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Abstract

ABSTRACT Background: Community pharmacy practice in the Kingdom of Saudi Arabia (KSA) faces many challenges. In KSA, there is a lack of empirical research about medication safety in this setting. Objective: To explore the safety problems associated with medication supply from community pharmacies in KSA and compare different stakeholder perspectives. Methods: Four focus groups and individual interviews were conducted in Riyadh, KSA, in February-May 2013. All group discussions were recorded, transcribed and translated from Arabic into English, except the professional group, which was conducted in English. Thematic analysis was performed using the Human Factors Framework (HFF). Results: The groups comprised "professionals" (n=8; one female), community pharmacists (n=4; all male) and two pharmacy user groups (females, n=11 and males, n=8). Medication safety problems identified were categorised into nine categories representing the HFF. Seven main themes were identified from these categories: commercial pressure on community pharmacy; illegal supply of prescription medication; lack of enforcement of regulations; the healthcare system; self-medication; patient trust in pharmacists: and communication failure. Themes that emerged only from the "professionals" and community pharmacists were the different role of the regulatory organisations and the reasons behind lack of enforcement, while the community pharmacist group focused on the relationship between owners and managers. Pharmacy users expressed a need for information about medication and that the primary role of the pharmacist should be as an information provider. Furthermore, they perceived pharmacists to be vendors rather than healthcare professionals. Conclusion: Many medication safety problems were identified, attributable to individuals (patient, pharmacist), pharmacy and organisational factors. These results will be used to develop interventions to improve medication safety.

Keywords	Patient safety;Community pharmacy; Human factors;Medication errors; Drug related side effects ;adverse reactions.
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To,
The Editors,

Research in Social and Administrative Pharmacy

Subject: Submission of an Original Article, "Using the Human Factors Framework to understand the origins of medication safety problems in community pharmacy in Saudi Arabia: A qualitative study"

Dear Sir/Ma'am

  We are submitting an Original Article, "Using the Human Factors Framework to understand the origins of medication safety problems in community pharmacy in Saudi Arabia: A qualitative study" for consideration for publication in Research in Social and Administrative Pharmacy.
.
Most medication safety studies are undertaken in secondary care, but the main burden of care is in primary care. However, less is known about medication safety outside hospital environments. Research undertaken in community pharmacy settings has mostly focused on detecting and measuring rated of medication errors and near misses. Community pharmacy in Saudi Arabia faces many challenges. There is a lack of empirical research about medication safety in this setting in Saudi Arabia and research is needed. Qualitative studies are limited in this setting in Saudi Arabia. This study aimed to identify and explore the main safety problems associated with medication supply from community pharmacies in Saudi Arabia.

This article provided insights about the medication safety problems that occur to patients using medication from the community pharmacy from different perspectives Policy makers, pharmacy owners, community pharmacist and pharmacy users. Human factors framework allowed a system approach in analysing the problems and safety in community pharmacy. Highlighting these problems provides evidence to policy makers, healthcare providers about the potential harm to patients and allow future interventions and research to focus on the quality and safety of community pharmacy and primary care generally.

I, Lobna Al Juffali (Corresponding author) certify that the manuscript is being submitted by me (Corresponding author) on behalf of all the authors.

This research has been reviewed and approved by the College Ethics Review Board, University of Aberdeen, UK.

Thank you

Sincerely,

Lobna Al Juffali

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Using the Human Factors Framework to understand the origins of medication safety problems in community pharmacy in Saudi Arabia: A qualitative study

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ABSTRACT

Background: Community pharmacy practice in the Kingdom of Saudi Arabia (KSA) faces many challenges. In KSA, there is a lack of empirical research about medication safety in this setting.

Objective: To explore the safety problems associated with medication supply from community pharmacies in KSA and compare different stakeholder perspectives.

Methods: Four focus groups and individual interviews were conducted in Riyadh, KSA, in February-May 2013. All group discussions were recorded, transcribed and translated from Arabic into English, except the professional group, which was conducted in English. Thematic analysis was performed using the Human Factors Framework (HFF).

Results: The groups comprised "professionals" (n=8; one female), community pharmacists (n=4; all male) and two pharmacy user groups (females, n=11 and males, n=8). Medication safety problems identified were categorised into nine categories representing the HFF. Seven main themes were identified from these categories: commercial pressure on community pharmacy; illegal supply of prescription medication; lack of enforcement of regulations; the healthcare system; self-medication; patient trust in pharmacists: and communication failure. Themes that emerged only from the "professionals" and community pharmacists were the different role of the regulatory organisations and the reasons behind lack of enforcement, while the community pharmacist group focused on the relationship between owners and managers. Pharmacy users expressed a need for information about medication and that the primary role of the pharmacist should be as an information provider. Furthermore, they perceived pharmacists to be vendors rather than healthcare professionals.

Conclusion: Many medication safety problems were identified, attributable to individuals (patient, pharmacist), pharmacy and organisational factors. These results will be used to develop interventions to improve medication safety.

BACKGROUND

The World Health Organisation has highlighted safety in primary care as an international challenge.[1] In primary healthcare, adverse drug events (ADEs) are reported to occur in 25% of outpatients, almost half of which (11%) are preventable.[2] Research undertaken in the community pharmacy setting has mostly focused on detecting and measuring medication errors and near misses.[3]

Studies in the Kingdom of Saudi Arabia (KSA) have shown high levels of hospital admissions associated with drug-related problems (DRPs), of which the most common causes were ADEs, a failure to receive medication and medication non-compliance.[4,5] A range of challenges to medication safety in KSA were identified: limited use of technology; illegal supply of prescription only medication (POM); communication gaps between healthcare institutions: under-reporting of ADEs and communication barriers.[6] Studies in KSA have mainly investigated the problems either from a pharmacist or a pharmacy user perspective using mostly surveys.[7-11] No qualitative studies have been conducted with pharmacy users or other stakeholders, such as policy makers and pharmacy owners.

The application of theory may help to understand patient safety problems and a number of relevant frameworks exist. [12-17] The Human Factors Framework (HFF) has potential to enhance clinical performance by understanding the effects of factors such as teamwork, tasks, equipment, workspace, culture and organisation on human behaviour and abilities, and applying insights to clinical settings. [14-18] The HFF aids understanding of people's capabilities and limitations, allowing design of better systems. It is a recognised tool to reduce medication error rates or mitigate adverse medication effects. [12]

The purpose of our study was to explore and compare different stakeholder perspectives regarding the safety problems associated with medication supply from community pharmacies in KSA using the HFF. The stakeholders for whom medication safety is important include service users, community pharmacists, pharmacy owners, as well as representatives from legal and regulatory authorities.

METHODS

This qualitative study comprised a series of focus groups and interviews. Focus groups were conducted with different stakeholders: healthcare professionals; community pharmacists; and pharmacy users. Individual interviews were conducted with community pharmacists only.

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57 ## Sampling and recruitment

58 The study was conducted in Riyadh, the capital of KSA. The healthcare professional group (PG)

59 was recruited purposively, identified through professional and personal networks.

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61 The community pharmacist group (CPG) was recruited using purposive, convenience and

62 snowballing methods. Personal visits to pharmacies and telephone calls were made to invite

63 participants. Telephone interviews were offered only to community pharmacists who could not

64 attend the focus group due to job commitments.

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66 Pharmacy users aged 18 and older were eligible to participate. Different recruitment strategies

67 were adopted to reflect the cultural constraints in Saudi society. For the female pharmacy user

68 group (FPG), community centres and sites for social activities were sought in Riyadh. A non-

69 profit childcare association providing free weekly parenting courses in community centres was

70 identified, to recruit female attendees who were of various ages and educational backgrounds.

71 For the male pharmacy user group (MPG), an announcement about a support group for

72 caregivers of Alzheimer patients was sent via Twitter from the Alzheimer Society account. This

73 support group is held once a month in a private training centre. The researcher (LJ) visited one

74 of these support group meetings for recruitment purposes.

75

76 All potential participants, irrespective of group, received an invitation letter and study

77 information sheet. A consent form was provided by e-mail or personally, one week prior to the

78 focus group. Each participant signed an individual informed consent statement prior to the

79 commencement of the focus groups.

80 ## Data collection

81 The focus groups were conducted using semi-structured topic guides (Supplementary Material)

82 (one for FPG and MPG and one for the PG and CPG), which were informed by the literature and

83 the HFF. Data were collected on participants' age, gender, and education background and

84 practice experience. The PG was moderated by MW. The remaining focus groups were

85 moderated by LJ, with SA in attendance. Before undertaking the group discussions, a pilot focus

86 group was conducted with first year undergraduate pharmacy students to test questions and

87 data collection methods.

88 ## Research ethics

89 This study was completed as part of the first author's PhD thesis who undertook specific

90 training regarding conducting and analysing qualitative research. Approval for this study was

91 received from The College Ethics Review Board, University of Aberdeen, UK.

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92 **Data management and analysis**

93 Each focus group was audio-recorded and transcribed verbatim by LJ. The groups were

94 undertaken in Arabic and the transcripts were then translated from Arabic into English, except

95 for the PG group, which was conducted in English. A member of the research team (LJ)

96 undertook the translation; a professional translator checked the accuracy of the translation. The

97 analysis used a priori and emergent codes; codes were identified independently from the data

98 by two researchers (LJ, MW). [19] The codes were then categorised using the HFF. Two coding

99 (Supplementary Material) indices were generated based on commonality of codes: one was

100 used to code the transcripts of the PG and CPG, while the other was for the pharmacy user

101 groups. The coding for each focus group was checked for accuracy by a second researcher (MW,

102 SA, or PK). A comparative analysis was then conducted to identify commonality, differences and

103 relationships through the themes categorised in the HFF to identify mega themes. [19] This

104 study was conducted and reported in accordance with COnsolidated Criteria for Reporting

105 Qualitative Studies (COREQ). [20]

106 # RESULTS

107 In total, 35 individuals participated across four focus groups and four interviews (Table 1). All

108 data collection was undertaken between February and May, 2013. The PG (n=8) comprised

109 representatives from several organisations responsible for regulating pharmacists and

110 pharmacy practice, as well as pharmacy academics and pharmacy owners. All participants in the

111 PG were Saud nationals. The CPG participants were Egyptian (n=3) and Yemeni (n=1).

112 **Table 1** Characteristics of participants

Focus Groups	Professionals	Community pharmacists		Pharmacy users	
	Focus group	Focus group	Individual Interviews	Female focus group	Male focus group
Total Individuals invited	15	75	5	15	9
Number of participants (male)	8 (7)	4 (4*)	4 (4*)	11 (0)	8 (8)
Age years (SD)	40.6 (7.1)	34.7 (10.6)	37.7 (13.8)	33.5 (5.8)	34 (5.9)
Duration of interaction (minutes)	104	86	19.2 (3) Mean (SD)	62	89

113 Only males are permitted to work in the community pharmacy setting in KSA.
114 SD Standard deviation
115
116 The data were categorised into nine categories representing the HFF (Table 2). From these

117 categories, seven main themes were identified (Table 3). Example of similarities and differences

118 of themes across all groups are presented in (Table 4). The themes are described in the text

119 supported by anonymised, verbatim quotes from participants' narratives (which are written in

120 italics and quotation marks). To illustrate which focus group generated the identified themes,

121 results are referred to below by the following letters: professionals (PG); community

122 pharmacist (CPG); female pharmacy users groups (FPG) and male pharmacy users groups

123 (MPG), followed by a hyphen and the number of the participant, e.g. PG-1 is participant 1 in the

124 PG, etc. For further quotes in the Supplementary Material.

125 **Table 2** Human Factors and sub-themes identified in the Focus groups

Human factors category	Sub-themes
External factors	Commercial pressure and commercialism Regulations and regulators The healthcare system in Kingdom of Saudi Arabia
Organisational and management factors	Pharmacy owners' and managers' roles Lack of patient database in community pharmacies
Work environment	Pharmacist working hours Type of pharmacy and its effect on medication safety
Team factors	Physician prescribing behaviour Communication between pharmacists and physicians
Individual factors: Pharmacists	Pharmacist competence and clinical skills Pharmacist adherence to law and regulations Pharmacist role as perceived by participants
Task factors	Illegal Supply of prescription-only medication to patients. Medication storage and transportation in community pharmacies Generic substitution
Communication and information exchange	Patient–pharmacist communication Factors affecting communication exchange Type of information requested by patients from pharmacists Patient medication information source Pharmacist versus physician information
Patient	Patient characteristics: risk factors for medication safety problems Patient trust in pharmacists Patient trust in physicians Patient beliefs and perceptions Patients' behaviour Patient role and responsibility towards medication safety
Medication	Medicines associated with the risk Medication availability and shortage Counterfeit medication
Others	Patient experiences with drug–drug interaction and adverse drug events Comparison with other countries regarding practice and quality of medication.

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131   **Table 3** Emergent themes identified

Emergent themes	Sub-themes
Commercialism and commercial pressure on community pharmacies in kingdom of Saudi Arabia	External factors • Commercial pressure and commercialism • Healthcare system role in commercialism Organisational and management factors • The role of pharmacy owners and managers Work environment • Type of pharmacy and its effect on medication safety • Pharmacist working hours • Low salaries Team factors • Physician prescribing behaviour Task factors • Patient counselling • Generic substitution • Medication storage and transportation Patient factors • Patient belief and perception about the business oriented practice • Patient behaviour
Illegal supply of prescription medication by pharmacist	External factors Individual factors: pharmacist Patient factors
Lack of enforcement of regulations	External factors • Regulations and regulators Individual factors: pharmacist • Pharmacist adherence to law and regulations Patient factors • Patient pressure on pharmacists to commit a misconduct Medication • Counterfeit medication as consequence
Healthcare system in kingdom of Saudi Arabia	External factors • The fragmented healthcare system • Lack of patient database in community pharmacies Organisational and management factors • Implementation of technology in community pharmacy
Patient medication-taking behaviour	• Self-medication • Sharing medication • Adherence to medication
Patient trust in pharmacists	No subthemes identified
Communication and information exchange	• Patient–pharmacist communication • Patient medication information source • Factors affecting communication exchange • Type of information requested by patients from pharmacists • Information received from pharmacist information compared to information received from physician Team factors • Communication between pharmacists and physicians

132

133 **Table 4** Example of similarities and differences of themes across all groups

Theme	Professionals	Pharmacists	Pharmacy users	
			Male	Female
Commercialism and commercial pressure on pharmacists.	✔	✔	✔	✔
Self-diagnosing and self-medication.	✔	✔	✔	✔
Lack of enforcement of regulations.	✔	✔	✔	✔
Illegal supply of prescription medication.	✔	✔	✔	✔
Fragmented healthcare system.	✔	✔	✔	
Patient trust in pharmacist.		✔	✔	✔
The primary role of the pharmacist should be as an information provider.		✔	✔	✔
Communication failure between pharmacists and patients.	✔	✔		
The need for information			✔	✔
Perception of pharmacists as salesmen rather than healthcare professionals.			✔	✔
Pharmacy design and its effect on counselling.			✔	✔

134

Commercialism and commercial pressure

136 Commercialism in community pharmacy practice in KSA emerged as a theme in all groups.
137 Participants identified factors and consequences of commercialism on patient safety. These
138 factors are presented here according to the HFF: external; organisational; work environment;
139 team; task; and patient factors.

External factors

141 Participants across all groups except the FPG discussed the role of pharmaceutical companies in
142 creating commercial pressure by paying bonuses to physicians and community pharmacists to
143 prescribe and dispense certain medications, which may not be needed.

144 *"In our country, the pharmacist gives you the medication that is suitable to him*
145 *or the medication for which he receives a commission, you go to the*
146 *pharmacist you say you have a headache he gives you Fevadol instead of*
147 *Panadol [generic substitute] for example he gives you the medication that suits*
148 *you, who he is an agent for it or gives him a commission for. Even in clinics, the*
149 *representative of the company comes to the physician and gives him the new*
150 *medications with tickets and gifts and the physician prescribes the*
151 *medications."* (MPG-5)

152 The PG participants suggested that recent rapid increases in the number of pharmacies,
153 combined with their proximity to each other, contributed to increased competition between

154 them. This pressured pharmacists to illegally supply POM to to maintain their business and
155 retain consumers/patients.

> 156 *"It is not logical that I will not sell the medication without* [prescription], *while my*
> 157 *neighbour is selling it without* [prescription]. *I would go broke."* (PG-2)

158 The PG participants also suggested that the pharmaceutical industry restricted certain generic
159 medicines to increase sales of newer, more expensive brands, contributing to medication
160 shortages.

> 161 *"I comment on availability issues. Some of it* [is] *truly shortages, and some of it is*
> 162 [not]. *Unfortunately, this is a commercial business. I know some pharmacies will*
> 163 *not introduce a product without getting fees or getting huge bonuses from the*
> 164 *company. The company will not be able to sell it that is again with the law how*
> 165 *far you can enforce the law on community pharmacy?"* (PG-4)
> 166

167 *Organisational and managerial factors*
168 Participants in the CPG believed that pressure from owners and managers of community
169 pharmacies contributed to creating a profit-oriented rather than patient-oriented pharmacy
170 practice.

> 171 *"Maybe he is being pushed by his managers to be money making…"* (MPG-3)

172 *Work environment*
173 The CPG, FPG and MPG perceived community pharmacies owned by commercial companies
174 (also known as chain pharmacies) to be safer than independent pharmacies. They explained
175 that chain pharmacies have more rigorous internal regulatory systems, offer training
176 programmes for the pharmacists and have lower individual workload owing to investment in
177 technology. Interestingly, the public group believed that independent pharmacies are less
178 affected than chain pharmacies by commercial pressures.
179

> 180 "[Chain pharmacies] *have a policy that we will not violate the law and the*
> 181 *patient will find what he wants; this is the mistake of the patient"* (CPG-1)
> 182

183 The CPG and MPG participants discussed long working hours and their effect on practice. They
184 believed that the long working hours were related to the owner's interest in maintaining their
185 profit.

> 186 *"He has long working hours and that leads many pharmacists to not refresh*
> 187 *their information, …there is no role for the Ministry to update your*

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information. For example, the pharmacist (CPG-4) graduated in 1986 and necessarily many improvements have taken place since that time."(CPG-2)

Team factors

The PG also acknowledged that pharmaceutical companies influence the prescribing behaviour of physicians through advertising and financial incentives, which tends to result in overprescribing.

"The quality of the physician usually they come with very low salaries but depending on the commissioning they get from the companies and still they have the commission we see the kind of prescription which is very weak even our pharmacists discover these mistakes it happens with me a lot so due to this kind of this low educated physicians."(PG-2)

Task factors

Participants in the pharmacy user groups felt that commercial pressure on pharmacists affected the advice and information provided. They suggested that advice given by the community pharmacists was for marketing purposes and not tailored to patients' actual needs.

"My problem is always that when I go, they give me the best and the latest on the market, that is to say, they do not give me the one appropriate for me. The problem is that they do not try to learn whether it is appropriate or not."(FPG-1)

Pharmacists substituting a prescribed branded medication with a different form of the same active substance (generic substitution) was an emerging theme across all groups. The PG stated that the problem is that community pharmacists provide medication alternatives to patients based on financial incentives and commission rather than patient benefit.

"If you go to a pharmacist and you say you have a mild or minor ailment and ask for a prescription, you have two products [options] one product will fit you, but that does not have a bonus, the other product has a bonus."(PG-4)

Participants discussed the problem of inappropriate storage conditions for medicines in community pharmacies and warehouses, attributed by some participants in the PG and pharmacy users' groups to a desire to cut costs.

"It is a matter of saving electricity just like groceries. At night, they disconnect the refrigerator containing milk to save electricity, and when they come back in the morning, they turn on the electricity." (MPG-4)

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Patient factors

On a number of occasions, participants in the PG as well as the pharmacy user groups referred to the way that patients perceive the community pharmacy as a grocery shop.

> *"We look in KSA at a pharmacy as a store … It should be a service, not a store."* (PG -3)

However, perceptions of pharmacists were highly varied amongst participants in the pharmacy user groups. Some considered pharmacists to be salesmen, while others perceived them as healthcare professionals.

> *"He is interested mainly in collecting money."* (FPG-3)

> *"People think that he is a seller, but he is well qualified in term of education. He spent a long time studying and understands drug composition maybe more than the physicians."* (FPG -2)

Participants in the pharmacy user groups acknowledged that they buy whatever they want from the pharmacy acting as a "consumer."

> *"As a consumer, I go to the pharmacy and take the antibiotic I want, I can take whatever medication I want without prescription."* (MPG-5)

Illegal supply of prescription medication by pharmacists

External factors

The PG suggested many reasons to explain the illegal supply of POM which they described as a violation of regulations, including patients perceiving medication as a commodity and patients who are stable on medication visiting the community pharmacy to refill their POM without a prescription. In addition, they suggested other "external factors" that were highlighted previously, such as the limited capacity of the healthcare system, the lack of regulation enforcement and commercial pressures.

> *"…So now you have lack of enforcement of the law, huge pharmacies, huge number of non-Saudi pharmacists and you can say there is nobody in charge that lead to where people are treating medications as a commodity rather than special products that need attention…"* (PG-4)

However, such practices were identified as a cause of hospital admission by the PG. Antibiotics were given as an example of medication supplied illegally in all groups, and participants in the CPG provided other examples, such as hypnotics and antidepressants.

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257 *Individual factors: pharmacists*

258 Participants in the CPG acknowledged that they sometimes illegally supply POM and provided

259 justifications for their actions.

260 *"I dispense everything; I am a pharmacist regardless of the laws, when you have a*
261 *patient in front of you needing to be treated it would be difficult especially if the*
262 *patient is poor and needs assistance you do not help him; for humanity"*(CPG-4)
263

264 **Lack of enforcement of regulations**

265 Lack of enforcement of regulations emerged as a theme in all groups. Factors and consequences

266 of lack of enforcement of regulations identified in this study are presented in this section

267 according to the HFF: external; pharmacist and patient.

268 *External factors*

269 Across all groups, participants agreed that the Saudi government issued regulations to uphold

270 the quality of community pharmacy practice. Participants also identified the roles played by

271 different regulatory bodies in inspecting and controlling medication supply. However, they all

272 agreed that governmental regulations are not enforced effectively.

273 *"...There is a complete difference between the law and the reality."* (CPG-2)
274

275 The PG suggested that there were too few governmental inspectors in relation to the large

276 number of community pharmacies. Furthermore, the community pharmacists perceived

277 inspectors to be inadequately trained.

278 *"...The number of inspectors who are supposed to enforce the law have almost*
279 *declined you don't have the same growth in the number of inspectors as you have*
280 *in the number of the pharmacies...so that automatically leads to the lack of*
281 *enforcement of the law so now you have lack of enforcement of the law, huge*
282 *pharmacies, huge number of expatriates pharmacists and you can say there is*
283 *nobody in charge."* (PG-4)
284

285 *Individual factors: pharmacists*

286 Pharmacists' adherence to regulations emerged during the discussion. One participant in the PG

287 group believed that all pharmacists would like to adhere to the law.

288 *"No professional pharmacist will like to break the law..."*(PG-4)☒

289 Conversely, the CPG admitted violating certain pharmacy practice regulations. There were

290 examples of pharmacist violations given in all the focus groups, such as illegal supply of POM,

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291 inappropriate storage conditions of medication, pharmacists working without licence, and

292 supplying medication without a label.

293 *"The air conditioning is not working, the expiry date of the medicine … also they*
294 *store medicines outside the refrigerator. We found some big problems we saw the*
295 *technician dispensing the medicine they are not allowed to dispense the medication*
296 *also find the pharmacist work without licence this is a big problem in the*
297 *pharmacy."* (PG-8)
298

299 *Patients factors*

300 Patients also influence pharmacists' behaviour in terms of not adhering to regulations due to

301 pressurising pharmacists to illegally supply medications. Participants in the CPG said that they

302 find themselves compelled to supply medication to patients in these situations, despite this

303 being prohibited by law.

304 *"Originally, it is prohibited by the Ministry of Health to dispense antibiotic as a*
305 *strip and if this is done it would be a violation and in case of not dispensing them*
306 *in this form, the patient will go to a second, third and fourth pharmacy until he*
307 *finds what he wants"* (CPG-1)
308

The healthcare system in Kingdom of Saudi Arabia

310 Participants in all groups discussed factors related to the healthcare system and their impact on

311 medication safety in Saudi Arabia. These factors are presented here according to the HFF:

312 external and organisational factors.

313 *External factors*

314 The structure of the Saudi healthcare system was an emerging theme. The PG and FPGs

315 discussed the fragmented healthcare system. Patients visiting different physicians for the same

316 medical problem and a lack of continuity in care are the results of the fragmented provision of

317 healthcare that could lead to medication duplication and compromised medication safety.

318 *"For example, the patient went to a physician who prescribed him Amlor*
319 [Amlopidine] *and then went to another physician who prescribed him Amlopine*
320 [Amlopidine]. *He imagined that they are different medications and took both."*
321 (CPG-4)
322

323 The PG discussed the limited capacity of the healthcare system and its inability to meet the

324 increasing healthcare needs of the population. They suggested that community pharmacies

325 could play a role in caring for patients to minimise the pressure on other healthcare facilities.

12

> *"Community pharmacy should work as primary centres ... take for example diabetic patient whatever the government invest and put amount of money in hospitals and primary care they will not be able to manage the whole diabetic population. They are huge [the diabetic population] so if you add hypertensive patients and asthmatic patient they are huge."* (PG-4)

Participants also discussed the lack of a patient database and filing system in community pharmacies: they perceived an electronic patient database with relevant medical information accessible to community pharmacists to be an important factor in medication safety.

> *"There should be a special file for each patient in each pharmacy, not only in the hospital."* (CPG-1)

Organisational and management factors

Participants suggested that solving the problem starts with the Saudi Ministry of Health, which should establish a national electronic health records database. The need to implement technologies such as electronic prescribing and to utilise drug information software, was discussed in both the PG and the CPG.

Patient medication taking behaviour

Patients' accounts of behaviours such as self-medication, sharing medication and adherence to medication emerged. Self–medication in the context of this study is the selection and use of medicines by individuals to treat self-recognized conditions or symptoms with POM or over the counter (OTC) medication. Participants in all groups agreed that self-medication is common in KSA.

> *"I went to the pharmacy and said [something] and then some medications were given to me, that is, we are treating ourselves."* (MPG-1)

The MPG proposed several reasons for self-medication such as cultural influences, the accessibility of medication, the large number of community pharmacies, and patients' previous experiences with a medication.

The CPG highlighted that patients even self-medicate with antidepressants without consulting a physician. They were also aware of medication abuse such as the use of steroids for weight gain and skin whitening.

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358   *"Most people request Seroxa* [antidepressant]*, and a segment of women take it*
359   *due to marriage pressures. They take psychiatric medicines as a tonic that*
360   *enables them to deal with the community in a better way."* (I-3)
361

362 Sharing medication emerged as a theme across the CPG, FPG and MPG. Participants discussed

363 sharing medication such as vitamins, painkillers and antibiotics with family members: "*As fruits*

364 *in the refrigerator."* (MPG-5)

365   *"Sometimes I think that the factor is economics and he doesn't want to pay for*
366   *something he doesn't want to continue using."* (CPG-1)
367
368 Patients do not adhere to their medications and do not follow instructions provided by

369 pharmacists as participants in the CPG and MPG described.

370   *"frankly, I never completed the period of the course*" (MPG-3)
371

372 The patient's role in medication safety was discussed in all groups, and there was general

373 agreement of the importance of educating patients.

374 **Patient trust in the pharmacist**

375 Patient trust in the pharmacist emerged in the CPG and pharmacy user groups. Participants in

376 the pharmacy user groups identified several factors that affect this trust, such as pharmacists'

377 age, an existing relationship with the patient, provision of advice, pharmacist nationality, and

378 knowledge of the sector in which the pharmacist worked, e.g. governmental or private. Some

379 participants perceived pharmacists having low levels of competence due to their non-Saudi

380 nationality, especially regarding recognising trade names of medication. Another reason for lack

381 of trust was due to the perception that pharmacists are business-oriented rather than patient-

382 oriented.

383   *"He has knowledge; he is old and calm, and he knows that I am coming for a*
384   *consultation. I tell him the physician prescribed this and this. He knows me, and I*
385   *buy some of the things. He knows my face, and he counsels me and gives me*
386   *some of his time. He says, 'no this is that and this is good', and he gives me*
387   *alternatives. He gives me advice. He is next to my home, and I trust his opinion."*
388   (MPG-4)
389
390 There was disagreement in the MPG that providing generic alternatives increases patients' trust

391 in pharmacists. Participants in the CPG identified several factors that cause patients to lose

392 confidence in the pharmacist. For example, when the pharmacist spends more time reading the

393 prescription due to bad physician handwriting or incomplete patient information, which leads

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pharmacists to ask the patient more questions. The CPG believed that patients trust physicians more than pharmacists.

> *"I may receive a prescription in which the age and the diagnosis are not mentioned and what is only mentioned is the name. In order to dispense the medication, I ask many questions, I ask until I know the meant medication. Asking many questions results in the loss of confidence between the patient and me. My questions are meaningful since I concentrate on certain points."* (CPG-3)

Communication and information exchange

Pharmacy users and the CPG discussed poor communication between pharmacists and patients, including the question of who should initiate communication.

> *"What I notice is that they take the prescription and put it on the counter, and that is all. They do not even say hello."* (MPG-1)

Pharmacy users expressed a need for information about medication and that the primary role of the pharmacist should be as information provider.

Barriers to effective communication identified by participants in all groups included language, culture, education, gender, having a third person (family member or friend) assigned by the patient to obtain the medication from the pharmacy, pharmacy layout and pharmacists' workload.

> *"I came across someone who didn't know whether the medication was for constipation or diarrhoea. He said he wanted something for diarrhoea. The matter is that he didn't want something for diarrhoea; he wanted something to cause diarrhoea. In brief, language has an effect."* (CPG-4)

The CPG suggested that patients' ability to access medication information from other sources, such as the internet or friends, and the role of TV advertising, can cause problems when communicating with a patient, as they come to the pharmacy influenced by information from these different sources.

> *"Patients come to me and say, 'I read that this drug is dangerous'. I ask him, 'Where did you read that?' and he says, 'The internet'."* (CPG-3)

The CPG also expressed concerns about the patient providing incomplete information or wrongly expressing symptoms to the pharmacist.The PG and MPG agreed on the need for clear and easily comprehensible information about medication in Arabic.

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428   DISCUSSION

429   The study identified a range of major medication safety problems in community pharmacy in
430   KSA from a range of perspectives. The factors and circumstances that contribute to these
431   problems are complex and interact with each other.

432   Commonalities existed across groups, and unsurprisingly the PG identified problems at a
433   systemic or regulatory level. For example, all groups discussed the lack of enforcement of
434   regulations. The professionals provided the reasons behind this, debating the role and
435   importance of each organisation involved in pharmacy practice. The community pharmacists
436   discussed the day-to-day problems that pharmacists face in terms of owners, patients and
437   inspectors. The FPG, of whom the majority were mothers, shared their personal experiences
438   with pharmacists and medications in their daily lives. The MPG also focused on regulations and
439   systems and compared current practice in KSA with other countries, such as the UK and USA.

440   Most studies of medication safety in community pharmacy have considered only one aspect of
441   safety, such as dispensing [21], prescribing errors [22-24] or workload [25]. Two studies have
442   adopted holistic approaches to identify medication safety problems. [26,27] Phipps et al.,
443   identified a number of social technical factors consistent with our findings, such as regulatory
444   and legal factors, group norms, trust in pharmacists, profitability versus safety, quality
445   assurance and workspace, and collaboration between prescribers and patients. [27]

446   Commercialisation of pharmacy practice in this study was attributed to corporatisation,
447   increased numbers of pharmacies, the absence of any governmental reimbursement and the
448   lack of enforcement of regulations by regulatory bodies. Subsequently, some pharmacists
449   illegally supply POMs, supply unnecessary medication or provide generic substitution based on
450   profit not patient benefit. Community pharmacies generally operate as private businesses, thus
451   the financial impact of any decisions made by community pharmacists is a concern that could
452   potentially influence the attitude of pharmacists to service provision, for example the reporting
453   of errors. [27] The Saudi pharmaceutical sector is the largest in the Gulf region, and has recently
454   been growing by 4.7% annually. [28] There has been a six-fold increase in the number of
455   community pharmacies in KSA over the past 30 years. [29] This huge market tends to promote
456   the 'corporatisation' of pharmacies, as has happened in the UK, in which there is a change in
457   ownership pattern from individuals to larger pharmacy chains. [30,31] Bush *et al.* describe the
458   impacts – often negative - on the professional autonomy of pharmacists working in these big
459   companies. [30]

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460   This current study suggests that failure to enforce regulations creates an environment in which

461   violations become routine practice. For example, lack of enforcement of regulations has been

462   attributed in this study and others conducted in KSA to the illegal supply of POM. [7-10] There is

463   a lack of studies exploring the association between violations in community pharmacy practice

464   and enforcement of regulations. [32] Lowe and Montagu [33], reviewed regulatory frameworks

465   in 24 low-income countries and many of the challenges described are similar to those identified

466   in this study, particularly in terms of fragmented pharmacy legislation and regulation, and

467   insufficient numbers of inspectors. [33] Two randomized intervention studies reported the

468   effect of enforcement of regulation on pharmacist compliance to regulations and improving

469   services such as giving advice to customers and a decrease in the illegal supply of some

470   medications. [34,35]

471   Self-medication was identified in this study as one factor contributing to medication safety in

472   community pharmacy. Patients who self-medicate usually diagnose and treat themselves based

473   on their own experience or that of family or friends, or information from the media and internet.

474   One reason for self-medication identified here was that patients could not afford or wanted to

475   avoid a physician visit. The main risks from self-medication identified previously include

476   misuse, a potential delay in treating a serious condition, masking of symptoms of a serious

477   condition through the use of a OTC medication, and drug interaction. [36,37] It is a cause for

478   concern that most of the risks previously identified relate to self-medication with OTC

479   medication, while self-medication with POM is present in KSA. [38]

480   Another important factor identified is the fragmented healthcare system in KSA. Healthcare

481   delivery in KSA occurs in 'mixed market' systems, with care delivered both by government and

482   private sector providers. [39,40] This allows patients to obtain healthcare from multiple

483   healthcare providers, which has been associated with a number of medication safety problems,

484   including duplicate interventions [41], multiple prescriptions, exposure to potential drug

485   interactions [42], and high costs for patients and the government. [43,44] Given there are no

486   patient medication records in Saudi community pharmacies, pharmacists will supply the

487   prescribed medication to patients not knowing their other medication, potentially leading to

488   medication duplication due to multiple prescriptions from multiple doctors.

489   The illegal supply of POM has been reported in many developing countries such as Mexico,

490   China and also in other countries in the Middle East. [45-47] The main reasons identified in KSA

491   were financial interests and the lack of enforcement of regulations. [7,8,11] Pharmacists in this

492   current study admitted to the illegal supply of POM and provided several justifications, which

493   were similar to findings from a qualitative study in India [48], that illegal supply of POMs is a

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494 form of "social work" to help poor patients who cannot afford a physician's visit. The Indian
495 study also cited commercial interest and the lack of pharmacist knowledge as reasons for this
496 behavior.[48]

497 The lack of communication between pharmacists and patients was identified as a medication
498 safety problem. The importance of establishing two-way communication in identifying [49] and
499 preventing ADEs [50,51] has been previously documented.

500 An important determinant in establishing a relationship with a pharmacist identified in this
501 study is trust in the pharmacist.[52] Participants were suspicious of pharmacists' motives and
502 their interest in profit rather than patient care. This is consistent with the findings of a study in
503 Ireland. [53]

504 Strategies to target these factors and develop systems that ensure safe use of medication within
505 community pharmacies are needed at different levels.

Strength and limitations of the study

507 The study findings identified several categories of HFF that are relevant to the community
508 pharmacy setting and provide a deeper understanding of community pharmacy practice,
509 including reasons for specific behaviours, such as the illegal supply of POM. Another strength of
510 the study is that all stakeholders were represented except general medical practitioners.

511 KSA is socially and culturally unique. As such, some factors identified in the current study may
512 not apply elsewhere. However, many factors identified are likely to have resonance in many
513 countries, for example pharmacist workload. [25] The number of participants in the CPG was
514 small, due to the long working hours of community pharmacist. Supplementary telephone
515 interviews helped to achieve data saturation; no new themes emerged in the telephone
516 interviews. [54]

517 Participants were recruited from Riyadh, the capital of KSA, and opinions might not represent
518 those of people across KSA. For example, problems relating to non-Arabic speakers may not be
519 present in more rural areas. More than six million people live in Riyadh, 40% of whom are non-
520 Saudi; this percentage is not the same in other regions. [55] Lastly the majority of participants
521 had a college education, so less educated individuals were under-represented.

CONCLUSION

523 Community pharmacy has been shown in this study to be a complex system involving many
524 interacting factors that influence medication safety. These factors were identified and

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525 categorised using the Human Factors Framework. Commercial pressures on the community
526 pharmacy sector and community pharmacists, a failure to enforce regulations, the fragmented
527 healthcare system and self-medication, are all factors that contribute to medication safety
528 problems. Strategies are needed at different levels to target these factors and develop systems
529 that ensure safe use of medication within community pharmacies.

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Ethical approval

544 The College Ethics Review Board, University of Aberdeen, UK

Data sharing statement

546 Audiotapes, notes and unpublished data from this study are securely stored and only available
547 to Lobna Al Juffali.

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689 ## Supplementary material

690 ## Appendix A

691 **Topic Guide for focus group (Pharmacy user's)**

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693 **Questions to be addressed during the focus group**

694   a.   What does medication safety mean to you?

695   Probes: Your personal experience of problems (adverse effect reactions)

696   b.   What medicines are safe?

697   Probes: Why do you think they are safe?

698   Probes: when you are familiar with a medicine does this makes it safe? How is that?

699   c.   What medicines do you think are associated with risk?

700   Probes: Why do you think they are unsafe?

701   d.   What medical conditions are most likely to cause problems with medicines?

702   e.   What patients are most at risks from medication?

703   Probes: Age, Gender, pregnant women, lactating women, etc

704   f.   What are the main problems that you can encounter in a community pharmacy in

705   terms of medication safety?

706   g.   How could community pharmacists help people with their medicines?

707   Probes: your suggestions

708   h. Any comments

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711 **Topic Guide for focus group (Professionals)**

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713 **Questions to be addressed during the focus group**

714 a. What are the main medication safety concerns associated with medicines supplied

715 from community pharmacies in Saudi Arabia?

716 Probes: Identify the problems and give examples from their point of view and experience.

717 b. Who are the patients most at risk from medication safety problems?

718 Probes: what are the medical conditions that have the highest risk to the patient?

719 Probes: who are the population who are at most risk (age, gender, etc)?

720 c. What types of medication are associated with safety problems in community

721   pharmacy?

722 d. What are the factors that contribute to these problems?

723 e. How can community pharmacists prevent and manage these problems?

724 f. What other agencies, organisations could help to improve medication safety with

725   medicines supplied from community pharmacies?

726 Probes: How could this is achieved?

727 g. Any other comments

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Appendix B

Coding index (expert and community pharmacist)

1. New prescription

1.1 Refill of a prescription medication

    1.1.1   With a prescription

    1.1.2   Without a prescription

1.2 Self–medication

    1.2.1   Internet

    1.2.2   TV/ Advertisement

    1.2.3   Family, Friends, neighbours

    1.2.4   Based on previous experience

2. Medication use process

2.1 Prescribing

    2.1.1   Prescriber

2.1.1.1 Lack of knowledge

2.1.1.2 Failure to communicate between pharmacist and prescriber

2.1.1.3 Unethical prescribing practices/violation of the law

        2.1.2 Prescription

2.1.2.1 Prescription incomplete information or ambiguous

2.1.2.2 Handwriting

2.1.2.3 Prescribing error

2.2 Dispensing

    2.2.1   Patient pressure to supply medication

    2.2.2   Incomplete patient information

2.2.2.1 Patient medical history

2.2.2.2 Medication record

    2.2.3   Dilemma between patient care and money (commercial pressure)

    2.2.4   Labelling

    2.2.5   Illegal supply of medications

2.2.5.1 Factors that contribute to illegal supply of medication

2.2.5.2 Common medications supplied without a prescription

2.2.5.3 consequences of supplying medication without prescription

    2.2.6 Generic substitution

2.3 Pharmacist-patient communication

    2.3.1 Language

    2.3.2 Literacy

    2.3.3 Cultural considerations

    2.3.4 Third party communicating patient information (family member or

    2.3.5 Inaccurate information (self-diagnosis)

2.4 Administration (Medication taking behaviour)

    2.4.1   Sharing medication

    2.4.2   Adherence

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900 **Coding index (Pharmacy users)**

901 **1   Patient** (related to the patient characteristics and others)
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903   1.1 Patient at risk of medication safety problems
904   1.1.1   Patient with chronic diseases
905   1.1.2   Patient with Allergies
906   1.1.3   Patients with serious operations
907   1.1.4   Patients with poly pharmacy
908   1.1.5   Patients with kidney problems
909   1.1.6   Patients with liver problems
910   1.1.7   Gender
911   1.1.7.1 Female
912   1.1.7.1.1   Pregnant
913   1.1.7.1.2   Hormones
914   1.1.7.1.3   More prone to disease
915   1.1.7.2 Male
916   1.1.8   Age
917   1.1.8.1 Paediatric
918   1.1.8.2 Geriatric
919   1.1.8.2.1 Bed ridden patients
920   1.1.9   Education
921   1.1.9.1 Patients
922   1.1.9.2 Care givers
923
924   1.2 Patients perceptions and believes
925   1.2.1   The medication is safe if it is written in the package insert that it is safe
926   1.2.2   Effective medicine are prescribed by the physician
927   1.2.3   Medications prescribe by the physician are safe
928   1.2.4   Illegal supply of medication by pharmacist are risky
929   1.2.5   Community pharmacies are not safe
930   1.2.6   Intervention of pharmacist is a must
931   1.2.7   Antibiotics has to be used as directed
932   1.2.8   Certain disease must be treated and others not important
933   1.2.9   Pharmacies are shops, groceries (for business)
934   1.2.10 Patient risk perception
935   1.2.10.1   Based on information provided
936   1.2.10.2   According to setting (hospital vs. community pharmacy)
937   1.2.10.3   Different routes are associated with different risks
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940   1.3 Patient /public awareness of medication safety
941   1.3.1   Patient responsibility and role
942   1.3.2   Patient awareness of regulations
943   1.3.3   Awareness of the importance of the correct dosage form
944   1.3.4   Awareness of the importance of the medication history
945   1.3.5   Awareness about asking about allergies
946   1.3.6   Awareness about the importance of asking about other medication
947
948   1.4 Patient perception and attitude towards healthcare professionals roles
949   1.4.1   Differentiate between health care professionals role
950   1.4.2   Physicians
951   1.4.2.1 Blame physician

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1146   # Appendix C

1147   ## Selected quotes from the focus groups, illustrating examples of the themes that emerged

Identified themes	Human factor category	Subthemes	*Quotes*
1. Commercialism and commercial pressure on community pharmacies in Saudi Arabia	External factors	Healthcare system role in commercialism	*"I mean the proportion of safety increased because the medical insurance makes everyone go to the doctor before they go to the pharmacist, and do not take the treatment directly from the pharmacy."* (I-4) "Listen, the biggest problem of the medical insurance is that the doctors prescribe medicines they want to sell or will gain benefit from. The most important purpose of most pharmaceutical companies, not all, nowadays, is the sales nothing else, therefore they influence some doctors to prescribe their medicines regardless the patient needs it or not... Ok. This is the main problem of the insurance, because the patient does not pay high amount, therefore the prescription contains medicines that are over the patient's need, prescribed just to be sold, no more" *(I-3)*
	Organisational and management factors	The role of Pharmacy owners and managers	*"Problems between you and the owner arise; he [the owner] asks what happened ... [you] pay a penalty, close the pharmacy and your license is suspended. These problems face us and affect our work."* (CPG-4)
	Work environment	Type of pharmacy and its effect on medication safety	*"We talk about the chain of pharmacy we spend a lot of time to train our pharmacists before going to be behind the counter to dispense medication...Chain of pharmacy or chain group it is easy to implement any regulations"* (PG-2) *"Street pharmacies [independent pharmacies] have more problems because the responsibility is like a burden on the pharmacist's shoulders. He becomes a physician. On the other hand, when I am in a place [where] there is a clinic, half of my time is spent on prescriptions from the clinic, and the physician upstairs is doing his duty, writing the medicine that suits the patient and explaining to him the safety of the medicine. The clinic helps me, but when I work in a street pharmacy, I almost work alone, so I have to exert extra effort to explain to patients."* (I-4) *"...If you will find small pharmacies you will find most of the medication they survive on availability [availability of medication] in chain pharmacies they survive on the biggest bonuses they get." (PG-4)*
		Pharmacist working hours	*"Often, pharmacists find themselves compelled to work in place of their colleagues for extra hours. For example, the average working hours are 15 or 17 hours [a day]. Seventeen hours is a [long time]. The maximum hours we have are 15 hours for certain periods in a month."* (CPG-1) *"I don't expect someone who is frustrated can produce...there should be controls regulating the rights and obligations of the pharmacist. I know someone working for the company (name). He tells me about what is happening he is responsible of choosing the best place to open a pharmacy and he schedules the pharmacist working schedule he says our profits are millions, do not blame the pharmacist they are frustrated."* (MPG-5)

		Low salaries	*"I don't expect anything from the pharmacist, because all pharmacists are frustrated and this is due to their low salaries and the nature of their work. In a pharmacy, I noticed a pharmacist working in the middle of a hot day on Friday and he used to walk three or four kilometres."*(MPG-5)
	Team factors	Physician prescribing behavior	*"The medication is prescribed due to a commission, and this has resulted in a loss of confidence between us and physicians."* (MPG-7) "Listen, the biggest problem of the medical insurance is that the Doctors prescribe medicines they want to sell or will gain benefit from. The most important purpose of most pharmaceutical companies, not all, nowadays, is the sales nothing else, therefore they influence some doctors to prescribe their medicines regardless the patient needs it or not. Ok." *(I-3)*
	Task factors	Patient counselling	*"The pharmacists' required trait is honesty. He should be honest when giving an opinion or at least not give advice if his advice is for commercial purposes. His positive role is absent here."*(MPG-3) *"My problem is always that when I go, they give me the best and the latest on the market, that is to say, they do not give me the one appropriate for me. The problem is that they do not try to learn whether it is appropriate or not."*(FPG-1)
		Generic substitution	*"He sometimes tells you about an alternative if one drug is expensive. I hear him saying, 'its price is seventy, but there is an alternative that is only forty'."*(FPG-2) *"Price is not the issue, [it is to] prevent you [the patient] from going to other pharmacy"*(FPG-5) *"When I talk to him and he gives me options*, [I think] *I came to ask you! Why do you give me options? What do you like?*[He asks] *Do you want this medicine or is it ok with you if I give you this or this?' No, I want*[him] *to show me"* (FPG-1)
2. Illegal supply of prescription medication by pharmacist	External factors		*"But in the past, we had same discussion by the way it is not logic that xxx dose not sell the medication without medications [means prescriptions] while my neighbour is selling without I will be broken and close my business. So, implementing in this time is very important as a chain of pharmacy owner and heading this kind of committee I think very willing we need some kind of cooperation from the Ministry of Health to encourage such way. Of course, I believe always about penalties you need to implement something you need to do it the penalties if there is a punishment for one pharmacy dispensing that everybody will commit with that."* (PG-2)
	Individual factors: Pharmacist		*"We are pharmacists, we have certificates and we know what to dispense, but there are laws controlling us."*(CPG-3) *"When you have a patient in front of you needing to be treated, it would be difficult, especially if the patient is poor and needs assistance, not to help him."*(CPG-4) "*We are not only pharmacists, but also marketers. ... I know why he wants the Liponex, whether he wants to sell or take four or five tablets ... The same happens with the psychological medication ... we may dispense it...Solving the problem of insomnia may not be that he cannot sleep, it may be depression, so we give him antidepressants like Liponex. A week prior to marriage anti-depressants may be needed, and we give Sirolex either for a man or a woman.*" (CPG-3) *"The CPs should not give medications without prescription ... because they are risky."*(FPG-8)

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3. Lack of enforcement of regulations	External factors	Regulations and regulators	*"We have three governing bodies in controlling the whole process* [medication supply]*: one controlling the medication SFDA, one controlling community pharmacy which is MOH, and one controlling the licensing pharmacist, I think either we have one governing body who is controlling the whole process and all effective collaborative efforts between these different agencies."* (PG-1) *"I disagree with (PG-1) about what he mentioned about that community pharmacy practice should be under one umbrella. I think this is different because even in Europe the authority who is licensing for the pharmacist is different from the authority licensing for the pharmacy."* (PG-2) "*The most important thing is the Ministry of Health, and it is important to inspect on the licenses of pharmacists. Does the pharmacist have a license or not? Does he have a card of the health certificate? There should be a follow-up on medicines in pharmacies. There are medicines sold which are trafficked. This would have to be controlled."* (I-3)
	Individual factors: Pharmacist	Pharmacist adherence to law and regulations	*"No professional pharmacist will like to break the law..."* (PG-4) *"... When someone comes requesting a combination, I make [prepare the medication as a compound] and hide it as if I am committing a crime."* (CPG-4) *"... There is the regulation but they are playing with regulations..."* (PG-8) "*Community pharmacy should have a sign state that no prescribed medication should be prescribed without a prescription from a physician we do have it in Arabic written everybody can read, ok. The problem community pharmacy pharmacists although there is a sign they are still selling medications without prescription.*" (PG-1) *"There is no enforcement on pharmacists for example to label products although the law is saying you have to label products the law is saying you have to dispense with prescription ... [moving his head] they are not doing. The only control that I can say fairly is the narcotic controlled medication."* (PG-4)
	Medication factors	Counterfeit medication as consequence	"*I have encountered a lot of counterfeit products It is not medicines but other things, for example, herbs. Many medicines are from natural herbal components, but their origins or their producers are not known, and even there is nothing written on it, and not licensed by the Saudi Ministry of Health."* (I-3) *"in Saudi Arabia counterfeit is not a major problem because the system we are going through and the good control of the port in general"* (PG-4) *"I think the worst that we suffer regarding medications is fraud ... they could be counterfeit"* (FPG-9)
4. Healthcare system in KSA	External factors	The fragmented healthcare system	*"...And I remember one time one patient like he has two different insurance he went to two different doctors and get the same medication from the different insurance ... so we also we need to connect all three [pharmacy, patient, health insurance system] together so we have a system for the insurance for this patient if he has two insurance so he will not abuse this insurance by getting the same kind of medication from different pharmacy or different hospitals."* (PG-5)
		Lack of patient database in community pharmacies	"when PG-6 mentioned about the filing lets go even to institutions in the government you find some patients going to different hospitals with no common filing this is a problem starting from the beginning not from the community which is in the end of the road this is one of the problems I know some people going to different hospitals to get the same medication this is I think a problem. However, I am just wondering about it. This the time I think the MOH to upgrade the behaviour *[to implement a filling system]*." (PG-2) "He dispenses medication based on what information you provide him; nothing *[is]* documented" *(MPG-7)*

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	Organizational and management factors	Implementation of technology in community pharmacy	*"In America, there is a program contains the name of the medication to be dispensed drug-drug interaction. This system is good and increases the safety of medications and as to the problem of expiration"*
5. Patient medication taking behavior		Self-medication	*'**CPG-2**: I add the point of the medication, which needs monitoring at intervals such as vitamin D3 and it is of no use being taken randomly without measuring the levels at start. I see them may take the Swiss vitamin D3 (big clap) Each week he takes one bottle just because he thinks he is suffering from osteoporosis* **CPG-4***: and this is what is common nowadays* **CPG-1:** *what is common nowadays is that they suffer from vitamin D deficiency and then take it without taking baseline levels."* *"As for the medicine with severe risk that contains cortisone, most women especially here in the KSAuse cortisone* [Steroids] *for weight gain, […] Unfortunately, they take it a lot and repeatedly. They may take it monthly for many times."* (I- 3) *"Yes, it is the core problem* [self-medication]*"* (MPG-5) *"Regrettably, the issue is the culture of the society, the easiness of obtaining some medications. No need to go far, in the United Arab Emirates, the antibiotic is taken through a prescription whereas in our country, you can take any kind of medications even it is controlled and even from private clinics."* (MPG-6)
		Sharing medication	**CPG-1:** Cooperation, that is, I have a pharmacy at home **CPG-5**: as fruits in the refrigerator. Moderator: Well, does that mean all your medications are shared? **CPG-1:** No, not to this extent, may be antibiotic without exaggeration. Moderator: Could give me examples? **CPG-5:** When I travel abroad I always have a packet of zithromyx and of course Fevadol, sprays and all medications that I will face a problem their not getting them. Moderator: do you share medications with the family, participant 4-3 and participant CPG-4? **CPG-4:** Personally, I am careful with regard to medications, particularly antibiotics and I am careful not to be taken by my children unless for a compelling reason or according to specific instructions. That is, cautiousness with medications, specially, antibiotics. As to sharing, I don't share may be Panadol or painkiller.
		Adherence to medication	*"Yesterday, I was chatting with one of my friends. He said: while we were moving from house to house, we found a drawer in my mother's room, when we open it; we found it full of medications. She used to bring medication from the hospital and place there so as not to use it. She admits only hypertension and cholesterol; in case of any other medical problems she hides its medication from her sons and daughters."* (MPG-6)

6. Patient trust in pharmacists			*"If working in the government sector, I think they could be honest as most of them are Saudis, with Saudi certificates, the foreigners you cannot know if they have qualification in the field or only salesmen [...] certain places offer fraud certificates, but I do not know more details."* (FPG-1) *"We have many cases … they do not know anything, sometimes they do not even know BID* [to be taken two times a day]*."* (PG-2) *"Many thanks for him now because he refused to give medicine that was inappropriate … the pharmacist was honest; he seemed to be newly appointed."* (FPG-3) *"Patients trust their doctor even if he made a mistake in something; patients never trust anybody else because they fully rely on the doctor."* (I-3) *"I see if there is commitment and standards from the pharmacist. [This is] part sincerity. He asks you some questions to make you feel that he is careful, not just give and take some time, they just can get a member of staff to do that."* (MPG-2)
7. Communication and information exchange		Patient–pharmacist communication	*"The pharmacist should care about communication with the patient and not get bored questioning the patient. Despite the feeling that the patient does not want to be asked a lot of questions, the pharmacist should do what is best for him ethically. The goal is the patient's benefit."* (CPG-1) *"My work depends on communication with my patients."* (CPG-4) *"I did not ask, but he was proactive. Just a little information about the medication and I will be thankful, as he is the specialist. I am sure that some of the medications have red lines [cautions]. Even if they are licensed, I need to be informed about the cautions on them."* (MPG-2) *"I think education* (being proactive) *is not the role of the pharmacist. It is impossible to explain everything to everyone. If the patient asks, he should answer; if the patient does not ask, it is not the role of the pharmacist to explain."* (MPG-4)
		Patient medication information source	*"I read a package insert with a lot of information warnings and side effects, I always get afraid … I immediately get my eye glasses and start reading… So even the words they use are harmful, especially when they say 1 in 100,000, some words hurt."* (MPG-4)
		Factors affecting communication exchange	*"The pharmacists they are male pharmacists, so the females most of them are sending their driver to get their medication they may not ask questions that can be a communication barrier. Many families send the driver to get the medication"* (PG-3) *"He gave him many options, maybe his child's age, I don't know, but he gave him options and explained [things] to him and gave him more time. I kept waiting. When it was my turn, he said to me, 'this is the best, so take it."* (FPG-1) *"…There is no chair in the reception, in the middle in front of him, a large space so he can put Strepsils and gum. You go abroad; there are chairs for waiting because he knows he will take some of my time to discuss information with the patient before me … no chairs for waiting, and if you wait, don't expect them to tell you anything."* (MPG-5)

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		Type of information requested by patients from pharmacists	**Moderator:** *what are the most questions that you may ask?* **MPG-2:** *the most important matter is to ask him about its side effects* **MPG-1**: *Correctly* **MPG-2:** *what does the medication do? What is it composed of? Should I continue? Should I continue the dose? May I reduce it? Is it taken when necessary?* **MPG-7:** *the important matter that I ask the pharmacist about is: for what problem is this medication taken for? That is in order to know whether the problem is actually a disease or not"*
		Information received from pharmacist information compared to information received from physician	*"The physician says, 'Because of so and so this is no longer of benefit', and when you go to the pharmacist, he gives another opinion. There is always a struggle inside of us about who to believe."* (MPG-1) *"This is not the role of the pharmacist. If I take two prescriptions, it is not his role to tell me … to take this medication with that medication. It is not the responsibility of the pharmacist, not all pharmacists know drug interactions."* (MPG-4) The opposite opinion was also expressed: *"Why did they study for five years?"* (MPG-5)
	Team factors	Communication between pharmacists and physicians	*"We also do not know how to communicate with physicians, secondly in order to communicate with him again we have to request his phone number. If I work at a pharmacy, which is far away from the clinic and try calling him my call is divert to an answer machine and they leave on hold the physician does not reply and you start from scratch to call again and stay on hold, you are keen to give the patient the right medication […] I think there is a safety problem with the prescription trying to communicate with him would be impossible."* (CPG-1)

1148 PG Professional Group
1149 FPG Female Pharmacy Users Group
1150 CPG Community Pharmacy Group
1151 MPG Male Pharmacy Users Group
1152 I   Interview participant

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