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A STUDY TO EVALUATE USAGE OF ANTIMICROBIAL AGENTS AT PRIMARY HEALTH CENTRES AND URBAN HEALTH CENTRES IN AHMEDABAD DISTRICT

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ABSTRACT: Aims and Objectives: To evaluate the use and the impact of interventions on the use of antimicrobial agents (AMAs) at Primary Health Centres (PHCs) and Urban Health Centres (UHCs) in Ahmedabad district. **Materials and methods:** This was an interventional and prospective study carried out at 5 PHCs and 5 UHCs of ahmedabad district. In pre-intervention phase, 30 adult patients from each centre who were prescribed AMAs were included. Educational interventions were done for the prescribers by giving them booklet and by PowerPoint presentation about the use of AMAs for common diseases observed in the pre-intervention phase. In post-intervention phase, similar to pre-intervention phase, 30 adult patients from each centre i.e. 5 PHCs and 5 UHCs who were prescribed AMA were included. The impact of intervention and appropriateness of AMA use was measured using Modified Kunin's Criteria. **Results:** Amongst a total of 300 patients, i.e. 150 each from PHCs and UHCs, the most commonly AMAs used were metronidazole and doxycycline respectively in pre-intervention phase. According to modified Kunin's criteria, appropriate antimicrobial treatment was given to only 12% patients at PHCs and 6.67% patients at UHCs in pre-intervention phase. In the post-intervention phase (n=300) the most commonly used AMAs were same as in pre-intervention phase. Appropriate antimicrobial treatment according to modified Kunin's criteria was given to 20% patients at PHCs and 9.33% patients at UHCs in post-intervention phase. **Conclusion:** AMAs were not appropriately prescribed at PHCs and UHCs according to modified Kunin's criteria, but educational intervention improved it but not significantly.

INTRODUCTION: Antimicrobials are considered as the greatest discovery of twentieth century ¹. They have been used since ages to treat life threatening infections. Evidence from studies of prescribing patterns suggests that antimicrobial agents' usage has increased steadily however they are used in inappropriate ways ².

This inappropriate prescribing practice can cause ineffective and unsafe drug treatment, worsening or prolonging of illness, adverse drug reaction and antimicrobial resistance ¹. The appropriateness of antimicrobial treatment can be evaluated by using modified Kunin's criteria ³ and method suggested by Gyssens et al ⁴.

The appropriate use of AMAs can be improved by various educational interventions. This includes distributing guidelines book, continued medical education (CME), awareness program, personal interviews and briefing, posters, frequent reminders by SMS and emails for encouragement.

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The health care system provided by the Government is divided into Primary Health Centres, Urban Health Centres and Tertiary Health Care hospitals. Among them PHCs and UHCs usually cover the rural areas and the urban slum areas. A lot of studies have been done on usage of antimicrobial agents in tertiary health care hospitals. However, there are no studies done in PHCs and UHCs which cover rural and urban slum areas. Hence this study was designed to study the usage of antimicrobial agents at PHC and UHC and to evaluate the impact of educational intervention of AMA prescribing.

MATERIALS AND METHODS:

This study was an interventional, continuous, prospective and multicentre study which included 5 PHC and 5 UHCs which accounted to approximately 10% of the total 43 PHCs and 57 UHCs in Ahmedabad district. The study was carried out from September 2012 to June 2014 over a period of 22 months. Adult patients of either gender, who were willing to participate in the study, who gave informed consent and who were prescribed antimicrobial agents were included. Patients who were not willing to participate in the study and give informed consent and pregnant females were excluded. A prior permission was obtained from Chief District Health Officer (CDHO) for conducting the study at Primary Health Centres. To conduct study at Urban Health Centres permission was taken from Family Welfare Officer (FWO). Prior permission from Institutional Ethics Committee (IEC) of Civil Hospital, Ahmedabad was also obtained before the conduct of the study. As per the inclusion and exclusion criteria the patients were enrolled after taking written informed consent. The study was divided into 3 phases: pre-intervention, intervention and post-intervention phases.

Study Procedure:

(A) Pre-intervention phase: A sample from each centre was calculated taking 10% of prescription having antimicrobial agent every month. 30 patients from each centre of PHCs and UHCs, i.e. total of 150 patients each from PHCs and UHCs were enrolled for the study. The detailed information of the patients like demographic data, clinical history, physical

examination, investigations and treatment prescribed was obtained from patients and was entered in pre-validated case record form.

(B) Intervention phase: Common diseases for which AMAs were prescribed were identified and according to it an information booklet for ideal treatment of infectious diseases was prepared. The booklet was prepared on the basis of the Standard Treatment Guidelines, 3rd edition, published by Delhi Society for Promotion of Rational Use of Drugs and pharmacology books i.e. Essentials of Medical Pharmacology, K. D. Tripathi and Goodman & Gillman's Pharmacological Basis of Therapeutics. It was validated by consulting 5 senior pharmacologists. In the intervention phase this booklet was distributed to prescribers at PHCs and UHCs. In the second part of the intervention a personal briefing with the help of PowerPoint presentation on the treatment of these common diseases was taken. The presentation was prepared using the details from the Information booklet. It was also validated by consulting 5 senior pharmacologists. The intervention phase comprised of 1 month.

(C) Post-intervention phase: After 1 month of the intervention, the investigator visited the same selected PHCs and UHCs. 30 patients who were prescribed AMA and who fit as per inclusion and exclusion criteria were enrolled again. The detailed information of the patients like demographic data, clinical history, physical examination, investigations and prescribed treatment was obtained from patients and was entered in pre-validated case record form.

Analysis:

The appropriateness of AMA treatment was measured using modified Kunin's criteria³. These criteria consider the choice, dose, route, frequency and duration for the appropriateness. AMA treatment was scored from 1 to 5, with 1 being the most appropriate and 5 being the most inappropriate AMA treatment. The data collected was compiled, entered in Microsoft Excel spreadsheet 2007 and analysed. Further analysis was done by using t test, chi-square test and

ANOVA test with Tukey Kramer test. In all the statistical tests, P value <0.05 was considered significant.

RESULTS:

This was an interventional and prospective study carried out in 5 PHCs and 5 UHCs (pre-intervention; intervention and post-intervention phase) in Ahmedabad district. As shown in **Table 1**, the mean age of the patients in the

preintervention phase was as 41.37±15.68 years (mean±S.D.) in PHCs and 44.25±14.65 years (mean±S.D.) in UHCs, while in the post intervention phase it was 39.72±14.46 years (mean±S.D.) and 44.35±13.9 years (mean±S.D.) respectively. There was no significant difference in the mean ages between pre and post intervention groups of PHCs (p=0.55) and UHCs (p=0.21) (paired t-test).

TABLE 1: DEMOGRAPHIC DETAILS

Parameter	PHCs		UHCs	
	Pre-intervention	Post-intervention	Pre-intervention	Post-intervention
Age (years) (mean±SD)	41.37±15.68	39.72±14.46	44.25±14.65	44.35±13.9
Male:female ratio	1.08:1	0.85:1	1.88:1	3.41:1
Weight (kg) (mean±SD)	53.97±9.49	53.68±10.1	52.61±8.5	54.85±8.43
Common occupations	Housewives, retired people, students	Housewives, retired people, farmers	Housewives, labourers, retired people	Labourers, retired people, housewives
Percentage of patient belonging to low socioeconomic class	79.33	73.33	86.67	84.67

As observed from **Table 1**, the gender ratio, weight and occupation of the patients were comparable in all the four groups. More than two-third of the patients belonged to poor socioeconomic class as per modified Kuppuswamy scale ⁵.

The most common chief complaint of the patients at PHCs and UHCs in both pre- and post-intervention phases was cough as shown in **Fig. 1** and **2**.

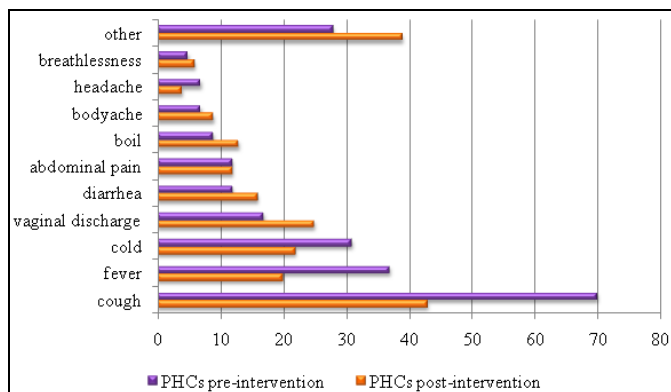


FIG. 1: CLINICAL PRESENTATION AT PRIMARY HEALTH CENTRES

Note: Other include vomiting, throat pain, giddiness, chest pain, itching, chills, nail pain, burning micturition, injury leg, pustule, pallor, toothache, worms in stool, joint pain, stomatitis, acne, post operative, backache, puffy face, trauma, otalgia, difficulty in walking, haemoptysis, pain and rigor

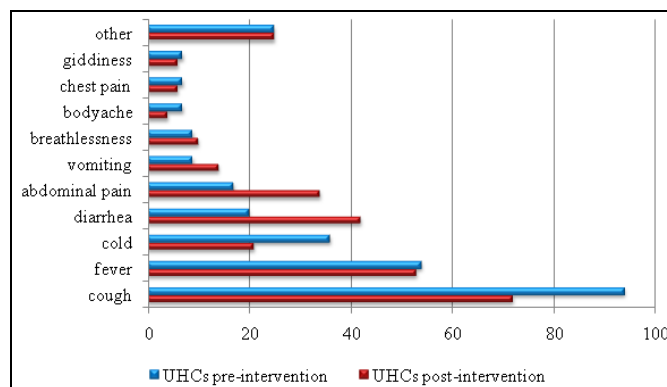


FIG.2: CLINICAL PRESENTATION AT URBAN HEALTH CENTRES

Note: Other include boil, headache, throat pain, itching, chills, nail pain, burning micturition, injury leg, pustule, pallor, toothache, worms in stool, joint pain, stomatitis, acne, post operative, backache, puffy face, trauma, otalgia, difficulty in walking, haemoptysis, pain and rigor

Laboratory investigations:

Out of 150 patients only 7 (4.67%) and 9 (6%) patients underwent for laboratory investigation i.e. peripheral smear for malarial parasites (PS for MP) in PHCs in the pre- and post-intervention phase respectively which was not significant using chi-square test (p=0.79). Total 34 (22.67%) patients underwent laboratory investigations i.e. PS for MP, rapid diagnostic test (RDT) for malaria and sputum for acid fast bacilli (AFB) in pre-intervention phase at UHCs (n=150). While 26 (17.33%) patients

underwent laboratory investigations i.e. PS for MP, RDT for malaria and sputum for AFB in post-intervention phase at UHCs (n=150). There was no significant difference between pre- and post-intervention phase at UHCs using chi-square test ($p=0.31$).

Diagnosis:

The most common diagnosis of the patients in pre-intervention as well as post-intervention phase at PHCs (n=150) was upper respiratory tract infection (pre= 44.67%, post=25.33%) followed by gastro-enteritis (pre= 12.67%, post=18%), vaginitis (pre= 11.33%, post=16.67%) and boil (pre= 6%, post=8.67%).

The most common diagnosis of the patients at UHCs (n=150) in the pre as well as post-intervention phase was upper respiratory tract infection (pre= 60.67%, post= 44.67%) followed by gastro-enteritis (pre= 10%, post= 20.67%) and malaria (pre=5.33%, post= 6.67%).

Antimicrobial agents:

The most common AMA used at PHCs in the pre-intervention phase (n=150) was metronidazole (23.33%) followed by amoxicillin (18.67%), cotrimoxazole (18.67%), norfloxacin (18%) and doxycycline (14.67%). Most common AMA used at PHCs in the post-intervention phase was metronidazole (30%) followed by norfloxacin (26.67%), amoxicillin (13.33%), doxycycline (13.33%) and cotrimoxazole (12%). The most common AMA used at UHCs in pre-intervention phase (n=150) was doxycycline (49.33%), followed by amoxicillin (16%), metronidazole (13.33%) and cotrimoxazole (6%). While post-intervention phase, the most common AMA used at UHCs was doxycycline (34.67%) followed by metronidazole (24.67%), amoxicillin (11.33%), norfloxacin (8.67%) and albendazole (8.67%).

About 20.67% (n=150) and 26.67% patients (n=150) were prescribed with multiple AMAs (metronidazole and norfloxacin; metronidazole, norfloxacin and clotrimazole; doxycycline and clotrimazole; and metronidazole and clotrimazole) in pre- and post-intervention phases respectively at PHCs. There was no significant difference between these groups using chi-square test ($p=0.11$). 12%

patients (n=150) and 21.33% patients (n=150) were prescribed with multiple AMAs at UHCs in pre- and post-intervention phases respectively. Patients were prescribed multiple AMAs significantly more in post-intervention phase as compared to pre-intervention phase using chi-square test ($p=0.04$). No fixed dose combinations (FDCs) of AMAs were prescribed in PHCs throughout study (n=300). While in UHCs, FDCs of ofloxacin+ornidazole (42.86%), amoxicillin+clavulanic acid (35.71%) and ACT (artemisinin-based combination therapy i.e. artesunate and sulphadoxine+pyrimethamine) (21.43%) were prescribed in 14 (9.33%) patients in pre-intervention phase (n=150).

And FDCs of ofloxacin+ornidazole (54.55%), amoxicillin+clavulanic acid (27.27%) and ACT (18.18%) were prescribed in 22 (14.66%) patients in post-intervention phase (n=150). There was no significant difference between pre- and post-intervention phases at UHCs who were prescribed FDCs of AMAs ($p=0.21$).

Majority of the patients were given AMA orally in the pre-interventional phase (93.05%) as well as post-interventional phase (90%) at PHCs. Similar observation was also found in UHCs (pre= 97.62%, post= 96.7%). In PHCs, mean duration of antimicrobial treatment was 3.33 ± 1.06 and 3.40 ± 1.14 days in pre- and post-intervention phases respectively. There was no significant difference between them using paired t-test ($p=0.55$). While in UHCs, the mean duration of antimicrobial treatment was 2.96 ± 1.84 and 2.88 ± 1.86 days in pre- and post-intervention phase respectively. There was no significant difference between them using paired t-test ($p=0.71$). All the AMAs were prescribed using generic name at both PHCs and UHCs in pre- as well as post-intervention phases (n=737).

Appropriateness of antimicrobial treatment:

Appropriateness was categorized according to modified Kunin's criteria at PHCs and UHCs. According to modified Kunin's criteria, categories 1 and 2 are considered appropriate while categories 3 to 5 are considered inappropriate. As shown in Figure 3, only 12% and 20% patients were prescribed AMAs appropriately at PHCs in pre- and post-intervention phase respectively. While at

UHCs, only 6.67% and 9.33% patients were prescribed AMAs appropriately in pre- and post-intervention phase respectively.

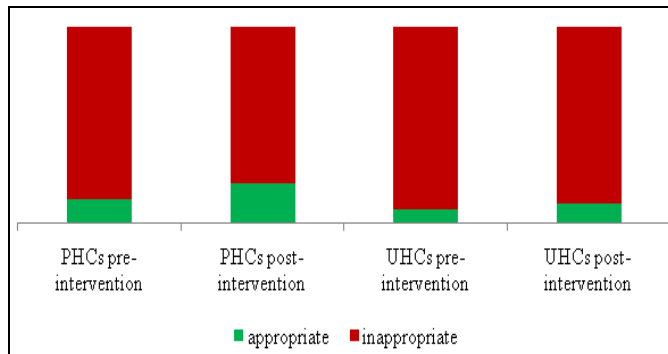


FIG.3: APPROPRIATENESS OF ANTIMICROBIAL AGENTS

As shown in **Table 2**, the inappropriate usage of AMAs was found according to inappropriate choice, dose, route, frequency and duration. A comparison was done between the pre-intervention and post-intervention groups of PHCs and UHCs. In all the groups post-intervention there was an improvement in the appropriateness in choice, dose, route, frequency and duration of usage of AMA though not significant in all cases. It was observed that significant improvement for choice and duration of AMA was observed at PHCs and UHCs after intervention. There was also significant improvement of the appropriate dose of AMA used at UHCs after intervention using chi-square test.

TABLE 2: INAPPROPRIATE USE OF ANTIMICROBIAL AGENTS

AMA administration	PHCs		UHCs	
	Pre-intervention (n=187)	Post-intervention (n=200)	Pre-intervention (n=168)	Post-intervention (n=182)
Inappropriate choice	101 (54.01%)	64 (32%) ¹	112 (66.67%)	91 (50%) ²
Inappropriate dose	25 (13.37%)	16 (8%)	39 (23.21%)	24 (13.19%) ³
Inappropriate route	3 (1.6%)	2 (1%)	4 (2.38%)	3 (1.65%)
Inappropriate frequency	44 (23.53%)	37 (18.5%)	51 (30.36%)	45 (24.73%)
Inappropriate duration	132 (70.59%)	104 (52%) ⁴	141 (83.93%)	110 (60.44%) ⁵

DISCUSSION: India is the country where the infectious disease burden is among the highest in the world but on the other hand reports have shown that AMA used to treat these infections are used inappropriately and irrationally. This has led to increased incidence of development of antimicrobial resistance⁶. There are studies available regarding the usage of AMAs in tertiary health care hospitals, however there are lack of studies conducted in PHCs and UHCs which provide health care facilities to rural and urban slum areas respectively. This study was done to evaluate the use of AMAs and appropriateness of their use by using modified Kunin's criteria³ at PHCs and UHCs. Improvement in appropriateness of AMA prescription was also measured after educational interventions of distribution of booklet regarding AMA use in various infectious diseases and by making presentation in front of the prescribing physicians.

The age range of the patients was 41 to 60 years and 18 to 40 years at PHCs and UHCs respectively. The reason behind this finding may be our inclusion criteria to include the adult patients aged

18 years or more. Older patients have multiple etiologies of diseases and are usually admitted. Khan et al also showed that most patients were in the age group of 41 to 60 years⁷. There was a little discrepancy in male:female ratio in our study at various sites. It might be because the flow of the patients at the study centre might vary on daily basis. Majority of the patients in our study belonged to low socioeconomic class which might be because PHCs and UHCs provide health services at negligible cost. Cough, fever, cold, abdominal pain, diarrhoea and vaginal discharge were the common complaints of the patients at all the centres.

All these complaints are clinical features of common infectious diseases like upper respiratory tract infection (URTI), gastroenteritis, vaginitis and malaria. Incidence of URTI is highest (18.8 billion in 2013) worldwide amongst acute disorders which is followed by diarrheal diseases (2.7 billion in 2013)⁸. Laboratory investigations like haemoglobin level, PS for MP, rapid diagnostic test (RDT) for malaria and sputum for acid fast bacilli (AFB) were done in only few patients. Moreover

the common diagnoses were URTI and gastroenteritis, which usually doesn't compel the physician to go for any laboratory tests especially at PHCs and UHCs where there is lack of specific laboratory investigations.

The most common diagnosis was upper respiratory tract infection in pre- as well as post-intervention phase at PHCs and UHCs. Other common diagnoses were gastroenteritis, vaginitis, helminthiasis, boil, malaria, typhoid and chikunguniya. However, an Indian study done at a tertiary care teaching hospital had common diagnosis like febrile illness, gastroenteritis and malaria⁹. This might be because complicated and serious patients are usually referred to a tertiary care hospital, whereas at PHCs and UHCs, the patients present with mild to moderate illness.

Most of the antimicrobial agents were prescribed singly in our study. More than 70% patients were treated with single AMA. Amane H and Kop P also showed similar results where single AMAs were prescribed to patients at a tertiary care hospital¹⁰. Majority of the patients at PHCs and UHCs in our study were prescribed AMAs like metronidazole, amoxicillin, doxycycline, cotrimoxazole, norfloxacin and albendazole. The most commonly used AMAs in PHCs and UHCs were metronidazole and doxycycline respectively. Common conditions in this study were URTI and gastroenteritis which are usually viral in origin and self limiting^{11, 12}. If bacterial in origin, URTI in majority of the cases is treated by means of amoxicillin, cephalixin, doxycycline and azithromycin¹³ and gastroenteritis by fluoroquinolones¹⁴.

A Greek study at primary health care level showed that penicillins were the most common AMAs prescribed followed by cephalosporins, macrolides, quinolones, imidazoles, sulphonamides, lincozamides and antifungals¹⁵. Kotwani A and Holloway K showed that most commonly used AMAs at outpatient department of public sector were amoxicillin, ofloxacin, ciprofloxacin, doxycycline and roxithromycin¹⁶. The reason for use of such AMA may be the most common diagnosis which was URTI followed by gastroenteritis for which drugs like penicillins and

fluoroquinolones are commonly prescribed. URTI and gastroenteritis are usually self-limiting. There is also lack of diagnostic facilities which help to arrive at more specific diagnosis about viral or bacterial in origin.

Very few patients in our study were prescribed 2 or more AMAs. Amane H and Kop P also showed that only 15.55% patients were prescribed 2 or more AMAs¹⁰. Combinations of AMAs used at our setup were metronidazole and norfloxacin; albendazole and metronidazole; ofloxacin+ornidazole and clotrimazole; roxithromycin and framycetin; and cefixime and lumefantrine. Unnecessary multiple AMAs were used in our study where only one AMA would suffice. Use of metronidazole and norfloxacin concomitantly is irrational, because they are used for the gastroenteritis which can be bacterial or amoebic dysentery that can be diagnosed and only one of the drugs could suffice. In majority of the cases a single patient doesn't require antibacterial as well as antiamoebic drugs¹⁷. However, most of the patients who were prescribed multiple antimicrobial in our study had more than one complaint like diarrhea and vaginitis; cough and boil; cough and vaginitis.

No FDCs of AMAs were prescribed at PHCs whereas few FDCs of AMAs were prescribed at UHCs. Most common FDC of AMA in our study was ofloxacin+ornidazole which was followed by amoxicillin+clavulanic acid and artemisinin-based combinations. FDCs of AMAs are not in government supply at PHCs which might be the reason for no prescription of FDC of AMAs there. Amoxicillin+clavulanic acid and artemisinin-bases combinations are rational FDCs which are included in essential medicines list by world health organisation¹⁸.

Availability of irrational combination of ofloxacin+ornidazole¹⁷ at UHCs is surprising and irrational. An Indian study showed most commonly used FDCs of AMAs were amoxicillin+clavulanic acid and ceftriaxone+sulbactam⁷. Amane H and Kop P showed that commonly used irrational FDCs included Norfloxacin + tinidazole; ofloxacin + ornidazole; ciprofloxacin + tinidazole; gatifloxacin + ornidazole; amoxicillin + cloxacillin and

ampicillin + cloxacillin¹⁰. Almost all the patients were prescribed AMAs by oral route in our study. This finding might be because at the primary health care majority of the patients visit OPD and hence managed by oral medications moreover if required for admission they are referred to higher centres. Appropriateness of antimicrobial treatment was evaluated by modified Kunin's criteria in our study. Antimicrobial treatment was appropriate in 12% and 6.67% patients at PHCs and UHCs respectively in pre-intervention phase. The appropriateness improved to 20% and 9.33% patients at PHCs and UHCs in post-intervention phase.

The most common inappropriateness in AMA prescriptions was duration of usage of AMA. Swindell PJ et al also have shown inappropriate duration of AMA usage as common occurrence¹⁹. In more than 50% cases the choice of AMA used was inappropriate in pre-intervention phase. URTI and gastroenteritis are self limiting infections which do not need usage of AMAs and hence usage of AMAs for them is not justified in our study. Lack of knowledge and lack of availability of specific drugs at PHCs and UHCs might be the reason for this inappropriateness. Moreover lack of specific diagnostic facilities for specific infections has lead to improper diagnosis and hence inappropriate prescribing. A study in the western world by Willemsen et al observed that inappropriate choice and unjustified use of AMA is present only in 16% patients unlike Indian studies⁴.

There was improvement in appropriateness of antimicrobial treatment after intervention, but it was not statistically significant. Prescribers can be updated regularly by educational intervention in form of a booklet or standard treatment guidelines provided by government which can be used for reference while prescribing. Educational intervention can be given by other means viz., continued medical education, seminars, workshops, training programs, etc. Though the difference in appropriateness of antimicrobial treatment after intervention was not significant but a small rise is a positive indicator that small intervention can change the behaviour of the prescriber to prescribe drugs rationally. This may be a stepping stone to start rational prescribing. Limited availability of drugs and laboratory facilities might be the reason

for this inappropriate antimicrobial treatment. Standard treatment guidelines are also not available for PHCs and UHCs which can improve appropriate treatment. A Turkey study has shown that appropriate use of AMAs was found to improve from 45.7% to 91.4% after implementation of antibiotic restriction policy²⁰. This shows that implementation of antimicrobial policy, educational intervention and availability of laboratory facilities and drugs may improve the appropriate antimicrobial treatment.

CONCLUSION: Antimicrobial agents are commonly used at PHCs and UHCs. They are used empirically in majority of the cases. Trend to prescribe single AMA is common; however few patients were prescribed multiple AMAs. Irrational FDCs were prescribed only at UHCs. AMAs were used inappropriately especially choice and duration. However, route and dose were appropriate. Educational intervention improved choice as well as duration of antimicrobial use. Hence, proper diagnosis with the help of proper laboratory investigations and use of continuous medical education of the medical officer can lead to better and judicious use of AMAs.

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CONFLICT OF INTEREST: The authors have no conflict of interest.

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