EVALUATION OF AVAILABILITY AND COST OF ESSENTIAL ANTIBIOTICS FOR PAEDIATRICS IN MBEYA, TANZANIA

By

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A dissertation submitted in Partial Fulfillment of the Requirements for the Msc. Programme (Pharmaceutical Management) of Muhimbili University of Health and Allied Sciences

Muhimbili University of Health and Allied Sciences

September, 2012

CERTIFICATION

The below undersigned certify that they have read and hereby recommend for examination of dissertation entitled **"Evaluation of availability and cost of essential antibiotics for paediatrics in Mbeya, Tanzania"** in partial fulfilment of the requirements for the degree of Msc Programme (Pharmaceutical Management) of Muhimbili University of Health and Allied Sciences.

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Prof. Appolinary A. R. Kamuhabwa
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DECLARATION
AND
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I, Kabandika Twaha declare that this Dissertation is my original work and that it has not been presented and will not be presented to any other university for a similar or any degree award.

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DEDICATION

"To my lovely parents and my daughter Fatma Twaha."

ABSTRACT

Background: Poor availability of essential medicines in public health facilities and high medicines prices in the private medicines outlets are still the leading problems in the management of child health in Tanzania. Children particularly newborns, surfer from the variety of disease conditions than do adults and may require different medicines. Antibiotics play a key role in treating infectious diseases which are the major cause of morbidity and mortality in the developing world. In trying to address accessibility of Essential Medicines, the WHO releases Essential Medicine List for children, after every two years and each country is required to adopt such a new list. In Tanzania, a separate list of essential medicines for children has not yet adopted. Integrated Management of Childhood Illness (IMCI) is used as the integrated approach strategy to improve child health.

Objective: The main objective of this study was to assess the availability, price and affordability of paediatric essential antibiotics in Mbeya Region.

Methods: This was a cross-sectional survey in accordance with WHO/HAI methodology to assess the availability, affordability and price of essential antibiotics for children in Mbeya Region. Data were collected from 1 Medical store Department (Mbeya zonal office), 8 public hospitals, 30 Private Pharmacies and 30 Accredited Drug Dispensing Outlets. Median price of these medicines was compared with Management Science for Health reference prices, expressed as median price ratios. Average stock out days per year was assessed using a designed form. The salary of the lowest–paid unskilled government worker and National Poverty Line income were used to assess affordability of paediatric essential antibiotics.

Results: The median availability of the lowest-price generics for paediatrics essential antibiotics at the Pharmacies, ADDO's and Public Hospitals was found to be 59.09%, 62.5%, and 45.5% antibiotics respectively. At the Zonal Medical stores department, only 13 out of the 22 antibiotics were in stock at the time of survey. The survey found that the median stock out days was 124 days per year. The median of Median Price Ratios of

retail patient's prices for 20 generics antibiotics were 1.774 for 30 pharmacies. Also the median MPRs of 8 generic antibiotics were 2.0097 for 30 ADDO's. National Health Insurance Funds patient prices were 177.74% higher than public hospitals procurement price. Essential medicine such as Amoxicillin-Clavulanic acid syrup was absent in most of public hospitals and also not affordable at the pharmacies for unskilled government workers in Mbeya.

Conclusion: The survey reveals poor availability of paediatric essential antibiotics in the public sector. The stock-out days of the medicines is still high in Mbeya Region. In most of private medicine outlets some of medicines prices were at higher prices and may not be affordable for majority of the population. Therefore the availability, price and affordability of antibiotics for paediatrics should be improved in order to ensure equity in access for basic treatment option of infections in children. Through adopting health financing approach at the public hospitals, consideration of other alternative strategies for control measures of medicines prices and drug subsidation for basic essential antibiotics in the private sectors will make these commodities readily available and affordable by the majority of the people.

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LIST OF ABBREVIATION

ADDO	Accredited Drug Dispensing Outlet
AIDS	Acquired Immune Deficiency Syndrome
ARI	Acute Respiratory Infection
DLDB	Duka la Dawa Baridi
DUE	Drug use evaluation
EML	Essential Medicines List
EMLc	Essential Medicines List for Children
HAI	Health Action International
HCP	Health Care Provider
HIV	Human Immunodeficiency Virus
IMR	Infant Mortality Rate
IMCI	Intergrated Management of Childhood Illness
LPGs	Lowest price-generics
MDG	Millennium Development Goal
MPR	Median Price Ratio
NEMLIT	National Essential Medicine List Tanzania
NHIF	National Health Insurance Funds
NMR	Neonatal Mortality Rate
OB	Originator brand

PPP	Public Private Partnership
RLS	Resource Limited Setting
RPMPP	Rational Pharmaceutical Management Plus Program.
STG	Standard Treatment Guideline
UNICEF	United Nations Children's Fund
UTI	Urinary Tract Infection
U5MR	Under Five Mortality Rate
WDI	World Development Indicator
WHO	World Health Organization

CHAPTER ONE: INTRODUCTION, STATEMENT OF THE PROBLEM, RATIONALE AND OBJECTIVES

1.1. Introduction

Essential medicines are those that satisfy the health care needs of the population and are intended to be available within the context of a functioning health system at all times in adequate amount, in the appropriate dosage form, and at the price the community can afford.[1] Diseases causing high morbidity and mortality in the under 5 years of age in resource limited settings (RLS) could be treated if children in these countries had access to existing medicines. It took 30 years before the WHO Essential Medicines List (EML) considered the issue of medicines for children, with the first EMLc for children being published in 2007. [2] Recent data indicate that less than half of the key pediatric essential medicines are available in countries of sub-Saharan Africa. Problems include substandard medicines, irrational use of medicines, inefficiency and even possible corruption in pharmaceutical management systems.[2]

Providing children with the appropriate medicines and giving them better access to effective treatments is essential for improving child health and achievement of Millennium Development Goal (MDG) 4 (to reduce child mortality by two-thirds), MDG 5 (Improve maternal health) and MDG 6 (to combat HIV/AIDS, malaria and other major diseases). It has been recommended that interventions to protect children may include mosquito nets, vitamin A capsules, immunization, antibiotics and involvement of private sectors for medicines supply.[3] Therefore, medicines may offer simple and cost-effective solutions to many health problems, provided they are available, affordable, and properly used.

Tanzania is one among the developing countries with high rates of child morbidity and mortality. Recent data show that Neonatal, Infant and Under-five Mortality Rate (NMR, IMR, and U5MR) were 26, 51, and 81 per 1000 live births respectively, as compared to that MDG target (by 2015) which is 19, 38 and 51 respectively.[4]

1.1.1. Rational medicines use and selection

Rational drug use can be defined as the rational use of drugs which requires that patients receive medications appropriate to their clinical needs in doses that meet their own individual requirements for an adequate period of time and at the lowest cost to them and their community.[5]

The process of rationale selection involved choosing medicine at the lowest price based on the country health situation. This is because it has a considerable impact on the quality of care and the cost of treatments, therefore the selection of drugs is one of the most cost-effective areas of intervention.[6]

1.1.1. Availability and Access to medicines

The right medicine in the right formulation should be made available for every child. This requires activities under rational use (ensuring that pediatric medicines are administered appropriately in the right doses and formulations), quality and safety (ensuring pediatric medicine meet international requirements for quality, safety and efficacy), and access (increasing production, procurement and supply of pediatric medicine).[7]

Access is defined as having medicines continuously available and affordable at the public or private health facilities or medicine outlets that are within one hour's walk from the homes of population.[8] Access to medicine is a broad concept and includes availability (physical access), affordability (economic access), geographical accessibility and acceptability (social-cultural access) cross linked with safe, efficacious, quality and cost- effectiveness.

Due to overuse and misuse of antibiotics, polypharmacy and low availability of medicines, WHO issued guidelines that, are to be implemented in each country so as to adhere to rational use of antibiotics. Also in recognizing that better access to medicine is a prerequisite for improving health outcome in children, the WHO published the first model list of essential medicine for children in 2007.[9] In Tanzania a separate list of

essential medicines for children has not been published. However, the existing national list includes pediatrics dosage forms and strength.[10]

After the release of the first model list of essential drugs for children, in October 2007, and the 3rd WHO Model List of Essential Medicines for Children (March 2011) [11], there were no sufficient data on affordability and availability in order to confirm the list in Tanzania. Development of Children Essential Medicines List offers many advantages at the health facilities such as its use in selection, procurement, distribution and supplies of medicine. This in turn improves availability of medicines in the public and private hospitals.

Unavailability of medicines in the public hospitals, polypharmacy, presence of high price of medicines in the market and irrational use of antibiotics has necessitated the need to conduct this survey. The information obtained from this study will be used to devise strategies for improvement of availability, affordability and accessibility of pediatrics antibiotics. In developing countries like Tanzania, high cost of newer products with proven advantages, pay for medicine out of pocket due to lack of health insurance and inadequate publicly subsidized services limits availability to essential medicines in the hard to reach areas.[12]

1.2. Statement of the problem

Poor accessibility of children essential antibiotics used in the treatment most of infections are probably the main cause of high morbidity and mortality in children under 5 years of age. Antibiotics play key major role in treating most infections provided they are available at the appropriate specific child dosage form and at a price community the can afford. For example, *Streptococcus pneumoniae* is the most significant cause of community-acquired bacterial pneumonia. This is the leading cause of deaths among children under five years of age worldwide.[13] In Tanzania, it has also been reported that pneumonia is the leading cause of NMR and accounts for about 28% of all causes of deaths.[14] In addition; a recent surveys conducted in Tanzania showed that some essential medicines were still more expensive and not affordable to communities.[15, 16] Also studies showed that, for a family with a father having diabetes and hypertension and a child having acute respiratory infection, the total cost of all treatment was not affordable in public, private and mission health sectors.

These results were too general and they showed that there is a need to conduct a survey based on therapeutic or age group (pediatric antibiotics) in order to know the magnitude of the problem on availability and affordability of antibiotics for paediatrics.

In Tanzania the last essential medicine review was conducted in 2007 for the Standard Treatment Guideline (STG) and Essential Medicine List (EML). A separate list of essential medicine for children has not been published and there are concerns that the existing list is not comprehensive for pediatrics use[10]. In addition, the feasibility and utilization of Essential Medicine for children (EMLc) in Tanzania are unclear and that there is information gap in provision of healthcare services for children despite having high rate of IMR, NMR and U5MR.

1.3. Rationale of the study

Detailed knowledge on price, availability and affordability of children antibiotics is important before the policies and measures on selection, procurement, distribution and use can be implemented. Therefore, this study is in line with WHO campaign published in 2007 titled "make medicines child size"[10]. This campaign is designed to raise awareness and accelerate action to address the need for improved availability and access to safe child-specific medicines for all children under 5 years of age.

The study measured real paid prices for paediatric antibiotics (originator brand and low price generic) and provided a comprehensive picture on the affordability and availability of the selected antibiotics for paediatrics.

It is expected that these findings can be utilized in many ways in providing better medicine for children such as development of key paediatric antibiotics essential list, using the list for procurement, distribution and supplies of children medicines, improving availability of paediatric antibiotics medicine in the public health facilities and having children antibiotics in the right formulations.

1.4. Objectives

1.4.1. Broad objective

To assess the availability and cost of paediatric essential antibiotics for the treatment of common childhood diseases in Mbeya Region

1.4.2. Specific objectives

1. To determine the availability of the commonly used selected set of essential key antibiotics for paediatric in the WHO recommended dosage form and strength in public hospitals.
2. To determine the availability of the commonly used selected set of essential key antibiotics for paediatric in the WHO recommended dosage form and strength in the private medicines outlets.
3. To investigate whether these commonly used selected essential antibiotics for paediatrics are available in the public hospitals and private medicines outlets in alternative dosage form or strength.
4. To determine the cost of the originator brand and the lowest-price generic equivalent of the commonly used selected essential antibiotics for paediatric in the private medicines outlets.
5. To assess the affordability of the commonly used essential antibiotics for paediatrics.

1.4.3. Research questions

i. What is the difference in the availability of individual paediatric antibiotics between public and private sectors?
ii. How do local prices of paediatrics antibiotics compare with international reference prices?
iii. What is the difference in price between originator brands (OB) and their lowest–price generic equivalent (LPG) for paediatric antibiotics?
iv. Do the prices of paediatric antibiotics vary significantly between medicines?
v. How does treatment affordability vary between OBs and LPGs for paediatric essential antibiotics?
vi. What is the average days-wages does the lowest-paid unskilled government worker / people living below poverty line need to purchase a standard course of paediatric antibiotics for treatment of common conditions?

CHAPTER TWO: LITERATURE REVIEW

Recent studies show some variations in the pattern of availability of individual medicines, high price of paediatric medicine, polypharmacy and irrational use of antitibiotics. In a study done in Tanzania, it was shown that majority of drug sellers/dispensers prescribed or dispensed branded drugs (85%) for most mothers/guardians who visited the drug shops.[17] In addition; antibiotics were prescribed to 31% of the children. Of the antibiotics dispensed, 38% were not prescribed by clinicians. Only 35% of the bloody diarrhea among simulated clients scenarios were accurately diagnosed for getting antibiotics as compared with 44% for watery diarrhea for which the use of antibiotics were wrongly advised. Furthermore, Antimicrobial agents were advised for Acute Respiratory Infection (38%), watery diarrhea (44%) and bloody diarrhea (35%), respectively, with no significant difference among the three common childhood conditions. The study demonstrated that antibiotics are overused in both the urban and rural settings of Kibaha district and this is due to both clinicians' and drug sellers' prescribing and dispensing practices in the public and private facilities. The use of branded drugs was most common than that of generic drugs in the private pharmacies, drug stores and ordinary shops.

To address the problems of availability and affordability of medicines in Tanzania, MSH and TFDA implemented strategies to provide a range of high quality essential medicines and pharmaceutical services at the reasonable price through the creation of ADDO programme which is based on converting the existing DLDBs.[18] Additionally, a study conducted in 2005 showed improvement on rationale use of antibiotics in the ADDOs compared to DLDBs in Ruvuma. [19] Currently, in the areas where ADDO has already started, ADDO program is not only to improve access to essential medicines, but also to provide training to dispensers in rational medicine use for the key common childhood

conditions to serve as a platform for other community-based public health interventions, such as improving child health.[20]

Also a recent survey conducted in the private Health Facilities and Mission Hospitals in Tanzania showed that medicines were still more expensive and therefore not affordable by the public.[15] However, it was noted that about 30% and 50% of Tanzanians in urban and rural areas, respectively live on less than one US dollar a day, thus highlighting the barrier of the price on access to medicines. In addition, not only these medicines are unaffordable for a large proportion of the public, but also it results in a major burden to the government budget during procurement process.

In most of the developing countries the cost of the medicines account for a large portion of total expenditures on health cost. Majority of people in developing countries do not have health insurance.[21] Also these medicines that are provided under exemption particularly for children through the public sectors are often unavailable.[22] Thus, parents are forced to purchase the medicines for their children from the private medicines outlets, where the price may be high and therefore unable to purchase the complete course to cure a specific infection.

Lack of reliable information on medicine price and availability hinders the government to develop sound pricing policies or evaluate the impact of price to the consumers.[12] In addition, negotiations of medicine price by the procurement personnel become limited because of the lack of appropriate source of information of medicines price and availability. Consequently, this has an impact to the Government, Insurance funds and Health facilities, resulting into difficulties in the process of selecting medicines.

In a comparative study in the state of Khartoum, Sudan showed that essential medicines list was not available in all the hospitals. [23] The study revealed problems in prescribing and dispensing practices and hence a need to institute cost- effective interventions to improve current drug use practices in paediatrics.

In a study conducted in Vietnam, it was shown that the resistance to commonly used antibiotics and multidrug resistance of *Streptococcus pneumoniae* were markedly high.[13] High dose of Amoxicillin was the only oral antibiotic that can possibly be used when treatment is required for community-acquired pneumococcal infections. Most of children had used antibiotics unnecessarily during their most recent illnesses and in the 28-day period during the study. Also there was serious lack of knowledge on appropriate antibiotics use among the health care providers as well as the caregivers. The study further showed that antibiotics were often prescribed and dispensed for common cold conditions.

A survey on the availability of key essential medicines for children in Sri Lanka revealed the mean availability of the basket of medicines to be 52% in the public hospitals, compared to 80% in the private pharmacies and 88% in the community pharmacies run by the State.[24] In addition, the availability of the medicines in the public hospitals and private pharmacies far from the capital Colombo was either equal to or greater than in hospitals and pharmacies close to Colombo.

Currently it is estimated that one third of the world's population do not have regular access to essential medicines.[25] Additionally, a survey conducted by the WHO in capital cities of 14 countries in Central Africa reported poor availability of key essential medicines for children.[26] Additionally, some examples of factors contributed to poor access of essential medicines in the third world countries are high price of medicines, lack of medicine information resources, medication errors, lack of efficient medicines policy, lack of regulatory capacity and dependence on a single supply of medicine.[2,16,27]

CHAPTER THREE: METHODOLOGY

3.0. Methods and materials

Table 1: Main sections of this survey

S/N	Section
1	Availability of essential paediatric antibiotics in the public hospitals and private medicines outlets.
2	Price variation across private medicine outlets
3	Treatment Affordability

3.1. Overview of Study area

3.1.1. Geographical locations

Mbeya is one of the Tanzanian's 29 administrative regions. The regional capital is Mbeya. It is bordered to the northwest by Tabora Region, to the northeast by Singida Region, to the East by Iringa Region, to the South by Zambia and Malawi, and to the West by Rukwa Region. Mbeya Region is occupied by several different ethnic groups including the Nyakyusa, Ndali, Nyiha, Nyamwanga, Safwa, Malila, Vwanji (or Wanji), Bungu, Sangu, Wanda and Sichela.

According to the 2002 Tanzania National Census, the population of the Mbeya Region was 2,070,046. Mbeya Regions is administratively divided into 8 districts: Chunya, Mbarali, Mbozi, Rungwe, Kyela, Ileje, Mbeya Urban and Mbeya Rural.

3.1.2. Selection criteria

Mbeya is among the big cities in Tanzania. Also from the baseline survey of the pharmaceutical sector in Tanzania in 2002, it was shown that from the three major cities i.e. Kilimanjaro, Mwanza and Dar es Salaam the use of more than one antibiotic for treating mild/acute pneumonia was below 6%. Mbeya was the only region with high percentage of about 42% whereby Amoxicillin was commonly prescribed concomitantly with Co-trimoxazole.[28] Also Mbeya was among the three regions where the use of antibiotics for non-pneumonia ARI was over 90%.

3.1.3 Background information

Mbeya region is divided in eight districts and every district is having one district Hospital and a number of Dispensaries, which are located within wards and villages. In Mbeya town there is Mbeya Referral Hospital. The referral Hospital caters for Southern Highland i.e. Mbeya itself, Iringa, Rukwa and Ruvuma regions.

There are also a number of hospitals which are being operated by religious organizations such as Igogwe Hospital, Chimala Hospital etc. Also there are a number of Private Hospitals operated by Private Organizations such as K'S Hospital, Zary Hospital, Uyole Hospital and a number of pharmacies scattered within Mbeya city. Selected area for this survey were all public hospitals in Mbeya Region; Mbeya Referral Hospital, Mbeya Regional Hospital, all the 6 public district hospitals (Mbozi, Chunya, Ileje, Kyela, Mbarali and Tukuyu), 30 ADDO's and all 30 registered pharmacies in Mbeya Region.

3.1.4. Mbeya referral hospital

Mbeya Consultant Hospital is a tertiary healthcare facility for the southern Highland zone in Tanzania covering the regions of Ruvuma, Rukwa, Iringa and Mbeya. It was built through the support of British Government and was inaugurated in 1985.

The functions of Mbeya Consultant Hospital are:

1. Provision of tertiary healthcare services to referred patients in the Southern Highlands Zone
2. Teaching
3. Conduct health related researches

3.1.5 Mbeya regional Hospital

This is the only Regional Hospital in Mbeya that was included in this study, which offers similar services like those at district hospital. However, it has specialists in various fields and it offers additional services which are not provided at the district hospitals.

3.1.6 District Hospitals

These are hospitals which provide all medical services except condition which require specialized care and are involved in planning, organizing and supervision of all health activities in the district. District hospitals serve as first referral level that is responsible for a district of a defined geographical area. The survey involved all Governmental district hospitals located in Mbeya.

3.1.7 Registered Medicines outlets

All 30 registered retail pharmacies and 30 ADDO’s were recruited in this survey. A list of registered medicines outlets was obtained from Pharmacy council – Mbeya Zonal Office or from the Districts/City Pharmacists who are familiar within the survey areas.

Figure 1: MAP OF MBEYA

3.1.8. Inclusion and Exclusion criteria

Inclusion

- Retail registered medicines outlets and public hospitals in Mbeya region.
- Health facilities and medicine outlets that are accessible
- Willingness to participate in the study

Exclusion

- Anti – tuberculosis: this group of antimicrobial agents is frequently used in high number and at high cost for long period of time and frequently at separate and specialized hospitals. Including these antimicrobial agents would significantly affect the results of most indicators.
- None accessible health facilities and medicines outlets

3.2. Methodology

Methodology Overview

Methodology of this survey was based on guidelines provided by:

- WHO/HAI medicine price methodology – 2nd edition.[12]
- Methodology of survey carried out in the Colombo District (capital city of Sri Lanka) as part of (better medicine for children project) children medicine survey (WHO/HQ) Study).[24]
- This survey also used the indicators that were adopted from Rational Pharmaceutical Management plus Program (How to Investigate Antimicrobial Drug Use in Hospitals) RPMPP [30], and the WHO manuals.[30]
- Measuring medicine prices in Peru: validation of key aspects of WHO/HAI survey methodology.[31]

3.2.1. Study Design

A cross sectional descriptive survey on assessing the availability and prices of paediatric antitibiotics in Mbeya Region was employed

3.2.2. Survey setting

This study examined the availability and price of essential antibiotics for children in Mbeya region. Data was collected from public hospitals and private medicines outlets situated in Mbeya.

3.2.3. Survey period and duration

The survey was conducted from April to May 2012. Prior to data collection, the principal investigator contacted the pharmacists of the survey area in order to ensure good cooperation. The Principal investigator visited the medicine outlets and recorded data on the standardized form with the support of a representative of the district health department in each survey area.

3.2.4. Survey areas

The study was conducted at the major urban center and additional survey areas that could be reached within one day from major urban by appropriate means of transportation (car, bus). [12]

3.2.5. Selecting the sample size

Selecting of public hospitals: All 8 public hospitals were selected in Mbeya region: Mbeya Referral Hospital and Mbeya Regional Hospital are located within the city. Chunya, Kyela, Mbozi, Ileje, Mbarali and Tukuyu public district hospitals are located more than 3 hours drives from the city centre and were included in the study.

Selecting retail private medicines outlets

Pharmacies

All thirty (30) retail pharmacies within Mbeya City were included in the study.

ADDO's

Selection of the (rural facilities) ADDO's was based on their proximity to the public district health Hospitals. Therefore five ADDO's near the public district hospital were included in the study. This is the recommendation by WHO/HAI standards.[12] A total of 30 ADDO's located within a distance of 3 hours drive from the main headquarter of the Mbeya region were included in the study:

Table 2: Summary: Selection of medicine outlets

Location	**Type**	**Number of surveyed private medicine outlets**
Mbeya city	Pharmacy	30
Chunya District	ADDO	5
Kyela District	ADDO	5
Mbozi District	ADDO	5
Ileje District	ADDO	5
Mbarali District	ADDO	5
Tukuyu District	ADDO	5

3.2.6. List of survey medicines

A list of essential paediatric antitibiotics was selected from WHO essential medicine list (EMLc, 2011), National Essential Medicine List (NEML) and WHO priority medicine for mothers and children. [32]

Table 3: A list of selected paediatric essential antibiotics surveyed and their presence in the Essential Medicine Lists and Health facilities

S/N	Antibiotics	Dosage and strength	WHO EMLc	NEML	Pharmacy	ADDO	Hospitals
1	Amoxicillin	Powder for suspension (as trihydrate),125mg/5ml as tryhydrate)	Yes	Yes	Yes	Yes	Yes
2	Amoxicillin + Clavulanicacid	Powder for suspension (as trihydrate) 125mg+31.25mg (as potassium salt) in 5ml,	Yes	Yes	Yes	No	Yes
3	Cefalexin	Powder for reconstitution with water: 125mg/5ml;	Yes	No	Yes	No	Yes
4	Azithromycin	Oral liquid 200mg/5ml	Yes	No	Yes	No	Yes
5	Chloromphenical	Suspension (as palmitate), 125mg/5ml	Yes	Yes	Yes	No	Yes
6	Cloxacillin	Powder for suspension (as sodium salt), 125mg/5ml	Yes	Yes	Yes	No	Yes
7	Erythromycin	Powder for suspension (as ethylsuccinate),(or estolate or state) 125mg/5ml in 100ml bottles	Yes	Yes	Yes	Yes	Yes
8	Metronidazole	Metronidazole Suspension as (benzoate) 200mg/5ml	Yes	Yes	Yes	Yes	Yes
9	Penicillin, phenoxy methyl-	Powder for suspension 125mg/5ml in 100ml	Yes	Yes	Yes	Yes	Yes
10	Sulphamethoxazole + trimethoprim	Oral liquid: 200mg + 40mg/5ml.	Yes	Yes	Yes	Yes	Yes
11	Fucloxacillin syrup	Oral liquid 125mg/5ml	No	Yes	Yes	No	Yes
12	Ampicillin	Powder for injection (as sodium salt) 500mg in	Yes	Yes	Yes	No	Yes

S/N	Antibiotics	Dosage and strength	WHO EMLc	NEML	Pharmacy	ADDO	Hospitals
		vial					
13	Benzyl Penicillin	Powder for injection 600mg= (1 million IU), 3g (=5million IU) as sodium or potassium salt	Yes	Yes	Yes	Yes	Yes
14	Cefazolin	Powder for injection; 1gm (as sodium salt) in vial.	Yes	No	No	No	No
15	Cefotaxime	Powder for injection: 250 mg per vial (as sodium salt)	Yes	No	No	No	No
16	Ceftazidime	Powder for injection (as pentahydrate) 250mg/vial	Yes	Yes	Yes	No	Yes
17	Ceftriaxone	Injection 250mg in vial	Yes	Yes	Yes	No	Yes
18	Chloramphenicol	Powder for inj. (as sodium succinate1g in vial	Yes	Yes	Yes	No	Yes
19	Chloromphenical	Oily suspension for injection 0.5gm(as sodium succinate))/ml in 2ml ampoule	Yes	Yes	Yes	No	Yes
20	Ciprofloxacin	IV solution (as lactate) 2mg/ml in 100ml bottle	Yes	Yes	Yes	No	Yes
21	*Clindamycin*	*Injection (as phosphate) 150mg/ml*	*Yes*	Yes	Yes	No	*****Yes
22	Cloxacillin	Powder for injection (as sodium salt) 250mg, 500mg in vial	Yes	Yes	Yes	No	Yes
23	Gentamicin	Injection (as sulphate) 40mg/ml in 2ml ampoule	Yes	Yes	Yes	No	Yes
24	Metronidazole	Injection (I.V) 5mg/ml in 100ml bottle	Yes	Yes	Yes	Yes	Yes
25	Procaine benzyl penicillin	Powder for injection (as sodium or potassium salt) 3g (3,000,000 IU) in vial, 1gm (=1 MU)	Yes	Yes	Yes	Yes	Yes
26	Sulphamethoxazole + trimethoprim	Injection : 80mg +16mg/ml in 5-ml ampoule	Yes	No	Yes	No	**Yes**
27	*Penicillin, benzathinebenzyl*	*Powder for injection 1.44g (2,400,000 IU) in vial, 900mg (=1.2 million IU)*	*Yes*	Yes	Yes	No	Yes
28	Kanamycin inj	Powder for injection, 1g	*No*	Yes	No	No	***Yes**
29	Fucloxacillin	*Injection 250mg*	*No*	Yes	No	No	Yes

Note: *****Kanamycin injection and *****Clindamycin injection was only surveyed at the Referral hospitals.

Table 4: Number of paediatric essential antibiotics for testing of the availability in the Public Hospitals

No.	Health facility	Total number of the survey paediatrics antibiotics
1	Referral Hospital	24
2	Regional Hospital	24
3	District Hospital	22

Table 5: Number of paediatric essential antibiotics for testing of the availability and price in the private medicine outlets

No.	Medicine outlets	Total number of the survey paediatric antibiotics
1	Pharmacies	25
2	ADDOs	8

3.2.8. Pretesting of data collection tools

Pre-testing the data collection tools was conducted in Dar es Salaam to access the availability of antibiotics intended to be surveyed. A total of four pharmacies based on their closed proximity to the public hospitals were used in pretesting.

3.3. Data collection and analysis

Data collection tools for availability and cost of paediatric essential antibiotics included:

I. ADDO's: List of paediatric antibiotics to assess the price and availability. **(Annex A)**

II. PRIVATE PHARMACIES: List of paediatric antibiotics to assess the price and availability. (**Annex B)**

III. PUBLIC HOSPITALS: List of paediatrics antibiotics to assess the availability and time out of stock. **(Annex C)**

Study variables

The variables of the study on availability and cost were as follows:

1. **Availability of paediatric essential antibiotics in the given dosage form and strength:** Each survey medicine with the specific dosage form and strength WHO.[11]
2. **Availability of paediatric essential antibiotics in alternative dosage form and strength:** If the survey medicine in the specific dosage form and strength as per WHO guideline was not available, data on availability of alternative dosage form/strength was collected.
3. **Price of the lowest-price generic equivalent:** If the medicine was available in the given dosage form and strength, the lowest priced generic equivalent was identified and its price recorded. If the lowest-priced generic equivalent was not available in the given dosage form and strength, the price of alternative dosage and strength was recorded.
4. **Price of the originator brand if available:** when the originator brand was available in the given dosage form and strength, or alternative dosage form and strength , the price was recorded

Table 6: Data collection guide

Where to look	Whom to ask	What to get
1. Hospital medical stores 2. Hospital pharmacy 3. Registered Pharmacies 4. Registered ADDO	1. Manager 2. Pharmacist in charge	1. Generic and brand names 2. Inventory record for study 3. Price

3.3.1. Availability evaluation and criteria

- **Percentage of medicine outlets which had the surveyed medicine on the day of survey**:
    - Percentage, calculated by dividing the number of Medicine outlets actually have the individual medicines on the day by the total number of medicine outlets surveyed multiplied by 100.

- **Calculation of average percentage availability:**
    - Percentage, calculated by dividing the number of key antibiotics in stock on that day by the number of key antibiotics that should be available multiplied by 100. The overall availability of antibiotics in facilities is reported as "the median percentage of stock availability of the medicines in the facilities on the day of data collection"

Table 7: Criteria used to describe the availability of essential antibiotics for paediatric [24]

S/N	Level of availability	Results
1	Absent	Medicines were not found in any of the facility surveyed
2	Less than 30%	Very low
3	30 – 49%	Low
4	50 – 80	Fairly high
5	Greater than80%	High

3.3.2. Stock out evaluation

Stock out duration was calculated by back revision for the Bin card/stock card/ledger that indicated which medicines have records covering at least 6 months within the previous 12 months.

The equivalent number of stock-out days per year for each medicine was computed by multiplying the number of days out of stock by 365 and dividing by the number of days covered for review. The total number of stock out days per year was computed for each antibiotic. The average number of stock-out days was finally calculated by dividing the total number of stock-out days by the number of key antibiotics reviewed.

The overall stock-out days of antibiotic in facilities is reported as “the median stock-out days of antibiotics per year in the facilities on the day of data collection”

3.3.3. Price criteria and evaluation

Both the price of generic equivalent and original bland were separately analyzed.

Indicators calculated:

- Median price of each paediatric antibiotic in local currency
- Median price of each paediatric antibiotic in US dollars (using the 1 USD dollar exchange rate equivalent to 1600 Tshs)
- Median price in relation to international standard price (median price ratio) MPR.
- Variation in price across pharmacies, $25^{th}/75^{th}$ percentiles and maximum and minimum values.

Median price: is a type of average value that splits a series of value in half when the series is put in ascending order. This is likely to be more valuable approach for estimating actual future prices when there is a skewed distribution.

Calculations of medicine price ratio: (MPR)

MPR = Medicine local unit price (USD)/international reference unit price

Median local unit price: prices of unit pack size from survey samples were pooled and median price calculated.[33]

International reference price: the reference price from MSH (Management Science for Health) International drug price guide was selected as the most useful standard, and they are updated annually**.** [34]

Interquartile range: is a measure of the spread used most commonly with the median. It represents central portion of the distribution, the 25^{th} percentile to 75^{th} percentile.[33]

The ideal value for MPRs used to represent acceptable local price ratios were:

1. *Procurement prices in the public sector: MPR is less than or equal to 1 (one)*
2. *Retail patient prices in the private medicine outlets: MPR is less than or equal to 2 (two)*

3.3.4. Public hospital procurement price and NHIF patient prices

The unit prices were converted to Median Price Ratio by dividing the unit price from an internationally recognized price index in the Management Science for Health brochure. Public hospitals procurement prices were collected from the MSD price catalogue 2011/12.[35] This is because of the fixed prices for all medicines procured from MSD. Also NHIF price catalogue March 2012 was used to record the patient price.[36]

3.3.5. Affordability evaluation

A course of treatment that costs the equivalent of one days' salary of the lowest-paid government workers was generally considered affordable; treatment that cost more than this are classes as unaffordable (WHO/HAI).[12] In contrast with WHO/HAI, we select two level of income to assess affordability both for unskilled workers minimum wage (4500 Tshs/day) [16] and people living below the poverty line (1.25 USD/day = 2000 Tshs/ day) [WDI 2011]. [37]

Calculations: Days wages = Median medicine price found in the facilities times the number of units in a standard course of treatment / daily wage of lowest paid unskilled government worker or daily income of national poverty line.

Note: Median Medicine prices information at the pharmacies were used to assess the affordability.

3.4. Data management and analysis

All collected data and completed forms were checked on daily basis by the principal investigator. If any of important information was missing, a follow-up by revisiting or telephone call was made to obtain any of remaining information.

Data was first cleaned and entered into Ms Excel 2007 on daily basis followed by transformation to SPSS v.17 for analysis. The Frequency distribution minimum and

maximum, median, 25th and 75th percentiles were used to show distribution outcome and explanatory of variables. Non parametric 95% confidence interval (CIs) were constructed and compared for outcome value based on order statistics by SPSS v.17. It was not feasible to calculate the p-values for differences across the medians, as they were computed using order statistics. Non-overlapping CIs was use to indicate where differences between two sectors were significant. [31, 38] One sample T–test was used to compare the median value in the average outcome of the results. The difference within the sector (one sample) was considered statistically significantly if the p-value is less than 0.05. Summary of the analysis: **(Annex D)**

3.5. Study limitation

Cross sectional study collect data at one point in time, Availability of antibiotics at the health facilities was assessed in one day survey. Consequently, some facilities may usually had a product in stock but it happened on the day of survey were out of stock. Private hospitals and health facilities in the rural areas were excluded from the survey due to financial and time constraints.

3.6. Ethical consideration

The principal investigator received a letter of Introductions to the surveyed area (Annex E). In addition, principal investigator also received a letter of endorsement explaining the objectives and confidentiality concerns, as a support if participants asked questions (ANNEX F). Contact information was also supplied in the letter for any concern or questions. In order to ensure confidentiality, no names of the participants were recorded in the questionnaires. Data were entered into the computer Microsoft excels 2007 using only study code number. Ethical clearance was obtained from MUHAS Research and Publication Committee.

CHAPTER FOUR: RESULTS

4.1.1 Availability of essential antibiotics for paediatrics in the public hospitals

This survey revealed that, in the public hospitals the median percentage availability of 22 paediatric essential antibiotics in the National Essential Medicines List was 45.5 % (ranging from 36.36% to 63.64); while for a total of 25 antibiotics for paediatrics the availability was only 42%. The injectables such as Ciprofloxacin, Co-trimoxazole, clindamycin and Kanamycin were only available at one Referral Hospital. None of the public hospitals surveyed had more than 80% availability or less than 30% availability of antibiotics (Table 8). MSD was the only single facility that supplies medicines to public hospitals which shows availability of 59.09% (Table 12).

Table 8: Availability of paediatric essential antibiotics in the public hospitals (N=8)

Level of availability	Number	Percentage (%)
Less than 30% (very low)	0	0%
30% – 49% (low)	5	62.50%
50% - 80% (fairly high)	3	37.5%
Greater than 80% (high)	0	0%
Total	8	100%

4.1.2 Availability of essential antibiotics for paediatrics in the Private Sector

The median percentage availability of 22 essential antibiotics for children on the NEML was satisfactory at 54.54% (ranging from 13.63% to 81.81%); while for a total of 25 paediatric antibiotics the availability was 54%. One pharmacy (3.33%) had less than 30% availability of essential antibiotics for children. Majority (56.7%) of the pharmacies had fairly high availability of essential antibiotics (Table 9).

In the ADDO's the median availability of 8 essential antibiotics was only 62.5% (ranging from 0% to 100%); while for total of 10 common medicines the availability was 70%. Also majority (70%) of the ADDO's had fairly high availability of essential antibiotics for children. However, four ADDO's (13%) had less than 30% availability of essential antibiotics (Table 9). The study revealed no significant difference (p=0.056) with respect to the availability of essential medicines in the ADDO's (Table 12).

Table 9: Availability of paediatric essential antibiotics in the ADDO's and Private Pharmacies

	ADDO's	**Pharmacies**
Level of availability	**No (%)**	**No (%)**
Less than 30% (very low)	4 (13.33%)	1(3.33%)
30% – 49% (low)	1 (3.33%)	11 (36.7%)
50% - 80% (fairly high)	21 (70%)	17 (56.7%)
Greater than 80% (high)	4 (13.33%)	1(3.33%)
Total	**30 (100%)**	**30 (100%)**

4.1.3. Availability of individual medicines.

Availability of Ciprofloxacin Injection, Metronidazole Intravenous Infusion, flucloxacilin and chloramphenical syrups in the pharmacies, ADDO's, and public hospitals were less than 30%. The availability of Six (6) generic antibiotics in the public hospitals, 7 generics antibiotics in pharmacies and 4 generics antibiotics in the ADDO's was more than 80%. Some essential generic antibiotics such as Ceftazidime injection, Chloromphenical oily suspension injection and flucloxacillin injection were absent from all the health facilities in Mbeya Region (Table10).

Table 10: Availability of generic antibiotics in the public and private health facilities in Mbeya Region

Level of availability	Pharmacies	ADDO's	Public Hospitals	Medical Store Department (Mbeya)
High (>80%)	Amoxicillin syrup, Cephalexin syrup, Chloramphenical syrup, Cloxacillin syrup, Erythromycin syrup, Metronidazole syrup and Co-trimoxazole syrup	Amoxycillin syrup, Erythromycin syrup, Metronidazole syrup, Cotrimoxazole syrup	Erythromycin syrup, chloromphenical injection, Benzyl Penicillin Injection, Gentamycin Injection, Metronidazole Intravenous Injection, Benzathine benzyl penicillin	N/A
Fairly high (50 - 80%)	Azithromycin syrup, Phenoxymethyl penicillin syrup, Ceftriaxone 250mg injection., Gentamycin injection, Procaine penicillin fortified, Benzathine penicillin injection, Metronidazole intreavenous injection, Chloromphenical Injection	NIL	Amoxycillin syrup, Metronidazole syrup, Ampicilin Injection, Ceftriaxone Injection, Cloxacillin Injection, Procaine Penicillin Fortified	N/A
Low (30- 49 %)	Amoxycillin-clavulanic syrup, Ampicillin injectopm, Benzyl penicillin Injection, Ciprofloxacin injection, Cloxacillin Injection	Phenoxymethyl penicillin syrup, Benzyl penicillin injection, Procaine penicillin fortified,	Phenoxymethyl penicillin syrup, Co-trimoxazole syrup,	N/A
Very low (< 30%)	Flucloxacillin syrup	Metronidazole Intravenous injection	Chloromphenical syrup, ciprofloxacin Injection, Cotrimoxazole Injection, clindamycin injection. Co-trimoxazole injection, *Kanamycin Injection, *Clindamycin Injection	N/A
Absent	Ceftazidime injection. Clindamycin Injection, Chloromphenical oily suspension injection. Co-trimoxazole injection, Flucloxacillin Injection	NIL	Amoxicillin-Clavulanic Acid syrup, Cephalexin syrup, Flucloxacilli syrup, Azithromycin syrup, cloxacillin syrup, Ceftazidime Injection, Flucloxacillin Injection.	Amoxicillin-Clavulanic Acid syrup,Cephalexin syrup, Flucloxacillin syrup, Azithromycin syrup, cloxacillin syrup, Ciprofloxacin Injection, Ceftazidime Injection, Flucloxacillin Injection.

Note: NA= Not applicable, *****Kanamycin injection and *****Clindamycin injection was only surveyed at the Referral hospitals.

4.1.4. Availability of paediatric essential antibiotics in alternative dosage forms and strengths

Medicines that were available in different strengths and pack sizes were also recorded. Three different generics of amoxicillin-clavulanic acid suspension such as Co-amoxy Mepha, Clavam-BD, and Augmentin were available in seven (7) out of 30 pharmacies. In addition, these medicines were sold at the highest prices ranging from 8000/= Tshs to 35000/= Tshs (Table 11).

Table 11: Availability of the essential antitibiotics for paediatric in alternative dosage forms or strengths in the private pharmacies

Antibiotic	Dosage form strength, pack size	Number of Pharmacy which had the alternative dosage forms or strength where the surveyed medicine was not available	Name of Antibiotic	Strength, pack size	Price Tshs (Min/ Max)
Amoxicillin clavulanic acid	Suspension 125mg +31.25mg/5ml (100Ml)	2	Co–amox mepha	400mg+57mg/5 ml (70ml)	32000/ 35000
		2	Clavam BD	200mg+28mg/5 ml.(100ml)	8000/ 100000
		2	Augmentin	400mg+57mg/5 ml (70ml)	17200/ 18000
		1	Augmentin	228mg (70ml)	15000

Table 12: Summary of the availability of essential antibiotic for paediatrics

TYPE OF HEALTH FACILITY	% Availability (Minimum/Maximum)	% Median Availability	Av. Interquartile range (25%, 75%)	Av. (95% CI)	P value
Pharmacy (22 LPG) (n=30)	13.63/81.81	59.09	(40.9,63.63)	(45 – 64)	0.628
ADDO's (8 LPG) (n=30)	0/100	62.5	(50,75)	(50– 62.5)	0.056
Hospitals (22 LPG) (n=8)	36.36/63.64	45.45	(42.04 , 50)	(40.9 - 50)	N/A
MSD (22 LPG)	N/A	59.09	N/A	N/A	N/A

Note: NA= Not Applicable, Av. = Availability

4.1.5. Stock-out days of essential antibiotic for paediatrics in the public sector

The median stock-out days per year was 124 days (ranging from 77.52 to 190) for the selected 15 essential generic antibiotics. For example, results from three public hospitals showed that one of the key essential antibiotics was not available for more than three months (90 days); while two other public hospitals scored less than that (Figure 2 below). Some facilities did not have proper records to enable calculation of stock-outs days of medicines for at least six months.

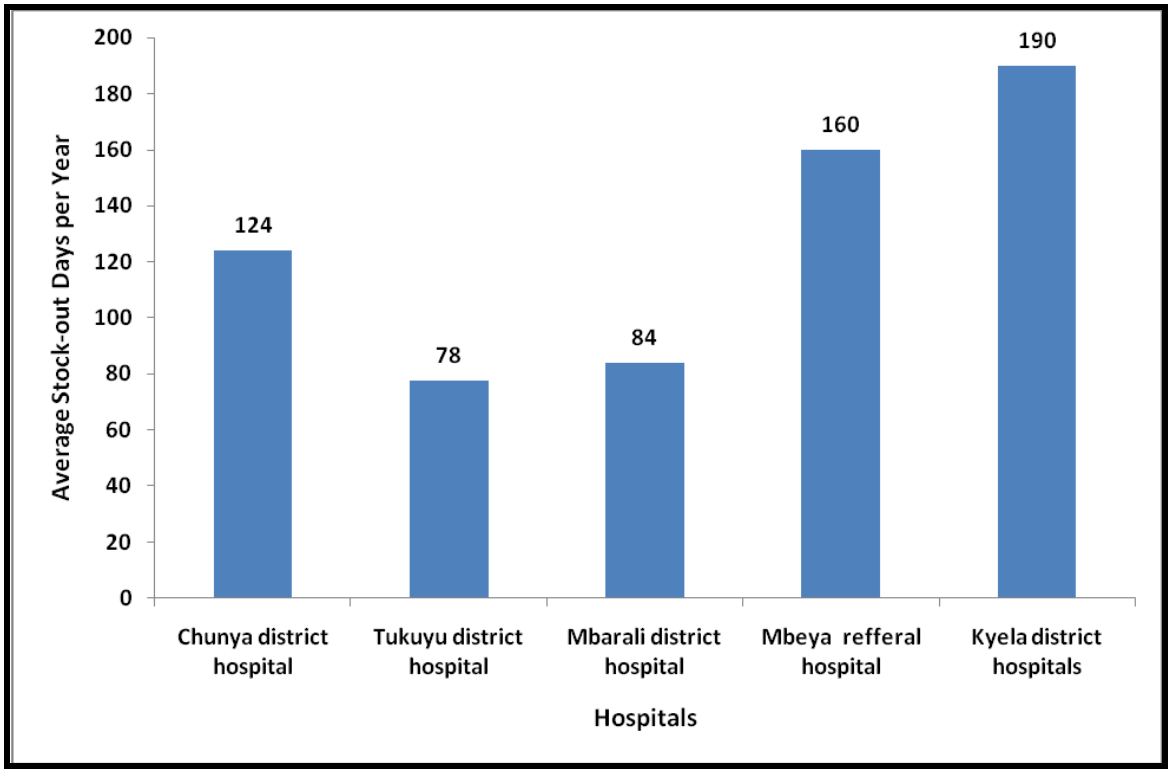

Figure 2: Variation of stock-out days of antibiotics for paediatrics per year in the public hospitals in Mbeya Region

4.2. Price of the medicines in the private retail medicine outlets

4.2.1. Prices of antibiotic for paediatrics in the Pharmacies

Data on prices for amoxycillin syrup was collected in all the private pharmacies in Mbeya region. The study revealed that the prices of LPGs differed from one pharmacy to the other for some of the antibiotics. Only three OB of Amoxycillin syrup, Amoxycillin-Clavulanic acid syrup, and cotrimoxazole injection was identified at the pharmacies. This shows that most of the originator brands were not marketed in Mbeya region (Table 14).

In the pharmacies, the median MPR of 22 LPGs was 1.7525 times the international reference prices (ranging 0.6793 – 3.8344). The median MPR of 3 innovator brands was

10.9028 times international reference prices (ranging 5.4688 – 14.2905). All MPRs of OB was higher than LPG at the pharmacies. Higher MPRs above the warning line (greater than 2) were noted for 8 medicines out of 22 LPGS. Cephalexin syrup and Ciprofloxacin injection had MPR of less than one. Median price ratio was not calculated for zinc sulphate solution since its International References Price was not available.

Table 13: Median Price Ratio for each medicine in the private pharmacies in Mbeya Region

No.	Medicines name	MPR (LPG)	MPR(OB)
1	Amoxicillin syrup 125mg/5ml	1.7361	10.9028
2	Amoxicillin + clavulanic acid (125+31.25mg/5ml) suspension	2.5	5.4688
3	Cephalexin syrup 125mg/5ml	0.6793	N/A
4	Azithromycin syrup 200mg/5ml	2.3148	N/A
5	Chloromphenical syrup 125mg/5ml	1.2708	N/A
6	Cloxacillin sodium syrup 125mg/5ml	1.25	N/A
7	Erythromycin syrup 125mg/5ml	1.0417	N/A
8	Metronidazole syrup 200mg/5ml	1.7689	N/A
9	Phenoxymethyl penicillin syrup (Pen-v) 125mg/5ml	1.3526	N/A
10	Co-trimoxazole syrup 200mg+40mg/5ml	2.1577	N/A
11	Ampicilin 500 mg injection	3.3003	N/A
12	Penicillin benzyl (3G pen G) 5MU	1.9981	N/A
13	Ceftriaxone 250 mg Vial	2.9647	N/A
14	Chloromphenical 1gm vial	1.7294	N/A
15	Ciprofloxacin 2mg/ml IV	0.9470	N/A

No.	Medicines name	MPR (LPG)	MPR(OB)
16	Cloxacillin sodium 500 mg vial	3.8344	N/A
17	Gentamycin injection 40mg /ml	2.1020	N/A
18	Metronidazole 5mg/ml Vial	1.5625	N/A
19	Procaine penicillin fortified (4 MU)	1.326	N/A
20	Penicillin benzathine (2.4 MU)	1.7806	N/A
21	Tab zinc sulphate	1.2097	N/A
22	Oral rehydration salt	2.1853	N/A
23	Co-trimoxazole Injection	N/A	14.2905
24	Zinc sulphate Solution	N/A	N/A

Note: NA = Not available.

4.2.2. Prices of medicines for paediatrics in the ADDO's

In the ADDO's, the median MPRs of 10 LPGs was 2.0497 times the international reference prices (ranging from 1.0417 to 2.6709). No Original Brands was found in ADDO's. High MPRs above warning line (greater than 2) were seen for seven medicines out of ten medicines. None of the medicines had MPR less than one (Table14).

Table 14: Median Price ratio of each paediatric antibiotics in the ADDO's in Mbeya Region

No.	Medicines name	Median Price Ratio
1	Amoxicillin syrup 125mg/5ml	2.0833
2	Erythromycin syrp 125mg/5ml	1.0417
3	Metronidazole syrp 200mg/5ml	1.7689
4	Phenoxymethyl penicililin syrp 125mg/5ml	1.3993
5	Septrine sryp 200mg+40mg/5ml	2.2321
6	Penicillin benzyl (3G Pen G : 5 MU)	2.6709
7	Metronidazole 5mg/ml vial	2.3138
8	Procaine penicillin fortified (4 MU)	2.0032
9	Tab Zinc sulphate	2.0161
10	Oral rehydration salt	2.1853

Table 15: Summary of the Median Price Ratios for Paediatric Antibiotics in the ADDO's and Private Pharmacies in Mbeya Region

Type of facility	Minimum/Maximum MPR	Median MPR	Interquartile range MPR (25%, 75%)	95% CI MPR	P value
Pharmacy (20 LPG) (n=30)	0.6793/3.8344	1.774	(1,28, 2.28)	(1.34 to 2.131)	0.514
ADDOs (8LPG) (n=30)	1.0417/2.6709	2.0097	(1.49 , 2.29)	(1.4 to 2.27)	0.610

4.3. Comparison of retail patient prices between ADDO's and private Pharmacies

MPRs were 2.0497 and 1.6493 for ADDO's and Pharmacies respectively in Mbeya region for the 10 commonly used medicines. The highest price above the warning line was seen for two out of ten medicines in the Pharmacies. However, in the ADDO's 8 out of 10 medicines had higher MPRs above the warning line. There were no price differences seen for Erythromycin and Metronidazole syrups. Overall, the results show that; in the ADDO's patient prices were slightly higher (24.3 %) than those in the Pharmacies (n = 10 medicines). But the differences in prices was not statistically significant this is because of the overlapping confidence interval and low number of medicines surveyed at the ADDO's [31,38] (Table 16 & 17).

Table 16: The difference in prices between medicines in the ADDO's and Pharmacies (n=10 medicines)

Name of medicine	MPR for LPG in the Pharmacies	MPR for LPG in the ADDO shops	Ratio for MPR for LPG between the ADDO shops and Pharmacies
Amoxicillin syrup 125mg/5ml	1.7361	2.0833	1.20
Erythromycin syrup 125mg/5ml	1.0417	1.0417	1.00
Metronidazole syrup 200mg/5ml	1.7689	1.7689	1.00
Phenoxymethyl penicillin (Pen-v) 125mg/5ml	1.3526	1.3993	1.03
Co-trimoxazole syrup 200mg+40mg/5ml	2.1577	2.2321	1.03
Penicillin benzyl (3G pen G) 5MU	1.9981	2.6709	1.34
Metronidazole 5mg/ml Vial	1.5625	2.3138	1.48
Procaine penicillin fortified (4 MU)	1.326	2.0032	1.51
Tablet Zinc sulphate	1.2097	2.0161	1.67
Oral rehydration salt	2.1853	2.1853	1.00
Median MPRs	**1.6493**	**2.0497**	**1.24**
P value	**0.906**	**0.610**	

4.4. Analysis of availability and prices of essential antibiotics for paediatrics in the retail private medicine outlets

Figure three shows that generic antibiotics located in the 4th quadrant have good access. For example, amoxycillin and cephalexin syrups have the availability of 100% and 83.33% and at prices of below the warning line (less than 2) of 1.7361 and 0.6793, respectively. On the other hand, generic antibiotics located in the 1st quadrant have poor accessibility to majority of the people. For example, Amoxycillin-Clavulanic acid was available in 40% in the pharmacies and was sold at a price of 2.5 times higher than the international references prices, which this is above the warning line (greater than 2). Ten medicines were in the 4th quadrant showing good access; only Amoxycillin-Clavulanic acid syrup and cloxacillin Injection were in the 1st quadrant showing low availability and high cost.

In the ADDO's, Metronidazole and Erythromycin syrups were in the 4th quadrant showing good access. On the other hand, Benzyl penicillin Injection, Metronidazole intravenous and fortified procaine penicillin were in the 1st quadrant showing low availability and high price (Figure 4)

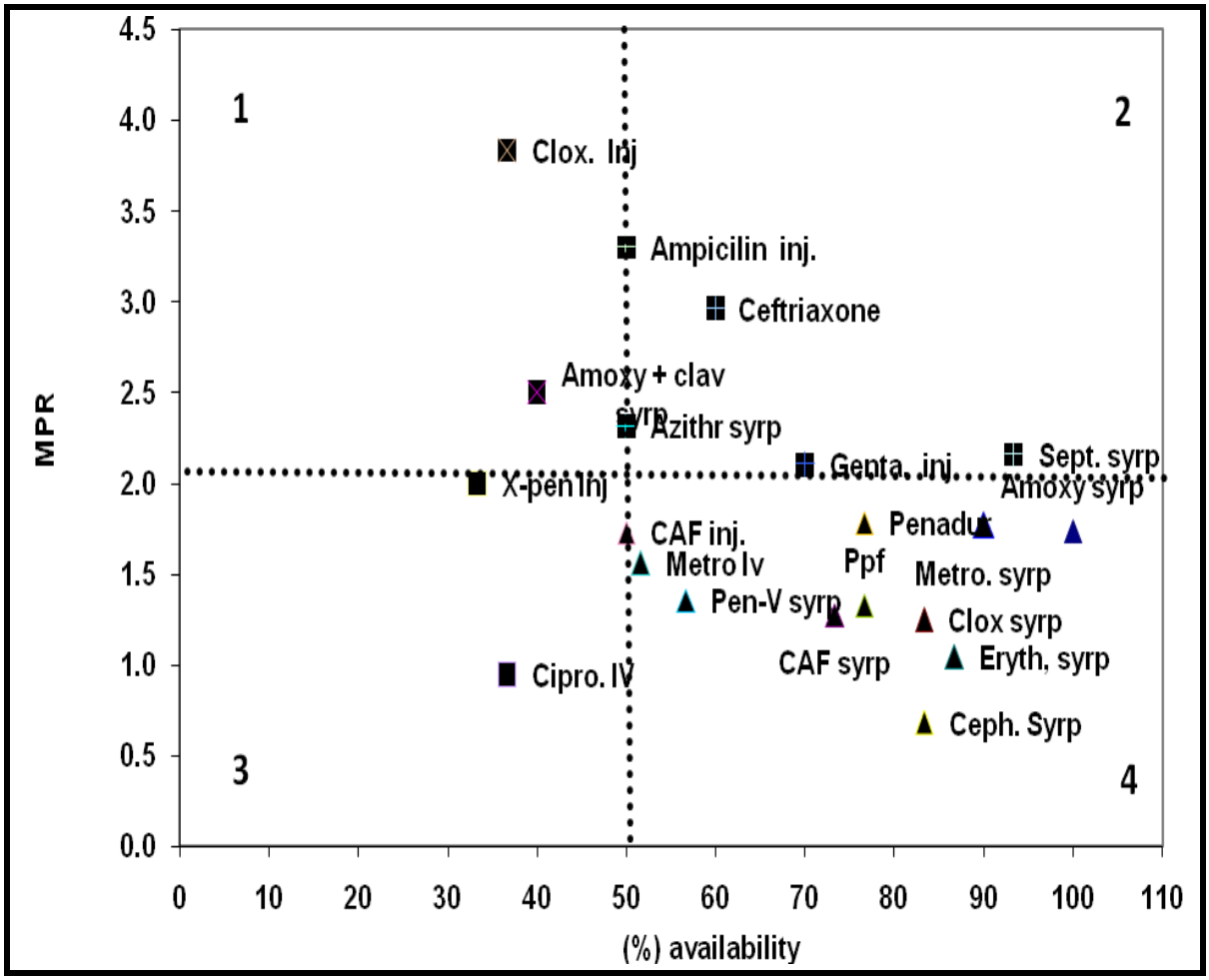

Figure 3: Analysis of paediatric essential antibiotics availability and retail prices in the retail private pharmacies

Note: From above figure 3: **1st quadrant** = high price, low availability; **2nd quadrant** = high availabilitiy, high price**; 3rd quadrant** = low availability, low price; and **4th quadrant** = high availability, low prices. Antibiotics in figure 3: x-pen = Benzyl penicillin, cipro = Ciprofloxacin, CAF = Chloramphenical, Ceph = Cephalexin, Eryth = Erythromycin, Clox = Cloxacillin, Metro = Metronidazole, Penadur = Penicillin Benzathinebenzyl, Sept = Co-trimoxazole, Amoxy = Amoxycillin, Genta = Gentamycin, Azith = Azithromycin, Amoxy-clav = Amoxycillin-Clavulanic acid suspension, Pen–V = Phenoxymethyl penicillin, Inj = Injection and Syrp = Syrup.

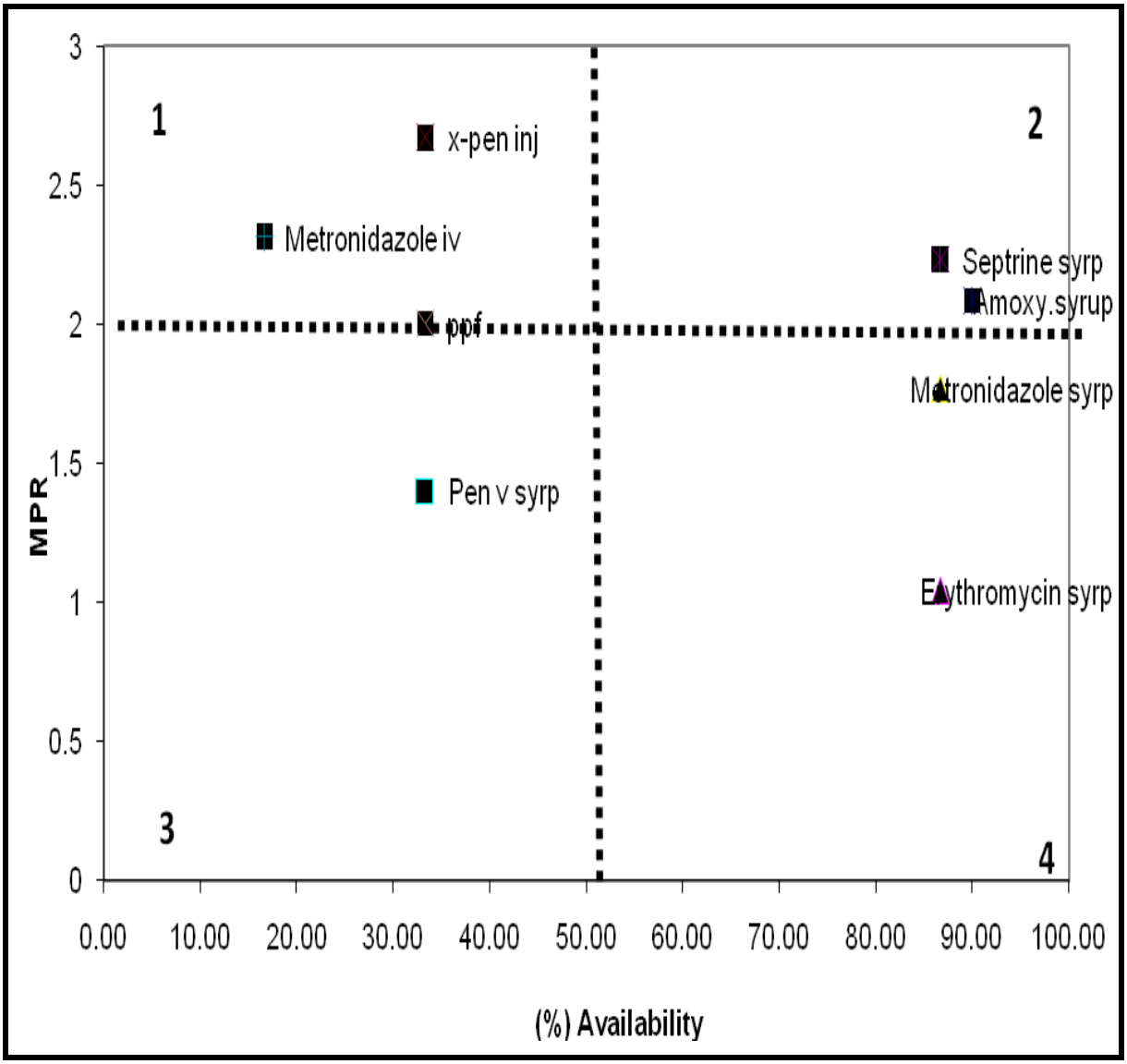

Figure 4: Analysis of paediatric essential antibiotics availability and retail prices in the ADDO's.

Note: From figure 4 above: **1st quadrant** = high price, low availability; **2nd quadrant** = high availabilitiy, high price**; 3rd quadrant** = low availability, low price; and **4th quadrant** = high availability, low prices. Antibiotics in figure 4; Pen V = Phenoxymethyl penicillin, syrp = Syrup, x-pen – benzyl penicillin, Inj = Injection, IV = Intravenous

4.5. Comparison of the public hospitals procurement prices, Private sector patient prices and NHIF patient prices for medicines in the health facilities

The public hospitals procurement price were 0.7591 times the international reference prices for 10 LPGs. This means that public hospitals procure medicines through MSD at a price below the available international market (efficient). NHIF patient prices for lowest price generics were more (177.74%) than those in the public hospitals procurement prices (n = 10 medicines) (Table 17).

The NHIF patient prices were slightly high compared to patient prices in the ADDO's and Pharmacies (n = 10 medicines). This shows that private medicine outlets will still make a reasonable profit by providing services to NHIF beneficiaries who may have missed the drugs at the public hospitals.

In addition, the availability of essential medicines was slightly high (80%) in the Pharmacies compared to 70% in the ADDO's (n = 10 medicines). The differences on availability between ADDO's and Pharmacies were not statistical significant difference this is because of the overlapping confidence intervals [31, 38] (Table 17).

Table 17: Summary of the Median availability and Median price ratios for patient prices in the public hospitals, ADDO's, Private Pharmacies and NHIF

Category	Pharmacies	ADDO's	NHIF patient prices	Public Hospital procurement price
Availability				
Median Availability across basket of 10 medicines	**80%**	**70%**	**N/A**	**N/A**
95% CI (Median Availability)	(70% to 80%)	(50% to 70%)	N/A	N/A
(25^{th}, 75^{th}) percentile	(70%, 90%)	(50%, 80%)	N/A	N/A
Minimum/Maximum	30%/100%	3.3%/100%	N/A	N/A
MPR				
Median MPR (10 medicines)	1.6493	2.0497	2.1083	0.7591
95% CI (Median MPR)	(1.33 to 1.998)	(1.74 to 2.23)	(1.4459 to 3.0242)	(0.2347,0.8547)
(25^{th} , 75^{th}) percentile	(1.297,2.04)	(1.677,2.25)	(1.5330, 2.9018)	(0.4427,0.8061)
Minimum/Maximum	1.0417/2.1853	1.0417/2.6709	1.3542/4.1667	0.0801/1.1111

Note: NA= Not Applicable.

4.6. Affordability of essential antibiotic for paediatrics

There was a considerable cost variation for essential antibiotics in treating different infectious diseases for children. The salary of the unskilled government worker (who earn 4500 Tshs per day) and the National poverty line income (who earn less than 1.25 U.S. Dollar/day = 2000 Tshs/day) were used to assess affordability.

The five scenario conditions of a child infected with pneumonia, urinary tract infection, Shigellosis, severe pneumonia and bacterial meningitis were used for affordability analysis. Affordability of innovator brands was not a major concern with this study because their availability was more limited and the expenditures for these conditions were unaffordable for majority of the population.

Overall, the results show that the cost of standard treatment regime in daily wages was 2.03 days wages (median) ranging from 0.63 to 22 for people living below the poverty line and 0.9 days wages (median) ranging from 0.3 to 9.8 for the lowest paid government worker (n = 15 treatment options). The differences on affordability for 15 treatment options between/among unskilled workers and people living below poverty line were not statistical significant difference this is because of the overlapping confidence intervals [31, 38] (Table 18).

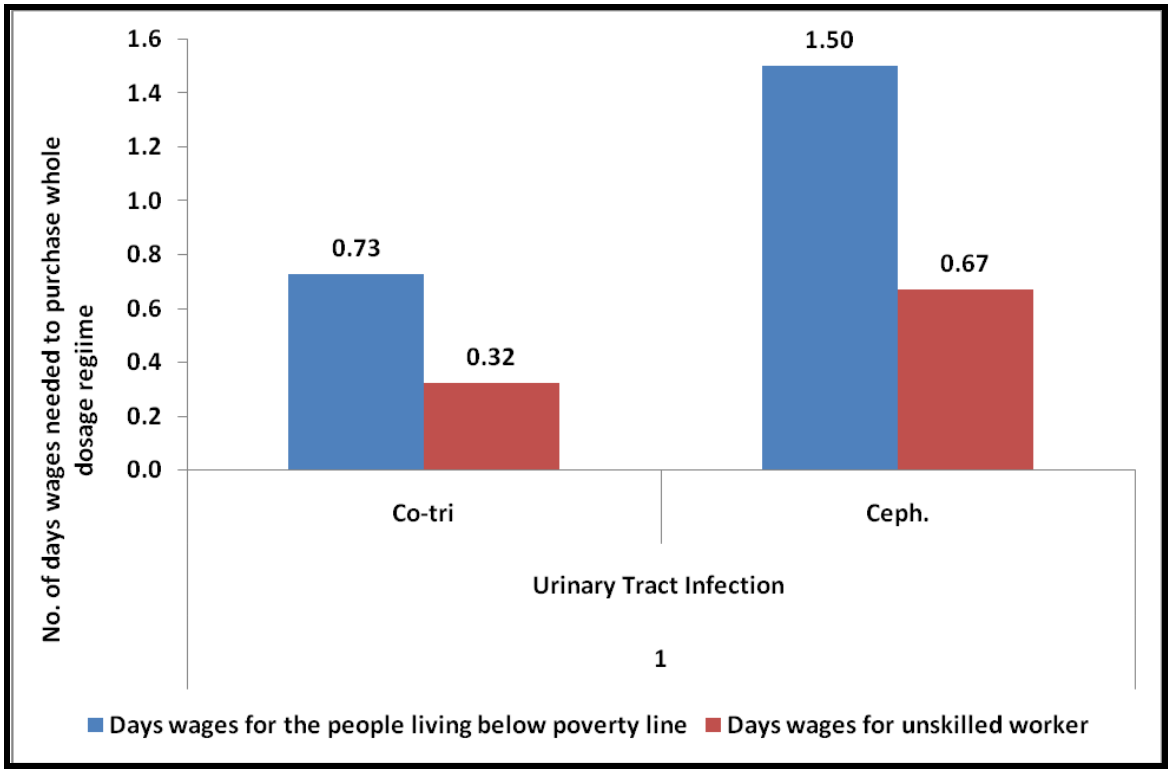

Figure 5: Affordability of treatment options with generic antibiotics at the private pharmacies for UTI.

Note: For Antibiotics in figure five : Co-tri = co-trimoxazole syrup, Ceph:= Cephalexin syrup

4.6.1. Urinary tract infection

According to the results presented in figure five, unskilled worker can afford the whole dosage regime treatment for both cephalexin and cotrimoxazole syrups. However, for people living below poverty line, expenditure on the whole dosage regime with cephalexin syrup is unaffordable (need more than one day's wages).

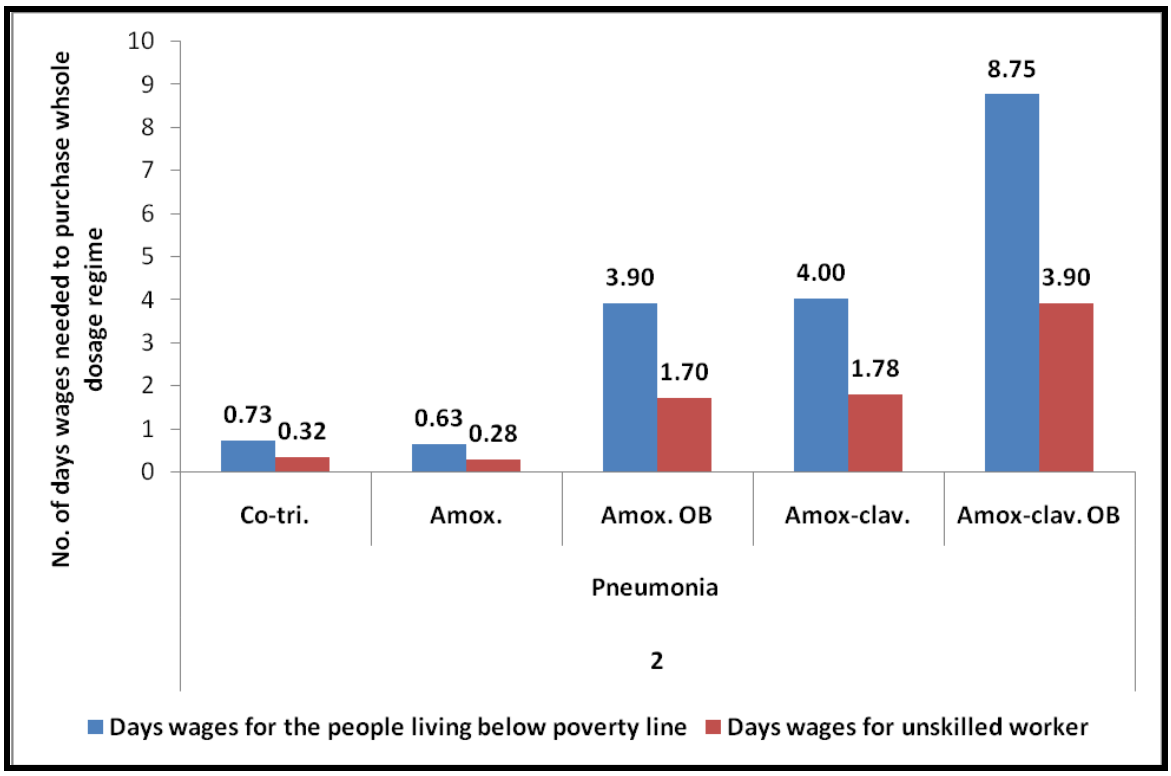

Figure 6: Affordability of treatment options with antibiotics at the private pharmacies for pneumonia.

Note: For antibiotics in figure 6 above; Co-tri = Cotrimoxazole syrup, Amox = Amoxycillin syrup, Amox-clav= Amoxycillin clavulanic acid suspension, OB = Original brand.

4.6.2. Pneumonia

Both for the lowest paid government worker and people living below the poverty line, expenditure on most of treatment option for Pneumonia was less than one day's income except for generics and original brand of Amoxycillin-clavulanic acid suspension. Also there is substantial difference seen in cost between original brand and generic brand. There is 11.9 times day's wages different for treatment of pneumonia with original brand of Amoxycillin-clavulanic acid suspension and generic co-trimoxazole for people living below the poverty line (Figure 6 above).

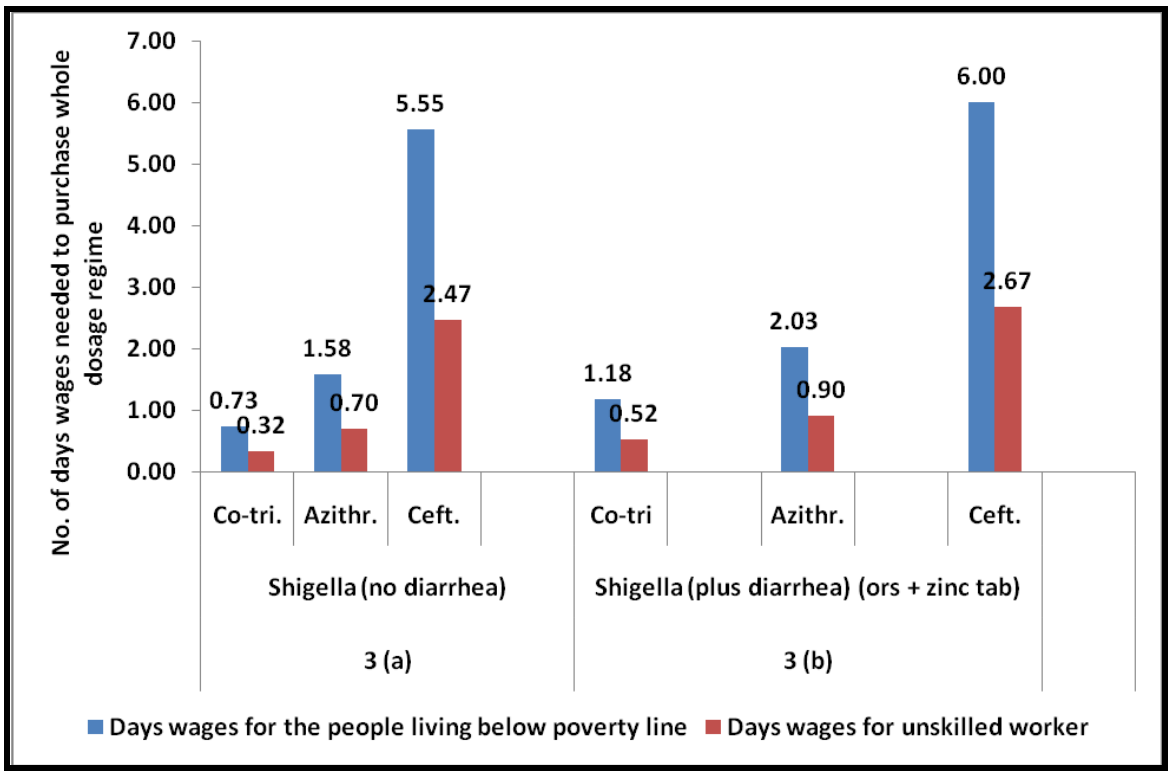

Figure 7: Affordability of treatment options with generic antibiotics at the private pharmacies for shigella infection

Note: For antibiotics in figure 7: Co-tri = Co-trimoxazole syrup, Ceft = Ceftriaxone, Azithr = Azithromycin

4.6.3. Shigella infection (Shigellosis)

For people living below the poverty line, expenditure on only one (1) treatment option conditions with co-trimoxazole was less than one day's income out of six (6) treatments options for diarrhea and non-diarrhea conditions of shigellosis. In addition, the lowest paid government worker, expenditure on most of the treatment was less than one day's income except for ceftriaxone injection (Figure 7 above).

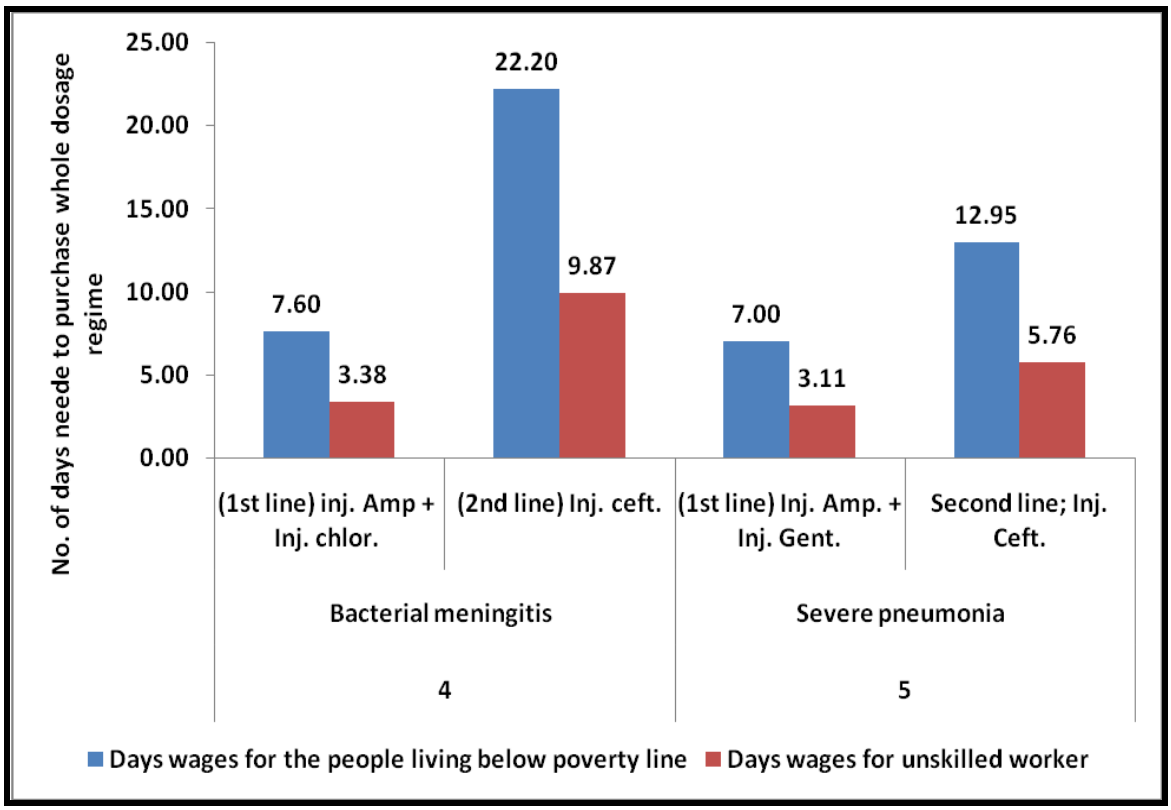

Figure 8: Affordability of treatment options with generic antibiotics at the private pharmacies for bacterial meningitis and severe pneumonia

Note: Antibiotics in figure 8 above: Amp = Ampicillin, Ceft = Ceftriaxone, Gent = Gentamycin, Chor = Chloramphenical, Inj = Injection.

4.6.4. Bacterial meningitis and severe pneumonia

4.6.4.1. Bacterial meningitis

For people living below the poverty line and unskilled worker the expenditure on treatment option with most of generic antibiotics need more than one day's wages for treatment of bacterial meningitis (Figure 8 above). Moreover, people living below poverty line cannot afford a one-day treatment cost for generic antibiotics used in treating first line and second line option for bacterial meningitis (Figure 9 below).

4.6.4.2. Severe pneumonia

In addition, unskilled government worker and people living below the poverty line cannot afford the whole dosage regime treatment cost of generic antibiotics used as the first and second line treatment options for severe pneumonia (figure 8 above). However, people living below poverty line can afford only one day treatment cost of first line antibiotics used in treating severe pneumonia. In contrast, the lowest paid government worker can afford one day treatment cost for most of treatment options in bacterial meningitis and severe pneumonia except for the second line antibiotic (ceftriaxone) use for bacterial meningitis (Figure 9 below).

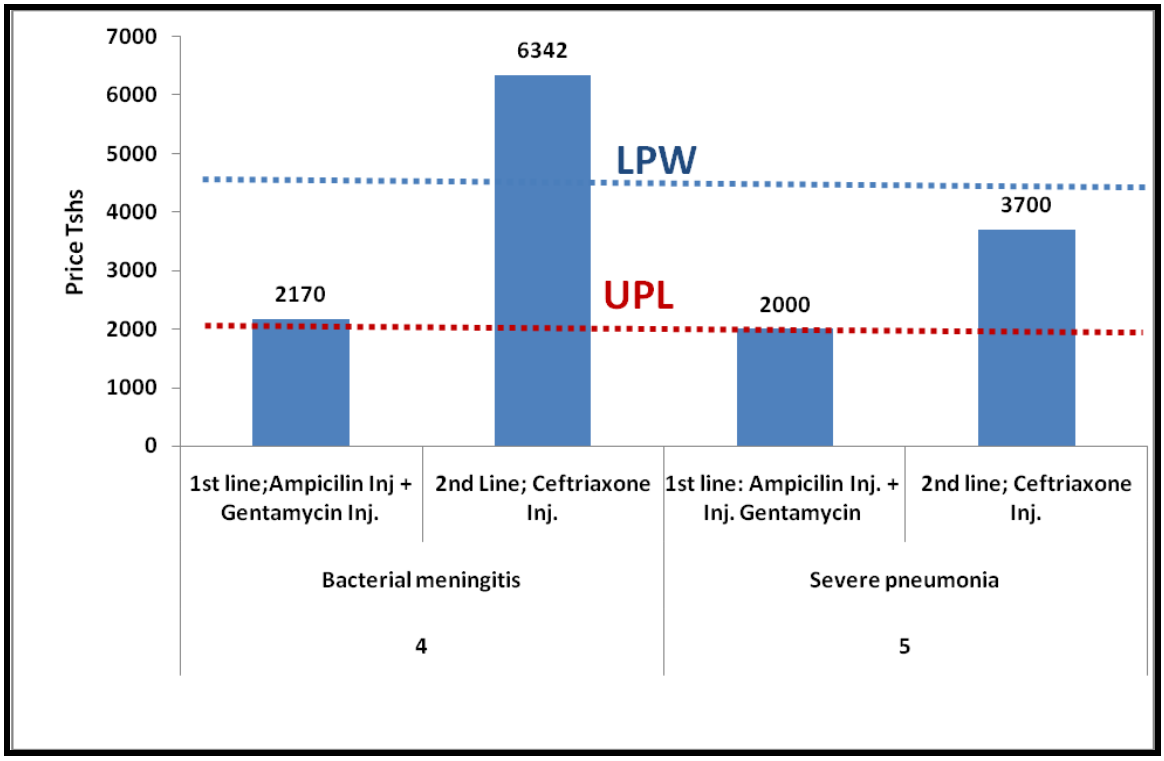

Figure 9: One day treatment cost for bacterial meningitis and severe pneumonia

Note : For antibiotics in figure nine above; Inj = Injection, LPW=Lowest paid government worker (4500 Tshs/day); UPL = Under poverty line (2000 Tanzanian shilling/day)

Table 18: Summary of the number of days-wages needed to purchase 15 treatment options with antibiotics

Outcome (variables)	**People living below the poverty line**	**Lowest paid government workers**
Median	2.025	0.9
Minimum/maximum	0.625/22	0.28/9.86
25^{th} and 75^{th} percentiles	0.73, 7	0.32, 3.11
95% Confidence intervals	0.63 to 7.6	0.28 to 3.38
P value	0.109	0.073

CHAPTER FIVE: DISCUSSION

Children are more prone to infectious diseases including, pneumonia, diarrhea and neonatal infections which are leading causes of death among children under the age of five years (WHO AND UNICEF, 2006). Many of these diseases could be cured if children received appropriate antibiotics and basic health care services. Medicines may offer simple and cost-effective solutions to many health problems, provided they are available, affordable, and rationally used. This study assessed the availability and prices of antibiotics for children and their impact on accessibility in Mbeya, Tanzania. Therefore, the study provides a baseline data for developing interventions in order to improve accessibility of children's essential medicines especially antibiotics.

Across all the surveyed public hospitals, none of the innovator brands of the studied antibiotics was available. Availability of the essential antibiotics listed in the NEMLIT was low in the public hospitals than in the private medicine outlets. The median availability of essential antibiotics in the 8 public hospitals was about 45.45% in Mbeya region. This is lower when compared with the findings of study that was conducted in Sri Lanka [24]. In the later study, availability of medicines in the public hospitals was (52%). However, the results of the present study are comparable to the availability of 45.3% and 43% that were reported in the studies that were conducted in the whole of Tanzania[16] and church health facilities of Uganda[27] respectively. Also, availability for some antibiotics such as ceftazidime injection and co-trimoxazole injection was extremely low or completely absent in most of the health facilities.

Poor availability may be due to the fact that some of these medicines were not included in the NEMLIT and MSD price catalogue, financial constraints of Government and Hospitals and inefficient pharmaceutical management at the health facilities. These conditions forced parents to purchase essential antibiotics in the private medicine outlets instead of getting them for free at the public hospitals.

The study revealed that availability of children essential antibiotics was 59% at MSD (Mbeya zonal office) which is the only source of medicines in the public health facilities. This is slightly higher than overall mean (54 %) availability in Tanzania [16]. In addition, the study shows that some medicines from the EML that should be available at MSD were out of stock during the day of survey. These include co-trimoxazole and metronidazole syrups. These results are not in line with the definition of essential medicines which state that "essential medicines should be 100 percent available at all time in all the health facilities" [1].

The low availability of these paediatric essential medicines in the MSD needs to be addressed as this affects the availability in the public health facilities, as evidenced by the findings of this study. In order to address availability of essential medicines for paediatrics including antibiotics, there is a need to have a separate and comprehensive National Essential Medicine List for Children (NEMLc) so that MSD and other Sectors dealing with medicines for children may update their catalogues. This in-turn will improve accessibility of medicines at the health facilities. Also there is need to improve and maintain logistic system at MSD in order to be effective and efficient. In other words, medicines should be available at all time with the minimum use of resources, including money, time and effort.

However, in the private sector in Mbeya region, there was greater availability of generic antibiotics for children than innovator brands. The overall results have shown that in the private sector the availability of essential antibiotics was fairly high (59%). This figure is slightly higher compared to the results of a recent study that was conducted in whole of Tanzania in which it was reported that the availability of essential antibiotics in the private pharmacies was 34.4%.[16] However, this figure is much lower compared to the figure reported in a study that was conducted in Sri Lanka (80%).[24] This low availability of essential antibiotics for paediatrics in the private sectors may due to low priority of children essential medicines or lack of awareness regarding the existing paediatric dosage forms in the market.

Regarding retail prices to patients in ADDO shops and Pharmacies, the prices of 10 commonly generic medicines that should be available in both medicine outlets were generally high in the ADDO shops. In the pharmacies, the median medicine prices for 20 LPGs were found to be 1.774 times international reference prices. This finding on medicines prices in the pharmacies is slightly higher compared to those reported in Oidisha, India [39] and Sri Lanka [24], but much lower compared to study conducted in Ghana. [40]

In addition, prices of both generic and innovator brands of essential medicines such as amoxicillin-clavulanic acid suspension were found to be much higher as compared to those reported in Sri Lanka[24], India[39] and Ghana[40]. Furthermore, this study reveals presence of medicines in alternative strengths or pack sizes such as amoxicillin-clavulanic which is sold at the highest prices. This is not in line with the definitions of essential medicines and rational use of medicines. [1, 5]

Cephalexin and Cloxacillin syrups were readily available in the private sector and at the price the majority of people could afford. However, these drugs were not listed in the MSD catalogue. In additional, cephalexin syrup was not included in the NEMLIT. As a result, these medicines were not available in the public health facilities. Current situation of rising in microbial resistance to antibiotics and the high cost for most of antibiotics results in finding treatment options that are readily available and affordable to the community. This shows that, there is need for the MOHSW and MSD to review their catalogue and to update the lists of essential medicines. In addition, the highest cost for most of 3rd and 4th generation cephalosporins are likely to decrease with the increasing availability of generics.[12, 34]

The survey found that median stock-out day per year of essential antibiotics for paediatrics in the public hospitals was 124. This gives an indication that one of the key essential antibiotics was not available for more than three month during the time of the year. To calculate this indicator, it was necessary to verify by means of proper records, the incidence and length of time of any stock-outs for at least the past six months. Out of

the 8 hospitals surveyed, only 5 hospitals had the proper records where the stock-out days were identified and recorded. Unlike the findings of this study, recent studied conducted in Tanzania, [16] Ghana [40] and Sri Lanka[24] did not indicate 'stock-out day's category' as in this study. Inclusion of this category is essential as it provides a broad picture of the availability of medicines for children at a given period of time.

This situation shows that; there is need to develop immediate interventions so as to minimize frequent stock-outs of medicines for children in the health facilities. In the public sector, stock-out could mean an insufficient supply to meet high demand, or alternatively, low priority of medicines for children especially antibiotics. It is necessary therefore to conduct further studies to investigate the causes of frequent stock-outs of these children`s essential medicines especially antibiotics.

Also the study shows that, if hospitals procure medicines from MSD and sell them to patients with health insurance coverage, a 177% markup (profit) will be made. In addition, NHIF patient price was generally higher than retail patient prices at the private medicine outlets. These findings indicate that private medicine outlets also would benefit by providing medicines services to NHIF beneficiaries. Moreover, this may influence more private medicine outlets to engage in the provision of medicines services to NHIF customer, thereby improving accessibility, availability and most likely affordability of essential medicines. On the other hand, majority of people in developing countries including Tanzania do not have access to health insurance. [21] Therefore this indicates that only minority of people who covered by the health insurance would benefit through these services in the private medicine outlets. Therefore, an option of NHIF to finance Drug revolving funds (DRF) at the hospitals would improve access of paediatric essential medicines. This advocates for the need to roll out health insurance coverage beyond the government employees. This is in line with suggestion by WHO that in order to make medicines financing sustainable, out-of-pocket expenses should be reduced through expansion of health insurance and other innovative external funding sources[41].

The study shows existence of various cost differences for antibacterial agents used as treatment options for children infectious diseases. This indicates that some antibiotics were not affordable by people living below the poverty line. The present situation of diseases such as HIV/AIDS and increasing resistance to medicines for most of the first line option are likely to result in switching to alternative treatment options that are not affordable at the community level.

In Tanzania, it has been reported that pneumonia is the leading cause of NMR and accounts for about 28% of all causes of death. [14] Medicines which are used to treat severe pneumonia seem to be not very affordable as shown in this study. In Mbeya, treatment options with essential medicine of Amoycillin-clavulanic acid are clearly not affordable in the private pharmacies. In addition, these medicines were mostly unavailable in the public hospitals during the time of the study.

Furthermore, the study shows that unskilled government workers require 0.3 days to purchase a full course of cotrimoxazole for respiratory infection. This finding was almost the same with the survey conducted in Tanzania[16], Ghana[40] and Srilanaka[24]. Also WHO studies on the review of medicines that are used for shigella infection revealed that co-trimoxazole shows treatment failure and now recommend the use of ceftriaxone and azithromycin.[42] However, the findings from this study show that people living below the poverty line can only afford treatment option of co-trimoxazole (already developed resistant) but cannot afford azithromycin syrup and ceftriaxone for shigella infection (without diarrhea). In addition, azithromycin syrup is not listed in NEML and MSD catalogue. The increasing rate of resistant strains for the baseline treatment and other treatment options that are not affordable is likely to lead to high risk of treatment failures, hence increasing morbidity, mortality and spread of resistance to children less than five years of age.

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1. Conclusion

The present survey had shown that while there is efficiency on procurement medicines and adherence to NEML for most of public hospitals, availability of essential antibiotics was very low public sector compared to private sector. In Mbeya region, the study shows that people living below poverty line cannot afford most of the basic treatment regimen for common infectious diseases.

6.2. Recommendations

From the findings and implications of the study, the following are recommended;

1. Managerial

- Key essential antibiotics for children should be given priority during selection and procurement. Pharmacy and Therapeutic committee should prepare and update the list regularly based on the primary, secondary and tertiary health facility levels

- Facilities should strengthen Drug Revolving Fund program through NHIF at the hospitals in order to sustain constant availability of essential medicines for children. While lowering prices at the private medicine outlets is a long term goal, a new financing approach at the hospitals by using Drug Revolving Funds through the NHIF might be a solution that needs to be achieved soon, since the profit that will be gained will be higher as shown by this study.

- Improving the human resources crisis on pharmaceutical management (selection, procurement, distribution and use) at the health facilities is needed. There is need for the government to work with professional organizations, regulatory bodies, training institutions to develop long term workforce plans. For example expanding the ability of existing training institution to train more ADDO dispensers in order to improve pharmaceutical services in the retail

pharmaceutical outlets in rural areas where there are few or no registered pharmacies and unqualified pharmaceutical personnel.

2. **Regulations, laws and policies**

- An option like, making key children essential antibiotics that can be used for the treatment of bacterial infections (bacterial meningitis, severe pneumonia, etc) for the course of 10 to 14 days to be available in the private sectors at subsidized prices, as it was done in the case of ALU and mosquito nets, will be helpful.

- There is need for improvement in policies on medicines pricing and individual medicines prices where there is evidence of excessive prices. Example, for IB and LPG such as Amoxycillin-clavulanic acid should be regularly reviewed as the evidence shown by this study. In addition, an intervention on fixing prices, where prices of essential antibiotics of interest are compared to that of similar product within a country or of identical products in other countries is an option.

- Manufacturers and pharmacies should strive to ensure availability of alternative medicines that are produced locally and affordable to the majority of people in the community. The manufacturers and pharmacy owners must adapt the WHO essential medicine policy when ensuring the availability of alternative medicines or when medicines are locally produced. This makes medicines affordable to the majority of the people in the community.

3. Education

- To promote rational use of antibiotics based on educational programs through selecting cost-effective medicines. This can be done through the continuing education (in-services), illustrated material (posters and leaflet), influencing opinion leaders and face to face contact (education outreach and patient education)

- Prices on medicines and availability should be regularly and widely disseminated. Surveillance on availability, cost and price components should regularly be conducted by the pharmacy division of the MoHSW so as to develop reliable information on medicine price and availability to be used by the government, insurance funds and health facilities.

4. International

- There is need to develop international and national-wide regulatory authorities to monitor medicines prices to increase access. This can be targeted at the supply of pharmaceuticals (manufacture) or the demand (wholesaler, retailer, doctor and patient).

- WHO, UNICEF, International partners and including other stakeholders must provide Technical assistance and financing to the financial management system. This will make a sustainable reliable source of medicine available to poor resources country.

CHAPTER SEVEN

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ANNEXES

ANNEX A: Availability and prices: ADDO's

MUHIMBILI UNIVERSITY SCHOOL OF HEALTH AND ALLIED SCIENCE

SCHOOL OF PHARMACY

DEPARTMENT - PHARMACEUTICS

Msc. PHARMACEUTICAL MANAGEMENT

SURVEY AREA: PRIVATE MEDICINES OUTLETS (ADDO SHOPS)

AVAILABILITY AND COST OF PAEDIATRICS ESSENTIAL ANTIBIOTICS IN MBEYA REGION - TANZANIA

Name of the ADDO Shop	
Address	
Date of visit	
Data collectors	
Name and contact details of the person who provide the data	

ANNEX B: Availability and Price of essential paediatric antibiotics at the ADDO

1	2	3	4		5	6		7	8	11	12
Na	**Generic name**	**Dosage form and Strengths**	**Medicine type**	**Manufacture**	**Brand or product name**	**Available (Yes/ No)**	**Alternatives found (Dosage and Strength,)**	**Pack size found (Number of ml/Inj.)**	**Price of pack size found (Tshs)**	**Unit price (4 digit) per inj/ml**	**Comments**
1	Amoxicillin	Powder for suspension (as trihydrate),125mg/5ml	Originator brand	GSK/ SKB	Amoxil						
			Lowest-price generic								
2	Erythromycin	Powder for suspension (as ethylsuccinate),(or estolate or state) 125mg/5ml in 100ml bottles	Originator brand	Abbott	Erytrhocin						
			Lowest-price generic								
3	Metronidazole	Metronidazole Suspension as (benzoate) 200mg/5ml i	Originator brand	P.fizer	Flagyl						
			Lowest-price generic								
4	Penicillin, phenoxy	Powder for suspension 125mg/5ml in 100ml	Originator brand		.						

1	2	3	4		5	6		7	8	11	12
Na	**Generic name**	**Dosage form and Strengths**	**Medicine type**	**Manufacture**	**Brand or product name**	**Available (Yes/ No)**	**Alternatives found (Dosage and Strength,)**	**Pack size found (Number of ml/Inj.)**	**Price of pack size found (Tshs)**	**Unit price (4 digit) per inj/ml**	**Comments**
	methyl-		Lowest-price generic								
5	Sulphamethoxazole + trimethoprim	Oral liquid: 200mg + 40mg/5ml.	Originator brand	Roche	Bactrim						
			Lowest-price generic								
INJECTABLE FORMULATION											
6	Benzyl Penicillin	Powder for injection 600mg= (1 million IU), 3g (=5million IU) as sodium or potassium salt	Originator brand								
			Lowest-price generic								
7	Metronidazole	Injection (I.V) 5mg/ml in 100ml bottle	Originator brand	Sanofi-Aventis	Flagyl						
			Lowest-price generic								
8	*Fortified*										

1	2	3	4		5	6		7	8	11	12
Na	**Generic name**	**Dosage form and Strengths**	**Medicine type**	**Manufacture**	**Brand or product name**	**Available (Yes/ No)**	**Alternatives found (Dosage and Strength,)**	**Pack size found (Number of ml/Inj.)**	**Price of pack size found (Tshs)**	**Unit price (4 digit) per inj/ml**	**Comments**
	Procaine penicillin										
9	*Zinc sulphate tab.*										
10	*Oral Rehydration Salt*										

ANNEX B: Availability and prices: Pharmacies

MUHIMBILI UNIVERSITY SCHOOL OF HEALTH AND ALLIED SCIENCE

SCHOOL OF PHARMACY

DEPARTMENT - PHARMACEUTICS

Msc. PHARMACEUTICAL MANAGEMENT

SURVEY AREA: PRIVATE MEDICINES OUTLETS

AVAILABILITY AND COST OF SELECTED CHILDREN'S ESSENTIAL ANTIBIIOTICS SURVEY

Name of the pharmacy	
Address	
Date of visit	
Data collectors	
Name and contact details of the person who provide the data	

Availability and Price of essential paediatric antibiotics at the Pharmacy

1	2	3	4		5	6		7	8	11	12
Na	**Generic name**	**Dosage form and Strengths**	**Medicine type**	**Manufacture**	**Brand or product name**	**Available (Yes/ No)**	**Alternatives found (Dosage and Strength,)**	**Pack size found (Number of ml/Inj.)**	**Price of pack size found (Tshs)**	**Unit price (4 digit) per inj/ml**	**Comments**
1	Amoxicillin	Powder for suspension (as trihydrate),125mg/5ml	Originator brand	GSK/ SKB	Amoxil						
			Lowest-price generic								
2	Amoxycillin + Clavulanic acid	Powder for suspension (as trihydrate) 125mg+31.25mg (as potassium salt) in 5ml	Originator brand	GSK/ SKB	Augmentin						
			Lowest-price generic								
3	Cephalexin	Powder for reconstitution with water: 125mg/5ml;	Originator brand	Eli Lillly	Keflex						
			Lowest-price generic								
4	Azithromycin	Oral liquid 200mg/5ml	Originator brand	Pfizer	Zithromax						
			Lowest-price generic								

1	2	3	4		5	6		7	8	11	12
Na	**Generic name**	**Dosage form and Strengths**	**Medicine type**	**Manufacture**	**Brand or product name**	**Available (Yes/ No)**	**Alternatives found (Dosage and Strength,)**	**Pack size found (Number of ml/Inj.)**	**Price of pack size found (Tshs)**	**Unit price (4 digit) per inj/ml**	**Comments**
5	Chloromphenicol	Suspension (as palmitate), 125mg/5ml	Originator brand	Parke-Davis	Chloromycetin						
			Lowest-price generic								
6	Cloxacillin	Powder for suspension (as sodium salt), 125mg/5ml in 100ml bottle	Originator brand								
			Lowest-price generic								
7	Erythromycin	Powder for suspension (as ethylsuccinate),(or estolate or state) 125mg/5ml in 100ml bottles	Originator brand	Abbott	Erytrhocin						
			Lowest-price generic								
8	Metronidazole	Metronidazole Suspension as (benzoate) 200mg/5ml i	Originator brand	P.fizer	Flagyl						
			Lowest-price generic								
9	Penicillin, phenoxy methyl-	Powder for suspension 125mg/5ml in 100ml	Originator brand								

1	2	3	4		5	6		7	8	11	12
Na	**Generic name**	**Dosage form and Strengths**	**Medicine type**	**Manufacture**	**Brand or product name**	**Available (Yes/ No)**	**Alternatives found (Dosage and Strength,)**	**Pack size found (Number of ml/Inj.)**	**Price of pack size found (Tshs)**	**Unit price (4 digit) per inj/ml**	**Comments**
			Lowest-price generic								
10	Sulphamethoxazole + trimethoprim	Oral liquid: 200mg + 40mg/5ml.	Originator brand	Roche	Bactrim						
			Lowest-price generic								
11	Ampicillin	Powder for injection (as sodium salt) 500mg in vial	Originator brand								
			Lowest-price generic								
12	Benzyl Penicillin	Powder for injection 600mg= (1 million IU), 3g (=5million IU) as sodium or potassium salt	Originator brand								
			Lowest-price generic								
13	Cefazolin	Powder for injection; 1gm (as sodium salt) in vial.	Originator brand								
			Lowest-price generic								

1	2	3	4		5	6		7	8	11	12
Na	**Generic name**	**Dosage form and Strengths**	**Medicine type**	**Manufacture**	**Brand or product name**	**Available (Yes/ No)**	**Alternatives found (Dosage and Strength,)**	**Pack size found (Number of ml/Inj.)**	**Price of pack size found (Tshs)**	**Unit price (4 digit) per inj/ml**	**Comments**
14	Cefotaxime #	Powder for injection: 250 mg per vial (as sodium salt)	Originator brand								
			Lowest-price generic								
15	Ceftazidime #	Powder for injection (as pentahydrate) 250mg in vial	Originator brand								
			Lowest-price generic								
16	Ceftriaxone	Injection 250mg in vial	Originator brand	Roche	Rocephin						
			Lowest-price generic								
17	Chloramphenicol	Powder for injection (as sodium succinate1g in vial	Originator brand	Parke-davis	Chloromycetin						
			Lowest-price generic								

1	2	3	4		5	6		7	8	11	12
Na	**Generic name**	**Dosage form and Strengths**	**Medicine type**	**Manufacture**	**Brand or product name**	**Available (Yes/ No)**	**Alternatives found (Dosage and Strength,)**	**Pack size found (Number of ml/Inj.)**	**Price of pack size found (Tshs)**	**Unit price (4 digit) per inj/ml**	**Comments**
18	Chloromphenicol	Oily suspension for injection 0.5gm(as sodium succinate))/ml in 2ml ampoule	Originator brand	Parke-davis/ Parkedatew	Chloromycetin						
			Lowest-price generic								
19	Ciprofloxacin	IV solution (as lactate) 2mg/ml in 100ml bottle	Originator brand	Bayer	Ciproxin						
			Lowest-price generic								
20	*Clindamycin #*	*Injection (as phosphate) 150mg/ml*	Originator brand								
			Lowest-price generic								
21	Cloxacillin	Inj. 500mg in vial	Originator brand								
			Lowest-price generic								
22	Gentamicin	I40mg/ml in 2ml ampoule	Originator brand	Schering Plough.	Garamycin						

1	2	3	4		5	6		7	8	11	12
Na	**Generic name**	**Dosage form and Strengths**	**Medicine type**	**Manufacture**	**Brand or product name**	**Available (Yes/ No)**	**Alternatives found (Dosage and Strength,)**	**Pack size found (Number of ml/Inj.)**	**Price of pack size found (Tshs)**	**Unit price (4 digit) per inj/ml**	**Comments**
			Lowest-price generic								
23	Metronidazole	Injection (I.V) 5mg/ml in 100ml bottle	Originator brand	Sanofi-Aventis	Flagyl						
			Lowest-price generic								
24	Procaine benzyl penicillin (fortified)	Powder for injection (as sodium or potassium salt) 3g (3,000,000 IU) in vial, 1gm (=1 million IU)	Originator brand								
			Lowest-price generic								
25	Sulphamethoxazole + trimethoprim	Injection : 80mg +16mg/ml in 5-ml ampoule	Originator brand	AR scientific	Bactrim						
			Lowest-price generic								
26	*Flucloxacillin*	*Oral 125mg/5ml*	Originator								
27	*Penicillin, benzathinebenzyl*	*Powder for injection 1.44g (2,400,000 IU) in vial,*	Originator brand	Penadur	Wyeth						

1	2	3	4		5	6		7	8	11	12
Na	**Generic name**	**Dosage form and Strengths**	**Medicine type**	**Manufacture**	**Brand or product name**	**Available (Yes/ No)**	**Alternatives found (Dosage and Strength,)**	**Pack size found (Number of ml/Inj.)**	**Price of pack size found (Tshs)**	**Unit price (4 digit) per inj/ml**	**Comments**
		900mg (=1.2 million IU)	Lowest-price generic								
28	*Zinc sulphate*	*Tab 20mg*									
29	*Zinc sulphate Soln*	*10mg/5ml*									
30	*Oral Rehydration Salt*										

ANNEX C: Availability and time out of stock –Public hospitals

MUHIMBILI UNIVERSITY SCHOOL OF HEALTH AND ALLIED SCIENCE

SCHOOL OF PHARMACY

DEPARTMENT – PHARMACEUTICS:

Msc. PHARMACEUTICAL MANAGEMENT

SURVEY AREA: PUBLIC HOSPITALS

AVAILABILITY AND TIME OUT OF STOCK FOR PAEDIATRICS ESSENTIAL ANTIBIOTICS

Name of the facility	
Address	
Date of visit	
Data collectors	
Name and contact details of the pharmacist who provide the data	
Approval authority	
This confirms that _____ from the department of Pharmaceutics, School of Pharmacy, Muhimbili University School of Health and Allied Science visited _____ on _____ and collect the data. Date _____ _____ Signature _____	

Instruction:

Review the stock sheet for each essential antibiotic. Record the current stock quantity in column 6 and then, for each month, record the number of days for which the product was out of stock, starting with last month and working backward.

Add the number of days out of stock for each month and enter the total in the last column.

Note: Stock that is on hand *but expired* is not counted for this indicator. *All* blanks should be filled in on this data collection form. Enter zero (0) if counts are nil or N/A if data for a particular item is not available

Availability of a Set of Key Antibiotics and Time Out of Stock

1	2	3	4		5	6	7	8	9	10	11	12	19
Na	**Antibacterial**	**Dosage and strength**	**Medicine type**	**Manufacture**	**Brand product names**	**Availability Yes / No**	**Days Out of Stock k**						
							M 1 Last month	**M 2**	**M 3**	**M 4**	**M 5**	**M 6**	**Total days out of stock.**
1	Amoxicillin	Powder for suspension (as trihydrate),125mg/5mll	Originator brand	GSK/ SKB	Amoxil								
			Lowest-price generic										
2	Amoxycillin + Clavulanicacid	Powder for suspension (as trihydrate) 125mg+31.25mg (as potassium salt) in 5ml	Originator brand	GSK/ SKB	Augmentin								
			Lowest-price generic										
3	Cefalexin	Powder for reconstitution with water: 125mg/5ml	Originator brand	Eli Lillly	Keflex								
			Lowest-price generic										
4	Azithromycin	Oral liquid 200mg/5ml	Originator brand	Pfizer	Zithromax								
			Lowest-price generic										

1	2	3	4		5	6	7	8	9	10	11	12	19
Na	**Antibacterial**	**Dosage and strength**	**Medicine type**	**Manufacture**	**Brand product names**	**Availability Yes / No**	**Days Out of Stock k**						
							M 1 Last month	**M 2**	**M 3**	**M 4**	**M 5**	**M 6**	**Total days out of stock.**
5	Chloromphenicol	Suspension (as palmitate), 125mg/5ml	Originator brand	Parke-Davis	Chloromycetin								
			Lowest-price generic										
6	Cloxacillin	Powder for suspension (as sodium salt), 125mg/5ml in 100ml bottle	Originator brand										
			Lowest-price generic										
7	Erythromycin	Powder for suspension (as ethylsuccinate),(or estolate or state) 125mg/5ml in 100ml bottles	Originator brand	Abbott	Erytrhocin								
			Lowest-price generic										
8	Metronidazole	Metronidazole Suspension as (benzoate) 200mg/5ml	Originator brand	P.fizer	Flagyl								
			Lowest-price generic										

1	2	3	4		5	6	7	8	9	10	11	12	19
Na	**Antibacterial**	**Dosage and strength**	**Medicine type**	**Manufacture**	**Brand product names**	**Availability Yes / No**	**Days Out of Stock k**						
							M 1 Last month	**M 2**	**M 3**	**M 4**	**M 5**	**M 6**	**Total days out of stock.**
9	Penicillin, phenoxy methyl-	Powder for suspension 125mg/5ml in 100ml	Originator brand										
			Lowest-price generic										
10	Sulphamethoxazole + trimethoprim	Oral liquid: 200mg + 40mg/5ml.	Originator brand	Roche	Bactrim								
			Lowest-price generic										
11	Flucloxacillin	Syrup 125mg/5ml	Originator brand										
			Lowest-price generic										
12	Ampicillin	Powder for injection (as sodium salt) 500mg in vial	Originator brand										
			Lowest-price generic										

1	2	3	4		5	6	7	8	9	10	11	12	19
Na	**Antibacterial**	**Dosage and strength**	**Medicine type**	**Manufacture**	**Brand product names**	**Availability Yes / No**	**Days Out of Stock k**						
							M 1 Last month	**M 2**	**M 3**	**M 4**	**M 5**	**M 6**	**Total days out of stock.**
13	Benzyl Penicillin	Powder for injection 600mg= (1 million IU), 3g (=5million IU) as sodium or potassium salt	Originator brand										
			Lowest-price generic										
14	Ceftazidime #	Powder for injection (as pentahydrate) 250mg in vial	Originator brand										
			Lowest-price generic										
15	Ceftriaxone	Injection 250mg in vial	Originator brand	Roche	Rocephin								
			Lowest-price generic										
16	Chloramphenicol	Powder for injection (as sodium succinate1g in vial	Originator brand	Parke-davis	Chloromycetin								
			Lowest-price generic										

1	2	3	4		5	6	7	8	9	10	11	12	19
Na	**Antibacterial**	**Dosage and strength**	**Medicine type**	**Manufacture**	**Brand product names**	**Availability Yes / No**	**Days Out of Stock k**						
							M 1 Last month	**M 2**	**M 3**	**M 4**	**M 5**	**M 6**	**Total days out of stock.**
17	Chloromphenical	Oily suspension for injection 0.5gm(as sodium succinate))/ml in 2ml ampoule	Originator brand	Parke-davis/ Parkedatew	Chloromycetin								
			Lowest-price generic										
18	Ciprofloxacin	IV solution (as lactate) 2mg/ml in 100ml bottle	Originator brand	Bayer	Ciproxin								
			Lowest-price generic										
19	*Clindamycin #*	*Injection (as phosphate) 150mg/ml*	Originator brand										
			Lowest-price generic										
20	Cloxacillin	Powder for injection (as sodium salt) 500mg in vial	Originator brand										
			Lowest-price generic										

1	2	3	4		5	6	7	8	9	10	11	12	19
Na	**Antibacterial**	**Dosage and strength**	**Medicine type**	**Manufacture**	**Brand product names**	**Availability Yes / No**	**Days Out of Stock k**						
							M 1 Last month	**M 2**	**M 3**	**M 4**	**M 5**	**M 6**	**Total days out of stock.**
21	Gentamicin	Injection (as sulphate) 10mg; 40mg/ml in 2ml ampoule	Originator brand	Schering Plough.	Garamycin								
			Lowest-price generic										
22	Metronidazole	Injection (I.V) 5mg/ml in 100ml bottle	Originator brand	Sanofi-Aventis	Flagyl								
			Lowest-price generic										
23	Procaine benzyl penicillin	Powder for injection (as sodium or potassium salt) 3g (3,000,000 IU) in vial, 1gm (=1 million IU)	Originator brand										
			Lowest-price generic										
24	Sulphamethoxazole + trimethoprim	Injection : 80mg +16mg/ml in 5-ml ampoule	Originator brand	AR scientific	Bactrim								
			Lowest-price generic										

1	2	3	4		5	6	7	8	9	10	11	12	19
Na	**Antibacterial**	**Dosage and strength**	**Medicine type**	**Manufacture**	**Brand product names**	**Availability Yes / No**	**Days Out of Stock k**						
							M 1 Last month	**M 2**	**M 3**	**M 4**	**M 5**	**M 6**	**Total days out of stock.**
25	*Penicillin, benzathinebenzyl*	*Powder for injection 1.44g (2,400,000 IU) in vial, 900mg (=1.2 million IU)*	Originator brand	Penadur	Wyeth								
			Lowest-price generic										
20	Kanamycin	Powder for injection, 1g	Originator brand										
			Lowest-price generic										
21	Flucloxacillin	Injection (sodim) 250mg	Originator brand										
			Lowest-price generic										

ANNEX D : Summary of analysis

	Question	Source of information
1	How do pattern of price compare with international reference price	MPRs of individual medicines and Median MPR for basket of medicines
2	Do price vary significantly across medicines outlets?	25^{th} and 75^{th} percentile and minimum and maximum, for MPRs of Individual medicines
3	Do price vary significantly between medicines?	25^{th} and 75^{th} percentile, and minimum and maximum for median MPR
4	What is the difference in price between originator brand medicines (OB) and their lowest-priced generic equivalents (LPG)	MPRs for the OB and LPG of individual medicines Median MPRSs for all medicines found as both product types (matched paired analysis)
5	What is the availability of medicines in the public and private sector?	Per cent availability of individual medicine Average % availability across all medicines
6	Does availability vary significantly between medicines?	Difference in % availability of individual medicines 25^{th} and 75^{th} percentile for average % availability
7	Does availability vary significantly between OB and LPG medicines?	Difference in % availability for OBs and LPGs of individual medicines Difference in average % availability for all OBs and LPGs
8	What is the difference in availability in public and private sectors	Difference in per cent availability of individual medicines across sectors
9	How does average per cent % availability vary across sectors? How does the relative availability of OBs and LPGs vary across sectors?	Average % availability of OBs and LPGs across sectors
10	How many days wages does the lowest paid unskilled government worker need to spend to purchase a standard course of treatment for common condition	Days wages = median medicine price found in facilities * # of units in a standard course of treatments/daily wages of lowest paid government worker.
11	How does treatment affordability vary between OBs and LPGs?	Difference in days wages between OBs and LPGs for the same treatment course
Sources: WHO/PSM/PAR/2008.3 [17]		

ANNEX E: Introduction letter from Director of postgraduate studies

District Executive Director

P. O. Box ……

……..

Re: INTRODUCTION LETTER

The bearer of this letter Mr. Kabandika, Twaha is a student at Muhimbili University of Health and Allied Science (MUHAS) pursuing taking Msc Pharmaceutical Management.

As part of his studies he intends to do a study titled: "Evaluation of availability and cost of paediatrics essential antibiotics in Mbeya Region-Tanzania"

The research has been approved by the Chairmen of MUHAS Research Ethics Committee. Kindly provide him the necessary assistance to facilitate the conduct of his research.

We thank you for your cooperation.

Tija Ukondwa

For: DIRECTOR, POSTGRADUATE SUDIES

ANNEX F: Introduction letter from principal supervisor

……..

……

REQUEST TO ALLOW A MASTERS STUDENTS TO COLLECT DATA FOR HIS DISSERTATION AT YOUR FACILITY

Mr. Twaha Kabandika is pursuing MSc. Pharmaceutical Management at Muhimbili University of Health and Allied Sciences. As part of the requirement for his dissertation, he is undertaking a survey on paediatrics antibiotics availability and price .The criteria employed in this survey are in accordance with the methods promoted by the World Health Organization and Health Action International and endorsed by Muhimbili University of Health and Allied Sciences**.**

The aim of this study is to identify availability and price differences of paediatrics essential antibiotics in public and private sectors. This work should contribute to better knowledge about retail price differences in our areas and internationally. This exercise will take about 2 hours and we will ensure that timing of the visit is convenient for your staff. The finding of the survey will only be used for research purpose.

On behalf of Muhimbili University of Health and Allied Science, I would be grateful if you would provide full access to the information needed for this survey.

Enclosed please find data collection form and a copy of ethical clearance for this study.

I thank you for your continued support and cooperation.

Signed _____Date_____

Dr. Appolinary A. R. Kamuhabwa

Unit of Pharmacology & Therapeutics -

School of Pharmacy, MUHAS

ANNEX G: International reference prices

No.	Antibiotics name	International reference price
	Amoxicillin syrup 125mg/5ml	0.0048
	Amoxicillin + clavulanic acid (125+31.25mg/5ml) susp	0.015
	Cephalexin syrup 125mg/5ml	0.0276
	Azithromycin syrup 200mg/5ml	0.0567
	Chloromphenical syrup 125mg/5ml	0.0075
	Cloxacillin sodium syrup 125mg/5ml	0.0075
	Erythromycin syrp 125mg/5ml	0.012
	Metronidazole syrp 200mg/5ml	0.0053
	Phenoxymethyl penicillin (Pen-v) 125mg/5ml	0.0067
	Cotrimoxazole syrp 200mg+40mg/5ml	0.0042
	Ampicilin 500 mg inj.	0.1481
	Penicillin benzyl (3G pen G) 5MU	0.2340
	Ceftriaxone 250 mg Vial	0.39
	Chloromphenical 1gm vial	0.3614
	Ciprofloxacin 2mg/ml IV	0.0099
	Cloxacillin sodium 500 mg vial	0.1630
	Gentamycin inj. 40mg /ml	4.5040
	Metronidazole 5mg/ml Vial	0.0052
	Procaine penicillin fortified (4 MU)	0.1824
	Cotrimoxazole inj. (80+16 mg/ml)	0.2974
	Flucloxacillin	No mpr
	Penicillin benzathine (2.4 MU)	0.2457

No.	Antibiotics name	International reference price
	Zinc tab	0.0310
	Ors	0.0858