Implementation of Artemisinin based Combination Therapy Policy in Treatment of Uncomplicated Malaria in Private Medicines Outlets: Practice of Medicines Dispenser's in Mwanza Region, Tanzania

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ABSTRACT

Introduction: A combination of Artemether-lumefantrine (ALu) is recommended by Tanzania MoHSW as first line therapy for uncomplicated malaria while Sulphadoxine–pyrimethamine (SP) is recommended only for intermittent preventive treatment during pregnancy (IPTp). Despite the change of the policy, SP is still being dispensed by private medicine outlets for treatment of uncomplicated malaria. Assessing dispensing practice of medicines dispenser's is therefore crucial.

Materials and Methods: The study was a descriptive cross-sectional study; simulated clients were used to capture quantitative data while qualitative data were captured using focus group discussion. The study population was private medicine outlets i.e Pharmacies and Accredited Drug Dispensing Outlets (ADDOs) located in Nyamagana and Sengerema District. For quantitative data the whole study had 65 outlets which constituted of 33 ADDOs and 32 Pharmacies while for qualitative data the study constituted 20 dispensers. The coded quantitative data were analyzed using Statistical Package for Social Sciences (Version 20.0) computer analysis software. Practice of dispensers was analyzed using cross-tabulation, chi-square and Fisher's exact test. Qualitative data were manually analyzed using content analysis.

Results: During malaria patient simulation 9.7 % of outlets dispensed ALU to simulated client while 85.5% dispensed SP. Results show that 90.6% of Pharmacies and 80% of ADDOs dispensed SP to simulated client even though SP is reserved for IPTp.

Conclusion: The study concluded that SP is still dispensed for uncomplicated malaria treatment rather than being reserved for IPTp where patient demand for a single dose medicine is one of driving factor for irrational dispensing and use of SP.

Keywords: ACT Policy, ALU, Dispensing practice, Private medicine outlets, SP, Mwanza.

INTRODUCTION

Malaria is a life-threatening blood disease caused by a parasite that is transmitted to humans by the *Anopheles* mosquito. Malaria is one of the leading causes of death in children under five years of age and accounts for up to 40% of outpatient visits in Tanzania.[1] A household survey in three regions in Tanzania, found that of those who sought care for fever in the prior 14 days, 41% sought care at a pharmacy and drug shop, whereas only 19% went to a government health facility.[2] A review of studies from some countries found that around half of caregivers initially sought medicines for the treatment of common childhood illnesses from private drug sellers.[3]

In the year 2005 Tanzania changed its malaria treatment policy for uncomplicated malaria from (SP) to artemisinin-based combination therapy (ACT) – specifically artemether-lumefantrine (ALU).[4] SP remains the medicine of choice for IPTp. It is particularly important that medicines used in pregnancy are known to be safe.[5]

The study done by Menendez in 2010 revealed that, there was reductions in neonatal mortality by up to 61.3% have been reported following IPTp administration.[6] The study done by Ramharter in Gabon revealed that; after introduction of IPTp, there was a marked benefit on the prevalence of low birth weight and premature birth for women adhering to national recommendations.[7]

Adherence to ACT policy is important in ensuring malaria treatment efficacy, as well as to reduce the likelihood of malaria parasite resistance to ACT.[8] In order to preserve SP efficacy for IPTp, all possible efforts should be made to avoid SP use for the treatment of clinical cases of malaria.[9] Therefore this study intended to examine practices of private medicines outlets in dispensing of ALU for treatment of uncomplicated malaria and to identify the extent at which

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SP is dispensed in treatment of uncomplicated malaria. The study involved over the counter malaria treatment only and not prescriptions.

MATERIAL AND METHODS

Study area and population

This study was a descriptive cross sectional study design which intended to capture qualitative and quantitative data; it was conducted in Mwanza region, which was conveniently selected as study site because it is highly populated and has high prevalence of malaria. The study population was medicine outlets i.e Private Pharmacies and ADDOs located in Nyamagana and Sengerema District. This study was conducted between October 2014 and May 2015**.**

Sample size and Sampling technique

For quantitative data the whole study had 65 medicines outlets which constituted of 33 ADDOs and 32 Pharmacies. The sample size was calculated using formula for calculating sample size for single proportion of the finite population.[10] For qualitative data the study constituted 20 dispensers. There are 45 pharmacies and 19 ADDOs in Nyamagana district while Sengerema has 2 pharmacies and 31 ADDOs. Therefore sampling unit constitutes of 47 Pharmacies and 50 ADDOs. That makes the total of 97 medicine outlets.

The selection of medicine outlets was based on random sampling process. One dispenser was involved per outlet. Purposive sampling was employed on the focus group discussion.

Data collection

The principal researcher collected qualitative data using focus group discussion while quantitative data were collected by two simulated clients as research assistants. The focus group discussion was conducted in four sessions of five participants in each group.

The simulated client form was used by two simulated clients who acted as if they had symptoms of uncomplicated malaria and seek over the counter treatment. The form was used to record medicines advised by dispensers and medicines which were dispensed after client demand for SP. Ethical clearance was sought from the Ethical Review Committee of Muhimbili University of Health and Allied Sciences (MUHAS). To protect dispensers' privacy, no names of staffs were recorded and names of outlets are not mentioned in connection with the study's results.

STATISTICAL ANALYSIS

All the collected data were counter-checked for their reliability and validity. The coded data were analyzed using Statistical Package for Social Sciences (Version 20.0) computer analysis software. A *P*-value of less than 0.05 was considered as statistically significance, at 95% confidence interval.

For qualitative data; information obtained was transcribed and translated immediately to obtain meaningful information. The analysis was done manually using a content analysis approach.

RESULTS

Results from simulated clients

Out of 65 medicines outlets, only 62 (95.4%) outlets participated in simulation, which involved 32 pharmacies and 30 ADDOs. Three ADDOs did not agree to dispense anti malarial without laboratory test results. After simulated clients explained their malaria symptoms, dispensers advised various antimalarials ; results revealed that most of dispensers of private medicine outlets; 40.3% advised the use of ALU and few of them; 5% only advised the use of sulfamethoxypyrazine/pyrimethamine (SPP), (Figure 1).

Results showed that there is relationship between type of the medicine outlet and the antimalarial advised by the dispenser, ($\chi 2$= 11.544; *P* value =0.003). Most of ADDO dispenser's i,e 56.7% advised the use of ALU while most of pharmacy dispenser's i.e 30.7% of dispenser's advised the use of Dihydroartemisinin Piperaquine (DPQ), (Figure 2).

Out of all 62 outlets; 11 outlets advised simulated clients to use SP while other 51 outlets advised simulated clients' medicine other than SP. Thus simulated clients requested those 51 outlets to give them SP since it is single dose medicine, some dispensers agreed while others disagreed. Results

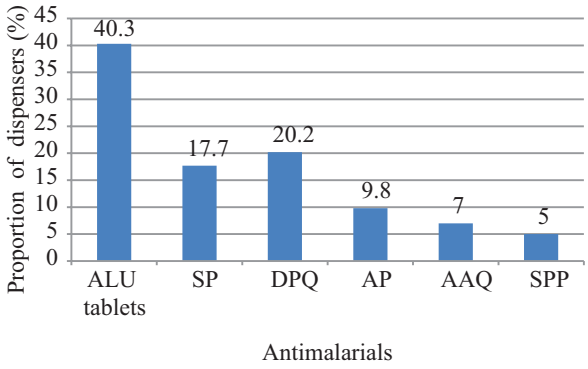

Figure-1: Medicines advised by dispensers to simulated clients in all medicine outlets (n=62)

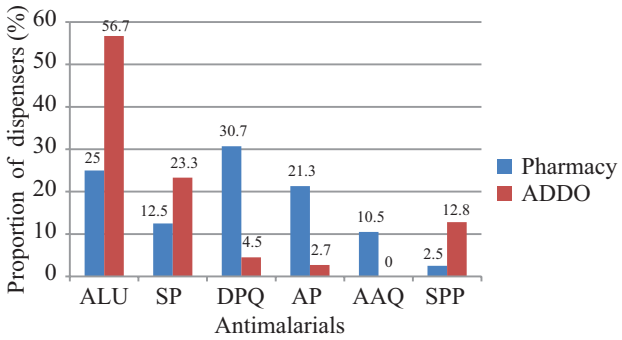

Figure-2: Medicines advised by dispensers to simulated clients, in Pharmacies (n=32), ADDOs (n=30)

Type of outlet	Dispenser's responses		Total
	Agree	Disagree	
Pharmacy	25(89.3%)	3(10.7%)	28(100%)
ADDO	18(78.3%)	5(21.7%)	23(100%)
Total	43(84.3%)	8(15.7%)	51(100%)

Table-1: Dispenser's responses after simulated clients demand for SP (n=51)

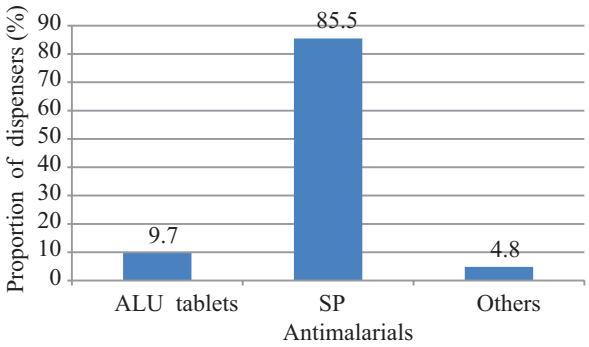

Figure-3: Medicines dispensed to simulated clients in all medicine outlets (n=62)

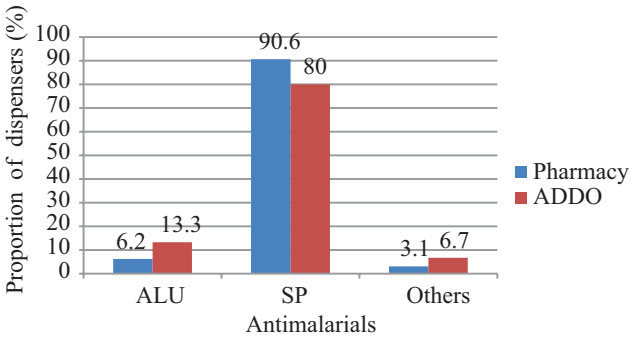

Figure-4: Medicines dispensed to simulated clients, in Pharmacies (n=32), ADDOs (30)

showed that after simulated clients demanded for SP in 51 outlets which initially advised other antimalarials; only 8 outlets (15.7%), (Table 1) disagreed to dispense it, reasons being SP was out of stock or it is reserved for IPTp. There is no relation between type of medicine outlet and dispenser's response, *P* Value =0.44.

Following dispenser's advice and simulated client's demand for SP, various antimalarials were finally dispensed; Study revealed that only 9.7 % of medicine dispenser's, dispensed ALU to simulated client. Most of medicine dispenser's i.e 85.5% dispensed SP while only 4.8% advised the use of other medicines which were DPQ, SPP and Artemisinin/ Piperaquine (AP), (Figure 3).

Results show that, most medicine dispensers from both Pharmacies and ADDOs i.e 90.6% of pharmacies and 80% of ADDOs dispensed SP to simulated client even though SP is reserved for IPTp. There is the no relationship between type of the medicine outlet and the medicine dispensed to simulated clients. *P* value= 0.47, (Figure 4).

Simulated clients reported price of medicines, revealed that SP and SPP were cheapest medicine with price ranging from Tsh1000/= to 1500/=, ALU and Artesunate/ Amodiaquine (AAQ) tablets ranged from Tsh2500/= to 3000/= while DPQ and AP were ranging between Tsh10, 000/= to 12,000/=.

Results from focus group discussion

On general overview in private medicine outlets, SP is mainly dispensed for treatment of uncomplicated malaria than IPTp. When medicines dispenser's asked, why they still dispense SP for the treatment of uncomplicated malaria even though it is prohibited, they had various responses such as; lack of knowledge to dispensers, inadequate training, lack of awareness to the community that SP is reserved for IPTp only, low cost of SP compared to ALU and other available antimalarial, patient demand for single dose medicine, complicated dosing schedule of ALU and clients belief that they can only be treated by SP. One of them said:

"*We dispense SP for treatment of malaria due to various reasons such as; poor adherence to ALU as it has a lot of tablets; ALU has high cost and is more needful e.g patients have to eat fat food before taking ALU. If the patient has only 1000tsh you can't give him/her ALU which is more than 2000Tsh."(*Participant 9)-Pharmacy.

Private medicine outlets face the following challenges when they advise clients to use ALU for those who ask for over the counter treatment of uncomplicated malaria: (1) Some clients complains that ALU has high price, many tablets and complicated dosing schedule so they need single dose medicine. (2) There are clients who believe they can be treated with SP only, for them there is no other medicine which is better than SP. (3) Other clients says that ALU always fails to treat them, others says it gives them they get side effects once they use it. (4) Some clients believe ALU has low quality/ substandard as there are lot brands of ALU, they believe ALU with leaf symbol is the best than those which are currently available.

One of respondents said*: "there are clients who believe they can be treated with SP only, for them there is no other medicine which is better than SP. There are clients who create habit of using sp for treatment of uncomplicated malaria, they say when they take SP it takes them only one day to be cured".* (Respondent 2)- Pharmacy.

Another respondent said; *"Most of our clients do not prefer to use ALU because of its high price, they can't afford to buy one dose of ALU for Tsh2500/= -3000/=, some adult clients request to buy half course or even 4 tablets only".* (Respondent 7)- ADDO

When asked which anti malarial medicine they prefer to dispense to the client for the over the counter treatment of malaria all of them said ALU. However SP is mainly dispensed for treatment of uncomplicated malaria than IPTp. Reasons given for the SP to be still dispensed by private facilities for the treatment of uncomplicated malaria even though it is prohibited, included; SP still treat some patients, failure of ALU, clients like to use medicine which are used to, single dose and few number of tablets, SP is cheap compared to ALU,

poor adherence to ALU**,** patient choice, lack of awareness to the community that SP is reserved for IPTp only. One of respondents said:

"*Clients complain are not treated by ALU but treated by SP; also many clients prefer medicine with few tablets*." (Participant 10) –ADDO.

Another respondent said*; "I prefer to advise my clients to use ALU and if client don't prefer ALU because it have many tablets, I will give him/her medicine of his/her choice."* (Participant 8)-Pharmacy.

DISCUSSION

Private medicines outlets are important source for treatment of uncomplicated malaria, including dispensing of antimalarials for self medication. ALU is the recommended first line antimalarial for treatment of uncomplicated malaria while SP is reserved for IPTp. Intermittent preventive treatment has recently been shown to be highly cost-effective for both prevention of maternal malaria and reduction of neonatal mortality in areas with moderate or high malaria transmission.[11] Despite the spread of SP resistance, IPTp continues to provide significant benefit, resulting in protection against both neonatal mortality (protective efficacy 18%) and low birth weight reduction by 21% under routine program conditions.[12]

In this study, proportion of dispensers in medicine outlets who dispense ALU, SP and other antimalarials for over the counter treatment of malaria were determined. Study results show that about 40% of all medicine outlets advised simulated clients to use ALU, but after simulated clients requested for SP since it is a single dose medicine, more than 80% of those who initially didn't advice on the use of SP agreed to dispense it. This entails that, without client pressure almost forty percent of private medicine outlets dispensers would dispense ALU to clients who seek over the counter treatment of malaria. All participants appeared in focus group discussion, know that ALU is the first line medicine for treatment of uncomplicated malaria, but only less than 10% dispensed it to simulated clients while about 85% dispensed SP. Difference in proportion between advised medicines and dispensed medicines were due to patient demand. However the percentage of anti malarial dispensed could have been different if availability of both ALU and SP could be 100%. In focus group discussion it was reported that dispensers grant the request of their customers; they reported client's choice as the factor of dispensing SP instead of ALU. There is relationship between type of the medicine outlet and anti malarial advised by dispensers. There is high chance for the patients to use ALU when she/he visit ADDO for self medication compared to when she/he go to the pharmacy. As it was revealed from this study, 56.7% of dispensers in ADDOs advised the use of ALU while almost 60% of dispensers in Pharmacies advised other antimalarials which were DPQ, AP, Artesunate/ Amodiaquine (AAQ) and SPP. High availability of other medicines with high price in Pharmacies than ADDOs is one of the contributing factors for the difference observed. However, there is no relationship between the type of the medicine outlet and antimalarial dispensed by dispensers with $P>0.05$, which indicate that both dispensers in Pharmacies and ADDOs are driven by patient demand which lead to irrational dispensing, this is supported by focus group discussion were dispensers from both pharmacies and ADDOs mentioned patient demand as factor for irrational dispensing. Other similar studies indicate similar results, e.g a study done in Kenya by Rusk in 2012 to determine if antimalarial drug knowledge predict antimalarial dispensing practice in drug outlets revealed that most of the medicine retailers surveyed (65%) were able to identify ALU as the Kenyan Ministry of Health recommended first-line anti-malarial therapy for uncomplicated malaria. However, the proportion of medicine retailers who recommended the correct treatment was low. Only 48% would recommend ALU to adults. It was discovered that customer demand has an influence on retailer behavior. Retailer training and education were found to be correlated with antimalarial drug knowledge, which in turn is correlated with dispensing practices.[13]

All participants in Focus group mentioned that, they prefer to advise their patients to use ALU. However the actual practice differs as per results from simulated clients. Even though the aim of SP to be allowed in private market is for IPTp refill, it was evident as it was mentioned by all participants that, SP is mainly dispensed for treatment of uncomplicated malaria instead of being reserved for IPTp. This will jeopardize its effectiveness in IPTp if the situation will remain the same. Dispensers had different opinions in effectiveness of ALU; even though most of them reported that, it is effective in treating Malaria with some cases of reported treatment failure. Hence they requested the MoHSW and other stakeholders to research on its effectiveness.

It was revealed from this study that, dispensers of private medicines outlets face the following challenges in ACT policy implementation; some clients are complaining that ALU has high price, cases of reported ALU failure, many tablets and complicated dosing schedule so they need single dose medicine. Other challenges being customers believe in SP to be the best medicine than ALU, clients demand and pressure. However the study done in Tanzania by Kabanywanyi; from patients perspective, show that upon proper pictorial instruction and making patient believe that ALU is effective in treatment of malaria 87.1% of patients found ALU easier to take and 87.7% believed that ALU was more effective than SP.[14]

As part of intervention Tanzania Food and Drug Authority (TFDA) has asked pharmaceutical manufactures to write the label on SP package which will indicate that is for IPTp only. Once those labeled batches enter into the market, other study could be done to compare the practice with what has been reported in this study. The limitation of this study is that, view of the National Drug Regulatory Authority was not sought in order to be able to clarify some of the issues such as reasons

for availability of SP in ADDOs and Pharmacies.

CONCLUSION

Results of this study indicate that less than half of dispensers in private medicine outlets would advise the use of ALU for treatment of uncomplicated malaria. However, SP is still dispensed for malaria treatment rather than being reserved for IPTp. Patient demand for a single dose medicine is one of driving factor for irrational dispensing and use of SP, other factors being affordability of SP and lack of awareness to the community that SP should be reserved for IPTp only. Intermittent preventive treatment of malaria during pregnancy is a key intervention in the national strategy for malaria control in Tanzania. Irrational dispensing of SP, which may result into SP developing resistance in IPTp and compromise the effort of the Ministry of Health and Social Welfare in reducing prevalence of malaria in pregnancy. Information to the community regarding proper use of SP and ALU should be disseminated through mass media. Tanzania Food and Drugs Authority (TFDA) should prohibit availability of SP to private medicine outlets and instead, it should be available in Private and public health facilities with Antenatal care clinics only.

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