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PREDICTORS OF ADHERENCE TO NATIONAL ANTI-MALARIAL TREATMENT GUIDELINES IN SOME NIGERIAN HOSPITALS

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ABSTRACT

Background: *Prescribers' adherence to guidelines is critical for the successful implementation of any new drug policy. Nigeria in 2005 changed its antimalarial drug policy to artemether-lumefantrine (AL) for treatment of uncomplicated malaria. New national guidelines were disseminated to health providers together with in-service training.*
Aim: This study aimed at assessing predictors of adherence to this new antimalarial treatment policy.
Methods: *The study was carried out in Enugu State of Nigeria. The study population was made up of all prescribers within the selected facilities under study. This study included one tertiary, three secondary and two primary facilities which were purposively selected from the three senatorial zones of Enugu state. To select the patients' records, systematic sampling was used. Based on the total number of cases per facility, a sampling interval "k", was calculated. A total of 600 patients' records between May 2005 and December 2009 were selected and reviewed (100 records from each of the selected facilities, 20 records per year). A total of 1038 antimalarial prescriptions from the selected 600 patients' case files were reviewed.*
Results: *The risk of adherence to NTG/NTP was higher among young prescribers who were less ten years in practice (OR = 21.05), prescribers with daily practice volume of less than 25 patients (OR = 7.271), prescribers who were aware of NTG/NTP (OR =9.847), and prescribers who received training on the new NTG/NTP (OR =29.311). The percentage adherence from May, 2005 to December, 2009 followed the same pattern with overall percentage adherence of 20.76%.*
Conclusion: *This study revealed that each of the variable, years of practice, practice volume, awareness and having received training at the introduction of the new antimalarial treatment policy made an independent contribution to predicting adherence to the new NTG/NTP.*

Key words*: Artemether –Lumefantrine, Nigeria, national antimalarial treatment guidelines, predictors, prescribers' adherence.*

Introduction

Malaria, a curable disease remains a leading cause of morbidity and mortality world-wide, especially in pregnant women and children, and particularly in tropical Africa, where at least 90% of the malaria deaths occur.[1] Malaria has severe economic implications. It has been estimated that it causes a reduction of 1.3% in the annual per capita economic growth rate of malaria endemic countries and the long term impact of this is a reduction of the GNP by more than a half.[2] Malaria Facts and Figures in Nigeria shows that is urgent need for introduction of new antimalarial treatment policy[3]

In an effort to combat this major public health problem, Nigeria adopted new malarial drug policy and strategic plan in May 2005. Federal Ministry of Health (FMOH) in conjunction with National Malaria and Vector Control Division, Abuja adopted new national antimalarial treatment policy (NTP)[4] and national antimalarial treatment guidelines (NTG).[5] The objective of NTG/NTP are to provide guidelines for the treatment of malaria in Nigeria, reduce morbidity, halt the progression of uncomplicated disease into severe and potentially fatal disease, and thereby reduce malaria mortality, reduce the impact of placental malaria infection and

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maternal malaria- associated anaemia through intermittent preventive treatment, and minimize the development of drug resistance.

The result of the 2002 efficacy studies indicated that Chloroquine and Sulfadoxine-Pyrimethamine (SP) were no longer adequate for national first line use. The need to move from monotherapy to more effective combination therapy was recognized. As a result, further efficacy trials were conducted in 2004 by Federal Ministry of Health on two suitable Artemisinin based combination therapy (Artemether-Lumefantrine; AL and Artesunate-Amodiaquine; AQ). Both combination therapies were found to be highly efficacious and thus suitable for use in the treatment of uncomplicated malaria[6]. The recommended ACT for uncomplicated malaria in Nigeria is Artemether-Lumefantrine.

The current national antimalarial drug policy in use in Nigeria supports the use of Artemether-Lumefantrine as drug of choice in the treatment of uncomplicated malaria caused by P.falciparum and other species whether they are confirmed in the laboratory or not in view of its effectiveness and prompt activity against all forms of plasmodium species. However, other ACTs (Table 1) may be used where AL is not available. Oral Quinine should be used for 7 days if there is treatment failure.[4]

Table 1: Dosage chart for Artemether-Lumefantrine and other artemisinin based combination

Artemether-Lumefantrine: The recommended drug of choice for treatment of uncomplicated malaria: 20mg Artemether +120mg Lumefantrine per tablet.		
Weight	Age	Number of tablets/dose
5-14kg	6 months – 3 years	1 tablet twice daily for 3 days ◯ x 2 x 3 days
15-24kg	4 – 8 years	2 tablets twice daily for 3 days ◯◯ x 2 x 3 days
25-34Kg	9- 14 ysears	3 tablets twice daily for 3 days ◯ ◯ ◯ 2 x 3 days
≥35Kg	>14 years	4 tablets twice daily for 3 days ◯ ◯ ◯ ◯ 2 x 3 days

Other artemisinin based combinations

Drugs	Dosage form	Comments
Amodiaquine-Artesunate	Tablet	Amodiaquine 10mg/kg and Artesunate 4mg/kg
Dihydroartemisinin+Piperaquine+Trimethoprim	Tablet	32mg dihydroartemisinin +320mg Piperaquine +90mg Trimethoprim
Artesunate-Mefloquine	Tablet	Artesunate 4mg/kg and Mefloquine 15-25mg/kg

Quinine I.M or I.V and Artemisinin derivatives (Artemether I.M, Artesunate I.V) are used for the treatment of severe malaria. Suppository of Artesunate can be used only as pre-referral treatment. Oral therapy commences once the patient can tolerate it to complete the dose or a full dose of AL is given.[5] In pregnancy, three doses of Sulfadoxine-Pyrimethamine (SP) should be used for intermittent preventive therapy (IPT). One full treatment dose during 2nd and 3rd trimesters and the last dose should be given not later than one month before the expected date of delivery.

In uncomplicated malaria during pregnancy Quinine is considered safe and can be used in all trimesters. Artemether-Lumefantrine is considered safe in 2nd and 3rd trimesters and can be used when there is no suitable alternatives.[4]

It is interesting to study the predictor of adherence to national antimalarial treatment guideline and policy, to ascertain whether antimalarial drug use conforms to the national set standards. Better strategic plan can be built with this knowledge. Nigerian health providers and patients might want to know the factors affecting complete adherence to the national set guidelines and the implications of using or not using the drugs stipulated by the national antimalarial drug policy especially in the light of comparable alternatives. The study will therefore give a picture of the situation and will also provide baseline information of Enugu state for subsequent follow-up studies. It will also raise awareness and expand knowledge on the new malaria treatment policy in the state. This study will also help health policy makers to design better strategic plans and implementation criteria in subsequent drug policies.

After the implementation of the new policy in May 2005, there is the need to assess the success or otherwise after a period. The NTP stressed the need for a routine monitoring and evaluation of antimalarial treatment policy to make the policy remain applicable to the evolution of the malaria situation. It recommended assessment of compliance to determine the influence of prescribers' compliance on treatment effectiveness. The success of a new treatment policy would depend on the adherence of health providers and patients to the standard guidelines[7]. This study falls in line with monitoring and evaluation of the policy which aims at assessing predictors of adherence to this new antimalarial treatment policy after four years of its introduction.

METHODS

Study Area

The study was carried out in Enugu State of Nigeria. Enugu state is in the South Eastern Nigeria. It is made up of seventeen (17) local government areas and is located between latitudes $5^0$56´N and $7^0$05´N and longitudes $6^0$53´E and $7^0$55´E[8]. It has a population of three million, two hundred and fifty seven thousand, two hundred and ninety eight (3,257,298)[9].

Study population

The study population was made up of all prescribers within the selected facilities under study. Seventy two (82.8%) out of eighty seven prescribers who were available at the time of data collection participated in the study.

Sample size determination of patients' records

Population of Enugu state is 3,257,298. Assuming that 50% of the population would have malaria in a year and that in any given month there would be approximately 135,721 cases of malaria.

Expected frequency of factor under study (i.e. percentage of patients treated according to NTG for malaria = 15%), assuming higher worst acceptable frequency of 18%. At confidence interval of 95%, the calculation gave a sample size of 544. Making allowance for losses, it was approximated to 600 patients treated for malaria. This was calculated with Epi info Statcalc version 6.

Sampling Method

This study included one tertiary, three secondary and two primary facilities which were purposively selected from the three senatorial zones of Enugu state. For each particular facility, the total number of malaria cases reported at OPD was counted using the OPD attendance book. To select the patients' records, systematic sampling was used. Based on the total number of cases per facility, a sampling interval "k", was calculated. Starting from a random point of total malaria cases per month over the five years under review, each "k"th record was noted and picked from the record archives as part of the sample. This continued until the total number of records required for the facility has been selected. A

total of 600 patients' records between May 2005 and December 2009 were selected and reviewed (100 records from each of the selected facilities, 20 records per year). A total of 1038 antimalarial prescriptions from the selected 600 patients' case files were reviewed.

Study Design

This was a cross sectional descriptive study that involved the collection of quantitative and qualitative data. The information in the case files was copied out and recorded in data collection forms specially prepared this study. The prescribers were identified from patients' prescriptions and information therein was recorded under each participating prescriber that wrote the prescriptions. Patient records were assessed for diagnosis made, the antimalarial prescribing patterns, choice of other malaria drugs prescribed, their doses to see if they tallied with the recommended doses according to age and weights of the patients and their prescribers were noted.

Only outpatient prescriptions that had antimalarial drugs and prescriptions written by participating prescriber were considered. Prescriptions without the name of the prescriber and folder without patient's information were excluded.

Three experienced research assistants were trained on how to cross check information from records to ascertain the correctness and consistency of the information.

Questionnaires were pre-tested in Nsukka and for a second time in Oji River to address mistakes and omissions.

Tools

Two tools were used to collect these data. The tools were:

***Provider Questionnaire*:** This self administered questionnaire was completed by all prescribers present on the day of the assessment. This questionnaire assessed prescribers' factors (predictors) that could affect adherence to national anti-malarial treatment guidelines and policy.

***Patient Record Review*:** This data collection form was used to extract information from patients' folders on the treatment of malaria in each of the facilities between May 2005 and December 2009 to ascertain trends in ACT prescribing implementation. To enhance quality, experienced field workers were used and all record review forms were critically examined and crosschecked at the end of each day to ensure completeness, consistency and accuracy of the data.

Data Analysis

The data were sorted, coded and entered into Statistical Package for the Social Sciences for Windows 14.0 (SPSS Inc., Chicago, IL) and subsequently analyzed.

Logistic regression was used to estimate the association of prescribers' factors (sex, rank, marital status, awareness, years in practice, received training on new NTG/NTP, areas of specialization, and practice volume) with adherence to NTG/NTP which was the dependent variable, the binary variables describing the adherence status were '0' for non-adherence and '1' for adherence. Explanatory variables which did not contribute significantly to explain adherence when they were fitted singly into the first model (unadjusted) were excluded from the model when all the explanatory variables that contributed significantly were simultaneously refitted into the model (adjusted). Careful stepwise model building was used to drop variables which did not contribute significantly to explaining adherence probabilities once the other variables were accounted for and new models were refitted until the final effects model which contained variables terms that contributed significantly at 95% CI after adjusting for other model terms. An odd ratio [OR] less than 1 indicates a prescriber is less likely to adhere to NTG/NTP and an [OR] greater

than 1 means a physician is more likely to adhere to NTG/NTP. P-value of less than 0.05 was interpreted as significant.

In this study, prescriber's adherence was defined if the reviewed record had: a diagnosis of malaria; the right antimalarial drug (as recommended in STG/NMP); and the right dosage as specified by the STG/NMP.

Provider awareness was defined if a provider: had heard that there was a new policy; had received training specifically with the introduction of the policy; had both or either copies of STG or NMP (May 2005).

$$Percentage\ adherence = \frac{Number\ of\ prescriptions\ written\ \ according\ to\ NTG/NTP\ per\ year}{Total\ number\ of\ prescription\ written\ in\ that\ year} X100$$

$$Percentage\ of\ use = \frac{Frequency\ of\ prescribed\ antimalarial\ drug\ (single\ or\ combination) per\ year}{Total\ number\ of\ prescribed\ antimalarial\ drugs\ in\ that\ year} X100$$

One antimalarial drug or one fixed combination was considered as single while more than one antimalarial drug (fixed combination or single) in a prescription were considered as combination. These combinations were considered as a unit antimalarial during the calculation (e.g. when Quinine and SP are prescribed in a prescription, the combination is considered QN-SP). 'Overall percentage adherence' and 'overall percentage of use' were the averages of 'percentage adherence' and 'percentage of use' respectively.

Ethical Clearance

The questionnaire was completed by self-administration. Investigators briefed the respondents on the purpose of the study and oral consent was obtained from the respondents. Ethical approval for the study was obtained from the individual hospital institutional review board. Confidentiality and anonymity of the patients' information were maintained during and after the study.

RESULTS

Table 2 shows the unadjusted descriptive association between prescribers' variables and adherence to NTG/NTP. Adherence was shown to be significantly associated with age ($p = 0.011$), years of practice ($p < 0.001$), practice volume ($p < 0.001$), awareness ($p < 0.001$) and received training on the new NTG/NTP ($p < 0.001$).

Table 3 provides the adjusted odds ratios and 95% confidence intervals that quantify the association between association between prescribers' variables and adherence to NTG/NTP. These estimates were obtained using multiple logistic regression models. The risk of adherence to NTG/NTP was higher among young prescribers who were less ten years in practice (OR = 21.05), prescribers with daily practice volume of less than 25 patients (OR = 7.271), prescribers who were aware of NTG/NTP (OR =9.847), and prescribers who received training on the new NTG/NTP (OR =29.311).

The general prescription pattern of antimalarial drugs (AL, AAQ, and A) showed sharp increase in percentage use from 2005 to 2007 and steady decreased to 2009. However, the overall percentage uses of these antimalarial drugs were greater than their baseline (2005) percentage uses see Fig 1. The percentage adherence from May, 2005 to December, 2009 followed the same pattern with overall percentage adherence of 20.76% see Fig 2.

The general prescription pattern of antimalarial drugs (SP, CHQ-SP, AT-SP, and AT) showed sharp decrease in percentage use from 2005 to 2007 and steady increased to 2009. However, the overall

percentage uses of these antimalarial drugs were less than their baseline (2005) percentage uses. Also, the overall percentage uses of QN, CHQ, AQ, and QN-SP were less than their baseline (2005) percentage uses see Fig 1.

Table 2: Unadjusted effects of predictor variables of prescribers (n=31) on adherence to NTG

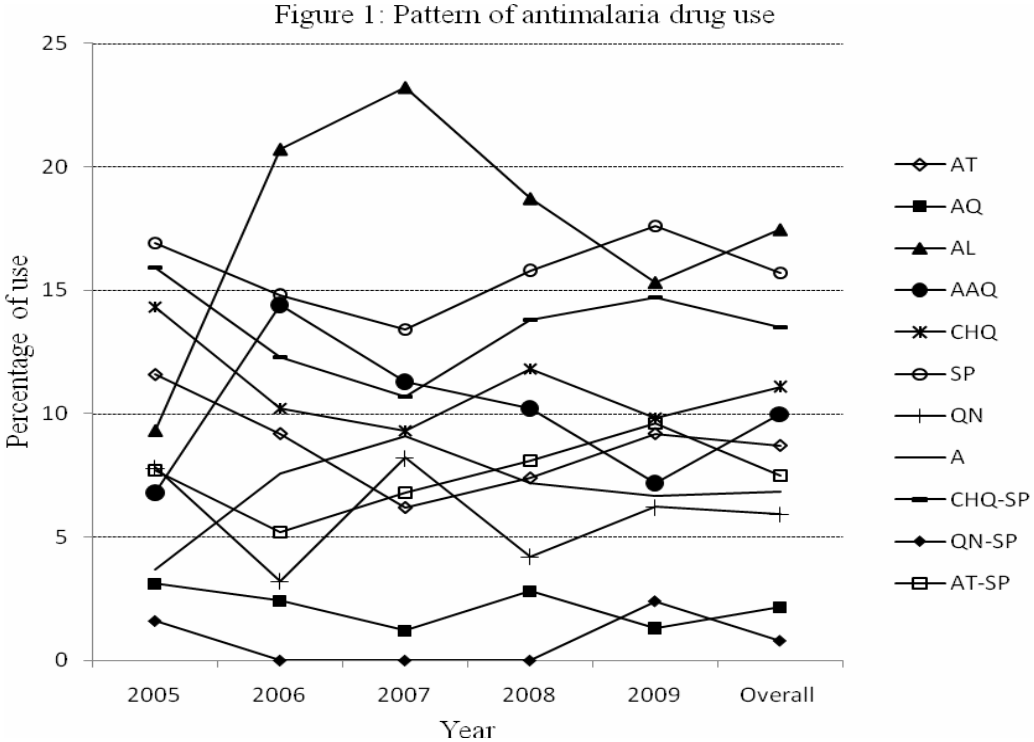
Predictors (Likelihood Ratio Test)	Odds Ratio (OR)	95% CI for OR
Age (X^2 (2) = 28; P-value =0.011)		
>20 -35	4.672	2.673 - 7.228
36 - 50	2.872	1.516 – 4.745
>50	Reference	
Sex (X^2 (1) = 2.052; P-value = 0.153)		
Male	0.639	0.092 – 1.284
Female	Reference	
Marital status (X^2 (1) = 0.945; P-value = 0.332)		
Single	1.274	0.723 – 1.941
Married	Reference	
Years of practice (years) (X^2 (2) = 113; P-value < 0.001)		
1-10	12.541	9.719 -18.376
11-20	5.872	2.836 – 6.105
>20	Reference	
Rank (X^2 (3) = 1.675; P-value = 0.316)		
Medical officers	1.243	0.467 – 2.163
Registrars	2.337	0.953 – 4.761
Senior registrars	0.726	0.095 – 2.630
Consultants	Reference	
Areas of specialization (X^2 (2) = 3.162; P-value = 0.179)		
General practitioner (GP)	1.652	0.367 – 3.189
Malariologist	3.287	0.367 – 4.742
Others	Reference	
Practice volume (patients per day) (X^2 (2) = 132; P-value < 0.001)		
1-25	9.525	4.783 – 11.985
26-50	3.642	1.094 – 8.381
>50	Reference	
Awareness (X^2 (1) = 176; P-value < 0.001)		
Yes	6.286	2.013 – 10.439
No	Reference	
Received training on the new NTG/NTP (X^2 (1) = 56; P-value < 0.001)		
Yes	11.413	6.948 – 15.744
No	Reference	

Table 3: Adjusted effects of predictor variables on adherence to NTG/NTP

*Predictors	Odds Ratio (OR)	95% CI for OR
Years of practice		
1-10	21.054	18.429 -28.427
11-20	7.741	4.421 – 11.636
>20	Reference	
Practice volume		
1-25	7.271	4.589 - 14.835
26-50	4.619	3.280 – 9.283
>50	Reference	
Awareness		
Yes	9.847	5.537 – 13.472
No	Reference	
Received training on the new NTG/NTP		
Yes	29.311	20.752 – 35.609
No	Reference	

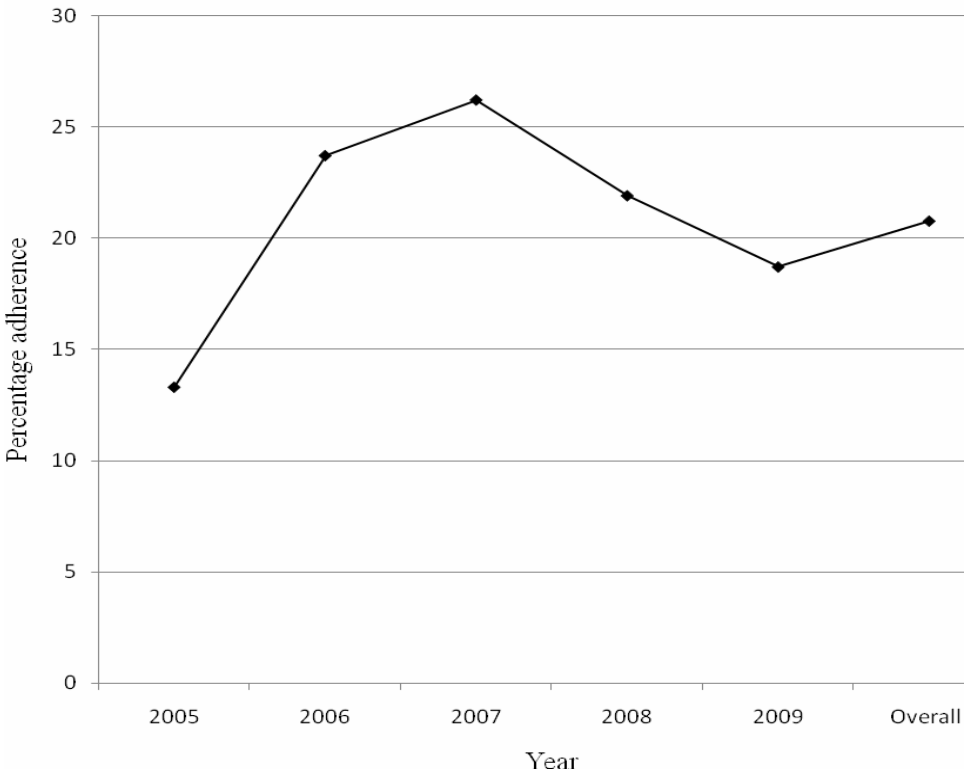
*Only predictors that contributed significantly in the final model after adjusting for other model terms were presented.

Figure 1: Pattern of antimalaria drug use



Artesunate (AT), Amodiaquine (AQ), Artemether-Lumefantrine (AL), Artesunate-Amodiaquine (AAQ), Chloroquine (CHQ), Sulfadoxine-Pyremethamine (SP), Quinine (QN), Artemether INJ (A), Chloroquine-SP (CHQ-SP), Quinine-SP (QN-SP), Artesunate-SP (AT-SP), Artesunate-MEF (AT-MEF)

Figure 2: Percentage adherence from May 2005 to December 2009



DISCUSION

Prescribers' adherence to guidelines is critical for the successful implementation of any new drug policy. However, this study revealed that Nigerian prescribers had poor adherence to national antimalarial treatment guidelines and policy. Adherence to AL has been suggested as a major constraint to its effectiveness[10].

Non adherence to national standard treatment guidelines for uncomplicated malaria by health professionals has been documented in many African countries [7,12-17] including Nigeria[18].

This study has revealed that prescribers that have practised for more than 10 years were less likely to adhere to national antimalarial treatment guidelines, this might be due negative perception this group of prescriber had over recommended ACTs and ultimately, the high cost of ACTs when compared with non-ACTs. This assertion was corroborated by Wasunna B et al[19] who identified perception and high cost of ACTs as factors affecting adherence to the new antimalarial treatment guideline.

AL was reported to be safe and effective for the treatment of acute uncomplicated malaria in Nigeria [20,21], issue of safety and efficacy are not reasons why long practising prescribers did not adhere to the new treatment guidelines, rather, their resistance to change might also be the major factor.

Practice volume was also an independent predictor of adherence to new malaria treatment guideline as prescribers who had workload of less 25 patients per day were about 7 times more likely to adhere to the new policy than those having more patients per day. The reasons for non-adherence related to more general health system factors, particularly the workload of health care staff, and the erratic nature of drug supply.

Under-staffing in the health facilities was the major factor leading to increased workload thereby affecting the delivery of quality care particularly in the health facilities. The desired quality of care cannot be fully realized when there is a shortage of health personnel. This has resulted in unskilled staff working beyond their normal level of competency.

Staff retention was a challenge since some of the prescribers who had been trained on the new guidelines had moved to other facilities leaving untrained ones at the facilities. Staffing issues were seen as a particular concern in AL prescription because of the additional time required for counselling, and direct observation of the first dose, record keeping, and confirmed diagnosis for patients in facilities with diagnostics, leading health workers to prefer prescribing other antimalarial drugs.

It is surprising that after more than four years of implementation of this new guideline that some prescribers were not aware of it. Prescribers who were aware of this new NTG/NTP were about 10 times more likely to adhere to the new policy than those who were not aware, while those that received training at the introduction of this new policy were about 29 times more likely to adhere than those who did not receive any training.

Some of the key messages delivered during training influenced health workers' prescribing decisions. These messages highlight the importance of the quality of training, it appears that in many cases the training was effective in getting across the messages delivered; the problem was that some messages might often be inaccurate. This implies a need for greater quality control during the training, perhaps through greater time spent on initial training of trainers, and monitoring of cascade training sessions by more senior staff. It also emphasizes the importance of follow up supervision of health workers in facilities, to monitor their practice, and give them the opportunity to ask further questions and resolve any confusion.

This study showed decline in percentage adherence to antimalarial treatment guideline after three years

of introduction (2007-2009) Fig 2, this trend explained the re-emergence of CHQ, SP and other antimalarial drugs both singly and in combination. The percentage of use of recommended antimalarial drugs (AL,AAQ and A) see Fig 1, rose to peak in 2007 and declined steadily to 2009. A trend if not checked could go beyond pre- implementation level. This decreasing adherence to recommended antimalarial drugs and increasing utilization of CHQ, SP and other antimalarial drugs could be attributed to continued supply to health facilities with large quantities of non-recommended antimalarials resulting in confusion among health workers.

This issue had been frequently documented during changes in antimalarial drug policy, for example, in Tanzania there were stockpiles of Chloroquine leading to implementation problems during SP introduction [22,23]. It is, therefore, essential that plans are put in place well in advance of the introduction of new drugs to ensure that stockpiles of medicines being replaced are removed from the supply chain.

CONCLUSION

This study revealed that each of the variable, years of practice, practice volume, awareness and having received training at the introduction of the new antimalarial treatment policy made an independent contribution to predicting adherence to the new NTG/NTP.

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