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AVAILABILITY AND AFFORDABILITY OF ESSENTIAL ANTIBIOTICS FOR PEDIATRICS IN SEMI-RURAL AREAS IN TANZANIA

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ABSTRACT: In this study, we assessed the availability, cost and affordability of essential antibiotics for paediatrics in a semi-rural region in Tanzania. Data were collected from 1 Medical Stores Department (MSD), 8 public hospitals, 30 Private Pharmacies and 30 Accredited Drug Dispensing Outlets (ADDO`s). The median price of tracer medicines and average stock-out days of per year were used to assess the cost and availability of medicines in the health facilities, respectively. The salary of the lowest paid unskilled government worker and national poverty line income were used to assess affordability of medicines. The median availability of the lowest-price generics of essential antibiotics for paediatrics in the pharmacies, ADDO's and public hospitals was 59.09%, 62.5%, and 45.5%, respectively. At MSD, only 13 out of the 22 antibiotics were in stock at the time of survey. The median stock out days was 124 days per year. The median price ratios (MPRs) of retail patient's prices for 20 generic antibiotics were 1.774 for 30 pharmacies, while for 8 generic antibiotics in 30 ADDO's, the median of MPRs were 2.0097. In most of private medicine outlets, prices of some essential antibiotics were not affordable for majority of the population. The results indicate the need to prioritize key essential antibiotics for children during selection and procurement in the health facilities. Moreover, ongoing efforts by the government to roll out health insurance coverage beyond the government employees should be sustained in order to improve accessibility of medicines to the majority of the population.

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 children under 5 years of age in resource limited settings could be treated if access to essential medicines is ensured.

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Tanzania is one of the developing countries with high rates of child morbidity and mortality. The country has performed poorly among others in millennium development goals (MDG 4&5) related to maternal and infant mortality. Currently, maternal mortality in Tanzania stands at 432/100,000, and the infant mortality rate stands at 81 per 1,000 live births which are still very high. An handicap to attainment of the national Vision 2025 and the current Five-Year Development Plan is the problem of recalcitrant infectious diseases, especially in children [2].

Due to overuse and misuse of antibiotics, polypharmacy and low availability of medicines, WHO issued guidelines that are to be implemented in each member country in order to enhance rational use of antibiotics. Also in recognizing that

better access to medicines is a prerequisite for improving health outcome in children, the WHO published the first model list of essential medicines (MLEMs) for children in 2007 [3]. In Tanzania, a separate list of essential medicines for children has not been published. However, the existing national list includes dosage forms and strengths of medicines for pediatrics [4]. Recent data indicate that less than half of the key pediatric essential medicines are available in countries of sub-Saharan Africa including Tanzania. Problems include the use of substandard medicines, irrational use of medicines and inefficiency in pharmaceutical management systems [5].

Development of a list of essential medicines for children may be useful at the health facility level for its use in selection, procurement, distribution and use of medicines. This in turn improves availability of medicines in the health facilities. However, after the release of the first MLEMs for children in October 2007, and the 3rd WHO MLEMs for children in March 2011 [6], there were no sufficient data on the availability and affordability of essential antibiotics for paediatrics in order to confirm its appropriateness for adaptation and use in Tanzania.

Increased bacterial resistance threatens therapeutic effectiveness of antibiotics. High level of antibiotic use is probably the main cause for the emergence of resistance. For instance, Streptococcus pneumoniae is the most significant cause of bacterial community-acquired pneumonia. This is also the leading cause of deaths among children under five years of age worldwide. In Tanzania, it has also been reported that pneumonia is the leading cause of neonatal mortality rate and accounts for about 28% of all causes of deaths [8]. In addition, a general recent survey conducted in Tanzania showed that some essential medicines were still more expensive and not affordable to communities [9, 10]. These results were too general and they showed that there is a need to conduct a survey based on therapeutic or age-specific group such as antibiotics for pediatrics in order to ascertain the magnitude of the problem for availability and affordability in the general population.

In Tanzania the last review of essential medicines was conducted in 2007 for the standard treatment guidelines and essential medicine list. A separate list of essential medicines for children has not been published and there are concerns that the existing list is not comprehensive enough for pediatrics use [4]. In addition, the feasibility and utilization of essential medicines for children in Tanzania are unclear and that there is information gap in the provision of healthcare services for children despite the high rate of infant and child mortality which are mainly caused by infectious diseases.

Data on price, availability and affordability of antibiotics for children 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 advocating for "make medicines child size" [4]. This campaign is designed to raise awareness and accelerate action to address the need for improved availability and access to safe child-specific medicines.

In this study, we assessed prices of antibiotics for paediatrics (originator brand and low price generics (LPGs)) and provided information on the availability and affordability of the selected medicines. It is expected that the findings of this study will form a basis for provision of optimal medicines for children, such as development of the list for key essential antibiotics for paediatrics. This will enable prioritization of these medicines during procurement and subsequent use in the health facilities.

Methodology:

Study area:

The study was conducted in a semi-rural region of Mbeya in Tanzania. Mbeya is one of the Tanzanian's 29 administrative regions. 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, Bungu, Sangu, Wanda and Sichela.

According to the 2012 Tanzania National Census, the population of the Mbeya region was 2,070,046 [11]. Mbeya region is administratively divided into 8 districts: Chunya, Mbarali, Mbozi, Rungwe, Kyela, Ileje, Mbeya Urban and Mbeya Rural.

The rationale for selecting Mbeya for this study was based on the results of the baseline survey for the pharmaceutical sector in Tanzania in 2002 which showed that among the three major cities i.e. Kilimanjaro, Mwanza and Dar es Salaam, the use of more than one antibiotics for treating mild and acute pneumonia was below 6%.

In this survey, Mbeya was the region with the highest percentage of antibiotics use of about 42% [12]. Also Mbeya was among the three regions in which the use of antibiotics for non-pneumonia acute respiratory infection was over 90%.

Health facilities in the study area:
Mbeya region is divided into eight districts and each district has 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, Iringa, Rukwa and Ruvuma regions. There are also a number of hospitals which are operated by private and religious organizations in the region. During the time of survey, the region had 30 private retail pharmacies, located within Mbeya city.

Selection of health facilities for the study:
The selected health facilities for this survey were all public hospitals in Mbeya region i.e. Mbeya referral hospital, Mbeya regional hospital; all the 6 public district hospitals (Mbozi, Chunya, Ileje, Kyela, Mbarali and Tukuyu); 30 Accredited Drug Dispensing Outlets (ADDO's); and all 30 registered retail private pharmacies in Mbeya region. Mbeya referral hospital is a tertiary healthcare facility for the southern Highland zone in Tanzania providing healthcare services the regions of Ruvuma, Rukwa, Iringa and Mbeya. Mbeya regional hospital on the other hand, offers similar services like those offered at district hospitals. However, it has specialists in various fields and it offers additional services which are not provided at the district hospital levels. District hospitals provide all medical services except conditions which require specialized care and are involved in planning, organizing and supervision of all healthcare activities in the district. A district hospital serves as a first referral level that is responsible for a district of a defined geographical area.

A list of registered medicines outlets was obtained from the Pharmacy Council in Tanzania. All thirty private retail pharmacies within Mbeya city were included in the study. Selection of the (rural facilities) ADDO's was based on their proximity to the public district health hospitals. Five ADDO's located in the close proximity of a public district hospital were included in the study [13]. Therefore, 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.

Methodological approach:
The study was conducted from February to June 2013. The methodology for this survey was based on guidelines provided by WHO/HAI medicine price methodology [13], and methodology of a survey used in the study conducted in the Colombo District, Sri Lanka as part of the children medicine survey (WHO/HQ) Study [14]. The survey also used the indicators that were adopted from Rational Pharmaceutical Management plus Program on how to investigate antimicrobial drug use in hospitals [15], WHO manuals [16], and assessment of prices of medicines [17].

List of surveyed medicines:
A list of essential antitibiotics for paediatric was selected from WHO essential medicines list (EMLc), National Essential Medicines List (NEML) and WHO priority medicines for mothers and children 18 (**Table 1**).

In total, there were 24 essential antibiotics for paediatrics in the referral hospital, 24 in the regional hospital, 22 in the district hospitals, 25 in the private pharmacies and 8 in the ADDO`s.

TABLE 1: LIST OF THE SELECTED ESSENTIAL ANTIBIOTICS FOR PAEDIATRICS 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	Chloramphenical	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	Phenoxy methyl penicillin,	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 vial	Yes	Yes	Yes	No	Yes
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	Chloramphenical	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	Powder for injection, 1g	No	Yes	No	No	Yes
29	Fucloxacillin	Injection 250mg	No	Yes	No	No	Yes

Data collection:

Data collection tools and study variables:

Data collection tools for assessment of the availability and cost of essential antibiotics for paediatrics included the list of antibiotics for paediatrics to assess the price and availability in the ADDO's; list of antibiotics for paediatrics to assess the price and availability in the private pharmacies; and list of antibiotics for paediatrics to assess the availability and time out of stocks in the public hospitals. The variables of the study on availability and cost of essential antibiotics for paediatrics were (i) availability of antibiotics in the given dosage form and strength: each survey medicine with the specific dosage form and strength WHO [6]; (ii) Availability of antibiotics in alternative dosage form and strength: if the survey medicine in the specific dosage form and strength as per WHO guidelines was not available, data on availability of alternative dosage form/strength were collected; (iii) Price of the lowest price generic (LPG0 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; and (iv) 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.

Assessment of the availability of essential antibiotics for paediatrics:

Percentage of medicine outlets which had the tracer medicines on the day of survey was calculated by dividing the number of medicine outlets that had stocks of the individual medicines during the day of survey to the total number of medicine outlets surveyed multiplied by 100. Calculation of average percentage availability was done by dividing the number of key antibiotics in stock during the day of survey by the number of key antibiotics that should have been available multiplied by 100. The overall availability of antibiotics in the facilities was reported as "the median percentage of stock availability of the medicines in the facilities on the day of data collection". The level of availability of essential antibiotics for paediatrics was then categorized as absent (medicines were not found in any of the health facility surveyed), Very low (<30%), Low (30–49%), Fairly high (50–80%), and High (>80%) [14].

Assessment of stock-out of essential antibiotics for paediatrics:

Duration of stock-out of antibiotics was calculated by back revision using records in the Bin card, stock card or ledger that indicated which medicines had records covering a period of at least 6 months within the previous 12 months. The equivalent number of stock-out days per year for each antibiotic 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 antibiotics in the facilities was reported as "the median stock-out days of antibiotics per year in the health facilities on the day of data collection".

Evaluation of prices of essential antibiotics for paediatrics in the health facilities:

Prices of generic equivalent and original brand were analyzed separately. The indicators used were; (i) Median price of each antibiotic in local currency, (ii) Median price of each antibiotic in United States Dollar (USD) (using exchange rate of 1 USD equivalent to 1,600 Tanzanian shillings (Tshs)), (iii) Median price in relation to international standard price (median price ratio (MPR)), (iv) Variation in price across pharmacies (25^{th}/75^{th} percentiles and maximum and minimum values). For the case of public hospital procurement price and National Health Insurance Fund (NHIF) patient prices, the unit prices were converted to MPR 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 for the year 2011/2012 [19]. This is because of the fixed prices for all medicines procured from MSD. Also NHIF price catalogue for March 2012 was used to record the patient price.

Assessment of the affordability of essential antibiotics for paediatrics by the general population:

A course of treatment that costs the equivalent of one days' salary of the lowest-paid government workers was generally considered affordable; treatments which cost more than this amount are classified as unaffordable (WHO/HAI) [13]. In this study, we selected two categories of income to assess affordability both for unskilled workers minimum wage (Tshs 4500 per day) [10], and people living below the poverty line (1.25 USD per day = Tshs 2,000 per day) [20]. Median medicine prices information in the pharmacies and ADDO`s were used to assess affordability.

Data management and analysis:

Collected data were entered into Ms Excel 2007 on daily basis followed by transformation into the Statistical Package for Social Sciences (SPSS, version 17) software for analysis. The frequency distribution minimum and maximum, median, 25^{th} and 75^{th} percentiles were used to show distribution outcome and explanatory of variables. Non-parametric 95% confidence intervals (CIs) were

calculated and compared for outcome values. Non-overlapping CIs were used to indicate differences in availability of antibiotics between public health facilities and private medicine outlets [17, 21]. One sample T–test was used to compare the median values in the average outcome of the results. Level of significance was considered at a p-value of less than 0.05 at the 95% confidence interval.

Ethical consideration:

Ethical clearance to conduct the study was granted by the Muhimbili University of Health and Allied Sciences Research and Publications Committee. Permission to conduct the study in the selected health facilities was granted by the hospitals` administration. In the case of pharmacies, permission to conduct the study in these premises was granted by the Pharmacy Council of Tanzania. Permission was also sought from the Distric Councils to conducted the study in the ADDO`s. Consent was sought from pharmacists and other drug dispensers in the health facilities. In order to ensure confidentiality, no names of the study participants were recorded in the questionnaires. Data were entered into the computer for analysis using only study code numbers.

RESULTS:

Availability of essential antibiotics for paediatrics in the health facilities:

In the public hospitals the median percentage availability of 22 essential antibiotics for paediatrics in the NEML was 45.5% (ranging from 36.36% to 63.64%); while for a total of 25 antibiotics for paediatrics the availability was only 42%. Injectables such as ciprofloxacin, co-trimoxazole, clindamycin and kanamycin were only available at Mbeya referral hospital. In the public hospitals, availability of antibiotics ranged between 30% and 80% **(Table 2)**. MSD was the only supplier of medicines to the public hospitals. Availability of the essential antibiotics for paediatrics at the MSD was only 59.1% during the time of survey.

In the private pharmacies and ADDO`s, the median percentage availability of 22 essential antibiotics for children in the NEML was 54.54% (ranging from 13.63% to 81.81%); while for a total of 25 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 2)**. There was no statistical significant differences (p = 0.628) with respect to the availability of essential antibiotics in the private pharmacies **(Table 3)**.

TABLE 2: AVAILABILITY OF ESSENTIAL ANTIBIOTICS FOR PAEDIATRICS IN THE PUBLIC HOSPITALS AND PRIVATE MEDICINE OUTLETS

Category of health facility	Level of availability	Number	Percentage
Public hospitals (n=8)	<30% (Very low)	0	0
	30%–49% (Low)	5	62.5
	50%-80% (Fairly high)	3	37.5
	>80% (High)	0	0
Private pharmacies (n=30)	<30% (Very low)	1	3.3
	30%–49% (Low)	11	36.7
	50%-80% (Fairly high)	17	56.7
	>80% (High)	1	3.3
ADDO`s (n=30)	<30% (Very low)	4	13.3
	30%–49% (Low)	1	3.33
	50%-80% (Fairly high)	21	70
	>80% (High)	4	13.3

In the ADDO's the median availability of 8 essential antibiotics was only 62.5% (ranging from 0% to 100%); while the availability of the 10 common antibiotics was 70%. However, four ADDO's (13%) had less than 30% availability of essential antibiotics **(Table 2)**. There were no statistical significant differences (p = 0.056) with respect to the availability of essential antibiotics in the ADDO's **(Table 3)**.

TABLE 3: SUMMARY OF THE AVAILABILITY OF ESSENTIAL ANTIBIOTICS FOR PAEDIATRICS IN THE PUBLIC HOSPITALS AND PRIVATE MEDICINE OUTLETS

Type of health facility	% Availability (minimum/maximum)	% Median availability	Availability Interquartile range (25%, 75%)	Availability (95% CI)	P-value
Hospitals (22 LPGs) (n=8)	36.36/63.64	45.45	(42.04, 50)	(40.9–50)	N/A
Pharmacy (22 LPGs) (n=30)	13.63/81.81	59.09	(40.9, 63.63)	(45–64)	0.628
ADDO's (8 LPGs) (n=30)	0/100	62.5	(50, 75)	(50–62.5)	0.056
MSD (22 LPGs)	N/A	59.09	N/A	N/A	N/A

N/A = Not Applicable; LPGs = Lowest Price Generics

With regard to the availability of individual antibiotics, ciprofloxacin injection, metronidazole intravenous infusion, flucloxacilin and chloramphenical syrups were available in less than 30% of the pharmacies, ADDO's, and public hospitals. The availability of 6 generic antibiotics in the public hospitals, 7 generic antibiotics in pharmacies and 4 generic antibiotics in the ADDO's was more than 80%. Some essential generic antibiotics such as ceftazidime injection, chloramphenical oily suspension injection and flucloxacillin injection were absent in all the health facilities during the time of survey.

Assessment of the availability of essential antibiotics for paediatric in alternative dosage forms and strengths showed that three different generics of amoxicillin-clavulanic acid suspension such as Co-amoxy Mepha, Clavam-BD, and Augmentin were available in 7 out of 30 pharmacies. These medicines were sold at the highest prices ranging from Tshs 8,000 to 35,000 per dose.

Stock-out days of essential antibiotics for paediatrics in the public hospitals:

The median stock-out days per year in the public hospitals was 124 days (ranging from 77.52 to 190) for the selected 15 essential generic antibiotics **(Fig. 1)**. 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). However, some hospitals did not have proper records to enable calculation of stock-outs days of medicines for at least the past six months.

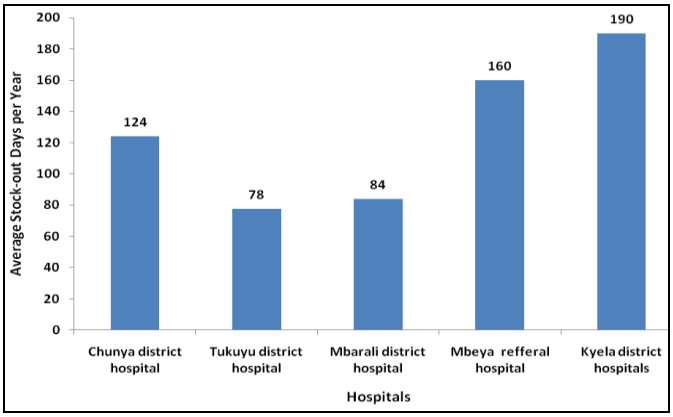

FIG.1: VARIATION OF STOCK-OUT DAYS OF ANTIBIOTICS FOR PAEDIATRICS PER YEAR IN THE PUBLIC HOSPITALS IN MBEYA REGION

Price of the antibiotics for paediatrics in the private retail medicine outlets:

Prices of antibiotics for paediatrics in the private retail 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 original brands of amoxycillin syrup, amoxycillin-clavulanic acid syrup, and co-trimoxazole injection were present in the pharmacies. This shows that most of the originator brands were not available in most of the health facilities in Mbeya region **(Table 4)**. In the pharmacies, the median MPR of 22 LPGs was 1.7525 times the international reference prices (ranging from 0.6793 to 3.8344). The median MPR of 3 innovator brands was 10.9028 times international reference prices (ranging from 5.4688 to 14.2905). All MPRs of original brands were higher than LPGs in the pharmacies. Higher MPRs above the warning line (>2) were noted for 8 antibiotics out of 22 LPGs. Cephalexin syrup and ciprofloxacin injection had MPR of less than one. MPR was not calculated for zinc sulphate solution since its international reference price was not available.

Prices of essential antibiotics 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 were found in ADDO's. High MPRs above the warning line (>2) were observed for seven out of ten antibiotics. None of the medicines had MPR of less than one **(Table 4)**.

TABLE 4: MEDIAN PRICE RATIO (MPR) FOR EACH ANTIBIOTIC FOR PAEDIATRICS IN THE ADDO'S IN MBEYA REGION

No.	Names of Medicines	MPRs
1.	Amoxicillin syrup 125mg/5ml	2.0833
2.	Erythromycin syrup 125mg/5ml	1.0417
3.	Metronidazole syrup 200mg/5ml	1.7689
4.	Phenoxymethyl penicililin syrup 125mg/5ml	1.3993
5.	Co-trimoxazole syrup 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

Comparison of retail patient prices between ADDOs and private pharmacies showed that MPRs were 2.0497 and 1.6493 for ADDOs and Pharmacies, respectively for the 10 commonly used medicines. The highest price above the warning line was seen for 2 out of 10 medicines in the pharmacies. However, in the ADDOs, 8 out of 10 medicines had higher MPRs above the warning line. Overall, the results show that in the ADDOs patient prices were slightly higher (24.3%) than in the pharmacies, but the differences in prices were not statistically significant **(Table 5)**.

TABLE 5: THE DIFFERENCE IN PRICES BETWEEN MEDICINES IN THE ADDO'S AND PHARMACIES

Names of Medicines	MPRs for LPGs in the ADDOs	MPRs for LPGs in the Pharmacies	Ratio for MPRs for LPGs between ADDOs and Pharmacies
Amoxicillin syrup 125mg/5ml	2.0833	1.7361	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	1.3993	1.3526	1.03
Co-trimoxazole syrup 200mg+40mg/5ml	2.2321	2.1577	1.03
Penicillin benzyl (3G pen G) 5 MU	2.6709	1.9981	1.34
Metronidazole 5mg/ml Vial	2.3138	1.5625	1.48
Procaine penicillin fortified (4 MU)	2.0032	1.326	1.51
Tablet Zinc sulphate	2.0161	1.2097	1.67
Oral rehydration salt	2.1853	2.1853	1.00
Median MPRs	2.0497	1.6493	1.24
P-value	0.610	0.906	

LPGs = Lowest Price Generics

Availability and prices of essential antibiotics for paediatrics in the retail private medicine outlets:

Generic antibiotics located in the 4th quadrant had good accessibility **(Fig.2)**. For example, amoxycillin and cephalexin syrups had availability of 100% and 83.33%, and at prices of below the warning line (<2) of 1.7361 and 0.6793, respectively. On the other hand, generic antibiotics located in the 1st quadrant had poor accessibility to majority of the people. For example, amoxycillin-clavulanic acid was available in only 40% of the pharmacies and was sold at a price of 2.5 times higher than the international reference prices. 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 **(Fig. 3)**.

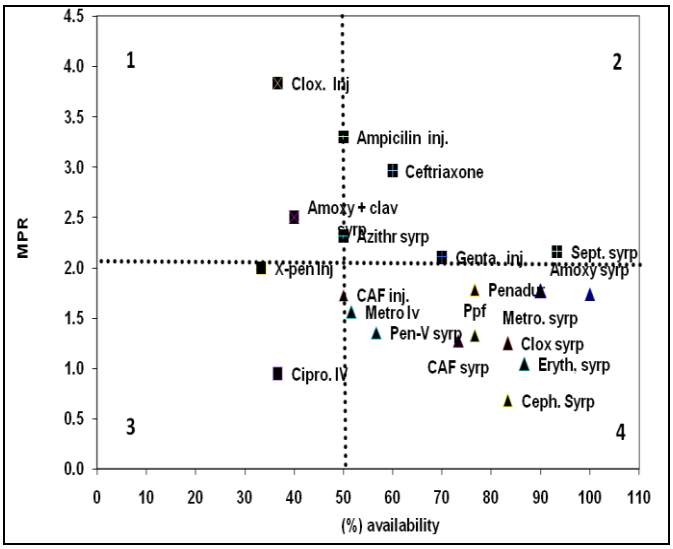

FIG.2: AVAILABILITY AND RETAIL PRICES OF ESSENTIAL ANTIBIOTICS FOR PAEDIATRICS IN THE RETAIL PRIVATE PHARMACIES

Note: From figure 2: **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 2: 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.

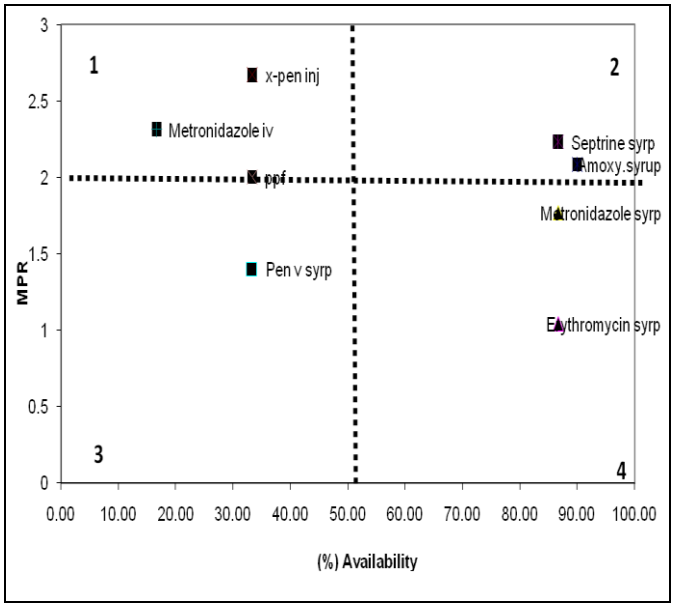

FIG. 3: AVAILABILITY AND RETAIL PRICES OF ESSENTIAL ANTIBIOTICS FOR PAEDIATRICS IN THE ADDO'S

Note: From 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; Pen V = Phenoxymethyl penicillin, syrp = Syrup, x-pen – benzyl penicillin, Inj = Injection, IV = Intravenous, ppf = Penicillin procaine fortified.

Comparison of the public hospitals procurement prices, retail private pharmacies and ADDO`s patient prices and NHIF patient prices for medicines in the health facilities showed that public hospitals procurement prices 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. NHIF patient prices for the lowest price of generic drugs were more (177.74%) than those in the public hospital procurement prices **(Table 6)**. The NHIF patient prices were slightly higher compared to patient prices in the ADDO's and retail pharmacies for the medicines. This shows that private medicine outlets will still make reasonable profits by providing services to NHIF beneficiaries who may have missed the drugs in the public hospitals. In addition, the availability of essential antibiotics was slightly higher (80%) in the retail pharmacies compared to ADDO's (70%). However, the differences in availability of essential antibiotics between ADDO's and retail pharmacies were not statistically significant (**Table 6).**

TABLE 6: SUMMARY OF THE MEDIAN AVAILABILITY AND MPRS FOR PATIENT PRICES IN THE PUBLIC HOSPITALS, ADDO'S, RETAIL PRIVATE PHARMACIES AND NHIF

Category	Pharmacies	ADDO's	NHIF patient prices	Public hospital procurement prices
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
(25th, 75th) percentile	(70%, 90%)	(50%, 80%)	N/A	N/A
Minimum/Maximum	30%/100%	3.3%/100%	N/A	N/A
Median Price Ratios (MPRs)				
Median MPRs (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 to 0.8547)
(25th,75th) 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

NA = Not Applicable

Affordability of essential antibiotics for paediatrics:

There was a considerable cost variation for essential antibiotics which are used for treatment of different infectious diseases in children. The salary of unskilled government worker (who earns Tshs 4500 per day) and the National Poverty Line Income (who earns less than 1.25 USD per day, equivalent to Tshs 2,000 per day) were used to assess affordability of medicines. The five scenario conditions of a child infected with pneumonia, urinary tract infection, Shigellosis, severe pneumonia and bacterial meningitis were used for analysis of affordability. Affordability of innovator brands was not a major concern in this study because their availability was more limited and the costs of these medicines were unaffordable for majority of the population. Overall, the cost of standard treatment regime for these bacterial infections was 2.03 days wages (ranging from 0.63

to 22) for people living below the poverty line, and 0.9 days wages (ranging from 0.3 to 9.8) for the lowest paid government worker (n = 15 treatment options). The differences on affordability for the 15 treatment options between unskilled workers and people living below poverty line were not statistically significant. With regard to urinary tract infection, the results show that unskilled worker can afford the whole dosage regime treatment for both cephalexin and co-trimoxazole syrups. However, for people living below the poverty line, expenditure on the whole dosage regime for cephalexin syrup is unaffordable.

For both the lowest paid government worker and people living below the poverty line, expenditure on most of the treatment options for pneumonia was less than one day's income except for generics and original brand of amoxycillin-clavulanic acid suspension. There was 11.9 times day's wages difference for treatment of pneumonia with original brand of amoxycillin-clavulanic acid suspension and generic co-trimoxazole for people living below the poverty line. On the other hand, for people living below the poverty line, expenditure on only one treatment option condition with co-trimoxazole was less than one day's income out of six treatment options for diarrhea and non-diarrhea conditions of shigellosis. In addition, expenditure by the lowest paid government worker on most of the treatment options for shigellosis was less than one day's income, except for ceftriaxone injection.

For people living below the poverty line and unskilled worker, the expenditure on treatment options with most of generic antibiotics would need more than one day's wages for treatment of bacterial meningitis. Moreover, people living below the poverty line are unlikely to afford a one-day treatment cost for generic antibiotics used as first and second line options for treatment of bacterial meningitis. 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. However, people living below the poverty line are likely to afford only one day treatment cost for the first line antibiotics used in the treatment of severe pneumonia. In general, the lowest paid government worker can afford one day treatment cost for most of treatment options in bacterial meningitis and severe pneumonia except for ceftriaxone, which is the second line antibiotic for treatment of bacterial meningitis in Tanzania.

DISCUSSION: Children are more prone to infectious diseases including, pneumonia and diarrhea which are leading causes of death, especially in children under the five years of age [22]. 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. In this study, we assessed the availability and prices of antibiotics for children and their impact on accessibility in a semi-rural region in Tanzania. Therefore, the findings of this study provide baseline data for developing interventions in order to improve accessibility of essential medicines for children in resource-limited settings.

Across all the surveyed public hospitals, none of the innovator brands of the studied antibiotics were 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 45.45% in Mbeya region, which is relatively lower compared to 52% which was reported in a similar study that was conducted in Sri Lanka [14]. However, the results of the present study are comparable to the availability of 45.3% and 43% that were reported in the previous studies that were conducted in other regions of Tanzania [10] and church-owned health facilities in Uganda [23], respectively.

Poor availability of essential antibiotics in this study may be due to the fact that some of these medicines were not included in the NEML and MSD catalogue of prices. Financial constraints facing the government and public hospitals, and inefficient pharmaceutical management in the health facilities are other factors likely to affect availability of medicines in these facilities. In Tanzania, essential medicines in the public health facilities are provided for free or at a subsidized

cost. However, due to unavailability and frequent stock-outs of essential medicines in the public health facilities, patients are required to purchase these medicines from private medicine outlets, which are expensive and in most cases unaffordable to the majority of the population [24, 25]. Under these circumstances, it is most likely that children are not appropriately treated, leading to increased bacterial resistance to the antibiotics [26].

The results show that availability of essential antibiotics for paediatrics was 59% at MSD which is the only supplier of medicines for the public health facilities. This is figure is slightly higher than the overall mean 54% availability of medicines that was previously reported in Tanzania [10]. In addition, the study shows that some antibiotics from the NEML that should be available at MSD were out of stock during the day of survey. The low availability of essential antibiotics at MSD is a major concern for management of bacterial infections in children in the public health facilities.

In order to address the shortage of essential medicines for paediatrics including antibiotics, there is a need to have a separate and comprehensive National Essential Medicine List for Children (NEMLc). The NEMLc will be a guide for MSD and other suppliers of medicines for prioritization of these medicines during procurement and subsequent use in the public health facilities.

Availability of generic antibiotics for children was much higher in the private medicine outlets than in the public hospitals. In the private medicine outlets, the availability of essential antibiotics was fairly high (59%). This figure is slightly higher compared to the results (34.4%) of a recent study that was conducted in several regions of Tanzania [10]. However, this figure is much lower compared to the figure of 80% that was reported in a study conducted in Sri Lanka [14]. Low availability of essential antibiotics for paediatrics in the private medicine outlets in this study may be due to low priorities of essential medicines for children or lack of awareness regarding the existing paediatric dosage forms in the market. In Tanzania, ADDO`s were established in 2000 to increase accessibility of essential medicines, especially in the rural areas with limited number of pharmacies [27]. In this study, retail prices of ten commonly used generic antibiotics for children were generally higher in the ADDOs than in the retail private pharmacies. This is in contrast to the purpose for which ADDOs were established for. In the pharmacies, the median medicine prices for 20 LPGs were found to be 1.774 times the international reference prices. The prices of medicines in the private pharmacies in this study are slightly higher compared to those reported in Oidisha, India [28] and Sri Lanka [14]; but much lower compared to those reported in a study conducted in Ghana [29].

In this study, 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 [14], India [28] and Ghana [29]. Moreover, alternative strengths or pack sizes of some essential antibiotics such as amoxicillin-clavulanic were sold at the highest prices. On the other hand, cephalexin and cloxacillin syrups were readily available in the private medicine outlets and at the prices the majority of people could afford. However, these drugs were not listed in the MSD catalogue. In addition, cephalexin syrup was not included in the NEML. As a result, these medicines were not available in the public health facilities. There is therefore a need for the Ministry of Health and Welfare to update the list of essential medicines to include formulations and strengthens of antibiotics for children. This will also enable MSD to update its catalogue for procurement and supply of essential medicines to the public health facilities in the country.

The median stock-out days 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 of them had proper records to allow quantification of stock-out days. In the public health facilities, frequent stock-out of medicines could mean an insufficient supply to meet high demand, or low

priority of medicines for children especially antibiotics [30].

In our previous study conducted in Tanzania we reported problems for pharmaceutical management in the health facilities [25, 31]. The major problem in pharmaceutical management is lack of knowledge among pharmaceutical personnel with respect to forecasting, ordering and storage of medicines. It these studies, it was found that poor pharmaceutical management led to frequent stock-out of drugs, expiry due to over stocking, or poor storage conditions in the health facilities. The results of this study therefore highlight the need for proper management of pharmaceuticals in the health facilities in order to enhance rational use of medicines.

If medicines are not available in the public health facilities, patients will have to purchase them from private medicine outlets such as retail pharmacies and ADDO`s [32]. In Tanzania, only about 20% of the population has medical insurance coverage. Majority of people with medical insurance are those who are employed in the formal sectors [33]. As a result, majority of the population would usually purchase medicines from private medicine outlets using their own money [24]. The results of this study show that, if public hospitals would procure medicines from MSD and sell them to patients with health insurance coverage, about 177% markup (profit) would be made by these facilities. In addition, NHIF patient price was generally higher than retail patient prices in the private medicine outlets. These findings indicate that private medicine outlets are also benefiting through provision of medicines services to NHIF beneficiaries. It is therefore necessary to expand medical insurance coverage beyond government employees in order to improve access to essential medicines in the country. 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 [34].

The study shows existence of various cost differences for antibacterial agents used as treatment options for infectious diseases in children. 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 options 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 neonatal mortality and accounts for about 28% of all causes of deaths [12]. Medicines which are used to treat severe pneumonia seem to be not affordable as shown in this study. In this study, treatment options with essential medicines such amoycillin-clavulanic acid were mostly unavailable in the public hospitals during the time of the study, and were clearly not affordable in the private pharmacies.

The study shows that unskilled government workers require 0.3 days to purchase a full course of co-trimoxazole for treatment of respiratory tract infection. These findings are similar to those reported in a survey which was conducted in other regions in Tanzania [10], Ghana [29] and Srilanka [14]. A recent study which was conducted in Tanzania indicated that co-trimoxazole which is being used for treatment of shigella infection shows high rate of resistance to a number of bacteria [26]. Due to increased resistance of bacteria to co-trimoxazole, ceftriaxone and azithromycin are recommended for treatment of shigella infection [35].

However, the findings from this study show that people living below the poverty line cannot afford azithromycin syrup and ceftriaxone for shigella infection in children. In addition, azithromycin syrup is not listed in NEML and MSD catalogue. Unaffordability of these key antibiotics among the general population implies that children are not properly treated with potential for increased resistant bacterial strains against the commonly used antibiotics. This contributes to the high morbidity and mortality rates in children as a result of treatment failure for infectious diseases.

CONCLUSION: The present study has shown that availability of essential antibiotics for paediatrics is very low in the public hospitals. Due to unavailability of essential medicines in the public health facilities, patients would be obliged to buy

these medicines from private medicine outlets. However, for people with low income such as those living below poverty line, most of the essential antibiotics from private medicine outlets are unaffordable. It is therefore necessary that key essential antibiotics for children be given priority during selection and procurement when the budget is limited. Medicines pricing policies should be instituted in order to control excessive pricing of for originator brands and LPGs such as amoxycillin-clavulanic acid. Due to high cost of medicines in the private medicine outlets, ongoing efforts by the government to roll out health insurance coverage beyond the government employees should be sustained in order to improve accessibility of medicines to the majority of population.

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