A comparative study between prescribed and over-the-counter antibiotics

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ABSTRACT

الأهداف: دراسة تأثير الخواص الديموغرافية الصيدلانية مثل العمر، والجنس، وسنوات الخبرة العملية على عملية صرف المضادات الحيوية التي يتم شراؤها بوصفة طبية أو بغير وصفة.

الطريقة: أجريت دراسة مقطعية في 24 صيدلية اختيرت اختياراً عشوائياً من بين 240 صيدلية في أبوظبي خلال الفترة من مارس حتى سبتمبر 2009م. تم جمع البيانات بواسطة استبيان مغلق وتحليله باستخدام برنامج إحصائي نسخة 17. تم حساب النسب الأحادية، ودرجة الأهمية، و 95% من مجال الثقة، كما أجري تحليل الانحدار اللوجيستي.

النتائج: نفذ الصيدلانيون المشاركون في الاستبيان على 1645 عملية صرف للمضادات الحيوية منها 1211 صرفت بوصفات طبية (73%) مقارنة بـ 434 عملية صرف تمت بدون وصفات طبية (26.4%). وكان لجنس المرضى وحالاتهم الاجتماعية الاقتصادية الأثر الكبير في الحصول على مضادات حيوية بدون وصفة طبية، وأظهرت النتائج أن أكثر المضادات الحيوية التي تصرف بوصفات طبية هي الكلاريثرومايسين (91.5%)، والسيفروكسيم (91.3%)، الكوأموكسيلاف (66.4%). بينما أشارت النتائج إلى أن أكثر المضادات الحيوية التي تصرف بدون وصفات طبية هي السيفرياكسون (53.3%)، والأموكسيسللين (47.8%)، والكوأموكسيلاف (33.6%). وحسب نتائج الاستبيان، فإن المضادات الحيوية التي تصرف بدون وصفات طبية إنما تصرف لمدة علاجية تتراوح من 5، 7 أيام، أو 10 أيام، مقارنة بالتي تصرف دون وصفة طبية حيث يتم وصفها لمدة تتراوح بين 7-3 أيام. وعادة ما يصرف الكوأموكسيلاف دون وصفة طبية لعلاج احتقان الحلق، فيما يصرف السيفترياكسون بمعدل ٍ مماثل سواء بوصفة طبية أو بغيرها، لعلاج الأمراض المنقولة جنسياً.

خاتمة: أن صرف المضادات الحيوية بدون وصفة طبية يعد أمراً غير قانوني وينطوي على خطورة بالغة، وهذا الواقع يحتم علينا إجراء مزيد من البحوث واللقاءات مع المرضى لاستقصاء آرائهم ومعرفتهم في هذا الصدد.

Objectives: To examine the influence of pharmacists' demographic characteristics on dispensing antibiotics purchased with and without a prescription in the community pharmacies.

Methods: This cross-sectional study was conducted in 24 randomly-selected community pharmacies located in Abu Dhabi, United Arab Emirates between March and September 2009. Data were collected through a closed-structured questionnaire and analyzed using the Statistical Package for Social Sciences Version 17. Descriptive statistics, odds ratios, significance and 95% CI and logistic regression analyses were then used to analyze the resulting data.

Results: Participating pharmacists conducted a total of 1645 antibiotic transactions (1211 [73.6%] dispensed with prescriptions versus and 434 [26.4%] without). Gender and socioeconomic status of the patients had a significant effect in acquiring antibiotics without prescription ($p=0.012$, $p=0.001$). Clarithromycin (91.5%), cefuroxime (91.3%), and co-amoxiclav (66.4%) were dispensed with prescription. Ceftriaxone (53.3%), amoxicillin (47.8%) and co-amoxiclav (33.6%) were dispensed without prescription. Dispensing of antibiotics with prescription were frequently given a 5, 7, or 10 day regimen, while those without prescription were frequently given 3-7 days duration. Co-amoxiclav for sore throat was commonly dispensed without prescription. Ceftriaxone for sexually transmitted diseases was dispensed at a similar rate, both with and without prescription.

Conclusions: Dispensing antibiotic without prescription is illegal and alarming. Patient interviews and interventions to improve the current prescribing pattern for both prescribers and pharmacists are highly warranted.

The alarming global increase in microorganisms resistant to antibiotics poses a major public health problem. Although the increasing resistance can be attributed to several factors, a major cause is the overall volume of antibiotic consumption and, in particular, wrong diagnosis, indiscriminate prescribing and dispensing errors.[1] In arrears to the steep increase in antibiotics use during the past decade, the professional activities of the community pharmacist have changed dramatically. In addition to assuring high quality in dispensing, responsibilities of the pharmacist have been extended to include detection, prevention, and resolution of drug-related problems.[1] Several studies related to the quality of dispensing, have been conducted. Pharmacists' social demographic, educational background[2,3] and opinion about their activity have been considered as the most likely determinants of the quality of dispensing.[4,5] In recent years, one study on antibiotics prescribing concluded that small doses and long duration were both associated with increased risk of antibiotic resistance.[6] Antibiotics consumption should be reduced to avoid and diminish its serious environmental impacts. There are several studies focusing on the disproportionate excessive use of antibiotics.[7,8] Setting a proper antibiotic polices and raising the community awareness of the dangerous of their inappropriate use of antibiotics may contribute in diminishing this prevalence. Promoting the appropriate use of antibiotics through various interventions will help avoid unwarranted prescribing and misuse of antibiotics.[1] For appropriate interventions to be carried out across the community, it is important to know to what extent the population uses antimicrobials. Enhanced surveillance could play a positive role in controlling antimicrobial over-use or misuse. Countries such as Denmark and Spain have a database of antibiotics prescribed for all patients in the country. Prescription information for various populations (such as, children versus adults) and between different provinces of the country have been analyzed to determine trends in antimicrobial use at the population level.[9,10] Antibiotic OTC dispensing is common specially in developing countries. In UAE, it is illegal to dispense an antibiotic without a prescription; therefore, we conducted this study to know to what extent, going beyond the minimum requirements of laws and regulations. The main objectives of this study were to examine the influence of pharmacists' demographic characteristics (age, gender and years of work experience) on the dispensing of antibiotics purchased with and without prescription, with respect to legality, rationale, and safety, and to study the pattern of dispensing antibiotics, both with and without prescription, with regard to frequency, cost, indications and reasons for dispensing.

Methods. The study was conducted in Abu Dhabi, United Arab Emirates (UAE). Pharmacies included in the study were identified from the UAE Ministry of Health database. Written approval to conduct the study was obtained from the Health Authority of Abu Dhabi (HAAD), UAE. The allocation of the study sites was accomplished based on the pharmacies geographical area in Abu Dhabi city. This was a cross-sectional study conducted in 24 community pharmacies randomly selected from a total of 240 located in Abu Dhabi UAE during March to September 2009. The random selection was carried out by sealed envelope technique. Each 10 pharmacies were represented by one pharmacy, based on the geographical location. The random selection of the 24 represented pharmacies was performed by a third party.

The World Health Organization (WHO) manual[11] recommends that 600 encounters (20 facilities and 30 patients or prescriptions) per facility are sufficient to reflect the power of a study and the statistical inferences. We used a multistage cluster sampling (pharmacies represented the cluster and pharmacists represented the population) that each pharmacy was represented by one pharmacist, which yielded 24 pharmacists. We explained the purpose of the study to the selected and consenting pharmacists by a structured information sheet. Confidentiality of information was maintained. The study research team developed a closed-structured questionnaire to examine the impact of demographic characteristics of the pharmacists (age, gender and years of practice experience) and patient demographic data (age, gender and socio-economic status) with respect to the dispensing of antibiotics, both with and without prescription, with regard to legality, rationale and safety. The data included the dispensed antibiotic information [trade name, generic name, strength, treatment duration, cost and mode of dispensing (with or without prescription)], as well as indication for use.

The socio-economic status of the patient was determined using a scale ranging from low (≤2000 Arab Emirates Dirham's AED), medium (>2000 AED and <5000), and high (≥5000 AED) based on each individual monthly income. The questionnaire was administered to each of the pharmacists representing

the 24 pharmacies. Pharmacists were asked to complete their demographic data and to collect the required data from patients' dispensed antibiotics, either with or without prescriptions. Data were collected during the period from March to June 2009, irrespective of the degree of completion of the questionnaires for the 100 patient encounters that involved antibiotics.

Data were entered and analyzed using SPSS version 17. Descriptive statistics were generated to determine patterns of distribution. Variables found in the univariate analysis (pharmacist code, age, gender and years of work experience, and patient socioeconomic status) were strained into a multivariate model ($p \geq 0.05$). Forward stepwise logistic regression was used. Odds ratios (OR), significance, and 95% confidence intervals were calculated for predicting the related factors of dispensing antibiotic without prescription.

Results. Of the 24 selected pharmacies, only 20 pharmacists completed the questionnaire; a response rate of 80%. Demographic characteristics of the participating pharmacists are shown in **Table 1**. Participating pharmacists dealt with a total of 1645 patient transactions involving antibiotics, which were dispensed either with prescriptions [n=1211, (73.6%)] or without prescriptions [n=434, (26.4%)]. Only one pharmacist did not dispense antibiotics without a prescription during the study period. Results have shown a highly significant association between pharmacists' age ($p=0.001$) and gender ($p=0.001$) and antibiotic dispensing practice. Male pharmacists had preponderance over female in dealing with OTC antibiotics. There was an increase seen in antibiotics dispensed without prescriptions with increasing years of pharmacists' experience. Of the 1645 reported transactions with antibiotics, 1211 (73.6%) patients presented at the pharmacy with prescriptions and 434

(26.4%) without prescription. Patient's demographics are shown in **Table 2**. Over 61% of the study population was between 31-50 years of age (pharmacists and patients). Gender and socioeconomic status significantly affect the manner in acquiring antibiotics without a prescription ($p=0.012$ and $p=0.001$). For example, females and individuals with low socioeconomic status tend to request antibiotics without a prescription more frequently.

Strong predictors for dispensing antibiotics without prescription using the logistic-regression model were pharmacist's age (OR 1.36; $p=0.001$), pharmacist's gender (OR 0.621; $p=0.001$), pharmacist's experience (OR 0.686; $p=0.001$), patient's socioeconomic (OR 1.836; $p=0.001$) patient's gender (OR 1.346; $p=0.012$) (**Table 3**).

The probability of dispensing antibiotics without prescription increased with pharmacists' age. Being a male patient with low socioeconomic status increased the likelihood of acquiring an antibiotic without a prescription. We did not identify any relationship between patient age, reason (diagnosis/symptoms), and acquiring an antibiotic without prescription. Over the study period, 25 types of antibiotics were dispensed with and without prescription. Mann-Whitney U test showed a significant difference between antibiotics dispensed with and without ($p<0.001$). Clarithromycin (91.5%), cefuroxime (91.3%), and co-amoxiclav (66.4%) were the most dispensed antibiotics with prescription. Ceftriaxone (53.3%), amoxicillin (47.8%) and co-amoxiclav (33.6%) were the most frequently dispensed antibiotics without prescription. Antibiotics such as ofloxacin, moxifloxacin, cefprozil, cefixime, cefidinir and spiramycin were dispensed with prescriptions, while cotrimoxazole and spectinomycin were dispensed without a prescription. Prescribed antibiotics frequently used for treatment duration of 5, 7

Table 1 - Demographic characteristics of the participating pharmacists (N=20).

Characteristics	n (%)
Age (years)	
26-30	3 (15)
31-40	8 (40)
41-51	9 (45)
Gender	
Male	10 (50)
Female	10 (50)
Years of work experience	
4-5	2 (10)
6-10	4 (20)
11-20	11 (55)
21-26	3 (15)

Table 2 - Demographic characteristics of patients with and without prescriptions.

Variable	Individuals n=1645	With prescription n=1211	Without prescription n=434	P-value
Age (years)				
17-28	484 (29.4)	360 (29.7)	124 (28.6)	
29-40	635 (38.6)	446 (36.8)	189 (43.5)	
41-52	375 (22.8)	306 (25.3)	69 (15.9)	
>52	151 (09.2)	099 (08.2)	52 (12.0)	
Gender				
Male	949 (57.7)	717 (59.2)	232 (53.5)	0.012
Female	696 (42.3)	494 (40.8)	202 (46.5)	
Socio economic status				
High	314 (19.1)	237 (19.6)	77 (17.7)	0.001
Medium	949 (57.7)	768 (63.4)	181 (41.7)	
Low	382 (23.2)	206 (17.0)	176 (40.6)	

Table 3 - Logistic regression model for factors associated with dispensing and acquiring antibiotic without prescription.

Variable	*P*-value	Odd ratio	95% CI	
			Lower	Upper
Pharmacist age	0.000	1.357	1.178	1.564
Pharmacist gender	0.000	0.621	0.476	0.811
Pharmacist experience	0.000	0.686	0.593	0.793
Patient-customer age	0.515	1.004	0.992	1.016
Patient-customer gender	0.012	1.346	1.067	1.698
Patient-customer socio economic	0.000	1.836	1.532	2.201
Reason	0.880	1.002	0.979	1.025
CI - confidence interval				

Table 4 - Distribution of J01 antibactirial and the cost of the 2 subgroups.

ATC	Name of therapeutic subgroup	Total cost	*Cost	
			With prescription	Without prescription
J01A	Tetracyclines	1207	1002	205
J01C	Penicillins	46435	32631	13804
J01D	Other beta-lactam antibacterials	42290	36786	5504
J01F	Macrolides	36088	31634	4454
J01M	Quinolones	25520	20616	4904
J01E	Sulphonamides & Trimethoprime	205	0	205
J01X	Other	367	292	75
Total		152112	122961	29151

*Cost in Emirates Dirham, 1$ = 3.67 ADH. ATC - Anatomical Therapeutic Chemical Classification, J01 - third level of ATC system

and 10 days, while those dispensed without prescription were used for 3-7 days. The mean treatment duration of prescribed antibiotics was 6.47±2.62 days. The mean treatment duration of without prescription antibiotics was 5.74±2.484 days. The duration between the 2 groups (prescribed antibiotics and antibiotics without prescription) showed significance difference (*p*<0.000). Each dispensed antibiotics was stratified according to the Anatomical Therapeutic Chemical Classification (ATC). The trend was expressed by the J01 (third level of ATC system). The total cost for each subgroup is presented in **Table 4**. The total retail cost of all dispensed antibiotics was 152,112 Arab Emirates Dirham's (AED) (US$41,560). Those dispensed with prescription was 122,961 AED (US$33,595); 80.8% of the total cost. Dispensed without prescription was 28,151AED (US$7,691); 19.2% of the total cost. The therapeutic subgroup (J01C) was the leading subgroup, with a total cost of 46,435 AED (US$12,687) on prescription antibiotics, and 13,804 AED (US$3771) on antibiotics dispensed without prescription (29.7%). The macrolide subgroup (J01F) yielded a total cost of 36,088 AED (US$9,860). Our research revealed that the most dispensed antibiotic, with or without prescription was co-amoxiclav and mainly prescribed for sore throat. It was also preferred over cefuroxime and clarithromycin by prescribing physicians, while azithromycin was more likely to be chosen by pharmacists. Our results indicate that co-amoxiclav and cefuroxime are frequently prescribed for cough, whereas amoxicillin and co-amoxiclav were offered by pharmacists without prescription for patients with cough. Co-amoxiclav and clarithromycin were dispensed both with and without prescription for influenza. Co-amoxiclav, cefuroxime, clarithromycin, and azithromycin were the most prescribed antibiotics for upper respiratory tract infections RTIs, whereas amoxicillin, co-amoxiclav and azithromycin were dispensed by pharmacists without prescription for this indication. Cefixime and moxifloxacin were only dispensed with prescription, and most commonly for RTIs. Results showed that ceftriaxone was similarly prescribed by physicians and dispensed without prescription for sexually transmitted diseases (STDs). Ciprofloxacin was the most widely prescribed antibiotic for urinary tract infections (UTI). Amoxicillin and macrolides (clarithromycin and azithromycin) were usually prescribed and dispensed without a prescription for *Helicobacter pylori*. Dentists and pharmacists favored amoxicillin and co-amoxiclav for toothaches.

Discussion. Abu Dhabi pharmacy practice and pharmacies are regulated by UAE Federal Law No. 4 (1983) for the pharmaceutical profession. In 2001, The General Abu Dhabi Health Service (GAHS) was established to oversee the practice of all Abu Dhabi hospitals and primary health centers and regulate the private pharmacy sector, including community pharmacies and drug stores. The GAHS was replaced in 2007 by 2 organizations: a regulatory body called HAAD, and an operational body called Abu Dhabi Health Services Company (SEHA).

In our study, we assessed pharmacist's demographic profile in terms of their age, gender and years of work experience with regard to dispensing antibiotics with or without prescription. It was conducted through a closed-structured questionnaire, which has contributed to the relatively high response rate of the selected sample of pharmacies, (80%) compared to 98.8% reported from Spain[12] and 37.7% conducted previously in the UAE.[13] The gender of participating pharmacists was equally distributed, while the participant gender rate in a Pakistani study[14] was predominantly males (99%). Our results revealed a significant association between the age of the pharmacist and the rate of dispensing antibiotics without prescription (p=0.001). Results also showed that 95% of the pharmacists in the study dispensed antibiotics without a prescription, which has exceeded the 85% rate reported in Brazil.[15] During the study period a total of 1645 transactions involving antibiotics were reported; 73.6% with a prescription from a physician or dentist and 26.4% without a prescription. These results were better than those reported in Jordan[16] (42.5%), Nigeria[17] (57.7%), Mongolia[18] (57.9%), and Palestine[19] (60%). Among the patients visiting the participating pharmacies during the study period, 57.7% were males and more likely to acquire and antibiotic without a prescription, especially, those with a low socioeconomic status.

Our logistic regression model results indicate that the risk factors associated with non-prescription antibiotic use were pharmacist age, gender, and years of work experience, as well as patient's socioeconomic status and gender [OR: 1.36, 0.621, 0.686, 1.836, 1.346]. Similar findings have been reported in Spain,[12] Jordan[20] and Brazil.[21]

Regarding specific antibiotics, our study revealed the top 10 dispensed antibiotics such as co-amoxiclav, clarithromycin, amoxicillin, cefuroxime, ciprofloxacin, azithromycin, ceftriaxone, moxifloxacin, cefdinir, and cefixime, in descending order. This pattern was similar to those from Croatia,[22] yet differs from those reported in Indonesia[23] where widely-restricted amphenicols (chloramphenicol group) are still in use despite their harmful aplastic anemia side effect. Healthcare providers continue prescribing antibiotics for respiratory infections, which were most likely viral in origin. Such a prescription pattern will likely contribute to the emergence and spread of resistance.[24,25] The most common reason for both prescribing as well as dispensing antibiotics without prescription was upper respiratory tract infections, mostly non-specific type in which sinus, pharyngeal, and lower airways symptoms were frequently present but not prominent. It is noticeable that pharmacists can have the same behavior of physicians in prescribing broad spectrum antibiotics[26] due to their ability to perform quick and simple examination on the patient with these respiratory infections. Another reason for this behavior could be due to the persistent requests from patient to the pharmacist to dispense antibiotics to them without prescription according to their previous treatment experiences to avoid the extra charges when consulting a physician. Although the major cause of urinary tract infection, *Escherichia coli*, is resistant to fluoroquinolones and quinolones,[27,28] the study revealed that both prescribers and dispensing pharmacists were still recommending them. Furthermore, no patient in our study population was treated by the drug of choice for this indication, nitrofurantoin.[29] Prevalence of dispensing antibiotics without prescription in Abu Dhabi has declined since the implementation of a mandatory medical insurance program (HAAD). This decline has reached 68.4% in 2005.[13,30] Our data showed a further decline of 26.4%, nearly half the rate reported in 2006. This is can be attributed to the insurance mandate, since patients must now acquire a prescription for their antibiotics. The enforcement of the mandate requires that the offending pharmacist will be suspended from practice for 30 days; therefore, few pharmacists were dispensing antibiotics without prescriptions. Furthermore, HAAD is now a member of The Alliance for the Prudent Use of Antibiotics (APUA). Health Authority Abu Dhabi is organizing pharmacist workshops on antibiotics overuse, antibiotics resistance, and a campaign to increase pharmacist adherence to the antibiotic mandate.

We conclude that lack of antibiotic usage guidelines can lead to misuse and over-prescribing, as reported in accordance to other similar studies.[12,13,20] Antimicrobial resistance is a worldwide threat affecting both industrialized and developing countries.[31] Controlling the use of antibiotics is of paramount importance in both the community and hospital settings. The first

step to overcome this is by identifying the prescribing, dispensing, and consumption of the antibiotics used in the community.[32] Therefore, we believe that in order to combat the problem of OTC dispensing of medicine, it is necessary to enhance pharmacists and patient awareness, perform random surveillance and legislate and impose rules and regulations.

Study limitation. We have utilized self-administered questionnaire by participating pharmacists to collect data; however, this method of data collection may experience the following limitations: 1) it may raise some discrepancies within the participating pharmacists with different work load and it may also increase the chances that the questionnaires been filled by the pharmacy technician.

In conclusions, prevalence of dispensing antibiotics by community pharmacists without prescription is illegal and alarming. Further research and patient interviews will provide greater insight into the problem. Pharmacists with long pharmacy practice dispense antibiotics as OTC more often than younger generation. Pharmacists and patients' perception, knowledge and attitude are crucial in developing interventions to improve the current practices of dispensing medicine. Insurance company may develop low-priced formulary antibiotics models to help low income patients to acquire their antibiotics after consulting the physicians. It is recommended to avail antibiotics, such as nitrofurantion for UTIs as an alternative to the quinolones in order to reduce resistance to ciprofloxacin also drug utilization research have become critical, in order to gain firsthand knowledge of what is being consumed. In the absence of this research, and subsequent guidelines, protocols and policies, it would not be possible to identify the problems and set priorities to improve and change current practice.

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