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Current Situation of Availability and Cost Effectiveness Analysis of Selected Drugs in Anantapur, AP, India

Meenu Singh, Y. Pragzna and Dharma DevBommi

ABSTRACT

World Health Organization (WHO) and Health Action International (HAI) recognized the need for a standard methodology to measure medicine prices in countries so that a clearer picture of what patients actually pay for medicines in low and middle-income countries could be obtained. These two organizations jointly published a manual, which described a methodology for collecting data and measuring medicine prices in various countries. By adopting this methodology, in present study we focused to obtain 1. Baseline data for the availability of medicines in the public and private sectors, 2. Cost Effectiveness Analysis or Affordability of model treatment regimen and 3. Comparison of national Most Sold Generics/MSGs in Anantapur. We did our survey in four phases namely survey planning and preparation, sampling, selection of medicines, MSG equivalents, affordability/ cost effectiveness analysis and availability. The results of the study provided stable baseline interventions to improve the availability of medicines in the public sector and reduce the prices in private sector.

Keywords: Affordability/ Cost effectiveness Analysis, Availability, MSGs (Most sold Generics), WHO (World Health Organization), HAI (Health Action International).

INTRODUCTION

The price of medicines is a crucial determinant of the health of citizens. WHO reported than one third of the world's population lacks reliable access to required medicines (Kotwani *et al.*, 2007). Many low income countries do not have policies for controlling medicine prices, WHO and HAI recognized the need for a standard methodology to measure medicine prices in countries so that a clearer picture of what patients actually pay for medicines in low and middle income countries could be obtained (Kotwani *et al.*, 2007). These two organizations jointly published a manual which described a methodology for collecting data and measuring medicine prices in various countries. This methodology was designed to collect, analyze and interpret the data in a standardized way. It requires a systemic survey of the prices and availability of a core list of medicines and allows for a supplementary list of medicines that are selected by each survey team (country) on the basis of their importance in treating major health problems. Selection of survey facilities, for generating data on prices to patients in both the private and public sectors, uses a sampling approach that selects one central area, the major urban city (usually the capital of the State/ Country) and three other administrative areas chosen randomly from a list of areas that can be reached within one day's travel from the central area.

Meenu Singh, Y. Pragzna,
Dharma DevBommi
Department of Pharmacology,
CMR College of Pharmacy,
Kandlakoya (V), Medchal Road,
Hyderabad – 501401, Andhra
Pradesh, India.

For Correspondence
Dharma DevBommi
CMR College of Pharmacy,
Kandlakoya (V), Medchal Road,
Hyderabad, Andhra Pradesh, INDIA
Phone No. 8099268635

In each of the four identified areas, at least five public health facilities are selected, including the main public hospital (tertiary care level).

The choice of private sector pharmacies sample is based on their proximity to the public health facilities surveyed, at least five public, five private pharmacies per survey area should be included (Kotwani *et al.*, 2007). Organizations like WHO and HAI have been actively pursuing policies to facilitate universal access to essential medicines. Indeed, access to essential medicines has been viewed as an integral component of the right to health, which is a basic human right (Hogerzeil H, 2003). Therefore, it is a global obligation to ensure availability and affordability of essential medicines. Worldwide, there are a multitude of medicines with a multitude of prices. The same medicine has different prices depending upon the source from which it is procured, the form in which it is marketed (e.g., brand or generic, oral or parenteral, course of treatment pack or bulk pack etc.), the taxes and duties that are levied by governments and the facilities from which it is procured by patients. It is an extremely complex task, whether for individuals or for governments, to ascertain the optimum availability and best prices for medicines. Therefore it is necessary to monitor these parameters on a regular basis (Myhr, 2003).

WHO and HAI have collaborated to develop a methodology for measuring medicines prices and availability (Myhr, 2003). This has already been field tested in many countries and is being refined in the process. Study was conducted in ANANTAPUR, following this methodology, to provide the baseline data for assessing medicine availability, affordability and availability of nationwide most sold generic (MSG) in the city. Although health policies and drug policies are formulated and revised periodically by the Government of India, the major responsibility of their implementation lies with state governments. Pricing of drugs is regulated to a limited extent by the Government of India through its Drug Prices Control Order (DPCO). The state Drug Control Authority is entrusted with the regulatory mandates of the Drugs and Cosmetics Act of 1940.

MATERIALS AND METHODS

The survey covered medicines in the public sector and private retail pharmacies based on the methodology developed by WHO/HAI for the collection, analysis and interpretation of data on medicine availability and pricing. A total of 25 medicines were sampled (Tripathi *et al.*, 2006). The data collectors were familiarized with the methodology of the survey. The required data and sufficient copies of “Data Collection Forms” were prepared in advance. From the conception up to the completion, the project took 40 days. The total duration of the project work was categorized into three phases: **1st phase:** The first phase was the literature review phase. This phase includes the study of the background research required for this project and prepared the data collection and analysis procedures suitable for the project. The total duration of this phase was 10 days. **2nd phase:** The second phase was the field work phase. This phase involves visiting the various data collection centers (public and private sectors) and collected the required data. The data were collected with the help

of a “Questionnaire” and recorded the findings in a tabulated manner. The total duration of this phase was 20 days. **3rd phase:** The third phase was the data analysis phase. In this phase the collected data were analyzed and tabulated accordingly. The data analysis phase enabled to understand the results of the project. The total duration in this phase was 10 days. 20 retail pharmacies and a government hospital were selected at 5 different areas in City and data was collected. The complete list of medicines surveyed and MSG equivalents are provided in the Medicine Price Data Collection Forms (Core and Supplementary Lists). The WHO/HAI manual provides a core list of 25 medicines. However, some core medicines were removed from the survey because of known limited availability in Anantapur.

The WHO/HAI methodology also provides for inclusion of up to 20 supplementary medicines reflecting local morbidity patterns. Accordingly, 15 such medicines were selected as indicated in Table 1. The supplementary medicines were selected only if they fulfilled the following criteria i.e. they must be commonly using medicines to treat various prevailing diseases, should have high level of use, and should easily be available at all health care units and ease of availability (See Table 2). Thus the final survey list contained 25 medicines - 10 core and 15 supplementary drugs. Overall this basket of drugs was expected to provide a reasonable representation of the availability, affordability and availability of national MSGs in ANANTAPUR. It should also be noted that the WHO/HAI survey methodology requires strict adherence to the specified dosage form and strength of a medicine. Therefore this report does not consider alternative strengths or forms which may have been available in ANANTAPUR during the study period.

Table 1: List of sampled medicines from the WHO core list.

Sl.No	Drugs	Dose	Dosage form
1.	Amlodipine	5mg	Tab
2.	Atenolol	50mg	Tab
3.	Artesunate	50mg	Tab
4.	Chloroquinie phosphate	500mg	Tab
5.	Glibenclamide	5mg	Tab
6.	Ibuprofen	400mg	Tab
7.	Insulin	10ml	Inj
8.	Mefloquine	250mg	Tab
9.	Quinine Sulphate	300mg	Tab
10.	Ranitidine	150mg	Tab

Table 2: List of supplementary medicines.

Sl.No	Drug	Strength	Dosage form
1	Aceclofenac	100 mg	Tab
2	Artether	150mg	Tab
3	Diclofenac sodium	3ml	Inj
4	Gliclazide	80 mg	Tab
5	Glimipiride	2mg	Tab
6	Lansoprazole	30mg	Inj
7	Losartan	50mg	Tab
8	Nimesulide	100 mg	Tab
9	Omeprazole	20 mg	Tab
10	Pantoprazole	40 mg	Tab
11	Pioglitazone	30 mg	Tab
12	Piroxicam	20 mg	Tab
13	Rabeprazole	20mg	Tab
14	Ramipril	5 mg	Tab
15	Telmisartan	40 mg	Tab

Most Sold Generic Equivalents and Cost Effectiveness Analysis

Innovator Brand (IB): IB denotes the originator brand of a particular therapeutic moiety developed by a particular pharmaceutical company. Most Sold Generic (MSG) is the generic equivalent of Innovator Brand (IB) that is most popular and most sold generic version of a particular medicine. WHO/HAI methodology indicates that a survey should be conducted to determine the Most Sold Generic equivalent (MSG) for the study medicines on a national basis. Since it was extremely difficult to do this on a regional (state) basis, this data was obtained centrally from the national coordinators for the study (Tripathi *et al.*, 2006). The WHO/HAI methodology incorporates affordability calculations based on how many day wages of an unskilled government worker would be required to purchase standard or model treatments using the survey medicines. A model treatment was considered “affordable” if it cost less than 5 days wages (Tripathi *et al.*, 2006). Daily wages of lowest paid unskilled government worker in Anantapur was INR 150 while that of unskilled labor in the unorganized sector is INR 100. These figures were taken as baseline for determination of affordability.

Stages of Study

The study was divided into various stages. The first stage was finding out products and areas preferable for the sales study and preparation of *Questionnaire* for the collection of product sales figures. Questionnaire was prepared for data collection in order to collect the information needed for the project. It included questions whose answers will provide required data. Selection and short listing of data collection resources: Approaching the different categories of public and private sectors for the purpose of collection of data for the project.

The second stage was study of selected drugs wherein following information was collected from the public and private sectors through the questionnaires. 1.Brand names for different drugs and their manufacturing companies, 2.Cost per strip/vial, 3.Most selling generic equivalent (MSG) in Anantapur, 4.Reason for being MSG in the city. Data was gathered by the data collectors during their visits to the individual pharmacies. Public procurement prices were obtained. Patient prices were not applicable at the public facilities as in public facilities; patients need not to pay for any medicines which are being dispensed. At private pharmacies, availability and the prices on the medicine/strips or vials were surveyed at each selected pharmacy. Since medicines sold in Anantapur, at the time of the survey, generally had the Maximum Retail Price (MRP) printed on the strip/vial. The data collectors had to enquire the retailers for the patient prices. All price data were recorded on the predesigned data collection forms. For data

analysis, the data entry was entered in the predesigned computerized Microsoft Excel software.

RESULTS AND DISCUSSIONS

Out of the 25 selected drugs, the MSG of 12 drugs at Anantapur region were matching with the national MSG. Although the availability of national level MSG was there in some retail pharmacies, low availability of the drugs, prescription of drugs by doctors and low procurement were reasons for not being the MSG at Anantapur.

Availability

The percentage availability of national MSG in the core list of medicines in private sector was as follows (See Table 3) :Ranitidine 150 mg tab-100%, Chloroquine phosphate 500 mg tab-100%, Quinine sulphate 300 mg tab-75%, Artesunate 50 mg tab-30%, Ibuprofen 400 mg tab-15%, Glibenclamide 5 mg tab-55%, Amlodipine 5 mg tab-0%, Mefloquine 250 mg tab-60%, Human insulin 10 ml inj-95%, Atenolol 50 mg tab-100%. The percentage availability of national MSG in the supplementary list of medicines in private sector was as follows : Telmisartan 40 mg tab-50%, Diclofenac 3 ml inj-100%, Gliclazide 80 mg tab-20%, Losartan 50 mg tab-60%, Omeprazole 20 mg tab-90%, Aceclofenac 100 mg tab-85%, Glimepiride 2 mg tab-15%, Pantoprazole 40 mg tab-35%, Nimesulide 100 mg tab-100%, Pioglitazone 30 mg tab-80%, Rabeprazole 20 mg tab-0%, Artheeter 150 mg inj-70%, Lansoprazole 30 mg tab-25%, Piroxicam 20 mg tab-60%, Ramipril 5 mg tab-30%. Public sector procurement in Anantapur adheres to a generics policy and therefore there is complete absence of any MSG products in this sector. The median availability of MSG medicines was 0% range for core medicines and 0% for supplementary medicines. Thus overall availability was poor. As many as 14 medicines were not encountered at all. At the private pharmacies, of the core list of medicines, median availability was 63% for MSGs and for the supplementary medicines it was 52.66%.

Comparison of National MSGs with City MSGs

For the drugs Ranitidine, Diclofenac sodium, Chloroquine phosphate, Aceclofenac, Quinine sulphate, Atenolol, Nimesulide, Pioglitazone, Arteether, Glibenclamide, Human insulin and Mefloquine, Anantapur MSG is same as National MSG (Table 4.1). While for the drugs Telmisartan, Gliclazide, Losartan, Omeprazole, Glimipiride, Pantoprazole, Artesunate, Ramipril, Rabiprazole, Ibuprofen, Amlodipine, Lansoprazole and Piroxicam, Anantapur MSG is different from National MSG (Table 4.2).

Table 3: Availability of medicines in the public and private sectors.

Sl. No	Brand name	Public sector	Private sector	National MSG	
				Public sector	Private sector(%)
1.	Aceclofenac, tab 100 mg	Nil	Yes	Nil	85
2.	Amlodipine, tab 5 mg	Yes	Yes	Nil	Nil
3.	Arteether, inj 150 mg	Nil	Yes	Nil	70
4.	Artesunate, tab 50 mg	Nil	Yes	Nil	30
5.	Atenolol, tab 50 mg	Yes	Yes	Nil	100

6.	Chloroquine phosphate, tab 500 mg	Yes	Yes	Nil	100
7.	Diclofenac, inj 3ml	No	Yes	Nil	100
8.	Glibenclamide, tab 5 mg	Yes	Yes	Nil	55
9.	Gliclazide, tab 80 mg	Nil	Yes	Nil	20
10.	Glimepiride, tab 2 mg	Nil	Yes	Nil	15
11.	Human insulin, inj 10 ml	Nil	Yes	Nil	95
12.	Ibuprofen, tab 400 mg	Yes	Yes	Nil	15
13.	Lansoprazole, tab 30 mg	Nil	Yes	Nil	25
14.	Losartan, tab 50 mg	Yes	Yes	Nil	60
15.	Mefloquine, tab 250 mg	Nil	Yes	Nil	60
16.	Nimesulide, tab 100 mg	Nil	Yes	Nil	100
17.	Omeprazole, tab 20 mg	Yes	Yes	Nil	90
18.	Pantoprazole, tab 40 mg	Yes	Yes	Nil	35
19.	Pioglitazone, tab 30 mg	Nil	Yes	Nil	80
20.	Piroxicam, tab 20 mg	Nil	Yes	Nil	30
21.	Quinine sulphate, tab 300 mg	Yes	Yes	Nil	75
22.	Rabeprazole, tab 20 mg	Nil	Yes	Nil	Nil
23.	Ramipril, tab 5 mg	Nil	Yes	Nil	30
24.	Ranitidine, tab 150 mg	Yes	Yes	Nil	100
25.	Telmisartan, tab 40 mg	Nil	Yes	Nil	50

Table. 4.1: Comparison of National level MSG with Anantapur MSG.

No	Drug	Strength	Dosage form	Nation level MSG	Surveyed area	MSG in Anantapur
1.	Aceclofenac	100 mg	Tab	Aceclo	Oldtown1 Ramnagar1	Aceclo
2.	Arteether	150 ml	Inj	E-mal	Oldtown2 Ramnagar2	E-mal
3.	Atenolol	50 mg	tab	Aten50	Sreekantam circle	Aten 50
4.	Chloroquine phosphate	500 mg	tab	Lariago	Saptagiri circle	Lariago
5.	Diclofenac sodium	3 ml	inj	Zobid	Saptagiri circle	Zobid
6.	Glibenclamide	5 mg	tab	Daonil	Oldtown2 Ramnagar2	Daonil
7.	Human insulin	10 ml	inj	Human mixtard	Sainagar	Human mixtard
8.	Mefloquine	250 mg	tab	Mefloc	Sainagar	Mefloc
9.	Nimesulide	100 mg	tab	Nise	Sreekantam circle	Nise
10.	Pioglitazone	30 mg	tab	Pioglit 30	Sreekantam circle	Pioglit 30
12.	Ranitidine	150 mg	tab	Zinetac	Saptagiri circle	Zinetac

Table. 4.2: Comparison of National level MSG with Anantapur MSG.

Sl. No	Drug	Strength	Dosage form	MSG in National wide	Surveyed area	MSG in Anantapur	Reason
1	Amlodipine	5 mg	tab	Stamcard	Sainagar	Stamlo	Doctor's trust
2	Artesunate	50 mg	tab	Faonil	Sreekantam circle	Lario	Doctor's trust
3	Gliclazide	80 mg	tab	Glycinorm	Saptagiri circle	Glizid	Doctor's trust
4	Glimipiride	2 mg	tab	Amaryl	Oldtown1 Ramnagar1	Glimy	Doctor's trust
5	Ibuprofen	400 mg	tab	Ibugesic	Oldtown2 Ramnagar2	Brufen	Doctor's trust
6	Lansoprazole	30 mg	tab	Lanzol	Sainagar	Lanzap	Doctor's trust
7	Losartan	50 mg	tab	Losakar	Oldtown1 Ramnagar1	Losar	Doctor's trust
8	Omeprazole	20 mg	tab	Ocid	Oldtown1 Ramnagar1	Omez	Aggressive marketing
9	Pantoprazole	40 mg	tab	Pantocid	Sreekantam circle	Pantop 40	Doctor's trust
10	Piroxicam	20 mg	tab	Pirox	Sainagar	Dolonex-DT	Doctor's trust
11	Rabiprazole	20 mg	tab	Rabecloc	Oldtown2 Ramnagar2	Razo 20	Doctor's trust
12	Ramipril	5 mg	tab	Cardace	Oldtown2 Ramnagar2	Ramistar	Doctor's trust
13	Telmisartan	40 mg	tab	Telma	Saptagiri circle	Telvas	Doctor's trust

Cost Effectiveness Analysis/Affordability

WHO/HAI methodology incorporates affordability calculations, based on how many day wages of an unskilled government worker would be required to purchase standard or model treatments using the survey medicines. A model treatment was considered "Affordable" if it cost less than 5 days wages. Daily wages of lowest paid unskilled government worker in Anantapur was INR 150 while that of unskilled labor in the unorganized sector was INR 100. These figures were taken as baseline for determination of "Affordability". Patients in the public sector do not need to pay for the medicines they receive, since these are fully subsidized by the government. It is clear that the prices obtained in public procurement are low and no patient would have to pay more than one day's wages to obtain any of the model treatments, if these were offered at procurement price. The picture is different in the private sector, as treatment here is 4 to 6 times in compare to public sector. It implies that even simple treatment regimens are unaffordable by "less than 5 days wages" criterion.

This study provides baseline data for interventional studies which can be planned to improve the availability of medicines in the public facility (Mendis *et al.*, 2007). Among the various reasons for poor availability of medicines could be : 1. Medicines which are not on the State's Essential Medicines List (EML) or procurement list are not purchased, 2. Inefficient distribution systems leading to frequent stock-outs, 3. Dispensaries having different EMLs and do not have medicines prescribed by specialists (e.g. Antipsychotic medicines). Public health facilities in Anantapur use only low-priced generic equivalents for free distribution. The availability situation in the public sector was found to be dismal, with 14 of the 25 medicines (56%) not being available at all. The reason for the poor availability can only be speculated on at the moment, but is likely to be multifactorial with reference to the following list: 1. Inadequate selection of essential medicines, 2. Failure of the distribution system, 3. Budgetary constraints limiting the extent of public procurement. It was also reiterated that the availability situation in the public sector may be

a little distorted by the survey methodology's insistence on fixed dosage forms and strengths. Thus, Diclofenac sodium injection was not available but only tablets were available. When it comes to pricing in the private sector, medicines in the private sector are definitely costlier than government procurement prices. Since the cost of production is unlikely to be grossly different for companies supplying to the government and those feeding the retail trade, other reasons will have to be sought to explain the higher prices in the private sector like: Profit margin of the manufacturer, Wholesale and retail trade margins, Addition of promotional cost to production and packaging cost.

The poor availability in the public sector also may indirectly push up prices in the private sector by forcing patients, who would have otherwise procured their medicines from public health facilities, to depend on private prescriptions (Irwin, 2003). Any demand-supply gap that occurs as a result is likely to be exploited by suppliers by keeping prices high to maximize their profits. Pharmaceutical manufacturers also keep a promotional pressure on doctors to generate demand for the drugs, beyond that mandated by scientific evidence of effectiveness and safety (Tripathi *et al.*, 2006). This survey clearly shows that a lot has to be done by the State governments to increase availability of medicines in the public facilities. One aspect is to go in for pooled procurement system to decrease the procurement price and better distribution system. Simultaneously in-depth studies should be done to find out the various reasons for poor availability of medicines and plan suitable interventions to improve the situation. This study has few limitations as well: WHO/HAI methodology was not strictly followed as the project was time bound and surveyed in smaller area (only district headquarters). IRP (International Reference Price) values of all the drugs that we had chosen could not be found out, due to which MPR (Median Price Ratio) values could not be calculated. No much work was done on Innovator brands, LPG (Low price Generics) brands of drugs due to non-availability in retail pharmacies. Difficult to get data on the procurement policies in public and private sectors as they could not be openly disclosed. The prices and availability of drugs in public and private sectors could not be completely compared as there was only one public facility in the town.

CONCLUSION

Public sector procurement in Anantapur adheres to a generics policy and therefore there was a complete absence of any MSG products in this sector. The median availability of MSG medicines was 0% range for core medicines and 0% for supplementary medicines. Thus overall availability was poor. As many as 14 medicines were not encountered at all. At the private pharmacies, of the core list of medicines, median availability was found to be 63% for MSGs and for the supplementary medicines was 52.66%.

The present survey has shown that while the government is procuring medicines at a very reasonable price, the availability of medicines is very low. This means that many patients have no option but to go to the private sector where there is generally better

availability of generic products but at a higher price. While it is to be expected that private sector retail prices would be higher than public sector procurement prices of generics, the differences observed seemed excessive. Therefore much could be done to improve availability in the public sector and to reduce medicine prices in the private sector. The drugs which were surveyed were affordable to both unskilled government labor and unskilled labor in the unorganized sector.

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ANNEXURES

GROUP-1

QUESTIONNAIRE – Market Survey for Comparative study of Different Brands/drugs

Name of the shop :

Name of the shopkeeper :

Address :

1) Telmisartan 40mg (Antihypertensive)

Sl.No	Brand	Company	Cost per strip/cost per vial
1.			
2.			
3.			
4.			
5.			

Highest selling Product/Brand:

Reason for highest sale:

- a) Price advantage -
- b) Aggressive marketing -
- c) Doctor's trust -
- d) Quality of product -
- e) Others -

Comment:

Other Brands, if any:

Sl.No	Brand	Company	Cost per strip/cost per vial
1.			
2.			
3.			

Highest selling Brand/Product :

Reason for highest sale:

- a) Price advantage -
- b) Aggressive marketing -
- c) Doctor's trust -
- d) Quality of product -
- e) Others -

Comment:

2) Ranitidine 150mg(antiulcer)

Sl.No	Brand	Company	Cost per strip/cost per vial

Highest selling drug:

Reason for highest sale:

- a) Price advantage -
- b) Aggressive marketing -
- c) Doctor's trust -
- d) Quality of product -
- e) Others -

Comment:

Other Brands :

Sl.No	Brand	Company	Cost per strip/cost per vial

Highest selling brand :

Reason for highest sale:

- a) Price advantage
- b) Aggressive marketing
- c) Doctor's trust
- d) Quality of product
- e) Others

Comment:

.....

3) Diclofenac sodium 3ml inj(NSAID's)

Sl.No	Brand	Company	Cost per strip/cost per vial

Highest selling drug:

Reason for highest sale:

- a) Price advantage
- b) Aggressive marketing
- c) Doctor's trust
- d) Quality of product
- e) Others

Other Brands :

Sl.No	Brand	Company	Cost per strip/cost per vial

Highest selling brand :

Reason for highest sale:

- a) Price advantage
- b) Aggressive marketing
- c) Doctor's trust
- d) Quality of product
- e) Others

4) Chloroquine Phosphate 500mg(Antimalarial)

Sl.No	Brand	Company	Cost per strip/cost per vial

Highest selling brand :

Reason for highest sale:

- a) Price advantage
- b) Aggressive marketing
- c) Doctor's trust
- d) Quality of product
- e) Others

Other Brands :

Sl.No	Brand	Company	Cost per strip/cost per vial

Highest selling brand :

Reason for highest sale:

- a) Price advantage
- b) Aggressive marketing
- c) Doctor's trust
- d) Quality of product
- e) Others