The Lancet: Monthly cost of $1-2 per person could ensure access to basic package of 201 essential medicines

Strong global and national leadership is needed as lack of access to essential medicines threatens progress towards universal health coverage.

The cost of providing a basic set of 201 essential medicines to all people in low- and middle-income countries could be as little as US$1-2 per person per month (US$13-25 per person per year), according to the first analysis of the cost of providing a basket of essential medicines by ***The Lancet Commission on Essential Medicines.***

However, one in five countries worldwide spend less than this per person per year on medicines, demonstrating the urgent need for additional financing to meet basic health care needs. At the same time, the world as a whole spends at least 8 times this amount on medicines, highlighting massive inequities and inefficiencies in financing and governance that restrict access to medicines for many people worldwide.

Essential medicines are defined as a core set of medicines to meet the priority health needs of populations, and include analgesics such as morphine, tuberculosis, HIV or malaria drugs, medicines for chronic diseases such as insulin or cancer medicines as well as vaccines and contraceptives. The Commission argues that access to affordable and quality-assured essential medicines is central to the Sustainable Development Goal target of achieving universal health coverage by 2030, and that strong government and international leadership is needed to effectively implement essential medicines policies and create accountability.

The Commission brings together a group of 21 international experts and makes recommendations to governments, civil society, national health institutions, national medicines regulatory agencies, and the pharmaceutical industry. The report will be launched in London on 8th November [1].

“Countries around the world, regardless of income level, face enormous challenges ensuring equitable access to affordable, quality-assured essential medicines,” says co-chair of the Commission Andy Gray, University of KwaZulu-Natal, Durban, South Africa. “Recent examples such as the EpiPen scandal in the USA, the high cost of Hepatitis C drugs or the failure to develop new antibiotics to treat resistant infections demonstrate that access to safe, quality and affordable medicines is a global issue, at the heart of advancing access to universal health coverage.” [2]

Paying for a basket of essential medicines

Based on disease prevalence, consumption of medicines and medicine prices, the Commission estimates that the cost of providing 201 medicines (378 different products) from WHO’s Model list of Essential Medicines [3] to the total populations of low- and middle-income countries (LMICs) is between US$77.4 and US$151.9 billion per year, or the equivalent of US$12.9-25.4 per person per year (table 1).

Recent estimates suggest that the average total spend on medicines in low-income countries (LICs) is US$8.6 per person per year (table 3) – with the majority of funding coming from individuals and households. Additional financing is therefore urgently needed to provide access to essential medicines.

Overall, 28 out of 31 LICs and 13 out of 47 LMICs spend less on medicines than the lower threshold identified in the model (figure 3) – a total of 41 countries, or 1 in 5 countries worldwide. Meanwhile, global expenditure on medicines is estimated at US$1.2 trillion in 2017 – approximately 8 times the upper threshold identified in the model.

The Commission highlights national and global policies (e.g. promoting generic medicines use, price transparency, pooled procurement) that, when implemented effectively, can make essential medicines affordable and translate into sustainable access for all. Related to this, the Commission warns that flexibilities included in the World Trade Organisation's Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), which provide governments with options that allow for the protection of public health including access to affordable medicines, are under continual threat from the TRIPS-plus obligations included in bilateral and regional trade agreements.

Regulatory systems must be strengthened to ensure quality and safety of medicines

Despite some progress, serious problems with medicine quality and safety persist in many low- and middle-income countries. At their most benign, poor quality medicines have no treatment effect, and at their worst cause human disasters. For instance, over 120,000 children in sub-Saharan Africa are estimated to have died in 2013 because of substandard antimalarial medicines.

In many cases, poor quality or unsafe medicines are the result of serious negligence in manufacturing (whether by accident or intent), followed by failures of the quality assurance process. In most high-income countries, National Medicines Regulatory Agencies provide quality assurance, but in the face of weak national regulatory systems in LMICs, many procurement agencies rely on WHO's prequalification programme. Good procurement methods can greatly improve the quality and safety of drugs (see figure 9, Kenya example). The Commission argues that the WHO pre-qualification programme must be evolved to cover a wider range of drugs. At the same time, national medicines regulatory authorities must focus on activities that add value, such as regional collaboration and enforcement of existing regulations; and their performance must be monitored independently.

The Commission also warns of inappropriate use of medicines, such as over or underuse (eg, overuse of opioids in the USA vs. underuse in pain management in many LICs), misuse (eg, antibiotics taken for a viral disease) or unnecessarily expensive use (eg, brand-name medicines are used despite the existence of generics). A key driver of inappropriate use is pharmaceutical promotion, which the authors say should be controlled and monitored by robust regulatory agencies.

Global R&D policy needs urgent reform

The current system, in which market exclusivity and patents are the main drivers of innovation, fails to incentivise research and development into essential medicines. The Commission says that pharmaceutical research must be re-focused on developing affordable new essential medicines to address high priority diseases, by adopting a new global R&D framework, including a Global Research Fund to finance R&D up-front and to delink the costs of R&D from the price of medicines.

Following the success of patent pools for HIV medicines, the Commission calls on the international community to create a general essential medicines patent pool, to licence patents to other companies in order to create a competitive generics market and improve access to medicines in LMICs.

Initiatives to address the lack of R&D on missing essential medicines are largely dependent on charitable donations, and have helped address some of these problems (eg, new medicines for HIV or tuberculosis), but they do not provide a long-term solution.

“Often, the public pay for medicines twice – first through government funded research, and then through high prices. The current system of developing new medicines is in crisis, as it largely fails to produce much-needed products to address the health needs of millions of people. When new essential medicines are developed, market exclusivity, through patents or other mechanisms, allows for pricing that potentially makes them unaffordable, even in high income countries,” says co-chair Professor Hans Hogerzeil, University of Groningen, Netherlands. “International agencies and national governments must take a much stronger lead in setting public-health based priorities for R&D, and use patent laws in the interest of public health.”

Finally, the Commission warns that lack of transparency and access to data on essential medicines is a general obstacle to the effective implementation and evaluation of essential medicines strategies, and propose a set of 24 indicators to measure progress.

“We believe that our recommendations can substantially improve access to essential medicines in high- and low-income areas alike,” says co-chair Professor Veronika J. Wirtz, Boston University School of Public Health, USA. “But if we cannot measure change, we cannot hold governments and health systems accountable for improving essential medicines as part of universal health coverage. Promoting accountability for improving essential medicines policies will require drastic changes in our approaches to transparency and implementing corrective actions across both sectors, public and private.”

Working alongside ***The Lancet Commission***, the Youth Commission on Essential Medicines [4], a group of 17 young commissioners from around the world, has provided comment on the report. In a linked Comment, the Youth Commission write: “The factors shaping access transcend borders and demand collaboration to comprehensively address the interaction between economics, trade, and intellectual property rights, rather than expansion of existing solutions which have not yet achieved access globally. If methods to improve access are continually implemented on an ad-hoc basis, the world will forgo opportunities for identifying and tackling the real drivers of inequity in access… The crisis in access to medicines is usually presented as a technical problem, but it is a problem of accountability. Today, no one is held accountable for not delivering access to essential medicines, and progress has not been monitored as the global challenge it represents.”

In a linked Comment, the Dutch Minister for Foreign Affairs Lilianne Ploumen and Minister for Health Edith Schippers discuss R&D of essential medicines, including recent negotiations on trade agreements, such as TRIPS. They write: “The system is broken but change is underway to fix it. Governments cannot do this alone. We need meaningful efforts by both the pharmaceutical industry and governments to invest in new medicines, provide full transparency on costs, prices, and who pays what beforehand, and respect the legal space for governments to protect public health. If we don’t succeed in these efforts, we cannot guarantee people’s access to innovative and affordable medicines. Without fixing this broken system we will not reach the Sustainable Development Goal to ensure healthy lives and wellbeing for all, at all ages. “Leave no one behind”, the UN’s slogan, will prove to be empty words.”

NOTES TO EDITORS

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Further information about the Commission: http://www.bu.edu/lancet-commission-essential-medicines-policies/
[1] To register for the launch event: https://www.eventbrite.co.uk/e/the-lancet-commission-on-essential-medicines-policies-registration-27989542475
[2] Quotes direct from authors and cannot be found in the text of the Commission
[3] WHO model list of essential medicines http://www.who.int/medicines/publications/essentialmedicines/en/
[4] For more information about the Youth Commission, see: http://ycemp.com/

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