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Mohamed E. Amin
Manchester Univeristy, mohamedezzat21@gmail.com

Amira Amine
Alexandria University, amiraamine@gmail.com

Mohammad Shoukry Newegy
Directorate of Health Affairs, Ministry of Health, mohsn1981@gmail.com

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Injudicious Provision of Subtherapeutic Doses of Antibiotics in Community Pharmacies

Mohamed E. K. Amin, BSc Pharm Sci, MS, PhD[1]; Amira Amine, MB BCh, MS, PhD[2]; Mohammad Shoukry Newegy, MB BCh[3]
College of Pharmacy, Natural & Health Sciences, Manchester University (USA); [2]High Institute of Public Health, Alexandria University (Egypt); [3]Directorate of Health Affairs, Ministry of Health (Egypt)

ABSTRACT

Background*: Egyptian pharmacists routinely provide antibiotics without a prescription. A few pills of common cold products are offered under the name "cold group". A cold group may contain one or more pills of antibiotics. This study aimed to estimate the proportion of pharmacies that provide subtherapeutic doses of antibiotics in community pharmacies as part of a CG or upon direct request from a simulated client.* ***Methods****: A probability sample of community pharmacies in Alexandria, Egypt was selected. A simulated client approached pharmacy staff using a standardized scenario. He initially requested a cold group and followed by requesting two antibiotic pills.* ***Results****: The simulated client visited 104 pharmacies and was sold an antibiotic at 68 pharmacies in total. A cold group with one or more antibiotic pills was provided in 31 pharmacies. Upon request for two antibiotic pills, 2-8 antibiotic pills were provided in 30 pharmacies whereas an antibiotic carton was provided in three pharmacies. In four pharmacies, the simulated client was sold a cold group containing an antibiotic as well as another antibiotic upon request. Beta-lactam antibiotics comprised 76% of antibiotics provided. In five encounters, the simulated client was told that the cold group contained an antibiotic when, in fact, it did not.* ***Conclusions:*** *Subtherapeutic doses of antibiotics are provided at dangerous rates in Alexandria's community pharmacies. Interventions are urgently needed to tackle different factors contributing to this dangerous practice.*

Keywords*:* subtherapeutic doses, antibiotics; simulated client; antimicrobial resistance; pharmacies; Egypt

INTRODUCTION

The whole world has a vital stake in maintaining the effectiveness of existing antibiotic entities to maintain improvements in life expectancy and quality that began in the last century. These improvements continue to be seriously threatened by the emergence and global spread of antibiotic resistant microbes[1]. The World Bank estimates that, by 2050, annual global gross domestic product (GDP) would fall by 1.1%-3.8% due to antimicrobial resistance with low-income countries losing up to 5% of their GDP [2].

The acquisition of antibiotics from pharmacies without a prescription is a global phenomenon. Getting antibiotics directly from the pharmacy without a prescription is possible in Africa, South America, Asia as well as in many parts of Europe even when this practice is illegal [3-11] Previous research indicates that antibiotics are readily dispensed for urinary tract infections, sore throat, bronchitis and diarrhea. Many of these studies have addressed dispensing antibiotics without a prescription in therapeutic doses. A much smaller subset of these studies provided some information on dispensing antibiotics in subtherapeutic doses. Studies in Mexico and Indonesia reveal high rates of providing patrons with antibiotics in small doses when simulated patients present symptoms of viral infections[12-14]

Corresponding Author: Mohamed E. K. Amin, BSc Pharm Sci, MS, PhD, Assistant Professor College of Pharmacy, Natural & Health Sciences, Manchester University, 10627 Diebold Rd., Fort Wayne, Indiana, USA 46845

Egypt is one of many countries where pharmacists routinely give antibiotics to patrons without a prescription. According to the Egyptian law, antibiotics are prescription medications that should not be sold without a prescription; however, as in many developing countries, laws related to selling antibiotics are not enforced. An observational study of antibiotic dispensing encounters was conducted at 36 community pharmacies in Cairo, Egypt. The results of this study indicated that antibiotics are frequently dispensed from community pharmacies in Egypt without appropriate prescriptions and for inappropriate indications [15]. Moreover, as in many developing countries, Egyptian pharmacies have antibiotic provision practices that are particularly dangerous. Some Egyptian pharmacies have been selling what is called a "cold group" to pharmacy patrons. The Cold Group (CG) is a term used to describe a group of pills, usually 3-9, provided at a pharmacy to a patient who has cold symptoms. To prepare CGs, pharmacy staff cut pills out of blister packs of different common cold products. A CG may or may not include 1-2 pills of antibiotics. Given the complexity of this situation, and since the term 'dispensing' does not accurately fit the described behaviors, it was decided that the term 'provision' would be used collectively to refer to giving patrons antibiotics in the form of a CG or antibiotic pills.

The misuse of antibiotics in different settings in Egypt has had alarming repercussions. It has been postulated that the observed high resistance of bacterial meningitis to commonly used antibiotics was due to the availability of antibiotics without a prescription [16]. A study that monitored selected nosocomial pathogens from 38 centers in 13 European, three Middle Eastern countries and South Africa found that the

overall extended spectrum-lactamase production rate for the combined Enterobacteriaceae was highest in Egypt [17].

This study uses the simulated client methodological approach to identify the proportion of pharmacies involved in the dangerous practice of providing subtherapeutic doses of antibiotics for common cold patients as part of CG and upon direct request. It also aims to identify the active ingredients of antibiotic products provided in subtherapeutic doses.

METHODS

Ethical approval

The High Institute of Public Health Institutional Review Board at Alexandria University, Alexandria, Egypt approved the study.

Sample

This study employed a cross-sectional, descriptive survey design. The target population consisted of community pharmacies in the Alexandria governorate, the units of analysis in the study. The Ministry of Health (MOH) provided a list of 3350 potentially open community pharmacies as the sampling frame. To determine sample size it was assumed that small doses of antibiotics will be provided in 50 % of pharmacies. The sample was calculated at 95% confidence level using an absolute precision of 10% and a design effect of 1 since we used systematic random sampling. Calculation results indicated that 94 pharmacies would be needed.

Substantial planning went into identifying and enrolling the sample. To achieve a target sample of at least 94 pharmacies, we took into account the potential for pharmacies being closed, inaccessible or not found by the data collector. Two recent studies indicated that the proportion of pharmacies in Alexandria that were open, reachable and accessible to data collectors ranged from 89-90%.[18, 19] We assumed that no more than 15 % of pharmacies will be closed, under renovation, unreachable, or inaccessible to the data collector. We also assumed that the SC's identity may be accidentally disclosed in no more than 5% of pharmacies. Thus, 113 pharmacies were selected using systematic random sampling to achieve a final sample size of at least 94 pharmacies.

Simulated client method

With the simulated client method, a confederate pretends to be a patron. This method, which has had increasing popularity in research assessing pharmacy services in developing countries, generates an objective snapshot on the actual behavior of pharmacy staff[20]. In this study, the SC was instructed to adhere to the script and maintain neutrality at all times in order not to influence behavior of pharmacy staff members. He was instructed not to present information to pharmacy staff unless the staff asked. Role-playing was used in training the data collector before the start of the survey. Additionally, one of the investigators and the SC visited four pharmacies together during training in which the SC practiced the role as described in the training. These visits served to ensure that the SC adhered to the script and that he correctly used the provided checklist after leaving pharmacies.

Data collection

The SC approached the pharmacy staff member about to serve the next patron asking for a CG. Whether the staff member provided a CG or not, the SC asked for two antibiotic pills. Right before leaving, the SC would ask the staff member if the product that was given to him was an antibiotic. If asked about symptoms, the SC stated that his brother is the one who is ill. Information on the SC's brother's condition were provided if the staff member asked for them. The SC's brother was a described as a 30 year old male who is not taking other medications, not likely allergic to other medications and has not been to a doctor for his common cold. He was having classic symptoms of a common cold or non-specific upper respiratory tract infection (URI) including fever, cough, rhinorrhea, nasal congestion, postnasal drip, sore throat, headache, and myalgia [21]. Pre-testing of the scenario was conducted by one of the researchers who acted as the SC in a convenience sample of four community pharmacies in Alexandria.

Each pharmacy was visited once by the SC. As instructed, the SC answered questions according to the scenario, accepted the information offered, and paid for whatever product(s) given. The SC took mental note of counselling provided and questions asked related to symptoms, use of other medications, use of herbs, non-pharmacological management of common cold and instructions for use of medications provided. Questions asked by pharmacy staff, and counselling given were recorded by the SC on a standard reporting sheet immediately after leaving the pharmacy. The reporting sheet also covered the price paid for product(s) given to the SC and pharmacy staff's answer to the question on whether the product given was an antibiotic or not. The SC handed purchased products to the second author while providing information on where they were given to him upon request for a CG or upon direct request for two antibiotic pills. Data collection took place in the period from January to February 2016.

Data Analysis

The number of CGs with and without an antibiotic was determined as well as the number of encounters in which an antibiotic was provided upon direct request for one. To identify whether specific antibiotics are likely to be given, the active constituent(s) of each antibiotic product purchased were identified and recorded. The answer provided by pharmacy staff in response to the question on whether the product that was provided was an antibiotic or not was checked by examining the actual component of the product. Finally, the mean CG price, antibiotic products given upon SC request, and over the counter products were calculated.

RESULTS

Antibiotic provision among sampled pharmacies

Out of the 113 pharmacies in the sample, nine were either closed or not found (Figure 1). The SC visited 104 pharmacies and was sold an antibiotic at 68 pharmacies in total. A CG with one or more antibiotic pills was provided in 31 pharmacies. Upon request for two antibiotic pills, 2-8 capsules of antibiotics were provided in 30 pharmacies whereas a full antibiotic carton was provided in three pharmacies. In four pharmacies, the SC was sold a CG containing an antibiotic as well as another antibiotic upon request for two antibiotic pills. In total, a CG was provided in 72 out of 104 pharmacies with 35 out of these 72 pharmacies including an antibiotic in the provided CG. It was interesting to note that in five encounters, the SC was told that the CG contained an antibiotic when, in fact, it did not.

Active ingredients of purchased antibiotics

Table 1 shows the active ingredients for antibiotic products provided either as one of the ingredients of a CG or upon request for two antibiotic pills. Beta-lactam antibiotics comprised 76 % of antibiotics provided to the SC.

Average price for provided products

The mean price for a CG containing an antibiotic 2.35 EGP (0.30 USD) was nearly the same as an antibiotic free one, which was 1.92 EGP (0.25 USD). The mean price for antibiotic products provided upon SC request for two antibiotic pills was 2.77 EGP (0.36 USD) while the mean price for OTC products provided upon SC request for two antibiotic pills was 4.60 EGP (0.59 USD).

Counselling provided

The SC reported being asked questions related to symptoms in 36 encounters and questions related to use of herbs in three pharmacies. Screening for other medications that the patient may have been taking was not carried out in any of the pharmacies. The SC reported receiving information on instructions for use of medications provided in 71 pharmacies and non-pharmacological issues related to management of common cold in two pharmacies.

DISCUSSION

This study reveals that injudicious provision of antibiotics is extremely high in community pharmacies in Alexandria, Egypt. Of particular concern is including antibiotics in nearly half of the CGs provided to pharmacy patrons. Results also show that cheap antibiotics particularly beta-lactam antibiotics are abused at a higher rates than other antibiotics.

In agreement with findings in this study, studies that shed some light on dispensing antibiotics in subtherapeutic doses reveal high rates of providing patrons with antibiotics in small doses when simulated patients present symptoms of viral infections [12-14]. A study in a Peruvian community in Mexico revealed that 72% of the purchases were for insufficient quantities of drugs with the main perceived reasons for drug use being acute respiratory tract ailments and gastroenteritis. Another study in Kenya revealed that, in addition to high rates of providing antibiotics in subtherapeutic doses, drugs were sold in envelopes without no instructions or labelling. Despite these similarities, the cold group phenomenon that exists in Egypt has some unique aspects. A patient may not know that a CG contains an antibiotic and would use a subtherapeutic dose of an antibiotic without knowing so. In many ways, this is different from situations when patrons knowingly request an antibiotic as demonstrated by direct SC demand in this study.

A better understanding is also needed for determinants that influence the use of subtherapeutic doses of antibiotics by pharmacy staff members and patrons. These include pharmacy staffing, client expectations, physician practice and regulatory measures.[22] More information is needed on characteristics of patrons who demand subtherapeutic doses of antibiotics. This is particularly important since earlier research points out that, as other forms of self-medication, antibiotic use is strongly influenced by cultural preferences and beliefs.[23] Understanding all these factors is important in developing of effective policies and programs to address inappropriate this dangerous phenomenon.

An additional concern is that many of the antibiotics that are misused are listed in essential drug lists that satisfy the primary health care needs of the population. Findings of the study indicate that the abuse of beta-lactam antibiotics is particularly high. The loss of efficacy for beta-lactam antibiotics as well as others listed in essential drug lists might reduce the capacity of health authorities to optimize pharmaceutical resources for dealing with priority conditions.

Findings from this study shed some light on behavior of pharmacy staff in relation to ethics and the provision of antibiotics. The ethical principles of beneficence and respect for autonomy pose a conflict in judgment regarding a pharmacy patron who requests an antibiotic that he/she clearly does not need. In this study, a number of pharmacy personnel have chosen to lie to a patient on the content of the pills they received. This is a subject that is worthy of a discussion since some health professionals think that on rare occasions deceiving patients can be morally acceptable, while others believe it would be hard to foresee the ultimate consequences of such actions.[24] In all cases, pharmacy staff should not be lying to patients simply to save time or effort spent in convincing the patient that an antibiotic is not needed.

Multicomponent interventions should take into consideration the influence of patient expectations on health professionals' behavior. Greater attention should be paid to patient education and comprehension, particularly for patients with low socioeconomic status. Educational components of interventions such as media campaigns should be informed

with behavioral change theories. Key messages should be clear to make sure that legitimate use of antibiotics is not discouraged. Future research should thoroughly evaluate how interventions impact knowledge, attitudes, and behaviors of targeted groups including interactions between patients and pharmacy staff.

As with all studies, this research had both strengths and weaknesses. The probability sample with the simulated client methodology improves the generalizability of the quantitative phase of the study. The study design made it possible to verify whether an antibiotic was provided or not through making an actual purchase of the product offered to the SC. It also made it possible to identify antibiotic products that are most likely to be abused.

Limitations of this paper merit discussion. The sample was limited to pharmacies in Alexandria, Egypt's second largest city. Further work should be conducted in other parts of Egypt, particularly rural parts to compare trends.

CONCLUSION

Subtherapeutic doses of antibiotics are provided at high rates in Alexandria's community pharmacies. More work is needed to understand factors associated with this dangerous practice.

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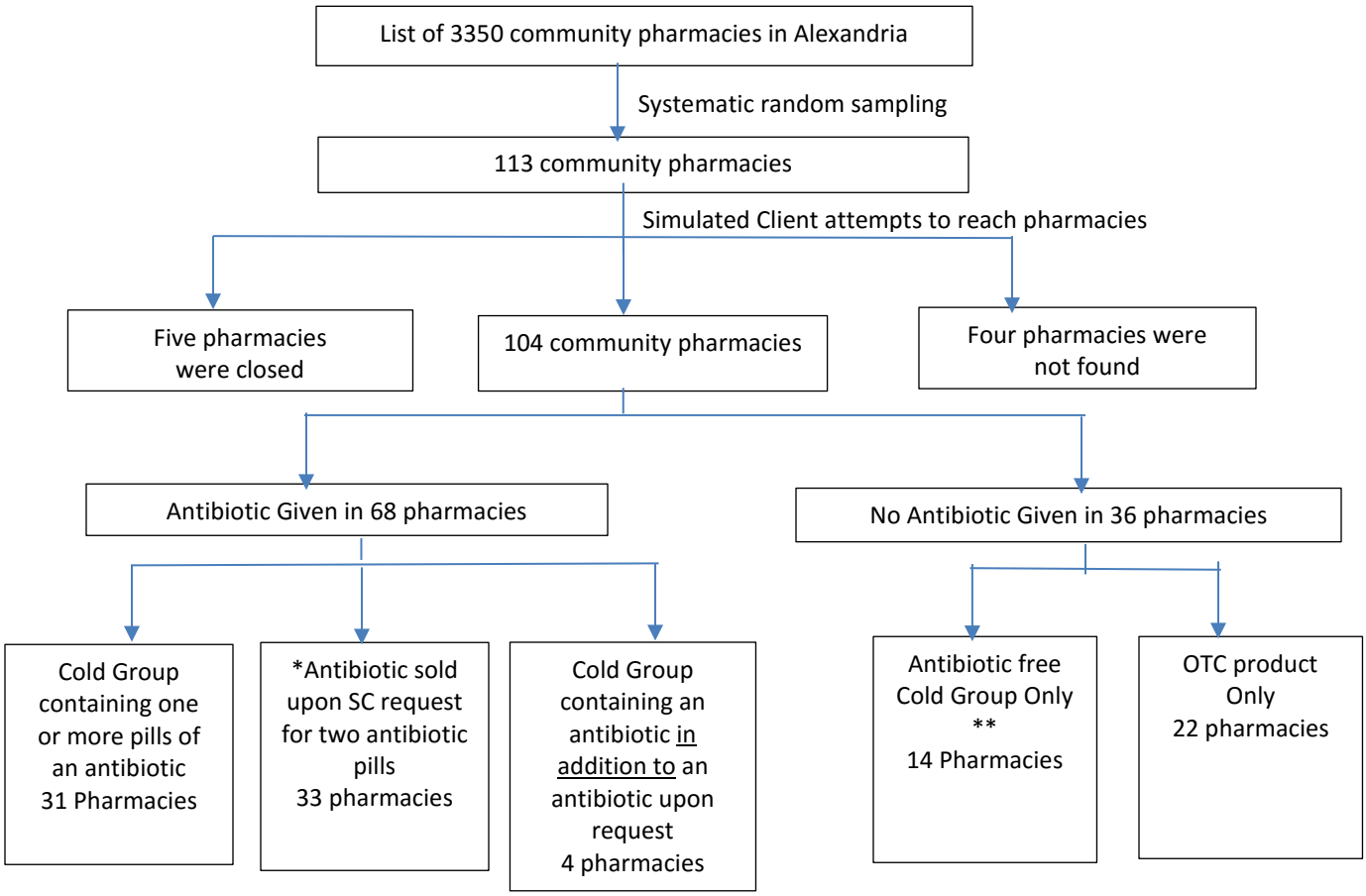
Figure 1: Sample identification and pattern of antibiotic provision



*Only three out 33 pharmacies provided full antibiotic cartons of antibiotics while the rest provided 2-8 pills of antibiotics.
** In five out of 14 pharmacies that gave an antibiotic free cold group, the SC was told that cold group contained an antibiotic when, in fact, it did not.

Table 1 Number of times in which an antibiotic chemical entity was provided to the simulated client

Antibiotic	Number of times in which antibiotic was included in a cold group	Number of times in which antibiotic was provided upon SC request	Total number of times in which antibiotic was provided
Ampicillin 250 mg + Flucloxacillin 250 mg	12	12	24
Amoxicillin 500mg	4	15	19
Tetracycline 250 mg	8	1	9
Ampicillin 50mg	6	1	7
Trimethoprim 80 mg/sulfamethoxazole 400 mg or Trimethoprim 160 mg/sulfamethoxazole 800 mg*	3	3	6
Cephalexin 500 mg	1	2	3
Cefadroxil 500mg	0	2	2
Azithromycin 500mg	0	1	1
Chloramphenicol 250mg	1	0	1
Total	**35**	**37****	**72*****

*Trimethoprim-sulfamethoxazole 160 mg-800 mg double-strength was only dispensed once. **A full antibiotic carton was only provided in three pharmacies. ***Antibiotics were sold 72 times in 68 pharmacies (In four pharmacies, the SC was sold a cold group containing an antibiotic in addition to an antibiotic upon request)