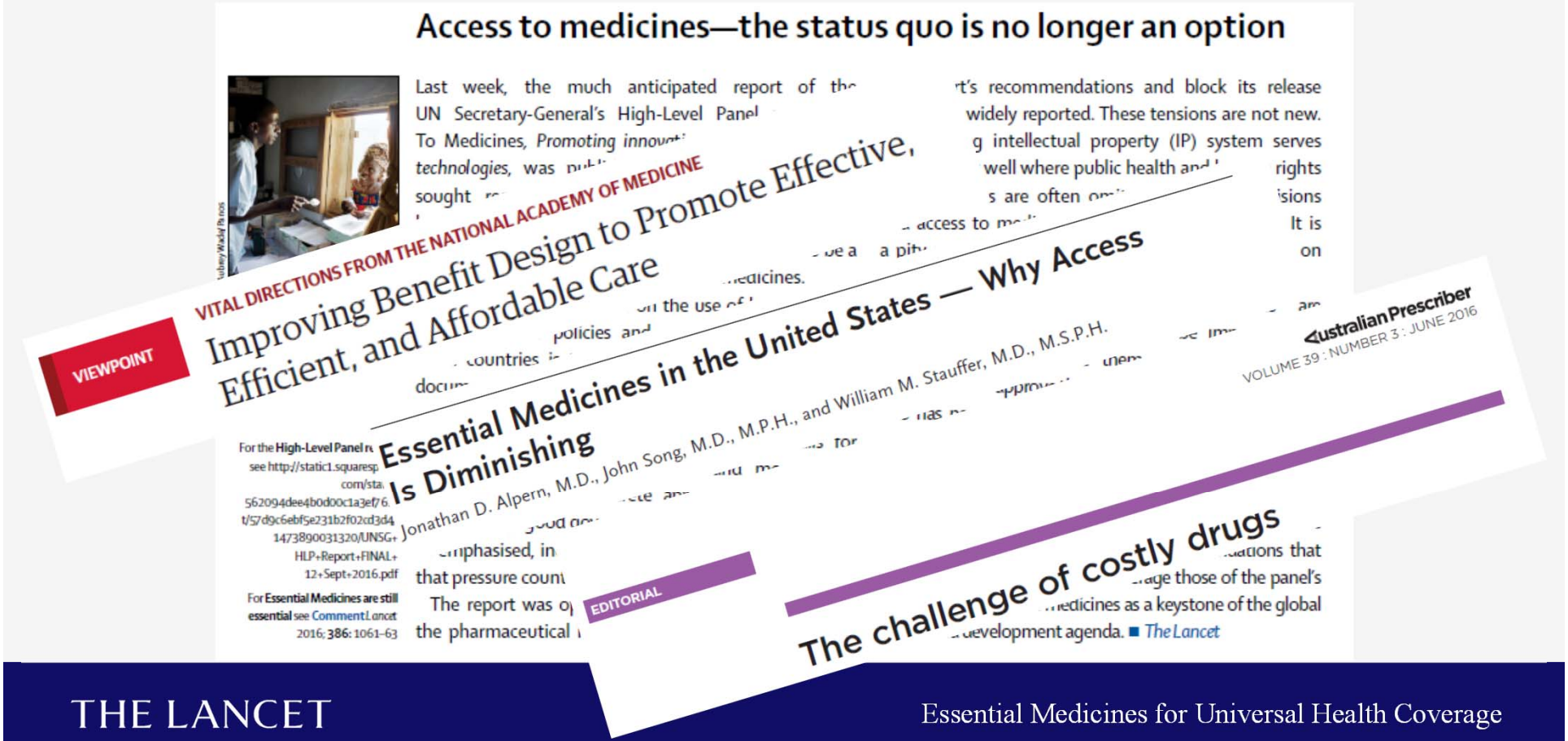
GRAPH 1: GENERIC COMPETITION AS A CATALYST FOR PRICE REDUCTION FOR A FIRST-LINE REGIMEN



2010 to present – UHC demands essential medicines



Affordability questions everywhere, for everyone



Impact of new, often biological medicines in high-income countries

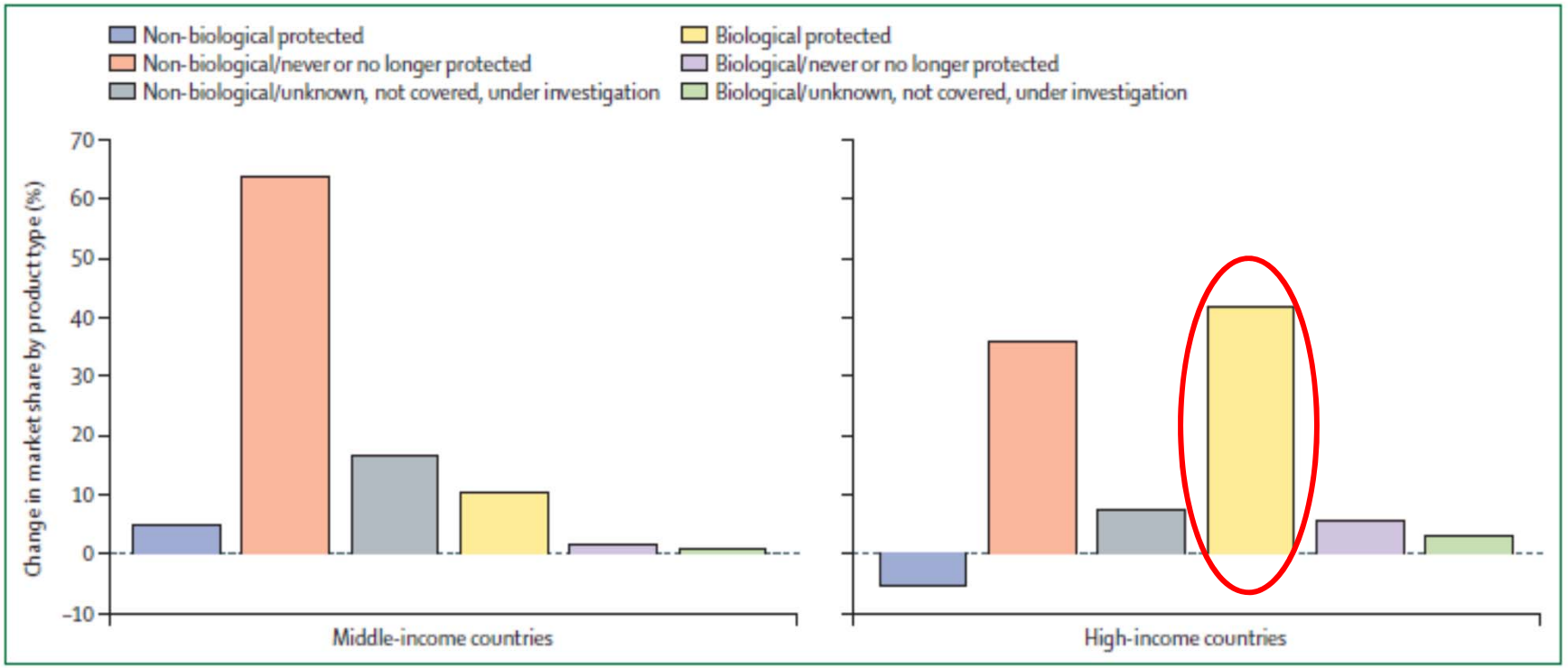


Figure 5: Percentage contribution to change in market share by type of product in middle-income and high-income countries in 2005–15

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

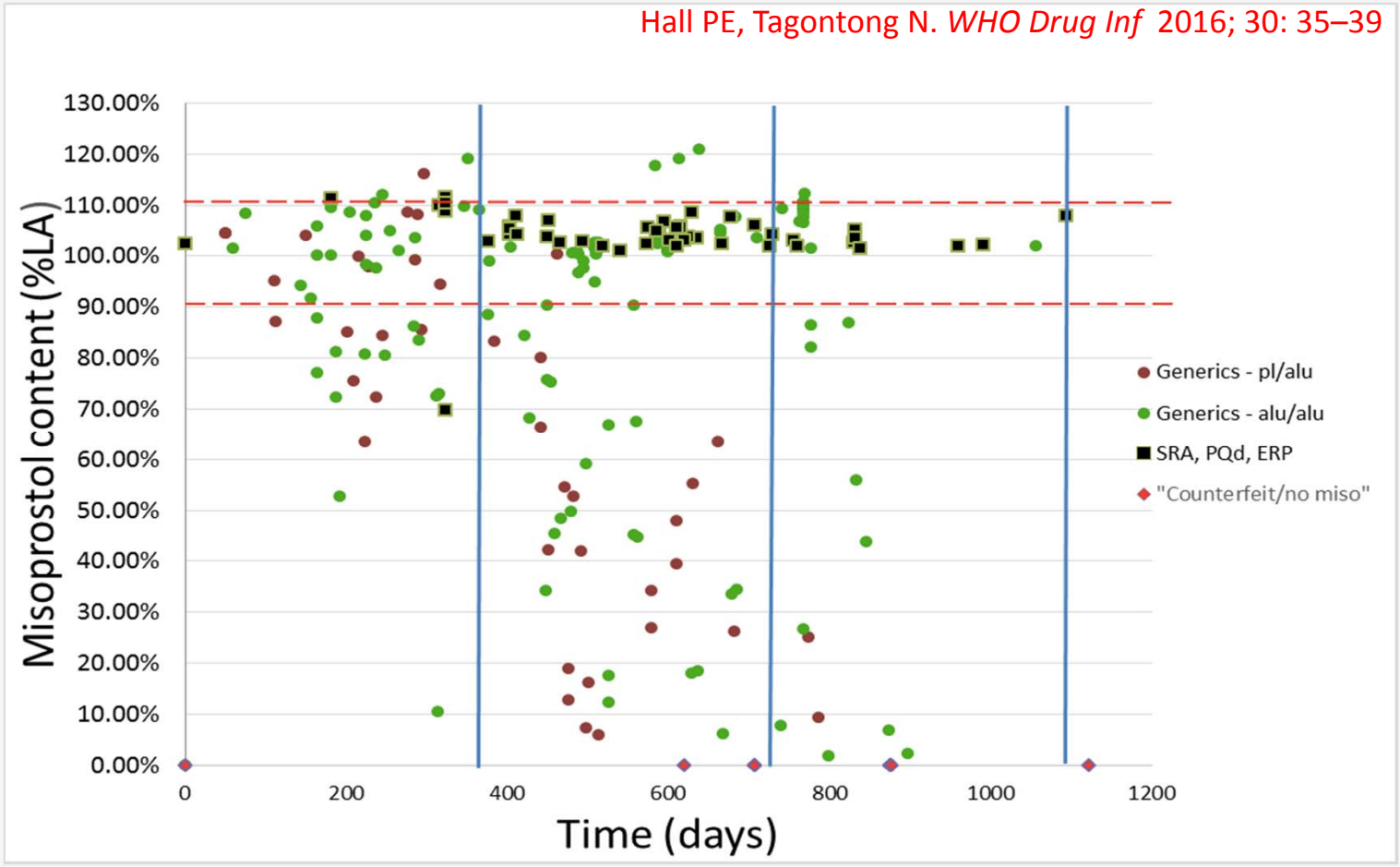
Examples of substandard quality medicines in LMICs

- 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:

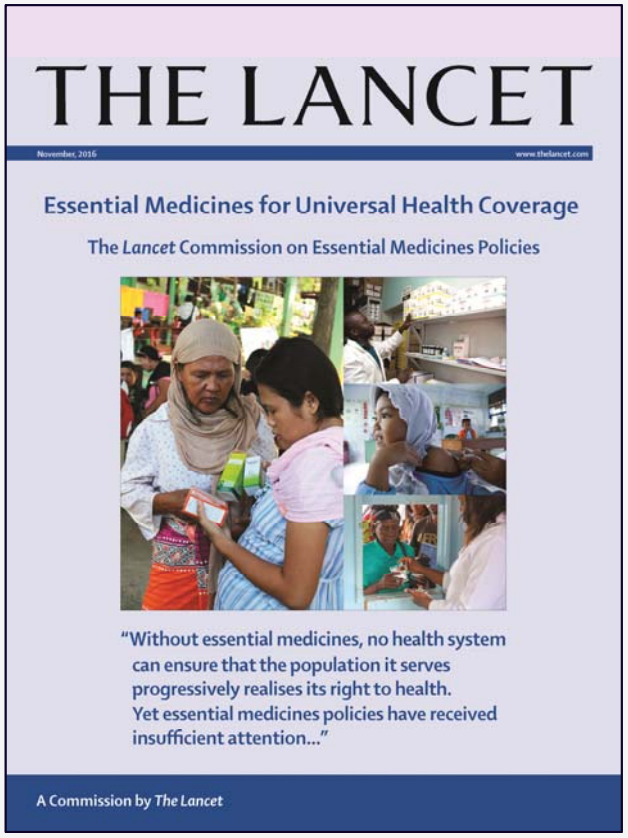
Active ingredient in misoprostol tablets in 15 LMICs

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:

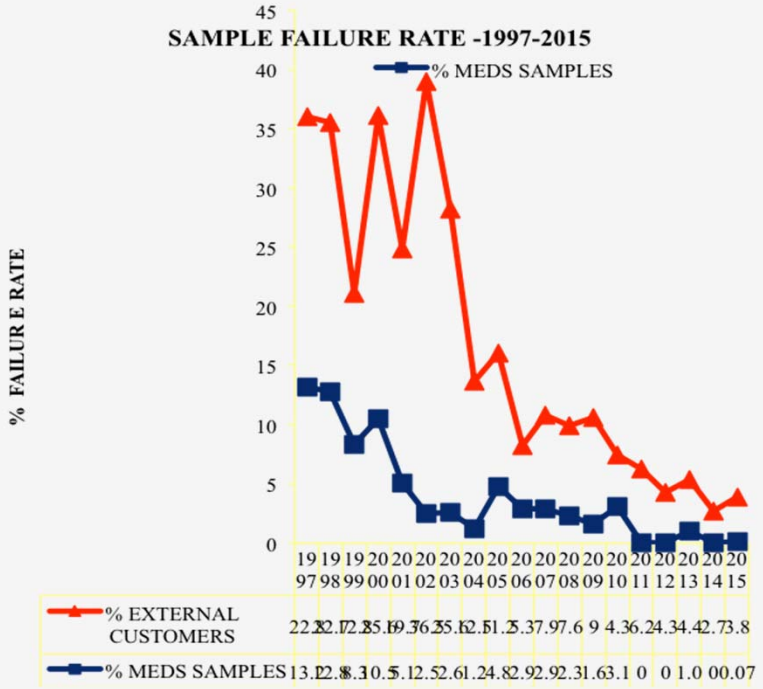
2) Evolve the WHO / UN Prequalification programme

- 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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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

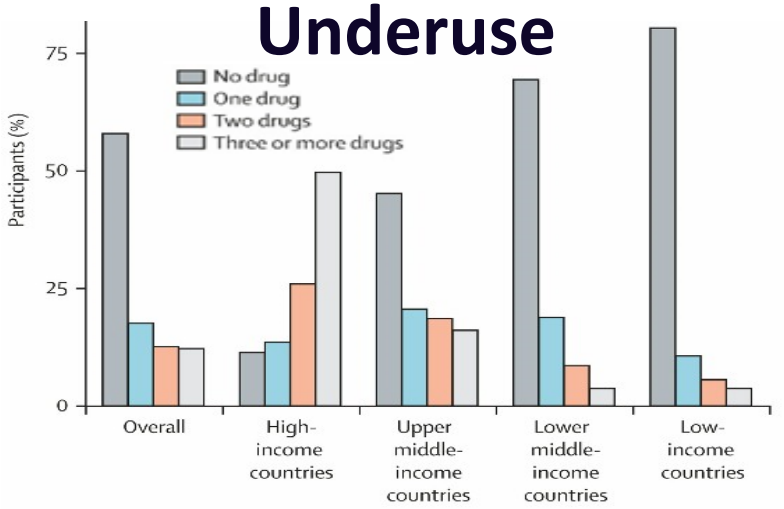
Appropriate Medicines Use =

RIGHT:

Overuse

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

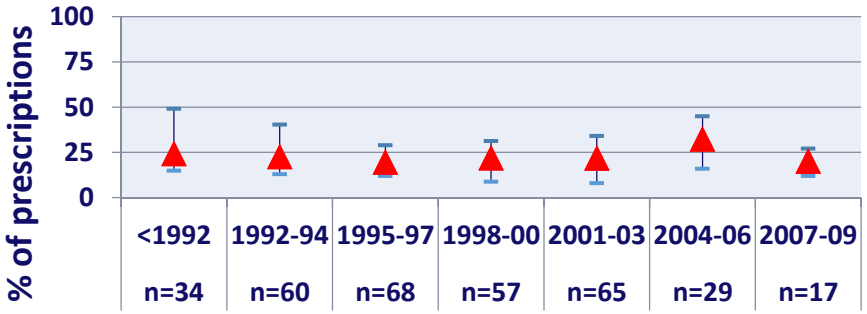
Underuse



Yusuf et al, Lancet, 2011

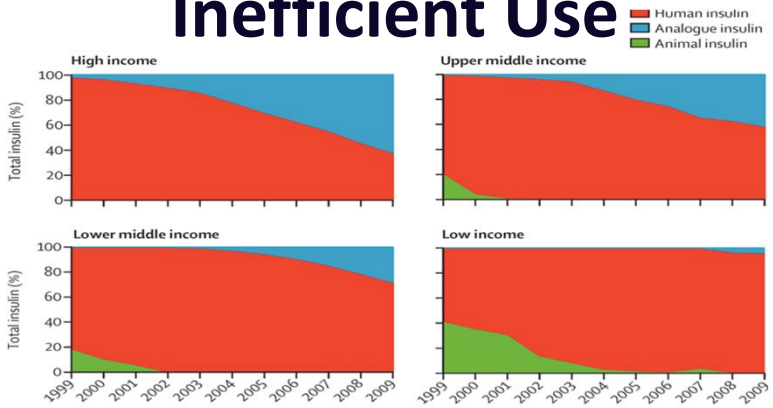
Misuse

Prescribing of injections



Holloway et al, TM&IH, 2013

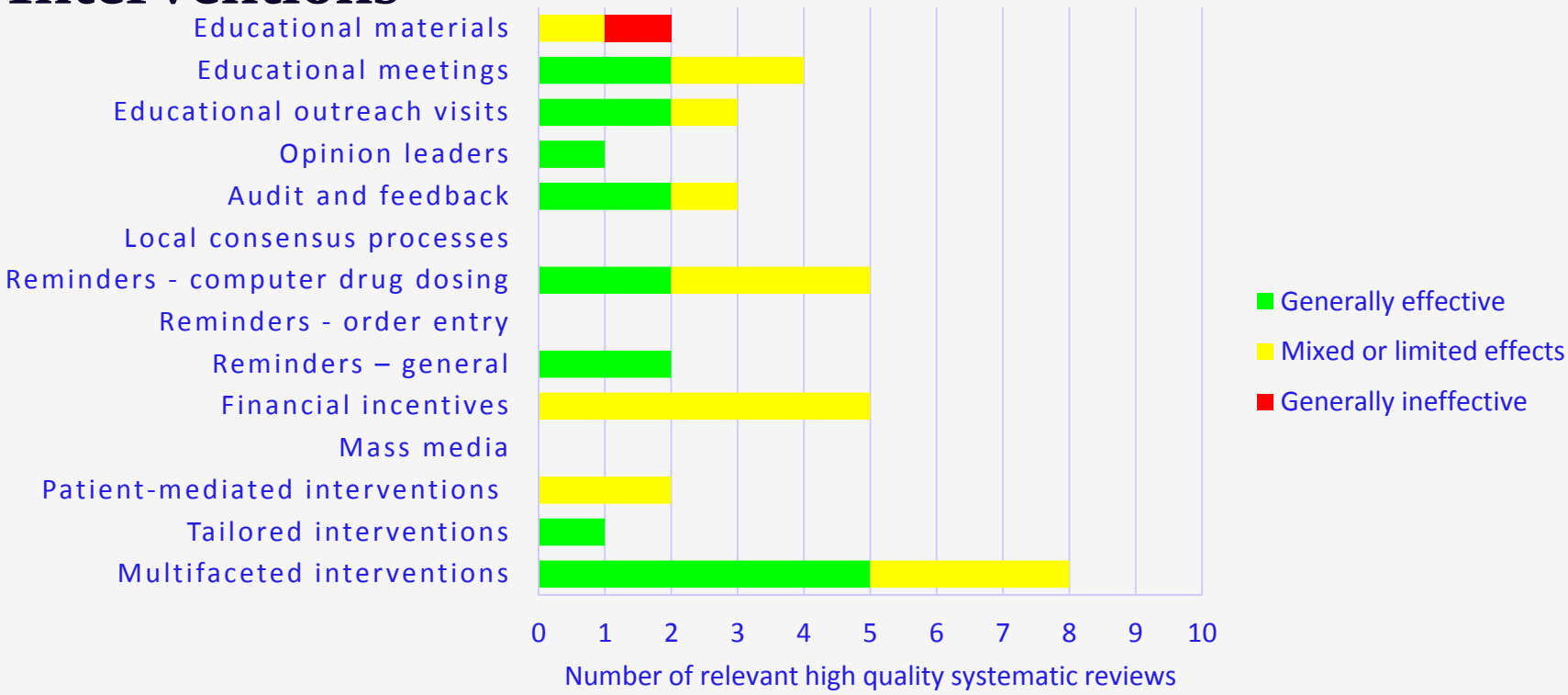
Inefficient Use



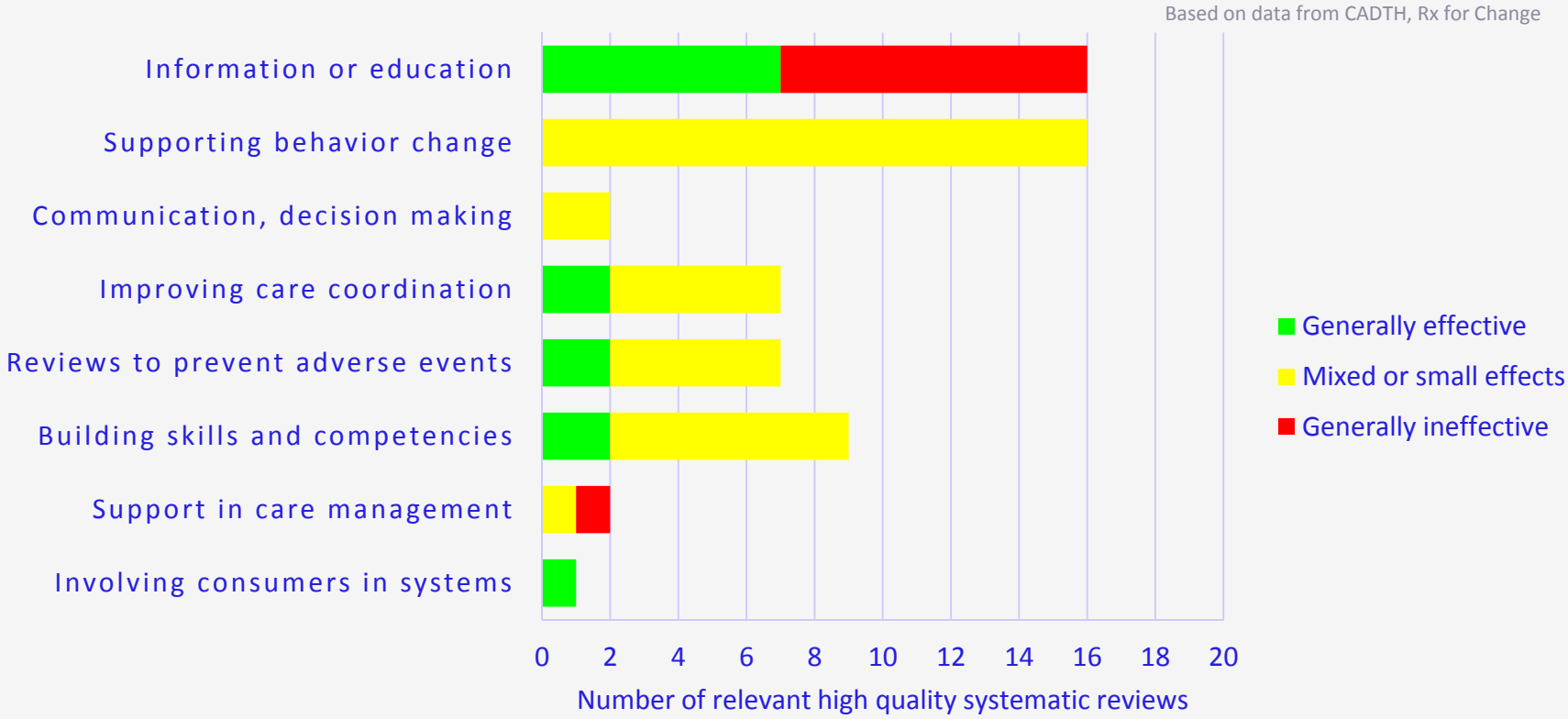
Beran et al, Lancet Diabetes & Endocrin, 2016

Good Evidence about Effective Prescriber-Targeted Interventions

Based on data from CADTH, Rx for Change



Consumer-Targeted Interventions More Challenging



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

NPS MEDICINEWISE

Performance measures	2015		2014	
	Target	**Actual**	**Target**	**Actual**
Reported PBS Savings (AU$ M)*	69.28	69.24	69.26	70.44
Reported MBS Savings (AU$ M)†	4.5	33.05	5.0	N/A
Number unique GP participants	14,000	14,447	14,000	13,129
Number consumer interactions	200,000	1,732,635	200,000	942,436

* 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

NPS MedicineWise. Annual Report 2015

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

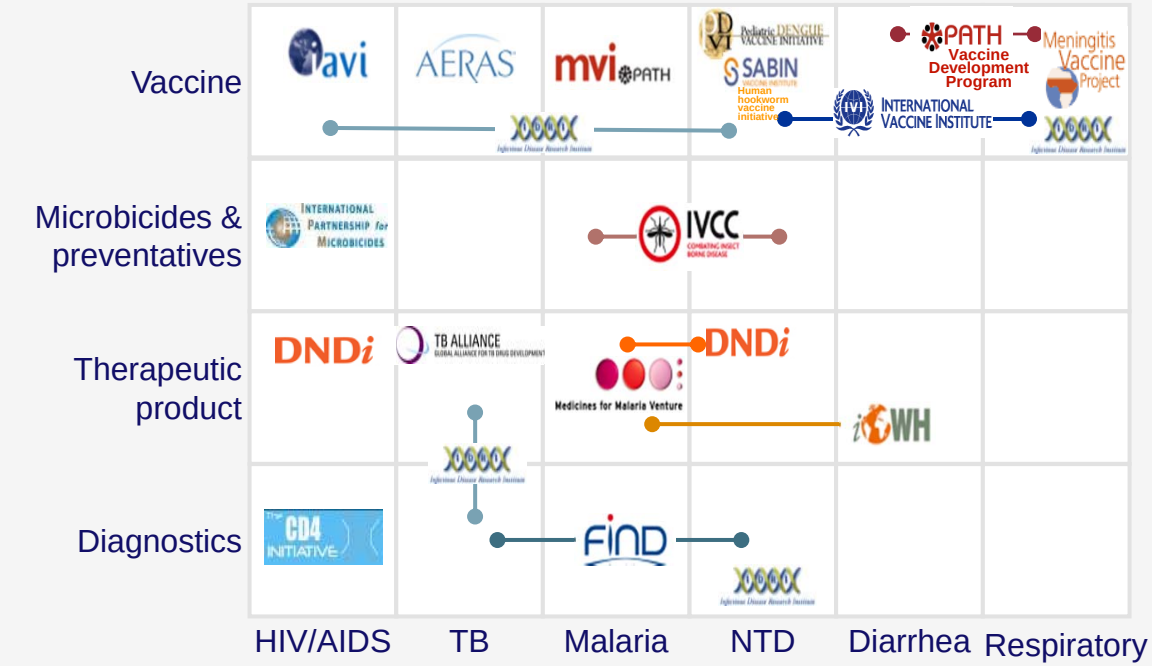
- **Essential medicines and diagnostics with insufficient profit potential are not developed**
  E.g. antibiotics, neglected diseases (e.g. Ebola), paediatric formulations (e.g. HIV)

- **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



Source: BILL & MELINDA GATES foundation BCG

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

*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

Publication Year	R&D Cost Estimate	Source
1991	**US$ 231 million** *(expressed in 1987 dollars)*	DiMasi
1993	**US$ 140-194 million** *(expressed in 1990 dollars)*	OTA
2003	**US$ 802 million**	DiMasi
2012	**US$ 1.5 billion**	OHE
2014	**US$ 2.5 billion**	DiMasi

- 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

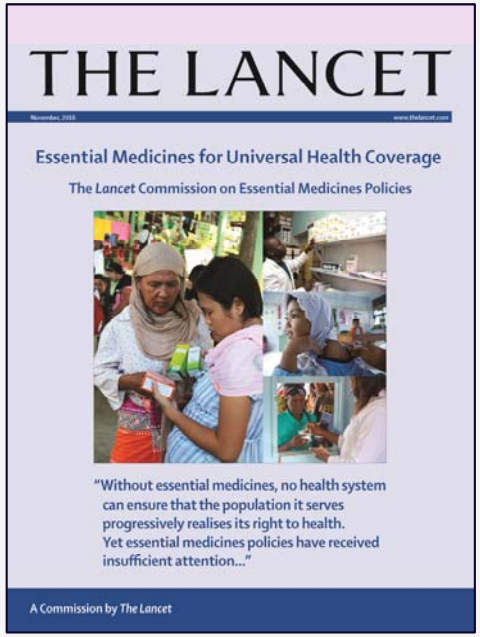
Towards a global R&D framework

- **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

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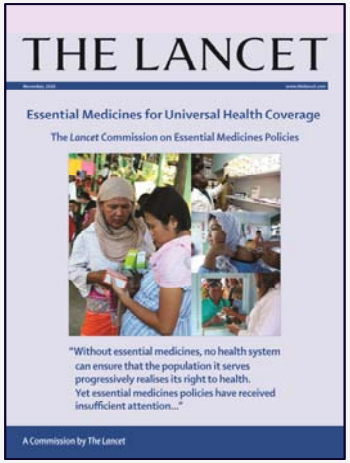
Essential Medicines for
Universal Health Coverage



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

1	Total pharmaceutical expenditure (TPE) as a % of total health expenditure
2	Per capita TPE
3	Public sector expenditure on pharmaceuticals as a % of TPE
4	**Household expenditure on pharmaceuticals as a % of total household expenditure**
5	Out-of-pocket expenditure on pharmaceuticals as a percentage of TPE

Indicators with specific focus on equity

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

Indicators to measure progress on making essential medicines affordable	
6	Median availability of a basket of essential medicines in the public and private sectors (%)
7	**Median consumer price ratio of a basket of essential medicines in the public and private sectors**
8	Median public sector procurement price of essential medicines as % of international reference price
9	Market share of multi-source medicines by volume and value in public and private sector

Well established indicators but gap in routinely measuring and reporting

Indicators measuring progress on ensuring quality and safety of essential medicines

10	**# 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**
11	Current and accumulated total # of medicines included in the WHO/UN Prequalification Programme (disaggregated by unique strength and dosage and pharmaceutical classes)
12	# of failed quality control samples of essential medicines procured as a % of total # of samples of procured products tested per year (per procurement agency)

New indicators which require validation

(cont.) Indicators measuring progress on ensuring quality and safety of essential medicines

13	# of pharmacovigilance reports for medicines submitted to the Uppsala Monitoring Centre per million population per year
14	**Results of quality testing are publicly available**
15	**# of core National Medicine Regulatory Agency performance indicators that are independently assessed and publicly reported**

New indicators which require validation

Established indicators in green

New indicators in blue

	Indicators measuring progress on promoting quality use of medicines
16	Existence of an independent national programme or institute promoting scientifically sound and cost-effective use of medicines (yes/no)
17	Stakeholder representation including civil society and patient representatives in the independent programme or institute is specifically provided for (yes/no)
18	**Quality of prescribing in public and private sector**
19	Adherence to national standard treatment guidelines for common conditions in public and private sectors*
20	A legally enforceable code of marketing practice is in place and implemented (yes/no)

New indicators which require validation

Composite indicator of five individual indicators

*Data should be stratified

	Indicators measuring progress on **developing new essential medicines**
21	# of licence agreements concerning essential medicines concluded through patent pooling, stratified by in-licence and out-licence
22	# 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
23	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)
24	**Share of the research pipeline reflecting new molecules for diseases within the scope of the ATM Index* per company**

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"

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Essential Medicines for Universal Health Coverage