

Fall 12-2019

**ACCESS TO ANTIBIOTICS WITHOUT PRESCRIPTION FOR
TRAVELERS AND COLOMBIAN CITIZENS AT COMMUNITY
PHARMACIES IN BOGOTA, COLOMBIA**

MARIE KASBAUM

Follow this and additional works at: https://digitalcommons.library.tmc.edu/uthsph_dissertsopen



Part of the [Community Psychology Commons](#), [Health Psychology Commons](#), and the [Public Health Commons](#)

ACCESS TO ANTIBIOTICS WITHOUT PRESCRIPTION FOR TRAVELERS AND
COLOMBIAN CITIZENS AT COMMUNITY PHARMACIES
IN BOGOTÁ, COLOMBIA

by

MARIE KASBAUM, BS

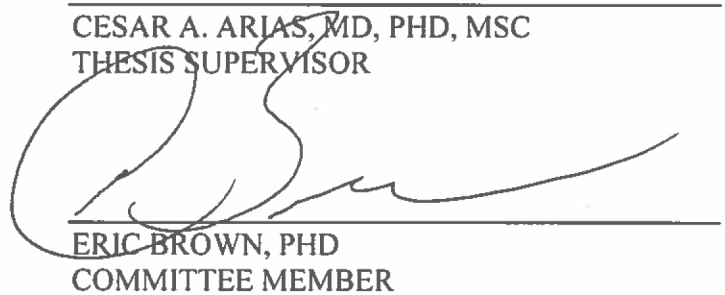
APPROVED:



SUSAN TORTOLERO EMERY, PHD
ACADEMIC ADVISOR



CESAR A. ARIAS, MD, PHD, MSC
THESIS SUPERVISOR



ERIC BROWN, PHD
COMMITTEE MEMBER

Copyright
by
Marie Kasbaum, BS, MPH
2019

ACCESS TO ANTIBIOTICS WITHOUT PRESCRIPTION FOR TRAVELERS AND
COLOMBIAN CITIZENS AT COMMUNITY PHARMACIES
IN BOGOTÁ, COLOMBIA

by

MARIE KASBAUM
BACHELOR OF SCIENCE, TEXAS A&M UNIVERSITY, 2016

Presented to the Faculty of The University of Texas

School of Public Health

in Partial Fulfillment

of the Requirements

for the Degree of

MASTER OF PUBLIC HEALTH

THE UNIVERSITY OF TEXAS
SCHOOL OF PUBLIC HEALTH
Houston, Texas
December, 2019

ACCESS TO ANTIBIOTICS WITHOUT PRESCRIPTION FOR TRAVELERS AND
COLOMBIAN CITIZENS AT COMMUNITY PHARMACIES
IN BOGOTÁ, COLOMBIA

Marie Kasbaum, MPH Candidate, BS
The University of Texas
School of Public Health, 2019

Thesis Chair: Cesar Arias, MD, MSc, PhD

The misuse of antibiotics has been shown to exacerbate the global antibiotic resistance crisis, which could have major consequences on public health worldwide (Auta et al., 2018). In Bogotá, Colombia, the non-prescription sale of antibiotics still occurs in pharmacies despite national regulations requiring a prescription from a physician or health agency before dispensing antibiotics to a patient (Vacca et al., 2011). The purpose of this study was to investigate the non-prescription sale of antibiotics in community pharmacies to foreign travelers and Colombian citizens in Bogotá, Colombia. Trained Simulated Clients (SCs) gathered experimental data in pharmacies distributed throughout 20 geographic districts within Bogotá to investigate an association between a pharmacy customer's Colombian citizenship status and their likelihood of being offered antibiotics without a prescription. Two groups of simulated clients (SCs) separately conducted trials at each pharmacy included in the study sample (N=94); one SC group was made up of foreign U.S. travelers, and the other SC group was a comparison group of Colombian citizens who are

native to Bogotá. In these trials, the SCs followed a standardized script and acted as though they were seeking medication from pharmacy vendors for a friend with traveler's diarrhea (TD). Antibiotics were offered to US travelers and to the Colombian group in 62 (68.13%) and 60 (65.96%) pharmacies, respectively. The traveler group was significantly more likely than the Colombian comparator group to be offered antibiotics without any prompting ($p < 0.05$). When pharmacy employees refused to sell antibiotics, the traveler group was significantly more likely to be given a clinical reason not to receive antibiotics. Refusal to Colombian citizens was more frequently due legal reasons ($p < 0.05$). This study provides insight on the non-prescription sale of antibiotics in Colombian pharmacies. The data can be used for future policy and antimicrobial stewardship interventions in Latin American countries to combat the misuse of antibiotics.

TABLE OF CONTENTS

List of Tables	i
List of Figures	i
Background	1
The Global AMR Crisis	1
Antibiotic Resistance in a Colombian Context	1
Travel Medicine and Antimicrobial Resistance	3
The Simulated Client Method	4
Public Health Significance	5
Community Partnership	6
Study Objectives	6
Hypothesis	7
Methods	7
Study Design	7
Study Subjects	10
Study Setting and Sample Selection	10
Data Analysis	11
Human Subjects and Privacy Considerations	11
Safety Considerations	12
Results	13
Discussion	19
References	24
Attachments	31
Data Collection Form	31
Trial Administrator Script	38

LIST OF TABLES

Table 1: Simulated Client (SC) Trial Outcomes in Sampled Community Pharmacies (N=94) in Bogotá, Colombia (2018).....	13
Table 2: Comparison of access to antibiotics without prescription between US Travelers and Colombian Citizens in community pharmacies (N=94) in Bogotá, Colombia (2018).....	15
Table 3: Medications offered to Simulated Clients (SCs) without prescription in community pharmacies in Bogotá, Colombia (2018).....	16
Table 4: Pharmacy responses to Simulated Clients (SCs) seeking antibiotics without prescription in community pharmacies in Bogotá, Colombia, stratified by the socioeconomic status (SES) of the pharmacy community (2018).....	17
Table 5: Questions Asked by Pharmacy Employees Before Giving Medical Recommendations to Simulated Clients Seeking Antibiotics Without Prescription in Bogotá, Colombia (2018).....	19

LIST OF FIGURES

Figure 1: Simulated Client (SC) Procedures During Pharmacy Visits.....	8
--	---

BACKGROUND

The Global Antimicrobial Resistance Crisis

The rise of antimicrobial resistance (AMR) in infectious pathogens is a public health crisis, with the potential for devastating global consequences (Michael, Dominey-Howes, & Labbate, 2014). The selection pressure of antibiotics to human bacteria is associated with the emergence of multidrug-resistant strains of pathogens (Laxminarayan et al., 2013). As pathogens develop resistance, the efficacy of antimicrobial drugs decreases markedly reducing the ability to treat human infections. If multi-resistant microbes continue to rise, the potential effects on human health globally could be devastating, healthcare costs will increase, and medical practices such as surgery and administration of chemotherapy would become extremely challenging for vulnerable patients (Laxminarayan et al., 2013). Recent data suggest that by the year 2050, AMR is projected to cause about 10 million deaths annually, killing roughly 1.8 million more people per year than the total number of deaths caused by cancer (O'Neill, 2014).

Antibiotic Resistance in the Colombian Context

Colombia is a “hot-bed” for emergence of antimicrobial-resistant organisms, reporting one of the highest rates of resistance in the region among common hospital-associated pathogens (Arias et al., 2003; Rojas et al., 2017). In 2017, Rojas et al. published a study suggesting that the mechanisms of spread of a major multi-drug resistant pathogen (*Klebsiella pneumoniae* producing carbapenemases) was “the perfect storm.” Indeed, the collaborative network of researchers in this study discovered the nearly simultaneous emergence of two evolutionary mechanisms in multidrug-resistant *K. pneumoniae* bacteria in

Colombian hospitals, *1*) a horizontal transfer of a carbapenemase-producing bacterial gene (which confers resistance against the carbapenems, the previously most efficacious class of drugs against these organisms), and *2*) spread of single genetic lineage (bacterial clone) disseminating across hospitals. These mechanisms set the stage for the rapid dissemination of multi-drug resistant bacteria and caused hyperendemicity due to the strained healthcare infrastructure of this developing country (Rojas et al., 2017).

The adherence to antibiotic prescribing guidelines in Colombian hospitals has also been investigated (Feinstein et al., 2017). However, outside of the hospitals, monitoring of pharmacy adherence to regulations on antibiotic sales is limited or non-existent (Wirtz et al., 2013). The pressing need for AMR education of pharmacy employees in Bogotá is evident. Community pharmacies in Colombia often are run by employees with little or no formal pharmacy education, and they regularly dispense medications to patients without a trained pharmacist even being on-site (Vacca et al., 2005). A 2005 study in Bogotá that focused on the knowledge and skills of pharmacists and non-professional pharmacy employees, found that two-thirds of employees dispensing medication had completed only secondary-level education, and more than half of dispensed medication was inappropriate for the clinical simulation (Vacca et al., 2005). A 2011 study found that more than 80 percent of all community pharmacies in Bogotá did not follow established regulations for sale of antibiotics with prescription (Vacca et al., 2011).

Antimicrobial resistance is often found in communities where it is common practice for pharmacies to sell antibiotics and other antimicrobial drugs to people without a prescription from a licensed healthcare professional (Morgan, Okeke, Laxminarayan,

Perencevich, & Weisenberg, 2011). This phenomenon is widespread throughout Latin America, and it is stimulated by a lack of regulations restricting the sale of antibiotics without prescriptions, or by very poor enforcement of such regulations (Wirtz et al., 2013). In 2005, Colombia first implemented laws to prohibit over-the-counter sales of antibiotics without prescriptions, but this policy only applied to the capital city of Bogotá (Santa-Ana-Tellez, Mantel-Teeuwisse, Dreser, Leufkens, & Wirtz, 2013). Despite these regulations, the absence of policy enforcement has allowed the non-prescription sale of antibiotics to continue in community pharmacies located in Bogotá, Colombia (Vacca et al., 2011). Due to the fact that about 80% of antibiotics worldwide are used in community settings, an understanding of dispensing practices in the community is urgently needed (Auta et al., 2018).

Travel Medicine and Antimicrobial Resistance

Rapid dissemination of multidrug-resistant bacteria that spreads throughout the globe by international travelers has made antimicrobial resistance a critical topic in the field of Travel Medicine (Bowers et al., 2015). This field studies the health of international travelers who may contract diseases not endemic to their home country, and also considers the public health impact that travelers can have on the communities within the destination country (Hill et al., 2006). Traveler's diarrhea (TD) is the most common disease contracted by international travelers worldwide, and is often treated with antibiotics (Hill et al., 2006). However, a growing body of evidence suggests that prescribing antibiotics for TD should be avoided when the presentation of disease is mild, because TD is usually self-limiting and because the unnecessary use of antibiotics exacerbates concerns about emergence of multi-

drug-resistant (MDR) pathogens developing in travelers who self-treat for TD with antibiotics (DuPont & Steffen, 2016). Studies have shown that acquisition of AMR microbes in the flora of international travelers is a growing threat to both the local communities they are visiting, and to their country of origin after returning home (Riddle & Connor, 2017).

Due to the Colombia's increasing political stability and growing travel infrastructure, tourism in Colombia is growing exponentially, with Bogotá receiving the majority of foreign visitors in the country (República de Colombia, 2018). A recent report from the U.S. Department of Commerce revealed that within just one year from 2016 to 2017, the annual number of international tourists traveling to Colombia increased by 24% (U.S. Department of Commerce, 2018). The stage has been set for outbreaks of resistant bacterial strains in Colombia, due to the rapid increase of foreign travelers to the city of Bogotá, the lack of oversight on the antibiotic selling practices in Colombian pharmacies, and the remarkable ability of resistant pathogens to acquire determinants of antibiotic resistance.

The Simulated Client Method

The Simulated Client Method (SCM) is an effective tool to observe and assess the behaviors of healthcare personnel in a natural setting. This method involves the use of simulated clients (who are often also referred to as pseudo-patients, covert clients, or simulated patients), who follow a standardized script when interacting with providers in a normal healthcare setting. During these interactions, the healthcare providers are unaware that they are being monitored by the simulated client (SC), which allows the observation of the providers' actual responses (Xu, Neto, & Moles, 2012). The SCM has often been used in

studies to assess the behaviors of community pharmacy employees when presented with requests for regulated medications without prescription (Auta et al., 2018).

Public Health Significance

As mentioned above, dispensing antibiotics without a prescription or without oversight by healthcare professionals poses a global public health threat due to the impact of these drugs in our microbiome. In 2015, the World Health Organization established an action plan to combat antimicrobial resistance for the Americas including improved education and training, increased surveillance, and a focus on prevention (World Health Organization, 2015). There is a notable lack of studies investigating the accessibility of antibiotics to foreign travelers without prescriptions in Colombian pharmacies. The current study will address this gap in scientific literature by investigating and comparing the access to antibiotics without prescriptions for travelers and Colombian citizens in community pharmacies in Bogotá. Identifying factors associated with antibiotic misuse has the potential to provide insight on what interventions, campaigns, or policies could be most effective to combat antimicrobial resistance. In order to create effective solutions for the global AMR crisis, policy makers need clear information on the public health consequences of this topic (Laxminarayan et al., 2013).

In an increasingly globalized world, it is important to understand the effect that foreign travelers may have on public health. This is the first simulated client study to compare the access to non-prescription antibiotic sales in community pharmacies between foreign travelers and local citizens in any country. The results of this study will potentially

give insight for the development of effective public health initiatives encouraging antibiotic stewardship in Latin American countries such as Colombia, and other developing countries.

Community Partnership

The current study was intentionally designed using community participatory-based research principles and has a great deal of community buy-in. We are collaborating with a local academic institution in Colombia (Universidad El Bosque, The International Center for Microbial Genomics), with local physicians and public health professionals based in Bogotá (Alejandro de la Hoz, M.D., and Alejandro Gomez, DrPH, MPH, PhD), and with experts in the field of antibiotic resistance research who are native to the region (Dr. Cesar A. Arias, M.D., PhD, and Jinnethe Reyes, PhD). We have consulted extensively with our Colombian colleagues to ensure this study is culturally appropriate and relevant to the public health needs of Bogotá, Colombia.

Study Objectives

The primary objective of this study was to investigate how the access to antibiotics without a prescription in chain pharmacies within Bogotá, Colombia differed by a pharmacy customer's nationality, specifically comparing local residents of Bogotá and foreign travelers from the United States. Secondary objectives of this study were to analyze differences in the levels of prompting that SCs needed to give pharmacy personnel before being offered antibiotics. Additionally, the study sought to assess the reasons for refusal to offer antibiotics without prescription given to the SCs by the pharmacy employees, and to describe the quality of interactions between pharmacy employees and clients.

Hypothesis

We postulated that offers to sell antibiotics without a prescription in major chain pharmacies of Bogotá occur at a higher rate for customers who are foreign visitors compared to customers who are native Colombians.

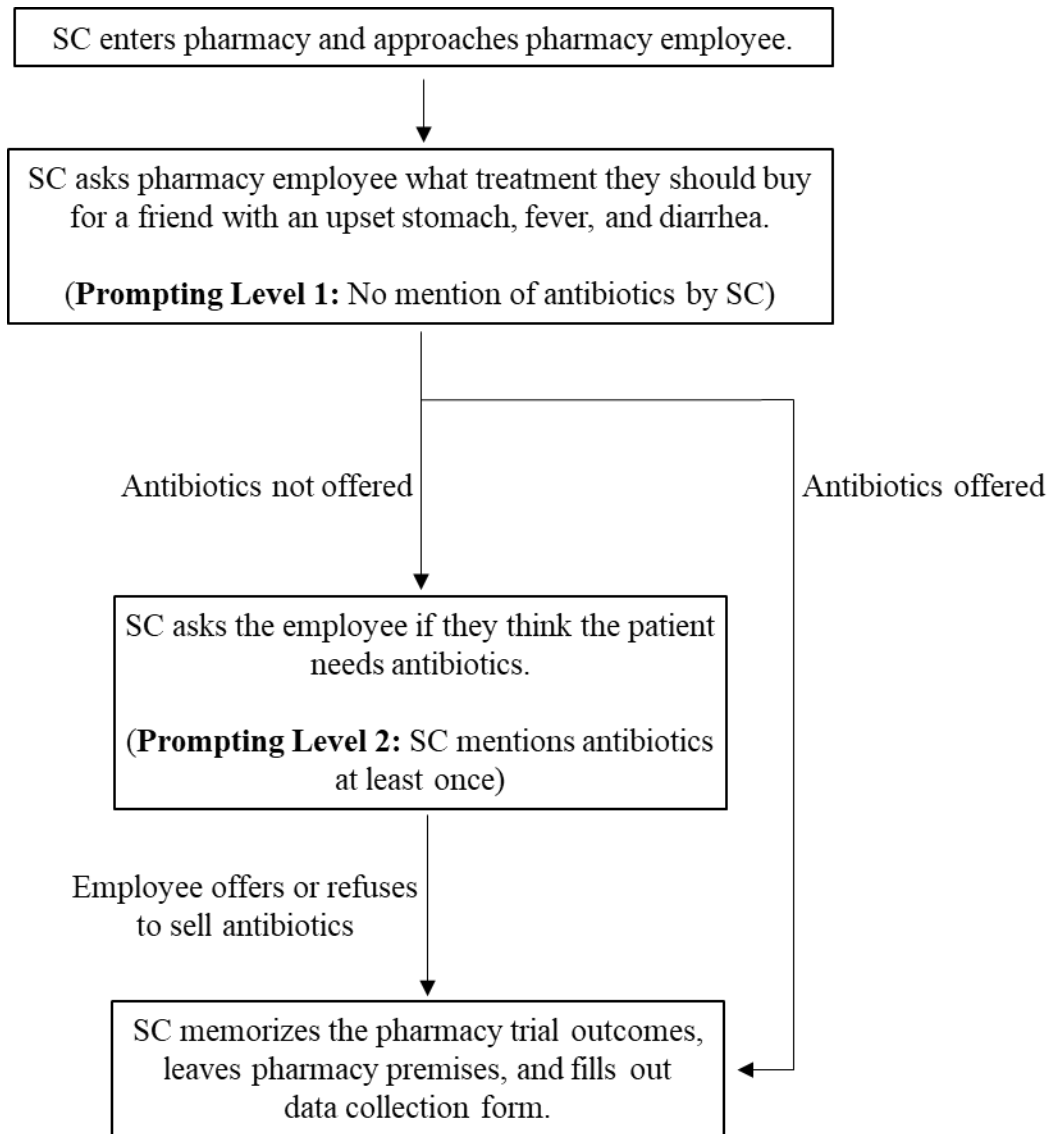
METHODS

Study Design

This cross-sectional study compares the access to antibiotics without prescription in Colombian community pharmacies between travelers from the US and local citizens from Bogotá, Colombia. Within the timeframe of July 2018 through September 2018, a group of simulated clients (SCs) from the US and a comparison group of SCs from Colombia separately visited each community pharmacy included in the study sample (N=94). During each pharmacy trial, both SC groups followed a standardized script (full script included on page 38 of this document) to present pharmacy vendors with a patient case displaying common symptoms of traveler's diarrhea (TD), and then observed the nature of the consequent medical consultation with the pharmacy employee. Pharmacy personnel were unaware they were being observed, in order to observe the most natural responses to the scenario as possible. All interactions with pharmacy personnel by both SC groups were conducted in Spanish, and no medication was purchased during any of the trials. After conducting the trial outlined in the script and observing the responses of the pharmacy employees, the SCs moved off the property of the pharmacy and recorded their observations

in the data collection form (included on page 31 of this document) within 10 minutes of leaving the trial site.

Figure 1: Simulated Client (SC) Procedures During Pharmacy Visits



The primary outcome assessed in this study was comparing the overall rates at which pharmacies offered antibiotics to the SCs belonging to the US traveler group and the SCs belonging to the Colombian comparison group. These data were then stratified into five

separate categories, operationalized as follows: *1*) the employee refused to sell antibiotics for legal reasons (meaning the employee cited the national Colombian policies restricting the non-prescription sale of antibiotics as their reason for not dispensing antibiotics), *2*) the employee refused to sell antibiotics for clinical reasons (meaning the employee believed antibiotics were not the best course of treatment for the patient), *3*) the employee cited both legal and clinical reasons when refusing to sell antibiotics without prescription, *4*) the employee offered to sell the SCs antibiotics with no prompting (meaning the SCs did not prompt the employee by mentioning antibiotics at all), and *5*) the employee offered to sell the SCs antibiotics with some prompting (meaning the SCs mentioned antibiotics one or more times before the employee offered to sell antibiotics).

Data were also gathered on the type of antimicrobial medications that were offered to the SCs without prescription, the socioeconomic status (SES) of each pharmacy's community, the locality (geographic district within Bogotá) of each pharmacy, and any questions the pharmacy employees asked the SCs before making their diagnosis and offering treatments. Colombia has an urban socio-economic stratification system for tax and utilities purposes, which designates areas by SES on a scale from 1 to 6, where Strata 1 represents the lowest income communities and Strata 6 represents the highest income communities. People living in Strata 0 or "unstratified" communities are usually considered to be homeless (Giménez-Santana, Caplan, & Drawve, 2018). In this study, low-income communities are defined as areas belonging to Strata 0 through 2, middle income communities are defined as

Strata 3 and 4 areas, and high-income communities are defined as areas belonging to Strata 5 and 6.

Study Subjects

The human subjects included in this study are the pharmacy employees working at chain-brand community pharmacies in Bogotá, Colombia. These human subjects were recruited as a sample of convenience, based on whichever pharmacy employee happened to interact with the simulated clients during each pharmacy site visit.

Study Setting and Sample Selection

The setting of this study was in community pharmacies that are part of a major pharmaceutical franchise within Bogotá, Colombia. The online tools of Google Maps and Civico.com were used to locate potential community pharmacies for the study sample. The inclusion criteria for the pharmacies included in the sample were as follows: *1)* the pharmacy must belong to a major pharmaceutical chain that has sites distributed throughout each of the 20 localities (geographic districts) of Bogotá, *2)* the pharmacy must be located within the city limits of Bogotá and, *3)* the employees of the pharmacy that interact with the simulated clients must be able to communicate in Spanish. Any pharmacy attached to or associated with a hospital was excluded.

In order to maximize the overall study sample size of pharmacies included in this study, SCs gathered data at every known location of pharmacies that met these criteria. Using the online tools and criteria listed above, 111 pharmacies were identified for the sample. However, only 94 pharmacies were included in the final study sample because 17 of

the pharmacies listed online did not have a valid address, had been permanently closed down prior to the study, or simply did not exist.

Data Analysis

The statistical program Stata 16.0 (StataCorp, College Station, Texas) was used to analyze data. Descriptive categorical data of the sampled pharmacies was reported as frequencies (with percentages). Pearson chi-square tests were used to compare categorical variables between pharmacies, where a p -value of less than 0.05 was considered statistically significant. Both groups of SCs conducted trials at the same 94 pharmacies, which were considered repeated measurements of a single sample of pharmacies. Therefore, the McNemar test and the McNemar-Bowker test were used to investigate differences in categorical variables between the US Traveler SC group's pharmacy trial outcomes and the Colombian Comparison SC group's pharmacy trial outcomes. A p -value of less than 0.05 was considered statistically significant for the repeated measures tests as well.

Human Subjects and Privacy Considerations

IRB approval for this study was given by the UTHealth Committee for the Protection of Human Subjects (CPHS), as well as the Institutional Committee for Research Ethics at Universidad El Bosque in Bogotá, Colombia. In order to gather data that gives an accurate representation of pharmacy practices and typical employee behaviors, subjects of this study were unaware of their participation in the research. A waiver of consent for the human subjects in this study has been approved by the UTHealth CPHS. Simulated Clients (SCs) were trained in maintaining subject confidentiality, and no descriptive or identifying information on subjects or their workplace were documented. The identity of the pharmacy

franchise chosen for this study and the addresses of the pharmacy trial sites are completely confidential. No children were included in this study.

There were no risks for the subjects of this study beyond what they would experience on a daily basis as a pharmacy employee. Each pharmacy encounter entailed a very short time commitment for the subjects, with interactions lasting an average of 5 minutes (but taking no more than 10 minutes), and a maximum of two encounters per subject. To minimize discomfort to subjects, SCs were trained in proper conduct, cultural awareness, and polite communication skills with potential subjects. SCs did not use any methods of coercion when interacting with pharmacy employees, and no medications were purchased in any of the pharmacies visited by the SCs.

Safety Considerations

To minimize any safety risks for the study personnel, the PI (Marie Kasbaum) consulted with Dr. Alejandro de la Hoz, MD who is a native of Bogotá and familiar with crime levels in the city. Participation of SCs that conducted trials in pharmacies was completely voluntary, and the SCs were free to withdraw from a trial at any time. Fortunately, there were no instances in which the SCs felt unsafe during the data collection process of this study, and all trials were conducted without any adverse events occurring.

RESULTS

The US traveler Simulated Clients (SCs) and the Colombian Comparison SCs sought antibiotics without a prescription in each of the pharmacies (N=94) included in the sample. 82 out of the 94 pharmacies (87.23%) offered antibiotics without prescription to at least one of the SC groups. Out of these pharmacies, 22 (23.40%) offered antibiotics to the US travelers but refused the Colombians, 20 (21.28%) offered antibiotics to the Colombian SCs but refused the US travelers, and 40 (42.55%) offered antibiotics to both SC groups. Only 12 (12.77%) of the pharmacies successfully adhered to national regulations by refusing to sell antibiotics without prescription to both SC groups (**Table 1**).

Table 1: Simulated Client (SC) Trial Outcomes in Sampled Community Pharmacies (N=94) in Bogotá, Colombia (2018)

Pharmacy Response to SCs Seeking Antibiotics Without Prescription	<i>n</i> (%) of pharmacies visited
Refused to sell Antibiotics to Both SC Groups	12 (12.77%)
Offered Antibiotics to US Traveler SCs, but Refused Colombian SCs	22 (23.40%)
Offered Antibiotics to Colombian SCs, but refused US Traveler SCs	20 (21.28%)
Offered Antibiotics to Both SC Groups	40 (42.55%)
Total	94 (100%)

Antibiotics were offered without prescription to the two groups at similar rates, as the US traveler SC group received offers in a total of 62 (68.13%) pharmacies and the Colombian Comparison SC group received offers in 60 (65.96%) pharmacies (**Table 2**). The

difference between the overall rates at which the SC groups were offered antibiotics was not significant (McNemar Test, $p = 0.76$).

Among the pharmacies that offered to sell antibiotics without prescription to at least one of the SC groups ($n=82$), US traveler SCs were offered antibiotics without any prompting in 58 (70.73%) pharmacies, and with prompting in 4 (4.88%) pharmacies. In comparison, the Colombian SCs received offers of antibiotics without prompting in 42 (51.22%) pharmacies, and with prompting in 18 (21.95%) pharmacies. When comparing the trial outcomes that resulted in an offer to sell antibiotics without prescription between the two groups, the US traveler SCs were significantly more likely than the Colombian comparator SCs to be offered antibiotics without any prompting (McNemar-Bowker Test, $p < 0.05$).

Among the pharmacies that refused to sell antibiotics to at least one of the SC groups ($n=54$), 25 (46.30%) pharmacies refused to sell antibiotics to the US travelers for clinical reasons and 4 (7.41%) refused to sell antibiotics to the US travelers for legal reasons, and 3 (5.56%) cited both clinical and legal reasons for refusing to sell antibiotics. When these 54 pharmacies refused to sell antibiotics to the Colombian SCs, 3 (5.56%) gave clinical reasons for refusal, 30 (55.56%) refused for legal reasons, and 1 (1.85%) gave both clinical and legal reasons. The rates at which the different reasons were given for refusing to sell antibiotics without prescription varied significantly between the two SC groups (McNemar-Bowker Test, $p < 0.05$).

Table 2: Comparison of access to antibiotics without prescription between US Travelers and Colombian Citizens in community pharmacies (N=94) in Bogotá, Colombia (2018)

Simulated Client (SC) Trial Outcomes	SC Group, <i>n</i> (%) of pharmacies		Test Statistic
	US Traveler Group	Colombian Comparison Group	<i>P</i> -value
Overall Comparison of Access Between SC Groups (N=94)			
Pharmacy offered to sell antibiotics without prescription	62 (65.96%)	60 (63.83%)	McNemar Test <i>p</i> = 0.76
Pharmacy refused to sell antibiotics without prescription	32 (34.04%)	34 (36.17%)	
Levels of Prompting: Levels of prompting given by SC before offers of antibiotics, among pharmacies that offered at least one SC group (n=82)			
Pharmacy offered to sell antibiotics without prompting (No mention of antibiotics by SC before offer)	58 (70.73%)	42 (51.22%)	McNemar-Bowker Test <i>p</i> < 0.05
Pharmacy offered to sell an antibiotic with prompting (Antibiotics mentioned by SC before offer)	4 (4.88%)	18 (21.95%)	
Pharmacy refused to sell antibiotics	20 (24.39%)	22 (26.83%)	
Reasons for Refusal: Reasons given for refusing to sell antibiotics, among pharmacies that refused at least one SC group (n=54)			
Pharmacy refused to sell antibiotics for clinical reasons	25 (46.30%)	3 (5.56%)	McNemar-Bowker Test <i>p</i> < 0.05
Pharmacy refused to sell antibiotics for legal reasons	4 (7.41%)	30 (55.56%)	
Pharmacy refused to sell antibiotics for both clinical and legal reasons	3 (5.56%)	1 (1.85%)	
Pharmacy offered to sell antibiotics	22 (40.74%)	20 (37.04%)	

**statistically significant p-values indicated by bold characters*

The antimicrobial compounds most commonly offered to both groups contained a metronidazole/nifuroxazide combination (**Table 3**). Indeed, 44 (70.97%) of the pharmacies that offered antibiotics to the US traveler group (n=62) and 41 (70%) of the

pharmacies that offered antibiotics to the Colombian group (n=60) chose the metronidazole/nifuroxazide combination. Medications containing sulfamethoxazole/trimethoprim (SMX-TMP) were the second most frequent antibiotics offered to both groups, as they were offered to the US traveler SCs in 10 (16.13%) and to the Colombian SCs in 10 (16.67%) of the antibiotic-dispensing pharmacies. Medications with metronidazole as the only antimicrobial ingredient were offered to the US traveler and Colombian groups in 2 (3.23%) and 4 (6.67%) of pharmacies, respectively. Nitazoxanide-containing medications were offered to the US traveler SCs in 5 (8.06%) pharmacies and to the Colombian SCs in 2 (3.33%) pharmacies. Furazolidone and amoxicillin were both offered to the Colombian SC group in 1 (1.67%) pharmacy, but were never offered to the US traveler SC group. A medication containing pyrantel/oxantel combination was also offered to the US travelers in 1 (1.61%) pharmacy, but was never offered to the Colombian comparison group.

Table 3: Medications offered to Simulated Clients (SCs) without prescription in community pharmacies in Bogotá, Colombia (2018)

Compounds Offered	SC Group, <i>n</i> (%) of pharmacy trials resulting in an offer of antibiotics	
	US Traveler Group (n=62)	Colombian Comparison Group (n=60)
Metronidazole	2 (3.23%)	4 (6.67%)
Metronidazole/Nifuroxazide	44 (70.97%)	42 (70.0%)
Sulfamethoxazole/TMP	10 (16.13%)	10 (16.67%)
Nitazoxanide	5 (8.06%)	2 (3.33%)
Furazolidone	0	1 (1.67%)
Amoxicillin	0	1 (1.67%)
Pyrantel/Oxantel	1 (1.61%)	0

As shown in **Table 4**, antibiotics were offered without prescription to US travelers in 9 (52.94%) of the pharmacies located in high-income communities, 43 (66.15%) of the pharmacies in middle-income communities, and 10 (83.33%) of the pharmacies in low-income communities. There was no significant difference found in the rates at which US travelers were offered antibiotics without prescription between these three socioeconomic (SES) levels ($\chi^2=2.90$, $p= 0.24$). However, there was a statistically significant difference found between the rates at which the Colombian SCs were offered antibiotics at the different SES levels ($\chi^2=7.82$, $p= 0.02$). The Colombian group was offered antibiotics in 7 (41.18%) of the pharmacies in high-income communities, 42 (64.62%) of the pharmacies in middle-income communities, and 11 (91.67%) of the pharmacies in low-income communities.

Table 4: Pharmacy responses to Simulated Clients (SCs) seeking antibiotics without prescription in community pharmacies in Bogotá, Colombia, stratified by the socioeconomic status (SES) of the pharmacy community (2018)

SES Level of Pharmacy Community	SC Group, <i>n</i> (%) of pharmacies					
	US Traveler Group			Colombian Comparison Group		
	Offered Antibiotics Without Prescription	Refused to Sell Antibiotics Without Prescription	(<i>P</i> -value)	Offered Antibiotics Without Prescription	Refused to Sell Antibiotics Without Prescription	(<i>P</i> -value)
High-Income (n= 17)	9 (52.94%)	8 (47.06%)		7 (41.18%)	10 (58.82%)	
Middle-Income (n=65)	43 (66.15%)	22 (33.85%)	$\chi^2(2) = 2.90$ ($p = 0.24$)	42 (64.62%)	23 (35.38%)	$\chi^2(2) = 7.82$ ($p = \mathbf{0.02}$)
Low-Income (n=12)	10 (83.33%)	2 (16.67%)		11 (91.67%)	1 (8.33%)	

χ^2 = Pearson Chi Square Test

*statistically significant *p*-values indicated by bold characters

After SCs presented the symptoms to pharmacy employees during trials, some of the pharmacy employees asked questions about the patient before deciding what treatments to offer (**Table 5**). For the US traveler SC group, 57 (60.64%) pharmacies asked follow-up questions about the patient after the SC presentation, while 37 (39.36%) of pharmacies did not ask any questions about the patient before offering treatments and/or medical advice. The US travelers were asked about the patient's age in 30 (31.91%) pharmacies, the duration of the patient's symptoms in 24 (25.53%) pharmacies, the patient's pregnancy status in 2 (2.13%) pharmacies, recent food exposures in 4 (4.26%) pharmacies, other illnesses or symptoms in 15 (15.96%) pharmacies, medications the patient might be currently taking in 8 (8.51%) pharmacies, the patient's nationality in 1 (1.06%) pharmacy, and any allergies the patient might have in 2 (2.13%) pharmacies.

The Colombian Comparison SC Group had a similar amount of pharmacies ask follow-up questions about the patient, with 56 (59.57%) pharmacies asking at least one question and 38 (40.43%) pharmacies neglecting to ask any follow-up questions about the patient. The Colombian SCs were asked about the patient's age in 16 (17.02%) pharmacies, the duration of symptoms in 40 (42.56%) pharmacies, the patient's pregnancy status in 5 (5.32%) pharmacies, recent food exposures in 17 (18.09%) pharmacies, other illnesses or symptoms in 4 (4.26%) pharmacies, and the patient's current medications in 2 (2.13%) pharmacies. The Colombian SCs were not asked about the patient's nationality or the patient's allergies in any of the pharmacies.

Table 5: Questions Asked by Pharmacy Employees Before Giving Medical Recommendations to Simulated Clients Seeking Antibiotics Without Prescription in Bogotá, Colombia (2018)

Question Asked	SC Group, <i>n</i> (%) of pharmacies	
	US Traveler Group (N= 94)	Colombian Comparison Group (N=94)
Pharmacy employee did not ask any questions about the patient before offering medications	37 (39.36%)	38 (40.43%)
“How old is the patient?”	30 (31.91%)	16 (17.02%)
“How many days has the patient been experiencing symptoms?”	24 (25.53%)	40 (42.56%)
“Is the patient pregnant?”	2 (2.13%)	5 (5.32%)
“Did the patient eat something that may have made her sick?”	4 (4.26%)	17 (18.09%)
“Does the patient have any other illnesses or symptoms?”	15 (15.96%)	4 (4.26%)
“Is the patient currently taking any medications?”	8 (8.51%)	2 (2.13%)
“Is the patient local to Bogotá?”	1 (1.06%)	0
“Does the patient have any allergies?”	2 (2.13%)	0

**Percentages may not add up to 100%, due to the fact that some pharmacies asked the SCs more than one question during the same trial.*

DISCUSSION

The non-prescription sale of antibiotics in community pharmacies commonly occurs in many countries around the world (Auta et al., 2018). This phenomenon has the potential to cause the emergence of antimicrobial-resistant pathogens, due to the well-documented associations between non-prescription antibiotic use and inappropriate treatment courses, drug doses, and medication choices (Morgan, Okeke, Laxminarayan, Perencevich, &

Weisenberg, 2011). A lack of enforcement of regulations enables community pharmacies in countries like Colombia to continue these dangerous drug-dispensing practices, putting public health at risk (Vacca et al., 2011). Many previous studies have used the simulated client method (SCM) to investigate the adherence to antimicrobial dispensing guidelines in community pharmacies (Auta et al., 2018). However, to the best of our knowledge, none have used the SCM to investigate antibiotic sales without prescription to international travelers in community pharmacies. The current study is the first to address this gap in the literature and use the SCM to compare the access that international travelers and local citizens have to antibiotics without prescription in community pharmacies in Colombia.

In the current study, a US traveler simulated client (SC) group and a Colombian comparison SC group sought antibiotics in 94 chain pharmacies distributed throughout the communities of Bogotá, Colombia. Our findings confirm that the non-prescription sale of antibiotics still regularly occurs in Bogotá, Colombia despite regulations, as over 87% of the sampled pharmacies offered to sell antibiotics without prescription to one or both of the SC groups. Less than 13% of the sampled pharmacies refused to sell antibiotics without prescriptions to both SC groups.

Overall, antibiotics were offered to both SC groups at similarly high frequencies, regardless of the SCs' nationality. However, the US traveler SCs were significantly more likely than the Colombian SCs to be offered antibiotics without any prompting (meaning that the pharmacy employee offered to sell antibiotics without the SC needing to mention the word "antibiotics"). Many SCM studies conducted in other countries on the non-prescription sale of antibiotics in community pharmacies involve SCs making "product requests" of

specific antimicrobial medications, but the US traveler SC group in the current study did not even have to use the word “antibiotics” in the majority of the sampled pharmacies before receiving an offer (Auta et al., 2018). Additionally, when pharmacies adhered to national regulations by refusing to sell antibiotics without prescription, it was found that their reasons for refusal varied significantly between the two SC groups. The refusals given to the Colombian SC group were most often based on legal reasons, while refusals given to US traveler SCs were most often based on clinical reasons.

The socioeconomic status (SES) of a pharmacy’s community was not found to be significantly associated with the rates at which pharmacies offered antibiotics to the US traveler SC group. However, there was a significant relationship found between the SES of the pharmacy’s community and the rates at which the Colombian SCs received offers of antibiotics without prescription, where the highest rates of pharmacies offering antibiotics were found in low-income communities and the lowest rates of pharmacies offering antibiotics were found in high-income communities.

During pharmacy trials, 7 different types of antimicrobial medications were offered to the SC groups at varying frequencies. However, none of these compounds are among the appropriate treatments for moderate traveler’s diarrhea (TD), according to consensus guidelines from the Centers for Disease Control and Prevention (CDC) for the treatment of TD (Connor, 2019). Because TD is typically a self-limiting condition, antibiotics can often be avoided by patients with TD unless their symptoms are severe (DuPont & Steffen, 2016). In the cases where the severity of the illness is high enough that antibiotics are needed, the CDC recommends the use of fluoroquinolones, azithromycin, or rifaximin (Connor, 2019). In the

current study, none of the antimicrobial compounds offered to SCs were among those recommended by the CDC for the treatment of TD.

During pharmacy trials in this study, the SCs followed a standardized script where the only information they initially provided pharmacy employees was the symptoms of their “friend” with TD. After each trial, SCs recorded what follow-up questions, if any, were asked about the patient before the pharmacy employee gave their medical recommendations and/or offered treatments. For both SC groups, about 40% of pharmacies did not ask any follow-up questions about the patients. When employees chose to ask follow-up questions about the patient, the most common questions were about the patient’s age, duration of TD symptoms, and recent food exposures. Only small percentages of the pharmacy employees asked about the patient’s pregnancy status, allergies, other medications she may be taking, or other illnesses she may have. The lack of questions asked by the pharmacy employees before making decisions on a treatment plan was particularly alarming, especially considering that the pharmacy employees thought they were only communicating with their patient’s friend (rather than having any direct contact or consultation with the actual patient).

One of the limitations of this study is the fact that pharmacy trials were only conducted in community pharmacies belonging to a large pharmaceutical franchise, so these results may not be generalizable to pharmacies that belong to smaller pharmaceutical companies or pharmacies that are independently owned. Another limitation is that we were unable to mitigate the risk of confounding that may have been caused by the manner the pharmacy employees interacted with SCs of different genders. All of the SCs in the US traveler group were female, while the SCs conducting trials in the Colombian group were

either male or female. Due to the fact that this was an unfunded, student-led study, the investigators had to recruit SCs willing to work as unpaid volunteers, and we were not able to recruit SCs of the same gender for both groups without the ability to compensate them for their time. However, in all SC encounters with pharmacy employees, the employees were told that the patient needing treatment for TD was female. Lastly, there is some chance of recall bias in this study, as the SCs could not take audio recordings during the pharmacy trials without first getting the consent of the pharmacy employees (which would have threatened the overall design of the study). To mitigate this risk of recall bias and limit the chance for SCs to forget trial outcomes, SCs filled out a data collection form following each pharmacy trial immediately after leaving the pharmacy's premises (which always occurred within 10 minutes of each pharmacy trial).

Overall, the findings of this study show that antibiotics without prescription are far too easy to access for both international travelers and Colombian citizens. While antibiotics were offered to the US traveler SC group and the Colombian SC group at similar rates, there were significant differences between the SC groups in the levels of prompting they needed to give pharmacy employees before receiving an offer and in the reasons the pharmacy employees gave them for refusing to sell antibiotics without prescription. This study demonstrates an urgent need for antimicrobial stewardship interventions for pharmacy employees and an increase in enforcement of existing regulations in Colombian community pharmacies.

REFERENCES

- Alvarez, C., Cortes, J., Arango, á., Correa, C., & Leal, A. (2006). Resistencia Antimicrobiana en Unidades de Cuidado Intensivo de Bogotá, Colombia, 2001-2003. *Revista de Salud Pública*, 8(1), pp. 86-101.
- Arias, C. A., Reyes, J., Zúñiga, M., Cortés, L., Cruz, C., Rico, L. (2003). Multicentre surveillance of antimicrobial resistance in enterococci and staphylococci from Colombian hospitals, 2001–2002. *Journal of Antimicrobial Chemotherapy*, 51(1), pp. 59-68.
- Andrade, L. O., Filho, A. P., Solar, O., Rígoli, F., Salazar, L. M., Serrate, P. C., . . . Atun, R. (2015). Social determinants of health, universal health coverage, and sustainable development: Case studies from Latin American countries. *The Lancet*, 385(9975), 1343-1351. doi:10.1016/s0140-6736(14)61494-x
- Auta, A., Hadi, M. A., Oga, E., Adewuyi, E. O., Abdu-Aguye, S. N., Adeloye, D., . . . Morgan, D. J. (2018). Global access to antibiotics without prescription in community pharmacies: A systematic review and meta-analysis. *Journal of Infection*. doi:10.1016/j.jinf.2018.07.001
- Bowers, J. R., Kitchel, B., Driebe, E. M., Maccannell, D. R., Roe, C., Lemmer, D., . . . Limbago, B. M. (2015). Genomic Analysis of the Emergence and Rapid Global Dissemination of the Clonal Group 258 *Klebsiella pneumoniae* Pandemic. *Plos One*, 10(7). doi:10.1371/journal.pone.0133727

Colombia. Concejo de Bogotá D. C. Acuerdo 79 (2003). Retrieved June 15, 2018, from:

<http://www.alcaldiabogota.gov.co/sisjur/normas/Norma1.jsp?i=6671>

Colombia - Travel and Tourism. U.S. Department of Commerce, National Travel and Tourism Office. (2018, August 17). Retrieved November 28, 2018, from

<https://www.export.gov/article?id=Colombia-Travel-and-Tourism>

Connor, B. A. (2019). Travelers' diarrhea - Chapter 2 - CDC 2020 yellow book. Retrieved December 11, 2019, from <https://wwwnc.cdc.gov/travel/yellowbook/2020/preparing-international-travelers/travelers-diarrhea#box203>

Dupont, H. L., & Steffen, R. (2016). Use of antimicrobial agents for treatment and prevention of travellers' diarrhoea in the face of enhanced risk of transient fecal carriage of multi-drug resistant enterobacteriaceae: Setting the stage for consensus recommendations. *Journal of Travel Medicine*, 23(6). doi:10.1093/jtm/taw054

Feinstein, M., Escandón-Vargas, K., Reyes, S., Hernández-Gómez, C., Pallares, C. J., & Villegas, M. V. (2017). Improved Outcomes When Antibiotic Prescribing Guidelines Are Followed by Healthcare Providers: A Colombian Example to Encourage Adherence in Hospital Settings. *Infection Control & Hospital Epidemiology*, 38(06), 756-758. doi:10.1017/ice.2017.45

- Founou, R. C., Founou, L. L., & Essack, S. Y. (2017). Clinical and economic impact of antibiotic resistance in developing countries: A systematic review and meta-analysis. *PloS one*, *12*(12), e0189621. doi:10.1371/journal.pone.0189621
- Giménez-Santana, A., Caplan, J. M., & Drawve, G. (2018). Risk Terrain Modeling and Socio-Economic Stratification: Identifying Risky Places for Violent Crime Victimization in Bogotá, Colombia. *European Journal on Criminal Policy and Research*, *24*(4), 417-431. doi:10.1007/s10610-018-9374-5
- Hill, D. R., Ericsson, C. D., Pearson, R. D., Keystone, J. S., Freedman, D. O., Kozarsky, P. E., . . . Ryan, E. T. (2006). The Practice of Travel Medicine: Guidelines by the Infectious Diseases Society of America. *Clinical Infectious Diseases*, *43*(12), 1499-1539. doi:10.1086/508782
- Hitch, G., & Fleming, N. (2018). Antibiotic resistance in travellers' diarrhoeal disease, an external perspective. *Journal of Travel Medicine*, *25*(Suppl_1). doi:10.1093/jtm/tay014
- Klein, E. Y., Boeckel, T. P., Martinez, E. M., Pant, S., Gandra, S., Levin, S. A., . . . Laxminarayan, R. (2018). Global increase and geographic convergence in antibiotic consumption between 2000 and 2015. *Proceedings of the National Academy of Sciences*, *115*(15). doi:10.1073/pnas.1717295115

Laxminarayan, R., Duse, A., Wattal, C., Zaidi, A. K., Wertheim, H. F., Sumpradit, N., . . .

Cars, O. (2013). Antibiotic resistance—the need for global solutions. *The Lancet Infectious Diseases*, 13(12), 1057-1098. doi:10.1016/s1473-3099(13)70318-9

Laxminarayan R, Heymann DL. Challenges of drug resistance in the developing world. *BMJ* 2012; **344**: e1567.

Michael, C. A., Dominey-Howes, D., & Labbate, M. (2014). The antimicrobial resistance crisis: causes, consequences, and management. *Frontiers in public health*, 2, 145.

doi:10.3389/fpubh.2014.00145 Morgan, D. J., Okeke, I. N., Laxminarayan, R., Perencevich, E. N., & Weisenberg, S. (2011). Non-prescription antimicrobial use worldwide: A systematic review. *The Lancet Infectious Diseases*, 11(9), 692-701. doi:10.1016/s1473-3099(11)70054-8

Morgan, D. J., Okeke, I. N., Laxminarayan, R., Perencevich, E. N., & Weisenberg, S. (2011). Non-prescription antimicrobial use worldwide: A systematic review. *The Lancet Infectious Diseases*, 11(9), 692-701. doi:10.1016/s1473-3099(11)70054-8

O'Neill J. Review on Antimicrobial Resistance Antimicrobial Resistance: Tackling a crisis for the health and wealth of nations. London: Review on Antimicrobial Resistance; 2014. Available from: https://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf

República de Colombia. Ministerio de Comercio, Industria y Turismo (2018). *Boletín*

Mensual Turismo Abril 2018. Retrieved June 17, 2018 from:

http://www.mincit.gov.co/loader.php?lServicio=Documentos&lFuncion=verPdf&id=83945&name=OEE_JR_Turismo_Abril_28-05-2018.pdf&prefijo=file

Riddle, M. S., & Connor, B. A. (2017, May 31). Perspectives: Antibiotics in Travelers’

Diarrhea - Balancing the Risks & Benefits. Retrieved November 26, 2018, from

<https://wwwnc.cdc.gov/travel/yellowbook/2018/the-pre-travel-consultation/perspectives-antibiotics-in-travelers-diarrhea--balancing-the-risks-and-benefits>

Rojas, L. J., Weinstock, G. M., Cadena, E. D., Diaz, L., Rios, R., Hanson, B. M., . . . Arias,

C. A. (2017). An Analysis of the Epidemic of *Klebsiella pneumoniae*

Carbapenemase-Producing *K. pneumoniae*: Convergence of Two Evolutionary

Mechanisms Creates the “Perfect Storm”. *The Journal of Infectious Diseases*, 217(1),

82-92. doi:10.1093/infdis/jix524

Santa-Ana-Tellez Y, Mantel-Teeuwisse AK, Dreser A, Leufkens HGM, Wirtz VJ (2013)

Impact of Over-the-Counter Restrictions on Antibiotic Consumption in Brazil and

Mexico. PLoS ONE 8(10): e75550. <https://doi.org/10.1371/journal.pone.0075550>

Steffen, R., Hill, D. R., & Dupont, H. L. (2015). Traveler’s Diarrhea: A Clinical

Review. *Jama*, 313(1), 71. doi:10.1001/jama.2014.17006

U.S. Department of Commerce, National Travel and Tourism Office. (2018). *Colombia-Travel and Tourism*. International Trade Administration

Vacca, C., Niño, C., & Reveiz, L. (2011). Restricción de la venta de antibióticos en farmacias de Bogotá, Colombia: estudio descriptivo. *Rev Panam Salud Publica*, 30(6), pp. 586-91.

Vacca, C., Orozco, J., Figueras, A., & Capellà, D. (2005). Assessment of Risks Related to Medicine Dispensing by Nonprofessionals in Colombia: Clinical Case Simulations. *Annals of Pharmacotherapy*, 39(3), pp. 527-532.

Wirtz, V. J., Herrera-Patino, J. J., Santa-Ana-Tellez, Y., Dreser, A., Elseviers, M., & Stichele, R. H. (2013). Analysing policy interventions to prohibit over-the-counter antibiotic sales in four Latin American countries. *Tropical Medicine & International Health*, 18(6), 665-673. doi:10.1111/tmi.12096

World Health Organization (2017). Global Priority List of Antibiotic-Resistant Bacteria to Guide Research, Discovery, and Development of New Antibiotics. Geneva, Switzerland: World Health Organization.

World Health Organization. (2015). *Plan of action on antimicrobial resistance*. (WHO 54th Directing Council 54, Working Document 12). Washington, D.C., USA. Retrieved June 17, 2018 from: <https://www.paho.org/hq/dmdocuments/2015/CD54-12-e.pdf>

Xu, T., Neto, A. C., & Moles, R. J. (2012). A systematic review of simulated-patient methods used in community pharmacy to assess the provision of non-prescription medicines. *International Journal of Pharmacy Practice*, 20(5), 307-319. doi:10.1111/j.2042-7174.2012.00201.x

DATA COLLECTION FORM INSTRUCTIONS

PURPOSE: To collect and record information about the observational trial.

To be completed immediately after interaction with pharmacy employee.

WHO USES IT: Trained study staff, approved by the PI

STAGE OF PROJECT FORM IS USED: Data Collection

REMINDER: All information obtained from or about the participant throughout this study is confidential and must not be shared with anyone except study staff for study purposes.

GENERAL INSTRUCTIONS: This form must be filled out by all trained trial administrators, immediately after conducting each trial (asking for antibiotics without a prescription; standardized trial script is attached). This form must be completed AFTER all study personnel have left the property of the pharmacy in which the trial was conducted.

DO NOT record any data that is not included in this form, particularly any identifying information about the pharmacy, pharmacy employees, or customers at the trial site.

Completing Questionnaire: Ensure all information is filled out in top right corner. Please answer the following questions to the best of your ability. Only pick **ONE** answer for each question. Please clearly mark your answer choice in **pen**.

Submitting questionnaire: Upon completion of questionnaire, please submit to PI.

****Ensure to fill out every part of this form, unless instructed otherwise.**

Trial Administrator Data Collection Form

Date Collected:

--	--

--	--

2	0	1	8
---	---	---	---

Day**Month****Year**

Trial Administrator I.D. Number:

--	--	--

Pharmacy ID Number:

--	--	--	--

Q1.) Draw an X in the appropriate box.

Trial Administrator Group	
Experimental Group (Travelers)	
Control Group (Colombian Citizens)	

Q2.) Draw an X in the box corresponding with the pharmacy's locality.

Pharmacy Locality	
La Candelaria	
Antonio Nariño	
Usaquén	
Chapinero	
Santa Fe	
San Cristóbal	
Usme	
Tunjuelito	
Bosa	
Kennedy	
Fontibón	
Engativá	
Suba	
Barrios Unidos	
Teusaquillo	
Los Mártires	
Puente Aranda	
Ciudad Bolívar	
Rafael Uribe Uribe	
Sumapaz	

Q3.) Draw an X in the appropriate box.

- If answers “a” or “b” are chosen, skip to question 8.
- If answers “c” or “d” are chosen, continue with Data Collection form.

Non-Prescription Sale of Antibiotic	
a.) Pharmacy refused to sell an antibiotic for clinical reasons	
b.) Pharmacy refused to sell an antibiotic for legal reasons	
c.) Pharmacy offered to sell an antibiotic without any prompting	
d.) Pharmacy offered to sell an antibiotic with prompting	

Q4.) Draw an X in the box corresponding with the course of antibiotics offered. If the type of antibiotic, dose, or dose duration offered is not listed, please write the correct information in the box labeled “Other.”

Antibiotic Brand	Antibiotic dose	
Krodex Compuesto	Metronidazol 600 mg / Nifuroxazida 200mg (capsules)	
	Metronidazol 300 mg / Nifuroxazida 200mg (capsules)	
	Other:	
Decasulf Forte	Sulfametoxazol 800mg / Trimetoprima 160mg (Tablets)	
	Sulfametoxazol 1600mg / Trimetoprima 320mg (Double Strength Tablets)	
	Trimetoprima 5 mL(80 mg)/ Sulfametoxazol 5 mL(400mg) (Suspension)	
	Other:	
Other	mg / mg	

Q5.) Fill out the dose duration suggested for the antibiotic that was offered.
(example: if a pharmacist says “take the medicine twice a day for 5 days,” write the following: 2 times daily / 5 days)

Q6.) If any additional instructions about the dose duration were given (such as the pharmacist suggesting the patient take multiple tablets for the first dose, etc.), please write them in the box below. If no additional instructions were given, write “N/A” in the box.

Q7.) In the box below, write the cost of the antibiotic offered by the employee, in Colombian Pesos (COP).

(Note: make sure to write the cost of just the antibiotic, and not the total cost of all items suggested by the pharmacy employee).

\$ _____ COP

Q8.) In the box below, write the total cost of ALL the items offered by the employee, in Colombian Pesos (COP).

(Note: if an antibiotic was offered, include that cost in the number written below)

\$ _____ COP

Q9.) Draw an X in each box corresponding to a non-antibiotic item suggested by the pharmacy employee. You may select multiple boxes. If any suggested items are not included in this list, please write the correct information in the box labeled “Other.”

Other Suggested Items or Non-Antibiotic Medications:	
N/A (No other items suggested)	
Adipina	
Electrolyte Drink	
Bisbacter (or other medication with bismuth subsalicylate)	
Probiotics	
Acetaminophen	
Ibuprofen	
Other:	

Q10.) Draw an X in each box corresponding to each question asked by the pharmacy employee about the patient. You may select multiple boxes. If the type of item is not included in this list, please write the correct information in the box labeled “Other.”

Questions Asked by Pharmacy Employee:	
“How old is the patient” or “Is the patient an adult?”	
“Is the patient pregnant?”	
“How many days has the patient been experiencing symptoms?”	
“Did the patient eat something that may have made her sick?”	
“Does the patient have any other illnesses or symptoms?”	
“Is the patient currently taking any medications?”	
“Is the patient local to Bogotá?”	
Other:	

End of Data Collection Form

TRIAL ADMINISTRATOR SCRIPT

PURPOSE: This script is to be used when interacting with pharmacy employees during observational trials.

WHO USES IT: Study staff that have been trained and approved by the PI. All trial administrators must be conversationally fluent in both Spanish and English.

STAGE OF PROJECT FORM IS USED: Data Collection

GENERAL INSTRUCTIONS: All trial administrators must be trained by the PI and must have the entire study script and the patient profile memorized before conducting trials in the field. Trial administrators may not visibly carry a copy of this script with them when in any of the pharmacies included in this study. Do NOT indicate to the pharmacy personnel that they are being interviewed for a scientific study or that the “patient” used for the patient case in this script is not real. During each trial, trained administrators must follow this script as closely as possible when interacting with study subject.. Deviation from the script is prohibited, especially in regards to the lines given for the presentation of the patient case to the pharmacy employee (section A), and the lines for the antibiotic prompting (sections B3 and C3). After finishing the script, immediately leave the pharmacy premises and fill out the Data Collection Form.

****ALL TRIALS ARE TO BE CONDUCTED SOLELY IN SPANISH.**

Trial Administrator Script

A: *Introduce symptoms of case to pharmacy employee and ask for treatment recommendations.*

Use the following language:

A: “Hola, tengo una amiga quien tiene fiebre, diarrea, y un dolor de estómago. ¿Qué le puede recomendar?”

English Translation: Hello, I have a friend who has a stomach ache, fever, and diarrhea. What can you recommend for her?

B: *Listen to pharmacy employee’s response.*

- *B1: If pharmacy employee recommends antibiotic, ask for price of antibiotic.*
- *B2: If pharmacy employee asks for more information about the case, refer to patient profile of case. Only provide information about the patient that is directly asked for by the employee.*
- *B3: If pharmacy employee only recommends non-antibiotic medications, prompt the employee by asking the question provided.*

Use the following language:

B1: “¿Cuánto cuesta este antibiótico, y cuál es el precio de todas las cosas?”

English Translation: What is the cost of this antibiotic, and what is the total price of all these things?

Continue to Prompt C4

B2: Patient Profile:

- Sex: Female
- Age: 24
- Medical allergies: None
- Symptoms: Stomach pain, diarrhea and fever lasting for 3 days
 - No temperature reading has been taken, but forehead feels hot to the touch.
- Pre-Existing Illnesses: None
- Current Medications: None
- Current Treatment: Pedialyte
- Patient History: Ate an empanada from a street vendor within the 24 hours before symptoms appeared
- Nationality
 - Experimental Group (Travelers): Patient is from the U.S. and is visiting Bogotá
 - Control Group (Colombian Citizens): Patient is native to Bogotá

Continue to Prompt B3

B3: “¿Son algunos de estos medicamentos antibióticos? ¿Cree que ella necesita antibióticos?”

English Translation: Are any of these medications antibiotics? Do you think she needs antibiotics?

Continue to Prompt C

C: *After asking for antibiotics, listen to pharmacy employee’s response.*

- **C1:** *If pharmacy employee recommends antibiotic, continue to Prompt B1*
- **C2:** *If pharmacy employee does not recommend antibiotics, continue to Prompt C3.*
- **C3:** *Make a mental note if the employee refuses to give antibiotics for clinical reasons (i.e. they don’t think antibiotics are the best treatment for this patient) or for legal reasons (i.e. they state that patients must have a doctor’s prescription to receive antibiotics).*
- **C4:** *Conclude the observational trial. This is an observational study and no medication will be purchased.*

Use the following language:

C3: “¿Por qué no cree que ella necesita los antibioticos?”

English Translation: Why don't you think she needs antibiotics?

Continue to Prompt C4

C4: “Gracias, voy a preguntar en otro lado.”

English Translation: Thank you, I will ask elsewhere.

Continue to Prompt D

D: *After leaving establishment, ensure that data collection sheet is filled out.*

End of Script.