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Dispensing medications without prescription at Saudi community pharmacy: Extent and perception

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KEYWORDS

Medications; Dispensing; Non-OTC drugs; Without prescription; Saudi Arabia; Jeddah **Abstract** *Objective:* To investigate the dispensing behavior of pharmacists in retail pharmacy practice and to assess their attitude toward dispensing non-OTC drugs and scrutinize the causes of their malpractice; if in fact was perceived.

Method: Between December 2010 and January 2011 retail pharmacies in Jeddah-KSA were visited randomly by a number of voluntary collaborators who played the role of asking for one or more of the following medications without providing a prescription: Co-amoxiclav (Augmentin) or Cefaclor (Ceclor), Captopril (Capoten) and Fluoxetine (Prozac).

Results: A total of 60 pharmacies were randomly included in this study; 100% of the pharmacists working were male, 96.7% of them were non-Saudis and only 2 (3.3%) were Saudis. In a total of 119 drug requests, almost all pharmacists (97.9%) handed out the antibiotic immediately, 100% dispensed captopril and 89.5% gave the antipsychotic simply by following the collaborator's request without even asking for a doctor's prescription. In the second part of the study (where a mini-questionnaire is administered), 85% of the pharmacists agreed to answer the mini-questionnaire, and 15% refused to participate. The highest reason given for their wrongdoing, was for that if the pharmacist did not, others – of neighboring pharmacies – would do the same, followed by that there is no available OTC list.

Conclusion: The study confirmed that pharmacists are still violating the law, which is leading to a profound malpractice in retail pharmacies around the country. Consequently, regulations should be reviewed and structured educational campaigns are a must to both pharmacists and public. The OTC list should be generated, implemented, and monitored by Saudi regulators and penalize violators.

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1. Introduction

Malpractice is a type of negligence that may arise from a professional's misconduct or failure to use adequate levels of care, skill or diligence in his performance, and further failing to follow generally accepted professional standards, and that breach of duty is the proximate cause of injury to a plaintiff

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who suffers harm. And when that takes place in the health care system, only then would it be health threatening, and thus worthy of investigating.

In 1978, a law regulating the profession of pharmacy in Saudi Arabia was passed. The law demanded professionalization of pharmacy performance and precluded the practice of pharmacy by persons other than licensed pharmacists. Furthermore a pharmacist is required to dispense drugs on prescription only, except those defined as OTC (Bawazir, 1992). This is of main concern; as an earlier study conducted by Al-Freihi et al. (1987), found that 85.4% of pharmacies dispensed antibiotics (a class known to be a prescription-only drug) promptly. Unfortunately, a study directed by S.Bawazeir in Riyadh in 1992 stated that more than 35% of drugs dispensed over-the-counter were prescription drugs (Bawazir, 1992). These findings draw high attention to the possible misuse of non-OTC drugs by the community, especially when no serious actions have been taken within the 5 years that separated these two studies.

On top of that, a more recent study conducted by Al Ghamdi, in 2001 surmised that despite the lack of pharmacist's adherence to the pharmaceutical law, which represented (98.9%), it did not indicate that they had abused their patients (Al-Ghamdi, 2001). Sadly this can only lead to further negligence of the law.

Therefore, the aim of the study; is to investigate the drug dispensing practice in retail pharmacies at Jeddah city and assess the adherence of pharmacists and attitude toward the regulations issued by pharmacy law.

2. Methodology

Betwen December 2010- January 2011 retail pharmacies in Jeddah-KSA were visited randomly by a number of voluntary collaborators who played the role of asking for one or more of the following medications mainly by name; without providing a prescription:

- 1. Antibiotics: Co-amoxiclav (Augmentin) or Cefaclor (Ceclor).
- 2. Antihypertensive: Captopril.
- 3. Antipsychotic: Fluoxetine (Prozac).

or alternatively by mentioning the chief complaint of either sore throat or depression. For the purpose of the study, Jeddah was divided into three main regions according to the abundance of pharmacies within each region (North 40%, center 30% and south 30%) covering a total of 60 pharmacies, and further sub-divided into chain, single and hospital pharmacies. During the training of the collaborators on how to perform the study's scenario, they were advised not to insist in case the medication was not dispensed or if the pharmacist asked for a prescription, in order not to influence the pharmacist's decision.

After the collaborator had played his role, he then invites the pharmacist to fill a simple highly confidential questionnaire to record the level of the pharmacist education only; excluding any other personal information such as: age, name, etc. to encourage them to answer the questionnaire freely and tick any attitudinal item(s) behind dispensing the drugs as follows:

Panel 1. Reasons to be selected by pharmacists.

A pharmacist has some authority to dispense the drug without the need of a Doctor's prescription

The drug dispensed is not a harmful drug

Other pharmacies would have done the same
The pharmacy policy does not prohibit this
The SFDA never provided us with an OTC list

There is no known fine or control by the SFDA

In addition a space was provided to the pharmacist at the end of this questionnaire to add any extra comments. Later, the pharmacist demographics and his reaction to the request—played scenario-was filled by the collaborator in a different designated form.

The study wanted to assure the pharmacist would feel comfortable answering the questionnaire given to them, explaining his "obvious" breach of law and in order to do that, collaborators were well trained and were asked to ask for as many drugs as the pharmacist would provide without being neither obvious nor ridiculing. Some asked for all and some only asked for one (specially when mentioning a drug-specific symptom such as sore throat).

To further question pharmacists' consideration of patient's age or degree of illness, a four phone scenario was selected to be added to the study method in order to explore whether if seeing the patient mattered at all in his decision making. They were four out of 38 requests because 10% is thought to reflect an image of the negligence that is affecting the community. Phone scenarios were specific for the antipsychotic medication being the most expensive and also the least expected to be given due to the potential harm it may cause and the utter requirement of a proper psychiatrist diagnosis and follow up.

Differences between pharmacies ownership, location, and different scenarios approached were compared using Mann-Whitney U test and Kruskal-Wallis. All statistical analyses were performed using SPSS (v16) software.

3. Results

A total of sixty pharmacies were included in this study; the ownership of these pharmacies was 78.3% as chain pharmacies, 18.3% as single pharmacies and 3.3% represents private hospital pharmacies Fig. 1.

All pharmacists working were male (100%), majority of them were non-Saudis (96.7%) and only 2 were Saudis (3.3%). Most of the pharmacists were of bachelor's degree holders (85%) and only 2% had Pharm.D degree. The mean age of the collaborators was 25 years (\pm 17), 5% of them were male. The pharmacists and collaborators' demographics are presented in Table 1:

In a total of 119 requests, 70% of the collaborators requested for the drug by mentioning its name, and 30% asked the pharmacist to recommend a medicine for their illness. The overall requests have yielded 48 requests of Antibiotics (40%), 38 requests of Antipsychotics (32%) and 33 requests of Antihypertensives (28%). The results were as follows:

4. Antibiotics

Almost all pharmacists (97.9%) handed out the drug either by recommending it or simply following the collaborator's re-

¹ http://legal-dictionary.thefreedictionary.com/malpractice.

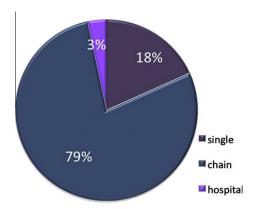


Figure 1 Ownership of pharmacies.

quest. Whereas, only one pharmacist (2.1%) refused to dispense any, and this pharmacy was located in a private hospital.

5. Antihypertensives

In all 33 cases, 100% of Captopril requests were consequently dispensed; the pharmacists gave neither reasoning nor questioning in all cases.

6. Antipsychotics

In a total of 38 requests; the majority of pharmacies (89.5%) gave the drug willingly and only 10.5% asked for a doctor's prescription Fig. 2.

Phone scenario results; revealed that out of four phone calls where the collaborator asked the pharmacist in charge to

Table 1 Demographic information of pharmacies in Jeddah; KSA (n = 60), pharmacists and collaborators.

Variable	Frequency	Percentage (%)
Pharmacy's ownership)	
Chain	47	78.3
Single	11	18.3
Hospital	2	3.3
Pharmacy's location		
North	24	40
South	18	30
Center	18	30
Pharmacist's national	ity	
Saudi	2	3.3
Non Saudi	58	96.7
Pharmacist's educatio	n	
Pharm.D	6	10
Bachelor	51	85
Post graduate	2	3.3
Technician	1	1.6
Collaborator's age		
< 18	2	3.3
19-30	53	88.3
31–55	1	1.7
> 55	4	6.7
Chief complain		
Mentioned	18	30
Not mentioned	42	70

recommend something for his depression, two pharmacists recommended Fluoxetine without any patient education, and two refused to dispense it and recommended the need of a doctor's visit.

Data of this study showed that there was no statistical difference in providing these items between pharmacy's ownership, location, and neither by way of getting the drug requested or by different scenarios approached.

In the second part of the study, majority of pharmacists (85%), who previously handed out the drug, agreed to administer the mini-questionnaire giving 15% to those who refused to participate claiming that they were busy Fig. 3. The highest reason given was for that if the pharmacist did not provide the drug, others would do the same (20.65%), followed by that there is no OTC list available (16.3%). Structured reasons are illustrated in Table 2.

In the space given in the questionnaire, the pharmacist's own reasons were mostly about that the country's policy permits providing these drugs without prescription, the CNS and chronic medications do not need any prescriptions or that, the patient asked for these drugs by name. However, all the reasons that were expressed by them were quoted as follows:

Reasons added	Frequency	Percent (%)
There is no need for a prescription	60	100
for chronic and CNS diseases		
The patient asked for the drug by name	56	93.3
Most people can only afford pharmacy visits	55	91.6
We do whatever the patient needs	45	75
and the pharmacist has enough		
knowledge to consult		
It is not a prescription drug in KSA	22	36.6
All drugs available in the retail	18	30
pharmacies are OTC-drugs, and		
the prescription drugs are only		
available at hospitals		
The customer might think that	14	23.3
the pharmacy is not good enough,		
which affects the pharmacy's reputation		
Some patients may get very aggressive	9	15
It all depends on the country's policy,	7	11.6
for example; in India every drug is		
only dispensed with a prescription		

7. Discussion

The results of this study complemented those of other regional Saudi studies, conducted in Riyadh and the eastern province. However this study expands on them by including two additional classes of drugs, to see how far a pharmacist could manipulate the regulations (regarding dispensing prescription medications) (Bawazir, 1992; Al-Ghamdi, 2001). The results of this study indicate that any drug -despite its class- could be easily purchased in Saudi pharmacies without a prescription. Unfortunately, hardly any pharmacist refused to dispense antibiotics and anti-hypertensives, in fact none of them asked for justification for the purchase even if the collaborator seemed to be in good health. Yet antipsychotics, which are supposed to be restricted, were freely dispensed in most visited pharmacies. The overall faulty dispense of medication in this study has exceeded the results of other European countries;

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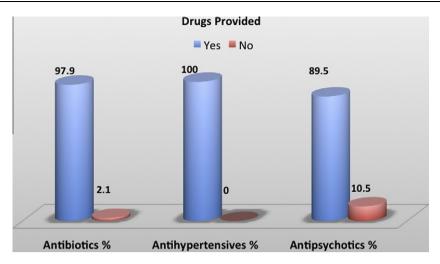


Figure 2 Pharmacist response to drug requests by class.

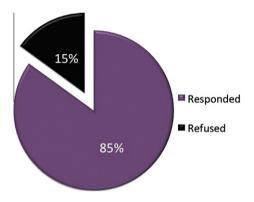


Figure 3 Pharmacists response rate.

Table 2 Pharmacist's responses to the reason(s) for providing drugs without prescription.

Reasons of dispensing the selected drugs	Frequency	Percent (%)
If I did not, other pharmacies would	38	20.65
There is no such thing as OTC list	30	16.30
Pharmacist has some authority to	26	14.13
dispense without the need of		
a doctor's prescription		
No fine or control by the SFDA	25	13.59
The pharmacy policy does not	22	11.96
prohibit dispensing without a prescription		
The drug dispensed is not a harmful drug	22	11.96
Others (reasons given by surveyed pharmacist)	21	11.41

although those were concerned about antibiotic abuse only, given that antihypertensives and antipsychotics are highly restricted, hence their suspension from the European studies (Llor and Cots, 2009; Vaananen et al., 2006; Borg and Scicluna, 2002).

Concerning the purchase of antibiotics, historically speaking, the number has not changed much, but rather increased for the total number of pharmacies violating the law. Even though antibiotic resistance is a growing health hazard in society, pharmacies overlook the risk of developing this growing

resistance (Bawazir, 1992; Al-Ghamdi, 2001; Memish et al., 2004). Pharmacists never asked questions regarding antibiotic resistance, including previous use of antibiotics. Dispensing them without a prescription adds to the selective pressure for antibiotic resistance (Memish et al., 2004). This leads in turn to increased costs to the community because of the need for pricier, broader-spectrum agents, extra visits to medical practitioners, and further prescriptions or hospitalizations for antibiotic failures. Broader-spectrum agents generate further resistance, leading steadily to multidrug resistance. Eliminating unnecessary antibiotic use cannot stop resistance emerging, but can reduce its frequency and prolong the useful life of older and cheaper antibiotics (McManus et al., 1997). Antihypertensives seemed to be the easiest drug class to be dispensed; no pharmacist refused to dispense Captopril and none of them asked for any justification for the purchase; alleging that chronic drugs should be dispensed knowing that 93.3% of pharmacists agreed to dispense medications when asked by name, because they think that patients know the importance of their medications and claiming to collaborators that "the benefit outweighs the risk of not dispensing".

For that reason, the study wanted to detect whether pharmacists would behave any differently when a symptom in fact was made or not. Collaborators faked symptoms that require a medical referral in order to prescribe a suitable antibiotic or proper psychiatric visits. As expected 30% visited pharmacies (with a chief complaint) who dispensed the suspected medications readily. It's worth mentioning that a pharmacist has the right to only provide the patient with symptomatic – over the counter – relievers and ask the patient to see a doctor if symptoms seemed to persist. However pharmacists indirectly diagnosed and prescribed a non-OTC drug accordingly.

Nevertheless, the pharmacists also added that if the patient showed a bad response to the medication or a side effect, only then would they recommend the patient to visit his doctor. Even though regular blood pressure check ups should be done on a regular basis at clinics, kidney or liver function may also be needed to be tested; and the doctor may occasionally change the dose to make sure the patient is getting the best results from his medication.²

² http://www.drugs.com/search.php?searchterm = captopril.

When it came to Antipsychotics, results show that only 10.5% of surveyed pharmacists were concerned, and encouraged the collaborator to see a doctor first. No pharmacist refused to dispense Fluoxetine when asked by name (Prozac) and again they mention that it is a chronic medication. Prozac is approved by the US-FDA for the treatment of major depression, obsessive-compulsive disorder, bulimia nervosa and panic disorders. Despite that, antidepressants can increase the risk of suicidal thinking and behavior in children, adolescents, and young adults and so, proper diagnosis, by a psychiatrist is a necessity; and this drug is prescribed only after failing many non-pharmacological approaches. Moreover, the SFDA has it classified as a prescription only medication under the drug's status.

Additionally, patients of all ages who are started on antidepressants or those taking a new dose should be monitored closely for clinical worsening, suicidality, and unusual behavior. That being said, pharmacists never asked wheather the drug was chronically used or not (but only assumed so) and no patient education or dosing information was given by them. However, to test whether the pharmacist in fact dispensed the drug because it was chronically used or not; our collaborators called the pharmacist in charge –in some pharmacies- and asked them to recommend something for depression, 50% of the called pharmacists recommended Prozac, and dispensed it. In spite of that, again no patient education was given.

On the whole, prescription medications were made available and when asked by name, no instructions were given at all. It was rather surprising and concerning to find that some pharmacists debated; all drugs available in retail pharmacies are OTC-drugs, and the prescription drugs are only available at hospitals (30%). Out of all sixty pharmacies visited, only one had an OTC list – that was not even provided by the *Saudi officials*- but rather done by a pharmaceutical company titled "The Saudi OTC directory" which was approved by the MOH (Ministry Of Health) and was the 8th edition (2009/1430). This "list" is supposed to be reviewed periodically – if not annually- and published by those responsible of the society's health and made available in every pharmacy around the country.

Shockingly some pharmacists mentioned that antibiotics are harmless to patients, undermining the degree of pharmacy and knowledge of a pharmacist, and this represents the danger implied to society, requiring an urgent reconsideration of the person behind the counter. In contrast, the same pharmacists claimed that they have enough knowledge to recommend the appropriate drug for the patient's illness, which is rather contradicting to the previously mentioned point.

This study could evince, that all available medications in the pharmacies of Jeddah are being sold without a prescription (just like an "over the counter" item; only placed behind the counter). Despite the obvious sign placed in every pharmacy stating that "It is strictly prohibited for the pharmacist to dispense any drug without a medical prescription signed by a licensed doctor excluding drugs that are listed in the Saudi formulary of non-prescription medications" instructed by the Saudi Ministry of Health.

There is a perceptible absence of the Saudi FDA controlling the dispensing pattern in the region, and some pharmacists are even blaming them for their own wrongdoing, by 13.59% assuring absolute absence of the SFDA that do not supervise nor have an observer eye on their practice.

This is a huge responsibility owing to the fact that pharmacists have not studied the Saudi pharmacy law nor read the regulations or guidelines of the country they're practicing pharmacy in, leading to further drawbacks.

This study is an attempt to shed light on the pharmacy law guidelines violated by most pharmacies.

Although this study has been conducted in Jeddah, it serves as good reference for the remaining cities in the kingdom. This is not the first study that explores pharmacist attitudes, and their self-reported behavior toward dispensing drugs (with no prescription); unfortunately results follow the last decade's disappointing trend smoothly.

This study does not underestimate the pharmacist's role in the society, but it rather gives a full image of the pharmacist's demographics, knowledge of non-OTC drugs and draws a clear image of their attitude toward dispensing. Reasons given were quite disreputable requiring an urgent reevaluation of who should be qualified to dispense such medications, and what medications should be dispensed. The study also revealed a negative attitude of most pharmacists to this type of study, who saw that such studies are a waste of time. They mentioned further that the kingdom is a third world country and that this is the dispensing pattern in such countries (mostly comparing it to their respective countries of origin) (Eckert et al., 1991; Snell, 1992; DeSantis et al., 1994).

It is noteworthy that studies performed abroad have found that structured educational campaigns that are lacking in the kingdom have helped curb the misuse of drugs.

Finally, it is worth mentioning that all sampled pharmacies had "the sign" clearly displayed; which proves that there is some degree of regulation by the MOH – yet little is done to ensure its contents are being followed.

8. Conclusion

In conclusion, the majority of pharmacists are violating the pharmacy law without recognizing the potential harm they're imposing the community to in Saudi Arabia. The Saudi regulatory authority could adopt several approaches, to stimulate both pharmacists' and public awareness. A judicious combination of regulation and educational campaigns is likely to be most successful. But, firstly, OTC list should be generated, implemented, and monitored by Saudi regulators and a penalty should be enforced on those violating the law.

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³ http://www.fda.gov/downloads/Drugs/DrugSafety/ucm088999.pdf.

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