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## Manuscript Details

<b>Manuscript number</b>	RSAP_2018_90
<b>Title</b>	Using the Human Factors Framework to understand the origins of medication safety problems in community pharmacy in Saudi Arabia: A qualitative study
<b>Article type</b>	Research Paper

### 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.

<b>Keywords</b>	Patient safety;Community pharmacy; Human factors;Medication errors; Drug related side effects ;adverse reactions.
<b>Manuscript category</b>	Research Paper
<b>Corresponding Author</b>	Lobna Al Juffali
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<b>Suggested reviewers</b>	Darren Ashcroft

## Submission Files Included in this PDF

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ANON, manuscript 2822018.docx [Manuscript (without Author Details)]

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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 rates 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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5 **Using the Human Factors Framework to understand the origins of**  
6 **medication safety problems in community pharmacy in Saudi Arabia: A**  
7 **qualitative study**  
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5 **1 ABSTRACT**  
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7 **2 Background:** Community pharmacy practice in the Kingdom of Saudi Arabia (KSA) faces many  
8 challenges. In KSA, there is a lack of empirical research about medication safety in this setting.  
9

10 **4 Objective:** To explore the safety problems associated with medication supply from community  
11 pharmacies in KSA and compare different stakeholder perspectives.  
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13

14 **6 Methods:** Four focus groups and individual interviews were conducted in Riyadh, KSA, in  
15 February-May 2013. All group discussions were recorded, transcribed and translated from  
16 Arabic into English, except the professional group, which was conducted in English. Thematic  
17 analysis was performed using the Human Factors Framework (HFF).  
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20 **10 Results:** The groups comprised “professionals” (n=8; one female), community pharmacists (n=4;  
21 all male) and two pharmacy user groups (females, n=11 and males, n=8). Medication safety  
22 problems identified were categorised into nine categories representing the HFF. Seven main  
23 themes were identified from these categories: commercial pressure on community pharmacy;  
24 illegal supply of prescription medication; lack of enforcement of regulations; the healthcare  
25 system; self-medication; patient trust in pharmacists; and communication failure. Themes that  
26 emerged only from the “professionals” and community pharmacists were the different role of  
27 the regulatory organisations and the reasons behind lack of enforcement, while the community  
28 pharmacist group focused on the relationship between owners and managers. Pharmacy users  
29 expressed a need for information about medication and that the primary role of the pharmacist  
30 should be as an information provider. Furthermore, they perceived pharmacists to be vendors  
31 rather than healthcare professionals.  
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40 **22 Conclusion:** Many medication safety problems were identified, attributable to individuals  
41 (patient, pharmacist), pharmacy and organisational factors. These results will be used to  
42 develop interventions to improve medication safety.  
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63 **26 BACKGROUND**  
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65 27 The World Health Organisation has highlighted safety in primary care as an international  
66 28 challenge.[1] In primary healthcare, adverse drug events (ADEs) are reported to occur in 25% of  
67 29 outpatients, almost half of which (11%) are preventable.[2] Research undertaken in the  
70 30 community pharmacy setting has mostly focused on detecting and measuring medication errors  
71 31 and near misses.[3]

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73 32 Studies in the Kingdom of Saudi Arabia (KSA) have shown high levels of hospital admissions  
74 33 associated with drug-related problems (DRPs), of which the most common causes were ADEs, a  
75 34 failure to receive medication and medication non-compliance.[4,5] A range of challenges to  
76 35 medication safety in KSA were identified: limited use of technology; illegal supply of  
77 36 prescription only medication (POM); communication gaps between healthcare institutions:  
78 37 under-reporting of ADEs and communication barriers.[6] Studies in KSA have mainly  
79 38 investigated the problems either from a pharmacist or a pharmacy user perspective using  
80 39 mostly surveys.[7-11] No qualitative studies have been conducted with pharmacy users or  
81 40 other stakeholders, such as policy makers and pharmacy owners.

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88 41 The application of theory may help to understand patient safety problems and a number of  
89 42 relevant frameworks exist. [12-17] The Human Factors Framework (HFF) has potential to  
90 43 enhance clinical performance by understanding the effects of factors such as teamwork, tasks,  
91 44 equipment, workspace, culture and organisation on human behaviour and abilities, and  
92 45 applying insights to clinical settings. [14-18] The HFF aids understanding of people's  
93 46 capabilities and limitations, allowing design of better systems. It is a recognised tool to reduce  
94 47 medication error rates or mitigate adverse medication effects. [12]

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99 48 The purpose of our study was to explore and compare different stakeholder perspectives  
100 49 regarding the safety problems associated with medication supply from community pharmacies  
101 50 in KSA using the HFF. The stakeholders for whom medication safety is important include service  
102 51 users, community pharmacists, pharmacy owners, as well as representatives from legal and  
103 52 regulatory authorities.

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108 **53 METHODS**  
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110 54 This qualitative study comprised a series of focus groups and interviews. Focus groups were  
111 55 conducted with different stakeholders: healthcare professionals; community pharmacists; and  
112 56 pharmacy users. Individual interviews were conducted with community pharmacists only.  
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121 **57 Sampling and recruitment**  
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123 **58** The study was conducted in Riyadh, the capital of KSA. The healthcare professional group (PG)  
124 **59** was recruited purposively, identified through professional and personal networks.  
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127 **61** The community pharmacist group (CPG) was recruited using purposive, convenience and  
128 **62** snowballing methods. Personal visits to pharmacies and telephone calls were made to invite  
129 **63** participants. Telephone interviews were offered only to community pharmacists who could not  
130 **64** attend the focus group due to job commitments.  
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133 **66** Pharmacy users aged 18 and older were eligible to participate. Different recruitment strategies  
134 **67** were adopted to reflect the cultural constraints in Saudi society. For the female pharmacy user  
135 **68** group (FPG), community centres and sites for social activities were sought in Riyadh. A non-  
136 **69** profit childcare association providing free weekly parenting courses in community centres was  
137 **70** identified, to recruit female attendees who were of various ages and educational backgrounds.  
138 **71** For the male pharmacy user group (MPG), an announcement about a support group for  
139 **72** caregivers of Alzheimer patients was sent via Twitter from the Alzheimer Society account. This  
140 **73** support group is held once a month in a private training centre. The researcher (LJ) visited one  
141 **74** of these support group meetings for recruitment purposes.  
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143 **75**

144 **76** All potential participants, irrespective of group, received an invitation letter and study  
145 **77** information sheet. A consent form was provided by e-mail or personally, one week prior to the  
146 **78** focus group. Each participant signed an individual informed consent statement prior to the  
147 **79** commencement of the focus groups.  
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150 **80 Data collection**  
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153 **81** The focus groups were conducted using semi-structured topic guides (Supplementary Material)  
154 **82** (one for FPG and MPG and one for the PG and CPG), which were informed by the literature and  
155 **83** the HFF. Data were collected on participants' age, gender, and education background and  
156 **84** practice experience. The PG was moderated by MW. The remaining focus groups were  
157 **85** moderated by LJ, with SA in attendance. Before undertaking the group discussions, a pilot focus  
158 **86** group was conducted with first year undergraduate pharmacy students to test questions and  
159 **87** data collection methods.  
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162 **88 Research ethics**  
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165 **89** This study was completed as part of the first author's PhD thesis who undertook specific  
166 **90** training regarding conducting and analysing qualitative research. Approval for this study was  
167 **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

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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
<b>External factors</b>	Commercial pressure and commercialism Regulations and regulators The healthcare system in Kingdom of Saudi Arabia
<b>Organisational and management factors</b>	Pharmacy owners' and managers' roles Lack of patient database in community pharmacies
<b>Work environment</b>	Pharmacist working hours Type of pharmacy and its effect on medication safety
<b>Team factors</b>	Physician prescribing behaviour Communication between pharmacists and physicians
<b>Individual factors: Pharmacists</b>	Pharmacist competence and clinical skills Pharmacist adherence to law and regulations Pharmacist role as perceived by participants
<b>Task factors</b>	Illegal Supply of prescription-only medication to patients. Medication storage and transportation in community pharmacies Generic substitution
<b>Communication and information exchange</b>	Patient-pharmacist communication Factors affecting communication exchange Type of information requested by patients from pharmacists Patient medication information source Pharmacist versus physician information
<b>Patient</b>	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
<b>Medication</b>	Medicines associated with the risk Medication availability and shortage Counterfeit medication
<b>Others</b>	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
<b>Commercialism and commercial pressure on community pharmacies in kingdom of Saudi Arabia</b>	External factors <ul style="list-style-type: none"> <li>• Commercial pressure and commercialism</li> <li>• Healthcare system role in commercialism</li> </ul> Organisational and management factors <ul style="list-style-type: none"> <li>• The role of pharmacy owners and managers</li> </ul> Work environment <ul style="list-style-type: none"> <li>• Type of pharmacy and its effect on medication safety</li> <li>• Pharmacist working hours</li> <li>• Low salaries</li> </ul> Team factors <ul style="list-style-type: none"> <li>• Physician prescribing behaviour</li> </ul> Task factors <ul style="list-style-type: none"> <li>• Patient counselling</li> <li>• Generic substitution</li> <li>• Medication storage and transportation</li> </ul> Patient factors <ul style="list-style-type: none"> <li>• Patient belief and perception about the business oriented practice</li> <li>• Patient behaviour</li> </ul>
<b>Illegal supply of prescription medication by pharmacist</b>	External factors Individual factors: pharmacist Patient factors
<b>Lack of enforcement of regulations</b>	External factors <ul style="list-style-type: none"> <li>• Regulations and regulators</li> </ul> Individual factors: pharmacist <ul style="list-style-type: none"> <li>• Pharmacist adherence to law and regulations</li> </ul> Patient factors <ul style="list-style-type: none"> <li>• Patient pressure on pharmacists to commit a misconduct</li> </ul> Medication <ul style="list-style-type: none"> <li>• Counterfeit medication as consequence</li> </ul>
<b>Healthcare system in kingdom of Saudi Arabia</b>	External factors <ul style="list-style-type: none"> <li>• The fragmented healthcare system</li> <li>• Lack of patient database in community pharmacies</li> </ul> Organisational and management factors <ul style="list-style-type: none"> <li>• Implementation of technology in community pharmacy</li> </ul>
<b>Patient medication-taking behaviour</b>	<ul style="list-style-type: none"> <li>• Self-medication</li> <li>• Sharing medication</li> <li>• Adherence to medication</li> </ul>
<b>Patient trust in pharmacists</b>	No subthemes identified
<b>Communication and information exchange</b>	<ul style="list-style-type: none"> <li>• Patient–pharmacist communication</li> <li>• Patient medication information source</li> <li>• Factors affecting communication exchange</li> <li>• Type of information requested by patients from pharmacists</li> <li>• Information received from pharmacist information compared to information received from physician</li> </ul> Team factors <ul style="list-style-type: none"> <li>• Communication between pharmacists and physicians</li> </ul>

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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.			✓	✓

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### 135 **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.

#### 140 *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

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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)*

### 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.

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)*

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

191 *Team factors*

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

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

200 *Task factors*

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

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

207  
208 Pharmacists substituting a prescribed branded medication with a different form of the same  
209 active substance (generic substitution) was an emerging theme across all groups. The PG stated  
210 that the problem is that community pharmacists provide medication alternatives to patients  
211 based on financial incentives and commission rather than patient benefit.

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

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

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

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223 **Patient factors**

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

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

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

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

232  
233 *"People think that he is a seller, but he is well qualified in term of education.*  
234 *He spent a long time studying and understands drug composition maybe more*  
235 *than the physicians."*(FPG -2)

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

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

241 **Illegal supply of prescription medication by pharmacists**

242 *External factors*

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

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

254 However, such practices were identified as a cause of hospital admission by the PG. Antibiotics  
255 were given as an example of medication supplied illegally in all groups, and participants in the  
256 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)*

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)*

309 **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)*

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.

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711 326 *“Community pharmacy should work as primary centres ... take for example diabetic*  
712 327 *patient whatever the government invest and put amount of money in hospitals and*  
713 328 *primary care they will not be able to manage the whole diabetic population. They are*  
714 329 *huge [the diabetic population] so if you add hypertensive patients and asthmatic*  
715 330 *patient they are huge.”(PG-4)*  
716 331

718  
719 332 Participants also discussed the lack of a patient database and filing system in community  
720 333 pharmacies: they perceived an electronic patient database with relevant medical information  
721  
722 334 accessible to community pharmacists to be an important factor in medication safety.

723  
724 335 *“There should be a special file for each patient in each pharmacy, not only in the*  
725 336 *hospital.”(CPG-1)*  
726 337

### 728 338 *Organisational and management factors*

729  
730 339 Participants suggested that solving the problem starts with the Saudi Ministry of Health, which  
731 340 should establish a national electronic health records database. The need to implement  
732 341 technologies such as electronic prescribing and to utilise drug information software, was  
733 342 discussed in both the PG and the CPG.

### 737 343 **Patient medication taking behaviour**

738 344 Patients’ accounts of behaviours such as self-medication, sharing medication and adherence to  
739 345 medication emerged. Self-medication in the context of this study is the selection and use of  
740 346 medicines by individuals to treat self-recognized conditions or symptoms with POM or over the  
741 347 counter (OTC) medication. Participants in all groups agreed that self-medication is common in  
742 348 KSA.

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747 349 *“I went to the pharmacy and said [something] and then some medications were*  
748 350 *given to me, that is, we are treating ourselves.”(MPG-1)*  
749

750  
751 351 The MPG proposed several reasons for self-medication such as cultural influences, the  
752 352 accessibility of medication, the large number of community pharmacies, and patients’ previous  
753 353 experiences with a medication.  
754 354

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757 355 The CPG highlighted that patients even self-medicate with antidepressants without consulting a  
758 356 physician. They were also aware of medication abuse such as the use of steroids for weight gain  
759 357 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)*

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)*

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)*

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)*

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

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

#### 401 **Communication and information exchange**

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

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

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

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

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

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

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

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425 The CPG also expressed concerns about the patient providing incomplete information or  
426 wrongly expressing symptoms to the pharmacist. The PG and MPG agreed on the need for clear  
427 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.

506 **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.

522 **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.

530

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### 535 **Contributors**

536 LA, MW, SA and PK were involved in all stages of the study. LA drafted the article, and all  
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539 None

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### 545 **Data sharing statement**

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

548

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689 **Supplementary material**

690 **Appendix A**

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

692

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

- a. What does medication safety mean to you?  
Probes: Your personal experience of problems (adverse effect reactions)
  
- b. What medicines are safe?  
Probes: Why do you think they are safe?  
  
Probes: when you are familiar with a medicine does this makes it safe? How is that?
  
- c. What medicines do you think are associated with risk?  
Probes: Why do you think they are unsafe?
  
- d. What medical conditions are most likely to cause problems with medicines?
  
- e. What patients are most at risks from medication?  
Probes: Age, Gender, pregnant women, lactating women, etc
  
- f. What are the main problems that you can encounter in a community pharmacy in terms of medication safety?
  
- g. How could community pharmacists help people with their medicines?  
Probes: your suggestions
  
- h. Any comments

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1417  
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1419 711 **Topic Guide for focus group (Professionals)**  
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1423 713 **Questions to be addressed during the focus group**  
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1425  
1426 714 a. What are the main medication safety concerns associated with medicines supplied  
1427  
1428 715 from community pharmacies in Saudi Arabia?

1429  
1430 716 Probes: Identify the problems and give examples from their point of view and experience.  
1431

1432  
1433 717 b. Who are the patients most at risk from medication safety problems?

1434  
1435 718 Probes: what are the medical conditions that have the highest risk to the patient?

1436  
1437 719 Probes: who are the population who are at most risk (age, gender, etc)?  
1438

1439  
1440 720 c. What types of medication are associated with safety problems in community  
1441  
1442 721 pharmacy?

1443  
1444 722 d. What are the factors that contribute to these problems?

1445  
1446 723 e. How can community pharmacists prevent and manage these problems?

1447  
1448 724 f. What other agencies, organisations could help to improve medication safety with  
1449  
1450 725 medicines supplied from community pharmacies?

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1452 726 Probes: How could this is achieved?  
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1455 727 g. Any other comments  
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735 **Appendix B**

736 **Coding index (expert and community pharmacist)**

737 **1. New prescription**

738 1.1 Refill of a prescription medication

739 1.1.1 With a prescription

740 1.1.2 Without a prescription

741 1.2 Self-medication

742 1.2.1 Internet

743 1.2.2 TV/ Advertisement

744 1.2.3 Family, Friends, neighbours

745 1.2.4 Based on previous experience

746  
747 **2. Medication use process**

748 2.1 Prescribing

749 2.1.1 Prescriber

750 2.1.1.1 Lack of knowledge

751 2.1.1.2 Failure to communicate between pharmacist and prescriber

752 2.1.1.3 Unethical prescribing practices/violation of the law

753 2.1.2 Prescription

754 2.1.2.1 Prescription incomplete information or ambiguous

755 2.1.2.2 Handwriting

756 2.1.2.3 Prescribing error

757 2.2 Dispensing

758 2.2.1 Patient pressure to supply medication

759 2.2.2 Incomplete patient information

760 2.2.2.1 Patient medical history

761 2.2.2.2 Medication record

762 2.2.3 Dilemma between patient care and money (commercial pressure)

763 2.2.4 Labelling

764 2.2.5 Illegal supply of medications

765 2.2.5.1 Factors that contribute to illegal supply of medication

766 2.2.5.2 Common medications supplied without a prescription

767 2.2.5.3 consequences of supplying medication without prescription

768 2.2.6 Generic substitution

769 2.3 Pharmacist-patient communication

770 2.3.1 Language

771 2.3.2 Literacy

772 2.3.3 Cultural considerations

773 2.3.4 Third party communicating patient information (family member or

774 2.3.5 Inaccurate information (self-diagnosis)

775  
776 2.4 Administration (Medication taking behaviour)

777 2.4.1 Sharing medication

778 2.4.2 Adherence

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1536			
1537	779	2.4.3	Drug abuse
1538	780	2.4.4	Drug misuse
1539	781		
1540	782	2.5	Monitoring
1541	783	2.5.1	No follow up
1542	784	2.5.2	Reasons for no follow up
1543	785	2.5.2.1	No computer system
1544	786	2.5.2.2	Others
1545	787		
1546	788	<b>3.</b>	<b>Medication</b>
1547	789	3.1	High alert medication
1548	790	3.1.1	Analgesics
1549	791	3.1.2	NSAIDS
1550	792	3.1.3	Antibiotics
1551	793	3.1.4	Cortisone
1552	793	3.1.4	Cortisone
1553	794	3.1.5	Control medication
1554	795	3.1.6	Psychotherapeutic agents
1555	796	3.1.7	Thyroxine
1556	797	3.1.8	Weight management agents
1557	797	3.1.8	Weight management agents
1558	798	3.1.9	Minoxidil
1559	799	3.1.10	Vitamins
1560	800	3.1.11	Hormonal replacement therapy
1561	801	3.1.12	Warfarin
1562	802	3.2	Other related medication problems
1563	803	3.2.1	Medications with unimproved indications
1564	804	3.2.2	Look alike, sound like medications
1565	804	3.2.2	Look alike, sound like medications
1566	805	3.2.3	Counterfeit medications
1567	806	3.2.4	Expiration date
1568	807	3.2.5	Bar coding
1569	808	3.2.6	Pricing
1570	809	3.2.7	Medication shortage and availability
1571	810		
1572	811	3.3	Herbal medication
1573	811	3.3	Herbal medication
1574	812	3.4	Medication distribution
1575	813	3.4.1	Transportation
1576	814	3.4.2	Storage
1577	815	3.5	Medication related problem concerning patient outcome
1578	816	3.5.1	Duplication of therapy
1579	817	3.5.2	Adverse drug effects
1580	818	3.5.3	Dosage regimen
1581	818	3.5.3	Dosage regimen
1582	819	3.5.3.1	Dose too high
1583	820	3.5.3.2	Dose too low
1584	821	3.5.4	Drug interaction
1585	822	<b>4.</b>	<b>Patient</b>
1586	823	4.1	Patient at risk of medication safety problems
1587	824	4.1.1	Patient with chronic diseases
1588	825	4.1.2	Patient with Allergies
1589	826	4.1.3	Patients with poly pharmacy
1590	827	4.1.4	Gender
1591			
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1595		
1596	828	4.1.4.1 Female
1597	829	4.1.4.2 Male
1598	830	4.1.5 Age
1599	831	4.15.1 Paediatric
1600	832	4.15.2 Geriatric
1601	833	4.1.6 Education
1602	834	4.1.7 Language
1603	835	4.1.8 Patients with no insurance
1604	836	4.2 Patient /public awareness of medication safety
1605	837	4.3 Patient perception and attitude towards healthcare professional roles
1606	838	4.3.1 Physician
1607	839	4.3.2 Pharmacist
1608		
1609	840	<b>5 Pharmacist</b>
1610	841	5.1 Scientific knowledge of pharmacist
1611	842	5.2 Continuing education/ training
1612	843	5.3 The quality of practice/unprofessional practice
1613	844	5.4 Nationality
1614	845	5.5 Pharmacist assessment/ licensing
1615	846	5.6 Working hours
1616	847	5.7 Stress
1617	848	5.8 Fatigue
1618	849	5.9 Salary
1619	850	5.10 Pharmacist perception of their role
1620	851	5.10.1 Compounding
1621	852	5.10.2 Providing clinical services
1622	853	5.10.3 Other
1623		
1624	854	<b>6 Pharmacy</b>
1625	855	6.1 Reimbursement for pharmacy
1626	856	6.2 Specialised pharmacy for each population (disease)
1627	857	6.3 Type of pharmacy
1628	858	6.3.1 Independent
1629	859	6.3.2 Chain pharmacy
1630	860	6.4 Location ,distribution and number
1631	861	6.5 Pharmacy owners/managers
1632	862	6.6 The use of technology
1633	863	6.6.1 Patient databases
1634	864	6.6.2 Drug information software's
1635		
1636	865	<b>7 Organisations and systems</b>
1637	866	7.1 Regulators
1638	867	7.1.1 Role of the Ministry of Health
1639	868	7.1.2 Role of Saudi Food and Drug Authority
1640	869	7.1.3 Role of other organisations
1641	870	7.2 Role of Universities
1642	871	7.3 Pharmaceutical companies and manufactures
1643	872	7.4 Accreditation
1644	873	7.5 Punishing and rewarding system
1645	874	7.6 International Organization for Standardization
1646	875	7.7 Regulation for pharmacy practice
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1654		
1655	876	7.7.1 The availability of regulation
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## 900 Coding index (Pharmacy users)

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		Low salaries	<i>"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."</i> (MPG-5)
	Team factors	Physician prescribing behavior	<i>"The medication is prescribed due to a commission, and this has resulted in a loss of confidence between us and physicians."</i> (MPG-7)  <i>"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> (I-3)
	Task factors	Patient counselling	<i>"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."</i> (MPG-3)  <i>"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."</i> (FPG-1)
		Generic substitution	<i>"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'."</i> (FPG-2)  <i>"Price is not the issue, [it is to] prevent you [the patient] from going to other pharmacy"</i> (FPG-5)  <i>"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"</i> (FPG-1)
<b>2. Illegal supply of prescription medication by pharmacist</b>	External factors		<i>"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."</i> (PG-2)
	Individual factors: Pharmacist		<i>"We are pharmacists, we have certificates and we know what to dispense, but there are laws controlling us."</i> (CPG-3)  <i>"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."</i> (CPG-4)  <i>" 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."</i> (CPG-3)  <i>"The CPs should not give medications without prescription ... because they are risky."</i> (FPG-8)

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<p><b>3. Lack of enforcement of regulations</b></p>	<p>External factors</p>	<p>Regulations and regulators</p>	<p><i>"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."</i>(PG-1)</p> <p><i>"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."</i>(PG-2)</p> <p><i>"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>(I-3)</p>
	<p>Individual factors: Pharmacist</p>	<p>Pharmacist adherence to law and regulations</p>	<p><i>"No professional pharmacist will like to break the law..."</i>(PG-4)</p> <p><i>"... When someone comes requesting a combination, I make [prepare the medication as a compound] and hide it as if I am committing a crime."</i>(CPG-4)</p> <p><i>"... There is the regulation but they are playing with regulations..."</i>(PG-8)</p> <p><i>"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."</i>(PG-1)</p> <p><i>"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."</i>(PG-4)</p>
	<p>Medication factors</p>	<p>Counterfeit medication as consequence</p>	<p><i>"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>(I-3)</p> <p><i>"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"</i>(PG-4)</p> <p><i>"I think the worst that we suffer regarding medications is fraud ... they could be counterfeit"</i>(FPG-9)</p>
<p><b>4. Healthcare system in KSA</b></p>	<p>External factors</p>	<p>The fragmented healthcare system</p>	<p><i>"...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."</i>(PG-5)</p>
		<p>Lack of patient database in community pharmacies</p>	<p><i>"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]."</i>(PG-2)</p> <p><i>"He dispenses medication based on what information you provide him; nothing [is] documented"</i>(MPG-7)</p>

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	Organizational and management factors	Implementation of technology in community pharmacy	<i>"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"</i>
5. Patient medication taking behavior		Self-medication	<p><b>CPG-2:</b> <i>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</i></p> <p><b>CPG-4:</b> <i>and this is what is common nowadays</i></p> <p><b>CPG-1:</b> <i>what is common nowadays is that they suffer from vitamin D deficiency and then take it without taking baseline levels."</i></p> <p><i>"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>(I- 3)</p> <p><i>"Yes, it is the core problem [self-medication]" (MPG-5)</i></p> <p><i>"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."</i>(MPG-6)</p>
		Sharing medication	<p><b>CPG-1:</b> Cooperation, that is, I have a pharmacy at home</p> <p><b>CPG-5:</b> as fruits in the refrigerator.</p> <p>Moderator: Well, does that mean all your medications are shared?</p> <p><b>CPG-1:</b> No, not to this extent, may be antibiotic without exaggeration.</p> <p>Moderator: Could give me examples?</p> <p><b>CPG-5:</b> 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.</p> <p>Moderator: do you share medications with the family, participant 4-3 and participant CPG-4?</p> <p><b>CPG-4:</b> 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.</p>
		Adherence to medication	<p><i>"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."</i>(MPG-6)</p>

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<p><b>6. Patient trust in pharmacists</b></p>			<p><i>"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."</i>(FPG-1)</p> <p><i>"We have many cases ... they do not know anything, sometimes they do not even know BID [to be taken two times a day]."</i> (PG-2)</p> <p><i>"Many thanks for him now because he refused to give medicine that was inappropriate ... the pharmacist was honest; he seemed to be newly appointed."</i>(FPG-3)</p> <p><i>"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>(I-3)</p> <p><i>"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."</i>(MPG-2)</p>
<p><b>7. Communication and information exchange</b></p>		<p>Patient-pharmacist communication</p>	<p><i>"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."</i>(CPG-1)</p> <p><i>"My work depends on communication with my patients."</i>(CPG-4)</p> <p><i>"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."</i>(MPG-2)</p> <p><i>"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."</i>(MPG-4)</p>
		<p>Patient medication information source</p>	<p><i>"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."</i> (MPG-4)</p>
		<p>Factors affecting communication exchange</p>	<p><i>"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"</i> (PG-3)</p> <p><i>"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)</i></p> <p><i>"...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."</i>(MPG-5)</p>

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		Type of information requested by patients from pharmacists	<p><b>Moderator:</b> <i>what are the most questions that you may ask?</i></p> <p><b>MPG-2:</b> <i>the most important matter is to ask him about its side effects</i></p> <p><b>MPG-1:</b> <i>Correctly</i></p> <p><b>MPG-2:</b> <i>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?</i></p> <p><b>MPG-7:</b> <i>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"</i></p>
		Information received from pharmacist information compared to information received from physician	<p><i>"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)</i></p> <p><i>"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)</i></p> <p>The opposite opinion was also expressed: <i>"Why did they study for five years?"(MPG-5)</i></p>
	Team factors	Communication between pharmacists and physicians	<p><i>"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)</i></p>

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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