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# Pregabalin dispensing patterns in Amman-Jordan: An observational study from community pharmacies

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## ABSTRACT

**Objectives:** Pregabalin is currently approved for the treatment of epilepsy, generalized anxiety disorder, neuropathic pain and fibromyalgia. Rising attention to the abuse liability of pregabalin causing addictive behaviors is partially based on case reports and published literature of pregabalin used in dosages that override the approved therapeutic range. This study was conducted to provide background data regarding the abuse/misuse of pregabalin from community pharmacy in Jordan.

**Methods:** A prospective cross-sectional observational study design was used, which was conducted at different community pharmacies in Amman-Jordan. During the study period (November 2016–January 2017), a total 77 requests for pregabalin were observed from 14 pharmacies. A structured interview was conducted with all customers to gather information regarding their demographic and their request of pregabalin.

**Results:** A total of 77 pregabalin requests from 77 customers in a community pharmacy setting were observed in this study. Spinal disc herniation was the most common complaint for which the customer asked for the medication (n = 27, 35.1%). Self-medication was the most frequent method of requesting pregabalin (n = 44, 57.1%), while a total of 33 customers (42.9%) asked for the product using a prescription. During the observation period the number of customers suspected of abusing pregabalin for non-medical reason was 35 (45.5%). A total of 33 out of the 35 suspected customers (94.3%) asked for the product without a prescription, and 19/35 weren't sold due to suspicion of abuse (54.3%).

**Conclusion:** The study underscores the need for regulatory efforts to manage pregabalin abuse, through the addition of pregabalin containing products to the controlled drug list which can't be purchased without a prescription. Also, pharmacists and customers must be educated at a community pharmacy level regarding potential hazards of pregabalin abuse.

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## 1. Introduction

Substance use disorder is a group of behavioral, cognitive and physiological symptoms resulting from applying the substance continuously despite significant negative effects (Kerridge et al., 2017). It may result as a consequence of drug abuse and misuse.

“Misuse” is a broad term which comprises many different forms of problematic consumption where the use of the substance does not follow medical instructions (Bronstein et al., 2011; Casati et al., 2012) while the term “abuse” refer to situation where the substance be used for nontherapeutic purposes to obtain psychotropic effects (Cicero et al., 2007). By definition, any medication can be misused, but only few have the abuse potential, such as those with mind-altering or body-shaping properties (Cooper, 2013).

The risks of addiction to prescription drugs rise when they are used in means other than prescribed (e.g. at higher doses, by other routes of administration, or mixed with alcohol or other drugs) (NIDA, 2014). The most commonly reported prescription medications to be abused worldwide are stimulants such as methylphenidate, central nervous system depressants such as sedatives

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(benzodiazepines) or some anticonvulsants like clonazepam (NIDA, 2014) or pregabalin (Loftus and Wright, 2014).

Pregabalin is an analogue of the gamma-aminobutyric acid mammalian neurotransmitter. They act as inhibitory modulators of neuronal excitability that reduce ectopic neuronal activation of hyperexcited neurons while normal activation remains unaffected (Papazisis and Tzachanis, 2014). Pregabalin is approved for the treatment of partial epilepsy; generalized anxiety disorder; peripheral and central neuropathic pain and fibromyalgia with an accepted dosage range of 150–600 mg/day (Papazisis and Tzachanis, 2014).

In Jordan, like other countries in the region, with the exception of controlled drugs, it is possible to buy any medicine without a prescription. This availability linked with relatively low price products and availability of pharmacies is speculated to lead to abuse of a wide variety of OTC and prescription drugs (Albsoul-Younes et al., 2010). In 2014 a study was conducted by Wazaify et al. to document any change that may have happened in the type and frequency of suspected abuse/misuse of medications that can be bought without prescription from community pharmacies in Jordan (Wazaify et al., 2017a). A recent concerning trend was the abuse of the anticonvulsant drug (pregabalin), which obtained from pharmacies without a prescription and was not been mentioned previously in Jordan (Wazaify et al., 2017a).

In 2014 a formal statement about the restriction of pregabalin products dispensing in Jordan appeared (JFDA, 2014). This was due to the occurrence of spontaneous reports which was observed by the Jordan Food and Drugs Administration (JFDA) pharmacovigilance center regarding pregabalin abuse containing products. Pregabalin containing products were placed on the list of restricted drugs use that require a medical prescription to dispense it. This list includes drugs with abuse liability, but not competent to be under scheduled controlled drugs (JFDA, 2014). But unfortunately, it is still possible to get such medications easily without fearing of legal accountability.

In 2017 another announcement was released in Jordan to emphasize the obligation on not to supply samples of drugs containing this substance or grant quantities of incentives on the quantities sold of this medicine (JFDA, 2017). Despite this announcement the pregabalin products still can be sold without a prescription and without fear of any legal accountability. So efforts are needed to support the addition of this drug to the controlled drug list (which can't be purchased without prescription in Jordan). In order to support this requirement, we aimed in this observational study to provide background data regarding the abuse/misuse of pregabalin products in a community pharmacy setting in Jordan. Up to the researchers' knowledge, this is the first study of its kind in Jordan to address this issue.

## 2. Methods

### 2.1. Study design, setting and subjects

The study was designed as a prospective cross-sectional observational study that was conducted at different community pharmacies in Amman, the capital of Jordan. Two researchers interviewed all customers of a number of community pharmacies asking for pregabalin products during the observational period (November 2016–January 2017). Customers verbally consenting to be interviewed.

A convenience sampling technique was used to select the involved pharmacist. This was based on the feasibility, geographical proximity to the researchers housing, and upon consenting to participate by the pharmacy manager of each community pharmacy. Researchers took every effort to cover most socioeconomic regions

in Amman (Dahiyat AlRasheed, Al-Jandaweel, Sweifieh, Sweileh, Khalda, Jbeiha, Sahab, Wadi-Alseir, Khrbet Alsouq, and Arjan).

### 2.2. Data collection instrument

Researchers used a pre-tested and pre-piloted data collection form which was adopted from Wazaify et al. 2017 study (Wazaify et al., 2017b). The method used in this study was a structured interview with all customers presented at the time of the survey. The data collection form was designed to gather customers information in an anonymous way without mentioning any information belonging to customers or pharmacists.

Information obtained in the interview include: (1) customers' demographic data including (age, gender and academic qualification, site of recruitment and shift of recruitment), (2) pharmacies and pharmacists information (pharmacy location, chain or independent pharmacy, pharmacists age, gender, and experience), (3) the name of pregabalin product, quantity, indication and duration of use, (4) the way of asking for the medication (prescription, customers' request (self-medication), or pharmacist dispenses), and (5) pharmacist response with the abuser customers and the signs that led the pharmacists and the researchers to suspect them, for example (the pattern and repeated requests, customers's appearance (if he confused or related to his face), pharmacists' familiarity with customers and the quantity requested).

### 2.3. Data collection procedure

A predetermined schedule was designed in order to observe each community pharmacy for one week. Data collection took place over November 2016–January 2017 through 14 pharmacies at different regions of Amman. Data were filled by the researchers after informing the pharmacists within pharmacies that the aim of this research was to measure the pregabalin drug misuse/abuse among customers in community pharmacies. To minimize the observers' effect (i.e. Hawthorne effect), the researchers noticed the interaction between customer and pharmacist standing beside the pharmacist on the dispensing counter, wearing lab coats. A collaboration was made between the researchers and the main pharmacists to detect the abuser customers. The data collection form was filled immediately after observations and any additional information thought to be important to the research was written at the end of the data collection form. Each researcher was the only observer in each community pharmacy.

### 2.4. Ethical consideration

This study was approved by Jordanian Ministry of health (Reference number: MOH REC170012). In addition, verbal consents were obtained from all pharmacists to use their demographic data. Written and signed consent forms were obtained from the pharmacy managers for their acceptance for the study to be conducted in their pharmacies.

### 2.5. Statistical analysis

All data were coded and entered into the Statistical Package for Social Sciences (SPSS) database (version 22) for statistical analysis (IBM Corporation, Armonk, NY, USA). Descriptive data were summarized as counts and percentages for categorical variables and mean and SD for continuous variables.

Univariate statistical analysis including chi square and Fisher exact tests were used to detect factors affecting pregabalin products selling among abuser patients. A p-value less than .05 was considered significant throughout the analysis.

### 3. Results

#### 3.1. Demographic characteristics of recruited pharmacists/pharmacies

Out of nineteen pharmacies who were approached, fourteen agreed to take part in the study, resulting in a response rate of 73.6%. The reason for rejection was mainly the lack of interest of the responsible pharmacist in this kind of research. Around 86% (n = 12) of the involved pharmacies were independent pharmacies, while the remaining 14% (n = 2) were chain pharmacies. Ten pharmacies (71.4%) were located in west Amman (areas with higher socioeconomic status) and seven pharmacies (50.0%) on a main road. Most of the pharmacists working in these pharmacies were females (n = 8, 57.1%) and half (n = 7, 50%) aged between 20 and 30 years. Social demographic details of involved pharmacists/pharmacies participating in the study are summarized in [Table 1](#).

#### 3.2. Demographic characteristics of study participants

For the total 14 pharmacies observed for the whole study duration, a total of 77 requests were reported for pregabalin. The average number of pregabalin product requests was 5.5 product/pharmacy. All of those 77 customers were interviewed, most of whom were male (n = 55, 71.4%) and between 21 and 40 years (n = 51, 66.2%), respectively. More than one-third of customers (n = 32, 41.6%) held a Bachelor degree. Most of the observations (n = 72, 93.5%) were recruited from independent pharmacies and during shift B working (ie- 4 pm–12 am; n = 53, 68.8%). No observations were made during working shift C (12 am–8 am) due to lack of research assistants covering this period. Demographic characteristics of customers are presented in [Table 2](#).

#### 3.3. Information regarding dispensed pregabalin products

Various neurologic complaints were presented by observed customers during the study period. The top two complaints were spinal disc herniation (n = 27, 35.1%) and chronic generalized pain (n = 17, 22.1%). Eight customers (10.4%) came to pharmacies asking for a specific pregabalin product and mentioned wanting this

**Table 1**  
Social demographic details of involved pharmacists/pharmacies participating in the study (N = 14).

Variable	N	%
<i>Age</i>		
20–30 years	7	50%
31–40 years	6	42.9%
41–50 years	0	0
>50 years	1	7.1%
<i>Gender</i>		
Male	6	42.9%
Female	8	57.1%
<i>Experience</i>		
<1 year	1	7.1%
1–5 years	3	21.4%
6–10 years	6	42.9%
>10 years	4	28.6%
<i>Type of pharmacy</i>		
Chain pharmacy	2	14.3%
Independent pharmacy	12	85.7%
<i>Location of pharmacy</i>		
East Amman (low socioeconomic status)	4	28.6%
West Amman (high socioeconomic status)	10	71.4%
<i>The road type</i>		
Main street	7	50%
Side/sub street	7	50%

**Table 2**

Demographic characteristics of study participants requesting pregabalin products from community pharmacies (N = 77).

Variable	N	%
<i>Age</i>		
<20 years	5	6.5%
21–40 years	51	66.2%
41–50 years	12	15.6%
50–60 years	8	10.4%
>60 years	1	1.3%
<i>Gender</i>		
Male	55	71.4%
Female	22	28.6%
<i>Academic qualification</i>		
Undergraduate	10	13%
Community colleges/Diploma	4	5.2%
Bachelor's degree	32	41.6%
High degree	1	1.3%
Don't know	30	39%
<i>Site of recruitment</i>		
Chain pharmacy	5	6.5%
Independent pharmacy	72	93.5%
<i>Shift of recruitment</i>		
A (8 am–4 pm)	24	31.2%
B (4 pm–12 am)	53	68.8%

specific medication (pregabalin) to feel the mood and get rest. Six customers (7.8%) also came to ask for specific pregabalin product and mentioned preferring the product for their psychological stress and anxiety. Several causes of the complaints were reported and included neuropathic pain, back or knee pain, muscle strain, fatigue, insomnia, and for his/her colon. Others refused to mention the complaints and argued that the product was for his/her mother or friend. A summary of complaints reported by customers is presented in [Table 3](#).

Observed customers were divided into two groups: those requesting a specific pregabalin product by name (direct self-medication) (n = 44, 57.1%) and those presenting with a prescription of pregabalin (n = 33, 42.9%). Concerning indirect self-dispensing by pharmacists, there was no observable role of the pharmacist during the study period in prescribing pregabalin product for customers.

Regarding pregabalin products; the most commonly prescribed products were Lyrica® (n = 26, 33.8%), followed by Zega® (n = 16, 20.8%). From pregabalin products, Zega® was the most frequently requested by direct self-medication method (n = 13/16, 81.2%). Concerning pregabalin concentrations; the most frequently prescribed concentrations were 150 mg (n = 37, 48.1%), followed by 75 mg (n = 30, 39.0%). Whereas 150 mg was the most concentrations requested by direct self-medication method, (n = 25/37,

**Table 3**

Complaints presented by customers during the study period (N = 77).

Customer Complaints	N	%
Disc	27	35.1%
Chronic pain*	17	22.1%
Neuropathic pain	9	11.7%
Mood and rest	8	10.4%
Stress and anxiety	6	7.8%
Other**	4	5.2%
Muscle strain	2	2.6%
Fatigue and exhaustion	2	2.6%
Insomnia	1	1.3%
For colon	1	1.3%

\* Chronic Pain: e.g. back pain, knee pain or joint pain.

\*\* Other: e.g. refuse to mention, e.g. for a family member or friend.

67.6%). A description of the pregabalin products/concentrations requested during the study are presented in [Table 4](#).

The analysis revealed that most observed customers (n = 54, 70.1%) asked specifically for pregabalin product in packs (range from one to three packs), while 23 customers (29.9%) asked specifically for one strip of pregabalin product. The total number of packs of pregabalin product requested during the study period was 63 packs.

#### 3.4. Misuse/abuse evaluation among study observed customers

Over the eight-week study period, 35 observed cases (45.5%) were suspected of pregabalin abuse. These suspected cases involved six pregabalin products of abuse; Lyrica® in ten cases, Galica® in ten cases, Zega® in nine cases, Neogaba® in three cases, Regab® in two cases, and Epigab® in one case. In these suspected cases pregabalin concentrations of abuse were 150 mg in 18 cases.

During the observation, information regarding customers suspected of abuse was collected. Almost all suspected abusers were male (32/35, 91.4%), and aged between 21 and 40 years (30/35, 85.7%). Most of them (33/35, 94.3%) presented no prescription and asked for the medication by name, whereas two of them (5.7%) had brought prescription to get pregabalin products.

Regarding pharmacist responses in selling the drug for suspected customers, responses were diverse; where the product was sold in 16 cases (45.7%) and not sold in remainder (n = 19, 54.3%). Among the 19 cases where the products were not sold, in 6 cases (17.1%) the pharmacist did not sell the requested product and claimed that the product was not available. In 10 cases, the pharmacist did not sell the requested product because of lack of prescription (28.6%), and in 3 cases (8.6%) the pharmacist did not sell the products because the drug was not actually in stock. Almost all customers 34/35 (97.1%) reported previously using the same drug they had requested. Customers' complaints, customers' familiarity, suspicious reasons and all the details are presented in [Supplementary Table S1](#).

#### 3.5. Factors affecting pregabalin products selling among abuser patients

The demographic details (pharmacist gender, age and year of experience, and pharmacy location, type and at which road) of pharmacists and pharmacies participating in the study did not appear to be significantly affecting the selling among abuser patients ( $p > .05$ ).

## 4. Discussion

To the best of authors' knowledge, this is the first study of its kind in Jordan to prospectively observe pregabalin products abuse/misuse in community pharmacy. This study presents novel data around the types of products and motives for pregabalin abuse in this country, and describes current methods that pharmacists use to manage such requests. Studies at present are restricted to measuring the abuse/misuse potential of pregabalin in general at different pharmacovigilance databases or by evaluating the prevalence of pregabalin abuse/misuse issue ([Bossard et al., 2016](#); [Schjerning et al., 2016](#); [Schwan et al., 2010](#); [Wazaify et al., 2017a](#)).

One of the strengths of this study is the prospective observation on real cases in a community pharmacy setting. In this study customers-pharmacist interactions involving pregabalin products were observed at different community pharmacies in Amman. Among the observed customers in this study, 71.4% were males. This was similar to a German study which was conducted to measure the number of cases of pregabalin abuse or dependence, where 64% of cases were male ([Gahr et al., 2013](#)).

It was found that the most common complaint reported by customers buying pregabalin from pharmacies was spinal disc herniation, followed by chronic generalized pain and neuropathic pain. In a German study, neuropathic pain was the most common medical indication for treatment with pregabalin reported by the Federal Institute for Drugs and Medical Devices database of ADR ([Gahr et al., 2013](#)).

In this study, Lyrica® followed by Zega® were the most commonly dispensed pregabalin products. Lyrica® as a product liable for abuse appeared in the literature from Jordan for the first time in 2014 ([Wazaify et al., 2017a](#)). It was not registered as a product liable for abuse in 2006 during the evaluation of misuse and abuse of prescription drugs in Jordan ([Albsoul-Younes et al., 2010](#)). Popularity of Lyrica® may have been driven by pharmacist sales incentives. In order to tackle this problem the JFDA released a new announcement in 2017, in particular for drug stores, not to grant incentives on the quantities sold of medicines containing pregabalin ([JFDA, 2017](#)).

The most frequently dispensed concentration of pregabalin was 150 mg, followed by 75 mg. Similar finding was observed in a previous study, which aimed to characterize customers dispensed pregabalin at higher than the maximum allowed dose based on data extracted from Swedish national registers ([Bodén et al., 2014](#)). In this cohort study, a higher pregabalin strengths, were the most concentrations reported ([Bodén et al., 2014](#)).

**Table 4**  
Pregabalin products/concentrations used by the customers (N = 77).

Pregabalin products used by the customers			Description method of request <sup>*</sup>	
Pregabalin products	N	%	Prescription	Self-medication
Lyrica®	26	33.8%	14 (53.8%)	12 (46.2%)
Zega®	16	20.8%	3 (18.8%)	13 (81.2%)
Galica®	13	16.9%	4 (30.8%)	9 (69.2%)
Regab®	11	14.3%	7 (63.6%)	4 (36.4%)
Neogaba®	7	9.1%	3 (42.8%)	4 (57.2%)
Epigab®	4	5.2%	2 (50.0%)	2 (50.0%)
Total	77	100%	33 (42.9%)	44 (57.1%)
Pregabalin concentrations used by the customers			Description method of request <sup>*</sup>	
Pregabalin concentrations	N	%	Prescription	Self-medication
150 mg	37	48.1%	12 (32.4%)	25 (67.6%)
75 mg	30	39.0%	17 (56.7%)	13 (43.3%)
300 mg	9	11.7%	3 (33.3%)	6 (66.7%)
50 mg	1	1.3%	1 (100%)	0 (0%)
Total	77	100%	33 (42.9%)	44 (57.1%)

<sup>\*</sup> percentage were calculated per each row.

Self-medication, whereby the customer requested specific medication by name without a prescription, was the most frequently reported pattern of sale in all pregabalin products (57.1%). This was similar to a Jordanian study conducted to measure self-medication patterns of all drugs supply that took place in the pharmacies, with self-medication was reported by 42.5% of Jordanians (Yousef et al., 2008). It is worth mentioning that in our study there was no role of pharmacists in prescribing pregabalin by indirect self-medication, since it is classified in Jordan as a prescription only medicine that require a written prescription by a physician (JFDA, 2014). This may be due to the observer effect where pharmacists may have behaved differently in the presence of the researchers.

Also, it was noted that some customers requested pregabalin (29.9%) by a strip without the outer package, which is considered illegal by JFDA (JFDA, 2017). This is concerning as one of the major stabilizing influences of packaging is to maintain storage conditions and protection from moisture. That moisture can affect a product's chemical and physical stability, which lead to a change in the expiration date of a drug product, and to a change in any of a drug product performance (e.g., dissolution, hardness) or appearance, if the drug found without its outer package (Waterman and MacDonald, 2010).

The high percentage of self-medication of pregabalin products in our study revealed a very low level of public awareness regarding safe use of this drug. Serious medical consequences such as psychotic symptoms with rhythmic EEG-changes can occur due to pregabalin product abuse/misuse (Olaizola et al., 2006). The generic brand Zega<sup>®</sup> was most frequently requested product by direct self-medication method. The bio-equivalence of the generic drug from the original brand may explain the increase in demand of the generic brand of pregabalin, which are cheaper.

During the observation period of 14 pharmacies, the number of customers suspected of abusing pregabalin was 35 (45.5%). Those cases were suspected, according to the pharmacist' prior knowledge of the customer. This high suspected abuse rate may have arisen since these medications are not scheduled as drugs of abuse by JFDA (JFDA, 2014), as well as the customer can get such medications easily without fearing of legal accountability. Selling pregabalin to suspected abused was not found to be associated with any pharmacy related sociodemographic characteristics.

The finding of the study should be interpreted with the two main limitations in mind. Firstly, the study was conducted in a single city at Amman, capital of Jordan, and hence the results might not be generalizable. Secondly, although every effort had been made to assure pharmacists of the confidentiality and anonymity of the study and that it is done solely for research purposes by an academic team. Still, the Hawthorn effect could not be totally negated, as some pharmacists may have behaved differently in the presence of the researchers, which may have affected the results.

## 5. Conclusion

All these findings call the attention for implementation of effective community pharmacy based interventions to raise customer, neurologist and pharmacist awareness and ultimately reduce the abuse rate of pregabalin products. Also, these findings should support the appeal for the addition of pregabalin preparations to controlled drugs list (which can't be purchased without prescription in Jordan).

## 6. Conflict of interest

None of the authors have any conflict of interest.

## Appendix A. Supplementary material

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.jsps.2018.01.012>.

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