

Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis

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Summary

Background WHO and Health Action International (HAI) have developed a standardised method for surveying medicine prices, availability, affordability, and price components in low-income and middle-income countries. Here, we present a secondary analysis of medicine prices and availability in 45 national and subnational surveys done using the WHO/HAI methodology.

Methods Data from 45 WHO/HAI surveys in 36 countries were adjusted for inflation or deflation and purchasing power parity. International reference prices from open international procurements for generic products were used as comparators. Results are presented for 15 medicines included in at least 80% of surveys and four individual medicines.

Findings Average public sector availability of generic medicines ranged from 29·4% to 54·4% across WHO regions. Median government procurement prices for 15 generic medicines were 1·11 times corresponding international reference prices, although purchasing efficiency ranged from 0·09 to 5·37 times international reference prices. Low procurement prices did not always translate into low patient prices. Private sector patients paid 9–25 times international reference prices for lowest-priced generic products and over 20 times international reference prices for originator products across WHO regions. Treatments for acute and chronic illness were largely unaffordable in many countries. In the private sector, wholesale mark-ups ranged from 2% to 380%, whereas retail mark-ups ranged from 10% to 552%. In countries where value added tax was applied to medicines, the amount charged varied from 4% to 15%.

Interpretation Overall, public and private sector prices for originator and generic medicines were substantially higher than would be expected if purchasing and distribution were efficient and mark-ups were reasonable. Policy options such as promoting generic medicines and alternative financing mechanisms are needed to increase availability, reduce prices, and improve affordability.

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Introduction

Medicines account for 20–60% of health spending in developing and transitional countries,¹ compared with 18% in countries of the Organisation for Economic Co-operation and Development.² Up to 90% of the population in developing countries purchase medicines through out-of-pocket payments,³ making medicines the largest family expenditure item after food. As a result, medicines are unaffordable for large sections of the global population and are a major burden on government budgets.

The organisation of a country's pharmaceutical sector can have implications for medicine availability, price, and affordability. In fully public systems, medicines are financed, procured, and distributed by a centralised government unit; in mixed systems, public funding from central budgets or social health insurance is used to reimburse patients or private pharmacies, or medicines are supplied through government medical stores and health facilities but paid for by patient fees; in fully private systems, patients or private insurance systems pay the entire cost of medicines purchased from private pharmacies and drug sellers. Most countries use a combination of these approaches.⁴

In 2001, a resolution endorsed by Member States of WHO called for the development of a standardised method for measuring medicine prices,⁵ which resulted in the launch of the WHO/Health Action International (HAI) Project on Medicine Prices and Availability. The project aims to contribute to target 17 of the Millennium Development Goals: "in cooperation with pharmaceutical companies, provide access to affordable, essential drugs in developing countries".

Before the WHO/HAI project, only a few small studies had been done in low-income and middle-income countries to measure medicine prices and make international comparisons.^{6–9} Lack of consistent or reproducible methodologies restricted the comparability of these studies, and left them open to criticism.¹⁰ As such, the WHO/HAI project's initial focus was on the development of a standardised method for measuring medicine prices, availability, affordability, and price components. After pilot testing in nine countries,¹¹ the methodology was launched in 2003.¹²

More than 50 WHO/HAI medicine pricing surveys have been done,^{13–15} and results are available on the HAI website.¹³ Other activities have included validation studies, secondary analyses of survey data by region and disease group,¹⁶ investigations into country price variations, and development of a methodology for routine medicine price monitoring. In addition to the WHO/HAI pricing surveys, other class-specific studies of medicine prices across countries have also been done.¹⁷

This paper presents a secondary analysis of medicine availability, price, affordability, and price components in 45 national and subnational surveys done using the WHO/HAI methodology.

Methods

WHO/HAI survey methodology

The WHO/HAI methodology has been published as a manual.¹² In the typical survey, data for the availability and price of a specific list of medicines are collected in at least four geographic or administrative areas in a sample of public health facilities, registered private retail medicine outlets, and optionally in medicine outlets in other sectors (eg, mission hospitals). Data are also collected on government procurement prices, generally at the central level. The methodology also includes estimating the add-on costs that contribute to the final price of medicines by tracking these backwards through the distribution chain. National surveys are usually undertaken, although subnational surveys are recommended in large countries.

Sampling

Medicine outlets are selected using a multistage clustered approach. Survey areas include the main urban centre plus three areas randomly selected from those that can be reached within a day's travel from the main urban centre. In each survey area, the main public hospital, plus four randomly-selected public medicine outlets reachable within 4 hours' travel from the main hospital, make up the public sector facility sample. The private sector and other sector samples are identified by selecting one medicine outlet in each sector that is geographically closest to each public outlet.

Medicines

Survey medicines include a standard list of 30 core medicines to allow international comparisons. Core medicines were selected to indicate a range of treatments for common acute and chronic conditions that cause substantial morbidity and mortality. They are recommended, usually as first-line courses of treatment, in global, regional, and national treatment guidelines; are available in standard formulations and are widely used in many countries or regions; and most are included in the WHO Model List of Essential Medicines. Medicines provided largely through donations or externally funded vertical programmes, such as antiretroviral or tuberculosis medicines, are not included because they do not indicate the typical functioning of the pharmaceutical sector. In each survey, medicines are removed from the core list if the corresponding disease is not prevalent in the country or if the specific formulation or dosage form is not available. The surveys also include up to 20 supplementary medicines identified for their local clinical relevance. For each medicine, data are collected for both the originator brand, defined as the product that was first authorised worldwide for marketing, and the lowest-priced generic equivalent found at each medicine outlet. Generics are defined as pharmaceutical products intended to be interchangeable with the originator brand product, manufactured without a licence from the originator manufacturer, and marketed after the expiry of patent or other exclusivity rights.

Data collection and analysis

Trained data collectors visit medicine outlets and record medicine availability and price using a standardised form. Several validation and data checking steps during and after collection ensure data quality. Data are entered into a preprogrammed spreadsheet (Excel) by two people using a double entry technique. Results are cross-checked, after which a data validation programme is run which highlights outliers that need verification.

Each sector's data are analysed separately. Availability is reported as the percentage of medicine outlets where a medicine was located on the day of the survey. To facilitate international comparisons, price results are presented as median price ratios, or the ratio of a medicine's median price across outlets to the Management Sciences for Health (MSH) median inter-national reference price for the year preceding the survey.¹⁸ MSH international reference prices were selected as the most useful reference standard because they are widely available, updated frequently, and fairly stable over time. They represent actual procurement prices for medicines offered to low-income and middle-income countries by non-profit suppliers and international tender prices. Most MSH prices are for generic products, and are usually ex-works prices (the price at the purchase site that does not include insurance and freight costs).¹⁸ Higher ratios are therefore expected for procurement prices that include insurance and freight. Survey medicines are generally off-patent and thus the generic comparator can be used as the reference price for both originator and generic products. At least four prices must be obtained for calculation of the median price ratio, except for procurement data where one price is sufficient. Affordability is estimated using the salary of the lowest-paid unskilled government

worker to establish the number of days' wages needed to purchase courses of treatment for common conditions. Because chronic diseases need ongoing treatment, affordability of a 30-day supply of medicines has been used to indicate monthly medicine expenditures. An example of the data generated from the WHO/HAI survey is provided in the webappendix.

Methodology of the secondary analysis

Data for the secondary analysis were obtained from the HAI global database of survey results.¹³ Composite data (eg, median price ratio, % availability) were obtained for individual medicines summarised across medicine outlets.

Survey inclusion criteria

All national and subnational surveys that were completed, verified, and included in the HAI database at the time of data extraction (May, 2008) were included in the analysis (table 1). Where repeat surveys were undertaken in a country, the most recent data set was used. Data from the pilot surveys were included where the methodology was consistent with subsequent surveys. Of the 45 surveys included, five were pilot surveys and 14 were subnational surveys.

Medicine selection

A preliminary analysis showed that eight medicines were included in at least 90% of the 45 surveys, 15 in 80% of surveys, and 20 in 70% of surveys. To increase comparability of the findings, summary results are presented for 15 medicines included in at least 80% of surveys, irrespective of their actual availability at individual facilities (table 2). Results are also presented individually for four commonly used medicines: amoxicillin 250 mg capsule or tablet, ciprofloxacin 500 mg capsule or tablet, glibenclamide 5 mg capsule or tablet, and salbutamol 200-dose inhaler 0.1 mg/dose. These medicines indicate how well summary data represent results for individual medicines, and could illustrate differences between treatments for chronic and acute conditions.

All surveys were standardised to the year 2004, using MSH 2003 international reference prices. 2004 was chosen as the base year since most surveys (26 of 45) were done that year. For those countries that did not use MSH 2003 international reference prices in their survey, some differences between original country results and the adjusted results are expected due to fluctuations in MSH prices over time. These fluctuations are small for older multisource medicines (eg, glibenclamide, salbutamol inhaler) but can be larger for medicines with few suppliers or those recently off patent (eg, ranitidine).¹⁹

Patient price data were corrected for inflation or deflation between the survey year and the base year (using the consumer price index) and also adjusted for the purchasing power parity of the national currency.²⁰ Despite debate on its relation to medicine price inflation, the consumer price index was used after consensus from consulted health economists, since it remains the most widely accepted inflator and deflator for internationally procured pharmaceutical prices and is available for all countries. Procurement data were adjusted for inflation or deflation and corrected for the exchange rates used in the surveys to standardise local prices to constant dollars. These were not adjusted for purchasing power parity, since most public sector procurements are made through competitive international tenders, and thus should be able to achieve comparable purchase prices irrespective of the purchasing power of the local currency.

Data analysis

Data were analysed by WHO Region: Africa, Americas, eastern Mediterranean, Europe, southeast Asia, and western Pacific (table 2). These regions were selected because WHO Regional offices have previously expressed interest in taking action on issues of medicine price and availability.²¹ To investigate whether trends exist across countries of similar economic status, data were also analysed by World Bank income group: low-income countries, lower-middle income countries, and upper-middle income countries.²² In the former analysis by World Bank income group, the high-income category was not included, since only two surveys (Kuwait and United Arab Emirates) fell into this category. Indian survey results are reported separately, because of the unique nature of the Indian pharmaceutical market.

Mean percent availability across WHO regions and World Bank income groups was calculated for the four commonly used individual medicines mentioned above as well as for the basket of 15 medicines in each country. Mean median price ratios were also calculated across WHO regions.

In each country and within World Bank income groups, the mean percent differences in price between originator brands and lowest-priced generics (the brand premium) were calculated for medicines available as both product types. The number of medicine pairs available in each survey ranged from seven to nine in India, one to 14 in low-income countries, three to 13 in lower-middle income countries, and nine to 12 in upper-middle income countries.

Field data for the actual mark-ups and other add-on costs that occur in the public and private sector distribution chains are reported by country. Limited data are available, since many countries did not undertake this aspect of the survey. Other countries only reported official fees and mark-ups, which were not included because their application in practice could not be verified.

Results

In the public sector, the availability of the basket of 15 generic medicines was low, ranging from 9·7% in Yemen to 79·2% in Mongolia (table 3). Regional availability ranged from 29·4% in Africa to 54·4% in the Americas; mean availability in the public sector was lower than in the private sector in all regions.

Even in the private sector, availability of generics was low, ranging from 50·1% in the western Pacific to 75·1% in southeast Asia. High private sector availability of generics was recorded in Syria (97·5%) and Chennai, India (91·8%), whereas low availability was seen in Chad (14·8%), Kuwait (36·3%), the Philippines (33·6%), and China (34·6% in Shandong and 38·3% in Shanghai).

Wide variations in availability were noted within WHO regions. In western Pacific countries, public sector availability of generics ranged from 22·2% in the Philippines to 79·2% in Mongolia. Similarly, private sector availability of generics in Africa ranged widely, from 14·8% in Chad to 79·1% in Ethiopia.

Public sector availability of generic medicines was similar across World Bank income groups (figure 1), ranging from 27·0% in upper-middle income countries to 44·3% in lower-middle income countries. However, a greater degree of variability was seen in low-income countries (9·7% in Yemen to 79·2% in Mongolia) than in higher income groups. Private sector availability was similar for low-income countries (60·7%), lower-middle income countries (64·3%), and

upper-middle income countries (65·8%). Originator brands were less available than generics in low-income countries (22·3%) and lower-middle income countries (43·7%), but only slightly less available in upper-middle income countries (61·8%). Within all income groups, country-level private sector availability varied widely; for lowest-priced generics it ranged from 14·8% (Chad) to 82·1% (Sudan, Khartoum) in low-income countries, and from 33·6% (Philippines) to 97·5% (Syria) in lower-middle income countries. Private sector availability of originator brands ranged from 0·3% (Mongolia) to 59·1% (Pakistan) in low-income countries, and from 8·2% (China, Shandong) to 80·8% (Morocco) in lower-middle income countries.

For the basket of 15 medicines studied, the average median price ratio in the 39 surveys with public procurement data was 1·11. Public sector procurements in the Americas, eastern Mediterranean, and southeast Asia achieved generic medicine prices that were close to or lower than international reference prices, whereas Africa, Europe, and western Pacific procurements averaged 34%–44% more than international reference prices (table 4). Results varied for the individual medicines examined, with salbutamol usually procured at prices lower than its international reference price in all regions except the Americas, while ciprofloxacin cost substantially more than its international reference price in all regions. Several countries were also procuring originator brand ciprofloxacin at many times the international reference price - eg, Morocco, the Philippines, and Nigeria were paying 66·7, 33·6, and 28·4 times the international reference price, respectively.

Public sector procurement prices for lowest-priced generics also varied widely within World Bank income group (figure 2). Median price ratios of lowest-priced generics in low-income countries ranged from 0·09 in Sudan (Khartoum) to 5·37 in Nigeria, whereas in lower-middle income countries, prices ranged from 0·33 in Jordan to 2·94 in the Philippines.

In many countries, medicines are free in the public sector, but availability is often poor. Where public sector patients pay for medicines, even lowest-priced generics can cost many times the international reference price; regional median price ratios for the basket of 15 medicines varied from 3·18 in the Americas to 11·95 in western Pacific countries (table 5). However, public sector patient prices were still generally lower than prices in the private sector in most regions. In Europe and western Pacific, prices of lowest-priced generics in the two sectors were similar, whereas originator brands in the private sector were more highly priced.

Similar to procurement prices, patient prices for ciprofloxacin 500 mg capsules or tablets were consistently high, with private sector median price ratios for lowest priced generics ranging from 19 to 53 across WHO regions. Prices of salbutamol 0·1 mg/dose inhaler were substantially lower in all WHO regions; median price ratios for lowest-priced generics ranged from 3 to 7 in the private sector.

The percentage difference in price between originator brands and lowest-priced generics (brand premium) in the private sector was over 300% in lower-middle income countries and low-income countries, whereas in upper-middle income countries it was substantially lower (152%), and in India it was only 6% (figure 3).

The affordability of treating one acute infection and three chronic illnesses was assessed in the public and private sectors (table 6). Many medicines were not consistently available in the public sector. Therefore even when the public sector provides medicines for free or at a low cost, patients might still need to purchase medicines from the private sector where they are frequently unaffordable. For example, a month's course of lowest-priced generic ranitidine (150 mg capsules or tablets, two a day for 30 days) to treat an ulcer cost more than 3 days' wages in Africa, eastern Mediterranean, and Europe.

Data for price components were only available for a few countries (table 7). In countries such as El Salvador, India, and Mali, multiple duties and taxes were applied. Although the amounts charged are small, they have a substantial cumulative effect if applied early in the supply chain. In countries where value added tax was applied, it varied from 4% (India) to 15% (Mongolia). Wholesale mark-ups ranged from 2% in Pakistan to a combined mark-up by importers, distributors, and wholesalers of 380% in El Salvador. Retail mark-ups ranged from 10% in Mongolia to 552% in El Salvador. Different mark-ups were often applied to originator brands and generics, with higher mark-ups generally applied to generics. Although add-on costs in the medicine supply chain can be substantial, in some cases the manufacturer's selling price is the largest contributor to the final price. In Pakistan, for example, the manufacturer's selling price for locally-produced generic amoxicillin represented 78% of the final medicine price in the private sector.

In several countries (China, Ethiopia, Malaysia, Mali, Mongolia, and Uganda), wholesale or retail mark-ups were also applied in the public sector, suggesting the use of medicine sales as a revenue-generating mechanism.

Discussion

The WHO/HAI survey methodology allows for the measurement of medicine prices and availability in a standardised way, with multiple steps to ensure data quality. The common list of core medicines with specified dosage forms and strengths allows for more reliable international comparisons, whereas supplementary medicines identified at the country level ensure local relevance.

The survey's target medicine list and outlet sample approach have been validated in a medicine prices survey done in Peru in 2005, which showed that more remote outlets were similar to those selected using the standardised methodology, and availability of therapeutic alternatives were generally similar to those of the WHO/HAI core medicines. The results of this single-country validation exercise suggest that the target medicine list and sample selection are methodologically sound. Further, originator brand prices from the WHO/HAI validation survey in Peru had a high (99%) correlation with pharmacy invoice prices from Intercontinental Medical Statistics Health.

Although international comparisons should compare prices of identical products across countries, the same product can still have a different role in the pharmaceutical market in different countries.²³ For this reason, results were reported for both individual medicines and for 15 medicines found in at least 80% of surveys. The list of core medicines has since been revised to 14 commonly found products, with additional lists to account for regional variations.²⁴

Despite its strengths, the WHO/HAI methodology has several limitations. First, differences in quality across products, and differences in patent status between countries, are not accounted for.²⁵ Second, availability and price are determined for the specific list of survey medicines, and do not account for alternate dosage forms of these products or therapeutic alternatives. Third, the reliability of median price ratios as a metric for comparison depends on the number of supplier prices used to determine the median international reference price for each medicine. When few supplier prices are available or when the buyer price is used as a proxy, median price ratio results can be skewed by a particularly high or low international reference price.

Availability data only refer to the day of data collection at each facility and might not indicate average availability of medicines over time. However, since surveys are done in several facilities over a period of time, the data provide a reasonable estimate of the overall situation and are

indicative of the real-life situation faced by patients on a daily basis. Additionally, in countries where survey medicines are not included on the national essential medicines list (government-approved selective list used for procurement or reimbursement), public sector facilities would not be expected to stock some of the survey medicines. We were unable to assess the current data this way due to lack of information on which medicines were on the national essential medicines lists at the time of the survey.

The daily wage of the lowest-paid government worker is used to estimate treatment affordability. However, in many countries a substantial proportion of the population earns less than this amount. Further, the need for other non-discretionary expenditures (eg, food or housing), seasonal fluctuations in income, the number of dependants who live on this wage, and the full costs of treatment, are not accounted for. Nevertheless, this wage is a universally available metric to assess the affordability of medicines. Others, such as the national minimum wage, have proven less reliable in other WHO surveys. Comparisons to the median daily wage or per head gross domestic product are possible where these are available, but are not as informative or easily interpreted. When the daily wage of the lowest-paid government worker was compared with the gross national income per head of population for ten countries in sub-Saharan Africa where pricing surveys had been done, a correlation ($R^2=0.2677$) between the two measures was obtained. Further work is underway to identify alternate measures of affordability that could be included in the WHO/HAI methodology.

Average public procurement prices for generics range from below international reference prices in some regions to moderately (34–44%) higher in others, which indicates that most countries procure medicines at competitive prices, but that procurement efficiency can be improved in some countries, especially in low-income countries and lower-middle income countries.

Public sector availability of medicines was consistently low, which could be due to variations in the products included in national essential medicines lists or poor compliance with their recommendations. In this sector, even when medicines are available for free or at low cost, access is limited by low availability. Low availability in the public sector can be due to a combination of factors, such as inadequate funding, lack of incentives for maintaining stocks, inability to forecast accurately, inefficient distribution systems, or leakage of medicines for private resale. Although availability in the private sector was consistently higher, in many countries it was also low, and high private sector prices could further hinder access. However, enforcing low prices could have a perverse effect on availability by providing a disincentive for stocking these products.

Wide variability in the availability of originator brands and generics was observed across countries in all income groups. Generics were more widely available than brands in the private sector in low-income countries and lower-middle income countries, whereas in upper-middle income countries the availability of brands and generics was similar. Since originator brands are generally more expensive, patients might be paying more to purchase these products when cheaper alternatives exist. In India, the low brand premium of 6% results in part from the large number of generic manufacturers in the country and the pricing regulations in force.

In some countries, similar patient prices are seen in public and private sector facilities. For example, median price ratios for lowest-priced generics in the public and private sectors of Khartoum State are 11.1 and 12.1, respectively. Given generally low public procurement costs, this suggests that some public facilities are using medicine sales to subsidise other parts of the health-care system. Similar observations have been made for the non-governmental organisation sectors in Senegal, Kenya, and Uganda, where revenue from medicine sales is being used to cover general operating expenses. Since public facilities are a primary treatment

option for the poor, such practices are inherently inequitable and alternate methods of equitable health-system financing should be used, such as insurance coverage for essential medicines. Alternative financing mechanisms are especially important for the very poor for whom any price would be unaffordable.

Although treatments for conditions such as acute respiratory infection and diabetes using lowest-priced generics were fairly affordable in most regions, costs escalate when originator brands are used. Although treatments seem affordable, substantial proportions of developing country populations are earning less than the lowest-paid government worker. Furthermore, this affordability measure only includes medicines and does not account for other treatment costs (eg, diagnostics). As such, the true degree of unaffordability is likely to be underestimated. For chronic disease medicines, affordability is assessed based on monthly treatment costs; given that these conditions need long-term treatment they can be much less affordable than a one-time expenditure to treat an acute illness.

Similar to results reported elsewhere,¹⁵ chronic disease medicines were unaffordable for large proportions of the population. Increased emphasis should be placed on reducing the cost of these medicines in light of the high burden of non-communicable diseases.²⁶ The affordability of chronic disease treatments is further constrained by the frequent need for more costly combination therapies, and by the ongoing nature of treatment. Although patients might be able to afford treatment for acute illness as a one-time expenditure, they may not be able to afford continuous treatment for chronic diseases.

Many countries still apply value added tax and other taxes and tariffs to medicines. Considering that these are essentially a tax on the sick, there is a strong rationale for exempting medicines from taxes.²⁷ Although the taxes and tariffs might be small, they can still have a large cumulative effect when applied early in the supply chain.

Price component studies have only been done in a few countries, which indicates the difficulty in collecting such information in opaque environments that allow for substantial, unjustified mark-ups. In countries where data were available, wide variations in importer, wholesale, and retail mark-ups were observed. Further research is needed to establish appropriate mark-up levels that promote medicine availability and affordability while ensuring the economic viability of the supply chain. Mark-ups were generally higher for generics than for originator brands, but if generics are low-priced, they could still result in a lower return. Higher mark-ups for generics might therefore be justified if they provide an incentive to stock low-priced products. Substantive mark-ups were also seen in the public sector of several countries, suggesting that public sectors are generating revenue from medicine sales to subsidise other parts of the health care system. While taxes or mark-ups added substantially to the selling price in some cases, in others the manufacturer's selling price was the major component of the final price. Additional data from various countries are needed to draw conclusions on the determinants of final medicine prices, recognising the need to maintain a viable supply chain to ensure access.

A range of policy options are available to address issues of high prices and low availability of medicines. The most appropriate actions to follow depend on a country's individual survey results and their underlying determinants, as well as local factors including existing pharmaceutical policies and market situations.

Low public sector availability can be addressed through improved procurement efficiency (eg, national pooled purchasing, procurement by generic name) and adequate, equitable, and sustainable financing. In practice this could mean schemes to make chronic disease medicines available in the private sector at subsidised prices, or through the promotion of differential

pricing schemes that offer reduced prices in poorer countries. Manufacturers of antiretrovirals,²⁸ antimalarials,²⁹ and insulin³⁰ all offer differentially-priced products.

Resource-constrained public sectors might need to target widespread access to a reduced number of essential generic medicines, rather than attempting to supply a larger number of both originator brand and generic medicines. As recommended elsewhere,^{15,31} improved public sector support is needed for chronic disease medicines.

Medicine prices can be reduced by eliminating duties and taxes on medicines,²⁷ a policy measure which has been implemented in many countries. Monitoring is needed to ensure that savings are passed on to patients. Regulating mark-ups is another strategy to avoid excessive add-on costs in the supply chain. However, maximum percentage mark-ups provide incentives to sell higher-priced products to obtain a higher return. Regressive mark-up schemes avoid this problem by allowing higher mark-ups for lower-priced products. In Syria, for example, private pharmacy mark-ups range from 30% when the pharmacy procurement price is 40 Syrian Pounds (SYP) or less, to 8% when the procurement price is 501 SYP or higher.³² Despite the positive effects of these policies on mark-ups, reducing the manufacturer's selling price will generally have a greater effect on the final cost.

Increased use of generic medicines could improve affordability in most countries where generic products are priced substantially lower than originator brands. Several options are available to promote use of generics, including preferential registration procedures, ensuring the quality of generic products, encouraging price competition, and increasing the confidence of physicians, pharmacists, and patients in the quality of generics. A multipronged approach will generally be needed in countries attempting to increase generic uptake.

Data from the WHO/HAI Project on Medicine Prices and Availability confirm that substantial opportunities exist to increase availability, lower prices, and improve affordability of medicines in all regions and at all levels of country development. Using such data, countries should develop and implement national policies to improve the availability and affordability of essential medicines. The evaluation of such policies, including measuring progress against predetermined benchmarks and timelines, is crucial. Medicine prices, availability, affordability, and price components should be surveyed at least every 2 years using the WHO/HAI methodology, and should be routinely monitored and reported on a more frequent basis. Currently, evidence is limited on the effect of various policy options to make medicines more affordable; regular monitoring will be needed to assess whether policies are effective.

Contributors

All authors contributed to the paper's conception and design, analysis and interpretation of the data, drafting of the article, and critical revision. All authors have seen and approved the final version.

Conflict of interest statement

We declare that we have no conflict of interest.

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Table 1: Surveys included in the secondary analysis

Country (survey date)	WHO region	World Bank Income Group (2007/08)
Armenia (11/2001) ^{†,‡}	European	lower-middle
Brazil, Rio de Janeiro State (10/2001) ^{†,‡,§}	Americas	upper-middle
Cameroon (05/2002) ^{†,‡}	Africa	lower-middle
Chad (05/2004)	Africa	low
China, Shandong Province (10/2004)	Western Pacific	lower-middle
China, Shanghai Province (09/2004)	Western Pacific	lower-middle
El Salvador (11/2006)	Americas	lower-middle
Ethiopia (09/2004)	Africa	low
Fiji (09/2004) [†]	Western Pacific	lower-middle
Ghana (10/2004)	Africa	low
India, Chennai State (01/2004)	South-East Asia	low
India, Haryana State (10/2004)	South-East Asia	low
India, Karnataka State (11/2004)	South-East Asia	low
India, Maharashtra State, 12 districts (10/2004)	South-East Asia	low
India, Maharashtra State, 4 regions (01/2005)	South-East Asia	low
India, Rajasthan State (06/2003)	South-East Asia	low
India, West Bengal State (12/2004)	South-East Asia	low
Indonesia (08/2004)	South-East Asia	lower-middle
Jordan (05/2004)	Eastern Mediterranean	lower-middle
Kazakhstan (11/2004)	European	upper-middle
Kenya (11/2004)	Africa	low
Kuwait (06/2004)	Eastern Mediterranean	high
Kyrgyzstan (02/2005) [†]	European	low
Lebanon (02/2004)	Eastern Mediterranean	upper-middle
Malaysia (10/2004)	Western Pacific	upper-middle
Mali (03/2004)	Africa	low
Mongolia (11/2004)	Western Pacific	low
Morocco (04/2004)	Eastern Mediterranean	lower-middle
Nigeria (09/2006)	Africa	low
Pakistan (07/2004)	Eastern Mediterranean	low
Peru (09/2005)	Americas	lower-middle
Philippines (02/2005)	Western Pacific	lower-middle
South Africa, Kwazulu Natal State (09/2001) ^{†,‡,§}	Africa	upper-middle
Sri Lanka (09/2001) ^{†,‡,§}	South-East Asia	lower-middle
Sudan, Gadarif State (02/2006)	Eastern Mediterranean	low
Sudan, Kordofan State (02/2006)	Eastern Mediterranean	low
Sudan, Khartoum State (06/2005)	Eastern Mediterranean	low
Syrian Arab Republic (12/2003) [†]	Eastern Mediterranean	lower-middle
Tajikistan (02/2005) [‡]	European	low
Tunisia (03/2004)	Eastern Mediterranean	lower-middle
Uganda (04/2004)	Africa	low
United Arab Emirates (12/2006)	Eastern Mediterranean	high
United Republic of Tanzania (09/2004)	Africa	low
Uzbekistan (12/2004) [†]	European	low
Yemen (07/2006)	Eastern Mediterranean	low

[†]Pilot studies. Except for South Africa, Kwazulu Natal State, availability data were excluded since they were not assessed using the current WHO/HAI methodology. [‡]Did not survey public sector medicine outlets. [§]Did not survey public sector procurement prices. [§]Private sector data on lowest-priced generic medicines excluded since they were not surveyed using the current WHO/HAI methodology.

Table 2. Basket of 15 medicines found in at least 80% of surveys

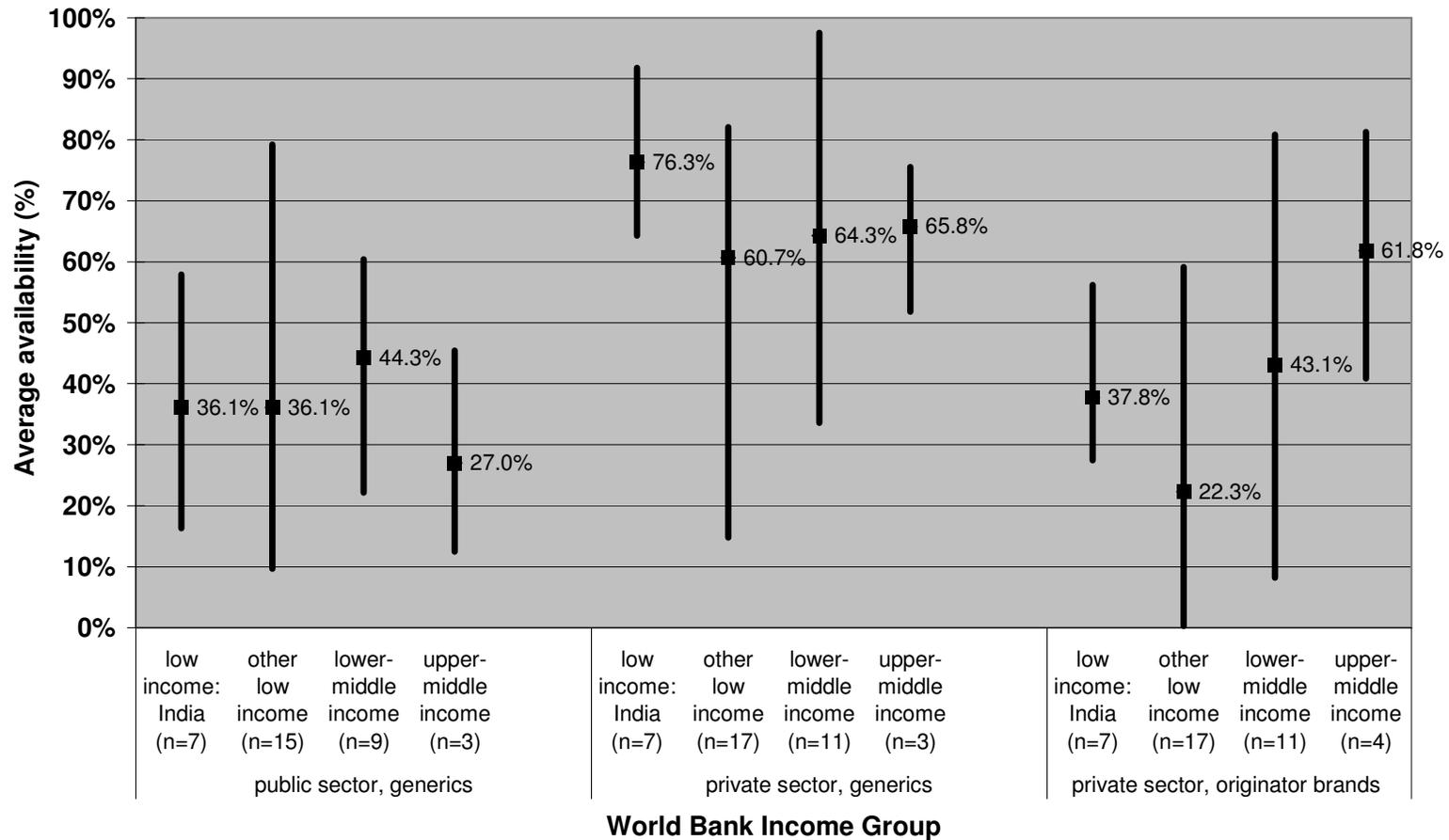
Medicine	Medicine category	% of surveys with medicine
Salbutamol 0.1 mg/dose inhaler	Antiasthmatic	100%
Captopril 25 mg capsule/tablet	Antihypertensive	96%
Ciprofloxacin 500 mg capsule/tablet	Antibacterial	96%
Amitriptyline 25 mg capsule/tablet	Antidepressant	93%
Omeprazole 20 mg capsule/tablet	Antacid	93%
Ranitidine 150 mg capsule/tablet	Antacid	93%
Aciclovir 200 mg capsule/tablet	Antiviral	91%
Glibenclamide 5 mg capsule/tablet	Antidiabetic	91%
Amoxicillin 250 mg capsule/tablet	Antibacterial	89%
Ceftriaxone 1 g/vial injection	Antibacterial	89%
Co-trimoxazole 8+40 mg/ml suspension	Antibacterial	89%
Fluoxetine 20 mg capsule/tablet	Antidepressant	89%
Hydrochlorothiazide 25 mg capsule/tablet	Antihypertensive	89%
Atenolol 50 mg capsule/tablet	Antihypertensive	87%
Beclometasone 0.05 mg/dose inhaler	Antiasthmatic	84%

Table 3. Average of country-level mean percentage availability of any generic product, by WHO region

	Mean availability (range) - public sector (%)							Mean availability (range) - private sector (%)						
	AFR n=8*	AMR n=2 [†]	EMR n=11 [‡]	EUR n=2 [§]	SEAR n=8	WPR n=5**	All surveys n=36	AFR n=8	AMR n=2	EMR n=12	EUR n=4	SEAR n=8	WPR n=6	All surveys n=40
Basket of 15 medicines	29.4 (20.3, 41.2)	54.4 (52.7, 56.0)	39.6 (9.7, 60.4)	40.5 (23.1, 57.9)	38.3 (16.3, 57.9)	43.0 (22.2, 79.2)	38.4 (9.7, 79.2)	54.6 (14.8, 79.1)	68.6 (66.6, 70.6)	68.9 (36.3, 97.5)	66.9 (61.4, 70.7)	75.1 (64.3, 91.8)	50.1 (33.6, 77.6)	64.2 (14.8, 97.5)
Amoxicillin 250 mg capsule/tablet	80.9 (66.7, 92.9)	42.3 (0.0, 84.6)	62.0 (0.0, 100)	45.0 (0.0, 90.0)	76.2 (45.8, 100)	74.0 (30.8, 100)	68.7 (0.0, 100)	65.7 (0.0, 100)	46.2 (30.8, 61.5)	69.4 (0.0, 100)	79.6 (70.0, 93.3)	93.7 (82.8, 100)	87.9 (72.5, 100)	76.0 (0.0, 100)
Ciprofloxacin 500 mg capsule/tablet	50.4 (4.2, 82.1)	94.2 (92.3, 96.2)	49.3 (0.0, 100)	42.5 (0.0, 85.0)	62.8 (0.0, 100)	24.5 (0.0, 75.0)	52.0 (0.0, 100)	79.3 (27.3, 96.0)	97.6 (96.2, 99.0)	92.3 (66.7, 100)	82.7 (43.3, 97.5)	92.8 (68.6, 100)	57.3 (0.0, 97.2)	82.4 (0.0, 100)
Glibenclamide 5mg capsule/tablet	37.3 (4.8, 79.4)	79.9 (63.4, 96.2)	69.1 (5.0, 100)	95.0 (90.0, 100)	53.4 (3.8, 100)	40.6 (0.0, 100)	56.6 (0.0, 100)	60.6 (0.0, 100)	90.8 (87.5, 94.2)	88.2 (44.0, 100)	89.4 (80.0, 100)	62.5 (20.0, 100)	45.0 (0., 94.4)	71.3 (0.0, 100)
Salbutamol 0.1 mg/dose inhaler	14.0 (0.0, 55.9)	88.4 (86.5, 90.4)	35.5 (0.0, 95.0)	42.5 (0.0, 85.0)	5.1 (0.0, 30.0)	48.3 (0.0, 100)	29.1 (0.0, 100)	47.0 (0.0, 95.0)	55.2 (50.0, 60.4)	63.8 (0.0, 100)	74.2 (35.0, 96.7)	79.0 (0.0, 100)	52.0 (7.8, 97.2)	60.8 (0.0, 100)

WHO Region: AFR=Africa. AMR=Americas. EMR=eastern Mediterranean. EUR=European. SEAR= southeast Asia. WPR=western Pacific. * South Africa did not survey the public sector; no availability data for Cameroon (pilot). [†] no availability data for Brazil, Rio de Janeiro State (pilot). [‡] Syria did not survey the public sector. [§] Kryrgyzstan and Uzbekistan did not survey the public sector; no availability data for Armenia (pilot). ^{||} No availability data for Sri Lanka (pilot). ** Fiji did not survey the public sector.

Figure 1. Average of country-level mean percentage availability of medicines, by World Bank Income Group



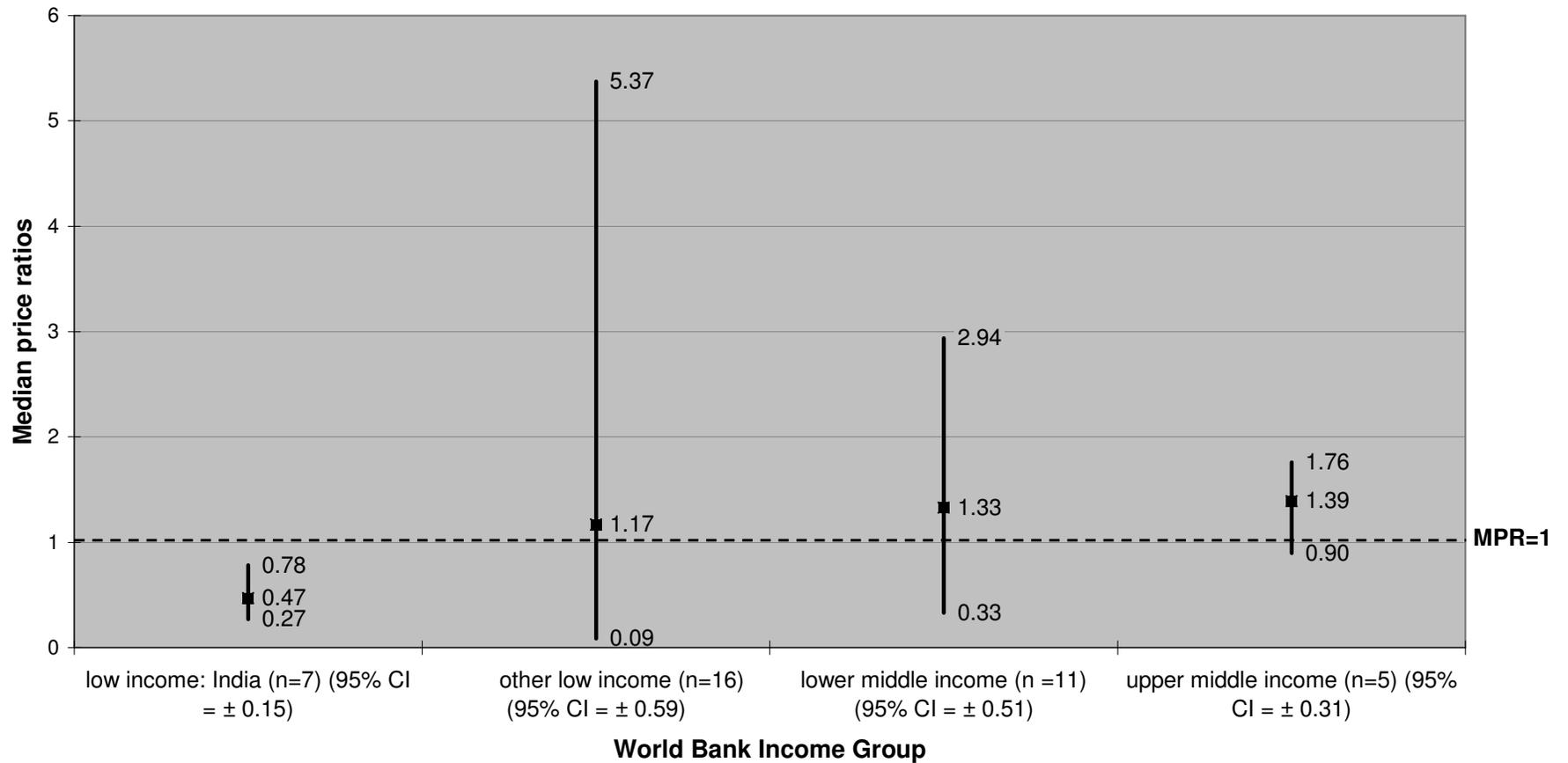
Data are mean (maximum/minimum).

Table 4. Median price ratios* of public sector procurement prices for lowest-priced generics, overall and by WHO region

	AFR	AMR	EMR	EUR	SEAR	WPR	All surveys
Median across basket of 15 medicines	1.34 (n=9) (0.55, 5.37)	1.15 (n=3) (0.70, 1.71)	1.01 (n=12) (0.09 [†] , 2.81)	1.40 (n=3) (1.11, 1.76)	0.63 (n=8) (0.27, 1.72)	1.44 (n=6) (0.59, 2.94)	1.11 (n=41) (0.09, 5.37)
Amoxicillin 250 mg capsule/tablet	1.18 (n=7) (0.64, 3.06)	1.70 (n=1) (1.70, 1.70)	1.14 (n=6) (0.58, 2.31)	2.46 (n=3) (1.94, 2.91)	1.28 (n=8) (0.68, 2.14)	1.23 (n=4) (0.70, 1.99)	1.36 (n=29) (0.58, 3.06)
Ciprofloxacin 500mg capsule/tablet	2.07 (n=6) (0.46, 7.10)	1.52 (n=3) (0.74, 2.92)	4.32 (n=10) (0.09, 25.35)	1.55 (n=3) (0.76, 2.90)	1.90 (n=7) (0.57, 6.28)	2.55 (n=1) (2.55, 2.55)	2.69 (n=30) (0.09, 25.35)
Glibenclamide 5mg capsule/tablet	3.42 (n=7) (0.60, 17.37)	1.03 (n=2) (0.70, 1.36)	1.95 (n=11) (0.41, 4.96)	3.10 (n=2) (2.50, 3.71)	1.52 (n=7) (0.27, 4.52)	1.68 (n=4) (0.30, 5.24)	2.15 (n=33) (0.27, 17.37)
Salbutamol 200-dose inhaler 0.1mg/dose	0.61 (n=5) (0.43, 1.04)	1.57 (n=3) (0.62, 3.01)	0.85 (n=8) (0.46, 1.54)	0.74 (n=2) (0.61, 0.87)	0.59 (n=1) (0.59, 0.59)	0.95 (n=4) (0.77, 1.10)	0.89 (n=23) (0.43, 3.01)

Data are mean (number of surveys) (range). WHO Region: AFR=Africa. AMR=Americas. EMR=eastern Mediterranean. EUR=European. SEAR= southeast Asia. WPR=western Pacific. *Ratio of the median procurement price to the MSH international reference price. [†] Based on a basket of 3 widely-available antibiotics (amoxicillin 250mg, ciprofloxacin 500mg and co-trimoxazole 8+40 mg/ml suspension).

Figure 2. Median price ratios for lowest priced generics in public procurement, by World Bank Income Group



Data are mean (maximum/minimum).

Table 5. Median price ratios* of originator brands and lowest-priced generics in the private sector, and of lowest-priced generics in the public sector, by WHO region

	AFR			AMR			EMR			EUR			SEAR			WPR		
	Private OB	Private LPG	Public LPG	Private OB	Private LPG	Public LPG	Private OB	Private LPG	Public LPG	Private OB	Private LPG	Public LPG	Private OB	Private LPG	Public LPG	Private OB	Private LPG	Public LPG
Median across basket of 15 medicines	62.92 (n=9)	21.23 (n=9)	6.79 (n=8)	52.66 (n=3)	25.21 (n=2)	3.18 (n=1)	24.54 (n=12)	13.75 (n=12)	6.88 (n=5)	24.96 (n=5)	8.69 (n=5)	8.19 (n=2)	21.28 (n=9)	9.61 (n=8)	6.84 (n=1)	34.21 (n=5)	11.25 (n=6)	11.95 (n=4)
Amoxicillin 250 mg capsule/tablet	59.01 (n=6)	7.69 (n=6)	5.96 (n= 6)	53.22 (n=1)	29.63 (n=2)	4.55 (n=1)	35.47 (n=5)	14.11 (n=9)	5.67 (n=5)	21.97 (n=1)	13.78 (n=5)	10.49 (n=1)	31.17 (n=4)	22.12 (n=8)	7.46 (n=1)	26.23 (n=2)	11.08 (n=5)	9.32 (n=3)
Ciprofloxacin 500mg capsule/tablet	268.46 (n=4)	22.04 (n=7)	21.07 (n= 6)	242.09 (n=3)	53.10 (n=2)	2.06 (n=1)	154.89 (n=7)	50.47 (n=12)	13.79 (n =4)	257.73 (n=2)	22.12 (n=5)	6.79 (n=1)	57.46 (n=8)	19.22 (n=8)	19.31 (n=1)	195.96 (n=3)	32.94 (n=4)	81.71 (n=1)
Glibenclamide 5mg capsule/tablet	161.97 (n=7)	33.87 (n=7)	17.65 (n=7)	211.86 (n=1)	67.56 (n=2)	3.18 (n=1)	59.85 (n=8)	25.06 (n=12)	17.97 (n=4)	12.77 (n=1)	12.98 (n=4)	10.54 (n=2)	48.10 (n=8)	19.06 (n=8)	17.65 (n=1)	99.57 (n=3)	34.59 (n=4)	56.97 (n=1)
Salbutamol 200-dose inhaler 0.1mg/dose	14.26 (n=8)	7.19 (n=6)	3.58 (n= 2)	9.05 (n=2)	5.58 (n=2)	1.82 (n=1)	6.00 (n=11)	3.28 (n=10)	3.02 (n=3)	5.58 (n=4)	4.05 (n=5)	3.73 (n=1)	6.47 (n=9)	4.56 (n=7)	---	8.60 (n=5)	4.32 (n=6)	4.64 (n=2)

WHO Region: AFR=Africa. AMR=Americas. EMR=eastern Mediterranean. EUR=European. SEAR= southeast Asia. WPR=western Pacific. OB=originator brand. LPG=lowest-priced generic.*Ratio of the median final (patient) price to the MSH international reference price

Figure 3. Median price difference between originator brands and lowest priced generics for matched pairs of medicines, private sector, by World Bank Income Group

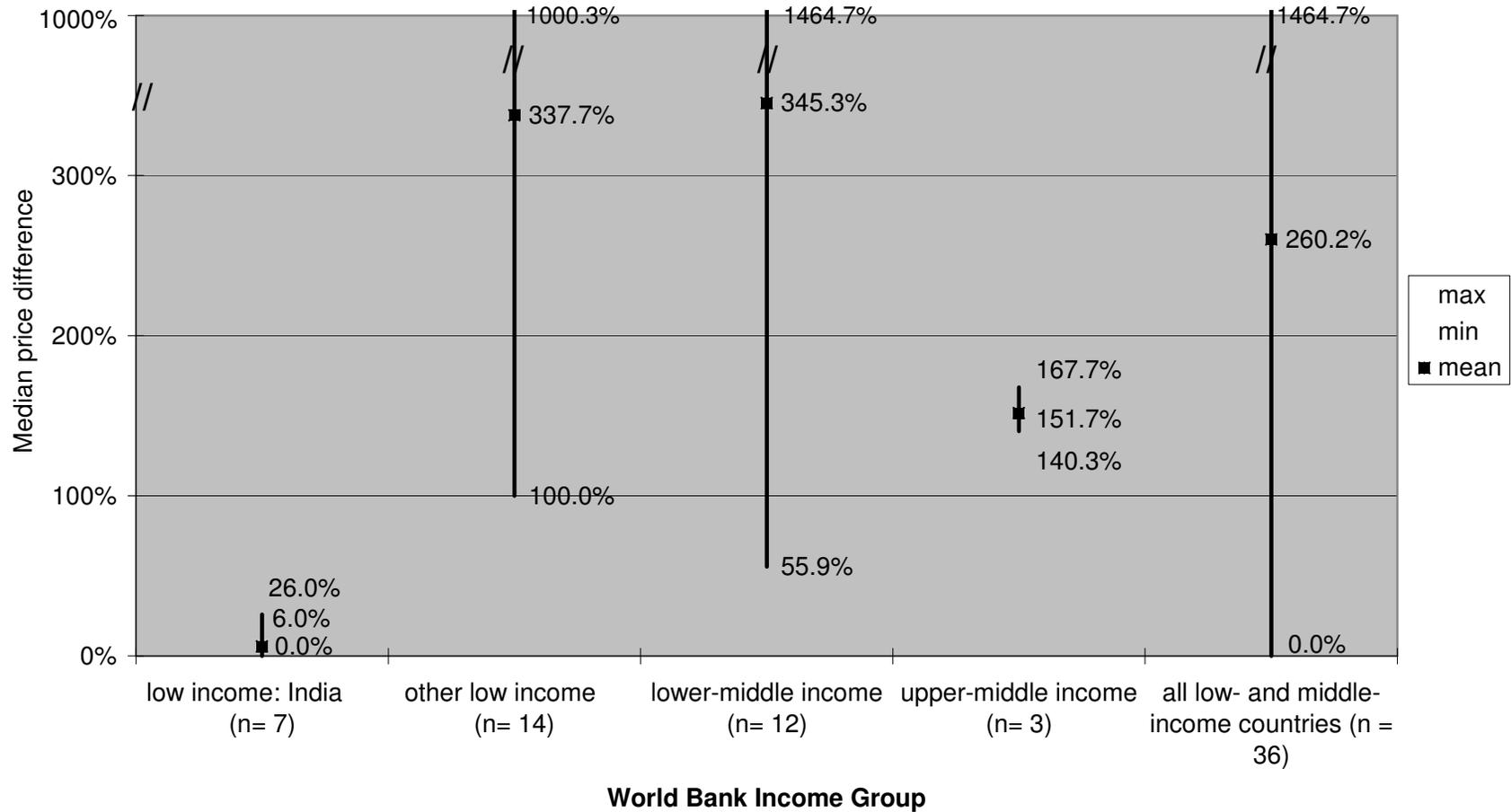


Table 6. Mean number of day's wages of the lowest-paid unskilled government worker needed to purchase a course of treatment, by WHO Region

		AFR	AMR	EMR	EUR	SEAR	WPR
Adult respiratory infection Amoxicillin 250mg capsule/tablet, three per day for 7 days	Private sector OB	2.9 (n=6)	1.9 (n=1)	1.6 (n=5)	1.4 (n=1)	1.2 (n=4)	0.5 (n=2)
	Private sector LPG	0.5 (n=6)	1.0 (n=2)	0.6 (n=8)	2.9 (n=5)	0.6 (n=8)	0.4 (n=4)
	Public sector LPG	0.5 (n=6)	0.2 (n=1)	0.3 (n=4)	7.9 (n=1)	0.4 (n=1)	0.4 (n=3)
Diabetes Glibenclamide 5mg capsule/tablet, two per day for 30 days*	Private sector OB	8.4 (n=7)	4.5 (n=1)	2.1 (n=8)	0.5 (n=1)	1.3 (n=8)	1.6 (n=3)
	Private sector LPG	1.8 (n=7)	1.5 (n=2)	0.9 (n=12)	1.8 (n=4)	0.4 (n=8)	0.7 (n=4)
	Public sector LPG	1.1 (n=7)	0.1 (n=1)	0.5 (n=4)	2.5 (n=2)	0.6 (n=1)	0.7 (n=1)
Asthma Salbutamol 0.1 mg/dose inhaler, 200 doses	Private sector OB	4.4 (n=8)	2.0 (n=3)	1.6 (n=11)	3.6 (n=4)	1.2 (n=9)	1.4 (n=5)
	Private sector LPG	2.5 (n=6)	1.0 (n=2)	0.8 (n=10)	5.0 (n=5)	0.6 (n=7)	0.7 (n=6)
	Public sector LPG	1.6 (n=2)	0.6 (n=1)	0.7 (n=3)	15.0 (n=1)	---	1.1 (n=2)
Ulcer Ranitidine 150 mg capsule/tablet, two per day for 30 days*	Private sector OB	35.4 (n=6)	9.0 (n=3)	8.5 (n=9)	21.1 (n=3)	2.7 (n=9)	5.5 (n=3)
	Private sector LPG	5.0 (n=6)	2.8 (n=2)	3.8 (n=11)	4.6 (n=5)	0.5 (n=8)	1.7 (n=6)
	Public sector LPG	6.3 (n=4)	0.6 (n=1)	1.3 (n=4)	6.3 (n=2)	2.2 (n=1)	1.2 (n=4)

WHO Region: AFR=Africa. AMR=Americas. EMR=eastern Mediterranean. EUR=European. SEAR= southeast Asia. WPR=western Pacific. OB=originator brand. LPG=lowest-priced generic. *One month has been used as the course of treatment for chronic diseases.

Table 7: Cumulative percentage mark-ups between manufacturer's selling price or Cost, Insurance and Freight price, and final patient price in the public and private sectors

Country	Total cumulative % mark-up, public sector	Total cumulative % mark-up, private sector
China (Shandong)*	24-35%	11-33%
El Salvador*		165-6894%
Ethiopia*	79-83%	76-148%
India†		29-694%
Malaysia‡	19-46%	65-149%
Mali*	77-84%	87-118%
Mongolia*	32%	68-98%
Morocco‡		53-93%
Uganda‡	30-66%	100-358%
United Republic of Tanzania*	17%	56%
Pakistan‡		28-35%

*Country surveys of price components using WHO/HAI standard methodology. †Kotwani A, Levison L. Price components and access to medicines in Delhi, India. http://www.dfidhealthrc.org/meta/documents/Price%20component%20Report_Delhi%20%20India_MeTA.pdf (accessed June 20, 2008).

‡Levison L. Investigating price components: medicine costs between procurement and point of delivery. Draft report on initial field studies. Unpublished (2008).