

RESEARCH ARTICLE

Over-The-Counter Sales of Antibiotics at Community Pharmacies in Belize: A Cross-Sectional Simulated Client Visit study

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ABSTRACT

Aim: In Belize, antibiotics are categorized as prescription-only drugs, and their sales over the counter without a prescription is prohibited. This study assessed the sales and dispensing of antibiotics in community pharmacies without a prescription. **Methods:** 36 community pharmacies in 4 districts of Belize were assessed for non-prescription sales of antibiotics using a simulated client method (SCM) approach from September to November 2019. **Results:** The majority (19; 52.8%) of the community pharmacies assessed refused to sell antibiotics without a prescription from a physician. Approximately 17 (47.2%) sold and dispensed antibiotics to simulated clients (SCs) without a prescription. Adequate patient counseling was provided by the pharmacists to the SCs. **Conclusion:** Some level of lack of compliance with the sales of antibiotics without prescription was observed among community pharmacists in this study. There is a need to reinforce stricter control on the sales and dispensing of antibiotics without prescription in the country of Belize.

KEYWORDS: Antibiotics; Antibiotic Resistance; Dispensing; Simulated Client; Over the Counter; Prescription; Belize.

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INTRODUCTION

The Belize Antibiotic Act (revised edition 2000) prohibits the sales of antibiotics to any person except on the prescription of a medical practitioner, dentist, or veterinary surgeon. For a while, the enforcement of this law has been very challenging for the Belize Ministry of Health due to insufficient human and financial resources and logistics [1]. The result is the indiscriminate sale of antibiotics by licensed community pharmacy operators in the country, which has the potential for promoting antibiotic resistance. Antibiotics resistance is presently a major challenge to food security, the environment, and global health [2-5]. Rapidly emerging resistant bacteria such as *Acinetobacter*, *M. tuberculosis*, *S. pneumoniae*, *P. aeruginosa*, *K. pneumoniae*, *Escherichia coli*, etc., currently threaten some of the major benefits derived from antibiotics making therapy costly, while increasing the budget of already overburdened health care systems [6]. Resistance to antibiotics has made the treatment of diseases like gonorrhoea, pneumonia, and tuberculosis to become difficult because the antibiotics used in their treatment are becoming less effective [2,6]. In addition,

resistant bacteria have the tendency to increase long-term disability by increasing the duration of therapy, hospital stay, loss of productivity, and a burden to immediate family members and the community [6-7]. The center for Disease Control and Prevention (CDC) reported that at least 2.8 million people get an antibiotic-resistant infection, and more than 35,000 people die each year in the USA, making antibiotic resistance a major global health challenge [3].

A number of reasons have been reported as motives for the sales of antibiotics without prescription. Prominent are economic gain, meeting customer demands, and weak regulation or enforcement of antibiotic laws [6-8]. In the case of Belize, weak regulatory enforcement due to limited human and financial resources has been reported as major challenges for the enforcement of the Antibiotics acts [1]. Economic gain and the desire by the pharmacists to meet client demands may be some of the reasons why some community pharmacists continue to sell antibiotics without prescription, thereby contravening the law prohibiting such practices.

Antibiotics improve the quality of life by preventing or eliminating infections, while significantly decreasing the morbidity and mortality from infectious bacterial diseases [5-6]. Their crucial role in medicine and agriculture cannot be overemphasized [5]. Despite successes recorded with the use of antibiotics, indiscriminate use for medicine and agriculture has continuously caused a significant decline in their therapeutic efficacy resulting in a global crisis [2-3,5]. The problem of antibiotic resistance to public health, though global, could be more serious in low-income countries like Belize, where resources for healthcare are insufficient and challenging. In addition, the paucity of information on the determinant of antibiotic use among low-income countries has been reported to interfere with effective intervention methods in promoting prudent antibiotic use while decreasing the chances of bacterial resistance [8-9].

In Belize, the sales of antibiotics at partial doses and in the absence of prescription used to be a common practice, hence the concerted effort by the Ministry of Health (MOH) through its drug inspectorate unit to discourage the illegal practice. If the practice persists, it could add to the burden of antibiotic resistance leading to a decline in antibiotic effectiveness in the therapeutic management of infections in the country. Hence, the present study aims to assess the possible sales of over-the-counter (OTC) antibiotics by community pharmacists without prescription. The study results will provide evidence of the effectiveness of the drug inspectorate units' effort to restrict the sales of antibiotics without prescription and to provide the need to develop further strategies to implement prudent sales of antibiotics by the community pharmacists. In addition, the findings of the study will guide the general public in the judicious use of antibiotics for the treatment of infections.

MATERIALS AND METHODS

The study design utilized a simulated client method (SCM) approach [10-11]. The community pharmacies surveyed were systematically selected from four districts in the country of Belize. For each selected district, the planned sample size was assumed as 15 to 35% of the total number of community pharmacies in the district based on the number of pharmacies located in the district, as obtained from the Ministry of Health. In each city or town where data were collected, the Simulated Clients (SCs) started from a most central area of the city or town randomly move in four distinct cardinal points to select participating pharmacies. A total of 40 community pharmacies were visited from September to November 2019. Data were obtained from 36 pharmacies giving a visit rate of 90%.

Procedure

The SCM approach has been used for years as a valid measure for data collection in healthcare research where it is difficult or challenging to access such data using other methods [12]. In this regard, it will be challenging to access antibiotic sales without using the SMC approach, hence the choice of the methodology. Stimulated clients (SCs) were recruited from 3rd-year pharmacy students enrolled in the Pharmaceutical Microbiology course for 2019 semester 1 at the University of Belize. The mean age of the students was 22.33 ± 2.27 , comprised of 12 females and three males.

A training was conducted for all SCs to play the role of undercover healthcare seeker by presenting pre-set fictitious scenarios to the pharmacist as a regular customer indistinguishable from other genuine clients. The SCs were paired for data collection, and each presented three different clinical scenarios as presented in a predetermined transcript described below. Each SC was trained to present the same scenario in any of the visited community pharmacies. The transcript was made up of a standardized pharmacy visiting process described by Chang et al. (2017) [10].

The participation of students SCs was part of their experiential learning experiencing in pharmaceutical research. In addition, their participation earned them a graded credit as part of the pharmaceutical microbiology course for the semester. Training sessions with the SCs included sufficient instructions and practice with the students to standardize the data collection procedure. Rehearsals and practices formed part of the quality control process to ensure standardization among SCs. The lack of disclosure of study participants and the simulated client method used in this study made the study ethically acceptable and with no risk to study participants. Throughout the study, emphasis on confidentiality was explained and reinforced to the SCs. Regular communication was maintained, and review sessions were held weekly to address challenges. Collected data were kept confidential and anonymous in the entire study.

Simulation Scenarios for Data Collection

A cross-sectional simulated client visit was made to community pharmacies in 4 districts of Belize. Three stages of the simulation were presented at each community pharmacy store to obtain an antibiotic without a prescription. Three clinical scenarios of the urinary tract, respiratory tract, and gastrointestinal tract were presented by trained SCs.

Stage 1. Asking for something to relieve symptoms (presenting a clinical scenario)

In each of the pharmacy stores, clinical scenarios were presented by the SCs. The first step was to ask the pharmacist for some medication to relieve the symptom presented. Three different clinical scenarios were used to attempt to purchase an antibiotic from the community pharmacies. These included a urinary tract infection (UTI) presented as difficulty and burning sensation on urination. Respiratory (Resp) tract infection was presented as pain in the throat with cough and difficulty breathing, while symptoms of a gastrointestinal tract infection (GIT) were presented as loose bowel with 4-5 episodes of diarrhea and slight fever.

Stage 2: Ask directly to be given an antibiotic (general demand for an antibiotic)

If at stage 1 the pharmacist does not dispense an antibiotic but other medications the SC will make a direct demand for an antibiotic.

Stage 3: Direct/Specific Demand for Antibiotics.

If the above 2 stages are not entertained, then the SC directly asks for a named antibiotic (for example, ciprofloxacin, amoxicillin, metronidazole, etc.). If the antibiotic was refused, the reason for refusal was requested. The sale, refusal, and reasons for refusal were memorized by the SC and later recorded. If the pharmacist agrees to sell the antibiotic, the SC notes the type of antibiotic and asks further questions to see if

patient counseling is provided. The SCs then give some excuse as to why they are not able to purchase the antibiotic and exit the pharmacy. As soon as the SCs exit the pharmacy, they complete a standard site visit summary form within 10 minutes. The form consists of pharmacy site information, whether the antibiotic was dispensed or not, and if patient counseling was given.

Data Analysis

Data were compiled, coded, and entered into Statistical Package for Social Sciences (SPSS) version 22 software. Analyzed data were presented as descriptive statistics using frequencies and percentages.

Ethics

The study protocol and students' involvement were part of the strategies for the future review of the bachelors of pharmacy degree program currently being implemented at the University of Belize. The Faculty of Health, University of Belize approved the study protocol as part of the faculty work plan for 2019. The study upheld the principles of the World Medical Association Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects", as amended in October 2013 [13].

RESULTS

The study was conducted in 36 community pharmacy stores in four districts in the country of Belize comprised of (16; 44.4%) from Belize district, (13; 36.1%) from Orange Walk district, (6; 16.7%) from Cayo district, and (1; 2.8%) from Corozal district. The majority (35; 97.2%) of the community pharmacies visited had a licensed registered pharmacist on duty. Antibiotics were obtained from community pharmacies (17; 47.2%), while the majority (19; 52.8%) of the community pharmacists refused to dispense antibiotics to SCs, demanding a prescription from a certified physician. A total of 86 interactions were observed in this study.

The majority of the community pharmacists that dispensed antibiotics made additional inquiries to SCs before the antibiotic was dispensed (Table 1).

The majority of the community pharmacists that dispensed antibiotics without a prescription provided patient counseling (Table 2).

Metronidazole (60%) was the main antibiotic sold over the counter for GIT scenarios (Table 3). Amoxicillin was dispensed for both UTI (33.3%) and respiratory tract scenarios (33.3%).

Table 1. Pharmacist Additional Inquiry to SCs.

Pharmacist inquiry	Simulated clinical scenarios (n=17)		
	UTI (n=6)	Resp (n=6)	GIT (n=5)
Asked further symptoms	6 (100%)	6 (100%)	5 (100%)
Prior medication allergy	4 (66.7%)	6 (100%)	5 (100%)
Concomitant use of medications	3 (50%)	4 (66.7%)	4 (80%)
Pregnancy status for female SCs	5 (83.3)	0 (0%)	0 (0%)
Additional inquiry	2 (33.3%)	5 (83.3%)	1 (20%)

Table 2. Patient Counseling to SC's in the Event the Antibiotic Was Dispensed.

Pharmacist counseling	Simulated clinical scenarios (n=17)		
	UTI (n=6)	Resp (n=6)	GIT (n=5)
Explained how to take antibiotic	6 (100%)	6 (100%)	5 (100%)
Explained duration of therapy	6 (100%)	6 (100%)	5 (100%)
Explained side effects	6 (100%)	5 (83.3%)	5 (100%)
Provided no counselling on dispensed antibiotics	0 (0%)	0 (0%)	0 (0%)

Table 3. Antibiotics Dispensed Without Prescription.

Antibiotics dispensed	Clinical scenarios presented and the percentage of community pharmacies dispensing (n=17)		
	UTI (n=6)	Resp (n=6)	GIT (n=5)
Amoxicillin	2 (33.3%)	2 (33.3%)	0 (0%)
Ampicillin	0 (0%)	1 (16.7%)	0 (0%)
Azithromycin	1 (16.7%)	2 (33.3%)	0 (0%)
Ciprofloxacin	2 (33.3%)	1 (16.7%)	1 (20%)
Tetracycline	1 (16.7%)	0 (0%)	1 (20%)
Metronidazole	0 (0%)	0 (0%)	3 (60%)

DISCUSSION

The results obtained from our study revealed that the majority (52.8%) of the pharmaceutical stores visited refused to dispense antibiotics to SCs without a prescription. The number of pharmaceutical stores that dispensed antibiotics in this study is still considered significant and hence, capable of causing antibiotics wastages, adverse reactions, and resistance [14].

Economic gain, meeting customer demands, and weak regulation or enforcement of antibiotic laws have been reported as reasons for non-prescription antibiotic sale and dispensing [6-8]. The results of this study resonate with previous studies conducted in other countries, where

dispensing antibiotics without prescription was found to be a common practice [15-17]. Furthermore, the level of antibiotics sold as observed in this study demonstrates notable progress by Belize's Ministry of Health efforts to restrict the sales of antibiotics without a prescription. The results of the study, therefore, provide useful information for a better approach in the enforcement of regulations for OTC sale of antibiotics without prescription in the country of Belize.

The majority of the antibiotics obtained from the community pharmacies were from a direct demand rather than presenting an infectious scenario. Metronidazole (60%) was the main antibiotic sold over the counter for

GIT scenarios (Table 3). Amoxicillin was dispensed for both UTI (33.3%) and respiratory tract scenarios (33.3%). Furthermore, the majority of the community pharmacists that dispensed antibiotics made additional inquiries to SCs before the antibiotic was dispensed (Table 1), in addition, the majority of the community pharmacist that dispensed antibiotics without a prescription provided patient counseling (Table 2). The desire for pharmacists and other healthcare professionals to satisfy their customers' health demands by supplying antibiotics while striving to remain in business has been reported [18-19]. However, the need to meet patients' demands and make sales to stay in business must be balanced by appropriate professionalism as well as a legal and ethical responsibility. For instance, in the case of antibiotics, the desire to meet patient's demands for antibiotics could result in antibiotic resistance, this, in turn, will lead to an extra cost to the client if they are to purchase more expensive broad-spectrum antibiotics, inclusive of additional hospitalization for antibiotic failures and further prescriptions. The rational use of antibiotics, therefore, becomes necessary for public health in the community because of the apparent scarcity in the development of newer antibiotics and the increase in the rise of antibiotic resistance [20-22].

In Belize, the field of pharmacy is still developing and may require some time to become comparable to that of developed nations. Despite this, the quality of the services provided to the SCs in this study was excellent and of high standards. The majority of the pharmacists made further inquiries about SCs symptoms, medication allergy, concomitant use of medications, and pregnancy status for female clients (Table 1). In addition, the pharmacists' skills were demonstrated in the provision of adequate patient counseling as evidenced by the majority refusing to dispense antibiotics without a prescription, explaining to the SCs how to take an antibiotic, duration of therapy, and side effects (Table 2). The role of pharmacists in promoting community pharmaceutical care and improved public healthcare services has been well documented [23-24]. As health care professionals, pharmacists have both legal and ethical responsibilities to provide safe and effective pharmaceutical services. Due to their strategic accessibility to the people in the community, pharmacists play a key role in reducing the incidence of antibiotic resistance, improving public health, and promoting the rational use of antibiotics [25]. In fulfilling this role, and in addition to the legal requirements for the sale of antibiotics, pharmacists have an ethical responsibility to ensure the appropriate sale and dispensing of antibiotics, knowing that inappropriate use contributes significantly to the larger problem of resistance. The World Health Organization [26] has

emphasized the improvement of the role of pharmacists as the main regulator and supplier of antibiotics. To this end, therefore, even though the client consultation and counseling provided by the pharmacists in this study is worthy of note yet, professionalism, legal, and ethical standards were not upheld in the sale of antibiotics without prescription. The opportunity to educate clients on the proper use of antibiotics would see the pharmacists providing service that is in the clients' best interest, rather than simply satisfying the demands. In Belize, pharmacists are often the first point of contact for patients in need of healthcare because of their ease of accessibility. Therefore, transforming the attitudes and knowledge of the public in regards to antibiotics and antibiotic resistance is the responsibility of the community pharmacists [25,27-28].

CONCLUSION

This study is limited to pharmaceutical stores in 4 districts and as such does not represent the entire country of Belize. The findings point to the need for additional attention to be given to the sale of antibiotics in community pharmacies in Belize. Among the facilities visited, no causal relationships regarding antibiotic dispensing were made since information regarding store owners and other characteristics were not obtained. There is a need to plan effective intervention strategies between community pharmacists, the general public, and the Ministry of Health to curb antibiotics' sale without a prescription. Robust nationwide mystery client studies should be part of monitoring the impact of MOH drug regulatory impact.

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AUTHORS' CONTRIBUTIONS

The participation of each author corresponds to the criteria of authorship and contributorship emphasized in the [Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals of the International Committee of Medical Journal Editors](#). Indeed, all the authors have actively participated in the redaction, the revision of the manuscript, and provided approval for this final revised version.

COMPETING INTERESTS

The authors declare no competing interests with this study.

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