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Too Costly & Too Scarce

Ewen, M.A.

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Summary

Medicine price matters. They matter to governments with limited pharmaceutical budgets. They matter to patients, especially those who have to pay for medicines out-of-pocket, including up to 90% of the population in many LMICs. Medicine availability also matters. It matters especially to the poor who rely on accessing the medicines they need in public health care facilities, either free-of-charge or at affordable prices. Low medicine availability in the public sector forces people to purchase medicines in the private sector, usually at far higher prices.

The consequences of high prices may trigger devastating and long-term consequences for families. This includes borrowing money, with many households remaining in debt for a considerable time after the illness; reducing consumption of other goods (often food); and/or selling assets. Selling assets integral to a household's livelihood, such as land or livestock, may trigger impoverishment. Taking on extra work or re-allocating work among household members may also have adverse consequences, particularly when children are removed from school to do the work of a sick parent.

Aims of the thesis

The aim of this thesis is twofold. Firstly, it aims to shed light on the prices governments and people pay for medicines in LMICs, the affordability of medicines for people on low incomes, and the availability of medicines in outlets. The second aim is to assess the impact of three factors on the price and availability of medicines: inclusion in the national EML, price transparency and comparing prices paid by other government purchasers, and local medicine production.

Prior to 2001, little was known about medicine prices and availability in LMICs. This thesis describes the work undertaken since then to develop the WHO/HAI survey tools, measure medicine prices, availability, affordability, and price components, and identify policy options to improve the situation. Multiple and often interlinked factors can influence medicine availability and affordability, hence the impact of some factors on availability and prices is assessed.

Hypotheses

Six hypotheses are proposed in this thesis (1) Medicine availability is suboptimal and affordability is poor in LMICs, and availability and affordability cannot be considered in isolation; (2) Barriers at various levels impact medicine availability, prices, and affordability; (3) Governments in LMICs are procuring medicines at prices far above international reference prices; (4) EMLs have a positive effect on availability; (5) Analysing procurement prices can lead to positive outcomes for the procurement process; and (6) Local production results in lower prices and improved availability.

Research questions

To determine whether these hypotheses are supported or not, the thesis was designed to answer the following research question: *What is the price, availability, affordability, and price components of commonly used medicines in LMICs and what are some of the factors influencing prices and availability?*

To answer this question, two sub-questions have been formulated:

- (1) *In LMICs, what is the availability, price, affordability, and price components of medicines used to treat communicable diseases and NCDs?*

This questions the actual availability, price, affordability, and price components of medicines in LMICs. Firstly, an overarching perspective is sought, including medicines to treat both communicable and NCDs, with data about their availability, price, and affordability assessed individually. Secondly, as a case study, the availability, price, and affordability of insulin is investigated, a medicine essential for the survival of people with type 1 diabetes and increasingly being used by people with type 2 diabetes. Thirdly, building on the foregoing, the question relates to the combined availability and affordability of medicines to treat four common NCDs: cardiovascular diseases, diabetes, chronic obstructive pulmonary diseases, and central nervous system conditions.

- (2) *In LMICs, what is the influence of the following factors on availability and/or prices:*
- (a) *Inclusion of medicines in national EMLs?*
 - (b) *Public sector procurement and price transparency?*
 - (c) *Local medicine production?*

These questions ask about the influence of three specific factors on medicine availability and/or prices. The first question focuses solely on medicine availability, and asks whether inclusion in a national EML results in greater availability in outlets. The second question focuses on public sector procurement of medicines, and the influence of price transparency and comparing prices paid by other purchasers, to identify potential savings. The final question asks if local medicine production influences the availability and prices of medicines in outlets in the manufacturing country.

Studies and key findings

The thesis consists of six studies (Chapters 2-7), undertaken using a mixed-methods approach (primary and secondary data analyses). The study in Chapter 2 is a secondary analysis to consolidate what is known about medicine prices, availability, and affordability in 36 LMICs. Data for 15 commonly used communicable and NCD medicines were analysed from surveys undertaken using the WHO/HAI methodology. Key overall findings include poor medicine availability, government procurement prices that were 11% above international reference prices, and patient prices nine-25 times the reference prices for lowest-priced generics in the private sector, and over 20 times the reference prices for originator brands. On average, originator brands were 260% higher priced than the lowest-priced generics, and standard treatments were largely unaffordable for those on low wages. A further finding was that mark-ups and other costs in the pharmaceutical supply chain can result in the patient paying double the manufacturer's selling price for a medicine.

The study in Chapter 3 is a literature review of insulin prices, availability, and affordability in LMICs, and the range and complexity of factors that contribute to poor access to insulin. The study found that in LMICs the availability of insulin was poor in the public and private sectors, insulin prices were high, and insulin was unaffordable in some settings (eg. the lowest-paid unskilled government worker in Mexico City would have to work five days to purchase a vial of human insulin in private pharmacies). A key factor thought to be contributing to high insulin prices is the market domination by only three companies.

WHO has set a voluntary target of 80% availability of affordable medicines, including generics, to treat major NCDs in the public and private sectors of countries by 2025. The study in Chapter 4 is a secondary analysis of availability and affordability data from 30 surveys, conducted in LMICs using the WHO/HAI methodology, to establish a baseline for the target for four NCDs: diabetes, cardiovascular disease, chronic obstructive airways diseases, and central nervous system disorders. Unlike other studies, availability and affordability were assessed in combination. The study found that in low- and lower-middle income countries, less than 20% of lowest-priced generics across the four NCDs met WHO's target in the public and private sectors. In upper-middle income countries, the situation was also far from satisfactory as only 32.3% and 37.4% met the target in public and private sectors, respectively. Analysing availability and affordability separately, and then in combination, gave very different results. The combination analysis more accurately reflects the need for medicines to be both available in outlets and affordable for those having to pay out-of-pocket.

The study in Chapter 5 is a secondary analysis of the availability of medicines in 23 LMICs included in national EMLs compared with medicines that are not on the national EML, using data from surveys undertaken using the WHO/HAI methodology. The aim was to ascertain if inclusion of medicines in national EMLs improved their availability in public and private sector outlets. The findings showed that medicines on the national EMLs were more available in outlets (40% and 78% in the public and private sectors, respectively) compared to medicines not on the EMLs (7% and 57%). While this confirms that efforts over the last 40 years to promote the development and implementation of national EMLs have positively influenced the provision of essential medicines, the availability of essential medicines in outlets is still far from optimal, especially in the public sector.

The study in Chapter 6 is a comparative assessment of the prices paid by UNRWA for 80 medicines, and the quantities purchased, with those from a neighbouring and host country (Jordan), a regional procurement organisation (GCC), a non-profit international supplier (the IDA Foundation), and MSH prices. The key finding of the study was that overall there was little difference between UNRWA prices and the comparator prices across the medicines where there were matches. However, there are some wide variations for individual medicines, indicating possible opportunities for UNRWA to buy at lower prices. UNRWA acted on the study findings, and in the following years negotiated a price reduction for insulin (their highest value medicine). The savings allowed UNRWA to purchase statins, which they previously did not buy due to insufficient funds.

The study in Chapter 7 is a comparative assessment of prices and availability of locally produced and imported medicines in Ethiopia and Tanzania, undertaken using an adaptation of the WHO/HAI methodology. The key finding of the study was the mixed influence of local production on prices in the two countries. In Ethiopia, local production did not result in lower tender prices or lower patient prices in the public sector. A different picture was seen in Tanzania. Local production did result in lower tender prices although it did not result in lower patient prices in the public sector.

Conclusions and policy recommendations

Of the six hypotheses, four were supported: medicine availability is suboptimal and affordability is poor in LMICs, and availability and affordability cannot be considered in isolation; barriers at various levels impact medicine availability, prices and affordability; EMLs have a positive effect on availability in outlets; and analysing procurement prices can lead to positive outcomes for the procurement process. Two hypotheses were not supported: the studies in Chapters 2 and 7 found that governments in LMICs are generally not procuring medicines at prices far above international reference prices (although some individual governments are) and while local production improved availability, it does not always result in lower prices.

Key policy recommendations from the studies include ensuring price transparency, limiting government procurements to medicines on national EMLs, comparing government procurement prices internationally, and promoting the use of lower-priced quality-assured generics through various supply-side and demand-side policies. This includes reducing barriers to market entry, permitting and promoting generic substitution by pharmacists, zero or low mark-ups in the public sector, regulated mark-ups applied regressively or use of dispensing fees in the private sector, and education of health care providers and patients to increase the acceptance of lower-priced generics. Additional recommendations for insulin include standardising national regulatory requirements, including insulin in WHO's prequalification programme, controlling prices, and education on biosimilars and the cost-benefits of human versus analogue insulins. Countries that support local manufacturers through local preferences should regularly review prices to ensure the policy is resulting in more affordable medicines for patients.

The pharmaceutical market is dynamic, hence it is vital that availability, prices, and affordability are regularly surveyed, with action taken where availability is found to be low and/or affordability is poor. Ensuring universal access to essential medicines is possible, but this thesis shows that more work is needed to ensure it is a reality.

