A new study on medicine prices using the WHO/HAI methodology was conducted in Brazil following a pilot survey in 2001, undertaken as part of the methodology development process. Field collection of data for the pilot survey took place in only one State, Rio de Janeiro. Now, a broader study has produced a representative picture of medicine prices and availability throughout the country. The project is a technical cooperation project between the Nucleus of Economic Advising on Regulation (Nurem) of the National Health Surveillance Agency (Anvisa) and the Center for Pharmaceutical Policies (NAF) of the Sergio Arouca National School of Public Health (ENSP) at the Oswaldo Cruz Foundation (Fiocruz) – a WHO/PAHO Collaborating Centre for Pharmaceutical Policies. It is also part of a cooperation programme between Anvisa and the Pan-American Health Organization (PAHO).

Brazil is a huge country of 180 million people, with a territory of 8.5 million square kilometers divided into 27 States. Consequently, it was decided to perform surveys in each of the five geographical regions of the country (North, Northeast, Center-West, Southeast and South).
The country’s health system is decentralized and organized in three levels of management: central, or national level (Ministry of Health (MOH)), state level (State Health Secretariats (SHS)) and local or municipal level (Municipal Health Secretariats (MHS)). These three levels have individual responsibilities in the provision of services, including shared roles in medicine provision. Municipalities manage medicine supply at most health-care facilities, however, and so were chosen as data collection sites.

Initially, 20 municipalities were selected in the five regions. The first five municipalities (major urban centres) were selected on the basis of having a Ministry of Justice Office of Consumer Rights (Procon). Anvisa intended to train Procon employees for future price surveys. Subsequently, the other 15 were selected according to the following criteria: presenting a minimum 1000 km distance from the major urban centres and hosting a public hospital; in addition, two of these municipalities were to present a low human development indicator score and one a higher score, similar to that of the major urban centre.

In some of the municipalities it was estimated that there were insufficient pharmacies in each of the surveyed sectors, and so 10 neighboring municipalities were identified to complete the sample, making a total of 30 municipalities. Field collection of data was performed in May 2007.

**Selection of surveyed medicines**

Besides adapting the core list of medicines included in the WHO/HAI Manual (which assures a minimum comparability of data among different countries) to those dosage forms available in the Brazilian pharmaceutical market, a supplementary list of medicines was selected. Selection criteria included being part of the Brazilian Essential Medicines List, and distribution by at least three Health Programmes of the MOH (Table 1).

**Sectors surveyed**

Sectors where prices were collected were defined according to where users acquire medicines in the health system.

- **Private sector**: this sector included any private pharmacy near public health facilities selected to anchor the sample, following the WHO/HAI methodology.
- **Public procurement sector**: corresponds to the WHO/HAI “procurement” category. In the Brazilian Public Health System medicines are free of charge. Since health facilities generally do not buy their own medicines, price data were collected in each municipality centrally at the MHS. Availability was checked in local medical stores and whenever this was not possible health facilities were also visited.
- **Brazil Popular Pharmacy sector**: in the WHO/HAI methodology, this sector is meant to include public facilities in which patients pay for drugs. This is not normally

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**Table 1. Supplementary list of medicines surveyed in the Brazilian study**

<table>
<thead>
<tr>
<th>Medicine category</th>
<th>Generic name</th>
<th>Dose</th>
<th>Dosage form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analgesics</td>
<td>paracetamol</td>
<td>500 mg</td>
<td>tablet/capsule</td>
</tr>
<tr>
<td>Antipiritics</td>
<td>amoxicillin</td>
<td>500 mg (a)</td>
<td>tablet/capsule</td>
</tr>
<tr>
<td>Antibacterials</td>
<td>benzathine benzylenicillin</td>
<td>1,200,000 UI</td>
<td>powder for injection</td>
</tr>
<tr>
<td>Antiamoebic preparations</td>
<td>ferrous sulfate</td>
<td>40 mg</td>
<td>tablet/capsule</td>
</tr>
<tr>
<td>Antiemetics</td>
<td>metoclopramide</td>
<td>10 mg</td>
<td>tablet/capsule</td>
</tr>
<tr>
<td>Antifungals</td>
<td>fluconazole</td>
<td>150 mg (a)</td>
<td>tablet/capsule</td>
</tr>
<tr>
<td>Anti-inflammatory agents</td>
<td>diclofenac</td>
<td>50 mg (a)</td>
<td>tablet/capsule</td>
</tr>
<tr>
<td></td>
<td>ibuprofen</td>
<td>300 mg</td>
<td>tablet/capsule</td>
</tr>
<tr>
<td></td>
<td>prednisone</td>
<td>20 mg</td>
<td>tablet/capsule</td>
</tr>
<tr>
<td>Antimalarials</td>
<td>artesunate</td>
<td>50 mg (a)</td>
<td>tablet/capsule</td>
</tr>
<tr>
<td>Antipsychotics</td>
<td>fluphenazine enantate (a)</td>
<td>25 mg/ml</td>
<td>injection</td>
</tr>
<tr>
<td>Anti-Parkinson drugs</td>
<td>biperiden</td>
<td>2 mg</td>
<td>tablet/capsule</td>
</tr>
<tr>
<td>Antiparasitic agents</td>
<td>albendazole</td>
<td>400 mg</td>
<td>tablet/capsule</td>
</tr>
<tr>
<td></td>
<td>benzyl benzoate</td>
<td>250 mg/ml</td>
<td>emulsion</td>
</tr>
<tr>
<td></td>
<td>metronidazole</td>
<td>40 mg/ml</td>
<td>suspension</td>
</tr>
<tr>
<td>Lipid modifying agents</td>
<td>simvastatin</td>
<td>40 mg</td>
<td>tablet/capsule</td>
</tr>
<tr>
<td>Sex hormones</td>
<td>medroxyprogesterone acetate</td>
<td>5 mg</td>
<td>tablet/capsule</td>
</tr>
<tr>
<td></td>
<td>ethinylestradiol and levonorgestrel</td>
<td>0,03 mg + 0,15 mg</td>
<td>tablet/capsule</td>
</tr>
</tbody>
</table>

(a) – from WHO/HAI Manual core list. Adapted to products available in the Brazilian pharmaceutical market.
the case in Brazil. Nevertheless, in 2004, the MOH established the “Brazil Popular Pharmacy” programme aimed at expanding access to drug treatment by means of a co-payment strategy, in which prices are heavily subsidized. This programme has two distinct components. The first includes a wide selection of medicines sold in MOH pharmacies. Twenty-six out of 43 surveyed medicines were found in these facilities. Their prices were centrally collected, since they do not vary across pharmacies. The second component encompasses a much more restrictive selection of products to treat hypertension and diabetes (recently contraceptives were also included), sold in private pharmacies that choose to take part in the programme. Four medicines were present in this selection and their prices were collected in the pharmacies.

New variables included in the study and data collection forms

In Brazil, generic medicines must be submitted to bioavailability tests in order to ensure bioequivalence to reference brand products. They are sold under their International Nonproprietary Names (INN), and are clearly labelled as “generic medicine”. Multi-source products not bioequivalent to the reference brand but having the same dosage form and strength (pharmaceutical equivalence) are called “similar” products. They must undergo bioavailability studies and sell under brand names. Most of these products were already in the market when generic medicines were enforced by Brazilian law in 1999.

Thus, in the private sector, prices and availability data of innovator brands and lowest-priced generics were collected, as stated in the WHO/HAI methodology. In addition, prices for the highest-priced generics, and lowest- and highest-priced “similar” products were also surveyed, as well as the number of generic and “similar” products encountered and their producers. These data are meant to give insight on the performance of the National Generic Medicines Policy and on market competition of multi-source products.

In the public procurement sector, medicines are mainly acquired through public tender, from private suppliers, or direct procurement from public pharmaceutical laboratories. Tendering by generic name is mandatory, and the lowest-priced product that meets specifications is usually purchased. As a result, the price paid in the last purchase was collected, whether belonging to an innovator brand, a generic or a “similar” product. The type (e.g. public laboratory, wholesaler) of supplier and name of producer were also identified in order to characterize the most prevalent types of suppliers, and possible relationships between prices and producers.

Data collection forms for each surveyed sector were printed in different colours and in order to avoid bias in data collection, prices were researched in a different order each time.

Field work and data handling

Adequate field work preparation was crucial to the success of data collection. MHS were previously contacted to arrange visits. Field researchers were carefully selected and trained at a two-day workshop, which included a field simulation performed in a municipality not included in the sample.

In order to ensure accuracy in data handling, data collection forms were revised and a double-entry procedure was performed, both in the WHO/HAI workbook, and in the database developed to include the new added variables. The ratio between maximum and minimum prices for each medicine, by sector, was used to identify outlier values.
These were checked for possible errors in form completion and data entry.

Difficulties encountered and recommendations for Brazil

During field work preparation and performance, some difficulties were encountered that if adequately handled may help planning for future studies:
- Innovator brand names may vary between countries. Careful adaptation of data collection forms prevents errors.
- Many MHS took a long time to agree to participate in the study. Be sure to contact authorities well in advance.
- Sometimes medicines are procured centrally and distributed directly to health facilities, without being stocked in central medical stores. In these cases, prices had to be collected in the MHS and availability checked elsewhere. Notwithstanding, not all health facilities are supposed to receive every medicine included in the study list. This depends on the particular health programmes that they are involved in. This may result in a biased perception of availability.
- Private retail pharmacies tend not to sell certain medicines, such as those for HIV/AIDS. These products must not be considered for evaluation of availability in these settings.
- Data collection forms for private pharmacies took around 1.5 hours to complete during the field simulation. Prior identification of the most frequently used producers and their codification helped to reduce the time spent in these facilities.

The Brazilian survey results will be publicized and discussed among health system managers. One article on experiences to date has already been published and two more are being finalized.

References


Elaine Silva Miranda, Cláudia Du Bocage Santos Pinto and Isabel Cristina Martins Emmerick work at the Center for Pharmaceutical Policies (NAF), Department of Biological Sciences, The Sergio Arouca National School of Public Health (ENSP) - Oswaldo Cruz Foundation (Fiocruz). André Luis de Almeida dos Reis works for Coordination of Intellectual Property (COOPI), National Health Surveillance Agency (Anvisa) and Mônica Rodrigues Campos works in the Department of Social Sciences, The Sergio Arouca National School of Public Health (ENSP), Oswaldo Cruz Foundation (Fiocruz).

The Medicines Transparency Alliance: increasing access to essential medicines

➤ Alison Dunn

Across the globe, one person in every three - about two billion people - lacks access to essential medicines. Millions die every year from illnesses, such as malaria, pneumonia and diarrhoea, which can be cured with the timely use of appropriate medicines. However, for these people, medicine costs are too high, the right medicines are not in the pharmacies, distribution systems are inefficient, counterfeit drugs permeate local markets and the most effective and cheapest medicines are not ethically promoted and prescribed.
Collaboration and Transparency

The Medicines Transparency Alliance (MeTA) is funded by the UK’s Department of International Development and works in collaboration with the World Bank and the World Health Organization. It is a multi-stakeholder initiative which was launched in May 2008 with the aim of improving access and affordability of medicines by creating a unique collaboration between governments, the private sector and civil society in seven countries around the world.

In Ghana, Jordan, Kyrgyzstan, Peru, Philippines, Uganda and Zambia representatives from these stakeholder groups have committed to work together to increase access to essential medicines through the disclosure and analysis of data around the medicines supply chain.

MeTA works on the principle that this process of dialogue and disclosure will identify inefficiencies and abuses in the supply chain - accountability will become clear, the problems will be tackled and access to essential medicines will be improved. Debate has been rife for many years in developing countries around where the responsibility for lack of access to essential medicines lies and this debate has very often been acrimonious and divisive.

MeTA has facilitated a process which has brought the parties concerned in this debate together around a table to consider not who is to blame but what can be done to improve access to medicines for poor people.

What has happened so far?
The MeTA pilot scheme has been running for two years. The first year of MeTA focused on setting up the systems and structures of a multi-stakeholder process and establishing ways of working. All participating countries successfully launched MeTA through a high profile national event. They have set up a representative multi-stakeholder council which meets regularly to take the work forward and agreed collectively a work plan until September 2010.

The second year has seen a move from discussion to action as each of the pilot countries has begun to implement this work plan. As a first step, a number of tools are being applied. The tools include: a pharmaceutical sector baseline scan; a disclosure tool; a household and health facility survey; communication and media scan; private sector, civil society and supply chain mapping; and drug price monitoring. New tools are being developed for measuring promotion and multi-stakeholder collaboration. The institutions involved in developing and using these tools include WHO, Harvard University, Health Action International and the Institute of Development Studies.

The countries are all very different – their priorities have been defined according to their national context and progress has been made at different rates. Nonetheless some significant steps have already been taken in each country. Highlights include:

- **Ghana**: Mini-lab testing funded by MeTA Ghana and the World Bank has led to the identification and recall of sub-standard medicines
- **Jordan**: The work of MeTA Jordan has prompted the revision of the Rational Drug List
- **Kyrgyzstan**: The MeTA Kyrgyzstan CSO coalition has agreed with regional authorities to participate in the procurement of the medicines in one of the regions of the country
- **Peru**: MeTA Peru focused its efforts on developing a Price Observatory to give the public access to accurate information
about medicine prices; the legislation for this has been signed, and the technology is being developed.

- **Philippines**: MeTA Philippines' Council members participated in the debates on the 'Universally Accessible Cheaper and Quality Medicines Act', which was signed into law in June 2008.

- **Uganda**: MeTA Uganda supported the National Drug Authority in making the database of registered medicines available on its web site which is now searchable online. The Government has invited the private sector to participate in the formulation of the next five-year strategic plan for pharmaceuticals in Uganda, which previously they have never been involved with.

- **Zambia**: MeTA Zambia initiated outreach programmes in two districts of the rural North Western Province and three 'road shows' were taken into other rural communities. This publicity campaign has already raised the public's awareness of their rights as patients and their entitlement to good quality, affordable medicine.

**What the stakeholders have to say......**

**Government**: “We have got civil society, government and the private sector sitting together at one table and discussing issues. As a government, for us, and as the pharmacy division, we are mandated to make sure there's good medicine, affordable medicine and quality medicine to society. We think MeTA will augment our work because this is our mandate to make sure people have affordable medicine, so we see MeTA not as a group that has come to take our work but to help us do our work better by engaging other stakeholders who hitherto were not engaging efficiently.”

*Seru Morries, Principal Pharmacist, Ministry of Health, Uganda*

**Business**: “I got involved in MeTA because I was asked to represent the local pharmaceutical manufacturing group, known as the Pharmaceutical Manufacturer’s Association of Ghana. My interest in MeTA - in fact the interest of the industry - is to actually make all of our information available. There is a certain perception that the local industry produces sub-standard drugs. I think it would be good that transparency comes up around this, to see how we are regulated, to see the quality of the drugs we make, and if the quality of the drugs we make is not up to standard I think we need to be held to book.”

*Paul Lartey, CEO, LaGray Chemical Company, Ghana*

**Civil society**: “One of the best things that happened to us is to bring together all these stakeholders round the table. Now we can transparently and openly agree to disagree, or agree to agree on certain points... There's a greater appreciation of what we have in our country from the legal perspective, from the trade perspective, from the scientific perspective and a human rights perspective, which is exactly what this is all about: helping the public to access better quality medicine.”

*Kenneth Hartigan-Go, Philippines*

**Summary**

Over the last two years, the activities of the seven pilot countries have been intense. The experiences have been very different in each country and often very challenging. Getting the right people round the table and building trust has taken time and patience – but has, in every case, been time well spent. Gaining consensus has also sometimes been less than straightforward, but frank exchanges and detailed negotiations are leading to policies and more realistic objectives. The pace of development and change for the MeTA work plans has been different - but these differences have highlighted where improvements can be made and where pitfalls can be avoided.

The pilot countries are now at a stage where they can share their experiences. They can explore with practitioners, academics and policy-makers how transparency and accountability in the pharmaceutical supply chain can be further strengthened to support increased access to medicines.

Beyond the pilot phase, technical support and communication materials will be provided to MeTA pilot countries to help them effectively communicate their work so that they can build on the impetus that the Medicines Transparency Alliance has created. Many of the countries have already begun to change policies and implement new processes to improve access to essential medicines. The Medicines Transparency Alliance is fundamentally shifting relationships and ways of working in the future.