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24 **Introduction**

25 Abuse and misuse of prescription drugs are reported to be a global problem (Lessenger &
26 Feinberg, 2008). Misuse of prescription drugs is defined by the National Institute on Drug
27 Abuse (NIDA) as taking a medication in a manner or dose other than prescribed; taking
28 someone else's prescription, even if for a legitimate medical complaint such as pain, or
29 taking a medication to feel euphoria (i.e., to get high). The latter definition is what is
30 described sometimes in the literature as drug abuse (Hughes et al., 1999; Wazaify et al.,
31 2006). While the updated definition of misuse of non prescription medicine (NPM) is to be
32 used for a legitimate medical purpose, but in an incorrect manner either in terms of dose or
33 duration (Wazaify et al., 2016). Abuse of NPM was defined as the use for a non-medical
34 purpose, e.g. to achieve mind-altering effects or weight loss (Fingleton et al., 2016). NPMs
35 misuse and abuse have increased lately, especially with the self-care revolution, the increasing
36 number and access to medicines and the wide availability of online health information (Wright
37 et al., 2015). By definition, any prescription or non-prescription drug can be misused, but
38 only specific products can be abused ~~as follows~~. (Fingleton et al., 2016). The most
39 commonly reported prescription medications to be abused worldwide are stimulants such
40 as methylphenidate and central nervous system (CNS) depressants such as sedatives (e.g.
41 benzodiazepines, opioids, or pregabalin (Loftus & Wright, 2014; (NIDA, 2014).

42

43 Pregabalin is an analogue of the gamma-aminobutyric acid (GABA) mammalian
44 neurotransmitter and its structurally related compound; gabapentin. They act as inhibitory
45 modulators of neuronal excitability that reduce ectopic neuronal activation of hyperexcited
46 neurons while normal activation remains unaffected (Papazisis & Tzachanis, 2014).
47 Pregabalin is approved for the treatment of partial epilepsy; generalized anxiety disorder;

48 peripheral and central neuropathic pain and fibromyalgia with an accepted dosage range of
49 150 mg to 600 mg/day (Papazisis & Tzachanis, 2014). The reported euphoria that occurs
50 as an adverse event in up to 10% of patients is the main cause that ~~would lead~~ contributes
51 to abuse (Schwan et al., 2010).

52

53 A study conducted in Germany revealed that 12.1% of urine specimens that had been
54 collected from addicts to heroin and other substances, tested positive for pregabalin without
55 medical purpose for its use (Grosshans, et al., 2013). Another study conducted in the UK
56 suggested that patients at high risk of addiction were prescribed higher than the
57 recommended dose of pregabalin. Pregabalin and gabapentin were used alongside opiates
58 to potentiate their effects. Also they can be used alone in higher than recommended doses
59 to produce sedation and psychedelic effects. ~~So, the author~~ This study concluded that the
60 quantities supplied should be limited because of the possibility of misuse (Loftus and
61 Wright, 2014).

62

63 In Jordan, like other countries in the region, with the exception of controlled drugs (e.g.
64 opioids and some benzodiazepines), almost any medicine can be bought from the
65 community pharmacy without a prescription (Wazaify & Scott, 2017). The Jordan Food
66 and Drug Administration (JFDA) is the legislative body that classifies medications into
67 prescription and Over-The-Counter (OTC) drugs. However, in many cases, this legislation
68 is not strictly enforced (Wazaify and Albsoul-Younes, 2005). ~~This a~~ Availability linked
69 with the affordability and perception of safety of such products by the general public
70 (Wazaify et al., 2008), may lead to the abuse of more and different kinds of ~~nonprescription~~

71 OTC-and prescription drugs (Albsoul-Younes et al., 2010). A study conducted in Jordan in
72 2014 highlighted the changes that may have happened ~~in~~-relating to this problem during
73 the previous 10 years. The study showed the retraction of some products' suspected of
74 abuse (e.g. misoprostol). ~~On the other hand~~, New products have additionally appeared on
75 the ~~new~~ list, such as the anticonvulsant, Lyrica[®] (Pregabalin) and ~~certain~~ specific
76 ophthalmic drops with sympathetic, antihistamine or anticholinergics properties (e.g.
77 cyclopentolate, Wazaify et al., 2016). This resulted in the ~~addition~~ inclusion of pregabalin
78 containing products to a list of restricted drugs where use ~~that~~-requires a medical
79 prescription. but was not competent to be under scheduled controlled drugs (JFDA, 2014).
80 In addition, it prohibited the supply of samples of drugs containing this substance or
81 granting quantities of incentives on the quantities sold of medicines (Jordan Food and
82 Drugs Administration, 2017a).

83 According to the Jordanian Drug and Pharmacy Practice Law (2013), opioids, opioid
84 derivatives, or opioid containing preparations are controlled as Schedules 1–8 drugs. The
85 pharmacist is required to keep a record of these special prescriptions and supply against
86 them, for JFDA inspection. As such, a pharmacist will be subject to prosecution if found
87 to be selling Schedules 1–8 products (Jordan Food and Drug Administration, 2017b).
88 However, some prescription-only-medicines that are liable for abuse are not scheduled yet
89 in many Middle Eastern countries (e.g. pregabalin (At the time this study was conducted),
90 performance enhancing hormones, some anticholinergic drugs).This aborts the chance to
91 trace any violation and allows some pharmacists to sell such preparations without a
92 prescription. (Wazaify & Scott, 2017).

93

94 Scheduling of pregabalin was documented in 2005 in the USA as schedule V of the
95 Controlled Substances Act (CSA; Drug Enforcement Administration, Department of
96 Justice, 2005). In Jordan, pregabalin has been scheduled to be controlled as schedule III
97 controlled drug ~~on~~ since December 7th, 2017, (Jordan Food and Drug Administratiuon,
98 2017c). This study ~~eam~~ was conducted prior to the scheduling of the drug in Jordan and
99 aimed to investigate the experience of community pharmacists regarding the abuse and
100 misuse of pregabalin products in their practice setting.

101

102 **Materials and Methods**

103 **Study design, setting and subjects**

104 This is a cross-sectional quantitative study that was conducted in Amman- Jordan between
105 November 2016 and January 2017 to evaluate the experience of community pharmacists'
106 regarding pregabalin products abuse and misuse. During the study period, 205 pharmacists
107 and pharmacy assistants were approached in different community pharmacies (independent
108 or chain) located in different regions in Amman, the capital of Jordan. They were asked to
109 participate in this study by filling a prevalidated, prepiloted questionnairebelow). *Drop and*
110 *Pick* technique was used in this part of the study to collect the data from pharmacies as
111 explained below.

112 **Study questionnaire and data collection**

113 A previously validated and tested questionnaire was used in this study. The questionnaire
114 was based originally on that used by Hughes et al. (1999). However, in order to be able to
115 use it in Jordan the questionnaire was translated to Arabic and then back-translated to
116 English in order to assure validity. Every effort was made during the review of literature

117 ~~review~~ to ensure content validity. Moreover, various drafts of the questionnaire were
118 evaluated individually by three senior academics who were PhD holders (Pharmacy
119 Practice, Public Health Policy and a Statistician) in order to ensure face validity. The final
120 version of the questionnaire was then distributed using drop and pick technique. Self-
121 reported method was used to fill out the questionnaire. In this approach, the ~~study~~
122 ~~researcher~~ first author (A.A) went to different community pharmacies and handed the
123 questionnaire personally to all pharmacists available in the shift. The completed surveys
124 were picked up at a later time. The questionnaire was anonymous and consisted of two
125 sections:

126 **Section One**

127 Limited demographic details were collected, so as to protect pharmacists' anonymity.
128 Participants were requested to state only the name of their area where their pharmacy was
129 located and to allocate it as being on a main road, a side street, or in a mall. Finally,
130 pharmacists were asked to state their gender and years of experience in the profession.

131 **Section Two**

132 Section two included the following points:

- 133 • Pharmacists' awareness regarding pregabalin liability for abuse and main side effects
- 134 • Pharmacists' experiences with customers suspected of abusing the drug and what the
135 signs that led the pharmacists and the researchers to suspect them, for example (the
136 pattern and repeated requests, pharmacists' familiarity with patients and the quantity
137 requested).
- 138 • Reporting of any pregabalin drug they had suspected in the past six months of being
139 abused, and if they noticed the request trends were changing. The main pregabalian

140 products available in the Jordanian market at the time of study were: Lyrica[®], Zega[®],
141 Galica[®], Regab[®], Epigab[®] and Neogaba[®]

- 142 • Description of suspected cases of abuse in their own pharmacies (if any), and a profile
143 of the typical abuser of each product identified.
- 144 • Maximum number of packs that they had been requested to sell and which they
145 suspected of being abused, and whether the patients who purchased (or attempted to
146 purchase) these products were regular or new customers.
- 147 • Information on any strategies the pharmacists had in place to limit suspected abusers'
148 access to the products.

149

150 **Statistical analysis**

151 The data of the completed questionnaire were coded and entered into SPSS software-
152 version 22 for analysis. Descriptive analysis was conducted and frequency distributions
153 were collected for responses to all questions. Chi square and Fisher exact tests were used
154 to detect significant relationship between variables. A p-value less than 0.05 was
155 considered significant throughout the analysis.

156

157 **Results**

158 **Demographic details of participating community pharmacy staff and pharmacies**

159 A total of 152 out of the 205 distributed questionnaires (response rate= 74.1%) were
160 returned. Questionnaires were filled by community pharmacists and pharmacy assistants
161 at different independent and chain pharmacies in Amman (N=90). One questionnaire was

162 excluded due to missing data, which ended up with a total of 151 questionnaires to be
163 analyzed.

164

165 The majority of respondent pharmacists (n=95, 62.9%) were between 20 and 30 years of
166 age and had a Bachelor of Pharmacy or Pharm. D degrees (n = 132; 87.4%). More than
167 half of participating pharmacists were female (n = 89, 58.9%) and almost one-third of the
168 pharmacists had up to one year of experience (n = 49, 32.5%). The majority of participating
169 staff (n = 98, 64.9%) reported that they would not receive bonus if they had not achieved
170 a target sale of products. Also, the majority of participating pharmacies were independent
171 (n = 64, 71.1%), and located on a main road (n = 62, 68.9%). More than third of
172 participating pharmacists (n=53, 35.1%) reported having incentive offers on pregabalin
173 sales from medication stores. A summary of participating pharmacies and staff is provided
174 in **Table 1**.

175 *Insert Table 1 about here*

176

177 **Pregabalin products suspected of abuse and misuse**

178 The majority of respondents (n= 132, 87.4%) suspected pregabalin product abuse/misuse
179 in community pharmacies. Almost half of respondents indicated that pregabalin requests
180 they had received were not accompanied by a prescription in most of the cases (n = 69,
181 45.7%). Most of the participated pharmacists (n=203/364, 55.8%) noticed an increased
182 pattern of abuse/misuse with time as described in **Figure 1**.

183 *Insert Figure 1 about here*

184

185 Among pregabalin products, Lyrica® was the most frequently reported to be suspected of
186 abuse (n=100 , 25.4%). It was reported to be mostly abused by male customers whose age
187 ranged between 26-50 years, followed by Galica® and Zega® (n=84, 21.4%), and (n=81,
188 20.6%) respectively. Regarding most commonly abused strengths, 75 mg was reported to
189 be the most frequently requested strength in community pharmacies (n=181, 46.05%). This
190 was mainly by males whose age ranged between 26-50 years, followed by 150 mg (n=144,
191 36.6%). Table 3 2 details the most frequently reported pregabalin products to be suspected
192 of abuse/misuse by community pharmacists in Jordan.

193

194 *Insert Table 2 about here*

195

196 **Pharmacists' methods to limit customers' access to pregabalin products**

197 Pharmacists employed several methods to limit customers' access to products they had
198 suspected of being abused. The two most commonly used methods, as stated by
199 pharmacists, were insisting to have a valid prescription to dispense the product (n = 81;
200 54.4%) and refusing the sale and/or of stating that the product was not available (n = 70;
201 47%). Only 7 (4.7%) pharmacists reported that they had not acted on the problem and they
202 had simply sold the requested products. These pharmacists ~~all~~ were all younger than 40
203 years of age (p = 0.636). Pharmacists with 1–5 or 6–10 years of experience had no
204 statistically significant difference in refusing to sell the product and/or insisting to have a
205 prescription to dispense the product (35.8% and 24.7%, respectively; p = 0.386) compared
206 to those with less experience (16%). Also, there was no statistically significant difference
207 in sale refusal/or insisting to have a prescription between pharmacists and pharmacy

208 assistants (88.9% vs. 11.1%; $p = 0.692$) or between pharmacy staff working in independent
209 and chain pharmacies (61.7% vs. 38.3%; $p = 0.803$). More staff working in independent
210 pharmacies (71.4%) than those working in chain pharmacies (28.6%) reported that they
211 simply sold the requested pregabalin products just like any other product. Yet, this
212 difference was not statistically significant ($p > 0.05$). Methods used to limit access to
213 pregabalin were also not associated with gender of the pharmacists ($p > 0.05$). Details of
214 the reported methods used by pharmacy staff to deal with suspected pregabalin abuse are
215 summarized in **Table 3**.

216

217 *Insert Table 3 about here*

218

219 The largest amount of commonly abused pregabalin products requested simultaneously by
220 a customer ranged between 1 and 50 packs (mean = 3.24 ± 5.3). In 81.9% ($n = 91$) of
221 suspected customer requests, the pharmacist refused to sell the product, either by claiming
222 that the product was not available ($n = 42$; 37.8%) or by insisting on having a prescription
223 to receive the product ($n = 49$; 44.1%). Only 15 pharmacists (13.5%) reported selling the
224 exact requested amount and five (4.5%) reported selling a smaller amount than that
225 requested.

226

227 **Pharmacy staff perspective regarding pregabalin requests**

228 The majority of pharmacists ($n=120$, 81.6%) reported that most of the customers requesting
229 these products were new customers to their pharmacy compared to 18.4% reported most
230 requests by regular customers ($n=27$). During the study, more than half ($n=78$, 52.7%) of

231 the responding pharmacy staff noticed a difference in requesting pregabalin after the
232 announcement to restrict amount of sale by Jordan Food and Drug Administration (JFDA)
233 in 2014. On the other hand, a little less proportion (n= 70; 47.3%) noticed that there had
234 been no difference in drug requests.

235

236 **Discussion**

237 This study highlighted community pharmacists' experiences regarding the suspected
238 abuse/misuse of pregabalin in their practice setting. To the best of authors' knowledge, this
239 is the first study in the literature to explore the problem of pregabalin abuse/misuse from
240 community pharmacists' perspective. A previous study conducted in Jordan investigated
241 the abuse/misuse of all drugs sold with or without a prescription in community pharmacies
242 highlighted the emergence of new drugs on the list of suspected drugs of abuse such as:
243 ophthalmic drops and pregabalin (Wazaify et al., 2016). This may be due to the re-
244 scheduling of some of the most common drugs of abuse in 2013 (e.g. Alprazolam) from
245 '*prescription-only-status*' to become controlled as schedule III drugs (Jordan Food and
246 Drug Administration, 2014). In other words, the restriction on commonly abused drugs,
247 has possibly led to some people looking for a legal and available alternative (Wazaify and
248 Scott, 2017). ~~The fact that~~ We speculate that this has resulted in more reported cases of
249 abuse of pregabalin products in community pharmacies.

250

251 At the time this study was conducted, pregabalin was classified as a prescription only
252 medicine that did require a prescription to be dispensed. However, the Pharmacy and Drug
253 law does not require pharmacists to keep records of these prescriptions (Jordanian Food

254 and Drugs Administration, 2017d; unlike the scheduled products described above), thus
255 making it difficult for regulators to trace violations and facilitating the pharmacists to
256 illicitly sell such preparations without a prescription (Wazaify & Scott, 2017). This practice
257 (i.e. selling prescription-only products without a prescription) has also been noted in other
258 Arab countries like Egypt (Jousilahti et al., 1997), Kuwait (Matowe et al., 2003), and
259 Palestine (Sweileh et al., 2004).

260

261 It is only after a series of studies that looked into this problem (Schwan et al., 2010; Millar
262 et al., 2013; Al-Husseini et al., 2017a) from different angles, that pregabalin has been
263 controlled in Jordan to be schedule III drug. (JFDA, 2017c). Since community pharmacists
264 are the most accessible health care professionals and the first defence line against abuse
265 of prescription and non-prescription products (Dole & Tommasello, 2002), it is believed
266 that the scheduling the drug and the consequent tightening of inspection on its sale in
267 community pharmacies would limit this problem. ~~Another point worth mentioning,~~ We
268 equally recognise however that the restriction and scheduling of prescription drugs may
269 limit access of genuine patients who need the drug for different legitimate indications (e.g.
270 neuropathy). The effect of such scheduling will only be revealed through further research
271 in the coming few years that follow the scheduling.

272

273 More than half of the pharmacists in our sample, confirmed that they had received
274 suspicious requests for pregabalin products, during the past six months, most of which was
275 the brand name Lyrica[®] and with a strength of 75 mg. In contrast to the observational part
276 of the study, *(Al-Husseini et al., 2018) the generic name Zega[®] and the concentration 150

277 mg were the most pregabalin products requested by self-medication method (Al-Husseini
278 et al, 2017b). This may be due to the fact that pharmacists in general believe that the
279 original brands are of higher quality and ~~to be~~ are more effective than the generic products
280 (Grover et al., 2011). Moreover, the original brand name is sometimes used as a substitute
281 for the less common generic name among people (e.g. Panadol vs. Paracetamol). Male
282 gender was the most commonly suspected of pregabalin abuse, in this study. This is similar
283 to different studies in the literature considering male sex as a risk factor to addictive
284 behaviour (Gahr et al., 2013; Gahr et al., 2014).

285

286 Another point worth mentioning is that some pharmacists reported that one of the main
287 reasons of increased pregabalin abuse recently was the incentive offers from medication
288 stores. This was believed to put pressure on the responsible pharmacist to buy and sell large
289 quantities of the drug to get such incentives. So it led the JFDA in 2017 to release an
290 announcement not to grant quantities of incentives on the quantities sold of medicines
291 containing pregabalin (Jordanian Food and Drugs Administration, 2017b).

292

293 Being classified as a prescription only medicine does not allow the pharmacist to dispense
294 the drug by him/herself without a prescription written by a physician, this is where the
295 professional and ethical judgement of the pharmacist is important. Where pharmacists need
296 to differentiate between being "*ethical*" and being "*legal*" as both terms, although relevant,
297 are definitely not interchangeable. Some pharmacists may respond and sell the requested
298 large amounts of products because they perceive this as being 'legal' since this drug is not
299 "scheduled". Moreover, 13.1 % of final year pharmacy students either disagreed/strongly

300 disagreed or were unsure that it was unethical to sell controlled drugs to suspected
301 misusers/abusers (Jaber et al., 2015). Thus, it is suggested that more focus should be
302 stressed on the teaching and practice of ethics to pharmacy graduates (Wazaify et al., 2010).

303

304 The methods employed by Jordanian pharmacists to limit the supply of pregabalin products
305 liable for abuse did not differ from those reported by pharmacists in other countries (Ball
306 & Wild, 1989; Paxton & Chapple, 1996; Hughes et al., 1999). Traditional methods used
307 by pharmacists have included refusal of sale of such products or keeping them out of sight
308 and/or requesting a medical prescription (Paxton and Chapple, 1996; Hughes et al., 1999;
309 Albsoul-Younes et al., 2010; Wazaify et al., 2016). These methods are of limited value as
310 patients may seek a supply from another pharmacies or what is known as “*pharmacy-*
311 *hopping*” (Van Hout, 2014). This problem could be minimized if pharmacists networked
312 more frequently with one another where a suspected abuser would be reported to other
313 pharmacies of the locality. A better and more comprehensive system is connecting all
314 pharmacies electronically on a national level to report about drugs of potential abuse
315 (Manchikanti et al., 2005). Moreover, an interventional harm minimization model to
316 identify and refer those at risk of prescription or nonprescription drug abuse could be
317 implemented in community pharmacies (Wazaify et al., 2006). Such model requires
318 training of community pharmacists and more collaborative work with physicians and
319 community addiction teams.

320

321 **Limitations of the Study**

322 This part of the study had been limited by the following: 1) the author's delivered the
323 questionnaires to respondents by hand. Although the success of this strategy was reflected
324 in the high response rate (74.1%), it also could have affected the anonymity of the
325 questionnaire and subsequently whether the pharmacy staff felt comfortable to freely report
326 their experience. We recommend that future studies use social media or specialized internet
327 pharmacists for these kinds of studies; 2) the data in this study were based on pharmacists'
328 and pharmacy assistants' perceptions of day-to-day events, which was highly subjective
329 and represented only a single point of view. A direct observational pharmacy-based study
330 (which was already conducted, Alhusseini et al., 2017) was considered more dependable
331 in this regard; 3) the questionnaire was filled by pharmacy personnel in community
332 pharmacies in Amman, the capital of Jordan, which is not representative of the whole
333 Jordan. It is recommended that future studies involve a larger number of community
334 pharmacies in different regions all over Jordan.

335

336 **Conclusion**

337 The majority of participating pharmacists had reported that pregabalin had the potential to
338 be abused, with most of suspected pregabalin abusers ~~were~~-male aged between 26 to 50
339 years old and from moderate socioeconomic class. In addition, most of the pregabalin
340 requests were not accompanied by a prescription and were noticed to be increased during
341 the past six months. All these findings call the attention for implementation of effective
342 community pharmacy based interventions to raise patient, neurologists and pharmacists
343 awareness regarding pregabalin potential for abuse and ultimately restrict prescribing and
344 or dispensing on this product to only those in medical need.

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