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Observational Studies of Prescription Pattern and Use of Antibiotics in Selected Rural Areas

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Abstract
Rising antibiotic resistance amidst indiscriminate antibiotic use is a growing public health concern. Efforts to curb this trend have had limited success, particularly in developing nations. This study investigated antibiotic prescription patterns in India relative to the WHO's Aware, Watch, and Revise (AWaRe) antibiotic grouping framework. Data was collected from retail and hospital-affiliated pharmacy outlets. Without prescription, 64% of antibiotics sold at retail outlets and 48% at hospital pharmacies. Lack of awareness on appropriate antibiotic use was observed among patients and pharmacists. Over-the-counter antibiotic purchases were higher in underserved communities with less healthcare access. Increased education on proper antibiotic use and resistance is urgently needed. More regulated antibiotic sales and expanded access to affordable healthcare are needed to curb rising antibiotic resistance. Better antibiotic stewardship through improved prescription practices aligning with the WHO's AWaRe framework can help optimize antibiotic use and preserve effectiveness of existing drugs.

***Keywords**:* Antibiotics misuse, AWaRe, Resistance, Prescription, OTC, Hospital pharmacy.

1. Introduction
Antibiotic misuse, including overuse, underuse and inappropriate use, threatens public health by accelerating antibiotic resistance. About 50% of antibiotic prescriptions are estimated to be unnecessary, while many antibiotics are purchased over-the-counter without a prescription (Demoz et al., 2020). To optimize antibiotic use, the WHO developed the AWaRe antibiotic classification framework. "Assess" antibiotics are least likely to contribute to resistance and should remain widely available. "Watch" antibiotics require close monitoring due to higher resistance risks. "Reserve" antibiotics should only be used as last resort to treat resistant infections. In India, broad-spectrum antibiotic consumption is rising due to limited healthcare assess for underserved communities (Roberts & Zembower, 2021). Most of the people in rural areas obtain medications from pharmacies. To understand trends contributing to antibiotic misuse, this study examined prescription and purchase patterns through observational studies. Data was collected from hospital-affiliated and retail pharmacies. These findings provide insight into drivers of misuse and noncompliance with global stewardship guidelines. Improving prescription practices and aligning with the AWaRe framework could optimize antibiotic use and slow resistance (Morelli & Capurso, 2012). However, expanding healthcare assess and enhancing public education on appropriate antibiotic use are also critical to addressing this public health threat. This study sheds light on areas for targeted interventions to improve antibiotic stewardship and regulation in India. Optimizing antibiotic use now is essential to preserve the effectiveness of existing drugs.

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2. Methodology

2.1 Study location and design

This observational study was conducted in East Godavari district, Andhra Pradesh, India. Data on antibiotic prescriptions and purchasing patterns was collected from both hospital-affiliated pharmacies and retail pharmacies (Kim et al., 2013). Sampling was conducted without bias towards patients' age or gender. Data obtained from the different pharmacy settings was compiled and analyzed to examine prescription patterns, customer approaches to antibiotic purchases, and use of antibiotics without prescriptions (Tamuno & Fadare, 2012).

The data collection sites included:

• Hospital-affiliated pharmacies attached to 3 major hospitals in the district: Government General Hospital, Kakinada and 2 prominent private medical facilities. Data on prescriptions received by these pharmacies over a 1-month period was analyzed.

• 5 retail pharmacies located outside hospital premises across urban and semi-urban localities within the district. Data on over-the-counter antibiotic sales and customer inquiries over the same 1-month period was recorded and examined. Collected data was coded and entered into IBM SPSS v25 for statistical analysis (Willems et al., 2019). Frequency distributions and cross-tabulations were generated to summarize patterns of antibiotic prescriptions, prescription non-compliance, and non-prescription antibiotic purchases and use (Tamuno & Fadare, 2012).

2.2 Data collection and analysis

Data was collected on antibiotic prescriptions for inpatients and outpatients at hospital pharmacies, and over-the-counter antibiotic purchases at retail pharmacies. Data sources included:

• Patient medical records and prescription charts from hospital pharmacies
• Sales records and registers from retail pharmacies
• A standardized data collection form administered to pharmacy staff

When sales records were unavailable, pharmacy staff were interviewed face-to-face using the data form to obtain prescription and sales data for the study period. The research team also directly observed customer antibiotic purchases and inquiries at retail pharmacies to validate staff-reported data.

Data on the following variables was collected:

• Type of antibiotic prescribed or purchased
• Indicated medical condition
• Prescriber specialty (for physician-prescribed antibiotics)
• Pharmacy setting (hospital-affiliated or retail)
• Social status, comorbidities, and diagnostic test results were not considered in the analysis.

Data was reviewed for completeness and accuracy. Microsoft Excel was used for data management and descriptive statistical analysis. JMP Pro software performed contingency analysis. The antibiotics were also categorized according to the WHO AWaRe groupings (Assess, Watch, Reserve) to evaluate prescription and purchasing patterns relative to WHO recommendations (Demoz et al., 2020).

3. Results

3.1 Hospital pharmacy

For the purpose of this study, the term 'hospital pharmacy' will be employed to refer to retail pharmacy outlets attached to a hospital. A total of 171 antibiotics prescriptions were obtained for the duration of this study and analyzed accordingly. These medications include; Roxithromycin, rifampicin + Isoniazid, rifampicin, ofloxacin + ornidazole, ofloxacin, metronidazole, linezolid, isoniazid, ethionamide, ethambutol, erythromycin, doxycycline, clofazimine, clindamycin, clarithromycin, ciprofloxacin, cefuroxime axetil, cefpodoximeproxetil, cefixime + ofloxacin, cefixime, cefalexin, azithromycin, amoxicillin + clavulanate, amoxicillin. These were first categorized based on the gender of those receiving such medication. The distribution of antibiotic usage in male and female are shown in Figure 1.

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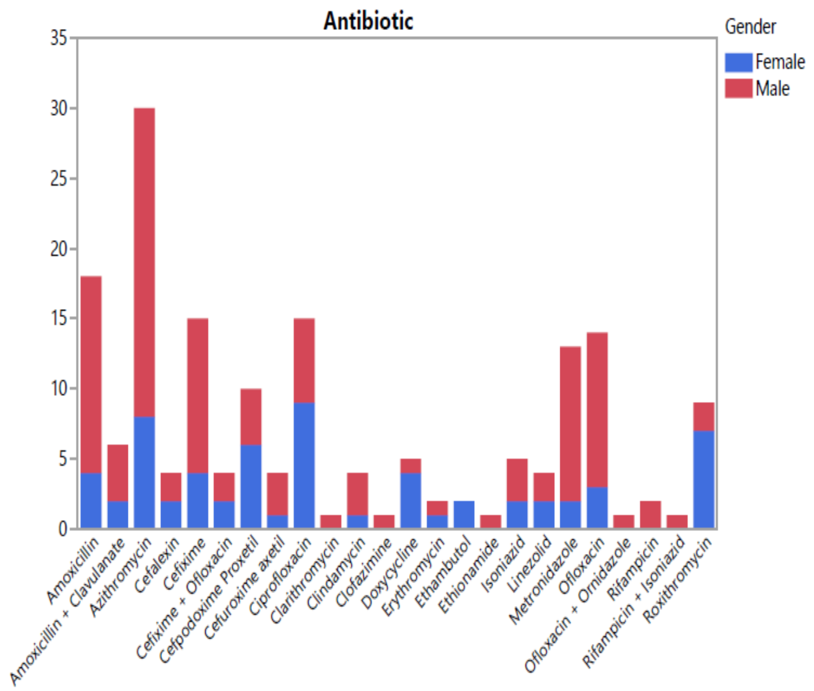

Figure 1: Gender ratio for Antibiotics prescribed

Data analysis for age by gender

A means for one-way anova of age by gender, showing the number of males and females who have purchased antibiotics within the study timeframe is shown in Table 1,2 and Figure 2.

Table 1: Analysis of variance for age by gender.

Source	**DF**	**Sum of Squares**	**mean square**	**F Ratio**	**Prob> F**
Gender	1	1499.608	1499.61	7.3284	0.0075
Error	169	34582.615	204.63		
C. Total	170	36082.222			

Table 2: Means for a one-way anova of age by gender.

Level	**Number**	**Mean**	**Std Error**	**Lower 95%**	**Upper 95%**
Female	62	38.3710	1.8167	34.785	41.957
Male	109	32.2110	1.3702	29.506	34.916

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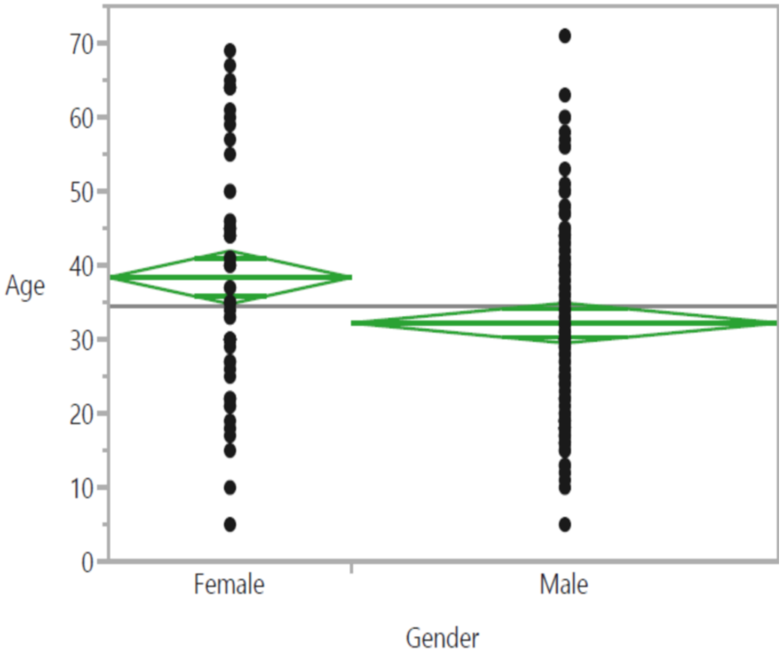

Figure 2: One-way ANOVA of age distribution by gender

Data analysis for age by purchase

This data analysis explains the relationship between the age of those who have used antibiotics within this period and their approach towards the purchase of antibiotic, i.e., if the purchased with a valid prescription or not. An analysis of variance for age by drug use approach is shown in Table 3, 4 and Figure 3. This shows the age distribution of those that have purchased antibiotics either with or without prescription.

Table 3: Analysis of variance for age by purchase

Source	DF	Sum of Squares	Mean Square	F Ratio	Prob> F
Prescription	1	1138.651	1138.65	5.5069	0.0201
Error	169	34943.571	206.77		
C. Total	170	36082.222			

Table 4: Means for a one-way anova of age by.

Level	Number	Mean	Std Error	Lower 95%	Upper 95%
No	82	31.7561	1.5879	28.621	34.891
Yes	89	36.9213	1.5242	33.912	39.930

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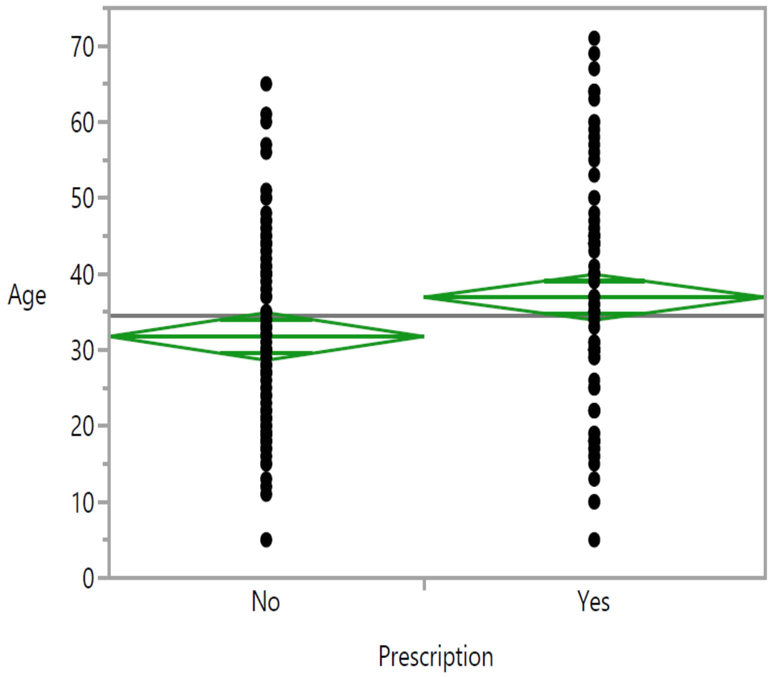

Figure 3: One-way ANOVA of age distribution by purchase approach

Data analysis of age by side effects

Considering the side-effects encountered, statistical analysis was performed to compare the age distribution with side-effects encountered during the studies. The analysis shows there are no significant differences in age distribution with side-effects seen during the study. For the mean calculation for the one-way anova, the number of side-effects seen is larger than those who didn't report any side-effects with a mean age of 34.974 years for those who reported a case of side-effect from the antibiotics used, and 33.327 years for those who didn't. The results are shown in Table 5, 6 and Figure 4. The contingency analysis of side effects by age is shown in Figure 5. Contingency analysis showed that the side effects encountered or reported among various age groups.

Table 5: One way ANOVA for age by side effects.

Source	**DF**	**Sum of Squares**	**Mean Square**	**F Ratio**	**Prob> F**
Side effects	1	101.191	101.191	0.4753	0.4915
Error	169	35981.032	212.906		
C. Total	170	36082.222			

Table 6: Means for a one-way ANOVA of age by side effects.

Level	**Number**	**Mean**	**Std Error**	**Lower 95%**	**Upper 95%**
No	55	33.3273	1.9675	29.443	37.211
Yes	116	34.9741	1.3548	32.300	37.649

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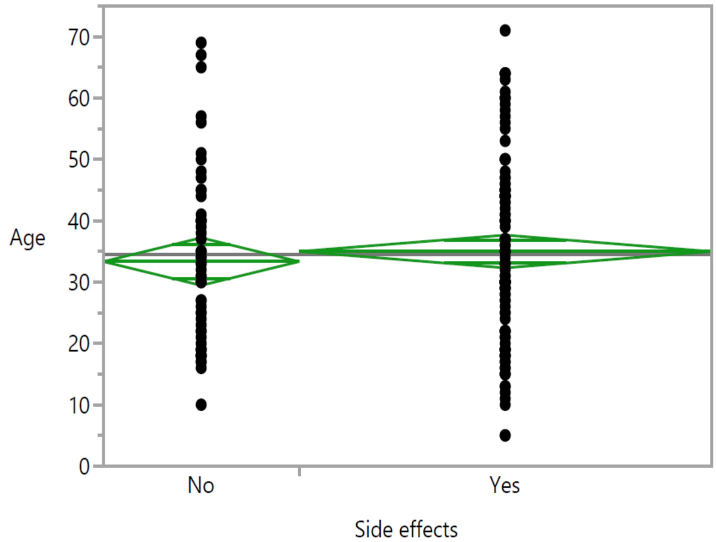

Figure 4: One-way analysis of age distribution by side-effect

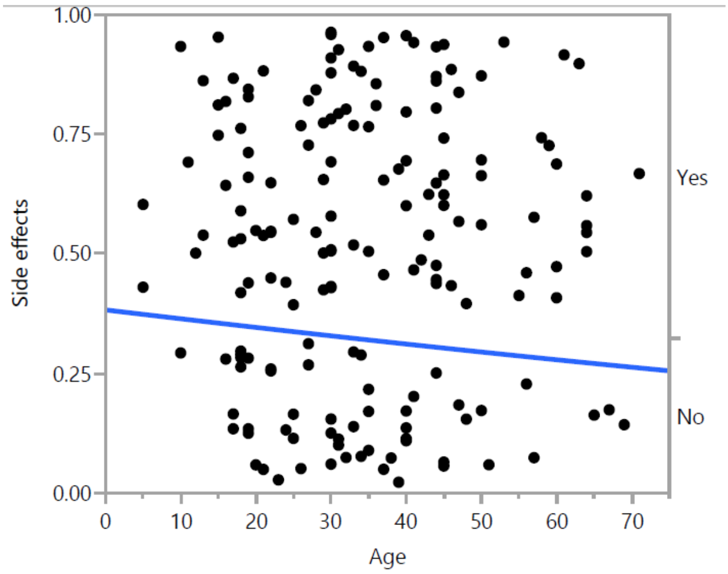

Figure 5: Contingency analysis of side effects by age.

Data analysis of side effects by gender

This was done to envisage the side effects encountered by both genders. The results are shown in Table 7

Table 7: Contingency analysis of side effects by gender

Gender	Side effects (No)	Side effects (Yes)	Total
Female	20	42	***62***
Male	35	74	***109***
Total	***55***	***116***	**171**

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3.2 Retail pharmacy outlets

For this study, the term "retail pharmacy outlet" will be employed to refer to pharmacy shops not attached to a hospital. Data collected from these shops were done separately to give a better perspective on general approach to purchasing antibiotics, especially in areas where hospitals aren't easily assessable, maybe due to distance or financial conditions (Cusini et al., 2010). For this, the focus of the observation was limited to oral dosage forms of the antibiotics. Figure 6 shows that the number of antibiotics sold without prescription is more than that sold with prescription.

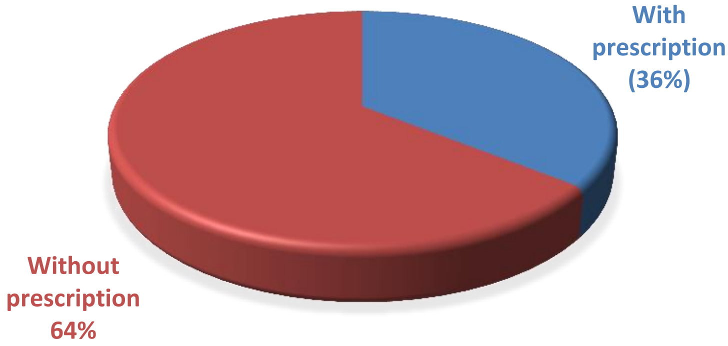

Figure 6: Antibiotics bought with and without prescription at retail pharmacy

Figure 7 compares the antibiotics purchasing approach from hospital pharmacies and other retail pharmacies not attached to a hospital shows a disparity in purchase or selling habits.

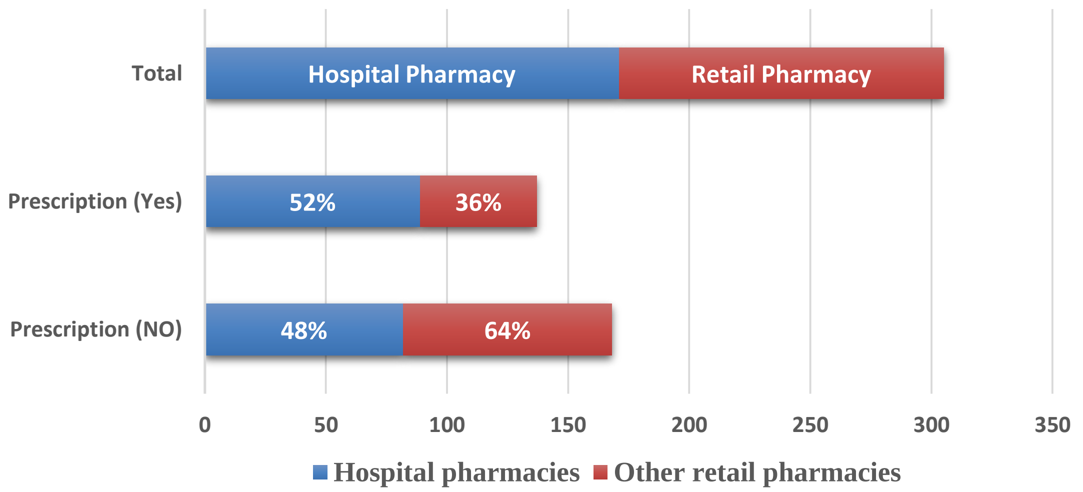

Figure 7: Data comparison from hospital pharmacies and retail pharmacy outlets

WHO published antibiotics categorization (assess, watch and reserve {AWaRe} groups).

The data obtained on antibiotics purchase from hospital pharmacies was compared to the WHO antibiotics (Kumar et al., 2009) grouping (AWaRe), and such showed that the watch group antibiotics were prescribed more (azithromycin, cefixime, cefpodoximeproxetil, cefpodoximeaxetil, ciprofloxacin, clarithromycin, erythromycin, ofloxacin, rifampicin and roxithromycin). This is followed by the assess groups (amoxicillin, amoxicillin clavulanate, cefalexin, clindamycin, doxycycline and metronidazole). Linezolid is classified under the reserve category. This categorization is shown in Figure 8.

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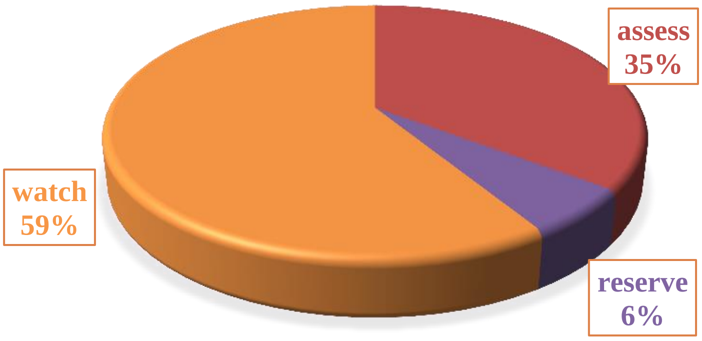

Figure 8: Percentage of Antibiotics in assess, watch and reserve groups from hospital pharmacies

The data from the retail pharmacy shops shows the watch group has more antibiotics (azithromycin, cefixime, ciprofloxacin, ofloxacin and roxithromycin) purchased by the customers. The assess group includes; amoxicillin, amoxicillin clavulanate and benzyl penicillin. Data is shown in Figure 9 No watch group was seen during this study.

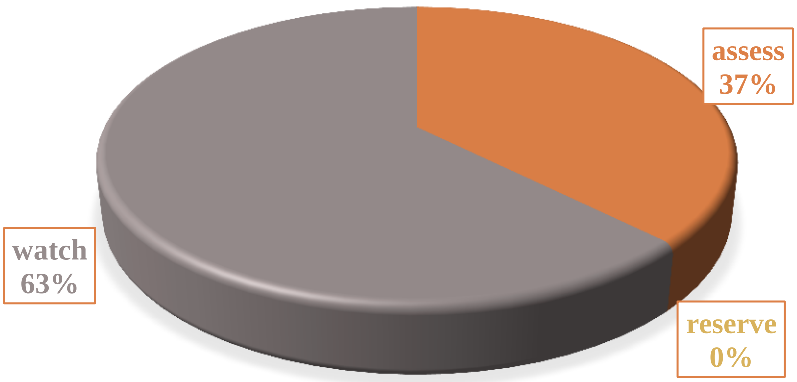

Figure 9: Percentage of Antibiotics in assess, watch and reserve groups from retail pharmacy outlets

4. Discussion

Over-the-counter antibiotic purchases without prescription were higher at retail pharmacies (64%) than hospital pharmacies (48%). Pharmacists reported selling antibiotics for non-indicated conditions like the common cold, contrary to guidelines. This indicates inappropriate antibiotic use (Bassetti et al., 2020). Many customers purchasing antibiotics, especially at small retail pharmacies, did not provide follow-up on treatment outcomes. A lack of therapeutic drug monitoring could obscure adverse drug reactions (Harbarth et al., 2003). Accessibility issues and financial constraints likely drive some non-prescription antibiotic purchases, especially in underserved communities. Long wait times at public hospitals may also contribute (Lee et al., 2012). Lack of awareness about antibiotic resistance, proper use, and prescribing guidelines was observed among patients, pharmacists and prescribers. Dependency on non-prescription antibiotics has increased in areas with limited healthcare access (McGregor et al., 2007). Of prescribed antibiotics, 35% at hospital pharmacies and 37% at retail pharmacies belonged to the WHO AWaRe "access" group, while 59% and 63% respectively were "watch" group antibiotics. Only hospital prescriptions included "reserve" group drugs (6%). Limited knowledge of the AWaRe classification was reported. In summary, interventions are needed to improve antibiotic stewardship and

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guideline compliance through increased public education, regulation of antibiotic sales, and expansion of affordable healthcare services (Uda et al., 2020). Better awareness of the AWaRe framework among prescribers and pharmacists could optimize antibiotic use (Valles et al., 2003).

5. Study Limitations

Limitations of this study include potential under-reporting of over-the-counter antibiotic sales and purchases due to recall and social desirability biases. The study also did not evaluate appropriateness of individual antibiotic prescriptions.

6. Conclusion

Many factors influence non-prescription antibiotic use, including limited healthcare access, costs and knowledge. Blaming any one party is insufficient. Antibiotic stewardship must be improved through public education campaigns to increase awareness of misuse risks among patients, healthcare providers and pharmacists. Expanded access to affordable healthcare and reduced wait times could also help by enabling prescribers to optimize antibiotic therapy. While encouraging appropriate prescribing, regulatory efforts are also needed to reduce over-the-counter antibiotic sales in pharmacies. Mandatory therapeutic drug monitoring and adverse drug reaction reporting could intercept problems early and improve public health outcomes. Close monitoring of patients on high-risk antibiotics is especially crucial. Together, these measures could optimize antibiotic use and slow antibiotic resistance - an urgent public health priority.

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A Brief Author Biography

Patrick Oliver Asogwa– I am an Assistant Professor in Aditya College of Pharmacy dedicated to pharmacological research, drug usage, toxicology, and pharmacokinetics.

Prakash Nathaniel Kumar Sarella – Associate Professor in Aditya College of Pharmacy and Pharmaceutical scientist with a passion for innovative drug delivery solutions. Over 6 years of experience in drug delivery research and development.

